

VEIN SPECIALIST

NEWSLETTER



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Promoting venous and lymphatic health

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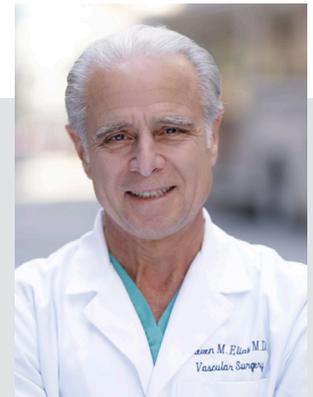
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Familiarity In Absentia

I know these people. You know these people. But who are they? Jones Beach State Park, Long Island, New York: the ocean, the sand, the people... is 15 minutes from where I grew up on Long Island. It was my "backyard." Summer and Winter. There is something beautiful about snow on the sand. There is a book of photographs by Joseph Szabo that takes you from the 1970's through the 1990's entitled simply Jones Beach. He photographed people. People at Jones Beach. When you peruse the book you don't know them but you do. They are all at Jones Beach.

In this issue of AVF Vein Specialist entitled: "And Now for Something Completely Different," thanks to Monty Python, we bring you a diffuse tableau of AVF members. Some you may know well and some you have never heard of. But they are all AVF members. Why is this issue "completely different"? Well, it's the end of 2020. Time to take stock. Learn a bit more about the people you know and the people you don't know. What do they think? Maybe it helps us reflect on what do we think. Isn't that why we read biographies?

As I stare at the photography in Joseph Szabo's Jones Beach highlighting the environs populating Jones Beach, it gives perspective. As you read the answers to the questions posed to our author members, learn something about them. Learn something about the AVF past, present and future. But more importantly, personalize, think how you would have answered the questions. Learn something about yourself. Let your mind wander to your own Jones Beach and enjoy this issue as something completely different.

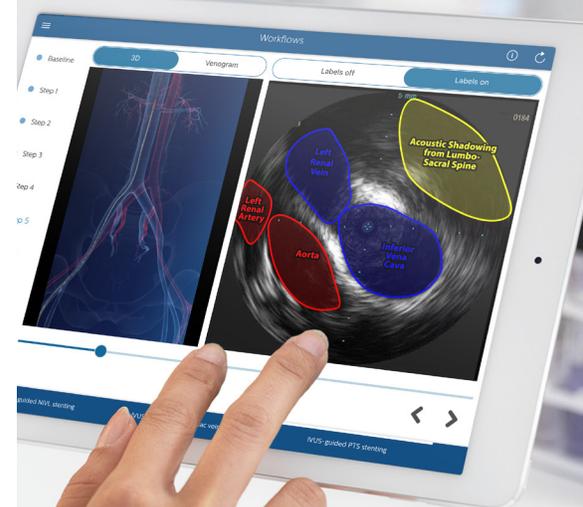


—Steve Elias, MD

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Where should the management of venous disease be going in the next five years?

Diagnosis and management of venous disease should be more evidence based than what it is currently. This would require generating data that can then be analyzed to create evidence-based guidelines. Currently, there are a lot of guidelines, but the data they are based on leaves a lot to be desired. E.g. what is the basis for the cut off diameter of 5mm for intervention on a refluxing saphenous vein? A recent study that evaluated 5,757 varicose vein procedures in the VQI VV registry concluded that 'Patients with a smaller vein size should not be denied intervention or coverage based on vein size.'

What is the one vein disease problem you think needs to be solved in the next five years?

I would approach this from a device perspective. A good aspiration thrombectomy device that can efficiently and effectively remove thrombus without significant blood loss at a relatively low cost would be great. I bring the latter aspect up given the high likelihood that reimbursements for interventions are going to decrease over time. A dedicated venous stent that can work well in all situations (stenotic lesions, CTO, across the inguinal ligament, confluence stenting, in the cava) would also be very helpful.

Will the future of venous care be based on hemodynamics or vein/coagulation biology?

Likely a combination of the two. Better understanding of both aspects will help us deal with stent failure (in-stent restenosis, stent compression, stent occlusion), recanalization following vein ablation and a variety of other aspects. I would like to also add the evolving impact of technology. How would it be if we could incorporate a microchip into a venous stent that has the capacity to evaluate flow dynamics and send the data back to the provider. This has the potential to obviate the need for in person follow ups except when a problem with the flow occurs. The future of management of venous and lymphatic disorders is going to be an exciting one.

What is the greatest future challenge in venous care? Obesity, hyper coagulable states?

Generating quality data to guide patient care as outlined above is likely going to be a challenge in the short term. On par with this is going to be our ability to ensure the best possible outcome for each and every patient. There are many facets to this latter issue some of which fall in the clinical - research sphere while others fall within the purview of societies vis a vis credentialing/certification. Another aspect that needs to be focused on is the diagnosis and management of lymphedema. The latter is often treated as a stepchild, but lymphatic disease is often intertwined with venous and so it becomes imperative to address both. Obesity also represents a challenge for which there is no easy solution as evidenced by the gradually increasing mean BMI of our nation with every passing year.

What about your relaxation, hobbies, passion outside of work, family?

Avid reader (currently on Volker Ullrich's Downfall) and travel buff (although this has been hobbled, as for most people, with the pandemic). Art enthusiast especially of Old Masters paintings.





Where should the management of venous disease going in the next five years?

Prevention and origin care. Source of venous hypertension and early recognition of pathology high risk for ulcerations

What is the one vein disease problem you think needs to be solved in the next five years?

Non axial reflux ulcer. Reliable mini ally invasive branch closures

Will the future of venous care be based on hemodynamics or vein/coagulation biology?

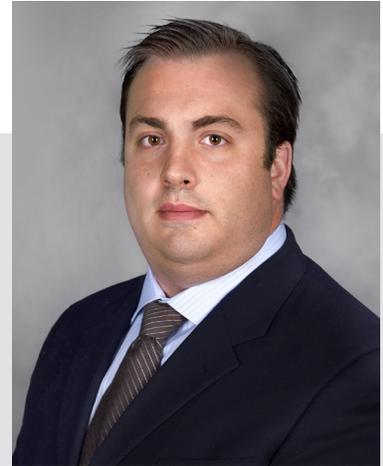
Hemodynamics. Coagulation part of the story but injury and stasis seem more related to hemodynamics

What is the greatest future challenge in venous care?

Obesity, hyper coagulable states? Still cosmetic stigmata. Getting people in and late presentations with obesity

What about your relaxation, hobbies, passion outside of work, family?

Car tinkering. Hunter/ jumper equestrian. Cooking with my family.



