Phase 1 Trial of Image-Guided Oncolyis by Clostridium Novyi-NT Spore Inoculation: Early Technical Insights

R. Murthy, S. Huang, H. Thorunn, F. Janku

Purpose: Hypoxic environments, as occurs in tumors, are favorable for Clostridium subspecies to germinate. Clostridium novyi-NT (C. novyi-NT) induces a microscopic & tumor-confined lysis after intratumoral (IT) injection in rat orthotropic brain tumor models & spontaneous solid tumors in dogs, with the commonest toxicity being the tradi-
tional accompanying symptoms of bacterial infections. A first-in-man phase I study selecting therapy-refractory solid tumors palpable or identifiable using imaging guid-
ance and amenable to percutaneous injection of C. novyi-NT spores is being conducted. Tumor environment hypoxia is dynamic, spatially heterogenic, and not evaluable using clinical imaging technology, thereby rendering a priori localization of the optimal IT location for spore inoculation impossible. In order to compensate for this unknown parameter, we employed a staged, multifocal IT delivery process to theoretically in-
crease the likelihood of spore deposition within a milieu conducive for germination. We present our initial experience with C. novyi-NT spore delivery adopting this approach.

Materials and Methods: Advanced solid tumor cancer patients with at least 1 in-
jectable tumor >1 cm are being enrolled in 5 dose-escalating cohorts to receive single
3-cc IT injections of 1E4, 3E4, 1E5, 3E5, or 1E6 C. novyi-NT spores.

Results: Four patients have been treated (3 in cohort 1, 1 in cohort 2). Median tumor diameter measured at point of guide needle access was 5.4 cm (2.3-8.9 cm). Sites included intramuscular upper extremity and subcutaneous fat abdominal lesion (2 each), which were uneventful; in toto delivery of the agent was accomplished. Two patients demonstrated clinical evidence of germination within 72 hours corroborated by imaging. Pathology confirmed oncolysis. The liquefied components of the tumor were managed with evacuation via percutaneous drainage and pre-specified protocol-
mandated multi-antimicrobial therapy.

Conclusions: Clostridium novyi-NT spores can be delivered using existing imag-
ing technologies and devices producing clinical evidence of germination and confirm-
ning the capability of inducing oncolysis in human neoplastic tissues.

Radiofrequency Thermal Ablation of Isolated Local Recurrence After Surgery for Renal Cell Carcinoma

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Purpose: To retrospectively assess safety and efficacy of radiofrequency thermal ablation (RFA) of retroperitoneal relapse after surgery for renal cell carcinoma (RCC). Material and Methods: After open radical nephrectomy or nephron-sparing surgery, 4 patients were treated for retroperitoneal relapse and 2 for multiple pancreatic histo-
logically proven metastasis of renal cell carcinoma with percutaneous RFA. Overall, 13 lesions were treated. Extensive staging showed no evidence of distant metastases.

Results: Disease progression after surgery occurred within a mean time of 27 months (range 12 to 84 months). Recurrent tumor size varied from 5 to 34 mm. Five patients previously had undergone surgical resection of retroperitoneal recurrent lesions. Five patients had neoadjuvant treatment and 2 patients had adjuvant treat-
ment. After RFA all lesions were completely ablated with no residual enhancement. After a mean follow up of 13 months (range 6 to 16 months) no recurrent or residual disease was evident.

Conclusions: Percutaneous RFA of surgical relapse of RCC is effective and should be assessed as first line loco-regional treatment on a larger patient group.

The Effect of Anti-reflux Catheters on Pulmonary Shunt Fraction in Patients with Hepatocellular Carcinoma

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Purpose: Anti-reflux catheters were initially designed to limit retrograde flow of infused particles in liver-directed embolotherapy. Recent nonclinical research sug-
gests that these devices may produce increased concentrations of infused micropar-
ticles within the target area of infusion. One suggested mechanism for this effect is increased downstream arterial pressure during infusion, which increases microsphere penetration. This study evaluated whether the increased downstream arterial pressure created by an anti-reflux catheter has an effect on lung shunt fraction (LSF). LSF is an important pre-treatment safety consideration in yttrium-90 (90Y) radioembolization.

Material and Methods: The 90Y pretreatment simulation was performed with 2 sequential, same day infusions of 100 MBi and 600 MBi 99mTc–macroaggregated albumin (MAA). Using near-identical techniques and catheter positions, infusion was performed with both anti-reflux (SureFire Medical, Denver, Colorado) and endhole catheters. Following each infusion, planar and single photon emission computed to-

mography imaging were performed and the LSFs were compared.

Results: Four patients with biopsy-proven hepatocellular carcinoma (HCC) and 3 pa-
tients with metastatic liver disease were evaluated using this method. The average LSF was 10.1% using the anti-reflux catheter; the average LSF was 8.8% with the endhole catheter. This difference was not statistically significant (p > 0.25). In 6 out of 7 patients, the total difference in LSF did not exceed 2.5%; however, in 1 patient with an 18-cm HCC, LSF increased from 13.34% to 20.50% using endhole and anti-reflux catheters, respectively (see Figure 1).

Conclusions: Data from this study cannot confirm that there is any difference in LSF when an anti-reflux catheter is used. However, for patients likely to have a large LSF, such as those with large HCC, it may be prudent to perform the 99mTc-MAA simulation study with an anti-reflux catheter if that catheter will be used in the pa-

tient’s 90Y treatment.

Retrospective Analysis of the Efficacy of the SilverHawk Atherectomy Device in Evaluation of Biliary Strictures

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Purpose: To determine the efficacy of the SilverHawk™ Atherectomy Catheter (FoxHollow Technologies, Redwood City, CA) at obtaining a tissue diagnosis in the setting of malignant biliary strictures.

Materials and Methods: Seventy-nine patients with malignant biliary strictures underwent percutaneous biliary cholangiography. After cannulation of the biliary sys-
tem, the FoxHollow SilverHawk device was used to obtain multiple biliary shavings, which were then sent for cytology and staining.

