Scientific Abstracts From the AMP Symposium

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AMP 2019-1. Endovenectomy of the Common Femoral Vein as Last Option in Severe Post-Thrombotic Syndrome

N.E. Santana, I.E. Sánchez

The common femoral vein (CFV) and iliac veins comprise the common channel for venous drainage of the lower extremities. Occlusive venous thrombosis of the CFV and iliac veins is associated with severe post-thrombotic syndrome, and in some cases, with non-healing vein ulcers. Chronic occlusion of the iliac veins can often be successfully treated with balloon dilation and stenting.

However, chronic occlusive disease of the CFV, which may accompany iliac veno-occlusive disease, presents an additional challenge. Following percutaneous intervention, relative obstruction of the CFV can persist, leading to incomplete drainage of the femoral and profundal femoris venous systems, and thereby mitigating the benefit of iliac vein recanalization and risking rethrombosis. Associated restenosis intrastent could occur, resulting in a large challenge for endovascular management. We report a patient with incapacitating post-thrombotic syndrome and a non-healing ulcer who first underwent angioplasty and stenting in the left common and external iliac veins, presenting an occlusion intrastent that was impossible to cross with endovascular techniques. For that reason, a common femoral endovenectomy was performed, which allowed the ulcer to heal in one month after surgery.

A 50-year-old man presented with left lower extremity pain, swelling, discoloration, and a venous ulcer above his lateral and medial malleolus. His medical history included systemic arterial hypertension and left lower extremity deep venous thrombosis (DVT) in 2012 (iliofemoral segment). This progressed to skin breakdown and venous ulceration of the left lower leg, which failed to heal despite local care and compression. He underwent angioplasty and stenting in the left common and external iliac vein in 2015, and his ulcer healed.

In 2018, he consulted with us again because he had a residual ulcer. At that time, he had left leg pain and edema that limited his daily activities. On physical examination, he had significant pigmentation changes to the level of the knee, and induration over the entire lower third of the leg. The lower leg was tight and painful to palpation, with a 3-cm diameter venous ulcer above the lateral malleolus and a 2-cm ulcer above the medial malleolus. Venous duplex scan demonstrated external iliac and common femoral veins with post-thrombotic chronic changes, and computed tomography angiography showed an occlusion of the stent at the common and external iliac veins. The patient was offered a hybrid procedure to treat his chronic proximal venous obstruction. This procedure consisted of an open endovenectomy of the CFV, accompanied by endoluminal recanalization of his iliac veins to reestablish unobstructed venous drainage from his femoral and profunda femoris veins to the vena cava.

AMP 2019-2. A Rare Case of Bilateral Posterior Tibial Artery Aneurysms Presenting as Unilateral Acute Limb Ischemia

M. Krishnaswamy, A. Hattam

PURPOSE. True aneurysms of the tibial arteries are extremely rare. Of the few previously described tibial artery aneurysms, there are scant reports of isolated true aneurysms of the posterior tibial artery (PT). In this report, we describe the second documented case of bilateral true PTA aneurysms. Unique aspects of this case are that the aneurysmal PT was the only patent tibial artery bilaterally, the aneurysm(s) were degenerative in nature, and initial patient presentation was due to aneurysm thrombosis that caused acute foot ischemia.

MATERIALS AND METHODS. A 75-year-old woman presented with a history of sudden onset paresthesia and ischemic rest pain involving the left foot and ankle. Capillary and superficial venous return were reduced, the foot was cold, and there were no palpable pedal pulses. The calf remained soft to palpate. There was no history of palpitations or arrhythmia, and the patient was in sinus cardiac rhythm both clinically and on electrocardiography. Computed tomography angiogram (CTA) demonstrated no significant stenosis in the supragenicular vessels bilaterally. On the symptomatic left side, the tibioperoneal trunk (TPT) and anterior tibial artery (AT) were patent proximally, with the AT and peroneal artery occluding in the distal calf. The dorsalis pedis was occluded; however, the plantar arteries reconstituted. Dominant flow to the foot was via the PT, which was occluded in the distal calf.

RESULTS. Emergent thromboembolectomy of the popliteal and tibial arteries was performed via a medial approach to the distal popliteal artery. Selective thromboembolectomy using Fogarty catheters to each tibial artery was unsuccessful. Subsequent exposure of the dominant PT at the ankle revealed a thrombosed aneurysm that was 10 mm in diameter. The aneurysm was opened, and it showed a mixture of old, organized, and fresh thrombus. The PT aneurysm was excised, and thrombectomy established adequate inflow and backflow to the excised PT segment. The PT was repaired using an interposition long saphenous vein graft. Follow-up at 16 months demonstrated that the patient had a well-perfused left foot with a palpable PT pulse.

