VENOUS Review

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inside this issue

CVR Welcomes DR. PAPPAS to the TEAM

New Technologies for the Treatment of Saphenous Vein Reflux

By Peter J. Pappas, MD, FACS

In the mid 1990s, a tectonic shift in the management of chronic venous insufficiency and patients suffering from varicose veins occurred. Traditional vein stripping and stab avulsions was challenged by a new endothermal technique. I first met Brian Farley, president and CEO of the then VNUS Inc. when I was a Vascular Fellow at UMDNJ-New Jersey Medical School. Brian had just obtained funding for a start-up company based on a new catheter technology using radio-frequency. Originally, Brian thought he could restore venous valve function by re-approximating the valve cusps through heating the endothelium adjacent to the valves. In his initial clinical studies, he learned that his catheter had a high vein occlusion rate. With that discovery, the era of endothermal ablation began. I remember sitting in the audience at the American Venous Forum when the first clinical data was reported. The technology was a tectonic shift in the way vein disease was treated in the United States. The majority of the academic world was slow to adopt the technology and wanted to see long-term data on the efficacy and durability of the technology. Those early studies identified two crucial observations: Endothermal ablations without tumescent anesthesia had a 9% skin burn incidence, and that heat induced ablations of the below-knee saphenous caused saphenous nerve neuritis. As a result of endothermal technologies and the aforementioned clinical observations, an explosion of new technologies for the treatment of chronic venous disease have emerged. This article will review currently approved technologies and briefly review their advantages and disadvantages.

TUMESCENT THERMAL TECHNOLOGIES

As the first technologies developed to treat varicose veins, thermal tumescent technologies have the longest track records and the most clinical data. There are currently two thermal technologies approved by the FDA and one that is still in development. The ClosureFast device (Medtronic, Minneapolis, MN) uses radiofrequency to generate heat, damage the venous endothelium and occlude the vein. Radiofrequency ablation (RFA) has the most clinical data as it was the first endothermal technology developed by Brian Farley and the VNUS company in the early 1990s. RFA has over a 90% closure rate at one year and an 88% rate at five years. Although approximately 10% of veins recannalize at one year, most are asymptomatic and do not require retreatment. RFA of the entire great or small saphenous is usually not performed due to concerns over injuring the Saphenous or Crural nerves. However, some investigators have reported that with liberal use of tumescence, the nerves can be pushed away from the veins and endothermal ablations can be performed safely in either vein. Technical concerns over the time it took to perform

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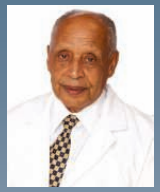

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New Technologies for the Treatment of Saphenous Vein Reflux *Continued from Page 1*

the procedure have disappeared with a redesign of the catheter into the current Closure Fast device. A major advantage of the Closure Fast device is decreased post-operative pain compared to endovenous laser technologies. This advantage is observed in the first post-operative week only and appears to be wavelength dependent (See below). As with all endovenous technologies there appears to be a 20% recurrence rate after five years. Recurrences occur in new venous segments with the anterior accessory or anterolateral accessory saphenous veins reported to be the most common areas for recurrences.

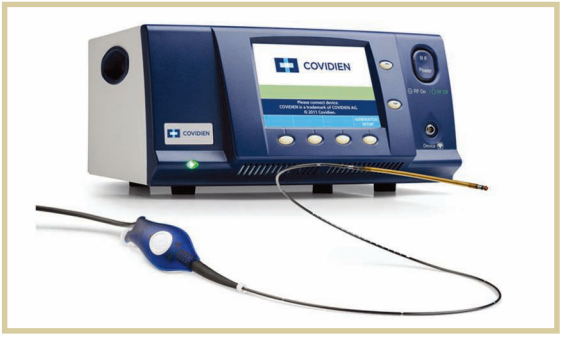
Endovenous laser technologies are the second form of heat induced technologies. Lasers emit light at various wavelengths. These wavelengths transmit energy to various intra-luminal contents causing them to generate heat and damage the venous endothelium. Depending on the wavelength, lasers can activate hemoglobin, chromophores and water. The very first lasers were bare-tipped, lower-frequency catheters that energized hemoglobin. They caused an intense inflammatory reaction that is associated with a tender post-operative phlebitic reaction in some patients. Higher frequency, water based lasers generate less heat and are reported to cause lower post procedure pain.