Results: A total of 81 biopsies were performed on 79 patients after successful per-

cutaneous transhepatic cholangiography and cannulation of the biliary system using

Figure 1. Imaging from patient with lung-shunt fraction that exceeded 2.5%.
Materials and Methods: Study subjects were selected among patients scheduled for ablation, which was $352.07. In addition, this compares well to previously published rates of pneumothorax. Comparison is made to a control group of 124 patients with lung masses having CT-guided percutaneous lung biopsy and/or fiducial marker placement using 19- or 17-gauge guiding needles. Biopsies were performed coaxially using corresponding 20- or 18-gauge biopsy guns by 3 fellowship-trained interventional radiologists. Fiducial marker placements were performed through the 17-gauge guiding needle. At the end of the procedure, an absorbable hemostatic gelatin powder mix (Surgifoam® [Ethicon U.S.]) during percutaneous computed tomography (CT)-guided lung biopsy and/or fiducial marker placement in 125 patients, and to compare with a control group of 124 patients who did not receive track embolization. A cost analysis of the track embolization technique is also presented.

Results: In our study population (n=125), the overall rate of procedure-related pneumothorax was 8.8% (n=11). The rate of pneumothorax requiring chest tube placement was 4% (n=5). This compares favorably with the control group (n=124), who had pneumothorax rate of 21% (n=26, p=0.007) and chest tube placement rate of 8% (n=10, p=0.18). In addition, this compares well to previously published rates of pneumothorax and chest tube placement of up to 61% and 15%, respectively. The average cost per patient using the track embolization technique was $262.40. This compares favorably with the average cost per patient in the non-track embolization group, which was $352.07.

Conclusions: Use of the track embolization technique during CT-guided percutaneous lung biopsy and/or fiducial marker placement decreases the rates of pneumothorax and chest tube placement. Cost analysis demonstrates an overall savings, which supports the use of Surgifoam for the track embolization technique. While use of Surgifoam for this purpose does lead to a small increase in cost for patients who do not develop a significant pneumothorax or require chest tube placement, the average cost per patient (due to decrease in chest tube placement, hospitalization, and follow-up imaging) is decreased when applying this technique to the entire group of patients.

Cone-Beam Computed Tomography Images Fusion in Prediction of Lung Ablation Volumes: A Feasibility Study

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Purpose: The purpose of this study was to assess the feasibility of 3D cone-beam computed tomography (CBCT) fusion imaging with “virtual probe” positioning for use in the prediction of ablation volume in lung tumors that are treated percutaneously. Materials and Methods: Study subjects were selected among patients scheduled for ablation. Pre-procedural computed tomography contrast enhanced scans (CCT) were merged with a CBCT volume (Phillips XperT CT dataset [Phillips Medical Systems, Best, the Netherlands]) obtained to plan the ablation. An off-line tumor segmentation within the angiography suite was performed to stabilize the number of antennae and their positions within the tumor to obtain the volume of ablation desired. The volume of ablation obtained, evaluated on CECT performed after 1 month, was compared with predicted volume of the pre-procedural tumor segmentation. Feasibility on the basis of accuracy evaluation (visual inspection and quantitative evaluation), technical success and the technical effectiveness were computed. Twenty of the patients with lung tumors treated by percutaneous thermal ablation were selected and treated on the basis of the 3D CBCT fusion imaging. Results: In all cases, the volume of ablation predicted was in accordance with that obtained. The difference between predicted ablation volumes and obtained volumes on CECT at 1 month was 1.8 cm³ (standard deviation 0.6, max 0.9) for microwave ablation and 0.9 cm³ (standard deviation ±1.1, min 0.1, max 0.7) for radio-frequency ablation.

Conclusions: Use of 3D CBCT fusion imaging on pre-procedural XperCT dataset to predict ablation volumes could be useful in the identification of expected volume. However, evaluation of additional patients is needed to obtain stronger evidence.

Targeted Radiofrequency Ablation & Cement Augmentation of Metastatic Vertebrae Lesions Using Three-Dimensional Fluoroscopic Imaging

M. Syed, E. Halpert

Purpose: Radiofrequency ablation and concomitant cement augmentation is an effective musculoskeletal interventional oncology procedure, particularly in the setting of unabating pain secondary to osseous metastatic disease. Conventionally this procedure is most commonly performed under traditional fluoroscopy, computed tomographic (CT) fluoroscopy, and, uncommonly, CT guidance. At our institution, we use a novel method consisting of software-based reconstruction of acquired fluoroscopy images into 3-dimensional (3-D) datasets (3-D spin acquisition) within the angiography suite using a ceiling-mounted C-arm. This allows for cross-sectional imaging within the angiography suite without the need for CT-fluoroscopy. At the same time it improves confidence of cannula placement with delineation of bony anatomy and measurable ablation zones when compared with traditional fluoroscopy (Figure 1).

Materials and Methods: A single-operator, single-institution retrospective review of 5 cases was performed. In all cases, patients demonstrated bony metastatic lesions with significant associated pain. Three-dimensional spin acquisition was used for cannula placement and navigation, as well as ablation and cement augmentation. An initial 3-D spin acquisition of the area of interest is obtained. Images of the spine are reconstructed on an outside computer, using a bone algorithm to determine the exact areas of interest (Figure 2). Images can be reconstructed to a minimum slice thickness. The computer then calculates the table position and C-arm angles for cannula placement and entry in the x, y, and z planes depending on the operator’s desired plane of entry. Once this is complete, the post-processed image coordinates are sent to the C-arm unit, and the appropriate angulations for both frontal and lateral projection are stored per-set into memory locations in the angiography console. The operator proceeds to cannulate and ablate, using 3-D spin acquisition to obtain images and reconstructing them in the axial plane to determine bony boundaries and an accurate zone of ablation. Upon conclusion, fluoroscopy is used to monitor cement augmentation, as is routinely done. A final 3-D acquisition is obtained allowing for a global post-procedure image of the areas of intervention.

Figure 1: 3-Dimensional fluoroscopic imaging is used to see how cannulas are positioned.

Figure 2: An image of the spine is reconstructed to determine areas of interest.
Results: All 5 patients demonstrated satisfactory results after ablation/augmentation with symptomatic relief of pain. No significant complications were documented.

