12000 Oral Abstract Session

Multi-site randomized trial of stepped palliative care (PC) for patients with advanced lung cancer.

Jennifer S. Temel, Vicki Jackson, Pallavi Kumar, Thomas William LeBlanc, Arif Kamal, Simone Rinaldi, Areej El-Jawahri, Christopher A Jones, Kathryn McGrath, Laura A Petrillo, Dustin Rabideau, Nora K. Horick, Kedie Pintro, Emily R. Gallagher, Kathryn Post, Anna Ruprecht, Joseph A. Greer; Massachusetts General Hospital, Division of Hematology and Oncology/Department of Medicine, Boston, MA; Massachusetts General Hospital, Harvard Medical School, Boston, MA; University of Pennsylvania, Philadelphia, PA; Duke University School of Medicine, Durham, NC; American Cancer Society, Charlotte, NC; Massachusetts General Hospital, Boston, MA; Duke University, Department of Medicine, Durham, NC

Background: Studies show that early PC (EPC) integrated with oncology care from the time of diagnosis of advanced cancer improves patient and caregiver outcomes. However, this care model has not been widely implemented given the shortage of PC clinicians and challenges in providing PC visits throughout the course of cancer treatment, especially as novel therapeutics prolong survival in this population. Therefore, to deliver more patient-centered and less resource-intensive PC, we evaluated a stepped PC (SPC) model in patients with advanced lung cancer. **Methods:** Between 2/12/18 and 12/15/22, we enrolled patients with advanced lung cancer, diagnosed in the past 12 weeks and an ECOG PS = 0-2 to a multi-site randomized trial of SPC versus EPC. All patients assigned to SPC started on Step 1, with an initial PC visit within four weeks of enrollment and subsequent PC visits scheduled only at the time of a change in cancer treatment or after a hospitalization. Patients on Step 1 also completed a measure of quality of life (QOL; Functional Assessment of Cancer Therapy-Lung [FACT-L]) every six weeks for up to 18 months from enrollment, and those with a greater than or equal to a 10-point decrease in their score from baseline were stepped up to meet with the PC clinician every four weeks (Step 2). Patients assigned to EPC had PC visits every four weeks from enrollment. The primary aim was to evaluate the non-inferiority of the effect of SPC versus EPC on QOL as measured by the FACT-L at week 24, using regression modeling. For the secondary outcomes, we conducted a superiority analysis of the number of PC visits between groups and non-inferiority analyses of patient-reported end-of-life (EOL) communication with clinicians and days enrolled in hospice, controlling for multiple comparisons with a False Discovery Rate of 0.15. **Results:** The sample (N = 507) included mostly patients with NSCLC (78.3%; mean age = 66.48 years; 51.4% female; 84.2% White). QOL scores at week 24 for patients assigned to SPC were non-inferior to those receiving EPC (adjusted means: 100.62 versus 97.75, $p < 0.0001$ for non-inferiority). Sixty-six patients (26.4%) assigned to SPC transitioned to Step 2 by 24 weeks. The mean number of PC visits by week 24 was lower for SPC versus EPC patients (adjusted means 2.44 v. 4.70, $p < 0.0001$). While the rate of EOL communication was non-inferior for SPC versus EPC (adjusted proportions: 0.30 v. 0.33, p = 0.09), non-inferiority was not demonstrated for days in hospice (adjusted means SPC = 19.72 v. EPC = 34.64, p = 0.9). **Conclusions:** A stepped care model, with PC visits scheduled only at key points in patients' cancer trajectories and using a decrement in QOL to trigger more intensive PC exposure, results in significantly fewer PC visits without sacrificing the benefits for patients' QOL. While SPC was associated with fewer days in hospice, this novel model holds promise as a more scalable way to deliver early PC to enhance patient-reported outcomes. Clinical trial information: NCT03337399. Research Sponsor: National Cancer Institute; R01CA215188.

12001 Oral Abstract Session

A mobile app–based program for facilitating advance care planning discussions between patients with advanced cancer and oncologists: A randomized controlled trial (J-SUPPORT 2104).

Kyoko Obama, Maiko Fujimori, Masako Okamura, Tatsunori Shimoi, Shunsuke Oyamada, Kan Yonemori, Taro Ueno, Shunsuke Kondo, Yuki Kojima, Tempei Miyaji, Takayo Sakiyama, Naomi Sakurai, Tatsuo Akechi, Narikazu Boku, Masanori Mori, Taichi Shimazu, Yoshikuni Nagashio, Tatsuya Yoshida, Takuhiro Yamaguchi, Yosuke Uchitomi; Institute for Cancer Control, National Cancer Center, Tokyo, Japan; Division of Survivorship Research/ Division of Behavioral Sciences, Institute for Cancer Control, National Cancer Center Japan, Tokyo, Japan; Institute for Cancer Control, National Cancer Center, Chuo-Ku, Japan; National Cancer Center Hospital, Chuo-Ku, Japan; Department of Biostatistics, Japanese Organisation for Research and Treatment of Cancer (JORTC) Data Center, Tokyo, Japan; National Cancer Center Hospital, Tokyo, Japan; SUSMED, Inc., Tokyo, Japan; Department of Medical Oncology, National Cancer Center Hospital, Tokyo, Japan; Division of Survivorship Research, National Cancer Center Institute for Cancer Control, National Cancer Center, Tokyo, Japan; General Incorporated Association Cancer Survivors Recruiting Project, Tokyo, Japan; Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan; IMSUT Hospital, The Institute of Medical Science, University of Tokyo, Minato City, Tokyo, Japan; Division of Palliative and Supportive Care, Seirei Mikatahara Hospital, Hamamatsu, Hamamatsu, Japan; National Cancer Center Institute for Cancer Control, National Cancer Center, Tokyo, Japan; Department of Hepatobiliary and Pancreatic Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Thoracic Oncology, and Department of Experimental Therapeutics, National Cancer Center Hospital, Tokyo, Japan; Division of Biostatistics, Tohoku University Graduate School of Medicine, Miyagi, Japan

Background: While timely advance care planning (ACP) discussions are recommended, patients find it difficult to express their values in life and preferences for treatment and care to oncologists during outpatient visits. This randomized controlled trial evaluated the effectiveness of a mobile app-based program designed to promote patient questioning behavior to elicit oncologists' empathic communication during ACP discussions in outpatient clinics. **Methods:** We developed an app-based program including ACP-related questions. The eligibility criteria were a diagnosis of advanced cancer, age of 20 years or greater, and oncologist-estimated life expectancy of approximately 1 year or less. Participants were randomized 1:1 to the app-based program (ACP) and usual care groups (UC). The ACP group completed three steps in the mobile app: 1) selecting questions for the oncologist, 2) organizing values and preferences, and 3) preparing for a discussion. Intervention providers consulted participants about the ACP discussions with their oncologists based on the three steps in the app and provided a feedback sheet to the oncologist. The primary endpoint was the score for the oncologist's empathic communication when discussing ACP in outpatient clinics. Two blinded coders evaluated the oncologist's empathic communication toward the patient, based on a manual scoring chart, by listening to the audio recording of the consultation. Scores ranged from 0 (*not applicable at all*) to 36 (*strongly applicable*). Secondary outcomes included patient-reported psychological distress and satisfaction with the oncologist's response to patient needs. Two-hundred fifty participants were required to detect the effect size 3.1 for the primary endpoint based on a two-sided significance level of 5% and a power of 80% assuming drop-out rate of 5%. **Results:** We enrolled 264 patients (132 per group, mean age [SD] = 61.0 [12.7] years, 70% female); most were diagnosed with breast (n = 77, 29.2%) or pancreatic (n = 25, 9.5%) cancer. The oncologist's empathic behavior scores were significantly higher in the APP group than the UC group (estimated value [95% CI]: 19.6 [17.9, 21.3] in the ACP group vs 12.0 [10.3, 13.7] in the UC group, $p < 0.0001$). The ACP group reported higher satisfaction with oncologists' response than the UC group (mean scores [SD]: 9.3 [1.2] vs 8.9 [1.3], $p = 0.03$) during consultation, while no significant intergroup differences were observed for psychological distress. **Conclusions:** Application-based interventions improved communication between patients with advanced cancer and their oncologists, including ACP discussions, without exacerbating patients' psychological distress. We are also analyzing surveys of 24 weeks of follow-up to determine the impact of ACP discussions on medical utilization and healthcare outcomes. Clinical trial information: NCT05045040. Research Sponsor: The Ministry of Health Labour and Welfare Japan; the Japan Society for the Promotion of Science.

12002 Oral Abstract Session

BE-a-PAL: A cluster-randomized trial of algorithm-based default palliative care referral among patients with advanced cancer.

Ravi Bharat Parikh, William J. Ferrell, Yang Li, Jinbo Chen, Larry Edward Bilbrey, Nicole Johnson, Jenna Steckel, Stephen Matthew Schleicher, Natalie R. Dickson, Justin E. Bekelman, Sandhya Mudumbi; Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; University of Pennsylvania, Philadelphia, PA; Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA; Tennessee Oncology, Nashville, TN; Tennessee Oncology PLLC, Nashville, TN; Tennessee Oncology, Lebanon, TN

Background: Patients with advanced solid malignancies often experience poor quality of life and aggressive end-of-life care. Early specialist palliative care (PC) can improve these outcomes. However, most patients do not receive a PC referral before death, with clinician inertia and difficulty identifying high-risk patients being barriers to initiating PC referrals. **Methods:** This was a 2-arm pragmatic cluster-randomized clinical trial. Eligible patients had stage 3 or 4 lung or non-colorectal gastrointestinal cancer. An automated electronic health record (EHR) algorithm, adapted from NCCN Palliative Care prognostic or psychosocial risk factors, assigned each patient a score from 0-20; high-risk patients with scores $\geq$2 (if stage III disease) or $\geq$1 (stage IV) were eligible. We randomized 15 clinics in a large community oncology network, stratifying randomization based on patient volume. In the intervention arm, oncologists received weekly default EHR notifications prompting specialty PC referral for high-risk patients. If oncologists did not opt out, a coordinator introduced specialty PC to patients using a standard script and offered to schedule a PC visit. In the control arm, oncologists referred to PC at their discretion. Adjusted Cox proportional hazards models with clustered standard errors assessed the primary outcome of completed PC visit at 12 weeks. Clustered logistic regression models assessed intervention impacts on change in quality of life (measured using PAL-14) from baseline to 9 weeks and intensive end-of-life care (no hospice enrollment prior to death, chemotherapy receipt within 14 days of death). To address acceptability of the intervention among clinicians, we conducted semi-structured interviews with 12 clinicians post-trial. **Results:** Among 562 patients (296 intervention; 266 control), mean age was 68.5, 79.5% were White, 48.8% were female, and 77.0% had lung cancer. Mean risk score was similar for intervention and control patients (3.0 vs. 3.2). In the intervention arm, 89% of clinicians allowed PC referrals and 79% of patients agreed to PC visits. Compared to control, the intervention resulted in higher rates of completed PC visits (46.6% vs. 11.3%, adjusted odds ratio 5.4, 95% CI 3.2 to 9.2). Among 179 decedents, compared to control, the intervention decreased end-of-life chemotherapy (6.5% vs. 16.1%, p = 0.06). There was no difference in quality of life or hospice among decedents. In interviews, clinicians viewed algorithm criteria as appropriate and the nurse coordinator as a resource to introduce PC to patients. Perceived barriers included staffing limitations and inappropriateness for PC due to low symptom burden or stable disease. **Conclusions:** In a large community oncology network, algorithm-based default PC referrals were acceptable to clinicians and led to $>$ 3-fold increase in specialty PC and decreased end-of-life chemotherapy. Clinical trial information: NCT05590962. Research Sponsor: Emerson Collective.

12003 Oral Abstract Session

Randomized trial of a multimodal intervention to enhance sexual function and quality of life (QOL) in hematopoietic stem cell transplant (HSCT) survivors.

Areej El-Jawahri, Jennifer B. Reese, Lara Traeger, Don S. Dizon, Sharon L. Bober, Julie Vanderklish, Nora K. Horick, Nora K. Horick, Richard Newcomb, Zachariah Michael DeFilipp, Yi-Bin Albert Chen, Jennifer S. Temel; Massachusetts General Hospital, Boston, MA; Fox Chase Cancer Center, Philadelphia, PA; Lifespan Cancer Institute, Rhode Island Hospital, Providence, RI; Dana-Farber Cancer Institute/Mass General Brigham, Boston, MA; Massachusetts General Hospital, Division of Hematology and Oncology/Department of Medicine, Boston, MA

Background: Sexual dysfunction is the most common complication affecting HSCT survivors and is associated with worse psychological distress and patient QOL. Yet, interventions to address sexual dysfunction in HSCT survivors are lacking. **Methods:** We conducted a single-center randomized clinical trial of a multimodal intervention to address sexual dysfunction in autologous and allogeneic HSCT survivors who were at least 3 months post-HSCT and endorsed sexual dysfunction causing distress. Patients were randomly assigned to the intervention or usual care. Intervention participants met with a trained HSCT clinician for three monthly visits that focused on 1) assessing the causes of their sexual dysfunction; 2) educating and empowering patients to address sexual health concerns; and 3) implementing therapeutic interventions (e.g., vaginal lubrication, medications, intimacy exercises, etc.). We assessed patient global satisfaction with sex, interest in sex, orgasm pleasure, erectile function, vaginal discomfort (PROMIS), QOL (Functional Assessment of Cancer Therapy-Bone Marrow Transplant), and psychological distress (Hospital Anxiety and Depression-Scale) at baseline, 3 and 6 months after enrollment. The primary endpoint was to compare patient global satisfaction with sex at 3 months between the study groups. We used linear regression models, adjusting for baseline scores, to evaluate the intervention effects on study outcomes at 3 and 6 months. **Results:** We enrolled 74.0% (125/169) of eligible patients (mean age = 55.5 (SD=14.0), 67% male). Overall, 93.7% (60/64) of those randomized to the intervention attended all three intervention visits. At 3 months, patients randomized to the intervention reported improved global satisfaction with sex (B=4.7, P<0.001), interest in sex (B=1.3, P<0.001), orgasm pleasure (B=3.3, P<0.001), erectile function (B=10.9, P<0.001), vaginal discomfort (B=-9.6, P=0.008), QOL (B=12.5, P<0.001), anxiety (B=-1.7, P=0.003), and depression symptoms (B=-2.0, P<0.001) compared to those assigned to usual care. The intervention led to sustained effects at 6 months with improvement in global satisfaction with sex (B=5.2, P< 0.001), interest in sex (B=0.9, P = 0.009), orgasm pleasure (B=3.6, P<0.001), erectile function (B=12.7, P<0.001), vaginal discomfort (B=-13.5, P<0.001), as well as QOL (B=9.2, P=0.002), anxiety (B=-2.0, P=0.001), and depression symptoms (B=-1.4, P=0.006). **Conclusions:** A multimodal intervention delivered by trained HSCT clinicians results in sustained improvements in sexual health outcomes, QOL, and psychological distress among HSCT survivors. A future multi-site trial is needed to demonstrate the generalizability of these findings across care settings in diverse HSCT survivors. Clinical trial information: NCT03803696. Research Sponsor: American Cancer Society; Leukemia and Lymphoma Society.

LBA12004 **Oral Abstract Session**

Alliance A222001: A randomized, double-blind, placebo controlled phase II study of oxybutynin versus placebo for the treatment of hot flashes in men receiving androgen deprivation therapy.

Brad J. Stish, Gina L. Mazza, Jones T. Nauseef, Michael Sandon Humeniuk, Thomas J. Smith, Cindy Tofthagen, Dayssy Alexandra Diaz Pardo, Christopher H. Chay, Andrew Jonathan Huang, Kushal Naha, Scott T. Tagawa, Selina Lai-ming Chow, Lucile L. Adams-Campbell, Paul J. Novotny, Charles L. Loprinzi; Mayo Clinic Department of Radiation Oncology, Rochester, MN; Mayo Clinic, Phoenix, AZ; Division of Hematology & Medical Oncology, Weill Cornell Medicine; Sandra and Edward Meyer Cancer Center, New York, NY; Gibbs Cancer Center, Spartanburg, SC; Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD; Mayo Clinic Florida, Jacksonville, FL; The Ohio State University, Columbus, OH; Messino Cancer Centers, Asheville, NC; Aspirus Regional Cancer Center, Wausau, WI; University of Missouri Hospital, Columbia, MO; Weill Cornell Medical College of Cornell University, New York, NY; Alliance for Clinical Trials in Oncology, Chicago, IL; Georgetown-Lombardi Comprehensive Cancer Center, Washington, DC; Mayo Clinic, Rochester, MN

12005 Oral Abstract Session

Risk prediction model for taxane-induced peripheral neuropathy (TIPN) in patients with early-stage cancer receiving taxane therapy: SWOG S1714.

Meghna S. Trivedi, Joseph M. Unger, Norah Lynn Henry, Amy Darke, Daniel Louis Hertz, Thomas Brannagan, Stephanie Smith, Bryan P. Schneider, William Johnson Irvin Jr., Amanda Redden Hathaway, Amy C. Vander Woude, Vinay K. Gudena, Paula Anel Cabrera-Galeana, Mary Orsted, Michael Leo LeBlanc, Michael Jordan Fisch, Dawn L. Hershman; Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center, New York, NY; SWOG Statistics and Data Management Center/Fred Hutchinson Cancer Research Center, Seattle, WA; University of Michigan Rogel Cancer Center, Ann Arbor, MI; University of Michigan College of Pharmacy, Ann Arbor, MI; Columbia University Medical Center, NY, NY; Lewis Cancer & Research Pavilion at St. Joseph's Candler/GA NCORP, Savannah, GA; Indiana University, Indianapolis, IN; Bon Secours Saint Francis Medical Center Cancer Institute/Southeast Clinical Oncology Research (SCOR), Midlothian, VA; University Cancer & Blood Center, Athens, GA; Cancer & Hematology Centers of Western Michigan, Grand Rapids, MI; Cone Health Cancer Center, Greensboro, NC; Instituto Nacional de Cancerología, Mexico City, DF, Mexico; HealthPartners Cancer Center at Regions Hospital, St. Paul, MN; The University of Texas MD Anderson Cancer Center; Carelon Medical Benefits Management, Houston, TX

Background: TIPN can impact the ability to complete cancer treatment as well as patient quality of life and functional status. To create a risk prediction model for TIPN, a prospective observational cohort study was conducted. **Methods:** S1714 enrolled patients > 18 years old with Stage I-III primary lung, breast, or ovarian cancer starting treatment with a taxane-based regimen. The primary endpoint was the occurrence of TIPN, defined as an increase of >8 points over baseline in the EORTC QLQ-CIPN20 sensory subscale score at any follow-up assessment through week 24. A 2-step training/test approach was used to develop a TIPN risk prediction model. With a 60% random sample of evaluable patients, best subset selection identified a best model from among a set of demographic, baseline comorbid, and treatment factors. Model building was based on logistic regression using K-fold cross-validation to minimize predictive error, assessed using logistic model deviance and concordance (c-Statistic). From the best identified model, a risk model was built by summing adverse risk factors and creating high vs low- risk groups by splitting at the median. The derived model was tested in the remaining 40% of evaluable patients. The aim was to detect a 15% absolute difference in TIPN between high vs low-risk groups. **Results:** Among 1336 enrolled patients, N = 1278 were evaluable: median age 55.2 years (range 23-85), 98.6% female, 11.9% Black/4.6% Asian/12.0% other race/11.3% Hispanic/Latino, 90.2% with breast cancer. Paclitaxel was administered to 60.2% and docetaxel to 39.8%; 98.5% planned full dose of taxane. The rate of TIPN was 62.0%. In the training set of N = 768 patients, adverse risk factors were receipt of paclitaxel (vs docetaxel); stage 2/3 (vs 1) disease; planned duration of taxane > 12 weeks (vs <12 weeks); diabetes, autoimmune disease, or moderate kidney disease (>1 vs none); and self-identification as Black, Native American, Pacific Islander, multiple race, or Hispanic ethnicity (vs non-Hispanic White or Asian). Patients with >2 factors (high risk; n = 501, 65.2%), compared to patients with 0 or 1 factor (low risk; n = 267, 34.8%), were more likely to experience TIPN (70.9% vs 48.7%, $p < .001$). In the test set (n = 510), TIPN was more common in the high vs low-risk groups (68.3% vs 50.9%; OR = 2.08, 95% CI, 1.43-3.04, $p < .001$), exceeding the target difference of 15%. In all patients, TIPN proportions by quartile of risk score were 39.5% (Q1), 53.3% (Q2), 65.3% (Q3), and 76.3% (Q4), with a nearly 5-fold increased risk of TIPN for those in the highest vs lowest quartiles (Q4 vs Q1, OR = 4.93, 95% CI, 3.17-7.68, $p < .001$). **Conclusions:** A limited set of demographic, baseline comorbid, and treatment factors can be used to predict TIPN risk and may help guide treatment decision making. Future work to refine risk prediction using biomarkers is ongoing. **Funding:** NIH/NCI/NCORP grant UG1CA189974 Clinical trial information: NCT03939481. Research Sponsor: NIH/NCI/NCORP; UG1CA189974.

LBA12006 **Oral Abstract Session**

Primary outcomes of the enhanced, EHR-facilitated cancer symptom control (E2C2) cluster-randomized, stepped wedge, pragmatic trial.

Andrea L. Cheville, Deirdre R. Pachman, Kurt Kroenke, Jeph Herrin, Veronica Grzegorczyk, Sandra A. Mitchell, Joan M. Griffin, Jennifer Ridgeway, Jessica Austin, Ashley Wilder Smith, Linda L. Chlan, Cindy Tofthagen, Kathryn Jean Ruddy; Mayo Clinic Department of Pediatric and Adolescent Medicine, Rochester, MN; Mayo Clinic, Rochester, MN; Indiana University School of Medicine and Regenstrief Institute, Indianapolis, IN; Yale University School of Medicine, New Haven, CT; National Cancer Institute, Bethesda, MD; Mayo Clinic, Scottsdale, AZ; Mayo Clinic Florida, Jacksonville, FL

LBA12007 **Oral Abstract Session**

Results from a randomised, open-label trial of a multimodal intervention (exercise, nutrition and anti-inflammatory medication) plus standard care versus standard care alone to attenuate cachexia in patients with advanced cancer undergoing chemotherapy.

Tora S. Solheim, Barry J A Laird, Trude R. Balstad, Guro Birgitte Stene, Vickie Baracos, Asta Bye, Olav Dajani, Andrew Eugene Hendifar, Florian Strasser, Martin Robert Chasen, Matthew Maddocks, Melanie R. Simpson, Eva Skovlund, Gareth Owen Griffiths, Jonathan Hicks, Janet Shirley Graham, Fiona Kyle, Joanna Bowden, Marie T. Fallon, Stein Kaasa; Cancer Clinic, St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway, Department of clinical and molecular medicine, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, Trondheim, Norway; Clinical Surgery University of Edinburgh, Royal Infirmary of Edinburgh.St Columba's Hospice, Boswall Road. Clinical Surgery University of Edinburgh, Royal Infirmary of Edinburgh, Edinburgh, United Kingdom; Department of Clinical and Molecular Medicine, Faculty of Medicine and Health Sciences, NTNU–Norwegian University of Science and Technology, Trondheim, Norway; Faculty of Medicine and Health Science, Department of Neuromedicine and Movement Science, The Norwegian University of Science and Technology, Trondheim, Norway; Department of Oncology, University of Alberta, Edmonton, AB, Canada; European Palliative Care Research Centre (PRC), Department of Oncology, Oslo University Hospital, and Institute of Clinical Medicine, University of Oslo. Department of Nursing and Health Promotion, Faculty of Health Sciences, OsloMet–Oslo Metropolitan Uni, Oslo, Norway; European Palliative Care Research Centre (PRC), Department of Oncology, Oslo University Hospital, and Institute of Clinical Medicine, University of Oslo, Oslo, Norway; Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA; Clinic for Medical Oncology and Hematology, Cantonal Hospital of St. Gallen, St. Gallen, Switzerland; University of Bern,, Bern, Switzerland; McMaster University and University of Toronto, Toronto, ON, Canada; Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation, Kings College, London, United Kingdom; Department of Public Health and Nursing, Norwegian University of Science and Technology – NTNU, Trondheim, Norway; Department of Public Health and Nursing, Norwegian University of Science and Technolology – NTNU., Trondheim, Norway; Southampton Clinical Trials Unit, University of Southampton and University Hospital Southampton NHS Foundation Trust, Southampton, United Kingdom; Department of Clinical Oncology, Beatson West of Scotland Cancer Centre, Glasgow, United Kingdom; Dept of Medical Oncology, Beatson West of Scotland Cancer Centre and University of Glasgow, Glasgow, United Kingdom; St. Georges Hospital NHS Foundation Trust, London, United Kingdom; NHS Fife, Edinburgh, United Kingdom; University of Edinburgh Cancer Research UK Centre, MRC IGMM, Edinburgh, United Kingdom

The full, final text of this abstract will be available at meetings.asco.org on the day of presentation and in the online supplement to the June 10, 2024, issue of the *Journal of Clinical Oncology*.

12008 Oral Abstract Session

Walking dose required to achieve a clinically meaningful reduction in cancer-related fatigue among patients with breast cancer receiving chemotherapy: A URCC NCORP nationwide prospective cohort study.

Lindsey Jean Mattick, Po-Ju Lin, Karen Michelle Mustian, Luke Joseph Peppone, Umang Gada, Stephen Rajan Samuel, Viktor Clark, Sule Yilmaz, Jeremy McGuire, Alison Katherine Conlin, Lora Rose Weiselberg, Jerry W. Mitchell, Michelle Christine Janelsins; James P. Wilmot Cancer Center, University of Rochester Medical Center, Rochester, NY; University of Rochester Medical Center, Rochester, NY; University of Rochester School of Medicine & Dentistry, Rochester, NY; University of Rochester, Rochester, NY; Providence Cancer Institute, Portland, OR; Monter Cancer Center, Lake Success, NY; Foundation Medicine, Inc., Powell, OH

Background: Exercise is recommended by ASCO as a treatment for cancer-related fatigue (CRF) - one of the most pervasive toxicities patients with breast cancer experience. Current oncology guidelines recommend aerobic exercise (e.g., walking) at a weekly dose of 150 minutes of moderate intensity or 75 minutes of vigorous intensity. While these recommendations exist and are effective for treating CRF, patients with breast cancer struggle to achieve these levels of exercise, especially at a vigorous intensity during chemotherapy. The purpose of this study was to determine the doses of low and moderate intensity walking required to elicit a clinically meaningful reduction in CRF. **Methods:** As part of a nationwide prospective cohort study, 580 female breast cancer patients (stage I-IIIC; receiving chemotherapy) were recruited from 19 University of Rochester Cancer Center NCI Community Oncology Research Program (URCC NCORP) Research Base locations. CRF (Multidimensional Fatigue Symptom Inventory) and exercise dose (i.e., walking via ACLS Physical Activity Measure) were measured at pre-chemotherapy, 1-month post-chemotherapy, and 6-months post-chemotherapy. Exercise dose was measured in METs (energy expenditure normalized for body weight and time; 1 MET = 1 kcal/kg/hr) and converted into walking time (minutes) and intensity (mph). A low-intensity walking pace is $<$ 2.5mph ($<$ 3 METs), and a moderate-intensity walking pace is 2.6-4.5mph (3.1-6 METs). **Results:** Pre-chemotherapy, patients with breast cancer averaged walking 40-60 minutes/week at a low intensity or 20-38 minutes/week at a moderate intensity (median: 2.0 MET hrs/wk). Linear mixed modeling demonstrated a higher amount of walking significantly predicts lower CRF at all three time points (β: -0.26, SE: 0.08; $p < 0.001$). Logistic regression identified that patients who increase their walking by 111-162 minutes at a low-intensity pace or 54-108 minutes at a moderate-intensity pace (i.e., 1 SD) are 43% more likely to experience a clinically meaningful reduction in CRF (- 4.5 MFSI total) from pre-chemotherapy to 1-month post-chemotherapy (SD: 5.4 MET hrs/wk; OR: 1.43, 95% CI: 1.19-1.72; $p < 0.001$). **Conclusions:** Over the course of chemotherapy, patients with breast cancer who can increase their walking at a low intensity pace ($<$ 2.5 mph) up to 151-222 min/wk or at a moderate intensity pace (2.6-4.5 mph) up to 74-146 min/wk are 43% more likely to have clinically meaningful lower levels of CRF post-chemotherapy. Research Sponsor: National Cancer Institute; UG1CA189961; National Cancer Institute; T32CA102618; National Cancer Institute; R01CA231014.

12009 Clinical Science Symposium

Patterns of depressive symptoms among survivors of early-stage breast cancer (BC).

Antonio Di Meglio, Cécile Charles, Julie Havas, Martina Pagliuca, Pietro Lapidari, Gwenn Menvielle, Leonor Fasse, Diane Boinon, Aurelie Bardet, Alicia Larive, Anne-Laure Martin, Sibille Everhard, Christelle Jouannaud, Marion Fournier, William Jacot, Laurence Vanlemmens, Coureche Kaderbhai, Stefan Michiels, Maria Alice B Franzoi, Ines Vaz-Luis; Cancer Survivorship Program, INSERM 981, Gustave Roussy, Villejuif, France; Bordeaux Population Health, Bordeaux, France; Cancer Survivorship Group, INSERM Unit 981, Gustave Roussy, Villejuif, France; Department for the Organization of Patient Pathways, Gustave Roussy, Villejuif, France; Gustave Roussy Cancer Centre, Villejuif, France; Department of Biostatistics and Epidemiology, Gustave-Roussy Cancer Campus, Paris-Saclay and Paris-Sud Universities, Villejuif, France; Unicancer, Le Kremlin-Bicêtre, France; Jean Godinot Cancer Institute, Reims, France; Institut Bergonie, Bordeaux, France; Institut du Cancer de Montpellier, Université de Montpellier, Montpellier, France; Centre Oscar Lambret, Lille, France; Georges François Leclerc Comprehensive Cancer Care Centre, Dijon, France; Oncostat, CESP, Inserm U1018, University Paris-Saclay, labeled Ligue Contre le Cancer, Gustave Roussy, Villejuif, France; Cancer Survivorship Program, INSERM Unit 981, Gustave Roussy, Villejuif, France

Background: Depressive symptoms are associated with impaired quality of life and increased mortality among survivors of BC. We aimed to identify long-term patterns of depressive symptoms and their determinants, including potential interventional targets. **Methods:** Patients with stage I-III BC were included from CANTO (NCT01993498). Depressive symptoms were assessed by HADS (range 0-21) at diagnosis (pre-treatment [tx]) and year (Y)1, 2, 4, and 6. Group-based trajectory modeling and multinomial logistic regression identified latent groups at similar patterns of depressive symptoms and group membership determinants, respectively. Cox regression evaluated associations with clinically suggestive post-tx symptoms (HADS ≥11). **Results:** Among 9087 patients, we identified five patterns of depressive symptoms. Two groups, either at very low (23%) or low burden (45%), had flat patterns that almost never met the threshold for clinically suggestive symptoms (highest mean score [95% CI]: 1.4 [1.2-1.6] and 3.9 [3.5-4.3] at Y6, respectively). A stable group (6%) reported high symptom burden at diagnosis with some further post-tx deterioration (11.1 [10.7-11.6] at Y6). Two groups had changing patterns with the sharpest slope during primary tx: a remission group (7%) reported overtime improvements (baseline to Y6: 9.8 [9.4-10.2] to 5.1 [4.4-5.7]), whereas a worsening group (20%) showed consistent deterioration (5.1 [4.8-5.5] to 8.0 [7.7-8.3]). Older patients (adjusted Odds Ratio [95%CI] per 10 years, 1.09 [1.01-1.18]), those with previous psychiatric morbidity (v no, 1.75 [1.34-2.27]), obesity (v normal, 2.58 [2.02-3.29]), and income <1500 Eur/month (v ≥3000, 1.49 [1.22-1.81]) were more likely to belong to the worsening group than to the very low burden group. The worsening group also reported larger post-tx life interference, worry, and negative impact on employment and relationships. Table reports rates of clinically suggestive symptoms over time. Weight gain >5% (adjusted Hazard Ratio v stable, 1.32 [1.08-1.61]), reduced physical activity (v maintained, 1.31 [1.04-1.65]), increased alcohol use (v decreased, 3.70 [1.91-7.20]), worsened fatigue (v stable, 2.01 [1.61-2.51]), cognitive dysfunction (v stable, 1.98 [1.57-2.48]) and body image dissatisfaction (v no, 1.69 [1.33-2.15]) during primary tx (between diagnosis and Y1) were associated with clinically suggestive post-tx symptoms. **Conclusions:** Early screening and proactive follow-up are crucial to intercept psychological vulnerability. Trials of risk reduction interventions targeting pattern determinants since diagnosis and mitigating the psychological impact of cancer and health risk behaviors during primary tx seem warranted. Research Sponsor: French National Cancer Institute (INCa); National Research Agency; ANR-10-COHO-0004 (CANTO); National Research Agency; ANR-18-IBHU-0002 (PRISM).

% Reporting clinically suggestive depressive symptoms by pattern and time point.

	Very Low Burden	Low Burden	Remission	Worsening Symptoms	Stable Symptoms
Diagnosis	0	<1	48	<1	54
Y1	0	<1	4	12	64
Y2	0	<1	<1	16	64
Y4	0	<1	3	18	59
Y6	0	<1	0	15	57

Patient and caregiver experience with the hope and prognostic uncertainty of immunotherapy: A qualitative study.

Mary Catherine Boulanger, Ayo Samuel Falade, Kelly Hsu, Robert Sommer, Ashley Zhou, Roshni Sarathy, Lara Traeger, Joseph A. Greer, Jennifer Temel, Laura A Petrillo; Massachusetts General Hospital, Boston, MA; Massachusetts General Brigham Salem Hospital, Salem, MA; University of Miami, Boston, MA

Background: Immunotherapy has revolutionized treatment for advanced melanoma and non-small cell lung cancer (NSCLC), dramatically improving survival. Yet, given that immunotherapy responses can vary widely, this new paradigm introduces challenges in prognostic communication between patients and oncology clinicians. In this study, we sought to explore how patients and caregivers learned about immunotherapy and their understanding of what to expect. **Methods:** We conducted a qualitative study including adults with advanced melanoma or metastatic NSCLC who were receiving oncology care at an academic medical center. We included patients with stage III or IV melanoma or stage IV NSCLC within 12 weeks of initiating immunotherapy or 12 months of discontinuing immunotherapy, as well as caregivers. Clinical and demographic data were collected in patient surveys and extracted from the electronic health record. We conducted in-depth interviews with patients and caregivers using a semi-structured interview guide with questions about how patients learned about immunotherapy from their clinicians and experienced the treatment. We used an adapted framework approach to analyze interview transcripts and synthesized concepts into themes. **Results:** 42 patients and 9 caregivers participated in this study. Patients' median age was 67, and most were male (62%), white (86%), married (55%), and had melanoma (62%). We identified four themes: (1) Patients' high expectations of immunotherapy were set by the oncology team (*"When I first found out I had melanoma, I thought it was a death sentence. I was very excited to find out that there were actually options and the potential for a cure."*); (2) Patients who did not have long-term responses experienced overwhelming disappointment ("*I went into the immunotherapy knowing this was going to save my life. And it's not."*); (3) Prognostic uncertainty particularly affected patients whose treatment was held or discontinued due to toxicity or progressive disease ("*I put everything on hold because there's no point in starting down any path because it's too uncertain."*); (4) Some patients and caregivers had conflicting preferences for receiving information ("*She [patient] and I [caregiver] process information totally differently. I try to be really respectful of what she needs, but I want more information."*). Patients and caregivers provided recommendations for educational resources and highlighted their unmet psychosocial needs. **Conclusions:** Patients and caregivers have optimistic expectations when initiating immunotherapy, which results in heightened disappointment among the subset with progression or toxicity. We identified that clinicians should elicit the information preferences of both patients and caregivers as these may be disparate. Our results point to the need to optimize prognostic communication and support for patients initiating immunotherapy. Research Sponsor: None.

Hope drives quality of life in patients with brain metastases, but the hope center remains elusive: An analysis of NRG-CC003.

Benjamin W. Corn, Rebecca Paulus, Vinai Gondi, Minesh P. Mehta, Shannon E. Fogh, Jeffrey Scott Wefel, Gregory M.M. Videtic, Alexander Sun, Harold Yoon, John H Heinzerling, Ronald C McGarry, Vijayananda Kundapur, Kiran Devisetty, Abraham Jing-Ching Wu, Andrew A Kanner, Stephanie L. Pugh, Benjamin Movsas, Lisa A. Kachnic; Sharei Zedek Hospital, Kesariya, Israel; NRG Oncology Statistics and Data Management Center, Philadelphia, PA; Northwestern Medicine Cancer Center Warrenville and Northwestern Medicine Proton Center, Warenville, IL; Baptist Health South Florida, Miami, FL; University of California, San Francisco, San Francisco, CA; The University of Texas MD Anderson Cancer Center, Houston, TX; Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH; Princess Margaret Hospital, Toronto, ON, Canada; Heartland NCORP, Cancer Care Specialists of Illinois, Decatur, IL; Levine Cancer Institute/Carolinas Medical Center, Charlotte, NC; The University of Kentucky Comprehensive Cancer Center, Lexington, KY; Saskatoon Cancer Center, Saskatchewan Cancer Agency, University of Saskatchewan, Saskatoon, SK, Canada; Wayne State University - Karmanos Cancer Institute, Detroit, MI; Memorial Sloan Kettering Cancer Center, New York, NY; Rabin Medical Center, Petah Tikva, Israel; Henry Ford Health System, Detroit, MI; Columbia University Herbert Irving Comprehensive Cancer Center, New York, NY

Background: NRG-CC003, a phase II/III study, randomized 393 patients with small cell lung cancer to prophylactic cranial irradiation (PCI) with or without Hippocampal Avoidance (HA). "Hopefulness" is a cognitive construct based on 3 components: goals; pathways to reach those goals; and agency (i.e., motivation to embark on the pathway). Hope can be measured with validated instruments. Since hope is cognitive in nature, the existence of a "hope center" in the brain – most likely in the hippocampus – has been hypothesized. One exploratory objective of NRG-CC003 posited that if hope levels (measured pre- and post-PCI) were better maintained in patients randomized to PCI+HA (in comparison to patients treated by PCI without hippocampal protection), then the hippocampus would, indeed, be implicated as part of the mechanism of hopefulness. **Methods:** In both arms, PCI consisted of 10 fractions of 2.5 Gy. The Adult Hope Scale (AHS) was administered at time-zero and at 6-months. With regard to patient reported outcome (PRO) measures, the EORTC QLQ-C30 was administered at baseline and then at 3, 6-, 12-, 18- and 24-month intervals. Comparisons of AHS scores by arm were made using Wilcoxon-Mann-Whitney tests, and correlation of AHS with EORTC QLQ-C30 by Pearson correlation coefficients. **Results:** Approximately 95% of patients completed the AHS at baseline and 67% filled out the questionnaire at 6-months which paralleled the completion rates of the conventional tools for QOL and neurocognition that were employed in the study. When comparing hope levels (change from baseline to 6 months) there was no significant difference ($p > 0.05$) between the two arms of the trial (PCI vs PCI + HA). There was a significant correlation for the components of hopefulness with QOL; specifically, between change in agency score and QLQ-C30 global health status ($p < 0.0001$) as well as between change in pathways score and QLQ-C30 global health status ($p = 0.022$). **Conclusions:** It is feasible to study hopefulness in the context of prospective trials conducted within the NCTN. The hippocampus could not be implicated as a critical structure in a central pathway that coordinates hopefulness. Whether these data categorically refute the "hope-hippocampal hypothesis" will be discussed vis-à-vis several caveats (e.g., selection of AHS; presence of sufficient cognitive reserve post-irradiation; adequacy of the dose-delta between the 2 arms to cause differential levels of damage to the purported hope center). For the first time, a validated tool prospectively established a relationship between hope and quality of life among patients with cancer. Given previous NRG studies correlating QOL with oncologic endpoints (e.g., local control and survival), modelling will be carried out to determine if hope mediates, results from, or is associated with these endpoints. Clinical trial information: NCT02635009. Research Sponsor: None.

Prospective and external validation of an objective performance status (OPS) in patients with metastatic solid malignancies using wearable accelerometry.

Christopher Manz, Eva Ruiz-Hispán, Tatiana Hernandez Guerrero, Bernard Doger de Spéville Uribe, Daniel Morillo, Ignacio Mahillo, Jesus Garcia-Foncillas, William J. Ferrell, Ian J Barnett, Emily R Schriver, Ravi Bharat Parikh, Victor Moreno; Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, MA; University Hospital Fundacion Jimenez Diaz, Madrid, Spain; START Madrid Fundacion Jimenez Diaz, Madrid, Spain; START Madrid - Hospital Universitario Fundación Jiménez Díaz, Madrid, Spain; Hospital Universitario Fundación Jiménez Díaz, Madrid, Spain; Department of Statistics, Instituto de Investigación Sanitaria-Fundación Jiménez Díaz University Hospital, Madrid, Spain; University of Pennsylvania, Philadelphia, PA; Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; Medical Oncology, START Madrid-FJD, University Hospital Fundación Jiménez Diaz, Madrid, Spain

Background: Performance status (PS) assessment is critical for clinical trial eligibility assessment and treatment selection. However, PS is based on the subjective impression of the clinician and is often inaccurate. Wearable accelerometers may allow clinicians to more objectively assess PS. In this analysis of 2 separate prospective studies, we define and externally validate an "Objective Performance Status" (OPS) by measuring the association between daily physical activity and overall survival among patients with metastatic cancer. **Methods:** We first measured daily physical activity (in step counts) using a wearable accelerometer over a prescreening period (median 14 d, range 3-28 d) in a Spanish observational prospective study (PIC123-18_FJD) embedded during the screening period for a phase 1 clinical trial in patients with locally advanced unresectable or metastatic solid and hematological malignancies. A multivariable Cox proportional hazards model was used to derive an OPS by measuring associations between mean daily steps with overall survival (OS), adjusting for patient demographics. We subsequently externally validated this OPS cutoff in a separate prospective cohort of patients with metastatic non-small cell lung and gastrointestinal cancers who wore a wearable accelerometer continuously for 6 months enrolled in a randomized trial of proactive symptom monitoring at a large academic center in the United States (**NCT04616768) Results:** Full data was available for 123 patients (70 in OPS derivation cohort; 53 external validation cohort). The cut-off selected to define the OPS was determined by univariate survival analysis to be mean daily step count = 1200 meterswith poor OPS ($\leq$1200 m/day, of whom 46% had clinician-recorded ECOG $\geq$1) had greater mortality than patients with good OPS ($>$1200 m/day, 85% with ECOG 0) (3.2 vs. 11.2 mos median OS, adjusted hazard ratio 5.76, 95% CI 2.98-11.1, p$\leq$0.001). In the external validation cohort, poor OPS strongly predicted mortality compared to good OPS (unadjusted HR 5.22, 95% CI 1.24-21.88, p = 0.02) and was a better predictor of mortality than clinician- (HR = 1.00, 95% CI 0.24-4.17, p = 1.0) or patient-reported ECOG (HR = 1.16, 95% CI 0.14-9.45, p = 0.89). **Conclusions:** The OPS is an independent, externally validated prognostic factor for survival and could serve as an objective surrogate for traditional methods of PS assessment in clinical trials and choice of therapy. Clinical trial information: NCT04616768 (external validation trial). Research Sponsor: Institute for Translational Medicine and Therapeutics; National Cancer Institute; K08CA263541; IT department, Hospital Universitario Fundación Jiménez Díaz, Madrid, Spain.

Concordance between OPS and clinician-reported ECOG.

		ECOG = 0	ECOG≥1	Kappa (95%CI)
Spanish trial	Distance (meters)			
	≥1200	36 (85.7%)	15 (53.6%)	0.34 (0.12-0.56)
	< 1200	6 (14.3%)	13 (46.4%)	
External validation trial	Distance (meters)			
	≥1200	17 (85.0%)	22 (33.3%)	0.15 (-0.04-0.35)
	< 1200	3 (15.0%)	11 (66.7%)	

12013 Rapid Oral Abstract Session

Effect of nurse-led multi-disciplinary treatment on patients with head and neck tumors: A randomized controlled trial.

Jingjing Wang, Lei Cai, Yiyan Pei, Juejin Li, Zhigong Wei, Ruidan Li, Yonglin Su, Xiaolin Hu, Xingchen Peng; Department of Biotherapy, Cancer Center, West China Hospital, Sichuan University, Chengdu, China; Institute of Hepatopancreatobiliary Surgery, Chongqing General Hospital, Chongqing University, Chongqing, Chongqing, China; West China School of Nursing, Sichuan University/Department of Nursing, West China Hospital, Sichuan University, Chengdu, China; Department of Rehabilitation, West China Hospital, Sichuan University, Chengdu, China

Background: Patients undergoing radiotherapy (RT) for head and neck tumors are prone to experiencing nutritional and psychological issues as a result of adverse events to the treatment, which may ultimately lead to radiotherapy interruption (RTI). We conducted a prospective, randomized controlled trial to assess the effect of nurse-led multi-disciplinary treatment (MDT) interventions, incorporating psychological and nutritional interventions, on RTI rates and quality of life (QoL) among patients undergoing RT for head and neck tumors. **Methods:** Patients with head and neck cancer undergoing RT at West China Hospital, Sichuan University were enrolled. Eligible patients were randomly assigned in a 1:1 ratio to receive either the standard oncology care (standard group) or the nurse-led, whole-course MDT care (MDT group). The MDT care included nutritional and psychological interventions provided by a team of a radiotherapist, an oncology specialty nurse, a dietitian, a psychotherapist and a rehabilitation therapist. The primary end point was RTI rate in the per-protocol set (PPS). Patients' QoL was assessed using the EORTC QLQ-C30 and EORTC QLQ-H&N35 questionnaires. Nutritional status was assessed using NRS 2002 and PG-SGA, and psychological status was assessed using DT, PHQ-9 and HADS. **Results:** A total of 233 patients were enrolled in the study. At the final follow-up, 112 patients in the standard group and 114 patients in the MDT group completed all follow-up assessments. The RTI rate in the MDT group was significantly lower than that in the standard group (MDT vs. standard: 11.4% vs. 25.9%, P= 0.005). Differences in QoL among patients favored MDT care over standard care, particularly in emotional function, GHS, fatigue, and insomnia. Baseline patients' nutritional and psychological status were similar between two groups. From mid-RT to 6 months after RT, the nutritional and psychological status of patients in the MDT group improved at certain follow-up points compared with the control group. The rehospitalization rate in the MDT group was significantly lower than that of control group (MDT vs. standard: 7.9% vs. 18.8%, P= 0.016). **Conclusions:** Nurse-led MDT interventions effectively reduces RTI, improves nutritional status of patients, and alleviates their psychological burden, making it a worthy approach for dissemination in developing countries. Clinical trial information: NCT05828004. Research Sponsor: None.

LBA12014 **Rapid Oral Abstract Session**

Preventive effect of naldemedine for opioid-induced constipation in patients with cancer starting opioids: A multicenter, double-blinded, randomized, placebo-controlled, phase 3 trial.

Jun Hamano, Takahiro Higashibata, Takaomi Kessoku, Shinya Kajiura, Mami Hirakawa, Keisuke Ariyoshi, Shunsuke Oyamada; Department of Palliative and Supportive Care, Institute of Medicine, University of Tsukuba, Tsukuba, Ibaraki, Japan; University of Tsukuba Hospital, Tsukuba, Japan; International University of Health and Welfare Narita Hospital, Narita, Japan; Third Department of Internal Medicine, University of Toyama, Toyama, Toyama-ken, Japan; St. Marianna University School of Medicine, Kawasaki, Japan; Department of Data Management, Japanese Organisation for Research and Treatment of Cancer (JORTC) Data Center, Tokyo, Japan; Department of Biostatistics, Japanese Organisation for Research and Treatment of Cancer (JORTC) Data Center, Tokyo, Japan

12015 Rapid Oral Abstract Session

The influence of yoga and cognitive behavioral therapy on mediational relationships between insomnia and cancer-related fatigue: A URCC NCORP RCT in 550 cancer survivors.

Po-Ju Lin, Brian James Altman, Richard Francis Dunne, Lindsey Jean Mattick, Alisha Chakrabarti, Stephen Rajan Samuel, Umang Gada, Eva Culakova, Anthony John Jaslowski, Charles S. Kuzma, Karen Michelle Mustian; James P. Wilmot Cancer Center, University of Rochester Medical Center, Rochester, NY; University of Rochester Medical Center, Rochester, NY; Cancer Research of Wisconsin and Northern Michigan Consortium (CROWN), Green Bay, WI; Southeast Clinical Oncology Research Consortium (SCOR), Winston-Salem, NC

Background: Cancer-related fatigue (CRF) often co-occurs with insomnia and both are incapacitating adverse toxicities of cancer and its treatment which may persist months and years after the completion of treatment. Yoga and Cognitive Behavioral Therapy for Insomnia (CBT-I) are promising behavioral approaches for improving CRF and insomnia among cancer survivors. However, the influence of changes in insomnia resulting from participating in yoga or CBT-I on the subsequent changes in CRF is not fully understood. **Methods:** We conducted mediation analyses on data collected from a multicenter phase III RCT among cancer survivors who were randomized to receive 1) Yoga for Cancer Survivors (YOCAS, 75-min./session, 2x/wk. for 4 wks.), 2) CBT-I (90-min./session, 1x/wk. for 8 wks.), or 3) a behavioral placebo (ASCO recommended Survivorship Education, 75-min/session, 2x/wk. for 4 wks.). Brief Fatigue Inventory and Insomnia Severity Index were used to assess CRF and insomnia, respectively, at pre-, mid-, and post-intervention. Causal mediation analyses were conducted to estimate the influence of changes in insomnia at mid-intervention resulting from participating in YOCAS, CBT-I, or behavioral placebo on subsequent changes in CRF at post-intervention. **Results:** 550 survivors (93% female; mean age 57 years; 75% were breast cancer survivors) completed baseline and post-intervention assessments. YOCAS, compared to placebo, significantly improved CRF and insomnia at mid-intervention (CRF: -0.38 ± 0.16, $p = 0.01$; Insomnia: -1.15 ± 0.35, $p < 0.01$) and post-intervention (CRF: -0.35 ± 0.17, $p = 0.03$; Insomnia: -1.43 ± 0.41, $p < 0.01$). Among YOCAS participants, improvement in insomnia at mid-intervention significantly influenced the subsequent reduction in CRF (-0.14 ± 0.06, $p = 0.01$) and accounted for 37% (95% CI: 0% - 78%) of the total reduction in CRF at post-intervention. CBT-I, compared to placebo, also significantly improved CRF and insomnia at mid- (CRF: -0.32 ± 0.18, $p = 0.06$; Insomnia: -2.64 ± 0.40, $p < 0.01$) and post-intervention (CRF: -0.59 ± 0.18, $p < 0.01$; Insomnia: -4.95 ± 0.46, $p < 0.01$). Among CBT-I participants, the improvement in insomnia at mid-intervention significantly influenced the subsequent reduction in CRF (-0.40 ± 0.09, $p < 0.01$) and accounted for 60% (95% CI: 21% - 99%) of the total reduction in CRF at post-intervention. **Conclusions:** Both YOCAS and CBT-I effectively improve CRF and insomnia among survivors. 37%-60% of the reduction in CRF resulting from participating in YOCAS or CBT-I is due to improvement in insomnia. Clinicians should consider prescribing YOCAS yoga or CBT-I for survivors who experience CRF and insomnia. Clinical trial information: NCT02613364. Research Sponsor: National Cancer Institute; UG1CA189961, T32CA102618.

12016 Rapid Oral Abstract Session

Identifying optimized assessment of nerve damage during chemotherapy.

Tiffany Li, Hannah C Timmins, Fawaz Mayez Mahfouz, David Mizrahi, Lisa Horvath, Michelle L. Harrison, Peter S. Grimison, Michael Friedlander, Gavin M. Marx, Frances M. Boyle, David Wyld, Robert Henderson, Tracy King, Sally E. Baron-Hay, Matthew C Kiernan, Claudia Rutherford, David Goldstein, Susanna B Park; The University of Sydney, Sydney, NSW, Australia; Chris O'Brien Lifehouse, Camperdown, Australia; Chris O'Brien Lifehouse, Sydney, NSW, Australia; Chris O'Brien Lifehouse, Sydney, NSW, Australia; Prince of Wales Hospital, Randwick, NSW, Australia; Northern Hematology and Oncology Group, Wahroonga, NSW, Australia; The Mater Hospital, North Sydney, NSW, Australia; University of Queensland, Brisbane, QLD, Australia; Royal Brisbane & Women's Hospital, Brisbane, QLD, Australia; Royal Prince Alfred Hospital, Sydney, NSW, Australia; Royal North Shore Hospital, St Leonards, NSW, Australia; Department of Medical Oncology, Sydney, NSW, Australia

Background: Chemotherapy-induced peripheral neurotoxicity (CIPN) is a significant and persisting toxicity of anticancer treatments, impacting dose delivery and quality of life. There is a lack of consensus on the optimal method of CIPN assessment in clinical settings. This study compared the validity and responsiveness of patient reported outcome measures (PROMs) against neurological, neurophysiological and sensory assessment approaches of CIPN. **Methods:** A multi-centre dual study design evaluated patients treated with neurotoxic chemotherapy across two cohorts: patients commencing treatment assessed prospectively and patients who completed treatment assessed cross-sectionally. CIPN was assessed via PROMs (EORTC-CIPN20, FACT/GOG-Ntx, PRO-CTCAE), neurological and neurophysiological assessment (Total Neuropathy Score, sural and tibial compound nerve amplitudes) and sensory functional measures (Grating orientation, Von Frey monofilament and 2-Point discrimination tasks). Convergent and known-groups validity were assessed cross-sectionally following treatment completion and responsiveness was evaluated prospectively during treatment. Neurological, neurophysiological, and sensory outcome measure scores were compared between high and low CIPN symptom reporters. **Results:** A total of 1,033 patients were recruited, incorporating 1,623 assessments. PROMs demonstrated superior ability to identify CIPN (convergent validity; α = 0.75-0.85, all $P < 0.001$), to discriminate between CIPN severity (known-groups validity; all $P < 0.001$) and to detect changes in CIPN development (responsiveness; Cohen's d = 0.65-0.83) compared to neurological, neurophysiological and sensory assessment approaches. These other measures did not achieve threshold for convergent validity ($\alpha < 0.7$). and did not demonstrate acceptable responsiveness (Cohen's $d < 0.5$). Neurological, neurophysiological, and sensory outcome measures were significantly impaired in patients who were high CIPN symptom reporters compared to low (all $P < 0.05$). **Conclusions:** PROMs represent a valid method of CIPN assessment, with preferential measurement properties over other approaches to assessing neuropathy. Adoption of PROMs in clinical practice will allow for accurate representation and early recognition of CIPN, leading to reduced long term morbidity in this key long-term toxicity in cancer survivors. Research Sponsor: National Health and Medical Research Council (NHMRC); Cancer Institute NSW.

12017 Rapid Oral Abstract Session

Technology-enhanced palliative care for patients with advanced cancer undergoing phase I therapies: A pilot randomized clinical trial (RCT).

David Hui, Ishwaria M. Subbiah, David S. Hong, Jennifer Ellefson, Josue Becerra, Vera J De la Cruz, Diana L. Urbauer, Sanjay Shete, Eduardo Bruera; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: Outpatient palliative care (PC) has been found to improve quality of life (QOL). It is not known if more frequent symptom monitoring and PC nursing contacts between clinic visits would offer additional benefits. We conducted a pilot RCT to examine the effect of a specialist PC referral with and without technology-enhancement (TEC) on symptoms in patients undergoing Phase I cancer therapies. **Methods:** This single-center parallel group RCT enrolled adult patients with advanced solid tumors prior to starting Phase I therapies and at least 1 Edmonton Symptom Assessment Scale (ESAS) symptom ≥4/10 and ESAS Global Distress Score (GDS) ≥20/90. Patients were randomized to PC alone or PC + TEC in a 1:1 ratio. Over the 12 w period, the PC group had in person or virtual outpatient visits with a PC physician, nurse, and as needed psychotherapist every 4 weeks; the PC + TEC group also received weekly symptom monitoring with ESAS electronically and weekly nursing phone call. The primary outcome was within-group change of GDS from baseline to 2 w; secondary outcomes included change in GDS over 4, 8, and 12 w, and change in QOL (FACIT-Sp) over 2, 4, 8 and 12 w. We estimated that a sample size of 50 patients per group would provide 90% power to detect a within-group GDS difference of 6 units with a 2-sided α of 2.5% and 20% attrition. **Results:** Between 12/15/2020 and 12/21/2022, 115 patients were enrolled and 101 were randomized (PC + TEC n = 57, PC n = 44). By 2 w, PC + TEC showed a significant within-group improvement in GDS (mean change -5 [95% CI -8.9, -1.2]; *P*= 0.01) but not PC alone (Table). PC+TEC group also had a significant improvement in GDS at 8 w and 12 w and in FACIT-SP at 2 w, 8 w and 12 w. PC alone group had a significant within-group improvement in GDS at 4 w and 12 w but no significant differences in QOL were detected. This study was not powered for between group comparison; however, FACIT-SP at 12 w was significantly higher in PC+TEC vs. PC alone (Table; mean difference 13.9; *P*= 0.02). **Conclusions:** Higher intensity of PC with closer monitoring showed within-group improvement in symptoms and QOL, while PC alone had some symptom reduction but no QOL improvement. Further studies are needed to confirm the QOL benefit of PC + TEC over PC alone. Clinical trial information: NCT04989556. Research Sponsor: American Cancer Society; CSDG-19-153-01; Andrew Sabin Family Foundation.

Change in outcomes.

Outcome	PC Mean Δ (95% CI); *P*	PC + TEC Mean Δ (95% CI); *P*	PC + TEC v. PC Mean Difference (95% CI)
GDS			
2 w	-2 (-5.8, 1.8); 0.29	-5 (-8.9, -1.2); 0.01	-3 (-8.5, 2.4)
4 w	-5.7 (-11.2, -0.2); 0.04	-3 (-7.3, 1.2); 0.16	2.6 (-4, 9.3)
8 w	-5.7 (-13, 1.6); 0.12	-8.1 (-14, -2.1); 0.009	-2.3 (-11.5, 6.8)
12 w	-8.6 (-15.3, -1.8); 0.02	-10.2 (-17.5, -2.9); 0.008	-1.6 (-12.2, 9)
FACIT-SP			
2 w	-2.1 (-8.4, 4.2); 0.50	5.6 (1.2, 10); 0.01	1.2 (-9.9, 12.4)
4 w	-0.3 (-8.4, 7.8); 0.94	3.1 (-1.4, 7.5); 0.17	3.4 (-5.3, 12)
8 w	-0.5 (-9.7, 8.7); 0.92	7.4 (0.3, 14.5); 0.04	7.9 (-3.1, 18.9)
12 w	-7.1 (-19.5, 5.3); 0.22	6.7 (0.9, 12.6); 0.03	13.9 (2.6, 25.1)

Targeting exercise and sedentary behavior for the prevention of allogeneic stem cell transplant-related cardiovascular dysfunction: The ALLO-Active trial.

Hayley T. Dillon, Erin Howden, Nicholas J. Saner, Tegan Ilsley, David S. Kliman, Stephen J. Foulkes, Christian J. Brakenridge, Andrew Spencer, Sharon J. Avery, Piet Claus, David W. Dunstan, Robin M. Daly, Steve F. Fraser, Neville Owen, Brigid M. Lynch, Bronwyn A. Kingwell, Andre La Gerche; Baker Heart and Diabetes Institute, Melbourne, VIC, Australia; Baker Heart & Diabetes Institute, Melbourne, VIC, Australia; Department of Haematology, Royal North Shore Hospital, Sydney, NSW, Australia; Baker Heart & Diabetes Institute, Alberta, VIC, Australia; Malignant Haematology and Stem Cell Transplantation Service, Alfred Health-Monash University, Melbourne, VIC, Australia; Malignant Haematology and Stem Cell Transplantation Service, Alfred Hospital, Melbourne, VIC, Australia; Katholieke Universiteit Leuven, Leuven, Leuven, Belgium; Deakin University, Melbourne, VIC, Australia; Deakin University, Burwood, VIC, Australia; Cancer Council Victoria, Melbourne, VIC, Australia; CSL Ltd, Melbourne, VIC, Australia

Targeting Exercise and Sedentary Behavior to Prevent Allogeneic Stem Cell Transplant-Related Cardiovascular Dysfunction: The ALLO-Active Trial **Background:** Allogeneic stem cell transplantation (allo-SCT) is a potentially life-saving therapy for hematological malignancy, however, quality of life and longevity post allo-SCT are hampered by exercise intolerance, cardiac dysfunction, and cardiovascular mortality. This randomized controlled trial evaluated the efficacy of a novel multi-component activity program on cardiorespiratory fitness (peak oxygen uptake [VO_{2peak}]) and cardiac function in adults undergoing allo-SCT. **Methods:** Sixty-two hematological malignancy patients scheduled for allo-SCT were randomized to a 4-month multi-component *Activity* program (n = 30) designed to increase aerobic and resistance exercise (3-day.week^{-1}) and reduce sedentary time ($\geq$30-min.day^{-1}), or to usual care (*UC*, n = 32). The *Activity* program was delivered over two distinct phases: *'Inpatient'*, which commenced upon admission for allo-SCT and continued until discharge (~4 weeks), and *'Outpatient'*,which commenced at discharge and continued for 12-weeks. Physiological assessments were conducted pre-admission, and 12-weeks post-discharge (4-months from baseline) and included: (1) cardiopulmonary exercise testing to quantify VO_{2peak}, (2) exercise cardiac magnetic resonance imaging to determine peak cardiac output and stroke volume index (COI_{peak} and SVI_{peak}), (3) standard of care resting echocardiography-derived left ventricular ejection fraction and global longitudinal strain, and (4) cardiac biochemistry (troponin, B-type natriuretic peptide). **Results:** Fifty-two patients (84%) completed follow-up (25 *Activity*; 27 *UC*), and median (IQR) intervention adherence was 73% (50-81). *Activity* preserved VO_{2peak} (-0.9ml.kg^{-1}.min^{-1} [95%CI -2.5, 0.8]) which showed a marked decline with *UC* (-3.4ml.kg^{-1}.min^{-1} [95%CI -4.9, -1.8]; interaction, p= 0.029). *Activity* also showed significant benefits on exercise cardiac function, as shown by a preservation of COI_{peak} (0.30L.min^{-1}.m^2, [95%CI -0.34, 0.41]) and SVI_{peak} (0.6ml.m^2 [95%CI -1.3, 2.5]), both of which declined with *UC* (COI_{peak}: -0.68L.min^{-1}.m^2, [95%CI -1.3, -0.32]; interaction, p= 0.008; SVI_{peak}: -2.7ml.m^2 [95%CI -4.6, -0.9], interaction, p =0.014). There were no treatment effects of *Activity* on cardiac injury biomarkers or global longitudinal strain and no changes in left ventricular ejection fraction in either group. **Conclusions:** Intervening early in the allo-SCT process with an exercise and sedentary behavior intervention can have significant benefits for the preservation of patient's cardiovascular reserve capacity. Our results may have important long-term implications for cardiovascular disease incidence and mortality in allo-SCT recipients. Clinical trial information: ANZCTR12619000741189. Research Sponsor: Wereld kanker Onderzoek Fonds (WKOF); 2019_1666.

