Scientific Abstracts From the AMP Symposium

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AMP 2018-1 Biosynthetic Prostheses: A New Tool for the Treatment of the Prosthetic Vascular Infections

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PURPOSE. It is well known that prosthetic infections cause a high morbidity and mortality rate, a great concern for the vascular surgeon. The current accepted treatment is based on the creation of an autologous vascular reconstruction and a total explantation of the infected grafts. We assess early results after a prosthetic graft replacement with biosynthetic collagen prosthesis in a case of graft infection and in the absence of a suitable autologous venous graft.

MATERIALS AND METHODS. Between January 2015 and November 2017, 6 patients with infected prosthetic vascular grafts underwent a replacement of an infected graft with a biosynthetic prosthesis. Different variables like the length of stay in hospital, mortality, limb salvage, graft patency, and reinfection were analyzed.

All patients were male adults with an average age of 65 years (range, 35-82). As a factor of cardiovascular risk, they suffered from arterial hypertension. One of them is immunocompromised due to a kidney transplantation. Three patients presented infected inguinal prosthetic grafts (Szilagyi 3: 1 patient with crossover with femoro-femoral venous graft, another 2 patients with an axillofemoral bypass graft, and the last patient received a femoral graft reconstruction previously). Two patients have an axillar and a humeral graft. There were 3 early infections (<3 months after implantation) and 3 late infections (>3 months after implantation). All infected grafts were surgically explanted and replaced by biosynthetic grafts. In all cases, there wasn't a suitable autologous vein graft. The replacement surgery was performed successfully in the 6 patients without intraoperative complications. Two patients were under a composite axillopopliteal graft with ePTFE bypass. Microbiological cultures revealed intraoperative infection in all cases.

RESULTS. The median length of stay was 39 days (range, 9-180). The average monitoring was 16.7 months (range, 2-68), a period over which the patients were free of diseases of any kind. During follow-up, we observed a >3 months graft reinfection in 1 patient (an explantation was performed). In the rest of the patients there was no graft reinfection, early or late occlusion, degeneration, or rupture of the grafts. There were no early or late major amputations. One patient died of pneumonia 2 months postoperatively at the hospital.

CONCLUSIONS. In our institution, in the absence of adequate autologous vein material, biosynthetic grafts seem to be a safe alternative to replace infected grafts, with a low reinfection and reocclusion rate.

AMP 2018-2 Successful One-Stage Revision of Total Femur Modular Endoprosthesis Infection in a Profoundly Immunocompromised Patient

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PURPOSE. Two-stage exchange including explantation of components and antibiotic spacer placement is considered the gold standard for prosthetic joint infection (PJI). However, one-stage exchange is currently being investigated. Two-stage revision requires stabilization of the joint between stages, which is difficult for the hip and knee in an infected total femur. The Infectious Diseases Society for America recommends consideration of a one-stage revision in patients with a total hip arthroplasty, healthy soft tissue envelope, low virulence pathogens, and good bone stock. We describe a successful one-stage revision 7 months after initial surgery in an immunocompromised patient.

MATERIALS AND METHODS. We describe an example of one-stage revision for PJI in immunocompromised patients. We also report a literature review using the keywords prosthetic joint infection and one-stage surgical revision limited to the last 15 years.

RESULTS. Our search revealed 78 results, 22 of which focused on the one-stage surgical revision. No studies considered immune status separately. Our patient is a 20-year-old female with localized Ewing sarcoma of the left distal femur who was status post complex *en bloc* resection of the entire femur followed by total femur arthroplasty with modular oncological endoprosthesis 7 months prior who is currently receiving adjuvant chemotherapy. She presented with acute-onset left hip pain, fever, and pancytopenia. Hip aspiration revealed WBCs of 0.554 with 17.5% PMNs and cultures grew *Enterobacter cloacae*. The patient underwent irrigation and debridement without explantation followed by appropriate IV antimicrobial therapy with persistent fevers and plateaued elevated C-reactive protein values. After interprofessional discussion, the patient and family decided to undergo a one-stage revision of all components to avoid a hemipelvectomy. The fever curve and CRP significantly improved and the patient continues to do well.

CONCLUSIONS. Clinical decision-making in the immunocompromised patient is difficult as we cannot use validated lab markers and aspiration cell counts from studies of immunocompetent patients. Furthermore, undergoing a complex arthroplasty procedure involves significant morbidity for all patients, especially the immunocompromised. Currently there are no RCTs comparing one stage versus two stages. Immunocompromised status should not be a strict contraindication for one-stage revision. However, we should continue to study how to balance surgical morbidity and eradication of infection.