Conclusions: Three-dimensional spin acquisition provides the ability to plan your position of entry accurately in the x, y, and z planes. Additionally, the same method of acquisition allows for cross-sectional and volume-based maximum intensity projection imaging of an acquired dataset, allowing the operator to visualize the area of interest 3-dimensionally in the pre-, intra-, and post-procedural stages of the planned procedure. This is particularly helpful in cases when it is important to make sure there is no breach of the spinal canal or to assess the overall area of canal augmentation. Three-dimensional spin acquisition can be performed efficiently within existing angiography suites provided the necessary retrograde package is available—without necessitating the need for additional hardware. An additional benefit is that this method does not increase procedure time. In fact, in cases of difficult anatomy, it may even help reduce fluoroscopy and procedure times.

At our institution, this is the imaging guiding method of choice for percutaneous radiofrequency ablation and/or cement augmentation of metastatic spinal lesions.

Implementation of a Standard Interventional Radiology Signout as a Communication Quality Improvement Initiative

J. Hoffmann, A. Fadl, J. Flug, A. Baadh, M. Hon, N. Georgiou

Purpose: As the complexity and volume of cases performed in Interventional Radiology (IR) continues to grow, the need for improved communication between covering physicians, residents, and ancillary staff is critical to improve patient outcomes and minimize errors. The IR section underwent a quality improvement initiative implementing a standardized sign-out system consisting of an electronic tool and a formalized daily sign-out session. Education regarding appropriate sign-out was targeted to residents-in-training to address the growing complexity and volume within the department. The purpose of this project is to improve intra-department communication regarding residents and management of interventional radiology patients.

Material and Methods: A standardized electronic was created to assist with post-procedural patient management. This was accessible to all interventional radiology attendees and resident physicians through a Health Insurance Portability and Accountability Act-compliant electronic database. A daily sign out session between IR staff and the on call resident was started. Baseline survey data (5-point Likert scale) was collected from the radiology residents regarding the initial informal sign-out system. The same survey was readministered 4 weeks after implementation.

Results: Data analysis was focused on resident responses, as they are most heavily involved in the signout process. This initial survey demonstrated that all radiology residents (n = 14) strongly agreed or agreed that an electronic accessible log of active IR cases would allow for improved signout and communication regarding these patients. After 1 month of implementation of the new signout system, survey data demonstrated a positive trend in resident comfort handling phone calls and questions regarding IR cases while on call. In addition, the follow-up data demonstrated resident agreement that the new system allows for improved signout and communication and creates a stronger emphasis on patient safety.

Conclusions: There is critical need for continuous coverage and effective handoff in IR. Implementing a standardized signout helps IR physicians improve patient care and minimize hand off errors. This process also increases resident comfort in handling questions about IR patients and allows the residents to more effectively communicate with referring physicians about these patients. Based on our initial survey data, follow-up actions will include implementation of additional resident education to explain how to use the case database. A longer-term follow-up survey is needed to evaluate long-term results, as it will take many months for all of the residents to rotate through IR department and fully become acclimated to the new system.

A Guide to Percutaneous Cryoablation of Renal Masses in Difficult Anatomic Locations

J. C. Hoffmann, A. Fadl, A. Baadh, O. Shoab, R. Eppeheimer, S. W. Stavropoulos

Purpose: To discuss the pathophysiology of renal cell carcinoma, describe indications for treatment of small renal masses, present technical aspects of percutaneous cryoablation, and highlight adjunctive techniques used to improve success and safety during cryoablation of renal masses in more difficult anatomic locations.

Material and Methods: A case-based format will be utilized to highlight techniques to improve outcomes in cryoablation of renal masses in difficult anatomic locations. Four major topics will be presented, including maximizing position of the patient, utilization of retrograde pyeloplasty, using hydrodissection to displace critical structures away from the zone of ablation, and angioplasty balloon interposition to displace adjacent structures from the ablation zone. In addition, combining ablation and embolization in the most difficult anatomic locations will be described.

Results: Utilizing adjunctive technique during cryoablation leads to successful cryoablation of renal masses in difficult anatomic locations. Placing patients in lateral decubitus position, with the affected side down, results in less aeration of the adjacent lung and reflux increased aeration of the contralateral lung. This allows for improved visualization as well as preserving renal parenchyma. A retrograde ureteral catheter can be placed to infuse warm saline into the ureter and renal pelvis in an attempt to protect these structures during cryoablation. Hydrodissection can be used to infuse normal saline through a trocar to displace critical structures away from the zone of ablation. Similar to the concept of combining ablation and embolization for treatment of 3 to 5 cm liver tumors, one can combine therapies in an attempt to achieve a synergistic effect. This is particularly useful when there is concern that a complete ablation may not be possible given lesion location in a poor surgical candidate.

Conclusions: Neophron-sparing therapies have been increasingly utilized in treatment of renal masses. Lesions typically considered more difficult to ablate include central lesions, size larger than 3 cm, upper pole location, endophytic, and adjacent to ureter, colon, or other abdominal organs. Multiple techniques can be used to maximize the likelihood of successful cryoablation of masses in difficult anatomic locations, including hydrodissection, retrograde pyeloplasty, maximizing patient positioning, and angioplasty balloon interposition.

Percutaneous Radiofrequency Ablation (RFA) for Renal Tumors Larger Than 4 cm


Purpose: To evaluate technical success and long-term outcomes of radiofrequency ablation of T1b renal tumors.

Material and Methods: Ninety-four biopsy proven renal tumors (size 8 to 65 mm) in 80 patients were treated with percutaneous RFA. Mean patient age was 67.8 years (range 37 to 90 years). The percutaneous ablation was carried out under US/CT guidance in all patients. Seven of 94 tumors were T1b staged (mean size 43.81 mm; range 40 to 47.2 mm). Imaging follow up was performed by contrast-enhanced CT at 24 hours, at 45 days, and then at 6-month intervals after treatment.

Results: In T1b tumors group, 4 lesions were completely ablated after a single RFA session while 3 patients had residual tumor: 1 was radically treated after a second session and another is still waiting for a second RFA. The last patient was not retreated due to deterioration of his performance status (ASA 4). The overall technical success rate of this cohort is therefore 71.4%. No major complications occurred.

