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NEWSLETTER

Compression Issue

February 2020 | [veinforum.org](#)

HERBAL REMEDIES FOR CHRONIC VENOUS INSUFFICIENCY – ALMOST THERE

Edgar Guzman, MD



Edgar Guzman, MD

Given the high prevalence and worldwide distribution of chronic venous insufficiency it is not surprising that diverse herbal agents have been proposed as potential therapies for this condition. As is the case with most herbal agents, proving efficacy, identifying the active principle(s) and standardizing dosages has been challenging.



Within this field two agents stand apart: diosmin, a citrus peel derived flavonoid and escin obtained from horse chestnut seeds. Both have been the subject of mechanistic studies exploring their mode of action as well as clinical trials shedding light on their utility. In contrast, ginkgo biloba, gotu kola, grape seeds, pine bark and butcher's broom lack the same level of scrutiny and for the most part have yielded negative clinical data.

The majority of the literature exploring the effects of diosmin utilized a preparation of micronized purified flavonoid fraction (MPFF) yielding 90% diosmin; administered at a dose of 500 mg/bid. In Europe, this preparation has long been commercialized under the brand name Daflon.

In the United States, diosmin is commercially available as Vasculera (diosmiplex 630mg/day). This preparation contains 600 mg of 95% MPFF. Once a day dosing is justified by the 32 hour half life of diosmin. In addition, diosmiplex contains 30 mg of Alka4-complex, a proprietary blend of magnesium



hydroxide, potassium chloride and potassium hydroxide in a matrix of calcium carbonate and cellulose. This compound offers delayed alcalinization in an acidic environment, which may prevent neutralization in the stomach and allow better systemic absorption. It is hypothesized that Alka4-complex may improve absorption of

diosmin and improve the pH of diseased veins. Pertinent studies testing these claims are being developed.

Although these preparations are different, extrapolating results seems reasonable given that the



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Edgar Guzman, MD



active ingredient is the same and doses are relatively similar. Per personal communication with medical advisors to the manufacturer, Vasculera dosing may be safely doubled to twice a day frequency. The effect of alkalinizing agents on venous disease is unproven to the best of my knowledge. I remain skeptical that miligram doses of alkaline agents have

meaningful effects on the body's pH buffering mechanisms and therefore, would not consider the addition of Alka4-complex to be a factor in creating diverging clinical results between the two preparations.

Diosmin has been shown to decrease capillary permeability and increase capillary resistance, at least in part by inhibition of leukocyte adhesion, activation and migration via reduction of VCAM-1 and ICAM-1 expression. These actions have been correlated with preservation of venous endothelium and valvular structures. Improvements in lymphatic transport have also been documented.¹



Meta-analysis exploring the effect of diosmin on venous ulcer healing concluded that addition of this drug to compression yielded a 32% increase in the likelihood of ulcer resolution at 6 months, shortening the average healing time from 21 to 16 weeks.² In addition, diosmin has also proven helpful in the management edema

and leg discomfort in less severe stages of venous insufficiency. Both the International European Society for Vascular Surgery and the American Working Group for Chronic Venous Disease have recommended the use of diosmin for venous ulcer healing and symptom control.³



Escin is widely available as horse chestnut seed extract (300mg, standardized to 20% escin BID). It has been experimentally shown to induce calcium dependent saphenous vein contraction ex-vivo.⁴ It also inhibits elastase and hyaluronidase activity as well as leukocyte activation.⁵

In clinical practice escin has failed to show effectiveness in enhancing venous ulcer healing. Horse chestnut extracts have been the object of multiple Cochrane

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reviews concluding that this preparation is efficacious and safe in the treatment of edema, pain and pruritus.⁶ The level of effectiveness has been likened to that of graded compression stockings.

