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ClariVein Mechanochemical Ablation: Background and Procedural Details

Richard L. Mueller, MD¹, and Jeffrey K. Raines, PhD, MME, RVT²

Abstract

Objectives: The 2 primary objectives of this publication are to provide a practical step-by-step procedure for the ClariVein system and a focused literature review of endovenous ablation. **Materials and Methods:** The ClariVein system is the first venous ablation technique to employ a hybrid (dual-injury) technique built into 1 catheter-based delivery system. Endomechanical abrasion is produced by the tip of the catheter's rotating wire (mechanical component); and endovenous chemical ablation (EVCA) is via simultaneous injection of sclerosant over the rotating wire (chemical component). The author is an early adopter of this technique and via experience has developed a detailed step-by-step protocol. **Discussion:** To date, there have been 2 pivotal clinical studies published using the ClariVein system. These data are compared with the results using other methods of endovenous ablation. **Conclusions:** The ClariVein system is an exciting addition to the phlebologist's toolbox and has the potential to become a first-line treatment.

Keywords

chronic venous disease, endovenous techniques, ultrasound guided, sclerotherapy, varicose veins, venous insufficiency

Introduction

ClariVein is a new, innovative, and nonthermal endovenous ablation system. It is also known as mechanochemical ablation (MOCA). ClariVein is the first venous ablation technique to employ a hybrid (dual-injury) technique built into 1 catheter-based delivery system. Endomechanical abrasion is produced by the tip of the catheter's rotating wire (mechanical component); and endovenous chemical ablation (EVCA) is via simultaneous injection of sclerosant over the rotating wire (chemical component).

The ClariVein system was developed in 2005 by Michael Tal, MD, a Yale University Interventional Radiologist, who describes getting the idea when confronted with a patient with severe sciatic vein varices. He was unable to offer thermal or chemical ablation due to concerns regarding nerve damage and of embolic complications secondary to foam sclerotherapy, respectively.¹

In trying to find a solution, Tal thought of a washing machine analogy. He concluded hand washing and scrubbing clean clothes works well. He realized soaking in high concentrations of detergent also works, but a washing machine combines mechanical agitation and detergent scrubbing resulting in cleaner clothes, more rapid performance, and a lower concentration of detergent.

Animal studies were performed to provide proof of concept with excellent results; to date, these studies have not been published.² Tal indicated in a slide presentation that in animal studies neither liquid sclerotherapy via catheter nor mechanical abrasion alone provided durable results; the combination did.¹

Tal cofounded Vascular Insights, LLC (Madison, Connecticut), which obtained 510(k) US Food and Drug Administration (FDA) clearance in May 2008 to market the ClariVein infusion catheter for the indication of infusion of physician-specified agents in the peripheral vasculature. This very broad and nonspecific indication does not specify an indication for vein closure, though it clearly does not preclude it. ClariVein obtained the CE mark in May 2010, allowing it to be marketed in Europe, with a specific indication as a vein occlusion catheter for the treatment of venous reflux disease. It is also approved in Canada. The pivotal first-in-man clinical trial was performed at Englewood Hospital, New Jersey, by Steve Elias, MD. These results were reported in 2009 and published in 2011.³ Clinical use began in Europe and the United States in 2010. Currently, approximately 400 physicians are using the device in the United States. Approximately 12000 procedures have been performed to date (John Marano, PhD, personal communication, Vascular Insights, LLC.)

ClariVein has numerous advantages when compared to thermal endovenous ablation techniques and conventional EVCA.

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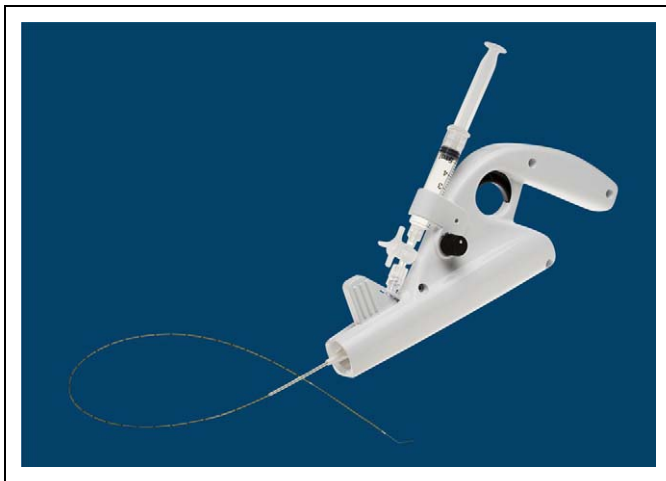


Figure 1. ClariVein assembled catheter and motor handle (Used with permission from Vascular Insights, LLC).