AMP 2018-3 A Retrospective Analysis of Orbital Atherectomy for Treating Calcified Iliac Artery Disease: A Single-Center Study

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PURPOSE. The current standard of care for the treatment of flow-limiting calcific iliac artery disease is balloon angioplasty and subsequent stent placement. However, the presence of calcified lesions may prevent adequate stent expansion or impede the delivery of large-bore devices such as TAVR or EVAR implants. Plaque modification through vessel preparation with orbital atherectomy (OA) may enable stent expansion and subsequent proper large device delivery with low rates of procedural complications.
MATERIALS AND METHODS. A single-center retrospective study of 13 subjects (14 interventions) treated with OA via iliac artery delivery was conducted. Patients were selected for treatment based on iliac artery disease or inability to deliver devices. The procedural complication rate was defined as the composite of flow-limiting dissection, perforation, slow flow, vessel closure, spasm, embolism, thrombosis. Technical success was assessed as angiographic luminal gain and subsequent successful delivery of large-bore devices through the treatment area, as well as freedom from procedural complications.
RESULTS. The cohort was comprised of 13 patients (age 72.4 ± 10.9 years; 9 males, 4 females) with 1 lesion per vessel, an average lesion length of 34.2 ± 10.8 mm, and an average reference vessel inner diameter of 9.2 ± 0.9 mm. Lesions were located in the common iliac arteries (with some extending into the common femoral arteries). The top three associated demographic risk factors were hypertension (92%), history of smoking (85%), and diabetes mellitus (54%). The mean total treatment time using OA per patient, per lesion site in the 14 interventions was 135.3 ± 51.9 seconds. The mean maximum balloon inflation pressure per treated lesion site was 10.9 ± 6.3 atm. The procedural complication and technical success rates were 0% and 100%, respectively.
CONCLUSIONS. Orbital atherectomy vessel preparation of severely calcified iliac artery lesions resulted in adequate stent expansion safely and enabled delivery of rigid/large-profile devices. Further studies are warranted to evaluate patient selection criteria, as well as long-term efficacy and safety rates.

AMP 2018-4 Efficacy of XTRACT in Atrial Fibrillation Patients With Peripheral Arterial Disease: Subset Analysis From PRISM Trial

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PURPOSE. We report clinical efficacy and safety on subset analysis of atrial fibrillation patients in the PRISM trial. This trial examined efficacy and safety of XTRACT (a power aspiration-based extraction technique) using Penumbra Indigo System as a frontline and secondary treatment for peripheral arterial occlusions.
MATERIALS AND METHODS. 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 (TIMI 0-1) prior to attempted endovascular treatment using XTRACT. The primary endpoints were vessel patency immediately post XTRACT and post any other subsequent endovascular procedure as measured by TIMI score, as well as the rate of procedural serious adverse events (SAE) within 24 hours of treatment. Subset analysis of 12 patients.
RESULTS. PRISM concluded a total of 79 patients. Among these patients, XTRACT was the primary treatment modality for 49.4% (39/79), while 50.6% (40/79) were treated with XTRACT secondary to failure from catheter-directed thrombolysis (CDT), other endovascular therapies, and distal emboli from preceding interventions. Overall, vessel patency (TIMI 2-3) among these patients was achieved in 87.2% (68/78) immediately after XTRACT, and in 96.2% of patients (76/79) following additional adjunctive interventions.
In this subgroup analysis of patients with atrial fibrillation (n = 12), 66.7% were female. XTRACT was the primary treatment modality for 7 patients (58.3%), while the remaining 5 patients (41.7%) were treated with XTRACT secondary to failure from CDT and/or other endovascular therapies. Frontline XTRACT was successful in 71.4% of patients (5/7); however, as secondary therapy, 100% of patients (5/5) were successfully revascularized to TIMI 2-3. Overall, vessel patency (TIMI 2-3) was achieved in 83.3% immediately after XTRACT, and in 100% of patients following additional adjunctive interventions.
Overall, procedural SAEs were reported in 8.9% of patients (7/79), whereas in the subgroup of atrial fibrillation, only 1 patient had SAE within 24 hours. None were device related.

CONCLUSIONS. 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 had failed in these atrial fibrillation patients. Future prospective trials are needed.

AMP 2018-5 Lower-Limb Amputation Prevention Strategies for Diabetic Foot Patients

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PURPOSE. Synthesis of main principles of amputation prevention for diabetic foot patients.

MATERIALS AND METHODS. A total of 714 diabetic foot patients were treated and continuously observed by the multidisciplinary team of our Diabetic Foot Department, January 2016 until June 2016 between ages 36-88 years. Clinical evaluation and therapeutic modalities implementation according to WIFI classification. For 10 patients with extensive infection and crepitus ischemia, grade evaluation was postponed after decompressive incisions, draining procedures and repetitive debridement procedures, systemic and local intensive treatment.

