

## **Imaging the Lymphatic Response to Manual Lymphatic Drainage and Pneumatic Compression Devices**

**John Rasmussen**<sup>1</sup>, Caroline Fife<sup>2,3</sup>, Eva Seveck-Muraca<sup>1</sup>

<sup>1</sup>University of Texas Health Science Center at Houston, <sup>2</sup>CHI St Luke's-The Woodlands Hospitals,

<sup>3</sup>Intellicure

**Objectives:** Manual lymphatic drainage (MLD), as a component of complete decongestive therapy, has formed the basis of the initial treatment for lymphedema (LED) and pneumatic compression (PC) has been used in the maintenance phase (at home treatment). The physiology, however, of methods to promote lymph drainage for both MLD and PC have not been rigorously established. Recent developments in near-infrared fluorescence lymphatic imaging (NIRFLI) has enabled the visualization of the lymphatic response to these therapies in near real-time and provides opportunities to assess the physiologic impact of these manual interventions. Herein we summarize the results of seven studies, published and unpublished, assessing the acute and longitudinal impact of MLD or PC therapy in subjects with phlebolymphedema or standard arm, leg or head and neck LED.

**Methods:** After informed consent and under FDA-approved INDs for off-label administration of indocyanine green (ICG) as an imaging agent for NIRFLI, we visualized lymphatic anatomy and contractile pumping activity in study subjects. Subjects received intradermal injections of ICG distal to the area of vascular interest, typically, in the hands and feet. Imaging was performed by illuminating the skin with NIR light and collecting the fluorescent light emanating from the ICG-laden lymph. While imaging times varied between each study, imaging was conducted immediately before and after treatment and, when possible, during treatment. In one study, NIRFLI, was also performed before and after two weeks of PC therapy in subjects with head and neck LED. Images were assessed for changes in lymphatic uptake and contractile pumping.

**Results:** Overall 69 subjects, 51 affected and 18 control, undergoing MLD or PC therapy were imaged. The first study of 10 LED and 12 control subjects showed a 23% and 28% increase in lymph velocity and a 9% and 23% reduction in propulsion period in symptomatic and control limbs, respectively, in response to MLD. Other NIRFLI studies demonstrated enhanced lymphatic uptake after PC therapy in control subjects and subjects diagnosed with phlebolymphedema or standard LED. One study, utilizing a clear PC device, demonstrated the ability to image the statistically significant improvement in lymphatic contractile propulsion during and after PC therapy. A recent, unpublished, study of 10 subjects with head and neck lymphedema, demonstrated enhanced lymphatic uptake in all subjects and a reduction of abnormal lymphatic anatomy in 75% of subjects following two weeks of daily, at home PC therapy.

**Conclusions:** NIRFLI enables the assessment of manual lymphatic interventions, demonstrating enhanced lymphatic uptake and improved lymphatic contractile pumping in response to MLD and PC therapy in subjects with LED.

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## **The Proportion and Causes of Lymphedema in a Large Administrative Insurance Data Base**

**Andrew Son**<sup>1</sup>, Thomas O' Donnell<sup>1</sup>, Jessica Izhakoff<sup>2</sup>, Timothy Niecko<sup>3</sup>, Julia Gaebler<sup>2</sup>, Mark lafrati<sup>1</sup>

<sup>1</sup>Dept of Surgery, Tufts Medical Center, <sup>2</sup>Health Advances, LLC, <sup>3</sup>Niecko Health Economics, LLC

**Objectives:** Lymphedema (LED) has been called the forgotten vascular disease given such limited knowledge about the prevalence of LED and in particular, its associated comorbidities and causes. Such information on the proportion of patients with LED and its causes may assist in diagnostic decisions and health care planning.

**Methods:** To determine the proportion of patients with LED and the possible causes of LED, de-identified HIPAA-compliant commercial administrative claims from the Blue Health Intelligence (BHI) Research Database (165 Million BC/BS members) were queried. To identify the proportion affected with LED and the comorbidities (potential causes) associated with LED, we analyzed a BHI study sample of 26,902 patients with LED who had been enrolled with continuous medical benefits for 12-months pre- and post- index date for the complete years 2012 through 2016. It is the purpose of this study to analyze the BHI data set: 1) to determine the proportion of LED that occurs in a "real world" setting; and 2) to identify the specific causes of lymphedema.

**Results:** Overall 84,579,269 patients were available for initial analysis from which 81,366 patients (0.10%) were identified with LED. From the total population (42,229,536) within the BHI data set for women, 74,807 (0.18%) women were identified with LED, while from the total population of men in the BHI data set (42,349, 733), a lesser number of men, 28,358 (0.07%) had LED. Based on an assessment of 26,902 eligible patients (determined by continuous enrollment criteria), breast cancer, which occurred in nearly 9000 subjects (32.1%), was the most common co-morbidity associated with LED. The category of venous disease as a whole, accounted for 10.4% of patients with LED. Within that category venous ulcer, compromised the majority of the venous disease group (9.6%). The combined entity of pelvic cancers in women (uterine, ovarian, and cervical cancer) accounted for 3.3% of all causes of lymphedema. Finally, melanoma was observed in 2.1% of patients with LED. Prostate cancer was a less frequent cause of LED, which was observed in 188 patients (0.7%). The sequelae of treating gender specific cancer (breast and pelvic) in women, accounted for more than 35% of patients with LED.

**Conclusions:** To our knowledge, this is the largest study to date providing the "real world" proportion of patients with LED and detailing the causes of LED. Our findings confirm the major role of cancer, particularly breast cancer, as an important cause of LED. Further, this study highlights the role of advanced venous disease as a cause of LED.

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## **Contemporary Lymphedema Management among insured US patients. Correlation of disease etiology with treatment choices.**

**Mark iafrati<sup>1</sup>**, Thomas O'Donnell<sup>1</sup>

<sup>1</sup>Vascular Surgery, Tufts Medical Center

### **Objectives:**

Lymphedema therapy aims to reduce edema and improve function, comfort, and skin hygiene. These non-surgical treatments can be categorized into: Conservative (CONS) - complex physical therapy with manual lymphatic drainage (MLD), massage, garments, and bandaging; Intermittent Pneumatic compression (PCD), simple non-programmable devices (SPCD), or advanced programmable pneumatic compression devices (APCD). We sought to define how frequently patients with a diagnosis of lymphedema (LED) are provided Lymphedema specific therapy, and to determine what diagnoses are most commonly associated with advanced targeted lymphedema therapies

### **Methods:**

To determine the frequency of the various treatments for LED and their relationship to the etiology of the lymphedema, we queried claims for the years 2012-16, from a de-identified HIPAA-compliant commercial administrative insurance data base with 165,000,000 members. We identified patients with a lymphedema diagnosis code who had at least 1 inpatient or 2 outpatient claims filed with BCBS, and who were enrolled in BCBS with continuous medical benefits for at least 12-months pre- and post- index date. Identified patients were then analyzed as to associated co-morbidities and the treatments coded in these claims. Treatments were grouped as: No treatment (No Tx), CONS, SPCD, and APCD.

**Results:** We identified 81,366 patients with a diagnosis of lymphedema of whom 26,902 had sufficient continuous medical benefits to meet inclusion criteria. 5,291 (19.7%) patients with a Dx of LED received NO LED specific TX. CONS therapies alone were utilized in 17,387(64.6%) of LED patients. Within this CONS group 73% utilized MLD as a component of care. SPCD was the only PCD code entered in 680 (2.5%) patients, while the more advanced APCDs were used in 3,544 (13.2%) LED patients. Within each of these TX groups, table 1 displays the two most common categories of co-morbidities (Cancer vs Venous diseases) coded in LED patients receiving TX. Table 1 represents findings from the study

### **Conclusion:**

Many LED patients receive no disease specific Tx for LED. In general, CONS TX which incorporates MLD and PCD therapy that incorporates APCD are considered more aggressive than approaches limited to No MLD or SPCD. These data demonstrate that cancer patients treated for LED are more likely than venous patients to receive the more aggressive MLD and APCD. These data raise the question; are there disease specific differences in severity of symptoms or response to therapy that justify what appears to be less aggressive treatment approach in venous compared to cancer patients or are treatment decisions driven by patient or physician preference, insurance constraints, or other factors?

| LED TX         | CONS   |       | PCD   |       |
|----------------|--------|-------|-------|-------|
|                | No MLD | MLD   | SPCD  | APCD  |
| CANCER         | 40.8%  | 74.7% | 16.5% | 44.3% |
| Venous disease | 25.4%  | 11.0% | 42.8% | 30.0% |
| Other Dx       | 33.9%  | 14.3% | 40.7% | 25.8% |
|                | 100%   | 100%  | 100%  | 100%  |

Table 1. Distribution of diagnoses according to therapy chosen

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## **Limb Salvage for "Hopeless" Lymphedema: Reviving the Charles Procedure**

Kuldeep Singh<sup>1</sup>, Katherine Hawkins<sup>1</sup>, Michael Cooper<sup>2</sup>, Garry Lachhar<sup>3</sup>, Saqib Zia<sup>1</sup>, Jonathan Schor<sup>1</sup>, Jonathan Deitch<sup>1</sup>

<sup>1</sup>Vascular Surgery, Staten Island University Hospital / Northwell Health, <sup>2</sup>Plastic Surgery, Staten Island University Hospital / Northwell Health, <sup>3</sup>School of Medicine, St. George's University

**Objectives:** The Charles procedure offers radical excision of lymphedematous tissue followed by skin grafting. This procedure is rarely offered, due to the potential for complications, but may provide excellent outcomes in improving quality of life. We describe our experience with a modified technique and a multi-disciplinary team approach in treating patients with advanced lymphedema.

**Methods:** Seven patients with severe lower extremity lymphedema were treated with radical surgical excision. Patient demographics, operative details, and post-operative follow up course were recorded. The operation entailed radical excision of the skin and lymphedematous tissues, in a modified Charles procedure. The dissection was taken to the level of the fascia from the dorsal forefoot or ankle and continued to the knee or thigh, with wound vacuum-assisted closure (VAC) for initial dressings. Split-thickness skin grafting was performed 5-7 days post-operatively. All patients were managed with a predefined post-op care protocol.

**Results:** Seven patients were referred to the clinic for evaluation of massive lower extremity lymphedema. There were four males and three females, with age range of 36-64 years. All patients had history of more than two years of lifestyle-limiting swelling and recurrent bouts of cellulitis requiring hospitalization and intravenous antibiotic treatment. Six patients had chronic wounds of the affected legs due to skin breakdown, and three had significant disability in ambulation. Comorbid conditions included obesity (in five patients); hypertension (in four patients); COPD or asthma (in three patients); depression (in three patients); and diabetes (in one patient). In the three patients with bilateral disease, intervention targeted the more severely affected limb. One patient in our series had disease confined only to the thigh. Post-operative complications included wound infection, requiring debridement or antibiotics, in four patients; re-admission for debridement in one patient; and reintubation post-operatively in one patient. Length of stay was an average of 27 days (range, 14 - 55 days). Patients were followed for an average of 15 months (range, 3 month - 3 years). All patients reported an improvement in quality of life post-operatively and had complete wound healing by final follow-up, without recurrence.

**Conclusion:** Although an underutilized procedure, the Charles procedure presents a viable means of limb salvage for severe lymphedema. We present a multidisciplinary approach with excellent patient outcomes in a series of six patients.

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## **Multidisciplinary Approach to Management of Severe lymphedema with One Stage Radical Excision and Split Thickness Skin Grafting**

Brent Robertson<sup>1</sup>, Mark Broering MD<sup>2</sup>, William Tobler MD<sup>3</sup>, Matthew Recht MD<sup>2</sup>, **Patrick Muck MD<sup>2</sup>**

<sup>1</sup>Trihealth, <sup>2</sup>Vascular Surgery, Trihealth - Good Samaritan Hospital, <sup>3</sup>Plastic Surgery, Trihealth - Good Samaritan Hospital

### **Objectives:**

Patients with severe lymphedema often experience recurrent cellulitis, ulcerative lesions, and deleterious effects on quality of life. Cumulative damage to extremities may result in limb deformity creating functional limitations with emotional and psychosocial distress. Physiologic or reductive surgical treatments are reserved for failure of conservative management. The reductive approach aims to remove lymphedematous tissue acquired from prolonged lymphatic stasis. One such reductive approach is the Charles procedure, direct excision followed by skin graft application to the defect. We present two cases of severe lymphedema treated with one stage direct excision via the Modified Charles procedure.

### **Methods:**

Two patients, mean age 42.5, were selected to undergo surgical reduction of severe lower extremity lymphedema. A skin incision was made exposing subcutaneous tissues. A Harmonic scalpel (Ethicon Inc), was used to cut and coagulate tissues down to the level of the fascia while maintaining hemostasis. The dissection was then carried circumferentially around the extremity to resect all skin and lymphedematous tissue. The specimen was removed and weighed. Split-thickness skin grafts were constructed using the resected specimen and applied to the operative defect. Finally, a negative pressure vacuum system was applied to facilitate wound healing. The patients were followed in the hospital until medically appropriate for discharge and subsequently followed in outpatient clinic.

**Results:** Mean operative time was 8 hours 55 minutes and blood loss 2450 cc. Patients were followed for wound healing and quality of life improvement. At 2 months post-operatively, patient 1 had significant wound epithelialization. He found employment and was able to walk over 1 mile daily. At 4 months post-operatively, the main complaint was focal wound tenderness. Figure 1 is a preoperative image and Figure 2 is a 4 month postoperative image. He continues to express satisfaction and improved functionality leading to overall improved quality of life. Patient 2 required readmission 1 week post-operatively for inadequate home wound care assistance. The patient has experienced improved mobility thus far. No significant wound complications have been encountered for either patient.

**Conclusion:** Direct surgical excision with reconstruction is an invasive treatment option with potentially severe complications. Initial results in our patients suggest the Modified Charles procedure is an effective management option for severe lymphedema refractory to conservative therapy. En bloc removal of lymphedematous tissue increases functionality and improves quality of life. Further longitudinal follow up is needed to assess progression of wound healing and percent skin graft take. A multidisciplinary approach to minimize operative time and blood loss, and to optimize skin grafting results, appears to benefit this difficult patient population.



Figure 1 Preoperative Image



Figure 2 Image 6 weeks after Charles Procedure

**Author Disclosures:** Brent Robertson Nothing to disclose, Mark Broering MD Nothing to disclose, William Tobler MD Nothing to disclose Matthew Recht MD Nothing to disclose, Patrick Muck MD Honorarium, consultant, Stock Holder Penumbra

DSI # 6

## **Primary chronic venous insufficiency is distinguished by attenuated circulating inflammatory mediators and healing networks**

**Ulka Sachdev**<sup>1</sup>, Derek Barclay<sup>1</sup>, Ruben Zamora<sup>1</sup>, Lena Vodovotz<sup>2</sup>, Julie Bitner<sup>1</sup>, Jinling Yin<sup>1</sup>, Efthymios Avgerinos<sup>1</sup>, Yoram Vodovotz<sup>1</sup>

<sup>1</sup>Surgery, University of Pittsburgh Medical Center, <sup>2</sup>Surgery, University of Pittsburgh

**Objectives:** Inflammation promotes venous leg ulcers (VLU) in post-thrombotic syndrome. However, it is not clear how inflammation affects VLU in primary venous reflux. Computational modeling has demonstrated differences in cytokine and chemokine networks in other wound healing paradigms. We hypothesize that serum inflammatory mediators are differentially expressed and disorganized in primary chronic venous insufficiency (CVI), which may be a mechanism for future VLU.

**Methods:** Subjects were recruited prospectively with institutional review board approval. Blood was obtained during sclerotherapy or endovenous thermal ablation for primary CVI without ulcer (CEAP C2-4). Control subjects without CVI underwent phlebotomy from great saphenous and antecubital veins. Demographics, venous clinical severity scores (VCSS), and body mass index (BMI) were collected. Twenty-five mediators previously shown to be important in wound healing were measured in serum with Luminex™. Values were compared using Mann-Whitney-U test. Pearson correlations among mediators (nodes; Figure 1 ●) that were  $\geq$  a specific threshold prompted connection between nodes (edges; Figure 1 —). Correlations were mapped as networks (Matlab®). “Complexity” was determined from # of connections for each mediator and total # of mediators. A robustness index measuring network strength was calculated by dividing # of connections at a Pearson correlation threshold of 0.95 / 0.7

**Results:** Demographics, BMI, VCSS, and mean/SEM mediator values (pg/ml) for patients (N=42) and controls (leg; N=7) are shown in Table 1. Significant differences ( $p < 0.05$ ) were demonstrated in 20/25 mediators; most reflected lower concentrations in patients. In controls, arm and leg values



were nearly identical to one another and across subjects. Figure 1 demonstrates networks of inflammatory mediators for each group, showing lower network complexity and robustness in CVI vs. controls. The robustness index for patients, control (leg) and control (arm) was 0.096, 0.169 and 0.241, respectively.

**Conclusion:** CVI associates not only with age and BMI, but also with diminished expression of many inflammatory compounds instrumental for wound healing. The relationship among these mediators are similarly weak. In contrast, mediators within competent veins show little variability and a high degree of correlation that is lacking in CVI. Dysregulated inflammatory networks in response to injury from venous hypertension may be a predisposing factor to further venous damage and VLU. Normalizing venous competency may improve baseline cytokine and chemokine interactions and the response to micro stresses that can lead to wounds.

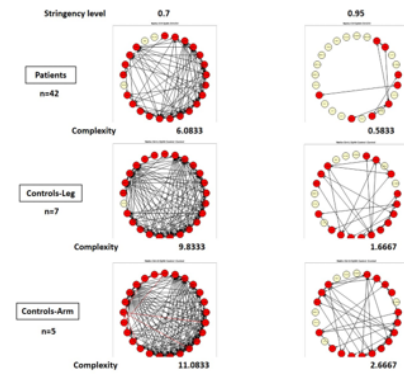


Figure 1. Inflammatory mediator networks in CVI patients and controls

|          | Patient (N=42) |       | Contol (N=7) |       | P      |
|----------|----------------|-------|--------------|-------|--------|
|          | Mean           | SEM   | Mean         | SEM   |        |
| GM-CSF   | 19.1           | 3.6   | 61.6         | 0.0   | <0.001 |
| IFNg     | 23             | 5.4   | 58.9         | 0.0   | <0.001 |
| IL-12p70 | 12.9           | 2.6   | 41           | 0.0   | <0.001 |
| IL-17A   | 10.1           | 2.2   | 27.5         | 0.0   | <0.001 |
| IL-7     | 10.3           | 1.5   | 30.5         | 0.0   | <0.001 |
| MIG      | 1227.2         | 195.4 | 313.4        | 0.0   | <0.001 |
| sIL-2ra  | 696.9          | 62.3  | 252.1        | 0.0   | <0.001 |
| IL-10    | 18             | 3.1   | 51.5         | 0.0   | 0.001  |
| IL-1b    | 7.5            | 1.5   | 20.9         | 0.0   | 0.001  |
| IL-4     | 37.7           | 9     | 107.4        | 0.0   | 0.001  |
| IFNa2    | 51.8           | 12.4  | 110.5        | 0.0   | 0.002  |
| IL-1RA   | 117.8          | 21.9  | 306.9        | 0.0   | 0.002  |
| MIP-1b   | 33.3           | 2.6   | 55.6         | 0.0   | 0.003  |
| IL-12p40 | 116.6          | 28.7  | 252.1        | 0.0   | 0.005  |
| IP-10    | 685.3          | 65.3  | 311.1        | 0.0   | 0.005  |
| IL-15    | 12.9           | 2.4   | 24           | 0.0   | 0.009  |
| TNFa     | 27.6           | 4.8   | 48.2         | 0.0   | 0.011  |
| IL-5     | 5              | 1.5   | 7.8          | 0.2   | 0.012  |
| IL-2     | 4.9            | 1.1   | 7.6          | 0.1   | 0.015  |
| IL-13    | 32.8           | 12.7  | 37.2         | 0.3   | 0.045  |
| IL-6     | 8.7            | 1.5   | 20.8         | 0.0   | 0.059  |
| IL-8     | 14.2           | 3.2   | 14.8         | 0.4   | 0.157  |
| Eotaxin  | 100.6          | 8.1   | 113          | 0.4   | 0.265  |
| MCP-1    | 343.7          | 29.9  | 334.7        | 0.3   | 0.658  |
| MIP-1a   | 5.9            | 1.8   | 2.6          | 0.2   | 1      |
|          | Range          |       | Range        |       |        |
| Age      | 55.7           | 31-88 | 34.7         | 21-47 | 0.008  |
| BMI      | 32             | 19-48 | 23           | 20-26 | 0.004  |
| VCSS     | 6.5            | 2-14  | 1.1          | 0-2   | <0.001 |
| Females  | 71%            |       | 43%          |       |        |

Table I. Demographics, mean/SEM shown for inflammatory mediators drawn from leg veins of patients and control subjects.

#### Author Disclosures:

Ulka Sachdev Nothing to Disclose, Derek Barclay Nothing to Disclose , Ruben Zamora Nothing to Disclose Lena Vodovotz Nothing to Disclose Julie Bitner Nothing to Disclose Jinling Yin Nothing to Disclose, Efthymios Avgerinos Nothing to Disclose Yoram Vodovotz Nothing to Disclose

DSI # 7

## **Reduced left jugular venous remodeling and graft patency in a preclinical Model**

Shirley Liu<sup>1</sup>, Tun Wang<sup>1</sup>, Juan Wang<sup>2</sup>, Toshihiko Isaji<sup>1</sup>, Laura Niklason<sup>2,3</sup>, Alan Dardik<sup>1</sup>  
<sup>1</sup>Surgery, Yale University, <sup>2</sup>Anesthesiology, Yale University, <sup>3</sup>Biomedical Engineering, Yale University

### **Objective:**

Venous remodeling, the adaptive structural and functional reorganization of the venous wall after intervention is still not well understood. Up to 60% of arteriovenous fistulae fail to mature adequately to sustain hemodialysis, as the vein fails to adequately thicken and dilate in response to arterial flow. To examine venous remodeling, we used a pig arteriovenous graft (AVG) model to expose veins to arterial flow without changing their geometry. Since humans have smaller diameter and cross-sectional area of the left internal jugular vein (IJV) compared to the right IJV, we hypothesized that left-sided AVG may have different remodeling and patency compared to right-sided AVG in a preclinical model.

