Selected Abstracts from the International Symposium on Endovascular Therapy (ISET)

2019 January 27–30, 2019, Hollywood, Florida

Abstract 1: Randomized Clinical Trial Using Autologous Adipose–Derived Mesenchymal Stem Cells for Hemodialysis Arteriovenous Fistula

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Purpose: To present the preliminary results and trial design of a phase 1 randomized clinical trial using autologous adipose–derived mesenchymal stem cells (AMSCs) for increasing maturation and preventing venous stenosis formation in arteriovenous fistulas used for hemodialysis.

Materials and Methods: A phase 1 single-institution study was performed under a physician IND investigating the role of AMSCs for increasing maturation and pre-venting venous stenosis formation in arteriovenous fistulas (AVFs) used for hemodialysis. This study enrolled all patients that met surgical and vein mapping criteria for placement of AVFs in either the radiocephalic or brachiocephalic location. Patients were randomized to either AMSC dose based on the surface area of the first 5 cm of the outflow vein calculated after the anastomosis was surgically created at a concentration of 500,000 cells/cm^2, which were applied by spraying the adventitia over 5 minutes' duration. Placebo patients received no cells. Patients were followed for 1 year using ultrasound evaluation of the AVF at 1, 2, 3, 6, and 12 months to assess for maturation, vein diameter, blood flow, and stenosis formation.

Results: Sixteen patients (4 women; mean age, 65.3 years) consented to enroll in the trial with 1 patient being a screen failure in operating room. These patients underwent the placement of a RCF (AMSC, 4; control, 3) or BCF (AMSC, 3; control, 3). There have been no adverse events related to the delivery of cells. By the end of December, 9 patients will have completed 1 year of follow-up, and another 3 completed 6-month follow-up. Interim data will be presented at the meeting in January.

Conclusions: Adventitial delivery of AMSCs is safe and the efficacy of the therapy will be presented as 1-year data becomes available on these patients.

Abstract 2: Comparing Hospital Utilization Outcomes (Catheter Based versus Systemic Therapy) for Submassive and Massive Pulmonary Embolism

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Purpose: Catheter-based intervention (CBI), ultrasound-accelerated thrombolysis, and catheter-directed thrombolysis for the treatment of pulmonary emboli (PE) has become increasingly popular and is an important alternative treatment option for patients with submassive and massive PE with contraindications to systemic anticoagulation. This retrospective study assesses the hospital utilization and economic impact of CBI versus systemic anticoagulation alone (SAA) for the treatment of acute massive and submassive PE by analyzing overall hospital and intensive care unit (ICU) length of stay (LOS) and rates of readmission in patients within the two treatment groups, evaluating the hypothesis that CBI may offset higher device or procedural costs by decreasing hospital utilization and resources.

Materials and Methods: An institutional review board–approved retrospective review of patient medical records with acute massive or submassive PE treated with CBI or SAA from November 2016 to September 2018 was performed at a single-center university hospital. Patients were divided into two groups: those treated with CBI and those treated with SAA. For each group, hospital LOS, ICU length of stay, and readmission rates related to PE were collected and compared.

Results: A total of 89 patients met the study criteria; 42 patients were treated using CBI, and 47 were treated with SAA. Average hospital and ICU LOS were not statistically significant ($P = 0.97$ and $P = 0.35$, respectively) for the CBI compared with the SAA-treated group (8.9 and 3.5 days vs 8.9 and 2.4 days, respectively). However, the 30-day readmission rates for PE-related causes between both groups were statistically significant, 23.1% for the SAA treatment group vs 7.1% for the CBI group ($P= 0.031$).

Conclusions: Interestingly, no significant difference in length of hospital or ICU stay was noted between the two groups. However, the 30-day readmission rates were significant and almost three times greater in the SAA treatment group. This finding is significant because almost 55% of patients were on noncommercial insurance plans (Medicare or state Medicaid) that impose payment adjustments and reduce health ratings for institutions with high readmission rates. Our study suggests that CBI, when compared with SAA for the treatment of massive and submissive PE, can avoid potential readmissions, thereby increasing hospital financial reimbursement rates and preventing potentially negative health ratings.

