The Patient Voice in Chronic Venous Disease Treatment: What We Have and What's Coming Next

With Kathleen Gibson, MD, FACS, FAVLS, DABVLM; Al Compaan; and Manj Gohel, MBChB, MD, FRCS, FEBVS

Chronic venous disease (CVD) research largely overlooks the patient and their experiences with their treatment.[1] In addition, anatomic closure—the commonly reported clinical outcome—does not account for residual saphenous reflux in untreated parts of the target vein.[2] As experienced interventionalists, our interactions with patients clearly define the disparity between what's known and what's needed in the clinical trial landscape. Medtronic invited us to be the Principal Investigators for a clinical trial that is attempting to fill these gaps. The VenaSeal Spectrum Program is unique for its novel endpoints: patient treatment satisfaction (measured by the Venous Treatment Satisfaction Questionnaire, or VenousTSQ[3]) and elimination of truncal reflux. As we look forward to the first outcome presentations this year, we wanted to highlight the importance of the patient experience in CVD with both a patient interview and case study.

AL COMPAAN'S PATIENT TESTIMONIAL

What were your earliest experiences with varicose veins?

Mr. Compaan: Initially, my varicose veins were asymptomatic but cosmetically unpleasant. They worsened in my 30s, and I began to experience symptoms: itching, mottled discoloration and minor swelling at the ankles, and periodic throbbing/aching after prolonged standing.

What prompted you to seek treatment?

Mr. Compaan: My general practitioner told me to wear compression stockings to mitigate the varicosities. I was not thrilled about this idea, so I never did. In August 2017, my left calf began to ache after a long flight. My general practitioner diagnosed a superficial blood clot, which resorbed over several weeks on aspirin. However, concerns remained about the potential for future clots.

What concerns did you have about treatment?

Mr. Compaan: My concerns were safety, invasiveness, recovery time, complications, and durability.

First, I sought a good clinic and a good doctor. I did my own research and liked Dr. Gibson's curriculum vitae and the range of treatment options offered in her clinic. My first visit was in late November 2017 for an ultrasound of both legs; the left leg was more dilated and symptomatic but both legs shared many of the same issues.

Various treatment options were discussed, including several involving ablation. Because my situation was viewed by my insurance as "cosmetic" and not medically necessary, I was on my own for payment. At the time, Dr. Gibson said there may be an opportunity to have the VenaSeal™ closure system (Medtronic) procedure as a Medtronic teaching/learning experience for other physicians, at no cost to me. The procedure was performed on my left leg in March 2018, with several observing physicians in attendance.

As I continued to have symptoms in my other leg, my right leg was treated with VenaSeal in February 2020 as part of a clinical trial.

What was your experience during and after the procedure?

Mr. Compaan: I did not experience any pain during either procedure. Local anesthetic was used at the insertion point with a minor needle prick. There was transitory discomfort as the catheter was moved (a pulling sensation), but

Dr. Gibson was very good about warning me when I would feel the next tug. Recovery was uneventful: I had no postprocedure discomfort and returned to work the next day.

For the procedure on my right leg, I did experience some discomfort in my knee such that 4 days after the procedure I returned to the clinic for an exam. I was reassured that it wasn't a clot, and the discomfort resolved in a week or so.

Has there been any overall change in your quality of life after having your veins treated?

Mr. Compaan: My experience was life changing. Importantly, I know that I have undergone remedial treatment and do not have to fear blood clots due to malfunctioning veins. The itching and swelling I had previously experienced are greatly mitigated, the achiness from standing for a long time is no more, and ankle swelling and discoloration are largely resolved. Cosmetically, the varicosities are noticeably diminished.

What should patients ask prior to a treatment for their CVD symptoms?

Mr. Compaan: Most importantly, is this procedure going to resolve my medical issue, and is this the best option for me? In this case, I asked Dr. Gibson: If these were your legs, what treatment would you choose? What are the benefits and drawbacks? How involved is the procedure? What are the potential complications? What will I experience during and after the procedure? What can I expect during recovery? How soon can I resume normal activities? Can I expect a positive outcome, and what is the long-term efficacy? Do I have to wear compression stockings?

Another question is: Does my insurance cover the procedure? I mention this last because it is an issue, perhaps a big issue, for patients considering vein treatment. Regardless, I absolutely would have moved forward with VenaSeal on both legs even if it meant paying 100% out of pocket. It was important for me to find an effective course of treatment for my vein issues, and I find great peace of mind knowing that I have had a lasting resolution.