### **Methods:**

Ten Yorkshire male pigs (mean weight 48kg, age 3.4 months) underwent ipsilateral or bilateral placement of AVG from the proximal common carotid artery to the distal IJV using PTFE (6mm diameter, 6-7cm length). Pigs were observed for 1, 2, or 3 weeks. Select pigs underwent ultrasound measurements of flow and ultrasound and caliper measurements of vessel diameters prior to graft placement. Vessels were harvested from two additional pigs that had underwent procedures unrelated to the IJV for control measurements. Grafts and vessels were excised and analyzed with histology.

### **Results:**

At baseline, there was no significant difference in peak systolic or end diastolic velocities between the left and right IJV. The left and right IJV also did not demonstrate any difference in caliper measured diameters or ultrasound-measured luminal diameters. Histologic analysis of preoperative

bilateral IJV showed no difference in wall thickness or intima-media surface area. 10 left-sided and 8 right-sided PTFE grafts were placed; 4/10 (40%) were patent on the left and 7/8 (88%) were patent on the right ( $p=0.03996$ , Chi-square). Post-operatively, the right IJV showed an increase in wall thickness (0.15 to 0.35mm,  $p<0.0001$ ) and intima-media surface area (0.17 to 0.35mm<sup>2</sup>,  $p=0.0024$ ) compared to baseline, but significant thickening was not seen on the left side. Left-sided grafts had increased luminal macrophages at the arterial anastomosis compared to right-sided grafts but there was no significant difference in macrophage number at the venous anastomosis.

#### Conclusion:

Left sided jugular veins do not thicken to the degree that right sided veins thicken upon exposure to the AVG environment. Lack of left jugular venous remodeling was associated with reduced graft patency in this preclinical model. These data suggest anatomic differences in different venous beds, emphasizing the need to understand the biology of venous remodeling to optimize graft patency.

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## American Venous Forum Annual Meeting Abstracts

#1

### **Venous thromboembolism (VTE) prophylaxis and its association with postoperative VTE, morbidity and mortality in a modern post-surgical cohort.**

**Danielle Sutzko**<sup>1</sup>, Andrea Obi<sup>2</sup>, Monita Karmakar<sup>1</sup>, Nicholas Osborne<sup>1</sup>, Peter Henke<sup>2</sup>

<sup>1</sup>Surgery, Section of Vascular Surgery, University of Michigan, <sup>2</sup>Surgery, Section of Vascular Surgery, University of Michigan Health System

#### Objectives:

Evidence based recommendations for venous thromboembolism (VTE) prevention include assessment of risk and application of mechanical and/or pharmacological prophylaxis. Trials and patient cohort series have suggested benefit as compared with no prophylaxis. However, whether this translates into real world benefit is less clear. We hypothesized that prescription of VTE

prophylaxis is high, and that it confers a decreased VTE incidence and mortality benefit using a multi-hospital quality consortium.

#### Methods:

This statewide, retrospective cohort study analyzed the primary outcomes of VTE incidence, morbidity and mortality amongst post-surgical patients with and without VTE prophylaxis between April 2013 and September 2017 from 73 hospitals. All inpatient surgical procedures (>24-hour admission) with complete variables regarding VTE prophylaxis were included. Logistic regressions with cluster robust standard errors were then used to evaluate independent risk factors for postoperative VTE despite appropriate VTE prophylaxis adjusting for patient demographics, premorbid conditions, family and personal history of deep venous thrombosis (DVT), intraoperative risk factors and case complexity.

#### Results:

Amongst 39,430 operations, the mean age was 60 ±15 years and 63% (N=24,765) were female. There were 572 (1.45%) postoperative VTE, including 214 (0.54%) pulmonary embolism (PE) and 404 (1.02%) DVTs. The overall mortality rate was 1.84% (N=727). VTE events were associated with a significantly increased mortality (OR 1.83, 95% CI [1.18-2.83], p=0.007) and postoperative complications (OR 3.24, 95% CI [2.67-3.95], p <0.001) after adjusting for confounders. At the hospital level, there was a significant positive correlation between hospital postoperative VTE and mortality (r=0.27; p<0.05). When examining various VTE prophylaxis regimens, those receiving heparin three times a day (TID) and low molecular weight heparin (LMWH) were significantly more likely to develop a postoperative VTE events (1.71 vs. 0.99%, OR 1.39; 95% CI [1.03–1.86], p=0.029) compared to those who received no therapy. There was no difference in mortality among the two groups. Further analysis of patients on appropriate VTE chemoprophylaxis identified presence of other complications (OR: 3.21, 95% CI[2.54-4.04] p<0.001), having a personal history of DVT (OR: 2.34, 95% CI[1.84-2.96], p<0.001), receiving PRBC during surgery (OR: 1.80, 95% CI[1.32-2.44], p<0.001), not smoking (OR: 1.37, 95% CI[1.06-1.78], p=0.015), not having prior history of peripheral vascular disease (OR: 1.97, 95% CI[1.37-2.83], p<0.001), and having high risk procedures as independent risk factors for developing breakthrough postoperative VTE.

#### Conclusion:

In modern day post-surgical care, VTE represents a continued source of morbidity and mortality. Contrary to our hypotheses, we found that postoperative VTE prophylaxis was broadly applied, yet

was associated with increased rather than decreased postoperative VTE and no effect on mortality.

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Monita Karmakar nothing to disclose, Nicholas Osborne nothing to disclose Peter Henke nothing to disclose

## #2

### **Utilization of the Caprini score integrated with a Trombodynamics test reduces the incidence of unpredicted, postoperative deep vein thrombosis**

**Kirill Lobastov<sup>1</sup>**, Galina Dementieva<sup>1</sup>, Natalia Soshitova<sup>2</sup>, Ekaterina Sautina<sup>1</sup>, Victor Barinov<sup>1</sup>, Leonid Laberko<sup>1</sup>, Grigoriy Rodoman<sup>1</sup>

<sup>1</sup>Department of General Surgery and Radiology, Pirogov Russian National Research Medical University, <sup>2</sup>GemaCore Ltd

#### Objectives:

Trombodynamics (TD) is a global assay for hemostasis that makes it possible to follow changes in parameters such as hypercoagulation and control an individual's response for blood thinners. The aim of this study was to compare how well the classic Caprini 2005 score and its modified version, taking into account the results of TD, predict postoperative deep vein thrombosis (DVT) in surgical patients with colorectal cancer.

#### Methods:

This prospective observational clinical study involved 80 patients (33 men and 47 women; mean age: 73.9±7.2 years) with colorectal cancer who underwent surgery. The patients were at a high risk for postoperative VTE (mean Caprini score: 9.9±2.0) and received combined prophylaxis (anti-embolic stockings and Enoxaparin 40 mg once daily) until discharge. Enoxaparin was administered at a fixed hour according to the time of blood sampling for TD. Duplex ultrasound was performed to detect postoperative DVT before and 5–7 days after surgery.

#### Results:

DVT was noted in 21 of the patients. Caprini scores significantly predicted DVT ( $p<0.0001$ ,  $AUC=0.839\pm0.045$ ). Analysis of ROC-curve coordinates revealed a cut-off point of 11 scores, with a sensitivity of 76.2% and a specificity of 74.6%.

The results of the TD test revealed significant hypercoagulation despite Enoxaparin being administered to patients with DVT. Regression analysis and ROC curves demonstrated that initial velocity of clot growth (Vin) and clot size (CS), measured 12 and 24 hours after Enoxaparin administration ( $AUC=0.697\pm0.063$ ;  $AUC=0.790\pm0.059$  and  $AUC=0.847\pm0.059$ ;  $AUC=0.803\pm0.069$ , respectively), best predicted postoperative DVT. The cut-off points for DVT prediction appear to be  $Vin>62.5\text{--}64.5\text{ }\mu\text{m/min}$  (normal range: 35–56  $\mu\text{m/min}$ ) and  $CS>1351.5\text{--}1333.5\text{ }\mu\text{m}$  (normal range: 800–1200  $\mu\text{m}$ ).

The identified thresholds for the TD parameters have been integrated into the Caprini score. The total Caprini scores were recalculated for patients with at least one TD parameter that exceeded the cut-off; we also reanalyzed the ROC curves. The best predictability was found for Caprini score considering the elevation of all four TD parameters together ( $AUC=0.924\pm0.029$ ) and increased cut-off up to 12 scores with sensitivity of 85.7% and specificity of 81.4%. Using cut-offs for the

original and modified scores, we calculated the number of patients whose values were under the cut-off level but who developed DVT nonetheless: 10.2% and 5.9%, respectively.

**Conclusion:**

Integrating TD parameters into the Caprini score increases one's ability to predict postoperative DVT and reduce the number of unpredicted complications.

**Author Disclosures** Kirill Lobastov nothing to disclose, Galina Dementieva nothing to disclose , Natalia Soshitova nothing to disclose, Ekaterina Sautina nothing to disclose, Victor Barinov nothing to disclose, Leonid Laberko nothing to disclose Grigoriy Rodoman nothing to disclose

#3

### **E-Selectin Inhibition: A New Way to Treat Proximal Deep Venous Thrombosis**

Daniel Myers<sup>1</sup>, Patrick Lester<sup>1</sup>, Raymond Adili<sup>1</sup>, Angela Hawley<sup>1</sup>, Laura Durham<sup>1</sup>, Veronica Dunivant<sup>1</sup>, Garrett Reynolds<sup>1</sup>, Suman Sood<sup>1</sup>, William Fogler<sup>2</sup>, John Magnani<sup>2</sup>, Mike Holinstat<sup>1</sup>, **Thomas Wakefield<sup>1</sup>**

<sup>1</sup>University of Michigan Medical School, <sup>2</sup>GlycoMimetics, Inc.

**Objectives:**

There is a close interrelationship between thrombosis and inflammation. In previous studies, we have shown the importance of P-selectin in thrombogenesis and thrombus resolution in many preclinical animal models. The role of E-selectin has been explored in rodent models and in a small pilot study of clinical calf vein deep vein thrombosis (DVT). The purpose of the present study is to determine the role of E-selectin in thrombosis in a primate model of proximal iliac vein thrombosis, a model close to the human condition.

**Methods:**

Iliac vein thrombosis was induced with a well characterized primate model. Through a transplant incision, the hypogastric vein and iliac vein branches were ligated. Thrombus was induced by balloon occlusion of the proximal and distal iliac vein for 6 hours. The balloons were then deflated and primates recovered. Starting on post-occlusion day 2, animals were treated (TRT) with the E-selectin inhibitor (GMI-1271), 25 mg/kg, SC, once daily (n=4). Non-treated control (CTR) animals received no treatment (n=5). All animals were evaluated by magnetic resonance venography (MRV), hematology (CBC), coagulation tests (bleeding time, PT, aPTT, fibrinogen and thromboelastography) at baseline, Day 2, Day 7, Day 14, and Day 21 with euthanasia. Additionally, platelet function and CD44 expression on leukocytes was determined.

**Results:**

E-selectin inhibition by GMI-1271 significantly increased vein recanalization by MRV versus CTR animals on Day 14 ( $P < 0.05$ ) and Day 21 ( $P < 0.0001$ ) [Figure 1A]. GMI-1271 significantly decreased vein wall inflammation by MRV with gadolinium vein wall enhancement versus CTR also on Day 14 ( $P < 0.0001$ ) and Day 21 ( $P < 0.0001$ ) [Figure 1B]. The thromboelastographic measure of clot strength (MA), showed significant decreases in animals treated with GMI-1271 versus CTRs at Day 2 ( $P < 0.05$ ) and Day 7 ( $P < 0.05$ ). Importantly, no significant differences in hematology or coagulation tests were noted between all groups, suggesting that E-selectin inhibition carries no bleeding

potential. GMI-1271 did not affect platelet function or aggregation, or CD44 expression on leukocytes. Additionally, no episodes of bleeding were noted in either groups.

Conclusion: The current study suggests that E-selectin modulates venous thrombus progression and its inhibition will increase thrombus recanalization and decrease vein wall inflammation, without affecting coagulation. The use of an E-selectin inhibitor such as GMI-1271 could potentially change how we treat DVT.



FIGURE 1A:

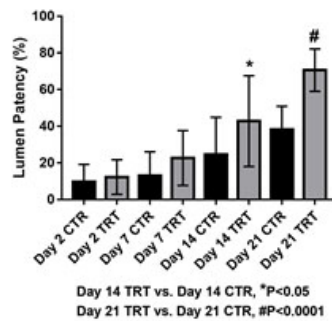


FIGURE 1B:

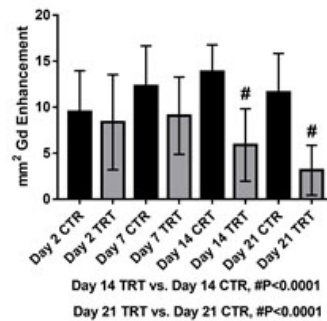


Figure 1A: Percent of vein recanalization

Figure 1B: Vein wall inflammation

**Author Disclosures** Daniel Myers nothing to disclose, Patrick Lester nothing to disclose, Raymond Adili nothing to disclose, Angela Hawley nothing to disclose, Laura Durham nothing to disclose, Veronica Dunivant nothing to disclose, Garrett Reynolds nothing to disclose, Suman Soo nothing to disclose, William Fogler Salary, Stock options GlycoMimetics, Inc., John Magnani Salary, Stock options GlycoMimetics, Inc., Mike Holinstat nothing to disclose, Thomas Wakefield nothing to disclose

#4

### **Association of inflammatory and hemostatic biomarkers with inflammasomes in septic patients at risk of developing coagulopathy.**

**Evi Kalodiki**<sup>1,2</sup>, Debra Hoppensteadt<sup>1</sup>, Richard Green<sup>1</sup>, Amanda Walborn<sup>1</sup>, Grace Wegryzn<sup>1</sup>, Jawed Fareed<sup>1</sup>

<sup>1</sup>Thrombosis Hemostasis, Loyola University Medical Centre, <sup>2</sup>Vascular Surgery, Josef Pflug Vascular Lab, Ealing Hospital & Imperial College & West London Vascular & Interventional Centre.

#### **Objectives:**

Sepsis is a catastrophic complication of infection which results in systemic inflammatory responses. Inflammasomes initiate the inflammatory cascade that results in the activation of caspase-1, leading to the upregulation of inflammatory cytokines such as IL-6 and IL-18. The NLRP3 inflammasome contributes to the innate immune response identification of pattern recognition receptors (PRRs) on pathogens including bacteria and viruses. While the role of inflammasome in the inflammatory response is known, it is not clear how inflammasome contributes to the hemostatic dysregulation observed in sepsis associated coagulopathy. The purpose of this study is to quantitate inflammasome levels in defined sepsis associated patients and to determine its potential relevance to various biomarkers of hemostatic dysregulation.

#### **Methods:**

Plasma samples from 52 adults with sepsis and suspected coagulopathy were analyzed. Samples were collected from intensive care unit (ICU) patients on day 0, under an institution review board (IRB) approved protocol. Samples were stored at -80°C prior to analysis. Platelet count was determined as part of standard clinical practice. Healthy control samples were purchased from George King Biomedical (Overland, KS). Prothrombin time (PT) and international normalized ratio (INR) were measured using recombiplastin reagent. Fibrinogen was measured using a clot based

method on ACL-ELITE coagulation analyzer. Cortisol, D-dimer, plasminogen activator inhibitor-1 (PAI-1), NLRP-3 inflammasomes, MP-TF, Fibronectin, and CD40L were measured using commercially available ELISA assays.

#### Results:

When comparing patients with sepsis and suspected disseminated intravascular coagulation (DIC) to the normal plasma samples, there was a significant elevation in NLRP-3 inflammasome levels in the sepsis cohort ( $p = < 0.0001$ ). Figure 1. Shows the NLRP-3 inflammasome concentration in the sepsis cohort did not correlate with other biomarkers. An elevated level of NLRP-3 inflammasomes was significantly associated with increased levels of PAI-1 ( $p < 0.0004$ ). No other inflammatory or hemostatic markers were significantly correlated with NLRP-3 inflammasomes. This is depicted in Table 1.

#### Conclusion:

The current study shows a significant relationship between inflammasomes and PAI-1 levels in patients with sepsis associated coagulopathy. The positive correlation between NLRP-3 inflammasomes and PAI-1 shows that the activation of inflammasomes may have a role in the upregulation of PAI-1 and the observed hemostatic dysregulation. The strong association between NLRP-3 inflammasome and PAI-1 in baseline samples of patients with sepsis and DIC also suggest that NLRP-3 inflammasome may contribute to the fibrinolytic dysregulation in sepsis and DIC.

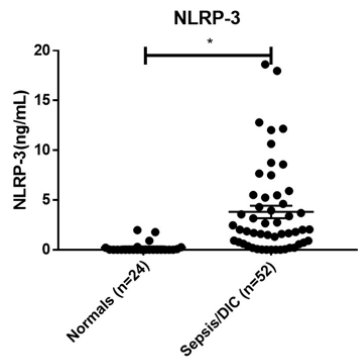


Figure 1. NLRP-3 inflammasomes in patients with sepsis and suspected DIC on day 0 (n=52) compared to normal healthy controls (n=24)

| NLRP-3 Inflammasome correlation | P<br>(Mann-Whitney) | Spearman r |
|---------------------------------|---------------------|------------|
| CD40L                           | 0.5716              | -0.08028   |
| PAI-1                           | 0.0041              | 0.3915     |
| MP-TF                           | 0.1491              | 0.2528     |
| Fibrinogen                      | 0.7685              | 0.04314    |
| Fibronectin                     | 0.8291              | -0.03067   |
| Cortisol                        | 0.0758              | 0.2484     |
| D-Dimer                         | 0.3272              | 0.1495     |

Table 1. Inflammatory and hemostatic biomarkers correlated with NLRP-3 inflammasome levels in patients with sepsis and suspected DIC.

Author Disclosures: Evi Kalodiki nothing to disclose, Debra Hoppensteadt nothing to disclose, Richard Green nothing to disclose, Amanda Walborn nothing to disclose, Grace Wegryzn nothing to disclose, Jawed Fareed nothing to disclose

#5

## Venous Reflux Changes After Physical Exercise

**Roman A. Tauraginskii**<sup>1</sup>, Fedor Lurie<sup>2,3</sup>, Sergei S. Simakov <sup>4</sup>, Denis A. Borsuk<sup>5</sup>

<sup>1</sup>International Institution of Health Care Research Institute of Clinical Medicine, <sup>2</sup>Jobst Vascular Institute, <sup>3</sup>University of Michigan, <sup>4</sup>Moscow Institute of Physics and Technology, <sup>5</sup>The clinic of Phlebology and laser surgery "Vasculab" Ltd.

Objectives:

It is known that the presence of venous reflux affects the arterial inflow to the lower limb. However, the effect of changes in arterial inflow on the parameters of venous reflux has not been studied.

The purpose of this investigation was to assess the influence of changes in arterial inflow during exercise on quantitative parameters of reflux.

#### Methods:

61 lower limbs of patients with primary incompetence of the great saphenous vein (GSV) were included in the study. The diameter (D-GSV), cross-sectional area (S) cm<sup>2</sup>, average velocity (TAMEAN) cm/sec, reflux time (RT) in seconds, were measured by duplex ultrasound. Reflux volume flow (Q) ml/sec and absolute reflux volume (ARV) ml were calculated. The measurements were performed standing at rest before physical exercise is "A," and 60 seconds after physical exercise is "B" (30 lifts to tiptoes at a frequency of 1 time per second). A decrease in the absolute volume of reflux after exercise was calculated ( $DRV = ARV \text{ (after)} - ARV \text{ (before)} / ARV \text{ (before)} * 100\%$ .) Automatic distal compression-decompression (120 mm Hg) was used as a provoking maneuver. Median and interquartile range were used for describing quantity parameters.

#### Results:

Before exercise ("A"), reflux parameters were: RT = 4.85 (3.71 - 6.00) sec; Q = 3.89 (2.03 - 5.81) ml/s; RV = 17.05 (10.32 - 25.34) ml. After physical exercise ("B") they change to RT = 2.86 (2.14 - 3.33) sec; Q = 3.61 (2.06 - 6.37) ml/s; RV = 10.07 (6.08 - 16.48) ml. The changes in RT and RV were statistically significant ( $p < 0.0001$ , and  $p = 0.0007$  correspondently, Fig 1).

DRV was statistically significant different only between groups D<sub>1</sub> and D<sub>3</sub> ( $p = 0.0002$ , Fig 2).

DVR was reversely related to the GSV diameter ( $r = -0.56$ ,  $p < 0.05$ ), and to the disease severity measured by VCSS ( $r = -0.41$ ,  $p < 0.0001$ ).

#### Conclusion:

The increase in arterial inflow during physical activity leads to the decrease in the volume of reflux, mainly due to decrease in RT. The decrease in the volume of reflux after exercise is inversely proportional to the diameter of the GSV.