– Jordan Knepper, MD



BO EKLÖF, MD, AVF PAST PRESIDENT, HELSINGBORG, SWEDEN

I was raised in Bofors, the main gun factory in the middle of Sweden. Except for school there was nothing to do but to play ice hockey, an ability that was appreciated the further south you moved in the country. At 16 in 1952, my family moved to Motala and I was selected to attend a camp for the junior national hockey team. At 19, I moved to medical school at Lund University and was immediately drafted to the hockey team in Malmö, then playing in the third division. After three victorious years (in 1958), we were able to reach the highest league in Sweden. My medical studies were now more serious, and with less time to practice I was not good enough for this league. Started a new team in Lund as captain and brought with me some of my fellow players from Malmö. Even got an offer to coach a team outside Lund for USD \$300 per year, which I turned down. Young Swedish hockey players drafted by NHL get better deals today.

How I ended up in Paradise together with Bob Kistner, Elna Masuda and Fedor Lurie. In 1981 I was recruited to Kuwait as prof/chair in surgery at the new medical school at Kuwait University. More than 75 Swedish academic physicians contributed to this development, where we graduated more than 400 Kuwaiti made doctors until the invasion by Saddam Hussein and his army on 2 August 1990. At that time, we were on vacation in our house in Trimiklini in the Troodos mountains in Cyprus. At 8 am, my friend and colleague Peter Neglén and his family, who lived in the same village, knocked on the door with the message from BBC that Kuwait was invaded by more than 200,000 soldiers. We realized that our mission in Kuwait was abruptly terminated, and I had no job. The same day a Kuwaiti colleague from the medical school who had arrived in Cyprus a couple of days earlier, brought a letter from Bob, who asked if it was not time to leave Kuwait and come to Honolulu as his partner. A fortunate stroke of serendipity. The same day as Saddam crushed our mission in Kuwait, Bob offered me to come to Paradise.

I am a passionate hunter. For the last 14 years, I have been a member of a hunting team at Krageholm Castle in the very south of Sweden. Beautiful nature between two lakes with plenty of wild animals: crown deer, fallow deer, roe deer, too many wild boars and geese. Everything has its time, so I left hunting this summer. Instead my son Jesper and I bought an old fishing boat which is harbored in the marina in our village, from where we go out fishing in Öresund, outside the island of Ven (vein!), so I am reminded of my professional passion all the time.



Bo Eklöf, MD



Early thrombus removal was stimulated by my mentors in Rochester N.Y in the end of the 60's. I brought venous thrombectomy (TE) to my Alma Mater in Lund. Jean Kunlin in Paris and Jörg Vollmar in Ulm, whom I visited, convinced me to add a temporary AVF to improve patency. In the middle of the 70's we started the Swedish RCT comparing TE+ AVF and anticoagulation (AK) with AK only, in patients with acute iliofemoral DVT. The results of early TE were significantly better. Since then I have been involved in more than 200 operations. My last operation in Honolulu in June 2003 was early TE in a young nurse, combined with angioplasty and stenting of a remaining iliac vein obstruction.

In the light of good long-term results of early surgical TE and the controversial results of the ATTRACT trial, I suggest resurrecting surgical TE + AVF in patients with acute iliofemoral DVT.

The plethora of new methods to treat CVD due to saphenous vein incompetence, and their easy applicability, has led to an abuse of indications to treat, by physicians not adequately trained. This appropriateness problem is a major issue today in venous disease.



ROBERT L. KISTNER, MD



What don't we know about you?

I'm glad you asked this question because I have noted changes that can affect my interaction with other people. As you know, aging eats away at the physical senses by degrees that can decrease one's level of vision, smell, hearing, strength, coordination, and non-visual things like memory, energy, ambition, etc. So, what you don't know about me is how well various faculties are working on a given day. Neither do I because recall seems to vary time to time. The only advantage for me is that I probably have a better excuse for not remembering your name when we meet in the hall than you do for not remembering my name.

What should we know about you?

I sincerely want to know your opinion in venous subjects. I am always interested in your opinion about what is right or wrong.

What shouldn't we know about you?

I have basic insecurities—but tend to be convinced I am probably right. Later experience of finding out I was wrong leads back to the wisdom of basic insecurities.

I often wished to be 4-6 inches taller – instead, I'm 2 inches shorter than I used to be.

What is the most memorable idea/trend/initiative in venous care that failed to prosper?

Failure of the majority to use the full CEAP in diagnosis of venous disease. This is a crime because the understanding of CVD requires each of the 4 elements of CEAP.

Name an idea in venous disease that was abandoned but could be rescued?

Lack of thorough evaluation of deep vein valve repair in severe CVD for the limited group of advanced cases that could benefit from it.

The widespread impression that these repairs are too technically difficult is wrong. Vascular surgeons can perform the procedure by attention to detail. The main problem is accurate diagnostic workup for selection of cases, and adequate training in the details of the surgical procedure.

When a successful technique for endovascular repair becomes available in the near future a new wave of valve repairs will probably be performed and sufficient numbers of well selected cases should allow more convincing studies of the clinical value of restoring competence to the deep veins.



– Robert L. Kistner, MD



Do you see any current examples of lessons NOT learned in venous disease?

Value of descending venography showing routes of venous reflux that are not appreciated with the usual testing for reflux.

The existence of axial reflux vs. lesser extent of reflux in advanced disease has been found by several investigators. The patterns of axial reflux vary widely and occur via multiple superficial and deep pathways, as identified by descending venography. These routes of reverse flow often show incompetent valves in truncal and non-truncal connected veins that are not seen on ascending venography.

This information requires time to map out by standing ultrasound, and the full information requires that the mapping includes the deep veins. It is possible that thermography will help in identifying routes of clinically important (axial) superficial reflux as a guide to superficial interventions because it is produced by inciting reverse flow in the veins through the Valsalva technique, but thermography probably won't help identify deep vein connections in the course of axial reflux.

It is not to be expected that there would be a routine revival of descending venography. However, there could be an improvement in technique of ultrasound exam of the leg veins by mapping the routes of reverse flow in the leg veins under Valsalva and other reflux techniques. In the case of workup for deep vein reconstruction there remains a place for descending venography to identify the sometimes multiple sites of axial reflux flow that may involve elements of all three anatomic divisions: superficial, perforator, and deep segments.

Lack of extended long-term follow-up of reflux progression in both PVI and Post-thrombotic diseases.

CVD is a lifelong degenerative disorder in which we only have data for 2-5 years in most clinical studies. The long-term results from Bonn, Germany (6.6 years) and Edinburgh (13 years) report continued progressive changes over the length of their studies, and multiple reports describe recurrent disease in at least 40-60% of very late follow-ups. Essentially all studies show marked increase in C4b-6 disease in Medicare-aged individuals.