DR. GOHEL'S PATIENT CASE

A male patient in his mid 60s presented to my clinic with bilateral chronic venous insufficiency and healed ulceration (CEAP [clinical, etiologic, anatomic, pathophysiologic] C5). Of note, he was still working in a physically active role, was taking anticoagulation (rivaroxaban) for atrial fibrillation, had well-controlled hypertension, and was an ex-smoker. An ankle-brachial index (ABI) assessment confirmed peripheral artery disease (PAD), with an ABI of 0.66 in the left leg. Physical examination confirmed advanced venous skin changes bilaterally, with prominent varicosities in the great saphenous vein (GSV) distribution (Figure 1A).

Duplex ultrasonography (DUS) was performed and confirmed the presence of superficial venous reflux in the GSV bilaterally, with the lowest point of reflux in the upper calf (Figure 1B). The GSV maximum diameter was 8 mm bilaterally.

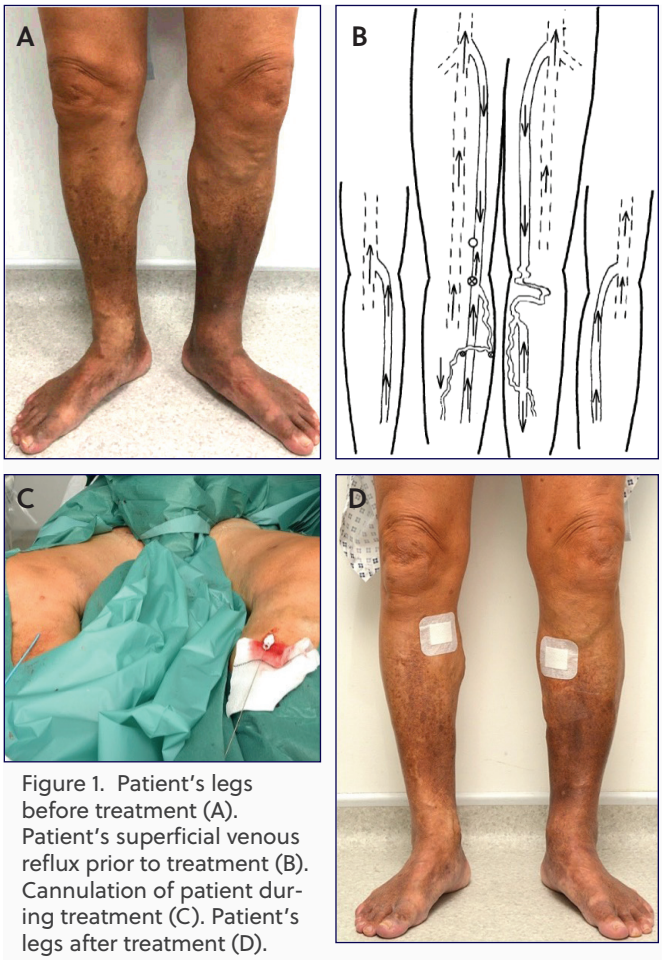

Figure 1. Patient's legs before treatment (A). Patient's superficial venous reflux prior to treatment (B). Cannulation of patient during treatment (C). Patient's legs after treatment (D).

Because the patient had healed ulceration with isolated superficial venous reflux, there was a clear rationale for endovenous intervention to treat the saphenous reflux and reduce the risk of recurrent ulceration. As part of a shared decision-making process, different treatment options and modalities were discussed with the patient. Specific reasons for choosing VenaSeal in this case were:

- Quick recovery because the patient wanted to minimize time off from work
- Ability to proceed with bilateral GSV ablation in a single procedure
- Avoidance of compression given his existing PAD and reduced ABI
- Avoidance of tumescence anesthesia, particularly as the patient was on anticoagulation

Bilateral GSV VenaSeal closure was performed under local anesthesia, with no interruption to anticoagulation. Cannulation was performed at the lowest point of reflux bilaterally (Figure 1C). Cyanoacrylate glue injections were performed per instructions for use. No adjuvant procedures were performed. Both GSVs were successfully closed, as confirmed by DUS.

Immediately postprocedure, a significant reduction was seen in the size of visible varicosities (Figure 1D). The patient was able to return to work the next day and had an uneventful recovery, with successful GSV closure at follow-up.

This case highlights some of the specific potential advantages of VenaSeal, particularly treatment of multisegment superficial reflux and avoidance of tumescent anesthesia or compression.

Disclosures
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