CONCLUSIONS. A consensus on the management of tibial artery aneurysms has yet to be defined. Though ligation of the aneurysmal artery is a valid surgical option in the emergency setting, we suggest reconstruction of the aneurysmal artery in circumstances where it is the sole arterial supply to the foot.

AMP 2019-3. National Medical Center "20 de Noviembre" Experience With Drug-Coated Balloons in Peripheral Arterial Disease.

N.E. Santana, I.E. Sánchez

PURPOSE. The main downside to percutaneous transluminal angioplasty (PTA) continues to be the high rates of in-stent restenosis. Restenosis occurs in more than 60% of patients treated with PTA, usually due to neointimal proliferation. In recent years, paclitaxel has been used as the drug of choice on drug-coated balloons (DCB). Thus, it is now possible to deliver an antiproliferative drug to a diseased artery segment, "leaving nothing behind." We conducted a retrospective analysis of the cases treated by DCB for peripheral arterial disease (PAD) in the National Medical Center "20 de Noviembre" in Mexico City.

MATERIALS AND METHODS. We analyzed all patients treated by DCB from January 2017 through September 2018. The variables studied were limb salvage rate at 6 months, anatomical segment treated (above-the-knee vs below-the-knee), Rutherford class, technical success rate, post-operative thrombosis, minor amputation rate, and major amputation rate.

RESULTS. A total of 25 patients were treated using DCB. Eighteen patients (72%) had below-the-knee disease, and 7 (28%) had above-the-knee disease. Twenty-four patients (96%) were Rutherford class 4 through 6, and 1 patients (4%) was Rutherford class 3. Technical success was achieved in 22 patients (85%), and 3 patients (12%) presented with acute ischemia after surgery. Twenty-one patients (84%) underwent minor amputation, 3 patients (12%) underwent major amputation, and 1 patient (4%) did not require any amputation. The limb salvage rate was 88%.

CONCLUSIONS. This report shows promising results of the use of DCB for patients with PAD. The results of this study are consistent with a number of previous publications. The limb salvage rate at 6 months in this cohort was high (88%), even considering that the vast majority of patients had critical limb ischemia.

AMP 2019-4. National Assessment of Availability and Utilization of SET for PAD in Patients With Intermittent Claudication

A. Dua, S. Sharma, O. Aalami

PURPOSE. Supervised exercise therapy (SET) is an inexpensive, low-risk, and effective option when compared with invasive therapies for treatment of patients with peripheral artery disease (PAD) and intermittent claudication (IC). Randomized controlled trials have demonstrated the benefits of SET in improving maximum walking distance in IC patients, and society guidelines recommend SET as first-line therapy. In 2017, the Centers for Medicare & Medicaid Services (CMS) added coverage of SET. We aimed to evaluate the availability and utilization of SET programs, determine the awareness of SET CMS coverage in the United States (U.S.), and gauge the academic interest in SET in the vascular community.

MATERIALS AND METHODS. An 8-question online survey was sent to 900 vascular surgeons, cardiologists, and vascular medicine physicians across the U.S. The most recent 2-year programs for the Vascular Annual Meeting (VAM), Midwestern Vascular Surgical Society (MVSS), Eastern Vascular Society (EVS), and Western Vascular Society (WVS) were reviewed to identify SET-related abstracts and gauge academic interest and awareness for SET within the vascular surgery community.

RESULTS. We received 131 (14.6%) physician responses to the survey. All 50 states were represented. The majority (54.2%) of responders stated that there was no SET program at their facility, and 5.4% did not know if there was a program at their facility. Of those who did have a SET program available, 81.1% had programs associated with cardiac rehabilitation, and 18.8% had a PAD-specific program. A significant number of physicians (48.9%) had never referred a patient for SET, and 26% were not aware that CMS covered SET sessions. Of the physicians who were aware of CMS reimbursement, 36% had never referred a patient to a SET program. Of all surveyed physicians, 97.7% indicated that they would refer patients to a SET program if one were available. Top barriers to utilization of a SET program included that there were no SET centers available and that the nearest SET program was not accessible without significant cost or travel expense to the patient. A review of major vascular meeting programs for the last 2 years yielded no identification of a SET-related abstract.

CONCLUSIONS. There is a lack of availability and utilization of SET for PAD patients with claudication, despite guideline recommendations. When SET is offered, it is typically through cardiac rehabilitation programs. Travel distance, lack of SET program availability, and low reimbursement rates are the primary areas that could be addressed to improve utilization of SET.