It is a solution to the main pitfalls of thermal ablation which include (i) need for tumescent anesthesia, (ii) risk of thermal injury to skin, nerves, muscle, and blood vessels, (iii) need for capital expenditure secondary to maintenance of a complex energy source, and (iv) postprocedure pain/phlebitis. ClariVein is an important emerging technique in endovenous therapy and a welcome addition to the practitioner's toolbox.

Objectives

The 2 primary objectives of this publication are (i) to provide a practical step-by-step procedure for the ClariVein system and (ii) presentation of a focused literature review of its place in endovenous ablation.

Materials and Methods

Device Description and Assembly

The device is composed of 2 sterile, single-use components that are assembled at the treatment table (Figure 1):

Cartridge Unit/Catheter. The catheter is linked via a plastic hub to a winged plastic cartridge that has a side port luer connection leading to the catheter lumen. The same lumen also contains the abrasion wire. A packaged 3-way stopcock is attached to the luer port, followed by attachment of a 5-mL syringe used to flush with saline. Later in the procedure, this syringe is used to inject liquid sclerosant.

Motor Unit/Handle. This is a single plastic handpiece that includes an internal 9V battery that drives the motor. The motor has 4 speeds that range from 2000 to 3500 rpm. The maximum speed is the default and used most often. The handpiece has a plastic clip to secure the syringe and a trigger to activate the motor using the index finger when the handle is gripped with one hand; the thumb is used to inject with the syringe via its plunger.

Once the 2 units are assembled, they cannot be disassembled. Since the catheter is steerable by its cartridge wing, it is important to position the catheter tip at the desired position within the target vein before attaching it to the motor unit. For orientation purposes, "proximal" with respect to the catheter or veins will refer to being toward the proximal portion of the truncal vein, while "distal" will refer to being toward the distal portion of the truncal vein.

The catheter is very low profile and easy to handle; its outer diameter is 2.67 French (0.89 mm or 0.035 inches in diameter). This is the same diameter as a standard guidewire. Its small profile also produces a high-resistance injection flow that results in slow, small-volume injections, though injection pressure is relatively high and relatively discontinuous, given the small volumes injected per unit time. The internal volume or dead space of the catheter/cartridge lumen that must be flushed is approximately 0.7 mL for the 45-cm catheter and 1.0 mL for the 65-cm catheter. The catheter is currently available in 45 and 65 cm lengths marked in centimeter increments. This length includes 2 cm of extruded wire when it is unsheathed. A 45-cm catheter comprises 42.5 cm of marked catheter plus 4.5 cm of tapered, unmarked plastic hub covering located at the most distal portion of the catheter (connection to the handle attachment wing). The plastic hub is 4.5 cm long; when the catheter is inserted into a microintroducer, the plastic hub extends approximately halfway into the hub of the microintroducer. This point is approximately at the 45-cm catheter length, though only a maximum of 42 cm can be inserted into the leg, due to inability of the plastic hub covered portion of the catheter to pass into the microintroducer and its hub. Given the 1 to 3 cm of catheter typically inside the leg, but outside the vein, only 39 to 41 cm of catheter can be placed within the vein.

The catheter's central lumen is both the infusion channel and the lumen containing the stainless steel abrasion wire (0.36 mm or 0.014 inches diameter). The wire can be in 2 positions: (i) sheathed, whereby only the small ball at the tip of the wire extends distal to the catheter tip or (ii) unsheathed, whereby 2 cm of the wire extends distal to the catheter tip. The wire tip's echogenic ball enhances ultrasound catheter guidance, prevents inadvertent catheter placement too far proximally, and reduces vein wall trauma. When the wire is sheathed, as when it is introduced into and traverses the target vein, the most distal 1 cm of the catheter tip is bent. When the wire is unsheathed, the distal 1 cm of the catheter tip is straight, with 2 cm of extruded wire, of which the most distal 0.75 cm is bent.