Abstract 3: BioMimics 3D Stent System: One-Year and (Interim) Two-Year Results of the MIMICS-2 Study

T. M. Sullivan, T. Zeller, M. Nakamura

Purpose: Endovascular treatment of femoropopliteal artery (FPA) disease is challenging; high rates of restenosis and multiple loading forces are problematic for innovative stent designs to overcome. The BioMimics 3D Vascular Stent System (Veryan, Horsham, UK) comprises a Nitinol stent with a unique 3D helical centerline designed to generate swirling blood flow and elevate wall shear stress in the stented segment and improve biomechanical performance. Preclinical studies showed how swirling blood flow reduces neointimal hyperplasia. MIMICS-RCT was the first randomized trial that compared two bare-metal stents in the treatment of FPA disease and demonstrated that stent design influences clinical outcome. Use of the BioMimics 3D helical stent resulted in higher patency at 2 years when compared with a straight stent control. The helical stent design accommodates longitudinal shortening of the FPA during knee and hip flexion. The MIMICS-2 study is designed to demonstrate the safety and effectiveness of BioMimics 3D in a large population and supported US premarket approval application.

Materials and Methods: This prospective, single-arm, multicenter trial with 3-year follow-up enrolled patients with symptomatic de novo occlusive disease of the native FPA. Core laboratories reviewed Duplex ultrasound, angiography, and x-ray imaging; clinical events were independently adjudicated. The primary safety endpoint was a composite of major adverse events (MAEs) comprising death, any target limb major amputation, or clinically driven target lesion revascularization (TLR) at 30 days. The primary effectiveness endpoint was 1-year primary patency. We present index procedure through 1-year results, including primary patency, revascularization rate, clinical and functional outcomes, and stent integrity and emerging, interim 2-year data.

Results: A total of 271 enrolled subjects had a mean age of 68 years; 66% were male, 81% were smokers, and 45% had diabetes. Core lab-reported mean lesion length was 81.2 ± 38.4 mm, and vessel diameter was 5.2 ± 0.9 mm; 46% of lesions were moderately to severely calcified and 30% were total occlusions. Technical success (percent of lesions with 50% residual, in-stent, stenosis), lesion success (successful stent implantation without device-related complications), and procedure success (lesion success without MAEs) were all 100%. Primary safety and effectiveness endpoints were met: freedom from MAEs through 30 days was 99.6% (268 of 269), and the Kaplan-Meier estimate of freedom from loss of primary patency at 1 year was 83%. This is similar to rates seen in drug-eluting stent and drug-coated balloon studies and to the earlier MIMICS-RCT. Freedom from CDTLR at 1 year was 88% by KM estimate. In 254 participants with matched assessments, 85% showed an improvement of 1 Rutherford category at 12 months, with a mean change from baseline of -1.9 ± 1.1. Core lab review confirmed there were no stent fractures at 1 year (0%, 0 of 229) and none to date at 2 years. Interim 2-year data suggest that fewer than 1 in 10 participants treated with BioMimics 3D requires reintervention in year 2. Updated interim 2-year data will be available at the time of presentation.

Conclusions: MIMICS-2 outcomes at 1-year confirm the safety and effectiveness of the BioMimics 3D stent, and accordingly, premarket approval was granted in October 2018. Emerging 2-year data show consistency with MIMICS-RCT data, which support the hypothesis that a helical centerline stent promotes naturally antiproliferative swirling flow, providing a clinically important point of differentiation in stent selection.

Abstract 4: Midterm Outcomes After Below-the-Ankle Interventions for Patients with Rutherford Class 5 and 6 Critical Limb Ischemia

M. Ozen, B. Arslan

Purpose: The purpose of this study is to evaluate our midterm experience of below-the-ankle revascularization cases in the setting of Rutherford class (RC) 5 and 6 patients.

Materials and Methods: Between January 2013 and September 2017, patients who underwent arterial revascularization for critical limb ischemia in our department were reviewed retrospectively using our departmental registry. Among these patients, interventions involving recanalization of below-the-ankle arterial branches were identified, and their demographics, comorbidities, and RCs were identified. All be low-the-ankle interventions with or without additional treatment levels were reviewed for technical success rates, 30-day mortality rates, mortality reasons, follow-up duration, and limb salvage rates.