Conclusions: RFA is safe and effective in T1b renal tumors in well-selected patients, but retreatment should be sometimes considered in order to achieve a satisfactory outcome.

Direct Puncture of Subcapsular Hepatocellular Carcinoma for Thermal Ablation Does Not Result in High Seeding Rates


Purpose: The risk of tumor seeding associated with thermal ablation of hepatocellular carcinoma (HCC) is now known to be low when biopsy is avoided, tract cautery is performed, and tumors are punctured through normal parenchyma. However, direct puncture of subcapsular HCC has been considered risky due to a purported high seed risk. The purpose of this study was to identify the rate of tumor seeding and other complications associated with radiofrequency (RF) and microwave (MW) ablation of subcapsular HCC.

Materials and Methods: This was a retrospective, institutional review board-approved, multicenter study. Our institutional RF and MW databases were reviewed for cases of subcapsular hepatic tumors that underwent thermal ablation via a direct puncture approach (traversing <5 mm of normal parenchyma). All cases underwent tract cautery of overlying normal hepatic parenchyma. Major complications, including tumor seeding, hemorrhage, and local tumor progression (LTP), were recorded.

Results: Sixty-seven HCCs in 61 patients were treated by RF and MW using a direct puncture. Average tumor size was 2.5 cm (±0.8) with 31 months mean follow-up. The overall LTP rate was 14.9%. There were no significant complications, including no cases of symptomatic hemorrhage. There was 1 case of tumor seeding in a patient who had undergone percutaneous biopsy 2 weeks before ablation. The seed was successfully surgically removed, and the patient is alive 13 years after ablation.

Conclusions: Direct puncture of subcapsular HCC for thermal ablation appears to be safe when performed with tract cautery. Similar to other large studies, the only case of seeding in our study was associated with prior percutaneous biopsy.

Evidence-Based Comparisons of Percutaneous Ablation Techniques

S. H. Shaihik, K. McGill, A. Astani, S. Schwartz

Purpose: Arterial interventions and ablation are 2 methods used in interventional oncology to treat patients with a high surgical risk or nonoperable malignancies. Percutaneous ablation techniques use thermal and nonthermal sources to directly destroy tumor cells. The purpose of this poster presentation is to review the principles and techniques of radiofrequency ablation (RFA), microwave ablation, and cryoablation, as well as irreversible electroporation. Additionally, evidence-based comparisons regarding the advantages, disadvantages, and complications associated with each modality will be discussed, along with the authors’ own institution’s experience.

Materials and Methods: A review of the literature on Medline using relevant keywords and a retrospective analysis of percutaneous ablation data from a busy interventional radiology department at a tertiary care center were performed for the past 5 years.
CIO Abstracts

Purpose: To report the safety outcomes of percutaneous magnetic resonance (MR)-guided irreversible electroporation (IRE) in the treatment of prostate adenocarcinoma.

Materials and Methods: One hundred thirty patients with prostate adenocarcinoma in various stages underwent IRE (Nanoknife; Angiodynamics, Queensbury, NY) treatments (n = 139) from May 2011 to July 2014. Of 130 patients, 22 had history of recurrences after other treatments (5 TURP, 3 HIFU, 8 IRE, 4 radiotherapy, 2 resection and radiation). All patients underwent magnetic resonance imaging (MRI) scans before and after IRE treatment. MRI-planned 3D-mapping biopsies of the prostate were also used to determine the exact location of tumor in 47% of the cases. Magnetic resonance imaging scans were obtained in all cases before and 10-24 hours after the treatments, as well as follow-up MRIs were obtained when patients were seen at 3, 7, 12, 18, 26, and 36-month intervals. Twenty-seven patients have not yet returned for the first 3-month follow-up visit and MRI. Retrospective analysis was performed on 103 patients who completed at least the first 3-month follow-up visit and MRI. Whole-gland ablation was performed in 23 cases, and only partial-gland ablation in 80 cases. The mean percentage of ablated prostate tissue was 64%. Irreversible electroporation prostate treatments occasionally included the following structures: urethra, neurovascular bundle, bladder, rectum, ureteral sphincter, and seminal vesicles (93, 82, 24, 2, 12, and 27, respectively).

Results: There were no complications related to the procedures. The average complication rate was 1-2 days. The Foley catheter was removed, on average, after 1.5 days. No pain medications above World Health Organization level I were required. Twelve patients (11%) reported a temporary partial (n = 8) or complete (n = 4) reduction in potency, which returned to the previous state after 6 to 9 months. None of them suffered long-term impotency. Five patients (4%) reported amenorrhea (n = 4) or hyponorrhea (n = 1). Eight patients (7.7%) developed urinary incontinence after procedure, which was transient except in 1 case (0.9%). Three patients (3%) reported an episode of infection (cystitis, epididymo-orchitis, focal bacterial infection) following procedure.

Conclusions: Irreversible electroporation offers a promising safety profile for the treatment of prostate adenocarcinoma. Both the post-procedural adverse events and recuperation period are favorable when compared with other conventional treatments. Further long-term prospective studies are warranted.

Acute Assessment of Portal Vein Patency Using Intraparenchymal Carbon Dioxide and a 25-Gauge Spinal Needle

C. A. Fauria, B. Bordlee, J. Caridi

Purpose: To demonstrate a rapid, safe, efficacious method of assessing portal vein patency in equivocal patients before liver transplant.

Materials and Methods: In a retrospective study of 5 patients (2 males, 3 females), all with known hepatocellular carcinoma, ascites, and equivocal portal vein patency by 3-dimensional imaging, a 25-gauge spinal needle (Cook Medical, Bloomington, IN) was inserted into the liver parenchyma without correcting either the ascites or coagulopathy (international normalized ratio as high as 0.9-2.4). Using the CO2mander™ (Portable Medical Devices, Fort Myers, FL) and AngiAssist™ delivery system (AngioAdvancements, Fort Myers, FL), approximately 10-20 cc of pharmaceutical grade CO2 was administered through the spinal needle directly into the hepatic parenchyma to assess patency of the portal venous system. Digital subtraction angiography images were obtained at 6 frames per second. The patients received a liver transplant based on the angiographic assessment.

