VENOUS ULCERATION

WHAT SHOULD BE TREATED FIRST?
Edgar Guzman, MD

In the arterial space, ischemic ulceration is understood to be the result of obstructive lesions often occurring at multiple levels. The treatment paradigm consists of addressing said lesions from proximal to distal with the goal of establishing in-line flow to the affected area.

If things were only this straightforward with venous leg ulcers! Anatomically, arteries of the lower extremities parallel the deep venous system, but there are no pertinent arterial analogues to the superficial venous system, perforator veins, unnamed branch varicosities or anomalous veins underlying areas of ulceration. Physiologically there is not only obstruction but also reflux to consider.

Beyond possible anatomy/pathophysiology permutations, the frequent coexistence of multiple problem areas and the growing spectrum of therapeutic options generate a daunting number of potential actionable steps.

For the purpose of the following discussion let us consider the familiar scenario of a middle-aged obese female with no prior venous thrombotic history, presenting with a classic medial ankle venous ulcer that has not responded to wound care and compression over a period of six months. The patient reports moderate swelling below the knee in the absence of compression and has extensive chronic stasis changes with inflammation. She has been shown to have a 9mm GSV with reflux times between 1500 and 2000ms. The vein communicates with multiple varicose branches in the vicinity of the ulcer. Interrogation of the deep venous system disclosed CFV reflux time of 3000ms. There is also scattered reflux across the deep venous system and two incompetent perforators communicating with a large plexus of engorged veins underlying the ulcer and surrounding area of chronic skin changes.

In an effort to simplify, let us agree that perforator ablation, branch varicosity ablation and peri-ulcer sclerotherapy would in this case be secondary strategies and that open surgery to restore valve competence or bypass occlusive lesions becomes a consideration after failure of less invasive options. So, the decision that remains is whether to pursue immediate ablation of her incompetent greater saphenous vein or to pursue further evaluation for iliofemoral obstruction with intent to treat this first.
The effect of Early (superficial) Venous Reflux Ablation was recently studied by the EVRA trial.¹ Twenty centers in the UK randomized 450 patients to compression+deferred ablation vs. early ablation+compression strategies. Ulcer healing at 24 weeks was achieved in 76.3% vs. 85.6% with either strategy. Median time for healing was 82 days vs. 56 days respectively. There were 12 instances of deep venous thrombosis in 389 patients that underwent ablation procedures (3.1%).

These findings support the notion that the majority of ulcers will heal with compression and also highlight the incremental contribution of superficial venous ablation towards healing. However, at one year, the rate of recurrent ulceration was 11.4% for the early ablation group and 16.5% for the delayed ablation group, suggesting that for these patients the underlying causes for ulceration were not corrected.

In contrast, iliofemoral stenting without additional venous procedures has been shown to yield ulcer recurrence rates of 6% at 1 year and 12% at 5 years, notwithstanding the presence of superficial, deep or perforator reflux.² In this series encompassing 528 treated limbs the rate of DVT was 2%.

A case series report of 192 limbs compared outcomes of GSV ablation, iliofemoral stenting or a combination of both. Interestingly, the outcome in terms of wound healing was equivalent for the three groups, with healing rates between 80 and 75%.³ It should be noted that this was not a randomized trial. Patients were assigned to the treatment arm considered more appropriate on the basis of their preprocedure workup. Therefore, the homogenously good results may reflect careful patient selection rather than absolute equivalency between techniques.

Clinical practice guidelines published by the American Venous Forum recommend ablation of superficial reflux for dermatitis at risk of ulceration and active or healed venous ulcers. Iliofemoral intervention is also recommended for the same population when occlusion or severe stenosis is present, once superficial and perforator incompetence has been addressed.⁴ To the best of my knowledge, there is no randomized trial comparing iliofemoral stenting first vs. superficial reflux ablation first strategies.
With the information presented so far, as well as taking into account cost and surgical risk considerations, I would consider GSV ablation first in the case presented. The reason for this is that there is substantial reflux in the GSV in the absence of compelling signs of iliofemoral venous pathology.