With growing awareness and use it is likely that diosmin and escin will prove to be useful adjuncts in the management of chronic venous insufficiency. Preparations of both agents are available in the US with easy access and affordability at a cost of less than \$50 per month. Diosmin offers a broader spectrum of clinical application and has been more extensively investigated than escin. It appears to have an excellent safety profile with three decades of use in European markets and several negative animal toxicology studies.



While the optimal dosage and role of diosmin within current multi modality venous therapy remains to be determined, the literature supports its benefits in ulcer healing. Use in this setting, specially when standard measures have failed, seems like a reasonable point for our community to gain experience with this compound.



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VTE RISK ASSESSMENT AND THE LOST ART OF THE HISTORY AND PHYSICAL

Joseph A. Caprini, MD, MS, FACS, RVT, DFSVS



Joseph A. Caprini, MD, MS, FACS, RVT, DFSVS

Many years ago when I was a student and surgical resident we spent a great deal of time perfecting our history-taking and physical exam skills. In those days these skills were essential for best patient care since we had no ultrasound, CT scans, or MRI exams available. It is not surprising that when becoming interested in thrombosis prophylaxis, I searched the literature looking for all reasons why people developed venous thrombosis and created a list of historical and physical factors associated with the development of venous thromboembolism (VTE). My colleagues and I then conducted a literature review to find appropriate clinical trial data to substantiate each item on the list. We discovered that the relative risk of VTE was different depending on the number and type of risk factors involved. For example, past VTE or active cancer has a much greater effect on VTE incidence than does obesity, age, or swollen legs. Additional literature suggested that the same risk factor may have different levels of power associated with VTE. Age represents one of those variables -- as age increases so does the VTE rate.



This led to assigning a relative risk score to each factor depending on the incidence of VTE found in prospective clinical trials. As one might expect, further research revealed that the more risk factors present, the greater was the risk of VTE. Putting all of this information together, a risk score was calculated to indicate the relative likelihood of an individual patient developing VTE. The score allowed prophylaxis to be tailored to the individual to obtain the best balance between efficacy and safety. Patients with low scores can receive physical methods of prophylaxis which are effective but have no bleeding risk. Higher-risk patients should receive heparin or low molecular weight heparin (LMWH), which have been shown to significantly reduce the VTE rate, and cut the death rate from fatal pulmonary emboli (PE) in half compared to placebo.

The highest-risk patients should receive a combination of physical and pharmacologic methods which have been shown to reduce the VTE rate to < 2% in studies over the past 25 years. Literature has also demonstrated that the length of prophylaxis, timing of the first dose, and selection of anticoagulant can be tailored according to the level of risk.

The Caprini score utilizes all of the above principles to calculate the individual's VTE risk and recommend a prophylaxis regime unique to each patient. The key element is a thorough history and physical including 37 elements. This results in a risk profile for that patient that one could term "thrombosis risk baggage". The

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Joseph A. Caprini, MD, MS, FACS, RVT, DFSVS

total risk of the patient is based on combining the baggage with the inherent risk of the operation based on complexity.¹

Completion of this score can be done using an app (Caprini DVT) available for IPHONE and Android platforms. A patient friendly form has been developed and is verified by the person responsible for the admitting history and physical preoperatively. Certain patient data can be automatically gathered in the EMR, and using the patient portal the patient can input personal data including family history of thrombosis and other past medical problems. We plan to develop software to interview the patient by phone prior to the procedure and automatically enter the data into the EMR. Using these tools hopefully will decrease the incidence of fatal postoperative pulmonary emboli.

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USE OF COMPRESSION STOCKINGS PRIOR TO SUPERFICIAL ENDOVENOUS ABLATIONS



Alessandra Puggioni, MD

What is the Evidence for the 3-month Compression Stocking Trial Insurance Requirement? Alessandra Puggioni, MD

In the past two decades there has been a substantial evolution of venous interventions and an unparalleled increase in the number of ablations performed, thanks to the associated low morbidity and high success rate of minimally invasive procedures compared to open surgery. This exponential growth has led health insurance companies to a trend of constantly adding various obstacles that block patients' paths to these effective treatments. The most common requirement by Medicare and the major private insurance payers is a trial of up to 3 months of compression stockings before authorization of invasive venous therapies can be granted.