RESULTS. All diabetic foot patients were controlled for meticulous normoglycemia, correction of vital organs and systems, metabolic disorders, comorbidity estimation and management. A total of 237 patients besides local sepsis presented symptoms for systemic sepsis including high leukocytosis with left shift, urinary output decrease, fever, procalcitonin and/or C-reactive protein, lactate concentration abnormalities. Affected and contralateral lower-extremity vascular status initially was evaluated by duplex scanner ultrasound. Further detailing was supported by CT arteriography. Revascularization was performed for those with critical ischemia grade 3; 4. Immediate revascularization was performed in 118 limbs, including 72 angioplasties with or without stenting and 46 limbs were treated by bypass grafting. Eleven cases complicated by lethal outcomes in first postoperative 10 days (cerebral or myocardial infarctions). Two above-knee amputations were performed for extensive tissue damage of foot and leg along with calcaneal destruction, three below-knee amputations for femoropopliteal bypass failure. There were 57 transmetatarsal amputations and in 214 cases 1 to 3 toe amputations were performed with metatarsal head resections and further weight bearing foot preservation. Two 1st toe amputations for diabetic foot patients were performed for melanoma maligna.

CONCLUSIONS. Diabetic foot patients develop more aggressive generalized macrovascular impair for ageing population, even for younger persons with unfavorable glycemic profile and HbA1C. Besides ischemia, diabetic foot patients suffer from distal sensor/motor/autonomic neuropathy complicated frequently with severe foot infection along with local and general immunosuppression, which overshadows prognosis for limb preservation and survival data. Infection alone is an independent risk factor for amputation in diabetic patients. Another devastating misfortune for diabetic foot patients may turn up foot and ankle biomechanical disarrangement in form of neuropathic osteoarthropathic deformity of Charcot foot threatening diabetic population without arterial impair. Charcot foot with near moderate or normal arterial supply is inappropriate for weight bearing and is complicated with severe osteopenia, spontaneous subluxations, fractures, and, eventually with infection of bone in the insensitive and unprotected neuropathic diabetic foot. The combination of Charcot foot and chronic venous insufficiency doubles osteopenia and demands appropriate orthopedic and vascular surgical correction.

AMP 2018-6 Occurrence of Critical Limb Ischemia

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PURPOSE. Critical limb ischemia (CLI) is the final prognosis of peripheral arterial disease (PAD). The mortality rate for CLI patients from initial diagnosis can surge 20% at 6 months to twenty-fold at 5 years. PAD is a slow, progressive circulation disorder, which is the leading cause of death, worldwide. PAD affects over ten million Americans. PAD is a buildup of plaque in the arteries; the plaque can consist of fat, calcium, cholesterol, fibrous tissue, or other substances in the blood. The plaque causes the arteries to harden and narrow along with a reduced blood flow, which inhibits perfusion of the organs, tissue, and muscle. The narrowed arteries can cause a functional restriction of blood flow through the vessel, which can impede the velocity of the blood flowing to the body. The muscle becomes ischemic from the reduced oxygen supply.

RISK FACTORS. There are multifactorial issues that place patients with PAD at a higher prevalence, such as smoking, diabetes mellitus, hypertension, history cardiovascular disease, chronic lung, and renal disease.

MATERIALS AND METHODS. History of Present Illness: N.F., a 45-year-old patient of Dr. Smith referred to Dr. Christopher LeSar for lower-extremity PAD. She had a previous left below-the-knee amputation (BKA). In July 2017, she was bitten on her ankle by an insect and developed cellulitis of the right foot. She was complaining of right calf claudication and rest pain with an unhealed lesion on the malleolus on the ankle. She has diabetes and blood sugar range 115 to 220. She also has hypertension; blood pressure was 138/70 on this visit. She has hyperlipidemia. She smoked for twelve years (1 pack a day) and she recently stopped approximately 3 weeks ago when the claudication would not subside. Physical Examination: N.F. is awake, alert, oriented, neurologically intact, in no acute distress, head is normocephalic. Abdomen is soft, round, obese, nontender. Bilateral radial pulses are +2. Grip strength is equal. Femoral and popliteal pulses unable to assess due to body hiatus. Dorsal pedal on the right is absent. Posterior tibial pulse on the right

is absent. She had a 0.3 cm x 0.3 cm ulcer with red streaking with crusty ends and a trace of edema noted in her right ankle region. Right ankle and shin with warmth and redness. Left BKA.
RESULTS. Treatment: An arterial duplex ultrasound and ankle-brachial index (ABI) of the affected limb was ordered. The ultrasound revealed monophasic flows with total occlusion of the superficial femoral artery (SFA) with a flat toe pressure and ABI 0.32. Arteriogram of the right lower extremity per Dr. LeSar and wound care was initiated by Vascular Institute of Chattanooga Wound Center, and she made a full recovery.
CONCLUSIONS. Treatment for CLI is not an easy choice; the treatment depends on the patient's age, comorbidities, severity of limb ischemia, and vascular anatomy. The plan of care for these PAD patients is to continue improving outcomes by increasing community awareness; initiating better-quality wound care, and improved medical therapy to prevent the PAD from progressing to CLI.