The centerline of rotation of the wire tip is 6.5 mm diameter (0.258 inches); therefore, for veins smaller than this diameter, the vessel wall is deformed and flexed by the rotating wire. Wire unsheathing is accomplished by attaching the cartridge unit to the handle unit, pulling the cartridge wing into the handle, and clicking to the first (proximal) lock position, then clicking the wing to the second (distal) lock position. At this position, the wing is also gently rotated counterclockwise into a lock position notch. This is done while the syringe is clipped into its holder on the handle. When unsheathing, the wire tip



Figure 2. Cartoon demonstrating ClariVein catheter, abrasion wire, and wire rotation (Used with permission from Vascular Insights, LLC).

extends proximally into the vein approximately 4 mm, while the catheter is pulled distally by approximately 1.5 cm, exposing the bent wire tip. Resheathing is accomplished by pushing the cartridge wing proximally from the second lock position back to the first lock position. This requires an initial clockwise release of the syringe.

One important advantage of the ClariVein system is the catheter's steerability. This is present due to the bent tip (while sheathed) and the cartridge wing. Moderately tortuous vein segments can be traversed, in contradistinction to catheters used for thermal ablation where these maneuvers are more difficult. Further, sclerosant longitudinal and radial delivery is ensured by the wire motion (Figure 2). Sclerosant wicking along the rotating wire creates a vortex spray of sclerosant in the wire's field of rotation.

Thus, the catheter's proximal 2 cm occupied by the extruded wire is treated with sclerosant and is not merely a region of mechanical-only treatment. The 2 assembled units are discarded at the end of the procedure and cannot be resterilized or disassembled.

Protocol

Overview. Detergent sclerosant (liquid) must be prediluted prior to the procedure. Target vein access is similar to thermal ablation procedures. This is performed percutaneously with ultrasound guidance at or distal to the most distal level of reflux in truncal or accessory veins, though retrograde access is optional for perforator veins or truncal veins. The only anesthesia needed for the ClariVein system is a small amount of 1% lidocaine at the access site, injected intradermally or subcutaneously. Access is via a 4- or 5-F microintroducer placed over a guidewire, an 18-gauge, 2-inch angiocath or a 3-F MicroSlide introducer (Galt Medical Corp, Garland, Texas). A syringe is connected to the open end of the microintroducer or angiocath while preparing the ClariVein catheter.

System Preparation. The catheter unit packaging is opened; the stopcock and 5-mL syringe are removed from the packaging. These units should only be opened after it is certain the procedure can proceed to completion due to the considerable costs of the 2 disposable units (~ \$600-\$700 each). The stopcock is placed onto the luer lock and tightened; the sidearm must face laterally when attached. The company now makes available an optional 1-way check valve luer adapter that can be used as an alternative syringe interface. The catheter is flushed with saline. The sclerosant should not be used for this purpose as blood seeping into the catheter could thrombose the catheter when mixing with sclerosant. The stopcock is turned to ensure the closed position is facing the syringe (use a 30° tilt to ensure simultaneous closure of the side port), which is now replaced with a 5-mL sterile syringe containing liquid sclerosant (either sodium tetradecyl sulfate [STS] or polidocanol [POLI]). Orienting the sclerosant syringe's volume hash marks at 3 o'clock and turning it clockwise ensures that the hash marks will be visible at 3 o'clock and not obstructed by the handle clip. Any air bubbles in the syringe are carefully purged through the open port to avoid air embolism as well as inadvertent foaming of the sclerosant.

Catheter. The catheter is packaged with the wire tip sheathed; the catheter is placed into the access device, without the need for any guidewire or exchanges. Using ultrasound guidance, the catheter tip is placed at the desired location (ie, proximal ablation edge). It is important to visualize the ball at the end of the angled abrasion wire, as if it is not visualized, the wire tip may be significantly more proximally placed in the vessel than realized, risking deep vein thrombosis (DVT) near the junctions (Figure 3, 4).