Whereas compression stockings are effective at controlling venous hypertension and alleviating its symptoms, venous ablations can directly correct pathologic superficial venous reflux.

The 2011 clinical practice guidelines document of the SVS and AVF lead by P. Gloviczki¹ suggested compression therapy for patients with symptomatic varicose veins (GRADE 2C), but recommended against compression therapy as the primary treatment if the patient is a candidate for saphenous ablation (GRADE 1B). The document clearly pointed out that there is no scientific evidence to support a trial of compression treatment before any intervention for simple varicose veins when saphenous ablation is both more efficacious and cost-effective, as supported by existing clinical evidence.

The role of compression in the era of endovenous interventions and wound care centers was discussed in a comprehensive review article by S. Raju, F. Lurie and T. O'Donnell.² These authors also agreed that while stockings are an appropriate initial treatment for edema and pain associated with CVI, there is no firm evidence that they have any prophylactic value to prevent or reduce varices and skin complications such as hyperpigmentation or lipodermatosclerosis. Compression alone is effective at healing venous ulcers in 60-90% of the cases, but 50% of those ulcers ultimately recur. Saphenous stripping/ligation plus compression has been proven by many studies to yield better long-term results in terms of recurrence than compression alone.

Unfortunately, non-compliance with stockings is high and ranges from approximately 30% to 80%. In about 40% of the cases there are compelling obstacles to wearing stockings such as obesity, frailty, arthritis, cellulitis, PVD, and a trial of compression is often extremely difficult or inappropriate. In the remaining 60% of cases there are no compelling reasons for not wearing

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What is the Evidence for the 3-month Compression Stocking Trial Insurance Requirement? Alessandra Puggioni, MD

stockings other than discomfort as compression is felt by some patients to actually negatively affect their quality of life.



The efficacy of treating venous ulcers with or without early venous ablations was evaluated in a prospective randomized trial (the EVRA RCT) across 20 centers in the UK.³ The study included 450 patients randomized to either early endovenous ablation within 2 weeks or deferred intervention performed once the ulcer healed with compression or after 6 months of conservative therapy. The trial showed that early endovenous interventions were associated with faster ulcer healing and longer ulcer-free time over one-year post randomization.

Another retrospective study followed 44,026 patients for a 2-year period undergoing early or late venous interventions and using compression stockings.⁴ They found early interventions were associated with lower CVI progression (29.2% vs. 42.5%, $P < .05$) and that delays of at least 8 months carry a significantly higher treatment-related cost per venous disease patient (\$4,445 versus \$17,564). It was estimated that each month of delay in interventional treatment was associated with a 7% higher risk of disease worsening and 1% overall increase in cost; both were statistically significant.

These reports support the notion that when dealing with a patient with chronic venous insufficiency (CVI) it is very important to identify beforehand if invasive treatments are indicated. An early discussion on minimally invasive venous interventions sets realistic patients' expectations, and it empowers them to make educated health decisions on how to control and prevent further progression of

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What is the Evidence for the 3-month Compression Stocking Trial Insurance Requirement? Alessandra Puggioni, MD



symptoms of venous insufficiency. A prompt multimodality treatment allows patients to return to normal function as soon as possible, especially in the presence of severe manifestations of CVI such as venous ulcers.

Delay in treatment may lead to extended periods of impaired quality of life due to leg pain, infections and ulcers which may also require hospitalization and an associated

increase in the mean total cost per treatment per patient.

While we all remain concerned about the ethical dilemma of “venous interventions inappropriateness”, the medical insurance companies have already been ahead of the game for quite some time. Demanding that we convince our well-educated, internet-savvy patients to wear medical grade compression stockings for up to 3 months -a practice without any convincing scientific merit⁵ - before becoming eligible to superficial venous interventions may delay treatment and cost more money and quality time to the patients.