Results: The number of CO2 injections per patient ranged from 1 to 5 requiring a 1.5 days. No pain medications above World Health Organization–level 1 were required. Forty percent of patients needed hospitalization after the procedures. The average recuperation period are favorable when compared with other conventional treatments.

Conclusions: Irreversible electroporation offers a promising safety profile for the treatment of prostate adenocarcinoma. Both the post-procedural adverse events and recuperation period are favorable when compared with other conventional treatments. Further long-term prospective studies are warranted.

Contrast-Enhanced Ultrasonography Improves Short-Term Response of Transcatheter Arterial Chemoembolization

J. Ren, X. Han, X. Duan, T. Li, K. Zhang, M. Zhang

Purpose: The study aimed to evaluate the early response rate of hepatocellular carcinoma managed by transcatheter arterial chemoembolization (TACE) with or without contrast-enhanced ultrasonography (CEUS)-guided percutaneous ethanol injection (PEI) or radiofrequency ablation (RFA).

Materials and Methods: Sixty patients diagnosed as having non-lesion hepatocellular carcinoma by contrast-enhancement computed tomography were randomly assigned to 2 groups—group A for TACE alone and group B for CEUS-guided PEI or RFA in addition to TACE. Percutaneous ethanol injection or RFA was administered in patients of group B 3 days after TACE if residual hepatocellular carcinoma was visible on CEUS. Two months later, all cases undertook contrast-enhancement computed tomography to assess the response of tumors by mRECIST (modified response evaluation criteria in solid tumors) criteria. The difference of response rates (complete response combined with partial response) between group A and group B and the size of hepatocellular carcinoma were analyzed by logistic regression.

Results: The success rate of TACE in group A and group B was 93.30% (89.5%) and 30.30% (100%), respectively. One patient of group A died of tumor rupture 3 days after TACE. Nineteen patients in group B with residual hepatocellular carcinoma were examined by CEUS and PEI or RFA in addition to TACE, and 17 cases (89.5%) were operated. One patient in group B died of hepatic encephalopathy 50 days after additional PEI. At the 2-month follow-up, the response rate of tumors in group B compared with group A was 66.7% to 40.0% (odds ratio [OR]=4.67; 95% confidence interval [CI], 1.284-1.746. p=0.019), respectively. The OR of response on tumor size was 0.452 (95% CI, 0.287-0.712, p=0.001).

Conclusions: The short-term response rate of CEUS-guided PEI or RFA in addition to TACE is higher than TACE alone.
surgery or transplantation in patients with unresectable HCC who can have placement of appropriately positioned hepatic arterial catheters. The purpose of this study is to evaluate treatment with 90Y in HCC patients who will then receive SOC sorafenib and to compare survival outcomes with those of patients receiving only sorafenib. The primary objective is to evaluate 90Y in patients with unresectable HCC where SOC sorafenib is planned.

Materials and Methods: This phase 3, open-label, multicenter, randomized study will evaluate 90Y treatment in ~90 patients with unresectable HCC. Eligible patients (where SOC sorafenib therapy is already planned) will be randomized 1:1 to control and treatment. Control patients will receive SOC sorafenib according to label. The treatment group will receive 90Y before SOC sorafenib. Primary outcome is overall survival from time of randomization. Secondary endpoints include time to progression/untreatable progression/symptomatic progression, tumor response, quality of life, and adverse events. Sorafenib patients will have study visits every 8 weeks for as long as the patient remains in the study. Patients randomized to 90Y will have pretreatment evaluations and treatment to the first lobe during weeks 3-4; patients with bilobar disease will have pretreatment evaluations and treatment to the second lobe during weeks 5-8. After 90Y treatment, study visits will occur every 8 weeks as long as the patient remains in the study. Follow-up visits will occur every 8 weeks from randomization until disease progression.

Results: This study is currently recruiting participants.

Conclusions: This study will evaluate the use of 90Y in advanced HCC patients given its potential to enhance survival with less toxicity than the current SOC.

Sheathless Transcatheter Arterial Chemoembolization: It Makes Cents!

K. Kansagra, J. Caridi

Purpose: To demonstrate that many interventional oncology cases can be performed without a hemostatic sheath, which lessens the potential complications and cost of the procedure.

Materials and Methods: Fifty-two noncoagulopathic patients (45 male, 7 female) 35-79 years of age underwent a drug-eluding bead procedure. In 24 patients, the procedure was attempted without a hemostatic sheath using a 0.038 in 4 Fr SORS 0 catheter and a high-flow microcatheter. In each of the remaining cases, either a 4 or 5 Fr hemostatic sheath was employed. If there was evidence of bleeding at the puncture site, the sheathless patients were converted to a 4 Fr sheath. Manual compression for hemostasis was performed in all cases. Bed rest for those with and without sheaths before ambulation was 6 and 2 hours, respectively.

Results: Of the 24 patients attempted sheathless, 20 (83%) were successful to completion. These 20 patients remained on bed rest for 2 hours and were ambulated and discharged the same day without evidence of post-operative puncture-site complications. Four (17%) of the 24 patients required conversion to a 4 Fr sheath. Of the remaining 28 patients who were treated using hemostatic sheaths and 6 hours of bed rest, 2 (5%) had mild bleeding at the puncture site. The intent of the procedure was accomplished in all cases.

Conclusions: Using a 4 Fr 0.038 end-hole catheter and high-flow microcatheter in interventional oncology is efficacious and safe. It also permits early ambulation and discharge, thereby eliminating the need for the added cost and risks of arterial closure devices.

Technical Development, Yttrium-90 Glass Microspheres: Minimally Embolic Device Engineered to Treat Hepatocellular Carcinoma

W. Mullett

Purpose: The goal of radioembolization for liver cancer is to maximize dose/limit toxicity. During transarterial radioembolization (TARE), radioactive particles that are injected into the tumor via the hepatic artery become trapped and emit radiation. Yttrium-90 glass microspheres (90Y, TheraSphere® [BTG, Farnham, UK]) are a minimally embolic device engineered for hepatocellular carcinoma (HCC). This is an overview of the technical development/design features of the 90Y glass microspheres, which are approved by a Food and Drug Administration humanitarian device exemption.