Wire Tip. For ablation of the great saphenous vein (GSV), Vascular Insights advises placement of the wire tip 2 cm distal to the saphenofemoral junction (SFJ) or just distal to the inferior

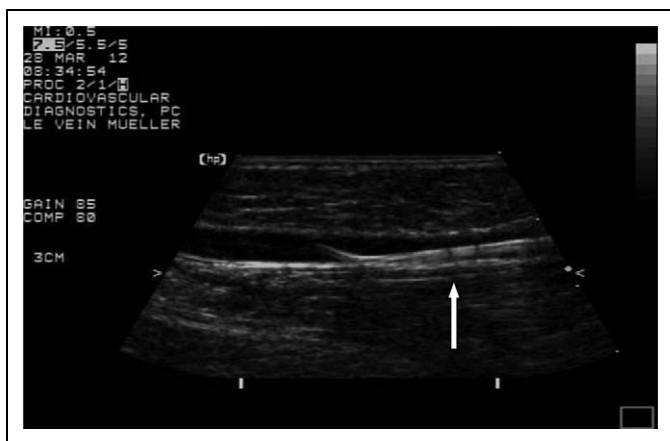


Figure 3. Sheathed catheter, with bent tip and only the ball of the abrasion wire (see inplane in Figure 4) protruding from the catheter tip, within the GSV (Copyright © 2012 Richard L. Mueller, MD, PC). GSV indicates great saphenous vein.

epigastric vein, whichever is more proximal. Other variations in proximal wire tip location exist. Steve Elias, MD, who conducted the first-in-man clinical trial, advises wire tip placement 1 cm from the SFJ (personal communication), and van Eckeren and colleagues, who published the second clinical study, currently advocate placement 5 mm distal to the SFJ (Michel Reijnen, MD, PhD, Personal Communication).⁴ For small saphenous vein (SSV) ablation, Vascular Insights advises placement of the wire tip just distal to the fascial curve, within the initial portion of the straight segment of the SSV and the saphenous sheath. If a gastrocnemius vein inserts into the SSV, the wire tip should be placed 2 cm distal to that insertion.

Handle. After placement at the desired location, the catheter cartridge is wedged to the handle unit. Prior to attachment, the trigger should be depressed briefly to test activate the battery; a small light-emitting diode (LED) indicator on the handle turns green when the trigger is engaged. This test is important since once the catheter cartridge and the motor handle are attached, they cannot be disassembled. If the motor does not work after it has been attached to the catheter, the catheter must be withdrawn from the extremity and the entire combined unit must be discarded and replaced. The motor will not turn or become audible until the components are attached, which is achieved by sliding the cartridge wing into the slotted groove in the handle unit. A click is felt at the first proximal stop position. This engages the 2 units irreversibly and connects the motor to the abrasion wire. The cartridge wing is then pulled back further into the handle groove.

At the distal end of the groove, the wing is turned slightly counterclockwise, clicking into the second stop position. This step unsheathes the proximal 2 cm of the bent abrasion wire. At the same time, the 5-mL syringe is snapped into the syringe clip and the unit is fully assembled. Unsheathing of the wire is monitored by ultrasound to ensure the wire tip position has not migrated too far proximally and the vessel has not been perforated. The small echogenic ball at the tip of the wire as well as the angled distal 0.75 cm of the wire both enable visualization

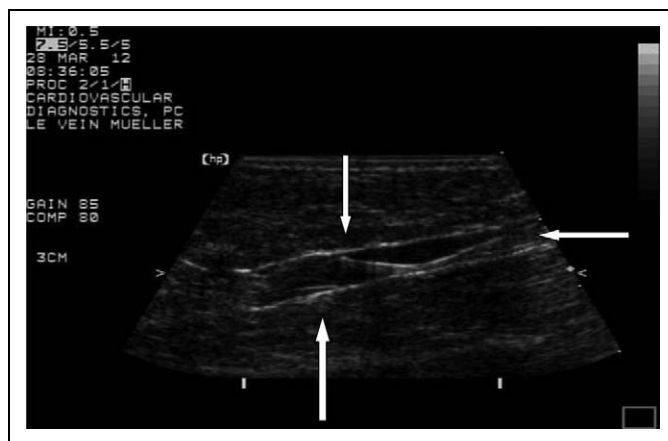


Figure 4. Sheathed catheter within the GSV (leftward arrow), with ball at tip of abrasion wire visible (downward arrow), placed just distal to a venous valve (upward arrow) (Copyright © 2012 Richard L. Mueller, MD, PC). GSV indicates great saphenous vein.

(Figure 5, 6). A final ultrasound color Doppler (and pulse wave [PW], if necessary) search for arteriovenous fistulae (AVF) near the target vein should be undertaken. However, this evaluation should be part of the preoperative diagnostic ultrasound used in developing the treatment plan. If an AVF is found near the target vein, the author advises aborting the procedure due to the risk of sclerosant movement into an artery, with risk of thrombosis, tissue loss, and gangrene. These risks are debatable, considering the pressure gradient that would have to be overcome by the sclerosant.