AMP 2019-5. Electrical Stimulation as Adjuvant Therapy in CLI May Be Related to Starling's Hypothesis

J.W. Hovorka, C. Martinez

PURPOSE. In some cases, critical limb ischemia (CLI) causes muscular atrophy. Laser Surgical Solutions RGV, LLC has used electrical stimulation (VeinoPlus) in patients with CLI and muscular atrophy. The Starling equation for fluid filtration, also known as Starling's hypothesis, relates to transendothelial fluid exchange in the capillaries. The curriculum for the Lymphology Association of North America simplifies the hypothesis such that the fluid absorption relies upon a difference in arteriolar and venular pressure. We have noticed that use of VeinoPlus for electrical stimulation of the calf musculature in patients with muscular atrophy has been clinically beneficial. We hypothesize that the mechanism relates to Starling's hypothesis such that arterial intervention may raise arterial and arteriolar pressure. Logically, whatever may be done to lower the venous or venular pressure would also be beneficial for patients with CLI.

MATERIALS AND METHODS. We retrospectively reviewed charts of five Rutherford 4 patients who also had muscular atrophy of the calf musculature that was greater than 2 cm in circumference. None of the patients could walk at the 10th percentile compared with age/sex-matched controls. Pre-revascularization physiologic studies included transcutaneous oximetry (TCOM), segmental pressures, pulse volume recording (PVR), and the 6-minute walk test (6MWT).
RESULTS. TCOM, segmental pressures, PVR waveform, and walking distance in the 6MWT were reported. All of these measurements showed improvement. These may be surrogates for arterial and arteriolar pressure, although for venous and/or venular pressure, standard vascular laboratory measurements are lacking.
CONCLUSIONS. CLI pathophysiology is complex and involves macrovascular and microvascular pathology. The need to identify optimal utilization of resources to improve outcome has been described elsewhere. Additional arterial inflow rather than intermittent pneumatic compression (IPC) may be necessary for optimal benefit in cases with muscular atrophy. Proposed objective measurements to further stratify patients, in addition to standard vascular laboratory physiologic measurements and vascular duplex, may include bioimpedance, arterial inflow by air plethysmography, standard ambulatory venous pressure measurement/venous air plethysmography and interstitial fluid pressure measurement, walking distance and patient-reported outcomes, and measurements for muscular volume. We propose a pilot study and seek consensus in identifying appropriate endpoints. While arterial revascularization does increase arterial and arteriolar pressure, decreasing the venous and venular pressure will also increase the arterial/venous pressure differential.

AMP 2019-6. Single-Center Study of Chocolate Balloon Angioplasty as an Adjunctive Therapy in Critical Limb Ischemia Patients

S. Vijaykumar, M. Thawabi, G. Chennu, S. Waxman, M. Cohen, J. Shao

PURPOSE. Severe symptomatic peripheral artery disease (PAD), especially critical limb ischemia (CLI), is associated with a high amputation rate and poor functional status, which increases morbidity and mortality in this population. This study analyzed the safety and efficacy outcomes of the Chocolate percutaneous transluminal angioplasty (PTA) balloon (Medtronic) as an adjunctive therapy in both above-the-knee (ATK) and below-the-knee (BTK) interventions in CLI patients.
MATERIALS AND METHODS. From October 2017 to November 2018, CLI patients who underwent Chocolate balloon PTA as an adjunctive therapy were enrolled from a single center. Data relating to patient characteristics included Rutherford classification and ATK/BTK lesion status. Procedure details were collected prospectively and included procedure time, fluoroscopy time, and contrast used. The primary outcome was all-cause mortality. Secondary outcomes included target vessel revascularization, ipsilateral major amputation, and bailout stenting rate.
RESULTS. Fifty patients and a total of 59 limbs underwent Chocolate balloon PTA. The baseline characteristics included a mean patient age of 71.8 years. Fifty percent of patients were males. Patients had a mean BMI of 27.8, and 64% of patients had diabetes mellitus, 96% had hypertension, 78% had hyperlipidemia, and 38% had chronic kidney disease. Fifty percent of patients were smokers. Rutherford classification (RC) of limbs included RC 4 (29 limbs), RC 5 (24 limbs), and RC 6 (6 limbs). Forty-five percent of lesions were ATK lesions, and 77% were complex BTK lesions. Adjunctive atherectomy (orbital) was performed on 98.4% of lesions. The average procedure time was approximately 149 minutes, while the average fluoroscopy time was approximately 40 minutes. The average amount of contrast used was 123 mL, and the average follow-up was 3.2 months from the index procedure. The all-cause mortality rate was 6% (3 patients). Target vessel revascularization occurred in 8 limbs (13.5%), ipsilateral major amputation occurred in 1 limb (1.7%), and bailout stenting occurred in zero limbs.
CONCLUSIONS. Balloon angioplasty, either as a primary or adjunctive therapy, remains the core of lower extremity endovascular intervention. The Chocolate PTA Balloon is proven to be safe, with a low bailout stenting rate, as well as efficacious, with a low target-vessel revascularization and high amputation-free survival rate in both ATK and complex BTK interventions in CLI patients.