We will probably be seeing some very long follow-up data emerge in the next decade from well-designed adequately financed studies with the passage of time. These analyses will require detailed pre-operative and post-operative data from the time of treatment through the follow-up, using all the elements of CEAP. Data from cohorts of successive 5-year follow-ups could lead to this type of analysis without the need to wait several decades for the answers.



SUSAN SMITH – BOSTON SCIENTIFIC



How will you be educating vein specialists in 2021?

Boston Scientific will be offering both virtual and in-person training events for physicians and fellows interested in deepening their knowledge and proficiency in treating venous disease. Based on feedback gathered from many of our customers, we're excited to offer both broad topics (e.g. treating complex venous disease) and targeted topics (directed toward our venous technologies) within our medical education programming. We also plan to continue to support third party training and education programs, both virtual and in person, and at the local, regional and national level. We are very impressed with the creativity and dedication of organizers of these virtual programs, and believe they are critical to advancements in the medical community, and especially in the venous space where new technologies are introduced frequently. This includes programs supported by AVF, Venous Symposium and other



– Susan Smith (Boston Scientific)

How do you analyze your ROI when supporting virtual education/meetings?

We do not track any ROI. If you were asking marketing about this, they may have another answer...

What makes it "worth it"? Programs aligned with our educational objectives. Compelling topics, formats that encourage learning in an effective environment, ability for interaction between faculty and attendees, discussions that enable physicians to better understand how to treat venous disease, how to select appropriate treatment for patients, safe and effective use of technology.

Will future venous devices incorporate biologic principles (e.g. anti proliferative drugs, anticoagulants)?

We continue to explore different approaches to improving the quality of life for those suffering from chronic venous disease – one area of interest is determining if there is a biologic agent that can help these patients – this exploration includes studying

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anti-proliferative, anticoagulants, and anti-inflammatory agents.

How has pandemic affected R&D – both clinical trials and new device development?

The clinical team has been tracking the effect of COVID on various aspects of clinical research. For studies that were enrolling, there was a significant decline in enrollment due to patients not coming in to clinics, coordinators and physicians working full time on the pandemic and not available to spend time on clinical research, and even some institutions that banned clinical studies for periods of time.

For patients already enrolled in studies, we saw a large uptick in the number of missed visits and resulting missing data. The studies whose protocols allowed the flexibility of remote visits during long-term follow-up (phone calls usually) fared a bit better; this was a lesson learned to allow flexibility in visits. Imaging was often missed at key time points that could threaten endpoints.

For ongoing studies, the process of monitoring to verify the data changed abruptly, as most sites would not allow sponsor or CRO personnel on site to monitor the studies. There has been a lot of work done in the past months to initiate remote



monitoring visits, including a platform to review the medical records remotely as well. This will likely continue even once the pandemic ends.

For adverse events that occurred during clinical trials, we are changing our data collection to include COVID as one of the options. Adjudication committee processes are also changing to include COVID monitoring to verify the data changed abruptly, as most sites would not allow sponsor or CRO personnel on site to monitor the studies. There has been a lot of work done in the past months to initiate remote monitoring visits, including a platform to review the medical records remotely as well. This will likely continue even once the pandemic ends.

New product development, like many other functions, have adapted to doing things virtually and development continues. Our R&D teams have been outstandingly resourceful but are experiencing some delays as 3rd party suppliers are delayed and the teams are not able to be in the labs together every day.

What about your relaxation, hobbies, passion outside of work, family?

I'm very involved in animal rescue (especially dogs) and participate in many initiatives supporting rescue/adoption. We currently have two rescue dogs, which is my limit, according to my husband. Hiking, gardening, cooking and trying new recipes with my Covid "pod" are some of my favorite weekend things to do, and I am looking forward to the time when my husband and I can travel again.



SCOTT CENTEA - ANGIODYNAMICS



How will you be educating vein specialists in 2021?

In 2021, we are looking forward to physically reengaging with our customers and driving physician training and education, which is very important to our partnerships. We are planning endovenous laser therapy (EVLT) training on new customer education and continuing education for providers, including advanced venous disease focusing on incompetent perforator veins (IPV's) wound care, and enhanced peer to peer education. The pandemic has definitely created training challenges, especially when it comes to in-person training but remain committed to providing education and support for EVLT and our physicians/partners. We have pivoted to virtual and hybrid training formats with great success, while increasing the frequency and variety of trainings. We will be launching an advanced venous course in the next few weeks to focus on use of our PVAK kit with IPV's, an underdiagnosed and undertreated segment of venous disease. These trainings will be offered virtually as lectures, roundtable discussions, and soon, virtual observation of a live case with interaction from attendees during the procedure.



– Scott Centea

How do you analyze your ROI when supporting virtual education/meetings?

We have been impressed with the creativity and turn out of this new virtual format for these recent meetings. A lot of thought and effort has gone into making these as valuable as possible for physicians as well as industry partners. Attendance at these meetings is a driving factor and so is relevant content. At AngioDynamics, we have a lot of important information to share, and proven success to back it up. When evaluating the success of meetings, we are looking to see inquiries from attendees, meaningful conversations had, and interactions with the content in our innovative virtual booths. Bottom line, when you provide relevant information and education that's being asked for by our partners the ROI is certainly there. We always measure our ability to advance care through education to improve outcomes for patient. If we can do that, the investment is always worth it.



Will future venous devices incorporate biologic principles (e.g. anti proliferative drugs, anticoagulants)?

I welcome innovation in this space but am not well versed enough to understand or comment about what biologics will bring to venous disease treatment? I will however take a moment and question the need for these hybrid devices when overall treatment success and safety with existing devices are really good. It begs the question can we improve upon "great?" I hope we do but we must also consider what influences adoption of novel devices and or innovative technology. Is it safe...check, does it work...check....does it improve outcomes...maybe, does it help the end user do their job better...maybe, and ultimately, does it reimburse and or have an economic value prop.

Again, any innovative solutions that target unmet needs in any space is always promising. However, I'm struggling to identify the true (patient) unmet need for superficial vein treatment. If treatment types and or other devices have proven to meet significant efficacy end-points with fantastic safety results and improved QoL what more are we looking to solve? I do think this space has seen it's share of innovation, most recently being the NTNT technologies. We do see the value in exploring patient tolerance and post-op tolerance from the procedure. Adoption, however has been slower than anticipated because of policy and commercial payor coverage, yet patients continue to be treated effectively and safely with other technologies (although more mature) still as effective in meeting the primary patient end-point. I think we may see more iterative advancements rather than truly revolutionary innovation in this space because of existing/ established policy and coverage. An example of this would be the newer RF device that has come to market. They believed in the RF modality but felt the end user experience could be improved upon especially when there's proven modalities, established reimbursement landscape and good policy coverage. I think this is why you'll see more iterative advancement rather innovative introductions. Between the higher prices of newer products, and the marginal nominal increase in efficacy, it appears

that the industry may be trying to solve for an unmet need that doesn't exist? Just my two pennies...

