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Journal of Arterial Venous And Lymphatic Interventions

Supplemental Abstracts Issue

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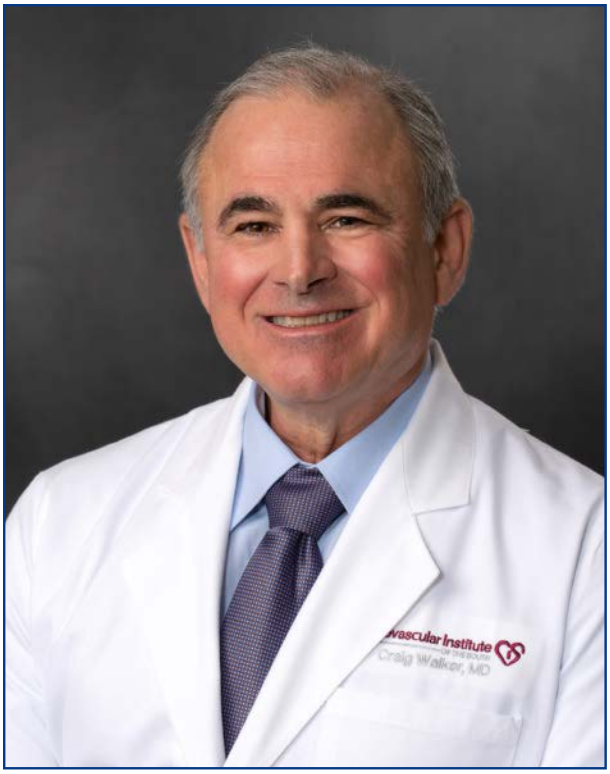

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Journal of Arterial, Venous, and Lymphatic Intervention

JAVELIN is an online, peer-reviewed journal that will focus on the diagnosis, medical treatment, and interventional therapy of arterial, venous, and lymphatic disorders. It will include case reports, step-by-step procedural instructions, new product introduction, recorded live cases, commentary on subjects of controversy, new breakthroughs in medical and interventional treatment, and submitted articles of interest. Articles will be archived for continued reference.

JAVELIN will have articles of interest to cardiologists, vascular surgeons, radiologists, nephrologists, wound-healing experts, podiatrists, family physicians, nurse practitioners, and internal medicine physicians. The “Fellows Corner” will focus on instructional cases and videos aimed at fellows and interventionists who are interested in continued basic education on peripheral vascular diagnosis, medical therapy, interventional techniques, and complication management. The “Fellows Corner” will include commentary from fellows in active training as well as a series on the basics of peripheral vascular intervention.

Advancements in diagnosis, treatment, interventional therapy, and wound healing for peripheral vascular disorders are progressing rapidly. JAVELIN will allow authors to utilize video images to enhance educational clarity and, if accepted, provide rapid turnover from the time of submission to peer review and subsequent publication. JAVELIN is now accepting articles for review and publication.

JAVELIN Editorial Board

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Surgery-first or Endovascular-first: A New Trainee's Approachto Critical Limb Ischemia

Authors:
Kristy Patel, OMS-3
Henry Szeto, DO

Background:
Peripheral artery disease is narrowing of arteries in your extremities, which can be severe enough to cause claudication and rest pain, also known as CLI.[1] This is diagnosed clinically with support from noninvasive testing such as an ankle-brachial index (ABI). Surgical treatment involves bypassing stenoses or occlusions with autologous saphenous vein or artificial grafts from the femoral artery to the popliteal artery or its branches. Endovascular treatments have advanced over the last three decades prompting the question of which treatment, endovascular or surgical, should be attempted first.[2]

Clinical Workup:
1. History and physical. Examine pulses and skin changes
2. Lifestyle modification with smoking cessation, glucose control, statin, and exercise
3. Noninvasive testing with ABI, pulse volume recordings (PVR), toe-brachial index (TBI), and/or transcutaneous oximetry (TcPO2)[1]

Procedure:
1. Transfemoral arterial access
2. Perform aortogram and runoff, if needed
3. Navigate to the target lesion and perform an angiogram
4. Intervention with balloon angioplasty, atherectomy, and/or stent placement
5. Post-intervention angiogram. Reassess
6. Access site closure[3]

Comparison of endovascular to open surgery:
Open surgery:
- Increased long-term durability, especially with autologous saphenous vein graft
- Higher upfront cost (operating room, postoperative care)
- Increased morbidity and mortality (wound infections, perioperative cardiovascular events)[2]

Endovascular:
- Decreased long-term durability. Need for repeat interventions
- Lower upfront cost, but potentially higher overall cost when factoring in repeat interventions
- Decreased morbidity and mortality[2]