Results: There were 347 patients who underwent lower extremity arterial revascularization procedure in our department during the review period. Of these, 50 patients had below-the-ankle interventions with RC 5 and 6 disease. Mean age was 66.5 years (34–93 years); 33 men and 27 women were included. Thirty-seven patients (74%) had diabetes, and 31 patients (62%) had chronic kidney disease. One of the patients expired within 30 days because of pneumonia, and three of the patients expired past 30 days, one because of cardiac arrest, and the two due to bleeding not related to their interventions. Our technical success rate for inline flow recanalization was 96.8%. Four patients had below-the-knee amputations at 2 months. Two patients had above-the-knee amputation; one is at 1 month, and the other one is at 6 months after their first below-the-ankle intervention. Overall limb salvage rate was 88% with an average follow-up duration of 16.7 months (1–43 months).

Conclusions: Below-the-ankle recanalization interventions are technically feasible, and midterm clinical outcomes are favorable. A randomized clinical trial may help to further identify the role of below-the-ankle interventions in improving limb salvage rates.

Abstract 5: Novel Laser-Based Atherectomy Catheter: Initial and Six-Month Results From the Eximo Medical B-Laser IDE Study

K. Rosenfield, J. Rundback, J. Laird

Purpose: To evaluate safety and efficacy of the B-Laser atherectomy (Eximo Medical Ltd, Israel) in treating a broad spectrum of infrainguinal peripheral artery disease (PAD).

Materials and Methods: The B-Laser atherectomy system is a novel 355-nm solid-state Nd:YAG short-pulse laser that uses four catheters (one with aspiration ports and one with both aspiration port and an "off-center" feature) containing an array of optical fibers surrounded by a blunt blade for atherectomy, developed for treatment of de novo and restenotic infrainguinal PAD, including ISR. The system has threefold higher affinity for atheroma than for endothelium and is indifferent to the presence of contrast material. We present the results of an IDE pivotal study performed in eight US and three EU sites. 97 (77 in the United States) patients with PAD (51 men, 72 years [46, 86], Rutherford class 2–4) were enrolled; 107 evaluable lesions were treated with B-Laser and evaluated by Corelab (SynvaCor, Springfield, IL). Calcification was seen in 83 of 107 (77.6%), and 26.2% were severe. Forty-six of 107 lesions (43%) were chronic total occlusions, and 22 (20.6%) were restenotic. Average lesion length was 5.4 cm [1, 24], and anatomical locations were ATK (76 of 107) and BTK (31 of 107). Procedural angiograms were evaluated by Corelab. Major adverse events (MAEs) (cardiovascular death, above-the-ankle amputation, and CD-TLR) and perioperative complications were recorded, as well as WIQ, ABI, and Rutherford class at baseline, 30 days and 6 months. DUS patency (PSVR 2.5), was evaluated by Corelab at 30 days and 6 months.

Results: Baseline stenosis was 85.7% ± 12.2%. Average reduction in residual stenosis after B-Laser alone was 33.6% ± 14.2% and was not affected by degree of calcification nor lesion length or type. Final stenosis postadjunctive therapy was 17.7% ± 11.0%. Patency by Duplex evaluation at 30 days and 6 months was 98% and 83%, respectively. ABI, Rutherford class, and WIQ all improved from baseline versus 30 days and 6 months (0.7 vs 1.0 vs 0.9; 2.8 vs 1 vs 0.7; and 21.7 vs 47.3 vs 49.7, respectively). There were 1 one up to 30 days (non–device-related death) and two TLRs (2.1%) at 6 months. There were no perioperative device-related complications requiring intervention. No instances of distal embolization were noted. There were no dissections after the balloon procedure. Bailout stenting was reported in one case (not at the atherectomy-treated area).

Conclusions: The B-Laser atherectomy system demonstrates a high level of safety and efficacy for de novo and restenotic infrainguinal arterial lesions.