How has pandemic affected R&D – both clinical trials and new device development?

The pandemic has had an impact on R&D and new device development. Patient enrollment for trials has been heavily impacted, making establishment of different protocols in different states very challenging. The same goes for new device development, as scheduling and setup have become more difficult. While challenging, we at Angiodynamics have embraced these obstacles and turned them into opportunities to do better and develop creative solutions that meet the needs of our partners. As tough as the pandemic has been and continues to be, we have not let it sideline or stop our work. We are dedicated to supporting our partners and their patients, and that dedication will never end.

What about your relaxation, hobbies, passion outside of work, family?

I love spending time with my 11-year-old triplets and my wife of 19 years. My family moved to upstate New York several years ago, and we love the year-round outdoor lifestyle. We hike and cycle in the warmer months, and snowboard in the winter. I also try to remain competitive in "senior league" soccer. Truth be told, I love my job. I love the challenges, the people, and having the opportunity to make an impact... which ultimately is a hobby, at times relaxing and very much a passion of mine.



Venous Education Series: Thank you to Our Faculty

– Hal Welch, MD

The American Venous Forum recently completed a four-part education event entitled Venous Education Series (VES). Chaired by Kellie Brown, and with an outstanding faculty, the VES was a first of its kind for the AVF and was, in my opinion, a resounding success with over 550 Fellows and Early Career registrants from around the world.

On behalf of the Board of Directors of the AVF, I would like to express my sincere thanks to Kellie, the session leaders, Ellen Dillavou, Steve Elias, Mark Meissner, and Ruth Bush and the outstanding faculty they enlisted (listed below) to provide this educational program. I would also like to thank our industry sponsors whose support was both exemplary and critical to the success of the program.

The presentations and faculty discussions will be available to those previously registered until January 31, 2021.



– Hal Welch, MD

Distinguished Faculty

Not Pictured Manju Kalra, MD



Makis Avgerinos, MD



Kathleen Gibson, MD



Kellie Brown, MD



Arjun Jayaraj, MD



David Rigberg, MD



Ruth Bush, MD



Peter Lawrence, MD



Cynthia Shortell, MD



Sheila Coogan, MD



William Marston, MD



Julianne Stoughton, MD



Ellen Dillavou, MD



Mark Meissner, MD



Suresh Vedantham, MD



Steve Elias, MD



Andrea Obi, MD

Agenda

Online Fellows and Early Career Venous Course Outline

VENOUS EDUCATION SERIES

OCTOBER 13
Venous Thromboembolic Disease – Ellen Dillavou

- Medical Management of Venous Disease
- Hypercoagulable Work Up
- Interventional management of Acute DVT
 - Including Filters, lysis, etc
- Interventional Management of PE

Ellen Dillavou
Andrea Obi
Suresh Vedantham
Makis Avgerinos

OCTOBER 27
Superficial Venous Disease – Steve Elias

- Work up of superficial venous disease
 - Includes ultrasound dx and classification
- Treatment of Axial Reflux
- Treatment of Venous Tributaries
- Management of Perforating Veins

Steve Elias
Sheila Coogan
Julianne Stoughton
Peter Lawrence

NOVEMBER 17
Abdominal and Pelvic Venous Disease – Mark Meissner

- Overview of Abdominal and Pelvic Venous Dz
- Evaluation and Mgt of Chronic Iliacaval Venous Dz
- Evaluation and Mgt of Left Renal Vein Obstruction
- Evaluation and Mgt of Pelvic Venous Reflux

Mark Meissner
Arjun Jayaraj
Manju Kalra
Kathy Gibson

DECEMBER 1
Interesting and Challenging Venous Disorders – Ruth Bush

- Evaluation of the Swollen Limb
- Venous Malformations
- Elbow Thrombosis
- Management of Venous Ulceration

Ruth Bush
Cynthia Shortell
David Rigberg
Bill Marston



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Venous Ulceration: We Need to Look Deep

– Natalie Sridharan, MD

Venous leg ulceration (VLU) remains a challenging disease to manage and a disabling disease for patients who suffer with ongoing pain, limited mobility, and frequent dressing changes. Despite adequate compression and aggressive superficial venous reflux treatment, some venous wounds are recalcitrant to healing. Some patients never heal and require wound care for life. Increasingly, the contribution of deep venous stenosis (DVS) from non-thrombotic iliac vein lesions (NIVL) or post-thrombotic syndrome (PTS) as a cause of venous ulceration has become more widely recognized.^{1,2} Diagnosis and treatment of this often-underappreciated pathology, which can be present in up to 37% of CEAP 5 or 6 patients, offers another treatment consideration for patients with an otherwise poor prognosis.³

Diagnosis of DVS remains somewhat elusive to the non-vein specialist as it requires a high clinical suspicion. Infringuinal venous duplex ultrasound is notably insufficient to diagnose deep venous stenosis or occlusion and a phasic common femoral vein wave form should not be used as false reassurance. However, with advanced training, experience and good imaging, many DVS can be diagnosed with suprainguinal transabdominal imaging. While CT venography and traditional venography may infer disease, IVUS is the gold standard to detect and accurately quantify deep venous pathology.⁴ IVUS imaging of deep veins in VLU patients has revealed that rather than limited to the classic May-Thurner left iliac vein compression, NIVL can exist in both right and left and in central and more distal locations of the iliac veins. In addition, the extent of post-thrombotic disease can be accurately identified so that treatment can be directed to all of the affected veins.

Treatment of these lesions has yielded some impressive results. Deep venous treatment alone has been shown to result in healing rates of up to 77% at 36 months and up to 87% when combined with treatment of truncal and perforator reflux.⁵ More recent research from our institution suggests stenting of DVS improves wound healing while treatment of truncal and perforator incompetence did not have a significant effect on wound healing in a multivariate model.⁶

Maybe due to the “permissive” nature of these lesions (which are widely present in many healthy individuals) and their perception as benign, DVS in VLU remains both underdiagnosed and undertreated. Shortcomings of the Wallstent (Bos. Sci.) including inaccuracy of deployment and poor predictability of final length lead to lower adoption by some vein specialists. Fortunately, newer dedicated venous stents are now widely available. These stents come in sizes appropriate for venous intervention with more precise



– Natalie Sridharan, MD



Figure 1



Figure 2



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deployment and improved radial force at the ends.

