PANEL DISCUSSION

Thermal or Nonthermal? Decision-Making, Pros and Cons, and Complications to Watch For

Moderator: Dr. med. Tobias Hirsch
Panelists: Antonios Gasparis, MD, FACS; Ramona Gupta, MD; and Kathleen Ozsvath, MD

Over the last 2 decades, endovenous procedures have become a standard form of varicose treatment. International guidelines recommend radiofrequency ablation (RFA) and laser treatment as first-line therapies, as they provide excellent results and are backed by a lot of evidence. Nonthermal, nontumescent (NTNT) procedures that avoid thermal trauma and tumescent anesthesia, such as foam sclerotherapy, mechanochemical ablation (MOCA), and acrylate sealing, round off the treatment portfolio. As a result, we now have a wide variety of devices at our disposal. Having more than one instrument in our toolbox means that an optimal solution can be found for every patient. To illuminate further on this topic, I've posed varying questions to Drs. Tony Gasparis, Ramona Gupta, and Kathleen Ozsvath about the basis for their decision-making.

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Dr. Gasparis, do we have data on the percentage of patients undergoing saphenous ablation for varicose vein treatment in the United States that utilizes NTNT methods? If not, what do you believe is the percentage?

Dr. Gasparis: NTNT refers to treatments such as polidocanol injectable foam (Varithena, Boston Scientific Corporation), cyanoacrylate (VenaSeal, Medtronic), and MOCA (ClariVein, Merit Medical Systems, Inc.). Accurate data on the percentage of patients undergoing saphenous ablation for varicose vein treatment in the United States that utilizes NTNT methods are not readily available. Thermal technology (TT) remains the predominant treatment modality partially because it has been around for > 20 years, but mostly because some insurance carriers still consider NTNT technologies experimental.

When reviewing the Centers for Medicare & Medicaid database (2018 data only available), NTNT accounted for approximately 20% of all ablation procedures performed in the Medicare population.[1] In the general population, I would think this number is lower because of reimbursement issues with private insurance carriers. In 2021, with some increase in coverage since 2018, my estimate is that NTNT treatment accounts for 10% to 20% of all ablation procedures in the United States.

Which of your patients would you primarily advise to have a nonthermal procedure such as polidocanol injectable foam, MOCA, or cyanoacrylate?

Dr. Gasparis: I discuss the options with patients. Most patients have questions before we even begin the dialogue. I start the discussion with their anatomy and review the reflux studies. The results of these studies together with patients' expectations will help determine which procedure is best. No matter which technique we decide upon, the risks and benefits, closure rates, recanalization rates, and possible complications are discussed.

From an anatomic perspective, patients with axial reflux in a below-knee great saphenous vein that needs to be treated and those with small saphenous vein pathology are patients in whom nerve injury with thermal ablation may be higher. Therefore, I advise NTNT treatment for these patients, as it has an extremely low incidence of nerve injury. From a patient perspective, for anxious patients with low pain tolerance, I offer NTNT because it does not require tumescent anesthesia.

Do anatomic conditions play a role (anatomy of the junctions, diameter, length of the reflux?)

Dr. Gasparis: Each technology has instructions for use (IFU) that the manufacturer has published and recommended. I strongly believe in following the IFU, but equally important is training and experience. With respect to anatomic conditions and treatment options:

- Vein diameter: For veins ≥ 12 mm, I preferentially use TT over NTNT
- Vein length: For vein < 10 cm in length, I favor TT over NTNT
- Location: For below-the-knee veins, I choose NTNT over TT

Which cases definitely warrant a "robust" thermal procedure?

Dr. Gasparis: The case in which a "robust" thermal procedure I feel is needed would be the patient with a large (> 12 mm) saphenous vein.

Do you see a special benefit of NTNT for the treatment of recurrent veins?

Dr. Gasparis: With respect to recurrent veins, NTNT has the following special benefits:

- If recurrence is due to failure of thermal closure of the saphenous vein, using a NTNT technology such as VenaSeal would be my next step to close the saphenous vein.
- If recurrence is due to neovascularization or there are extensive postthrombotic changes in the saphenous vein, using a NTNT technology such as a Varithena may be more appropriate.
- If recurrence of disease is due to below-knee saphenous disease, NTNT technology would be preferential.

1. Centers for Medicare & Medicaid Services. Medicare provide utilization and payment data: physician and other supplier. Accessed June 15, 2021. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier

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Dr. Gupta, acrylate embolization has been used in vascular medicine for > 30 years. Why do you think that the topic of hypersensitivity did not enter scientific discourse until it started being used to treat varicose veins?

Dr. Gupta: Cyanoacrylates are widely used "super glues" with many applications across vascular medicine and also with uses in dentistry and the cosmetic industry. Cutaneous allergic reactions to cyanoacrylates are type IV hypersensitivity reactions (HSRs) that are a T lymphocyte–mediated response to a recognized foreign antigen, not an antibody-mediated reaction as in other HSRs. Similar type IV HSRs with other medical uses of cyanoacrylates are well described in the literature including reactions to Dermabond (Ethicon) for skin closure and adhesives used for glucose sensors, eyelash extensions, and artificial nails.