I believe there is a role for iliofemoral stenting first in cases in which there are documented lesions or clinical signs that strongly suggest them, such as whole-limb swelling or formation of venous collaterals around this segment, particularly in the absence of significant infrainguinal pathology. Iliofemoral intervention may also be of use in the prevention of ulcer recurrence, particularly if there is persistent inflammation after ulcer healing.

Given the complexities vein disease offers, perhaps the best recommendation is to keep an open mind and tailor intervention according to initial findings and ongoing response to therapy.

References

Incompetent perforating veins (IPVs) play a significant role in the progression of venous insufficiency, with studies highlighting the value of interrupting IPVs in treating venous ulcerations\(^1\). Historically, treating perforator veins has been a major challenge when compared to saphenous veins. Current practice guidelines of the Society for Vascular Surgery and the American Venous Forum define pathologic perforator veins (PPVs) as veins that demonstrate > 0.5 seconds of reflux and measure > 3.5 mm in diameter. These guidelines suggest treating PPVs in patients with Clinical, Etiologic, Anatomic, and Pathophysiologic (CEAP) clinical class of 5 or 6, with percutaneous thermal ablation or sclerotherapy, over the open surgical approach, in addition to standard compression therapy\(^2\).

The SeCure study (A Prospective Safety and Effectiveness Study: VenaCure Endovenous Laser Treatment) is a single-arm, prospective, multi-center, non-blinded clinical trial with a sample size of 83 patients (125 perforator veins) evaluating the safety and effectiveness of the 400 Micron Perforator & Accessory Vein Ablation Kit* (AngioDynamics, Inc) for the treatment of IPVs. The study enrolled patients with CEAP class 4b, 5 and 6 attributable to the IPVs. The primary objective of the study was demonstrating successful ablation of IPVs, as measured via duplex ultrasound imaging performed 10 days post procedure. Secondary objectives were demonstrating procedural technical success rate (successful access and entry into the incompetent perforator veins to be ablated and the ability to deliver the intended laser energy); one, three, six, nine and 12-month primary ablation closure rates; and changes in revised Venous Clinical Severity Score (rVCSS), including quality of life, ulcer healing and procedure-related adverse events. The treatment was performed with a 400 Micron Perforator & Accessory Vein Ablation Kit in combination with the VenaCure 1470 Pro laser that can be placed through a micropuncture needle or a catheter.

Acute primary ablation success rate, considered as the primary endpoint after the 10-day visit, was 76.8% which was statistically significant (p < 0.05) when compared to radiofrequency ablation (RFA) success rate of 70% (from published literature). Also, successful primary ablation was demonstrated in one, three, six, nine and 12-month follow ups. The higher success rate of 96-98% is generally seen with saphenous veins, whereas perforator success rates (for thermal ablation) have oscillated between 60-80%\(^1,3\). The success rate reported in the SeCure study was in congruence with the literature. Apart from the primary ablation success rate, the SeCure trial also investigated several other clinical outcomes such as procedural technical success rate, changes in rVCSS, CEAP symptoms and quality of life (VEINES QoL). At each time point, the mean rVCSS and the quality of life were significantly improved from baseline (p < 0.05), with favorable trends in ulcer healing.
With very few device-related complications, SeCure is one of the few studies that have measured specific clinical outcome assessments and quality of life indications when treating IPVs. Patients were selected and enrolled using clearly defined inclusion and exclusion criteria with risks being minimized by requiring participants to report for routine clinic visits. Participating centers had physicians with experience performing interventional vascular procedures in high volume venous centers.