With mounting favorable evidence regarding the benefits of treating DVS, it is up to vein specialists to treat the appropriate patients. Further research is desperately needed to define where exactly deep venous stenting fits in the VLU algorithm. In addition, the frequency and modality of stent surveillance as well as the best medical management post operatively is not well delineated.

One recent case illustrates these points. Mr. A is a 60-year-old ambulatory male with a history of longstanding right leg VLU (Figure 1). He has been wearing Unna's boots for years. Despite aggressive treatment of superficial varicosities including right GSV RFA, stab phlebectomies, and foam sclerotherapy, his wound has remained open. Venous duplex did not demonstrate deep venous reflux. CTV was obtained and there appeared to be some compression of the right iliac vein behind the right iliac artery. Given high clinical suspicion, venogram and IVUS was pursued which confirmed this finding of >70% diameter reduction at this location (Figure 2). This was treated with an 18 mm Venovo stent (Figure 3) with a good result and the wound has finally made progress toward healing (Figure 4). He is currently maintained on aspirin and Eliquis.

VLU is truly a disabling disease for many patients. I had a patient in clinic recently tell me her whole goal is to be able to "wear dress pants again" – a simple but seemingly unattainable goal for many patients. I believe the future treatment of this pathology is bright as we continue to look deep, improve the diagnosis of DVS, and integrate management of DVS into the VLU treatment algorithm.



Figure 3



Figure 4

1. Raju S, Neglén P. High prevalence of nonthrombotic iliac vein lesions in chronic venous disease: a permissive role in pathogenicity. *J Vasc Surg.* 2006;44:136-143.
2. Neglén P, Thrasher TL, Raju S. Venous outflow obstruction: an underestimated contributor to chronic venous disease. *J Vasc Surg.* 2003;38:879-885.
3. Marston W, Fish D, Unger J, Keagy B. Incidence of and risk factors for ilio caval venous obstruction in patients with active or healed venous leg ulcers. *J Vasc Surg.* 2011;53(5):1303-1308.
4. Murphy E, Johns B, Alias M, et al. VESS25. Inadequacies of venographic assessment of anatomic variables in ilio caval disease. *J Vasc Surg.* 2016;63(suppl):33S-34S.
5. Hager E, Harlander-Locke M, Lawrence P, et. al. Treatment of deep venous stenosis and superficial reflux affects healing of venous leg ulcers refractory to conservative treatment. *J Vasc Surg Venous Lymphat Disord.* 2018;6:288-289.
6. Mohapatra A, Salem K, Avgerinos E, et. al. Deep vein stenting is the only therapy to improve venous leg ulcerations in patients with deep venous stenosis. *J Vasc Surg Venous Lymphat Disord.* 2019;8:312.



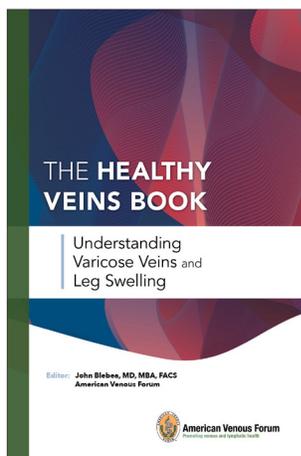
**COMING
SOON**

AVF to Launch New Resources for Members and Patients

– John Blebea, MD – Chair, Patient Education Committee
John Forbes, MBA – AVF Executive Director

The American Venous Forum is pleased to announce the upcoming availability of valuable new resources to support your practice. Developed by members as tools to provide to your patients as well as to enhance your office operation, these items will be offered via AVF beginning in the next few months.

As the keystone to AVF's resources for patients, in 2021 the AVF's Patient Education Committee will publish *The Healthy Veins Book: Understanding Varicose Veins and Leg Swelling*. This comprehensive volume edited by AVF's Patient Education Committee Chair John Blebea, MD, MBA comprises more than 20 chapters contributed by 51 leading practitioners covering what your patients want to know about the diagnosis and treatment of varicose veins, deep vein disease, leg swelling, and other conditions in an easily readable format complete with many helpful illustrations, glossary, and index. As Dr. Blebea describes, "AVF's Patient Education Committee wants to ensure that



you have a reliable, consistent source to help with patient communication. This book will be central to your patient education efforts."

In addition to the complete volume, the committee has prepared a series of brochures designed for your office literature rack—as well as for online reference—to give to patients that explains the basics of frequently encountered conditions. The brochures, written by leading experts and approved by AVF's Board of Directors, cover:

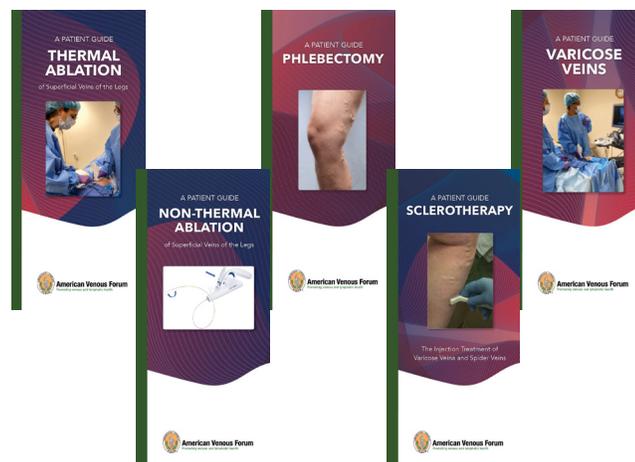
- Venous disease and varicose veins
- Phlebectomy
- Sclerotherapy ablation
- Nonthermal ablation
- Thermal ablation