The third type of heat-induced technology is steam. Steam is used to generate heat, which damages the venous endothelium and ablates the vein. This technology is not available in the United States yet. A possible advantage of this technology is the ability of steam to travel into side branches of the axial saphenous vein. A limitation of heat based catheter technologies is their inability to treat veins other than an axial segment. In addition, tortuous veins often require a second or third puncture or the use of a foam sclerosant in order to treat the symptomatic segment. Steam may therefore treat more than just the axial vein.

NON TUMESCENT, NON THERMAL TECHNOLOGIES

A major disadvantage of all the thermal technologies is the need for tumescent anesthesia. As stated above, prior to the use of tumescence, there was a reported 9% rate of skin burns observed after RFA. Skin burns disappeared as a complication with the standard use of tumescence. Despite this advantage, the patient must endure several skin punctures and the sensation of fluid instillation into the saphenous canal. In an effort to further minimize any discomfort associated with endoluminal ablations, several non-tumescent technologies have been developed.

One of the first devices developed was the Clarivein device (Vascular Insights LLC, Quincy, MA). The Clarivein device utilizes mechanochemical methods to ablate the saphenous vein. The device consists of a rotating wire (3,500 rpm) that abrades the venous endothelium. A liquid sclerosant (sodium tetradecyl sulfate or polidoconol) is simultaneously injected intra-luminally as the device is withdrawn caudally while the wire rotates. The wire and sclerosant both damage the venous endothelium resulting in venous occlusion. One-year occlusion rates are approximately 90%. Long-term data are pending (See graph#1). The advantage of this technology is the avoidance of tumescence and the ability to treat below-knee saphenous veins without injuring the saphenous or crural nerves.



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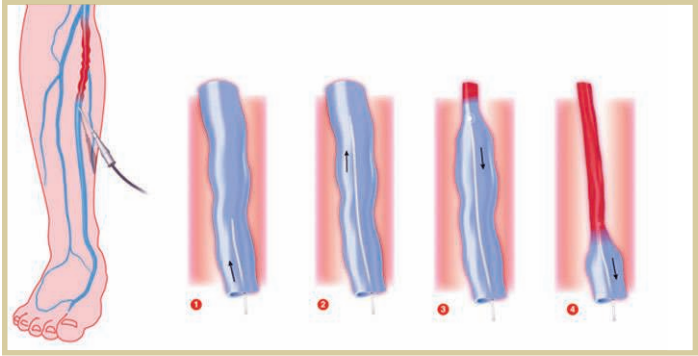

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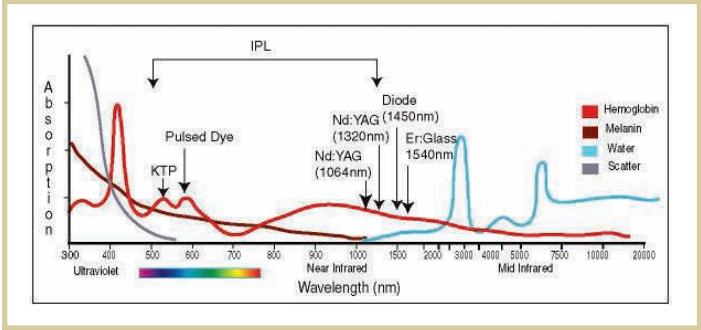

Image 003

Image 004

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New Technologies for the Treatment of Saphenous Vein Reflux *Continued from Page 2*

It is anticipated that a new CPT code for mechanochemical ablation will be available in 2017. The lack of a CPT code has impeded the widespread adoption of this technology.