12019 Rapid Oral Abstract Session

Patient reported symptoms after cancer diagnosis and the risk of short- and long-term severe mental health events among adolescents and young adults (AYA): A population-based study.

Sumit Gupta, Qing Li, Rinku Sutradhar, Natalie G. Coburn; Division of Haematology/Oncology, The Hospital for Sick Children, Toronto, ON, Canada; ICES, Toronto, ON, Canada; Institute for Clinical Evaluative Science, Toronto, ON, Canada; Sunnybrook Health Sciences Centre, Toronto, ON, Canada

Background: AYA with cancer are a vulnerable sub-population at risk of adverse mental health outcomes during and after cancer treatment. Tools to identify AYA at highest risk are required to guide screening and interventions. In a population-based cohort of AYA with cancer, we determined whether self-reported symptoms were associated with subsequent short- and long-term severe mental health events (SMHE). **Methods:** All Ontario, Canada AYA diagnosed with cancer aged 15-29 between 2010-2018 were identified and linked to healthcare databases, including one capturing self-reported Edmonton Symptom Assessment System (ESAS) scores at cancer-related visits. Scores for depression, anxiety, and poor well-being were categorized as not measured, mild (0-3), moderate (4-6), or severe (7-9). SMHE were defined as emergency room visits or hospitalizations for mental health reasons. First, we used Cox proportional hazard models to determine the association of ESAS scores (time-varying variable) with subsequent SMHE. Second, among 5-year survivors, we determined the association of maximum ESAS score within the first year of diagnosis with long-term SMHE (i.e. starting at 5 years from cancer diagnosis). All analyses were adjusted for patient and disease variables, including mental healthcare use prior to cancer diagnosis. **Results:** 5,435 AYA met inclusion criteria. Median age at cancer diagnosis was 25 years [interquartile range 22-27]. Hematologic cancers were most common (1,748; 32.2%). Symptom severity was associated with subsequent SMHE risk. For example, AYA reporting severe anxiety were at more than three-fold higher risk of SMHE compared to those reporting mild anxiety [adjusted hazard ratio (aHR) 3.6, 95th confidence interval (CI) 1.9-6.7; $p < 0.001$]. Similar risk was seen among AYA reporting severe vs. mild depression (aHR 3.5, 1.7-7.3; $p < 0.001$). Among 3,518 (64.7%) 5-year survivors, symptom severity also predicted long-term SMHE. For example, starting at 5 years post cancer diagnosis, the subsequent 3-year cumulative incidence of a SMHE among those who reported severe depression at any time during the first year post cancer diagnosis was 10.5% (95CI 6.9-15.9) compared to 2.4% (95CI 1.7-3.3) among those who only reported mild depression (aHR 3.0, 95CI 1.8-4.9; $p < 0.0001$). Similar results were seen pertaining to severe anxiety and severe impact on well-being. AYA endorsing severe anxiety represented 13.1% of the cohort but accounted for 25.8% of AYA experiencing SMHEs during the first three years of survivorship. **Conclusions:** Systematic symptom screening in the first year after cancer diagnosis identifies a proportion of AYA at high risk of both short and long-term SMHE who may benefit from targeted screening and interventions. Future work will determine whether interventions during cancer treatment mitigate this risk. Research Sponsor: Terry Fox Research Institute; Canadian Institutes of Health Research.

12020 Rapid Oral Abstract Session

A randomized, double-blind controlled trial of medicinal cannabis vs placebo for symptom management in patients with advanced cancer receiving palliative care.

Janet Rea Hardy, Ristan Greer, Taylan Gurgenci, Alison Kearney, Rahul Ladwa, Georgie Huggett, Phillip Good; Mater Research - University of Queensland, South Brisbane, QLD, Australia; Torus Research, Brisbane, QLD, Australia; Mater Research Institute - University of Queensland, South Brisbane, Australia; Royal Brisbane and Women's Hospital, Brisbane, QLD, Australia; Princess Alexandra Hospital and Faculty of Medicine at University of Queensland, Brisbane, QLD, Australia; Mater Misericordiae Ltd, South Brisbane, Australia; St. Vincent's Private Hospital, Brisbane, QLD, Australia

Background: Medicinal cannabis remains very popular amongst cancer patients. In our previous study (JCO 2023; 41(7):1444-1452), cannabidiol (CBD) did not improve symptom management above that provided by standard palliative care alone. This study utilized the same design to test whether the addition of tetrahydrocannabinol(THC) to CBD resulted in improved symptom control. **Methods:** Patients with advanced cancer and a total symptom distress score (TSDS) of ≥10/90 as measured by the Edmonton Symptom Assessment Scale (ESAS) who were receiving palliative care were randomised to a 10mg/ml THC:10mg/ml CBD combination oil (MC) or matched placebo. The dose was escalated according to tolerance and perceived efficacy from 2.5 to 30mg/day over 14 days and continued at that dose to day 28. The primary outcome was the change in TSDS from baseline at day 14. Secondary outcomes included change in individual symptoms, patient-selected dose, global impression of change, anxiety/depression, opioid use, quality of life and toxicity. **Results:** Of the 144 randomized from Sept 2019 to July 2023 (72 to MC, 72 to placebo), 56 and 65 participants reached the primary analysis point at 14 days, and 33 and 50 to day 28. The most common cancers were breast, lung and gynecological. Most participants were of reasonable performance status (AKPS 70%) and were taking opioids at baseline. Mean baseline TSDS scores were 37.6/90 (MC) and 36.5/90 (placebo). Mean TSDS scores fell over time with no difference between arms at day 14 (-6.3 (SD 12.3) MC and -6.98 (SD 12.6), p = 0.76) or day 28 (-9.24 (SD 15.3) and 8.42 (SD 13.6), p = 0.8). Adjusted for baseline, there was a significant improvement in pain score from baseline in favor of MC (-1.41 (2.15) vs -0.46 (2.82), p = 0.04) and in overall wellbeing in favor of placebo (-0.48 (2.78) and -1.29 (2.74), p = 0.02) at day 14. The median (range) patient selected dose of oil at day 14 was 1.5ml (0.5-3.0) (equivalent to a dose of 15mgTHC/15mg CBD) and 3.0ml (0.5-3.0) for placebo. Side-effects were generally mild. More participants on MC reported confusion (26/69 and 12/72, p = 0.005), feeling high (21/69 and 10/72, p = 0.02) and an exaggerated sense of well-being (10/69 and 2/72, p = 0.01) as worse than baseline. Those on MC reported an improved global impression of change over time but this lost significance when considering those who exited early. **Conclusions:** Although showing no advantage over placebo with respect to improving total symptom distress, a 1:1 THC:CBD medicinal cannabis oil resulted in a statistically significant improvement in cancer-related pain at the expense of increased psychomimetic toxicity. Trial registration: ACTRN 12619000037101. Sponsor: Australian Government Medical Research Future Fund. Clinical trial information: ACTRN12619000037101. Research Sponsor: Medical Research Future Fund; APP1152232.

12021 Poster Session

Predictors of cardiotoxicity in patients with early breast cancer treated with doxorubicin and/or trastuzumab: Implications of race/ethnicity and insurance status.

Shahzaad Khadeem Jahangier, Rubina Qamar; Advocate Aurora Health, Milwaukee, WI

Background: Approximately 4.1 million women in the US are living with breast cancer[1]. Cardiac dysfunction is a significant adverse effect of commonly used breast cancer therapies like doxorubicin (D) and trastuzumab (T). The cardiotoxicity (CTox) associated with these agents manifests as a reduction in left ventricular ejection fraction (LVEF) with or without signs and symptoms of heart failure. Purpose: Identify high-risk populations susceptible to developing CTox, with a focus on identifying individuals who could potentially benefit from the early initiation of empiric cardioprotective therapies. **Methods:** We investigated the relationship of race/ethnicity, insurance status, treatment regimen and comorbidities including hypertension (HTN), hyperlipidemia (HLD), diabetes mellitus (DM), tobacco use, BMI, age, and radiation therapy on the development of CTox from D and/or T. A total of 133 newly diagnosed stage I-III invasive breast cancer patients were enrolled in a prospective clinical trial (2013-2017) and received standard of care D and/or T based systemic therapy. Echocardiogram data was collected every 6 months for two years and then based on clinical need for a total of six years. CTox was defined as a >10% drop in LVEF, and/or LVEF <50%. **Results:** Our study included a population of 133 patients comprising Black (22%), White (77%), and Hispanic (1.5%) individuals. Among these patients, 32 developed CTox (Black 41%, White 19%, Hispanic 50%). Of all patients, 29% had State insurance while 71% had Private insurance. Prevalence rates for comorbidities were as follows: HTN (41%), HLD (32%), DM (13%), and tobacco use (36%). In a univariate logistic regression model, race/ethnicity, HTN, insurance status, and tobacco use were most strongly associated with Ctox. When controlling for tobacco use and HTN, race/ethnicity was not significantly associated with Ctox. However, direct comparisons of levels of race/ethnicity showed that Black patients were more likely to develop Ctox when compared to White patients (OR 2.60, 95% CI = 1.01-6.65, P = 0.045). HTN patients were also more likely to develop Ctox, when controlling for ethnicity and tobacco use (OR 2.62, 95% CI = 1.10-6.43, P = 0.031). In a separate multivariate analysis, we examined insurance as a surrogate for socioeconomic status. State insurance was associated with an increased risk of developing CTox when controlling for race/ethnicity and HTN (OR 3.73, 95% CI = 1.47-9.58, P = 0.006). Furthermore, in all models, HLD, DM, BMI, age, and radiation field were not found to be significantly associated with increased CTox. **Conclusions:** In our well characterized population of patients with stage I-III breast cancer, who were prospectively followed and received standard of care systemic therapy, we observed an association between insurance status with increased risk of CTox from treatment regimen. Research Sponsor: None.

The predictive role of mammographic breast calcifications in cardiovascular disease among women undergoing breast cancer screening: Insights from a retrospective database analysis of breast cancer screening.

Usman Ali Akbar, Umer Rizwan, Rida Hussain, Ahmed Muaaz Umer, Andrea Dwiggins, Sabir Hussain, Michael Cheshire; West Virginia University Camden Clark Medical Center, Parkersburg, WV; Camden Clark Medical Center, Parkersburg, WV; West Virginia School of Osteopathic Medicine, Lewisburg, WV; WVU Camden Clark Medical Center, Parkersburg, WV

Background: Cancer screenings, particularly mammography, are crucial in early detection and management of breast cancer, the most common cancer among women worldwide. Despite advances, disparities persist in cancer outcomes and cardiovascular health, highlighting the need for an integrative approach to care. **Methods:** We conducted a retrospective cohort analysis of 22,118 female patients over 40 years of age diagnosed with breast arterial calcification (BAC) on mammography using the TriNetX database. Each patient with BAC was matched to a control based on age, lab values, socioeconomic class, and co-morbidities. None had ASCVD events before screening. Outcomes included acute myocardial infarction, heart failure, cardiomyopathy, and thromboembolic events. **Results:** Comparing cohorts with and without BAC, we found no significant difference in all-cause mortality (OR: 1.003, P=0.960). However, BAC was associated with increased risks of acute myocardial infarction (OR: 1.281, P=0.003), heart failure (OR: 1.106, P=0.021), cardiomyopathy (OR: 1.437, P<0.001), and DVT/PE (OR: 1.178, P=0.006), particularly DVT (OR: 1.243, P=0.003). Ischemic stroke, CVD, and other cardiovascular conditions showed no significant risk differences, highlighting BAC's predictive value for specific cardiovascular outcomes (Table). **Conclusions:** Our findings affirm BAC on mammography as a significant predictor of specific cardiovascular conditions, such as acute myocardial infarction and heart failure, highlighting its utility in cardiovascular risk stratification. Research Sponsor: None.

Cardiovascular outcomes in propensity score-matched cohort patients with or without BAC detected on screening mammogram.

Outcome	Risk Difference (%)	OR (95% CI)	P Value	95% CI of OR	Event Rates (Calcification Cohort)	Event Rates (No Calcification Cohort)
All-Cause Mortality	0.0	1.003 (0.908-1.106)	0.960	(0.908-1.106)	823/22084	821/22084
Acute Myocardial Infarction	0.3	1.281 (1.085-1.511)	0.003	(1.085-1.511)	323/22084	253/22084
Heart Failure	0.5	1.106 (1.015-1.206)	0.021	(1.015-1.206)	1148/22084	1043/22084
Ischemic Stroke	-0.0	0.985 (0.697-1.391)	0.930	(0.697-1.391)	64/22084	65/22084
DVT/PE	0.4	1.178 (1.048-1.324)	0.006	(1.048-1.324)	631/22084	538/22084
Cardiac Arrest	0.0	1.133 (0.817-1.571)	0.454	(0.817-1.571)	77/22084	68/22084
Peripheral Vascular Disease	0.3	1.092 (0.981-1.215)	0.107	(0.981-1.215)	722/22084	663/22084
CABG/PCI	0.2	1.197 (0.996-1.440)	0.055	(0.996-1.440)	251/22084	210/22084

BAC: Breast Arterial Calcification, OR: Odds Ratio, DVT: Deep Vein Thrombosis, PE: Pulmonary Embolism, AMI: Acute Myocardial Infarction, CABG: Coronary Artery Bypass Grafting, PCI: Percutaneous Coronary Intervention, ASCVD: Atherosclerotic Cardiovascular Disease.

12023 Poster Session

Development and validation of a deep learning–based cardiovascular disease risk prediction model for long-term breast cancer survivors.

Sinae Oh, Jae Yong Shim; National Health Insurance Ilsan Hospital, Gyeonggi-Do, South Korea; Yonsei University College of Medicine, Seoul, South Korea

Background: Previous efforts in predicting cardiotoxicity risk among patients with breast cancer have mostly focused on preventing and monitoring of cardiovascular complications during cancer therapy. We aimed to develop prediction models for the risk of chronic cardiovascular complications in breast cancer survivors during long-term follow-up. **Methods:** We used the Korean National Health Insurance Service databases between 2005 and 2021, including 5,131 5-year female breast cancer survivors diagnosed in 2006. The study cohort was randomized on a 4:1 ratio into the derivation and validation cohort. The primary outcome was the occurrence of major adverse cardiovascular events (MACEs), a composite of acute myocardial infarction, congestive heart failure, and stroke, at any time before the final follow-up at 10 years. We used the Cox proportional hazards model (CoxPH) with the least absolute shrinkage and selection operator penalty to determine the order of clinical factors based on their absolute coefficient value. We developed a deep learning survival model (DeepSurv) and compared its performance with traditional models such as CoxPH and random survival forest (RSF) using the same dataset. Model performance was assessed by discrimination and calibration. **Results:** During the 48054.1 person-years of follow-up, 325 (6.3%) patients developed MACE. We identified 18 relevant clinical factors without zero coefficients, including age, hypertension, atrial fibrillation, stroke, diabetes mellitus, myocardial infarction, household income, congestive heart failure, hemoglobin level, systolic blood pressure, peripheral arterial occlusive disease, chronic kidney disease, aromatase inhibitor use, alcohol consumption, cigarette smoking, tamoxifen use, radiotherapy, and total cholesterol level. The CoxPH, RSF, and DeepSurv model yielded time-dependent concordance index values of 0.713, 0.721, and 0.729, respectively, in the validation cohort. all models demonstrated good integrated Brier scores of 0.031 or less. **Conclusions:** We developed and validated a deep learning survival model that predict MACEs in individual 5-year breast cancer survivors, incorporating both conventional and breast cancer treatment-related cardiovascular risk factors, and demonstrated good calibration and discrimination. These models can assist breast cancer survivors and clinicians in optimally selecting risk-reducing strategies based on individual MACEs risk. Research Sponsor: None.

12024 Poster Session

DTx-based cardio-oncology rehabilitation for lung cancer survivors: A randomized controlled trial.

Guangqi Li, Zhen Lei, Hu Liao, Xuelei Ma; West China Hospital, Chengdu, Sichuan, China; Recovery Plus USA Inc., Chengdu, China; Institute of Thoracic Oncology and Department of Thoracic Surgery, West China Hospital, Sichuan University, Chengdu, China; West China Hospital, Sichuan University, Chengdu, China

Background: Cardio-oncology rehabilitation holds significant importance for lung cancer survivors, particularly those diagnosed at an early stage requiring lobectomy, where the maximal oxygen uptake peak ($VO2_{PEAK}$) stands out as a robust prognositic predictor. Home-based cardiac telerehabilitation serves as a substitute for traditional center-based rehabilitation, demonstrating higher participation and completion rates. Despite the potential benefits, wearable devices and mobile apps, which offer tailored video guides, real-time monitoring, individualized safety alerts, and exercise-specific feedback, have not gained widespread adoption in clinical practice. Here, we present findings on the efficacy, safety, and compliance of a 3-month cardio-oncology rehabilitation program based on digital therapeutics (DTx) for lung cancer survivors. **Methods:** Early-stage lung cancer survivors post-lobectomy, not requiring radiotherapy or chemotherapy, were randomly assigned to receive cardiac telerehabilitation or usual care for 5 months. For pts in the telerehabilitation group, exercise prescriptions with video guides and real-time HR monitoring were implemented using the R Plus Health APP, a software as medical device approved by CFDA for remote cardiac rehab. The AI-driven prescriptions were generated based on CPET, modified by physiologists, and dynamically optimized according to feedback. Pts in the usual care group received routine instructions. Outcome measurements included $VO2_{PEAK}$ (primary outcome), FEV1, DLCO, cardiac function, safety, compliance, and scales assessing symptoms (MDASI), psychology (HADS), sleep (PSQI), fatigue (MSFI-SF), and quality of life (QLQ-C30). **Results:** 40 of 47 (85%) pts completed the trial (24 in the telerehabilitation group and 16 in the usual care group). Pts in the telerehabilitation group engaged in exercise an average of 3.6 times per week. The average exercise duration was 168.3 min per week, with an average effective exercise duration (when the required heart rate was reached) of 106.3 min per week. The average prescription compliance rate (effective exercise duration/lower limit of prescription duration) was 116%. Cardiac telerehabilitation was associated with a higher average $VO2_{PEAK}$ improvement (3.660±3.232 vs 1.088±3.230 mL/Kg/min, p=0.023), better alleviation of affective interference (-1.091±1.788 vs 0.310±1.330, p=0.017), and more anxiety relief (-0.377±0.584 vs -0.020±0.321, p=0.045) compared with usual care. Other efficacy outcomes did not show significant differences between the two groups. No exercise-related adverse events occurred during the intervention. **Conclusions:** DTx-based cardio-oncology rehabilitation demonstrated improvements in cardiorespiratory fitness and reductions in affective interference and anxiety among lung cancer survivors, indicating high compliance and safety. Clinical trial information: ChiCTR2200064000. Research Sponsor: Recovery Plus USA Inc.

The effect of sodium glucose cotransporter-2 inhibitors on mortality and cardiovascular outcomes of patients with prostate cancer receiving luteinizing hormone releasing hormone agonists.

Zhiting Tang, Cho Han Chiang, Yu-Cheng Chang, Xin Ya See, Qian Wang, Kuan-Yu Chi, Cho Hung Chiang; Department of Medicine, Unity Hospital, Rochester Regional Health, Rochester, NY; Mount Auburn Hospital, Harvard Medical School, Cambridge, MA; Department of Medicine, Danbury Hospital, Danbury, CT; Unity Hospital, Rochester Regional Health, Rochester, NY; University Hospitals Seidman Cancer Center and Case Western Reserve University, Cleveland, OH; Department of Medicine, Jacobi Medical Center, Albert Einstein College of Medicine, Bronx, NY; National Taiwan University Hospital, Taipei, Taiwan

Background: Luteinizing hormone releasing hormone agonists (LHRHa) are the standard of care treatment for prostate cancer but associated with an increased risk of cardiotoxicity. Recent studies suggest that sodium glucose cotransporter-2 inhibitors (SGLT2i), a class of antidiabetic drugs, reduce the risk of cardiovascular events compared to other glucose-lowering agents. We aim to investigate the potential cardioprotective effect of SGLT2i in prostate cancer patients with T2DM undergoing LHRHa therapy. **Methods:** We performed a retrospective, propensity score matched study using the TriNetX database, a network comprising deidentified data across more than 120 participating healthcare institutions. We included patients with prostate cancer and T2DM who were treated with LHRHa for prostate cancer and received either SGLT2i or dipeptidyl peptidase 4 inhibitors (DPP4i) for diabetes. The primary outcomes were all-cause mortality, incident hypertension, and incident major cardiovascular adverse events (MACE), which was defined as a composite of heart failure, myocardial infarction, and atrial fibrillation/flutter within 5 years of LHRHa initiation. **Results:** We matched 932 patients treated with an SGLT2i to patients treated with a DPP4i. The median age was 73 years for both cohorts. A total of 110 and 275 patients died in the SGLT2i and DPP4i cohorts, respectively. In Cox proportional hazard analyses, SGLT2i was associated with a reduction in the risk of all-cause mortality (Hazard ratio (HR), 0.65 [95% CI, 0.52 to 0.81]), hypertension (HR, 0.40 [95% CI: 0.22-0.70]) and major adverse cardiovascular events (HR, 0.70 [95% CI, 0.50 to 0.97]) compared to DPP4i. Similarly, SGLT2i was associated with a statistically significant reduction in heart failure and myocardial infarction. There appeared to be a tendency toward a lower risk of atrial fibrillation/flutter. **Conclusions:** The use of SGLT2i was associated with a lower risk of mortality, hypertension, and cardiovascular events in patients with prostate cancer and T2DM undergoing LHRHa therapy. Research Sponsor: None.

	SGLT2i		DPP4i			
Outcomes	No. of at Risk Patients	No. of Cases	No. of at Risk Patients	No. of Cases	Hazard Ratio[a] (95% CI)	P-value (Log-Rank)
All-cause mortality	932	110	932	275	0.65 (0.52-0.81)	<0.001
Hypertension	92	16	93	45	0.40 (0.22-0.70)	0.001
MACE	521	55	516	112	0.70 (0.50-0.97)	0.029
Heart failure	625	59	632	113	0.72 (0.53-0.99)	0.044
Myocardial infarction	793	23	823	72	0.53 (0.33-0.86)	0.009
Atrial fibrillation and flutter	706	28	711	66	0.68 (0.44-1.04)	0.073

[a]After propensity score matching by incorporating variables: age, sex, metastatic disease, androgen deprivation therapy, radiation therapy, underlying comorbidities, use of cardiovascular and diabetes medications, smoking status, and hemoglobin A1c.

The impact of glucagon-like peptide 1 agonists on anthracycline or human epidermal growth factor receptor 2 inhibitor-associated cardiotoxicity in patients with breast cancer and diabetes mellitus.

Cho Han Chiang, Yu-Cheng Chang, Zhiting Tang, Xin Ya See, Kuan-Yu Chi, Yu Chang, Cho Hung Chiang, Azin Ghamari, Lauren Mary Curtis, Tomas G. Neilan; Mount Auburn Hospital, Harvard Medical School, Cambridge, MA; Danbury Hospital, Danbury, CT; Department of Medicine, Unity Hospital, Rochester Regional Health, Rochester, NY; Unity Hospital, Rochester Regional Health, Rochester, NY; Department of Medicine, Jacobi Medical Center, Albert Einstein College of Medicine, Bronx, NY; National Cheng Kung University College of Medicine, Tainan, Taiwan; National Taiwan University Hospital, Taipei, Taiwan; Massachusetts General Hospital, Boston, MA; Mount Auburn Hospital, Cambridge, MA

Background: Anthracyclines or human epidermal growth factor receptor 2 (HER-2) inhibitors are associated with the potential for major adverse cardiovascular outcomes (MACE) among patients with breast cancer. Diabetes mellitus (DM) further increases the risk of MACE. Glucagon-like peptide 1 agonists (GLP1a) have been shown to improve MACE in the non-cancer population; however, there are no data testing whether GLP1a reduce the risk for MACE associated with anthracyclines or HER-2 inhibitors. Therefore, we hypothesized that GLP1a may decrease the risk for MACE among patients with breast cancer and DM receiving anthracycline or HER-2 inhibitors. **Methods:** We performed a retrospective, propensity score-matched cohort study using the TriNetX Analytics Network database, which contains de-identified data from over 120 participating healthcare institutions. We included adult breast cancer patients with type 2 DM who were treated with an anthracycline or HER-2 inhibitor therapy.We matched patients receiving a GLP1a with patients receiving non-GLP1a second-line diabetes medication based on the following variables: age, sex, pre-existing cardiac disease, the use of radiation, metastatic disease, cancer therapy, underlying comorbidities, and use of cardiovascular and diabetes medications. The primary outcome of interest, MACE, was defined as a composite of heart failure, myocardial infarction, and atrial fibrillation/flutter. Secondary outcomes included a composite of heart failure hospitalization and incident heart failure. Safety outcomes included all-cause mortality within 5 years of therapy initiation. **Results:** We matched 724 patients receiving a GLP1a treatment with patients receiving non-GLP1a treatment. The median age was 60 years for both cohorts. The prevalence of hypertension (81%), metastatic disease (61%), and radiation therapy (42%) was similar between cohorts, as was the use of anthracyclines and HER-2 inhibitors. In Cox proportional hazard analyses, the group receiving GLP1a treatment was associated with a lower risk of MACE (Hazard ratio (HR), 0.59 [95% CI: 0.41-0.86]), and heart failure hospitalization (HR, 0.56 [95% CI: 0.37-0.83]), and all-cause mortality (HR, 0.67 [95% CI: 0.48-0.93]) compared with non-GLP1a. **Conclusions:** GLP1a were associated with a reduction in major adverse cardiovascular events, incident heart failure and heart failure hospitalization, and all-cause mortality among anthracycline or HER-2 inhibitor-treated patients with breast cancer and DM. Research Sponsor: None.

	GLP1a		Non-GLP1a			
Outcomes	At Risk Patients	Cases	At Risk Patients	Cases	Hazard Ratio(95% CI)	P-value (Log-Rank)
MACE	564	41	553	81	0.59 (0.41-0.86)	0.006
Incident heart failure and heart failure hospitalization	597	35	590	75	0.56 (0.37-0.83)	0.004
All-cause mortality	724	56	724	105	0.67 (0.48-0.93)	0.015

12027 Poster Session

Cardiac and mortality outcomes in patients with breast cancer undergoing trastuzumab-based therapies.

Max Puthenpura, Heya Batah, Hardik Patel, Lorenzo Braghieri, Arianne Clare Agdamag, Diego Sadler, Halle C. F. Moore, Rohit Moudgil; Cleveland Clinic Foundation, Cleveland, OH

Background: Trastuzumab is a cornerstone treatment for HER2-positive breast cancer. It is traditionally associated with adverse cardiac outcomes. However, the role of multi-line trastuzumab therapy on cardiac outcomes remains unknown. We examined the cardiac and mortality outcomes of multi-line trastuzumab therapies compared to single-line treatments. **Methods:** This is a single-center retrospective study of 275 adult patients from 2010 – 2017 who completed at least one course of trastuzumab-based therapy without interruption for toxicity. This included any breast cancer stage or type with longitudinal data available for comparison. The primary endpoint was Major Adverse Cardiovascular Events (MACE) defined as non-fatal stroke, non-fatal myocardial infarction (MI), acute heart failure (AHF) admission, and AHF readmission within 5 years of starting treatment. All-cause mortality was collected with cardiac death specified. Cox regression analysis compared cardiac and all-cause mortality at 1, 3, and 5 years from starting treatment. Logistical regression was used to analyze MACE outcomes within 5 years. **Results:** Patients were all female, averaged 56.7 years old when starting treatment, and 96% Caucasian. 220 patients had only one line of trastuzumab-based therapy while 55 had at least two lines of treatment. The two groups had no significant difference at 1 year for all-cause mortality. However, multi-line therapies were associated with a higher likelihood of all-cause mortality within 3 years (Hazard Ratio (HR) 5.0 [1.8-14.0]; p = 0.002) and 5 years (HR 3.8 [1.2–8.7]; p = 0.002) when compared to single-line therapy. For the single-line therapy patients, 58.3% of deaths were cancer-related at 3 years from starting treatment, and 61.5% as of 5 years. Multi-line therapy patients demonstrated 100% cancer-related death at both 3 and 5 years from starting treatment. Multi-line therapies were also independently associated with higher MACE outcomes within 5 years compared to single-line therapy (Odds Ratio 5.2 [1.5-17.9]; p = 0.009). Of the single-line therapy population, 0.5% had a non-fatal stroke, 0.5% had a non-fatal MI, 2.7% an AHF admission, and 1.4% an AHF readmission. Of the multi-line therapy patients, 7.2% had non-fatal strokes, 1.8% a non-fatal MI, 3.6% an AHF admission, and they had no AHF readmissions. There was no significant difference in cardiac mortality at any point. **Conclusions:** Multi-line trastuzumab therapy in breast cancer is associated with higher all-cause mortality after 1 year from starting treatment. Most importantly, multi-line therapies were identified as an independent risk factor for MACE, particularly heart failure and stroke, within 5 years. Therefore, survivors should be closely monitored for cardiac events after the first year of starting treatment and identified for early stroke prevention strategies. Research Sponsor: None.

12028 Poster Session

Exploring the prevalence and disparities of heart failure in patients with lung cancer and the associated risk factor analysis.

Julia Vinagolu, Saad Javaid, Kelly Frasier, Vivian Li, Nataly Ortega Yaguachi, Evadne Rodriguez, Olivia Del Castillo, Raquel Batista, Kenlee Jonas, Laura Palma; State University of New York, Upstate Medical University, Syracuse, NY; Wyckoff Heights Medical Center, Brooklyn, NY; Nuvance Health/Vassar Brothers Medical Center, Poughkeepsie, NY; Lake Erie College of Osteopathic Medicine, Erie, PA; University of Missouri-Columbia, School of Medicine, Columbia, MO; Dutchess Community College, Beacon, NY

Background: Lung cancer is the leading cause of cancer-related death in the United States. Previous studies have suggested that patients with lung cancers are at increased risk of cardiovascular comorbidities that increase the risk of death in these patients. We studied the disparities in the prevalence of heart failure and risk factor analysis in lung cancer patients. **Methods:** We utilized the National Inpatient sample (2019-2020) to identify the patients who were admitted with a primary diagnosis of lung cancer (local/regional + advanced metastatic disease) and had a concurrent diagnosis of Heart Failure (HF). Baseline demographic characteristics were analyzed to determine the disparities in the prevalence of HF in lung cancer patients. Multivariate logistic regression analysis was done to assess the association of heart failure with lung cancer. **Results:** A total of 221320 patients had lung cancer, and 25495 had concurrent HF. The mean age of patients with and without HF was 73 and 68, respectively, $p<0.001$. HF patients had a greater percentage of males than females (55% vs 44%, $P<0.001$). Female patients were less likely to have HF (OR=0.82(0.77-0.88), $p<0.001$), and older age was associated with increased risk of HF in lung cancer patients (46-64 years, OR=8.23(1.13-59.49), p=0.03, >65 years OR=15.08(2.07-109), p=0.007). In Lung cancer patients hyperlipidemia had the greatest risk of association with HF (OR=1.85(1.71-1.99), $p<0.001$), followed by obesity (OR=1.78(1.60-1.99), $p<0.001$), Diabetes (OR=1.70(1.56-1.85), $p<0.001$), End stage renal disease (OR=1.61(1.25-2.06), $p<0.001$) and COPD(OR=1.45(1.34-1.56), $p<0.001$). Hypertension was associated with decreased odds of HF (OR=0.01(0.01-0.015), $p<0.001$). Compared to the white population, the Black race had increased odds of association with HF (OR=1.40(1.25-1.56), $p<0.001$). Compared to Medicare, patients with Medicaid and private insurance were less likely to have HF (OR 0.76(0.65-0.89), p=0.001; OR=0.59(0.52-0.66), $p<0.001$, respectively). Patients in high-income groups had decreased likelihood of concurrent HF ($65,000-$85,999, OR=0.88(0.80-0.98), p=0.02 and >$86,000, OR=0.88(0.78-0.99), p=0.04). **Conclusions:** Lung cancer patients of Black race, older age, and those with medicare insurance are at a higher risk of developing heart failure. The presence of hyperlipidemia, obesity, diabetes, end-stage renal disease, and COPD is considered to be among the most significant risk factors for the development of heart failure in lung cancer patients. Addressing underlying risk factors can enhance patient outcomes and promote overall quality of life in patients with lung cancer. Research Sponsor: None.

12029 Poster Session

Fasting mimicking diet reduces anti-OX40/anti PD-L1 and anti-PD-1/anti-CTLA-4 cardiovascular side effects in preclinical melanoma models.

Vincenzo Quagliariello, Salvatore Cortellino, Gloria Delfanti, Annabella Di Mauro, Fabiana Tatangelo, Vanessa Spagnolo, Euplio Visco, Giulia Casorati, Claudia Chiodoni, Paolo Della Bona, Olga Blazevits, Paolo Antonio Ascierto, Nicola Maurea, Valter Longo; IRCCS Fondazione G. Pascale, Napoli, Italy; IRCCS CROB, Rionero in Vulture, Italy; IRCCS- S. Raffaele Scientific Institute, Milan, Italy; Pathology Unit, Istituto Nazionale Tumori- IRCCS- Fondazione G. Pascale, Naples, Italy; National Cancer Institute of Naples, Napoli, Italy; IFOM, Milan, Italy; San Raffaele Institute, Milan, Italy; Fondazione IRCCS Isttuto Nazionale Tumori, Milan, Italy; Istituto Nazionale Tumori IRCCS Fondazione G. Pascale, Naples, Italy; Istituto Nazionale per lo Studio e la Cura dei Tumori "Fondazione G. Pascale"-IRCCS, Division of Cardiology, Naples, Italy; IFOM the FIRC Institute of Molecular Oncology, Milan, Italy

Background: Several strategies based on immune checkpoint inhibitors (ICIs) have been developed or are under investigation as cancer therapeutics with the potential to increase survival. However, ICIs-induced side effects ranging from autoimmune endocrine disorders to mucositis and to a rare but clinically significant cardiotoxicity with high rate of mortality represent important limitations. Cardiovascular complications in ICIs-treated patients includes myocarditis, vasculitis, arrhythmia, fibrosis and heart failure. Moreover, both the limited efficacy in a large portion of patients and the acquisition of resistance represent additional limitations for ICIs, underlining the need for new immunotherapy strategies. Fasting mimicking diets (FMDs) applied for several days periodically are emerging as highly promising enhancers of a wide variety of cancer therapies including immunotherapy. Here, a preclinical study in melanoma-bearing mice treated with two combinatorial ICIs therapies (anti-OX-40/PDL-1 or antiCTLA-4/anti-PD-1) during a standard or FMD was performed. **Methods:** Melanoma or lung cancer-bearing mice (C57BL/6J female mice, 6–8 weeks old) were treated with two combinatorial ICIs therapies (anti-OX-40/PDL-1 or antiCTLA-4/anti-PD-1) during a standard diet or FMD for 21 days. Tumors were measured every 3–4 days using a digital caliper. Mice were monitored for tumor growth and survival. Mice were killed when tumor volume reached 1.5 cm3. Flow cytometry analysis of tumor-infiltrating lymphocytes and apoptosis, collagen quantification in myocardial tissues, quantification of CD3+ and CD8+ cells in myocardial tissues, of plasma and myocardial cytokines, and several pro-inflammatory biomarkers were performed through selective ELISA methods and western blotting analysis. **Results:** FMD cycles in combination with anti-OX40/anti-PD-L1 also show a trend for increased effects against a lung cancer model. As importantly, the cardiac fibrosis, necrosis and hypertrophy caused by immune checkpoint inhibitors are prevented/reversed by FMD treatment in both cancer models whereas immune infiltration of $CD3^+$ and $CD8^+$ cells in myocardial tissues and systemic and myocardial markers of oxidative stress and inflammation are reduced. These results indicate that FMD cycles in combination with immunotherapy can delay cancer growth while reducing side effects including cardiotoxicity. **Conclusions:** This study sets the stage for clinical trials aimed at assessing the ability of FMD to increase the efficacy of immunotherapy while reducing its side effects. These results also indicate that the anti-inflammatory and protective effects of FMD cycles in combination with ICI could affect other organs and systems.
Research Sponsor: Ministero della Salute, Ricerca Corrente.

12030 Poster Session

Impact of protein-energy malnutrition on patients with breast cancer hospitalized for acute decompensated heart failure: Insight from the NIS database 2020.

Elvis Obomanu, Phuuwadith Wattanachayakul, Colton Jones, Yajur Arya, Arshi Syal, Karecia Byfield, Sarah Eidbo, Akshay Ratnani, Sakditad Saowapa, Natchaya Polpichai, Chalothorn Wannaphut, Carlo Casipit, Bruce Adrian Casipit, Ryan Mayo; Department of Internal Medicine, Jefferson-Einstein Hospital, Philadelphia, PA; Department of Internal Medicine,Jefferson-Einstein Hospital, Philadelphia, PA; Jefferson Einstein Hospital, Philadelphia, PA; Department of Medicine, Texas Tech University, Lubbock, TX; Department of Medicine, Weiss Memorial Hospital, Chicago, IL; Department of Medicine, John A. Burns School of Medicine, University of Hawaii, Honolulu, HI; Depatment of Hematology-Oncology, Jefferson-Einstein Hospital, Philadelphia, PA

Background: The breast cancer patient is at risk of acute decompensated heart failure (ADHF) and protein-energy malnutrition (PEM) either from the effects of chemoradiation or primary cancer. There have been several studies on patients with breast cancer and ADHF. However, the exact impact of concurrent PEM on patients with breast cancer admitted for ADHF is unclear. We aim to assess how PEM impacts breast cancer patients admitted with ADHF. **Methods:** We examined the 2020 US National Inpatient Sample (NIS) to explore how concurrent PEM affects breast cancer patients admitted for ADHF. Participants aged 18 and older were identified using relevant ICD-10 CM codes. A survey multivariate logistic and linear regression analysis was used to calculate the odds ratio (OR) for the outcomes of interest. **Results:** We identified 30,555 breast cancer patients with ADHF, with a mean age of 77±10 years; 99% were female. Caucasian accounted for 71.4%, followed by Black (17.5%), Mexican American (5%), and Asian (3%). Of these, 6.07% (1854/30,555) had a concurrent PEM diagnosis. In a survey multivariable regression model adjusting for patient and hospital factors, comorbid PEM was significantly associated with prolonged length of stay (β 2.09, 95% CI: 1.68–2.49, P <0.001), increased risk of in-hospital mortality (aOR 2.61, 95% CI: 1.60–4.29, P <0.001), increased risk of cardiogenic shock (aOR 3.17, 95% CI: 1.78–2.59, P< 0.001), anemia (aOR 1.43, 95% CI: 1.14 to 1.80, p 0.002), and total hospital charge $28,285 (95% CI: $21,743–34,827, P< 0.001). Adverse events such as respiratory failure (aOR 1.17, 95% CI 0.91 to 1.50, p 0.212) and DVT (aOR 1.15, 95% CI 0.40 to 3.31, p 0.802) were observed but did not reach statistical significance. **Conclusions:** Our study demonstrated that comorbid PEM among hospitalized breast cancer patients for ADHF is associated with increased risks of in-hospital mortality, anemia, cardiogenic shock, prolonged length of hospital stays, and total hospital charges. The study also highlights that nutritional status may be a useful prognostic marker in breast cancer patients who are at risk for various cardiovascular morbidities associated with cancer treatment and the primary disease. Additional longitudinal cohort studies are required to improve the understanding of this association.
Research Sponsor: None.

12031 Poster Session

Molecular predictors and mechanisms of immune checkpoint inhibitor-induced myocarditis: A case-control study with translational correlates.

Steph A. Pang, Manuel Flores Molina, Pamela Thébault, Yuming Zheng, Hsiang Chou, Christophe Goncalves, Jingtao Wang, Sabin Dragos Filimon, Paulo Ricardo Santos Nunes Filho, Mariana Pilon Capella, Khashayar Esfahani, Caroline Maude Michel, Jun Ding, Sonia Victoria Del Rincon, Marie Hudson, Réjean Lapointe, Wilson H. Miller Jr.; Lady Davis Institute and Segal Cancer Centre, Sir Mortimer B. Davis Jewish General Hospital, Departments of Medicine and Oncology, McGill University, Montreal, QC, Canada; Centre de recherche du CHUM, Institut du Cancer de Montréal, Université de Montréal, Montreal, QC, Canada; Meakins-Christie Laboratories, Department of Medicine, McGill University Health Centre, Montreal, QC, Canada; Sir Mortimer B. Davis Jewish General Hospital, Division of Cardiology, McGill University, Montreal, QC, Canada; Lady Davis Institute and Segal Cancer Centre, Sir Mortimer B. Davis Jewish General Hospital, Departments of Medicine and Oncology, Montreal, QC, Canada; Lady Davis Institute and Sir Mortimer B. Davis Jewish General Hospital, Division of Rheumatology, McGill University, Montreal, QC, Canada; Lady Davis Institute and Segal Cancer Centre, Sir Mortimer B. Davis Jewish General Hospital, Departments of Medicine and Oncology, McGill University, Montréal, QC, Canada

Background: Myocarditis from immune checkpoint inhibition (ICI) has been reported in 0.04-1.14% of patients on ICI, with mortality up to 50%. Self-antigens driving ICI-myocarditis are largely unknown. Shared T cell clones between heart and tumor have not yet been identified. We present the Montreal Immune-Related Adverse Events (MIRAE) myocarditis project, which seeks to elucidate cellular and molecular drivers of ICI-myocarditis. **Methods:** Our case-control study comprises 3 groups of patients on ICI: 1) ICI-myocarditis (per ASCO diagnostic criteria); 2) non-ICI troponemia (elevated troponins from non-immune etiology); and 3) controls matched by tumor type, sex, and age, with no troponemia. We analyzed blood from prior to ICI, at time of troponemia, or at 3-6 months after ICI initiation. Our multiomics pipeline spans cytokine profiling, immune cell subpopulation profiling of peripheral blood mononuclear cells (PBMCs) via single cell RNA and T/B cell receptor sequencing, spatial single-cell imaging proteomics, and spatial transcriptomics to localize sources of upregulated cytokines and to visualize cell-cell interactions. **Results:** Of 560 patients treated with ICI in our biobank, 4.3% had ICI-myocarditis. 19 myocarditis stored samples were included in our study. All 19 patients received steroids. Additional treatments were mycophenolate (32%), tofacitinib (21%), plasmapheresis (21%), IVIG (21%) and alemtuzumab (5%). 5 patients (26%) developed arrhythmias. 10 (47%) had concurrent irAE. There were no major cardiac adverse events nor deaths from myocarditis or other irAE. These encouraging results may reflect our hospital protocol of troponin screening during first 3 cycles of ICI, leading to earlier diagnosis and treatment. Elevations of blood neutrophil-to-lymphocyte ratio, alanine transaminase, and aspartate aminotransferase were associated with ICI-myocarditis. Plasma cytokine profiling of 13 ICI-myocarditis cases and controls revealed significant elevations of IP10, IL10, IL15 and IL13 at time of myocarditis. Subpopulation profiling of PBMCs is ongoing. Spatial phenotyping of an ICI-myocarditis biopsy demonstrated T cell and macrophage infiltration among cardiocytes and granulocyte accumulation within fibrotic tissue. Spatial transcriptomics analysis is ongoing for the ICI-myocarditis biopsy and 2 controls. **Conclusions:** This is one of the largest translational studies of ICI-myocarditis and controls. Our patients had improved clinical outcomes compared to those reported in the literature, which may be a result from our early screening. Our multiomics analyses of their biospecimens contributes novel data, such as spatial proteomics and transcriptomics analyses on heart tissue. Advancing our understanding of ICI-myocarditis will allow us to design screening strategies and more targeted treatments for ICI-myocarditis. Research Sponsor: Donation to the Jewish General Hospital Clinical Research Unit by Cathy Monticciolo-Cianci in memory of her mother Maria Monticciolo.

12032 Poster Session

Effect of anti CTLA-4 and PD-1 monoclonal antibodies on systemic SDF-1 and galectin-3 levels through NLRP3 and MyD-88 pathways in preclinical models.

Martina Iovine, Vincenzo Quagliariello, Margherita Passariello, Francesca Bruzzese, Giuseppe Palma, Antonio Luciano, Carlo Maurea, Massimiliano Berretta, Ilaria Giacobbe, Matteo Barbato, Vienna Giordano, Raffaele Arianna, Francesca Izzo, Paolo Antonio Ascierto, Irma Bisceglia, Maria Laura Canale, Claudia De Lorenzo, Nicola Maurea; Division of Cardiology, Istituto Nazionale Tumori –IRCCS- Fondazione G. Pascale, Naples, Italy; IRCCS Fondazione G. Pascale, Napoli, Italy; Department of Molecular Medicine and Medical Biotechnology, University of Naples "Federico II", Naples, Italy; Sperimentazione Animale, Istituto Nazionale Tumori-IRCCS-Fondazione G. Pascale, Naples, Italy; University of Salerno, Salerno, Italy; University of Messina, Medical oncology, Messina, Italy; Division of Cardiology, Istituto Nazionale Tumori-IRCCS-Fondazione G. Pascale, Naples, Italy; Istituto Nazionale Tumori IRCCS Fondazione G. Pascale, Naples, Italy; Servizi Cardiologici Integrati, Azienda Ospedaliera San Camillo-Forlanini, Rome, Italy; Division of Cardiology, Azienda USL Toscana Nord-Ovest, Versilia Hospital, Lido Di Camaiore, Italy; Department of Molecular Medicine and Medical Biotechnology, University of Naples Federico II, Napoli, Italy; Istituto Nazionale per lo Studio e la Cura dei Tumori "Fondazione G. Pascale"-IRCCS, Division of Cardiology, Naples, Italy

Background: Immune checkpoint inhibitors (ICIs) have significantly changed the oncology clinic in recent years, improving survival expectations in cancer patients. ICI therapy have a broad spectrum of side effects from endocrinopathies to cardiovascular diseases. In this study, pro-inflammatory and pro-fibrotic effects of short-term ICIs therapy in preclinical models were analyzed. **Methods:** Firstly, in a human in vitro model, human cardiomyocytes co-cultured with hPBMC were exposed to ICIs (with CTLA-4 or PD-1 blocking agents, at 200 nM) for 72h. After treatment, production of DAMPs and 12 cytokines were analyzed in the supernatant through colorimetric and enzymatic assays. C57/Bl6 mice were treated with CTLA-4 or PD-1 blocking agents (15 mg/kg) for 10 days. Before (T0), after three days (T3) and ten days (T10), ejection fraction, radial/longitudinal strain were calculated by using echocardiography. Fibrosis, necrosis, hypertrophy and vascular NF-kB expression were analyzed through Immunohistochemistry. Myocardial expression of DAMPs (S100- Calgranulin, Fibronectin and Galectine-3), MyD88, NLRP3 and twelve cytokines have been analyzed. Systemic levels of SDF-1, IL-1β and IL-6 were analyzed before, during and after ICIs therapy. **Results:** Radial and longitudinal strain were decreased after 10 days of ICIs therapy. Histological analysis of NF-kB expression shows that short-term anti-CTLA-4 or anti-PD-1 treatment increased vascular and myocardial inflammation. Myocardial fibrosis and expression of galectin-3, pro-collagen 1-α and MMP-9 were increased after treatment with all ICIs. Both anti-CTLA-4 or anti-PD-1 treatments increased the expression of DAMPs, NLRP3 and MyD88 and induced both in vitro and in vivo the secretion of IL-1β, TNF-α and IL-6. Systemic levels of SDF-1, IL-1β and IL-6 were increased during and after treatment with ICIs. **Conclusions:** Short therapy with PD-1 and CTLA-4 blocking agents increases vascular expression of NF-kB, systemic SDF-1, IL-1β, IL-6 levels and myocardial NLRP3 in preclinical models. The overall picture of the study suggests new putative biomarkers of ICIs-mediated systemic and myocardial damages potentially useful in clinical cardioncology. Research Sponsor: Ministero della Salute, Ricerca Corrente.

12033 Poster Session

Predictive factors for cardiac events following concurrent chemotherapy and radiation with durvalumab consolidation for unresectable non-metastatic non-small cell lung cancer.

Nikita Pankaj Patel, Danielle Dressler, Mengou Zhu, Yingzhe Liu, Zequn Sun, Jyoti D. Patel; Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, IL; Biostatistics, Feinberg School of Medicine, Northwestern University, Chicago, IL

Background: The PACIFIC trial was a randomized phase 3 study which evaluated the use of Durvalumab as consolidation therapy after definitive chemoradiation for patients with unresectable non-metastatic NSCLC. There was a significant improvement in progression free survival and overall survival. It was established as a standard approach for management. Due to nonspecific activation of the immune system, immune related adverse events are commonly associated with ICIs. Immune related cardiotoxicity is less common however may present as arrhythmia, pericarditis, valvular disease, cardiomyopathy, and there is more recent data to suggest an acceleration of atherosclerotic plaque burden likely due to inflammation that can result from immune activation. In this population, there are usually several other risk factors for cardiac disease including age, history of tobacco use, exposure to cardiotoxic chemotherapy and chest radiation. The objective of this study is to quantify, characterize, and identify potential risk factors for cardiac events (CEs) that occur after exposure to concurrent chemotherapy and radiation followed by Durvalumab in patients with unresectable non-metastatic NSCLC. **Methods:** Patients who received concurrent chemotherapy and radiation followed by Durvalumab for treatment of NSCLC at a large academic medical center between January 1, 2017 and April 1, 2021 were retrospectively identified. Demographics, treatment history, cardiovascular comorbidities (pre-existing arrhythmia, coronary artery disease, diabetes mellitus, heart failure, hypertension, hyperlipidemia, cerebral vascular accident, peripheral artery disease, tobacco use) and CEs occurring within 5 years of treatment were collected by chart review. Logistic regression analysis was used to identify potential risk factors for cardiac events in this patient population. **Results:** Among 115 patients, 29 (25%) experienced CEs including 15 new/worsening arrhythmia, 11 new/worsening cardiomyopathy, and 9 new/worsening coronary artery disease. There were no cardiac deaths identified. The most common arrhythmia was atrial fibrillation. Pre-existing arrhythmia, dyslipidemia, and number of pack years showed significant association with cardiac events ($p<0.05$). Cumulative dose of radiation was found to be marginally significant on logistic regression analysis ($p=0.07$). Patients on a statin had a slightly lower odds of cardiac event (OR 0.03, $p=0.02$). **Conclusions:** Cardiac events following exposure to concurrent chemotherapy and Durvalumab may occur in up to 25% of patients with unresectable non-metastatic NSCLC. Further retrospective analysis of changes in coronary atherosclerotic plaque burden across PET-CT with ICI exposure and correlation with cardiac events is underway. Research Sponsor: None.

12034 Poster Session

Goals of care discordance in advanced cancer compared to other advanced conditions.

Manan P Shah, Neil S Wenger, John A Glaspy, Ron D Hays, Rebecca L Sudore, Maryam Rahimi, Lisa Gibbs, Sidharth Anand, Anne M Walling; Division of Hematology/Oncology, University of California, Los Angeles, Los Angeles, CA; Division of General Internal Medicine and Health Services Research, University of California, Los Angeles, Los Angeles, CA; Division of Hematology and Oncology, UCLA Department of Medicine, Los Angeles, CA; Department of Medicine, University of California, San Francisco, San Francisco, CA; Departments of Medicine and Family Medicine, University of California, Irvine, Irvine, CA; Division of Hematology and Oncology, UCLA Department of Medicine, Santa Monica, CA

Background: Optimal care for patients with advanced cancer requires understanding patients' goals of care and communicating treatment intent. We explored goals of care, perceived treatment intent, and mortality in patients with advanced cancer compared to other advanced conditions. **Methods:** We performed a cross-sectional analysis of survey data from a multi-site trial of advance care planning in patients with advanced cancer, end-stage liver disease, end-stage renal disease, chronic obstructive pulmonary disease, congestive heart failure, and advanced age (> 75 years). Patients described their physical health and quality of life. They also reported whether their preferred goals of care and their current treatment focus "on extending your life as much as possible, even if it means having more pain and discomfort," or "relieving your pain and discomfort as much as possible, even if that means not living as long," or "not sure." We compared patients' preference for life-extending care (LEC) versus comfort-focused care (CFC) with their perception of current treatment intent as LEC versus CFC. We evaluated the relationship between patients' goals of care and perceived treatment intent with 24-month mortality in advanced cancer versus other advanced conditions. We used the chi-square test for statistical analyses. **Results:** Among 1099 patients, those with advanced cancer (n = 231) were more likely to report very good or excellent physical health (33% v 22%, $p < .001$) and very good or excellent quality of life (58% v 41%, $p < .001$) compared to other advanced conditions (n = 868). Patients with cancer had a similar 24-month mortality (16% v 13%, p = .25) and preferred LEC as often as patients with other conditions (25% v 23%, p = .58). Patients with cancer were more likely to report receiving LEC than those with other conditions (51% v 35%, $p < .001$). Patients with cancer were more likely to have a discordant goal of CFC while describing their treatment as LEC compared to other conditions (36% v 25%, p = .04). Among 113 patients with cancer who preferred CFC, there was no difference in 24-month mortality between those who reported receiving LEC versus CFC (24% v 15%, p = .31). **Conclusions:** Compared to patients with other advanced conditions, patients with advanced cancer reported better physical health and quality of life, but had similar mortality and goals of care. However, patients with advanced cancer were more likely to report receiving LEC and also more likely to have a discordant goal of CFC while receiving LEC. Among patients with advanced cancer preferring CFC, those who reported receiving LEC instead of CFC did not have improved survival. Good physical health and quality of life may prompt more aggressive care in patients with advanced cancer compared to other advanced conditions. These findings highlight the importance of oncologists explicitly eliciting patients' goals of care and ensuring that patients understand the intent of treatment. Research Sponsor: None.

12035 Poster Session

Using natural language processing to qualitatively assess goals of care conversations for patients with cancer.

Melissa Greene, Gloria Broadwater, Donna Niedzwiecki, Thomas William LeBlanc, Jessica Ma, David J. Casarett, Brittany Anne Davidson; Duke University School of Medicine, Durham, NC; Department of Biostatistics & Bioinformatics & CALGB Statistical Center, Duke Cancer Institute, Durham, NC; Duke University, Durham, NC; Division of General Internal Medicine, Department of Medicine, Duke University Medical Center, Durham, NC; Duke Cancer Institute, Durham, NC

Background: The importance of goals of care (GOC) discussions during end-of-life (EOL) care is well known. Institutions are increasingly tracking the frequency and timing of GOC documentation, but qualitative assessments of this content on a large scale have been limited given the person-power required and constraints of electronic health systems. Our aim is to use natural language processing to qualitatively assess the content of GOC documentation and associations with EOL care in patients who died with cancer. **Methods:** This is a retrospective review of patients with solid or hematologic malignancies who died between 2018-2022 with documented GOC notes in the last 12 months of life at a single academic National Cancer Institute-designated cancer center. Eight GOC components were identified based on prior literature: current understanding of patient's illness, information preferences, disclosure of prognosis, goals, fears, acceptable function, trade-offs, and family involvement. GOC notes were extracted from the electronic health record and text annotation software Clinical Regex was utilized to search for the aggregate presence of these GOC components. Associations between these 8 components and receipt of aggressive EOL care (chemotherapy within 14 days of death, no hospice care, or hospice admission $\leq$3 days of death) were evaluated. **Results:** 2,031 patients met inclusion criteria. The most common disease sites were gynecologic (22.6%), gastrointestinal (20.3%), and thoracic (16.7%). The most common GOC components addressed were family involvement (75.0%), patient goals (72.0%), acceptable function, and decision making & information preferences (both 65.8%). Only 5.4% had all 8 components addressed in documentation the last 12 months of life. More comprehensive GOC notes were associated with lower rates of aggressive EOL care; 73.2% received aggressive EOL when 0/8 components were documented, compared to 56.8% and 50.3% when 6 or 7 components were discussed, respectively. In multivariate logistic regression, GOC components documented ($\leq$6 vs $\geq$7), primary tumor site, and inpatient palliative care referral were independent predictors of aggressive EOL care (p-values $<$0.0001). **Conclusions:** GOC conversation documentation is largely not comprehensive. Increasingly comprehensive documentation is associated with a lower likelihood of receiving aggressive EOL care, suggesting opportunities to improve both the quality and documentation of GOC conversations may impact the EOL care for patients with cancer. Opportunities for increasing outpatient palliative care referrals may also improve the quality of the EOL experience for patients. Research Sponsor: Duke Division of Gynecologic Oncology.

# of GOC components discussed and percentage that received aggressive EOL care.

Number of GOC Components Addressed	Received Aggressive EOL Care
0	73.2%
≥ 1	60.7%
≥ 2	60.0%
≥ 3	60.6%
≥ 4	61.1%
≥ 5	59.0%
≥ 6	56.8%
≥ 7	50.3%
All 8	53.6%

12036 Poster Session

End-of-life care preferences in patients with gallbladder cancer: Shifting patterns and disparities over two decades.

Karan Jatwani, Mahnoor Sukaina, Atulya Aman Khosla, Nitya Batra, Rahul Mishra, Mohammad Arfat Ganiyani, Madhan Srinivasan Kumar, Rohit Singh, Shahid Sattar Ahmed; Roswell Park Comprehensive Cancer Center, Buffalo, NY; Karachi Medical and Dental College, Karachi, Pakistan; Department of Internal Medicine, William Beaumont University Hospital, Royal Oak, MI; Corewell Health William Beaumont University Hospital, Royal Oak, MI; Department of Internal Medicine, Anne Arundel Medical Center, Annapolis, MD; Miami Cancer Institute, Baptist Health South Florida, Miami, FL; Saint Vincent Hospital, Worcester, MA; University of Vermont Medical Center, Burlington, VT; Division of Hematology Oncology, University of Vermont Larner College of Medicine, Burlington, VT

Background: Gallbladder cancer (GBC) is an aggressive malignancy with a combined survival rate of 20%. Some studies have reported less than 10 percent utilization of palliative care services in this population. Place of Death (PoD) is an important determinant of patient and caregiver preference and cost of caregiving at the end of life (EOL). We evaluate trends in PoD for patients with GBC in the U.S. from 2003 to 2020 based on the CDC WONDER (Wide-ranging Online Data for Epidemiologic Research) database. **Methods:** We analyzed data using the CDC WONDER database from January 01, 2003, to December 31, 2020. The data for deaths due to GBC was pooled using the International Classification of Diseases-10th revision code as C23, including all Gallbladder Cancers. The inclusion criteria included patients aged $>$ 18. PoD was defined as deaths at home or hospice versus medical facilities. Annual percentage change (APC), average annual percentage change (AAPC), and joint point analysis were done using the Joinpoint Regression Program, Version 5.0.2. **Results:** The analysis demonstrated a total of 37,576 deaths from GBC. Fifty-eight percent of deaths (21,805) were at home or hospice; AAPC: 3.23%, CI 1.4 to 5.0 ($p = 0.0002$). A significantly increasing trend of dying at medical facilities was seen amongst African Americans (AA); AAPC: 1.06%, CI 0.02 to 2.10, ($p = 0.04$), while Whites had a significant increase in the utilization of home or hospice-based care; AAPC: 2.7%, CI 2.1 to 3.2; $p < 0.0001$). On age stratification, there was a significant decline in using medical facilities as PoD for the $>$ 65 yrs cohort; AAPC: -2.65% CI -3.1 to -2.1 ($p < 0.0001$). In contrast, the middle age group (45-64 yrs) had a trend towards decline, which was not significant in the usage of medical facilities as PoD with AAPC: -0.42% CI -1.24 to -0.4 ($p = 0.29$). **Conclusions:** To our knowledge, this is the first study providing valuable insights into the evolving PoD preferences among GBC patients in the U.S. The racial disparities highlight the need for targeted interventions and culturally sensitive end-of-life care for different demographic groups. The age-related trends underscore the importance of tailoring end-of-life care strategies to specific age cohorts. The findings emphasize the importance of policies promoting and supporting home and hospice-based care for GBC patients. Targeted efforts are warranted to address disparities in PoD preferences among racial and age groups. Research Sponsor: None.

12037 Poster Session

Efficacy and safety of immune checkpoint inhibitors in advanced solid tumors with hepatitis B infection.

Ruiqi Niu, Yingying Du, Hesheng Qian, Jingdan Pang, Xinyan Zeng, Sheng Chen, Jing Wang, Wentian Wu, Changchun Shao; The First Affiliated Hospital of Anhui Medical University, Hefei, China; Department of Oncology, Fuyang Cancer Hospital, Fuyang, China

Background: Hepatitis B virus (HBV) infection is related to cirrhosis and hepatocellular carcinoma (HCC). The breakthroughs of immunotherapy (IO) have dramatically changed treatment paradigms in malignancies based on considerable survival benefits. Advanced tumor patients are under risk of HBV reactivation after IO, and serum HBV DNA positive (HBV+) is regarded as the exclusion of clinical study. It is urgent to explore the impact of HBV infection on the efficacy and safety of IO. **Methods:** A retrospective review of advanced tumors patients with HBV infection who received IO was performed at the First Affiliated Hospital of Anhui Medical University and Fuyang Cancer Hospital between January 1, 2019, and August 31, 2023. 563 patients were included, of which 346 were HCC patients. The long-term efficacy is overall survival (OS). CTCAE 5.0 was used to evaluate the hepatic adverse event. **Results:** In advanced tumor, patients who have had HBV+ had higher incidence of hepatic adverse events (hAE) ($P<0.001$) and severe hepatic adverse events (hSAE) ($P=0.001$) than HBV negative (HBV-). Among HBeAg positive(HBeAg+) hepatitis patients, there was no difference in hAE ($P=0.131$) and hSAE ($P=0.431$) between HBV+ and HBV- patients. However, in HBeAg negative (HBeAg-) patients, HBV+ patients have a significantly higher incidence of hAE ($P=0.003$) and hSAE ($P=0.001$) than HBV-. In HCC, there was no statistical difference in OS between HBV+ and HBV- patients (P=0.132), with 91.0% patients received antiviral treatment. HBV+ patients had more hAE ($P=0.023$) and hSAE ($P=0.020$). HBV+ HBeAg- patients had more hSAE than HBV- ($P=0.022$). In HBeAg+ patients, there was no difference in OS ($P=0.755$), hAE ($P=0.199$) and hSAE ($P=0.426$) between HBV+ and HBV-. In non-HCC, antiviral treatment brought more hAE ($P=0.025$), which existed in HBeAg- ($P=0.029$) and HBV- ($P=0.047$). Thirty HCC patients converted HBV- to HBV+ during IO (mOS: 527d, 95%*CI*: 266.22-787.78), of which 2 patients had an ALT flare, of which 28 patients had hAE and 10 patients had hSAE. **Conclusions:** HBV+ patients have higher incidence of hAE and hSAE. In HCC, HBV+ patients are more likely to occur hAE and hSAE. HBV+ HCC patients had worse OS than who remained HBV- during ICIs. For non-HCC patients with antiviral treatment, there was no difference in OS or AEs and SAEs, regardless of infection status and HBV status. In HBeAg+ HCC patients, there was no statistical difference in OS, hAE, and hSAE regardless of HBV activity. Antiviral treatment was associated with a higher incidence of hAE and hSAE irrespective of tumor, infection status, and HBV DNA status. In advanced HCC, 18.9% of HBV- patients turned HBV+, which not only have worse OS and greater hepatic toxicity. Dynamic monitoring of HBV-related serological indicators and liver enzymes is needed for hepatitis B patientsduring IO, and HBV reactivation is a sign of poor clinical prognosis. Research Sponsor: None.