Treatment. A right-handed operator holds the handle with the right hand, and the catheter near the access device hub with the left hand. The stopcock is set to the off position at the open side port. The right index finger depresses the motor trigger located in the handle; the right thumb delivers sclerosant by pressing the syringe plunger. The motor is activated, spinning the wire, which produces venospasm (Figure 7 A and B). For treatment of both the GSV and SSV, Vascular Insights advises 3 seconds of wire rotation and simultaneous pullback for a distance of approximately 0.5 cm to create venospasm at the proximal ablation edge, followed by continued spinning and pullback with delivery of sclerosant.

For the GSV, Elias rotates during pullback without injection for 1 cm (starting at 1 cm distal to the SFJ), then begins infusion at 2 cm distal to the SFJ. Reijnen starts 0.5 cm distal to the SFJ, rotates without pullback for 3 seconds, and then combines pullback, rotation, and infusion.⁴ Wire rotation without pullback is technically difficult as the wire tends to snag on either the vein wall or a valve cusp, causing mild pain. Snagging requires that the motor be turned off, the wire resheathed by pushing the cartridge wing slightly clockwise and then toward the first lock position, the catheter gently tugged distally, the wire unsheathed, advanced proximally toward the point of snagging, and treatment resumed.

Alternatively, the resheathed wire can be pushed proximal to the point of snagging, the catheter rotated, then pulled



Figure 5. Image of unsheathed, angled abrasion wire protruding 2 cm proximal to the tip of the catheter (arrow) in the GSV. GSV indicates great saphenous vein.

distally, and treatment resumed. Tissue is often noted to be adherent to the wire tip upon withdrawal, representing vein wall and or valve cusp avulsion. Such snagging is usually first detected by an audible change in the sound of the motor (ie, more high pitched and lower volume), patient pain, or resistance to pullback. Unless the wire snags, the patient typically identifies no sensation or describes buzzing, scratching, or vibration in the leg that is not uncomfortable unless the vein is very superficial, relatively small diameter, or when the catheter traverses the knee segment. To assess whether pain is due to snagging or other reasons, the catheter should be slid gently proximally and then distally to see whether it moves freely. Manual compression is advised by the company over the length of treated vein whenever vein diameter is greater than 10 mm; a second pass might also be required.

It is noteworthy since the initial 0.5 cm pullback is without injection and the initial 0.7 to 1 mL of liquid delivered is saline flush rather than sclerosant, the proximal 3.5 to 7 cm for the 45-cm catheter or 5 to 10 cm for the 65-cm catheter in most cases is not treated by sclerosant but solely by wire abrasion. Nonetheless, as with thermal ablation techniques, there is very frequently proximal propagation of acute treatment that results in proximal thrombus for several centimeters. Wire tip positions are calculated with this net effect in mind. In the author's experience, it is not unusual to see the proximal ablation edge 1 to 3 cm proximal to the wire tip (3 to 5 cm proximal to the catheter tip). Furthermore, in terms of assessing the length of "treated vein" based on catheter length in the leg, treatment is stopped when 3 to 4 cm of catheter (+2 cm of wire) is left in the leg. Given that target vein depths are typically 0.2 to 2 cm and access is angled by approximately 1 cm, 1 to 3 cm of the 3 to 4 cm of catheter left in the leg are extravascular, leaving approximately 1 cm of catheter within the vein at the time of cessation of treatment. Treated vein length is the total marked catheter length (42.5 or 62.5 cm) minus marked catheter length measured outside the leg minus 4 to 6 cm (2 cm wire, 1 cm in the vein, and 1-3 cm in the leg outside the vein when treatment is stopped).

The catheter is pulled back slowly (see next section for details on pullback rate), using gentle traction with the left hand's index finger and thumb, with the back of the left index finger ensuring that the access device is not pulled out inadvertently if the introducer is loose. A vibration is felt in the fingers holding the catheter, which undulates very slightly throughout its course. The operator can also feel the wire tip's spinning under the skin by touching the skin or even with the probe overlying the skin.

It is important to remember that the access device must be pulled out of the vein and skin over the catheter well before the catheter tip reaches the tip of the access device (microintroducer sheaths are typically 9 cm long, angiocaths are 1.5 to 2 inches long). If this is not done in timely fashion, the rotating wire will wind up treating the inside of the cannula and that vein segment will undoubtedly remain patent.