Materials and Methods: Key optimized design considerations for the 90Y glass microspheres are the choice of radionuclide, microsphere stability/uniformity+specific activity, and dose preparation/delivery approach. 90Y radionuclide plays an important role in dose delivery. 90Y is a high-energy β-emitter with a suitable t1/2 and long particle penetration distance. Optimal radiation penetration ensures complete tumor dose coverage. Incorporating the 90Y isotope into a glass matrix yields highly radioactive, stable microspheres. Y2O3/A2O3/SiO2 are melted and formed into spheres of uniform size/shape. The stable Y2O3 (40% of glass formulation) converts to 90Y active, stable microspheres. Y2O3/Al2O3/SiO2 are melted and formed into spheres of uniform size/shape. The stable Y2O3 (40% of glass formulation) converts to 90Y active, stable microspheres. Minimally embolic 90Y also permits possible retreatment. Padia (2013) illustrated radiation uptake in the local region of target tumor, which demonstrated retreatment possibilities 1 month after treatment.

Conclusions: The overarching goal of TARE is to maximize tumor dose with minimal toxicity. 90Y glass microspheres enable direct delivery of optimized, localized radioactive dose to tumor tissue via the vasculature and are minimally embolic and contained in a highly stable matrix.

Treatments of Hepatocellular Carcinoma Using Microwave Ablation or Transarterial Arterial Chemoembolization: A Lesion-by-Lesion Analysis of Local Tumor Control Stratified by Tumor Size


Purpose: Barcelona (BCLC) Guidelines support thermal ablation as first-line therapy for early hepatocellular carcinoma (HCC), while transcatheter arterial chemoembolization (TACE) is reserved for more advanced disease. However, TACE has been extensively used for the treatment of small HCCs when ablation is not feasible or at the discretion of the physician operator. Unfortunately, there is a paucity of data examining local tumor control rates for small tumors treated with each modality, partly because the modalities are assessed by different criteria (local tumor progression [LTP] for ablation vs mRECIST for TACE). The purpose of this study was to compare the local control for TACE and microwave ablation (MWA) on a lesion-by-lesion basis, focusing on early HCC.

Materials and Methods: This study was institutional review board approved and HIPAA compliant. Cases of HCC <5 cm treated by MWA or TACE (doxorubicin, mitomycin C, and cisplatin mixed with lipiodol) were retrospectively reviewed. In cases of large and/or multifocal tumors treated with TACE, only individual tumors <3 cm were included. Tumors were divided into 2 groups, ≤3 cm and 3.1-5 cm, and followed by computed tomography or magnetic resonance imaging using mRECIST criteria and LTP. Comparisons were performed by Kruskal-Wallis and Fisher’s exact tests.

Results: The MWA group included 120 HCCs in 78 patients (male/female: 63/15; mean age: 60.7±6.7 years), and the TACE group included 50 HCCs in 27 patients (male/female: 21/6; mean age: 63.4±8.2 years). Mean follow-up was slightly longer for the MWA group (9.6 vs 7.0 months). Model for end-stage liver disease scores were higher for the MWA group (10.1±2.5 vs 7.4±3.9; p<0.001). Overall, LTP was significantly lower for MWA compared with TACE (5.8% vs 60%; p<0.0001). Accordingly, complete response (CR) was greater after MWA (94.2% vs 38%; p<0.001). These trends held for both tumor size classifications (LTP: 5.7% vs 54.5% for 0-3 cm and 7.7% vs 70.6% for 3.1-5 cm; p<0.0001). Similarly, HCCs of all sizes were more likely to demonstrate complete and partial response (PR) after MWA according to mRECIST criteria (Table).

Table. Hepatocellular Carcinoma Response, Stratified by Tumor Size

<table>
<thead>
<tr>
<th>Tumor Size</th>
<th>mRECIST Response (%)</th>
<th>CR</th>
<th>PR</th>
<th>SD</th>
<th>PD</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCC ≤3 cm</td>
<td>MWA</td>
<td>94.3</td>
<td>2.9</td>
<td>1</td>
<td>1.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>TACE</td>
<td>42.4</td>
<td>18.2</td>
<td>30.3</td>
<td>9.1</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>HCC 3.1-5 cm</td>
<td>MWA</td>
<td>92.3</td>
<td>7.0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TACE</td>
<td>29.4</td>
<td>42.6</td>
<td>23.5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CR, complete response; HCC, hepatocellular carcinoma; mRECIST, modified Response Evaluation Criteria in Solid Tumors; MWA, microwave ablation; PD, progressive disease; PR, partial response; SD, stable disease; TACE, transcatheter arterial chemoembolization.

Conclusion: A direct comparison between TACE and MWA for early HCC is not feasible at our center, as patients were triaged according to BCLC criteria. However, for individual small HCCs, particularly in the ≤3-cm cohort, MWA was significantly superior to TACE for local tumor control. This result supports the use of ablation as first-line therapy for small HCCs, as recommended in the Barcelona Guidelines.

Treatment of Hepatocellular Carcinoma Using Transarterial Chemoembolization With Oncoze™ Microspheres

B. Bordlee Jr., K. Kansagra, C. Fauria, S. Beech, J. Caridi

Purpose: To evaluate the efficacy of doxorubicin-laden Oncoze™ (Celonova, San Antonio, TX) in the treatment of hepatocellular carcinoma (HCC).
**Yttrium-90 Glass Microspheres for Metastatic Colorectal Carcinoma of the Liver for Patients Who Failed First-Line Chemotherapy**

A. Karpf

**Purpose:** Colorectal cancer (CRC) is the third most common cancer in the U.S. Half of patients diagnosed with CRC develop liver disease. Unresectable liver metastases are responsible for morbidity/mortality. Typically, patients with metastatic CRC receive an oxaliplatin- or irinotecan-based regimen as first-line chemotherapy with or without bevacizumab. On progression, patients are treated with the regimen they did not receive during first-line chemotherapy. A study to evaluate yttrium-90 glass microspheres (TheraSphere® [BTG, Farnham, UK]) in patients with unresectable metastatic colorectal cancer (mCRC) of the liver showed that patients with good performance status, no extrahepatic metastases, and ≤25% tumor may benefit from 90Y. 90Y glass microspheres are approved by the Food and Drug Administration under a humanitarian device exemption. This study will evaluate outcomes in this patient subset when 90Y is added to second-line standard of care (SOC) chemotherapy. The objective is to evaluate efficacy/safety of 90Y in patients with liver mCRC that has progressed after first-line chemotherapy.