AMP 2018-7 Percutaneous Deep Vein Arterialization for Treatment of Late-Stage Critical Limb Ischemia, Early Feasibility Results
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PURPOSE. Within critical limb ischemia (CLI) there is a broad spectrum of severity, from milder degrees of vascular insufficiency to no-option situations where occlusive lesions are so complex that current available surgical and endovascular techniques are not sufficient and amputation is considered the only solution. We report the interim results of the multicenter PROMISE Early Feasibility Trial using the LimFlow Stent Graft System (LimFlow, Inc.; Santa Clara, California) for percutaneous deep vein arterialization (pDVA) in these no-option patients.
MATERIALS AND METHODS. Ten no-option CLI patients (median age, 67 years; 3 women) were enrolled to determine the safety, effectiveness, and feasibility of the LimFlow Stent Graft System. All patients were Rutherford Category 5 or 6. Eight were classified at high risk of amputation based on the SVS WIfI classification. The primary safety endpoint was Amputation Free Survival (AFS, freedom from mortality and freedom from above-ankle amputation of the index limb) at 30 days with a secondary safety endpoint of AFS at 6 months. Other secondary endpoints included patency, wound healing, and technical success.
RESULTS. The primary safety endpoint was achieved in 100% of patients, with no deaths or above-the-ankle amputations at 30 days. The technical success rate was 100%.
CONCLUSIONS. pDVA using the LimFlow Stent Graft System is a novel approach for treating patients with no-option CLI and may reduce amputation in this population for whom amputation would otherwise be considered inevitable. Initial findings from this early feasibility trial appear promising, and additional study via pivotal trial is warranted.

AMP 2018-8 Percutaneous Angioplasty With Drug-Eluting Balloon for Infrainguinal Venous Bypass Stenosis
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PURPOSE. Open surgical repair has better results than percutaneous transluminal angioplasty in treating infrainguinal venous bypass stenosis. The endovascular treatment has significant risk of restenosis which need new intervention. The use of drug-eluting balloon in peripheral artery disease is proved. We report our experience with such balloon for treatment of infrainguinal venous graft stenosis.
MATERIALS AND METHODS. From November 2012 to April 2018, 10 patients (6 women and 4 men) with 12 infrainguinal venous bypass stenosis had 14 percutaneous transluminal angioplasties with drug-eluting balloons. They were reviewed prospectively. Six had femoropopliteal bypass above the knee, three had femoropopliteal bypass below the knee, and three had femorotibial bypass. Four were treated at least one time before with simple balloon angioplasty and had early restenosis.
RESULTS. Six lesions were at the distal anastomosis, two at the proximal anastomosis, and four were far from the anastomosis. The immediate angiographic results were always good. One patient died of acute myocardial infarction on the first post-operative day. Two patients developed restenosis after 15 and 29 months follow-up and had new balloon angioplasty with coated balloon. One of those bypasses was thrombosed 1 year after the second intervention. Another bypass was thrombosed after 33 months of follow-up. None of the others patients developed restenosis. Follow-up is going on.
CONCLUSIONS. The use of drug-eluting balloon to treat infrainguinal venous bypass stenosis is minimally invasive and safe. Randomized studies are mandatory to compare drug-eluting balloon angioplasty with simple balloon angioplasty and with open surgical repair.

AMP 2018-9 Efficacy of Indirect Endovascular Revascularization in Patients With Diabetic Ischemic Foot
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PURPOSE. Determine if the indirect revascularization of the compromised angiosomes allows wound healing and pain relief. Determine the more frequently affected artery. Determine the time of complete healing and the percentages of amputation and mortality.

MATERIALS AND METHODS. This is a prospective, observational, cross-sectional, descriptive study in which 42 patients received in the Diabetic Foot Unit were included. This unit is attached to the Vascular and Endovascular Surgery Service of the Enrique Garcés Hospital in the city of Quito, Ecuador.
Between January 2015 and July 2017, ulcerative lesions of the lower limb submitted to successful endovascular procedures in the infrapopliteal sector and the collateral nutrient vessel was revascularized and not that of the direct line to the angiosome. The follow-up was done in the ambulatory Unit of Diabetic Foot. These parameters were collected in a base template.
RESULTS. Of 41 patients undergoing indirect revascularization, we obtained during the follow-up a median patient age of 71 years, of which 56% were male and 44% female. 100% of the patients were diabetic and hypertensive. Smoking was more frequent in men than in women (12 vs 2). Chronic renal failure and dyslipidemia were more frequent in women, but men had the most ischemic heart disease. The angiosome most frequently involved is that corresponding to the tibialis anterior. The peroneal artery was the most frequently revascularized. The median time of wound healing was 15 weeks. No complications were determined at 3 months, 6 months, or 12 months of follow-up. Mortality represented 2.4% (1/41 patients).
CONCLUSIONS. Indirect revascularization is a feasible therapeutic option in patients with ischemic diabetic foot presenting high rates of salvage of the lower limb, clinical improvement, and with minimal cardiovascular complications, mainly when it is not possible to revascularize the artery responsible for the ischemic site as long as there is a development of enough collaterals to obtain an adequate plantar arch. N