12038 Poster Session

Trajectories of cancer-related behavioral symptoms (CRBS) burden after breast cancer (BC).

Martina Pagliuca, Julie Havas, Pietro Lapidari, Gwenn Menvielle, Leonor Fasse, Diane Boinon, Anne-Laure Martin, Sibille Everhard, Christelle Jouannaud, Marion Fournier, William Jacot, Laurence Vanlemmens, Coureche Kaderbhai, Florence Joly, Michelino De Laurentiis, Florian Scotte, Stefan Michiels, Maria Alice B Franzoi, Ines Maria Vaz Duarte Luis, Antonio Di Meglio; Cancer Survivorship Program, INSERM 981, Gustave Roussy, Villejuif, France; Cancer Survivorship Group, INSERM Unit 981, Gustave Roussy, Villejuif, France; Department for the Organization of Patient Pathways, Gustave Roussy, Villejuif, France; Unicancer, Le Kremlin-Bicêtre, France; Jean Godinot Cancer Institute, Reims, France; Institut Bergonie, Bordeaux, France; Institut du Cancer de Montpellier, Université de Montpellier, Montpellier, France; Centre Oscar Lambret, Lille, France; Georges François Leclerc Comprehensive Cancer Care Centre, Dijon, France; Department of Medical Oncology, Centre François Baclesse, Caen, France; Departmente of Breast and Thoracic Oncology, IRCCS Istituto Nazionale Tumori "Fondazione Pascale", Napoli, Italy; Département Interdisciplinaire d'Organisation des Parcours Patients (DIOPP), Gustave Roussy, Villejuif, France; Oncostat, CESP, Inserm U1018, University Paris-Saclay, labeled Ligue Contre le Cancer, Gustave Roussy, Villejuif, France; Cancer Survivorship Program, INSERM Unit 981, Gustave Roussy, Villejuif, France

Background: Fatigue, cognitive impairment, anxiety, depression, and insomnia are prevalent CRBS that share common risk factors and often aggregate in clusters. We aimed to characterize the evolution of CRBS burden after early-stage BC. **Methods:** Patients with stage I-III BC were included from the CANTO cohort (NCT01993498). Group-based trajectory modeled CRBS burden as assessed by Behavioral Symptoms Score (BSS) reported at diagnosis and at year (Y)1, Y2, Y4, and Y6 post-diagnosis (continuous, range 0-5; 1 point per clinically meaningful symptom reported among fatigue [EORTC QLQ-C30 ≥40/100], cognitive impairment [<75/100], insomnia [>50/100], anxiety or depression [HADS ≥11/21]). Trajectory membership factors were investigated using multinomial regression. **Results:** Among 10782 patients with BSS available at ≥1 time point, we identified 6 trajectories of CRBS: low-burden (21%), late-onset (5%), early-onset (11%), progressively improving (15%), high-burden (37%), and very high-burden (10%). The early-onset group did not report clinically meaningful symptoms at diagnosis but experienced early and persistent post-treatment (tx) worsening: at Y1, 50% had cognitive impairment, 48% fatigue, 45% insomnia, 13% anxiety, and 4% depression. 19% of patients in the early-onset group reported a cluster of ≥3 CRBS at Y1 (Table). Factors associated with membership to early-onset (v low-burden) group included age (adjusted Odds Ratio for 10-year decrement, 1.22 [95% CI 1.04 - 1.34]), monthly income <1500 euro (v ≥3000, 1.48 [1.08 - 2.04]), BMI ≥25 kg/m2 (v <25, 1.27 [1.07 - 1.52]), psychiatric comorbidity (v no, 1.44 [1.12 - 1.86]), chemotherapy (v no, 1.48 [1.19 - 1.84]) and endocrine tx (v no, 1.49 [1.19 - 1.86]). The early-onset group was also characterized by high and persistent rates of post-tx amenorrhea (77% at Y1 and 69% at Y6). In the early-onset group, overweight/obesity (49%) and inactivity (41%) were common at diagnosis. Over time, patterns of behavioral traits including increasing BMI were similar in the early-onset and the persistently high burden groups, whereas trends toward increased physical activity were observed in groups at low burden or progressively improving CRBS (both p for trend <.001). **Conclusions:** Longitudinal trajectories of CRBS were heterogeneous in this large prospective cohort. Clinicians should be aware that initially asymptomatic women may develop clinically meaningful post-tx CRBS, including several reporting clusters of ≥3 CRBS for years after diagnosis. This study highlights factors that can help screening patient at risk of deteriorated symptom burden and suggests potentially interventional targets, capitalizing on healthy lifestyle promotion. Research Sponsor: Conquer Cancer, the ASCO Foundation; Foundation ARC; "Investment for the Future" National Research Agency (ANR); National Research Agency (ANR); National Research Agency (ANR).

% Reporting ≥3 CRBS (cluster) by trajectory and time point.

	Low-Burden	Late-Onset	Early-Onset	Progressively Improving	High-Burden	Very High-Burden
Diagnosis	0	0	0	14	28	83
Y1	0	0	19	2	30	88
Y2	0	0	19	1	30	91
Y4	0	5	13	0	31	89
Y6	0	4	16	0	24	81

12039 Poster Session

PROSTOX, a signature of late GU toxicity after SBRT radiotherapy in MIRAGE, a prospective trial.

Amar Upadhyaya Kishan, Kristen McGreevy, Luca Faustino Valle, Michael L. Steinberg, Maria Casado, Minsong Cao, Joanne B. Weidhaas, Donatello Telesca; Department of Radiation Oncology, University of California, Los Angeles, Los Angeles, CA; Department of Biostatistics, University of California, Los Angeles, Los Angeles, CA

Background: PROSTOX is a germline genetic signature previously found to predict late Grade > 2 genito-urinary (GU) toxicity after stereotactic body radiotherapy (SBRT). MIRAGE is a clinical trial evaluating toxicity in patients treated with CT or MRI-guided SBRT. We evaluated the ability of PROSTOX to predict toxicity in MIRAGE at 2-year follow-up. **Methods:** We evaluated PROSTOX's performance in MIRAGE using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), F1 score, and AUC. We also evaluated the predictive utility of PROSTOX as well as defined a new signature of acute toxicity. We performed a gene ontology (GO) analysis to assess the biological relevance of the biomarkers involved in PROSTOX. Variants were mapped to their corresponding genes, and GO analysis was conducted with an adjusted p-value cutoff of 0.05. We set the genomic background to all the measured variants to account for and remove bias from the pre-selection of variants. All analyses were conducted in R using biomaRt and clusterProfiler packages. **Results:** The validation study included 62 and 57 patients receiving MRI and CT-SBRT treatment, respectively. There were 10 patients in the MRI arm and 16 patients in the CT arm with late GU toxicity. Ages of the patients ranged from 51-86 with a mean of 71 years old. PROSTOX predicted late GU toxicity with an AUC of 0.77 and 0.75 in the MRI and CT treated groups, respectively. Compared to the original training LOOCV metrics, in the Mirage MRI and CT groups PROSTOX resulted in higher sensitivity (0.942, 0.927) and F1 score (0.933, 0.884), but a lower specificity (0.600, 0.563) and NPV (0.667, 0.750). PROSTOX did not predict acute toxicity, but a unique genetic signature for acute toxicity was identified in the MRI-treated cohort (AUC=0.764). However, this signature was not as predictive in the CT-treated cohort (AUC=0.63). The GO analysis revealed 14 pathways enriched in the PROSTOX signature (adjusted p-value < 0.05). Notably, all pathways related to RNA, which appeared to fall into three main categories: RNA regulation, RNA processes, and transcription. Of the 24 unique genes involved in PROSTOX, 15 were conserved across all enriched pathways. **Conclusions:** Our study successfully validated PROSTOX to accurately predict late GU toxicity in patients treated with SBRT, regardless of delivery method. PROSTOX does not predict acute GU toxicity, which appears to have a unique signature but may be impacted by treatment approach. Our GO analysis identified RNA pathways, related to the regulatory mechanisms that control RNA synthesis within the cell, including the biochemical processes necessary for the synthesis, modification, degradation, and turnover of RNA molecules in predicting late GU toxicity. These findings provide insight into potential molecular mechanisms contributing to radiation-induced late toxicity and could lead to therapeutic strategies in the future. Clinical trial information: NCT04384770. Research Sponsor: None.

The utility of procalcitonin in febrile neutropenia.

Jonathan Nilles, Nicole A. Shonka; University of Nebraska Medical Center, Omaha, NE

Background: The utility of procalcitonin (PCT) in febrile neutropenia (FN) in oncology patients on active therapy has not been well validated. FN constitutes a critical oncologic emergency, often characterized by subtle manifestations of infection, and timely diagnosis and treatment is vital. Although a potential harbinger of dangerous infection, FN can also occur without an identifiable infection, in which case hospitalization and antibiotics may be unnecessary. PCT, an amino acid, is elevated specifically during bacterial infections in the non-cancer population and correlates with infection severity. Clinicians employ PCT levels as a diagnostic adjunct, discerning bacterial from viral infections and analyzing PCT changes to guide treatment decisions. We examined oncology patients presenting with FN to correlate PCT levels and trends with confirmed infections. **Methods:** We identified patients with neutropenic fever, cancer, and a PCT result seen at our institution from 12/1/2017-12/1/2022. Patients were determined to have a confirmed infection if they had a positive bacterial blood culture. Demographics and clinical characteristics were compared between infection status and induction chemotherapy or transplant status using a Wilcoxon Rank Sum test for continuous variables and a Chi-Square or Fisher's Exact test for categorical variables. Baseline (at time of initial FN) and highest PCT levels were compared by patient and disease characteristics and proven infection using Wilcoxon Rank Sum test. Logistic regression was used to determine the association of log-transformed PCT (baseline and highest) with proven infection (yes/no) while adjusting for covariates. All tests were two-tailed with $p< 0.05$ considered statistically significant. **Results:** Of 365 patients, 61 (16.7%) had an identified infection. Median baseline and peak PCT of 1.26 and 1.51 ng/mL, respectively, were significantly greater for these patients as compared to those with negative cultures at 0.54 and 0.65 ng/mL, respectively (P= 0.01 and <0.01). For every unit increase in the log transformed baseline PCT, the odds of having a proven infection increased by 23%. There were no significant differences in patient or clinical characteristics between those with and without infection. Of those admitted for induction chemotherapy and transplant who developed FN, PCT at time of initial fever was higher at 0.97 vs 0.56 ng/mL (p=0.02). Interestingly, median baseline and median peak PCT differed between gender with females 0.51 and males 0.72 ng/mL (p=0.02) at baseline, and 0.63 vs 0.83 ng/mL (p=0.04), respectively, at peak. **Conclusions:** PCT levels in cancer patients with FN are significantly associated with culture positive infection. This data can help guide treatment and de-escalation of antibiotics in cancer patients admitted with FN. Further evaluation should be taken to determine how to best use PCT to determine the need for admission and antibiotic prescription. Research Sponsor: None.

12041 Poster Session

The impact of body mass index (BMI) on overall survival (OS) among patients receiving immune checkpoint inhibitors (ICIs): A population-based study.

Zac Coyne, Rinku Sutradhar, Vivian Aghanya, Yosuf Kaliwal, Yue Niu, Ning Liu, Ying Liu, Melanie Lynn Powis, Geoffrey Liu, Jeffrey M. Peppercorn, Monika K. Krzyzanowska, Lawson Eng; Princess Margaret Cancer Centre, Toronto, ON, Canada; Institute for Clinical Evaluative Science, Toronto, ON, Canada; Institute for Clinical Evaluative Sciences, Toronto, ON, Canada; Inst for Clinical Evaluative Sci, Toronto, ON, Canada; Princess Margaret, University Health Network, Toronto, ON, Canada; Department of Medical Oncology and Hematology, University Health Network, Princess Margaret Cancer Centre, Toronto, ON, Canada; Massachusetts General Hospital, Boston, MA; Princess Margaret Cancer Centre, University of Toronto, Toronto, ON, Canada

Background: While obesity is a risk factor for cancer, BMI has been previously identified as a potential prognostic marker in different solid tumors. Prior studies have identified that among cancer survivors receiving ICIs, higher BMI may be associated with better OS, but there have been heterogeneous results among studies. Here we use population-level administrative data to evaluate the association between BMI and OS among patients receiving ICIs. **Methods:** We used administrative data deterministically linked across databases to identify a cohort of solid tumors patients initiating ICI therapy in Ontario, Canada from June 2012 to October 2018 and obtained information on socio-demographics including BMI at start of ICI, clinical covariates, and OS. We applied multivariable Cox proportional hazards models to evaluate the impact of BMI on OS, adjusting for sex, age, cancer center, autoimmune history, recent hospitalization and comorbidity score. Subgroup analyses were performed based on disease site and sex. **Results:** Among 4863 patients, median age was 67, 57% male; 46% had lung cancer, 35% melanoma, 9% renal cancers; 40% received nivolumab, 36% pembrolizumab, 17% ipilimumab. Median BMI was 26.1, with 3% low, 29% normal, 27% overweight, 19% obese. Median OS 317 days. Overall, greater BMI was associated with better OS (aHR=0.98 per unit, 95% CI [0.97-0.99] $p<0.001$). When compared to normal BMI, obese (aHR=0.77 [0.70-0.85] $P<0.001$) and overweight patients (aHR=0.85 [0.78-0.93] $p<0.001$) had better OS while those with low BMI had poorer OS (aHR=1.39 [1.16-1.66] $P<0.001$). Among melanoma patients, those who were obese had better OS (aHR=0.84 [0.71-0.98] p=0.03) and low BMI patients had poorer OS (aHR=1.80 [1.20-2.69] p=0.004) when compared to normal BMI. For lung and renal patients, increased BMI was associated with better OS when BMI was evaluated continuously (aHR_{lung}=0.99 per unit [0.98-1.00] p=0.05; aHR_{renal}=0.98 per unit [0.95-0.99] p=0.04), but no significant associations were observed when BMI was evaluated categorically ($p>0.05$). Among males, patients who were obese (aHR=0.70 [0.62-0.80] $p<0.001$) and overweight (aHR=0.80 [0.72-0.90] $p<0.001$) had better OS compared to those with normal BMI, while those with low BMI had poorer OS (aHR=1.58 [1.22-2.06] $p<0.001$). However, among females, low BMI were associated with poorer OS (aHR=1.29 [1.01-1.65] p=0.04) compared to normal BMI, while no significant associations with OS were observed for overweight (aHR=0.93,p=0.30) or obese (aHR=0.89, p=0.12) patients. **Conclusions:** BMI was identified as a potential prognostic factor among cancer survivors receiving ICIs where greater BMI was associated with better OS. This association varied by cancer type and sex and is particularly notable in melanoma and among males. Further studies understanding these prognostic associations are warranted. Research Sponsor: Conquer Cancer, the ASCO Foundation.

In-hospital outcomes and mortality of drug-induced pneumonitis and radiation pneumonitis in patients with thoracic cancer.

Yi Lee, Kim Abbegail Tan Aldecoa, Keisuke Shirai; Dartmouth-Hitchcock Medical Center, Lebanon, NH; Trinity Health Oakland Hospital/Wayne State University, Pontiac, MI

Background: Pneumonitis is one of the challenging adverse events in thoracic oncology patients undergoing cancer therapy. The cancer treatments, including targeted agents, systemic chemotherapy, immune-checkpoint inhibitors, and radiation therapy have recently advanced, however, the data on incidence of drug-induced and radiation pneumonitis (DP and RP) and their association with in-hospital outcomes is limited. **Methods:** Data from the National Inpatient Sample Database from 2016 to 2019 were analyzed. Adult patients with primary lung cancer were included and categorized into three groups: (1). Patients without pneumonitis, (2). Patients with DP, (3). Patients with RP. Outcomes included in-hospital mortality, intensive care unit (ICU) admission, and hospital length of stay (LOS). Data were extracted using ICD-10 codes. **Results:** Our analysis included 1,631,940 hospitalized primary lung cancer patients (based on a weighted sample). Among all, 4,515 patients had DP, and 16,905 patients had RP. Overall, 69.3% had smoking history, however, no significant difference between DP and RP. There was a higher prevalence of chronic obstructive pulmonary disease (COPD) in RP than DP (66.5% vs 53.2%; $p<0.05$) (Table). The in-hospital mortality rate was highest in DP compared to other groups. Coarsened exact matching method was used to balance covariates between non-pneumonitis and pneumonitis patients (DP and RP). Multivariate logistic regression showed that pneumonitis patients had higher odds of intubation (OR: 1.57; 95% CI: 1.24-1.99; $p<0.05$) and mortality (OR: 1.48; 95% CI: 1.28-1.71; $p<0.05$) than non-pneumonitis. Pneumonitis patients also had 23% longer length of stay than non-pneumonitis patients. We then compared the outcomes between DP and RP using the same matching algorithm, however, there was no significant difference in the outcomes between the two groups. Over the study years, the trend for DP significantly increased, whereas the RP trend was stable. **Conclusions:** Hospitalized pneumonitis patients had relatively poor clinical outcomes compared to patients without pneumonitis. The trend of hospitalized drug-induced pneumonitis is increasingly common. Research Sponsor: None.

	Without Pneumonitis (N=1,610,520)	DP(N=4,515)	RP(N=16,905)	p-value
Age (years)*	69.2 (10.5)	68.3 (10.1)	70.7 (9.7)	$<0.05^a$; $<0.05^b$
Male	822,265 (51.1%)	2,570 (57%)	9,270 (54.9%)	$<0.05^a$; $<0.05^b$
Smoking	412,445 (25.6%)	455 (10.1%)	2080 (12.3%)	$<0.05^a$; 0.33^b
Chronic obstructive pulmonary disease	839,000 (52.1%)	2,400 (53.2%)	11,235 (66.5%)	$<0.05^a$; $<0.05^b$
Metastatic cancer	767,315 (47.6%)	2,700 (59.8%)	5,750 (34%)	$<0.05^a$; $<0.05^b$
Length of stay*	4 (3, 7)	6 (4, 10)	5 (3, 9)	$<0.05^a$; $<0.05^b$
Palliative care	262,480 (16.3%)	1,045 (23.1%)	2,575 (15.2%)	$<0.05^a$; $<0.05^b$
In-hospital mortality	137,970 (8.6%)	730 (16.2%)	1,870 (11.1%)	$<0.05^a$; $<0.05^b$

12043 Poster Session

Body mass index and the risk of subsequent cancers among older cancer survivors.

Clara Bodelon, Hyuna Sung, Ellen Mitchell, Emily L Deubler, Christina C Newton, Ahmedin Jemal, Lauren R. Teras, Alpa Patel; American Cancer Society, Atlanta, GA

Background: Little is known about the etiology of second primary cancers among survivors of older adult-onset cancers. Descriptive studies have suggested that lifestyle factors, including body mass index (BMI), may be important. Here we investigated whether BMI is associated with the risk of a subsequent malignancy among older adult cancer survivors. **Methods:** This analysis was conducted among men and women enrolled in the Cancer Prevention Study II Nutrition cohort who were diagnosed with a first non-metastatic incident cancer between 1992 and 2015. Survivors were followed-up until 2017 for the diagnosis of a subsequent primary malignancy at a different organ to avoid the inclusion of recurrences, as their etiology may differ. Analyses were restricted to those who were younger than 85 years at their initial diagnosis. Subsequent malignancies were included if they were diagnosed at least 60 days after the first cancer. Outcomes of interest were second cancers and obesity-related second cancer as defined by the IARC. BMI at the time or before their first cancer was self-reported (median: 1.3 years from BMI report to diagnosis). Participants who were underweight (BMI$<$18.5 kg/m^2) were excluded. Cox regression was used to compute hazard ratios (HR) and 95% confidence intervals (CI) to estimate the risk of second cancers associated with BMI. Models were adjusted for age, sex, race, diagnosis year, and stage of the first cancer. **Results:** This cohort included 26,894 participants diagnosed with a first cancer. The median age at diagnosis of the first cancer was 72.5 years (interquartile range (IQR): 67.7, 77.0). Most participants were women (59%), overweight or obese (60%) and diagnosed with localized disease (71%). During a median of follow-up of 7.5 years (IQR: 3.2, 13.1), 3,748 participants were diagnosed with a second cancer, including 1,140 obesity-related second cancers. Approximately 90% of second malignancies were diagnosed at least 1 year, and 70% at least 5 years after the first cancer. Compared with cancer survivors whose BMI was in the normal range (18.5$\leq$BMI$<$25), those who were overweight or obese were at an increased risk of any second cancer (25$\leq$BMI$<$30: HR=1.12, 95% CI: 1.05, 1.21; BMI$\geq$30: HR=1.29, 95% CI: 1.18, 1.42) and BMI-related cancers (25$\leq$BMI$<$30: HR=1.37, 95% CI: 1.20, 1.57; BMI$\geq$30: HR=1.60, 95% CI: 1.36, 1.88). In particular, obesity was associated with increased risks of breast (HR=1.43, 95% CI: 1.03, 1.98) and colorectal (HR=1.91, 95% CI: 1.42, 1.56) second cancers. **Conclusions:** Older adult cancer survivors who were overweight or obese at the time of their first cancer diagnosis were at higher risk of developing a second cancer, especially a BMI-related cancer. These findings have important public health implications given the high prevalence of overweight and obesity in this population. Weight loss strategies should be considered and heightened awareness of second cancers among physicians of older cancer survivors. Research Sponsor: None.

Head and neck cancer survivors: Long-term nutrition impact symptoms, eating problems, and barriers to care impact psychosocial health.

M Claire Saxton, Richa Ruwala, Alyssa Jaisle, Kirstin Fearnley, Elif Andac-Jones; Cancer Support Community, Washington, DC

Background: Head and neck cancer (HNC) survivors experience significant long-term side effects of their treatment, and health-related quality-of-life (HRQoL) assessments of HNC survivors are still early in development. This survey captured long-term nutrition impact symptoms, eating problems, psychosocial impact, and barriers to accessing health care of HNC survivors. **Methods:** The Cancer Support Community (CSC) conducted an online survey with participants from CSC, Head and Neck Cancer Alliance, and Support for People with Oral and Head and Neck Cancer (SPOHNC). 172 "long-term survivors" (LTS), at least 2 years past initial diagnosis completed the survey. Most respondents were white (94%) & female (58%). The average age was 64. The most common treatments reported were radiation (93%), surgery (66%), and chemotherapy (59%). **Results:** Physical and psychosocial issues are prevalent and persistent among LTS. Almost all (99%) LTS reported experiencing eating problems since diagnosis, and 92% had symptoms persist into the last 7 days. Dry mouth (85% ever/68% in last week) and problems swallowing (82%/62%) were most common. Prevalence of side effects was independent of stage of cancer and time since initial diagnosis. 42% of LTS reported still not eating a solid food diet (30% "soft" food; 9% feeding tube; 4% liquid or pureed food). 63% ever used a feeding tube. For those no longer using a feeding tube, 71% used it for $\leq$6 months. Current users had feeding tubes for a median of 39 months. Weaning from a feeding tube was most likely before 14 months. 62% of LTS reported still feeling self-conscious when eating, 45% feeling embarrassed about their eating habits, 44% having their daily activities affected by eating problems, 37% said they avoid going out in public when it involves eating or drinking. Despite this, 27% reported never seeing a health care professional (HCP) or mental health professional (MHP) to manage their eating problems & psychosocial impact. Only 11% of LTS ever met with MHPs to address their distress. Female LTS of younger age and those with Medicare insurance were more likely to meet with HCPs (except dentists for Medicare recipients) and MHPs. Financial, transportation, & logistical concerns were top barriers to receiving care. 19% reported cost of care as a moderate to great barrier to cancer treatment. LTS reported difficulty paying for dental work (29%), supplemental nutrition drinks (11%), and other products to manage eating problems (9%). **Conclusions:** Although HNC'S are generally considered "curable," the nature of the disease and the required aggressive treatment regimens leave LTS with a broad range of common physical and psychosocial issues that are rarely addressed. Survey data highlight almost universal, long-term persistence of eating and nutrition problems which cause significant psychosocial impact over LTS's lifetime. Research Sponsor: Bristol Myers Squibb; Merck.

12045 Poster Session

Late mortality and chronic health conditions in long-term survivors of nasopharyngeal cancers: The 20-year follow-up of territory-wide Hong Kong Nasopharyngeal Cancer Survivor Study (HKNPCSS).

Chi Leung Chiang, Ching Lung Cheung, Sik-Kwan Chan, Philip Chun Ming Au, Ka Shun Fong, Chor Wing Sing, Charlene Hoi Lam Wong, James Chung Hang Chow, Ken Ka Man Cheung, Winnie Wing Yan Tin, Edwin Chun Yin Wong, Tracy Tsz Shan Lau, Kenneth Chun Wai Wong, Ann Sum Yin Chan, Victor Ho-Fun Lee, Anne Wing Mui Lee, Wai Tong Ng, Ian Chi Kei Wong; Department of Clinical Oncology, The University of Hong Kong, Hong Kong, Hong Kong; Department of Pharmacy and Pharmacology, The University of Hong Kong, Hong Kong, Hong Kong; Department of Clinical Oncology, Queen Elizabeth Hospital, Hong Kong, Hong Kong; Department of Clinical Oncology, Tuen Mun Hospital, Hong Kong, Hong Kong; Department of Clinical Oncology, Pamela Youde Nethersole Eastern Hospital, Hong Kong, Hong Kong; Department of Oncology, Princess Margaret Hospital, Hong Kong, Hong Kong; Department of Clinical Oncology, Prince of Wales Hospital, Hong Kong, Hong Kong; Department of Clinical Oncology, Queen Mary Hospital, Hong Kong, Hong Kong; Clinical Oncology Center, The University of Hong Kong – Shenzhen Hospital, China, Hong Kong, Hong Kong

Background: The survival rate of patients with nasopharyngeal cancer (NPC) has significantly improved in the last decade. However, there are only a few studies that have quantified the long-term morbidity and mortality that follow NPC treatment. This study aims to analyze the chronic health conditions, all-cause mortality, and cause-specific mortality among NPC survivors. **Methods:** The Hong Kong NPC Survivor Study (HKNPCSS) is a retrospective cohort study conducted across all six oncology centers in Hong Kong. It included longitudinal follow-up of 5-year survivors diagnosed with NPC between 1997 to 2015. We compared the standardized mortality ratio (SMRs) of 7893 survivors to a matched population in terms of age, sex, and calendar year. We also calculated the frequencies of chronic conditions of 7893 survivors and 23679 healthy individuals with matched age, sex, and date of cohort entry. Chronic health conditions were classified using the Common Terminology Criteria for Adverse Events. Cox proportional hazard models were used to estimate hazard ratios (HRs) for chronic health conditions. **Results:** The mean age of NPC survivors was 49.1 years, while healthy individuals had a mean age of 50.5 years. Among the 7893 NPC survivors, the 20-year cumulative all-cause mortality was 34.0% (95% CI, 29.1%-38.9%), with 1668 (59.9%) of 2785 deaths attributed to health-related causes. The SMR for NPC survivors compared to the general population was 3.81 (95% CI, 3.67-3.95), with the highest SMRs observed for pulmonary (SMR: 6.18, 95% CI, 5.73-6.64) and cardiovascular (SMR: 2.12, 95% CI, 1.90-2.36) causes. Among the survivors, 59.2% (n=4674) had severe, life-threatening, or fatal (grade 3-5) health conditions, with a 20-year cumulative incidence of 59.0% (95% CI, 56.4%-61.5%). The adjusted hazard ratio (HR) of grade 3-5 chronic condition in NPC survivors, compared to healthy cohorts, was 7.02 (95% CI, 6.64-7.42). Gastrointestinal (HR: 20.7), hearing, visual, and nasal (HR: 15.4), and neurological (HR: 8.39) conditions had the highest risks. Intensity modulated radiotherapy (IMRT), compared to non-IMRT, was associated with reduced risks of all-cause mortality (HR: 0.83, 95% CI, 0.74-0.91) and a trend towards reduced grade 3-5 chronic health conditions (HR: 0.89, 95% CI, 0.75-1.05). **Conclusions:** Even 20 years after diagnosis, NPC survivors still face increased risks of late mortality and morbidity. The findings emphasize the need for a comprehensive survivorship program to improve outcomes for NPC survivors. Research Sponsor: None.

Impact of chemotherapy-induced peripheral neuropathy permanence on patients' preference to discontinue chemotherapy.

Yerial Jun, Xueting Tao, Ciao-Sin Chelsea Chen, Jennifer J. Griggs, Kelley M. Kidwell, Daniel Louis Hertz; University of Michigan College of Pharmacy, Ann Arbor, MI; University of Michigan School of Public Health, Ann Arbor, MI; Rogel Cancer Center, University of Michigan, Ann Arbor, MI; Department of Biostatistics, University of Michigan, Ann Arbor, MI

Background: Chemotherapy-induced peripheral neuropathy (CIPN) diminishes patients' functional ability and quality of life; approximately 40% of patients experience CIPN symptoms 3 years after treatment. Due to the absence of effective CIPN treatments, ASCO guidelines recommend discontinuing chemotherapy in patients experiencing intolerable CIPN symptoms. Little is known about patient's preference to continue or discontinue chemotherapy when experiencing CIPN, and whether the potential permanence of CIPN symptoms affects this decision. The objective of this prospective observational study was to determine the effect of CIPN symptom permanence on patients' preference to discontinue chemotherapy. **Methods:** Patients receiving taxane and/or platinum chemotherapy for breast or colorectal cancer were enrolled in a prospective observational clinical study. Patients reported their CIPN severity using the EORTC CIPN20 patient-reported outcome questionnaire at the start of each treatment cycle. At the same time, patients were asked if they would prefer to continue or discontinue chemotherapy treatment under the hypothetical scenario that their current CIPN symptoms would be temporary or permanent. A generalized linear mixed effects model was used to determine the effect of CIPN severity, permanence, and other clinical variables on a patient's decision to discontinue (vs. continue) chemotherapy treatment. **Results:** A total of 66 patients completed data collection at least one time, of whom 55 (83%) had breast cancer, 12 (18%) had metastatic disease, and 52 (79%) received a taxane. The odds a patient would prefer to discontinue chemotherapy treatment if their CIPN symptoms would be permanent (vs. temporary) were nearly 30 times greater (odds ratio (OR)=30.15, 95% confidence interval (CI): 15.73-57.79, $p<0.001$, Table). There was a statistical trend toward preferring to discontinue chemotherapy treatment as CIPN symptom severity increased (OR=1.09, 95% CI: 1.00-1.19, p=0.063). **Conclusions:** The potential for CIPN symptoms to be permanent has a huge effect on whether patients want to continue or discontinue chemotherapy treatment. Additional data is needed on the incidence and predictors of permanent CIPN. More importantly, shared decision-making tools that convey the risk of permanent CIPN, and the potential risk of discontinuing chemotherapy treatment, are needed to facilitate patient-centered treatment decisions so that each patient with cancer achieves their personal treatment goals. Research Sponsor: Rogel Cancer Center.

	Odds Ratio (95% CI)	P-value
CIPN Permanent (vs. Temporary)	30.15 (15.73-57.79)	<0.001
CIPN Severity (CIPN20 Sum Score)	1.09 (1.00-1.19)	0.063
Duration of chemotherapy treatment	1.01 (1.00-1.01)	0.205
Taxane-containing chemotherapy	0.88 (0.41-1.87)	0.739
Platinun-containing chemotherapy	1.03 (0.39-2.72)	0.958

Delayed immune-related adverse events in patients with advanced melanoma treated with immune checkpoint inhibitors.

Arkhjamil Angeles, Eric Sonke, Thao Phuong Nguyen, Gaurav Bahl, Vincent Isaac Poon, Vanessa Bernstein, Alison Margaret Weppler, Kerry J. Savage; BC Cancer, Vancouver, BC, Canada; BC Cancer, Abbotsford, BC, Canada; BC Cancer Agency Vancouver Island Centre, Victoria, BC, Canada; BCCA, Vancouver Centre, Vancouver, BC, Canada

Background: Immune checkpoint inhibitors (ICIs) have changed the treatment landscape of melanoma but can have serious or life-altering immune-related adverse events (irAEs). Most toxicities associated with ICIs occur within the first few months (mo) of treatment initiation, but delayed irAEs occurring 12 mo after ICI start are not well characterized. Further, clinical trials often have limited follow-up of AEs and thus, real world data is valuable. **Methods:** Patients (pts) ≥18 years with advanced melanoma who received ≥1 cycle of an ICI at BC Cancer from 2012-2019 with ≥12 mo of follow-up from time of ICI initiation were identified using the BC Cancer Registry and Pharmacy databases. Data on baseline clinicopathologic factors prior to the first cycle of ICI, and delayed irAE history and management were extracted. Delayed irAEs were graded using CTCAEv5. **Results:** In total, 530 pts treated with ≥1 cycle of an ICI were identified of which 309 pts had ≥12 mo of follow-up. Median follow-up for alive pts was 65.3 mo (13.0-143.5 mo). 96 (31%), 147 (48%), 19 (6%), and 47 (15%) pts received combination ICI (nivolumab/ipilimumab ± nivolumab maintenance), PD-1 inhibitor monotherapy (nivolumab or pembrolizumab), CTLA-4 inhibitor monotherapy (ipilimumab), and sequential CTLA-4 and PD-1 inhibitors, respectively. A total of 142 delayed irAEs were recorded in 94 (30%) pts. Median time to onset of delayed irAEs was 20.0 mo (12.2-80.6 mo). The most common delayed irAEs were dermatologic (27%), gastrointestinal (23%), and rheumatologic (20%). Most delayed irAEs were grade ≤2 (84%), but some were grade ≥3 (16%). Of individual delayed irAEs, 75 (51%) occurred on ICI treatment at time of onset, 39 (26%) after ≤3 mo of the last ICI cycle, and 34 (23%) after >3 mo of the last ICI cycle. 79 (56%) and 20 (14%) delayed irAEs were treated with systemic steroids and immunomodulators, respectively. Further, 12 (8%) delayed irAEs led to hospitalization, and 64 (45%) required subspecialty consultation. Pts with a history of autoimmune disease were more likely to have a delayed irAE (p=0.02), as were pts who achieved a partial or complete response (p=0.02). There was a trend towards a greater frequency of delayed irAEs in pts treated with PD-1 (37%) compared with combination (28%), CTLA-4 (11%), or sequential CTLA-4 and PD-1 (28%) (p=0.068). **Conclusions:** Delayed irAEs occurred in almost a third of pts with advanced melanoma treated with ICIs and followed for at least 1 year. Extended follow-up to monitor for delayed irAEs should be considered as many events required immunosuppressive therapy and rarely, may be life threatening. Research Sponsor: None.

Delayed irAEs.

Event	Any Grade, n (%)	Grade 1 or 2, n (%)	Grade 3 or 4, n (%)
All	142 (100%)	119 (84%)	23 (16%)
Dermatologic	39 (27%)	36 (25%)	3 (2%)
Endocrine	15 (11%)	11 (8%)	4 (3%)
Gastrointestinal	33 (23%)	27 (19%)	6 (4%)
Rheumatologic	29 (20%)	26 (18%)	3 (2%)
Respiratory	15 (11%)	14 (10%)	1 (1%)
Other	11 (8%)	5 (3%)	6 (4%)

12048 Poster Session

Defining musical toxicity after breast cancer treatment: A classification tree analysis.

Jessica Frances Burlile, Joshua Cameron, Heather Gunn, Nicole Larson, Judy Caroline Boughey, Mary Megan Mrdutt, Fergus Couch, Janet E. Olson, Jennifer L. Bradt, Yasamin Sharifzadeh, Kathryn Jean Ruddy, Dean Shumway, Charles L. Loprinzi, Elizabeth Jane Cathcart-Rake; Mayo Clinic, Rochester, MN; Mayo Clinic Department of Quantitative Health Sciences, Rochester, MN; Division of Epidemiology, Mayo Clinic, Rochester, MN; Mayo Clinic Department of Physical Medicine and Rehabilitation, Rochester, MN; Department of Medical Oncology, Mayo Clinic, Rochester, MN; Department of Radiation Oncology, Mayo Clinic, Rochester, MN

Background: Playing music has been an important part of human culture for millennia. Today more than half of American households have at least one person who plays music, and in the UK 43% of adults play an instrument. Despite the overlap between musicians and people diagnosed with cancer, the effect of cancer treatment on musicianship has not been well-studied. We previously reported that 26% of a musician breast cancer survivor cohort reported difficulty with musicianship after treatment, and here we conduct further analysis to identify treatment and disease factors associated with this difficulty, termed acute musical toxicity (AMT). **Methods:** The Musical Toxicity Questionnaire was distributed to participants who had previously enrolled in the Mayo Clinic Breast Cancer Registry. PROMIS (Patient-Reported Outcomes Measurement Information System) scores were available through the Registry and treatment details were collected retrospectively. Due to the inter-dependency and high correlation between treatment and disease-related variables, a classification tree analysis (CTA) was performed to identify the combination of variables that most accurately classified patients by AMT. Sixteen variables were analyzed by the algorithm. Logistic regression was utilized for examining associations between AMT and continuous variables. **Results:** Of the 4075 surveys distributed, 1871 were returned and 535 respondents identified as musicians. Median time from diagnosis was 5.2 years, respondents were mostly stage I or II (71%), and 32% were node positive (N+). Over a quarter (26% or 144 respondents) reported AMT. In the final CTA model, being N+ was strongly associated with AMT (42% of those N+ had AMT, 20% of those not N+ had AMT). For respondents who were N+, those who received endocrine therapy were more likely to have AMT than those who did not (46% vs 21% respectively). Subsequent leaves identified not undergoing axillary lymph node dissection (ALND) and receiving chemotherapy as associated with AMT. For respondents who did not receive chemotherapy, breast reconstruction was associated with AMT (60% vs 19%). Variables such as mastectomy, radiation volume, specific chemotherapies, and stage of disease were not selected by the algorithm. The odds of having AMT decreased by 9.7% and 17% with each additional point in the composite mental health ($p=0.003$) and physical health ($p<0.001$) PROMIS scores, respectively. The odds of having AMT increased by 3.5% with each lymph node removed ($p=0.001$). **Conclusions:** The final model suggests that the group with the largest proportion of AMT was N+, received endocrine therapy, did not have ALND, and received chemotherapy. Both physical and mental health PROMIS scores were associated with AMT, although the directionality of this relationship requires more study. Care teams should counsel patients on potential musical toxicity and engage in shared decision making with musical patients. Research Sponsor: Mayo Fellows Association; Mayo Clinic Department of Radiation Oncology.

12049 Poster Session

Risk and impacts of drug-induced liver injury (DILI) due to immune-checkpoint inhibitors (ICI) on overall survival in patients with newly diagnosed cancer: A retrospective cohort study.

Mohamed I. Elsaid, Alexa Simon Meara, Dwight Hall Owen, Ashish Manne, Fode Tounkara, Khalid Mumtaz, Electra D. Paskett, Chyke Doubeni, Aditi Shendre, Lang Li, Claire F. Verschraegen; The Ohio State University Wexner Medical Center and Comprehensive Cancer Center, Columbus, OH; The Ohio State University Comprehensive Cancer Center, Columbus, OH; The Ohio State University, Columbus, OH; The Ohio State University Wexner Medical Center, Columbus, OH; The Ohio State University College of Medicine, Columbus, OH; Department of Biomedical Informatics, The Ohio State University, Columbus, OH; Department of Biomedical Informatics, The Ohio State University College of Medicine, Columbus, OH; The Ohio State University James Comprehensive Cancer Center, Columbus, OH

Background: The risk and impact of drug-induced liver injury (DILI) due to ICI treatment on newly diagnosed cancer patients have not been fully investigated. This study aims to assess the incidence and impact of ICI related DILI on overall survival. **Methods:** We included patients with newly diagnosed cancer treated with ICIs between 01/2012 and 12/2020 at the Ohio State University Comprehensive Cancer Center. DILI was defined using ICD-9 and ICD-10 codes for abnormal results of liver function, acute hepatitis, drug-induced liver injury, or toxic liver disease. History of Liver Disease (HLD) before ICI infusion was defined using ICD-9 and ICD-10 codes for any liver disease, including primary and secondary liver malignant neoplasms. To examine the causal effects of ICI-related DILI, patients who developed hepatocellular carcinoma or metastatic liver disease were excluded. Kaplan Meier method was used to estimate DILI risk post-ICI infusion in patients with and without HLD. Crude and Adjusted Cox proportional models were used to examine the association between DILI, modeled as time-dependent, and overall survival. **Results:** A total of 2,816 patients were included in the study, with a median age of 62 years, 58% male, and 90% white non-Hispanics. An estimated 11% of patients developed DILI during follow-up. The median (interquartile range) follow-up time from ICI infusion to DILI was 8.7 (3.0–20.1) months. The overall risk of DILI was 25.3%, which was significantly higher in patients with HLD than in those without HLD (17.8% vs. 30.8%, Log-Rank P $<$0.001). The median (interquartile range) survival time was 10.4 (3.7–22.7) months. During follow-up, a total of 1390 (49.4%) patients died. DILI was significantly associated with a higher risk of all-cause mortality in all regression models. The crude risk of all-cause mortality was 40% higher in patients with DILI than in those without DILI [HR: 1.40; 95% CI: 1.15–1.70]. In the fully adjusted models, DILI was associated with a 63% higher risk of all-cause mortality [adjusted HR: 1.63; 95% CI: 1.34–1.99]. DILI's effects on the overall survival risk remained significant when we further adjusted for HLD status [HR: 1.57; 95% CI: 1.29–1.93]. **Conclusions:** The findings from this retrospective cohort study highlight the significant risk and detrimental impact of DILI on overall survival in patients treated with ICIs. Notably, the incidence of DILI was significantly higher among patients with HLD, underscoring the elevated vulnerability of this subgroup. Furthermore, DILI was a significant predictor of increased all-cause mortality regardless of HLD status. These results underscore the need for vigilant monitoring and management of liver function in patients receiving ICIs, particularly in those with pre-existing liver conditions, to mitigate the risk of DILI and improve survival outcomes. Research Sponsor: None.

12050 Poster Session

Physical activity and dexamethasone for cancer related fatigue: A preliminary placebo controlled randomized control trial.

Sriram Yennu, Vicente Valero, Brandon George Smaglo, Michael J. Overman, Arvind Dasari, Robert A. Wolff, Kanwal Pratap Singh Raghav, Carlos Hernando Barcenas, Naifa Lamki Busaidy, Bryan M. Fellman, Karen Basen-Engquist, Debashish Tripathy, Eduardo Bruera; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: Despite high frequency and significant impact on quality of life, there are limited treatment options available for cancer related fatigue (CRF) in patients with advanced cancer. The primary aim of the study was to determine the feasibility (adherence, safety, and satisfaction) of the combination therapy, physical activity (PA) plus Dexamethasone (Dex); and PA plus placebo (Pl) for CRF. The secondary aim was to explore the effects of PA+Dex, and PA+Pl on CRF as assessed by Functional Assessment of Cancer Illness Therapy–fatigue (FACIT-F). **Methods:** In this phase 2, randomized, double blind, placebo controlled trial, patients with advanced cancer with CRF $\geq$ 4/10 on Edmonton Symptom Assessment Scale were eligible. Patients were randomized to standardized PA for 4 weeks plus either 4mg of Dex (PA+Dex arm), or Pl (PA+PL arm) BID for the first 7 days. Changes in FACIT-F scores from baseline to Day 8, and Day 29 were assessed. Other outcomes included change in quality-of-life scores. **Results:** A total of64 (89%) patients were evaluable. The median (IQR) changes in FACIT-F scores at Day 8 and Day 29 from baseline were 9 (2,16), P< 0.001; 5.75 (0,12.5), P=0.015 for PA+ Dex arm, and 3.5 (-2.13, 10), P=0.054; 6.50 (2.5, 15.5), P=0.006 for PA+ Pl arm respectively. Exploratory Linear Mixed Model (LMM) analysis showed significant treatment effect of PA +Dex, with treatment having improvement of 5.63 units for FACIT-F scores (95% Cl 1.74,9.52), P=0.005. Effect sizes for improvement of FACIT-F scores at Day 8 and Day 29 were -3.49, -2.43 in PA+Dex arm; and -1.93, -2.72 in PA+Pl arm, respectively. Effect sizes for change in fatigue related symptoms and quality of life scores as assessed by Patient-Reported Outcome Measurement Information System-Fatigue T-scores, Multidimensional Fatigue Symptom Inventory-Short Form total, and Functional Assessment of Cancer Therapy -General scores at Day 8, and Day 29 in PA+ Dex arm were 2.93 (P=0.005), 2.82 (P=0.005); 2.27 (P=0.023), 2.68 (P=0.007); -2.39 (P=0.017), -3.26 (P=0.001) respectively. Adherence to Dex and Pl were 91% and 92%, respectively, Satisfaction rates with PA+Dex and PA+Pl arms were 98% and 79%, respectively. There was no significant difference in grade $\geq$3 adverse events between the two arms (P = 0.36). **Conclusions:** Satisfaction, and tolerability to the combination therapy, and medication adherence was excellent.PA + Dex significantly improved CRF at day 8 and 29. The improvement was sustained 3 weeks after discontinuation of Dex. Further larger studies are justified. Clinical trial information: NCT03583255. Research Sponsor: U.S. National Institutes of Health.

Efficacy of treatment with traditional Chinese patent medicine (*Fufang E'jiao Syrup*) for cancer-related fatigue in patients with advanced cancer: A randomized, double-blinded, placebo-controlled, multicenter trial.

Shan Shan Gu, Yun Xu, Jun J. Mao, Lingyun Sun, Ning Cui, Feiye Wang, Jing Dong, Xingyu Guo, Li Fu, Jinghui Wang, Jiyan Shi, Yumei Zeng, Yidan Hu, Zipei Zhang; Department of Oncology, Xiyuan Hospital of China Academy of Chinese Medical Sciences, Beijing, China; Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY; Xiyuan Hospital of China Academy of Chinese Medical Sciences, Beijing, China; School of Beijing University of Chinese Medicine, Beijing, China

Background: There is ongoing interest in finding effective drugs for cancer-related fatigue (CRF) in advanced cancer patients, although studies have had mixed results. *Fufang E'jiao Syrup* (FFEJS), a traditional Chinese patent medicine, has shown promise in alleviating CRF. This trial aims to investigate whether FFEJS could reduce fatigue and improve quality of life in advanced cancer patients. **Methods:** This prospective, multicenter, double-blinded, placebo-controlled trial was implemented at 29 hospitals in China, enrolling 611 advanced non-small cell lung cancer, colorectal cancer, and gastric cancer patients with Visual Analogue Scale for Fatigue ≥ 4 points. The study was conducted between September 23, 2019 and April 7, 2022, with a final follow-up on May 25, 2022. Participants were randomized to receive FFEJS (20 ml, 3 times per day) or a matching placebo orally for six weeks. The safety assessments were extended until the fourth week after the trial ended. The primary outcome was the change in total mean score (range: 0 [no fatigue] to 10 [extreme fatigue] points) on the Revised Piper Fatigue Scale-Chinese Version (RPFS-CV) from baseline to week 6. Secondary outcomes include quality of life (Functional Assessment of Chronic Illness Therapy-Fatigue, FACIT-F) and adverse events. FFEJS were compared with the placebo group using a linear mixed model. **Results:** Among 611 patients randomized (FFEJS: 303 and placebo: 308; 210 non-small cell lung cancer [34.4%], 201 colorectal cancer [32.9%], 200 gastric cancer [32.7%]; mean [SD] age, 62.8 [9.3] years; 413 [68.3%] man; mean [SD] baseline RPFS-CV total mean score, 4.86 [1.30] points), 503 (82.3%) completed the primary end point. By the end of week 6, the FFEJS group achieved normal fatigue levels (RPFS-CV < 4) compared to the placebo group (FFEJS: 3.78 vs Placebo: 4.39, adjusted mean difference 0.59 points [95% CI, 0.45 to 0.76 points]; $P < .001$). The adjusted mean difference for a favorable shift to a higher FACIT-F total score at week 6 comparing FFEJS with placebo was 2.77 points (97.36 vs 94.23 points; [95% CI, 0.56-4.96 points]; $P = .02$). There was no difference in adverse events occurrence between FFEJS and the placebo groups (110 [20%] vs 122 [18%], $P = .38$). **Conclusions:** In this randomized clinical trial among advanced cancer patients with CRF, FFEJS reducedfatigue severity and improved quality of life compared to placebo. Research is needed to assess the mechanism, clinical effect, and long-term safety of FFEJS for CRF in advanced cancer patients. Clinical trial information: NCT04147312. Research Sponsor: National Key Research and Development Program of China; 2018YFC1707406.

12054 Poster Session

Attitudes and beliefs regarding sexual dysfunction among patients with advanced cancer receiving palliative care.

Patricia Bramati, Sonal Admane, Minxing Chen, Aline Rozman de moraes, Guadalupe Padilla, McKenna Erck, Marvin Omar Delgado-Guay, Eduardo Bruera; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: Sexual dysfunction (SD) is highly prevalent among patients with advanced cancer, but it is not regularly assessed by palliative care (PC) specialists. This study aims to investigate the frequency of SD, and its impact in PC patients with cancer, as well as the barriers they face to have an open communication with PC providers. **Methods:** AdultPC patients with cancer seen at the outpatient Supportive Care Clinic were invited to participate in a 25-item questionnaire about SD. The survey was voluntary and anonymous. **Results:** A total of 100 patients (54 women and 46 men) completed the survey. The mean age was 55 (range 24-78), 90% were Caucasians, 16% Hispanics and 77% were married or lived with a partner. In the month and within six months before the survey, the patients received treatment with chemotherapy (44 and 37%), radiation (14 and 13%), or surgery (4 and 20%), respectively. Only 29 patients (29%) would like to discuss their SD with a provider -this was consistent across gender (p= 0.827) and age groups (p= 0.194)-, even though 81% had experienced SD in the previous year and merely 45% were satisfied with their sexual function. Only 20 (20%) reported that their clinician had ever asked them about SD. Most of the patients (79%) responded that it was appropriate for the clinician to inquire about SD but only 32% thought that clinicians should always ask. Patients *"strongly agreed or agreed"* that the SD worsened their depression (39%), anxiety (28%), pain (14%), fatigue (13%), and wellbeing (39%). Factors that worsened the current sexual desire included medications in 33/59 participants, treatments (chemotherapy, radiation or surgery) in 61/80, miscommunication with the partner in 31/66, urinary incontinence in 17/24, weigh loss in 18/36, body image in 45/64, tube/lines (nephrostomy, colostomy, urinary catheter, etc) in 12/18, and oxygen in 4/12. When asked why they did not discuss SD, 64% said that discussing other symptoms was more important, 35% said that they wanted to keep it private, 29% because a family member was present, and 17% because of lack of time. **Conclusions:** SD is very common among PC patients with cancer and it worsens their emotional and physical symptoms as well as their overall wellbeing. About only a third of the respondents said they would want to discuss it with their provider, and almost two-thirds said that talking about other symptoms was more important. Our findings do not support the notion that PC specialists should always initiate a discussion about SD with their PC patients with cancer. Future studies should try to better identify which PC patients are open to talk about SD and exploring its therapies. Research Sponsor: None.

12055 Poster Session

The safety and efficacy of diclofenac sodium suppository as adjunctive opioids in the treatment of cancer pain: A prospective, multi-center, real-world study.

Jianping He, Yan Zhang, Yaogui Wu, Huarong Zhao, Jinqi Yang, Zhenhua Zhang, Hongmei Qiao, Yufeng Cao, Zhenhua Yan, Yang Wang, Guoyi Ji, Shudong Zhan, Yarui Zhang, Yu Sun, Peng Meng, Xiuliang Zhang, Xiang Wang, Zhifeng Guo, Shoulei Ren, Wentian Zhang; Division of Abdominal Tumor Multimodality Treatment, Cancer Center, West China Hospital, Sichuan University, Chengdu, China; Gastrointestinal Cancer Center, Peking University Cancer Hospital & Institute, Beijing, China; The Renmin Hospital of Wuhan University, Wuhan, China; People's Hospital of Hejiang County, Luzhou, China; Yanggu People's Hospital, Liaocheng, China; People's Hospital of NingGuo, Anhui, Ningguo, China; Baoji High-Tech Hospital, Baoji, China; Qingdao Hiser Hospital Affiliated of Qingdao University, Qingdao, China; Ruzhou Hospital of Traditional Chinese Medicine, Ruzhou, China; Tieli Medical Service Community Central Hospital, Tieli, China; The First People's Hospital of SiPing, Siping, China; Gaoyou Hospital of Traditional Chinese Medicine, Yangzhou, China; Tianjin Union Medical Center, Tianjin, China; Anqiu City People's Hospital, Anqiu, China; Yantai Hospital of Traditional Chinese Medicine, Yantai, China; People's Hospital of Pingyi County, Linyi, China; Xiangxiang People's Hospital of Hunan Province, Xaingxiang, China; Chifeng City Hospital, Chifeng, China; Sunshine Union Hospital, Weifang, China; Lingshou County Hospital of Integrated Traditional Chinese and Western Medicine, Shi Jia Zhuang, China

Background: Cancer pain is one of the most common and unbearable symptoms for cancer patients (pts), seriously affecting their quality of life. Diclofenac sodium is a potent third-generation non-steroidal anti-inflammatory drug known for its significant analgesic, anti-inflammatory, and antipyretic effects. It is commonly used to treat different types of cancer pain. The objective of this study was to assess the safety and effectiveness of diclofenac sodium suppository when used alongside opioids for managing cancer pain in pts with solid tumors. **Methods:** In this prospective, multi-center, real-world study, we enrolled pts diagnosed with malignancy, Eastern Cooperative Oncology Group (ECOG) performance status of 0-3, numeric rating scale (NRS) score $\geq$ 3, and sustained cancer pain, who required additional analgesic medication were enrolled. Diclofenac sodium suppository is an anal administration suppository, prescribed once a day at a dosage of 50 mg. This study was conducted across 20 centers to observe the clinical characteristics of pain relief in pts with cancer pain . The primary endpoint of the study was to assess the safety of the medication. The secondary endpoints included evaluating the incidence of breakthrough pain (BP), NRS score, and Brief Pain Inventory (BPI) score on the second and sixth days of medication. **Results:** Of the 506 pts that were screened, 437 pts met the inclusion criteria. This included 10 pts who did not receive planned treatment and 2 pts who did not undergo post-baseline efficacy evaluation. Among the 425 pts in the full analysis set (FAS), 261 were man, and 169 (39.8%) had baseline BP. The mean age was 63.0$\pm$11.3 years old. Among 425 response-evaluable pts, compared to the baseline, the incidence of BP was reduced on the second (20.0% vs 39.8%), and sixth days (14.8% vs 39.8%) of medication and the difference was statistically significant ($P < 0.001$, $P < 0.001$). For pts with baseline BP, 56.2% and 66.9% pts achieved BP relief on the second and sixth days of medication, respectively. From the baseline evaluation, the mean NRS scores for the three visits (baseline, second day, sixth day) were 5.28 $\pm$ 1.71, 3.73 $\pm$ 1.71, and 2.91 $\pm$ 1.88, respectively. The mean pain intensity at each visit was decreased compared to the baseline, and the difference was statistically significant ($P < 0.001$, $P < 0.001$). 427 pts were included for safety analysis and 5 pts experienced any grade treatment emergent adverse events (TEAEs). All TEAEs were grade 1-2. TEAE leading to treatment discontinuation was occurred in one pt. **Conclusions:** This study demonstrated that diclofenac sodium suppository was an effective treatment option for managing breakthrough pain in patients with persistent cancer pain who required additional analgesic therapy. Moreover, diclofenac sodium suppository was found to be well tolerated when administered anally. Research Sponsor: None.

Systemic inflammation-modified PG-SGA index in the survival prediction of advanced cancers.

Yu Min, Tingting Dai, Xuemei Li, Lei Cai, Jitao Zhou, Xingchen Peng; West China Hospital, Chengdu, Sichuan, China; West China Hospital, Chengdu, China; Institute of Hepatopancreatobiliary Surgery, Chongqing General Hospital, Chongqing University, Chongqing, China; Division of Abdominal Tumor Multimodality Treatment, Department of Radiation Oncology, State Key Laboratory of Biotherapy and Cancer Center, West China Hospital, Sichuan University, Chengdu, China; Department of Biotherapy, Cancer Center, West China Hospital, Sichuan University, Chengdu, China

Background: The tight association between inflammation and nutrition has been established. Whether the systemic inflammatory indicators could increase the predictive power of nutrition assessment tools in the survival of advanced cancers remains unclear. **Methods:** In this retrospective study, advanced cancer patients were enrolled from the West China Hospital between Nov 2019 and Sep 2023. Five systemic inflammatory indicators were selected including the systemic inflammatory index (SII), neutrophil to lymphocyte ratio (NLR), platelet to lymphocyte ratio (PLR), lymphocyte to monocyte ratio (LMR), and advanced lung cancer inflammation index (ALI). Nutritional status was evaluated by the PG-SGA. Kaplan-Meier curves, restricted cubic splines (RCS), and Cox regression analyses were used to estimate the effects of systemic inflammation indices as well as systemic inflammation-modified PG-SGA index on the survival of cancer patients. Stratified and sensitive analyses were conducted to determine the high-risk subgroups and check the robustness of the main findings. **Results:** In total, there were 1,065 advanced-stage cancer patients included in this study, with a mean age of 58.18 years old. Advanced lung cancer (265 cases, 24.9%) accounted for relatively higher proportions of the whole study population, followed by colorectal cancer (167 cases, 15.7%), esophagus cancer (143 cases, 13.4%), and gastric cancer (139 cases, 13.0%). With a median follow-up of 1,300 days, 501 deaths (47.04%) were observed. Multivariate Cox regression analysis showed that ALI maintained the best predictive power in predicting the all-cause mortality of advanced-stage cancer patients when compared with other systemic inflammation indicators (4^{th} quartile: hazard ratio (HR)= 0.38, 95% confidence interval (CI): 0.29, 0.50, $P<0.001$), with a C-index of 0.615. The novel inflammation-modified PG-SGA/ALI index showed better predictive value in identifying the high-risk subgroups of advanced-stage cancer patients, with an AUC of ROC of 0.68 in 365-day mortality, 0.65 in 730-day mortality, and 0.64 in 1300-day survival prediction, respectively. The C-index (0.626), calibration curves, and decision curve analysis validated the promising predictive accuracy of the PG-SGA/ALI index in predicting the all-cause mortality of advanced-stage cancer patients. No significant interaction was observed between subgroups. A series of sensitive analyses supported the consistent findings as we determined in the main regression. **Conclusions:** Our study highlights that the PG-SGA/ALI index has superior predictive value than original PG-SGA criteria in short- and long-term survival prediction of advanced cancers. The PG-SGA/ALI index would be a more accurate tool for nutritional evaluation and prognosis prediction among cancer patients during clinical practice. Research Sponsor: National Key Research and Development Program of China; 2021YFE0206600.

"Let's talk about sex, fertility and menopause": The Irish experience for those diagnosed with metastatic breast cancer (MBC)—An all-Ireland patient-led survey (CTRIAL-IE 23-05).

Yvonne O'Meara, Siobhan Gaynor, Emer Mulvaney, Frances K Duane, Catherine Weadick, Helen Greally, Rachel J Keogh, Mary Jane O'Leary, Ann McBrien, Eibhlin Mulroe, Ieva Teiserskyte, Isabel Beristain, Jacinta Marron, Sarah McLoughlin, Victoria Donachie, Seamus O'Reilly; University College Dublin, Dublin, Ireland; Cancer Trials Ireland, Dublin 2, Ireland; St. Luke's Radiation Oncology Network and Trinity St. James's Cancer Institute, Dublin, Ireland; Department of Medical Oncology, Cork University Hospital, Cork, Ireland; Cancer Care West, Galway, Ireland; University Hospital Galway, Galway, Ireland; Marymount University Hospice, Cork, Ireland; MBC patient, Northern Ireland, United Kingdom; Cancer Trials Ireland and Cork University Hospital, Dublin, Ireland

Background: Therapeutic advances have improved MBC survival rates, but patient expressed needs such as sexual wellness have not been evaluated in Ireland to date. Heretofore, the patient's voice has not been central to such an assessment, compromising MBC care. **Methods:** An anonymous online survey was designed by a cohort of 30 patients with MBC facilitated by a multidisciplinary breast cancer specialist taskforce. A questionnaire asked individuals to report their experience across three domains: sexual wellness, fertility and menopause. Patients with MBC 18 years or older living on the island of Ireland were eligible to participate. The survey was publicised in the media and in oncology clinics nationally and was available for 10 weeks. The survey consisted of a mixture of open and closed questions and results were summarised by means of counts and percentages for categorical variables and by means of mean, standard deviation, median and range for continuous variables. **Results:** Between July-October 2023, 246 patients completed the survey. The median age was 52.5 and 98% of responders were female. Over 75% of patients were not offered advice or support on the effects of MBC and the side effects of treatment on sexual wellness. This is despite over 60% of patients experiencing changes in their sex lives, with only 22.8% of those seeking medical advice. Those who did not seek advice stated fear of being dismissed or misunderstood (26.9%) and being uncomfortable discussing the topic (44.4%) as their reasoning. Less than half of patients < 50 years considered that sufficient information was provided on the impact of treatment on fertility. Over 95% of patients were menopausal or experienced permanent changes to their menstrual cycle but 29.3% of patients who sought support reported that they did not receive it. Participants who did not seek support, were asked what supports could have been provided (Table). **Conclusions:** Patient-led research demonstrates that the patients' voice is imperative to identify meaningful health interventions. MBC impacts sexual wellness for the majority of patients, a minority of whom seek medical advice, and a majority of whom are uncomfortable discussing the topic. The majority of participants <50 years felt oncofertility advice was insufficient, suggesting that improvements are needed in the information and support given to younger cancer patients regarding their fertility. Support with menopausal symptoms was commonly sought but resources were limited. The majority of patients would welcome availability of a complex menopause clinic and access to improved curated information resources on sexual wellness and fertility. Research Sponsor: Irish Cancer Society.