**Materials and Methods:** This is an open-label, multicenter, randomized study to evaluate 90Y treatment in ~340 eligible patients in whom SOC second-line chemotherapy with either an oxaliplatin- or irinotecan-based regimen is planned. Eligible patients will be randomized 1:1 to control or treatment. Treatment patients will receive a first cycle of second-line chemotherapy within 21 days of randomization and at least 14 days after the last dose of first-line agents including vascular endothelial growth factor inhibitors. 90Y will be administered in place of the second chemotherapy cycle. Control patients will receive planned SOC second-line chemotherapy. The primary endpoint is progression-free survival. Secondary endpoints are overall survival, hepatic progression-free survival, time to symptomatic progression, tumor response rate, and adverse events. Patients will have regular study visits as long as they participate, at which time safety/efficacy data will be collected and recorded.

**Results:** This study is currently recruiting participants.

**Conclusions:** Given the potential benefit to mCRC patients, this phase 3 study will evaluate 90Y in the second-line setting in patients who have progressed following SOC first-line chemotherapy.

**A Recipe From the Interventionalist’s Cookbook: How to Make a Computed Tomographic Biopsy Phantom**

A. Baadh, A. Fadl, N. Georgiou

**Purpose:** Computed tomographic (CT)-guided biopsy is a common procedure performed by diagnostic and interventional radiologists, with more than 600,000 performed annually in the U.S. Training in interventional radiology predominantly uses the apprenticeship model, where clinical and technical skills of invasive procedures are learned while being performed on patients, which places both the patient and proceduralist at unnecessary risk. Medical education is moving toward increased use of simulation for the training and assessment of procedural skills as it allows learners to strengthen their technical skills without inferring risk to either patient or learner. A CT biopsy phantom that is inexpensive and easy to produce would be an asset for radiology student, resident, and fellow education. This exhibit will describe the planning, development, and construction of a phantom that is made from ingredients that are widely available.

**Materials and Methods:** To review the benefits of simulation training for diagnostic and interventional radiologists. Detail the specific role of simulation for radiology trainees learning to perform image-guided procedures. Demonstrate an easy and inexpensive way to make a reusable phantom to teach, practice, and evaluate the image-guided percutaneous biopsy skill set.

**Results:** Hand-eye coordination is critical for successful percutaneous image-guided biopsy. Commercial CT biopsy phantoms are available to assist the trainee; however, these devices cost upward of $2200 and must be replaced after repeated use. This exhibit will demonstrate the construction of a CT biopsy phantom using common, non-toxic ingredients that cost approximately $20. Concepts used when making ultrasound procedure phantoms were significantly modified to optimize background and lesion visualization under CT guidance. The phantom allows the trainee to learn sterile technique, skin preparation, anesthetic injection, grid placement, and skin marking. Once the basic principles have been learned, the trainee gains insight into lesion localization, needle placement, and repositioning under CT guidance. Finally, familiarity with various needles, trocars, and biopsy devices is achieved. The phantom allows core biopsies to be obtained and examined, which confirms technical success. Mastering these core fundamentals increases skill and confidence, leading to improved patient care and safety.

**Conclusions:** General and interventional radiologists must be proficient and confident in performing CT-guided biopsies. Medical simulation training is an evolving component of radiology education that should be used in all teaching programs. We describe the construction of a low-cost, easily made, and reusable CT biopsy phantom that can be used for radiology education.

**Phase 1 Trial of Image-Guided Vaccination of Autologous Dendritic Cell in Advanced Cancer: Technical Aspects**

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**Purpose:** The therapeutic goals of cancer vaccination are the induction of tumor regression secondary to the production of tumor specific immune factors and local inflammatory cytokines, as well as the induction of long-term anti-tumor surveillance to prevent recurrence. Dendritic cells (DC) are quintessential in the anti-tumor immune response armamentarium. A major barrier that hinders the efficacy of cancer vaccination with DC is the hostile environment of the local tumor milieu that inhibits activation and subsequent maturation of DC required to process and exposes the entire repertoire of antigens to the downstream cascade of immune mediators. DCVax® (Direct Northwest Biotherapeutics, Inc., Bethesda, Maryland) are autologous dendritic cells activated ex vivo with bacillus Calmette Guérin and interferon gamma for direct intratumoral injection; this approach attempts to circumvent the aforementioned barriers thereby maximizing the potential to induce anti-tumor immune responses.

**Material and Methods:** Advanced cancer patients with at least 1 injectable tumor were enrolled in dose escalating cohorts to receive IT injections of 2, 6, or 15 million activated autologous DC (aDC) in order to determine the maximal tolerated dose. Each patient was designated to receive up to 4 IT injections at weeks 0, 1, 2, and 8 with options for 24 and 40 weeks dependent upon tolerance and response. Tumors > 1 cm were accessed at operator preference with a single 1718/19G Chiba Needle (Cook Medical, Bloomington, Indiana) utilizing ultrasound/computed tomography/magnetic resonance imaging. Tumor biopsy was obtained for viability and research. 20/22G Chiba needles were autoclaved and inserted coaxially via the guide needle into the tumor periphery. Aliquots of the 1 cc injectate were deposited in up to 4 locations during withdrawal towards the guide needle from the periphery. Patients were observed for acute toxicity 2 hours after each outpatient administration.

**Results:** Thirty-three patients received at least 1 IT injection; total 122 injections, range 1 to 6, median 4. Injection sites included tumors in liver, lung, mediastinum, extremity soft tissue & lymph nodes. Biopsies were obtained without complications. IT injections of 4 were well tolerated with the anticipated, self-limited side effects of fever, chills and minor injection site discomfort. No unanticipated nor serious adverse events occurred.

**Conclusions:** Outpatient image guided multisession aDC tumor vaccination is technically safe and well tolerated. Concomitant biopsy did not impact the safety profile.