AMP 2018-10 Treatment of Complex Lower Extremity Wounds With Combined Urinary Bladder Matrix and Negative Pressure Therapy

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PURPOSE. To review the essentials in wound healing and describe a new surgical treatment modality of acellular urinary bladder matrix with negative pressure wound therapy for limb salvage.
MATERIALS AND METHODS. A retrospective review was performed of 4 patients with complex lower-extremity wounds. All patients were treated with surgical debridement of the wound and placement of acellular urinary bladder matrix (UBM) and negative pressure wound therapy. Two patients had traumatic wounds. One patient had diabetes and a previous contralateral below knee amputation. One patient had diabetes and pyoderma gangrenosum. Nutritional status and blood sugar control was addressed with each patient. Each patient was surgically debrided and the presence of infection treated if indicated. The urinary bladder matrix was applied to the wound and then covered with negative pressure therapy. The patients' wound healing statuses were assessed weekly at the time of the dressing change. Additional UBM was applied if there was any remaining deficit in the depth of the wound.
RESULTS. Limb salvage and wound closure were achieved in all 4 patients with the combined treatment of urinary bladder matrix and negative pressure wound therapy. Patients had substantial pain relief and positive feedback with once-weekly dressing changes.
CONCLUSIONS. In the treatment of complex lower-extremity wounds, acellular urinary bladder matrix has shown successful coverage of complex wounds with aesthetically pleasing results. Combined therapy of UBM and negative pressure has provided significant advantages for pain control and improved convenience of once-weekly dressing changes.

AMP 2018-11 Single Versus Dual Access Approach for Chronic Total Occlusion Recanalization in Peripheral Arterial Disease

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PURPOSE. Critical limb ischemia is the worst form of PAD, with 20% mortality within 6 months of diagnosis and 20% of patients receiving an amputation within 1 year. The biggest challenge in endovascular revascularization is multilevel chronic total occlusions (CTO), which account for 40%-50% of lesions. Treatment failure occurs in approximately 20%-40% due to inability to cross the lesion when utilizing single access. Few limited prior studies have shown that dual access, after failure of either antegrade or retrograde approach, can increase the success rate in superficial femoral artery CTOs. The purpose of this study is to evaluate the efficacy and safety of initial dual antegrade and retrograde access approach compared to single antegrade or retrograde approach for crossing any level of CTO.
MATERIALS AND METHODS. A retrospective analysis was conducted of patients who had at least 1 lower-extremity CTO treated by a single operator at a community hospital between August 2013 and January 2018. Patient and procedural demographics were collected and analyzed. Rutherford classes III-VI were included. Chi-Square and Fisher's exact test were performed along with propensity score-matched (PSM) analysis with a confidence interval of 95%. The primary endpoint was crossing and treatment success. Patient and procedural demographics were analyzed to determine variables of treatment success and failure.
RESULTS. 141 patients were included with 88 in the single access cohort and 53 in the dual access cohort. Crossing success in the dual access cohort was 92.5% and 73.6% in the single access cohort (P=.010). Average lesion length was 145.7 ± 92.1 mm and 146.4 ± 111.0 mm, respectively. Dual access showed to be a very strong indicator of crossing success (P<.001 all-subject, and P=.001 PSM)

and going subintimal was an indicator of failure (P<.001 all-subject, and P=.001 PSM). There was a low rate of complications with no statistical difference between both cohorts.

CONCLUSIONS. Our study demonstrated initial dual-access approach compared to single access has shown significant success in crossing and treating peripheral CTOs. We believe this could have a major impact on successfully reducing the amputation rates.

AMP 2018-12 Primary and Secondary Acoustic Pulse Thrombolysis Treatment in Acute Limb Ischemia: A Single-Center Experience

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PURPOSE. The optimal treatment strategy for acute limb ischemia (ALI) from thromboembolism remains controversial. Catheter-directed thrombolysis (CDT) and surgical thrombectomy have shown benefits, yet are associated with significant morbidity and mortality. An alternative to standard CDT, acoustic-pulse thrombolysis (APT), delivers low-intensity, high-frequency ultrasound waves accompanied with low-dose thrombolytics. Also, the optimal timing for intervention remains unclear as PTA can aid in visualization and increase flow but it can also be a cause of distal embolization. We evaluated the safety and efficacy of APT in the treatment of ALI. We also evaluated the treatment strategies of primary APT and delayed PTA and primary PTA with delayed APT.