The next device developed is the VenaSeal device. VenaSeal was originally developed by Sapheon, Inc (Morrisville, NC) and purchased by Covidien which is now owned by Medtronic (Minneapolis, MN). The VenaSeal system was originally approved in Australia, Canada, Europe and Hong Kong and received FDA approval in the United States in February 2015. VenaSeal utilizes Cyanoacrylate Glue to occlude the vein. The glue is placed in the Saphenous vein with a delivery device designed so that the glue matures in the lumen and not in the delivery catheter (See below). When the glue mixes with blood or plasma, it polymerizes and adheres to the wall of the saphenous vein. Cyanoacrylate glue is not a new substance. It has been used as an embolic agent for years. The one year results for the VenaSeal device were recently published by Morrison et al. in the Journal of Vascular Surgery: 2015:61(4); 985-994. As with the other technologies discussed, one-year occlusion rates were greater than 90%. Long-term data on the durability, recanalization rates and recurrence rates are not available yet. The interesting fact about this technology is that although Cyanoacrylate glue could be considered a drug, the FDA approved this technology as a device.

The next technology currently available for endovenous ablation is Varithena (BTG International Inc., West Conshohocken, PA). Varithena is polidocanol endovenous microfoam. Polidocanol is a drug whose chemical composition is changed into a microfoam by mixing it with O_2 and CO_2 in a proprietary canister. The mixture process changes the liquid into a foam with uniformly sized bubble particles that carry the chemical sclerosant to the venous endothelium. Varithena should not be confused with foam made in the office utilizing the Teshari method. The Teshari method utilizes oxygen and nitrogen from the air. Bubble sizes are not uniform and there have been reports of serious adverse events in patients with patent foramen ovales due to large bubbles. BTG has spent 10 years developing and clinically testing their technology and have demonstrated an impressive safety profile for their product. The studies submitted to the FDA demonstrated no pulmonary emboli, no cerebral vascular events, deep vein thrombosis rates of 1.1% and one-year occlusion rates of 85%. The disadvantages of Varithena is that once the canister is punctured, it has a one to two week shelf life. In addition, the drug is costly. Many practitioners are not getting reimbursed from third-party payers adequately, limiting wide-spread adoption of Varithena for axial saphenous vein ablation.

A new technology that is not FDA approved yet is the V-Block (VVT Medical Ltd, Kfar Saba, Israel). This technology utilizes an occlusion device that is released distal to the sapheno-femoral juntion with subsequent release of liquid sclerosant below it. The sclerosant is released through a dual-syringe system. The syringe aspirates blood, collapsing the vein, while simultaneously injecting sclerosant. The occlusion device is a conical nitinol filter covered by a thin membrane of polytetrafluoroethylene (See image on right). Initial results in fifty patients demonstrated a 100% occlusion rate at 4.6 months.

Conclusion: Over the past 20 years, technological advancements for the treatment of patients with superficial venous insufficiency have exploded. Thermal technologies are by far the most commonly utilized procedures in the United States today. However, a desire by clinicians for non-thermal, non-tumescent devices has led to the development of many new technologies. The emergence of these newer technologies will depend on long term durability, quality of life improvement, cost and proper reimbursement to clinicians by third party payers. The clinicians at CVR strive to provide state-of-the-art care to our patients and are committed to be the leaders in vein care delivery in the United States.

Image 007

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CVR Provides Educational Opportunities

Center for Vein Restoration & Howard Community College: A New Partnership is Born! In an effort to support our growing practice and the need for vascular technologists with a sound foundation in venous insufficiency testing, CVR has developed a partnership with Howard Community College, Diagnostic Medical Sonography Program in Columbia, Maryland. In addition, we also have students from University of Maryland, Baltimore College come to our facilities for their clinical internships.

CVR will not only serve as an internship site for HCC's and UMBC's growing vascular program but our collaboration will also provide an avenue for direct access to potential employment opportunities with CVR. In November, CVR will host first-year students from HCC's DMS program by allowing them to tour our facilities to provide them with an early insight into the functions of a vascular lab.

CVR TO OPEN SCHOOL OF VASCULAR ULTRASOUND

We're also proud to announce that, as a new milestone in our commitment to professional development, we will open the CVR School of Vascular Ultrasound late in 2016. The school will offer training in vascular ultrasound (currently planned at 12-18 months) – and will provide students all prerequisites necessary to obtain credentialing:

- Students will be able to take the didactic portion of their training online using CVR's course
- Students will be able to get their Required Clinical Ultrasound/Vascular experience (12 months of full-time clinical ultrasound/vascular experience) at a CVR clinic in every state in which we operate
- After successfully completing these required courses, students will be able to take their exams in order to earn their credentials: RDMS (Registered Diagnostic Medical Sonographer) and RVT (Registered Vascular Technologist)

HOWARD COMMUNITY COLLEGE

As described by the American Registry for Diagnostic Medical Sonography (ARDMS): The RVT and RDMS credential raise the standard of vascular ultrasound practice worldwide and promotes best practices for enhanced patient safety. The RVT credential is designed to certify medical professionals in the vascular ultrasound field. By earning the RVT credential, healthcare professionals gain a critical edge in promoting public safety in vascular ultrasound.