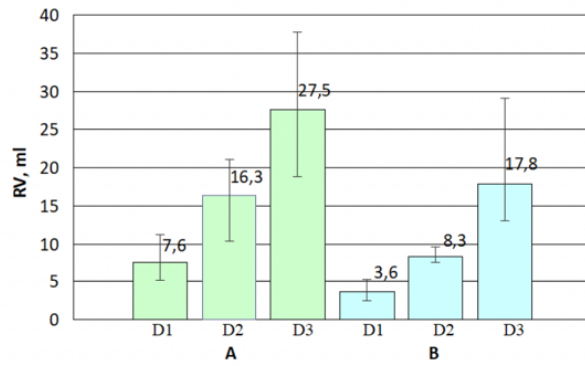


Figure 1. Reflux volume (RV) depending on D-GSV groups  
 A – before physical exercise  
 B – after physical exercise

All groups have statistically significant difference

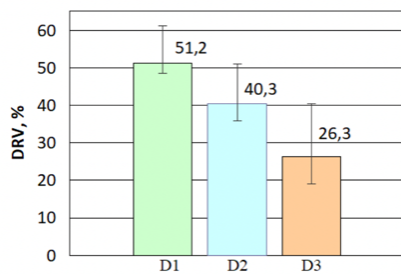


Figure 2. Decrease reflux volume changes depending on D-GSV groups

\*D<sub>1</sub> and D<sub>3</sub> (p = 0.0002)

D<sub>1</sub> and D<sub>2</sub> (p = 0.099)

D<sub>2</sub> and D<sub>3</sub> (p = 0.0581)

Author Disclosures Roman A. Tauraginskii nothing to disclose, Fedor Lurie<sup>2</sup> nothing to disclose, Sergei S. Simakov nothing to disclose, Denis A. Borsuk nothing to disclose

## **In-vivo and ex-vivo thrombin generation in non-comorbid patients with suspected deep venous thrombosis**

**Evi Kalodiki**<sup>1,2</sup>, Fredrik Wexels<sup>3</sup>, Ola Dahl<sup>3</sup>, Jeanine Walenga<sup>3</sup>, Walter Jeske<sup>3</sup>, Omer Iqbal, Debra Hoppensteadt<sup>3</sup>, Jawed Fareed<sup>3</sup>

<sup>1</sup>Loyola University Medical Centre, <sup>2</sup>Vascular Surgery, Josef Pflug Vascular Lab, Ealing Hospital & Imperial College & West London Vascular & Interventional Centre., <sup>3</sup>Thrombosis Hemostasis, Loyola University Medical Centre

### **Objectives:**

Thrombin generation in-vivo can be assessed by measuring prothrombin fragment 1+2 (F1+2) and D-dimer. The F1+2 is generated during prothrombin conversion to thrombin and thus reflects thrombin

generation. Degradation of cross-linked fibrin produces D-dimer which reflects both ongoing coagulation and blood clot dissolution. Ex-vivo, thrombin generation can be assessed by the thrombin generation assay where the endogenous thrombin potential (ETP) reflects the total enzymatic activity of thrombin. The aim was to compare thrombin generation in-vivo and ex-vivo in patients with suspected deep vein thrombosis (DVT).

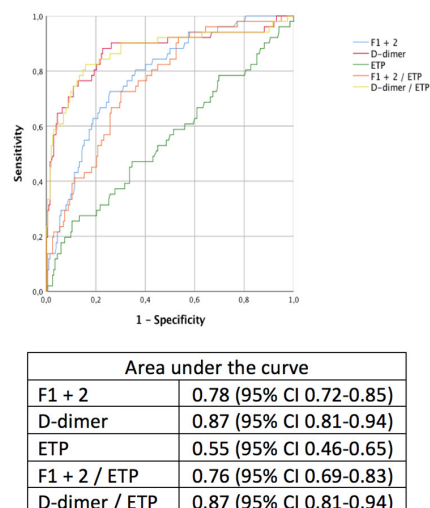
**Methods:** Patients with clinically suspected DVT and without known comorbidities or on anticoagulants were included. Blood samples were collected before examination with compression ultrasound of the lower extremities. In-vivo parameters were analyzed with commercially available ELISA. The ETP was measured by the calibrated automated thrombogram assay. Differences between DVT negative and positive patients were assessed with the Mann-Whitney U test. The area under the curve (AUC) of the receiver operator characteristic (ROC) was used to determine the overall performance of the measured parameters.

**Results:** The median age of the n=253 patients (111 male) was 54 (range 18-93) years. The DVT was confirmed by imaging in n=51 (20%) patients. There was no significant age difference between the DVT negative and positive groups ( $p=0.810$ ). The DVT positive group had more males ( $p<0.001$ ). Levels of the measured parameters in the DVT negative and positive groups are shown in Figure 1.

### **Conclusion:**

A cohort without comorbidities or on anticoagulants was selected in an attempt to show the isolated impact of lower extremity thrombosis on thrombin generation measured both in-vivo and ex-vivo. Levels of in-vivo thrombin generation were increased in patients diagnosed with DVT versus those without. However, ex-vivo ETP levels did not differ. Increased ETP levels are associated with increased risk of venous thromboembolism. Our observed discrepancy between in-vivo and ex-vivo parameters might be explained by a consumption of potential to generate thrombin ex-vivo after an event that generates thrombin in-vivo. Patients with high levels of in-vivo thrombin generation parameters should thus have lower levels of ETP. A ratio of the in-vivo biomarkers and ETP were therefore expected to have higher overall performance to diagnose DVT than F1+2 and D-dimer alone, which were not observed. The DVT increased the levels of F1+2 and D-dimer but levels of ex-vivo thrombin generation measured by ETP were not different from those without DVT.

Figure 1



F1 + 2, prothrombin fragment 1 + 2; ETP, endogenous thrombin potential; CI, confidence interval.

Figure 1. Levels of the measured parameters in the DVT negative and positive groups

**Author Disclosures:** Evi Kalodiki nothing to disclose, Fredrik Wexels nothing to disclose, Ola Dahl nothing to disclose, Jeanine Walenga nothing to disclose, Walter Jeske nothing to disclose, Omer Iqbal<sup>3</sup> nothing to disclose, Debra Hoppensteadt nothing to disclose, Jawed Fareed nothing to disclose

#7

## Overuse of Lower Extremity Venous Duplex by the Emergency Department for Detection of DVT &ndash; Pilot Study to Evaluate Use of D-dimers as a Screening Tool in Low Risk Patients

**Victoria Lee<sup>1</sup>**, Caron Rockman<sup>1</sup>, Mikel Sadek<sup>1</sup>, Glenn Jacobowitz<sup>1</sup>

<sup>1</sup>Vascular Surgery, NYU Langone Medical Center

**Objectives:** As the cost of healthcare remains a major concern for patients, providers, and payers, it has become increasingly important to evaluate resource utilization behaviors. The purpose of this study was to evaluate the utilization patterns of the Emergency Department in the ordering of lower extremity venous duplexes for detection of acute deep venous thrombosis (DVT) and the use of D-dimer as a screening test in low risk (by Wells Criteria) patients. Estimated cost of D-dimer at our institution is \$15, and venous duplex scan is \$300.

**Methods:** All venous duplexes that were ordered by the Emergency Department over the course of 10 days were evaluated. After-hours duplexes were those ordered between the hours of 9pm-7am on weekdays, and between the hours of 4pm-7am on weekends. Studies were evaluated for

patient presenting complaint, indication for duplex as documented in ER provider notes, results of the duplex (positive vs negative for DVT), D-dimer studies and Wells Criteria scores.

**Results:**

68 lower extremity venous duplexes were performed for ED patients during this 10-day period, 28% of which were performed after-hours (n=19). Only 13% (n= 9) of these patients received concomitant D-dimer serum tests, of which 56% (5/9) were positive. 26 studies were bilateral, and only 5 studies were positive for acute DVT in one (n = 4) or both (n = 1) legs. Of 42 unilateral studies, only 9% (n=4) were positive for acute DVT.

Among patients with Wells Criteria score <2, only 5/63 (8%) had a D-dimer sent. Among these, one had a positive duplex scan. 5 (8%) other positive duplex scans occurring in the low-risk population did not have concomitant D-dimers sent.

No patients with negative D-dimers had acute DVT on duplex.

**Conclusion:** Based on the preliminary results of our pilot study, it appears there is significant over-utilization of venous duplex imaging by the ER for DVT screening with under-utilization of D-dimer in low risk patients. Use of D-dimers instead of duplex scan in low risk (Well Criteria score <2) patients would have potentially saved \$16,359 over a 10-day period, which would be approximately \$597,104 per annum. Larger studies are recommended to examine the overuse of duplex ultrasound in the Emergency Room setting.

**Author Disclosures:** Victoria Lee nothing to disclose, Caron Rockman nothing to disclose, Mikel Sadek nothing to disclose, Glenn Jacobowitz nothing to disclose



## #8

### Reference Data from the Vascular Lab and its application to Chronic Venous Disease Treatment

Joel Crawford<sup>1</sup>, Antonios Gasparis<sup>2</sup>, Nicos Labropoulos<sup>3</sup>

<sup>1</sup>Vascular Surgery, RWJBarnabas Health, <sup>2</sup>Vascular and Endovascular Surgery, Stony Brook University Hospital, <sup>3</sup>Vascular and Endovascular Surgery, Stony Brook University

**Objectives:** There have been several population studies describing the incidence and prevalence of CVD. This prospective study was designed to determine in detail the distribution of reflux and obstruction in all lower limb veins to provide reference data for the management of CVD patients.

**Methods:** Consecutive patients presenting to a university vascular clinic and undergoing a duplex ultrasound examination was included in the study. Patients with C2 CVD class or higher regardless of symptoms or cosmetic concerns were evaluated. Every patient received a detailed history and physical exam by vascular surgeon including all demographic information. All patients then had a bilateral lower extremity venous ultrasound for reflux and obstruction. The exam was performed in the standing position with the exception of iliac veins and IVC that were assessed in supine position. Location and extent of reflux, vein diameters and presence of obstruction was recorded. Obstruction was characterized partial or complete for each venous segment. History of objectively documented venous thrombosis and findings on ultrasound indicating previous thrombosis were noted.

**Results:** 491 patients presented for evaluation. Excluded were 241 patients which 49 had undergone previous treatment and 192 had only C0 and/or C1 disease bilaterally. The remaining 250 patients were 32.8% Male and 67.2% Female. The mean BMI was 28.3 (Range 19.2-44). 55.2% identified as White, 11.2% as Black/African American, 23.6% as Hispanic/Latino/Spanish Origin and 0.8% identified as American Indian/Alaska Native. Asymptomatic patients accounted for 17% of the cohort and symptomatic 83%. CEAP Class was distributed as 43% C2, 28.8% C3, 15.2% C4, 7.6% C5, and 4.8% C6. In the superficial veins 70.4% of patients had only unilateral disease while 29.6% had bilateral disease. Axial reflux was found in one vein 53.2% of the time, two veins 27.6%, three veins 4.8%, four veins 4%, five veins 0.8% and six veins 0.4%. Calculation of potential ablations was performed excluding superficial reflux in 2.6% of limbs who had small diameter, 5.6% with segmental reflux, 4.4% with tributary reflux, and 6.0% with nonsaphenous reflux who would receive adjunct procedures including microphlebectomy or ultrasound guided foam sclerotherapy. These adjunct procedures would account for 18.6% of therapy while 64.0% would be ablative therapy. Past DVT was found in 7.2%, 2.8% had concurrent SVT and DVT.

**Conclusion:** From this data we can assume that the average patient presenting with venous complaints would have symptomatic disease, with great saphenous vein reflux and would require one or two ablations based on the prevalence of saphenous reflux in the population. Patients who had at least one saphenous vein with reflux would have an average of 1.6 ablations/patient.

**Author Disclosures:** Joel Crawford nothing to disclose, Antonios Gasparis nothing to disclose, Nicos Labropoulos nothing to disclose

## #9

### **Continuous Aspiration Thrombectomy of Acute IVC and IVC Filter Occlusions -Does It Work and Is It Safe?**

Mark Broering<sup>1</sup>, Brent Robertson<sup>1</sup>, Aaron Kulwicki<sup>1</sup>, Brian Kuhn<sup>1</sup>, Matthew Recht<sup>1</sup>, **Patrick Muck<sup>1</sup>**

<sup>1</sup>Vascular Surgery, Trihealth - Good Samaritan Hospital

#### Objectives:

Acute thrombosis of the inferior vena cava(IVC) and IVC filters has significant morbidity. Traditional endovascular management is pharmacomechanical with varying amount of thrombolytics. Hemorrhagic complications from thrombolytics can be life threatening. Rheolytic thrombectomy is effective but complications include blood loss and renal insufficiency. Continuous Aspiration Thrombectomy(CAT) has recently emerged as a viable option for patients with Deep Vein Thrombosis. Early results suggest CAT may minimize blood loss, hemorrhagic complications and renal insufficiency. This study evaluated the safety and efficacy of CAT in treating acute inferior vena cava thrombus and acutely occluded IVC filters.

#### Methods:

This is a single-center, retrospective study conducted to analyze patients with acute inferior vena cava thrombus and acutely occluded IVC filters, undergoing continuous aspiration thrombectomy(CAT). Patients were treated between December 2015 to September 2018. All patients underwent CAT. The primary endpoint was the periprocedural success defined as an antegrade flow following CAT. Secondary endpoints were total lytic dose, hemorrhagic complications and blood loss.

#### Results:

A total of 156 vacuum-assisted thrombectomy procedures were performed. Of these, twenty-one procedures were performed on patients with acute DVT, eight of which were presented with thrombus in the inferior vena cava or had an acute IVC filter occlusion. Antegrade flow was established after VAC in seven of these patients. The mean pre- and postoperative blood loss were 12.3/36.6 and 9.8/29.5 respectively. Access-site hematomas were reported in 2 patients. No other complications such as perforation, intracranial hemorrhage or retroperitoneal bleeds were reported. The range of lytic dose was 0 to 35 mg with an average of 20.5 mg.

#### Conclusion:

CAT is an emerging technology for arterial and venous thromboembolism. This is the first study analyzing CAT for acute IVC thrombus and occluded IVC filters. The study results suggest that the CAT is safe and promising for the treatment of acute IVC thrombosis and acutely occluded IVC filters. Further investigation is necessary to establish a protocol for CAT in patients with IVC pathology.

**Author Disclosures:** Mark Broering MD nothing to disclose, Brent Robertson MD nothing to disclose, Aaron Kulwicki MD nothing to disclose, Brian Kuhn MD nothing to disclose, Matthew Recht MD honorarium Penumbra, Patrick Muck MD Honorarium, stock holder Penumbra

## #10

### **Vein Surgery Practice Patterns Differ Between Vascular Surgeons and Other Physicians**

John Vossler<sup>1</sup>, Elna Masuda<sup>2</sup>

<sup>1</sup>Department of Surgery, University of Hawaii, <sup>2</sup>Department of Vascular Surgery, University of Hawaii

#### Objectives:

A dramatic increase in utilization of venous procedures has occurred over the past decade. Significant variation in practice pattern amongst physicians has become apparent. Given the destructive nature of these procedures, this variation has the potential to lead to large disparities in the quality of care delivered to patients with venous disease. The aim of this study is to determine the variation in vein surgery practice patterns between vascular surgeons and other physicians.

#### Methods:

A retrospective review of a health insurance procedure claims database for the years 2014-2016 was conducted. All ablation, sclerotherapy, and phlebectomy procedures were included. Physicians were classified as vascular surgeon or other physician based on ABS vascular surgery board eligibility. Indications for each procedure were classified as “neither symptoms or complications”, “symptoms only”, “complications only”, or “both symptoms and complications” based on the diagnosis codes associated with each procedure. Procedures performed on the same date were assumed to be part of the same case. The number of procedures and cases per patient was calculated. Distribution of indications for procedure and average procedures and cases per patient were compared between vascular surgeons and other physicians by Chi-squared test and Welch’s t-test, respectively.

#### Results:

A total of 368 procedures performed over 219 cases on 135 patients by 6 vascular surgeons and 11 other physicians were analyzed. The distribution of indication for procedures for vascular surgeons (neither symptoms or complications =0, symptoms only =27, complications only =97, both symptoms and complications =71) was significantly different than for other physicians (neither symptoms or complications =10, symptoms only =81, complications only =61, both symptoms and complications =21) ( $p<0.0001$ ) (Figure 1). Vascular surgeons performed the same number of procedures per patient as other physicians ( $2.37\pm1.39$  vs  $2.73\pm2.03$ ,  $p=0.964$ ), but did this over fewer cases ( $1.41\pm0.62$  vs  $1.86\pm0.97$ ,  $p=0.002$ ) (Figure 2).

#### Conclusion:

Vein surgery practice patterns differ between vascular surgeons and other physicians. This study found that vascular surgeons perform surgery for more severe venous disease than other physicians. It also found that vascular surgeons do so in a more cost and time efficient fashion by performing a similar number of procedures in a smaller number of cases per patient. Further study is necessary to determine the impact of this difference in practice patterns on patient outcomes.

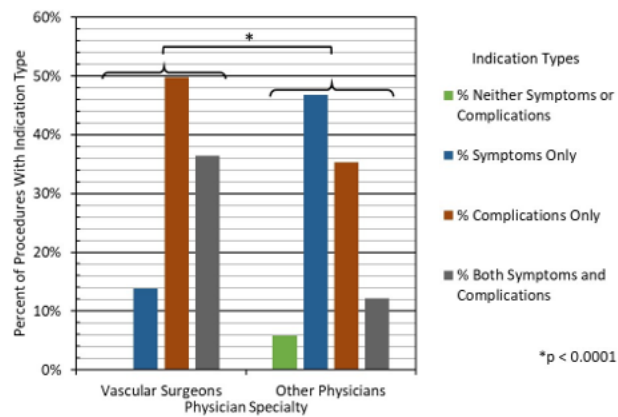


Figure 1. Indications for Procedure by Specialty

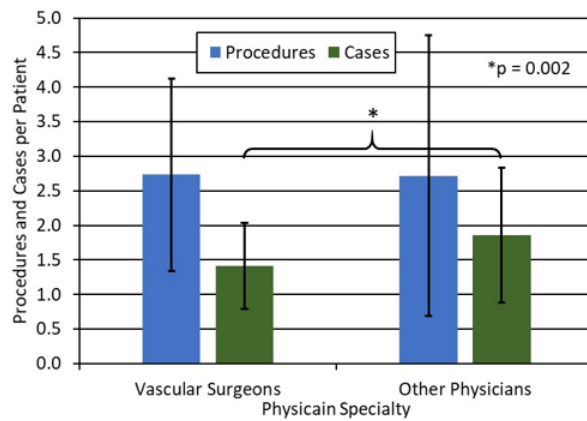


Figure 2. Procedures and Cases per Patient

Author Disclosures: John Vossler nothing to disclose, Elna Masuda nothing to disclose

## American Venous Forum International Session

### #1 – International

## **Initial results of a clinical feasibility study for endovenous deep vein valve formation to treat chronic venous insufficiency**

**Thodur Vasudevan FRACS(Vasc), FRACS(Gen), FRCS<sup>1</sup>**, Ramon L. Varcoe, MBBS, MS, FRACS, PhD<sup>2</sup>, David A. Robinson MBBS, FRACS<sup>3</sup>, Andrew A. Hill, MBChB FRACS<sup>4</sup>, Andrew Holden, MBChB, FRANZCR, EBIR<sup>5</sup>

<sup>1</sup>Vascular Surgery, Waikato Hospital, <sup>2</sup>Vascular Surgery, University of New South Wales and Prince of Wales Hospital, <sup>3</sup>Royal Prince Alfred Hospital, <sup>4</sup>Vascular Surgery, Auckland City Hospital, <sup>5</sup>Interventional Radiology, Auckland City Hospital

**Background:** Chronic Venous Insufficiency (CVI), due to superficial and deep vein reflux (DVR) and venous obstruction, is widespread and associated with significant morbidity. DVR correlates with increased symptoms. Historically, therapeutic approaches to DVR involved difficult and morbid surgical procedures, or unsuccessful attempts to implant valves. The study objectives are to assess the safety and effectiveness of endovenous formation of autogenous deep vein valves in subjects with DVR and significant associated symptoms. The study is ongoing, and results are presented for the first 10 treated subjects.

### **Methods:**

Subjects with DVR and correlating symptoms of CVI (CEAP classification C4-C6) were treated with an endovenous autogenous valve formation system in 4 centers in New Zealand and Australia. Subjects with outflow obstruction were excluded. Retrograde percutaneous access was obtained through the common femoral vein, and contrast venography and intravascular ultrasound (IVUS) were used to assess reflux and to identify potential treatment sites. If the subject was deemed eligible, the 16Fr study device was introduced and used to form monocuspid valves in femoropopliteal vein segments spanning 7-11mm in diameter. IVUS and venography were used to assess valve functionality. Post procedurally, subjects were prescribed 7 days of LMWH injections, followed by 6-months of anticoagulation. Follow-up included duplex ultrasound, physical examination and questionnaires. Deep vein thrombosis (DVT) was defined as a treated vein found to be non-compressible with visible echogenic thrombus or dilated with decreased flow by ultrasound. Mural thrombus was a deposition that did not fit the DVT criteria.

### **Results:**

The subjects were clinical class C4 (n=3), C5 (n=2) and C6 (n=5), and of both primary (n=8) and secondary (n=2) etiology. One or more monocuspid valves were successfully formed in 9/10 subjects. 1 valve formation was completed in 4 subjects, 2 formations in 4 subjects, 3 formations in 1 subject, and the anatomy did not accommodate successful valve formation in 1 subject. Follow-up ranged from 30 to 210 days with a median of 30 days. During this time, no occlusive DVT were reported, and adverse events related to the device or procedure included access site related events (n=7) and mural thrombus (n=3). All mural thrombi resolved by 90-days. At 30-days, there was a median change in reflux time (seconds) in the proximal femoral vein of 0.3 (-1.9 to 4.3), distal femoral vein of 0.4 (-1.4 to 5.6), and mid popliteal vein of 0.2 (-3.3 to 6.7). 7/10 subjects had a  $\geq 4$ -point improvement in the venous clinical severity score.

### **Conclusion:**

Endovenous valve formation in the deep venous system is feasible, and initial experience suggests it may be safe and effective treatment for chronic venous insufficiency.

Author Disclosures: Thodur Vasudevan FRACS(Vasc), FRACS(Gen), FRCS<sup>1</sup> nothing to disclose, Ramon L. Varcoe, MBBS, MS, FRACS, PhD<sup>2</sup> nothing to disclose, David A. Robinson MBBS, FRACS<sup>3</sup> nothing to disclose, Andrew A. Hill, MBChB FRACS<sup>4</sup> nothing to disclose, Andrew Holden, MBChB, FRANZCR, EBIR nothing to disclose

## **A Randomized Trial of Moderate (Class 2), High (Class 3) and Very High (Class 4) Elastic Compression in the Prevention of Recurrence of Venous Ulceration**

**Dragan Milic**<sup>1,2,3</sup>, Sasa Zivic<sup>2</sup>, Dragan Bogdanovic<sup>3</sup>

<sup>1</sup>Medical School University of Nis, <sup>2</sup>Clinic for Cardiovascular and Transplant Surgery Clinical Centre Nis, <sup>3</sup>State University of Novi Pazar, Department of Biomedical Sciences

**Background:** Venous leg ulcers (VLU) are an important health problem because of their high prevalence and associated high cost of care. Despite many available contemporary treatment modalities (surgery, endovenous thermal ablation, foam sclerotherapy, use of compression treatment...) recurrence rates remain high and range according to different studies between 25–70%. Numerous studies have suggested that regular use of compression stockings reduces VLU recurrences. However, there are limited data concerning two important questions: for how long should compression hosiery be worn after ulcer healing and which class of compression hosiery achieves better results in the prevention of VLU recurrences. The aim of this study was to establish the efficacy of three different strengths of compression (Class 2, Class 3 and Class 4) in the prevention of VLU recurrences.