It seems to me that not only we have lost control of ethics in the treatment of venous disease, we have also lost control of our ability to deliver prompt, quality care for it.

How do we justify in our daily practices recommending a trial of compression stockings for CVI when such trial is not evidence-based and of unproven efficacy? Fortunately, minimally invasive treatments for CVI are available, and hopefully they will be appropriately offered and performed without delays, to patients' benefit.

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PHILIPS INTRODUCES A NEW FELLOWSHIP CASE SUBMISSION PROGRAM



Denysse Castaneda
Philips Global Product
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Denysse Castaneda, Philips Global Product Marketing Manager

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- Submission deadline is April 31, 2020 at 4pm PST
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Susan Emanuele, Fellowship Engagement Strategy North America, comments "It is critical for fellows to understand new technology and treatment options for a holistic approach. This is all about the patient and knowing what to do at the right moment." Paul Khait, Head of Global Training, Education, & Market Enablement, adds "Investing in these next-generation leaders in cardiac and vascular specialists is one of our strategic imperatives within Image Guided Therapy Devices."

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A NEW MODEL FOR IMPROVED LYMPHEDEMA CARE



Robyn A Smith, M.Ed.,
COTA/L, CLWT, CLT, LASH-
FKT

Robyn A Smith, M.Ed., COTA/L, CLWT, CLT, LASH-FKT

Compete Decongestive Physiotherapy (CDP) is the Gold Standard of Lymphedema Care. However, it was developed based on single-payer, governmental health care. Utilization of this treatment model in United States therapy-- where reimbursement differs widely--leads to challenges in providing efficacious lymphedema management. The European Model utilizes therapy up to 3 sessions daily, 6-7 days per week which is not feasible in the United States. Short Stretch Bandaging (SSB) is specified for compression; SSB has been shown to lose 50% of compression levels in the first 2 hours of wear. This loss of compression is moot in the European patient as they will return to have bandages re-applied multiple times throughout the day/week. In contrast, the U.S. lymphedema patients are being seen 2-3 visits per week. These patients would only be in correct compression levels 4-6 hrs. per week.

The Americas Model-CDP™ (AmCDP), a new model of lymphedema management, is currently being used in two studies showing increased efficacy for patients. With AmCDP, utilization of Adjustable Velcro Wraps replaces SSB along with adding Intermittent Pneumatic Compression (Pumps) as adjunct to the treatment provided by a Certified Lymphedema Therapist (CLT) allows outcomes to mimic the success of the European Model, all within the U.S. reimbursement structure. AmCDP provides a 3-fold win situation for Patient-Provider-Payer.



Additional information on The Americas Model-CDP studies can be accessed at www.researchgate.com.

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WHAT'S NEW IN COMPRESSION? IMPROVED THERAPY COMPLIANCE THROUGH TECHNOLOGY ADVANCEMENTS IN EASE OF USE, MONITORING, AND SAFETY

Michelle Morais, RN, Nurse Educator, Vascular Medicine at NormaTec



Michelle Morais, RN,
Nurse Educator, Vascular
Medicine at NormaTec

Compression therapy has far-reaching physiological benefits for patients. Recent advancements by devices like the NormaTec Via Series are raising the bar for patient results and practitioner insights. The newest NormaTec PCDs have been re-engineered for maximum convenience and efficacy, allowing patients to heal at home while providing compliance monitoring for clinicians. These new devices are trendsetters for ease-of-use, providing a non-invasive and fully customizable experience.

Achieving desirable healthcare outcomes is directly related to therapy compliance. For patients suffering from vascular disorders like lymphedema, venous insufficiency, and venous stasis ulcerations, the Via Series makes compression therapy accessible, effective, and uncomplicated. At only 3.2 pounds, the devices are lightweight and fit comfortably in the hand. The intuitive user-interface features straightforward controls and an easy-to-read screen for adjusting time and pressure settings in real time. Attachments are simple to don and connect with a single hose.