Further information on the school including information on how to enrol, will be announced later this year. We look forward to helping the next generation of VTs embark an exciting career!

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QUESTIONS & Answers

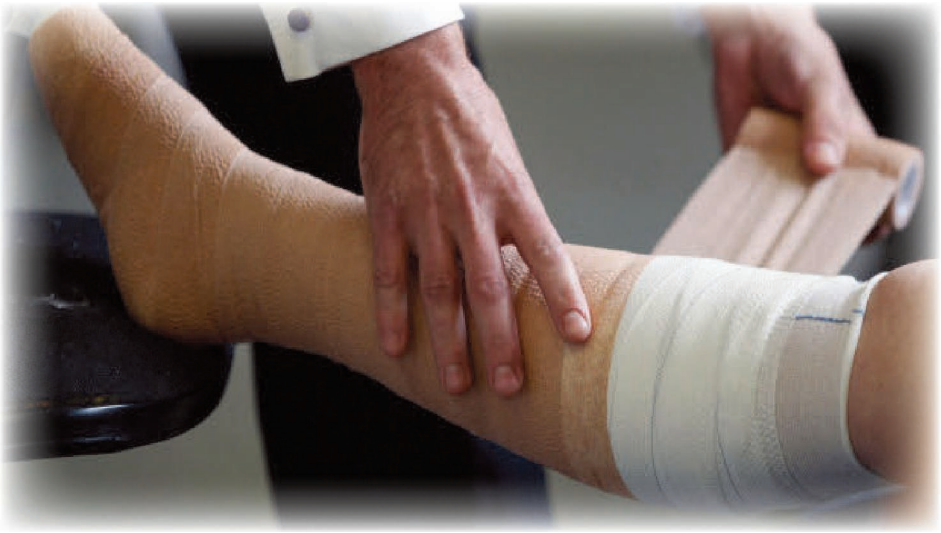
In each issue of Venous Review, our medical team answers questions we've received from referring physicians.

This Issue's Guest Q & A Editors Are

Candice Coombs, PT, DPT, CLT
Lymphedema Therapist

Jeffrey Takahashi, MD

What is lymphedema therapy?



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Q: Can you explain lymphedema therapy and why this would be recommended?

A: Lymphedema is an abnormal accumulation of protein-rich fluid in a body part resulting in chronic swelling. Lymphedema can cause an increased risk of infections and wounds, deformity of limbs and significant physical disability if left untreated. The gold standard for the treatment of lymphedema is Complete Decongestive Therapy (CDT). CDT is a two-phase system comprised of a clinical or intensive phase and a maintenance phase. The intensive phase of CDT is directed by a Certified Lymphedema Therapist and consists of skin and nail care, Manual Lymph Drainage (MLD), compression bandaging, exercise and self-care education.

The goal of the intensive phase is to decongest the affected body part while reducing the risk of infection. Skin and nail care are essential during CDT to decrease the risk of infection. MLD is a gentle, manual technique applied directly to the skin which stimulates the entire lymphatic system to mobilize lymph fluid away from the affected body part and toward unaffected or healthy lymph nodes and vessels. Compression bandaging involves application of short, stretch bandages over foam padding to the affected body part to promote the movement of lymph fluid from the limbs or distal aspects of the body towards the trunk.

Exercises performed during the intensive phase of CDT are called remedial exercises. Remedial exercises are most effective when performed with compression bandages applied to affected body part. Remedial exercises involve active, repetitive, non-resistive motion of the involved body part. Self-care education is vital to the long-term success of CDT. Patients and their caregivers are educated on self-MLD and bandaging techniques, proper skin and nail care and given a home exercise program. Self-care education is essential for the transition to the maintenance phase of CDT.