The SeCure study showed that the 400 Micron Perforator & Accessory Vein Ablation Kit used in combination with the VenaCure 1470 Pro laser treats PPVs, with superior closure rates (compared to RFA), significant gains in the patients’ quality of life and promising ulcer healing trend. The successful results from the SeCure study led to the 510(k) clearance by the FDA of the 400-micron fiber with the VenaCure 1470 Pro laser for the treatment of IPVs.

The VenaCure EVLT 400 μm Perforator and Accessory Vein Ablation Kit is intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosities.

The VenaCure EVLT 400 μm Perforator and Accessory Vein Ablation Kit is indicated for treatment of incompetence and reflux of superficial veins in the lower extremity, and for treatment of incompetent (i.e. refluxing) perforator veins (IPVs).

The SeCure study was sponsored by AngioDynamics, Inc. Dr. Kathleen Gibson (Vascular Surgeon, Lake Washington Vascular, Bellevue, WA) was the Principal Investigator of the SeCure study. For additional information on the SeCure study, please visit clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT02215369).

The SeCure study data discussed above was presented at the American College of Phlebology meeting (6-8 November 2018, Nashville, TN); VEITH Symposium (13–17 November 2018, New York, NY) and the International Vein Congress (25-27 April 2019, Miami, FL). The manuscript from the SeCure study is currently under peer review.
References:


* AngioDynamics and VenaCure are trademarks and/or registered trademarks of AngioDynamics, Inc., an affiliate or subsidiary. All other trademarks are property of their respective owners. ANGM 1161 US Rev 01 09/2019

IMPORTANT RISK INFORMATION

Indications for Use: The VenaCure EVLT 400 μm Perforator and Accessory Vein Ablation Kit is intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosities.

The VenaCure EVLT 400 μm Perforator and Accessory Vein Ablation Kit is indicated for treatment of incompetence and reflux of superficial veins in the lower extremity, and for treatment of incompetent (i.e. refluxing) perforator veins (IPVs).

Contraindications: Contraindications include but are not limited to the following, Patients with thrombus in the vein segment to be treated. Patients with an aneurysmal section in the vein segment to be treated. Patients with peripheral arterial disease as determined by an Ankle-Brachial Index < 0.9. Patients with an inability to ambulate. Patients with deep vein thrombosis (DVT). Patients who are pregnant or breast feeding. Patients in general poor health. Other contraindications may be raised by the individual physician at the time of treatment.

Extremely tortuous vein segments may require treatment by alternative techniques (phlebectomy, sclerotherapy).

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.
Dear Colleagues,

One of the missions of the American Venous Forum (AVF) is promoting high quality research in venous and lymphatic disease. The AVF Research Committee was created to implement this mission. One of the main responsibilities of the Committee over the past three decades has been reviewing applications for the AVF-JOBST Grant, the largest and one of the most prestigious awards in venous and lymphatic disease. The Research Committee has also contributed to a number of recent AVF initiatives: introducing the Day of Innovation and Science and the Best Paper Session at the Annual Meetings. These initiatives are intended to improve awareness and understanding of the current evidence in the field of venous and lymphatic pathology. The Committee aims to continue and to expand its role in initiating and promoting innovative and clinically relevant research projects. An imperative part of this process is the identification and recognition of current knowledge gaps in venous and lymphatic disease.

Judicious integration of the results from high quality evidence into daily practice is critical for delivering the best patient care. Depending on the abundance and the quality of data, as well as personal clinical experience, the interpretation of published studies by different physicians may vary broadly. Known discrepancies between systematic reviews and clinical guidelines all founded on the same body of evidence reinforce this statement. Even carefully designed randomized controlled trials may have internal flaws and sometimes raise more questions than provide answers. Recently published “Compression stockings to prevent post-thrombotic syndrome” (SOX trial1) and “Pharmacomechanical Catheter-Directed Thrombolysis for Deep-Vein Thrombosis” (ATTRACT trial2) clearly illustrate this principle. As a result, despite major advancements in experimental and clinical phlebology there are many controversies in diagnosis and treatment of venous disease. Multiple grey areas underlie significant variations in practice patterns in the United States and all over the world. Better understanding of current practices among experienced physicians and reasoning behind those practices appears to be one of the keys to guide scientifically relevant and clinically-oriented research projects. The Research Committee has been actively working in this direction.