AMP 2019-7. Treatment of Severe Claudication Using Crosser, Diamondback, Balloon PTA in a Patient With Aorta-Bifemoral Grafts

T. Bob-Manuel, R. Patel

PURPOSE. Revascularization of chronic total occlusions in the peripheral vessels is particularly challenging due to anatomy, lesion length, and calcification. In patients who have had aorto-bifemoral bypass grafts, there is an additional challenge of gaining access to the infrainguinal lower extremity vasculature. Alternative access sites and newer technologies can facilitate treatment in these cases.
MATERIALS AND METHODS. A 76-year-old man with a history of tobacco abuse and coronary artery disease was referred for worsening Fontaine Stage IIb claudication (left leg worse than right leg) upon ambulation. The claudication had occcurred for the past 2 years after 2 failed percutaneous transluminal angioplasty attempts at an outside hospital. The patient denied signs or symptoms of critical limb ischemia (CLI). Computed tomography angiography of his abdomen with run-off showed bilateral mid superficial femoral artery (SFA) chronic total occlusions (CTOs) with collaterals to the distal SFAs. During his initial consultation with our group, the patient was placed on cilostazol and started a structured walking program. He showed improvement in his time to claudication, but the claudication still significantly impaired his quality of life. Ipsilateral, antegrade access was used to cross the left CFA CTO with a 6S 154 cm Crosser CTO Recanalization Device (BD). Orbital atherectomy was performed using a Diamondback

360 Peripheral Classic Crown 2 mm × 30 mm × 145cm (CSI). Angioplasty was performed with the .035-inch scoring UltraScore balloon (BD) at 6 atmospheres for 120 seconds. An angioplasty was performed with a Lutonix drug-coated balloon (DCB) (VD) at 6 atmospheres for 180 seconds. There were no complications.

RESULTS. Post procedure, the patient no longer experienced left lower extremity claudication. Four weeks later, he returned for the same procedure on the right SFA CTO. He no longer experiences claudication.

CONCLUSIONS. Patients with prior failed peripheral CTOs should be transferred or referred to tertiary centers that have experience in treating these lesions. Ipsilateral, antegrade CFA access can be useful in patients with SFA CTOs who have undergone aorto-bifemoral bypass grafting. Crosser, Diamondback, and DCBs can be safely used to treat long, calcified SFA CTOs.

AMP 2019-8. Amputation Rates for Patients with Diabetic Foot Ulcers at the Community Level: An Income-Based Analysis

E. Ge, D. Krawczyk

Using longitudinal accrual data from amputation rates of the high-risk population with a diabetic foot ulcer, standardized income and gender, we evaluated outcomes of lower limb amputation (LLA) in London, Ontario. Previous studies using a population-based cohort nationally showed the lowest income quintile at a significantly higher association of LLA. However, using the high-risk population strategy, we show that a community-level analysis indicates the highest income quintile as encountering a significantly higher risk of LLA. Using community-level data based on admission to hospitals for an LLA due to a diabetic foot ulcer as the amputation rate denominator helps pinpoint at-risk groups that are not found in general diabetic datasets and large population-based studies.

The study population consisted of two groups: all patients with a diabetic foot ulcer from 2006-2009 (N= 251, 69.93% male) and all patients with a non-traumatic lower limb amputation from 2006-2009 (N=111, 71.17% male). And all patients with a diabetic foot ulcer from 2011-2014 (N=306, 69.93% male) and all patients with a LLA from 2011-2014 (N=108, 75% male). These accrual data were compiled by the Institute for Clinical Evaluative Sciences where DAD Evaluative Services allowed access to the use of the Canadian Institute for Health Information's Discharge Abstract database (CIHI DADD), which houses information on hospital admissions, and the Canadian Institute for Health Information's National Ambulatory Care Reporting System Metadata (CIHI NARCS), which houses data from all hospital-based, emergency, and community based ambulatory care in outpatient and day surgery.