The author prefers to pull the access cannula out of the leg and back over the free catheter prior to starting therapy, so as not to have to interrupt therapy later and also to make pullback of the catheter easier with one hand. Alternatively, this can be performed when there is at least 12 cm of ClariVein catheter left in the leg.

Treatment is monitored continuously by ultrasound, which reveals a whirling undulation of the abrasion wire appearing to be rotating at several cycles per second and thus far slower than the 3500 rpm speed typically employed (Figure 7 A and B). This is an optical illusion similar to the wagon train wheel explanation for why a movie of a rapidly spinning wheel seems to be rotating much slower and even in the opposite direction of rotation. Wire snagging (slowing), malfunction, or vessel perforation can be identified and the motor can be stopped if needed.

If the wire is seen to approach a valve, wire rotation can be stopped, the wire can be pulled distal to the valve, and treatment resumed. If a tributary or perforator merits treatment, pullback can be slowed and/or infusion rate can be increased (and a second catheter pass delivered, if desired) while passing the ostium, in order to try to disperse sclerosant into these target branch veins. This collateral spread of sclerosant liquid via paths of least resistance into tributaries can be beneficial, when treating refluxing target tributaries or perforators, or can be a modest adverse effect when a normal vein is occluded, which is commonly noted and either be asymptomatic or cause a self-limited phlebotic syndrome for up to 2 weeks. In our experience, pain at follow-up is nearly always due to such collateral superficial venous thromboses (SVTs), or at times due to focal vein perforations during treatment. We have noted rapidly resolving focal tenderness and pigmentation at the site of these collateral SVTs. Further ClariVein treatment can safely proceed after the resolution of symptoms (Rick Bernstein, MD, personal communication).

Sclerosant dispersal can be noted as an echogenic mobile haze (and possible foam formation, although bubble density is far less than with conventional foam sclerosants) within the undulating motion of the abrasion wire (Figure 8).

A white mark is on the catheter 6 cm distal to the catheter tip (8 cm distal to the wire tip). This mark alerts the user to the



Figure 6. Unsheathed abrasion wire within GSV, with ball at wire tip better visualized and abutting the anterior vein wall (Copyright © 2012 Richard L. Mueller, MD, PC). GSV indicates great saphenous vein.

limited catheter length remaining (1 cm black marks are not numbered) when the white mark is seen at skin level. When another 2 cm of catheter is pulled back, treatment is stopped (3 cm for a superficial vein, whereby there is a shorter length of subcutaneous, extravascular catheter between vein and skin). This limits sclerosant extravasation as well as tissue trauma by the wire. Of note, pinkish liquid is often noted to be extruded at the skin near the end of treatment. This liquid is extravasated sclerosant mixed with blood “pushed back” distally by the vein spasm more proximally. Extravasation also likely and commonly occurs during wire snagging.

The fact that no cases of skin ulceration or necrosis have been reported to date with ClariVein supports the recent realization that sclerosant extravasation itself is only rarely a cause of skin necrosis. If sclerosant volume is greater than 5 mL, treatment is interrupted to reload the syringe with more sclerosant.

Since there is approximately 0.7 to 1 mL of sclerosant remaining in the catheter when the syringe is emptied, if treatment is nearly completed, but sclerosant has run out, 0.7 to 1 mL of saline flush can be used for the final portion of treatment, which will deliver an equal volume of sclerosant already in the catheter.

When the motor trigger is disengaged and sclerosant infusion stopped, ultrasound imaging of the vein is performed to assess the treated vein for closure. All modalities should be used, including gray scale assessment of vein compressibility and assurance of vessel spasm, as well as PW and color Doppler to assess for patency of the treated vein (Figure 9 A and B). This is performed before removing the catheter, as immediate retreatment without repeat access is possible. Often the vein is partially compressible, or becomes noncompressible with visible coagulation of gel-like echogenic intraluminal densities over several minutes of real-time observation. Unlike thermal ablation, this partial compressibility is not a treatment failure; hence the need for color and PW Doppler to document closure. We have observed several cases where full non-compressibility was not seen until the first follow-up

ultrasound 3 to 5 days after the procedure, or even weeks later. In our experience, even if there is partial compressibility of the vein, there is typically no flow by color or PW spectral Doppler interrogation. In contrast to thermal ablation, where immediate posttreatment assessment of vein patency is hampered by tumescent anesthesia, there is no such imaging challenge with ClariVein.

