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Treating the Underlying Disease

Using Varithena® to aggressively treat CEAP 5/6 venous insufficiency.

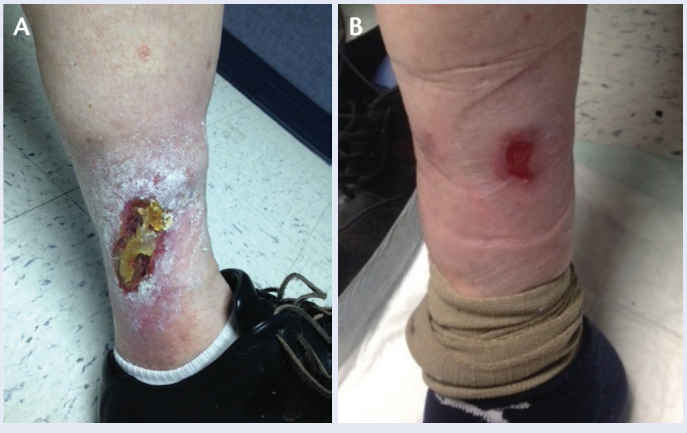
By Paramjit Chopra, MD

My 56-year-old male patient, an executive and photographer who travels extensively, was extremely frustrated that 12 months of therapy at a wound care center had not healed the 2-cm diameter venous ulcer on the medial side of his right leg above the ankle. Eight years earlier, he had truncal ablation in both legs to treat his venous disease. On duplex ultrasound, we found perforators and venous hypertension around the region of the ulcer, which was mildly infected and had lipodermatosclerosis. To ablate the veins around the wound, we injected 12 mL of Varithena® through a 20-G angiocath in a large varicose branch in the mid-leg. I followed the foam on ultrasound along the partially recanalized saphenous vein and branches to the mid-thigh. We wrapped the leg and he wore compression garments for 3 weeks.

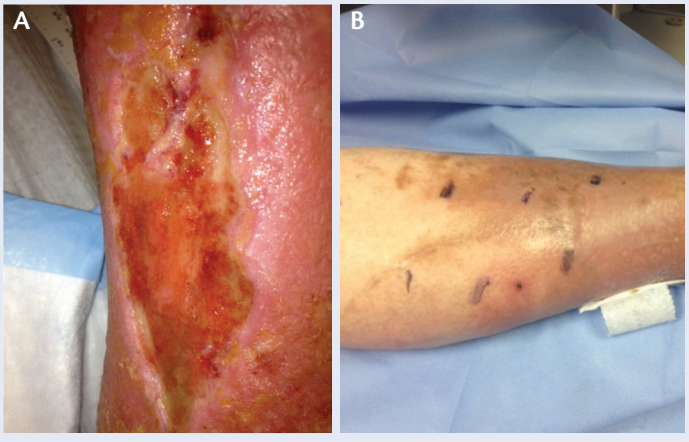
In a follow-up session, we injected 6 mL of Varithena® into a very tortuous, large branch behind the leg on one of the truncal veins, following the same compression regimen after the procedure. Eight weeks later, the patient's wound was healed, he had resumed running and his very active lifestyle, and he had no symptoms of venous disease. He continued concomitant wound management at a wound care center.

Roughly 20% of our patients with varicose veins present with venous ulcers, and up to 50% of our older patients have C6 disease (active venous ulcer). Often these patients have concomitant arterial and venous disease. We treat the arterial disease first to ensure patients have no ischemia, and then we work on eliminating the venous hypertension. Until the venous hypertension is resolved, the tissues will continue to be ischemic, preventing the wound from healing naturally or with concomitant standard wound care.

CASE



CEAP 6 before (A) and after (B) Varithena.



CEAP 6 before (A) and after (B) Varithena and wound care.

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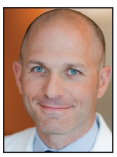
We may use a combination of ablation technologies to treat the areas of venous incompetence and hypertension contributing to the patient's ulcer. As a Microfoam UDSS™ (Uniform Density, Size, and Stability) procedure, Varithena® allows us to effectively treat problematic incompetent veins that wire-based ablation devices cannot, such as circular collateral branches in the saphenous fascia and tortuous branches. We may thermally ablate the saphenous vein and the very large perforators and inject Varithena® in accessory branches. Conversely, we may inject Varithena® to treat the branches and the microfoam will shut down the incompetent perforators.

We carefully watch the perforators under ultrasound and compress the vein to prevent foam from entering the deep system. During and shortly after the foam injection, I have the patient "pump" the calf muscles to ensure good flow through the deep system and to allow any foam to wash away. I also encourage the patient to walk around immediately after compression has been applied and recommend that the patient remains active and walks as much as possible.