MATERIALS AND METHODS. We retrospectively studied patients who were diagnosed with ALI at our institution (Feb. 2016–Aug 2017). Patients (pts) treated with APT using the EkoSonic Endovascular System (EKOS Corp.) and received a repeat angiogram after APT treatment were included. The severity of ischemia included Rutherford ALI class I-IIb. The primary endpoint was technical success by angiographic assessment and freedom from in-hospital amputation.

RESULTS. A total of 19 pts (mean age 66 ± 12.4 years, 11 males) were retrospectively studied. There were 21 episodes of APT for either primary or secondary APT treatment of ALI in 34 (89%) native arteries and 4 (11%) prosthetic bypass grafts. A pre-existing diagnosis of peripheral artery disease was present in 14 (74%) pts. Average duration of symptoms was 3.45 ± 3.26 days. Mean treatment time was 21 ± 3.75 hours. Primary APT treatment was conducted in 10 (53%) pts and 9 (47%) received PTA prior to APT treatment. Technical success was achieved in 17 (89%) pts, with primary APT treatment success at 80% and secondary APT treatment at 100%. Fischer's exact test showed no statistical difference in primary vs secondary treatment (P=.474). Two (11%) major amputations and 1 (5%) major complication, fasciotomy, were documented.

CONCLUSIONS. APT is a safe and effective treatment strategy for ALI with a low rate of complications and amputations. Further, large randomized control trials are needed to evaluate the timing and duration of of APT with optimal timing of angioplasty.

AMP 2018-13 The FLEX Dynamic Scoring Catheter as Vessel Preparation in Below-the-Knee Lesions

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PURPOSE. Below-the-knee (BTK) lesions continue to be a challenge for interventionalists. Refinements in vessel preparation are required to improve the overall procedural and patient outcomes.

MATERIALS AND METHODS. The FLEX Dynamic Scoring Catheter, a non-balloon-based scoring device, creates continuous, controlled-depth, longitudinal micro-incisions regardless of lesion length. A retrospective review was conducted on 33 real-world BTK lesions (11 physicians, 12 institutions) that had been prepped prior to angioplasty with the FLEX by physician's discretion. This review focused on the luminal gain achieved, balloon opening pressures (the lowest pressure required to fully efface the lesion), and dissection rates.

RESULTS. The average lesion length treated was 129 mm (4-315 mm). Moderate to severe calcification was present in 63.6% of the lesions. The average baseline stenosis was 92.6%, with 42.4% of the cases presenting with a chronic total occlusion. At the physician's discretion a FLEX Catheter was deployed to prepare the lesion for angioplasty. Luminal gain was evaluated after vessel prep, noting an average luminal gain of 32.6% by the FLEX alone. The lesions were subsequently treated with angioplasty, 63.6% plain old balloon angioplasty (POBA), 15.2% drug-coated balloon (DCB), and 21.2% had both. The average balloon opening pressures observed were 4 atm (2-8 atm), with an average maximal pressure at 7.6 atm (3-18 atm). Average residual stenosis post treatment was 9.4% (0-30%). In 97% of the cases no dissections occurred, 1 minor type A dissection was noted. Zero flow-limiting dissections, perforations, or embolization were reported.

CONCLUSIONS. The results obtained in this subset of BTK lesions suggest vessel prep by the FLEX can impact overall angioplasty (POBA and DCB) outcomes safely and efficiently. The FLEX created improvement in luminal gain, allowing for vessel expansion without adverse events. Further studies are warranted.

AMP 2018-14 XableCath - A Novel Metallic Tip Catheter Facilitating Crossing of Obstructive Lower-Extremity Arterial Lesions

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PURPOSE. To investigate the efficacy and safety of a metallic-tip recanalization catheter in modifying arterial obstructive lesions in the lower extremity to facilitate endovascular therapy.