The devices have numerous safety features that meet or exceed demanding UL 2601 and CE standards, including built-in protection against clinically inappropriate pressures and reverse gradients so that adverse settings cannot be inadvertently programmed. All of these features, along with NormaTec's patented Pulse technology and custom calibration phase, contribute to an optimal patient experience, enhanced compliance, and superior outcomes.



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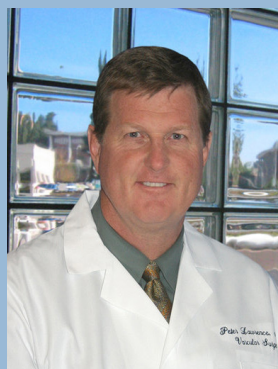
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MARCH JVS-VL BEST ARTICLES



Peter Gloviczki, MD



Peter Lawrence, MD

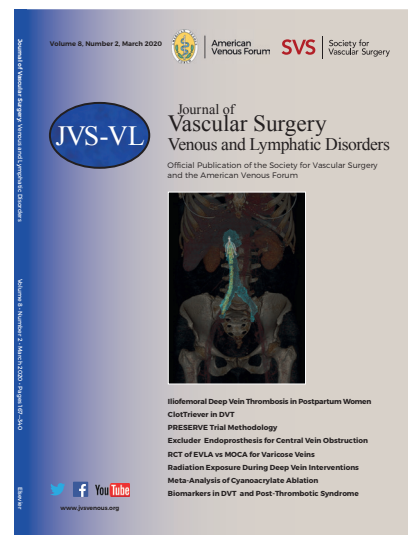
Peter Gloviczki, MD & Peter Lawrence, MD

The Journal of Vascular Surgery - Venous and Lymphatic Disorders (JVS-VL) continues to thrive, through a fruitful collaboration between the American Venous Forum and the Society for Vascular Surgery. The journal is in the 8th year of publication, has an impact factor of 2.696, with a total of over 10,000 print and electronic subscriptions per year. In January, we selected the new editorial board, and the AVF has 9 society representatives at positions ranging from Associate, to Assistant, to Editorial Board members. There are also other AVF members who are on the editorial board, but not as official AVF representatives.

In January the Journal of Vascular Surgery Journals added a new journal, Vascular Science, edited by Alan Dardik, with John Curci, Ulf Hedin, and Ulka Sachdev as Associate Editors, as well as an internationally recognized Editorial Board. The Vascular Science journal is now accepting basic science and translational papers, while the JVS-VL will also continue to accept basic research and translational papers, so there will be several excellent avenues for publishing basic and translational research related to venous disease.

We continue to be grateful to the many members of the AVF who contributed to both our Impact Factor and submitting papers to our journals.

The Editors' Choice for the March issue of the JVS-VL is "Technical success and short-term outcomes after treatment of lower extremity deep vein thrombosis (DVT) with the ClotTrieve® System: A preliminary experience" by Benarroch-Gampel and coauthors from Emory University. They report on 12 patients who developed symptoms from an acute or recurrent iliofemoral DVT and were treated using a recently FDA approved clot retrieval device. One patient presented with phlegmasia cerulea dolens, with the remaining patients presenting with disabling pain and swelling. Access was obtained in the prone position via the popliteal vein or small saphenous vein. Lytic therapy was not used in any case. Complete clot evacuation was obtained in all patients in a single session, without repeat interventions. There was symptom resolution prior to discharge in 100% of cases, and no incidence of postoperative anemia or acute kidney failure. At early follow-up, 92% of patients continued to report significant symptom resolution, while 20% developed recurrent DVT on follow-up duplex ultrasound. The



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Peter Gloviczki, MD & Peter Lawrence, MD

thrombectomy system was safe and effective in removing large volumes of acute thrombus in a single session, without the need for lytic therapy, intensive care unit admission, or repeat intervention.