Information on Menopausal Symptoms as Standard of Care for all Women Undergoing Cancer Treatment	*76.8%*
Referral to complex menopause clinic	*73.2%*
Referral to website	***14.3%***
Other	*17.9%*

12058 Poster Session

Self-expressed needs and gaps in our care of metastatic breast cancer (MBC): An all-Ireland patient-led online survey (CTRIAL-IE 23-05).

Siobhan Gaynor, Frances K Duane, Emer Mulvaney, Catherine Weadick, Helen Greally, Rachel J Keogh, Yvonne O'Meara, Mary Jane O'Leary, Ann McBrien, Eibhlin Mulroe, Ieva Teiserskyte, Isabel Beristain, Jacinta Marron, Sarah McLoughlin, Victoria Donachie, Seamus O'Reilly; Cancer Trials Ireland, Dublin 2, Ireland; St. Luke's Radiation Oncology Network and Trinity St. James's Cancer Institute, Dublin, Ireland; Department of Medical Oncology, Cork University Hospital, Cork, Ireland; Cancer Care West, Galway, Ireland; University Hospital Galway, Galway, Ireland; University College Dublin, Dublin, Ireland; Marymount University Hospice, Cork, Ireland; MBC patient, Northern Ireland, United Kingdom; Cancer Trials Ireland and Cork University Hospital, Dublin, Ireland

Background: Therapeutic advances have improved MBC survival rates, but patient self-expressed information needs have not been evaluated in Ireland to date. Heretofore, the patient's voice has not been central to such an assessment, potentially leading to incorrect assumptions about MBC care. **Methods:** An anonymous online survey was designed by a cohort of 30 patients with MBC facilitated by a multidisciplinary breast cancer specialist taskforce. A questionnaire asked individuals to report their experience across three domains: credible information sources, palliative care access, and mental health. Patients with MBC 18 years or older living on the Island of Ireland were eligible to participate. The survey was publicised in the media and in oncology clinics nationally and was available for 10 weeks. The survey consisted of a mixture of open and closed questions and results were summarized by means of counts and percentages for categorical variables and by means of mean, standard deviation, median and range for continuous variables. **Results:** Between July-October 2023, 246 patients completed the survey. The median age of responders was 52.5. 99.4% of patients wished to have access to their personal medical records. Over 95% sought information about metastatic breast cancer outside of the clinic. The go-to information source varied (mostly online). No dedicated comprehensive information source on MBC was identified. Over 83% of patients with MBC were amenable to early palliative care referral but oncology teams did not raise this to the majority. Over 87% of patients reported mental health issues and the majority did seek support (88.4%). Living with uncertainty while awaiting scan results commonly led to feelings of anxiousness (79.5%), fearfulness (54.1%) and depression (15.2%). **Conclusions:** Patient-led research demonstrates that the patients' voice is imperative to identify meaningful health interventions. System change including rapid streamlined access to personal medical records and the provision of a credible online information source dedicated to MBC may empower patients to enable them to live well for as long as possible. Routine discussion around early palliative care referral and an opt out approach may be of benefit. Acknowledging the high burden of mental health issues among this patient group and ongoing development of support services is crucial. Minimising the time patients live with uncertainty waiting for scan results should be prioritised. Research Sponsor: Irish Cancer Society.

12059 Poster Session

Informal caregiving for older adults on systemic treatment for hepatocellular carcinoma.

Meng Wu, Deborah Watman, Sasha Perez, Yingtong Chen, Christopher D. Woodrell; Icahn School of Medicine at Mount Sinai, New York, NY

Background: Hepatocellular carcinoma (HCC) disproportionately affects older adults who are often supported by informal or unpaid family caregivers (CGs). Despite rising incidence of advanced HCC worldwide, little is known about the experiences and unmet supportive needs of patients (pts) and their informal CGs, particularly in the context of contemporary first-line immunotherapy-based treatment. **Methods:** As part of two cross-sectional descriptive studies conducted in parallel at a single academic center, we interviewed non-dyadic older pts on systemic HCC treatment and family CGs and examined themes of informal caregiving. Eligible CGs were ≥18 years old and identified by pts; eligible pts were ≥60 years old and on systemic treatment for BCLC stage B or C HCC. CGs completed the Zarit Burden Interview (ZBI). Participants completed semi-structured interviews focused on pt and CG experiences and needs, which were transcribed and analyzed using an inductive approach by at least two investigators. **Results:** Transcripts (n=16) from 11/2021-11/2023 of interviews with CGs (n=8) and pts (n=8) were analyzed. CGs were 87.5% female. Their median ZBI score was 20/88, indicating little or no burden, although scores ranged from 2-64; higher scores indicate greater burden. Four themes emerged: CG tasks, sources of burden, sources of support, and views of palliative care. CG tasks included coordinating medical appointments and transport, attending appointments, advocating for pt interests, and helping with household chores. Two sources of burden most commonly identified were logistics of medical visits and supporting pts through physical and emotional symptoms. CGs recognized multiple sources of support, including spouses, family, friends, church groups, and therapists. Pts were 87.5% male, median aged 70, 25% Black, 50% non-Hispanic white, and 25% Hispanic. Their responses about caregiving, in contrast to the CGs interviewed, showed strong themes of independence. Representative quotes include, "I don't need any help," "I am independent..so far," and "I live alone, I've got my own place, I do the best I can for myself." Some shared that the support of CGs is more spiritual or emotional, "I feel stronger because you're there," which was needed mostly with new diagnoses or disease progression. **Conclusions:** Levels of burden varied among CG participants; pt participants felt independent for the most part while receiving their treatments, consistent with improved functional status and quality of life experienced by those receiving combination therapy. The task of juggling logistics for numerous medical visits between multiple subspecialties emerged as a major challenge. Strategies to optimize care coordination, including increased use of navigation for those with advanced HCC, may help pts and their CGs live better as they live longer on improved treatments. Research Sponsor: National Institute on Aging.

An anti-EpCAM x anti-CD3 bispecific antibody, M701, for the treatment of malignant ascites due to epithelial cancer: Interim results of a prospective randomized controlled phase II trial.

Rongbo Lin, Jianming Xu, Rongrui Liu, Ning Li, Guiling Li, Tao Zhang, Jun Zhao, Jiayi Li, Meili Sun, Ke Wang, Hanxiang An, Weijie Zhang, Huiting Xu, Shan Zeng, Mingjun Zhang, Pengfei Zhou, Shaoyi Huang, Xiong Wang; Fujian Cancer Hospital, Fuzhou, China; The First Medical Center of Chinese PLA General Hospital, Beijing, Beijing, China; Department of Gastrointestinal Oncology, The Fifth Medical Center, Chinese PLA General Hospital, Beijing, China; Henan Cancer Hospital, Zhengzhou, China; Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China; Cancer Center, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China; Changzhi People's Hospital, Changzhi, China; The First Affiliated Hospital of Xiamen University, Xiamen, China; Department of Oncology, Jinan Central Hospital, Central Hospital Affiliated to Shandong First Medical University, Jinan, China; Tianjin Medical University Cancer Institute and Hospital, Tianjin, China; Shanxi Bethune Hospital, Taiyuan, China; Department of Medical Oncology, The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China; Hubei Cancer Hospital, Wuhan, China; Xiangya Hospital of Central South University, Changsha, China; The Second Hospital of Anhui Medical University, Hefei, China; Wuhan YZY Biopharma Co, Ltd, Wuhan, China

Background: Malignant ascites (MA) is a significant complication in patients with late-stage epithelial cancer, associated with poor prognosis, reduced quality of life, and severe symptoms. It is usually caused by tumor cells seeding into the peritoneum, which obstructs lymphatic drainage and increases capillary permeability. Currently, there is no approved drug therapy specifically for the treatment of MA worldwide. **Methods:** Patients with MA due to epithelial cancer, who had received at least two prior systemic chemotherapy regimens, were enrolled and randomly assigned to the experimental arm (Arm E) and control arm (Arm C). Arm E received paracentesis and intraperitoneal (IP) infusions of 50, 400, 400, and 400μg of M701 on days 1, 4, 11, and 18. Additional M701 infusions could be given every 2 weeks without requiring punctures. Arm C received paracentesis alone as needed from day 1 to day 18. Both arms received systemic tumor treatment as determined by investigators. The primary endpoint was puncture-free survival (PuFS), defined as the time from random assignment to the next puncture or death, whichever occurred first. Secondary endpoints included overall survival (OS) and incidence of adverse events (AEs). **Results:** As of December 15, 2023, a total of 84 pts were enrolled, with 43 in Arm E and 41 in Arm C. The characteristics of Pts are outlined in the table. PuFS was significantly longer in Arm E compared to Arm C (median 54 vs 24 days, hazard ratios (HR) = 0.39, 95% CI 0.21-0.72, p=0.001). Subgroup analysis of PuFS indicated that patients with different types of cancer (gastric, colorectal and ovarian) all benefited from M701 infusion. OS analysis demonstrated a trend towards prolonged survival in Arm E compared to Arm C (median 113 vs 76 days, HR=0.56, 95% CI 0.31-1.03, p=0.0575). The 6-month survival rates were 35.2% and 15.8%, respectively. Subgroup analysis showed that patients with gastric cancer had significantly longer OS than the controls (median 128 vs 64 days, HR= 0.45, 95%CI 0.20-1.00, p=0.0438). Grade 3 or higher treatment-emergent AEs occurred in 52% of patients in Arm E and 57.5% of patients in Arm C. Serious AEs occurred in 38% and 50% of patients in the two arms, respectively. Only 2 cases of cytokine release syndrome (both grade 2) were reported in patients treated with M701. **Conclusions:** IP infusions of M701, based on systemic tumor therapy, were well tolerated and did not pose a higher risk compared to the control arm. Epithelial cancer patients with MA who received M701 treatment had longer PuFS and OS. These results are promising and support the pivotal trial of M701 as a novel treatment for MA. Research Sponsor: Wuhan YZY Biopharma Co., Ltd.

Characteristics	Arm E (n=43)	Arm C (n=41)
Age (yrs), Median	54	54
Gender, Male	33%	34%
ECOG (0-1)	89%	88%
Cancer Type :		
Gastric	49%	49%
Ovarian	30%	32%
Colorectal	19%	17%
Previous paracentesis	63%	54%
Previous IP Chemotherapy	58%	56%

12061 Poster Session

Experience of young patients with cancer discussing cannabis with their providers.

Amrit Baral, Bria-Necole A. Diggs, Ranya Marrakchi El Fellah, Nicolas Hernandez Ortega, Jessica Yasmine Islam, Marlene Camacho-Rivera, Frank J. Penedo, Denise Christina Vidot; Department of Public Health Sciences, University of Miami Miller School of Medicine, Miami, FL; University of Miami Miller School of Medicine, Miami, FL; Sylvester Comprehensive Cancer Center, Miami, FL; H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL; SUNY Downstate Medical Center, Brooklyn, NY; University of Miami Sylvester Comprehensive Cancer Center, Miami, FL; University of Miami, Coral Gables, FL

Background: Although cannabis use among cancer patients to manage cancer treatment-related symptoms continues to grow, little is known about patterns in patient-provider communication regarding cannabis use. We examined demographic differences in cannabis communication among cancer patients and providers at a National Cancer Institute designated cancer center. **Methods:** We used data of 495 cancer patients via an anonymous electronic survey administered at the University of Miami via REDCap. Participants with consent to contact notations in their electronic medical record were recruited via phone calls and personalized messages in their MyUCHART portal. Self-reported responses on patients' disclosure of cannabis use to healthcare providers and their comfort on discussing cannabis with cancer doctors were analyzed. Age was categorized as: 20-39y, 40-59y and ≥60y. Chi-squared/Fisher's exact tests and logistic regression analyses were conducted adjusting for age, sex, and ethnicity. **Results:** The sample was 51.8% male, 39.4% Hispanic, and mean age was 45.9y (SD=15.1) (41.1% were between 20-39y); 43.8% were undergoing treatment and 35.4% were in follow-up/finished treatment. Almost half (45.5%) reported current (past 30-days) cannabis use. Younger (20-39y) patients had higher prevalence of not disclosing cannabis use than older (>60y) patients (36.8% vs 23.9% $p<0.01$). There were no sex or ethnicity statistical differences. Majority (67.7%) of current cannabis users reported comfort discussing cannabis use with their provider. However, among individuals aged 20-39y, 40.8% reported feeling uncomfortable discussing cannabis with their cancer doctor. In the 40-59y age group, 21.0% expressed discomfort, while only 5.6% of those over 60 years reported similar unease. After adjusting for age, sex, and ethnicity, newly diagnosed cancer patients had lower odds (aOR:0.41, 95% CI: 0.17-0.99) of feeling comfortable discussing cannabis use compared to those in follow-up/finished treatment group. **Conclusions:** Age was a significant factor in disclosing cannabis use to healthcare providers, with disparities noted by age group. These insights highlight the importance of considering age-related factors and treatment status when addressing cannabis use discussions within the oncology setting. Research Sponsor: National Cancer Institute.

Factors associated with sexual function and sexual satisfaction in young women with breast cancer.

Ana Ferrigno Guajardo, Alan Fonseca, Melina Miaja, Marlid Cruz-Ramos, Bryan Vaca-Cartagena, Fernanda Mesa-Chavez, Alejandra Platas, Ana Laura Rodriguez, Paula Anel Cabrera-Galeana, Alejandro Mohar, Cynthia Villarreal-Garza; Department of Medicine, Yale University School of Medicine, New Haven, CT; Departamento de Tumores Mamarios, Instituto Nacional de Cancerología, Mexico City, Mexico; Tecnologico de Monterrey, Escuela de Medicina y Ciencias de la Salud, Monterrey, Mexico; Departamento de Tumores Mamarios, Instituto Nacional de Cancerología/CONAHCYT, Mexico City, Mexico; Médicos e Investigadores en la Lucha contra el Cáncer de Mama (MILC), Mexico City, Mexico; Instituto Nacional de Cancerología, Mexico City, DF, Mexico; Unidad de Investigacion Biomedica en Cancer, Instituto Nacional de Cancerologia/Instituto de Investigaciones Biomedicas/UNAM, Mexico City, Mexico; Centro de Cáncer de Mama, Hospital Zambrano Hellion-Tecnológico de Monterrey, San Pedro Garza Garcia, NL, Mexico

Background: Young women with breast cancer (YWBC) are vulnerable to sexual dysfunction and dissatisfaction due to age-specific psychosocial concerns and treatment side effects. This study aimed to identify factors associated with sexual health in a prospective cohort of YWBC. **Methods:** Patients aged ≤40 yrs with non-metastatic BC from 3 referral centers completed emotional health, quality of life (QoL), and sexual health assessments at baseline, 6 mos, 1 yr, 2-3 yrs, and 4-5 yrs post-diagnosis. Sexual activity was defined as having had intercourse in the 4 wks preceding each assessment. Female sexual dysfunction (FSD) was defined as a total score <26.55 in the Female Sexual Function Index (FSFI), while hypoactive sexual desire disorder (HSDD) was defined as a score <5 in the desire subscale. Sexual enjoyment was classified with the Sexual Satisfaction Index (SSI), with <110 indicating dissatisfaction. **Results:** A total of 474 patients with a median age of 36 yrs were included, of which most were married/in a domestic partnership (65%), unemployed (61%), and had an educational level <high school (51%). Most had stage II (49%) or III (39%) disease. The most common molecular subtype was HR+/HER2- (53%), followed by HR-/HER- (26%) and HR+/HER2+ (14%). The prevalence of relevant outcomes at each assessment are shown in the Table. Factors associated with being sexually inactive were low educational level (χ^2=7.7), being single (χ^2=112.6), having children (χ^2=8.12), and higher treatment side effects burden (p=0.002). Factors associated with worse sexual function were being single (χ^2=13.8), amenorrhea (χ^2=40.8), HADS-D ≥8 (χ^2=11.7), and HADS-A ≥8 (χ^2=13.9). Factors associated with lower sexual satisfaction were low educational level (χ^2=10.3), being single (χ^2=15.5), having undergone bilateral oophorectomy (χ^2=5.74), amenorrhea (χ^2=8.48), HADS-D ≥8 (χ^2=14.98,), and HADS-A ≥8 (χ^2=13.91). Additionally, both FSFI and SSI scores directly correlated with QoL (QLQ SumScore) and body image (QLQ-BRBI), and inversely correlated with systemic therapy side effects (QLQ-BRST) (p<0.001). When analyzing sexual health outcomes according to type of treatment (total vs partial mastectomy, chemotherapy vs no, hormone therapy vs no, anti-HER2 agent vs no), no significant differences were found. **Conclusions:** Sexual dysfunction and dissatisfaction are highly prevalent in YWBC the first 5 yrs post-diagnosis. As poor sexual health correlates with inferior QoL, patients at an increased risk might benefit from early targeted interventions. Research Sponsor: None.

	Baseline	6 mos	1 yr	2-3 yrs	4-5 yrs
Sexually active	351/424 (83%)	297/368 (81%)	288/338 (85%)	244/311 (79%)	197/230 (86%)
FSD	82/244 (34%)	108/221 (49%)	86/215 (40%)	80/203 (39%)	109/174 (37%)
Low sexual satisfaction	88/344 (26%)	82/290 (28%)	92/280 (33%)	67/238 (28%)	71/184 (39%)
HSDD	371/403 (92%)	338/355 (95%)	302/327 (92%)	277/300 (92%)	219/230 (95%)

12063 Poster Session

Accuracy of medical oncology prognosis for patients with metastatic cancer evaluated for enrollment onto an ongoing randomized clinical trial.

Shearwood McClelland III; University Hospitals Seidman Cancer Center, Department of Radiation Oncology, Case Western Reserve University School of Medicine, Cleveland, OH

Background: For patients with metastatic cancer, a key aspect of interdisciplinary care has involved the overall prognosis provided by Medical Oncology, which often dictates the intensity and direction of further care while impacting all other disciplines, most prominently Radiation Oncology, Surgical Oncology and Palliative Medicine. Despite the millions of patients for whom such prognoses have been ascribed, the success rate of Medical Oncology prognosis has been sparsely described. This study represents prospective evaluation of Medical Oncology prognosis accuracy for patients having been considered for enrollment onto an ongoing Phase 2 randomized controlled oncology trial. **Methods:** The ongoing Spine Patient Optimal Radiosurgery Treatment for Symptomatic MEtastatic Neoplasms (SPORTSMEN) clinical trial (clinicaltrials.gov number NCT05617716) is a Phase 2 randomized clinical trial examining optimal radiation therapy treatment of symptomatic spinal metastases with a primary endpoint of pain freedom at 3 months post-treatment. A key eligibility criteria for trial enrollment is overall prognosis exceeding 3 months, typically provided by Medical Oncology. During the first year of trial enrollment, Medical Oncology prognosis for patients considered for SPORTSMEN inclusion was prospectively assessed for accuracy. **Results:** From January 2023 through December 2023, a total of 27 patients with documented Medical Oncology prognosis were considered for SPORTSMEN enrollment. Medical Oncology administered a prognosis exceeding three months in 26 patients, and less than three months in one patient. Of patients with a prognosis exceeding three months, 12 (46%) succumbed to death or hospice care prior to three months; the patient ascribed a prognosis of less than three months did not survive to exceed this threshold. The Medical Oncology prognosis overall was proven correct for 15 of 27 patients (56%). Medical Oncologist prognostic accuracy was 13/19 (68.4%) for outpatients, and 2/8 (25%) for inpatients; this difference was statistically significant (p=0.0381). **Conclusions:** In patients with symptomatic metastatic spine disease, the estimated prognosis provided by Medical Oncology is often optimistic, as nearly half of patients assigned a prognosis of greater than three months failed to reach this threshold before experiencing death or hospice. These findings indicate that providers considering enrolling patients on clinical trials should expect a prognosis overestimation rate exceeding 40%. Consequently, a more heuristic approach to assessing patient prognosis may be necessary to avoid unwarranted prognostic optimism, particularly for inpatients. Such an approach could potentially provide a more compassionate and cost-effective management of these patients' remaining lifespan thereby optimizing quality-of-life. Research Sponsor: None.

12064 Poster Session

Chemotherapy-induced peripheral neuropathy research: A National Institute of Health (NIH) grant portfolio analysis.

Rachel D. Altshuler, Lori M. Minasian, Catherine Schweppe, Nina S. Kadan-Lottick; National Cancer Institute, Rockville, MD; Division of Cancer Prevention, National Cancer Institute, Bethesda, MD; Georgetown University Lombardi Comprehensive Cancer Center, Washington, DC

Background: Chemotherapy-induced peripheral neuropathy (CIPN) is a common, debilitating cancer treatment-related toxicity associated with considerable discomfort, functional loss, and impaired quality of life both acutely and long-term. Unfortunately, limited prevention and treatment options for CIPN currently exist. In this portfolio analysis, we sought to describe the landscape of CIPN research and identify gaps and opportunities to meet the needs of patients with CIPN. **Methods:** Using the NIH Query View Report system to search all NIH-funded competitive grants awarded between fiscal years 2014-2023, we identified 660 grants containing text pertaining to CIPN in the Abstract or Specific Aims. Grants were then manually reviewed and 480 were excluded as not specifically addressing CIPN. We categorized the final 180 grants as preclinical, clinical, or preclinical/clinical, followed by ascertainment of preclinical model, clinical population, CIPN assessment techniques, and/or clinical trial design, as applicable. **Results:** Of the 180 grants, 119 were preclinical, 51 clinical, and 10 with both preclinical and clinical components. The larger number of CIPN grants (n=27) were awarded in fiscal year 2022 vs. the lowest number (n=10) in 2014. Among the preclinical grants, 89% of grants utilized rodent models of CIPN, of which 19% proposed tumor-bearing models. A large majority of preclinical grants investigated paclitaxel (71%), followed by oxaliplatin (23%); none proposed studies of newer immune therapies. Among clinical grants, 41% (n=21) were interventional trials, 38% were prospective observational studies, and 15% retrospective studies. Clinical grants most frequently focused on breast cancer patients (41%), followed by unspecified cancer diagnoses (33%) and colorectal cancer (18%). For age of eligibility, 11% included patients younger than 18 years, while a higher proportion included 18-39 (82%), 40-64 (88%), and ≥65 (89%). The 21 interventional study grants investigated behavioral interventions (44%), pharmacological agents (28%), and devices (28%). **Conclusions:** The number of CIPN grants awarded annually by NIH have generally increased since fiscal year 2014, indicating increased investment by NIH. However, multiple gaps and opportunities remain. At the preclinical level, in addition to current rodent models and the narrow range of treatment exposures, novel strategies to mimic human CIPN conditions may improve translatability. Clinical studies are needed in younger patients that can be impacted by CIPN long-term. Also, there are important gaps in the CIPN-associated cancer diagnoses and therapy exposures (including novel agents) in current studies. Addressing the highlighted gaps may identify avenues to study additional interventions that achieve the highest impact in the populations that most need them. Research Sponsor: None.

Symptom burden in adolescents and young adults with cancer: A subgroup analysis of the enhanced, EHR-facilitated cancer symptom control (E2C2) trial.

Michael H. Storandt, Zhaohui Jin, Oudom Kour, Kathryn Jean Ruddy, Deirdre R. Pachman, Kurt Kroenke, Joan M. Griffin, Jessica Austin, Linda L. Chlan, Ewan Kemar Cobran, Jacob Greenmyer, Veronica Grzegorczyk, Wendy A Allen-Rhoades, Shawna L. Ehlers, Ashley Wilder Smith, Sandra A. Mitchell, Qian Shi, Andrea L. Cheville; Mayo Clinic, Rochester, MN; Indiana University School of Medicine and Regenstrief Institute, Indianapolis, IN; Mayo Clinic, Scottsdale, AZ; National Cancer Institute, Bethesda, MD

Background: Incidence of cancer, including colorectal, breast, pancreas, kidney, and uterine cancer, is increasing in younger populations. Adolescents and young adults (AYA, defined as age 15-39) with cancer face unique challenges. This study aimed to characterize how symptom burden differs between AYA and non-AYA (aged 40+) patients with cancer. **Methods:** We performed a subgroup analysis of the E2C2 study, a cluster-randomized, pragmatic trial examining the effectiveness of routine symptom assessment and guideline-based management on patient-centered and healthcare utilization metrics during and following cancer treatment. Six symptoms [Sleep disturbance, Pain, Physical function impairment, Anxiety, Depression, and Energy deficit/fatigue (SPPADE)] were evaluated using 11-point numerical rating scales (NRS). Symptom severity was classified as mild (0-3), moderate (4-6), or severe (7-10). We conducted a subgroup analysis of symptom burden among AYA patients (defined as age 18-39 in this study), using their first-reported NRS scores. **Results:** The E2C2 cohort included 2,598 AYA patients and 38,061 non-AYA patients who completed >1 SPPADE NRS on at least one survey. AYA patients were more likely than non-AYA patients to report severe anxiety ($p<0.0001$) and depression ($p<0.0001$) (Table). Non-AYA patients were more likely to report severe pain ($p=0.02179$), fatigue ($p=0.0022$), and physical function limitations ($p<0.0001$). Sociodemographic differences were also noted. A higher proportion of AYA patients held a bachelor's degree or higher (38% vs 28%), were employed (73% vs 37%), and lived in an urban setting (67% vs 56%), compared to non-AYA patients. Non-AYA patients were more likely to have government insurance (63% vs 21%) and to be married (72% vs 59%). **Conclusions:** AYA patients with cancer were more likely to report severe depression and anxiety compared to their counterparts age 40 and above, underscoring the need for targeted and tailored psycho-oncology care for this population. Research Sponsor: National Cancer Institute; UM1CA233033 (PI Cheville, Mayo Clinic, Rochester, MN).

	AYA (N=2,598)	Non-AYA (N=38,061)	P value±
Female gender, n (%)	1599 (61.5)	21695 (57.0)	
Age, median	34.5	66.1	
White, n (%)	2276 (87.6)	36056 (94.7)	
Sleep disturbance, n (%)			0.3033
Severe	269 (10.4)	4148 (10.9)	
Moderate	576 (22.2)	8780 (23.1)	
Mild	1737 (66.9)	24863 (65.3)	
Pain, n (%)			0.02179
Severe	202 (8.5)	3417 (9.0)	
Moderate	469 (18.1)	7295 (19.2)	
Mild	1908 (73.4)	27000 (70.9)	
Anxiety, n (%)			<0.0001
Severe	278 (10.7)	2945 (7.7)	
Moderate	679 (26.1)	7113 (18.9)	
Mild	1622 (62.4)	27667 (72.7)	
Depression, n (%)			<0.0001
Severe	193 (7.4)	2481 (6.5)	
Moderate	540 (20.8)	6497 (17.1)	
Mild	1847 (71.1)	28775 (75.6)	
Fatigue, n (%)			0.0022
Severe	346 (13.3)	5941 (15.6)	
Moderate	726 (27.9)	10805 (28.4)	
Mild	1507 (58.0)	20959 (55.1)	
Physical Function, n (%)			<0.0001
Severe	176 (6.8)	4207 (11.1)	
Moderate	563 (21.7)	10166 (26.7)	
Mild	1852 (71.3)	23596 (62.0)	

±*p* values derived from Chi-square.

12066 Poster Session

Functional impairments, fatigue, and pain in newly diagnosed solid-tumors: Retrospective path analysis.

Dori Michelle Beeler, Danielle Boselli, Patrick L. Meadors, Declan Walsh; Department of Supportive Oncology, Levine Cancer Institute, Atrium Health, Charlotte, NC; Department of Cancer Biostatistics, Levine Cancer Institute, Atrium Health, Charlotte, NC

Background: A large patient cohort study found functional impairments (FI) are associated with cancer-related fatigue (CRF). This was before anti-cancer treatment for solid tumors. Another found functional limitations increased with self-reported pain severity. We hypothesize that both (a) a direct association between pain and CRF and (b) an indirect association between the symptoms through a mediation pathway involving FI may exist. Our retrospective, single-institutional study evaluated this model. **Methods:** We sourced Electronic Distress Screening (EDS) and Cancer Registry databases (Jan 2017 - Jan 2022). Patients identified were ≥18 years old and completed EDS within two (±2) weeks of a solid tumor diagnosis and before any anti-cancer therapy. Three EDS questions assessed FI with a two-week recall: 1) "How well have you managed your daily life?"; 2) "Has your physical health kept you from doing things like household chores or climbing stairs?"; 3) "Do you have limited movement in any body part?". Pain and CRF were assessed on a numerical rating scale [0 (none) to 10 (worst possible)]. Structural equation modeling tested the multiple mediation model. The 95% confidence intervals of the estimated total and FI domain-specific indirect effects, the effects of pain on CRF working through FI, were assessed to exclude zero. **Results:** N=4326. Median age = 63 years (range 18 - 97); 69% female and 78% White. The commonest tumor site groups were breast (30%), upper GI (17%), and gynecologic (16%); 21% had Stage 4 disease. Median CRF was 4 (range 0-10); 57% had clinically significant CRF (fatigue ≥4). Median pain was 3 (range 0-10); 51% had clinically significant pain (pain ≥3). A significant minority had FI. N=753 (17%) had either "very poor" or "fairly poor" management of day-to-day life. N=778 (18%) had "a lot" of difficulty in performing chores. N=1252 (29%) had limited movement of any body part. FI partially mediated the pain/CRF relationship (indirect effect (IE_{total})=0.25, 95% CI 0.24-0.27). Two mediators had statistically significant contributions to the total indirect effect: management of daily life (IE_{manage}=0.12, 95% CI 0.11-0.13); and difficulty in performing chores (IE_{chores}=0.13, 95% CI 0.11-0.14). The limited movement of any body part did not impact the pain/CRF relationship ($IE_{movement}$=-0.01, 95% CI -0.01-0.01). **Conclusions:** Most patients had clinically significant pain and CRF at diagnosis. A significant minority had FI at diagnosis. FI partially mediated the direct relationship between pain/CRF severity. This helps us understand that FI accounts for some of the relationship between pain and CRF. It is insufficient to conduct symptom assessments without also evaluating FI before treatment or at diagnosis. Research Sponsor: None.

Incidence of osteonecrosis of the jaw (ONJ) in the randomized non-inferiority phase III trial SAKK 96/12 REDUSE comparing denosumab (DN) administered every 4 weeks (q4w) versus every 12 weeks (q12w).

Roger Anton Fredy Von Moos, Andreas Mueller, Stefanie Hayoz, Michael Thomas Mark, Stefanie Fischer, Razvan A. Popescu, Mathias Konrad Fehr, Claudine Egger, Sandro Anchisi, Florian Schmid, Khalil Zaman, Christoph J Ackermann, Alexander Schreiber, Priska Bützberger, Catrina Uhlmann Nussbaum, Marc Küng, Corinne Schaer, Silke Gillessen, Arnoud J. Templeton; Department of Medical Oncology, Kantonsspital Graubuenden, Chur, Switzerland; Med Onkologie, Winterthur, Switzerland; Swiss Group for Clinical Cancer Research (SAKK), Bern, Switzerland; Kantonsspital Graubünden, Chur and Università della Svizzera Italiana, Lugano, Lugano, Switzerland; Cantonal Hospital St. Gallen, St. Gallen, Switzerland; Tumor Center Aarau, Aarau, Switzerland; Kantonsspital Frauenfeld, Frauenfeld, Switzerland; Spital Limmattal, Schlieren, Schlieren, Switzerland; Spital Wallis, Sion, Sion, Switzerland; University Hospital Zürich, Zürich, Switzerland; Lausanne University Hospital CHUV, Lausanne, Switzerland; Spital STS AG Thun, Thun, Switzerland; Kantonsspital Aarau, Aarau, Switzerland; Kantonsspital Baden, Baden, Switzerland; Cantonal Hospital Olten, Olten, Switzerland; HFR Hôpital Cantonal, Fribourg, Switzerland; SAKK, Bern, Switzerland; Istituto Oncologico della Svizzera Italiana (IOSI), EOC, Bellinzona and Faculty of Biomedical Sciences, Università della Svizzera Italiana, Lugano, Switzerland; St. Claraspital, Basel, Switzerland

Background: ONJ is a well-known adverse event of bone-modifying agents that can significantly impact quality of life. It is recognized that the risk of ONJ increases with the duration of treatment and can reach rates of up to 10%. Here, we report ONJ rates in a randomized non-inferiority phase 3 study investigating the optimal dose of DN. **Methods:** Patients with metastatic breast cancer (mBC) or metastatic castration resistant prostate cancer (mCRPC) (planned *N*=1380) were randomized 1:1 to receive DN q4w (Arm A) versus q12w (Arm B) after a 3-month induction phase with application q4w. Incidence of ONJ is a key secondary outcome of the study (NCT02051218). An oral inspection at baseline as well as before each application of DN was mandatory. In patients with risk factors for ONJ a prophylactic dentist visit was recommended. Data from patients who received at least 1 dose of DN and who were randomized at least one year before data cut-off (December 11, 2023) were included in this interim safety analysis. Since the differentiation between ONJ and tooth infection can be difficult, we also report this outcome. **Results:** 1271 patients with a median follow-up time of 3 years were analyzed. During the 3-month induction phase 2/1271 patients experienced an ONJ. In Arm A 48/575 (8.3%), in Arm B 32/561 (5.7%) patients experienced an ONJ. Time to first ONJ and/or tooth infection differs remarkably with a clear advantage for the 3-months arm (HR 0.67; 95% CI 0.48-0.93). Details are shown in the table. **Conclusions:** The observed ONJ rate of 8.3% is in line with the literature for patients who received denosumab q4w for over two years (mBC: 6.0%, mCRPC: 8.2%). Administration of DN q12w reduces the risk of ONJ and/or tooth infections substantially. The numerical difference of events to the standard arm as well as the time to first ONJ and/or tooth infection is clinically relevant with a risk reduction by 33%. Efficacy data for the primary endpoint time to first symptomatic skeletal event is eagerly awaited. Clinical trial information: NCT02051218. Research Sponsor: Santesuisse (Health Insurance association Switzerland); State Secretariat for Education, Research and innovation.

Term	Baseline (N=1271)	First 16 Weeks (N=1271)	Rest of Treatment Arm A (N=575)	Rest of Treatment Arm B (N=561)
ONJ	0 (0.0%)	2 (0.2%)	48 (8.3%)	32 (5.7%)
Tooth infection or tooth abscess	0 (0.0%)	10 (0.8%)	43 (7.5%)	28 (5.0%)
ONJ or tooth infection/abscess	0 (0.0%)	12 (0.9%)	81 (14.1%)	55 (9.8%)

Trends and racial disparities in palliative care utilization among patients with prostate cancer: A ten-year retrospective study.

Stanley Ozogbo, Ayobami Gbenga Olafimihan, Inimfon Jackson, Chiamaka Elsie Nwachukwu, Gbolahan Olatunji, Emmanuel Kokori, Nicholas Aderinto, Tochukwu Nzeako, James J. Kim; Internal Medicine Residency, St Elizabeth Youngstown Hospital, Youngstown, OH; John H. Stroger, Jr. Hospital of Cook County, Chicago, IL; The University of Texas MD Anderson Cancer Center, Philadelphia, PA; Tulane University, New Orleans, LA; University of Ilorin, Ilorin, Kwara, Nigeria; Ladoke Akintola University of Technology, Ogbomosho, Oyo, Nigeria; Christina Care Hospital, Newark, DE; Bon Secours Mercy Health Cancer Center, Youngstown, OH

Background: Due to improvements in cancer therapies and treatment strategies, survivorship among patients with prostate cancer continues to increase, thus necessitating the utilization of palliative care services for symptom management. We examined the prevalence, trends and predictors of palliative care utilization among hospitalized prostate cancer patients in the US. **Methods:** A retrospective longitudinal study using the Nationwide Inpatient Sample (NIS) database (2010-2019) was conducted. Using join point regression and multivariable logistic regression, trends and factors associated with palliative care receipt were assessed. **Results:** The overall prevalence of palliative care utilization in the cohort of over 2 million admissions with prostate cancer, was 5.3%. Over the decade, there was a significant increase in palliative care consultations from 2,970 to 7,509 per 100,000 prostate cancer hospitalizations (p-trend <0.001) with an average annual percentage change of 7.7% over the study period. Individuals ≥ 70 years with prostate cancer had higher odds (aOR): 1.06; 95% CI: 1.01-1.12) of receiving palliative care relative to those < 70 years. Compared to non-Hispanic whites, non-Hispanic blacks were less likely to receive palliative care services (aOR: 0.93; 95% CI: 0.88-0.98). Patients on Medicaid (aOR: 1.51; 95% CI: 1.38-1.65), private insurance (aOR: 1.3; 95% CI: 1.23-1.38) and other insurance types (aOR: 2.2; 95% CI: 1.85-2.55) had higher odds of palliative care utilization when compared to those on Medicare. Prostate cancer patients discharged to facilities or with home health care were more likely (aOR: 6.4; 95% CI: 6.03-6.8) to receive palliative care. Other factors associated with palliative care receipt were non-elective admissions, admission to urban, large and teaching facilities. Furthermore, longer length of hospital stays (≥ 5 days vs <5 days) was associated with higher utilization of palliative care (aOR: 1.08; 95% CI: 1.05-1.13). **Conclusions:** Though the trends in palliative care utilization have improved over the years, it remains suboptimal. Additionally, black patients were less likely to receive palliative care. Further studies are needed to explain these disparities and generate interventions to narrow the identified gaps. Addressing the highlighted sociodemographic and hospital-level disparities will ensure optimal utilization of palliative care in this patient population. Research Sponsor: None.

Racial disparities and factors associated with use of palliative care among hospitalized patients with metastatic prostate cancer.

Variables	OR (95% CI)	Unadjusted	Adjusted
Age	"70 years and above" vs "Less than 70"	2.6 (2.52-2.72)	1.06 (1.01-1.11)
Race/Ethnicity	Non-Hispanic Black vs Non-Hispanic White	1.17 (1.12-1.23)	0.93 (0.88-0.98)
	Hispanic vs Non-Hispanic White	1.1 (1.03-1.17)	0.998 (0.93-1.08)

12069 Poster Session

Characterizing disparities in receipt of palliative care for Asian Americans, Native Hawaiians, and Pacific Islanders with metastatic cancer in the United States.

Khushi Kohli, Mahi Kohli, Bhav Jain, Nishwant Swami, Sruthi Ranganathan, Fumiko Chino, Puneeth Iyengar, Divya Yerramilli, Edward Christopher Christopher Dee; Harvard University, Cambridge, MA; Olathe North High School, Olathe, KS; Stanford University School of Medicine, Stanford, CA; Hospital of the University of Pennsylvania, Philadelphia, PA; University of Cambridge, Cambridge, United Kingdom; Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Despite the benefits of early palliative care (PC), inequities exist in receipt of PC for patients diagnosed with metastatic cancer. We sought to characterize disparities in receipt of PC for disaggregated Asian American, Native Hawaiian, and Pacific Islander (AA&NHPI) patients with metastatic prostate, breast, or lung cancer. **Methods:** The National Cancer Database (NCDB) allows for evaluation of receipt of palliative care as part of first line of treatment. Therefore, we analyzed patients with metastatic breast, lung, or prostate cancer between 2004-2018 who were White (largest reference group) or of self-identified Asian Indian/Pakistani, Chinese, Filipino, Native Hawaiian, Hmong, Japanese, Kampuchean, Korean, Laotian, Pacific Islander, Thai, or Vietnamese descent. Multivariable logistic regressions defined adjusted odds ratios and 95% confidence intervals of receiving palliative care when comparing i) White vs. AA&NHPI patients as a single cohort and ii) White vs. disaggregated AA&NHPI patients, adjusting for clinical, socioeconomic, and demographic covariates. **Results:** Among 775,289 individuals diagnosed with metastatic cancer, no significant differences in PC receipt were observed between White patients and aggregated AA&NHPI patients among patients with prostate cancer, breast cancer, or lung cancer. However, disaggregated analyses revealed reduced palliative care receipt for patients with breast cancer of Asian Indian/Pakistani descent (AOR=0.75, P=0.011) and for patients with lung cancer of Chinese, Vietnamese, Thai, and Asian Indian/Pakistani descent compared to White patients (Chinese AOR=0.88, P=0.001; Vietnamese AOR=0.89, P=0.032; Thai AOR=0.64, P=0.016; Asian Indian/Pakistani AOR=0.83, P=0.001). Receipt of PC was greater for patients of Japanese and Hawaiian descent with prostate cancer (Japanese AOR=1.92, P=0.001; Hawaiian AOR=2.09, P=0.009), breast cancer (Japanese AOR=1.72, P=0.001; Hawaiian AOR=1.70, P=0.021), and lung cancer (Japanese AOR=1.92, P $<$0.001; Hawaiian AOR=2.95, P$<$0.001), as well as patients of Pacific Islander descent with lung cancer (AOR=1.62, P$<$0.001). **Conclusions:** Although in aggregate AA&NHPI patients were no less likely to receive PC than White patients, we found significant within-group disparities among AA&NHPI patients with metastatic cancer. Patients of Asian Indian/Pakistani, Chinese, Vietnamese, and Thai descent were less likely to receive PC, underscoring the need for i) disaggregated research on PC access and ii) targeted interventions to address cultural, socioeconomic, and healthcare system barriers that contribute to the disparities in PC among patients with cancer. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; P30 CA008748.

An Indian real-world experience of intravenous fosnetupitant-palonosetron (IV NEPA) in preventing delayed and extended delayed CINV.

Hanmant V. Barkate, Dr. Amullya Pednekar, Pragya Shukla, Shaunak Valame, Siddhartha Nanda, Abhinandan Hanji, Naval Kishore Shakya, Arun Kumar Verma, Sagar B Bhagat, Saiprasad Patil, Sumit Bhushan; Glenmark Pharmaceuticals Ltd, Mumbai, India; Delhi State Cancer Institute, Delhi, India; Jawaharlal Nehru Cancer Hospital and Research Centre, Bhopal, India; All India Institute of Medical Sciences (AIIMS), Raipur, India; Hanji Cancer Hospital, Belgavi, India; Lakshya Cancer Hospital and Research Centre, Lucknow, India; Subharti Medical College and Hospital, Meerat, India; Glenmark Pharmaceuticals Ltd., Mumbai, India

Background: Although the reports suggest 15-25% cancer patients receiving highly- and moderately emetogenic chemotherapy (HEC and MEC) experience nausea and vomiting beyond day 5, majority of clinical trials focus on delayed chemotherapy induced nausea and vomiting (CINV) only during the first 5 days of treatment. Here we present a real world observational data with fixed combination of IntraVenous (Fos)NEtupitant and Palonosetron (IV NEPA) in preventing nausea/vomiting in delayed and extended delayed phase among patients receiving HEC/MEC. **Methods:** An open label, single arm, multicentre, phase IV prospective trial was conducted at six centres following individual Institutional Ethics Committee approval (CTRI/2023/04/051951). Patients in acute (0-24hrs), delayed (>24-120hrs), extended delayed (>120-240hrs) phases and extended overall phase (0-240hrs) were assessed for complete response (CR) (no vomiting and no need of rescue medication), complete protection (CP) [CR + no significant nausea (5mm to <25mm) on visual analogue scale], complete control (CC) [CR + no nausea (<5mm)] and safety. **Results:** Among 178 patients (Males-114, Females-64), 90 (50.56%) received HEC and 88 (49.44%) received MEC regimen. Cisplatin-Paclitaxel (19.10%) and Carboplatin-Paclitaxel (35.39%) were the most common HEC and MEC regimens respectively. Overall, CR in delayed and extended delayed phases were 93.26% and 96.07% respectively. Furthermore, CP and CC in delayed and extended delayed phases were 92.13% and 96.07% and 81.46% and 90.45% respectively (Table). In general, IV NEPA was well tolerated, as only 9.55% of patients experienced adverse events with 95.83% of them being mild in nature. Headache (2.25%) and injection site reactions (1.68%) were the most common adverse effect reported. **Conclusions:** IV NEPA demonstrated high efficacy and good tolerability in a real world Indian setting, exhibiting response rates of >92% in both delayed and extended delayed phases in patients receiving HEC/MEC regimens.Clinical trial information: CTRI/2023/04/051951. Research Sponsor: Glenmark Pharmaceuticals Limited.

CINV efficacy assessment in HEC/MEC regimens.

	Acute Phase (0-24 hrs)			Delayed Phase (>24-120 hrs)			Extended Delayed Phase (>120-240 hrs)			Extended Overall Phase (0-240 hrs)		
PARAMETER	HEC (N=90)	MEC (N=88)	Overall (N=178)	HEC (N=90)	MEC (N=88)	Overall (N=178)	HEC (N=90)	MEC (N=88)	Overall (N=178)	HEC (N=90)	MEC (N=88)	Overall (N=178)
Complete Response	67 (74.44%)	83 (94.32%)	150 (84.27%)	81 (90%)	85 (96.59%)	166 (93.26%)	85 (94.44%)	86 (97.73%)	171 (96.07%)	62 (68.89%)	81 (92.04%)	143 (80.34%)
Complete Protection	66 (73.33%)	83 (94.32%)	149 (83.71)	79 (87.78%)	85 (96.59%)	164 (92.13%)	85 (94.44%)	86 (97.73%)	171 (96.07%)	60 (66.67%)	81 (92.04%)	141 (79.21%)
Complete control	43 (47.78%)	75 (85.23%)	118 (66.29%)	64 (71.11%)	81 (92.04%)	145 (81.46%)	76 (84.44%)	85 (96.59%)	161 (90.45%)	36 (40%)	73 (82.95%	109 (61.24%)

When pain management meets harm reduction: Patients with cancer navigate the opioid crisis—2016 to 2020 National Inpatient Sample analysis.

Himal Kharel, Zeni Kharel, Samikchhya Keshary Bhandari, Nishan Babu Pokhrel, Purva Shah, Aditya Sanjeevi, Aniket Rao, Abdullah Ahmad Orakzai, Basant Eltaher, Tripti Jain, Saad Jamshed; Rochester General Hospital, Rochester, NY; Tribhuvan University Teaching Hospital, Kathmandu, Bagmati, Nepal; Norwalk Hospital, Norwalk, CT

Background: The opioid crisis is a growing public health concern in the United States. In this retrospective study, we aim to look at the trends and predictors of opioid overdose-related mortality in cancer patients. **Methods:** A retrospective analysis of the National Inpatient Sample database (NIS) from 2016 to 2020 was conducted using International Classification of Diseases-10(ICD-10) codes to identify hospitalizations related to opioid overdose. The 2016-2020 mark was chosen because 2016 is the first NIS year with full implementation of ICD-10 code and there is absence of data after 2020. STATA version SE18.0 was used for statistical analysis. We used multivariate regression analysis to calculate the effects of various demographic and non-demographic variables including age, sex, Charlson Comorbidity Index(CCI), race, median household income, type of insurance, hospital bed size, hospital region, chronic lung disease, neuromuscular disease, and alcohol use disorder on opioid overdose-related mortality. **Results:** There were 6980 hospitalizations with opioid overdose in cancer patients. Mean age was 62.3 years and 49.9% were females. 97.9% of patients had high CCI. The trend of opioid overdose-related mortality in cancer patients is shown in the table. Unlike increasing opioid overdose related mortality in the general population (which, per CDC, increased by 62.44% from 2016 to 2020), we found that opioid-related admissions and mortality in cancer patients are stable over five years. Significant predictors of mortality (p-value <0.05) included male sex, African-American race, lower-median household income, and chronic lung disease with the odds ratio 1.64, 2.62, 2.13, and 1.69 respectively. **Conclusions:** The ongoing opioid crisis has led to tighter regulations regarding opioid prescriptions, subsequently creating increasing obstacles for cancer patients to access opioids. This analysis indicates that hospitalizations and deaths related to opioids in cancer patients have remained relatively stable, in contrast to the general population. Therefore, it is crucial to establish distinct regulations for cancer patients compared to the general population to ensure appropriate access to opioids for effective pain management. In addition, this study identified key predictors of mortality from opioid overdose in cancer patients, highlighting the complex interplay of socio-economic factors in medical care. The limitations of this study include multivariate model's inability to account for all variables, coding errors, and an increased risk of bias due to the retrospective nature of the data. Research Sponsor: None.

Year	Number of Admissions With Opioid Overdose in Cancer Patients	Number of Deaths Due to Opioid Overdose in Cancer Patients (%)
2016	1345	95 (7.05%)
2017	1620	100 (6.2%)
2018	1435	75 (5.2%)
2019	1305	60 (4.5%)
2020	1275	100 (7.8%)
Total	**6980**	**430 (6.2%)**

12072 Poster Session

Impact of palliative care on hospital length of stay and charges in hospitalized patients with cancer at end of life.

Tien-Chan Hsieh, Guangchen Zou; Division of Hematology-Oncology, Department of Medicine, UMass Chan Medical School, Worcester, MA; Johns Hopkins Medicine, Baltimore, MD

Background: Early palliative care has been shown to enhance the quality of life and survival for cancer patients. However, the economic implications of using palliative care in hospitalized cancer patients remain inconclusive. While palliative care can prevent aggressive interventions in end-of-life patients, it may also prolong hospitalization. **Methods:** This retrospective study used four years of National Inpatient Sample data (2016-2019) to explore the association between palliative care and hospital length of stay and charges among cancer patients aged 18 and above, hospitalized for at least 7 days and died. Hospital charges were divided by length of stay to derive the average daily charges. Continuous variables, length of stay and average daily charges, were standardized by subtracting means and dividing by standard deviations. We top-coded length of stay and average daily charges at the 99th percentile. Length of stay was also modeled into categories: 7-13, 14-20, 21-27, and 28+ days. A mixed-effects model with individual hospitals as a random effect was employed to account for potential variations in clinical practices and billing at the institutional level. **Results:** The study included 59,355 distinct cancer hospitalizations, totaling 296,775 weighted hospitalizations. Palliative care utilization was observed in 54.0%, and Do-not-resuscitate (DNR) status was noted in 57.9%. The observed palliative care use and DNR status were most prevalent in the 7-13 days group (56.6% and 61.3%) and least in the 28+ days group (46.9% and 48.8%). 85.2% didn't receive cardiopulmonary resuscitation (CPR) and that rate was similar across all length of stay groups. In linear mixed-effects models using standardized length of stay, palliative use was associated with shorter length of stay (adjusted Odds Ratio {aOR} 0.89; confidence interval {CI} 0.88-0.90). After adjustment for covariates, DNR was also associated with shorter hospitalization (aOR: 0.81; CI: 0.80-0.82). Receiving CPR had lower adjusted risk for longer hospitalization (aOR: 0.94; CI: 0.93-0.95). In multivariate model, daily charges were inversely correlated to the length of stay (aOR: 0.92; CI: 0.92-0.92). When using average charges per day as dependent variable, palliative care use was associated with less charges (aOR: 0.83; CI: 0.83-0.84). DNR also showed a lower adjusted odds for hospital charges (aOR: 0.89; CI: 0.88-0.89). Receiving CPR had higher adjusted risk of higher charges (aOR: 1.23; CI: 1.22-1.24). **Conclusions:** The use of palliative care was associated with a shorter length of stay and lower hospital charges per day among cancer patients who died in the hospital after adjusting for covariates. Many of the 46% who died without palliative care could have benefitted from it. Interventions aimed at promoting palliative care services among inpatient cancer patients nearing the end of life might yield economic benefits. Research Sponsor: None.

Prevalence of cannabis related potential medication interactions (PMI) among patients with cancer during treatment.

Elyssa Kim, Jennifer Cullen, Prateek Mendiratta, Megan Farrell, Shalena Finklea, Lauren Huang, Erika Trapl, Alexandre Chan, Stanton L. Gerson, Richard T. Lee; City of Hope, Duarte, CA, CA; Case Western Reserve University School of Medicine, Cleveland, OH; University Hospitals Seidman Cancer Center, Cleveland, OH; Case Western Reserve University, Cleveland, OH; Case Western Reserve University, Cleveland, CA; University of California, Irvine, Irvine, CA; City of Hope, Duarte, CA

Background: The utilization of cannabis is increasing among patients with cancer; however, limited information exists about PMI with cannabis during treatment for cancer. **Methods:** An NCI-funded cross-sectional survey study was conducted at a comprehensive cancer center among patients undergoing anticancer therapy. Subjects completed a survey about utilization of medications including supplements and cannabis – specifically reasons for use and type of cannabis. All patients actively taking any cannabis were identified and included for analysis. Lexicomp and Natural Medicines Comprehensive Database interaction software were used to determine PMIs. **Results:** A total of 61 patients (19.5%) were identified from 313 participants as actively using a form of cannabis. Subjects had a mean age of 58 (SD±13.3) and mostly self-identified as being White (70%) with one-fifth being Black (21%). The most common types of cancer were lung (18%), breast (15%), lymphoma (12%) and colorectal (12%). The most prevalent modes of cannabis intake were smoking (36%), gummies (33%), and oil/tincture/liquid (16%). The most common reasons for cannabis use included insomnia (46%), pain (41%), and mood (39%). The median number of medications used were 6 (range, 1-16) and supplements (including cannabis) were 3 (range, 1-14). A total of 1157 PMIs and 569 unique PMIs were identified among active cannabis users. The most common PMIs were prescription-supplement interactions (31.7%) and prescription-cannabis interactions (27%). Nearly two-thirds of the PMIs (61%) were labelled as moderate, followed by major interactions (18%). Among these patients, there were 412 cannabis interactions (36% of PMIs) with 124 being unique. Of these cannabis PMIs, 71% were interactions with non-anticancer prescription medications, 17% with over-the-counter medications, and 10% with anticancer agents. Most of the cannabis PMIs were categorized as moderate (87%) and major (12%) severity, and the level of evidence of these PMIs were rated as poor (60%). The most common cannabis-related PMIs were with acetaminophen (9.5%), dexamethasone (8%), and ondansetron (6.3%). The most common chemotherapy PMIs were with paclitaxel (4%) and doxorubicin (2%). **Conclusions:** This is one of the first studies to assess cannabis-related drug interactions in patients receiving cancer treatment, and results indicates a significant proportion of cannabis users are at risk for moderate to major PMIs including with chemotherapy. Research Sponsor: None.

Top 10 most common cannabis PMIs.

PMI	Prevalence (%)
Acetaminophen	39 (9.5%)
Dexamethasone	33 (8.0%)
Ondansetron	26 (6.3%)
Prochlorperazine	19 (4.6%)
Paclitaxel	16 (3.9%)
Claritin	14 (3.4%)
Gabapentin	14 (3.4%)
Omeprazole	10 (2.4%)
Lidocaine	10 (2.4%)
Diphenhydramine	10 (2.4%)

12074 Poster Session

Exploring “good days” in advanced cancer: Activities, behaviors, and quality of life.

David Lazris, Svea Cheng, Christianna Bartel, Krina Durica, Jennifer Fedor, Leeann Chen, Yael Schenker, Carissa A. Low; University of Pittsburgh Medical Center (UPMC), Pittsburgh, PA; University of Pittsburgh School of Medicine, Pittsburgh, PA; University of Pittsburgh, Pittsburgh, PA; Palliative Research Center (PaRC) and Department of Medicine, Division of General Internal Medicine, Section of Palliative Care and Medical Ethics, University of Pittsburgh, Pittsburgh, PA

Background: Advancements in cancer treatments have contributed to people living longer with Stage IV cancer. People living with advanced cancer face significant and unique psychological challenges related to dynamic treatment schedules, fluctuating physical symptoms, and uncertainty regarding prognosis. Understanding what constitutes a “good day” may help patients, their family members, and clinicians to recognize and prioritize factors that improve quality of life. The goal of this project was to understand activities and behaviors that characterize a “good day” among people living with advanced cancer. **Methods:** We enrolled 20 patients with advanced cancer (M 63 years old, range 41-75; 65% female; 65% white and 35% black; mean 1.5 years since Stage IV diagnosis [range 9 days to 7.5 years]). Participants completed semi-structured interviews and two weeks of nightly diaries, using a 1-5 rating scale (1 = very bad, 5 = very good) to rate their daily quality of life and document various activities and experiences. We conducted t-tests to determine differences in “goodness” on days with and without different experiences along with a Pearson correlation between each patients’ mean goodness rating and Patient-Reported Outcomes Measurement Information System (PROMIS) scores. **Results:** Interviews revealed themes of "good days," including emphasizing control, normalcy, positive impact, and presence. Loss of control, uncertainty, disruptive symptoms, negative healthcare experiences, and unmet goals were more common on “bad days.” Nightly diaries revealed significant correlations between active engagement in social, hobby, club, religious, cooking, reading, and meditation activities and reporting a good day (all p values $<$ .05). Mean diary goodness ratings correlated positively with Ability to Participate in Social Roles/Activities ($r(19) = .54$, $p = .016$) and inversely with Anxiety ($r(19) = -.63$, $p = .004$) and Depression ($r(19) = -.53$, $p = .020$) and was marginally inversely correlated with Fatigue ($r(19) = -.44$, $p = .059$) and Pain Interference ($r(19) = -.46$, $p = .050$). No significant correlations were observed with Physical Function ($r(19) = .15$, $p = .544$), Cognitive Function ($r(19) = .36$, $p = .134$), and Sleep Disturbance ($r(19) = -.26$, $p = .286$). **Conclusions:** Preliminary findings suggest that days on which individuals with advanced cancer are able to engage in activities that give them a sense of normalcy, control, self-identity, and connection to others are better than days without these activities. This is further supported by the positive correlation between goodness ratings and the ability to participate in social roles and activities. Understanding the individual’s values, perceived social roles, and priorities may help care teams support people with advanced cancer to optimize their quality of life and functioning and navigate treatment decisions. Research Sponsor: Henry L. Hillman Foundation; NCI Cancer Center Support Grant; P30CA047904.

12075 Poster Session

Behavioral economic interventions to embed early palliative care in community oncology (BE-EPiC): A pragmatic cluster-randomized trial.

Ramy Sedhom, William J. Ferrell, Jinbo Chen, Katherine Villarin, Yang Li, Kara Berwanger, Bethann Scarborough, Randall A. Oyer, Pallavi Kumar, Niharika Ganta, Shanthi Sivendran, Kevin Volpp, Justin E. Bekelman, Ravi Bharat Parikh; Penn Medicine, Philadelphia, PA; University of Pennsylvania, Philadelphia, PA; Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA; Penn Medicine Lancaster General Health, Lancaster, PA; Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

Background: Among patients with cancer, early outpatient specialty palliative care (PC) concurrent with cancer-directed treatment improves quality of life and symptom burden, decreases aggressive end-of-life care, and is endorsed by national guidelines. However, nearly half of patients with advanced cancer do not receive specialty PC prior to dying. The objective of this study was to test the impact of oncologist-directed default PC referral orders on early PC utilization and quality of life. **Methods:** This 2-arm pragmatic randomized trial was conducted in a large, rural community oncology practice. Eligible patients met one of 5 NCCN guideline-based indications (uncontrolled symptoms, recent hospitalization or ED visit, ECOG PS$\geq$3; active stage IV malignancy; CNS metastasis) for specialty PC referral. Four teams, consisting of unique physicians, advance practice providers, and social workers, were randomized in a 1:1 fashion to intervention vs. control. Clinicians and care team members in the intervention arm received an electronic health record (EHR) message with a default pended PC referral order for eligible patients. Clinicians could opt out. Clinicians in the control arm received no EHR message. An adjusted cox proportional hazards model with clustered standard errors was used to assess the primary outcome of completed PC visits within 24 weeks of enrollment. Adjusted logistic regression models with inverse probability censoring weighting to account for differential mortality risk were used to assess secondary outcomes of absolute and change in quality of life per FACT-G score at 9 weeks, among intervention patients who received PC, compared to a random subset of controls. **Results:** Among 266 eligible patients, 252 (94.7%) were White, 147 (55.3%) were female, and 204 (78%) had stage IV disease. The most common cancers were gastrointestinal (26.3%), breast (19%), and lung (17%). In the intervention arm, physicians opted-out of 62% of referrals. Rates of completed palliative care visits were 14.6% in the intervention arm vs. 8.1% in the control arm (adjusted hazard ratio 1.34 [95% CI 1.25-1.54], $p<0.001$). Patient-reported quality of life was greater in the intervention arm than the control arm (mean change in FACT-G score at 9 weeks: 6.56 [SD 8.9] intervention vs. -4.48 [SD 13.5] control; adjusted difference 11.4, $p=0.05$). Rates of intensive end-of-life care were similar in both control and intervention groups. **Conclusions:** Compared with controls, default referrals to specialty PC among patients who met guideline-based criteria led to increases in completed palliative care visits and improved quality of life. Default PC referrals may be an effective strategy to improve access to early specialty palliative care in community oncology, although effect sizes were tempered by high opt-out rates. Clinical trial information: NCT05365997. Research Sponsor: NCCN Foundation.

12076 Poster Session

Risk-stratified multidisciplinary ambulatory management of malignant bowel obstruction (MAMBO) program in women with advanced gynaecological cancers: A prospective study.

Vikas Garg, Husam Alqaisi, Pamela Soberanis Pina, Ana Veneziani, Anmol Kaur Pannu, Brooke Grant, Dina Braik, Crystal Wang, Arundhati Shukla, Azieb Tesfu, Oyinlade Odujoko, Ainhoa Madariaga, Yeh Chen Lee, Lisa Wang, Nazlin Jivraj, Valerie Bowering, Robert C Grant, Neesha C. Dhani, Amit M. Oza, Stephanie Lheureux; Princess Margaret Cancer Centre, Toronto, ON, Canada; Division of Medical Oncology and Hematology, Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada; UHN - Princess Margaret Cancer Centre, Toronto, ON, Canada; Princess Margaret Cancer Centre- University Health Network, Toronto, ON, Canada; UHN, Princess Margaret Cancer Center, Toronto, ON, Canada; 12 de Octubre University Hospital, Madrid, Spain; Prince of Wales Hospital and University of New South Wales, Randwick, NSW, Australia; Department of biostatistics, Princess Margaret Cancer Centre, University Health Network, University of Toronto, Toronto, ON, Canada; Princess Margaret, Toronto, ON, Canada; Princess Margaret, University Health Network, Toronto, ON, Canada

Background: Malignant bowel obstruction (MBO) is a dreaded complication encountered in patients (pts) with advanced gynaecological cancers. Survival is short, with most pts requiring long hospital stay for managing symptoms. The aim of this study was to validate prospectively the feasibility of the MBO outpatient management by a systematic risk-stratified multidisciplinary ambulatory approach in pts with advanced gynaecological cancers. **Methods:** This prospective single site study enrolled pts diagnosed with or at risk of MBO due to gynaecological cancers (NCT03260647) and actively managed by the MBO interdisciplinary team including the outpatient nurse led program (PMID 31550202). Eligible pts underwent comprehensive assessments, and the team provided tailored management recommendations. Those identified as "at-risk" were systematically followed by the nursing team for 4 weeks (wks) and discharged upon complete symptom resolution. MBO patients were proactively monitored for $\geq$ 4 wks, transitioning to the "at-risk" category upon MBO resolution. The primary endpoint of the study was the ratio of days alive and out of the hospital to days in the hospital within the initial 60 days post-MBO diagnosis. Secondary endpoints included overall survival (OS), the rate of total parenteral nutrition (TPN) administration, and the rate of symptom resolution. **Results:** A total of 92 pts were enrolled, predominantly with ovarian cancer (91%), median age of 62 years (range, 31-83). At enrolment, 49% (n=45) presented with MBO, while 51% (n=47) were deemed "at risk." Proactive outpatient management by the nursing team resulted in symptom resolution in 93% of "at-risk" pts, with 7% progressing to develop MBO during the first 4 wks in the program. Throughout the study, 62% (n=57) of pts experienced MBO. At the onset of MBO, 81% (n=46) were platinum-resistant with a median of 4 prior lines of therapy (range, 0-11). While 93% of pts (n=53) required in-patient management, the median time for hospitalization durations within the first 30 and 60 days after MBO diagnosis were 7 (range, 0-30) and 12.5 (range, 0-57) days respectively. Ratio of days in hospital/days out hospital within 60 days, median (range): 0.3 (0-19). During MBO, systemic therapy was administered to 77% (n=44) of pts, predominantly with weekly paclitaxel (38%, n=21). Surgical intervention was performed in 11% of pts, included primarily diverting ileostomy in 4 pts. TPN was administered to 33% (n=19) of pts. MBO resolution occurred in 42% (n=24) pts within 60 days, with recurrent episodes in 11% (n=6) pts and MBO symptoms persisted in 58% (n=33). The median OS in pts who had an episode of MBO was 5.7 months (95% CI, 3.6-8.4). **Conclusions:** This study confirms the feasibility of the ambulatory MBO management with pts managed mainly outside hospital during the 60 days with reduced hospitalization days. Clinical trial information: NCT03260647. Research Sponsor: Princess Margaret Cancer Foundation.