– John Blebea, MD



– John Forbes, MBA



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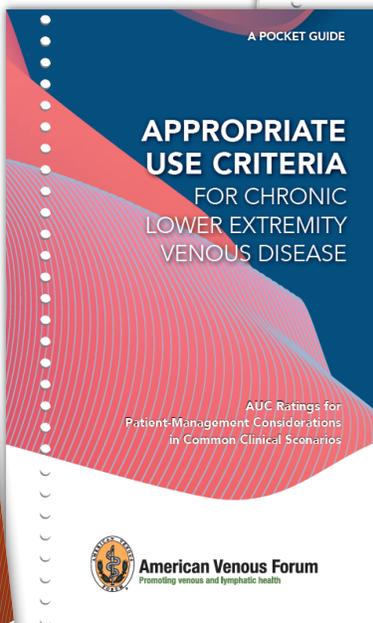
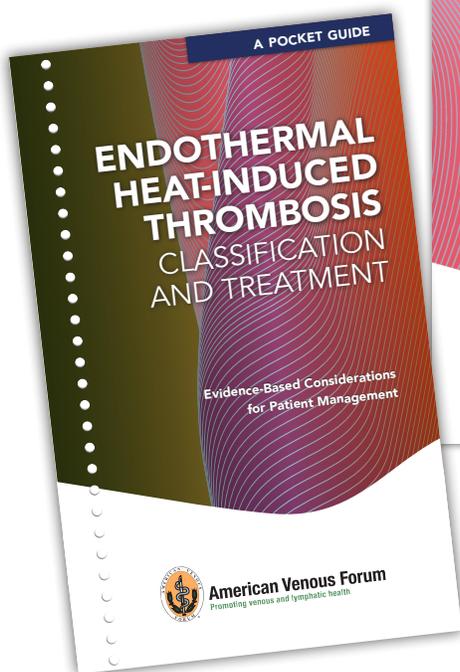
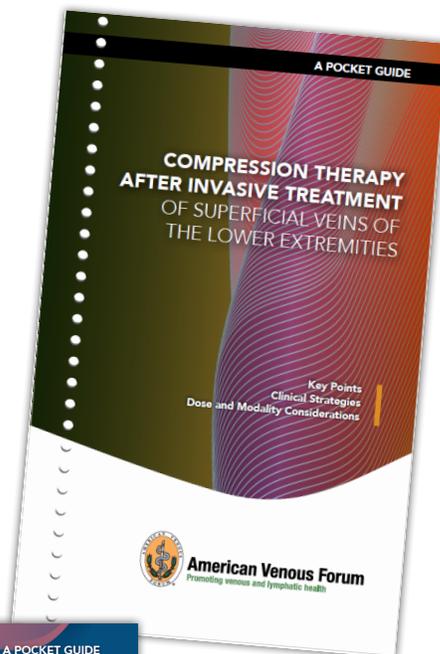
**COMING
SOON**

Watch for availability and ordering details in upcoming messages from AVF!

In addition to patient education materials, AVF is making available standardized forms that incorporate common language for your use in documenting informed consent for common procedures. Soon to be available on the AVF's member website, the forms can be printed or integrated into your practice's electronic medical record for ease of use. Watch the website for their appearance in the near future.

Another tool that the AVF is preparing for your use is a series of pocket guides based on recently published clinical practice guidelines. Conveniently sized and spiral bound to fit in a lab coat, the concise booklets present the basics of guidelines for easy reference in your busy practice. The ongoing series begins with:

- Compression Therapy after Invasive Treatment of Superficial Veins of the Lower
- Appropriate Use Criteria for Chronic Lower Extremity Disease
- EHIT guidelines



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A “Study Before Stent” Approach to Transform our Venous Research Culture

– Suresh Vedantham, MD and Harold Welch, MD

The news that the American Venous Forum (AVF) has renewed its groundbreaking partnership with the Chronic Venous Thrombosis – Relief with Adjunctive Catheter-Directed Therapy (C-TRACT) Clinical Trial is truly wonderful for venous disease patients and providers. Every day, AVF members observe the devastating impact that post-thrombotic syndrome (PTS) exerts upon patients’ lives – that is most certainly NOT news to them. At AVF meetings, it has become cliché to acknowledge the potential for iliac vein stent placement to help patients, the dearth of high-quality data with which to understand its long-term benefit-risk ratio, and the problematic nature of implanting permanent devices into patients without such insight.

So the question is not whether AVF members are aware of the crucial questions C-TRACT seeks to address, nor is the AVF’s historical commitment to venous outcomes assessment in doubt. Indeed, many elements of C-TRACT’s design are solidly rooted in past AVF accomplishments. No, the real question facing us now is, **can the modern AVF become even more relevant to finding the answers?**

Because, speaking candidly, the C-TRACT Trial has big challenges to overcome. Thanks in part to the AVF, during 2020, the C-TRACT site network increased in size to 33 Clinical Centers. Prompted by the coronavirus pandemic, the study protocol has been streamlined to reduce burden on patients and providers. However, the study has enrolled just 85 of 374 needed patients with moderate-or-severe PTS – and with thousands of stent implantations each year, it is clear that we have not succeeded in convincing providers to refer patients to the study. But with a \$12 million taxpayer commitment, it is crucial for the study to succeed, both for patient care and for NIH to continue to want to invest research dollars into the venous community.

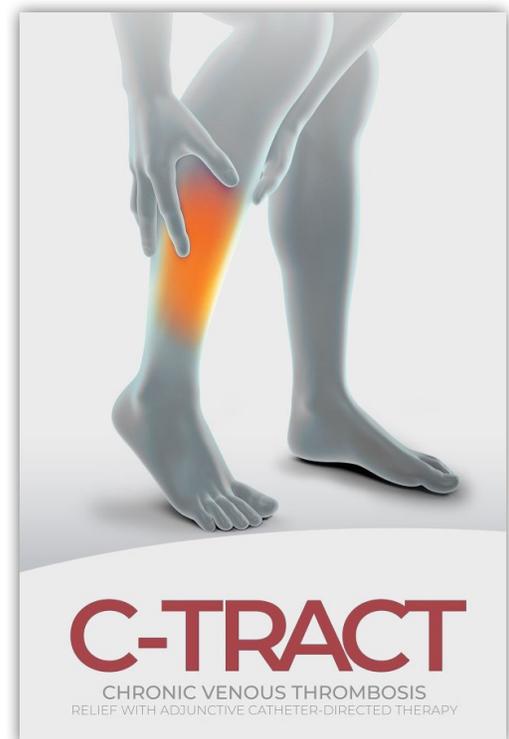
So it’s clear that this partnership can do more, and travel further. The leaders of the AVF and the C-TRACT Trial hereby call on all venous providers to: (1) **adopt a “study before stent” approach** - embrace randomization of patients into this study as the first, best choice for PTS management that will secure terrific care for them now and insightful, evidence-based care for everyone’s later. Essentially, PTS patients should not be stented without first considering if they are study-eligible; (2) **download the C-TRACT Referral App** by typing “C-TRACT” into your smartphone’s app store; and (3) **use the App to refer every patient you see with moderate-or-severe PTS to the study**, and ask your local colleagues



– Suresh Vedantham, MD



– Harold Welch, MD



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(e.g., hematologists, vascular internists) to do the same. Use of the tool is HIPAA-compliant, IRB-approved, and will prompt the study's coordinating center to contact you quickly to discuss your patient.

By supporting C-TRACT, you will be supporting the AVF's efforts to improve venous care, defend its accessibility, and to build an effective clinical trial support culture within the venous community. Ultimately, this will enable the AVF to help answer many more clinical questions that are relevant to your patients.