In 2015, the Research Committee elaborated the first survey that aimed to investigate the use of adjunctive therapies for venous ulcers. The survey received 124 responses and the results were published later in Phlebology (Aziz F., Raffetto J., Diaz J.A. et al.; 2015)3. The results of the survey demonstrated that the only agreement between specialists was compression therapy use. The vast majority of physicians consider adjunctive therapeutic options in patients who do not respond well to compression. There was a wide variation in usage of additional therapies, such as negative pressure wound therapy, hyperbaric oxygenation, topical dressings, human skin substitutes, extracellular matrix biologics, and skin grafts. The survey demonstrated that there is a need for high-quality data to

The results of another questionnaire on endovenous ablation for patients with primary superficial venous reflux were published in Journal of Vascular Surgery in 2017 (Aziz F., Diaz J.A., Blebea J.; 2015)4. The study demonstrated that 4 out of 5 physicians prefer radiofrequency ablation over laser therapy to eliminate saphenous reflux. Higher cost-effectiveness was mentioned as a main reason of this preference with more that 60% of respondents reported significant initial capital investments that determined subsequent selection of endovenous treatment modality. Better patient satisfaction was also mentioned in favor of radiofrequency.

The Research Committee has recently developed two surveys devoted to determining the variety of practice patterns in management of venous thromboembolism. The first survey aims to collect information on current practices to manage the first episode of unprovoked femoropopliteal deep vein thrombosis (DVT). The survey will address expected variations in utilizing anticoagulation and compression therapy, and physical activity recommendations. The survey will be launched in the fall of 2019 on the AVF website. The results of the survey will be presented at the AVF 2020 Annual Meeting. Another survey will address the problem of extended anticoagulation therapy in patients with DVT. ACCP guidelines suggest extending anticoagulation beyond 3 months for patients with unprovoked or recurrent DVT. However, an individual patient-based approach to extend anticoagulation has never been suggested. The survey aims to analyze the current practices among the members of the AVF and will be launched at the AVF 2020 Annual Meeting.

The Research Committee strongly encourages all AVF members to participate in these surveys and highly appreciates all respondents in advance. It is only by open communication, close collaboration, and constant re-evaluation of our daily practices that we can improve the clinical outcomes for patients suffering from venous and lymphatic diseases. The Research Committee will provide the AVF members with a timely update on the results of the surveys. We believe, the results will be interesting and educational for all practicing physicians taking care of patients with DVT, and will hope to advance knowledge of the field. New survey ideas from the AVF membership are always welcome, and will be reviewed by the Research Committee on the monthly regular basis. Thank you again for your time, attention, and contribution.

Maxim E. Shaydakov, MD, PhD, RPVI
On behalf of the AVF Research Committee

Maxim Shaydakov, MD, PhD, RPVI

AVF RESEARCH COMMITTEE SURVEYS continued
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References:


FALL EARLY CAREER COURSE

Nasim Hedayati, MD, FACS, RPVI

This year’s American Venous Forum Fall Fellows, Residents and Early Career Course will be held at the beautiful campus of the University of California, Davis in Sacramento December 6-7, 2019. The course has been renamed to underscore the educational mission of the AVF by reaching a wider audience of young physicians in practice.

The AVF Fellows course has been the brainchild of Dr. Steve Elias who started the program 15 years ago in Englewood, New Jersey. The AVF took over the administrative responsibilities five years ago and subsequently a Fall course was started to meet the demands and make the course more accessible to the west coast residents and fellows. The course has been of particular benefit to early career physicians who may not have had much exposure to venous interventions during their training but who commonly find that their practices includes many patients with venous disease.