Abstract 6: Efficacy of XTRACT on Atrial Fibrillation Patients with Peripheral Arterial Disease: Subset Analysis from PRISM

J. F. Benenati, G. L. Adams, C. Teigen, L. Sewall, R. Saxon

Purpose: We report the efficacy and safety on a subset analysis of patients with atrial fibrillation in the PRISM trial. This trial examined efficacy and safety of XTRACT (a power aspiration-based extraction technique) using the Penumbra Indigo System (Penumbra, Inc., Alameda, CA) as a frontline and secondary treatment for peripheral arterial occlusions.

Materials and Methods: The PRISM trial was a single-arm, multicenter, retrospective analysis of patients with acute or subacute arterial occlusions who met the inclusion criteria of peripheral arterial occlusion (Thrombolysis in Myocardial Infarction [TIMI] score 0–1). The primary endpoints were vessel patency immediately after XTRACT and after any other subsequent endovascular procedure as measured by TIMI score and the rate of serious adverse events (SAEs) within 24 hours of treatment. **Results:** PRISM enrolled 79 patients at five sites in the United States. XTRACT was the frontline treatment for 49.4% (39 of 79) of patients, and 50.6% (40 of 79) were treated with XTRACT secondary to failure from catheter-directed thrombolysis and/ or other endovascular therapies. Overall, vessel patency (TIMI 2–3) was achieved in 87.2% (68 of 78) of patients immediately after XTRACT and in 96.2% (76 of 79) of patients after additional adjunctive interventions. In the subgroup analysis of patients with atrial fibrillation (n = 12; 8 women), XTRACT was the frontline treatment for 7 patients (58.3%) and the secondary treatment for 5 patients (41.7%). Vessel patency (TIMI 2–3) was achieved in 71.4% (5 of 7) of patients with XTRACT as the frontline treatment and 100% (5 of 5) of patients with XTRACT as a secondary treatment. Overall, vessel patency (TIMI 2-–3) was achieved in 83.3% (10 of 12) immediately after XTRACT and in 100% (12 of 12) of patients after additional adjunctive interventions. SAEs within 24 hours were reported in 8.9% (7 of 79) patients overall and 8.3% (1 of 12) of patients with atrial fibrillation. None were device related.

Conclusions: The Penumbra Indigo system using XTRACT technique is a safe and effective intervention in atrial fibrillation patients with underlying peripheral arterial occlusions. XTRACT was useful both as a frontline therapy and as a salvage technique when other endovascular techniques or thrombolysis had failed. Future prospective trials are needed.

Abstract 7: Utilization of the Occlusion Perfusion Catheter to Administer Antiproliferative Medications in Peripheral Arterial Disease Intervention

F. T. Bunch, P. K. Nair

Purpose: The objective of this study was to assess the safety and efficacy of paclitaxel administration using a novel drug delivery catheter for the prevention of restenosis in infrapopliteal de novo and restenotic lesions.

Materials and Methods: Restenosis continues to be a great challenge after percutaneous revascularization procedures for peripheral arterial disease, particularly for below-the-knee applications. A prospective, nonrandomized, open-label, multicenter registry of a novel delivery catheter delivering liquid paclitaxel was conducted in 35 patients. The primary efficacy endpoint at 6 months is defined as freedom from clinically driven target lesion revascularization (CD-TLR) and target lesion patency as evaluated by duplex Doppler ultrasound. The primary safety endpoint at 1 months is freedom from target limb revascularization, major amputation in the target limb, and target limb–related death.

Results: A total of 35 patients enrolled in the study, with a lesion length of 111.9 ± 81.2 mm and a diameter stenosis of 93.3 ± 8.94%. To date, all patients tolerated the procedure well with no reports of adverse procedural events. Thirty-one have completed their 1-month follow-up. Twenty-eight have completed their 3-month follow-up. Twenty-two have completed their 6-month follow-up. In all follow-up cases, freedom from CD-TLR is 95.5%. Patency is 84.2% (n = 19) as evaluated by an independent core lab. Additionally, zero patients (0%) have demonstrated thrombosis, major amputation in the target limb, or target limb–related death at their follow-up intervals.