If the vein is found to be truly patent, immediate retreatment can be accomplished by passing the sheathed catheter tip proximally again, then retreating immediately, if total sclerosant dose is not projected to be excessive. Flushing of sclerosant is not necessary in this case, as retreatment will be performed quickly.

If the vein is proven to be occluded, the wire tip is resheathed by unclipping the syringe, slight clockwise twisting of the cartridge wing, and pushing the wing proximally along the handle groove from second lock position back to the first. The wire is now protected from damage and hence the vein near the access site. The catheter is now withdrawn from the skin. The wire should be unsheathed again in order to inspect it for tissue debris (innocuous) or damage to the wire or catheter, and to exclude the possibility of retained hardware. There have been no reports of wire breakage or retention within the body (Vascular Insights, personal communication). Manual pressure is applied at the access site. Unless a second vein segment is treated at the same treatment session, the entire ClariVein device is discarded and cannot be resterilized.

We report the approximate length of treated vein as well as the volume, concentration, and type of sclerosant infused, along with sclerosant lot number and expiration date. The proximal and distal limits of the ablation zone and the location of the target vein are also reported. Actual volume of sclerosant delivered is total syringe volume administered minus approximately 0.7 to 1 mL remaining in the catheter when it is removed.

Miscellaneous Issues. Because currently the maximal length of the catheter is 65 cm, in some patients if a full-length GSV ablation is planned, it may need to be performed with 2 separate access sites. The more tortuous segment should be treated first, as once the catheter and handle units are assembled, they cannot be disassembled. As the unattached catheter cartridge has maximal steerability, the more tortuous segment should be traversed with it before attachment to the handle and treatment of the 2 segments. In such a case, sclerosant within the catheter should be flushed with saline after the first segment is treated, in order to prevent clotting within the catheter when it is placed within the second segment. Another issue with catheter length arises if vein treatment length needs to be at the upper range of the rated catheter length.

For the 65-cm catheter, the total vein length of the catheter (including extruded wire) that can fit into a standard microintroducer sheath and be within the extremity from skin level proximally is only 62 cm (and even less length inside the vein). This is due to the hub of the sheath blocking 2.5 cm of catheter and to a 4.5 cm long distal portion of the catheter that is covered with a tapered, clear plastic hub 2.0 mm in diameter (0.080 inches) that connects catheter to the winged handle

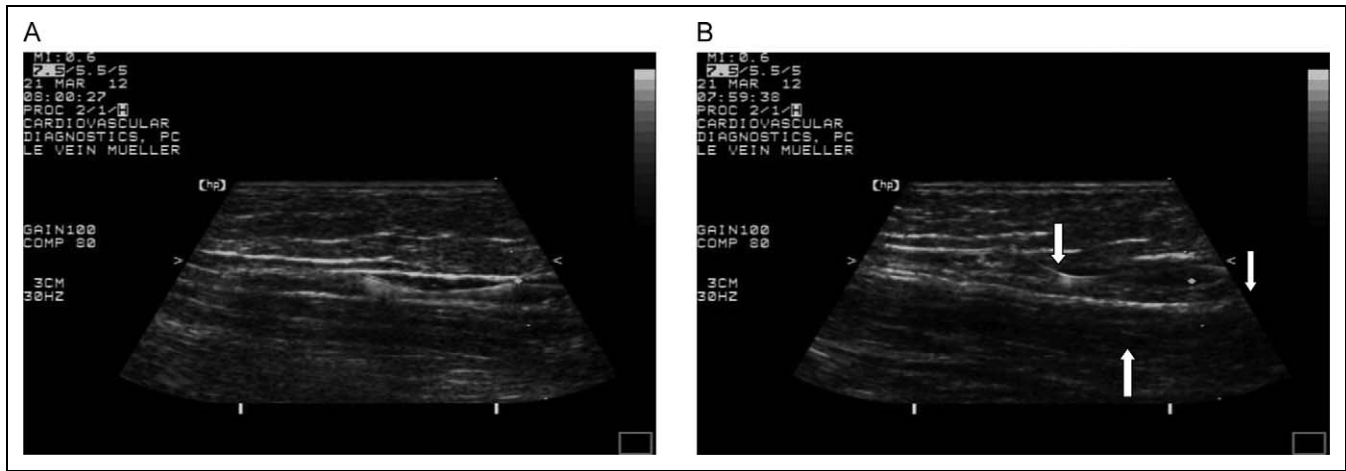


Figure 7. A and B, Wire undulating in GSV during treatment. Vein spasm is evident (Copyright © 2012 Richard L. Mueller, MD, PC). GSV indicates great saphenous vein.

