CASE REPORT

Successful Treatment Of A Chronic Venous Leg Ulcer Using The VenaSeal™ Closure System

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Abstract: The VenaSeal™ procedure is a minimally-invasive intervention for the treatment of lower extremity superficial venous insufficiency. The VenaSeal closure system uses a medical-grade cyanoacrylate glue to seal incompetent veins. This adhesive collapses the vein walls, preventing blood flow in the treated incompetent superficial veins and forcing blood to travel in the deep venous circulation. This results in the relief of lower extremity superficial venous congestion and improvement in the side effects of venous insufficiency such as swelling, achiness, symptomatic varicosities and venous ulcers. In this report, we describe a case of a 62-year-old man who underwent successful VenaSeal therapy of the great saphenous vein (GSV) for treatment of a venous leg ulcer (VLU).

Key words: *VenaSeal closure system, lower extremity superficial venous insufficiency, cyanoacrylate glue, venous leg ulcer.*

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Introduction

Venous leg ulcers are late indicators of chronic venous insufficiency (CVI) and long-standing venous hypertension.[1] Under normal circumstances, competent intraluminal valves and calf muscle contraction promote the antegrade flow of blood and prevent retrograde flow along the veins of the leg.[2] Obstruction and retrograde venous flow will lead to eventual chronic venous hypertension that can result in the formation of venous leg ulcers (VLUs).[3] VLUs are the most common type of lower extremity chronic wounds that impact approximately 1-3% of the elderly population in the United States and Europe.[4] VLUs are not only burdensome to the patient but have a significant financial burden on the worldwide health-care system.[5] Evaluation of these patients starts with taking a thorough history and performing a physical examination with appropriate description of the wound, including its area, depth, edges, infection signs and the presence of any skin colour changes. Confirming adequate arterial blood-flow is also important in evaluating ulcer etiology, as 20% of patients with VLUs have concomitant arterial disease.[6] Colour flow duplex ultrasound of the superficial veins is another inexpensive, non-invasive and highly informative diagnostic test to assess venous valve incompetence.[7] The mainstay of care for VLUs is with compression therapy and wound management, with the ultimate goal of reducing leg edema to facilitate wound closure. Conservative treatment measures include medical compression, intermittent pneumatic compression (IPC), manual lymphatic drainage and extracorporeal shockwave therapy (REF). Compression therapy is the most practical and economical intervention for the treatment of VLUs.[8] Advanced cases that have failed standard therapy may benefit from invasive interventions that aim to obliterate or remove incompetent veins through various techniques, including vein stripping, endovenous ablation with thermal and non-thermal modalities and sclerotherapy.[2] Studies have shown improved healing time and decreased

ulcer recurrence with early endovenous intervention.[9] The VenaSeal closure system is a non-thermal endovenous therapy used in the treatment of venous insufficiency. The VenaSeal™ closure system employs medical-grade cyanoacrylate glue for the permanent closure of lower extremity superficial truncal veins by endovascular embolization with coaptation. The system consists of a single sterile patient kit that includes the VenaSeal adhesive and delivery system components. This case report describes the treatment and outcome in the use of the VenaSeal Closure system for treatment of a VLU in a single patient with chronic venous insufficiency who failed standard therapies. Written consent was obtained from the patient for sharing the details of his treatment in this report.

Patient History And Treatment Plan

A 62-year-old man with an 18-year history of recurrent bilateral lower extremity venous stasis ulcers presented with an active left leg venous ulcer. The patient had a past medical history of hypercholesterolemia, hypertension and diabetes mellitus. He had no other surgical or medical history and was not a smoker.

Despite compliance with wearing high-grade compression stockings, the ulcers recurred annually. On examination, the patient had palpable pedal pulses and no evidence of significant lower extremity peripheral arterial disease on a Doppler ultrasound. A lower extremity venous duplex scan demonstrated a valvular incompetence of > 0.5 seconds in the great saphenous veins bilaterally, with the longest durations being 2.07s and 0.77s in the right and left veins, respectively. Physical examination of the right leg revealed a medial malleolar ulcer measuring 727.82mm^2. Treatment options for venous stasis and venous ulcers were discussed with the patient, including the risks and benefits of saphenous vein stripping, as well as the VenaSeal closure system. The patient decided to proceed with the VenaSeal procedure.