The maintenance phase focuses on maintaining the results achieved during the intensive phase and is directed by the patient and/or their caregivers at home. Maintenance may involve the patient and/or their caregiver performing compression bandaging and MLD, regular performance of remedial exercises, daily skin and nail care, daily use of compression garments and use of home pneumatic compression devices. Compression garments are essential to the success of the maintenance phase as they will aid in maintenance of the newly reduced size of the affected body part. Patients may return to the intensive phase of CDT for brief periods of time throughout their life as needed then transition back to maintenance phase.

CVR now offers Lymphedema Therapy at the following locations:

- Alexandria, VA
- Fairfax, VA
- Greenbelt, MD
- Glen Burnie, MD

QUESTIONS & Answers

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Candice Coombs, PT, DPT, CLT
Lymphedema Therapist

Jeffrey Takahashi, MD

What is the success rate for endovenous thermal ablation?

Q. What is the success rate for endovenous thermal ablation of the great saphenous vein (GSV) or small saphenous vein (SSV) in patients with chronic venous insufficiency (CVI)?

A: Before I can answer that question, we need to first take a step back and understand how the "success rate" of a particular procedure or treatment is generally defined. We first need to know the immediate (and long term) TECHNICAL success rate, i.e. was closure of the saphenous vein achieved immediately following the procedure and if so, has it remained closed as determined by duplex ultrasound examinations in subsequent follow up (e.g. 1 week, 6 months, 1 year, 3 years, 5 years, etc.) evaluations? We then need to know the CLINICAL success rate, i.e. the patient and the physician noticed a significant difference in symptoms (e.g. aching pain, heaviness, swelling, etc.) or signs (e.g. shrinkage of visible varicose veins or ulcer healing) following the procedure?

With regard to endovenous thermal ablation of the incompetent great or small saphenous veins, we should further divide the clinical success rate into that component which is observed by the physician versus that which is reported by the patient. There are many standardized physician generated measurement tools available, one example of which is the Venous Clinical Severity Score (VCSS). From the patient's perspective, which is equally if not arguably more important, there are generalized patient related outcome measurement tools available.

Now that we have reviewed the technical and clinical components of reported success rates, I can answer the question at hand by reporting that the technical success rate for endovenous thermal ablation of both the GSV and SSV has consistently been reported to be well over 90% at 1 year with durable results seen up to 5 years, when looking at continued closure of the vein by serial ultrasound examinations.

The clinical success rate, as reported by both the physician and the patient, is similarly very high but dependent on several factors, including the use of adjunctive procedures such as ambulatory phlebectomy and/or ultrasound guided foam sclerotherapy, as necessary. Another important predictor of long-term clinical success is maintaining periodic follow up evaluations so that recurring problems (e.g. neovascularization) can be addressed before they escalate. For this reason, at Center for Vein Restoration, we emphasize to our patients the importance of continued follow up visits in order to maintain the benefits that result from our state-of-the-art methods and clinical expertise in the treatment of chronic venous insufficiency.

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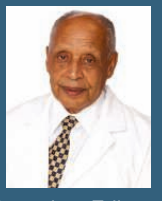

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Life is as busy and rewarding as ever here at Center for Vein Restoration. Our momentum continues as we prepare to open our 45th clinic. Our mission is to serve as many patients as possible suffering from venous insufficiency and we're grateful for the opportunity to help patients across the US feel better, live better and look better.

In this edition of Venous Review, we examine the explosion in new technologies for the treatment of saphenous vein reflux, discussing the pros and cons of both tumescent thermal (radiofrequency, laser and steam ablation) and non-tumescent/non-thermal technologies (mechanical ablation, glue, microfoam, and dual-syringe administered sclerosant).

Additionally, we're happy to report on our efforts to educate professionals and students about treatment of venous disease and what's exciting about our specialty – including the launch later this year of the CVR School of Vascular Ultrasound.

As always, we hope you find the information in our newsletter helpful to you and your patients. We appreciate your support and trust as we work to bring relief to just some of the 30 million Americans suffering from vein disease.

Yours in good health,

Sanjiv Lakhanpal, MD, FACS
Editor-in-Chief