MATERIALS AND METHODS. Between 10/2010 and 04/2018, 49 patients (21 female, mean age 72 years, 51% diabetic, 59% Rutherford class 3-4, 41% Rutherford class 5-6) with 53 separate arterial lesions of the lower extremity were treated with XableCath [.014, 018, .035 blunt (31) and abrasion tip (21)] catheters (XableCath, Inc.; Salt Lake City, Utah) in 3 medical units (Germany, Miami, Atlanta). The lesions (8 iliac, 36 femoro-popliteal, 2 below-knee popliteal, 7 tibial) were 79% moderately or severely calcified; 53% total occlusion; 72% balloon impassible; 15% wire impassible; and an average length of 5.6 cm. Access was done via the radial, brachial, femoral, tibial, and pedal arteries using 4-7 Fr sheaths. The primary endpoint was successful XableCath passage through the target lesion enabling subsequent therapy (angioplasty and/or stenting). Secondary endpoints were the absence of major adverse events attributable to XableCath use: perforation, dissection, thrombosis, or distal embolization. All patients were seen post procedure at a mean 5.9 weeks.

RESULTS. Clinical success was achieved in 98% of cases: XableCath successfully passed through 52/53 occluding lesions enabling subsequent angioplasty and/or stenting. In 2 cases, an abrasion-tip catheter was used after failed passage of a blunt tip. The solitary failure was a blunt-tip attempt; an abrasion-tip catheter was not available for that case. All 19 pts with critical ischemia had successful limb salvage. There were no cases of arterial dissection, rupture, thrombosis, or distal embolization attributable to XableCath. After balloon angioplasty, 2 minor dissections occurred and were successfully stented, 1 access-site femoral pseudoaneurysm was noted post-operatively and treated surgically.

CONCLUSIONS. The metallic-tip XableCath is easy to use, effective, and safe in modifying severe arterial obstructive lesions in the lower extremity facilitating subsequent endoluminal therapy to be performed successfully.

AMP 2018-15 Efficacy of XTRACT in Atrial Fibrillation Patients With Peripheral Arterial Disease - Subset Analysis From PRISM Trial

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

MATERIALS AND METHODS. PRISM was a single-arm, multicenter, retrospective analysis of patients (pts) with acute or subacute arterial occlusions who met the inclusion criteria of peripheral arterial occlusion (TIMI 0-1) prior to attempted endovascular treatment using XTRACT. The primary endpoints were vessel patency immediately post XTRACT and post any other subsequent endovascular procedure as measured by TIMI score, as well as the rate of procedural serious adverse events (SAE) within 24 hours of treatment. Subset analysis of 12 pts.

RESULTS. PRISM concluded a total of 79 pts. Among these, XTRACT was the primary treatment modality for 49.4% (39/79), while 50.6% (40/79) were treated with XTRACT secondary to failure from catheter-directed thrombolysis (CDT), other endovascular therapies, and distal emboli from preceding interventions. Overall, vessel patency (TIMI 2-3) among these pts was achieved in 87.2% (68/78) immediately after XTRACT, and in 96.2% (76/79) following additional adjunctive interventions.
In this subgroup analysis, pts with atrial fibrillation (N = 12), 66.7% were female. XTRACT was the primary treatment modality for 7 pts (58.3%), while the remaining 5 (41.7%) were treated with XTRACT secondary to failure from CDT and/or other endovascular therapies. Frontline XTRACT was successful in 71.4% (5/7); however as secondary therapy, 100% (5/5) of pts were successfully revascularized to TIMI 2-3. Overall, vessel patency (TIMI 2-3) was achieved in 83.3% immediately after XTRACT, and in 100% of pts following additional adjunctive interventions.
Overall, procedural SAEs were reported in 8.9% (7/79) pts, whereas in subgroup of atrial fibrillation, only 1 patient had SAE within 24 hours. None were device related.

CONCLUSIONS. 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 had failed in these atrial fibrillation patients. Future prospective trials are needed.

AMP 2018-16 Treatment of Severe Diabetic Foot Ulcers With Recombinant Human Epidermal Growth Factor

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PURPOSE. To evaluate the results of local treatment of severe diabetic foot ulcers (Wagner 3-4) with recombinant human epidermal growth factor (Heberprot-P®) used in daily medical practice.

MATERIALS AND METHODS. From March 2011 to Dec. 2014, 124 patients (pts; 67% men) diagnosed with diabetic foot ulcer (42% Wagner 3 and 57% Wagner 4) who had received peri and intralesional administration of 75 g of Heberprot-P®, were included in this retrospective analysis. These were outpatients seen at the nutrition, diabetes, and vascular departments of Argentine public and private hospitals.

RESULTS. Granulation response was shown in 91% of pts. The complete granulation response rate obtained was 70.3%, with a complete ulcer closure in 69.2% of the pts. Mean wound healing time was 13 weeks. After 6-month follow-up, there were 10.4% amputations and 4.2% recurrence. The treatment was well tolerated. Adverse events (AEs) were reported in 29% of pts. The most frequent were shiver, local infection, pain in the application site, fever, and arterial hypotension, all with mild to moderate intensity. Three serious AEs (SAEs) were reported: 2 were pts with lower limb infections and the third a case of anaphylactic reaction, all with complete recovery. No deaths were reported.