Treatment

The patient underwent endovenous ablation of the right great saphenous vein (GSV) using the VenaSeal Closure System (Medtronic plc, Minneapolis, MN) in an ambulatory clinic. With the patient lying in the supine position, the right leg was prepped with chlorhexidine solution and draped. A diagnostic evaluation of his right GSV was carried out using ultrasound. After careful preparation and diagnostic examination, the skin overlying the right GSV below the knee was infused with lidocaine solution, and a small incision was made with an 11 blade. Seldinger technique was used to access the right GSV with an access needle followed by a starter wire. A 7 French (Fr) short sheath (Terumo Corporation, Tokyo, Japan) was then advanced to the vein in a retrograde direction. A J-wire was then advanced to the right saphenofemoral junction. The VenaSeal catheter was advanced 10 cm proximal to the junction and the injection catheter was advanced to 5 cm proximal to the junction within the VenaSeal catheter. An initial injection of adhesive was dispensed, and pressure was immediately applied to the vein for three minutes. Adhesive injections were then serially administered in 3 cm increments, with pressure held on each segment. Once the complete length of the target vein had been injected proximal to the access site, the catheter was removed. Pressure was then applied to the entry site for several minutes until adequate hemostasis was achieved.

To ablate the GSV below the venous ulcer, the above steps were repeated in the antegrade direction. Seldinger technique was used to access the right GSV with an access needle followed by a starter wire. A 7 Fr short sheath was advanced into the GSV and a J-wire was then advanced distally. The VenaSeal catheter was advanced into the GSV distal to the leg ulcer at the right medial maleolus. An initial injection of adhesive was dispensed and pressure was applied to the vein for three minutes. Serial injections were then applied in 3 cm increments. Once the complete length of the target vein distal to the access site had been injected, the catheter was removed and pressure was held for a further few minutes at the second entry site. Complete vein blockage was confirmed using ultrasound. A total of 2 mL of adhesive was administered to close the GSV. The procedure was

completed in 90 minutes with no complications. The skin access sites were cleaned, a dressing was applied and a compression stocking was donned onto the right leg before the patient was discharged.

Clinical Outcome

At one week follow-up post-VenaSeal treatment, the patient reported full compliance with compression stockings and no complications. A duplex ultrasound of the patient's right lower extremity confirmed full closure of the target GSV. There was no evidence of deep venous thrombosis (DVT) and the deep venous system appeared patent and compressible. The superficial venous valvular incompetency of >0.5 seconds (longest duration 2.07 seconds) noted one month prior was no longer observed.

At one month follow-up post-endovenous VenaSeal treatment, the patient reported full compliance with compression stockings and no complications. Venous duplex scans of the patient's right lower extremity confirmed persistent GSV ablation. Physical examination indicated that the ulcer was reduced to 535 mm^2 in size.

Venous duplex scans of the patient's right lower extremity at one, two and three months post-treatment confirmed persistent GSV ablation, no change in venous valvular competency and no evidence of DVT. The patient reported full compliance with compression stockings at these time points. On physical exam, ulcer healing was noted at each time point, with an ulcer size of 535 mm^2 at one month (27% healing), 306 mm^2 at 2 months (58% healing) and 105 mm^2 at three months (86% healing).

On physical examination at six months post-VenaSeal closure, the right venous ulcer had healed completely and the patient reported no skin breakdown or ulcer recurrence. A venous duplex ultrasound of the patient's right lower extremity

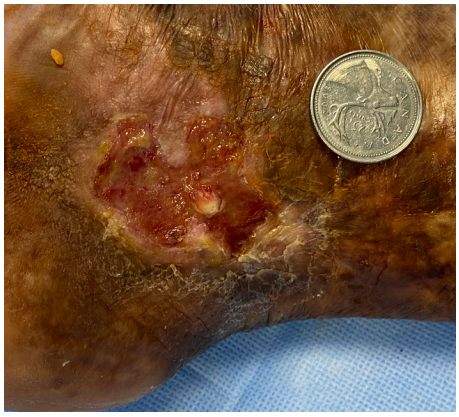

Figure 1: Baseline.