12077 Poster Session

Abuse potential and analgesic efficacy of different IV opioid infusion rates among patients hospitalized with cancer pain: A randomized crossover trial.

Joseph Anthony Arthur, Akhila Reddy, Josiah Halm, Aline Rozman De Moraes, Irma Lopez-Quinones, Raul Laureano, Diana L. Urbauer, Eduardo Bruera; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: There is insufficient data on the effect of fast intravenous (IV) opioid infusion rate on their potential for abuse when administered for pain relief. No study has simultaneously evaluated the analgesic efficacy, abuse potential, and adverse effects of different IV opioid infusion rates to determine their risk-benefit ratio in routine inpatient care. We compared the abuse potential, analgesic efficacy, and adverse effect profile of the standard IV hydromorphone bolus infusion rate with a slower experimental rate among hospitalized patients with cancer pain. **Methods:** This double-blind, double dummy, randomized controlled, 2X2 crossover trial was conducted in the inpatient location at MD Anderson Cancer Center. Eligible patients were hospitalized patients with cancer, aged 18 years or older, who required IV opioids for moderate to severe pain. During the first period, participants were randomly assigned to receive IV hydromorphone 1mg administered over 15 minutes (experimental rate) in sequence A, or over 2 minutes (standard rate) in sequence B. Outcomes were measured at baseline, 15, 30, 60, and 120 minutes post-intervention Participants crossed over to receive treatments in the alternate sequence during the second period after a 6-hour wash out period. Abuse liability potential was measured by the Drug Effect Questionnaire (DEQ-5), change in Numerical Rating Scale pain scores, and rates of subjective and objective adverse effects. **Results:** Eighty-threeeligible patients were randomly allocated to sequences A (42, 51%) or B (41, 49%). There was no significant difference in the mean (SD) peak DEQ-5 "drug liking" subscale between the faster standard and slower experimental infusion rates (24.00 vs 24.34, p=0.82). Similarly, no significant differences were observed with other DEQ-5 subscales. 92% and 94% of experimental and standard IV hydromorphone rate recipients respectively had clinical improvements in pain scores over 120 minutes (OR=0.67, 95% CI: 0.06-5.82, p=0.65). No significant differences were observed in NRS pain scores between the 2 groups at all time points. Drowsiness and oxygen desaturation were the most common subjective and objective adverse events observed (up to 52% and 22% of all patients respectively). Drowsiness was more frequent in the standard group than the experimental group (50% vs 29% at 15 minutes [p= 0.03], and 52% vs 31% at 60 minutes [p=0.03]). **Conclusions:** The standard 2-minute IV hydromorphone bolus produced comparable abuse potential and analgesic effects but more sedation than an experimental 15-minute rate. The findings support a 2-minute bolus infusion rate for pain relief with relatively nominal abuse potential, but a slower 15-minute rate may be more desirable to minimize sedation and preserve cognition for critically important inpatient activities. Clinical trial information: NCT04296305. Research Sponsor: MD Anderson Cancer Center Institutional Research Grant.

12078 Poster Session

Cannabis use for cancer-related symptoms in rural versus urban Minnesota.

Maria Borrero, Patricia Jewett, Dylan M. Zylla, Helen M. Parsons, Jeanette Y Ziegenfuss, Anne Hudson Blaes; University of Minnesota, Minneapolis, MN; HealthPartners Cancer Research Center, Minneapolis, MN; HealthPartners Institute for Education and Research, Bloomington, MN; University of Minnesota Masonic Cancer Center, Minneapolis, MN

Background: Minnesota currently has a medical cannabis program and recently legalized recreational cannabis in 2023. Evidence suggests that cannabis may have positive effects on various aspects of a cancer patient's quality of life. However, little is known about any differences in cannabis use between rural and urban cancer patient populations. We compared cannabis use, behaviors, attitudes, access, and associations with cancer-related symptom burden in rural versus urban Minnesotans with cancer. **Methods:** We conducted a cross-sectional survey between 2021 and 2022. Study participants were adults diagnosed in 2018-2019 with cancer and treated at an academic cancer center and its community clinic affiliates in Minnesota. Participants were sent self-administered surveys. 775 surveys were completed and returned. Analysis was restricted to 688 who reported residential ZIP codes to classify them as living in urban versus rural areas based on ZIP-code level Rural Urban Commuting Area codes. Our primary outcomes were cannabis use and perceptions. Secondary outcomes included patterns of use, behavior, attitudes, and self-reported symptom burden. **Results:** Of 688 participants, 54% were classified as rural and 46% as urban. Of all respondents across both groups, 60% reported never using cannabis, 56% reported cannabis use during cancer treatment, and 21% reported use since cancer diagnosis. The majority of respondents in both groups believed there are potential benefits of cannabis. Those in the urban group reported greater interest in trying medical cannabis in the future compared with rural group. The majority of respondents reported never discussing cannabis use with their healthcare provider, and even fewer reported their provider recommending cannabis to them. Both urban and rural groups reported improvement in pain, stress, insomnia, appetite, and digestion. The rural group experienced more improvement in fatigue and stress compared to the urban group. Nearly no one reported worsening of any symptoms measures after the use of cannabis. **Conclusions:** Cannabis use, perceptions, and attitudes were overall similar in a cohort of rural and urban patients with cancer. Both groups experienced significant cancer related symptom burden improvement after use of cannabis. While the urban cohort showed greater interest in future cannabis use, the rural cohort reported greatest benefits in relief of stress and fatigue after cannabis use, two important measures of quality of life. Our data suggest that providers rarely recommend or talk about cannabis use to cancer patients. Research Sponsor: None.

Patterns of Cannabis Use	Everyone (N=688)	Rural (N=372)	Urban (N=316)	P
	N (%)	N (%)	N (%)	
Use since cancer diagnosis				
Yes	139 (20.8)	65 (18.0)	74 (24.0)	0.05
Believed there are potential benefits				
Yes	547 (89.1)	287 (87.5)	260 (90.9)	0.18
Believed there are potential risks				
Yes	447 (77.1)	247 (79.2)	200 (74.6)	0.19

12079 Poster Session

Proactive, automated monitoring of uncontrolled symptoms in prostate cancer survivors across the cancer control continuum.

Miguel Muniz, Daniel S Childs, Kathryn Jean Ruddy, Veronica Grzegorczyk, Deirdre R. Pachman, Alicia K. Morgans, Ewan Kemar Cobran, Joan M. Griffin, Ashley Wilder Smith, Kurt Kroenke, Charles L. Loprinzi, Brian Addis Costello, Jacob Orme, Irbaz Bin Riaz, A. Oliver Sartor, Sandra A. Mitchell, Andrea L. Cheville; Department of Medical Oncology, Mayo Clinic, Rochester, MN; Mayo Clinic, Rochester, MN; Dana-Farber Cancer Institute, Boston, MA; Mayo Clinic College of Medicine and Science, Scottsdale, AZ; National Cancer Institute, Bethesda, MD; Indiana University School of Medicine and Regenstrief Institute, Indianapolis, IN; Mayo Clinic Rochester, Rochester, MN; Mayo Clinic, Scottsdale, AZ; National Cancer Institute, Rockville, MD

Background: Many troublesome symptoms experienced by men with prostate cancer are not specific to a particular disease state or treatment modality. As such, these issues' scope is neither fully appreciated nor characterized in the reporting of clinical trial data. A modern accounting of poorly controlled symptoms is needed to better inform survivorship and supportive care efforts. **Methods:** Data are drawn from the Enhanced, EHR-facilitated Cancer Symptom Control (E2C2) study, a cluster-randomized stepped wedge trial examining the effectiveness of routine symptom assessment and management on patient-centered outcomes and healthcare utilization (NCT03892967). This is a population-level study supporting patients with cancer, who are cared for in medical oncology clinics across the Midwest United States. The trial utilizes an automated symptom monitoring system with EHR-enabled algorithms for symptom triage and intervention. The current analysis focuses on pre-intervention surveys. The cohort includes E2C2 participants with prostate cancer (as determined by the Mayo Clinic Cancer Registry) receiving curative or palliative-intent therapies, along with prostate cancer survivors who previously completed their treatment. The prevalence of SPPADE symptoms (sleep disturbance, pain, impaired physical function, anxiety, depression, fatigue [low energy]) was assessed using 0 to 10 numerical rating scales (NRS), with scores of 4-6 indicating moderate symptoms and 7-10 indicating severe symptoms. **Results:** A total of 1,388 men with prostate cancer completed a pre-intervention survey between March 2019 and January 2023. The median age at completion of first survey was 74 years. The cohort includes patients living in diverse settings, including urban (n=718, 52%), micropolitan (n=250, 18%), small town (n=218, 16%), and rural (n=200, 14%) environments. The proportion of patients experiencing moderate-to-severe symptoms (NRS score ≥4) was 47% for fatigue, 40% for impaired physical function, 32% for sleep disturbance, 27% for pain, 22% for anxiety, and 20% for depression/emotional distress. The three domains with the highest prevalence of severe symptoms (NRS score ≥7) were fatigue (17%), impaired physical function (12%), and sleep disturbance (10%). **Conclusions:** Proactive symptom monitoring identifies a high overall burden of moderate-to-severe symptoms, particularly fatigue and impaired physical function, among prostate cancer patients and survivors. Collaborative care approaches and symptom control trials are needed to mitigate and manage these burdensome symptoms. Clinical trial information: NCT03892967.
Research Sponsor: National Center for Advancing Translational Sciences (NCATS), a component of the National Institutes of Health (NIH).; UL1TR002377; National Cancer Institute of the National Institutes of Health (NIH).; UM1CA233033

	Sleep	Pain	Anxiety	Depression	Fatigue	Impaired Physical Function
Moderate symptoms, n (%)	306 (22)	248 (18)	208 (15)	198 (14)	406 (30)	386 (28)
Severe symptoms, n (%)	139 (10)	119 (9)	94 (7)	84 (6)	234 (17)	165 (12)
Mean NRS score (SD)	2.62 (2.56)	2.30 (2.51)	2.06 (2.30)	1.88 (2.27)	3.55 (2.63)	2.98 (2.65)

12080 Poster Session

Real-world quality analysis of palliative care utilization in patients with brain metastases at three academic institutes.

Rohit Singh, Alissa A. Thomas, Emily Kopp, Ryan Amidon, Wendy Novicoff, Samantha R Schuetz, Joe A Bovi, Guneet Sarai, Ausia N Iqbal, Camilo E. Fadul; University of Vermont Medical Center, Burlington, VT; University of Vermont College of Medicine, Burlington, VT; University of Virginia Health System, Charlottesville, VA; Medical College of Wisconsin, Wauwatosa, WI; University of Virginia, Charlottesville, VA; Beth Israel Deaconess medical center, Boston, MA; Medical College of Wisconsin, Milwaukee, WI; University of Virginia Medical Center, Charlottesville, VA; University of Virginia School of Medicine, Charlottesville, VA

Background: Brain metastases (BMETs) are a devastating complication of cancer, occurring in up to 30-50% of patients with advanced solid tumors. Median survival after diagnosis of BMETs can be limited, with 3-6 months survival for patients with poorer performance status (Updated Recursive Partition analysis [U-RPA] classification class 2b and 3). Early integration of palliative care (PC) can improve a patient's quality of life. Per guidelines, patients with advanced cancer should be referred to an interdisciplinary team, including PC, early in the disease. We aimed to assess the utilization and impact of PC in patients with BMETs at three academic centers. **Methods:** We obtained data from the electronic medical record (EMR) of all patients diagnosed with BMETS at the University of Virginia, the Medical College of Wisconsin, and the University of Vermont between 1 January 2017 and 31 December 2019. Inclusion criteria were age 18+ years, diagnosis of BMETs secondary to a solid tumor malignancy (excluding leptomeningeal metastases), and >3 months of follow-up treatment. Patients were included if considered at high risk for mortality, which was defined as KPS <70 (U-RPA Class 3) or KPS 70-80 and age > 65 (U-RPA Class 2b). Chi-squared and Fisher's exact tests compared survival, hospice referral, emergency visits, readmissions, and advance directives (AD) on the file between the PC and non-PC groups. **Results:** In total, of the 309 patients that were assessed, 220 patients were class 2b, and 89 were class 3 per U-RPA classification. The mean age was 66 in both groups, and 167 (54%) were seen by PC. The median survival for patients seen by PC was 7.8 months compared to 8.3 months (p 0.056). There was no statistically significant difference in survival between the two groups. 80% of patients in the group seen by PC enrolled with hospice care compared to 58% in the non-PC group (p 0.0002). 80% of patients had an AD on file in the group seen by PC compared to 56% in the non-PC group (p <0.0001). In terms of ED visits or re-hospitalization, there was a trend for more ED visits/readmissions in the group seen by PC compared to the non-PC group (p 0.057). **Conclusions:** In this real-world quality analysis, we found that there is under-utilization of formal PC consultation in patients with BMETs. There was no difference in survival between groups, indicating PC is not synonymous with end-of-life or hospice care. PC was associated with more patients completing ADs and more patients using hospice. Health systems and policy initiatives promoting palliative care utilization earlier in the disease course may support patient values and preferences at the end of life. Research Sponsor: None.

Outcomes based on palliative care utilization.

Outcome	Palliative Care (n=167)	No Palliative Care (n=142)	P-value
Median Survival	7.8 months	8.3 months	0.056
Hospice Utilization	80%	58%	0.0002
Advance Directives Completed	80%	56%	<0.0001

12081 Poster Session

Effect of palliative care on economic burden in lung cancer admissions: Insights from the NIS database.

Ekrem Turk, Ayobami Gbenga Olafimihan, Lina James George, Badri Aryal, Youjin Oh, Vaishali Deenadayalan, Kunnal Batra; John H. Stroger, Jr. Hospital of Cook County, Chicago, IL; John H. Stroger, Jr. Hospital of Cook County, Chicago

Background: Lung cancer (LC) remains the leading cause of cancer mortality globally, presenting substantial challenges in symptom management and quality of life (QoL) for affected patients. Despite the crucial role of palliative care (PC) in alleviating suffering and enhancing QoL, its integration into LC treatment is inconsistent, attributed to healthcare provider perceptions and systemic barriers. This study examines the utilization of PC consultations in LC admissions using the National Inpatient Sample (NIS) database, seeking to identify patterns of use and opportunities for improved care integration. **Methods:** The study queried the NIS database from 2016 to 2020 for adult hospitalized patients with a primary diagnosis of LC using ICD-10 codes. The primary outcome examined was the impact of PC consultations on length of stay (LOS), total hospital charges (THC), and healthcare utilization, with inpatient mortality as a secondary outcome. Baseline characteristics were assessed using t-tests and chi-square tests, while multivariable logistic regression analysis adjusted for age, gender, race, Charlson index, insurance type, and household income was employed to evaluate the outcomes. **Results:** Among 584,055 LC patients, 50.4% was female and 14.6% had a PC consult. These patients were typically older (68.4 vs. 70.6 years, $p < 0.001$), more likely to be male (51.1% vs. 49.3%, $p < 0.001$) and African American (13.3% vs. 11.9% $p < 0.001$), and had Medicaid coverage (11.1% vs. 9.7%, $p < 0.001$) compared to their counterparts . PC was more frequently consulted in non-teaching hospitals (16.3% vs 14.1%, $p < 0.001$). Patients with PC consults also had a higher Charlson Comorbidity index 6.4 vs. 4.9 ($p < 0.001$). The overall inpatient mortality rate was 7.4%, with a significantly higher rate in patients with PC (32%) versus without (3.2%) ($p < 0.001$). While PC was associated with a longer LOS (7.6 vs. 5.9 days, $p < 0.001$), it resulted in lower THC ($74,399 vs. $84,233, adjusted difference: $6,874 $p < 0.0001$) and increased discharges with home health care and to nursing homes. **Conclusions:** PC consultations in LC patients are associated with reduced THC despite a slight increase in LOS. This finding emphasizes the economic and therapeutic value of PC in the treatment of LC, advocating for its earlier and broader integration. By addressing both symptom management and healthcare costs, palliative care can play a significant role in enhancing the comprehensive care of lung cancer patients, highlighting the need for overcoming existing barriers to its adoption. Research Sponsor: None.

PRIMARY OUTCOME	LC with PCC	LC without PCC	Adjusted Odds Ratio/ Mean Difference	95% Confidence Interval	P-value
Total Charge ($)	74,399	84,233	6874	4912 - 8835	<0.0001
SECONDARY OUTCOMES					
Length of stay	7.6 day	5.9 day	1.3 day	1.16 – 1.53	<0.0001
Home health	30.3%	24.6%	1.26	1.2 – 1.3	<0.0001
Nursing Home	26.2%	10.8%	2.53	2.4 – 2.66	<0.0001
Mortality	11.81%	2.81%	3.70	2.06 - 6.63	<0.0001

LBA12082 **Poster Session**

Randomized double-blind placebo-controlled trial evaluating pregabalin for chronic cough in patients with lung cancer.

Vanita Noronha, Nandini Sharrel Menon, Vijay Maruti Patil, Minit Jalan Shah, Amit Joshi, Srushti Jain, Kavita Prakash Nawale, Rohan Surve, Gunj Bafna, Shweta Jogdhankar, Priyanka Shelar, Ashish Singh, Sushmita Salian, Pundlik Jadhav, Hetakshi Shah, Neha Jagdish Mer, Ananya Vohra, Swaratika Majumdar, Rajendra A. Badwe, Kumar Prabhash; Tata Memorial Centre, Mumbai, India; P.D. Hinduja Hospital, Mumbai, India; Tata Memorial Hospital, Mumbai, India; Advanced Centre for Treatment, Research and Education in Cancer (ACTREC), Tata Memorial Centre, Navi Mumbai, India; MS Ramaiah Memorial Hospital, Bengaluru, India; Emeritus Professor, Tata Memorial Centre (TMC), Mumbai, India; Tata Memorial Hospital, Tata Memorial Centre, Mumbai, India

12083 Poster Session

Impact of steroids indication on the efficacy of immunotherapy in a multi-tumor cohort of patients: Time and dose-dependent evaluation.

Pablo Gajate, Victor Albarrán, Patricia Guerrero, Coral García de Quevedo Suero, Carlos González, Jesús Chamorro, Diana I. Rosero, Jaime Moreno-Doval, Juan Carlos Calvo, Patricia Pérez de Aguado, Victor Alia, Pilar Sotoca, Ana Maria Barrill, Maria San Román, Ainara Soria Rivas, Maria Eugenia Olmedo Garcia, Cristina Saavedra Serrano, Alfonso Cortés Salgado, Federico Longo, Pilar Garrido; Medical Oncology Department, University Hospital Ramón y Cajal, Madrid, Spain; Medical Oncology Department, Ramón y Cajal University Hospital, Madrid, Spain; Hospital Universitario Ramón y Cajal, Madrid, Spain; Medical Oncology Department, Ramón y Cajal Hospital, Madrid, Spain; Medical Oncology Department. Hospital Universitario Ramón y Cajal, Madrid, Spain; Hospital Universitario de Ramon y Cajal, Madrid, Spain; Medical Oncology Departmente. Ramón y Cajal Hospital, Instituto Ramón y Cajal de Investigación Sanitaria (IRICYS), CIBERONC, Madrid, Spain; Medical Oncology Department, Hospital Ramón y Cajal, Universidad de Alcalá, Madrid, Spain

Background: The detrimental impact of steroids (ST) on patients receiving immune checkpoint inhibitors (ICI) has been described in several studies. However, the influence of indication, time of administration, and dosage is more controversial. **Methods:** This is a retrospective analysis of 475 patients with advanced solid tumors treated with ICI at a tertiary university hospital, between 2015 and 2022. Data related to baseline characteristics and clinical outcomes were collected. For each patient, the daily ST dose (equivalent in mg/kg of prednisone) and indication were registered until progression or death. We evaluated the impact of ST indication on the objective response rate (ORR) and progression-free survival (PFS). In addition, we analyzed the potential influence of cumulative dose (CD) (patients were divided into quartiles (Q) based on the total dose of steroids received throughout ICI treatment) and time of administration (30 days from C1 (D1-30), 3 months from C1 (D1-D90) and after 6 months (m) from C1 (>6m)). **Results:** We analyzed 475 pts with advanced solid tumors (NSCLC: 33.9%; urothelial: 17.3%; renal: 13.7%; melanoma: 11.2%; head and neck: 11.0%; others: 12.9%) treated with ICI (anti-PD1 [64.4%], anti-PDL1 [20.4%], anti-PD1 plus anti-CTLA4 [13.3%] or anti-CTLA4 [1.9%]). 49.5% of pts received ST during ICI treatment (20.6% due to an immune-related adverse event [irAE] and 33.9% with other indications). 24.2% of patients received ST in D1-30 (5.7% irAE vs 20.6% other indications), 32.6% in D1-D90 (10.7% vs 25.1%) and 17.1% in >6m (12% vs 8%). The ORR was significantly higher in pts who received ST for irAES than in those treated with ST for other reasons both in D1-30 (40% vs 15.3%; $p = 0.028$) and in D1-90 (42.6% vs 17%; $p = 0.001$). Furthermore, the ORR was very similar to that of patients who did not receive any ST treatment (40% vs 37.8% in D1-30, and 42.6% vs 37.7% in D1-90). There was an inverse correlation between the CD of ST in D1-30 and the ORR (37.78% [no steroids], 29.63% [Q1], 21.42% [Q2], 11.11% [Q3] and 22.22% [Q4]). However, this association was not observed among patients receiving ST for irAEs during D1-30 (37.8% [no steroids], 100% [Q1], 0% [Q2], 33.3% [Q3] and 42.9% [Q4]; $p = 0.21$) and in D1-90 (37.7% [no steroids], 0% [Q1], 41.7% [Q2], 42.9% [Q3] and 52.9% [Q4]; $p = 0.29$). Finally, among patients without progression after 6 months from C1, PFS tended to be longer in those exposed to ST. However, PFS was similar regardless of the reason for ST use. **Conclusions:** Exposure to ST is associated with poorer ICI outcomes. Our study showed that the impact of ST is time- and dose-dependent. Interestingly, these results were not observed among patients exposed to ST due to irAEs, suggesting that immune toxicity may attenuate ST detrimental effects. Research Sponsor: None.

12084 Poster Session

Patient-reported symptom interference with activity- and mood-related functioning prior to start of an early-phase oncology combination trial including immune checkpoint blockade.

Goldy C George, Sarina A. Piha-Paul, Ecaterina Elena Dumbrava, Vivek Subbiah, Siqing Fu, Apostolia Maria Tsimberidou, Shubham Pant, Grace Appleton, Laila Noor, Timothy A. Yap, Jordi Rodon Ahnert, Funda Meric-Bernstam, Charles S Cleeland, Tito R. Mendoza, David S. Hong; Department of Symptom Research, The University of Texas MD Anderson Cancer Center, Houston, TX; Department of Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center, Houston, TX

Background: We examined symptom interference with activity- and mood-related functioning at baseline in early-stage trials of combination treatments that included at least one immune checkpoint inhibitor, and its association with quality of life (QOL)-, clinical-, and trial-related factors. **Methods:** Patients scheduled to begin an early-phase trial of a combination treatment with immune checkpoint blockade, and who had not received trial-related treatment were recruited into a prospective longitudinal study design (NCI R01CA242565), and completed the following validated patient-reported outcome (PRO) measures prior to trial start: MD Anderson Symptom Inventory- Immunotherapy (score range: 0-10, higher scores = worse symptom interference); NCI's PRO Common Terminology Criteria for Adverse Events (0-4, higher = worse severity); EuroQoL-5 dimensions assessing health status (0-100, higher = better health) and problems with self-care, and the Sloan Global QOL scale (0-10, higher = better QOL). Statistical tests included Spearman's correlation rho (r) and multivariable linear regression. **Results:** 977 baseline PRO measures were completed by 247 patients (median age = 59 y; 46% female). Worst symptom-related interference was with activity (3.0 on a 0-10 scale), work (2.9), and enjoyment of life (2.4). Composite score means were 2.8 for symptom interference with walking, activity, and work (WAW; activity-related functioning), and 2.1 for interference with relationships, enjoyment of life, and mood (REM; mood-related functioning). Symptoms most associated with worse WAW were fatigue ($P<0.001$) and appetite loss ($P=0.001$). Worse WAW was linked to worse REM ($r=0.78$, $P<0.001$). Diminished sexual interest/mood (DSI) was associated with worse WAW ($r=0.35$, $P<0.001$) and REM ($r=0.33$, $P<0.001$). Worse WAW was linked to shorter trial duration ($P=0.003$) and worse response (progression of disease/immune-related progression) on the clinical trial ($P=0.05$). **Conclusions:** This first, comprehensive and prospective examination of symptom interference with functioning at trial baseline found that worse symptom interference was linked to worse QOL, poorer clinical outcomes, and shorter trial duration. These findings suggest that baseline patient-reported symptom interference with functioning can serve as a potential biomarker of poor prognosis in investigational trials, and that trial patients may benefit from initiation of supportive care prior to trial start. Research Sponsor: NIH / NCI; NCI R01CA242565.

Spearman correlations.

Factor	WAW	REM	DSI
Global QOL	−0.48*	−0.41*	−0.32*
Self-rated health	−0.60*	−0.48*	−0.41*
Problems with self-care	0.33*	0.24*	0.09
ECOG performance status	0.24*	0.23*	0.24*
Serum albumin	−0.28*	−0.09	−0.26*
Lactate dehydrogenase	0.23*	0.22*	0.28*
Platelets	0.21*	0.12	0.15
Neutrophils	0.18†	−0.01	0.10

†$P<0.05$; *$P<0.01$.

12085 Poster Session

Prescribers of opioids for head and neck cancer (HNC) survivors.

Talya Salz, Akriti Mishra Meza, Patrick T Bradshaw, Sankeerth Jinna, Natalie Moryl, Anuja Kriplani, Kathryn Ries Tringale, James Flory, Deborah Korenstein, Allison Lipitz-Snyderman; Memorial Sloan Kettering Cancer Center, New York, NY; University of California, Berkeley, Berkeley, CA; Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY; Department of Medicine, Icahn School of Medicine at Mount Sinai, New York, NY

Background: Older HNC survivors often experience post-treatment pain, and they have concerningly high rates of unsafe opioid prescribing per CDC guidelines (e.g., high doses, concurrent benzodiazepines). Because interventions to improve opioid safety should target providers who prescribe opioids to HNC survivors, we aimed to identify post-treatment opioid prescriber specialty. **Methods:** Using the national linked Surveillance, Epidemiology, and End Results (SEER) registry and Medicare claims data, we identified adults age >65 diagnosed 2014-2017 with stage I-III HNC and who had ≥6 months treatment-free follow-up prior to censoring at further treatment, new cancer, hospice, death, or end 2019. Each opioid fill was assigned to a prescriber specialty: oncology (medical, radiation), surgery, primary care (internal medicine, family practice, geriatrics), pain, or other. Prescriber patterns (number of fills, duration of fill, annual opioid receipt) were summarized across follow-up and stratified by year. Multinomial logistic regression models captured trends in prescribing, accounting for clinical and sociodemographic characteristics. **Results:** Among 5547 HNC survivors, 2951 (53%) had ≥1 opioid fill (median 2.1 years follow-up). Primary care providers (PCPs) prescribed 49% of all fills (46%-53% each year). PCPs prescribed opioids to 49% of survivors with ≥1 opioid fill, a greater share than other specialties. PCPs prescribed longer supplies of opioids (median 30 days/fill and median 45 days/year) than oncologists or surgeons. The likelihood of an opioid being prescribed by an oncologist or surgeon was ≥5 times lower than by a PCP. Over follow-up, rates of opioid prescribing by oncologists decreased relative to rates of prescribing by PCPs (Table). **Conclusions:** Primary care involvement in opioid prescribing remains high over post-treatment HNC survivorship. Interventions to address unsafe opioid prescribing for HNC survivors should target the primary care setting, as is typical for opioid-reduction efforts in the non-cancer population. Research Sponsor: Seaver Cancer and Aging Award.

Patterns of opioid prescribing by specialty.

	Number of Fills From Each Specialty	Number of Survivors with ≥1 Fill From Each Specialty	Duration of Fills From Each Specialty, Days	Annual Duration From Each Specialty, Days	Likelihood of Opioid Prescribed by Each Specialty	Yearly Change in Likelihood of Opioid Prescribed by Each specialty
Prescriber Specialty	N (%)	N (%)	Median (IQR)	Median (IQR)	Probability Ratio (95% CI)	Adjusted Relative Probability Ratio (95% CI)
Any	23462	2951	28 (10, 30)	15 (5, 66)		
Oncology	2038 (9)	525 (18)	20 (10, 30)	30 (14, 65)	.18 (.15, .21)	.51 (.40, .66)
Surgery	2133 (9)	1159 (39)	5 (4, 10)	5 (3, 10)	.18 (.16, .21)	.90 (.82, 1.00)
PCP	11610 (49)	1460 (49)	30 (15, 30)	45 (14, 166)	Ref.	Ref.
Pain	3341 (14)	276 (9)	30 (30, 30)	114 (30, 264)	.29 (.23, .36)	1.04 (.92, 1.17)
Other	1717 (7)	876 (30)	5 (3, 15)	5 (3, 8)	.15 (.12, .18)	1.03 (.92, 1.17)
Missing	2623 (11)	702 (24)	28 (9, 30)	13 (5, 46)		

12087 Poster Session

Retrospective analysis of peripheral neuropathy in blood cancer survivors evaluated for cellular therapy.

Elizabeth S Hile, Chao Xu, Desirae R Feierabend, Abby Cha, Rachel Neuhold, Abby McIntire, Phuong Phi, Ryan David Nipp, Adam Steven Asch, George Basil Selby; The University of Oklahoma Health Sciences Center, Stephenson Cancer Center, Oklahoma City, OK; University of Oklahoma Health Sciences Center, Oklahoma City, OK; OU Health Stephenson Cancer Center, Oklahoma City, OK; University of Oklahoma Health Sciences Center Stephenson Cancer Center, Oklahoma City, OK; Oklahoma State University, Stillwater, OK; Department of Hematology & Oncology, College of Medicine, University of Oklahoma Health Sciences Center, Oklahoma City, OK; Stephenson Cancer Center, Oklahoma City, OK

Background: Blood cancer survivors (BCS) sustain peripheral neuromotor decline from toxic therapies but also aging, diabetes and cancer. Peripheral neuropathy (PN) threatens balance and quality of life, and pre-existing nerve deficits raise future PN risk. The evaluation for cellular therapies is an opportunity to identify functional deficits and optimize their management before additional toxic exposures or disease progression. PN is often diagnosed by paresthesias, but toe strength and sensory deficits also impact balance. We aim to quantify the prevalence of these 3 PN manifestations and walking difficulty in BCS evaluated at our center for possible cellular therapies and compare BCS with and without paresthesias. **Methods:** We retrospectively analyzed clinical data from 5 years of physical therapy (PT) evaluations during the medical assessment for cellular therapy. As count (%) or mean ± SD we described foot paresthesias [Functional Assessment of Cancer Therapy (FACT) Item NTX2], hallux extension weakness (Medical Research Council Grade ≤4 either side), hallux vibration deficit (biothesiometer ≥24.7 V), and reported trouble walking (FACT An6). We then dichotomized the cohort by NTX2 and compared groups with Chi-square, Fisher's exact or Wilcoxon rank sum tests. **Results:** 598 (87.6%) of 683 BCS evaluated by PT had FACT data (79.1% White, 5.5% Latinos); 1 in 2 BCS reported paresthesias, 71.2% as moderate-severe. See table for group comparisons. Race (p=.654) & ethnicity (p=.608) were n.s. 506 BCS with FACT (84.6%) had both strength and sensory data; we found ≥ 1 hallux deficit in 396 (78.3%), more commonly with paresthesias (86.3% vs. 69.5%, p<.001). **Conclusions:** At cellular therapy evaluation, 1 in 2 BCS reported foot paresthesias, and 3 in 4 had strength or sensory hallux deficit. Regardless of the cause, these deficits could contribute to the trouble walking reported by 44%. BCS with paresthesias were older and had more myeloma, diabetes, chemotherapy, hallux deficits, and trouble walking. But trouble walking and hallux deficits were also common without paresthesias. Research is needed to quantify hallux-gait relationships in BCS, and to establish the highest-value rehabilitative approaches to improve strength and walking before further toxic exposures. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; P30CA225520.

Characteristic n(%) or mean ± SD	BCS with FACT n=598 (100%)	No Foot Paresthesias n=293 (49.0%)	Foot Paresthesias n=305 (51.0%)	Group Comparison p-value (sig <.05)
Age (yrs)	57±13	55±15	60±12	<.001
BMI (kg/m^2)	30±12	31±15	30±8.1	.664
Female	234 (39.1)	114 (38.9)	120 (39.3)	>.999
Multiple Myeloma	219 (36.6)	78 (26.6)	141 (46.2)	<.001
Diabetes	130 (21.7)	48 (16.4)	82 (26.9)	.016
Prior Chemotherapy	563 (94.1)	268 (91.5)	295 (96.7)	.034
Trouble Walking	264 (44.1)	91 (31.1)	173 (56.7)	<.001
Hallux Weakness n=558	335 (56.0) 60.0%	139 (47.4) 50.9%	196 (64.3) 68.8%	<.001
Hallux Sensory Deficit n=445	200 (33.4) 44.9%	76 (25.9) 34.5%	124 (40.7) 55.1%	<.001

12089 Poster Session

A meta-analysis GWAS of taxane-induced peripheral neuropathy in patients with breast cancer.

Yuanchu James Yang, Kerry Roe Schaffer, Guanglong Jiang, Tam C Tran, Peter J Sauer, Chenjie Zeng, Bryan P. Schneider, Ben Ho Park, Joshua C Denny; Vanderbilt University School of Medicine, Nashville, TN; Indiana University, Indianapolis, IN; National Human Genome Research Institute, Bethesda, MD; Indiana University Melvin and Bren Simon Comprehensive Cancer Center, Indianapolis, IN; Vanderbilt-Ingram Cancer Center, Nashville, TN

Background: Taxane-induced peripheral neuropathy (TIPN) is a common dose-limiting toxicity in the medical management of breast cancer patients. Despite the clinical efficacy of taxane treatment, there is significant heterogeneity in the development of neuropathy and its severity, and no clear genetic etiologies have yet been identified. We sought to discover genetic risk variants in two large electronic health record linked DNA biobanks. **Methods:** A meta-analysis genome wide association study (GWAS) was performed with participants in the *All of Us* Research Program and BioVU biobanks. All participants of the study population were of female sex at birth and had a breast cancer diagnosis. Cases were defined as taxane-exposed participants who received their first neuropathy diagnosis code within one year after first taxane exposure. Controls were defined as taxane-exposed participants without a neuropathy diagnosis code and without gabapentin initiation after taxane exposure. GWAS was performed with PLINK version 2.0 using age at taxane initiation, number of taxane cycles received, and the first 10 principal components as covariates. Expression quantitative trait loci (eQTL) analysis was performed with the GTEx 8.0 and EyeGEx databases. **Results:** The *All of Us* cohort had 196 cases and 254 controls. The BioVU cohort had 244 cases and 528 controls. In our meta-analysis GWAS, rs3065465 (chr11:69138693; closest gene by distance is *LOC338694*)was associated with TIPN (OR=2.14, P= 8.27E-09) and was similar across different genetic ancestries (Table). The eQTL analysis of rs3065465 shows significant association with mRNA expression of *TPCN2*(P= 6.44E-06), a cation channel involved in neuronal differentiation and intracellular calcium homeostasis. **Conclusions:** rs3065465represents a potential novel genetic marker for TIPN risk in breast cancer patients. Research Sponsor: National Cancer Institute; 5U54CA163072.

Associations of rs3065465 with TIPN by genetic ancestry groups in the meta-analyses. OR=Odds Ratio.

Genetic Ancestry	Effect Allele Frequency	*All of Us* OR (P)	BioVU OR (P)	Meta-analysis OR (P)
All (n=1222)	0.808	2.57 (1.08E-05)	1.91 (1.05E-04)	2.14 (8.27E-09)
European Predominant (n=954)	0.841	3.10. (6.37E-05)	1.92 (6.09E-04)	2.23 (3.82E-07)
African Predominant (n=142)	0.636	3.98 (0.0751)	2.34 (0.0381)	2.63 (0.00761)
Admixed Americans (n=98)	0.806	2.12 (0.172)	N/A	N/A

Novel screening approach for cancer cachexia using metagenomic gut microbiome profiling in patients with advanced non-small cell lung cancer.

Taiki Hakozaki, Eder Mendez Salazar, Takayuki Kobayashi, Shota Fukuoka, Shohei Koyama, Hiroyoshi Nishikawa, Daisuke Motooka, Shota Nakamura, Yusuke Okuma, Yukio Hosomi, Haruko Takeyama, Masahito Hosokawa, Bertrand Routy; Centre De Recherche Du Centre Hospitalier De L'université De Montréal (CRCHUM), Montréal, QC, Canada; Tokyo Metropolitan Cancer and Infectious Diseases Center, Komagome Hospital, Tokyo, Japan; Cancer Institute Hospital, Japanese Foundation for Cancer Research, Tokyo, Japan; Exploratory Oncology Research & Clinical Trial Center, National Cancer Center, Chiba, Japan; Research Institute for Microbial Diseases, Osaka University, Osaka, Japan; Department of Thoracic Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Thoracic Oncology and Respiratory Medicine, Tokyo Metropolitan Cancer and Infectious Diseases Center, Komagome Hospital, Tokyo, Japan; Faculty of Science and Engineering, Waseda University, Tokyo, Japan

Background: Cancer cachexia (CC) is a multifactorial syndrome involving immune-metabolic crosstalk across multiple organs and has been associated with a negative clinical impact in patients with non-small cell lung cancer (NSCLC) amenable to immune checkpoint inhibitors (ICIs). In parallel, the gut microbiome (GM) has emerged as a key contributor to ICI response. In this study, we aimed to evaluate the association between CC and GM composition and its metabolic potentials. **Methods:** We collected fecal samples from 139 patients with advanced NSCLC treated with ICI. In addition to 16S rRNA sequencing for all patients, shotgun metagenomic microbiome profiling was performed for 69 patients to estimate the species-level composition and functional capacity of the GM. Cancer cachexia was diagnosed according to the international consensus based on the body weight changes over the previous six months. Survival time was calculated using the Kaplan-Meier method. GM diversity indices, differential abundance, and functional profiles based on the MetaCyc database were compared between the patients with and without CC. **Results:** Median progression-free survival (PFS) and overall survival (OS) were significantly shorter in the cachexia group compared to the non-cachexia group [4.5 vs. 11.5 months ($p < 0.001$) and 10.8 vs. 44.9 months ($p < 0.01$), respectively]. Both GM profiling techniques revealed a significant difference in beta diversity between both groups ($p < 0.01$). In addition, metagenomic analyses revealed the distinct characteristics of GM at the species level between the groups. The CC group showed an overrepresentation of the commensal bacteria, such as *Escherichia coli, Ruthenibacterium lactatiformans, Hungatella hathewayi*,and *Eggerthella lenta*, whereas the non-CC group showed an enrichment of *Parabacteroides distasonis*, *Eubacterium rectale*,and *Roseburia inulinivorans*. Moreover, functional analysis revealed the significantly different metabolic potentials of GM in the CC group. The CC group showed an enrichment of pathways, such as D-arabinose degradation II, L-lysine degradation, and octan oxidation. Finally, the clustering of patients based on significant metabolic pathways or gene reactions provided a high predictive ability to discriminate between patients with and without CC. **Conclusions:** The shotgun metagenomic approach allowed for the characterization of the altered gut microbes and their metabolic potentials in patients with CC. Stratification based on the GM profiles may be useful as a novel screening method for CC, which is progressive and may involve more multistage pathology than identified by the conventional approach. Research Sponsor: The Japanese Respiratory Society.

12091 Poster Session

Sleep apnea and glymphatic dysfunction as a mediator of executive dysfunction and neurodegenerative risk in cancer related cognitive impairment (CRCI).

Sophie Kushman, Alique Gabrielle Topalian, Rhonna Shatz; University of Cincinnati, Cincinnati, OH; University of Cincinnati/University of Cincinnati Medical Center, Cincinnati, OH; University of Cincinnati College of Medicine, Cincinnati, OH

Background: Cancer survivors often experience cognitive changes, formally known as Cancer-Related Cognitive Impairment (CRCI), during or after treatment. CRCI commonly consists of executive dysfunction, which includes impairments in short-term memory, sustained attention/inhibitory control, cognitive flexibility, processing speed, and top-down processing. CRCI may be impacted by comorbidities and can increase neurodegenerative disease risk. Sleep disorders and disruptions (SDs) impair executive function in the general population. SDs may contribute to CRCI by impeding progression to deep sleep stages associated with enhanced glymphatic flow (GF) and clearance of inflammatory byproducts, leading to ventriculomegaly (VM- enlarged ventricles). VM is associated with cognitive impairment in other disorders, such as normal pressure hydrocephalus. Using data from the University of Cincinnati Cancer Cognitive Registry, we investigated relationships between the incidence and type of SD in CRCI, SDs and executive dysfunction, and evidence of altered GF in SD as measured by Evans Indices (EIs). SDs are known to be prevalent in CRCI patients. We hypothesize that evidence of impaired GF as measured by EIs will be present and associated with SDs and executive dysfunction. Identifying modifiable contributors to CRCI and their mechanisms of action are critical steps towards increasing quality of life in survivors. **Methods:** 174 patients referred for CRCI between 10/2021-10/2023 underwent assessments for CRCI and sleep hygiene with a cognitive battery, subjective questionnaires, and nocturnal polysomnography. Retrospective data gathered from Epic was entered into a REDCap registry. MRIs were analyzed in McKesson to calculate EIs. **Results:** Our data demonstrated the presence of SDs in 84% of patients and obstructive sleep apnea in 45%. Measures of apnea severity (apnea-hypopnea index-AHI) and GF (EIs) inversely correlated with executive function scores. This implicates sleep-related GF as a potential mediator of CRCI. **Conclusions:** CRCI and accompanying increased neurodegenerative risk may be the result of restricted cerebral spinal fluid exchange due to SDs in conjunction with systemic inflammation from cancer and its treatment. Sleep assessments should be routine in CRCI evaluations. Longitudinal assessments will help determine the relationship of SDs and their treatment to the course of CRCI and risk of neurodegenerative disease. Research Sponsor: None.

Novel genome-wide significant germline genetic variants associated with venous thrombo-embolism (VTE) and arterial embolism (ATE) risk in patients with *ALK* and *ROS1* fusion non-small cell lung cancer (NSCLC).

Sam Khan, Beatriz Jimenez, Katrina Hueniken, Tianzhichao Hou, Devalben Patel, Tracy Stockley, Ming-Sound Tsao, Alona Zer, Mor Moskovitz, Yehuda Rosenberg, Penelope Ann Bradbury, Lawson Eng, Natasha B. Leighl, Adrian G. Sacher, Geoffrey Liu, Frances A. Shepherd; Department of Medical Oncology and Hematology, University Health Network, Princess Margaret Cancer Centre, Toronto, ON, Canada; Rambam Health, Haifa, Israel; Rabin Medical Center Davidoff Cancer Centre, Beilinson Campus, Petah Tikva, Israel; Princess Margaret Cancer Centre, Toronto, ON, Canada

Background: In a recent meta-analysis, non small cell lung cancers (NSCLC) with *ALK* or *ROS1* fusions had higher rates of VTE compared to *KRAS* or *EGFR* mutant NSCLC, and were associated with increased ATE risk, particularly around diagnosis. The underlying mechanisms of how these somatic fusions affect thrombosis remain unclear. We examined clinico-demographic and germline genetic factors associated with VTE and ATE in NSCLC patients with *ALK/ROS1* fusions in this first comprehensive genome wide association analysis (GWAS). **Methods:** In this prospective cohort, germline DNA from whole blood was obtained from 150 patients with *ALK* fusions and 32 with *ROS1* fusions at Princess Margaret Cancer Centre (recruited 2014- 2023). Clinico-demographic, treatment and outcome data were collected from electronic medical charts. Overall survival (OS) by VTE or ATE status was assessed via Cox regression, treating ATE and VTE as time-varying covariates. Genotyping utilized the Infinium Global Screening Array (v3.0 Illumina); quality-control removed 3 patients from final analysis. Using linear regression, outcomes were weighted; no VTE/ATE events (0), one VTE/ATE event (1), or multiple ATE/VTEs (>2). Global significance was set at $p < 5 \times 10^{-8}$ and adjusted for age, sex, body mass index (BMI), and ethnic/population stratification (top 3 principal components). **Results:** There were 97 females (54%) and 82 males (46%), mean age was 57.4 years, 70% had stage 4 disease, 96% adenocarcinoma; 35% experienced VTE/ATE at any time; 13% had 2+ VTE/ATE events. For those with VTE, 32 scored 1, 22 scored 2 and 6 scored 3 on Khorana score. Higher BMI was a significant risk factor for VTE/ATE (adjusted odds ratio 1.59 per 5-unit increase, p=0.01). Shorter OS was observed in patients with VTE (Hazard ratio (HR)=3.15, p<0.001) and ATE (HR=2.51, p=0.036), compared to those without. Two novel GWAS gene peaks on the Manhattan plot (previously not reported to be associated with VTE/ATE) had globally significant associations with risk of VTE/ATE: at Chromosome 6q15 (intergenic region between *RNGTT* and LOC101928936; 5/10 top variants with top risk-allele p=3.594E-09) and at 15p22 (*TLN2* gene; 2/10 top variants p=1.095E-08). *TLN2* is a cytoskeletal protein involved in the assembly of actin filaments and linkages with extracellular matrices. Additional identified variants potentially associated with VTE/ATE in *ALK/ROS1* fusion patients were found in: *CTBP2*, *NALCN*, *WDR7*, *PAX7*, *ZNF385D*, *SORBS2*, and *CSMD1*. **Conclusions:** Two novel globally significant variants, associated with VTE/ATE, are unique to patients with *ALK/ROS1* fusion NSCLC. If validated, these biomarkers may help identify *ALK/ROS1* patients who are at highest risk of VTE/ATE who may benefit from prophylactic anticoagulation. Further investigation and clinical evaluation are warranted. Research Sponsor: Princess Margaret Cancer Foundation; Princess Margaret Cancer Foundation; Princess Margaret Cancer Foundation; OSI Pharmaceuticals Chair.

12093 Poster Session

Trichology to predict efficacy of scalp cooling: New pathologic insights besides encouraging clinical results.

Dorthe Schaffrin-Nabe, Anke Josten-Nabe, Andrea Tannapfel, Adrian Heinze, Merle Schaffrin, Rudolf Voigtmann; Praxis für Hämatologie und Onkologie, Bochum, Germany; Institute of Pathology, Ruhr-University, Bochum, Germany; Noack Statistik GmbH, Bonn, Germany

Background: Chemotherapy continues to be an essential element of tumour-specific systemic therapy. The associated hair loss impacts patients 'quality of life in addition. Sensor-controlled scalp cooling has proven itself as a method of preventing alopecia. This study evaluates the grade of hair preservation as well as predictive factors, including (ultra)structural changes of the hair follicle during treatment, offering potential for enhanced therapeutic strategies. **Methods:** Scalp cooling, was evaluated in 81 patients (79 women, 2 men, median age 56 years) undergoing breast carcinoma treatment (4x EC 90/600 mg/m² BSA followed by 12x PAC w). Key outcomes included hair preservation (Hair Mass Index = HMI), avoidance of visible hair loss (HMI $\geq$ 50), and prevention of severe hair loss (all measured by Cross Section Trichometer). Parameters such as hair density (HMI), trichologic parameters like hair shaft and bulb diameter, anagen rate, shaft surface damage and melanosomes changes were measured through (ultrastructural) microscopy. **Results:** Over the half (53%) of patients avoided successfully noticeable hair loss (HMI post $\geq$ 50). Most important predictors of successful hair preservation in different analyses included lower post-therapeutic shaft surface damage (via scanning electron microscopy) (β = -.30, p = .034), larger pre-treatment shaft diameter (via light microscopy) (OR = 1.11, p = .011), and stable melanosome density (via transmission electron microscopy) (β = .35, p = .013). Higher anagen ratio (β = .30, p = 0.009) and larger hair shaft diameter (β = .29, p=0,023) plays a crucial role in hair prevention, considering only light-microspcopic parameters. Comorbidity (OR = 0.12, p = .024) and alopecia causing medication (e.g. antihypertensiva) (β = -.31, p = .017) led to increased hair loss. Patients with fewer hair loss over the course reported higher quality of life (r = .25, p = .042) and lower psychological burden (r = -.42, p $<$ .001). Data indicate that optimal pre-therapeutic hair density (HMI =/$>$ 69), coupled with the absence of comorbidities and alopecia-inducing medications, substantially enhances the efficacy of scalp cooling, elevating the probability of preventing severe hair loss (HMI $\geq$ 50) by nearly sevenfold (OR = 6.98, CI95% [1.01;48.33]. **Conclusions:** Scalp cooling proves effective in preventing visible hair loss in 53% of patients, with mini-organ (hair follicle) characteristics influencing outcomes. It does not only prevent hair loss but also enhances quality of life, underscoring the need for personalized approaches in managing chemotherapy-induced alopecia. The study confirms the method's safety and effectiveness without increasing scalp metastasis risk. Research Sponsor: None.

12094 Poster Session

Cognitive symptoms in patients with cancer receiving PD-1/PD-L1 checkpoint inhibitors: Insights from a cross-sectional pilot study.

GeeSu Yang, Upendra P. Hegde; University of Connecticut, Storrs, CT; University of Connecticut Health Center, Farmington, CT

Background: Cancer-related cognitive impairment is common with traditional therapeutic modalities, affecting memory, psychomotor speed, attention, and executive function of up to 75% of adults with cancer. Over the past decade, immune checkpoint inhibitors (ICIs) have emerged as novel and efficacious treatments due to their ability to penetrate the blood-brain barrier and improve survival rates. However, they come with significant short- and long-term complications, including neurological toxicities. Despite their benefits, the impact of ICIs on cognitive function is not well understood. This study aims to examine the frequency and severity of cognitive impairment and the factors correlated among adults with cancer receiving ICIs. **Methods:** We collected questionnaire data on cognitive function using the Functional Assessment of Cancer Therapy-Cognitive Function (FACT-Cog) and other concurrent symptoms, as well as saliva samples of a subset of inflammatory cytokines from patients treated with PD-1/PD-L1 checkpoint inhibitors between 2022 and 2023. Sample characteristics were described using mean, frequency, and percentage. To analyze the relationship among symptoms and demographics, we used Pearson's correlation and the Mann-Whitney U test. Saliva cytokines were analyzed using ELISA assays. This study is IRB approved. **Results:** Twenty-three patients (male: n=11, female: n=12) have received ICIs for an average of eight months, with a mean age of 70.87±11.63 years. 78.3% had melanoma/skin cancer, 8.7% had head and neck cancer, and 13% had other malignancies. Pembrolizumab was administered to 47.8%, and Nivolumab to 26.1%. The mean scores of FACT-Cog for perceived cognitive impairment (PCI) and perceived cognitive abilities (PCA) were 60.87±13.06 (maximum: 72) and 22.30±6.70 (maximum: 28), respectively. 26.1% of participants (n=6) reported lower scores than the cut-off in both PCI (cut-off: ≤55.1) and PCA (cut-off: ≤19.5). Lower FACT-Cog PCI scores were significantly correlated with older age (r=-.511, p<.05), greater fatigue (r=-.483, p<.05) and pain (r=-.558, p<.01). Participants with PCA and PCI scores below the cut-off showed higher mean concentrations of IL-1β (mean±SE: 188.22±133.72 vs. 80.99±14.73pg/mL), CRP (6659.47±3027.58 vs. 3910.71±1022.41pg/mL), and IL-6 (109.24±56.07 vs. 30.22±6.26pg/mL) compared to those with scores above the cut-off, although the results were not significant. This suggests that increased inflammatory cytokines may be associated with cognitive impairment. **Conclusions:** This preliminary study suggests that some patients may experience cognitive impairment during ICI treatment. As cancer patients are more at risk for cognitive impairment before treatment, a longitudinal study is warranted to confirm cognitive function both pre- and post-immunotherapy, along with objective measures of cognitive performance. Research Sponsor: The Rockefeller University Heilbrunn Family Center for Research Nursing; American Society for Pain Management Nursing; Global Korean Nursing Foundation; Oncology Nursing Foundation.

12095 Poster Session

Association of lung cancer-associated cachexia with the metastatic spread to pleura.

Bartosz Sekula, Pawel Szymanski, Magda Konkel, Alicja Zielińska, Gioia Altobelli, Mikołaj Szewczykowski, Edmund Naczk, Magdalena Dróżka, Witold Rzyman, Rafal Dziadziuszko, Marcin Tomasz Skrzypski; The Medical University of Gdańsk, Department of Oncology and Radiotherapy, Gdansk, Poland; Clinic of Oncology and Radiotherapy at University Gdansk, Gdansk, Poland; The Medical University of Gdańsk, Department of Pneumonology and Allergology, Gdansk, Poland; The Medical University of Gdańsk, Department of Thoracic Surgery, Gdańsk, Poland; Medical University of Gdansk, Gdansk, Poland; Department of Oncology and Radiotherapy, Medical University of Gdansk, Gdansk, Pomorskie, Poland

Background: Cancer-associated cachexia (CAC), a major contributor to mortality in patients with non-small cell lung cancer (NSCLC), is characterized by alterations in body composition. Here, we explore the associations between body composition changes and the pattern of lung cancer metastatic spread. **Methods:** Computer tomography (CT) images from cancer diagnosis and recurrence were used to quantify subcutaneous and visceral adipose tissue (SAT, VAT) and skeletal muscle (SKM) tissue areas at the 3rd lumbar vertebrae level, using an DAFS AI-based software, Voronoi Analytics, in 101 NSCLC pts, who relapsed after surgical treatment of the primary tumor at the Medical University of Gdansk Hospital. The decrease in SKM, SAT and VAT of more than 5% or 10% at cancer relapse was compared with the pattern of cancer recurrence. **Results:** The median time to recurrence after primary tumor resection was 1.6 years (0.4–6.4 years). There were 38% local or regional recurrences, 59% distant recurrences, and 13% second primary lung cancers. Among the cases with distant recurrence, there were 19% brain recurrences, 22% pleural metastases, 34% lung metastases, 17% bone metastases, and 11% cases of liver relapse. More than one site of distant recurrence occurred in 51 (50%) of patients. Loss of $>$ 5% of SKM, SAT and VAT occurred in 61%, 33% and 41% respectively. Loss of $>$5% or $>$10% of SKM was associated with the pleural metastases at the time of cancer recurrence, ($P < 0.001$). Median muscle loss was −11.6% for patients with pleural relapse and −5.3 % for patients with other metastatic locations ($P < 0.001$). There were no significant associations between other body composition changes and the pattern of recurrences, tumor histology or age. **Conclusions:** NSCLC relapse to the pleura after surgical treatment of the primary tumor, appears to be associated with a decrease in the skeletal muscle compartment. This finding may inform the design of the future studies aiming to investigate molecular correlates of sarcopenia and cancer-associated cachexia. Research Sponsor: Medical University of Gdansk intramural founds.

12096 Poster Session

Mental healthcare utilization and psychosocial outcomes among patients with recently diagnosed cancer: A National Health Interview Survey report.

Tamar Parmet, Timothy S. Sannes, Kristin Kilbourn; University of Colorado Denver Anschutz Medical Center, Aurora, CO; UMass Memorial Cancer Center, Worchester, MA; University of Colorado Denver, Denver, CO

Background: Individual's diagnosed with cancer (IWC) often experience heightened psychosocial distress. Studies suggest 25-50% of IWC experience some form of psychosocial distress (Mehnert-Theuerkauf et al., 2023). Further, research shows that an individual's risk of developing a new mental disorder increases by 30% during the first year after being diagnosed with cancer (Hu et al., 2023). Although many IWC experience distress, literature depicts the underutilization of psychosocial services, with estimates suggesting that fewer then 10% of IWC receive support for their distress (Forsyth et al., 2013). This is concerning as research in rodents and humans shows that unaddressed distress can lead to faster growing tumors and rapidly advancing disease (Eckerling et al., 2021). The present study aimed to characterize mental healthcare utilization among Americans recently diagnosed with various types of cancer. We also aimed to illustrate prevalence of anxiety and depression in this population. **Methods:** Data from the 2022 National Health Interview Survey was used in this report. A total of 667 recently diagnosed IWC were included in the final analytic sample. Cancer type was divided into five subcategories: blood cancers (n=76), breast cancer (n=193), gynecologic cancer (n=87), colorectal cancer (n=72), lung cancer (n=62), and prostate cancer (n=177). Participants' mental healthcare utilization at the time of the survey and within the last 12 months was assessed. The General Anxiety Disorder-7 (GAD-7) was used to measure participants' anxiety levels and the Personal Health Questionnaire Depression Scale (PHQ-8) was used to assess depressive symptoms. **Results:** Over 28% of recently diagnosed IWC reported moderate-severe levels of anxiety on the GAD7, and 43% of participants reported high levels depression on the PHQ8. One-way ANOVA demonstrated significant differences in PHQ8 ($F(5, 666)=3.332$, $p=0.006$) and GAD7 ($F(5,666)=3.35$, $p=0.005$) scores across cancer groups. Post Hoc testing found that participants coping with colorectal cancers reported the highest levels of anxiety and depression compared to other cancer types. Of newly diagnosed patients, only 1.2% of patients reported currently receiving psychosocial support from a mental health professional, and only 13.6% reported receiving therapy from a mental health professional in the last year. **Conclusions:** Consistent with many studies, psychosocial distress among recently diagnosed IWC was very common, yet mental health care utilization remained low. These results indicate that efforts to target newly diagnosed IWC with psychosocial support interventions remains challenged. As such, our results underscore the importance of developing novel means of reaching IWC, and particularly colorectal cancer, as these individuals continue to struggle with significant levels of psychosocial distress. Research Sponsor: None.

12097 Poster Session

Exploring lived experiences in oral cavity cancer: An Asia-Pacific perspective on psychosocial challenges and opportunities for enhanced patient-centric care.

Hye Ryun Kim, Puma Sundaresan, Tracey E Nicholls, Hai-Ling Teng, Con Stylianou, Khoi Tuan Nguyen, Edwin Pun Hui, Yu-Chung Li, Jennifer Si, Ying Jie Yew, Regina Gowindah, Pei-Jen Lou; Division of Medical Oncology, Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, Korea, Republic of (South); Head and Neck Cancer Australia, Sydney, Australia; Flinders Medical Centre Otolaryngology Head & Neck Surgery, Adelaide, Australia; The Association of Head and Neck Cancer Care, Taipei, Taiwan; MSD (Australia) Pty Ltd, Sydney, Australia; The HCM Oncology Hospital, Medical Oncology Department, Ho Chi Minh, Viet Nam; Department of Clinical Oncology, State Key Laboratory of Translational Oncology, Sir YK Pao Center for Cancer, The Chinese University of Hong Kong, Shatin, Hong Kong; Hong Kong United Oncology Centre, Hong Kong, Hong Kong; Oracle Life Sciences, Singapore, Singapore; Department of Otolaryngology, National Taiwan University Hospital and National Taiwan University and College of Medicine, Taipei, Taiwan

Background: Locally advanced oral cavity squamous cell carcinoma (LA OC SCC) is profoundly emotionally taxing, characterized by a dual burden of undergoing treatment and adapting to post-treatment changes. The research explores lived experiences including psychosocial aspects, to identify approaches to establish a resilient supportive system for patients to improve coping and reduce anxiety and distress. **Methods:** A total of115in-depth interviews were conducted across Australia, Hong Kong, South Korea, Taiwan and Vietnam. Informants were LA OC SCC patients who underwent surgery and adjuvant chemoradiotherapy, their caregivers, multidisciplinary team (surgeons and clinical, radiation and medical oncologists) and supportive care HCPs (nursing, case managers/care coordinators, psychologists, speech therapists, dietitians, and dentists). Interview guide design and thematic analysis were guided by the Psycho-Onco Emotional Anxiety (POEM) framework and the Capability, Opportunity, Motivation, Behaviour (COM-B) model. **Results:** The POEM framework illuminated patients' lived cancer experiences, emotions and psychological thoughts and processes influenced by beliefs of the world, others and self which impact coping responses that maintain or drive anxiety. Key themes emerged: physical and functional impairments result in negative psychosocial impact; constraints hinder person-centered care communications with HCPs and interpersonal dynamics with significant others; and personal and interpersonal experiences result in negative coping, exacerbated by inadequate health services and social support. Multimodal therapeutic interventions for LA OC SCC lead to physical and functional impairments implicating psychosocial and psychosexual quality of life. LA OC SCC stigma, societal norms and highly socially constrained patients grapple with distress from inadequate psychosocial support. Furthermore, HCPs may have preconceptions of LA OC SCC patients hindering patient-centered approaches to care and management. In certain regions, insufficient hospital support systems exacerbate the toll of strained interpersonal relationships and caregiver burden on physical, psychological and emotional well-being. Consequently, treatment adherence, self-care and survivorship experiences of patients and caregivers are affected. **Conclusions:** Utilizing the POEM framework, the study delved into nuanced patient and caregiver-narrated experiences in 5 Asia-Pacific countries/territories with distinctive supportive care systems. Findings underscore the imperative of improving patient-centric care through enhanced psychosocial support for patients and caregivers, identifying specific areas where health services can be better equipped to support holistic patient health delivery, especially psychosocial health. Research Sponsor: MSD International GmbH (Singapore Branch).