Readers may earn CME credit for our next highlighted article, entitled “Laser Ablation Versus Mechanochemical Ablation in Treatment of Primary Varicose Veins: A Randomized Clinical Trial” by Tawfik and coauthors from Egypt. They performed a prospective randomized trial on 100 patients to compare standard EVLA with a new mechanochemical (MOCA) procedure, called Flebogrif. The authors reported a 100% closure rate with each device, but the MOCA procedure was performed more rapidly and with a lower incidence of superficial phlebitis and more rapid return to work. There were several limitations in this study, since some patients had concomitant sclerotherapy, as well as treatment of small saphenous veins and anterior accessory saphenous veins, in addition to the GVS ablation, so further studies with other ablation devices will be required to compare outcomes in multiple superficial truncal veins and also provide long-term outcomes with Flebogrif.

The third article, by Dr. Lim and co-authors from Guys and St. Thomas hospitals in London, UK, “Patient radiation exposure for endovascular deep venous interventions”, addressed the total patient exposure to radiation from preop CT imaging, endovenous procedures, and post-procedure. 206 patients had deep venous procedures for DVT and May-Thurner syndrome, including lysis, stenting, and venacaval reconstruction. They found that the combined pre-, intra-, and post- procedure radiation exposure cumulative dose-area product (DAP) for DVT thrombolysis was 9.2 (0.2 – 176.0) Gy_{cm}² for lower extremity. For unilateral chronic iliofemoral venous stenting and endovascular inferior vena cava reconstruction, the median cumulative DAP was 32.4 (0.1 – 289.6) Gy_{cm}² and 60.8 (2.5 – 269.1) Gy_{cm}², respectively. Although there was a great range of radiation, the authors conclude that the mean patient doses for deep venous interventions are comparable or less than most endovascular arterial procedures.

The final article highlighted this month is “Mid-term outcomes in postpartum women following endovenous treatment for acute iliofemoral deep vein thrombosis”, by Lestak and co-authors from Kings College and St Thomas hospital in London. They reported on the outcomes of interventional treatment for acute iliofemoral DVT in postpartum women who had a median age of 28 years, and who had interventions at a median of 3 weeks post birth. No major or minor complications were reported in any patients. Cumulative patency at 1 year was 64% in postpartum women, compared to 93% in non-postpartum women, but there was no difference in primary and primary-assisted patency;

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MARCH JVS-VL BEST ARTICLES *continued*

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55% of patients required reintervention for re-thrombosis, which was unsuccessful in all patients with 100% vessel re-occlusion, but successful in cases with partial occlusion. Re-occlusion occurred when clot was not fully lysed and stented beyond residual disease at the initial procedure. The authors conclude that initial complete lysis and adequate stenting is essential to prevent re-occlusion, for which re-intervention carries a low likelihood of success.

These are just four of the many excellent articles from the March issue of the JVS-VL. To access these articles for free, visit us on www.jvsvenous.org. We hope you also enjoy the rest of the March issue. Please look at the editor summary videos and visual abstracts for more detailed reviews of each of the papers.

Peter Gloviczki, MD
Peter Lawrence, MD

AVF 32ND ANNUAL MEETING



AVF 32nd Annual Meeting
March 3 – 6, 2020

Omni Amelia Island
Plantation
Amelia Island, FL

[More Information](#)

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GOT A VENOUS OR LYMPHATIC QUESTION? AVF EXCHANGE HAS THE ANSWER!



Anil Hingorani, MD

Anil Hingorani, MD

The American Venous Forum is adding a new membership benefit – AVF EXCHANGE!