Please visit <https://bloodclotstudy.wustl.edu/c-tract/> or e-mail Dr. Suresh Vedantham, National Principal Investigator, for more information (vedanthams@mir.wustl.edu).

C-TRACT
CHRONIC VENOUS THROMBOSIS
RELIEF WITH ADJUNCTIVE CATHETER-DIRECTED THERAPY

Are Your Patients Eligible?

- 1) Are they 18 years of age or older?
- 2) Have they been diagnosed with a blood clot in the leg (3+ months ago)?
- 3) Do they now have leg heaviness, fatigue, swelling, aching, or pain?

If the answer to all 3 of these questions is YES, then they might be the perfect fit for the study.

RESOURCES TO SHARE WITH YOUR PATIENTS

The **C-TRACT** team is dedicated to providing the resources you need to **stay informed** about the trial. You can always contact a member of the trial team for more resources or to get any of your questions answered.

Your patient may be eligible to participate in the C-TRACT Study
Chronic Venous Thrombosis: Relief with Adjunctive Catheter-Directed Therapy

For Therapeutic Endpoints (PTE) in a Prospective (APC) comparison of deep vein thrombosis (DVT) PTE versus fibrinolytic therapy such as alteplase, reteplase, and tenecteplase, and venous clots. In addition, venous clots are treated with catheter-directed therapy (CDT) to improve venous flow, reduce pain, swelling, and improve quality of life (QoL).

Please refer your patients to this pivotal NIH-sponsored clinical trial!
Our C-TRACT Clinical Center throughout the US are ready to work with you and your patients. Let us know if you have a patient, and we will contact them.

Eligibility:

- In patients with acute deep vein thrombosis (DVT) to determine if the use of endovascular therapy (EVT) provides more improvement in PTE severity & QoL versus best medical treatment.

Secondary Objectives:

- To compare PTE severity, QoL, venous ulcer healing, and safety over 24 months follow-up.
- To identify baseline and post-treatment predictors of therapeutic response to EVT.
- To compare the overall costs and indirect costs effectiveness of EVT.

For study information, please contact the following:

- Email: Dr. Suresh Vedantham at svedanth@wustl.edu
- Email the study website at <https://bloodclotstudy.wustl.edu> or <https://bloodclotstudy.com>
- Call 1-800-451-CLUST (2587)

Download the C-TRACT patient app for your mobile device using the QR code to receive the latest information on the study.

C-TRACT

Just ask 3 quick questions – if all are YES, use the App to notify the C-TRACT Team. They will respond quickly and will help you further explore eligibility and site referral feasibility.

<https://bloodclotstudy.wustl.edu/c-tract/join-this-study/>
@WUSTLmed #bloodclots

The C-TRACT team is here to HELP you and your patients stay informed about the trial. Use the Referral App to contact us about a patient.

<https://bloodclotstudy.wustl.edu/c-tract/current-status-of-c-tract-study>
@WUSTLmed #CTRACT #DVT #PTS

Acknowledgements

The C-TRACT Clinical Trial is supported by NHLBI grants UH3-HL138325 (Dr. Suresh Vedantham at Washington University in St. Louis) and U24-HL137835 (Dr. Sameer Parpia at McMaster University). The content in this article is solely the responsibility of the authors, and not the NHLBI or NIH.



The American Venous Forum Foundation Needs Your Help!

The AVF Foundation supports key AVF strategic initiatives including:

- Development and updating of clinical practice guidelines
- Dedicated venous and lymphatic research
- Education and training for practitioners at all stages of their careers
- Patient education tools and the Venous Patient Outreach Survey which will maximize their effectiveness

Your donation to the AVF Foundation will further the American Venous Forum's vision to promote venous & lymphatic health by:

- **Guiding** the delivery of quality patient care
- **Training** the next generation of venous practitioners
- **Supporting** current practitioners with advocacy, clinical guidance, research and development opportunities
- **Educating** the public about venous & lymphatic disease and treatments



PLEASE JOIN US and GIVE NOW
at www.AVFFoundation.org

Together we can make a difference in the lives of
venous and lymphatic patients!



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December 2020 | veinforum.org 21

AVF Member Community



JOURNAL WATCH | Journal of the American College of Surgeons

COVID-19 Associated Thrombosis and Coagulopathy: Review of the Pathophysiology and Implications for Antithrombotic Management

Luis Ortega-Paz, Davide Capodanno, Gilles Montalescot, and Dominick J Angiolillo

Originally published 24 Nov 2020 • <https://doi.org/10.1161/JAHA.120.019650>
Journal of the American Heart Association. ;0

The article is a review article of the pathophysiology of the cardiovascular involvement following infection by SARS-CoV-2, with a focus on thrombotic and thromboembolic manifestations and implications for antithrombotic management. It is well written and quite comprehensive. It does focus on the clinical implications of the data.



JOURNAL WATCH | Journal of Vascular Surgery - Venous and Lymphatic Disorders

Interface pressure changes under compression bandages during period of wearing

Junjie Ning, MD • Wudi Ma, MD • John Fish, MD • Jihad Abbas, MD
Andrew Seiwert, MD • Todd Russell, MD • Fedor Lurie, MD, PhD

Published: November 11, 2020 DOI: <https://doi.org/10.1016/j.jvsv.2020.11.007>

New data on examining how compression works (and doesn't) for venous stasis ulcers. In this series of 20 patients, Dr. Lurie and his group investigate the effectiveness of 3 types of compression bandages in maintaining pressure on the calf using pressure sensors under the bandages. These data help in the understanding of how compression helps with healing of venous stasis ulcers and which type of bandages may be more effective.



New AVF Members - Welcome to the Community!

D Temesgen Andualem Desta VES MIT - India

Dr Adharsh Kumar Maruthu Pandiyan VES MIT - India

Ahmed Pasha Member-In-Training - Minnesota, U.S.

Thomas McCrorey Physician Membership National, Nevada, U.S.