### **Methods:**

An open, prospective, randomized, single-center study, with a 10-year follow-up was performed. Four hundred and seventy seven patients (240 men, 237 women; mean age 59 years) with recently healed venous ulcers and no significant arterial disease, rheumatoid disease, or diabetes mellitus, were randomized into 3 groups:

Group A) 149 patients who were wearing a class 2 elastic stocking (Rudo, Nis, Serbia).

Group B) 167 patients who were wearing a heelless open-toed elastic class III compression device knitted in tubular form - Tubulcus® (Laboratoires Innothera, Arcueil, France), and

Group C) 161 patients who were wearing a multilayer compression system comprised of Tubulcus® compression device and one elastic bandage 15 centimeters wide and 5 meters long (Niva, Novi Sad, Serbia).

The main outcome measures were recurrence of leg ulceration and compliance with treatment.

### **Results:**

One hundred and seventeen patients (24.52%) did not comply with their randomized compression class, 24 (16.1%) in class 2, 34 (20.36%) in class 3 and 59 (36.65%) in class 4 ( $p < 0.05$ ). Overall, 65% (234/360) of patients had recurrent leg ulceration by 10 years. Recurrence occurred in 120 (96%) of 125 class 2 compression cases, in 89 (66.9%) of 133 patients of class 3 compression cases and in 25 (24.5%) of 102 patients of class 4 compression cases ( $p < 0.05$ ) (Graph. Kaplan-Meier survival analysis showing ulcer recurrence at ten years).

### **Conclusion:**

The results obtained in this study suggest that compression systems with the higher compression class provide statistically significant lower recurrence rate compared to elastic compression of lower class.

**Author Disclosure:** Dragan Milic nothing to disclose, Sasa Zivic nothing to disclose, Dragan Bogdanovic nothing to disclose

## **Stationary blood particle aggregates and vein valve shape: A new classification of vein damage**

**Johann Chris Ragg<sup>1</sup>**

<sup>1</sup>interventional phlebology, angioclinic vein centers

**Background:** Using novel high resolution ultrasound systems (HRU), valvular structures and low-flow microaggregates may be depicted today in a more detailed way. We recently reported the existence of particle aggregations within valve sinus which are neither sludge nor thrombus, detected by high resolution ultrasound (AVF Servier Travel Award 2017). This consecutive study on 180 single vein valves showing motion-resistant aggregates (MRA) compares valve structures, cusp motility and extent of aggregates, resulting in a new approach to vein damage classification.

**Methods:** In 100 consecutive patients (68 f, 32 m; 42 - 64 yr/o.) presenting with unilateral epifascial venous insufficiency, a total of 180 saphenous vein valves with MRA were selected for closer high resolution ultrasound analysis (14 – 16 MHz, peak up to 40 MHz, Vevo MD). Video recordings (manual 3-D scans) were provided for review and analysis by five experienced ultrasound investigators.

**Results:** Six different stages of valve changes could be determined: Stage 1: Alteration of sinus hemodynamics (reduction of flushed sinus volume) was present in 102/180 cases (56.7%). Stage 2: Restriction of cusp function due to aggregates while maintaining valve closure was seen in 64 cases (35.6%). 6/180 cases (3.3%) showed fixation of cusps (without visible motility) but yet without reflux (stage 3), whereas in 8/180 cases (4.5%) there was fixation of cusps causing diastolic gap and reflux (stage 4, fig. 1.). Stages 5 and 6 were all related to segments with significant reflux (> 1000 ms, > 10 cm/s), showing valve regression resp. finally loss of valve structures and aggregates.

**Conclusion:** Permanent blood cell aggregates at the valve sinus seem to indicate successive stages of venous insufficiency, correlating with specific relations of sinus shape and flow. Analysis of valves and aggregates allows a new staging of vein damage, and thus a more detailed determination of the individual history of disease with potential impact for early stage treatment or prevention.

Author Disclosure: Johann Chris Ragg nothing to disclose

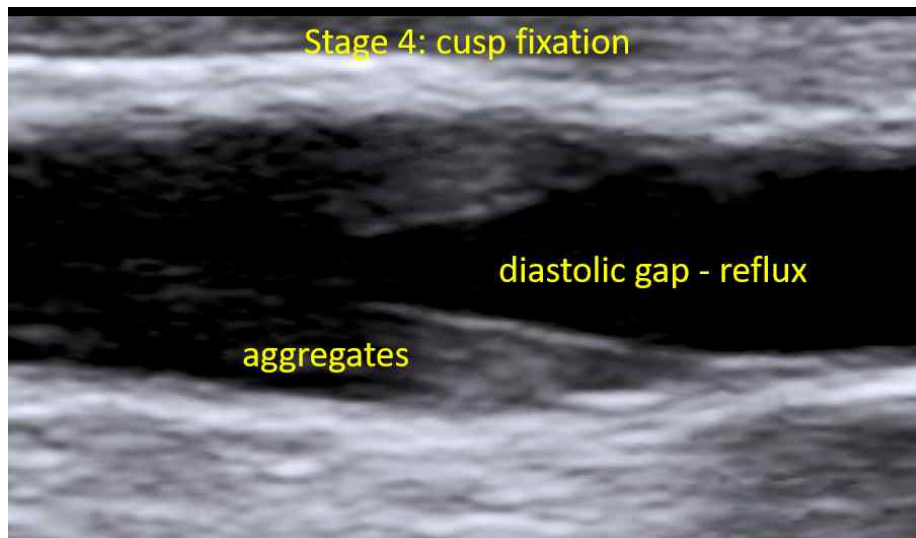


Figure 1. Aggregates identified with fixation of valve cusps.

#4- International

### **Comparative efficacy and safety of direct oral anticoagulants and warfarin for the treatment of deep vein thrombosis and the prevention of postthrombotic syndrome**

**Takashi Yamaki<sup>1</sup>**, Yumiko Sasaki<sup>1</sup>, Kazuki Hashimoto<sup>1</sup>, Wataru Kamei<sup>1</sup>, Yuki Hasegawa<sup>1</sup>, Atsuyoshi Osada<sup>1</sup>, Hisato Konoeda<sup>1</sup>, Hiroyuki Sakurai<sup>1</sup>

<sup>1</sup>Plastic and Reconstructive Surgery, Tokyo Women's Medical University

**Background:** Background: In recent years, clinical trials have shown that direct oral anticoagulants (DOACs) are at least as effective and safe as oral warfarin for the treatment of venous thromboembolism (VTE). However, there are few studies comparing efficacy and safety among different DOACs for VTE. The purpose of this study was to compare antithrombotic and haemorrhagic effects of different DOACs and warfarin in patients with acute deep vein thrombosis (DVT). Additionally, we studied preventive effects of these anticoagulants on the postthrombotic syndrome (PTS).

**Methods:** Consecutive patients with acute DVT who were treated with anticoagulants were enrolled. The cumulative incidence of VTE recurrence and bleeding events were assessed. Furthermore, we assessed cumulative complete thrombus resolution and development of PTS.

**Results:** During the 3-year period, 264 patients were treated with anticoagulation alone. Of these, 69 patients (26%) received apixaban, 64 (24%) received edoxaban, 67 (25%) received rivaroxaban, and 64 (25%) received warfarin. There were no significant differences in mean age ( $P=0.131$ ), gender distribution ( $P=0.858$ ), body mass index ( $P=0.392$ ), distribution of DVT (proximal versus distal,  $P=0.072$ ), proportion of concomitant pulmonary embolism ( $P=0.317$ ) and duration of anticoagulation ( $P=0.117$ ) between the groups. The higher incidence of the recurrent VTE was found in warfarin group, however this was not statistically significant (log rank  $P=0.478$ ). Similarly,



the bleeding events were more common in warfarin and rivaroxaban groups, and the less bleeding complications were noted in apixaban group, this did not result in any significant difference (log rank  $P=0.303$ ). In contrast, apixaban showed earlier thrombus resolution, and the cumulative thrombus resolution was the highest in apixaban group, followed by rivaroxaban group (log rank  $P=0.022$ ). The development of PTS was higher in rivaroxaban and warfarin groups, but no significant difference was found in cumulative development of PTS (log rank  $P=0.943$ ).

**Conclusion:** Although, DOACs did not appear to differ in the recurrent VTE events, the bleeding complications and the development of PTS, apixaban showed the earliest thrombus resolution among the anticoagulants studied. These results suggest that apixaban seems to be safer and more effective than some of its competitors in the management of acute DVT.

Author Disclosure: Takashi Yamaki nothing to disclose, Yumiko Sasaki nothing to disclose, Kazuki Hashimoto nothing to disclose, Wataru Kamei nothing to disclose, Yuki Hasegawa nothing to disclose, Atsuyoshi Osada nothing to disclose, Hisato Konoeda nothing to disclose, Hiroyuki Sakurai nothing to disclose

## #5- International

### Global management of venous leg ulceration: pre EVRA publication

**F. Heatley<sup>1</sup>, S. Onida<sup>1</sup>, A.H. Davies<sup>1</sup>**

<sup>1</sup> Department of Surgery and Cancer, Imperial College London, United Kingdom

**Background:** Various guidelines exist worldwide for the diagnosis and management of venous leg ulcers, however these guidelines are difficult to implement and may not be followed resulting in disparate treatment of patients globally.

**Methods:** An online, 26 question survey was created to evaluate the current global management of venous leg ulceration. The survey was classed as a service evaluation according to the HRA decision tool and therefore did not require HRA /ethical approval. The link to the survey was emailed globally via several vascular and venous societies to approximately 15000 participants using local, national and international mailing lists (November 2017 to February 2018).

**Results:** 799 complete responses were received from 86 countries. The respondent physicians saw a median of 10 patients per month. The median time of referral from primary to secondary care was 6 weeks. 60% respondents arranged an ABPI on first visit and 84% performed a venous duplex, with 95% prescribing compression for those not contraindicated. Seventy eight per cent thought that treatment of superficial truncal venous reflux by endovenous intervention or surgery benefits ulcer healing, whereas 80%

thought it benefits recurrence. Fifty nine per cent performed endovenous intervention or surgery prior to ulcer healing with 73% performing a duplex ultrasound post intervention to assess technical success.

Forty six per cent agreed that they would change practice if the EVRA study results were positive, with 43% stating they would not, but 86% of those already treated prior to ulcer healing.

**Conclusions:** The survey showed a diversity of treatment pathways. The need to develop a robust clear pathway for patients with leg ulceration is clearly required. The latter should be informed by the results of the EVRA trial.

Previously presented at the Royal Society of Medicine's Venous Forum, London, UK on 25<sup>th</sup> June 2018.

Author Disclosure: F. Heatley nothing to disclose, S. Onida-nothing to disclose, A.H. Davies nothing to disclose

#6- International

## **Graduated compression lower limb volume control in different muscle pump activation conditions and related limb shape impact**

**Sergio Giancesini**<sup>1,2</sup>, Joseph Raffetto<sup>3</sup>, Giovanni Mosti<sup>4</sup>, Elisa Maietti<sup>5</sup>, Maria Grazia Sibilla<sup>1</sup>, Paolo Zamboni<sup>1</sup>, Erica Menegatti<sup>1</sup>.

<sup>1</sup>Vascular Diseases Center, Translational Surgery Unit, University of Ferrara, Ferrara, Italy.

<sup>2</sup>Uniformed Services University of the Health Sciences, Bethesda, MD, USA.

<sup>3</sup>Harvard Medical School, VA Boston Healthcare System, Brigham and Women's Hospital, Boston, MA, USA.

<sup>4</sup>Angiology Department, Clinica MD Barbantini, Lucca, Italy

<sup>5</sup>Center for Clinical Epidemiology - Department of Medical Sciences, University of Ferrara - Italy

Background:

Literature supports graduated compression stockings (GCS) use for leg edema. Nevertheless, there is a paucity of data on the GCS effect related to sitting, standing and walking on limb edema. Different limb shapes data and their impact on GCS exerted pressure are lacking. This investigation provides evidence-based information on GCS effect on edema reduction and the limb shape impact on GCS pressure.

Methods:

Thirty healthy individuals (15M-15F, mean age  $32\pm5$ ) were included.

All the subjects underwent lower limb volume (Kuhnke formula) and bioimpedance (Biodex XpertII™) measurement, before and after sitting for 30 minutes, wearing below-ankle non-compressive socks. The same assessment was repeated 7 days later, in the same subjects, but wearing a below-knee 16-20 mmHg

GCS.

At 7 days interval, one week with below-ankle non-compressive socks and one week with below-knee 16-20 mmHg GCS, all the subjects repeated the same protocol including standing and walking.

Ten subjects underwent bioimpedance assessment before and after sitting, standing and walking. In the same group, B and B1 interface pressure values were measured.

## Results

ts:

All 60 limbs completed the data collection. Sitting or walking, without GCS, led to no significant volume changes, while volume was decreased by the use of GCS ( $-4.8\%$ ,  $p<0.00001$ ;  $-4.4\%$ ,  $p<0.00001$ , respectively).

Standing up, without GCS, led to an increase in volume ( $2.7\%$ ,  $p<0.0001$ ), while limb volume was decreased ( $4.6\%$ ,  $p<0.0001$ ) by use of GCS (Table).

Bioimpedance showed an extracellular water reduction only while walking with GCS (from  $40.55\pm1.66\%$  to  $40.45\pm1.71\%$ ,  $p<0.017$ ).

Mean interface pressure was  $19\pm5$  mm Hg (B) and  $16\pm5$  mmHg (B1). The interface pressure variation from B to B1 was not homogenous among participants (mean percentage variation of

$-13\pm25\%$ , ranging from  $-54\%$  to  $16\%$ ).

The figure shows a negative linear trend between pressure variation and circumference percentage increase. The sub-analysis excluding the two outliers shows a strong negative linear correlation (Pearson's coefficient:  $r=-0.96$ ).

## Conclusion

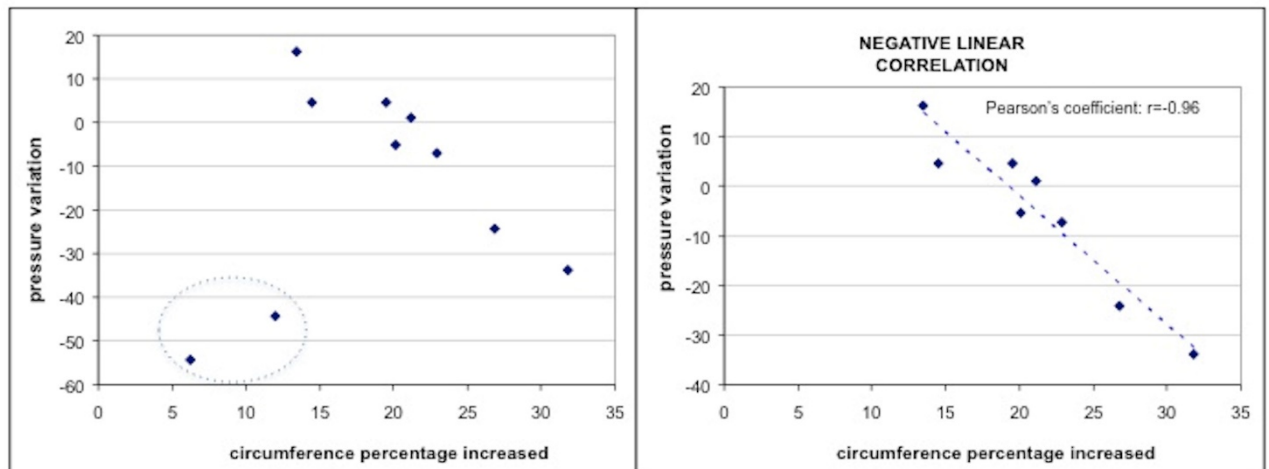
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GCS lead to a significant limb volume reduction irrespective of limb position and muscle pump function. However, extracellular fluid is only mobilized during muscle walking with GCS. Interestingly, leg shape variation influences the interface pressure gradient, indicating the importance of proper fitting of both B and B1 during prescription.

These data provide a foundation to future investigations dealing with GCS effect on fluid mobilization and with limb geometry impact on compression performance

**Table** Lower limb volume (mL) assessment by truncated cone formula (Kuhnke formula), pre and post exercise (walking) or postural condition (standing and sitting), with and without graduated compression stockings (GCS).

|                            | Limb Volume<br>(mL)<br>Pre Sampling<br>(mean±SD) | Limb Volume<br>(mL)<br>Post Sampling<br>(mean±SD) | Mean %<br>variation | p*     |   |
|----------------------------|--|---|---------------------|--------|---|
| <b>WALKING<br/>NO GCS</b>  | 2513 ± 406                                       | 2525 ± 413  | 0.4%                | ns     | — |
| <b>WALKING<br/>GCS</b>     | 2469 ± 432                                       | 2361 ± 416  | - 4.4%              | 0.0001 | ↓ |
| <b>STANDING<br/>NO GCS</b> | 2493 ± 399                                       | 2561 ± 392  | 2.7%                | 0.0001 | ↑ |
| <b>STANDING<br/>GCS</b>    | 2497 ± 386                                       | 2381 ± 367  | - 4.6%              | 0.0001 |   |
| <b>SITTING<br/>NO GCS</b>  | 2534 ± 402                                       | 2547 ± 380  | 0.5%                | ns     | — |
| <b>SITTING<br/>GCS</b>     | 2483 ± 400                                       | 2362 ± 406  | - 4.8%              | 0.0001 | ↓ |



**Figure:** Negative linear trend between lower limb circumference and interface pressure variation. Excluding the two outliers leads to a strong negative correlation (Pearson's coefficient:  $r=-0.96$ ).

Author Disclosure: Sergio Giancesini nothing to disclose, Joseph Raffetto noting to disclose, Giovanni Mosti nothing to disclose, Elisa Maietti nothing to disclose, Maria Grazia Sibilla nothing to disclose, Paolo Zamboni nothing to disclose, Erica Menegatti nothing to disclose

#7- International

## **Total laparoscopic removal of inferior vena cava filters**

**Peng Jiang<sup>1</sup>**, Jianlong Liu<sup>1</sup>

<sup>1</sup>vascular surgery, Beijing Jishuitan Hospital, Beijing, China

### **Background:**

Indwelling inferior vena cava (IVC) filters can cause significant complications. With more frequent use of optional IVC filters, there has been increasing need for filter retrieval procedures. Perforations of inferior vena caval wall by the struts of the filter are quite frequent. These complicated filters has increased due to low retrieval rates. Some filters cannot be removed through endovascular techniques. In this study, we report our experience of total laparoscopic removal of IVC filters in eight patients when the struts were nonretrievable through an endovascular approach.

### **Methods:**

Retrospective analysis was performed of eight patients who underwent filter laparoscopic retrieval procedures between December 2016 and July 2018. Seven patients had COOK Celest filter placed. One patient had BARD Denali filter implanted. All patients failed to attempt to remove the filter by means of the standard percutaneous procedure. Eight cases of IVC filter removal due to caval perforation were identified by CTV. Patient demographics, clinical presentation, laparoscopic indication and technique, and outcomes were recorded.

### **Results:**

Six patients were male and the median age was 45 years old(24-58). All IVC filters were the retrievable type and had an average indwelling time of 4.2 months(2-10). Each patient has been attempted to remove at least 2 times through endovascular retrieval. One filter was implanted above left renal vein. Seven patients underwent total laparoscopic surgical removal of complicated IVC filters, which included six Cook Celest filters and one BARD Denali filter. One patient performed open surgical removal of the filter that could not be removed by laparoscopy. The total removal rate was 100%, and the laparoscopic retrieval rate was 87.5%. All patients recovered well after operation. No mortality occurred related to laparoscopic and open removal.

### **Conclusion:**

Total laparoscopic removal with minimally invasive IVC manipulation is feasible for extraction of complicated IVC filters that cannot be removed with an endovascular procedure. Laparoscopic removal is associated with excellent outcomes and minimal morbidity.

Author Disclosures: Peng Jiang nothing to disclose, Jianlong Liu nothing to disclose

#8- International

## **Is compression required post radio-frequency ablation? - A randomized controlled trial.**

**Madu Onwudike<sup>1,2</sup>, Kazim Abbas<sup>1</sup>, Thompson Paula<sup>2</sup>**

<sup>1</sup>Vascular Surgery, Manchester University NHS Foundation Trust, <sup>2</sup>Vascular Surgery, Bolton Hospitals NHS Foundation Trust

### **Background:**

With endovenous procedures becoming increasingly preferred to open surgical operations, Radiofrequency Ablation (RFA) is now established as an efficacious endothermal modality for superficial truncal incompetence. Post-procedure limb compression, hitherto routine following open varicose vein surgery, has been extended to endovenous procedures. There is however, no robust evidence to support this practice.

This study comparatively evaluates the outcome, with and without the use of postoperative compression, following RFA.

### **Methods:**

This single-center, prospective randomized controlled trial recruited adult patients, undergoing RFA, into two groups (A: compression stocking for 2 weeks, B: no compression). Duplex scan was performed at 2 weeks, but the primary outcome was successful obliteration of target vein as determined by Duplex Ultrasound Scan (DUS) at 12-14 weeks. Secondary outcome measures included QOL scores [Aberdeen Varicose Vein Severity Score (AVSS) & Venous Clinical Severity Score (VCSS)], patient satisfaction and complications. To detect 2.5% difference in success rate between the groups, assuming 90% power and a Type 1 error of 5%, a minimum of 39 patients were required in each arm. Stata 15 (Stata Corp, USA) was used to perform statistical analysis. Ethical approval was granted by Regional NHS National Research Ethics Service. The study was registered with ISRCTN (Registration Number: 18119345.)

### **Results:**

In total, 100 patients were recruited ( Group A: 51; B: 49) with no significance difference in age, gender and CEAP, mean AVSS (17.7 v 15.7) and VCSS (10.2 v 10.4) between groups. At 2 weeks the occlusion rate of the target vein was similar in both groups at 96.1% and 95.9% respectively with no significant change at 12 weeks. There was no significant difference in the incidence of DVT. One patient in each group did not achieve vein occlusion and three patients in each group did not attend for the final ultrasound scan.

There was no statistical difference in mean AVSS (5.7 v 5.0 ) and mean VCSS (3.2 v 3.7) score at 12 weeks .