The superficial venous space has seen significant growth in the past 10 years with the emergence of newer NTNT technologies, one of these being VenaSeal cyanoacrylate adhesive closure (CAC). Given this competitive market, clinicians must engage in discourse regarding the efficacy of the newer therapies as compared with other new and existing treatment options. For example, the risk of an HSR with VenaSeal may be preferable to the risk of a skin burn using a thermal, tumescent technology in a patient with a suprafascial great saphenous vein. Recent studies indicate that the rate of HSRs after CAC of incompetent saphenous veins is approximately 6%.[1] Awareness and recognition of an HSR enables clinicians to initiate appropriate treatment, avoid misdiagnosis, and/or delay treatment.

What form of assessment do you use to identify patients who might react to the material?

Dr. Gupta: Our protocol is to screen patients for allergies in general and known hypersensitivities to adhesives and glues. We also question patients regarding their history of skin conditions such as psoriasis and atopic dermatitis. In those patients with an uncertain allergy history, we partner with our colleagues in allergy/immunology to offer skin testing. In those patients who have a positive skin test, CAC is not offered as a treatment option.

Various data show that insufficient perforator veins have a particularly high recurrence rate. Do you see any advantages of thermal treatment using laser or RFA over ultrasound-guided foam sclerotherapy (UGFS)?

Dr. Gupta: Insufficient perforator veins play a well-known role in the development of chronic venous insufficiency and ulceration, and successful closure of incompetent perforators is predictive of wound healing. UGFS is my first-line therapy in the treatment of perforators. As compared to RFA and laser, UGFS is fast, technically straightforward, minimally painful, and less expensive. Closure rates with UGFS are lower than RFA/laser, and all three modalities show a higher failure rate in those patients with morbid obesity (body mass index > 50 kg/m^2). When UGFS fails, laser and RFA are excellent second-line therapies with reliably high closure rates.

1. Gibson K, Minjarez R, Rinehardt E, Ferris B. Frequency and severity of hypersensitivity reactions in patients after VenaSeal™ cyanoacrylate treatment of superficial venous insufficiency. Phlebology. 2020;35:337-344. doi: 10.1177/0268355519878618

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Dr. Ozsvath, a frequently discussed side effect of acrylate bonding is the development of a phlebitis-like reaction within the first few days after treatment. Have you also observed this reaction in your patients?

Dr. Ozsvath: When cyanoacrylate was first released, practitioners were inexperienced in recognizing and treating this particular side effect. Once discussion ensued among vein specialists, we gained insight. As data were collected, papers were published regarding identifying and treating this HSR. We also began to understand the pathophysiology behind it. When I first encountered it, I reached out to colleagues who were able to describe their management of the reaction. I also worked with a local allergist at my institution to come up with a reasonable treatment plan that we have since made into our standard protocol for this issue.

Understanding and recognizing the HSR is the most important first step. I screen patients to find out if they get HSRs to adhesives. Because most patients who do have hypersensitivity to adhesives are aware of it, asking about it will bring it to light. This has essentially made it much easier to rule out the use of cyanoacrylate in that patient population. For others, it is a very good option to consider. Fortunately, the reaction can be treated and controlled effectively in most cases. I have never had any patient with a HSR have any long-term sequelae. I have never had to remove such a vein, although it has been described in the literature.

Do you see any way to prevent or minimize this reaction?

Dr. Ozsvath: The easiest and best way is to ask the patient if they have sensitivity to adhesives. Most people don't think of a dermal reaction to a bandage as an allergy, per se. If you ask about drug allergies, this may be omitted. I have patients take nonsteroidal anti-inflammatory medications periprocedurally, and I explain the reaction as a possible risk. The patients are educated before the procedure and then are told to call with any questions. If they develop an issue, they are seen in the office. Then, depending on severity, an oral steroid taper is prescribed together with an antihistamine. I have also spent time teaching the office staff, nurses, and mid-level practitioners to recognize the reaction.

Another important technical detail is the importance of resheathing the catheter prior to removing it from the vein so that cyanoacrylate is not exposed to the skin and subcutaneous tissue. Additionally, I am careful to make the final administration of cyanoacrylate at the distal end of the treated vein in a way that the adhesive is not too close to the venipuncture site. This minimizes the risk of extravasation into the surrounding tissue. As with all techniques, patient selection is paramount.

In your opinion, are nerve lesions a relevant issue in thermal procedures?

Dr. Ozsvath: Neuropathy is certainly well described and can definitely complicate thermal ablation. I discuss this with patients as a possible complication. There are several things I do to help minimize this risk. From an anatomic point, it is important to think about where to access the vein and how far distally the vein actually needs to be treated. Sometimes other techniques can be used to treat distally diseased veins if needed, concurrently or separately. I also use plenty of tumescent solution to "push" the nerve away from the vein especially in areas that are at risk. In my experience, I have found that RFA has a lower rate of post-procedural neuropathy compared to laser. Additionally, there is a learning curve with all procedures. Early in my experience, although neuropathy occurred rarely, it was fortunately self-limiting. Proper patient selection, access location, and plenty of tumescent solution have greatly diminished the frequency of neuropathy in patients I treat with thermal ablation. ■

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