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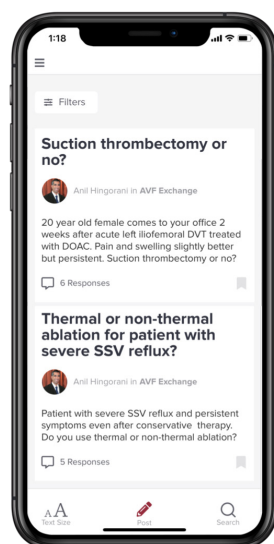
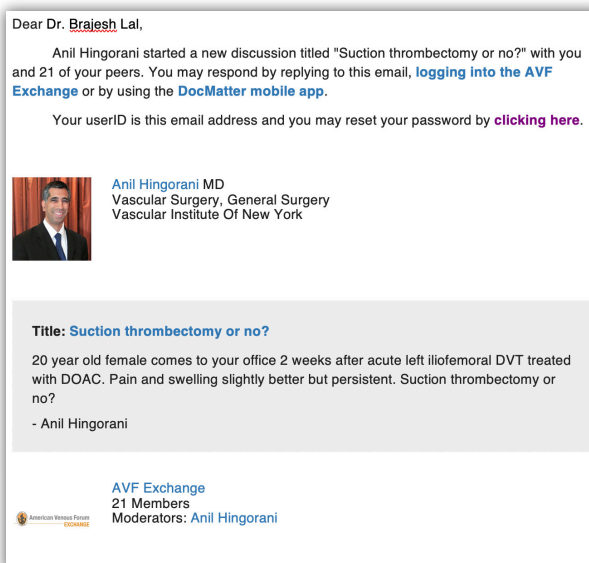
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GOT A VENOUS OR LYMPHATIC QUESTION? AVF EXCHANGE HAS THE ANSWER! *continued*

Anil Hingorani, MD



Venous disease diagnosis and treatment is rapidly expanding, making it increasingly difficult to keep up to date. This community allows you to keep abreast of new developments even before the presentations, publications and chapters. And all of this in a stress-free informal environment!

Looking forward to seeing you on **AVF EXCHANGE!**

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NEW AT VENOUS2020: AVF CENTRAL

Jeffrey Mendola



Jeffrey Mendola

Last year at AVF's Annual Meeting, we introduced **"Coffee Talks with Venous and Lymphatic Visionaries"** in the exhibit hall during the morning and afternoon breaks. These popular discussions are back again this year and will be held in AVF CENTRAL, a new innovation of our Annual Meeting located in the exhibit area. This year's lineup of Key Opinion Leaders will include:

- Thursday, March 5th (9:35am)
 - Drs. Elna Masuda, Daniel Monahan and Peter Pappas will tackle a couple of tough Deep Venous cases.
- Friday, March 6th (9:15am)
 - Drs. William Marston, Robert McLafferty and Marc Passman will delve into a pair of difficult Superficial Venous cases.

This year, our coffee talks will be just one of the many activities taking place in **AVF CENTRAL**.

AVF CENTRAL will also include:

- AVF EXCHANGE – Explore this exciting new member forum and even develop your profile with on-site help from the Exchange team.
- Recharge with the AVF – Plug in at our cell phone recharging station.
- AVF Apparel – Peruse samples of AVF apparel and place your orders.
- Sign up now for upcoming [AVF Educational Courses](#):
 - VENOUS2021 with Early Bird discount rates (ONLY available at VENOUS2020)
 - Fall Fellows & Early Career Course – Free for AVF members, early bird discounted rate for non-members
- AVF Membership – Learn more about the expanded benefits of AVF Membership, become a new member, or take this opportunity to renew.
- AVF Career Center – View current venous job opportunities and learn how to share openings at your institution.
- American Venous Forum Foundation – Hear about how the Foundation supports the mission of the AVF and become a donor.
- "AVF's Got Talent" – Purchase your ticket to this year's exciting, entertaining Gala featuring performances by your friends and colleagues.
- The Newsstand – Visit our newsstand stocked with current issues of VEIN SPECIALIST AVF Newsletter, JVS-VL, Vein Therapy News, Venous News, Endoscopy Today, upcoming venous meetings and more.

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