The total number of new cases of amputation was significantly lower (111 in accrual years 2006-2009 and 108 from 2011-2014, *P*-value <.0000001) in comparison to other studies that have shown an increase in the total number of new cases of amputation incidences when comparing total population of people with diabetes and a decline in the rate. Our analysis shows a decrease in amputation rate by 9% in London, Ontario comparing the accrual year periods. Because there is a smaller denominator used, a growing population overall does not skew the outcomes nor underestimate the rate. For amputation rate among diabetic foot ulcer patients, the risk of acquiring an amputation was greater in the highest income quintile for both accrual year periods. Compared to amputation rates in the top quintile, the relative risk for those in the lowest (5), second-lowest (4), middle (3) and second-highest (2) were lower when compared to the highest quintile reference category, which is 0.67, 0.72, 0.79, and 0.70, respectively, from 2006-2009. From 2011 to 2014, the relative risk for those in the lowest (5), second-lowest (4), middle (3) and second-highest (2) was 0.04, 0.10, 0.16 and 0.09; this is also significantly lower than the highest income quintile reference category, respectively. The lowest income quintile, although having the highest number of diabetic foot ulcers compared to the highest income quintile (96 versus 30 in accrual years 2006-2009; and 99 versus 45 in accrual years 2011-2014) had a lower rate of amputations (43% and 31% for lowest income quintile category comparatively 60% and 47% for highest income quintile category, in respective accrual year periods). Other studies have demonstrated that diabetes affects the poor when looking at population-based data, but when looking at end-stage foot complications, in this analysis, individuals of a higher income quintile have more amputations (60% versus 43%, respectively, from 2006-2009; and 47% versus 31%, respectively, from 2011-2014). Reasons for the outcome of this paper could stem from multiple factors. A diabetic foot ulcer (DFU), by contrast to other chronic diseases that are higher at a low-income quintile, here, like a breast cancer diagnosis, are at a higher risk for treatment by amputation in the highest income quintile.

AMP 2019-9. Reducing the Body Burden of Lead is Associated With Resolution of Critical Limb Ischemia

F. Ujueta, G. Lamas, I. Arenas, T. Yates, B. Olivieri, R. Beasley, A. Navas-Acien

PURPOSE. Epidemiologic studies have found that lead and cadmium exposure are associated with an increased risk of atherosclerosis. We report on estimated changes in total body burden of lead and cadmium in 7 patients with diabetes and critical limb ischemia (CLI) whose treatment with edetate disodium infusions led to resolution of CLI.

MATERIALS AND METHODS. Seven patients with diabetes and CLI completed 40 intravenous infusions of edetate disodium-based chelation as part of a 10-patient pilot study. The presence of CLI was based on a Rutherford Clinical Severity Scale of 4 or 5. All patients demonstrated marked improvement and resolution of CLI following the infusions. Urine was collected using metal-free containers and analyzed using Inductively Coupled Plasma-Mass Spectrometry. Collection occurred at baseline, before and after chelation treatment, and at infusions 20 and 40. Total body lead burden was estimated as post-chelation urine lead. Cadmium burden was estimated as baseline urine cadmium. Each was expressed per gram of creatinine (Cr). Statistical analyses were paired t-tests on

log-transformed values.
RESULTS. The mean age of patients was 76 ± 8.3 years, and 57% of patients were male. Baseline urine creatinine was 0.92 ± 0.24 mg/dL (mean ± SD). Coronary artery disease was found in 86% (6 patients), while 29% (2 patients) had a smoking history and 57% (4 patients) had a non-healing ulcer or dry gangrene. The SVS WIFI (wound, ischemia, foot infection) risk staging score was high risk in 43% (3 patients) and moderate in 57% (4 patients). Following the first infusion, urine lead increased by 3733% and urine cadmium increased by 553%, compared with baseline (P <.001 for both). Over the course of 40 infusions, post-chelation urine lead decreased by 39% (1.28 μg/g Cr ± 0.29 to 0.78 μg/g Cr ± 0.91, P <.001). Almost half of that change (45%) was already present at 20 infusions. In contrast, there was no significant change in pre-chelation urinary levels of cadmium over the 40 infusions (-0.48 μg/g Cr ± 0.22 vs -0.34 μg/g Cr ± 0.36, P=NS).
CONCLUSIONS. This analysis of a small number of patients with diabetes and CLI suggests that edetate disodium-based chelation may reduce lead body burden in conjunction with a strongly positive clinical response to the therapy. While causality cannot be established, these data suggest future directions for investigation, which are currently being carried out in TACT2 and TACT3A.