97% of the 93 patients who returned their satisfaction survey would recommend RFA procedure and this did not differ between groups.

### **Conclusion:**

The outcome of RFA without post-treatment compression is no worse than with compression.

Use of compression post RFA did not improve success rate, quality of life scores or patient satisfaction or postoperative complications. It may be concluded that the widely-practiced use of compression post RFA adds no clinical benefit for the patients.

Author Disclosures: Madu Onwudike nothing to disclose, Kazim Abbas nothing to disclose, Thompson Paula nothing to disclose

## Serum <sup>1</sup>H NMR Metabolomic Profiling in Acute DVT

Marina kafeza<sup>1</sup>, Richmond Bergner<sup>2</sup>, Joseph Shalhoub<sup>2</sup>, Sarah Onida<sup>2</sup>, Elaine Holmes<sup>2</sup>, **Alun H. Davies<sup>2</sup>**

<sup>1</sup>Academic Section of Vascular Surgery Department of Surgery & Cancer Faculty of Medicine, Imperial College London, <sup>2</sup>Imperial College London

### Background:

Deep Vein Thrombosis biomarker research is an area of great interest, given the significant morbidity and mortality associated with the disease. High throughput metabolomic profiling of circulating metabolites has emerged as a promising method in biomarker research. An untargeted metabolic profiling approach using <sup>1</sup>H nuclear magnetic resonance (NMR) spectroscopy may reveal possible diagnostic biomarkers of acute DVT.

### Methods:

Comprehensive untargeted metabolic profiling of serum of patients with acute DVT (DVT+) compared to serum of patients with similar symptoms and excluded DVT (DVT-) and non-symptomatic volunteers (controls) was undertaken using <sup>1</sup>H-NMR spectroscopy. Multivariate analysis including principal component analysis (PCA) and Orthogonal Partial Least Squares Discriminant Analysis (OPLS-DA) was performed to assess whether there was a differential metabolic profile when comparing serum of DVT patients and controls, followed by univariate analysis to identify possible compounds responsible for any difference between the groups.

Results: In total 121 patients were included in the study including 41 patients with acute DVT (DVT+), 40 Controls and 40 patients with similar symptoms and excluded DVT (DVT-). Multivariate analysis of the blood samples showed a differential metabolic profiling when comparing the serum of DVT (+) to controls or DVT (-) ( $R^2=0.806$  and  $Q^2=0.352$  and  $R^2=0.848$ ,  $Q^2=0.199$  respectively). Univariate analysis showed that the compounds responsible for the metabolic difference between DVT (+) and Controls were N-acetyl glucosamines, histidine, tyrosine, alanine, choline and lipids. N-acetyl glucosamine was also driving the metabolic difference between DVT (+) and DVT (-) groups.

### Conclusion:

The study proves the presence of a specific metabolic signature of acute DVT and utility of metabolomic approach to identify possible diagnostic DVT biomarkers in serum.

Author Disclosures: Marina kafeza nothing to disclose, Richmond Bergner nothing to disclose, Joseph Shalhoub nothing to disclose, Sarah Onida nothing to disclose, Elaine Holmes nothing to disclose, Alun H. Davies Nothing to disclose

#11

## **Risk of acute kidney injury with intervention for acute deep venous thrombosis**

Sarah Sternbach<sup>1</sup>, Yaron Sternbach<sup>2</sup>, John Taggart<sup>2</sup>, **Kathleen Ozsvath<sup>3</sup>**

<sup>1</sup>Albany Medical Center, <sup>2</sup>Vascular Surgery, Albany medical Center, <sup>3</sup>Vascular Surgery, Albany medical center

### **Objectives:**

The treatment of acute deep venous thrombosis (DVT) continues to evolve. While catheter-directed thrombolysis with mechanical thrombectomy has been used to treat patients successfully, such treatment regimens carry an inherent risk of nephropathy that has yet to be quantified. The goal of this study was to determine the risk of acute kidney injury, in patients treated for acute DVT with mechanical thrombectomy and lysis.

**Methods:** A retrospective review of prospectively collected data was conducted for 152 patients presenting to the two hospitals in Albany, New York where lysis is performed by the Vascular Group, a large single specialty vascular surgery group comprised of board certified vascular surgeons. Data collection included demographics, pre/post procedural creatinine (Cr) and Glomerular Filtration Rate (GFR), number of interventions within the acute episode, total contrast dosage, adjuvant procedures, and anatomic location of the DVT. All interventions were performed by vascular surgeons adept at evaluation and endogenous treatment. Decisions regarding initiation of therapy and method of intervention were made at the discretion of the treating surgeons.

**Results:** Over 5 years (2012-2017), 152 patients underwent intervention for treatment of acute DVT. Group 1 included 144 patients who had no significant peri-procedural renal changes. Group 2 had eight patients, comprised of those patients with changes in their renal function peri-procedurally. Mean age, number of procedures, anatomic location of the DVT, and contrast dose was similar in the two groups. Patients in group 2 did have both a higher baseline creatinine (0.87 vs 1.35,  $p=0.03$ ) lower GFR 58.6 vs 48.3,  $p=0.046$ ). Patients with abnormal GFR were more likely to sugar peri-procedural renal impairment ( $p=0.0023$ ). The addition of mechanical thrombectomy to any procedure conferred and increased risk of acute renal impairment ( $p=0.039$ ). No patient required permanent hemodialysis (HD) though two patients with normal initial renal function required temporary HD following intervention.

**Conclusion:** This study represents initial evidence that for patients undergoing intervention for acute DVT, there is a small (5.2%) but real risk of temporary peri-procedural renal impairment. Predisposing factors in the present study are limited to impaired renal function at admission, although normal renal function isn't completely protective. Renal tubular necrosis may complicate mechanical thrombectomy and augment the risk of nephropathy posed by the use of iodinated contrast agents. While intervention for acute DVT can be safely undertaken, additional investigation is necessary in order to clarify what specific elements of mechanical thrombectomy pose the greatest risk to patients and how that risk may best be mitigated in the future.

**Author Disclosures:** Sarah Sternbach nothing to disclose, Yaron Sternbach nothing to disclose, John Taggart nothing to disclose, Kathleen Ozsvath nothing to disclose



## **A pathologic perforator may predict the presence of an ipsilateral central venous stenosis**

**Mikel Sadek<sup>1</sup>**, Lowell Kabnick<sup>1</sup>, Thomas Maldonado<sup>1</sup>, Caron Rockman<sup>1</sup>, Neal Cayne<sup>1</sup>, Todd Berland<sup>1</sup>, Glenn Jacobowitz<sup>1</sup>

<sup>1</sup>New York University Langone Health

### **Objectives:**

The treatment of a refluxing perforator is indicated in the setting of severe venous insufficiency (i.e. pathologic perforator), but there are minimal data characterizing the presence of a concomitant ipsilateral central venous stenosis. Consequently, central venous stenosis may be underdiagnosed and undertreated in this cohort of patients with active or healed venous stasis ulcerations. This study sought to evaluate whether the presence of a pathologic perforator is predictive of the presence of an ipsilateral central venous stenosis.

### **Methods:**

This was a retrospective review of a prospectively maintained institutional VQI database, from 5/2016–4/2018. Consecutive patients were identified who underwent laser ablation of a pathologic perforator per AVF guidelines, and most had not undergone dedicated central venous imaging. Patients were identified who underwent incidental abdominal imaging that allowed for evaluation of the central veins (e.g. MR, CT, venogram/IVUS). The patients were divided into those who had imaging (Group A) and those who did not (Group B). Of those patients who underwent imaging, the primary outcome was the presence of an ipsilateral central venous stenosis, as measured by orthogonal diameter reduction of >50% on axial imaging, or by cross-sectional surface area reduction of >50% using IVUS.

### **Results:**

63 patient limbs underwent ablation of a pathologic perforator (Group A, N=18 vs. Group B, N=45). Of the total cohort, 47.6% were men, average VCSS was  $8.8 \pm 5.4$ , right-sided treatments occurred in 44.4%, and average perforator diameter was  $5.7 \pm 3.3$ mm. Demographic variables did not differ significantly between groups. Right-sided procedures trended more in Group A as compared to Group B (Group A: 61.1% vs. Group B: 37.8%,  $P=0.09$ ). Imaging was as follows (CT, N=10; MR, N=6, venogram/ivus, N=2). Limbs with pathologic perforators demonstrated ipsilateral central venous stenoses in 83.3% vs. the contralateral limbs, which demonstrated central venous stenoses in 44.4%,  $P=0.04$ . In perforator-treated limbs, the average iliac vein diameter decreased from  $15.5 \pm 4.1$ mm to  $4.5 \pm 1.6$ mm,  $P < 0.01$ . This represented an average stenosis of  $70.2 \pm 11.0\%$  in the perforator-treated limb versus  $45.4 \pm 31.1\%$  in the unaffected limb,  $P=0.009$ . Concomitant central venous stenting was performed rarely (Group A:2 vs. Group B:0,  $P=0.07$ ), presumably due to the lack of imaging and diagnosis.

### **Conclusion:**

To conclude, this study suggests that the majority of patients who undergo treatment for a pathologic perforator have ipsilateral central venous stenosis. The identification of central venous stenosis in limbs with a treated pathologic perforator supports the concept that multi-level disease may underlie severe venous insufficiency, and that this is often underdiagnosed and

undertreated. Ongoing evaluation will demonstrate whether identification and treatment of central venous stenosis in patients with a pathologic perforator will result in improved outcomes.

**Author Disclosures:** Mikel Sadek nothing to disclose, Lowell Kabnick stock options, contractor Bard & Ventiti, Thomas Maldonado nothing to disclose, Caron Rockman nothing to disclose, Neal Cayne nothing to disclose, Todd Berland nothing to disclose, Glenn Jacobowitz nothing to disclose

#13

## **Spine stabilization is a risk factor for the development of pelvic iliac vein lesions**

Golta Rasouli<sup>1</sup>, Maxwell Tran<sup>1</sup>, Vinay Satwah<sup>1</sup>, Sanjiv Lakhanpal<sup>1</sup>, **Peter Pappas<sup>1</sup>**

<sup>1</sup>Center For Vein Restoration

**Objectives:** Open lumbar spine stabilization surgery often requires mobilization of the left and/or right common iliac veins and the placement of plates and screws that can impinge on iliac veins. We reviewed our venography experience over the past three years to determine if there is an association between spine stabilization surgery and the development of iliac vein lesions and symptomatic iliac vein outflow obstruction.

**Methods:** A retrospective chart review was performed to identify patients who underwent venography, with or without, venous stenting and had a history of previous lumbar spine stabilization.

**Results:** From January 2014 to April 2018, venograms were performed in 1713 limbs in 1245 patients at the Center for Vascular Medicine. Of the 1245 patients, 17 patients had a history of lumbar spine stabilization procedures: Four Anterior/Posterior (AP/Post) and 13 Posterior. Nine had single level and eight had two or three level fusions. All 17 patients demonstrated pelvic lesions which included the following: One left Common Iliac Vein (CIV) aneurysm, 5 left CIV stenoses, three bilateral CIV stenoses, 2 Lt CIV + Inferior Venacava occlusions and 2 External Iliac Vein stenoses. The aneurysm patient was treated with anticoagulation, 8 patients underwent stenting, one patient refused stenting due to relocation to another country, one IVC/CIV occlusion could not be crossed, fear of dislodging a thrombus and the proximity to a protruding posteriorly placed screw prevented stenting in two patients, 4 patients had a venoplasty alone due to under-sizing of a stenosis or missed lesions with IVUS after review by a blinded reviewer. Lesions in AP patients were extremely stenotic, required pre-dilatation and resulted in a residual stenosis requiring venoplasty at a second setting in one patient.

**Conclusion:** Lumbar spine stabilization surgery may be a risk factor for developing symptomatic venous outflow obstruction lesions. During venography and stenting in patients with AP approaches, significant scarring may be encountered resulting in a residual stenosis after stent placement. Pre dilatation venoplasty, prior to stent deployment, is recommended to prevent stent migration. Furthermore, a history of spine stabilization surgery in patients presenting with pelvic or lower extremity pain/swelling, should prompt consideration of a pelvic venous duplex to assess for the presence of an iliac venous outflow lesion.

**Author Disclosures:** Golta Rasouli nothing to disclose, Maxwell Tran nothing to disclose, Vinay Satwah honorarium Tactile medical Inc. Sanjiv Lakhanpal nothing to disclose, Peter Pappas nothing to disclose

#14

## **Outcomes of Left Renal Vein Stenting in Patients with Nutcracker Syndrome**

**Efthymios D. Avgerinos<sup>1</sup>**, Zein Saadeddin<sup>1</sup>, Rishab Humar<sup>1</sup>, Karim Salem<sup>1</sup>, Michael Singh<sup>1</sup>, Eric S. Hager<sup>1</sup>, Michel Makaroun<sup>1</sup>, Rabih A. Chaer<sup>1</sup>

<sup>1</sup>Department of Surgery, Division of Vascular Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pa

### **Objectives:**

Nutcracker syndrome (NCS) is a rare condition that can present with hematuria, flank pain, pelvic varicosities, or chronic pelvic congestion related to left renal vein (LRV) compression. Open surgery, specifically LRV transposition, has been the mainstay of treatment, but over the past few years, LRV stenting has emerged as a valid alternative without sufficient evidence to support it. This study aims to assess outcomes of renal vein stenting in the treatment of NCS.

### **Methods:**

A retrospective chart review of patients with NCS who underwent LRV stenting between 2010 and 2018 was performed. Endpoints were perioperative adverse outcomes, symptom relief and stent patency. Symptom resolution was classified as complete, partial and none based on the interpretation of medical records on clinical follow-up. Standard descriptive statistics and survival analysis were used.

### **Results:**

Seventeen patients (16 female, mean age  $35.8 \pm 14.6$  years, mean BMI  $21.3 \pm 4.1$  kg/m<sup>2</sup>) diagnosed with NCS and treated with LRV stenting were identified. Five of these had a prior LRV transposition that had failed within a mean of  $7.0 \pm 4.9$  months. Ten patients had coexisting pelvic congestion syndrome treated with gonadal vein embolization. The most frequent sign and symptom were hematuria (9/17 patients) and flank pain (14/17 patients), respectively. All patients received self-expanding stents (mean diameter  $12.7 \pm 1.6$  mm), the smaller ones typically placed in the previously transposed LRVs. No perioperative complications occurred. Eight patients were discharged on the same day, the remaining stayed longer for pain control (mean hospital stay  $1.0 \pm 1.3$  days). At an average follow-up of  $33 \pm 25$  months, 13 (76.5%) patients had symptom relief (9 complete, 4 partial). Three of the 4 patients whose symptoms persisted had previous LRV transposition surgery. Five out of 9 patients who presented with hematuria had it resolved.

Three patients underwent a reintervention. Two of these had successful balloon venoplasty for restenosis. The third patient had persistent debilitating pain despite a patent stent and eventually underwent renal auto transplantation with no symptom relief. Two-year primary and primary-assisted patencies were 81.8% and 90%, respectively. No stent migration occurred.

### **Conclusion:**

Endovascular treatment with renal vein stenting is safe and effective, providing good mid-term patency rates and symptom relief. Minimally invasive approaches may have a potential role in the treatment of NCS. Larger series and longer follow-up are needed to better assess its comparative performance against LRV transposition.

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nothing to disclose, Eric S. Hager nothing to disclose, Michel Makaroun nothing to disclose, Rabih A. Chaer nothing to disclose

#15

## **Medical compression stockings significantly increase local tissue factor levels in advanced chronic venous insufficiency patients and healthy volunteers**

**Christopher R Lattimer**<sup>1,2</sup>, Evi Kalodiki<sup>1,2</sup>, Patrick Van Dreden<sup>3</sup>, Aurelie Rousseau<sup>3</sup>, Grigorios T Gerotziakas<sup>4,5</sup>

<sup>1</sup>Vascular Surgery, Josef Pflug Vascular Laboratory, Ealing Hospital and Imperial College, <sup>2</sup>West London Vascular and Interventional Centre, <sup>3</sup>Clinical Research Department, Stago, <sup>4</sup>Haematology, Hopitaux Universitaires de l'Est Parisien - APHP, <sup>5</sup>Cancer Biology and Therapeutics, Centre de Recherche Saint-Antoine, Sorbonne Universite

### **Objectives:**

Evidence that medical compression stockings (MCS) prevent deep vein thrombosis (DVT) is weak. Furthermore, the body position that predisposes to DVT is not fully known. It is assumed that standing is protective through involuntary leg muscle contractions and lying stationary may be provoking DVT. Previous work using ultrasound has shown the presence of venous sludge in the popliteal veins, in both positions. The aim was to investigate the effect of standing, lying and compression on thrombogenicity. This was achieved by taking local venous blood samples and measuring an array of factors considered relevant in thrombogenesis.

### **Methods:**

Patients with advanced chronic venous insufficiency (CVI) awaiting endothermal ablation (C4<sub>a,b</sub>) and healthy volunteers (n=14 legs, in each group, 1 leg per subject) had local leg blood samples taken after 1 hour of: standing (S), lying (L) and standing with compression (C), on separate days. Knee-length MCSs of 23-32 mmHg were administered. Platelet poor plasma samples were analyzed for Procoagulant phospholipids (PPL), tissue factor (TFa), D-dimers (D-Di), Fibrin monomer (FM), and activated VIIa-antithrombin complexes (VIIa-AT). This was in addition to a thrombin generation test using the PPP-Reagent® which measured: Lagtime, endogenous thrombin potential (ETP), Peak, time to Peak (ttPeak) and mean rate index (MRI).

### **Results:**

The most responsive was TFa, with significant increases after a MCS was worn in standing, compared to lying and standing with compression, in both volunteers and patients (Fig 1). Standing and compression made no difference to D-Di or VIIa-AT in either group (Table 1). Thrombin generation testing revealed no differences in the volunteer group but in the patients, compression appeared to have a favorable significant effect in 4/5 measurements compared to lying (Table 1).

### **Conclusion:**

Local tissue factor concentrations were elevated significantly with a MCS. This was on a background of unaffected D-Di and VIIa-AT, thereby questioning the thrombogenic significance of the elevated tissue factor. However, compression reduced thrombin generation parameters but only in patients with CVI. Patients demonstrated also significantly reduced thrombin generation when standing compared to lying. This research supports our hypothesis that standing and compression may offer additional protection from thrombosis, but only in patients.

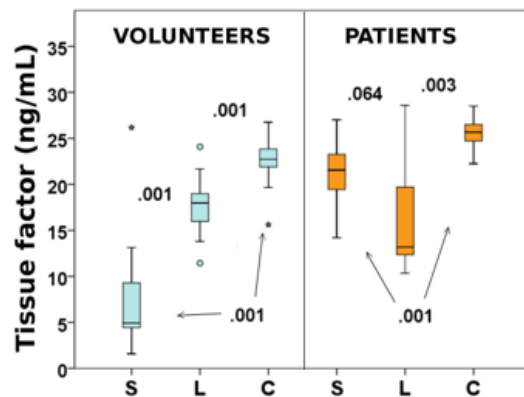


Figure 1. Local Tissue Factor concentrations in response to standing (S), lying (L) and compression (C), in volunteers and patients. Significance levels are shown (Wilcoxon)

|               | VOLUNTEERS       |                  |                    | PATIENTS (C <sub>4</sub> ) |                   |                    |
|---------------|------------------|------------------|--------------------|----------------------------|-------------------|--------------------|
| Parameters    | Standing         | Lying            | Compression        | Standing                   | Lying             | Compression        |
| PPL (s)       | 67.7 [63.5-80]*  | 76.7 [66.6-92.6] | 71.5 [67-80.7]     | 82.8 [74.7-91.2]           | 89.5 [76.3-96.5]  | 77.1 [67.6-81.8]*  |
| TFa (ng/mL)   | 4.94 [4.03-10]*  | 17 [15.5-19.1]   | 22.7 [21.7-23.9]** | 21.6 [18.7-23.3]           | 13.2 [12.2-20.4]  | 25.7 [24.6-26.7]** |
| D-Di (µg/mL)  | 0.27 [0.27-0.34] | 0.27 [0.27-0.32] | 0.27 [0.27-0.45]   | 0.35 [0.27-0.9]            | 0.34 [0.28-0.63]  | 0.29 [0.27-0.53]   |
| FM (µg/mL)    | 5 [5-5.8]        | 5 [5-60.3]       | 5 [5-50.4]         | 5 [5-7.32]                 | 5 [5-5.07]        | 5 [5-5]            |
| F.VIIa (U/mL) | 74.7 [55.2-300]  | 71.9 [54.3-545]  | 17.3 [10.6-241]*   | 26.7 [19.7-55.5]           | 28.1 [19.9-55.9]  | 32.5 [24.6-67.5]   |
| Lagtime (min) | 6.74 [5.49-8.92] | 5.91 [4.74-7.16] | 5.67 [4.67-6.93]   | 6.75 [5.04-9.13]           | 6.46 [5.06-7.42]  | 7.25 [5.33-8.88]   |
| ETP (µM/min)  | 1.1 [0.75-1.25]  | 1.1 [0.72-1.72]  | 1 [0.77-1.54]      | 0.94 [0.84-1.08]           | 1.08 [0.68-1.38]  | 0.96 [0.43-1.11]*  |
| Peak (nM)     | 150 [95.5-194]   | 1.69 [95.2-349]  | 136 [97.3-291]     | 150 [101-182]              | 175 [108-214]*    | 150 [62.8-185]*    |
| ttPeak (min)  | 10.8 [9-12.3]    | 8.83 [7.87-11.2] | 9.83 [7.55-10.8]   | 10.8 [8.51-13.7]           | 10 [7.9-11.9]*    | 10.9 [8.67-12.9]*  |
| MRI           | 40.8 [21.7-61.1] | 48.6 [24.3-150]  | 36.7 [24.1-107]    | 44.9 [21.3-56.6]           | 51.3 [31.3-89.4]* | 41.9 [18.8-56.7]*  |
| VIIa-AT (pM)  | 102 [82.5-179]   | 115 [57.4-227]   | 82.9 [53.6-194]    | 118 [91.4-161]             | 111 [97-133]      | 118 [101-146]      |

\*  $p < 0.05$  versus standing    °  $p < 0.05$  versus lying

Table 1. Median [inter-quartile range] values in 3 different laboratory situations for 1 hour.