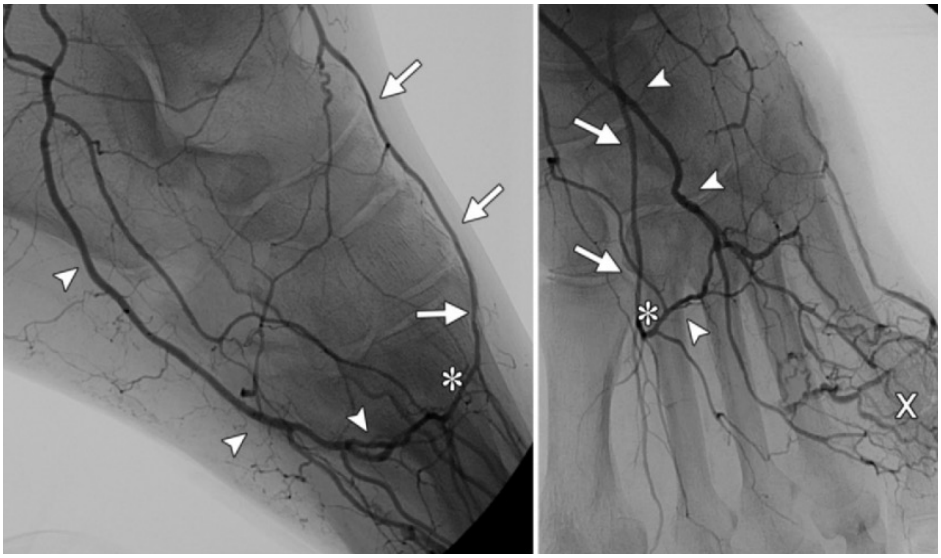

Figure 8: Lateral oblique (left) and anteroposterior (right) angiographic projections show the pedal-plantar loop in the foot of a diabetic patient. The dorsalis pedis artery (arrows) is connected via the deep perforating artery (*) in the first metatarsal space with the plantar arch and lateral plantar artery (arrowheads). Note the enhancing lesion at the head of the fifth metatarsal bone (X).[4]

Postprocedural Care:

1. Consider antiplatelet or anticoagulation therapy
2. Follow-up in 2-6 weeks with noninvasive testing
3. Reinforce lifestyle modifications[3]

Conclusion and Teaching Points:

Landmark Trials:

- BASIL Lancet 2005
- BEST-CLI (ongoing)
- BASIL-2 (ongoing)

Limitations of BASIL:

- Patients enrolled with severe limb ischemia, rather than the stricter definition of CLI. Did not provide objective data in inclusion criteria such as ABI.
- Patency and revision were not included as nendpoints. Primary endpoint was amputation-free survival.
- Only balloon angioplasty was studied, excluding other endovascular therapies.
- No characteristics of arterial lesions.[5]

Sources:

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3) Keefe, Nicole A., IR Playbook: A Comprehensive Introduction to Interventional Radiology. Springer Nature, 2019.

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Discovery of Small Molecule Inhibitors for the Conversion of Phenylpyruvate to Phenylacetic Acid

Authors:
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Abstract:
A recent study in our lab showed that dietary phenylalanine fermentation into phenylacetic acid (PAA) by gut microbiota produced an intermediate, phenylpyruvate (PPY), which is critical in the production of phenylacetylglutamine (PAG). PAG has recently been linked to cardiovascular health and increased risk of thrombosis in patients. However, further testing needs to be conducted in order to gain a deeper understanding of the gut microbial enzymes involved in the conversion of PPY to PAA. A previous study conducted in our lab showed that porA, a bacterial gene, found in Clostridium sporogenes, a gram-negative bacterium, encodes the α subunit of α -ketoisovalerate: ferredoxin oxidoreductase which facilitates the production of PAA. However, some unpublished studies have shown that not all gut commensals require the gene porA to produce PAA. Using both heterologous protein expression in E. coli and genetic knockouts, our lab successfully identified two human commensal gene clusters. One encodes phenylpyruvate:ferredoxin oxidoreductase (PPFOR), and the other phenylpyruvate decarboxylase (PPDC). Together, both enzymes play a key role in the production of PAA via oxidative and non-oxidative phenylpyruvate decarboxylation, respectively. This study successfully identified non-lethal small molecule inhibitors of microbial PAA production and looks promising in the discovery of drugs for PAG-facilitated development of cardiovascular disease.

Development of an Ex Vivo Bioreactor System to Model Arteriovenous Fistula Hemodynamics

Authors:
Linda Liu[1]
Saami K. Yazdani, PhD[2]

Category: Cardiovascular Disease

Background:
Currently, in vivo evaluation of catheter-based devices to treat arteriovenous fistulas (AVFs) stenosis is an expensive and time-consuming proposition. The most utilized models consist of AVF animal models, since there are currently no benchtop AVF models that incorporate the use of biological tissue to evaluate catheter-based treatments. The purpose of this study was to, thus, develop an ex vivo bioreactor system that simulates AVF hemodynamics using porcine carotid arteries and jugular veins.