Psychological adjustment and perception of patients' relatives and healthcare providers regarding continuous deep sedation until death: A mixed-methods study.

Leonor Fasse, Marie Locatelli, Ines Maria Vaz Duarte Luis, Jean Bernard Le-Provost, Florian Scotte, Ingrid Joffin, Adrien Evin, Cécile Flahault; Paris Cité University, Paris, France; Cancer Survivorship Program, INSERM 981, Gustave Roussy, Villejuif, France; Gustave Roussy, Département d'Organisation du Parcours Patient, Villejuif, France; Gustave Roussy Cancer Campus, Interdisciplinary Cancer Pathway Department, Villejuif, France; Diaconesses Hospital, Paris, France; CHU de Nantes, Nantes, France

Background: France is currently in the midst of societal discussions concerning new legislation on active assistance in dying. Continuous Deep Sedation Until Death (CDSUD) is considered by some a "French exception" since 2016, but 8 years later, findings suggest that this procedure is not really clear to all, including patients, their relatives and their healthcare providers (HCP). The primary objective of this original research is to document the psychological adjustment of patients' relatives and HCPs in the cancer context. **Methods:** APSY-SED (ID-RCB 2021-A03042-39) is a multicentric prospective, longitudinal and observational study, using a mixed-methods design. A lexicometric analysis of the semi-structured interviews was performed using Iramuteq software. A questionnaire survey was conducted, encompassing for relatives: anxiety and depressive symptoms (STAI-S, BDI-II); for HCPs: Professional Stress and Professional experience (Karasek questionnaire). We present here the main results at T1 (when CDSUD is implemented). **Results:** Main quantitative results are presented in Table I. Regarding qualitative findings, fifteen research interviews with relatives and 15 interviews with HCP were analyzed. Most frequent words associated with CDSUD were its "objectives", its specific "temporality", the mention of "euthanasia", and "saying goodbye". Confusion between CDSUD and euthanasia persists in relatives and HCPs. **Conclusions:** On average, relatives reported severe anxiety in the context of CDSUD. The qualitative findings regarding the main concerns shared by the relatives concerning the CDSUD temporality perceived as brutal, shed light on this anxiety. The second assessment time of this study, 6 months after death, including measures of depression, anxiety, intensity of grief reactions, will allow to specify the adjustement at mid-term. This is the first empirical study carried out in France on the adjustment of relatives and HCPs caring for patients with cancer for whom CDSUD is discussed. Research Sponsor: the French National Cancer Institute (InCa).

Characteristics of relatives and HCPs at T1.

Relatives (n=37)	**Age (years)**	**50.48 (16.4)**	
	Men, n (%)	19 (51.3)	**Standardized cutoff**
	Mean STAI state score (SD)	50.3 (2.9)	For male: >50= severe anxiety For female: >51= severe anxiety
	Mean BDI score (SD)	13.3 (7.9)	0-13=minimal depression 14-19= mild depression
Healthcare Professionals (n=30)	Age (years)	38.5 (11.6)	
	Women, n (%)	21 (70)	
	Nurses, n (%)	18 (60)	
	Doctors, n (%)	8 (26.6)	
	Auxiliary nurses (%)	7 (23.3)	
	Average length of work with patients with cancer (years)	7.81 (2.4)	
	Karasek Questionnaire:		
	Mean Job latitude score (SD)	75.4 (8.2)	
	Mean Job demand score (SD)	24.03 (3.5)	
	Mean Social support score (SD)	25.7 (3.2)	
	Job strain threshold= demand score > 20 and latitude score < 71, n (%)	7 (23.3)	

12099 Poster Session

Decades old communication training influences seen in patient-centric communication skills of transplant hematologists.

Justine Hung, Rachel Rodenbach, Toby Christopher Campbell; University of Wisconsin Hospital and Clinics, Madison, WI; University of Wisconsin, Madison, WI; University of Wisconsin Carbone Cancer Center, Madison, WI

Background: Competency in communication skills was added as a requirement for residencies in 1999. Numerous strategies have since been incorporated into all phases of medical education and beyond. "Ask-tell-ask" and "NURSE" are commonly taught strategies used to guide conversations between physicians and patients. "Ask-tell-ask" provides a structure for assessing and delivering medical knowledge to a patient. "NURSE" outlines methods for incorporating empathy into the medical provider's statements. We evaluated for the presence of these communication strategies in a high-stakes discussion between a transplant hematologist and a simulated patient facing a new diagnosis of high-risk myelodysplastic syndrome (MDS). **Methods:** This is a sub-analysis from a mixed-methods, observational study. Our team recruited hematologists who routinely perform hematopoietic cell transplants and designed a patient scenario of a 67-year-old man with recently diagnosed high-risk MDS referred to hematology. Video-recorded virtual encounters simulated an initial hematology consultation appointment between the hematologist and an actor trained to portray the patient. We analyzed transcripts and coded for themes in the discussion content and structure. We evaluated for the use of known communication strategies "ask-tell-ask", and "NURSE" empathic responses. **Results:** Of 37 hematologists from 25 academic centers who participated, 73% reported receiving at least some formal communication training. Hematologists " when teaching patients about their disease and treatment options. For example, nearly all hematologists opened the encounter by asking the patient a perception question regarding their understanding of their disease; nearly all incorporated at least one "NURSE" empathic statement after telling the patient about their disease and its prognostic implications. Most explored the patient's goals for treatment and described treatment options utilizing an "ask-tell-ask" approach. Nearly all concluded the encounter with a summary and strategy for next steps. **Conclusions:** While it is commonly held that teaching communication is difficult, these conversations between hematologists and patient actors show the impact of communication training delivered over the past twenty years through the routine incorporation of well-described strategies of "ask-tell-ask" and "NURSE". This observational study provides a window into how these teachings have permeated into medical practice and hematology/oncology specifically. The incorporation of commonly taught communication strategies into these physician-patient encounters provides evidence that teaching high-quality communication may change physician behavior in a sustained and diffuse way. Research Sponsor: None.

12100 Poster Session

The adherence and response of a combined approach of online self-help cognitive behavioral therapy and phone-based psychological guidance among French patients with cancer with insomnia.

Diane Boinon, Arnaud Pages, Jonathan Journiac, Maria Alice B Franzoi, Ines Maria Vaz Duarte Luis, Cécile Charles, Louise Zanni, Leonor Fasse, Dominique Hernot, Alexandra Monod, Jean Bernard Le-Provost, Florian Scotte, Estelle Guerdoux, Guilhem Paillard-Brunet, Josée Savard, Sarah Dauchy; Department for the Organization of Patient Pathways, Gustave Roussy, Villejuif, France; INSERM, Centre for Epidemiology and Population Health, Oncostat team, CESP U1018, Villejuif, France; Université Paris Cité, Boulogne-Billancourt, France; Gustave Roussy, Villejuif, France; Cancer Survivorship Program, INSERM 981, Gustave Roussy, Villejuif, France; Bordeaux Population Health, Bordeaux, France; Paris Cité University, Paris, France; Gustave Roussy, Département d'Organisation du Parcours Patient, Villejuif, France; Gustave Roussy, Patient Pathway Division, Villejuif, France; Psycho-oncology Unit, Institut Régional du Cancer de Montpellier, Montpellier, France; Psycho-oncology Unit, Centre Léon Berard, Lyon, France; Université Laval, Québec, QC, Canada; Département médico-universitaire de psychiatrie et d'addictologie, AP-HP Centre – Université Paris Cité, Paris, France

Background: Insomnia affects 30–60% of patients with cancer. Cognitive behavioral therapy for insomnia (CBT- I) is the gold-standard treatment for insomnia. However, the uptake of CBT-I in routine care remains low. Technology can be leveraged to facilitate the access and delivery of CBT-I. Nevertheless, adherence rates to online self-help interventions seem low (50-60%), and is associated with reduced intervention efficacy. The Sleep-4-All-2.0 is a prospective multicentric single arm study that evaluated an approach that combined a validated online self-help CBT-I program (Insomnet, 6 modules) to a phone-based guidance with a psychologist (3 orientation meetings). This study assessed: 1) how this combined approach performed in terms of adherence, behavior change and insomnia remission rates compared to prior literature investigating self-help CBT-I, and 2) the patients' characteristics that are associated with a better or a poorer response. **Methods:** Data were collected with online questionnaires to compare outcomes: adherence (5 to 6 modules completed), behavior change (ad hoc questionnaire), insomnia remission (Insomnia Severity Index, ISI < 8), sleep perception (ad hoc questionnaire), response to the program (changes in ISI score) at post intervention (week 6, 12 and 24). A descriptive analysis of patient characteristics at each time point was performed. Then, multivariate analyses were conducted: mixed models with a random effect at patient level (repeated measures) and fixed effects for the other variables. The following variables at baseline were used in the adjusted models: socio-demographic and clinical variables, ISI score, symptoms (ESAS), digital skills, barriers to change, motivation, social support and the referring professional. **Results:** Among the 348 patients included: 79% were women, 59% had breast cancer and 68% were undergoing treatment. A total of 310 patients (89%) initiated Insomnet. The adherence rate was 74% and 79% have changed their behavior. Insomnia remission rates were 34%, 46% and 50% at week 6, 12 and 24, respectively. Insomnia was no longer a problem for 48%, 63% and 66% at week 6, 12 and 24, respectively. Female gender (β=-1.22; p=0.05) and unemployed patients (β=-1.77; $p<0.01$) were associated with a decrease in ISI scores. Sleep medication (β=1.58; $p<0.01$), patients with a high sleepiness score (ESAS) (β=0.25; p=0.02) and patients with less digital skills (β=1.85; $p<0.01$) were associated with an increase in ISI scores. **Conclusions:** A combination of online self-help CBT-I with phone-based guidance showed satisfactory rates of program adherence, change behavior and insomnia remission. However, some patient profiles such as the ones with lower digital skills and severe insomnia at baseline seemed to benefit less from this approach, and may require further care intensification. Clinical trial information: CONVENTION DE RECHERCHE no. 2020-1-PL SHS-03-IGR-1. Research Sponsor: Institut National du Cancer; 237 192.12 EUR.

12101 Poster Session

Disclosure of metastatic breast cancer information: Patients' understanding and patients' and oncologists' experiences.

Fernanda Mesa-Chavez, Giovanni M Carrillo, Daniela Vazquez Juarez, Alexandra Garcilazo Reyes, Maricela Garcia Garces, Janeth Esquivel-Gutierrez, Enrique Jose Zamudio Lozoya, Lucía Téllez, Katia Hinojosa, Brizio Moreno-Jaime, Omar Peña-Curiel, Rubi Janday-Najera, Ervin Saúl Enciso López, Haydee Cristina Verduzco-Aguirre, Diana Flores-Estrada, Yanin Chavarri Guerra, Benito Sanchez-Llamas, Alejandra Platas, Cynthia Villarreal-Garza; Tecnologico de Monterrey, Escuela de Medicina y Ciencias de la Salud, Monterrey, Mexico; Centro de Cáncer de Mama, Hospital Zambrano Hellion-Tecnológico de Monterrey, San Pedro Garza Garcia, NL, Mexico; Instituto Nacional de Cancerología, Mexico City, DF, Mexico; Centro Oncologico Estatal ISSEMYM, Toluca, Mexico; Centro Estatal de Cancerología Chihuahua, Chihuahua, Mexico; Hospital General de Querétaro, Querétaro, Mexico; Hospital Regional ISSSTE León, León, Mexico; Tecnologico de Monterrey, Monterrey, Mexico; UNEME-DEDICAM, Monterrey, Mexico; Hospital General ISSSTE Dr. Aquiles Calles Ramírez, Tepic, Mexico; Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran, Mexico City, Mexico; Instituto Nacional de Cancerologia, Mexico City, Mexico; Instituto Nacional de Ciencias Medicas y Nutrición Salvador Zubirán, Mexico City, Mexico; Nucleo Oncologico De Occidente SC, Guadalajara, Mexico; Médicos e Investigadores en la Lucha contra el Cáncer de Mama (MILC), Mexico City, Mexico; Breast Cancer Center, Hospital Zambrano Hellion TecSalud, Tecnologico de Monterrey, San Pedro Garza Garcia, NL, Mexico

Background: Patients with metastatic breast cancer (mBC) require knowledge on their advanced stage to fully participate in health decision making. However, both patients and oncologists face communication challenges when discussing this information. This study explored patients' knowledge on their mBC, and patients' and oncologists' experiences regarding the provision of mBC information. **Methods:** Patients at 8 cancer centers in Mexico answered an online survey 3-7 days after mBC and treatment (Tx) were disclosed. Knowledge about stage and Tx objectives, illness uncertainty (SF-MUIS), and satisfaction were assessed. Their medical oncologists also answered an online survey exploring their perceptions, experience, and distress levels (distress thermometer) when sharing mBC information. All participants signed an informed consent. The study was funded by a Pfizer grant. **Results:** 19 oncologists and 50 patients were included. Patients' median age was 52 years (31-73); most had ≤high school education (58%) and had recurrent mBC (58%). Most (74%) were aware of their mBC stage, 14% were not, and 12% were not sure. All oncologists declared having explained the non-curability of mBC. However, when asked if mBC was curable (as explained by the oncologist), only 50% of patients stated it was incurable, 40% were not sure, and 10% believed it was curable. While most considered their Tx main objective (as explained by the oncologist) was to improve lifespan and quality of life (68%); 32% believed it was to cure their mBC. Only 60% were aware their Tx had no established end date. Most (86%) were satisfied with the way their oncologist provided mBC information. Oncologists reported discussing prognosis in 96% of cases, yet only 42% of patients stated having this conversation. These patients rated having prognostic information as very useful for making Tx decisions (95%), preparing for the future (95%), and keeping hope (100%). Moderate/high levels of illness uncertainty were reported by 56% of patients. Uncertainty was associated with not discussing prognostic information (OR 7.9, 95%CI 2.2-28.1). When sharing mBC information, oncologists felt anxious and stressed in 54% and 58% of cases, respectively. In 22% of consultations, their distress thermometer score was ≥4/10, suggesting high levels of distress. Perceptions of the way mBC information was provided. **Conclusions:** Patients' perceptions of the information provided by their oncologists were generally positive. Yet, a considerable proportion were unaware of their incurable mBC stage and its Tx objectives and duration. Interventions to facilitate these conversations for both patients and oncologists are crucial to improve patients' understanding and enable their active participation in care decisions. Research Sponsor: Pfizer.

	Patients	Oncologists
Was useful	100%	96%
Was easy to understand	96%	82%
Will aid to make plans	90%	48%
Gave hope	96%	70%
Caused distress	52%	28%

12102 Poster Session

Racial and ethnic differences in patient-reported provider communication among patients with cancer.

Nishwant Swami, Tej A. Patel, Edward Christopher Christopher Dee, Bridgette Thom, Fumiko Chino; Hospital of the University of Pennsylvania, Philadelphia, PA; University of Pennsylvania, Philadelphia, PA; Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Patient-provider communication is essential for improving patient experience and understanding. Given significant care coordination in cancer treatment, effective communication is crucial to ensure timely care, optimal patient outcomes, and shared decision making. Improved patient-provider communication also provides opportunities to promote equitable cancer care. We used national survey data to assess racial/ethnic differences in perceptions of provider communication among patients with cancer. **Methods:** 2011-2021 biannual data from the US Medical Expenditure Panel Survey was used to select cancer survivors aged ≥18. Primary outcomes included how often patients reported their providers (1) treated them with respect, (2) listened carefully, (3) explained things in a way they understood, and (4) spent enough time. Survey-adjusted percentages with chi-square tests characterized differences in patient-reported communication by racial/ethnic group. Multivariable ordinal logistic regression (MVA) models adjusting for survey year, insurance status, income level, geography, sex, and age generated adjusted odds ratios (aORs) with 95% CI to examine associations of race/ethnicity and provider communication. **Results:** 5,085 patients representing 10,950,670 survivors met inclusion criteria. American Indian (AI) survivors reported the lowest rates of effective provider communication across all four domains (55%: always listened, 42%: always spent enough time, 58%: always showed respect, and 50%: always explained; $p<.001$), while non-Hispanic Black (NHB) patients reported the highest rates of effective communication in listening (72%), explaining (70%), respect (74%), and spending enough time (63%; $p<.001$). On MVA, NHB, non-Hispanic Asian (NHA), and Hispanic (HSP) patients were more likely to report feeling listened to (NHB: OR 1.54 95% CI 1.19-1.98; NHA: OR 1.87 95% CI 1.14-3.05; HSP: OR 1.39 95% CI 1.06-1.83) when compared to non-Hispanic White (NHW) patients. NHB and HSP patients reported feeling more respected (NHB: OR 1.40 95% CI 1.109-1.81; HSP: OR 1.39 95% CI 1.04-1.86) when compared to NHW patients. NHB patients were more likely to report that doctors explained well (OR: 1.31 95% CI 1.02-1.67). **Conclusions:** This national analysis finds that cancer survivors from historically (and presently) marginalized groups – including Black, Asian, and Hispanic patients - were more likely to perceive effective provider communication when compared to non-Hispanic White patients. Considering known disparities in cancer care access and outcomes, these results may reflect differing patient expectations of effective provider communication or the positive results of concerted efforts to improve provider communication to marginalized groups. Univariate analysis also revealed less effective communication for AI patients, suggesting potential unmet needs. Research Sponsor: None.

12103 Poster Session

A decision support intervention for patients with advanced lung cancer amid growing therapeutic complexity: Results of a randomized controlled trial.

Matthias Villalobos, Laura Unsoeld, Nicole Deis, Anja Siegle, Michael Thomas; Dept. of Thoracic Oncology, Thoraxklinik, Heidelberg University Hospital and National Center for Tumor Diseases (NCT), NCT Heidelberg, Translational Lung Research Center Heidelberg (TLRC-H), Member of the German Center for Lung Research (DZL), Heidelberg, Germany; Baden- Wuerttemberg Cooperative State University Stuttgart (DHBW), Stuttgart, Germany; Department of Thoracic Oncology, Thoraxklinik, Heidelberg University Hospital and National Center for Tumor Diseases (NCT), NCT Heidelberg, and Translational Lung Research Center Heidelberg (TLRC-H), Member of the German Center for Lung Research (DZL), Heidelberg, Germany

Background: In the last decade the therapeutic algorithms in lung cancer have changed dramatically because of the continuous approval of new drugs, leading to steadily improving survival. However, recent studies show that the growing complexity has also led to a negative impact on prognostic awareness and patient-physician communication. In a setting of mostly frail patients, this uncertainty jeopardizes goal-concordant care. Consequently, the guideline recommendations of patient-empowerment and shared decision-making are more important than ever, but evidence-based, comprehensively implemented tools are still lacking. **Methods:** Randomized controlled, open, mono-center trial (n=138) with two arms: A) use of a decision aid incl. clarification of personal values accompanied by a decision-coaching session vs. B) usual care; stratified block randomization according to the characteristic of preferred decision-making at baseline; primary endpoint: clarity of personal values (Value Clarity Subscale of the Decisional Conflict Scale). Secondary outcomes: patients' self-efficacy (DSES), decisional conflict (DCS), perceived preparation for and involvement in decision-making (PDMS and PICS), general health and emotional state (EQ-5D-5L and HADS). In addition to the descriptive evaluation, group comparisons between the two arms were performed (non-parametric comparison: van Elteren test). **Results:** The evaluation showed high values for decisional conflict in both groups (total mean score arm A 41,25 and arm B 38,65), exposing relevant conflict in 57,6% of patients, highest in the subscale for information (64,4%) and uncertainty (58,9%). PDMS showed that most patients considered the intervention helpful ("prepare for the next visit with your doctor": 83,8%, "prepare to talk to your doctor about what matters most to you": 81,6%, "help to know that decision depends on what matters most to you": 81,6%). The PICS-subscale "patient information" (active information-seeking behavior) showed a statistically significant difference between the two groups (arm A: 2,86 vs arm B: 3,12; p=0,048). All other outcomes showed no significant differences with equally high DCS scores in both arms' follow-up. **Conclusions:** Patients with advanced lung cancer show a strikingly high decisional conflict. Despite successfully empowering perceived preparation for decision-making and decreasing information needs in the encounter with the physician, the intervention was not strong enough to improve significantly the decisional conflict. In a setting of constantly changing oncological information and increasing prognostic uncertainty, tailored support that flexibly adapts to individual needs in decision-making is urgently needed. Clinical trial information: DRKS00028023. Research Sponsor: Bristol Myers Squibb-Stiftung Immunonkologie.

12104 Poster Session

Young lung cancer: Psychosocial needs assessment.

Narjust Florez, Lauren Kiel, Miki Horiguchi, Rebekah Kaufman, Danielle Haradon, Michelle Sanchez, Ruth Lederman, Emma Voligny, Tom Nguyen, Stephanie McDonald, Fatima Wilder, Cristina Pozo-Kaderman, Pasi A. Janne, Bruce E. Johnson, Ann H. Partridge, Andrea Catherine Enzinger; Dana-Farber Cancer Institute, Boston, MA; Brigham and Women's Hospital, Boston, MA

Background: Young patients (≤50 years) with lung cancer (LC) face unique needs, including mental health and financial challenges, which are understudied to date. We report preliminary results of an ongoing cohort, prospective study exploring psychosocial needs in patients with LC, focusing on the experiences of young patients. **Methods:** Eligible patients (pts) were age ≥18 years old, with LC stages I-IV, receiving care at Dana-Farber Cancer Institute, and enrolled within 1 year of diagnosis. The FACT-G and COST questionnaires assessed psychosocial and financial distress, with higher scores indicating a more favorable well-being. Descriptive statistics summarized demographics, clinical characteristics, and prevalence of psychosocial needs. **Results:** 139 pts were enrolled from April 2023 - January 2024; 61 young pts were included in this analysis. 69% identified as female, 70% as White, 8% as Black, and 22% as another race (Table). Since LC diagnosis, 22 pts (36%) reported being diagnosed with at least one mental health condition. Of a possible total score of 108, the mean FACT-G score was 71 (SD: 20). Mean scores for physical, social, emotional, and functional subscales were 19, 22, 14, and 16 (out of 28, 28, 24, and 28), indicating significant burden in the emotional and functional domains. A majority reported feeling sad or anxious (53%, 59%), and 57% were worried about premature death. Most pts (62%) reported (somewhat-very much) having a lack of energy and nearly half reported having substantial pain and being bothered from treatment side effects (42%, 47%, respectively). Many pts were able to work and enjoy their usual recreational activities (66%, 72%, respectively). Nearly all reported receiving adequate emotional support from their family (95%) and friends (93%) and feeling comfortable discussing their LC with them (93%). When asked if they were satisfied with their sex life, 64% (35/55) stated that they were. Of a maximum score of 44, the mean COST score was 24 (SD: 12), consistent with high financial toxicity in this population. Notably, 40% of pts reported having no or only a little money to pay for treatments and 42% stated that out-of-pocket medical costs were considerably more than expected. 45% felt financially stressed and 41% were concerned about loss of employment; 47% stated that their LC caused a substantial financial hardship and 57% noted significant worry about future financial issues. **Conclusions:** Young pts with LC report ample financial toxicity and issues impacting physical, emotional, and functional well-being. Fewer social issues were reported. This study will help elucidate the needs of young pts with LC with the ultimate goal of mitigating the disease's psychosocial impact. Research Sponsor: LUNGevity Foundation.

Patient Characteristics	Total
Hispanic/LatinX	5 (9%)
Diagnosed ≤ 6 mos. ago	33 (54%)
NSCLC	43 (71%)
Currently undergoing treatment	48 (81%)
Targeted therapy	23 (48%)
Chemotherapy	10 (21%)
Immunotherapy	2 (4%)
Chemotherapy + Immunotherapy	7 (15%)

12105 Poster Session

Electronic capture of cancer patients' health related social needs in a community oncology network.

Puneeth Indurlal, Jessica Neeb, Dana Weber, Lydia Mills, Judi Payne-De Bock, Evan Osborne, Erin Crum, Lalan S. Wilfong; McKesson, The US Oncology Network, The Woodlands, TX; McKesson, The US Oncology Network, Greenwood, IN; The US Oncology Network, The Woodlands, TX; McKesson Specialty Health, Spring, TX; McKesson Specialty Health, The US Oncology Network, The Woodlands, TX; McKesson, The Woodlands, TX

Background: Health related social needs (HRSN) are known to have an impact on cancer patient outcomes and experience. Practices in The US Oncology Network (The Network) use the National Comprehensive Cancer Network (NCCN) Distress Thermometer (DT) as the screening tool for HRSNs. With the deployment of the NCCN DT in the electronic health record (EHR), we seek to evaluate the distress and HRSNs reported by cancer patients. **Methods:** Data collected using the EHR-based NCCN DT for seven practices in The Network between July and December 2023 was used to evaluate the positive finding rate, types of distress reported, and plan of action for reported problems. Screenings were conducted at different points in the care continuum depending on practice standards and preferences. **Results:** Between July and December 2023, a total of 269,666 screenings for 219,720 unique patients were recorded using the EHR-based NCCN DT, of which 3.1% (8,332) were recorded as patient declined. 117,363 (43.5%) screenings had a positive finding (≥1 problem, or score ≥1). Nearly 2 in 5 screenings (103,767, 38.5%) had a problem reported, with 58.2% (60,373) of those screenings reporting a problem in more than 1 problem area. A numeric distress value was recorded in 94.6% (255,046) of the screenings, with 27.2% (73,338) having a distress score of ≥ 1 and 11.6% (31,264) with a score of ≥ 4. Problem list responses are reported in the table. A distress action plan was recorded for 55.7% (65,333) of the positive findings, of which a majority (79.6%) of patients declined any assistance. Most of the action plans for referrals to appropriate assistance services were recorded for screenings with ≥3 problems reported (58.0% vs 24.6%), or with distress scores of ≥4 (65.6% vs 9.9%). **Conclusions:** HRSN's are commonplace among cancer patients, and screening aids with identifying and addressing distress. Electronic capture of DT in the EHR helps oncology practices use data to facilitate holistic patient care, design and optimize support services (social work, navigation, symptom management programs), as well as gather and organize community resources to address HRSNs and ultimately identify disparities and work toward advancing health equity. Research Sponsor: None.

Problem List	Concern Reported	Top 3 Concern Areas
Physical	83.2% (86,369)	Fatigue (46.4%, 48,106) Pain (41.4%, 42,956) Sleep (34.4%, 35,729)
Emotional	53.5% (55,501)	Worry or Anxiety (38.7%, 40,177) Sadness or Depression (19.7%, 20,420) Loss of interest or enjoyment (10.9%, 11,266)
Practical	38.4% (39,884)	Finances (14.8%, 15,369) Taking care of myself (14.0%, 14,528) Work (10.4%, 10,764)
Social	15.3% (15,845)	Relationship with spouse or partner (5.8%, 6,000) Relationship with family (5.5%, 5,657) Relationship with children (5.3%, 5,525)
Spiritual	7.2% (7,424)	Sense of meaning or purpose (3.4%, 3,512) Death, dying, or afterlife (3.1%, 3,264) Conflict between beliefs and cancer treatments (1.0%, 998)
Other	5.8% (5,981)	

12106 Poster Session

Investigating the mediating role of mental adjustment in the relationship between perceived stress and quality of life in patients with cancer.

Maria-Chidi Christiana Onyedibe, Runcie C. W. Chidebe; University of Nigeria Nsukka, Nsukka, Enugu State, Nigeria; Project Pink Blue- Health and Psychological Trust Centre, Abuja, FCT, Nigeria

Background: Cancer patients undergo a multifaceted journey fraught with substantial psychological distress and coping hurdles, profoundly influencing their overall well-being. The intricate nexus between perceived stress and diminished Health-Related Quality of Life (HRQoL) in this population has garnered significant attention. However, the pivotal role played by mental adjustment to cancer (MAC) as a potential mediator in this intricate relationship remains inadequately explored. Given the paramount importance of understanding the psychological dynamics inherent to cancer care, our study sought to delve into the mediating influence exerted by MAC on the association between perceived stress and HRQoL among individuals grappling with cancer. **Methods:** The study enrolled 214 cancer patients (74 male, 140 female, mean age = 50.57, SD= 13.07) from a University Teaching Hospital in South-West Nigeria. Participants completed assessments utilizing the Impact of Event Scale, Mental Adjustment to Cancer, and Health-Related Quality of Life (measured by the Functional Assessment of Cancer Therapy–General). The study utilized a cross-sectional design, and data analysis was performed using mediation analysis with PROCESS procedures in SPSS. **Results:** Results indicated that perceived stress was associated with lower HRQoL (β = -.71, $p < .001$, CI, -1.02, -.39). Among the five dimensions of MAC, three sub-dimensions: helplessness (β = -.49, $p < .05$, CI, -.95, -.02), anxious occupation (β = -1.45, $p < .05$, CI, -1.92, -.96) and cognitive avoidance (β = 1.43, $p < .001$, CI, .61 – 2.25) were significantly associated with HRQoL. Mediation analysis showed that only two dimensions—helplessness and anxious preoccupation — mediated the relationship between cancer-related stress and HRQoL. The indirect effect for both helplessness (β = -.14, SE = .069, CI -.24, -.01) and anxious preoccupation (β = -.31, SE = .09, CI -.51, -.15) were significant. The findings indicate that stress related to cancer may lead to elevated levels of helplessness and anxious preoccupation, subsequently contributing to a decrease in Health-Related Quality of Life (HRQoL). **Conclusions:** This study provides valuable insights into the intricate relationship between perceived stress, mental adjustment to cancer, and HRQoL, offering implications for targeted interventions aimed at enhancing the well-being of individuals grappling with the challenges of cancer diagnosis and treatment. By tailoring interventions to address these nuanced dynamics, healthcare providers can foster improved overall well-being and adaptive capacities in individuals navigating the complexities of cancer care. Key words: Cancer patients, mental adjustment to cancer, perceived stress, health-related quality of life Research Sponsor: None.

12107 Poster Session

Association between psychological distress and treatment efficacy in patients with newly diagnosed SCLC.

Fang Wu, Shuxing Wang, Yue Zeng, Yurong Peng, Junqi Liu, Xinyu Tian, Shijiao Yao, Aoxi Liang, Chao Deng, Zhenhua Qiu, Fang Ma, Xianling Liu, Chunhong Hu; Department of Oncology, The Second Xiangya Hospital, Central South University, Changsha, China; Department of Oncology, the Second Xiangya Hospital, Central South University, Changsha, China; The second Xiangya Hospital, Central South University, Changsha, China; Department of Oncology, the Second Xiangya Hospital of Central South University, Changsha, China

Background: Small cell lung cancer (SCLC) is a highly aggressive neuroendocrine malignancy known for its rapid doubling time and high growth fraction. Despite advancements, treating SCLC remains challenging, necessitating improved strategies. Prior research indicates that psychological distress can impact cancer treatment efficacy, with severe psychological distress correlating with poorer prognosis. Our study delves into the psychological distress distribution among SCLC patients and identifies potential treatment targets. **Methods:** Patients newly diagnosed with SCLC, receiving either chemotherapy or immunotherapy as first-line treatment, were enrolled. Psychological distress, encompassing depression and anxiety symptoms, was assessed using the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder-7 (GAD-7) scales. Psychological distress hormone levels, including serum cortisol and adrenocorticotropic hormone (ACTH), were measured using ELISA kits before treatment initiation. Objective response rate (ORR) and median progression-free survival (PFS) were determined through chi-square tests, Kaplan-Meier analysis, and Cox regression methods. **Results:** A total of 97 patients diagnosed with SCLC were included in the study, with an average age of 61.5 years. Among them, 70 cases (72.1%) were classified as extensive stage, while 27 cases (27.8%) were limited stage. Psychological distress was present in 53 patients (54.0%). Patients experiencing psychological distress exhibited a significantly lower objective response rate (ORR) compared to those without distress (50.9% vs. 72.7%; P = 0.037), along with a shorter median progression-free survival (PFS) (8.40 vs. 19.47 months; 95% CI 7.84-12.96; P = 0.004). Furthermore, elevated serum cortisol levels ($P < 0.001$) were observed in patients with psychological distress. In addition, higher serum cortisol concentration (P = 0.011) was associated with a poorer response to chemotherapy and immunotherapy. **Conclusions:** Psychological distress is prevalent among patients with SCLC. Notably, those experiencing psychological distress tend to exhibit poorer responses to chemotherapy and immunotherapy. Our investigation has uncovered a potential mechanism involving neuroendocrine hormone resistance to treatment modalities. Clinical trial information: NCT05477979. Research Sponsor: None.

12108 Poster Session

The role of personalized therapy in cancer associated depression among 10,673 patients.

Ghada Elnashar, Ellie H. Jhun, Jason Walker, Julie England, Victor Tam, Cathryn Jennissen, Greyson Twist, Pashtoon Murtaza Kasi, James Michael Kelley; OneOme, LLC, Minneapolis, MN; Weill Cornell Medicine, Englander Institute of Precision Medicine, NewYork-Presbyterian Hospital, New York, NY

Background: Pharmacogenomics can help reduce the trial and error of antidepressant management in cancer patients. Depression is a major contributor to morbidity and mortality in cancer patients. Additionally genetic variation can affect metabolism for many antidepressants in various ways. *CYP2D6* and *CYP2C19* impact the pharmacokinetics of anti-depressants, which normally take weeks before clinical outcomes are achieved. Here we underline actionable phenotype frequencies stratified by ethnicity/race for *CYP2C19*and *CYP2D6* in patients investigated for cancer, from a depression standpoint. **Methods:** A retrospective analysis of 10,673 patients genotyped for *CYP2D6* and *CYP2C19* was conducted (OneOme LLC, Minneapolis, MN). 1,616 tests were found to be ordered by oncologists and analyzed separately as a sample subset. Phenotype and allele frequencies were calculated and compared to self-reported ethnicity/race. **Results:** See table. **Conclusions:** This is the largest cohort to date to our knowledge that looks at the role of personalized therapy in cancer associated depression. Our data show that different tested ethnic group can show a predilection towards certain metabolic patterns. PMs may experience an increased risk of side effects with antidepressant therapy, whereas UMs may observe a reduction in treatment efficacy. Utilizing PGx to guide drug selection and dosing for cancer patients with depression can reduce trial and error, limit the burden of a very debilitating disease, and improve patients' quality of life. Since our analyses showed very similar frequencies, we speculate that cancer patients suffering from depression can benefit from early identification. Research Sponsor: None.

Gene	General Analysis (N=10,673)	Sub-Analysis (N=1,616)
CYP2C19	3% Poor metabolizer (PM) 4% Ultra-rapid metabolizer (UM) The highest percent of *CYP2C19*PMs at 11% was found within the collective Asian tested population.	3% PM 4% UM
CYP2D6	6% PM 3% UM Native Hawaiian and American Indian Alaska Native had more CYP2D6 PMs within the tested sets at 14% and 13%, respectively.	6% PM 3% UM

12109 Poster Session

"Things we deal with in exchange for cure": How hematologists discuss graft versus host disease with patients considering allogeneic stem cell transplant.

Thorunn Halldora Thordardottir, Rachel Rodenbach, Aric C. Hall, Markus Brauer, Earlise Ward, Cardinale B. Smith, Toby Christopher Campbell; University of Wisconsin Carbone Cancer Center, Madison, WI; James P. Wilmot Cancer Center, University of Rochester Medical Center, Rochester, NY; University of Wisconsin, Madison, WI; Icahn School of Medicine at Mount Sinai, New York, NY

Background: Graft versus host disease (GVHD) remains an important complication of allogeneic stem cell transplant (alloSCT). Severe forms can impact quality of life long term or prove fatal. While disparities exist in routine doctor-patient communication, the complexity of alloSCT adds barriers and magnifies disparities in healthcare. How hematologists discuss risks may impact patients' perception and understanding. Here we explore how hematologists explain GVHD and identify differences based on patient race. **Methods:** This is a secondary analysis of a qualitative study of video-recorded virtual encounters. We recruited transplant hematologists in the US and randomly assigned them to meet with a patient actor of Black or white race trained to portray the same 67 years old man with newly diagnosed high-risk myeloid neoplasm referred for discussion of treatment options including alloSCT. The clinical case was designed to represent a realistic transplant candidate and to enable hematologists to focus on treatment decision making. **Results:** 37 hematologists from 25 centers participated (65% male, 35% non-white, median age 44). All hematologists shared that transplant carries risks; however, they varied in the extent to which they discussed GVHD. 16% (6/37) of them did not mention GVHD and 19% (7/37) briefly introduced it, deferring more discussion to a later visit. Two thirds discussed GVHD (10/17 with the Black patient and 14/20 with the white patient) but provided variable details. Most described a spectrum of severity: that GVHD is a major, potentially life-threatening risk of transplant but most develop mild and treatable form. They explained that monitoring for GVHD was the main reason for frequent clinic visits. Some discussed that chronic GVHD could be a primary driver of impaired quality of life after transplant, where "we are sometimes trading one disease for another". Extensive conversations on differences between acute and chronic forms, manifestations, risk factors, treatment and prognosis occurred in 12% (2/17) of visits with the Black patient vs 25% (5/20) with the white patient. Hematologists gave different quantitative GVHD risk estimates ranging from 'two thirds" to "the historical 30% has been taken down to 10%". **Conclusions:** GVHD was included in most alloSCT decision making visits, however over a third of hematologists did not provide meaningful information about it in their first conversation with a patient. The information provided varied with risk of the condition quoted as 10-66%. Few provided extensive details but these were twice as likely to be given to the white patient. GVHD is an important and potentially life-limiting toxicity of alloSCT, this study suggests patients are asked to make transplant decisions based on variable information which may contribute to disparities in this already difficult to access therapy. Research Sponsor: University of Wisconsin Office of the Vice Chancellor for Research and Graduate Education; #AAI9733.

12110 Poster Session

Coping in caregivers of patients with primary malignant brain tumors: A mediation analysis of a randomized controlled trial.

Deborah Anne Forst, Kelcie D Willis, Sumita Madhok Strander, Jessica Devon Whitman, Daniel Chiu, Nora K. Horick, Kedie Pintro, Areej El-Jawahri, Joseph A. Greer, Jennifer S. Temel, Jamie M. Jacobs; Massachusetts General Hospital, Boston, MA; Harvard Medical School, Harvard University, Boston, MA

Background: Caregivers of patients with primary malignant brain tumors (PMBT) experience immense psychological distress and lack tailored supportive care resources. In a recently completed randomized controlled trial, we demonstrated that a brief telehealth-based psychological intervention ("NeuroCARE") for caregivers of patients with PMBT led to decreased anxiety and depression symptoms as well as greater caregiving self-efficacy and coping ability compared to usual care (UC). To explore active drivers of the intervention, we examined whether improvements in caregivers' coping ability mediated the effects of NeuroCARE on psychosocial outcomes. **Methods:** From October 2019 to June 2022, we enrolled 120 adult caregivers (mean age 53 years, 83% female, 70% spouse/partner) of patients newly diagnosed with a PMBT to a trial of NeuroCARE vs. UC. Eligible caregivers had elevated baseline anxiety (Generalized Anxiety Disorder-7 $\geq$ 5). Caregivers self-reported their anxiety symptoms (Hospital Anxiety and Depression Scale-Anxiety), depression symptoms (Hospital Anxiety and Depression Scale-Depression), coping skills (Measure of Current Status), and caregiving self-efficacy (Lewis Cancer Self-Efficacy Scale) at baseline and 11 weeks (post-intervention). We ran three causal mediation regression models with bias-corrected bootstrapping to examine whether intervention effects on anxiety symptoms, depression symptoms, and self-efficacy at 11 weeks were mediated by changes in coping ability from baseline to 11-weeks. **Results:** Improvements in anxiety symptoms at 11 weeks in caregivers assigned to NeuroCARE, compared to those receiving UC, were mediated by increased coping ability across the 11 weeks. Improved coping ability led to a 1.44 decrease in anxiety on the HADS-A for patients assigned to NeuroCARE (indirect effect = -1.44, bootstrapped SE = 0.49, 95% CI [-2.50, -0.54]). This indirect effect accounted for 75% of the total intervention effect on anxiety. Similarly, NeuroCARE-related reductions in 11-week depression symptoms were mediated by improved coping ability (indirect effect = -1.43, bootstrapped SE = 0.38, 95% CI [-2.21, -0.74], 82% of the total effect), as were increases in caregiving self-efficacy (indirect effect = 11.03, bootstrapped SE = 2.59, 95% CI [6.30, 16.53], 63% of the total effect). **Conclusions:** The beneficial effects of the intervention on caregivers' anxiety symptoms, depression symptoms, and self-efficacy were driven indirectly by caregivers' use of evidence-based coping skills learned in NeuroCARE. The identification of coping as an active intervention component is critical for optimizing the scalability and sustainability of NeuroCARE for this highly burdened and distressed PMBT caregiver population. Clinical trial information: NCT04109209. Research Sponsor: Conquer Cancer, the ASCO Foundation; 2019CDA-7743456038.

12111 Poster Session

Sociodemographic characteristics associated with reading online health education materials among patients with cancer.

Melissa Christina White, Arun Bhardwaj, Amanda Christman, Nosayaba Osazuwa-Peters; Duke University Medical Center, Durham, NC; Navigating Cancer, Seattle, WA; Duke University School of Medicine, Durham, NC

Background: Health literacy is an important aspect of navigating cancer care. There are over 18 million cancer survivors currently in the United States, and the number is expected to continue increasing. As new therapeutic options emerge for cancer patients, it is important that patients are able to read and understand literature from their clinical encounters regarding their treatment options and prognosis. Very little real-world data exists describing cancer patients' reading of cancer information. We aimed to identify baseline characteristics associated with reading online health education materials among patients during active cancer care. **Methods:** We used retrospective data from *Navigating Cancer* for individuals ≥18 years, with confirmed cases of cancer between 2017 and 2023. We performed an unadjusted comparison of baseline characteristics between patients who read at least one article versus those who did not read, using chi-square test. Multivariable logistic regression estimated associations between patients' sociodemographic characteristics and online health education material reading status (read vs. not read). **Results:** Among 2,903 eligible patients with cancer included in the study, approximately 65% (n= 1890) read the online health educational materials. On average, females dominated both reading status categories ($female_{read}$=70%; $female_{not\_read}$=70.98%). However, on average patients in the "not read" category differed with a relatively higher proportion of younger adults ($\leq 40_{read}$=14.81% vs. $\leq 40_{not\_read}$=20.04%) and lower rates of graduate education ($graduate_{read}$=27.2% vs. $graduate_{not\_read}$=19.74%). In the fully-adjusted model, age group was associated with reading status, with a 31% lower odds for patients with cancer ≤ 40 years (aOR = 0.69, 95% CI 0.55-0.87; P=0.001), and a 38% lower odds for older patients 80+ years (aOR = 0.62, 95% CI 0.42-0.93; P=0.022) relative to patients 40-60 years. Also, education was a significant predictor, with a 36% reduced odds for patients with a high school diploma or less (aOR=0.64, 95% CI 0.53-0.76; $P<0.001$), but 26% higher odds for graduates (aOR = 1.26, 95% Ci 1.03-1.55; P=0.022), relative to patients with some college education. Similarly, White patients relative to Non-White patients with cancer (aOR = 1.27, 95% CI 1.08-1.49; P=0.004) showed 27% increased odds of reading online educational materials. **Conclusions:** This study showed an association between age, race, educational status and odds of reading online cancer health education among cancer survivors. Given the focus on patient-centered cancer care and equity in physician-patient cancer communication, it is important that clinical providers recognize factors associated with reading of cancer education materials in their patient population. Research Sponsor: None.

Exploring the structure of psychological distress and its symptoms: A psychometric network analysis.

Alessandro Rossi, Maria Marconi, Stefania Mannarini, Andrea Calcaterra, Luigi De Cicco, Claudio Verusio, Giuseppe Di Lucca; Department of Philosophy, Sociology, Education, and Applied Psychology, Section of Applied Psychology, University of Padova, Padova, Italy; Department of Medical Oncology, ASST Valle Olona, Presidio Ospedaliero di Saronno, Saronno, Italy; Department of Mental Health, ASST Valle Olona, Busto Arsizio, Italy; Division of Radiotherapy, ASST Valle Olona, Busto Arsizio, Italy; Department of Oncology, ASST Valle Olona, Saronno, Italy; Ospedale Civile Di Saronno, Lissone, Italy

Background: Psychological research is currently surging in oncological settings, with the construct of psychological distress gaining significant attention. Several studies have demonstrated that psychological distress can have profound adverse effects on adherence, therapy compliance, medical treatments, and overall quality of life (NCCN, 2015). However, it remains a challenging endeavor to attain a clear understanding of the implications of psychological distress in the daily lives of oncology patients. To address this gap, our study aimed to identify the central symptoms of psychological distress and elucidate their relationships. **Methods:** Oncological outpatients (N = 504; $mean_{age}$ = 67.15, *SD* = 10.16; 50% females) were recruited at the Presidio Ospedaliero of Saronno, ASST Valle Olona, Italy. The Psychological Distress Inventory-Revised (PDI-R; Rossi et al., 2022), utilized to measure internal, external, and general distress, demonstrated high internal consistency in assessing patients' psychological distress. As a preliminary step before conducting confirmatory factor analysis, we employed an analysis to assess the structural validity of the PDI-R. Subsequently, we performed a Psychometric Network Analysis with the EBICglasso algorithm (5000 bootstrap) to uncover the network structure of psychological distress and identify nodes with greater strength and expected influence. **Results:** The preliminary analysis indicated that the factorial structure demonstrates excellent fit indices [RMSEA = 0.055; CFI = 0.997; SRMR = 0.041]. Additionally, the Psychometric Network Analysis showed a high accuracy (CS-coefficient = 0.75). Psychological distress symptoms spontaneously clustered into internal and external distress, as per the model, with all symptoms showing noteworthy interconnections. Notably, the strongest connections were observed within the 'external distress' facet. On one hand, the Network Analysis revealed that item #7 (External distress: 'diminished interest in the world'; z = 1.480), item #2 (Internal distress: 'moments of dejection or depression'; z = 1.141), and item #8 (External distress: 'the illness has negatively influenced your relationships with others'; z = 0.542) were identified as nodes with both the highest strength and expected influence. **Conclusions:** These findings have meaningful implications for clinical practice, as clinical interventions should prioritize addressing symptoms that exhibit the strongest connections within the network. Given that these central nodes have the potential to influence all other connected symptoms, they represent crucial focal points for clinicians. Tailoring more targeted and efficient therapeutic approaches to address these central symptoms can have beneficial effects on medical treatments and enhance the overall quality of life for patients. Research Sponsor: None.

12113 Poster Session

Examining patient preferences in the delivery of healthcare education.

Tomas Dvorak, Lauren Skinner, Leticia Valentin, Julio Hajdenberg; Orlando Health Cancer Institute, Orlando, FL; Orlando Health, Orlando, FL; Black Diamond Therapeutics, Boston, MA

Background: Important component of patient-centered care includes providing patient education. While traditionally provided on paper, electronic methods are becoming increasingly common. In this study, we evaluated a socially assistive robot (SAR Robot) delivering education information to patients via narration of a video, compared with same information provided via a paper-based brochure (Brochure). **Methods:** The study was a 2-arm, unblinded, randomized trial with a cross-over design, approved by local IRB. Arm 1 was Brochure first, followed by SAR Robot, and Arm 2 was SAR Robot first, followed by a paper Brochure. Questionnaires were completed after each step. The education information provided was on "Diet and Cancer", and the Brochure and the SAR Robot video were adapted from the same script developed by the study authors. Likert scale was used to assess effectiveness of each method and the enjoyment of the SAR Robot experience. Statistics were performed to assess for significance. **Results:** Between 2021 and 2023, 129 patients were enrolled at Orlando Health Cancer Institute, randomized to Arm 1 (n=64) vs Arm 2 (n=65); 122 patients were analyzable. There were no differences in demographics. Brochure was judged to be Very Effective by 50% in Arm 1 (Brochure first) and 63% in Arm 2 (Brochure second). SAR Robot was judged to be Very Effective by 60% in Arm 1 and 60% in Arm 2. Composite rates of Effective or Very Effective were 97% for Brochure and 88% for Robot SAR. Patients and guests preferred Brochure in 27% in Arm 1 and 17% in Arm 2. They preferred the SAR Robot in 39% in Arm 1 and 42% in Arm 2. They preferred both in 34% and 42%, and of these majority preferred the SAR Robot for explanation and Brochure to take home. There was no statistical difference between arms in effectiveness. There were no differences across demographics. Answering the "My experience with the SAR Robot today was enjoyable" question, 47% of patients responded Strongly Agree, and further 41% responded Agree, 11% were Neutral, and only 1% responded Disagree. There was a significant correlation between enjoying the SAR Robot experience and effectiveness of the SAR Robot; there was no correlation between enjoying the SAR Robot experience and effectiveness of the Brochure. There was no statistical correlation between enjoying the SAR Rabot experience and demographics. **Conclusions:** Patient reported no significant difference in effectiveness of obtaining education information via a standard paper brochure or from a socially assisted robot. However, they preferred to receive that information from the socially assisted robot, or in combination with the paper brochure to take home. Significant majority of them (88%) enjoyed the socially assisted robot experience during their visit. Providing patient education materials via socially assisted robots may improve patient experience during their clinic visit, without compromising the quality of their education. Research Sponsor: None.

12114 Poster Session

Neurofilament light chains: A biomarker for vincristine-related neuropathy.

Gretchen A McNally, Menglin Xu, Timothy Voorhees, Robert A. Baiocchi, David Alan Bond, Naren Epperla, Kami J. Maddocks, Yazeed Sawhala, Bhuvaneswari Ramaswamy, Maryam B. Lustberg; The Ohio State University James Cancer Center, Columbus, OH; The Ohio State University Comprehensive Cancer Center, Columbus, OH; The Ohio State University - Division of Hematology, Columbus, OH; The Ohio State University, Columbus, OH; The Ohio State University Comprehensive Cancer Center, Division of Hematology, Columbus, OH; Ohio State University Comprehensive Canvcer Hospital, Columbus, OH; Smilow Cancer Hospital, Yale Cancer Center, New Haven, CT

Background: Sensory vincristine-related neuropathy is a well-known toxicity of front-line lymphoma treatments, potentially negatively impacting both disease outcomes as well as the long-term quality of life of cancer survivors. Most aggressive non-Hodgkin lymphomas are curable with the multi-agent chemotherapy regimens CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) or infusional dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin). This pilot study aimed to characterize and describe chemotherapy-induced peripheral neuropathy (CIPN) outcomes, utilizing patient and clinician-reported outcome measures and neurofilament light chains (NF-L). Nf-L, released in response to axonal damage, is emerging as a sensitive blood-based biomarker for CIPN. Studies in rats have demonstrated repeated vincristine exposure correlated with increased serum NF-L light chains and progressive damage. This has not previously been reported in humans. **Methods:** A single-center prospective study assessed CIPN toxicity in people with aggressive non-Hodgkin's lymphoma treated with CHOP and EPOCH. Patient-reported outcome (PRO) measures included the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Chemotherapy Induced Peripheral Neuropathy (EORTC QLQ-CIPN20) questionnaire. Items 19 and 20 were excluded. The clinician-reported outcome measure was the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE v5.0). Outcomes were evaluated at three time points: (1) Baseline, (2) Immediately before cycle four, and (3) Immediately before cycle six. Blood samples were collected from participants and processed for plasma Nf-L chain analysis. **Results:** There were 26 participants at baseline (CHOP: n = 17, EPOCH: n = 9), 21 participants at time point 2 (CHOP: n = 17, EPOCH: n = 7), and 16 participants at time point 3 (CHOP: n = 10, EPOCH n = 6). The mean CIPN-18 scores increased at each time point and were not significantly different by chemotherapy type. Five of the 16 participants (31.3%) experienced CIPN $\geq$ grade 1 at time point 3. A significant relationship existed between the CIPN-18 and the CTCAE (r- 0.39, p =0.002) and between CIPN-18 and Nf-L levels (r= 0.42, p = 0.002). The mean Nf-L levels increased from the first time point (mean = 54.4 pg/mL, 16-187.9 pg/mL) to the second time point (mean = 108.7 pg/mL, 37-232.2 pg/mL) and remained significantly elevated at Time Point 3 (mean = 92pg/mL, 34-172.2 pg/mL). **Conclusions:** One-third of all participants were experiencing symptoms of CIPN by the third time point (cycle six of therapy), as measured by the CTCAE $>$ 0 and the CIPN-18 $>$ 20. Our study lays the groundwork for using Nf-L as a potential biomarker, in combination with PROs, to identify, recognize, and measure vincristine-induced neurotoxicity. Research Sponsor: OSU Comprehensive Cancer Center.

12115 Poster Session

Comparative analysis of efficacy and safety profiles between conventional pegfilgrastim and its biosimilar agents in patients receiving cytotoxic chemotherapy: A systemic review and meta-analysis.

Saad Nasir, Insia Ali, Mohammad Saad Salim Naviwala, Zayan Alidina, Hiba Idrees, Munira Moosajee; Aga Khan University Hospital, Karachi, Pakistan

Background: While pegfilgrastim forms the cornerstone in chemotherapy-induced neutropenia prophylaxis, its newer biosimilar agents show potential as compelling options. However, despite head-to-head randomized clinical trials (RCTs) demonstrating comparable efficacy between these biosimilar agents of pegfilgrastim and the conventional pegfilgrastim, a lack of evidence exists to suggest definite clinical benefit. This could be attributed to the low statistical power in the clinical trials. Our systemic review and meta-analysis aim to pool the available evidence and provide a comprehensive understanding of the landscape in the prevention of chemotherapy-induced neutropenia. **Methods:** A literature search was conducted on online databases including, MEDLINE (PubMed), Embase, SCOPUS, and the Cochrane CENTRAL from their inception to October 2023 to identify phase II or III RCTs comparing the efficacy and safety profiles of the conventional pegfilgrastim and its biosimilar agents. Included studies reported at least one key outcome: the duration of severe neutropenia (DSN) in days after the first cycle of chemotherapy (primary outcome), incidence of febrile neutropenia (FN), and bone pain. Pooled risk ratios (RR) and weighted mean difference (WMD) with 95% confidence interval (CI) were calculated using a random-effects model. Heterogeneity was assessed using I^2 statistics. **Results:** We identified 10 RCTs involving 2237 patients. Our analysis showed a statistically significant and favorable outcome for biosimilar agents in reducing DSN (WMD -0.08 days, 95% CI, -0.15, -0.01, P=0.03, I^2=0%). No significant differences were observed in the incidence of FN (RR: 0.98, 95% CI, 0.62, 1.53, I^2=0%) or bone pain (RR: 0.98, 95% CI, 0.82, 1.17, I^2=0%). In the subgroup analysis based on the subtype of biosimilar agents, eflapegrastim had a statistically significant impact in decreasing DSN compared to the conventional pegfilgrastim (WMD -0.13 days, 95% CI -0.24, -0.03, P=0.01, I^2=0%). **Conclusions:** Growing evidence supports cost-effective biosimilars of pegfilgrastim as comparable in efficacy and safety. Eflapegrastim emerges as a promising alternative, demonstrating a clinically meaningful benefit over the conventional pegfilgrastim. Research Sponsor: None.

Patterns of immune-related adverse events (irAEs) in adolescent and young adult (AYA) patients with melanoma receiving immune checkpoint inhibitors (ICIs).

Jiasen He, Ida John, Faraz Afridi, Mianen Sun, Yinghong Wang, Michael Roth, Jennifer Leigh McQuade; The University of Texas MD Anderson Cancer Center, Houston, TX; MD Anderson Hematology/Oncology Fellowship, Houston, TX; Department of Melanoma Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX

Background: ICIs are increasingly used in AYAs with cancer, however, limited data exists on the frequency and pattern of irAEs in this population and the ability to rechallenge with ICIs after irAEs. **Methods:** This retrospective study analyzed AYAs aged 15-39 with melanoma who received treatment with ICIs at MD Anderson Cancer Center from 2013 to 2023. Treatment cessation was defined as switching therapies or pausing the original treatment for over 3 months, and rechallenge as resuming immunotherapy post-cessation. **Results:** A total of 136 pts were included, 80 were male (59%), with median age at 33 years (range, 15-39 years) upon initial ICI exposure. The majority had non-acral cutaneous melanoma (107, 79%) and 83 (63%) had a BRAF V600E/R/K alteration. Ninety-three percent patients had stage III/IV cancer at ICI treatment initiation. Targeted therapy was used in 20 patients (15%) prior to starting ICI and 16 patients (12%) concurrently. Combination immunotherapy was utilized in 43% of cases, while monotherapy in 57%. The initial intent for ICIs was adjuvant in 51% of the cases, palliative in 37% and neoadjuvant in 12%. The incidence of any-grade and grade III/IV irAEs with 1st line ICI therapy was 60% and 21% for the full cohort (with combination of CTLA-4/PD-1 blockers 70% and 33%; with PD-1 blockers monotherapy was 50% and 9%, respectively). Forty-eight AYAs had multi-system irAEs (35%) and 23 were grade III/IV. Thirty-two (24%) patients had their initial ICI stopped due to irAEs with hepatitis (31%, 10/32) and colitis (28%, 9/32) being the most common causes. Eighteen patients (13%) had irAE-related hospitalizations. Specific irAEs are listed in the table. Seventy-two (53%) patients were rechallenged with ICIs. Of these, 51 had previous irAEs and among these, 71% had recurrent irAEs. Seventy-six percent (36/51) experienced irAEs again with 33% (17/51) having the same irAEs. Twenty-six percent of patients (13/51) had grade III/IV irAEs. **Conclusions:** In AYAs with melanoma who were treated with ICIs, irAE is one of the major reasons for treatment interruption. The incidence of irAEs in AYAs appears somewhat lower than the rates previously reported in registrational trials, though this should be interpreted with caution given retrospective nature of current study. Patients with prior irAEs have a higher risk of recurrent or new irAEs upon rechallenge, however, the majority were low grade without serious negative outcome. Research Sponsor: None.

irAEs during initial and rechallenge of ICIs.

irAEs Any Grade/ Grade III&IV N (%)	Total	Cutaneous	GI/Colitis	GI/Hepatitis	Lung	Endocrine	Multi-system
Initial N=136	81(60)/ 27 (21)	26 (19)/ 0 (0)	34(25)/ 10(7)	30 (22)/ 10 (7)	2(2)/ 1(1)	34(25)/ 5(4)	48(35)/ 23(17)
Rechallenge After prior irAEs N=51	36(71)/ 13(26)	8(16)/ 0(0)	14 (28)/ 7 (14)	14 (28)/ 4 (8)	2(4)/ 1(2)	8(16)/ 1 (2)*	21(41)/ 9 (18)

*Did not include chronic inactive endocrine irAEs.

12118 Poster Session

Pooled analysis on characteristics of nausea and vomiting in patients receiving trastuzumab deruxtecan (T-DXd) in clinical studies.

Yeon Hee Park, Javier Cortés, Shanu Modi, Sara A. Hurvitz, Giampaolo Bianchini, Hiroji Iwata, Kohei Shitara, Salvatore Siena, Yasushi Goto, Geoffrey Yuyat Ku, Powell Andrew Charles, Sandra M. Swain, Meena Arunachalam, Martin Janek, Yingkai Cheng, Changan Chu, Purnima Verma, Elton Mathias, Maha Karnoub, Hope S. Rugo; Sungkyunkwan University School of Medicine, Samsung Medical Centre, Seoul, South Korea; International Breast Cancer Center (IBCC), Pangaea Oncology, Quironsalud Group, Barcelona, Spain; Memorial Sloan Kettering Cancer Center, New York, NY; University of Washington School of Medicine and Fred Hutchinson Cancer Center, Seattle, WA; Università Vita-Salute San Raffaele, Milan, Italy; Aichi Cancer Center Hospital, Nagoya, Japan; National Cancer Center Hospital East, Kashiwa, Japan; Università degli Studi di Milano and Niguarda Cancer Center, Milan, Italy; Department of Thoracic Oncology, National Cancer Center Hospital, Tokyo, Japan; Tisch Cancer Institute, Mount Sinai Hospital, New York, NY; Georgetown University, Washington, DC; Daiichi Sankyo, Inc., Basking Ridge, NJ; University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center, San Francisco, CA

Background: The efficacy and safety profile of T-DXd has been established in patients (pts) with various tumor types, and nausea and vomiting are the most common treatment-emergent adverse events (TEAEs). T-DXd study protocols were refined over time to recommend prophylaxis (eg, neurokinin or serotonin receptor antagonists and/or steroids) before T-DXd treatment, in line with antiemetic and institutional guidelines. We conducted a pooled, post hoc analysis capturing safety information across tumor types; we report results on nausea and vomiting. While this analysis was not designed to assess antiemetic effectiveness, it reveals the incidence of nausea and vomiting in clinical trials of T-DXd 5.4 mg/kg in more detail across a large dataset. **Methods:** 1449 pts treated with ≥1 dose of 5.4 mg/kg T-DXd (every 3 wks) were included from 7 phase 1-3 clinical trials in metastatic HER2+ and HER2-low breast cancer, HER2+ gastric cancer, and HER2-mutant non–small cell lung cancer (DESTINY-Breast01, -Breast02, -Breast03, -Breast04, -Lung01, -Lung02, and the first-in-human phase 1 study J101 in multiple tumor types; study enrollment starting 2015-2021). Regardless of antiemetic use (including prophylaxis), the incidence, severity, time to onset, and duration of nausea and vomiting TEAEs were assessed along with event outcomes. **Results:** Of 1449 pts receiving T-DXd 5.4 mg/kg (median [range] number of 3-wk treatment cycles: 13 [1-60]), 74.6% (n=1081) experienced nausea, and 41.6% (n=603) reported vomiting. Most pts had grade 1/2 nausea (41.2%/27.6%) and/or vomiting (26.2%/12.8%). Grade 3 TEAEs of nausea were reported in 5.8% of pts, with grade ≥3 TEAEs of vomiting observed in 2.6% of pts. By the data cutoff for each trial, 66.9% of pts with nausea and 87.6% with vomiting had their symptoms resolve. Most pts who experienced nausea and vomiting did so during the initial 21 days (cycle 1; n=879 [81.3%] and 336 [55.7%], respectively; 35.8% of all pts received antiemetic prophylaxis at cycle 1); both TEAEs declined notably in subsequent cycles. Rates of drug discontinuation, dose reduction, and drug interruption due to nausea and vomiting were generally low (Table). **Conclusions:** Most nausea and vomiting events were reported during the first 3 wks of treatment and resolved. Appropriate prophylaxis of nausea and vomiting is a key management strategy and allows pts to benefit from longer treatment durations with T-DXd. Ongoing studies are exploring the implementation and impact of prophylaxis for T-DXd–related emesis. Clinical trial information: NCT03248492, NCT03523585, NCT03529110, NCT03734029, NCT03505710, NCT04644237, NCT02564900. Research Sponsor: This study was funded by Daiichi Sankyo, Inc., and AstraZeneca. Medical writing support (ApotheCom) was funded by Daiichi Sankyo, Inc.