**The Track Embolization Technique to Improve Safety of Image-Guided Percutaneous Solid Abdominal Organ Biopsy**

J. C. Hoffmann, A. Baadh, A. Fadl, A. Morim, D. Danda, O. Shoai, N. Georgiou, M. Hon

**Purpose:** To describe the procedural steps of the track embolization technique used during percutaneous image-guided solid abdominal organ biopsy to decrease risk of complications and present outcomes data for the initial study population. The procedural steps of this technique do vary from the track embolization technique used in the lung/thorax, and these key differences will be described in detail.

**Materials and Methods:** To our knowledge, the track embolization technique has never been described for use during image-guided percutaneous solid abdominal organ biopsy. This technique involves embolization of the biopsy track with active Surgifox® (Ethicon U.S.) injection via the trocar as it is withdrawn. This is a variation of a technique used during percutaneous lung biopsy that we described separately, with multiple important technical differences. We describe the procedural steps in detail, as well as present outcomes in 224 consecutive solid abdominal organ biopsies (liver, spleen, and kidney) performed at a single tertiary care institution from October 2011 through September 2013.

**Results:** In this patient population, there was no hemorrhage, pseudoaneurysm, or other vascular injury diagnosed after percutaneous image-guided biopsy. This compares well with published rates of vascular complication in the radiology literature ranging from 2% to 12%, particularly in more vascular organs such as the liver, spleen, and kidneys. No complications occurred in any of the procedures.

**Conclusions:** Track embolization with Surgifox® injection can be used during image-guided percutaneous biopsy of solid abdominal organs to decrease rates of vascular complication. The results reported regarding the initial study population suggest that a larger, prospective study is indicated for further evaluation.
Yttrium-90 Infusion: Incidence and Outcomes of Delivery System Occlusions


Purpose: To evaluate the incidence, cause, and management of delivery system occlusions during Yttrium-90 (90Y) microsphere infusions and to identify techniques to prevent occlusions.

Materials and Methods: We retrospectively reviewed 886 consecutive radioembolization deliveries in 498 patients (mean age 65 years; 299 male) performed between June 2001 and July 2013 at a single academic tertiary care hospital. Procedural details about occlusion events were reviewed in detail. Statistical analysis assessed association between catheter occlusions and patient and procedural characteristics.

Results: Eleven occlusions occurred during 886 90Y microsphere deliveries (1.2%). Five occlusions were associated with contained leakage of radioactive material, and 1 was associated with a spill. All but 1 patient completed their treatment the same day, and 5 required repeat catheterization. One patient returned a week later to complete treatment. Significantly higher number of occlusions occurred with deliveries of resin (11/492; 2.2%) versus glass (0/394; 0%) spheres (p=0.002). Occlusions were more likely to occur within the proximal portion of the delivery apparatus (p=0.002). There was no significant relationship to any patient characteristics, and there was no improvement with operator experience. The most common cause of occlusion was resin sphere delivery device failure. As a result, this delivery device has undergone design modifications.

Conclusions: Yttrium-90 microsphere delivery device occlusion is uncommon but does occur. Understanding causes and how to troubleshoot can limit the incidence and detrimental effects and has led to design improvement.

A Novel Dual Infusion Protocol to Evaluate Differences in Embolic Therapies Among Different Infusion Catheters

A.C. Bourgeois, Y. Bradley, J. McElmurray, N. Keefe, A. Pasciak

Purpose: The selection of infusion catheters for use in transcatheter liver–directed embolotherapy is largely dependent upon operator preference, device familiarity, and empirical evidence. This is at least partially attributable to the absence of a standardized protocol for evaluation of performance in the delivery of liver-directed therapies. Since recent studies have suggested that differences in microsphere distribution may result from varying infusion catheters, a method of objective evaluation of infusion catheters in human patients is warranted. This protocol provides a novel, same-day, dual-infusion technique in which differences in embolic distribution among varying catheters can be directly compared.

Materials and Methods: An initial bolus infusion of 99mTc-macroaggregated albumin (MAA) was administered to patients with a nominal activity of 110 MBq for the purposes of lung shunt fraction evaluation prior to yttrium-90 radioembolization. A second, same-day 99mTc-MAA infusion of 600 MBq was performed with a different microcatheter but otherwise identical technique. Archived fluoroscopic images confirmed near-identical catheter placement. Differences in 99mTc-MAA distribution within tumor and non-target sites were evaluated via single photon emission computed tomography imaging on a qualitative and semi-quantitative basis (see Figure 1). Considering only the physical decay of the 99mTc from first infusion at the time the second infusion was imaged, the maximum remaining activity from the first infusion was < 15% of the activity injected in the second infusion, which rendered the effect residual persistent activity negligible.

Results: This method has been employed in several cases at the authors’ institution with reproducible alterations in MAA distributions among variable catheters, which confirms its validity.

Conclusions: This dual-infusion method is a conceptually similar technique to that used in same-day renal and cardiac perfusion studies and could be employed for objective comparison of microcatheter performance in liver directed therapy.

Retention of Persistent Disease After Renal Radiofrequency Ablation

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Purpose: The purpose of this study was to evaluate the efficacy of retreatment with ultrasound- and computed tomography (CT)-guided radiofrequency ablation (RFA) in persistent disease of renal masses after percutaneous ablation.

Materials and Methods: After renal percutaneous RFA, 9 of 81 (11%) patients had persistent disease detected with CT scan at 24 hours because of difficult location and/or size > 3 cm. Mean lesion size before the first treatment was 4.3 cm (range 3.2 to 4.7 cm). Retreatment was planned before patient’s discharge and scheduled within the next month.

Results: Six patients (66%) had a second RFA with a complete local result and without evidence of recurrence during a mean follow-up period of 23.3 months (range 7 to 56 months). Of the remaining 3 of 9 patients, 2 patients were not retreated due to high-grade comorbidities (American Society of Anesthesiologists scores of 3 and 4, respectively). One patient has not been retreated pending pulmonary infiltrate resolution.

Conclusions: Ultrasound- and CT-guided RFA is effective for retreatment of persistent disease after renal tumor ablation.