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## **Effectiveness of the PowerWire® RF guidewire in recanalizing chronically occluded iliac venous stents**

Newton Neidert<sup>1</sup>, Haraldur Bjarnason<sup>1</sup>

<sup>1</sup>Mayo Clinic, Rochester, MN

### **Objectives:**

Iliac venous stenting is a commonly performed procedure in treating post-thrombotic and non-thrombotic iliac venous disease. While overall stent patency rates are high, stent occlusion does occur. Recanalizing chronically occluded stents is technically challenging and often impossible with conventional guidewires and catheters. The PowerWire® RF guidewire is a 0.035" guidewire that delivers radiofrequency energy at the end of the guidewire.

### **Methods:**

Retrospective chart review of patients with chronically occluded iliac venous stents who underwent an iliac venous recanalization attempt using the PowerWire® RF guidewire from March 2015 to June 2018. A total of 15 patients underwent a recanalization attempt with the PowerWire® RF guidewire. All patients had initial unsuccessful attempts at recanalizing the occluded iliac vein stents with conventional guidewires. Successful recanalization was defined as restoration of antegrade iliac venous flow following angioplasty alone or angioplasty and placement of additional stents.

### **Results:**

Percutaneous recanalization of chronically occluded iliac venous stents using the PowerWire® RF guidewire was successful in 10 patients. Cumulative 6 month patency rate was 62%. Cumulative 12 month patency rate was 43%. There were two complications that occurred with utilization of the PowerWire® RF guidewire. One patient had transient foot drop of the ipsilateral limb that was successfully recanalized. One patient had self-limited perforation of the left common iliac artery during unsuccessful recanalization.

### **Conclusion:**

The PowerWire® RF guidewire is an effective and relatively safe device for recanalizing chronically occluded iliac venous stents.

**Author Disclosures:** Newton Neidert nothing to disclose, Haraldur Bjarnasom nothing to disclose,

#17

## **Impact of presence of IVC filter on ilio caval stent outcomes**

Arjun Jayaraj<sup>1</sup>, Laura Lamanilao<sup>1</sup>, Seshadri Raju<sup>1</sup>

<sup>1</sup>RANE Center for Venous and Lymphatic Disease at St. Dominic Hospital

**Objectives:** The impact of presence of an IVC filter in patients undergoing stenting for symptomatic femoroiliocaval obstruction has not been explored in detail. This study attempts to fill this gap by evaluating clinical and stent related outcomes in such patients. The incidence of deep venous thrombosis (DVT) in this setting is also analyzed.

**Methods:** A retrospective review of contemporaneously entered EMR data on initial ilio-caval stents placed in patients with an indwelling IVC filter (or placed post stenting) over a 15-year period from 2000 to 2015 was performed. A separate cohort that underwent initial stenting during the time frame but which did not have an IVC filter was utilized as the control group. Clinical outcomes were evaluated through use of the venous clinical severity score (VCSS). Incidence of deep venous

thrombosis was reviewed in both groups. Kaplan Meier analysis was used to assess stent patency post intervention while paired T-test was used to examine pre and post intervention outcomes within and in between groups.

#### **Results:**

A total of 57 patients underwent placement of a femoroiliocaval stent in the setting of a pre-existing (46) or post stent (11) IVC filter [filter group]. The control group had 359 patients. There was no difference in VCSS at baseline between the two groups. Over a median follow up of 59 months, VCSS went from 5 to 2 at 12 months ( $p=0.84$ ) in the filter group and from 5 to 3.5 in the control group ( $p<0.01$ ). However, there was no statistically significant difference in the VCSS scores between the two groups was at 12 months ( $p=0.09$ ). The incidence of ipsilateral DVT in the filter group was 7% and that in the treatment group was 3% ( $p=0.10$ ). There were no contralateral DVT's in either group. Median primary, primary assisted and secondary patencies in the filter/control groups were 116/64 ( $p<0.01$ ), 137/58 ( $p<0.01$ ) and 29/30 months ( $p=0.77$ ).

#### **Conclusion:**

Presence of an IVC filter does not appear to impact clinical outcomes following femoroiliocaval stenting. However, counterintuitively, they appear to confer better primary and primary assisted stent patencies.

**Author Disclosures:** Arjun Jayaraj nothing to disclose, Laura Lamanilao nothing to disclose, Seshadri Raju nothing to disclose

## **#18**

### **Improvement in quality of life after iliac vein stenting in a prospective clinical study of a nitinol venous stent**

**William Marston<sup>1</sup>**, Mahmood Razavi<sup>2</sup>

<sup>1</sup>University of North Carolina School of Medicine, <sup>2</sup>St. Joseph's Hospital, Orange CA

#### **Objectives:**

Stenting of the ilio-femoral venous outflow tract is recommended to treat patients with significant limb symptoms related to obstruction. However, it remains unclear which patients benefit most from iliac vein stenting. In this prospective clinical trial studying the performance of a nitinol stent designed for the treatment of venous obstructive pathology, quality of life (QOL) measures were related to patient and procedural characteristics to determine which patients benefit most from venous stenting.

#### **Methods:**

One hundred seventy patients with chronic ilio-femoral venous obstruction (IFVO) were enrolled in a prospective pivotal trial studying the effectiveness of a nitinol venous stent (Veniti, Inc.). Prior to intervention QOL was measured with the venous clinical severity score (VCSS) and CIVIQ-2 score. Venography was performed and the presence of vessel stenosis of  $>50\%$  was required for study inclusion. Intravascular ultrasound (IVUS) was also performed before and after stent insertion to allow calculation of lumen diameter and area. QOL was measured with VCSS and CIVIQ-2 at 1, 6 and 12 months after stenting and repeat venography and IVUS were performed at 12 months.

#### **Results:**

One-hundred forty of the cohort had QOL measures performed before stenting and at 12 months of follow-up. Of these, 133 had IVUS measurements at the time of stent insertion and 94 had IVUS

at 12 months. Both VCSS and CIVIQ-2 improved significantly at 1 and 12 months after stenting as noted in Table 1. Improvement in VCSS was similar in patients treated for non-thrombotic ( $5.2 \pm 5.6$  points) compared to post-thrombotic ( $4.0 \pm 3.9$  points) disease. Patients who experienced significant improvement in VCSS ( $\geq 3$  points,  $n=91$ ) had a significantly higher mean maximal area stenosis on IVUS before stenting ( $70.1 \pm 20\%$ ) than 32 patients who had  $< 2$  points improvement on VCSS ( $57.2 \pm 25.9\%$ ,  $p = .007$ ). VCSS improvement at 12 months did not correlate with the maximal % diameter or % area stenosis on IVUS at 12 months.

**Conclusion:**

The majority of patients treated with venous stenting for symptomatic IFVO experience significant reduction in symptoms which is durable to 12 months of follow-up. QOL improvement was significantly more frequent in patients stented for more severe venous obstruction.

**Author Disclosures:** William Marston honorarium Veniti, Mahmood Razavi Honorarium Veniti, Boston Scientific



|         | Pre-stent   | 1 month post-stent | 12 month post-stent | p value pre vs 1 month | p value pre vs 12 month |
|---------|-------------|--------------------|---------------------|------------------------|-------------------------|
| VCSS    | 9.9 ± 5.0   | 6.3 ± 4.3          | 5.7 ± 4.3           | <0.00001               | <0.000001               |
| CIVIQ-2 | 0.44 ± 0.24 | 0.30 ± 0.25        | 0.27 ± 0.25         | <0.00001               | <0.00001                |

Table 1. VCSS and CIVIQ-2 at 1 and 12 months.

#19

## Relevance of thrombophilia testing in patients undergoing ilio-femoral venous stenting for post-thrombotic occlusion

Laura Tincknell<sup>1</sup>, Adam Gwozdz<sup>1</sup>, Nicholas Jackson<sup>1</sup>, Justinas Silickas<sup>1</sup>, Alberto Smith<sup>1</sup>, Prakash Saha<sup>1</sup>, Karen Breen<sup>2</sup>, Stephen Black<sup>1</sup>

<sup>1</sup>Academic Department of Vascular Surgery, School of Cardiovascular Medicine and Science, St Thomas' Hospital, King's College London, UK, <sup>2</sup>Department of Haematology, St Thomas' Hospital, King's College London, UK

### Objectives:

Inherited and acquired thrombophilias increase the risk of venous thromboembolism (VTE), and the antiphospholipid antibody syndrome (APS), an acquired thrombophilia, is associated with a high risk of recurrent VTE. Post-operative anticoagulation therapies remain tailored, with APS patients requiring long-term vitamin K antagonists (VKA) compared with direct oral anticoagulants (DOACs) for patients with inherited thrombophilia. As such, ilio-femoral venous stenting in patients with thrombophilia is controversial. The aim of this study was to examine the association of thrombophilia with cumulative patency and re-intervention rates following stenting for post-thrombotic occlusion.

### Methods:

Consecutive patients (2012-2017) receiving a nitinol venous stent for post-thrombotic disease with a minimum of one-year follow-up were included for analysis. Thrombophilia testing was performed when VTE occurred at a young age with: weak provoking factors; or strong family history; or recurrence. Patients with strong risk factors for VTE were not tested and excluded from analysis. All patients were given therapeutic dose low molecular weight heparin divided twice daily for 2wks post-procedure, followed by a VKA for 6mths. Patients with APS continued on long-term VKA therapy at 6mths, while all other patients were transitioned to DOACs. Stent patency was assessed using duplex ultrasonography 24hrs, 2wks, 6wks, 3mths, 6mths, 1yr and yearly post intervention, and re-interventions performed when there was a reduction in stent diameter of >50% or occlusion.

### Results:

Of 205 patients treated, 138 (67%) were tested for thrombophilia, of which 59/138 (43%) had an inherited 30/59 (51%) or acquired 29 (49%) thrombophilia (Table 1). Cumulative patency was 88% for patients with thrombophilia, and 89% in patients without (median follow-up 1.7yrs; range 52-258wks). Additionally, 64/138 (46%) patients required re-intervention to maintain patency, of which 28/59 (47%) occurred in patients with thrombophilia, and 36/79 (45%) without. Inherited or acquired thrombophilia was not associated with cumulative patency loss ( $P=0.402$ ), or higher risk of re-intervention ( $P=0.255$ ).

### Conclusion:

Thrombophilia assessment for APS should be performed in patients undergoing ilio-femoral venous stenting without strong provoking factors for VTE as prolonged anticoagulation with VKA is advised in this patient group due to their increased risk of VTE recurrence. Furthermore, patients with inherited or acquired thrombophilia should not be excluded from ilio-femoral venous stenting as patency outcomes are good in conjunction with appropriate post-operative anticoagulation therapy.

| Thrombophilia Type                            | Patients tested for thrombophilia<br>n=138 |
|---|--|
| Thrombophilia negative                        | 79 (57%)                                   |
| Inherited                                     | 30 (22%)                                   |
| Factor V Leiden                               | 22 (16%)                                   |
| Prothrombin gene mutation                     | 0 (0%)                                     |
| Protein C                                     | 2 (1%)                                     |
| Protein S                                     | 2 (1%)                                     |
| Antithrombin                                  | 4 (3%)                                     |
| Acquired (Antiphospholipid antibody syndrome) | 29 (21%)                                   |

Table 1. Outcome of thrombophilia testing in patients without strong provoking factors for VTE

**Author Disclosures:** Laura Tincknell nothing to disclose, Adam Gwozdz nothing to disclose, Nicholas Jackson nothing to disclose, Justinas Silickas nothing to disclose, Alberto Smith nothing to disclose, Prakash Saha nothing to disclose, Karen Breen nothing to disclose, Stephen Black nothing to disclose,

#20

## Single versus multiple-stage catheter-directed thrombolysis does not impact iliac vein stent length or patency rates

Catherine Go<sup>1</sup>, Zein Saadeddin<sup>1</sup>, Rabih Chaer<sup>1</sup>, Mohammad Eslami<sup>1</sup>, Yash Pandya<sup>2</sup>, Eric Hager<sup>1</sup>, Michael Singh<sup>1</sup>, **Efthymios Avgerinos<sup>1</sup>**

<sup>1</sup>Vascular Surgery, UPMC, <sup>2</sup>School of Medicine, University of Pittsburgh

**Objectives:** Incomplete venous thrombolysis and residual non-stented iliac vein disease are known predictors of recurrent deep venous thrombosis (DVT). Controversy exists whether the number of thrombolysis sessions affects total stent treatment length or stent patency. The goal of this study was to evaluate the outcomes of patients who underwent single vs multiple catheter-directed lysis (CDT) sessions with regards to stent extent and patency.

**Methods:** Consecutive patients who underwent thrombolysis and stenting for acute ileofemoral DVT between 2007 and 2018 were identified and divided into two groups based on number of treatments performed (one vs multiple sessions). Operative notes and venograms were reviewed to determine the number of lytic sessions performed and stent information including size, location, total number, and length treated. Endpoints include total stented length, 30-day and long-term outcomes. Chi square comparisons, logistic regression, and survival analysis were used to determine outcomes.

**Results:** Seventy-nine patients underwent lysis and stenting (6 bilateral interventions, mean age 45.9±17 years, 48 female). Ten patients (12 limbs) underwent single-stage treatment with pharmacomechanical thrombolysis (PMT) and the remaining 69 (73 limbs) 2-4 treatments combining PMT and CDT. Patients who underwent a single-staged procedure were older and more likely to have a malignancy. These patients also received less tPA when compared to the multiple-stage group (17.2±7.0 vs 27.3±11.7 mg, P=0.010). Average stent length was 8.8±5.2 cm for the single-stage group versus 9.2±4.6 cm for the multiple-stage group (P=0.764). When dividing patients into 1 or 2 treatments (52 patients) versus 3 or 4 (27 patients), there was no significant difference in total stent length (P=0.489). Patients who underwent a single-staged procedure had

no difference in average length of stay than those who underwent multiple sessions (8.5 days vs 5.9 days,  $P=0.269$ ). The overall 30-day rethrombosis rate was 14.8%. Three-year patency was 72.2% and 74.8% for the single and multiple stages respectively. The major predictor for loss of primary patency was incomplete lysis (hazard ratio [HR]=7.69;  $P<0.01$ ) but not number of procedures (HR=1.01;  $P=0.994$ ). The overall rate of post-thrombotic syndrome (Villalta score  $\geq 5$ ) was 9.3% at 5 years.

**Conclusion:** Single- vs multiple-staged thrombolysis for DVT is not associated with a difference in extent of stent coverage. Patency rates remain high for iliac stenting irrespective of the number of lytic sessions, provided that lysis is complete and the diseased segments are appropriately stented. Preoperative factors including patient's age and comorbidities may contribute to the decision to proceed with single vs multiple lysis sessions and deserve further investigation.

**Author Disclosures:** Catherine Go nothing to disclose, Zein Saadeddin nothing to disclose, Rabih Chaer nothing to disclose, Mohammad Eslami nothing to disclose, Yash Pandya nothing to disclose, Eric Hager nothing to disclose, Michael Singh nothing to disclose, Efthymios Avgerinos nothing to disclose,

#21

## **Instent restenosis following ilio caval stenting - Characteristics and outcomes**

**Arjun Jayaraj<sup>1</sup>**, William Walker<sup>1</sup>, Seshadri Raju<sup>1</sup>

<sup>1</sup>RANE Center for Venous and Lymphatic Disease at St. Dominic Hospital

**Objectives:** With increasing utilization of ilio-caval stenting, complications of such stenting have also become more common. Instent restenosis (ISR), an outcome that is responsible for a majority of reinterventions, is one that has not been studied in detail. Characteristics of ISR in addition to outcomes following reintervention are evaluated.

**Methods:** A retrospective review of contemporaneously entered EMR data on 372 limbs with initial unilateral ilio-caval stents (247 Left and 125 Right) placed over a 3-year period from 2015 to 2017 was performed. ISR was estimated from stent and flow channel diameters measured using duplex ultrasound. Characteristics evaluated included onset of ISR post stent placement and progression over time. Regression analysis was performed to evaluate risk factors for development of ISR. Outcomes following reintervention for ISR were also appraised. Kaplan Meier analysis was used to assess stent patency post intervention while paired T-test was used to examine pre and post intervention outcomes.

### **Results:**

361 limbs underwent stenting for stenotic lesions, while 11 underwent stenting for chronic native vein occlusions. ISR was noted as early as post intervention day 1. It progressed to a maximal value by 6 months and stabilized thereafter. The overall median ISR across stented common femoral, external iliac and common iliac segments at 12 months was 43.75 %. The segment most commonly affected by ISR was the external iliac vein (77.5%). Up to 89% of stents can have some degree of ISR at 12 months. Variables evaluated as predictors for ISR included age, gender, thrombophilia, thrombotic/non-thrombotic lesion, inflow, stent compression, shear rate and flow rate. Of these, only lack of stent compression was a significant predictor of ISR at 6 and 12 months. Over a median follow up of 13 months, 50/372 (13%) limbs underwent reintervention for ISR and 12 (3%) underwent reintervention for stent occlusion (8 acute [ $<30$ days] and 4 chronic [ $>30$  days]).

Post reintervention, VCSS scores improved from 6 to 4 for the ISR cohort ( $p<0.001$ ). Median primary, primary assisted and secondary patencies following reintervention for ISR were 37, 38, and 17 months respectively.

**Conclusion:**

ISR occurs early following ilio caval stenting but stabilizes around 6 months. Progression of ISR to stent occlusion is rare. No statistically significant, modifiable predictor for ISR was noted. Post reintervention for ISR, good clinical outcomes and stent patencies can be expected.

**Author Disclosures:** Arjun Jayaraj nothing to disclose, William Walker nothing to disclose, Seshadri Raju Stock Veniti, US Patent Venous Stent Design, Patent Holder IVUS

#22

**Comparison of Open vs Robotic Nephrectomy and IVC Reconstruction for Renal Cell Carcinoma with IVC Tumor Thrombus**

**Victor Davila**<sup>1</sup>, Kyle Rose<sup>2</sup>, Kate Peng<sup>3</sup>, Andrew Meltzer<sup>1</sup>, William Stone<sup>1</sup>, Samuel Money<sup>1</sup>, Erik Castle<sup>2</sup>

<sup>1</sup>Vascular Surgery, Mayo Clinic Arizona, <sup>2</sup>Urology, Mayo Clinic Arizona, <sup>3</sup>General Surgery, Mayo Clinic Arizona

**Objectives:**

Vascular surgeons are frequently involved in inferior vena cava (IVC) reconstruction during nephrectomy for renal cell carcinoma (RCC) with tumor thrombus. Robotic nephrectomy for RCC claims shorter length of stay (LoS), faster return to work, decreased pain medication requirements, etc. Our goal is to compare our robotic nephrectomy with IVC reconstruction experience to our open experience.

**Methods:**

We performed a single institution retrospective review of patients undergoing open or robotic nephrectomy for RCC with IVC tumor thrombus between January 1998 and January 2018. Patient characteristics, surgical records, and follow up/survival data were recorded. Tumor level was classified according to the Mayo Clinic Tumor Thrombus Level (VTT).

**Results:**

57 patients (49 male) underwent nephrectomy with tumor thrombectomy and IVC reconstruction. 38 (66%) had open procedures for RCC with level 1 (n=6), level 2 (n=21), and level 3 (n=11) VTT. Average operative time was 251min (range=108-375) and average blood loss was 2482mL (range=50-10950). Average LoS was 10.79 days (range=1-95). There were two (3.5%) deaths within 30 days. Short-term complications include atrial fibrillation (n=2), ileus (n=2), seroma (n=1), sepsis (n=1), pulmonary embolus (PE) (n=1), urinary tract infection (n=1), pneumothorax (n=1). Long-term complications include deep vein thrombosis (DVT) (n=1), intra-abdominal abscess (n=1).

19 patients (33%) underwent robotic nephrectomy for RCC with level 1 (n=1), level 2 (n=17), and level 3 (n=1) VTT. Average operative time was 283min (range=182-382) and average blood loss was 942mL (range=100-3000). Average LoS was 3.11days (range 1-8). There were no deaths within 30 days. Short-term complications include PE (n=1) and DVT (n=1). Long-term complications include pleural effusion requiring thoracentesis (n=1). All IVC reconstructions were performed by primary closure. There were 3 (15.7%) cases requiring open conversion; two for

control of the retro-hepatic IVC and one for posterior lumbar venous bleeding unable to be controlled robotically.

Postoperative imaging was completed in 12 (63.2%) of the patients undergoing a robotic procedures, at a median of 340 days postoperatively. The vena cava was patent in all studies. The median percentage of postoperative to preoperative IVC diameter was 58% (axial), and 45% (sagittal). When comparing open vs robotic procedures, the robotic approach had a shorter LoS (p-value < 0.05), less intraoperative blood loss (p-value < 0.01), and similar operative times (p-value=ns).

**Conclusion:**

Robotic nephrectomy and IVC reconstruction for RCC with level 1-3 VTT can be performed safely and effectively. The minimally invasive approach offers patients a shorter LoS, less intraoperative blood loss, and similar operative times compared to open surgery. Post-operative IVC diameter is

maintained after robotic reconstruction. Proper patient selection and robotic expertise are essential to optimize outcomes.

**Author Disclosures:** Victor Davila nothing to disclose, Kyle Rose nothing to disclose, Kate Peng nothing to disclose, Andrew Meltzer nothing to disclose, William Stone nothing to disclose, Samuel Money nothing to disclose, Erik Castle nothing to disclose

#23

## **Operative Strategies for Inferior Vena Cava Reconstruction in Oncologic Surgery**

**Colby Ruiz, MS<sup>4</sup>**<sup>1</sup>, Corey Kalbaugh, PhD<sup>2</sup>, Sydney Browder<sup>2</sup>, Katharine McGinigle, MD<sup>2</sup>, Melina Kibbe, MD<sup>2</sup>, Mark Farber, MD<sup>2</sup>, Jason Crowner, MD<sup>2</sup>, William Marston, MD<sup>2</sup>, Luigi Pascarella, MD<sup>2</sup>

<sup>1</sup>School of Medicine, University of North Carolina at Chapel Hill, <sup>2</sup>Department of Vascular Surgery, University of North Carolina at Chapel Hill

### **Objectives:**

Tumor involvement of the Inferior Vena Cava (IVC) can result from primary caval leiomyosarcoma, local invasion by retroperitoneal malignancy, or from metastases. While ligation of the IVC may be well tolerated if collateral circulation can be adequately preserved, collaterals must often be ligated during oncologic resection. Reconstruction of the IVC may be performed by primary repair, patch angioplasty, or interposition graft. The purpose of our study is to describe different strategies of IVC reconstruction at our institution and to measure outcomes associated with IVC reconstruction among patients with retroperitoneal malignancy.