Methods:
A novel vascular bioreactor was developed consisting of a gear pump equipped with pressure and flow sensors. The test section was a freshly harvested porcine carotid artery and porcine jugular vein. A signal generator was used to create a waveform that served as the input signal for a gear pump to create pulsatile flow through the bioreactor. Pressure was monitored using a catheter pressure transducer and flow rate was monitored using an ultrasonic flow meter. The model was also designed to be compatible with ultrasound to measure the inner diameter of the artery and the vein.

Results:
The signal generator and gear pump were calibrated to output a flow rate of 790 mL/min with systolic/diastolic pressures of 130/70 mmHg. The average flow rate measured through the porcine arteries and veins was 750 mL/min. The average systolic/diastolic pressures in the vessels were 125/72 mmHg.

Conclusions:
This bioreactor represents the first benchtop AVF model to incorporate living biological tissue. We successfully modeled the system to incorporate the extreme hemodynamic conditions associated with AVF vascular accesses. Future applications of this novel bioreactor will include evaluating the performance of catheter-based therapies, including the assessment of drug delivery and retention of drug-coated balloons and other local drug delivery devices.

An Assessment of Cardiovascular Disease Risk Factors in Physically Active Asymptomatic African American Men

Author:
Fredreka Living, DrPH, MBA, MHSA – Capella University

Category: Cardiovascular Disease

Abstract:
The prevalence of cardiovascular disease (CVD) has been well documented as the leading epidemiological chronic health condition globally, nationally, and locally. This widespread disease manifests in many ways and has been lined to many different types of hear diseases. Cardiovascular disease has been labeled as undetectable, limiting the probability of detection. A physical assessment and proper treatment by a licensed and trained physician can possibly decrease the death rate, if discovered early. There is an increased risk for cardiovascular disease due to the vast number of occurrences in the United States. Louisiana, a state identified for its Creole and Cajun culture, tasty foods, and warm southern hospitality, is among the top states with the highest incidents of cardiovascular disease. Over the last several decades, many residents of Louisiana have suffered from cardiovascular disease. This research addressed the following modifiable risk factors associated with cardiovascular disease: Body Mass Index (BMI), stress, smoking and tobacco usage, alcohol usage, and unhealthy eating habits. Furthermore, this research study assessed risk factors of CVD in physically active, asymptomatic African American men. It found that in the Lafayette Metropolitan Statistical Area (MSA), although these men were physically active, they were still at risk for CVD due to stress, unhealthy eating habits, BMI, and alcohol usage. Therefore, it is extremely important to inform individuals about the health belief model (HBM) to support decisions about healthier lifestyle.

Below-the-Knee Digital Anatomy 3D Printed Model for Peripheral Intervention Training

Author:
Charles E. Taylor, PhD[1,2,3]

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Department of Prosthodontics, Louisiana State University Health Sciences Center (LSUHSC), New Orleans, LA, USA[2]
Craft and Hawkins Department of Petroleum Engineering, Louisiana State University (LSU), Baton Rouge, LA, USA3

Category: Limb Salvage

Background:
Utilization of 3D printed vascular models for interventional training has been shown to have significant impact in structural heart, neurovascular, and aortic cases. Limb salvage cases with interventional zones below-the-knee (BTK) that extend into the plantar and tarsal arteries lack sufficient in vitro training platforms. With increasing clinical evidence of lower limb salvage achieved in the catheter lab, addressing the learning curve in these techniques and providing an in-vitro platform for product assessment could increase the adoption this treatment path. Critical to simulation in these cases is the presentation of the pathologies (plaques, calcifications) and acuity of the geometry from knee to tarsal. The Stratasys J750 Digital Anatomy Printer (DAP) utilizes PolyJet technology that enables multi-material printing with resins that mimic anatomical tissues with precision (14-micron resolution) and working volume (19-inch x 15-inch x 8-inch). Yielding a training model that incorporates the analogous tissues and pathologies of cardiovascular anatomy below-the-knee would have significant implications on cath lab training for limb salvage.

Methods:
Utilizing the National Institutes of Health (NIH) Visible Human Project (VHP) female cryoslice dataset tissues of the specimen's segmentation of the tissue groups from the tibial plateau to the first metatarsal was performed; the specimen was preserved in plantarflexion. Segmentation was performed using Object Research Systems (ORS) Dragonfly software (Montreal, Canada). Segmentation meshes were processed using MeshLab and Blender to produce inferred tissue boundaries and structures (e.g. endothelium) that are not resolved in the cryoslice data but can be produced in the printing process. Pathologies in the model were designed to published clinical

reports in terms of geometry and stiffness from OCT and histology data. Nominal settings for the tissues were selected: moderately compliant arterial walls, slightly stiff venous walls, and moderately stiff plaques. Orthopedic tissues only included the periosteal boundary (hollow) and were printed in the VeroWhite resin. After post-print cleaning, the models were mounted in the Tiger Cardiovascular Simulator (TCS) and perfused with a 40:60 glycerin:water mixture that approximates the asymptotic dynamic viscosity of blood.