CONCLUSIONS. In this retrospective analysis, local administration of Heberprot-P® during a brief period was effective to induce healing of ulcers in a high percentage of patients with severe diabetic foot ulcers (Wagner 3 and 4). The recurrence rate was low, thus, further amputations were avoided and patients' quality of life improved. Local treatment with Heberprot-P® was well tolerated since a low incidence of SAEs was observed.

AMP 2018-17 Office-Based PAD Evaluation and Supervised Exercise Therapy (SET) Covered by Medicare (Michigan-Ohio Model)

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PURPOSE. A Supervised Exercise Therapy (SET) program must be conducted in a hospital outpatient setting or in a physician's office and under the 'direct supervision' of a physician or physician assistant, nurse practitioner, or clinical nurse specialist who must be trained in both basic and advanced life support techniques. Physical therapists not practicing in these settings are not covered at this time. Currently, CPT Code 93668 covers Peripheral Arterial Disease (PAD) Rehabilitation. At this point, we are unsure whether a new code will be developed or if code 93668 will be revised. We are expecting more information when CMS releases the final National Coverage Determination contractor instructions and will share that information as it becomes available.

MATERIALS AND METHODS. Key points in the 2014 clinical evidence update included management of intermittent claudication; exercise programs; and the association of supervised exercise with increases in MWD (Maximal Walking Distance) compared with home-based or other unsupervised exercise programs. Additionally, supervised exercise is associated with greater increases in walking distance in people with aorto-iliac disease than either stenting or optimum medical care, and supervised exercise appears to be more cost-effective than either angioplasty alone or supervised exercise plus angioplasty in people with intermittent claudication (IC) due to femoropopliteal occlusion.

RESULTS. The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover SET for beneficiaries with IC for the treatment of symptomatic PAD. Up to 36 sessions over a 12-week period are covered if all of the following components of a SET program are met.

CONCLUSIONS. PAD affects 12%-20% of Americans age 60 and older, and the incidence of PAD increases considerably with age. Supervised exercise therapy has been demonstrated to be an effective therapy to lessen the symptoms of IC and improve walking distance in patients with PAD in numerous trials. Stakeholders such as the American Heart Association (AHA) have long recommended supervised exercise as a first-line, non-invasive, low-risk therapy for individuals with PAD who suffer from claudication. Despite the disease burden and the substantial evidence supporting supervised exercise therapy as a safe and effective treatment for PAD, it is currently covered by Medicare.

AMP 2018-18 Wound Healing After Angiosome-Directed Revascularization in CLI With Concomitant Femoropopliteal Paclitaxel Intervention

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PURPOSE. To report a retrospective cohort analysis of wound-healing rates in patients with chronic non-healing wounds treated with femoropopliteal pacliaxel endovascular technology and concurrent tibial artery balloon angioplasty.

MATERIALS AND METHODS. Forty-four consecutive patients with critical limb ischemia and associated non-healing wounds (Rutherford V-VI) underwent tibial artery balloon angioplasty with concomitant femoropopliteal paclitaxel eluting stent (DES)

implantation or angioplasty with paclitaxel-coated balloons (DCB). Patients were followed after their initial procedure for wound healing, defined as complete healing of the index wound documented at subsequent inpatient or outpatient visits at 3-, 6-, and 12-month intervals.

RESULTS. The rate of wound healing increased over the follow-up period. At 3 months, the proportion of patients with wounds was greater than the proportion whose wounds had healed (79.5% vs 20.5%; $P<.0001$). At 6 months, the rate of healed patients were not statistically different from non-healed patients (43.2% vs 56.8%; $P=.2046$). Finally after 12 months of follow-up, the rate of healed wounds was greater than non-healed patients (68.2% vs 31.8%; $P=.0007$). Angiosome directed tibial artery angioplasty was found to be associated with a higher rate of wound healing compared with non-angiosome directed angioplasty (83.3% vs 50%; $P=.001$). Cox regression analysis revealed that patients treated via a non-angiosome directed approach were less likely to experience wound healing by 12 months (adjusted hazard ratio 3.481; $P=.039$). Lesion length and recurrent target lesions were not associated with restenosis. Wound classification according to the Society for Vascular Surgery Lower Extremity Guidelines Committee was not found to be influential over the rates of wound healing. The effect of femoropopliteal intervention with either DES or DCB was not significantly associated with wound healing (hazard ratios 1.661 vs 1.584; P-values 0.676 vs 0.631, respectively).

CONCLUSIONS. These findings are consistent with previous studies that have shown that angiosome-directed therapy is a valuable treatment strategy in patients undergoing endovascular revascularization for the treatment of non-healing arterial ulcers. Patients treated with an angiosome-directed angioplasty approach have higher rates of wound healing after 1 year.