Conclusions: The preliminary data obtained in this multicenter study of real-world de novo and restenotic lesions demonstrates a favorable safety and efficacy profile up to 6 months.

Abstract 8: Surgical Outcomes of Hyperglycemic Versus Normoglycemic Patients Undergoing Endovascular Intervention

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Purpose: Diabetes (DM) has been shown to increase perioperative morbidity, long-term cardiovascular events, extended hospital stay, patient costs, readmission, and reintervention rates after endovascular interventions. However, the effects of hyperglycemia and its role on patient outcomes are for the most part overlooked or underestimated because of the widespread acceptance of using DM as the main indicator of adverse events after interventions. The aim of this study was to assess the outcomes of hyperglycemic patients versus normoglycemic patients along with those already diagnosed with DM.

Materials and Methods: This retrospective study was approved by the institutional review board. A total of 637 patients who underwent endovascular interventions at Mayo Clinic, Florida, between the years 2014 and 2017 were analyzed. Patient demographics, risk factors (including diagnosis of DM, hemoglobin A1c [HbA1c], and glucose levels), type of surgical intervention, and 30-day and long-term outcomes were assessed. Groups were generated based on a state of normoversus hyperglycemia and a diagnosis of DM. Patients were considered hyperglycemic if their glucose levels were above 180 mg/dL. Statistical analysis between groups was performed using both a two-sided Fisher's exact test and an unpaired t-test for categorical data. Statistical significance was defined as a P value less than 0.05.

Results: Among 637 patients, 35 were considered hyperglycemic at the time of surgery (hyper+), and of these, 30 were diagnosed with DM. 599 were considered nonhyperglycemic (hyper-), and of these, 121 were diagnosed with DM. The average blood glucose level (standard deviation) and HbA1c for the hyper+ group was 230.7 mg/ dL (49.8) and 7.8 (1.4), respectively. As for the hyper-group, the averages (standard deviation) were 103.2 mg/dL (21.4) and 6.1 (1.0), respectively. There was a significant difference in outcomes between hyper+ and hyper- patients. Hyper+ patients had significantly higher length of stay (P = 0.0215), 30-day graft thrombosis (P = 0.0072), limb loss (P = <0.0001), sepsis (P = 0.0345), readmission (P = 0.0173), reoperation (P = 0.0005), long-term myocardial infarction (P = 0.0345), limb loss (P = 0.0084), and readmission (borderline significant; P = 0.0618). DM hyper+ patients had significantly higher prevalence of 30-day graft thrombosis (P = 0.0439) and limb loss (P = 0.0034) compared with DM hyper-. Average glucose levels of hyper+ patients with each poor outcome were calculated. The highest average blood glucose levels were seen in patients with 30-day graft thrombosis (299 mg/dL), sepsis (283 mg/dL), and readmission (274 mg/dL).

Conclusions: Patients who were hyperglycemic at the time of surgery and underwent endovascular interventions were more likely to have worse outcomes compared with those who were normoglycemic. Additionally, patients with the diagnosis of DM and hyperglycemic state before surgery had a significantly higher prevalence of 30-day limb loss and graft thrombosis compared with those with DM who were normoglycemic. Therefore, hyperglycemia should be considered a significant contributor to worse outcomes, and the perioperative management should be adjusted according to the dynamic relationship between a DM diagnosis and a hyperglycemic state.

Abstract 9: High versus Low Chronic Outward Force of SFA Nitinol Stents: BIOFLEX-COF Randomized Trial Interim Report

A. Wressnegger, M. A. Funovics

Purpose: Nitinol stents exert a continuous force on the vascular wall, termed chronic outward force (COF). COF depends on two factors, stent material ("stiffness" of the stent) and stent oversizing (ratio of vessel diameter to stent diameter). Animal data have shown increased neointimal hyperplasia in stents with high COF in the superficial femoral artery (SFA). Human data is currently lacking. The BIOFLEX-COF study is the first randomized controlled trial to assess a possible correlation between COF and neointimal hyperplasia.