The Fall Early Career Course offers didactic lectures as well as many hands-on sessions to better serve the need of the residents, fellows and early career physicians with understanding superficial and deep venous diseases and the latest treatment options. We have an outstanding faculty that will make this another memorable meeting.

Our industry partnerships have enabled the AVF to make this course accessible to a large number of attendees over the years who have greatly benefited from attending this course. All attendees will also get a one-year free membership to the American Venous Forum, which is a wonderful organization dedicated to research and clinical innovation educating health professionals, patients, and policy makers about venous and lymphatic diseases.

We ask our AVF members to encourage their residents and fellows to attend this course. Please use the following link to register for the course. We hope to see you all in Sacramento.

Nasim Hedayati, MD, FACS, RPVI

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Register Today

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Dear Colleagues:

We belong to a breed of specialists that share a passion for venous diseases. Most of us are vascular surgeons, trained in arterial diseases and little exposure to venous was considered in our academic programs.

That trend is changing, in part due to public awareness on this kind of problem, but most of all, due to the passion and emotion we imprint in teaching and organizing meetings where we can discuss cases and strategies on venous diseases. These meetings are fueled by a growing industry that saw a few years ago what we knew in our hearts would come. No matter what machine, diode, catheter, stocking, software or instrument is out there, it requires our intuition and mind to use it appropriately, making our breed of specialists a pivotal part of the whole process.

The International Committee of the American Venous Forum is making an effort to broaden the roots of knowledge by creating new spaces, in order to listen to the experiences of our international members, so we can know what is happening out there, and perhaps, joint efforts to try to make a change in our patients, regardless of their geographical location. Some very interesting strategies are being taking place currently to make access easy for our international colleagues. On behalf of the AVF, I would like to thank the members of the AVF International Committee who are committed to helping advance the mission of the AVF and help improve the science, understanding and practice of venous disease throughout the world. The members of the Committee include:

AVF International Committee Members

Jorge Ulloa, MD - Chair
Enrico Ascher, MD
Ruth Bush, MD
Patrick Carpenter, MD
Rabih Chaeer, MD
Alun Davies, MD
Zoe Deol, MD
Sergio Gianesini, MD
Nasim Hedayati, MD
Anil Hingorani, MD
Mehmet Kurtoglu, MD
Patrick Muck, MD
Alvaro Esteban Orredo, MD
Kurosh Parsi, MD
Malay Patel, MD
Paul Pittaluga, MD

We count on you to come to our next meeting in Florida, to share, discuss, debate, teach and learn, at the International Session of the AVF meeting.

Join this breed of excellency in venous diseases, just ask me how.
AVF AT AVLS CONGRESS

HOW “WE” DO IT: TIPS FROM US AND FEEDBACK FROM YOU
Hal Welch, MD

As part of our reciprocal agreement, the AVF will have a two and a half hour session at the AVLS Congress, on Thursday, November 7th (8:00am–10:30am) in Phoenix, AZ. Moderated by Dr. Harold Welch, AVF President-Elect, the session will follow the theme of the AVLS Congress, and be interactive and practical. Six AVF Leaders will participate in the AVF Symposium session, How “We” Do It: Tips From Us, and Feedback From You.

Speakers and topics from the AVF will include:

- Dr. Brajesh Lal (AVF President) – Integrating National Registries into Your Practice and Making Them Work For You
- Dr. Elna Masuda (AVF Past President / AVFF President) – Overuse of Ablation for the Wrong Indications: A Growing Problem?
- Dr. Harold Welch (AVF President Elect) – Endovenous Ablation and Phlebectomy
- Dr. Antonios Gasparis (AVF Vice President) – Treatment Protocol for Pelvic Venous Reflux
- Dr. Joseph Raffetto (Board of Directors Member and Research Committee) – Practical Venous Leg Ulcer Wound Care and Treatment
- Dr. Patricia Thorpe (Early Career Committee) – Deep Venous Intervention for Post-Thrombotic Iliac Vein Occlusion: How I Do It

After the presentations, there will be ample time for discussion and feedback from the audience on these important topics in venous disease and treatment. The AVF is pleased to collaborate with the AVLS and be an integral part of their Congress.