T-DXd 5.4 mg/kg discontinuation, dose reduction, and interruption due to nausea/vomiting for all tumor types (N=1449).

n (%)	Total Events	Drug Discontinuation	Dose Reduction	Drug Interruption
Nausea				
Any-grade	1081 (74.6)	1 (0.1)	70 (4.8)	23 (1.6)
Grade 3	84 (5.8)	0	49 (3.4)	5 (0.3)
Vomiting				
Any-grade	603 (41.6)	3 (0.2)	20 (1.4)	8 (0.6)
Grade ≥3	38 (2.6)	0	11 (0.8)	3 (0.2)

12119 Poster Session

Frequency of certain germline polymorphisms among ethnicities and adverse drug reaction risk associated with colorectal cancer therapies.

Cathryn Jennissen, Jason Walker, Ghada Elnashar, Julie England, Annmarie Hawe, Ellie H. Jhun, Victor Tam, Greyson Twist, Pashtoon Murtaza Kasi, James Michael Kelley; OneOme, LLC, Minneapolis, MN; Weill Cornell Medicine, Englander Institute of Precision Medicine, NewYork-Presbyterian Hospital, New York, NY

Background: Chemotherapy regimens used to treat colorectal cancer (CRC) often include a combination of a fluoropyrimidine (i.e., fluorouracil or capecitabine), folinic acid, irinotecan, and/or oxaliplatin as first-line therapy in metastatic disease. Adverse drug reactions (ADRs) related to these regimens, such as neutropenia, severe diarrhea, and mucositis, can be severe or even life-threatening. Fluoropyrimidine (FP) and irinotecan-related toxicities in CRC are associated with certain germline polymorphisms in *DPYD* (*2A, *13, HapB3, and c.2846A>T) and *UGT1A1* (*28 allele), respectively. Clinically actionable recommendations are available per the FDA and the Clinical Pharmacogenetics Implementation Consortium (CPIC) for *DPYD* poor metabolizers (PMs) and intermediate metabolizers (IMs) due to increased risk for FP-induced ADRs. The FDA also provides dosing guidance for *UGT1A1*PMs in an effort to minimize irinotecan-induced toxicities. The objective of this research was to observe the frequency of *DPYD*variants (*2A, *13, HapB3, c.2846A>T, c.557A>G), *UGT1A1* variants (*6, *28), and associated phenotypes in various racial and ethnic groups. **Methods:** A retrospective analysis of 8,640 samples genotyped for *DPYD* and *UGT1A1* was conducted (OneOme, Minneapolis, MN). Phenotype and carrier frequencies were analyzed and stratified by self-reported ethnicity and race. **Results:** *DPYD* variants with reduced or no function were observed in 6% of all samples tested where 6% of patients having clinically actionable IM or PM status. *UGT1A1* carrier frequency was 56% with 12% of patients with clinically actionable PM status. **Conclusions:** A significant proportion of patients carry DPYD and/or UGT1A1 variants that result in decreased metabolism of FPs and irinotecan, respectively. In this large sample size, a 6% DPYD risk variant carrier frequency is significantly more than an estimated 2%, as previously reported. The FDA and CPIC provide clinically actionable recommendations for these commonly used colorectal and other gastrointestinal cancer therapies in an effort to avoid severe and even life-threatening toxicities that may be potentiated by these germline variations. Research Sponsor: None.

Ethnicity/Race	American Indian or Alaska Native/First Nation/Inuit/Métis	Ashkenazi or Sephardi Jewish	Asian (East, Central/ South)	Black/ Sub-Saharan African/ African American	Hispanic or Latino	Native Hawaiian or Other Pacific Islander	Near/ Middle Eastern	White or Caucasian	Unknown / not provided	Total
# samples	36	46	130	257	205	11	46	6205	1704	8640
% *DPYD* CF† of risk variants (*2A, *13, HapB3, c.2846A>T)	14%	0%	4%	1%	1%	18%	2%	6%	5%	6%
% *DPYD*CF† ofc.557A>G	0%	0%	0%	3%	0.5%	0%	0%	0.03%	1%	0.4%
% *DPYD* actionable phenotypes	14%	0%	4%	1%	1%	18%	2%	6%	5%	6%
% *UGT1A1*CF† (*6, *28)	71%	72%	58%	67%	63%	36%	63%	54%	60%	56%
% *UGT1A1*actionable phenotypes	8%	24%	12%	19%	15%	9%	22%	11%	15%	12%

†CF = carrier frequency.

12120 Poster Session

Impact of prophylactic laser therapy on mucositis in patients with head and neck cancer (HNC) undergoing radiotherapy in Brazil.

Renata Ferrari, Ana Carolina Felizardo, Lourenço Siqueira, Luana Abreu, Daniele Araujo, Leticia Araujo, Tauana Fernandes, Clara Lopes, Rafaela Peixoto, Bianca Melo, Ana Maria Costa, Ruan Silva, Claudia Andrade, Mariana Laloni, Bruno Lemos Ferrari, Carlos G. M. Ferreira, Pedro De Marchi, William Nassib William Jr., Cristiane Decat Bergerot; Oncoclinicas & Co - Medica Scientia Innovation Research (MEDSIR), São Paulo, Brazil

Background: Approximately70-90% of patients with HNC undergoing (chemo) radiotherapy experience any grade mucositis. Older age and nutritional status are recognized risk factors. We conducted this single-arm, observational study to test the primary hypothesis that prophylactic laser therapy would reduce the incidence of mucositis among patients with HNC treated in eight cancer centers among the Oncoclinicas Network in Southeast Brazil. **Methods:** Patients with HNC scheduled for radiotherapy +/- chemotherapy underwent oral health assessments and nutritional risk evaluations using the Patient-Generated Subjective Global Assessment (PG-SGA) before initiating treatment. Prophylactic laser therapy was administered daily throughout all sessions of radiotherapy. Daily follow-up assessments were conducted by a stomatologist to monitor mucositis progression, using the mucositis question from the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. The study's primary endpoint was any grade mucositis. With 118 patients, the study would have 80% power with 2-sided alpha of 0.05 to detect a reduction in the cumulative incidence of grade 3+ mucositis from 70% (literature historical control) to 45% with a two-sided alpha of 5% (Chi-square test). Secondary endpoints included incidence of mucositis according to age, sex, stage, primary tumor site, HPV status, concurrent chemotherapy use, treatment setting (adjuvant vs. definitive), and nutritional risk. **Results:** Of the 118 patients who participated in the study, the median age was 62 years (range, 23-87), 67% were male, with a primary tumor site in the oral cavity (33%), oropharynx (30%, 53% of which were HPV-related), or elsewhere (37%), at stage I/II (30%), III (27%) or IVA/B (43%). Nutritional risk was present in 54% of the patients. Treatment was delivered in the adjuvant (52%) or definitive (48%) settings, with (55%) or without (45%) concurrent chemotherapy. Radiation doses were 60-70 Gy, or $\geq$ 70 Gy in 91% and 9% of the cases, respectively. Overall, 90% of patients adhered to all prescribed laser therapy sessions. The cumulative incidence of any grade mucositis was 65% (95% confidence interval [CI] 14.6-34.8%), significantly lower than historical controls (P=0.001). The incidence of grade 3/4 mucositis was 28% (95% CI 29.8-52.3%). Analysis of secondary endpoints will be presented at the meeting. The average time from mucositis onset to resolution was 23 days (SD=15.4). **Conclusions:** The study met its primary endpoint, demonstrating a statistically significant reduction in the cumulative incidence of any grade mucositis with prophylactic laser therapy, as compared to historical controls. The data support further evaluation of this strategy in randomized clinical trials. Research Sponsor: None.

12121 Poster Session

Routine, prospective DPYD genotyping guided dose-individualisation for patients receiving fluoropyrimidines: Implementation, prevalence and patient safety outcomes from a multi-institutional clinical trial.

Mark Nalder, Tivya Kulasegaran, Ben Lundie, Rick Woods, Melissa A. Eastgate, David Wyld, Matthew E. Burge; Royal Brisbane and Women's Hospital and University of Queensland, Brisbane, Australia; Royal Brisbane And Women's Hospital, Brisbane, Australia; Pathology Queensland, Brisbane, Australia; Royal Brisbane and Women's Hospital, Herston, Australia; Royal Brisbane and Women's Hospital, Herston, QLD, Australia; Royal Brisbane and Women's Hospital, Brisbane, QLD, Australia

Background: Prospective data regarding the prevalence of DPYD variant alleles and the impact of genotype guided dosing on safety and efficacy of fluoropyrimidines (FP) remains limited. We assessed the feasibility and safety impact of routine, prospective, DPYD genotype guided FP dosing. **Methods:** Adult patients (>18 years), commencing FP for the first time were enrolled. Sanger PCR sequencing was designed to target DPYD variants NM_000110.4:c.1905+1G>A (DPYD*2A), NM_000110.4:c.1679T>G (DPYD*13), NM_000110.4:c.1236G>A and NM_000110.4:c.2846A>T. Dose reductions were implemented as per current international pharmacogenomic guidelines. Gr3/4 toxicity, dose reductions/delays and hospital admissions were reviewed for the first 60 days after commencement. For comparison purposes, a retrospective review of patients receiving FP without testing in a prior year was completed. **Results:** Between July 2021 – May 2023, 334 patients were enrolled for testing. 95% ECOG 0-1. 57% curative treatment intent. Mean time from phlebotomy to result 6.9 days (range 2-15). Clinician/patient acceptance was high (>95% of eligible patients starting FP were enrolled). 20 (6.0%) variant DPYD allele carriers were detected. 11 heterozygous for c.1236G>A, 5 heterozygous for C.1905+1G>A, 3 heterozygous for c.2846A>T and 1 homozygous for c.1236G>A. 295 of patients tested proceeded to receive FP. 62% received Infusional-FP, 38% Capecitabine. 39 patients commenced treatment prior to DPYD result being available (treating clinician decision). Dose modification recommendations were followed in all but two patients. 24% experienced FP related Grade 3/4 toxicity within 60 days. (23% DPYD wild type, 37% DPYD variant) versus 35% in the retrospective cohort. 16% had FP related dose delays (16% DPYD wild type, 12% DPYD variant) versus 25% retrospective cohort. 14% had FP related dose reductions (13% DPYD wild type, 25% DPYD variant) versus 12% retrospective cohort. 13% had FP related hospital admissions (13% DPYD wild type, 19% DPYD variant) versus 17% retrospective cohort. 1 death in the DPYD wild type cohort was deemed potentially related to FP. **Conclusions:** Prospective DPYD genotype guided dosing was feasible in clinical practice, with prevalence of variant alleles comparable to published literature. There was a modest reduction in risk of FP related severe toxicity, dose delays, and hospital admissions with DPYD guided dosing compared to a historical, untested cohort. Clinical trial information: ACTRN12621001117808. Research Sponsor: None.

12122 Poster Session

Aromatase inhibitor musculoskeletal toxicity (AIMT) in patients (pts) with early breast cancer (EBC): Prevalence, management, and association with non-adherence to AI.

Pietro Lapidari, Maryam B. Lustberg, Julie Havas, Martina Pagliuca, Maria Alice B Franzoi, Gwenn Menvielle, Barbara Pistilli, Christelle Jouannaud, Baptiste Sauterey, Olivier Tredan, Paul H. Cottu, Christelle Levy, Florence Lerebours, Sibille Everhard, Anne-Laure Martin, Ines Maria Vaz Duarte Luis, Antonio Di Meglio; Cancer Survivorship Program, INSERM 981, Gustave Roussy, Villejuif, France; Yale School of Medicine, New Haven, CT; Cancer Survivorship Group, INSERM Unit 981, Gustave Roussy, Villejuif, France; Cancer Survivorship Program, INSERM Unit 981, Gustave Roussy, Villejuif, France; Breast Cancer Unit, Gustave Roussy, Villejuif, France; Jean Godinot Cancer Institute, Reims, France; ICO institut de cancerologie de l'ouest, Angers, France; Medical Oncology, Centre Léon Bérard, Lyon, France; Medical Oncology, Institut Curie, Universite, Paris, France; Centre François Baclesse, Caen, France; Institut Curie, Saint Cloud, France; Unicancer, Le Kremlin-Bicêtre, France

Background: AIMT may lead to treatment discontinuation and detriment on clinical outcomes in pts with EBC. Recommended supportive care (SC) management include adequate physical activity (PA) levels, acupuncture, and physical therapy. Reasonable pharmacologic approaches include duloxetine use and switching AI. We assessed prevalence of AIMT, SC use, and non-adherence to AI. **Methods:** Postmenopausal pts with EBC treated with adjuvant AI were included from the longitudinal CANTO cohort (NCT01993498). AIMT was defined as any grade (G) articular or muscular pain (CTCAE v4.0) after 3-6 months (Y0), 1 (Y1), 3 (Y3) and 5 years (Y5) of AI. Non-pharmacologic SC included adherence to PA recommendations (≥10 MET-h/week), consulting with an acupuncturist, physical therapist, or osteopath. Pharmacological SC included use of duloxetine, oral complementary-alternative medicine (OCAM), and switching to a different AI. Non-adherence was defined as any interruption and/or permanent discontinuation of AI. Multivariable logistic regressions tested associations of reporting AIMT with subsequent SC use and with non-adherence to AI. **Results:** Among 4854 pts, 85.9% reported AIMT overall (G3 17.5%): 61.0% at Y0 (G3 9.9%), 68.5% at Y1 (G3 8.7%), 65.4% at Y3 (G3 9.0%), and 57.0% at Y5 (G3 8.8%). Pts with AIMT were younger, with higher rate of previous musculoskeletal problems, and more frequently received chemotherapy. First and second prescribed AIs were mostly letrozole (54%) and exemestane (56%), respectively. Pts reporting AIMT at Y0 were less likely, by Y1, to adhere to PA recommendations (59.3% vs 62.6%), and slightly more likely to consult with an acupuncturist (9.0% vs 7.6%), physical therapist (46.0% vs 35.0%), or osteopath (22.4 vs 16.3%) compared to pts without AIMT. Results were consistent at remaining time-points. In multivariable models, reporting AIMT was consistently associated over time only with subsequent physical therapy consultations (adjusted [a]OR [95%CI]: Y1, 1.48 [1.24-1.78]; Y3, 1.40 [1.13-1.74]; Y5, 1.45 [1.10-1.91]), but not with other non-pharmacological SC. Only 1.4% of pts with AIMT reported duloxetine use, while 25.3% OCAM use. Switching AI was reported by 19.7% of pts with AIMT (aOR of AI switch vs no AIMT 2.47 [1.59-3.83]). 18.4% of pts reporting AIMT were non-adherent to AI: 6.0% had interruptions and 17.8% permanent discontinuations. Reporting overall AIMT was associated with non-adherence to AI (aOR vs no AIMT 2.38 [1.49-3.79]). **Conclusions:** Despite AIMT was highly prevalent and associated with non-adherence to AI in this prospective cohort, uptake of recommended SC strategies to manage AIMT seemed suboptimal and inconsistent over time. This large study highlights gaps in the implementation of guideline-concordant SC and warrants efforts to maximize treatment retention among pts with EBC treated with adjuvant AI. Research Sponsor: Career Pathway Grant in Symptom Management from Conquer Cancer, the American Society of Clinical Oncology (ASCO); ANR-10-COHO-0004 (CANTO); ANR-18-IBHU-0002 (PRISM); ANR-17-RHUS-008 (MYPROBE); Rising Tide Foundation for Clinical Cancer Research.

12123 Poster Session

Phase I/II trial of gabapentin plus intranasal ketamine for the prevention and treatment of pain in patients undergoing radiotherapy for head and neck cancer.

Natalie A Lockney, Derek Smith, Lindsay Mundy, Phyllis Kilpatrick, Taylor Butler, Zachary Kohutek, Anthony Cmelak, Sean All, Ryan Whitaker, Barbara A. Murphy; Vanderbilt University Medical Center, Nashville, TN

Background: Pain is ubiquitous in head and neck cancer (HNC) patients undergoing radiotherapy (RT) with up to 40% developing chronic pain. Gabapentin initiated concurrently with RT reduces pain intensity, opioid use, and dysphagia; however, gabapentin may not fully control pain, and dose escalation may be limited by toxicity. Novel non-opioid analgesic combinations administered concurrent with RT may address these limitations. Ketamine is an N-methyl-D-aspartate (NMDA) receptor antagonist. The NMDA receptor modulates mood and pain and is involved in central sensitization. Blocking the NMDA receptor may decrease the development and severity of neuropathic pain and decrease/prevent central sensitization. In combination with other analgesics, ketamine may enhance acute and chronic pain control at lower doses thus avoiding dose-limited toxicities. We report results from the dose-finding phase I study of gabapentin plus intranasal (NAS) ketamine in HNC patients undergoing RT; phase II is ongoing. **Methods:** Eligibility: locally advanced non-metastatic HNC planned for primary or adjuvant RT with or without concurrent chemotherapy. Primary objective of phase I was to determine the maximum tolerated dose (MTD) or maximum planned dose (MPD) for NAS ketamine combined with gabapentin (300mg TID). Planned dose levels (DL) were DL1: 10 mg TID, DL2: 20 mg TID, DL3: 30 mg TID and DL 4: 40 mg TID. A phase II expansion was planned at the MTD/MPD to confirm safety and feasibility. **Results:** Eleven patients were enrolled during phase I, which has been completed. No dose limiting toxicities (DLTs) were noted at DL1, DL2 or DL3. Two DLTs were reported at DL4: grade 2 dizziness and grade 2 sedation. The MTD was ketamine 30 mg NAS TID. Six patients are enrolled on the phase II trial at the MTD which is ongoing. **Conclusions:** The MTD of NAS ketamine was 30mg TID combined with gabapentin 300mg. The Phase II expansion is ongoing. Clinical trial information: NCT05156060. Research Sponsor: Ingram Industries Pain and Symptom Management Program Endowment.

12124 Poster Session

Organ-specific immune-related adverse events and survival in patients with cancer with immune checkpoint inhibitors.

Jun Wang, Xinyue Han, Yingcui Chen, Hong Xie, Yuekai Zhang, Yu Cui, Yaping Guan; Department of Oncology, The First Affiliated Hospital with Shandong First Medical University, Jinan, China

Background: Immunotherapy with immune checkpoint inhibitors (ICIs) can lead to immune-related adverse events (irAEs). This study was designed to assess whether the occurrence of irAEs or different irAE characteristics correlates with survival outcomes in advanced cancer patients treated with ICIs. **Methods:** This cohort study included a panel of patients with advanced cancer who received ICI therapy at a single institute. Kaplan–Meier curves were generated to describe progression-free survival (PFS) and overall survival (OS) in patients with irAEs or specific irAE characteristics. **Results:** A total of 238 patients were enrolled, and 83 (34.9%) patients developed at least one irAE. The irAE development was associated with prolonged OS (not reached vs 17.8 months, HR: 0.48, $p < 0.001$), PFS (8.7 vs 4.8 months, HR: 0.63, $p = 0.003$), and an improved objective response rate (24.1% vs 10.3%, $p = 0.005$). However, irAE characteristics, including severity, number of organs or systems affected, and timing of onset, were not associated with OS. Furthermore, we observed that only skin and endocrine toxicities independently protected against OS and PFS. Based on the results from organ-specific irAEs, the first development of skin or endocrine toxicities as protective irAEs rather than other irAEs was an independent indicator for predicting OS (HR: 0.24, $p < 0.001$) and PFS (HR: 0.43, $p< 0.001$). A prognostic irAE score based on organ-specific irAEs was developed to show the effect of total protective irAEs on patient outcomes. **Conclusions:** Not all irAEs are associated with prolonged survival. Identification of organ-specific irAEs but not other irAE characteristics is useful for stratifying patients who actually respond to and benefit from ICIs across different cancer types. Research Sponsor: None.

12125 Poster Session

Association between hyperglycemia and the development of chemotherapy-induced peripheral neuropathy among patients with breast cancer.

Miriam Pearl Klahr, Khadija Faheem, Rohit R. Raghunathan, Dawn L. Hershman, Melissa Kate Accordino; Columbia University Irving Medical Center, New York, NY; Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center, New York, NY; Columbia University, New York, NY

Background: Poorly controlled diabetes is a predictor of chemotherapy induced peripheral neuropathy (CIPN), and hyperglycemia (HG) may mediate CIPN risk. The association between CIPN and HG is not well studied. Our objective was to evaluate the association between HG and CIPN development. **Methods:** The CONTRoL trial was a phase IIB randomized adaptive sequential selection trial that evaluated cryotherapy vs. compression vs. placebo to prevent CIPN in patients with Stage I-III breast cancer during taxane therapy. Patients completed the Functional Assessment of Cancer Therapy Neurotoxicity (FACT-NTX) survey at baseline, week-12, and week-24. CIPN development was defined as ≥ 5-point increase in FACT-NTX from baseline. We included patients who completed FACT-NTX at baseline and week-12. HG (any glucose ≥ 140 mmol/L) was assessed via chart review of random glucose laboratory results collected from time of taxane initiation through week-24. Patients were divided into two groups based on CIPN development (yes/no). For each group we calculated the proportion of patients with HG, and mean glucose at baseline, week-12 and week-24 with values obtained +/-7 days of specified timeframe; 95% confidence intervals were constructed. **Results:** Sixty-three patients participated in the CONTRoL study and 59 patients were included in this analysis. All 59 patients had ≥1 recorded glucose value during the 24-week period (n= 410 total values), with a median of 6 values (range 1-12) per patient. When comparing patients who did and did not develop CIPN, 29.4% vs. 20.0% were Black (p=0.72), 41.2% vs. 52.0% were Hispanic/Latino (p=0.69), 17.6% vs. 8.0% had diabetes (p=0.49) and 64.7% vs. 48.0% received docetaxel (p=0.31). There were higher rates of HG, 47.1% vs. 36.0%, in patients who developed CIPN vs. those who did not (p=0.56). Mean glucose was higher in patients who developed CIPN compared to those who did not at all timepoints (Table). **Conclusions:** In this secondary analysis, we found that almost half of patients with CIPN had HG compared to about a third of patients without CIPN, and that patients with CIPN had higher mean glucose at all timepoints compared to patients without CIPN. Due to the small sample size, differences were not statistically significant, but notable trends were observed. Further research is needed to confirm this finding and evaluate the impact of glucose lowering interventions on preventing the development of CIPN. Clinical trial information: NCT03873272. Research Sponsor: None.

Mean random glucose values at baseline, week-12 and week-24 (n=131 glucose values) stratified by CIPN development (n=59 patients).

	Patients without CIPN (n=25)	Patients with CIPN (n=34)	P-value
Baseline (n=57)	99.8 mmol/L (95%CI 90.9-108.7)	101.2 mmol/L (95%CI 88.4-113.0)	0.89
Week-12 (n=54)	122.9 mmol/L (95%CI 103.7-142.1)	132.2 mmol/L (95%CI 114.6-149.8)	0.47
Week-24 (n=20)	102.9 mmol/L (95%CI 88.5-177.3)	121.2 mmol/L (95%CI 76.8-165.7)	0.35

Acupuncture as a modality of treatment for chemotherapy-induced peripheral neuropathy in breast cancer: A phase 3 randomized controlled trial (ABC-CIPN).

Jyoti Bajpai, Venkatesh Kapu, Jasmine Modi, Sushmita Rath, Akash Pawar, Altaf Siddiqui, Sadhana Kannan, Anbarasan Sekar, Sravan Kumar Chintala, Laboni Sarkar, PRABHAT GHANSHYAM BHARGAVA, Seema Gulia, Rajiv Sarin, Shripad Dinanath Banavali, Rajendra A. Badwe, Sudeep Gupta; Tata Memorial Centre, Mumbai, India; Department of Medical Oncology, Mumbai, India; Acushashtra, Mumbai, Maharashtra, India; Tata Memorial Hospital, Mumbai, India; Tata Memorial Hospital, Advance Centre for Treatment, Research and Education in Cancer, Navi Mumbai, India; Tata Memorial Hospital, Mumbai, Maharashtra, India; Tata Memorial Hospital, Tata Memorial Centre, Mumbai, India; Tata Memorial Hospital and Homi Bhabha National Institute, Mumbai, India; Tata Memorial Centre, Homi Bhabha National Institute, Mumbai, India

Background: Chemotherapy-induced peripheral neuropathy (CIPN) is a major adverse effect in early breast cancer (EBC) and is an unmet need. The study aimed to evaluate the efficacy & safety, of acupuncture on CIPN. **Methods:** We conducted a prospective, single-center, open-label, phase 3 randomized controlled trial at a tertiary care Indian center. EBC, ≥18 years with ≥grade (gr) 1 CIPN after paclitaxel chemotherapy were block randomized (1:1), & stratified by age (≥/<60 years), to Test (Acupuncture with usual care including pregabalin 75 mg & duloxetine 30 mg, both twice a day per orally, for 4 weeks) & control arm (Usual care alone). Acupuncture was delivered for 12 sessions in gr 1 & 18 sessions in ≥2 CIPN. The primary endpoint was to assess the efficacy of acupuncture in improving QOL as assessed by the sensory score (SS) of QLQ-CIPN20, Pain symptom score (PSS) of QLQ-C30, and total pain score (TPS) by Pain detect scale, and overall QoL by QLQ-C30 at 8 weeks in comparison to baseline (CTRI/2021/01/030480). **Results:** The median (IQR) age was 50 (43-57) years. Women in test arm in comparison to the control had a significantly higher improvement (decrease) of 26.23 (95% CI 18.52-33.93) versus (Vs) 6.32 (95% CI -1.23 to 13.87) points respectively in CIPN SS at week 8 compared to baseline(least-squares mean difference (LSMD), 19.90 points (95%CI, 11.80-28, P<0.0001). Similarly, patients in test arm had a higher improvement (decrease) of 7.31 (95% CI 5.47-9.13) points Vs 1.12 (95% CI -0.67-2.91) points (LSMD, 6.20 points; 95% CI, 4.30- 8.10; P<0.0001) in TPS of pain detect scale and improvement (decrease) of about 11.56 (95% CI 4.22-18.91) points Vs 3.27 (95% CI -3.93 to 10.47, P=0.0151, in PSS of EORTC QOL-C-30 scale. Additionally, higher improvement (enhanced) in overall QOL, in the test Vs control arm, -7.143(95% CI -13.95 to -0.331) Vs -0.654 (95% CI -7.33 to 6.023); P=0.0020, was noted at week 8. Using the mixed-model approach over the 6 months (secondary end points), average EORTC QLQ-CIPN20 SS was 29.8 (SE, 2.34) in test Vs 38.2 (SE, 2.3) in control arm [difference -8.0 points (95% CI, -14.9 to -1.9; P = 0.0020)]. Average QoL score was 9.71(SE, 0.729) in test Vs 12.21 (SE, 0.716) in control arm [difference 14.3 points (95% CI, 8.2 to 20.5; P = 0.0007)] & average TPS (pain detect) was 18.0 (SE, 2.72) Vs 18.3 (SE, 2.67) [difference -2.5 points (95% CI, -4.5 to -0.5; P=0.0001)] & PSS (QLQ-C30 scale) was 29.4 (SE, 2.45) Vs 37.2 (SE, 2.41) [difference -7.8 points (95% CI, -14.6 to -0.9; P=0.0001)] in test Vs control arm respectively. **Conclusions:** Early breast cancer women with CIPN after (neo) adjuvant taxane therapy experienced a significant and clinically meaningful improvement in taxane induced CIPN related quality of life as a result of an 8 week acupuncture protocol. The results are potentially practice changing and merits consideration as a new standard of care globally in this unmet need. Clinical trial information: CTRI/2021/01/030480. Research Sponsor: TMC-Research Administrative Council (TRAC).

Direct oral anticoagulant versus low molecular weight heparin for venous thromboembolism in patients receiving immune checkpoint inhibitors.

Cho Han Chiang, Yu-Cheng Chang, Zhiting Tang, Xin Ya See, Kuan-Yu Chi, Yu Chang, Cho Hung Chiang, Jingyi Gong, Lauren Mary Curtis, Tomas G. Neilan; Mount Auburn Hospital, Harvard Medical School, Cambridge, MA; Department of Medicine, Danbury Hospital, Danbury, CT; Department of Medicine, Unity Hospital, Rochester Regional Health, Rochester, NY; Unity Hospital, Rochester Regional Health, Rochester, NY; Department of Medicine, Jacobi Medical Center, Albert Einstein College of Medicine, Bronx, NY; National Cheng Kung University College of Medicine, Tainan, Taiwan; National Taiwan University Hospital, Taipei, Taiwan; Brigham and Women's Hospital, Boston, MA; Mount Auburn Hospital, Cambridge, MA; Massachusetts General Hospital, Boston, MA

Background: The two most common therapies for the treatment of cancer-associated venous thromboembolism (VTE) are low molecular weight heparin (LMWHs) and direct oral anticoagulants (DOACs). However, there is a paucity of data on the optimal anticoagulation strategy specifically among patients receiving immune checkpoint inhibitors (ICIs). Therefore, we aimed to evaluate the comparable safety and efficacy of DOACs versus LMWHs in the treatment of VTE among patients receiving ICIs. **Methods:** We conducted a retrospective, propensity score-matched cohort study using the TriNetX Analytics Network, which contains de-identified data from over 120 healthcare institutions and 250 million patients. We included adult cancer patients who have received ICI therapy including nivolumab, pembrolizumab, atezolizumab, durvalumab, avelumab, cemiplimab, ipilimumab, dostarlimab and who also received a diagnosis of VTE. Patients treated with DOACs were matched in a 1:1 ratio to patients treated with LMWHs based on the variables: age, sex, metastatic disease, cancer therapy, underlying comorbidities, Khorana score, and history of intracranial and gastrointestinal bleeding. The primary outcome was the occurrence of a new VTE, a composite of pulmonary embolism (PE) and deep venous thrombosis (DVT). The safety outcomes included all-cause mortality, intracranial hemorrhage, and gastrointestinal bleeding within 2 years following the start of anticoagulation therapy. **Results:** We matched 4608 ICI-treated patients on a DOAC to 4608 ICI-treated patients on a LMWH. In a Cox proportional hazard analysis, patients receiving DOACs or LMWH had a similar risk of a subsequent VTE event (Hazard ratio (HR), 1.13 [95% CI: 0.84-1.50]). When comparing different types of VTEs, the DOAC group was associated with a lower risk of PE (HR, 0.72 [95% CI: 0.54-0.96]) and a similar risk of DVT (HR, 0.87 [95% CI: 0.70-1.09]) compared to LMWHs. Furthermore, DOACs were associated with a lower risk of intracranial hemorrhage and all-cause mortality. There were no detectable differences in the risk of gastrointestinal bleeding between the two groups. **Conclusions:** DOACs were associated with a similar risk for subsequent VTE events but a lower risk of intracranial bleeding as well as an improvement in mortality compared to LMWHs among ICI-treated patients with a diagnosis of VTE. Prospective trials are needed to validate these findings. Research Sponsor: None.

	DOAC		LMWH			
Outcomes	Patients at Risk	Cases	Patients at Risk	Cases	Hazard Ratio (95% CI)	P-value (Log-Rank)
Composite VTE	967	97	1185	91	1.13 (0.84-1.50)	0.42
Pulmonary embolism	2318	83	2359	105	0.72 (0.54-0.96)	0.025
Deep venous thrombosis	2639	152	2866	161	0.87 (0.70-1.09)	0.22
All-cause mortality	4608	2144	4608	2996	0.55 (0.52-0.59)	<0.001
Intracranial hemorrhage	4411	90	4395	108	0.69 (0.52-0.91)	0.008
Gastrointestinal bleeding	4035	186	4012	178	0.87 (0.71-1.08)	0.20

Effect of enhanced recovery after radiotherapy (ERAR) on the quality of life in patients with nasopharyngeal carcinoma after radiotherapy: A randomized controlled trial.

Nan Lin, Xueyan Zhou, Xuelei Ma; West China Hospital, Chengdu, China; West China Hospital, Sichuan University, Chengdu, China

Background: Nasopharyngeal carcinoma (NPC) is a common disease in Southern China and Southeast Asia. Radiotherapy is an essential treatment for locoregionally advanced NPC (LA-NPC). Although Enhanced Recovery After Surgery (ERAS) is widely used in surgical settings, the guidelines do not systematically address the specific roles of various disciplines involved in radiotherapy rehabilitation. Therefore, we propose the concept of Enhanced Recovery After Radiotherapy (ERAR), which is considered to be a vital complement to radiology. **Methods:** We enrolled patients with stage III to IVA LA-NPC in this study. Participants completed baseline surveys before random assignment. ERAR interventions were implemented during radiotherapy to develop systematic management plans in the aspects of nursing, oral care, psychology, rehabilitation, nutrition, and skin health. The control group received conventional radiotherapy. Outcomes were evaluated at the 17th and 33rd radiotherapy sessions. We used generalized estimating equations to evaluate group by time effects on the outcomes, controlling for key covariates. **Results:** A total of 108 LA-NPC patients with a mean age of 48.3 ± 11.0 years were enrolled in the study group from August 2021 to September 2023. Across all time points, the ERAR group showed significant improvements in Hospital Anxiety and Depression Scale (HADS) anxiety (P <.001), HADS depression (P <.001), distress thermometer (P =.049), quality of life (P =.014), NRS2002 (P =.040), weight loss (P <.001), and Oral Health Impact Profile-14 (OHIP-14) (P =.040) scores compared with the conventional care group. **Conclusions:** The ERAR pathway has a significant benefit on reducing acute radiation-induced toxicity in patients with LA-NPC. It is hoped that this study will provide a reference for clinicians and promote the implementation of a standardized protocol for rapid recovery from radiotherapy. Clinical trial information: ChiCTR2300075874. Research Sponsor: None.

Outcome	Type of Outcome	Interaction Estimate (SE)	Interaction *P* Value
HADS Anxiety	Continuous	0.55(0.09)	<0.001[a]
HADS Depression	Continuous	0.48(0.08)	<0.001[a]
DT	Continuous	0.19(0.10)	0.049[a]
QLQ-C30-Quality of life	Continuous	-0.12(0.05)	0.014[a]
NRS2002	Continuous	0.11(0.06)	0.040[a]
Weight Loss	Continuous	-0.02(0.01)	0.001[a]
OHIP-14	Continuous	-0.57(0.17)	0.001[a]

SE, Standard Error.

12129 Poster Session

Deep mapping of the cytokine release syndrome inflammatory continuum: Comprehensive grade-specific profiling and differentiation from sepsis in patients receiving immune checkpoint therapy.

Michel Obeid, Douglas Daoudlarian, Amandine Segot, Sofiya Latifyan, Hasna Bouchaab, Nuria Mederos, Karim Abdelhamid, Nabila Ferahta, Athina Stravodimou, Keyvan Shabafrouz, Solange Peters, Giuseppe Pantaleo; CHUV, Lausanne, Switzerland; Department of Oncology, University of Lausanne, Lausanne, Switzerland; Lausanne University Hospital, Lausanne, Switzerland; University Hospital of Lausanne, Lausanne, Switzerland; Oncology Department, Lausanne University and CHUV, Lausanne, Switzerland

Background: The delineation of cytokine release syndrome (irCRS) from sepsis and its transition to compensatory anti-inflammatory response syndrome (irCARS) is crucial during ICI therapy for personalized care. **Methods:** We conducted an extensive biological and immune profiling on PBMC and serum from 38 oncology patients with various irCRS grades, including immune-related hemophagocytic lymphohistiocytosis irHLH (n=9) and sepsis during ICI treatment (n=8). **Results:** Our results show a dominant Th1 response in irCRS. Early markers of irCRS increased progressively with clinical severity in different grades, especially CXCL9, CXCL10 and IFN-γ levels. Starting with low-grade (G) (G1 and 2), a concomitant irCARS response was detected, characterized by an initial increase in IL-1RA and a significant upregulation of IL-10 specifically in G4. 3 subclusters with different overall survival (OS) and cytokine profiles were identified using routine biomarkers. Cluster 1 (C1, n=7) and Cluster 2 (C2, n=17) showed a 2-year OS of 100% and 48.49%, respectively (HR=4.025 [95% CI = 1.052-15.39], *p*=0.0419) and differed with higher levels of CCL3/11, CXCL10 and Il-1RA. Cluster 3 (C3, n=3) had the lowest OS, 6-month OS of 0%, and a distinct biological profile with highest levels of CXCL8/12/13, IL1-RA, IL-6, IL-21, HGF, significantly different from C1 (HR=111.4 [95% CI=6.63-1871], *p*=0.0011) and C2 (HR=30.04 [95% CI=2.686-335.9], *p*=0.0256). In 12 patients with severe irCRS (G3 and 4) and refractory to steroids, treatment with tocilizumab (TCZ) resulted in 100% resolution. In irHLH patients (n=9), the clusters retained their prognostic impact. Similarly, in irHLH with poor prognosis (irHLH cluster 3, n=3), high levels of CXCL8/12/13, IL-6 and IL-21 were identified. 13 patients with sepsis-like symptoms (irHLH, n=8; or sepsis during ICI, n=5) showed distinct cytokine and immune cell profiles. irHLH showed elevated IL-1-RA, IL-10, IL-18, IFN-γ, CXCL9/10, CCL2/3/4 while sepsis was characterized by increased IL-7. In irHLH, higher HLA-DR+/CD38+ populations were seen in T cells, monocytes, DCs and NK cells. There was significant CD62L downregulation in neutrophils during sepsis. Our decision tree using ferritin, EGF, IL-6 and leukocytes effectively discriminated irHLH from sepsis and G3 irCRS. High CXCL-9 levels predicted the diagnosis and severity of irHLH more accurately than the conventional HScore. **Conclusions:** We've identified a panel of biomarkers associated with OS. CXCL9 emerges as a superior marker, outperforming HScore. The successful treatment with TCZ underscores the importance of targeted interventions. Our decision tree enhances diagnostic accuracy for sepsis-like symptoms, aiding in the differentiation between irCRS, irHLH, and sepsis. This supports the optimal implementation of personalized strategies. Research Sponsor: None.

Patterns and risk factors of immune-related adverse events in a real-world cohort with lung cancer receiving immunotherapy.

Xiao Hu, Anastasia Gurinovich, Stacey Pan, Yana Salei, Jeffrey Lin, Susan K. Parsons; Tufts Medical Center (Cancer Center), Boston, MA; Tufts Medical Center, Boston, MA; Tufts Medical Center/Tufts University School of Medicine, Boston, MA

Background: Immune checkpoint inhibitors (ICIs) have emerged as a core pillar of lung cancer (LC) therapy, but ICIs are commonly associated with a spectrum of immune-related adverse effects (irAEs). The real-world patterns and risk factors of irAEs in LC remain uncertain. **Methods:** Patients with LC newly started on ICIs between 10/01/2018 and 09/30/2021 were retrospectively collected from the Tufts Medical Center cancer registry and pharmacy records. irAEs occurring within 12 months after initiation of ICIs were identified. Univariable logistic regression was used to assess the risk factors of irAEs. Those with p-value$<$0.20 were included in multivariable logistic regression analysis (MVA), along with clinically relevant factors. **Results:** Of 125 LC adult patients (median age: 70 years, 68 males), 104 had non-small cell lung cancer (NSCLC), 123 had advanced stages, and 16 had preexisting autoimmune diseases (ADs). Six patients were treated with dual-agent ICIs. Pembrolizumab was the most often used single agent (67.2%). In total 50 irAEs occurred in 39 patients. The most common irAEs were endocrinopathies (34%), pneumonitis (20%), dermatitis (14%), and gastrointestinal toxicity (14%) with the median onset time of 148, 136, 19, and 68 days, respectively. 70% of irAEs were grade 1 or 2. 44% of irAEs were treated with immunosuppression, 38% were referred to specialist care, and 30% required hospitalizations. 56% of irAEs resolved within 12 months and 67.9 % of those were rechallenged with ICIs. In exploratory univariable analyses among all the patients, age, small cell lung cancer (SCLC), PDL1 positivity (TPS$\geq$1%), concurrent NSAIDs use, and radiation therapy had p$<$ 0.2. In MVA, SCLC remained significantly associated with irAEs (OR=4.14, 95% CI [1.50, 12.09], p=0.007). Among NSCLC subset (N=104), age, PDL1 positivity, concurrent NSAIDs, and acetaminophen use had p$<$0.2. Age (OR=0.94, 95% CI [0.883, 0.990], p=0.026) and PDL1 positivity (OR=3.17, 95% CI [1.12, 9.87], p=0.036) remained significant in MVA (Table). **Conclusions:** Our study described the real-world patterns of irAEs in LC patients. SCLC was found to be an independent risk factor of irAEs in our cohort. In NSCLC, younger age and PDL1 positivity were associated with irAEs occurrence. Future studies are required to validate these findings in larger samples. Research Sponsor: Tufts University School of Medicine.

Multivariable regression analyses for the risk factors of IrAEs.

	All Patients (N=125)		NSCLC Patients (N=104)	
Factors	**OR**	**p-value**	**OR**	**p-value**
Age	0.962	0.085	0.937	**0.026**
Female[#]	1.411	0.429	1.001	0.999
SCLC	4.141	**0.007**		
PDL1 positivity*			3.172	**0.036**
Preexisting ADs[#]	0.952	0.946	0.341	0.366
Concurrent NSAIDs	0.408	0.215	0.207	0.167
Concurrent acetaminophen			0.623	0.506
Concurrent radiation	0.165	0.098		

[#]Sex and ADs history were included in both MVAs as clinically relevant factors.
*PDL1 status was not included in the MVA of all patients given only 4 SCLC cases had PDL1 results.

12131 Poster Session

The influence of sarcopenia and myosteatosis on severe laboratory toxicity and overall mortality in older adults with cancer receiving chemotherapy.

Efthymios Papadopoulos, Andy Kin On Wong, Sharon Hiu Ching Law, Sarah Costa, Angela Cheung, Dmitry Rozenberg, Shabbir M.H. Alibhai; Louisiana State University, Baton Rouge, LA; University Health Network, Toronto, ON, Canada; University of Toronto, University Health Network, Toronto, ON, Canada; Toronto General Hospital, Toronto, ON, Canada; Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada

Background: Older adults with cancer often present with suboptimal muscle quantity and quality prior to treatment due to disease-related catabolic effects combined with the aging process. Muscle catabolism is further exacerbated by cancer treatments leading to worse metabolic health, patient quality of life, and clinical outcomes. Our objective was to examine the impact of sarcopenia and myosteatosis on severe laboratory toxicity and overall mortality in older adults with cancer receiving chemotherapy. **Methods:** This was a retrospective cohort study of older adults who had undergone chemotherapy at the Princess Margaret Cancer Centre, Toronto, Canada from June 2015 to June 2022. A computed tomography scan after diagnosis but prior to treatment was used to assess skeletal muscle index (SMI) and skeletal muscle density (SMD) for each participant. Sarcopenia was defined as the presence of low muscle strength (grip strength $<$35.5kg for males and $<$20kg for females), low SMI, and low physical performance (walking speed $<$0.8m/s or a total Short Physical Performance Battery score of $\leq$8) prior to chemotherapy initiation. Myosteatosis was assessed through SMD in Hounsfield Units using previously published cut-offs. Severe laboratory toxicity was defined as occurrence of a grade $\geq$3 adverse event per the Common Terminology Criteria for Adverse Events (version 4.0). Severe laboratory toxicity and overall mortality were assessed from treatment initiation until treatment termination or loss to follow up. Multivariable logistic regression was used to determine the role of sarcopenia and myosteatosis in predicting occurrence of severe laboratory toxicity. Multivariable Cox regression was used to assess the risk of overall mortality. **Results:** A total of 115 older adults (mean age: 77.1 y) were included, of whom 63.5% had metastatic disease. Sarcopenia was identified in 27% of the cohort, whereas 80% had myosteatosis. A total of 132 severe laboratory toxicities occurred during the study period in 41 participants (35.7%). Sarcopenia was a significant predictor of severe laboratory toxicity (adjusted odds ratio (aOR) =3.19, 95%CI= 1.19 to 8.52, p= 0.012) after adjusting for sex, body mass index, and hemoglobin. Myosteatosis was significantly associated with overall mortality (adjusted hazard ratio (aHR)= 2.51, 95%CI= 1.12-5.61, p=0.025) after adjusting for albumin, alkaline phosphatase, and treatment intent. **Conclusions:** Sarcopenia may be used to inform the risk of severe laboratory toxicity in older adults prior to chemotherapy. Pre-treatment myosteatosis defined by low SMD predicts overall mortality in the same cohort. Optimization of skeletal muscle health through targeted exercise and nutritional interventions may improve patient quality of life and clinical outcomes in older adults with cancer receiving chemotherapy. Research Sponsor: None.

12132 Poster Session

Women's insights on sexual health after breast cancer (WISH-BREAST).

Laila Agrawal, Eleonora Teplinsky, Yana Feygin, Theresa Kluthe, Corinne Menn; Norton Cancer Institute, Louisville, KY; Valley Health System, Paramus, NJ; Norton Healthcare, Louisville, KY; Alloy Health, New York, NY

Background: Sexual health is a prevalent and distressing toxicity in women after cancer treatment. Sexual health needs and treatment require multidisciplinary management and despite the existence of guidelines on the management of sexual health, are often overlooked in the clinical setting. **Methods:** An anonymous online survey regarding sexual health for people with a current or prior breast cancer diagnosis was distributed through a social media platform (Instagram) and e-mail. Questions included demographics, breast cancer history and treatment, sexual health symptoms, and experience with medical care for sexual health symptoms. **Results:** Out of 1775 respondents, 1462 answered the question of whether or not sexual health changed after breast cancer diagnosis or treatment & were included in this analysis. Mean age: 47.7 years. 87.3% of respondents identified as white and 1.6% as Black. Stage: 0 (8.5%), 1 (38.4%), 2 (34.2%), 3 (14.8%) & 4 (2.9%). Estrogen receptor positive (81.5%), HER2 positive (27%), triple negative (12.9%). Breast cancer diagnosis or treatments caused a moderate to great deal of change to sexual health in 89.5% of respondents and a moderate to great deal of distress in 85%. The sexual health concerns are summarized in the table. 73% of participants did not receive information about sexual health from their healthcare team. Among participants who reported a change to sexual health, only 12% were satisfied with how their sexual health concerns were addressed. Treatment was not offered for sexual health concerns to 39% of respondents and 63% had not been referred to any specialists for sexual health concerns. 46% of participants had not been offered non-hormonal treatments for genitourinary concerns, 55% were told vaginal hormones were not an option, and 83% were not offered treatment for low libido despite lower sexual desire. 80% of respondents received information about sexual health from social media. Of those, 62% stated that their primary source of information on social media were health care professional accounts. **Conclusions:** In this online survey, sexual health concerns were highly prevalent and distressing after breast cancer diagnosis. There was a very low level of discussion with medical professionals and treatments were infrequently offered to patients, despite the existence of medical guidelines on sexual health care for women after cancer. Patients are turning to social media, & specifically to medical professional accounts, for information. Future efforts to address sexual needs for breast cancer survivors and thrivers are warranted. Research Sponsor: None.

Sexual Health Symptom	%
Decreased interest in sex or libido	85.8%
Vaginal dryness	78.2%
Decreased lubrication	71.8%
Decreased arousal	69.2%
Body image concerns	60.0%
Painful sex	59.4%
Fatigue	46.1%
Decreased, muted or difficulty with orgasm	41.0%
Sex is not pleasurable	33.9%

Early combination with mycophenolate mofetil for immune-related hepatitis in patients with solid tumors treated with immune checkpoint inhibitors.

Yukiko Shimoda Igawa, Tatsuya Yoshida, Yuri Yoshinami, Yukiko Hibino, Takamichi Arima, Jun Sato, Yuta Maruki, Hirokazu Shoji, Kenjiro Namikawa, Kazuki Sudo, Yoshitaka Honma, Hironobu Hashimoto, Naoya Yamazaki, Takuji Okusaka, Kan Yonemori, Noboru Yamamoto, Yuichiro Ohe, Ken Kato; Department of Thoracic Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Thoracic Oncology, and Department of Experimental Therapeutics, National Cancer Center Hospital, Tokyo, Japan; Department of Gastrointestinal Medical Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Medical Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Pharmacy, National Cancer Center Hospital, Tokyo, Japan; Department of Experimental Therapeutics, National Cancer Center Hospital, Tokyo, Japan; Department of Hepatobiliary and Pancreatic Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Dermatologic Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Head and Neck, Esophageal Medical Oncology, National Cancer Center Hospital, Tokyo, Japan

Background: Hepatitis, as an immune-related adverse event (irAE), occurs in 2%-10% of patients treated with immune checkpoint inhibitors (ICIs). Although guidelines recommend the use of mycophenolate mofetil (MMF) for steroid-refractory and steroid-resistant ir-hepatitis, there has been no evidence on the efficacy of MMF. **Methods:** We retrospectively reviewed consecutive patients with solid tumors who developed grade 2 or higher ir-hepatitis requiring systemic steroids after ICIs (nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab and ipilimumab) between January 2015 and August 2023. The changes in aspartate aminotransferase (AST), alanine aminotransferase (ALT), and total bilirubin level, according to the CTCAE version 5.0, were used to assess ir-hepatitis. ALT improvement was calculated as the ratio of the change in ALT values from onset to day 7, normalized by the ALT values at onset. **Results:** Among 4405 patients treated with ICI during the study period, 130 patients (3%) developed grade 2 or higher ir-hepatitis requiring systemic steroids. The median age was 62 (range: 19-85) years-old, and 122 patients (94%) had an ECOG performance status (PS) 0/1. These patients included 67 (52%) with melanoma, 35 (27%) with lung cancer, 7 (5%) with esophageal cancer, and 21 (16%) with other cancers. Among 123 evaluable patients, 46 patients (46/123, 37%) received MMF including 20 patients experiencing steroid-refractory and 26 steroid-resistant. The median duration from the start of systemic steroids to MMF was 11 days (range: 0-113 days). Improvement of hepatitis to grade 1 with MMF was observed in 40 patients (40/46, 87%) with a median time of 18 (range: 3-176) days. Of the patients evaluated for the impact of the timing of MMF on the improvement of ir-hepatitis (n=38), ALT improvement at day 7 after ir-hepatitis onset in patients who initiated MMF within 3 days of ir-hepatitis onset (early combination group, n=8) was significantly higher compared with the patients who initiated MMF after 3 days of ir-hepatitis onset (late combination group, n=30) (72.3% vs. 41.7%, p=0.02). Additionally, among patients evaluable for systemic steroid dosage (n=45), the total systemic steroid dosage in patients in the early combination group (n=8) was significantly less than in the late combination group (n=37) (median: 2120mg vs 4005 mg, p=0.02). **Conclusions:** MMF was effective for both steroid-refractory and steroid -resistant ir-hepatitis. Early combination with MMF in addition to systemic steroids can lead to a more rapid improvement of ir-hepatitis compared to late combination with MMF consequently reducing the total systemic steroid dosage. Research Sponsor: None.

Group	n	ALT Improvement at Day 7 (Interquartile Range: IQR), %	p
MMF early combination	8	72.3 (49.9-80.5)	0.02
MMF late combination	30	41.7 (27.3-53.0)	

LBA12134 **Poster Session**

A randomized trial to assess the effect of oral cryotherapy in the prevention of mucositis in patients with head and neck cancer receiving chemo-radiotherapy.

Nandini Sharrel Menon, Vijay Maruti Patil, Vanita Noronha, Arunkumar Ravichandran, Minit Jalan Shah, Sarbani Laskar, Ashwini Budrukkar, Monali Swain, Shwetabh Sinha, Anuj Kumar S, Devanshi Kalra, Gargi Patlekar, Ami Patel, Priyanka Bhagyavant, Anokhi Shah, Alok Parekh, Jaspreet Kaur, Swapnil Nirankari, Raveendranath Puviarasan, Kumar Prabhash; Tata Memorial Centre, Mumbai, India; Hinduja Hospital, Mumbai, India; Tata Memorial Hospital, Tata Memorial Centre, Mumbai, India; Jawaharlal Institute of Post-Graduate Medical Education & Research, Pondicherry, India; Tata Memorial Hospital, Mumbai, India; Cancer Research and Statistic Foundation, Dahisar, India; Tata Memorial Cancer Centre, Mumbai, India

12135 Poster Session

The influence of psychosocial factors on first-time chemotherapy-induced nausea and vomiting: A prospective multicenter cohort study.

Xiaoxiao Shi, Liang Xu, Jie Liu, Ying Wang, Xiaoyun Yang, Hongyu Zhuo, Jie Zhang, Ye Chen, Hongmei Xiao, Ke Xie, Wuning Zhong, Yu Jiang, Yaotiao Deng; Department of Oncology, Chengdu Shang Jin Nan Fu Hospital/ Shang Jin Hospital of West China Hospital, Sichuan University, Chengdu, China; Breast Disease Center, Cancer Center, West China Hospital, Sichuan University, Chengdu, China; West China Hospital of Sichuan University, Chengdu, China; Department of Oncology, Sichuan Provincial People's Hospital, University of Electronic Science and Technology of China, Chengdu, China; Department of Oncology, Panzhihua University Affiliated Hospital, Panzhihua, China; Department of Oncology, The First Affiliated Hospital of Chongqing Medical University, Chongqing, China; Department of Medical Oncology, Cancer Center, West China Hospital, Sichuan University, Chengdu, China; Oncology Department, Affiliated Hospital of Zunyi Medical University, Zunyi, China; Department of Oncology, Sichuan Academy of Medical Sciences and Sichuan Provincial People's Hospital, School of Medicine, University of Electronic Science and Technology of China, Chengdu, China; Department of Breast, Bone & Soft Tissue Oncology, Guangxi Medical University Cancer Hospital, Nanning, China

Background: Previous studies have suggested that if cancer patients experience no chemotherapy-induced nausea and vomiting (CINV) or mild symptoms during their first chemotherapy cycle, they are less likely to experience CINV in subsequent cycles, suggesting that the optimal intervention time may be before the first chemotherapy cycle. Consequently, attention should be paid to relevant risk factors. Currently, there is a lack of data on psychosocial risk factors related to chemotherapy among cancer patients in China. **Methods:** This study was a multicenter, prospective cohort study that included cancer patients from seven hospitals' oncology departments who were scheduled to undergo their first chemotherapy cycle. The chemotherapy regimens administered were either highly or moderately emetogenic protocols. Demographic and baseline clinical characteristics were recorded by clinical oncologists. Participants were asked to complete the Distress Thermometer (DT), the Mini-Mental Adjustment to Cancer (Mini-MAC), and a risk factor questionnaire the day before chemotherapy, and to keep a daily diary describing their CINV experiencing for 21 days after chemotherapy. **Results:** Between October 2022 and November 2023, a total of 1100 cancer patients were enrolled in this study and 972 cancer patients completed all the questionnaires. A total of 64.1% reported CINV during the first chemotherapy cycle. In logistic regression analysis, CINV was predicted by higher PS score (OR=1.411, p=0.049), highly emetogenic regimens (OR=1.846, p=0.004), failure to follow anti-emetics guidelines (OR=2.323, $p<0.001$), history of nausea/vomiting for other reasons(OR=1.817, p=0.001), lower number of hours slept before the night of chemotherapy (OR=8.987, $p<0.001$), expectancy of CINV(OR=1.505, p=0.032), maladaptive coping (OR = 1.03, p = 0.024) and distress (OR = 1.157, p =0.021). **Conclusions:** Psychosocial factors significantly correlate with chemotherapy-induced nausea and vomiting (CINV) among Chinese cancer patients. These findings underscore the importance of integrating psychosocial assessments into the management of CINV, potentially improving treatment outcomes and patient experiences. Research Sponsor: None.

12136 Poster Session

AI-based radiomics model for predicting immune checkpoint inhibitor–related pneumonitis (CIP) in patients with advanced NSCLC: An external validation study.

Seyoung Lee, Haojia Li, Amogh Hiremath, Jeeyeon Lee, Haseok Kim, Kai Zhang, Salie Lee, Monica Yadav, Liam IL Young Chung, Hye Sung Kim, Trie Arni Djunadi, Yuchan Kim, Ilene Hong, Grace Kang, Amy Cho, Yury Velichko, Vamsidhar Velcheti, Anant Madabhushi, Nathaniel Braman, Young Kwang Chae; School of Medicine, Kyungpook National University, Daegu, South Korea; Picture Health, Cleveland, OH; Kyungpook National University Hospital, Daegu, South Korea; University of Texas at Austin, Weatherford, TX; Picture Health Inc., Cleveland, OH; Feinberg School of Medicine, Chicago, IL; Feinberg School of Medicine, Northwestern University, Chicago, IL; Richmond University Medical Center, Staten Island, NY; Northwestern University, Chicago, IL; NYU Perlmutter Cancer Center, New York, NY

Background: The growing implementation of immunotherapy in advanced non-small cell lung cancer (NSCLC) management has led to an increase in adverse events, notably immune checkpoint inhibitor-related pneumonitis (CIP). CIP, a significant and potentially fatal complication, often necessitates the discontinuation of immunotherapy, thereby impacting patient outcomes severely. The absence of biomarkers for early detection and management of CIP represents an urgent and unmet clinical need. This expanded study explores the potential of Artificial Intelligence (AI) algorithms in predicting CIP in NSCLC patients undergoing immunotherapy from pre-treatment CT scans. **Methods:** A cohort of 220 stage III-IV NSCLC patients receiving immunotherapy was considered. The patients were divided into a training set (D1, n=105, Institution A), an internal validation set (D2, n=45, Institution A), and an external validation set (D3, N=70, Institutions B and C). Manual delineation of the tumor on baseline CT was performed by three physicians working in consensus. The Picture Health Px platform was employed for AI-powered deep phenotyping of the tumor and its surrounding habitat, including segmentation of the tumor associated vasculature and featurization. Quantitative features relating to the twistedness of the tumor-associated vasculature and tumoral heterogeneity patterns were extracted. These features were used to train a neural network classifier for CIP prediction. Weighting techniques during training were used to compensate for the rarity of CIP. A threshold for CIP classification was set within D1 and applied to the testing sets. **Results:** 43.6% of patients received an immunotherapy-only regimen and 56.4% received combined immunochemotherapy. Of these, 18.2.% experienced pneumonitis events, with 50.0% being CIP. The CIP subgroup had 50.0% grade 1 CIP, 30.0% grade 2, and 20.0% grade 3. The cross-validated AUC on D1 was 0.76 (95% CI: 0.62-0.90). The AUC was 0.61, 0.62, and 0.64, respectively, on D2, D3, and all validation data combined (D2+D3). The model correctly identified 71.4% of grade 1/2 CIP events and 33.3% of grade 3 CIP, with a corresponding false positive rate of 33.0%. Severe/grade 3 IO-related pneumonitis prediction was likely limited by the small number of severe cases from the training institution (n=1). **Conclusions:** We demonstrated a radiomic AI signature could identify patients at risk of CIP prior to treatment across multiple external institutions. This approach could improve the identification and management of CIP in NSCLC patients on immunotherapy, thereby enhancing patient outcomes. Expanded training and validation to account for rare, but possibly fatal, high grade CIPs is needed to expand the clinical benefit of radiologic predictors of pneumonitis to the most severe cases. Research Sponsor: None.

12137 Poster Session

Quantification of treatment-related time toxicity in patients with advanced stage cancer.

Yuhang Zhou, Madeline Campbell Fitzpatrick, Marisabel Hurtado Castillo, William Steele Sessions, Kyaw Lwin Aung, Om Narayan Pandey, Boone Wilder Goodgame; University of Texas at Austin, Austin, TX

Background: Treatment-related Time Toxicity (TrTT) in cancer patients is a recently proposed metric to describe the burden of time spent in pursuing medical care, including office/hospital visits, side effect management, lab tests, imaging scans, and travel time. Time toxicity is a valuable concept in patient-centered shared-decision making, especially in the palliative management of end-stage cancer patients with limited life expectancy. Despite tremendous progress in cancer treatment, most of the guideline-recommended treatment options convey short survival benefits of around 3-6 months when compared to supportive care. While medication toxicities are meticulously reviewed with patients, the cumulative burden and impact of time are rarely included in the discussion, partly due to the lack of standardized measurement of TrTT, and the absence of data from clinical trials. Thus, there is a compelling need for the quantification of time toxicity to guide clinical practice and patient preference. **Methods:** This was an observational analysis of the time toxicity from palliative treatment for patients with incurable solid tumors at a regional safety-net oncology office that focuses on underserved communities. Time toxicity is calculated as the number of days a patient spent with any healthcare-related encounters during a 3-month period from our medical record system. **Results:** The median age of the total 94 included patients was 57. 54% of the population were Hispanic. The ratios for mild, moderate, and severe time toxicity were 38%, 44%, and 18%, respectively. Immunotherapy was associated with significantly less time toxicity (TrTT = 8.5 days, 95% CI = 6.3-9.7) compared to chemotherapy (26.3 days, 95% CI = 18.3-34.4, $P < 0.001$), while targeted therapy (13.4, 95% CI = 7.0-19.8, P = 0.01) and hormone therapy (11.9, 95% CI = 4.1-19.7, $P < 0.01$) also has lower TrTT than chemotherapy. Patients with a worse performance status (ECOG PS 3-4, 30.1 days, 95% CI = 18.3-41.9) experienced higher time toxicity than fitter patients (PS 0-2, 16.7 days, 95% CI = 13.2-20.2, $P < 0.05$). Among different cancer types, gastrointestinal malignancies were associated with the highest time toxicity with average TrTT of 30.2 days/3 months (95% CI =22.5-37.2). **Conclusions:** This is the first comprehensive study to quantify real-world Treatment-Related Time Toxicity across multiple cancer and therapy types in an underserved population. We found 18% of patients with incurable solid malignancies experienced severe time toxicity (> 1 in 3 days). Higher TrTT was associated with cytotoxic chemotherapies, GI malignancies, and poor performance status. Time toxicity should be taken into account with other quality-of-life outcomes in treatment pathways and patient-centered oncology care. Research Sponsor: None.

12138 Poster Session

Comparing the characteristics and outcomes of hospitalizations between cancer and non-cancer survivors.