In the past, we would use physician-compounded foam to "spot weld" the veins that could not be treated with a wire-based device. Because we mixed the foam with room air, it contained nitrogen bubbles, which, should the sclerosant get into the deep system, could cause a deep vein thrombosis or a pulmonary embolism. This happened with one of my patients very early in my career. Varithena® is formulated with oxygen and carbon dioxide and less than 0.8% nitrogen, so it poses little risk of complications, including neurological or cerebrovascular adverse events, if a small amount gets into the deep system. In the Varithena® clinical trial program, which included more than 1,300 patients, there were no cerebrovascular events.[1] I can safely use up to 15 mL of Varithena® in one session with a patient, which allows me to be more aggressive with therapy, versus only 5 mL of physician-compounded foam.

Varithena® is the essential non-tumescent, non-thermal (NTNT) choice in my endovascular set of tools. I can often treat patients' severe venous disease rapidly and completely so that their ulcers can begin to heal and we can prevent recurrent ulceration.

1. Varithena® prescribing information. Provensis Ltd., a BTG International group company. 06/2016



By Brian L. Ferris, MD

Chronic venous disease (CVD) is the most prevalent vascular disease in the United States, affecting an estimated 40% of women and 20% of men.[1] The contributing etiologies and diagnoses of CVD are varicose veins, superficial venous thrombosis, deep venous thrombosis, venous insufficiency, and postthrombotic syndrome. Up to 2% of the population may have a venous ulcer and 20% with chronic venous insufficiency may develop a venous ulcer,[2] a C6 classification based on the CEAP (Clinical- Etiological- Anatomical- Pathological) system. A venous ulcer, which may not respond to local wound care and antibiotics, can lead to a futile cycle of ineffective treatment, pain, reduced mobility, and frustration for patients.

Varithena® is uniquely suited to treating truncal saphenous reflux as well as pathologic varicosities involved with ulcer formation. As a microfoam UDSS (Uniform Density, Size, and Stability) procedure, Varithena® is particularly effective in ablating veins that are inaccessible by wire-based devices, such as tortuous superficial veins, serpentine truncal veins, phlebosclerotic veins with areas of partial obstruction, or veins with chronic thrombophlebitis.

Varithena® is also an FDA-approved modality to treat the underlying, often complex varicose veins directly underneath areas of lipodermatosclerosis contributing to the development of ulcers. By locally ablating pathologic varicosities, possibly fed by perforating veins, in the area of stasis changes with Varithena®, we can often improve lipiodermatosclerosis by making the skin less sclerotic, indurated, and less chronically erythematous. Although patients with C6 venous disease (active venous ulcer) can technically only improve to C5 (healed venous ulcer), it's exciting to think that we can potentially move patients to a C4a classification (pigmentation or eczema) by more extensively treating their persistent venous disorder.

When a patient presents with a venous ulcer for the first time, we address the most pressing problem—the open wound. We treat the wound with compression therapy, local wound care, and culture-specific antibiotics as needed, and perhaps additional medical therapy (such as pentoxifyline). Then we use Varithena® to treat the branches and tributaries that are causing pressure as well as the cluster veins under the bad skin when indicated. Even if we could access problematic veins remotely to proceed with thermal ablation technologies, we prefer not to drag a device through an area of lipodermatosclerosis. Thermal ablation could pose a risk of thermal injury or infection due to the challenges of providing sufficient tumescent anesthesia as a result of scarring from the stasis changes.

When all medical and wound care measures have failed, we may proceed with superficial venous ablation. With Varithena®, we do not have to worry about filling a leg with chronic edema with tumescent anesthesia as we would if we performed catheter ablation. We recently used Varithena® to treat a 72-year-old male patient with great success. He had undergone multiple prior procedures to ablate incompetent saphenous trunks and to ligate pathologic perforating veins. But he remained in compression with recurrent stasis dermatitis and intermittently recurring ulceration. After treating his underlying venous disease with

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the Varithena® procedure, his legs feel better and his skin changes have already become less indurated.

Varithena® is also an effective minimally invasive modality to treat patients with neovascularization following vein stripping or in patients who develop serpentine truncal reflux from pelvic sources or high saphenofemoral junction branches that have become abnormal natively or after thermal ablation. These serpentine veins can't be crossed with a catheter and are a known source of recurrent or progressive varicose veins.

As we better understand the complexity of venous disease, we need to take a more comprehensive approach to treating advanced diseases that progress to lipodermatosclerosis and ulcers. Varithena® is an essential NTNT choice to aggressively treat venous insufficiency to prevent new or recurrent ulcers. ■

1. Beebe-Dimmer JL, Pfeifer JR, Engle JS, et al. The epidemiology of chronic venous insufficiency and varicose veins. Ann Epidemiol. 2005;15:175–184.
2. O'Donnell TF Jr, Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2014;602:3S–59S.

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