Dr Mitta VES MIT - India

Georval Victorin VES MIT - Saint Lucia

Constanca Azevedo VES MIT - Vila das aves, Portugal

Carlos flores VES MIT - Chile

Royal Patel VES MIT - India

Ricardo Ribeiro Member-In-Training - Portugal



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AVF *Advocacy Corner*

Update for “Stark Laws” or Anti-kickback Statute

– Harold J. Welch, MD – President, AVF

Mark D. Iafrazi, MD – Chair, AVF Health Policy Committee

The threat of running afoul of the US Government’s “Stark Laws” or “Anti-kickback Statute” (AKS) has thrown many administrators or well-meaning providers into a cold sweat because of the potentially devastating penalties for violations of these sometimes arcane regulations. Not only are these regulations challenging to understand, they can conflict with each other. Change being the only constant, on December 2, 2020 the Department of Health and Human Services (HHS) Office of Inspector General published a new “FINAL Rule” regarding AKS and provider inducements, while CMS has clarified issues related to Self-referral. The attached document was prepared by the AMA in which the AVF now participates as a member of the surgical specialties section. The AMA actively lobbied for changes that would support our providers and patients. Several important changes were included in this Final Rule. This summary concisely explains a number of items which can directly impact the rules which govern the practice of medicine for many of our members. For instance:

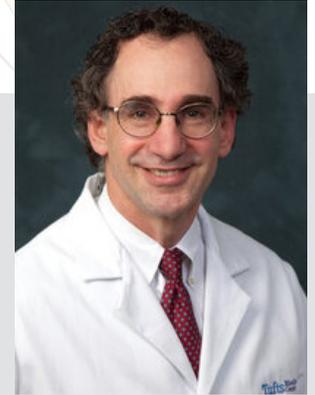
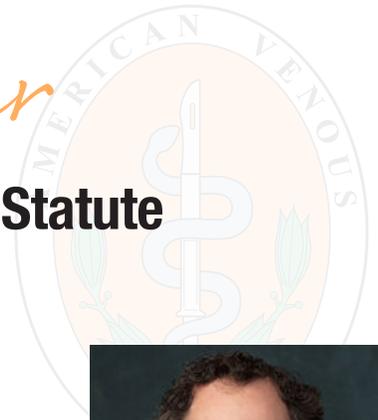
- 1) Is there a dollar amount below which physician remuneration is exempt from these regulations?
- 2) Can I accept donations to provide cyber security technology and services from vendors, donors, patients?
- 3) Can I supply transportation for patients to or from my office/ hospital? How far and in what circumstances?

To read the AMA summary open the attached document. To learn even more you may read the entire entries in the Federal register by clicking the links below.

<https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the>

<https://www.federalregister.gov/public-inspection/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the>

Enjoy this light reading. Perhaps considering sharing it with your attorney. There may well be opportunities.



– Mark D. Iafrazi, MD



– Harold Welch, MD



AVF Advocacy Corner

Treatment for Varicose Veins of the Lower Extremity

– Mark Iafrazi, MD – Chair, AVF Health Policy Committee

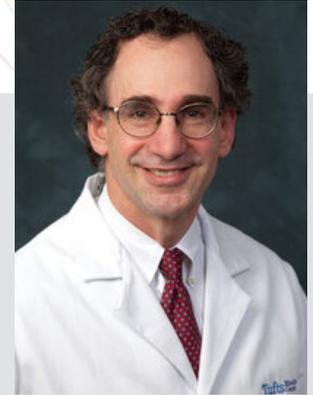
As you may have heard, the BCBS policy in force in North Carolina imposes a one vein per leg per life restriction. The policy was recently up for review.

After reaching out, the HPC received support from many of you regarding the proposed response to the BCBS NC coverage policy.

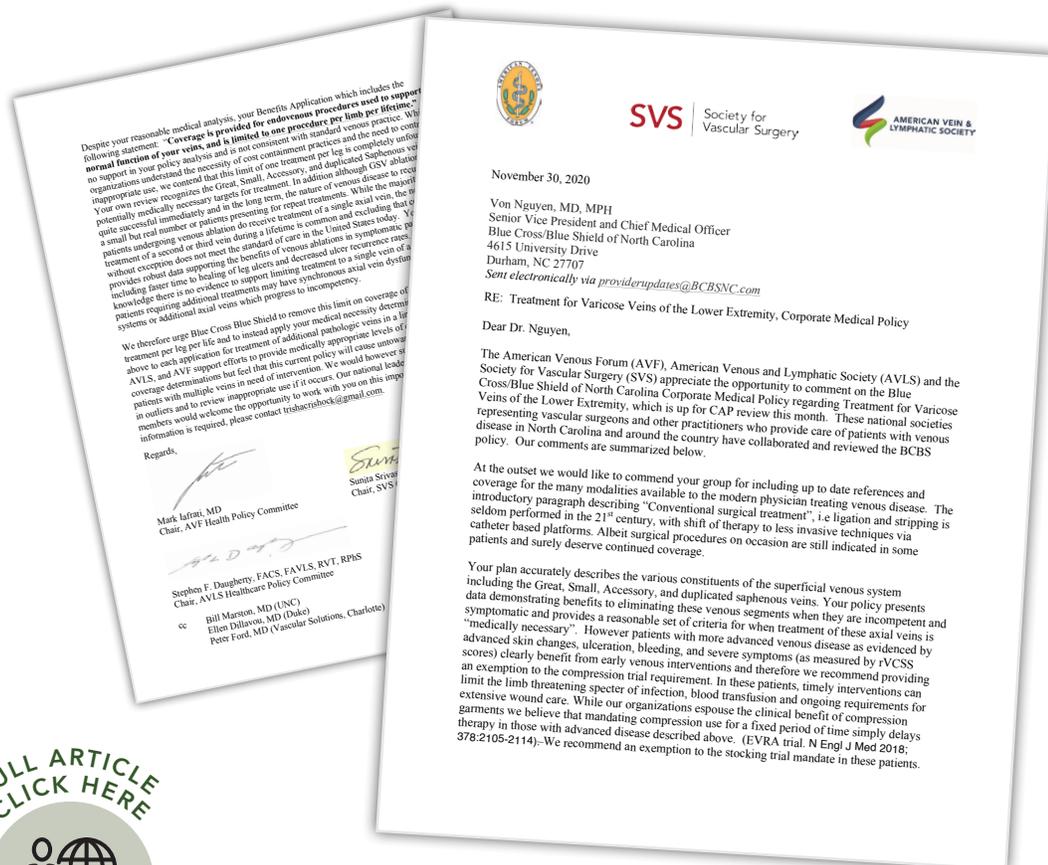
Due to your quick reply with a very tight deadline, we were able to submit a joint letter from the AVLS, SVS and AVF prior to the deadline.

I am pleased that we continue to be able to provide constructive feedback to payors across the country with a unified expert opinion and that these efforts are starting to yield tangible benefits to our members and our patients.

I am look forward to continuing a collaborative approach in 2021 as there remain plenty of challenges on the road ahead.



– Mark D. Iafrazi, MD



FULL ARTICLE
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**Disclaimer: The information featured in this newsletter selected by AVF, which offers educational materials, are not intended to be representative of patients with venous disease generally and should not be considered medical advice. Patients should consult their doctor to determine the best treatment decision for their individual disease.*

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