Lawson Eng, Amol A Verma, Xin You, Afsaneh Raissi, Deva Thiruchelvam, Alejandro Berlin, Christine Brezden-Masley, Kelvin K. Chan, Katherine Enright, Genevieve Bouchard-Fortier, Lauren Linett, Melanie Lynn Powis, Haider Samawi, Geoffrey Liu, Monika K. Krzyzanowska, Fahad Razak; Department of Medical Oncology and Hematology, University Health Network, Princess Margaret Cancer Centre, Toronto, ON, Canada; Division of General Internal Medicine, St Michael's Hospital, University of Toronto, Toronto, ON, Canada; Unity Health - St Michael's Hospital, Toronto, ON, Canada; St. Michael's Hospital and University of Toronto, Toronto, ON, Canada; Institute of Clinical Evaluative Sciences, Toronto, ON, Canada; Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada; Sinai Health System, Mountain Sinai Hospital, University of Toronto, Toronto, ON, Canada; Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, ON, Canada; Trillium Health Partners - Credit Valley Hospital, Mississauga, ON, Canada; Princess Margaret Cancer Centre, Toronto, ON, Canada; University Health Network, Princess Margaret Cancer Center, Toronto, ON, Canada; Princess Margaret, University Health Network, Toronto, ON, Canada; Juravinski Hospital and Cancer Centre, Hamilton, ON, Canada

Background: Cancer prevalence is rising, with a corresponding increase in hospitalizations across the cancer continuum. However, little is known about how in-hospital patterns of care and outcomes of cancer survivors compare with non-cancer survivors as administrative data may not capture in-hospital details (e.g., investigations and medications) required for characterization. Understanding differences in how cancer and non-cancer inpatients are managed and their outcomes can help optimize their acute care delivery. **Methods:** In a multicenter registry of all patients (pts) admitted to medical wards across 26 hospitals (Ontario, Canada) from 2015-2022, we deterministically linked population-level administrative data, including ambulatory oncology data for cancer survivors, with each hospital's electronic information (pharmacy, orders, notes, laboratory, imaging) at the patient level. Multivariable regression models compared resource use and outcomes between cancer and non-cancer pts for the top 5 discharge diagnoses among non-cancer pts. **Results:** Of 1,221,067 hospitalizations belonging to 666,569 pts, 30% of medical ward hospitalizations were for pts with a cancer history, with median admission date 4 years post-diagnosis; most common cancer sites were genitourinary (21%), gastrointestinal (20%), breast (12%), lung (10%). Most common discharge diagnoses among cancer pts were heart failure (HF) (5%), palliative care (5%), urinary tract infection (UTI) (2%), pneumonia (2%) renal failure (2%); while for non-cancer pts were HF (5%), myocardial infarction (3%), coronary artery disease (3%), COPD (2%) and UTI (2%). Compared to non-cancer pts, cancer pts were older (72 vs 66), had greater length of stay (LOS; 10 vs 8.7 days), in-hospital mortality (11% vs 6%) and 30 day re-admission rates (16% vs 11%) and were more likely to receive CTs (21% vs 15%), MRIs (9% vs 8%) and interventional procedures (6% vs 4%) ($p < 0.001$, all comparisons). When evaluating the top 5 discharge diagnoses among non-cancer patients, cancer survivors had higher LOS (aOR=1.06 95% [1.05-1.07] $p<0.001$), in-hospital mortality (aOR=1.20 [1.14-1.26] $p<0.001$), and 30 day re-admission rates (aOR=1.24 [1.14-1.35] $p<0.001$) and were more likely to receive CTs (aOR=1.25 [1.21-1.30] $p<0.001$), MRIs (aOR=1.36 [1.25-1.48] $p<0.001$) and interventional procedures (aOR=1.36 [1.25-1.47] $p<0.001$). Subgroup analyses focusing on cancer survivors admitted 3 and 5 years out from their diagnosis showed resource use and outcomes were closer to non-cancer patients. **Conclusions:** Cancer survivors represent a unique population on medical wards and have higher resource use, mortality and LOS compared to non-cancer patients, even for the same non-cancer diagnoses. Specialized models of care for hospitalized cancer survivors may be warranted, in particular for those admitted closer to their diagnosis date. Research Sponsor: Conquer Cancer, the ASCO Foundation; Canadian Institute of Health Research; Canadian Cancer Society Research Institute; Hold'Em For Life; University of Toronto; St Michael's Hospital.

12139 Poster Session

Interventions of the nurse navigator in the identification and management of toxicities after the start of treatment in patients with cancer using antineoplastic therapy.

Anna Carolina R Messias, Cristiane Decat Bergerot, Andre Faria, Camila Tolomelli Gregoli, Alice Sousa Vidal, Juliana Torres Carneiro, Bruno Lemos Ferrari; Oncoclinicas & Co - Medica Scientia Innovation Research (MEDSIR), São Paulo, Brazil

Background: Monitoring symptoms during chemotherapy is crucial as patients experience adverse effects, requiring therapeutic modifications, supportive care, and education. Patient navigation provides individualized assistance, overcoming barriers to healthcare access for patients, families, and caregivers. A previous study (Tabriz et al. JAMA Netw Open 2023) has shown that 52% of emergency room (ER) visits can be preventable. Thus, this study sought to determine effect of a nurse navigation program on reducing the rate of ER visit. **Methods:** This retrospective study was conducted from June to December 2023 in two cancer centers within the Oncoclinicas Network, located in the Southeast and Northwest regions of Brazil. Eligible patients were diagnosed with breast, lung, and gastrointestinal cancer, and were undergoing treatment with chemotherapy and/or immunotherapy. These patients were monitored by nurse navigators at post-therapy. Interventions were categorized as home management (care provided at patient's home), outpatient (referral to the treatment clinic), and hospital (referral to emergency care). All toxicities were graded according to the Common Terminology Criteria for Adverse Events 5.0. **Results:** A total of 531 patients were included in the analysis, with the majority aged over 61 years old (44.4%), diagnosed breast (%) or colon (%) cancers. Throughout the six month study period, 3,201 toxicities were identified, with the majority graded between 1 and 2 (95.9%). This resulted in 91.9% of patients being managed at home or referred to the outpatient care. The cumulative proportion of patients having their symptoms managed at home or outpatient care is significantly higher than historical controls (P=0.001). **Conclusions:** Our findings highlight the effectiveness of a nurse navigation program in managing toxicities and symptoms, preventing ER visit. These findings underscore the importance of this program in optimizing patient care and reducing the burden on healthcare facilities. Further research and implementation of such programs may contribute to improved outcomes and patient satisfaction in oncological care. Research Sponsor: None.

12140 Poster Session

Association of a germline single nucleotide polymorphism (SNP) in the interleukin-7 (IL7) gene with immune-related adverse events (irAEs) in the CheckMate 025 trial.

Eddy Saad, Chris Labaki, Renee Maria Saliby, Karl Semaan, Marc Eid, Maxine Sun, Elad Sharon, Sai Vikram Vemula, Saurabh Gupta, Eliezer Mendel Van Allen, Alexander Gusev, Toni K. CHOUEIRI; Dana-Farber Cancer Institute, Boston, MA; Department Medicine, Beth Israel Deaconess Medical Center, Boston, MA; DFCI/PCC Fellowship Program - Attendings, Boston, MA; Bristol Myers Squibb, Princeton, NJ; The Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, Boston, MA

Background: Immune checkpoint inhibitors (ICIs) have dramatically improved outcomes of patients (pts) with metastatic renal cell carcinoma (mRCC). Unfortunately, adverse events (AEs) can limit treatment efficacy and worsen patient outcomes. Recently, a germline IL7 SNP (rs16906115) was identified as a potential biomarker for prediction of irAEs. We aimed to characterize the association between a germline IL7 SNP (rs16906115) and AEs in a prospective clinical trial of patients with mRCC treated with nivolumab (NIVO) or everolimus (EVE). **Methods:** Whole-exome sequencing (WES) data of tumor and peripheral blood samples from CheckMate 025 (NCT01668784) were used to infer somatic alterations using the Cancer Genome Analysis pipeline, as well as SNP carrier status using the STITCH pipeline. Within each treatment arm, time to incident adverse events (AEs) were compared between carriers (SNP+) and non-carriers (SNP-) via multivariable Cox regression, controlling for age, sex and sample purity, followed by a SNP´treatment interaction term in the whole cohort. Overall survival (OS) and progression-free survival (PFS) were also assessed. Finally, a recurrent event analysis for AEs was conducted using the Andersen-Gill model, controlling for the same variables. **Results:** In total, 382 pts were included (NIVO: n=189, EVE: n=193), among which 56 (14.7%) were SNP+. There were no differences in clinical and pathological characteristics between SNP+ and SNP-, except for sex (SNP+ 16.1% vs. SNP- 30.1% females, P=0.046). Similarly, no differences in somatic alterations, including single nucleotide and copy number variants were seen between SNP+ and SNP-. SNP carrier status had no effect on OS nor PFS in both treatment arms (all $P \geq 0.47$). Regarding AEs, 63 pts (33.3%) in the NIVO arm experienced at least 1 grade 2+ AE, compared to 78 pts (40.4%) in the EVE arm. The most common types of grade 2+ AEs were cutaneous (21.0%), hepatobiliary (16.8%) and endocrine (15.8%) in the NIVO arm, and respiratory (30.1%), cutaneous (22.3%) and gastrointestinal (19.4%) in the EVE arm. The rate of grade 2+ AEs was significantly higher in SNP+ vs. SNP- in the NIVO arm (HR=2.91 [1.48-5.72]), but not in the EVE arm (HR=0.63[0.3-1.29], SNP´treatment $P_{interaction}$=0.002). The rate of recurrent grade 2+ AEs was also significantly higher in SNP+ vs. SNP- in the NIVO arm (HR=3.43[1.83-6.43]), whereas a trend for fewer recurrent grade 2+ AEs was seen in SNP+ vs. SNP- in the EVE arm (HR=0.46[0.17-1.25], SNP´treatment $P_{interaction}$=0.0005). **Conclusions:** The IL7 SNP (rs16906115) is associated with significantly higher rates of grade 2+ AEs, including recurrent events, in pts with mRCC treated with NIVO but not with EVE, with no effect on survival outcomes. These results affirm the SNP's predictive potential as a biomarker for irAEs to guide therapeutic decisions in pts treated with ICIs. Research Sponsor: None.

12141 Poster Session

Pilot evaluation of portable scalp cooling for chemotherapy-associated alopecia in early-stage breast cancer.

David B. Page, Erin Hong, Lakhvir Kaur, Sarah Gauntt, Holley Gedney, Evthokia Hobbs, Kelly Shea Perlewitz, Amanda Seino, Zheng Zhu Topp, Alison Katherine Conlin; Providence Cancer Institute, Portland, OR

Background: Chemotherapy-induced alopecia significantly impacts quality of life (QOL). First-generation scalp cooling systems PAXMAN and Dignicap, while effective in reducing alopecia, are not universally adopted due to their lack of portability. Amma is a second-generation, portable and battery-powered scalp cooling system that offers the opportunity for widespread clinical usage by allowing self-administration and mobility. Here, we report first-in-human outcomes of Amma in a preliminary cohort receiving curative-intent taxane-based chemotherapy for early-stage breast cancer. **Methods:** We conducted a pilot clinical trial (NCT05508984) of the Amma system at Providence Cancer Institute in Oregon. Key inclusion criteria included: no baseline alopecia [Dean's scale 0], intent to receive 4-6 cycles of taxane-based, anthracycline-sparing therapy, willingness to participate in quality-of-life questionnaires, and serial scalp photography. The primary outcome was the feasibility of Amma devices for adoption within the clinic ascertained by patient reported outcomes (PRO) and provider feedback. The secondary outcome was efficacy defined as the proportion of subjects achieving $<$ 50% hair loss [Dean's scale 0-2] at 30 days post-treatment, and tolerability assessed by common terminology criteria for adverse events (CTCAE). **Results:** 14 participants were enrolled and evaluable from 9/2022-1/2024. Participants received docetaxel/cyclophosphamide (TC x 4, n=10) or weekly paclitaxel/trastuzumab+/- pertuzumab (TH(P), n=4). 93% of participants (n=13/14) successfully completed treatment. One participant discontinued scalp cooling prematurely. Primary efficacy endpoint of $<$50% hair loss was achieved in 64% participants (n=9/14, [95% CI: 0.39, 0.89]) (TC: n=5/10; TH(P): n=4/4). On the validated "Was it Worth It?" questionnaire, 92% reported the treatment "worthwhile", 85% would repeat participation, and 100% would recommend it to others. After treatment, 93% reported a similar or increased QOL with participation and 71% deemed the experience "better than expected", paralleling PRO outcomes from previously published trials using first-generation cooling devices. Provider feedback was favorable regarding feasibility of treatment. **Conclusions:** Scalp cooling with the portable Amma system was both feasible and effective in this pilot study. Point estimates of efficacy were like those reported for PAXMAN (Dean's 0-2: 50%) and DigniCap (66%). A follow-up clinical trial is planned with a primary outcome of efficacy in patients receiving taxane-based chemotherapy (NCT06215469, PI: Rugo). Clinical trial information: NCT05508984. Research Sponsor: None.

12142 Poster Session

Harmonization radiomics model to predict immune checkpoint inhibitor-related pneumonitis (CIP) in patients with non-small cell lung cancer (NSCLC).

Monica Yadav, Jeeyeon Lee, Haseok Kim, Seyoung Lee, Taegyu Um, Salie Lee, Trie Arni Djunadi, Liam IL Young Chung, Jisang Yu, Darren Rodrigues, Nicolo Gennaro, Leeseul Kim, Yuchan Kim, Myungwoo Nam, Ilene Hong, Jessica Jang, Amy Cho, Grace Kang, Yury Velichko, Young Kwang Chae; Feinberg School of Medicine, Northwestern University, Chicago, IL; Kyungpook National University Hospital, Daegu, South Korea; University of Texas at Austin, Weatherford, TX; School of Medicine, Kyungpook National University, Daegu, South Korea; Feinberg School of Medicine, Chicago, IL; Richmond University Medical Center, Staten Island, NY; Northwestern University Feinberg School of Medicine, Chicago, IL; Dignity Health - St. Rose Dominican Hospital, Henderson, NV; Northwestern University, Chicago, IL; Ascension Saint Francis Hospital, Evanston, IL; Lincoln Medical and Mental Health Center, Bronx, NY; Northwestern Medicine Devleopmental Therapeutics Institute, Chicago, IL; Developmental Therapeutics, Robert H. Lurie Comprehensive Cancer Center, Northwestern University Feinberg School of Medicine, Chicago, IL

Background: The increasing use of immunotherapy in advanced non-small cell lung cancer (NSCLC) presents a significant challenge in managing adverse events, particularly checkpoint inhibitor-associated pneumonitis (CIP). This potentially life-threatening complication often necessitates discontinuation of immunotherapy, even in patients experiencing tumor response. Presently, there are no reliable models to predict the onset of CIP. This research utilizes CT radiomics to create an innovative approach for anticipating the risk of CIP in patients with NSCLC. **Methods:** This IRB-approved, retrospective study analyzed data from 159 stage III-IV NSCLC patients undergoing immunotherapy. We categorized patients into pneumonitis (further subdivided into immunotherapy-induced, radiation-induced, and others) and non-pneumonitis groups. Using LIFEx software, we extracted 3D-radiomic features from both tumors and surrounding 1cm thick peritumoral regions. To address scanner-associated variations, a linear mixed-effect radiomics harmonization model was applied. A Random Forest algorithm was then used to develop a classification model predicting CIP occurrence based on the pre-treatment CT radiomic and clinical data. The dataset was split into training (70%) and test (30%) sets. The accuracy of predictions was evaluated using confusion matrix statistics and bootstrapping with 1,000 iterations for median and 95% confidence interval (CI). The performance metrics included sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area under the ROC curve (AUC). **Results:** 159 patients were analyzed, of which only 19 had checkpoint inhibitor-related pneumonitis. Among which, 17 (54.8%) patients had grade 1 pneumonitis, 12 (38.7%) patients had grade 2 pneumonitis, 2 (6.5%) patients had grade 3 pneumonitis, and none had grade 4 or grade 5 pneumonitis. The model achieved a sensitivity of 0.98 (0.97, 0.99), a specificity of 0.08 (0.05, 0.14), a PPV of 0.91 (0.90, 0.91), and an NPV of 0.33 $\pm$ 0.23 for predicting CIP. The AUC of 0.59 (0.56, 0.66) indicates that the model may predict checkpoint inhibitor-associated pneumonitis with an accuracy of 59%. **Conclusions:** The study provides insights into the potential of radiomic analysis coupled with AI algorithms and the use of harmonization model in predicting CIP among NSCLC patients treated with immunotherapy. However, larger studies are needed to validate our findings and the utility of harmonization models in predicting CIP. Research Sponsor: None.

12143 Poster Session

Improving chemotherapy-induced alopecia for women receiving anthracycline plus taxane chemotherapy using the Paxman scalp cooling system at lower temperatures.

Shari Beth Goldfarb, Alanna Jamner, Nicolas Toumbacaris, Allison Gordon, Yuan Chen, Nadia Abdo, Analisa Dacunto, Victoria Susana Blinder, Monica N. Fornier, Cassandra Chang, Mario E. Lacouture; Memorial Sloan Kettering Cancer Center, New York, NY; Dermatology Service, Memorial Sloan Kettering Cancer Center, New York, NY; NYU Langone Health, New York, NY

Background: Chemotherapy-induced alopecia (CIA) not only impacts physical appearance but may also be detrimental to patient's psychological well-being. To address CIA, patients often use scalp cooling devices such as the FDA-approved Paxman Scalp Cooling System (PSCS), currently approved at -5°C. This study explores the potential benefits of lower temperatures, -7.5°C and -10°C, to improve the efficacy of PSCS in minimizing CIA. **Methods:** This prospective study analyzed data from 33 women with stage I-III breast cancer receiving anthracycline and taxane chemo at MSKCC from 12/2019–10/2022. Photography, trichoscopy, and toxicity checks were conducted at baseline, weeks 4, 8 (primary endpoint), end of treatment (EOT), and 24 weeks post-chemotherapy. 23 patients reached week 8, while 10 withdrew prior due to lack of efficacy (5/10), change in treatment (3/10), or anxiety (2/10). Successful hair preservation (HP) was defined as CTCAE v4 grade 0 or 1 alopecia. **Results:** At baseline, all patients had grade 0 alopecia. At week 4, 81% achieved successful HP (17/21), and at week 8, over half maintained it (53%; 9/17). The majority had HP at EOT (69%; 11/16). At 24 weeks post-chemotherapy, all patients demonstrated continued HP (100%; 11/11) and all evaluated patients at 18 months post-treatment had grade 0 alopecia (100%,4/4). Among women with baseline photographs and trichoscopy (n=25), median average hair count at baseline was 154.0 per cm^2 and width 70.2 per cm^2. By week 4 (n=21), the median average hair count decreased by 20.0%, and width decreased by 8.0% compared to baseline. By week 8 (n=17), average count improved by 15% compared to week 4 (-3% from baseline) and average width decreased by 6% (-7.5% baseline). At EOT hair count decreased 37.8% and width decreased by 11.6% compared to baseline (n=16). At 24 weeks post-EOT there was a 13% increase in median average hair count with no measurable change in width compared to baseline (n=12). No patients (0%; 0/33) reported dose-limiting toxicities (DLTs) at -7.5°C (n=7) or -10°C (n=26). **Conclusions:** Patients successfully tolerated scalp cooling at lower temperatures, with no reported dose-limiting toxicities and successful HP. This study indicates higher HP rate at EOT (69%; 11/16) compared to studies using PSCS at -5°C. Post-EOT data shows successful hair regrowth with a higher average hair count than pre-treatment. A larger sample size is needed to assess the additional benefit of lower temperatures on HP and regrowth. Clinical trial information: NCT. Research Sponsor: None.

Folliscope average hair count and width data.

Timepoint	Baseline	Week 4	Week 8	EOT	24 Post- EOT
Hair Count	154 (58, 216)	78 (48, 156)	108 (59,174)	131 (98,139)	175 (144, 249)
Hair Count % Change	0	-20 (-50, 0)	-3 (-53, 16)	-38 (-43, -1)	13 (-9, 36)
Hair Width	70 (61, 73)	62 (0, 66)	64 (54, 66)	64 (59, 66)	75 (64, 77)
Hair Width % Change	0 (0, 0)	-8 (-10, 0)	-8 (-23, -4)	-12 (-21, -9)	0 (-6, 4)

*Median avg (IQR)

Risk assessment of myelosuppression with PARP inhibitors in prostate cancer: Insights from FAERS.

Karan Jatwani, Mayur Sarangdhar, Venkatesh Kolli, Atulya Aman Khosla, Dharmesh Gopalakrishnan; Roswell Park Comprehensive Cancer Center, Buffalo, NY; Cincinnati Children's Hospital Medical Center, Cincinnati, OH; Cincinnati Children s Hospital Medical Center, Cincinnati, OH; Department of Internal Medicine, William Beaumont University Hospital, Royal Oak, MI

Background: DNA damage repair defects are prevalent in 15% of Prostate cancer. FDA has approved four PARP inhibitors to be used for metastatic castration resistant prostate cancer (mCRPC). Based on the approvals, currently Olaparib, Niraparib, Rucaparib and Talazoparib have been approved alone or in combination with an Androgen receptor pathway inhibitor (ARPI). All these agents have myelosuppressive (MS) events . We aimed to assess the pharmacovigilance (PV), reporting rate, and reaction outcomes of different approved PARP inhibitors in the mCRPC setting reported to the United States Food and Drug Administration Adverse Event Reporting System (FAERS). **Methods:** We analyzed MS events in 2,137 patients on PARP inhibitors. MS event reports were submitted to FAERS between 2004-2023 and analyzed using the AERS*Mine* framework. MS incidences were analyzed within different PARP inhibitors utilized for prostate cancer. Our primary composite endpoint was the PV of MS caused by olaparib, rucaparib, niraparib and talazoparib for the treatment of mCRPC. PARP inhibitors were analyzed as mutually exclusive cohorts. Standard PV metrics were used to determine MS association with PARP inhibitors and two-way ANOVA testing was used to evaluate for statistical significance across the treatment groups. **Results:** 2,137 prostate cancer patients on PARP inhibitors were identified. MS events (n=677)– olaparib (227/831, 27.32%), rucaparib (n = 171/495, 34.55%), niraparib (63/111, 56.76%), and talazoparib (34/47, 72.34%). MS events were further categorized into five classes – anemia (n = 311, 45.94%), leukopenia (n = 123, 18.17%), thrombocytopenia (n = 107, 15.81%), pancytopenia (n = 102, 15.07%), and myelodysplastic syndrome (MDS) or Acute Myeloid Leukemia (AML, 34, 5.02%). Anemia rates across the four cohorts were identical (table). Leukopenia rates were highest in talazoparib cohort (27.66%). Thrombocytopenia rates were highest in niraparib cohort (24.32%). For pancytopenia, rates were highest in talazoparib 10.64%. MDS/AML rates were Talazoparib (2.13%), Olaparib (1.8%). The relative rates of MS events were significantly different across the PARP inhibitors ($p < 0.05$, Table). **Conclusions:** This is the first study specific to prostate cancer analyzing the relative rates of MS events across different PARP inhibitors. Talazoparib exhibited the highest incidence of myelosuppression. This underscores the careful patient selection and vigilant monitoring needed in PARP inhibitors. Prompt recognition of myelosuppression is needed to optimize the safety and efficacy of PARP inhibitor therapies in prostate cancer. Research Sponsor: None.

	Olaparib, n = 831 (%)	Rucaparib, n = 495 (%)	Niraparib, n = 111 (%)	Talazoparib, n = 47 (%)
ANEMIA (311)	14.56	13.94	14.41	14.89
LEUKOPENIA (123)	3.01	8.08	13.51	27.66
THROMBOCYTOPENIA (107)	3.25	4.04	24.32	17.02
PANCYTOPENIA (102)	4.69	8.48	4.50	10.64
MDS/AML (34)	1.81	0.00	0.00	2.13

12145 Poster Session

Risk assessment of cardiovascular adverse events with BTK inhibitors in hematological malignancies: Insights from FAERS.

Muhammad Salman Faisal, Karan Jatwani, Venkatesh Kolli, Noha Soror, Mayur Sarangdhar; Roswell Park Comprehensive Cancer Center, Buffalo, NY; Cincinnati Children s Hospital Medical Center, Cincinnati, OH; University of Oklahoma, Oklahoma City, OK; Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Background: Burton tyrosine Kinase inhibitors (BTKi) have revolutionized the care of chronic lymphocytic leukemia (CLL) and non-Hodgkin lymphomas (NHL) – including relapsed/refractory mantle cell, ABC diffuse large B cell lymphoma and and lymphoplasmacytic lymphoma. Ibrutinib was the first BTKi to be approved. The newer covalent BTKi include acalabrutinib and zanubrutinib, both of which are approved for frontline and relapsed CLL as well as relapsed NHL. All these agents have cardiovascular adverse events. We aimed to assess the pharmacovigilance (PV), reporting rate, severity, and reaction outcomes of different approved BTKi in the CLL as cancer reported to the United States Food and Drug Administration Adverse Event Reporting System (FAERS). **Methods:** We analyzed cardiovascular events in 86,370 patients on BTKi. Cardiovascular event reports were submitted to FAERS between 2004-2023 and analyzed using the AERS*Mine* framework. We compared these incidences within different BTKI. We divided cardiovascular events to three categories: cardiac arrythmia, major coronary or vascular event (MACE) and pericardial complication including effusion or hemorrhage. Our primary composite endpoint was the PV of cardiovascular events caused by BTKI. To mitigate confounding, BTKI were analyzed as mutually exclusive cohorts: Ibrutinib (n = 79,278), acalabrutinib (5200), and zanubrutinib (1354). Two-way ANOVA testing was done to evaluate for statistical significance across the different groups. **Results:** Across the 86,370 patients on BTKI, we identified 8500 reports of cardiovascular events – ibrutinib (10.15%), acalabrutinib (5.73%), and Zanubrutinib (4.72%). Arrythmia risk was higher with ibrutinib (6.6%) compared to acalabrutinib (3.12%) and zanubrutinib (2.29%). The major difference in the groups was driven by atrial fibrillation (5.1% vs 2.1% vs 1.8%). The MACE rate was 2.79% vs. 2.4% vs. 2%, and pericardial events were 0.72% vs. 0.21% vs. 0.44% in the ibrutinib, acalabrutinib, and zanubrutinib groups, respectively. All the AEs were to have statistical significance (p = 0.011) across all the BTKI as mentioned in table 1. **Conclusions:** We report the prevalence rate of BTKI-related cardiovascular events in a large cohort of patients. Ibrutinib has demonstrated a higher incidence of toxicity, especially in cardiac arrythmias, while smaller but significant differences exist in other toxicities, including major cardiovascular events and pericardial effusion or hemorrhage. Patient selection and toxicity monitoring are important aspects of the care of these patients, who stay on these therapies for indefinite periods. Research Sponsor: None.

	Ibrutinib	Acalabrutinib	Zanubrutinib
Cardiac Arrythmia	6.64	3.12	2.29
Atrial fibrillation	5.13	2.15	1.77
Ventricular Tachycardia	0.33	0.12	0.07
Ventricular fibrillation	0.15	0.02	0.00
MACE	2.79	2.40	1.99
Pericardial event	0.72	0.21	0.44

TPS12146 **Poster Session**

The CROWN study: Cardiac outcomes with near-complete estrogen deprivation.

Rani Bansal, Emily H. Douglas, Katherine C. Ansley, Carolyn J. Park, Karl M. Richardson, Susan Faye Dent, Carey K. Anders, Kelly E. Westbrook, Mary Helen Helen Hackney, Hetal Ravikumar Vachhani, Elizabeth Barrows, Sarah Hatcher, Ralph D'Agostino Jr., Jennifer Jordan, Alexandra Thomas; Duke Cancer Institute, Durham, NC; Wake Forest University School of Medicine, Winston-Salem, NC; Duke University School of Medicine, Durham, NC; Virginia Commonwealth University, Richmond, VA; VCU Health, Richmond, VA; VCU, Richmond, VA; Duke University, Durham, NC

Background: Treatment for premenopausal women with high/intermediate risk hormone receptor (HR)-positive breast cancer (BC) includes the concurrent use of ovarian function suppression (OFS) and an aromatase inhibitor (AI) to induce near-complete estrogen deprivation (NCED). The long-term cardiovascular (CV) sequela for women treated with NCED is unknown. Premature menopause in non-cancer populations is associated with CV morbidity. Given the overall CV injury associated with BC treatment and the future life-years of these women, the CV impact of NCED warrants further study. The CROWN study uses sophisticated imaging assessments of cardiac dysfunction and biomarker and demographic correlates to understand the evolution of CV injury with the goal of developing tools to assess and mitigate CV risk. **Methods:** This is an NIH funded prospective cohort study conducted at 3 regional NCI-supported Cancer Centers (Duke University, Wake Forest University and Virginia Commonwealth University) that includes premenopausal women, age $\leq$ 55, with Stage I-III BC following completion of planned chemotherapy, surgery and radiation with an ECOG 0-2. HR-positive BC patients are receiving an AI and OFS. Women with HR-negative BC are included as comparators. CV imaging and biomarkers will be obtained at baseline, 1 year and 2 years (Table). These assessments include serial cardiac magnetic resonance (CMR) and coronary computed tomography angiography (CCTA) imaging as well as laboratory measurements, including exploratory biomarkers. The primary objective is to determine the 24-month difference in stress myocardial blood flow as measured by adenosine CMR imaging in both groups. Correlation of CMR imaging with CCTA detail of coronary plaque changes is planned. The relevance of pre-existing risk factors on study outcomes, including an emphasis on race and dynamic change in modifiable and treatment related risk factors will also be assessed. We plan to enroll 90 women,65 in the NCED group and 25 in the HR-negative group, allowing for a 10% drop out rate. The first primary statistical analyses will include testing hypotheses between group (NCED vs HR-negative) and within group (longitudinal changes within the NCED group). Secondary analyses involve developing predictive equations to determine if patient demographics, clinical parameters and serum biomarkers are associated with CV changes over time. We have currently enrolled 34 women (31 NCED and 3 HR-negative). 2 out of 3 patients entering the 2nd year of the study have returned for their year 1 imaging. Retention will be a key component of this study as analysis of the primary and secondary endpoints are dependent on completion of imaging. Clinical trial information: NCT05309655. Research Sponsor: NHLBI; R01HL153939.

Study procedures.

Evaluation/Procedure	Baseline	Year 1	Year 2
Vitals	X	X	X
Body measurements: (Height, Weight, BMI, Waist circumference)	X	X	X
Labs/Biomarkers	X	X	X
CMR	X	X	X
CCTA	X		X
EKG	X	X	X
Patient questionnaires	X	X	X

TPS12147 Poster Session

Telehealth cognitive-behavioral therapy for cancer-related cognitive impairment: 2024 update of a model for remote clinical trial participation.

Robert J. Ferguson, Lauren Terhorst, Eric Terkpertey, Jessica N. Bailey, Carolyn Impagliazzo, Brenna C. McDonald; University of Pittsburgh School of Medicine, UPMC Hillman Cancer Center, Pittsburgh, PA; University of Pittsburgh, Pittsburgh, PA; Indiana University School of Medicine, Indianapolis, IN; UPMC Health Plan, Pittsburgh, PA

Background: Cancer-related cognitive impairment (CRCI) consists of persistent memory symptoms that adversely affects survivor quality of life (QOL). Memory and Attention Adaptation Training (MAAT) is an evidence-based cognitive behavioral therapy (CBT) for CRCI with demonstrated efficacy in telehealth delivery. MAAT consists of 8 weekly (45 minute) video visits. The aims of this study are to confirm MAAT telehealth efficacy in a phase III RCT (MAAT vs Supportive Therapy; ST) across large catchment areas of two comprehensive cancer centers. A secondary aim is to evaluate treatment-induced brain activation as assessed by functional MRI (fMRI). We present remote treatment and data capture methods of this open NCI-sponsored (R01CA244673) randomized clinical trial (NCT 04586530). These methods have high success in participant accrual despite starting the trial in COVID-19 pandemic conditions and can be readily adopted to other clinical trials to enhance rural/underserved enrollment. **Methods:** We are enrolling 200 adult, stage I-III breast cancer survivors 1-5 years post-chemotherapy with cognitive complaints. Individuals with CNS disease, previous brain injury, dementia or psychiatric disorder are excluded. All study procedures are completed from the participant's home (except fMRI). Eligibility screening is a structured phone interview followed by detailed informed consent online (Research Electronic Data Capture: REDCap) with phone guidance. Consented participants complete baseline brief phone-based neurocognitive assessment and validated patient-reported outcome measures (PROs) of cognition and quality of life via REDCap. Participants are randomized to MAAT or ST and assigned treating clinicians at respective cancer centers. All 8 visits are completed through secure telehealth platforms, followed by repeat phone/online assessment post-treatment and again at 6 months. Enrollment began 3/2021. As of 12/12/2023 (33.5 months), 116 participants are enrolled (58% of the planned sample), 116 randomized (MAAT 58; ST 58), with 81 completing post-treatment assessments. If all assessments and treatment visits were in person, travel burden per participant is 977 miles/22 hours driven, and $640 (US 2023 Federal rate). Thus, study travel savings to date are $74,240. Participant feedback indicates telehealth makes participation possible, similar to previous MAAT research. The current RCT demonstrates utility, efficiency and cost-savings of telehealth and remote data capture technology in the conduct of cancer control research. Methods described here can also be adopted for cancer therapeutic trials. Comprehensive cancer centers, where most clinical trials are based, can enhance participation of remote and/or underserved populations that have higher rates of cancer, more disease burden and less opportunity for trial participation. Clinical trial information: NCT04586530. Research Sponsor: National Cancer Institute; National Cancer Institute.

TPS12148 **Poster Session**

Enhancing prostate cancer diagnosis communication: A multicenter study evaluating the impact of animated videos, CartDiag Prostate study.

Carole Helissey, Marie Pautas, Laurent Brureau, Anatole Cessot, Hugo Picchi, Audrey Le Roy, Marie-Anne Audisio, Aline Barhli, Hélène Vanquaethem, Antoine Schernberg; Clinical Research Unit, Department of Medical Oncology, HIA Bégin, Saint-Mandé, Paris, France; Military Hospital Begin, Saint-Mandé, France; GH Pointe a Pitre, Pointe-à-Pitre, France; Clinique Hartman, Levallois, France; Hôpital d'Instruction des Armées de Bégin, Saint-Mande, France; Military hospital Begin, Paris, France

Background: Prostate cancer is the leading cancer among men. Advances in therapeutic techniques, personalized medicine, and the integration of targeted therapies have significantly improved patient outcomes, resulting in a 5-year overall survival of 93%. However, effective patient care requires a shared decision-making framework and clear communication between healthcare professionals and patients. The initial step in patient care involves disclosing the cancer diagnosis during a dedicated consultation, laying the foundation for the patient-physician trust relationship. Nowadays, less than 50% of patients declared that they understood the information provided during the announcement consultation. The main objective of our study is to assess the effect of the announcement system, reinforced by animated videos, on patients' overall understanding of their diagnosis and treatment. **Methods:** To enhance the disclosure process, animated videos were developed to outline the patient care journey. This multicenter, controlled before-and-after study aimed to evaluate the impact of the usual disclosure process enhanced by animated videos on patients' understanding of advanced or metastatic prostate cancer. Patients were sequentially assigned to two arms: the standard arm (first 45 patients) received usual written and oral information, while the intervention arm (next 45 patients) received written and oral information supplemented by animated videos. To evaluate the effect of the enhanced disclosure process on patients' overall understanding of their diagnosis and treatment using the EORTC QLQ-INFO25 questionnaire at baseline (Day 0) and after 1 month (Day 30), compared to the standard group without enhanced disclosure. This prospective study is the first to assess the impact of supplementing the standard disclosure process with animated videos positively impacts patients' comprehension of advanced or metastatic prostate cancer. The findings will support the potential value of integrating visual aids into the diagnostic disclosure consultation to enhance patient understanding and promote informed decision-making. Clinical trial information: NCT06117696. Research Sponsor: None.

TPS12149 Poster Session

Comparison of prophylactic effects for chemotherapy-induced neutropenia between same-day vs next-day administration of pegteograstim in chemotherapy regimen composed of day 1 intensive myelosuppressive agent: A randomized phase III trial (CONCISE, KCSG PC22-11).

Kwonoh Park, Sang-Bo Oh, Yun Jeong Hong, Seok Jae Huh, Il-Hwan Kim, Seong-Hoon Shin; Hanyang University Seoul Hospital, Hanyang University College of Medicine, Seoul, South Korea; Medical Oncology and Hematology, Department of Internal Medicine, Pusan National University Yangsan Hospital, Yangsan, South Korea; Department of Neurology, Uijeongbu St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Uijeongbu, South Korea; Department of Internal medicine, Dong-A University College of Medicine, Busan, South Korea; Haeundae Paik Hospital, Inje University College of Medicine, Busan, South Korea; Division of Medical Oncology, Department of internal medicine, KOSIN University Gospel Hospital, Busan, South Korea

Background: Administration of peg-GCSF 24 to 72 hours after chemotherapy is usually recommended. Next-day administration (after 24 hours) resulted in fewer duration of Gr4 chemotherapy-induced neutropenia (CIN) and decreased severity of CIN than same-day (within 4 hours). However, patients sometimes receive same-day Peg-GCSF for the sake of convenience. In addition, a few prior studies showed that the same-day method is comparable or superior to the next-day in preventing CIN, especially in regimens that include day 1 myelosuppressive agents. Thus, we aim to test hypothesis that same-day administration of pegteograstim, a new formulation of peg-GCSF, is non-inferior to next-day administration in terms of Gr4 CIN duration. **Methods:** This study is a randomized, multicenter, open-label, investigator-initiated phase 3 study. Patients with adjuvant/neoadjuvant or 1st palliative chemotherapy comprising intensively myleosuppressive agents on day 1 (mFOLFIRINOX, ECb, EP, FOLFIRI, and FOLFOX) are enrolled. The patients are assigned to the same-day arm or the next-day arm in a 1:1 ratio. Randomizations are stratified according to number of CIN risk (1 vs $\geq$2), setting (perioperative vs palliative), and interval (2- vs 3-week). In the same-day, pegteograstim 6 mg is SC injected within 4 hrs after chemotherapy, while 24-36 hrs in the next-day. CBC test is performed daily from day 5 to 9 during the cycle 1. From cycle 2 to 4, treatments are performed in accordance with general practice, including checking for febrile neutropenia (FN), dose intensity, and safety. The primary endpoint is duration of Gr4 CIN (during cycle 1), and secondary endpoints include incidence of Gr 3-4 CIN (cycle 1), severity of CIN (cycle 1), time to recovery ANC 1000/$\mu\ell$ (cycle 1), incidence of FN, CIN-related dose delay, and dose intensity. In order to verify non-inferiority of 0.6 days of Gr4 CIN duration, we estimated a significance level of 5%, power of 80%, and drop-out rate of 15%. This results in the need for a total of 160 patients, 80 in each arm. We are currently recruiting patients (since Nov 2022). Clinical trial information: KCT0007694. Research Sponsor: None.

TPS12150 **Poster Session**

Role of celecoxib in reducing cognitive impairment in patients receiving definitive chemoradiation for head and neck carcinoma: A phase II randomized placebo controlled trial (CELCI-HN study).

Aparna Sharma, ATUL SHARMA, Alok Thakar, Suman Bhasker, Kapil Sikka, Amit Chirom Singh, Rajeev Kumar, Raja Pramanik, Vaibhav Patil, akash kumar, Babita Kataria, Abhinav Singhal, Smriti Panda, Aman Sharma, Yousra Izzuddeen, Chethan R; All India Institute of Medical Sciences (AIIMS), Delhi, India; IRCH, All India Institute of Medical Sciences (AIIMS), New Delhi, New Delhi, India; All India Institute of Medical Sciences, New Delhi, India; All India Institute of Medical Sciences (AIIMS), New Delhi, India; Department of Otorhinolaryngology & Head and Neck Surgery, All India Institute of Medical Sciences (AIIMS), New Delhi, India; Department of Oto-laryngology &Head and Neck Surgery, All India Institute of Medical Sciences (AIIMS), New Delhi, India; National Cancer Institute-All India Institute of Medical Science (AIIMS), Jhajjar, India; Radiation Oncology, NCI AIIMS, New Delhi, India; All India Institute of Medical Science, New Delhi, India

Background: Head and neck squamous cell carcinoma (HNSCC) is common in the Indian subcontinent and majority (65%) patients present in an advanced stage. Chemotherapy related cognitive impairment (CRCI) is a poorly defined and underestimated phenomenon in the HNSCC population. Through this study, we are attempting to establish evidence of activity of agents targeting neuro-inflammation in reducing or halting cognitive decline associated with definitive chemoradiotherapy for head and neck malignancies without adding to treatment-associated toxicity. This study can potentially aid in developing a cost effective approach with a readily available and cheap agent like celecoxib in improving the quality of life in this cohort of patients. **Methods:** This is a single center, double blinded placebo controlled phase 2 randomized trial. We intend to randomize 92 non metastatic HNSCC patients registered at a large tertiary cancer center of North India {Department of Medical Oncology (Head and Neck Cancer Clinic, All India Institute of Medical Sciences-National Cancer Institute, India)} planned for definitive chemoradiation (CTRT) with or without induction chemotherapy. Patients in the experimental arm will receive celecoxib 100 mg or matched placebo tablet orally twice a day starting with day 1 of initiation of definitive chemoradiotherapy/induction chemotherapy for a duration of 6 months or until unacceptable toxicity. Our primary objective is to determine the activity of celecoxib versus placebo in reducing cognitive decline in patients undergoing definitive CTRT with or without induction chemotherapy in HNSCC through patient reported outcome tools (FACT cog questionnaire). Secondary objectives include assessment of adverse event profile (measured using CTCAE v5.0), objective assessment of neurocognitive decline using neuropsychological battery of tests, to identify predictors of cognitive decline on the basis of site of malignancy, radiation dose to the base of skull and brainstem, age, comorbidities and educational status. Tertiary objective include evaluation of inflammatory biomarkers e.g serum COX-2, serum Interleukin and tumor necrosis factors-alpha levels at the end of therapy and on follow up. Clinical trial information: CTRI/2022/09/045579. Research Sponsor: Conquer Cancer, the ASCO Foundation.

TPS12151 Poster Session

A randomized phase III clinical trial of acupuncture for chemotherapy-induced peripheral neuropathy treatment (ACT).

Mingxiao Yang, Ivana Lopez-Nieves, Anna Tanasijevic, Lauren Piluson, Mehul Shrivastava, Matthew Weitzman, Iris Zhi, Jun J. Mao, Ting Bao; Dana-Farber Cancer Institute, Boston, MA; Memorial Sloan Kettering Cancer Center, New York, NY; Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Chemotherapy-induced peripheral neuropathy (CIPN) is a common and potentially dose-limiting side effect of neurotoxic chemotherapy among people who experience cancer, presenting pain, numbness, tingling, and motor weakness. CIPN worsens quality of life and disrupts active treatment regimens. Currently, duloxetine is the only ASCO-recommended painful CIPN treatment after chemotherapy completion. Still, it has undesirable side effects, i.e., fatigue, sleep disturbance, and digestive symptoms, posing a pressing need for well-tolerated, evidence-based interventions. Our pilot study demonstrated the feasibility and preliminary efficacy of acupuncture in relieving CIPN pain. Based on that, we developed the ACT trial to evaluate the effect of acupuncture on improving pain and other related symptoms among cancer survivors with CIPN pain. **Methods:** ACT is a prospective phase III multicenter, parallel two-arm randomized clinical trial at Dana-Farber Cancer Institute (DFCI) and Memorial Sloan Kettering Cancer Center (MSK) (ClinicalTrials.gov Identifier: NCT04917796). ACT aims to determine the efficacy of an eight-week electroacupuncture (EA) treatment vs. sham acupuncture (SA) on improving CIPN symptoms severity in cancer survivors. We plan to enroll 250 participants to detect an effect size of at least 0.45 for the primary pain outcome at 12 weeks post-randomization between EA vs. SA, with 80% power and a 1% Type I error rate, assuming a 10% loss to follow-up. Major eligibility criteria include 1) adults who have no evidence of disease or stable diseases, 2) who have completed neurotoxic chemotherapy such as platinum agents, taxanes, vinca alkaloids, and bortezomib at least three months before enrollment, and 3) who have a clinical diagnosis of CIPN with moderate to severe pain, defined as a score of at least four on the Brief Pain Inventory (BPI) average pain item. We randomly allocate participants to receive ten real or sham acupuncture treatments over eight weeks at two centers and their regional clinics. Aside from patient-reported outcome measures (i.e., BPI, Functional Assessment of Cancer Therapy/Gynecologic Oncology Group-Neurotoxicity, EORTC Quality of Life Questionnaire-CIPN 20), we conduct quantitative sensory testing to assess changes in sensory function. The primary study endpoint is week 12, and the secondary study endpoint is week 24. Progress: 1) We are currently transitioning this trial to a multicenter trial, with DFCI being the coordinating center and MSK a subsite; 2) As of January 18, 2024, a total of 133 of the planned 250 participants have been enrolled; 3) The DSMB last reviewed the trial in December 2023, and suggested that the trial continue as planned at MSK. We anticipate initiating participant enrollment at DFCI in February 2024. Accrual completion is expected by December 2024. Clinical trial information: NCT04917796. Research Sponsor: U.S. National Institutes of Health; R37 CA248563; National Cancer Institute/U.S. National Institutes of Health; P30 CA008748.

TPS12152 Poster Session

A randomized phase III clinical trial of yoga for chemotherapy-induced peripheral neuropathy treatment (YCT).

Mingxiao Yang, Marissa Mumford, Katherine Han, Anna Tanasijevic, Lauren Piluson, Mehul Shrivastava, Iris Zhi, Jun J. Mao, Ting Bao; Dana-Farber Cancer Institute, Boston, MA; Memorial Sloan Kettering Cancer Center, New York, NY; Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Chemotherapy-induced peripheral neuropathy (CIPN) is common and debilitating among cancer survivors receiving neurotoxic chemotherapy, which can cause functional disabilities and significantly increase the risk of falls. There are limited approaches to managing CIPN symptoms and related functional limitations. Our pilot study demonstrated yoga therapy's feasibility and preliminary efficacy in improving CIPN pain and functional outcomes. We developed the YCT trial to assess the effect of yoga therapy on improving pain and balance symptoms among cancer survivors with CIPN pain. **Methods:** YCT is a prospective phase III multicenter, parallel three-arm randomized clinical trial at Dana-Farber Cancer Institute (DFCI) and Memorial Sloan Kettering Cancer Center (MSK) (ClinicalTrials.gov Identifier: NCT05121558). YCT aims to determine the efficacy of an eight-week yoga treatment vs. education control (EC) vs. usual care (UC) in improving CIPN pain and balance in cancer survivors. We plan to enroll and randomize 268 participants (2:1:1) to yoga, EC, and UC groups to detect an effect size of at least 0.48 for the primary pain outcome at eight weeks post-randomization between yoga vs. EC, with 80% power and a 2.5% Type I error rate, assuming 12% attrition by week 8 and 20% attrition by week 24. Major eligibility criteria include 1) adults who have no evidence of disease or stable diseases, 2) who have completed neurotoxic chemotherapy such as platinum agents, taxanes, vinca alkaloids, and bortezomib at least three months before enrollment, 3) who have a clinical diagnosis of CIPN with moderate to severe pain, defined as a score of at least four on the Brief Pain Inventory (BPI) average pain item, and 4) who experience self-identified CIPN balance difficulty. Eligible subjects in the yoga arm will receive hourly gentle therapeutic yoga classes taught by protocol-trained oncology yoga instructors, twice weekly for eight weeks, and practice home-based yoga. Subjects in the EC arm will receive hourly education classes taught by protocol-trained healthcare instructors twice weekly for eight weeks. Subjects in the UC arm will continue usual care for eight weeks. We offer free yoga sessions for participants in control groups after study completion. Aside from patient-reported outcome measures (i.e., BPI, FACT/GOG-Ntx, QLQ-CIPN 20), we measured functional improvements by functional reach, timed up-and-go, and chair-to-stand tests. We also conducted quantitative sensory testing to assess changes in sensory function. Progress: 1) We are transitioning this trial to a multicenter trial, with DFCI being the coordinating center and MSK a subsite; 2) As of January 18, 2024, 104 of the planned 268 participants have been enrolled. We anticipate initiating participant enrollment at DFCI in February 2024. Anticipated accrual completion: March 2025. Clinical trial information: NCT05121558. Research Sponsor: National Cancer Institute; R01 CA251470.

TPS12153 Poster Session

Randomized, placebo-controlled trial of atorvastatin to prevent hearing loss in patients with head and neck squamous cell carcinoma receiving cisplatin based chemoradiation (CRT).

Nicole C. Schmitt, Katharine Fernandez, Shawn Newlands, Paul Allen, Adam Kaufman, Garnett P. McMillan, Jeffrey M. Switchenko, William A. Stokes, Ranee Mehra, Anant Mandawat, Robert Shamburek, Nabil F. Saba, Lisa L. Cunningham; Emory University, Atlanta, GA; NIDCD/NIH, Bethesda, MD; University of Rochester, Rochester, NY; University of Maryland, Baltimore, MD; National Center for Rehabilitative Auditory Research, Portland, OR; Department of Biostatistics and Bioinformatics, Emory University, Atlanta, GA; Emory University Hospital Midtown, Atlanta, GA; University of Maryland Marlene and Stewart Greenebaum Cancer Center, Baltimore, MD; NIH/NHLBI, Bethesda, MD; Emory University Winship Cancer Institute, Atlanta, GA; NIH/NIDCD, Bethesda, MD

Background: Cisplatin chemotherapy is associated with several adverse effects, including a permanent, high-frequency, sensorineural hearing loss in about 50% of patients. Preclinical studies suggest that statin drugs can mitigate cisplatin ototoxicity (Fernandez et al., Hearing Research 2020). In our prior combined retrospective/prospective dataset of patients with head and neck squamous cell carcinoma (HNSCC) treated with cisplatin-based CRT, the incidence of CTCAE grade $\geq$ 2 hearing loss was 29.4% in statin non-users, versus 9.7% in atorvastatin users (Fernandez et al., J Clin Invest 2021). An adjusted odds ratio analysis indicated that atorvastatin users are significantly less likely to develop hearing loss versus statin non-users (odds ratio 0.47), providing the rationale for a randomized, controlled, prospective study. **Methods:** This multi-center, randomized, placebo-controlled study is enrolling patients with previously-untreated, locally advanced head and neck squamous cell carcinoma (HNSCC) for which cisplatin-based chemoradiation is indicated, either in the definitive or adjuvant setting. Patients who will be treated with cisplatin (at 75-100 mg/m2 bolus every three weeks or 40 mg/m2 weekly) are eligible. Patients currently taking a statin or those without measurable hearing in at least one ear are excluded. A baseline audiogram is performed, and patients are randomized to atorvastatin (40 mg/day) or placebo, which is started 2-7 days before CRT and taken daily until 3 months after completion of CRT. Post-treatment audiometry is repeated at 3 months and 2 years after CRT, along with collection of patient-reported outcomes on hearing, tinnitus, and peripheral neuropathy. Patients are monitored for liver and muscle toxicity, with dose de-escalation or cessation of atorvastatin as needed. The primary endpoint is the incidence of CTCAE grade $\geq$2 hearing loss at 3 months after CRT. Secondary endpoints include other treatment related grade 3-4 adverse events, overall survival, and disease-free survival. Up to 214 subjects will be enrolled at 4 U.S. sites (NIH Clinical Center, Emory University, University of Maryland, University of Rochester). Funding: NIH/NIDCD, U01 DC020452 and intramural project ZIA DC000079. Clinical trial information: NCT04915183. Research Sponsor: NIH/NIDCD; U01 DC020452, ZIA DC000079.

TPS12154 Poster Session

Acupuncture for preventing progression of taxane-induced peripheral neuropathy (ATP): A phase II randomized, placebo-controlled trial.

Iris Zhi, Katherine Han, Danne Kim, Lauren Piluson, Matthew Weitzman, Raymond E Baser, Qing Susan Li, Ting Bao, Jun J. Mao; Memorial Sloan Kettering Cancer Center, New York, NY; Dana-Farber Cancer Institute, Boston, MA; Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Chemotherapy-induced peripheral neuropathy (CIPN) from chemotherapy drugs such as taxanes can be detrimental to cancer survival, increasing the risk of falls and worsening physical functions. The current management of worsening and persistent CIPN during chemotherapy is dose reduction or discontinuation of chemotherapy. There is no effective treatment or preventative measure for CIPN. **Methods:** Trial design: The ATP trial is a two-arm, parallel, randomized controlled trial comparing weekly real acupuncture (RA) versus sham acupuncture (SA) during preplanned curative intent taxane containing regimens in patients with breast cancer. Eligibility criteria: English or Spanish-proficient; aged ≥18 years; histological diagnoses of invasive carcinoma of the breast; and plan to receive curative intent chemotherapy regimen containing paclitaxel or nab-paclitaxel weekly or biweekly as standard of care, developed CIPN grade ≥1 based on the NCI-CTCAE version 5.0, while receiving taxane; ≥ four weeks of paclitaxel or nab-paclitaxel weekly or biweekly planned, as standard of care and at treating physician's discretion; willing to adhere to requirement that no new pain medication or dose changes be taken throughout the first 12 weeks of the study period; and willing to adhere to all study-related procedures. Specific aims: The primary aim is to evaluate the effectiveness of RA versus SA in preventing taxane-induced peripheral neuropathy progression as measured by Neuropathic Pain Scale (NPS) in patients with early-stage breast cancer who are receiving curative intent neurotoxic chemotherapy. The secondary aim is to evaluate the effectiveness of RA versus SA on chemotherapy relative dose intensity (RDI) and CIPN-related chemotherapy discontinuation. Statistical methods: We will randomize 80 patients, 40 to each arm. All randomized patients will be evaluable in the Intent to Treat (ITT) analyses because all will have completed the baseline assessment before randomization. We will use a linear mixed model (LMM) to compare the change in NPS between the arms from baseline to week 4. Based on our pilot data, a difference in CIPN grade from 1 to 2 corresponded to a difference in NPS from 12 to 22, a difference of ten points in 27 patients. The NPS standard deviation (SD) in patients with grade 1 CIPN was 17. With 80 patients we will have 80% power to detect a difference between arms as small as 10 points on the NPS, assuming a one-sided test, type I error of 5%, correlation between baseline and follow-up measurements of 0.5, SD of 17, and 15% attrition at week 4. Present accrual and target accrual: We accrued 43 participants in the intervention phase by the end of January 2024; the target accrual is 80 participants. Clinical trial information: NCT05458284. Research Sponsor: Gateway for Cancer Research.

TPS12155 Poster Session

Guard 01: A randomized, multicentre, controlled trail on the prophylactic use of efbemalenograstim alfa for concurrent chemo-radiotherapy induced neutropenia.

Yuanyuan Chen, QiWen Li, Chunyan Chen, Yi Ouyang, Ming Chen; State Key Laboratory of Oncology in South China, Guangdong Key Laboratory of Nasopharyngeal Carcinoma Diagnosis and Therapy, Guangdong Provincial Clinical Research Center for Cancer, Sun Yat-sen University Cancer Center, Guangzhou, China; Department of Radiation Oncology, Sun Yat-sen University Cancer Center, State Key Laboratory of Oncology in South China, Collaborative Innovation Center of Cancer Medicine, Guangzhou, China; Sun Yat-sen University Cancer Center, Guangzhou, China

Background: Concurrent chemo-radiotherapy plays a crucial role in the treatment of various advanced-stage malignant tumors. However, it is often associated with significant hematologic toxicity, especially leukopenia and neutropenia, which may lead to treatment interruptions, reduced efficacy, and even severe infections. Efbemalenograstim alfa is a novel long-acting recombinant human granulocyte colony stimulating factor (rhG-CSF) combined of an immunoglobulin (Ig) G2-Fc fragment and two rhG-CSF molecules. Although efbemalenograstim alfa has been confirmed to be effective in the prevention of chemotherapy induced neutropenia by a number of clinical studies, its prophylactic efficacy during concurrent chemo-radiotherapy was seldom investigated. Guard-01 is aimed to evaluate the effectiveness and safety of primary preventive use of efbemalenograstim alfa in concurrent chemo-radiotherapy. **Methods:** This study is a multicenter, open-label, randomized, controlled clinical trial involving 120 patients who are planned to receive definitive concurrent chemo-radiotherapy with non-small cell lung cancer, small cell lung cancer, esophageal cancer, nasopharyngeal carcinoma, head and neck squamous cell carcinoma, or cervical cancer. Patients will be randomized into efbemalenograstim alfa arm or control arm in a 1:1 ratio on the first day of the first concurrent chemo-radiotherapy cycle. The stratification factor is chemotherapy regimen of the patients. Approximately 48 ($\pm$4) hours after the completion of each chemotherapy cycle, patients in the efbemalenograstim alfa arm will receive efbemalenograstim alfa (20 mg per dose, subcutaneous injection) for prevention. Patients in the control arm will receive rhG-CSF (5 μg/kg/day) when the absolute neutrophil count (ANC) is less than 1.0×10^9/L, and treatment will be discontinued when ANC reaches $\geq5\times10^9$/L. The primary endpoint is the incidence of grade $\geq$3 neutropenia (ANC$<1.0\times10^9$/L) during concurrent chemo-radiotherapy. The trial is opened in November 2023 and will be conducted in 8 hospitals with the aim of recruiting 120 evaluable patients (4 patients are recruited untilled 29-Jan-2024). Clinical trial information: ChiCTR2300077504. Research Sponsor: None.

TPS12156 Poster Session

Preventing chemotherapy-induced peripheral neuropathy with acupuncture, a multinational parallel randomized controlled trials project (PACT).

Weidong Lu, Anita Giobbie-Hurder, Anna Tanasijevic, Sylvia Baedorf Kassis, Ellie Diederich, Aliya Sahraoui, Sung Hwan Park, Young Ju Jeong, Im Hee Shin, Chang Yao, Xiping Zhang, Hyun Jung Jung, Na-Rang Lee, Yao Yao, Chao Bao, Ting Bao, EunMee Yang, Robert Knoerl, Barbara E Bierer, Jennifer A. Ligibel; Dana-Farber Cancer Institute, Boston, MA; The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital, Boston, MA; Daegu Catholic University, School of Medicine, Daegu, South Korea; Jiangsu Province Hospital of Chinese Medicine, Nanjing, China; Daegu Haany University, College of Korean Medicine, Daegu, South Korea; Daegu Catholic University Medical Center, Daegu, South Korea; The Osher Center for Integrative Medicine, Harvard Medical School and Brigham and Women's Hospital, Boston, MA; University of Michigan School of Nursing, Ann Arbor, MI

Background: Chemotherapy-induced peripheral neuropathy (CIPN) is a significant challenge for patients (pts) with breast cancer treated with taxanes and platinum compounds. CIPN severely affects quality of life, leading to paresthesia and pain, and often results in dose modifications and discontinuation of treatment. Although preliminary trials suggest the effectiveness of acupuncture in managing existing symptoms of CIPN, the use of acupuncture to prevent CIPN is not well studied. Prior studies provide inconclusive results, underscoring the need for more rigorous investigation. We designed an international study, PACT, to evaluate the impact of acupuncture on the prevention of CIPN in breast cancer pts who undergo adjuvant or neoadjuvant taxane-based chemotherapy. **Methods:** PACT is a coordinated multi-national study consisting of three parallel randomized trials in USA, China, and South Korea, using the same inclusion/exclusion criteria, randomization, interventions, and validated measures. PACT is designed to evaluate the effectiveness of acupuncture in preventing CIPN in pts undergoing taxane-based chemotherapy for early-stage breast cancer. Participants include pts with newly diagnosed stage I-III breast cancer without preexisting neuropathy, scheduled for adjuvant or neoadjuvant taxane-based chemotherapy. Target enrollment is 140 pts from three sites: Dana-Farber Cancer Institute (USA) (n=100), Jiangsu Province Hospital of Chinese Medicine (China) (n = 20) and the Daegu Catholic University Medical Center (South Korea) (n=20), randomized (1:1) to the acupuncture arm or a control. The acupuncture arm receives a standardized protocol of 1-2 sessions per week for 12 weeks (total of 14 sessions). The control arm receives relaxation exercises with nature scenery videos for 14 sessions. The follow-up period for both arms is 12 weeks. Main measures include The European Organisation for Research and Treatment of Cancer (EORTC) QLQ-CIPN20, QLQ-30 and Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) CIPN items. The primary outcome measure is the change in CIPN severity, assessed using the EORTC QLQ-CIPN20 sensory subscale, between baseline and week 12, with secondary outcomes including occurrence of CIPN and maximum CIPN scores, pain, sleep quality, and overall quality of life. A planned pooled analysis of individual patient data will be performed. The ethics review committee of each site has approved the study. Today, 89 (64%) of the planned 140 participants have been enrolled. Clinical trial information: NCT05528263, ChiCTR2200066714, KCT0008470. Research Sponsor: The Ministry of Health & Welfare, Republic of Korea; HI20C1753.

TPS12157 Poster Session

LOOP: An observational, prospective, multicenter study of patients with non-small cell lung cancer in the US receiving standard-of-care and initiating an approved therapy with risk of pneumonitis/ILD.

Elisabeth C Piault-Louis, Melissa Marvel, Michael David Newton, Vincent Haddad, Emmette R Hutchison, Joseph T Hughes, Alicyn K Campbell, Ethan Basch; AstraZeneca, South San Francisco, CA; AstraZeneca, Gaithersburg, MD; AstraZeneca, Cambridge, United Kingdom; AstraZeneca, Waltham, MA; The University of North Carolina at Chapel Hill, Chapel Hill, NC

Background: A wide range of oncology treatments are associated with a risk of pneumonitis or ILD, which is an uncommon but serious side effect with potential for significant morbidity and mortality (Conte et al 2022). The development of pneumonitis/ILD remains unpredictable and relatively uncommon in a single practice or hospital setting. Risk of drug-induced pneumonitis/ILD remains a limiting factor to prescribing life-saving treatments. A non-invasive, patient-centric multimodal solution for remote data capture could support recognition and tracking of pulmonary symptoms in addition to providing insight for the clinical team to personalize the monitoring of patients according to their medical history or specific physiological markers. **Methods:** LOOP is an observational, prospective, multicenter study conducted in the US. Stage III and IV NSCLC patients receiving SoC and initiating treatment with an FDA-approved ICI (alone or in combination with other agents), ADC, or small molecule EGFR inhibitor are eligible to participate. The primary objective is to enable the development and refinement of an algorithm including documentation of its performance (specificity, sensitivity and odd ratio to inform risk of pulmonary/respiratory/thoracic-related events including ILD). A secondary objective proposes to characterize the risk factors, signs, and symptoms leading to onset, diagnosis, and treatment of pneumonitis/ILD in patients receiving SoC. The study will collect patient-generated data outside of point-of-care for six months, using questionnaires and a medical pulse-oximeter device . Clinical data available per SoC in the medical records will be collected. Approximately 600 patients will be enrolled over 13 months to accrue approximately 100 pneumonitis/ILD events. Events will include all grades of pneumonitis, including ILD and radiation pneumonitis, as determined by the Investigator. Qualitative interviews will be conducted to inform a more granular understanding of the patient specific experience of developing ILD. Logistic regression, area under curve, descriptive statistics and relevant visualizations will map the relationship between pneumonitis/ILD and patient's health status. The study is currently enrolling; the protocol was approved by a central IRB. Clinical trial information: NCT06192004. Research Sponsor: None.