AMP 2019-10. Occlusion Perfusion Catheter (OPC): A Universal Drug Delivery Device – Next Generation
R. Teeslink
PURPOSE. Advanced Catheter Therapies (ACT) has designed the Occlusion Perfusion catheter (OPC) to function as a universal agent delivery system that will accommodate any therapeutic agent, including pharmaceuticals, biologics, and live cells.
MATERIALS AND METHODS. The OPC is a 5-lumen catheter designed with proximal and distal occlusion balloons, a center space-occupying balloon, an inflow port, an outflow port, and a guidewire lumen compatible with a standard .014-inch wire. The OPC is a 5 French catheter and is compatible with a 6 French sheath. A fiber optic pressure sensor is incorporated into the inflow lumen to monitor the treatment chamber pressure. Occlusion balloons define the treatment region. The proximal and distal occlusion balloons are inflated simultaneously to control blood flow and create a treatment chamber. In addition, they serve to prevent systemic distribution of the agent. The fourth and fifth lumens are for inflow and outflow ports located within the established treatment chamber. The trapped blood is removed from the treatment chamber by flushing with saline. The space-occupying balloon can be inflated to minimize the amount of therapeutic agent required, when indicated. This balloon never touches the vessel wall. After the blood has been evacuated, the therapeutic agent is delivered. A sensor monitor controls and optimizes pressure within the chamber for penetration into the media of the vessel wall, both longitudinally and circumferentially.
RESULTS.
Pre-clinical:
- Confocal analysis of the vessel wall demonstrated delivery of fluorescent paclitaxel within the media and adventitia, circumferentially and longitudinally.
- Pharmacokinetic analysis demonstrated a straight line of .1 mcg/mL for 72 hours. According to Axel et al, (*Circulation*. 1997;96(2):636-645), the effective range of paclitaxel is .085-.85 mcg/mL to affect a 90% to 99% inhibition of human arterial smooth muscle cell (SMC).
- 7-day scanning electron microscope demonstrated that paclitaxel delayed healing effect.
- 28-day histology demonstrated normal endothelium.
- Live cell testing demonstrated that the OPC can deliver live cells with minimal mechanical damage at a wide range of pressures.
- The OPC demonstrated the ability to deliver the agent through bare metal stents circumferentially and longitudinally.
- The OPC demonstrated the delivery of the agent into the media, circumferentially and longitudinally, even with a high burden of calcification.

Clinical:
- Copper BTK Cohort at 6 months (n=28):
- The primary patency was 89.3% (25/28 patients).
- 6-month freedom from clinically driven target lesion revascularization (CD-TLR) was 96.4% (27/28 patients) .
- 9-month freedom from CD-TLR was 89.5% (17/19 patients).

CONCLUSIONS. The OPC:
- Delivers an agent circumferentially and longitudinally into the vessel wall.
- Delivers the effective range of paclitaxel for 90% to 99% inhibition of human arterial SMC, maintaining normal intimal endothelial function by non-coating.
- Delivers multiple agents.
- Supports multiple uses in the same patient, above and below the knee.
- Controls pressure within the chamber, negating the requirement for accurate balloon-to-wall measurements.
- Delivers live cells with minimal mechanical damage to the cell membrane.
- Negates blood/agent admixture.

- Minimizes systemic effect via flushing.
- Decreases cost.

AMP 2019-11. A New Technology in Access Needles

R. Teeslink

PURPOSE. The American Nurses Association created 10 golden rules of safety that they recommended following in designing a safety needle. InjectiMed has designed and developed an endovascular guidewire introducer needle, SafetyNet, that encompasses all 10 of these golden rules.

MATERIALS AND METHODS. InjectiMed technology is based on a design where a safety guard, with a movable trap, based against the needle, slides along the needle and stops on a slight bulge at the distal end of the needle, capturing the tip. The blood containment chamber slides alongside the needle as it is positioned between the rear of the safety guard and the movable trap that closes the distal end of the chamber. The SafetyNet has an access control grip at the housing/hub interface, giving improved control for penetrating tough scar tissue and more consistently obtaining a one-wall stick. Two bevel-up indicators, one on a notch on the hub, and three raised chevrons on top of the Hi-Viz housing, help to determine the bevel orientation without the clinician taking eyes off the monitor. There is an echogenic tip located at the distal end of the bevel that extends to the needle tip.

RESULTS. Multiple sites have evaluated the SafetyNet and have rated the needle with a 100% acceptance of the unique concept, safety aspects, sharpness, echogenic tip, and user friendliness.

CONCLUSIONS. Features and benefits:

1) Allows access with no change in technique.
2) Designed to be activated with a single hand.
3) Manipulation of guidewire and control of bleeding possible with free hand.
4) Brightly colored housing allows high visibility.
5) Grip at the housing/hub interface gives improved control.
6) Two bevel-up indicators: one indicator is a notch on the hub, and the other is three raised chevrons on top of the Hi-Viz housing.
7) An echogenic tip is located at the distal end of the needle, extending to the bevel tip.
8) Patented dual-feature safety guard designed to:

-Instantly shield the sharp needle tip.
-Contain blood in the needle tip.
-Protect caregivers from cross-contamination.