Results:

An integrated synthetic tissue print was rendered correctly, with metrology on the static structure yielding confirming the accuracy ($p<0.05$) to the designed geometry and dynamic characterization in the TCS validating the material properties to those reported in literature ($p<0.1$). Dynamic characterization was performed using pulsatile pressures at the popliteal (125/70 mmHg) and tibial arteries (140/65 mmHg) (posterior and anterior) for a popliteal peak flowrate of 10 mL/sec.

Conclusion:

A 3D printed below-the-knee perfused in-vitro model was successfully achieved using the LSUHSC Digital Fabrication Center DAP system. The model includes the plaques and calcifications consistent with a limb salvage patient case, presenting a unique capability to the clinical community for training and surgical method development.

Comparative SEM Analysis of FDA-approved DCBs

Authors:
Estefanny Villar-Matamoros[1]
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Wake Forest University Department of Engineering, Winston-Salem, NC, USA[1]

Category: Peripheral Artery Disease

Background:
Peripheral artery disease (PAD), characterized by cholesterol plaque build-up in the arterial wall, affects approximately 200 million people globally. Drug coated balloons (DCBs) have become the preferred endovascular intervention to treat plaque lesions in peripheral vascular beds. While DCBs have been successful, patient outcomes have been inconsistent. Due to the variability of DCB formulations, there is a lack of predictability with treatments currently available. The goal of the study was to evaluate the DCB coatings scanning electron microscopy (SEM) analysis.

Methods:
Three FDA-approved DCBs were evaluated. These included IN.PACT (Medtronic, Minneapolis, MN) Stellarex (Philips, Amsterdam, NL), and Lutonix (BD Scientific, Becton, Dickinson and Company, NJ). The coatings of these DCBs were acutely evaluated by SEM. The DCB coatings were imaged while on the balloon (standard manufacturer packaging), scraped and hydrated. Hydration of the coating was accomplished by submerging balloons in phosphate buffered saline. To image the coating, all samples were first gold coated (LUXORTM benchtop sputter coater , NanoScience Technologies) and then imaged using the PhenomXL (ThermoScientific, Waltham, MA) SEM.

Results:
A total of 9 DCB samples were successfully evaluated at high and low magnifications. Overall, differences in excipients between the various FDA-approved DCBs were identified. In the hydrated samples, crystalline drug (paclitaxel) material could be identified as the ratio of drug to excipient was modified.

Conclusion:
SEM analysis demonstrated varying coatings between the FDA-approved DCBs. When hydrated, the crystalline nature of the drugs was clearly visible. The preliminary observations will be applied in our on-going investigation to demonstrate the rate of dissolution of various FDA-approved DCBs in a biorelevant environment.

An Ex-Vivo Study to Determine the Impact of Delivery Parameters on Drug Transfer and Retention of Drug-Coated Balloons

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S.K. Yazdani[1]

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Category: Peripheral Artery Disease

Background:
Drug-coated balloons (DCB) have become the standard treatment for peripheral artery disease. Clinical data suggests that varying DCB delivery parameters directly impacts patient outcomes. Differences in delivery parameters can potentially alter the retention of the drug coating on DCBs. The purpose of this study was to determine the impact of varying inflation parameters on paclitaxel delivery and retention using a commercially available DCB

Methods:
Harvested porcine carotid arteries were utilized in an ex-vivo pulsatile flow bioreactor system. The DCBs were then deployed at a DCB-to-artery ratio of 1:1 or 1.25:1, an inflation time of 30 seconds or 1 minute and transit time of 30 seconds or 3 minutes. The amount of drug retention in arterial tissue was evaluated by pharmacokinetic analysis at 1 h and 1 day post DCB deployment.

Results:
Arterial paclitaxel levels were found to be less at an inflation ratio of 1:1 with 3-minute transit time as compared to 30 seconds of transit time at 1 hour (12.3 ± 1.6 ng/mg vs. 391 ± 139 ng/mg, $p = 0.036$). At 1-day, DCBs deployed at a ratio of 1:1 resulted in less drug retention as compared to 1.25:1 (61.3 ± 23.1 ng/mg vs. 404 ± 195 ng/mg, $p = 0.013$)

Conclusion:
Arterial paclitaxel retention is influenced by DCB delivery parameters with less drugs retained with extended transit times and sub-optimal expansion of the balloon. Optimization of delivery parameters can serve as an effective strategy to enhance clinical DCB outcomes.

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