Materials and Methods: Eighty-six patients with symptomatic SFA lesions were randomized into high and low COF groups. In the low COF group, a soft stent (Pulsar, Biotronik AG, Bülach, Switzerland) was implanted with minimal oversizing. In the high COF group, a stiffer stent (LifeStent Flexstar, Bard Peripheral Vascular Inc., Tempe, Arizona) was implanted with substantial oversizing. A predefined sizing table was used to choose stent diameters in each group. The study intended to achieve at least a two- to threefold difference in absolute COF between groups. The outcome parameter was the amount of the in-stent neointima 1 and 2 years after implantation assessed by computed tomography angiography every millimeter along the stent axis.

Results: Recruitment was completed; the technical success rate was 100%. Three patients had to be excluded because of technical documentation problems. In the remaining 83 patients, nominal stent diameters used were significantly lower in the low COF group (P <0.001), resulting in a fourfold higher COF in high COF group compared with the low COF group (P <0.001). No significant differences in the occurrence of serious adverse events (SAEs) was observed between groups. Lesion characteristics (eg, target lesion length and percent stenosis) were similar in both groups. The only significant difference in baseline characteristics was observed in the occurrence of coronary heart disease, which was more frequent in the low COF group (19 patients vs 10 patients; P = 0.046).

Conclusions: Recruitment of BIOFLEX-COF is complete. A pronounced difference in COF between groups could be verified even though stent diameters chosen were according to the manufacturer's instructions and within clinically routinely used ranges. The amount of SAEs did not differ significantly between groups and were comparable to previously published data. One-year outcome data are expected by end of 2019, which for the first time will allow correlation analysis of COF and neointima formation in humans.

Abstract 10: Transcarotid Artery Revascularization: A Novel Approach to Tackling High-Risk Carotid Lesions

T. Ciszak, P. J. Patel, P. J. Rossi, R. Hieb, M. Malinowski

Purpose: Transcarotid artery revascularization (TCAR) using the ENROUTE Neuroprotection System (Silk Road Medical Inc, Sunnyvale, CA) is a novel approach toward carotid artery stenting (CAS). This minimally invasive approach uses intraprocedure high-rate flow reversal NPS and is designed for CAS in patients who are deemed too high risk for carotid artery endarterectomy (CEA). The system has shown superior stroke and death outcomes compared with prior registry results from both CEA and transfemoral CAS. The purpose of this study is to review of both short- and long-term outcomes in patients who underwent TCAR and so to underscore high-risk anatomical lesion that are made easier with TCAR over a transfemoral approach.

Materials and Methods: We performed an institutional review board–approved single-center retrospective review of patients who underwent TCAR procedures between August 2017 and September 2018. All interventions were performed in patients deemed at high risk for complications from CEA, symptomatic patients with 50% stenosis, or asymptomatic patients with 70% stenosis. A hybrid OR was used for all procedures and co-staffed with a vascular surgeon and an interventional radiologist. Patients were followed in clinic at 1, 6, and 12 months postprocedure. Demographic data, anatomical considerations, and complications were reviewed.

Results: Twenty-nine TCARs were performed on 28 patients, with an age range of 59 to 85 years (M:F, 19:9). Technical success rate was 100%, with no acute device, technical, or access site complications. All lesions were successfully crossed, and 30 stents were deployed (one lesion required two overlapping stents). One patient underwent bilateral TCAR on separate occasions, and another patient underwent concurrent TCAR and TVAR. Fifteen anatomically challenging lesions were identified: 7 high carotid bifurcations, 4 stenoses at or above C2 level, 3 long-segment lesions, and 1 tortuous ICA. One adverse outcome was reported within 30 days (ipsilateral intraparenchymal hemorrhage), with an overall adverse-free event rate of 97%. No myocardial infarction or death occurred. All patients remained neurologically symptom free at their follow-up, and the average time to follow-up was 151 days.

Conclusions: TCAR is a safe and novel approach to CAS using cerebral flow reversal as a means of providing neuroprotection. It can be used to tackle lesions deemed too high risk for TF-CAS or CEA. This procedure requires a high technical skillset and is best performed using a multidisciplinary team with a vascular surgeon and an interventional radiologist.