AMP 2019-12. A New Vessel Closure Device Specifically Designed for Small Arterial Vessel Closure of the Extremities

R. Teeslink

PURPOSE. EnSite Vascular has designed a small vessel closure device (VCD), SiteSeal SV, specifically for brachial, radial, pedal, and popliteal arteries. SiteSeal SV simulates manual compression but removes the associated variables, leaving nothing behind. It applies invariant pressure to the vessel wall access site by utilizing an internal stainless spring that functions as a shock absorber to dampen blood vessel pressure fluctuations.

MATERIALS AND METHODS. An incline plane is molded into the base of the SiteSeal SV, and an elastic strap is attached to one of the two strap support openings. The device is placed with the incline plane on the skin surface and the raised portion pointing towards the heart. The elastic strap is pulled under the extremity at the level of the access site from right to left. The velcro end is inserted through the second strap support opening. The SiteSeal SV device is placed over the access sheath, centered over the access site. Pressure is applied to load the spring, and the elastic strap is pulled up and over the device. The elastic band is wrapped until adequate pressure establishes hemostasis and the velcro tip locks the strap in place. With the SiteSeal SV securely in place, the sheath is removed from the access site. Distal pulses are checked for adequate blood flow. Pressure can be adjusted by increasing or decreasing the elastic strap pressure.

RESULTS. Twenty brachial accesses have been closed with no hematomas, or most importantly, no false aneurysms or occlusions post procedure at discharge and at 24-hour follow-up.

CONCLUSIONS. SiteSeal SV is a simple to use, atraumatic, single VCD that establishes small-vessel hemostasis. There have been no significant complications.

- Large base: length 2.5 inches, width 1.25 inches.
- North end incorporates an incline plane positioned above the arteriotomy site to control inflow blood pressure.
- South end of the base positioned below the arteriotomy site controls backflow bleeding from collateral vessels.
- Minimizes any margin of error in device placement.
- There is a modulation effect from the spring.
- Both the spring and elastic strap allow for ultimate tension flexibility in controlling blood flow.

- Intuitive application by health care professionals.

AMP 2019-13 A New Closure Device: How to Close Large Bore Sheaths, Leaving Nothing Behind

R. Teeslink

PURPOSE. EnSite Vascular has designed a large bore closure device, SiteSeal, which simulates external compression but removes the associated variables, leaving nothing behind. It applies invariant pressure to the vessel wall access site by utilizing internal stainless steel springs that function as shock absorbers to dampen blood vessel pressure fluctuations.

MATERIALS AND METHODS. SiteSeal utilizes a number 2 Vicryl suture to make a Z stitch, which holds the SiteSeal device in place and closes the arteriotomy site in a linear fashion. The obturator is reinserted into the sheath, and the Z stitch is placed by entering the soft tissue at the skin insertion site of the sheath. The first entrance is 1 cm east of the sheath, passing under the sheath and exiting 1 cm west of the sheath. The second entrance is 1 cm above the skin insertion of the sheath, and 1 cm to the east. The needle crosses up and over the sheath and back down into the soft tissue, and it exits 1 cm west of the sheath. The two ends of the Z stitch form a double half-knot, which creates an "X" over the arteriotomy site when closed. Hemostatic powder is placed around the sheath and half knot. The device is cocked by turning the cross bar horizontally and applying pressure, which loads the springs. It is then centered over the sheath at the arteriotomy site, with the incline plane facing north. The dilator is removed from the sheath. The two suture ends are pulled tight against the sheath as pressure is applied to the device, closing the Z stitch into an "X" over the arteriotomy site, and the sheath is removed. The suture ends are pulled up through the designed slots and tied into the notched slot of the cross bar. The loaded springs are released by turning the cross bar back to a vertical position. Once the device is activated, the pressure created by the Z stitch continues to elevate the artery and folds in the soft tissues surrounding the arteriotomy site, closing the site in a linear fashion. The roof is placed and Tegaderm (3M) is applied for stabilization.

RESULTS. Forty-five endovascalar aneurysm repair (EVAR) and 23 Impella procedures have been performed using SiteSeal. There has been no hematoma formation at discharge, 24-hour follow-up, 7-day follow-up, and 30-day follow-up.

CONCLUSIONS. SiteSeal has the ability to close large bore sheaths with a single device, leaving nothing behind.

Associated advantages are:

- Not limited by sheath size, including EVAR, thoracic endovascular aortic repair, and transcatheter aortic valve replacement
- No patient limitation: size, anti-coagulation, calcification, etc.
- Simple and rapid deployment.
- Allows immediate re-access.
- Minimizes patient discomfort, allowing immediate head elevation to 30 degrees with no restriction of leg movement.
- Early ambulation.
- Nothing is left behind, which minimizes the potential risk of vessel wall injury, infection, or embolization.