VENOUS2020

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HEALTHY VEINS FOR HEALTHY LIFE - THE AVF FOUNDATION IN ACTION

Jeff Mendola

The American Venous Forum and AVF Foundation would like to thank our dedicated Vision Partners and Members who supported Healthy Veins for Healthy Life in 2019 and share the impact of this support on the AVF, its members, and venous professionals around the globe via the four pillars of Healthy Veins.

I. To Educate is to Empower: Increase education and awareness of venous disease among healthcare professionals

a. Our 2019 AVF Annual Meeting welcomed almost 300 attendees from 28 countries and resulted in a record number of abstract submissions – many of which were referred to the Journal of Vascular Surgery Venous and Lymphatic Disorders (JVS-VL) for publication.

b. AVF leadership presented Venous sessions at a range of venues including the AVLS Annual Congress, VEITHsymposium, Venous Symposium, SVS Vascular Annual Meeting and European Venous Forum Annual Meeting.

c. More than 100 Residents, Fellows and Medical Students benefitted from AVF Early Career educational programs this past year.

II. New Knowledge Improves Lives: Support cutting-edge research and clinical innovation in venous and lymphatic disease that will advance patient care.

a. The AVF-JOBST Research Grant is entering its 25th year and has greatly helped to advance the understanding and treatment of venous disease.

b. The impact factor for our Journal, the JVS-VL, rose dramatically from 1.619 to 2.696 making it the highest ranked venous publication and in the top 25% of all ranked medical journals!
AVF FOUNDATION continued

HEALTHY VEINS FOR HEALTHY LIFE - THE AVF FOUNDATION IN ACTION
Jeff Mendola

III. Advocate for Access: Promote evidence-based best practices to ensure patients have access to the highest quality care.

a. Clinical Practice Guidelines for Compression Therapy After Invasive Treatment of Superficial Veins of the Lower Extremities was published in the January 2019 issue of the JVS-VL.

b. Led by Dr. Elna Masuda, we completed the first phase of a multi-society collaboration committed to addressing inappropriate venous care for patients. Initial Appropriate Use Criteria (AUC) results were presented at the 2019 AVF Annual Meeting.

c. The Endovenous Heat Induced Thrombus (EHIT) writing committee is in the final stage before publication.

d. Our Health Policy Committee (HPC) has worked on several letters addressing the need for coverage for non-thermal techniques, specifically mechanic-chemical treatment of axial venous insufficiency.

e. A joint letter with SVS and AVLS was sent to the SDMS regarding the cleaning of Ultrasound equipment.

f. The AVF was invited to join Evidence Street, used by Blue Cross Blue Shield to collect research and evidence to help them create their policies on treatment and reimbursement for their patients.

g. Members of the HPC met with CMS to discuss ways in which AVF could better provide information used to determine policy. When the HPC became aware of local LCDs not supporting point of service care and CMS proposed cuts to supplies used to treat venous disease, the AVF responded.

IV. Empower and Enable Vein Care to Improve Quality of Life & Reduce Disability: Educate those who are unaware of venous and lymphatic disease and increase access to care for the underserved.

a. The Venous Patient Outreach Survey (vPOS) Committee is working to identify the venous information patients are looking for, where they are looking for it, and how they prefer to receive it. This critical data will be used to design a patient education program to meet the actual needs of our future patients.

b. An update of the Patient’s Guide to Venous and Lymphatic Disease has begun.
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Benefits of Membership
• Complimentary subscription to the Journal of Vascular Surgery: Venous and Lymphatic Disorders

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Networking & Public Awareness
• Find a Vein Specialist listing – public online directory

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