**Methods:** All patients undergoing IVC reconstruction at our tertiary care hospital between November 2004 and February 2018 were identified using billing data (CPT code 34502). Patients who underwent resection of the IVC for tumor involvement were enrolled in our study and data were collected on demographics, operative intervention, type of reconstruction, postoperative course, and one-year outcomes. Patency rates were assessed by reviewing postoperative imaging including contrasted CT, MRI, ultrasound, and venogram. One-year mortality and patency were calculated using Kaplan-Meier analysis methods.

### **Results:**

We identified 52 (46% female) patients that underwent IVC reconstruction for retroperitoneal malignancy. Mean age was 53.6 years (range: 23-80). Procedures performed included primary repair (n=17, 33%), patch angioplasty (n=18, 35%), interposition grafting (n=16, 31%), or primary repair plus bypass (n=1, 2%). Mean length of stay was 16 days and did not vary significantly by group. Patients undergoing interposition graft were discharged on aspirin 81mg daily. Thirty-day survival rate was 96.2% (95% CI: 90.9-100) and 1-year survival rate was 75.1% (95% CI: 62.8-87.4). There were no intraoperative deaths. Thirty-day primary patency rate was 96% (95% CI 90.7-100.0) and one-year primary patency rate was 88.8% (95% CI: 79.4-98.2). Seven patients (14%) developed non-occlusive thrombus within the IVC. Mortality was known to be due to oncologic progression in 29% of deceased patients.

**Conclusion:** IVC reconstruction is a safe option for patients requiring IVC resection during oncologic surgery, as evidenced by one-year survival of 75% and one-year primary patency approaching 90%. Overall rate of postoperative thrombus development was low and similar across all groups. In the management of primary and secondary retroperitoneal malignancy with IVC infiltration, IVC reconstruction should be considered in order to achieve appropriate oncologic resection while minimizing possible complications from caval interruption.

Figure. Primary Patency following IVC reconstruction (N=52)

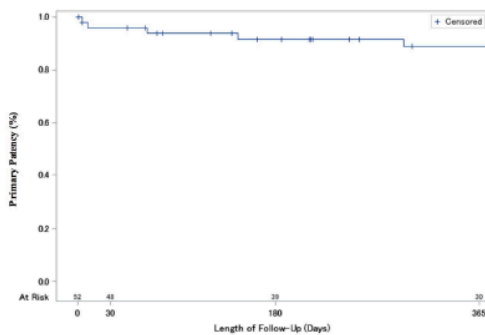
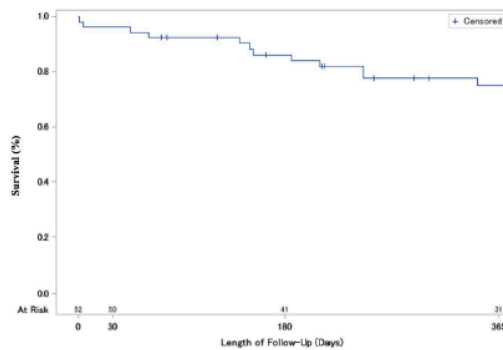


Figure. Survival following IVC reconstruction (N=52)



**Author Disclosures:** Colby Ruiz, nothing to disclose, Corey Kalbaugh nothing to disclose, Sydney Browder nothing to disclose, Katharine McGinagle nothing to disclose, Melina Kibbe nothing to disclose, Mark Farber nothing to disclose, Jason Crowner nothing to disclose, William Marston consultant Veniti, Luigi Pascarella nothing to disclose

#24

## Effect of etiology and inflow on outcomes of endovascular recanalization for nonmalignant inferior vena cava occlusion

**Aleem Mirza**<sup>1</sup>, Manju Kalra<sup>1</sup>, Newton Neidert<sup>2</sup>, Melissa Neisen<sup>2</sup>, Young Erben<sup>1</sup>, Haraldur Bjarnason<sup>2</sup>

<sup>1</sup>Vascular and Endovascular Surgery, Mayo Clinic Rochester, <sup>2</sup>Division of Vascular and Interventional Radiology, Mayo Clinic Rochester

**Objectives:** The aim of this study was to determine factors affecting outcomes of inferior vena cava (IVC) recanalization for nonmalignant obstruction, with focus on venous inflow and etiology of IVC occlusion.

### Methods:

Data from consecutive patients undergoing IVC recanalization between January 2001 to December 2017 were retrospectively reviewed. Patients were grouped by etiology of IVC obstruction, including post-thrombotic (PT), retroperitoneal fibrosis (RPF), and hypoplasia (HP). Patency of the femoral, deep femoral, and Great Saphenous veins was evaluated and the venous inflow was graded



assigning a point to each for stenosis/occlusion, for a total possible unilateral score of 3 and a composite score of 6. A score of 6 indicated no inflow stenosis/occlusion, whereas a score of 0 indicated disease of all 6 inflow veins. Primary outcomes included primary, primary assisted, and secondary patency rates.

**Results:** There were 114 patients over the 18 year period (64% male, mean age  $42 \pm 15$  years). Etiology was PT in 96 (84%), RPF in 5 (5%), and HP in 13 (11%) patients. Clinical, Etiology, Anatomy, and Pathophysiology classes included 3, 4a, 4b, 5, and 6 in 23, 17, 3, 11, and 23 patients respectively. Forty-four (38%) patients had an IVC filter, all of who had post-thrombotic etiology, and 33 (29%) had a thrombophilia. Inflow grading was 6 in 20 (18%), indicating no disease, 4 in 36 (32%), and 3 or less in 32 (30%). There was no mortality related to the procedure. Periprocedural complications occurred in 11% of patients. Median follow-up was 15.2 months (interquartile range 6.4 - 35.8, max. 141.6). Kaplan-Meier analysis of primary, primary assisted and secondary patency in the entire cohort at 1 and 5 years was 78%, 85%, 95% and 66%, 85%, 95% respectively. Early failures occurred in 12 PT, 2 HP, and 0 RPF ( $P=0.94$ ). No factors studied, including female gender, etiology of IVC occlusion or thrombophilia affected patency ( $P>0.05$ ). Median venous inflow in PT, RPF and HP was 4, 5.5, and 5 respectively. Patients with grade 0-3 had similar patency rates to those with grade 4-6 ( $P>0.05$ ). Presence of an IVC filter crushed aside during IVC stenting did not adversely affect stent patency.

**Conclusion:**

Mid-term results of endovascular recanalization are excellent regardless of the etiology of IVC occlusion. This cohort was predominantly post-thrombotic with small numbers of RPF and HP, resulting insufficient statistical power to demonstrate the effect of venous inflow on patency.

**Author Disclosures:** Aleem Mirza nothing to disclose, Manju Kalra nothing to disclose, Newton Neidert nothing to disclose, Melissa Neisen nothing to disclose, Young Erben nothing to disclose, Haraldur Bjarnasonn nothing to disclose

#25

## **Clinical Response to Combination Therapy in the Treatment of Varicose Veins**

**R. Gregory Conway**<sup>1</sup>, Jose I. Almeida<sup>2</sup>, Lowell Kabnick<sup>3</sup>, Thomas W. Wakefield<sup>4</sup>, Andrea G. Buchwald<sup>5</sup>, Brajesh K. Lal<sup>1</sup>

<sup>1</sup>University of Maryland School of Medicine, <sup>2</sup>Miami Vein Center, <sup>3</sup>Division of Vascular and Endovascular Surgery, New York University Langone Medical Center, <sup>4</sup>Section of Vascular Surgery, University of Michigan Medical School, <sup>5</sup>University of Colorado School of Public Health

**Objectives:**

Varicose vein ablation procedures are being performed with increasing frequency; however, there is a lack of consensus on the relative efficacy of combined treatment of saphenous incompetence and symptomatic varicosities versus a staged approach. In this study, we examine the impact on symptom severity when a procedure to eliminate varicosities is added to standard endovenous saphenous ablation.

**Methods:**

The American Venous Registry Varicose Vein Module was established by the American Venous Forum in 2010 and collected data from 53 physicians from 37 clinical centers over a 2-year time-period. Our analysis includes patients with CEAP C2<sub>s</sub> disease-severity and without prior treatment. Combination therapy (CT) is defined as the use of a varicosity-treating secondary procedure (stab

phlebectomy or injection of sclerosant into varicosity) in combination with endovenous saphenous vein ablation. Unimodal therapy (UT) is defined as endovenous saphenous vein ablation alone (radiofrequency or laser). Symptom severity change is assessed using the pre-treatment and 1-month follow-up Venous Clinical Severity Scores (VCSS). Bivariate statistics are calculated comparing the CT and UT groups, with p-values calculated using the Student t-test or Pearson's Chi-Square test as appropriate. A multivariable linear regression model assesses the association of CT to the change in VCSS.

#### Results:

One-thousand thirty-one patients are included for analysis (UT 478, CT 553). Unimodal therapy patients are older (35.9% were >64 years vs 20.7%;  $p<0.001$ ), more likely Caucasian (79.3% vs 65.5%;  $p<0.001$ ), have a higher initial VCSS (7.28 vs 6.15;  $p<0.001$ ), and are assessed at an earlier follow-up visit (25.9 days post-op vs 32.9 days;  $p<0.001$ ). Compared to UT, CT is associated with an additional 1-point reduction in VCSS on bivariate analysis (-3.50 points for UT vs -4.54 for CT;  $p<0.001$ , Table). Thrombotic complications are no different between the two groups (UT 1.04% vs CT 0.72%,  $p=0.58$ ). On the multivariable model, after adjustment for follow-up day, age group, ethnicity and initial VCSS, CT was associated with a reduction in VCSS of 1.07 points beyond the reduction seen in UT alone ( $p < 0.001$ ).

#### Conclusion:

Invasive treatment for C2s class chronic venous insufficiency improves symptom severity. While treatment of venous reflux is essential to address venous symptoms, our results suggest that patients further benefit from additional direct treatment of varicosities. For select patients, combined-therapy may present a more effective treatment strategy than saphenous-ablation alone.

|                             | Total<br>(N=1031) | Unimodal Therapy<br>(N=478) | Combination Therapy<br>(N=553) | P-Value              |
|-----------------------------|-------------------|-----------------------------|--------------------------------|----------------------|
| Day of Follow-up, mean (SD) | 29.7 (8.23)       | 25.9 (0.40)                 | 32.9 (6.20)                    | < 0.001 <sup>‡</sup> |
| Age (years), n (%)          |                   |                             |                                | < 0.001 <sup>*</sup> |
| <45                         | 253 (24.6)        | 85 (17.9)                   | 168 (30.4)                     |                      |
| 45 – 55                     | 221 (21.5)        | 103 (21.6)                  | 118 (21.4)                     |                      |
| 55 – 64                     | 269 (26.2)        | 117 (24.6)                  | 152 (27.5)                     |                      |
| >64                         | 285 (27.7)        | 171 (35.9)                  | 114 (20.7)                     |                      |
| Female, n (%)               | 733 (71.1)        | 342 (71.6)                  | 391 (70.7)                     | 0.766 <sup>*</sup>   |
| Caucasian, n (%)            | 741 (71.9)        | 379 (79.3)                  | 362 (65.5)                     | < 0.001 <sup>*</sup> |
| Initial VCSS, mean (SD)     | 6.68 (3.87)       | 7.28 (4.52)                 | 6.15 (3.10)                    | < 0.001 <sup>‡</sup> |
| VCSS Change, mean (SD)      | -4.06 (3.27)      | -3.50 (3.95)                | -4.54 (2.46)                   | < 0.001 <sup>‡</sup> |

\*Pearson's Chi-Square, ‡ Student T-Test

Table 1. Compared to UT, CT is associated with an additional 1-point reduction in VCSS on bivariate analysis

Author Disclosures: R. Gregory Conway nothing to disclose, Jose I. Almeida nothing to disclose, Lowell Kabnick stock options, consultant Bard & Veniti, Thomas W. Wakefield nothing to disclose, Andrea G. Buchwald nothing to disclose, Brajesh K. Lal nothing to disclose

#26

## Economic benefit of a novel dual mode ambulatory compression device for treatment of chronic venous leg ulcers

William Marston<sup>1</sup>, Robert Kirsner, Arthur Tallis, Jodi Walters, Alik Farber

<sup>1</sup>University of North Carolina

### Objectives:

Compression is critical to heal chronic venous leg ulcers (VLU). A novel dual mode ambulatory pneumatic compression device (APC) was tested in comparison to multilayered compression bandaging systems for the treatment of non-healing VLUs in a prospective randomized clinical trial (RCT).

### Methods:

Patients with VLUs measuring between 2 and 50 cm<sup>2</sup> present for 1 to 12 months were randomized to treatment with the APC (ACT group), [Actitouch; Tactile Medical] or multilayered compression bandaging (MLB) with either Profore (Smith and Nephew) or Coban 2 (3M Health Care) compression systems. Patients in the ACT group were asked to wear the device for sustained or intermittent compression throughout the day and wear a light compression stocking at night. The ACT group patients were seen every 2-3 weeks for follow-up to 16 weeks allowing more in home care. The MLB group was seen in the outpatient clinic weekly. Other aspects of VLU ulcer care were standardized between the two groups. The primary study objective was compare wound size reduction at 16 weeks between the 2 groups in a non-inferiority RCT. Secondary objectives assessed the effect of each therapy on medical resource utilization and the direct cost of care.

### Results:

Fifty-eight patients were randomized to treatment with either MLB (n=30) or ACT (n=28). Both groups experienced similar rates of wound healing during the 16-week follow-up period with ACT

group patients decreasing from  $4.01 \pm 2.4 \text{ cm}^2$  to  $1.21 \pm 2.5 \text{ cm}^2$  and MLB treated wounds decreasing from  $7.6 \pm 7.9 \text{ cm}^2$  to  $2.5 \pm 6.1 \text{ cm}^2$ . There was no significant difference between groups in the % wound closure, the incidence of complete wound healing or improvement in Venous Clinical Severity Score. ACT treated wounds had lower utilization of non-study related clinic visits compared to the MLB cohort (50.0% vs. 63.3%, respectively). In addition, there were fewer ACT scheduled patient visits without any associated complications resulting in lower direct medical costs compared to the MLB cohort (-difference (-\$2733,  $p = 0.06$ ). The trial was halted prior to full randomization to make improvements to the ACT device in order to increase patient comfort and usability, as suggested by both participating physicians and patients.

#### Conclusion:

In this preliminary RCT, a novel APC achieved similar VLU wound healing results in comparison to multilayer compression bandaging, but with lower direct costs. The study has led to important changes in device design that will allow confirmation of these findings in a larger RCT.

**Author Disclosures:** William Marston nothing to disclose, Robert Kirsner nothing to disclose, Arthur Tallis nothing to disclose, Jodi Walters nothing to disclose, Alik Farber nothing to disclose

#27

### **The impact of great saphenous vein size on gender, clinical severity, and outcome of patients undergoing vein ablation for varicose veins**

**Scott Bendix**<sup>1</sup>, Edward Peterson<sup>2</sup>, Loay Kabbani<sup>1</sup>, Mitchell Weaver<sup>1</sup>, Judith Lin<sup>1</sup>

<sup>1</sup>Vascular Surgery, Henry Ford Hospital, <sup>2</sup>Public Health Sciences, Henry Ford Hospital

**Objectives:** Policies of insurance carriers have used truncal vein size as a criteria for coverage. The objective of this study was to compare the effect of great saphenous vein (GSV) size  $\geq 5 \text{ mm}$  versus  $< 5 \text{ mm}$  on patient presentation and clinical outcomes.

#### **Methods:**

Patients in a national cohort were prospectively captured in the Vascular Quality Initiative (VQI) Varicose Vein Registry (VVR). From January 2015 to October 2017, the VQI VVR database was queried for all patients undergoing varicose vein procedures. Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification, Venous Clinical Severity Score (VCSS), and patient-reported outcomes (PROs) were compared between GSV size  $< 5 \text{ mm}$  (group 1) versus size  $\geq 5 \text{ mm}$  (group 2) before and after the procedures. Two-sample Wilcoxon test was performed to assess the difference between the two groups as defined by GSV size. To assess for improvement after procedure in this population, a matched-pairs signed-rank Wilcoxon test was performed for each group separately.

#### **Results:**

During the study period, 5757 vein ablation procedures were performed for GSV: 770 GSV size  $< 5 \text{ mm}$  and 4987 size  $\geq 5 \text{ mm}$ . Group 1 were more likely female (81.7% vs 68.4%,  $P=0.001$ ) and older age (56.8 years vs 55.6 years,  $P=0.012$ ). CEAP scores were higher in group 2 compared to group 1 ( $P=0.001$ ). Maximal GSV diameter in group 2 was significantly higher (8.32 mm vs 3.86 mm,  $P=0.001$ ). 64% of group 2 underwent RF thermal ablation compared to 59.2% of group 1 ( $P=0.001$ ). There were no mortality in either group. Group 2 had more complications post-procedure (0.6% vs 0%,  $P=0.027$ ), required post-operative anticoagulation (8.8% vs 5%,  $P=0.001$ ), developed partial recanalization rate (0.8% vs 0.3%,  $P=0.001$ ), and missed more work days (2.32 days vs 1.6 days) as compared to group 1. Similar rate of hematoma developed in both groups,

but a higher rate of paresthesia in group 1. Both groups had improvement in their VCSS and HASTI scores. The degree of symptomatic improvement between the groups was similar (table 1).

**Conclusion:**

All patients demonstrate improvement in both clinical outcomes and patient-reported outcomes after endovenous ablation regardless of size. Patients with preoperative GSV size  $\geq 5$  mm have similar improvement in their symptomatology but sustain an increased complication rate. Patients with smaller vein size should not be denied intervention or coverage based on size criteria.

Table 1.

|                   | Group 1 GSV < 5 mm | Group 2 GSV $\geq$ 5 mm | P value |
|-------------------|--------------------|-------------------------|---------|
| VCSS improvement  | 2.78               | 3.16                    | 0.833   |
| HASTI improvement | 5.61               | 5.71                    | 0.719   |

**Author Disclosures:** Scott Bendix nothing to disclose, Edward Peterson nothing to disclose, Loay Kabbani nothing to disclose, Mitchell Weaver nothing to disclose, Judith Lin nothing to disclose

#28

## **Unexpected frequency and clinical significance of non-target superficial and deep vein occlusion after foam-form sclerotherapy**

**Kirill Lobastov**<sup>1</sup>, Athena Vorontsova<sup>1</sup>, Victor Barinov<sup>1</sup>, Leonid Laberko<sup>1</sup>

<sup>1</sup>Department of General Surgery and Radiology, Pirogov Russian National Research Medical University

### **Objectives:**

Ultrasound-guided foam-form sclerotherapy (UGFS) appears to be a safe procedure associated with a low number of clinically relevant venous thromboembolism events. However, the incidence and clinical relevance of silent occlusions of deep and superficial veins that were not a target for treatment have not been carefully studied. The aim of this study was to address this knowledge gap.

**Methods:** This retrospective analysis focused on the electronic medical records (EMR) of patients treated with UGFS at a private clinic in Moscow between 2015 and 2017. In accordance with the internal protocol, all patients underwent serial duplex ultrasound (DUS) at 1–2 weeks and 1, 3, 6, 12 months after UGFS with mandatory fixation of the results in the EMR. Serial DUS was used to identify non-target venous occlusion recognized as incomplete compression of any deep and/or superficial vein not subjected for obliteration. The analysis included patients who underwent at least one DUS 1–2 weeks after UGFS.

### **Results:**

The analysis included data on 257 lower limbs of 196 patients with varicose veins (VVs): 139 women and 57 men (mean age: 44.2±12.2 years) with the following CEAP clinical class distribution: C2-74.0%, C3-20.0%, C4-4.5%, and C5-1.5%. Ultrasound-guided foam-form sclerotherapy was performed in addition to laser ablation of GSV-54.9%, SSV-10.5%, perforating veins-26.1%, Giacomini vein-3.9% or AASV-1.9%.

Non-target venous occlusion was detected in 60 limbs (23.3%) and was symptomatic only in three cases (1.2%). The majority of occlusions were localized in the untreated GSV trunk (n=23) or the calf muscle veins (n=15). Specific drug treatment was prescribed only for two patients. 91%, 66%, 37%, and 11% of all limbs were followed-up at 1, 3, 6, and 12 months respectively. There were no cases of thrombus progression or symptomatic pulmonary embolism. At six months, no occlusions

persisted. Recurrence of VVs at 12 months was noted in 16 cases (6.2%) by DUS. There were no differences between limbs as a function of occlusions (10.0% vs. 5.1%,  $p=0.218$ ).

**Conclusion:** The frequency of non-target vein occlusion after UGFS revealed by serial DUS may be as high as 23.3%. These occlusions tend to resolve by 6 months and do not affect clinical outcomes.

**Author Disclosures:** Kirill Lobastov nothing to disclose, Athena Vorontsova nothing to disclose, Victor Barinov nothing to disclose, Leonid Laberko nothing to disclose

#29

### **Early results of a randomized clinical trial of mechanochemical ablation versus cyanoacrylate adhesive for the treatment of varicose veins (MOCCA)**

Amjad Belramman<sup>1</sup>, Roshan Bootun<sup>1</sup>, Tjun Yip Tang<sup>2</sup>, **Tristan R A Lane**<sup>1</sup>, Alun H Davies<sup>1</sup>

<sup>1</sup>Section of Vascular Surgery, Imperial College London, <sup>2</sup>Singapore General Hospital

#### **Objectives:**

Endovenous thermal ablation techniques have become the first line treatment of truncal veins. However, these techniques use heat and have need of tumescent anesthesia which are often associated with pain. To overcome these side effects, novel non-thermal techniques such as mechanochemical ablation (MOCA) and cyanoacrylate embolization (CAE) have been developed; these do not require tumescence nor use heat. This randomized control trial is aimed at assessing the degree of pain resulting from MOCA compared with CAE. We are herein reporting the early results of this randomized clinical trial.

#### **Methods:**

Patients with saphenous vein incompetence were randomized to receive treatment with either MOCA or CAE. The primary end point is pain score immediately following completion of truncal ablation, measured by a 100mm visual analogue scale (VAS). The secondary end points include entire treatment pain scores, clinical scores and quality of life scores. Additional assessments also include ecchymosis scores, occlusion rates, time to return to usual activities/work at two weeks. Patients are reviewed at 2 weeks, 3 months, 6 months and 12 months.