AMP 2019-14. The Use of Decellularized Dermal Allograft in Conjunction With Endovascular Revascularization Promotes Limb Salvage

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PURPOSE. There are currently 30.3 million Americans diagnosed as having diabetes, and a quarter of them will develop a diabetic foot ulcer in their lifetime. Individuals with diabetes frequently develop peripheral vascular disease (PVD) and have 2- to 4-times higher risk of diabetic foot ulcers than non-diabetic patients. Concurrent diabetic foot ulcers and PVD increases the risk of major limb amputation in this patient population, and the 5-year mortality rate. The use of a next-generation decellularized dermal allograft (DDA) in conjunction with endovascular revascularization can significantly decrease wound healing times, thus preventing limb loss, improving quality of life, and reducing overall cost. This case study demonstrates the efficacy of decellularized dermal allograft (DDA) in conjunction with endovascular revascularization to promote limb salvage.

MATERIALS AND METHODS. *Patient A:* A 74-year-old diabetic man with PVD presented with a non-healing wound that resulted in transmetatarsal amputation that failed to heal. He subsequently underwent right lower extremity angioplasty with wound debridement and placement of DDA.

Patient B: A 64-year-old diabetic woman with PVD presented with a non-healing ulcer on the left shin. The ulcer had previously failed split-thickness skin grafting. She subsequently underwent left lower extremity angioplasty with ulcer debridement and placement of DDA.

RESULTS. Patient A, treated with DDA in conjunction with endovascular revascularization, showed significant improvement in the first 4 weeks, with a reduction in surface area of 57% and development of robust granulation tissue. He subsequently underwent split thickness skin graft at the 6-week mark and demonstrated full healing within 10 days. Patient B, also treated with DDA in conjunction with endovascular revascularization, exhibited a reduction in wound surface area of 66% in the first 4 weeks and had complete wound healing within 8 weeks. Additionally, ankle-brachial index in her left lower extremity improved from 0.6 to 0.95 post-operatively.

CONCLUSIONS. The use of a next-generation DDA demonstrated significant improvement in two diabetic patients with PVD and multiple co-morbidities. Given its efficacy in one application, DDA provides an effective option that should be strongly considered as

an adjunctive treatment to facilitate rapid improvement of wounds, ultimately allowing closure of soft tissue defects and reducing the expense of diabetic limb salvage.

AMP 2019-15. Percutaneous Technique for Venous Arterialization: A New Concept

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PURPOSE. Revascularization is not feasible for a significant proportion of CLI patients because of the absence of outflow vessels in the foot, the so-called "desert foot." To overcome this limitation, venous arterialization, which involves an arteriovenous (AV) fistula and flow inversion in the venous system, has been utilized. Recently, percutaneous approaches have been proposed, and one of the most studied approaches uses a specialized device that relies on ultrasound location. We propose a percutaneous technique that would rely on conventional devices and extravascular revascularization. Due to the experimental nature of this procedure, a swine model was used.

MATERIALS AND METHODS. International and local guidelines for proper conduct of animal experiments were followed, and adult swine subjects were used. Femoral vessels were chosen to create the AV fistula, given that they are sufficiently superficial and that they somewhat approximate the diameter of human tibial vessels. The internal jugular (any side) or the inferior vena cava were chosen as the proximal access (6 French sheath). It should be noted that proximal arterial access should be practiced in humans, but, given the spatial vessel disposition in swine, venous proximal access was utilized. A retrograde needle puncture of the femoral artery and vein was made under ultrasound-guidance (long axis), at an acute angle (30 degrees), in an attempt to advance the needle inside the artery before puncturing the vein. A guidewire was advanced and a 5-French sheath was placed through the artery and vein. Under fluoroscopic guidance, an .018-inch working guidewire was brought down from the proximal access, and flossing was done through the 5 French AV sheath. A .035-inch crossing catheter was brought down from the proximal access and out through the 5 French AV sheath. While keeping moderate proximal and distal compression in order to avoid the formation of a hematoma, the AV sheath was removed. The crossing catheter/guidewire was pulled under ultrasound guidance until the tip of the crossing catheter could be seen inside the artery. Once this was achieved, the guidewire inside the artery was pushed forward. A guidewire went down from the vein to the artery, over which a balloon and a covered stent could be deployed.

RESULTS. It was possible to establish an arteriovenous connection in two swine subjects after the technique was somewhat refined.

CONCLUSIONS. The proposed technique concept is technically feasible and should be tested in human patients with CLI who have no alternative option.