Figure 2: One month post procedure.

Figure 3: Two month post procedure.

Figure 4: Three months post procedure.

Figure 5: Six months post procedure.

Figure 6: Twelve months post procedure.

confirmed the ongoing ablation of the GSV with no change in valvular competency and no DVT. Mildly dilated subcutaneous channels were noted in the lower leg suggestive of lymphedema. The patient reported full compliance with compression stockings.

At a one year follow-up, a venous duplex ultrasound of the patient's lower leg confirmed continued GSV ablation, no change in venous valvular competency and no evidence of DVT. The patient reported continued full compliance with compression stockings and no evidence of lymphedema was noted on ultrasound. On physical examination, there was no evidence of skin breakdown or ulcerations. At a five year follow-up by phone, the patient denied any skin breakdown or recurrence of his right leg wound and reported feeling well (See Figures 1-6).

Discussion

Compression-based therapies are often used as the first line of treatment for VLUs.[7] However, when used alone, these therapies have been linked to recurrence and low healing rates.[8] In this case report, we describe a patient with an 18-year history of recurrent VLUs despite standard care treatments, including compression therapy. Thermal and non-thermal minimally invasive endovenous closure techniques provide an alternative treatment to those suffering from recurrent venous ulcers as they are linked with decreased healing times and low recurrence rates,[9] as was the case for our patient.

The VenaSeal adhesive is made from an n-butyl-2-cyanoacrylate formulation. The delivery components aid in the positioning and delivery of the cyanoacrylate adhesive within the target vein. Once the adhesive is administered into the vein, it polymerizes when in contact with body tissues through an anionic mechanism.[10] This reaction obstructs venous blood flow, resulting in long-term blockage.

A 12 month follow up of the Venaseal Sapheon Closure System Pivotal Study (VeClose) demonstrated that cyanoacrylate closure was effective and non-inferior to thermal ablation in the treatment of GSV incompetence.[9] The study involved the randomization of 222 patients with CVI to either treatment option. When compared to radiofrequency ablation (RFA), which employs thermal energy rather than an adhesive to treat CVI, patients who underwent cyanoacrylate closure had faster therapeutic success and a reduced risk of vein recanalization.[9] A five year follow-up of the VeClose study revealed long-term success and durability of the VenaSeal closure system in patients with saphenous incompetence, with lasting closure and recanalization-free survival rate.[11] Furthermore, due to the positive outcomes associated with VenaSeal treatment, 100% of patients in the study who received cyanoacrylate closure reported being satisfied with their therapy.[11]

Kolluri et al. conducted a meta-analysis of 20 randomized controlled trials that compared the efficacy of the VenaSeal closure system with other endovenous procedures for the treatment of CVI.[12] Therapies that were studied included endovenous laser therapy (EVLT), RFA, mechanochemical ablation, sclerotherapy and surgery. When compared to other treatments, VenaSeal had the highest probability of anatomic success of complete closure of the treated vein within six months of intervention.[12] In addition, the VenaSeal closure system ranked first in the reduction of postoperative pain and lowest in the incidence of adverse events. The occurrence of DVT with Venaseal was the lowest of all treatments.[12] These findings are consistent with our patient, since no adverse reactions, such as DVT, were seen after therapy.

Although studies have revealed lower adverse reactions to VenaSeal compared to other therapies, there have nonetheless been reports of allergic and inflammatory responses to the cyanoacrylate glue.[13] The VenaSeal Closure system should not be administered to individuals with hypersensitivity to adhesive and cyanoacrylates.[10]

Conclusion

This report describes a unique therapeutic approach involving treatment of a chronic venous ulcer secondary to CVI using the VenaSeal Closure System. The patient had a significant 18-year history of chronic, bilateral and recurring venous

ulcers for which he had undergone standard of care treatment with wound care and compression therapy. Using the VenaSeal Closure System, the culprit refluxing right GSV was fully ablated by the endovenous VenaSeal treatment, and the target GSV remained closed as verified by a duplex ultrasound up to one year post-treatment with no wound recurrence at a five year follow-up.

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