#### **Results:**

Eighty-four patients have been recruited so far (66% women with mean age 56 years). The vein treated was the great saphenous vein (GSV) in 86% of cases and 51% of the cases were randomized to cyanoacrylate ablation. Both groups had similar baseline characteristics. Patients in both groups experienced similar maximum pain score by VAS (CAE median 24 mm (IQR 9-45) versus MOCA median 23 mm (IQR 11-49);  $p = 0.464$ ) and number scale (CAE median 3 (IQR 1-5) versus MOCA median 3 (IQR 2-5);  $p = 0.333$ ). Average pain score was also similar between treatment groups. Eighty-three percent (70 patients) of population attended the 2-week follow-up. Post-procedure ecchymosis score, recovery time, clinical and quality of life scores were similar between groups.

#### **Conclusion:**

The early results of this trial showed that pain score is comparable between CAE and MOCA endovenous ablation. The results also indicated similar improvement in quality of life, clinical

improvement and recovery time. Recruitment of patients is ongoing, and longer-term follow-up data are currently being collected.

**Author Disclosures:** Amjad Belramman nothing to disclose, Roshan Bootun nothing to disclose Tjun Yip Tang nothing to disclose, Tristan R A Lane nothing to disclose, Alun H Davies nothing to disclose

#30

## **Diagnosis and therapy of vein insufficiency in children**

**Johann Chris Ragg<sup>1</sup>**

<sup>1</sup>interventional phlebology, angioclinic vein centers

**Objectives:** Venous insufficiency of the lower extremities is usually regarded to be a genetically determined, long-term acquired disease. Children have rarely been examined.

**Methods:** In an ongoing study, until 5/2018 a total of 170 legs in 85 children of angioclinic vein patients, aged 6 – 18 (38 m, 47 f) were examined with high frequency ultrasound (Siemens X 700, Mindray M9, 14-16 MHz; Vevo MD, 16 – 32 MHz). Investigation time was limited to 15 minutes. In case of visible vein changes (protruding, more intense colour, increased diameter), ultrasound started here. Otherwise, systematic screening of saphenous veins and medial perforators was performed.

### **Results:**

In 47/85 children (55.3%), resp. 59/170 legs (34.7%) relevant venous pathology was found. Focal valvular defects of the GSV: 14/170 (8.2%), segmental GSV reflux without varices: 15/170 (8.8%), same but with varices: 11/170 (6.5%), GSV sidebranch reflux only: 13/170 (7.6%), total GSV reflux 3/170 (1.8%), focal SSV valve lesion: 2/170 (1.2%), segmental SSV reflux: 1/170, 0.6%, medial perforator reflux: None. In the subgroup of 6-8 y/o kids, 9/30 legs (30.0%) already showed pathology (Fig. 1). Among the cases allowing diagnosis of lesion type (n = 53), unilateral commissural mismatch was the most frequent pattern (24/53, 45.3%). While some findings may be treated at a suitable age (14 – 18) with today's methods (side branches: microfoam, saphenous: thermal, MOCA, biomatrix foam), vein saving methods are still missing for single valve insufficiency and stages prior to clinical reflux.

**Conclusion:** The unexpected high incidence of detected valve lesions in children, in particular in the younger ones, should be best explained by congenital disease. It is a merit of today's ultrasound systems that these lesions now can be detected. New strategies for systematic early detection, coaching and cost-effective therapy have now to be developed.

**Author Disclosures:** Johann Chris Ragg nothing to disclose

#31



## **Clinical effectiveness of MOCA versus RF for symptomatic Great or Small Saphenous Vein Reflux**

Aditya Gupta<sup>1</sup>, Eddie Fernandez<sup>1</sup>, Sanjiv Lakhanpal<sup>1</sup>, **Peter Pappas<sup>1</sup>**

<sup>1</sup>Center For Vein Restoration

### **Objectives:**

Mechanochemical ablation (MOCA) is a non-thermal technology approved by the Food and Drug Administration (FDA) for the delivery of sclerosing agents to treat symptomatic saphenous vein reflux. Although the technology is considered durable, its effectiveness compared to radiofrequency ablation (RF) in the Great and Small Saphenous Veins (GSV/SSV) is ill defined.

**Methods:** Data were prospectively collected in the Center for Vein Restoration's (CVR) electronic medical record system (NexGen Healthcare Information System, Irvine, California) and retrospectively analyzed. Patients were divided into the following treatment categories and stratified by CEAP class: MOCA GSV, MOCA SSV, RF GSV and RF SSV. The revised venous clinical severity score (rVCSS) was utilized to determine CVD treatment effectiveness in patients who underwent RF and MOCA only in the GSV or SSV distributions. Patients with multiple treatment modalities were excluded from the analysis. In addition, the CIVIQ 20 was utilized to assess quality of life pre and post intervention at one month. All statistical analyses were performed utilizing Graphpad Prism 7 (GraphPad Software Inc, La Jolla, California ). Treatment outcomes were assessed utilizing unpaired t-tests and two way analysis of variance.

**Results:** From January 2015 to December 2017, 21,383 patients (34,014 limbs) underwent thermal or MOCA procedures for their chronic venous disease (CVD). The average age of the cohort was 57.1±14.04 and 73% were female. Patients/limbs were divided into the following groups: MOCA GSV (342/545), MOCA SSV (41/62), RF GSV(15,069/25,153) and RF SSV(1,450/2087). Pre and post rVCSS and CIVIQ 20 data were analyzed at one month. All post rVCSS outcomes for RF in the GSV or SSV demonstrated significant improvement compared to pre intervention scores regardless of CEAP class ( $p \leq 0.001$ ). Patients treated with MOCA demonstrated improvement in all CEAP classes except for C5 MOCA GSV patients and C6 MOCA SSV patients ( $p \leq 0.001$ ). CIVIQ 20 scores at one month were similar regardless of treatment modality or treatment outcome. CIVIQ 20 scores ranged from 50 pre intervention to 35 post intervention at one month.

**Conclusion:** MOCA appears to be as effective as RF in the GSV across CEAP class. By rVCSS, MOCA may not be as effective as RF in patients with C5 and C6 disease in the GSV and SSV distribution respectively. However, patient reported outcomes between treatment modalities are similar. MOCA in the SSV appears safe. Further assessment and long term data is required.

**Author Disclosures:** Aditya Gupta nothing to disclose, Eddie Fernandez nothing to disclose, Sanjiv Lakhanpal nothing to disclose, Peter Pappas nothing to disclose

## **Explanted Saphenous Vein Histopathology 5.5 Years After Cyanoacrylate Closure: A Case Study**

**Jose Almeida**<sup>1,2</sup>, Stephen Murray<sup>3</sup>

<sup>1</sup>Vascular Surgery, Miami Vein, <sup>2</sup>Division of Vascular and Endovascular Surgery, University of Miami Miller School of Medicine, <sup>3</sup>Vascular Surgery, Providence Vascular Institute

### **Objectives:**

VenaSeal cyanoacrylate closure (CAC) requires implantation of a device, not a drug. This case reports on the histopathology on an explanted segment of a great saphenous vein (GSV) treated 5.5 years prior with CAC, and compares to an untreated control segment.

### **Methods:**

A segment of left GSV from a 65-year-old male 5.5 years after CAC was localized with duplex ultrasound and surgically excised at mid-thigh; an untreated control segment was excised from mid-calf.

### **Results:**

The vessel was non-palpable. Ultrasound demonstrated echo-dense vessel with no venous flow. Microscopically, the segments demonstrated lumen filled by collagenized mature fibrous tissue and remnants of polymer material. Histopathology examination revealed CA encapsulated by multinucleated giant cells and chronic granulomatous inflammation within the vein wall, and focally extending to the adventitial layer. The control vein exhibits thickening of the medial wall consistent with chronic reflux pathophysiology.

### **Conclusion:**

These findings demonstrate the presence of cyanoacrylate implant in a GSV treated 5.5 years prior. The CA is intermittently dispersed throughout the vein as well as encapsulated by multinucleated giant cells and chronic granulomatous inflammation.

**Author Disclosures:** Jose Almeida nothing to disclose, Stephen Murray nothing to disclose

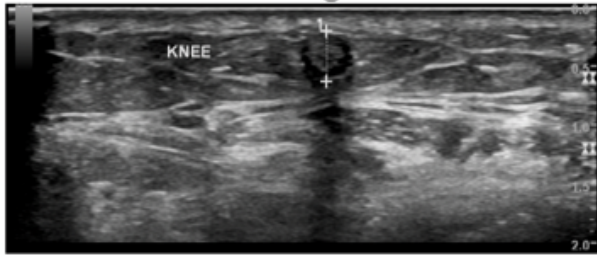


Figure 1. Ultrasound demonstrated echo-dense vessel with no venous flow.

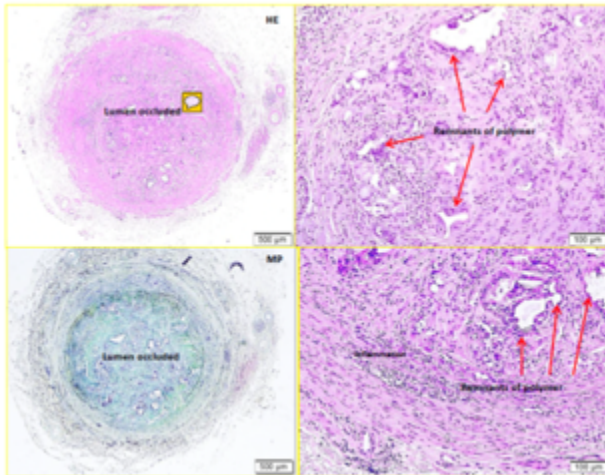


Figure 2. Microscopic and Histopathologic examinations of the explanted saphenous vein.

Author Disclosures: Jose Almeida nothing to disclose, Stephen Murray nothing to disclose

### #33

## Contemporary Trends in the Treatment Types and Costs of Lower Extremity Superficial Venous Disease

Nathan Itoga<sup>1</sup>, Elizabeth George<sup>1</sup>, Celine Deslarzes-Dubuis<sup>1</sup>, Kara Rothenberg<sup>1</sup>, John Harris<sup>1</sup>

<sup>1</sup>Surgery, Stanford University

**Objectives:** The treatment of lower extremity superficial venous disease has evolved from purely open procedures to less invasive procedures with innovation and advances in technology. The purpose of this study was to evaluate the contemporary trends in the treatment type and treatment related costs for superficial venous disease.

**Methods:** Using the Marketscan Truven Database, a comprehensive database of all private insurance claims in the United States, we investigated the treatment of lower extremity venous insufficiency from 2007 - 2016. We extracted CPT codes from the outpatient claims file and classified treatment into five categories: sclerotherapy, laser ablation, radiofrequency ablation, stab phlebectomy, and open venous ligation/ stripping. We used multivariate regression to evaluate patient characteristics and physician specialty as it related to treatment reimbursements.

### Results:

From 2007-16 we identified 448,051 patients who underwent 1,301,565 procedures for lower extremity superficial venous disease. The average (mean  $\pm$  SD) number of procedures per patient was  $3.33 \pm 3.56$ , with a median of 2 procedures per patient (interquartile range 1-4). The volume of each type of procedure by year is depicted in Figure 1. Sclerotherapy consistently had the highest procedure volume followed by laser ablation. All procedure types saw a decline in volume following a peak in 2012; however, open venous ligation started to see waning volumes beginning in 2010. This decrease in volume corresponded with a decrease in the overall annual total cost of treatment; down to \$157 million in 2016 from its peak of \$297 million in 2012. The average payment per patient per year continued to rise by over \$1,000 from \$3,203 in 2007 to \$4,280 in 2016. When analyzing physician specialty, compared to radiologists, cardiologists were associated with a \$733 decrease in payment per patient, and vascular surgeons were associated with a \$163 decrease in payment per patient.

### Conclusion:

The treatment for lower extremity venous insufficiency continues to evolve and favor less invasive open procedures. Although the overall number of procedures for superficial venous disease decreased in patients with private insurance, the average payments per patient has continued to increase indicating physicians continue to maximize reimbursements. Further work is needed to evaluate the efficacy of procedural reimbursements, especially in the setting of repeat procedures.

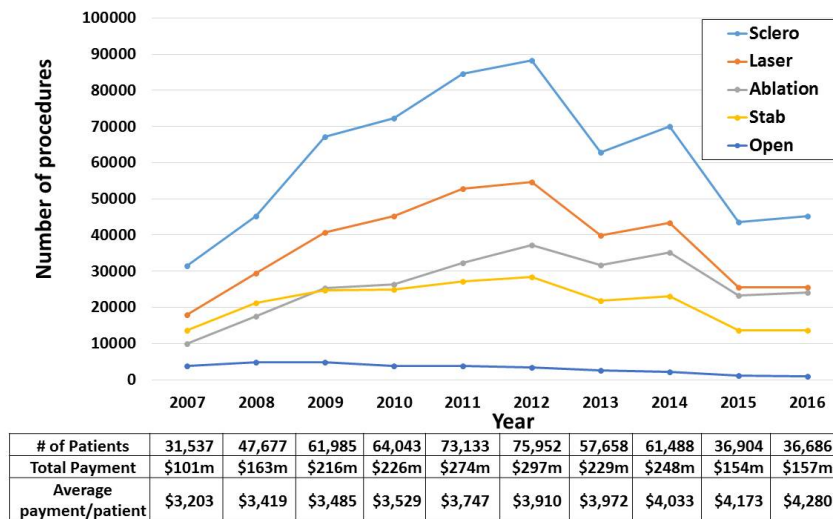


Figure 1. The volume of each type of procedure by year with payment information.

Author Disclosures: Nathan Itoga nothing to disclose, Elizabeth George nothing to disclose, Celine Deslarzes-Dubuis nothing to disclose, Kara Rothenberg nothing to disclose, John Harris nothing to disclose

#34

## The Location of Reflux in the Saphenous Vein does not Impact the Outcomes of Vein Ablation

Afsha Aurshina<sup>1</sup>, Jonathan Cardella<sup>2</sup>, Kristine Orion<sup>2</sup>, Bauer Sumpio<sup>2</sup>, Haoran Zhou<sup>3</sup>, Yawei Zhang<sup>3</sup>, Alan Dardik<sup>2</sup>, **Cassius Iyad Ochoa Chaar**<sup>2</sup>

<sup>1</sup>General Surgery, Yale University School of Medicine, <sup>2</sup>Vascular Surgery, Yale University School of Medicine, <sup>3</sup>Yale University School of Public Health

### Objectives:

Varicose veins are commonly caused by valvular reflux in the saphenous vein. Most insurance companies approve venous ablation (VA) for treatment of junctional reflux only and deny therapy for symptomatic patients with significant reflux below the junction of the saphenous vein with the deep system. We hypothesize that there is no difference in outcomes of VA between patients treated for junctional reflux and patients treated for reflux below the junction with the deep system.

### Methods:

A retrospective single center review of consecutive patients undergoing VA using radiofrequency in an outpatient office was performed from 2012-2016. Patients' electronic medical records were reviewed for characteristics, imaging, and outcomes. A telephone survey inquiring about intensity of symptoms on a numeric rating scale (NRS) 0-10 prior and after treatment was also conducted. Patients were divided based on the location of reflux at the saphenofemoral/saphenopopliteal junction or below the junction. Patient characteristics and outcomes were compared between the 2 groups. Clinical success was defined by improvement or resolution of symptoms. Technical success was defined by vein closure on duplex ultrasound.

### Results:

There were 265 patients (Junctional reflux = 224 (84.5%) vs reflux below junction = 41 (15.5%)) who underwent VA of 343 veins. The mean age of the patient population was  $58.8 \pm 15$ . There was no difference in age ( $P=.59$ ), sex ( $P=.61$ ), or race ( $P=.88$ ) between the groups. Patients with junctional reflux were

significantly more likely to undergo bilateral treatment (A = 33.3% vs B= 12.2%, P=.006). There was no difference in CEAP score (P=0.67), laterality (P=0.66) or type of vein treated (P=0.59). (Table 1) On ultrasound, veins with junctional reflux were noted to have significantly larger diameters (P=0.004), however veins with reflux below the junction had higher reflux time (P<.0001). The clinical success (P=0.98), technical success (P=0.12), and complications (P=0.29) were not different between groups. The survey results demonstrated no difference in improvement in pain (P=0.24) or swelling (P=0.07) and recurrence in pain (P=0.32) or swelling (P=0.84) after 2 years. (Table 2)

#### Conclusion:

The location of reflux in the saphenous vein does not impact patient presentation or outcomes of VA. Absence of junctional reflux should not be used by insurance companies as a criterion for denial of VA

**Author Disclosures:** Afsha Aurshina nothing to disclose, Jonathan Cardella nothing to disclose, Kristine Orion nothing to disclose, Bauer Sumpio nothing to disclose, Haoran Zhou nothing to disclose, Yawei Zhang nothing to disclose, Alan Dardik nothing to disclose, Cassius Iyad nothing to disclose, Ochoa Chaar nothing to disclose,

## #35

### Segmental saphenous ablation for chronic venous disease management

**Sergio Giancesini<sup>1</sup>**, Erica Menegatti, Savino Occhionorelli, Maria Grazia Sibilla, Jacopo Salviato, Paolo Zamboni

<sup>1</sup>University of Ferrara

#### Objectives:

Endovenous thermal ablation for chronic venous disease (CVD) treatment is recommended over traditional surgery by international guidelines.

Nevertheless, the indication is associated with its mini-invasiveness rather than with the recurrence rate, which remains the same despite the constant technical evolution of the different devices.

Indeed, the strategy remains the same ablative one of the surgical stripping. In a 2015 Cochrane analysis, venous hemodynamics application in a saphenous sparing strategy was associated to a decreased recurrence rate compared to the traditional stripping.

Aim of the present investigation is to assess the safety and efficacy of a 6 cm endovenous segmental ablation of the sapheno-femoral junction in a saphenous sparing strategy.

#### Methods:

Eighty-five lower limbs of 79 patients (mean age 55±10; 30/49 M/F) affected by CVD (C3EpAsPr) were included.

All the patients underwent a 6 cm great saphenous vein (GSV) ablation distal to the superficial epigastric vein confluence. Of these patients, 41 were operated on by radiofrequency (ClosureFAST™) and 38 patients by laser (LASEmaR 1500®).

The procedure was indicated in case of terminal valve incompetence with presence of a re-entry perforator along the GSV.

Incompetent tributaries along the leg were flush ligated.

Follow up was performed at 1 year by clinical and ultrasound evaluation. Venous Clinical Severity Score (VCSS) and Aberdeen Varicose Vein Questionnaire (AVVQ) were filled in before the procedure and at 1 year.

#### Results:

At 12±1 months mean follow up a recanalization was recorded in 5/85 (5.8%) cases (2 radiofrequencies, 3 lasers), of which just 2 (1 radiofrequency, 1 laser) showed also a reflux recurrence. No significant

differences in recurrence rate were reported in the comparison between radiofrequency and laser. AVVQ improved from  $18.0 \pm 4.1$  to  $4.7 \pm 3.0$  in the radiofrequency group and from  $17.4 \pm 4.6$  to  $3.9 \pm 2.0$  in the LASER-group ( $p < 0.0001$ ). VCSS improved from  $6.9 \pm 0.8$  to  $2.0 \pm 1.5$  in the radiofrequency group and from  $7.0 \pm 0.9$  to  $2.6 \pm 1.6$  in the laser group ( $p < 0.0001$ ). No significant differences between the radiofrequency and laser groups were reported in the AVVQ and VCSS post-operative variation. No significant complications were reported.

#### Conclusion:

A 6 cm segmental GSV shrinkage is safe and feasible, both by radiofrequency and 1470 nm laser, without significant differences between the two devices. One-year follow up reports a recurrence rate that is competitive with the traditional ablation of all the GSV trunk, paving the way for innovations both in technology and in strategy.

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#36

## **Venous Diameters, Clinical Severity and Quality of Life &ndash; Does Size Really Matter?**

Matthew Tan<sup>1</sup>, Sharon Sutanto<sup>1</sup>, Sarah Onida<sup>1</sup>, **Alun Davies<sup>1</sup>**

<sup>1</sup>Imperial College London

#### Objectives:

Chronic venous disease (CVD) leads to a significant impact on health-related quality of life (HRQoL). Truncal vein diameter is often recorded as part of the duplex ultrasound assessment, and has been used as a measure to ration interventions. Studies have correlated truncal vein diameter to clinical severity and HRQoL scores in small populations, but the relationship is currently unclear. A review is required to synthesise the evidence regarding these relationships to better inform CVD management.

#### Methods:

A systematic review was performed. Medline and EMBASE databases were searched from 1946 to 31<sup>st</sup> August 2018. Reference lists of included studies were also searched to identify relevant papers. Database searches, title, abstract and full text screens, and reference searches were performed by two independent reviewers. Full text studies in English reporting on the relationship between great and small saphenous vein diameters and clinical severity and/or HRQoL scores as measured using validated instruments were included. Non-English studies, papers only reporting on duplex findings, clinical severity or HRQoL without assessing their relationship, and papers focusing on non-truncal superficial veins were excluded.

#### Results:

11 eligible studies were identified, reporting on a total of 2,732 symptomatic limbs with C0-1 disease and limbs with C2-6 disease (range 22-681). Four studies reported correlations between truncal vein diameter and both clinical severity and HRQoL, while seven reported the relationship with clinical severity only. Multiple validated classification systems and instruments were used for both HRQoL (AVVQ, CIVIQ, VEINES-QoL/Sym, VVSymQ) and clinical severity (CEAP, VCSS). Seven studies reported correlations between vein diameters and CEAP stage, with the majority of studies observing a trend of increasing diameter with increasing clinical severity. Weak correlations were observed in four studies between

diameters and VCSS, with one study reporting correlations to individual components of the VCSS. However, no significant relationship between truncal diameters and HRQoL scores was reported in any study included in this review.

**Conclusion:**

While more studies are required to improve the available evidence, included studies suggest that truncal vein diameter correlates to disease severity. Truncal diameters appear to be a weak predictor of HRQoL and have no relationship to patients' perceived impact of CVD. As such, vein diameter should not be used as a measure to decide who needs venous intervention.

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