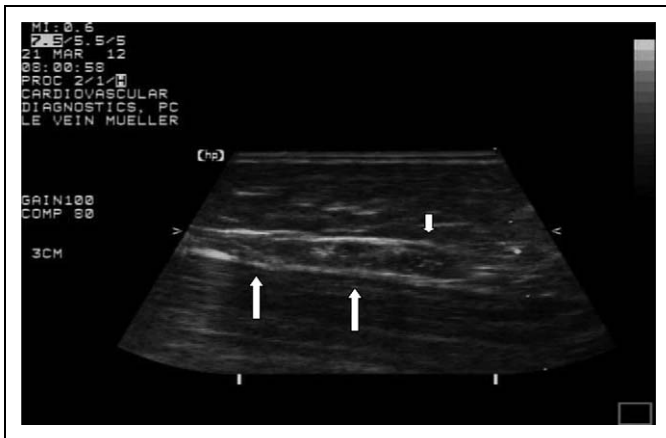


Figure 8. Abrasion wire undulating during rotation in the GSV (up arrows), with the vein in spasm and sclerosant dispersion (heterogeneous appearance, including micro bubbles [down arrow]) evident (Copyright © 2012 Richard L. Mueller, MD, PC). GSV indicates great saphenous vein.

insert. This plastic hub cannot fit a 4- to 5-F introducer but would fit inside a 6-F introducer; however, 2.5 cm of catheter would still be excluded from the leg due to the introducer's hub.

To extend the length of catheter that can be inserted inside the extremity, if the catheter cannot reach proximally to the ideal ablation starting position, a peel away introducer or sheath can be used. The 5F peel way introducer that we use has an outer diameter of 2.4 mm (0.094 inches); the track in the skin and vein wall should allow for insertion of the catheter into the introducer, removal of the introducer out of the leg, peeling away the introducer, and entry of the hub base of the catheter to just inside skin level, extending the length of the catheter by 4.5 cm (with 1-3 cm less within the vein). Another technique that can be used to extend the therapeutic "reach" of either sized catheter is to inject a mini-bolus of sclerosant (approximately 0.4 mL slowly) at the onset of starting rotation and pullback. We have noted successful

proximal propagation of ablation thrombus for several centimeters with this technique and even with usual technique, in some cases.

Postprocedure. Several minutes of foot dorsiflexion is performed by the patient to activate the calf muscle pump and clear sclerosant from deep veins. An immediate ultrasound is performed to assess for patency of the deep veins of the treated leg and to assess the proximal ablation edge position, especially in the area of the junctions. The patient should be taken off the treatment table expeditiously in order to start walking for at least 10 minutes postprocedure as well as 10 minutes every hour for the remainder of the day and 30 to 60 min/d for 14 days. In our practice, a simple dressing is placed at the access site, followed by application of thigh high class I compression stockings. Compression is continuous for 48 hours, then daytime only for the remainder of 2 weeks. All reasonable exercise is permitted beginning on the first postoperative day. Follow-up ultrasound and clinical evaluations are within 3 to 5 days, 1 month, and then every 3 months for the first year postprocedure.

Tortuous Target Veins. For target veins where access is near tortuous segments or branching veins, if the microintroducer's guidewire consistently goes into the wrong channel, and another site cannot be tried, one can pass the short microintroducer cannula (or preferably, a much shorter angiocath) into the wrong channel, then introduce the ClariVein catheter tip within the device, carefully pull it back under ultrasound control, and use the steerable tip of the ClariVein catheter to selectively enter the desired lumen as soon as the introducer is pulled back far enough. Other options include leg flexion or straightening, manual or ultrasound probe skin traction or pressure to help guide the wire, retrograde access, using an angled steerable (with torque device) Bentson-type Glide wire (Terumo Corporation, Tokyo, Japan), or straightening the guidewire path with injection of saline via the catheter. Venospasm can be treated with injection of nitroglycerin (0.4 mg) via the catheter.

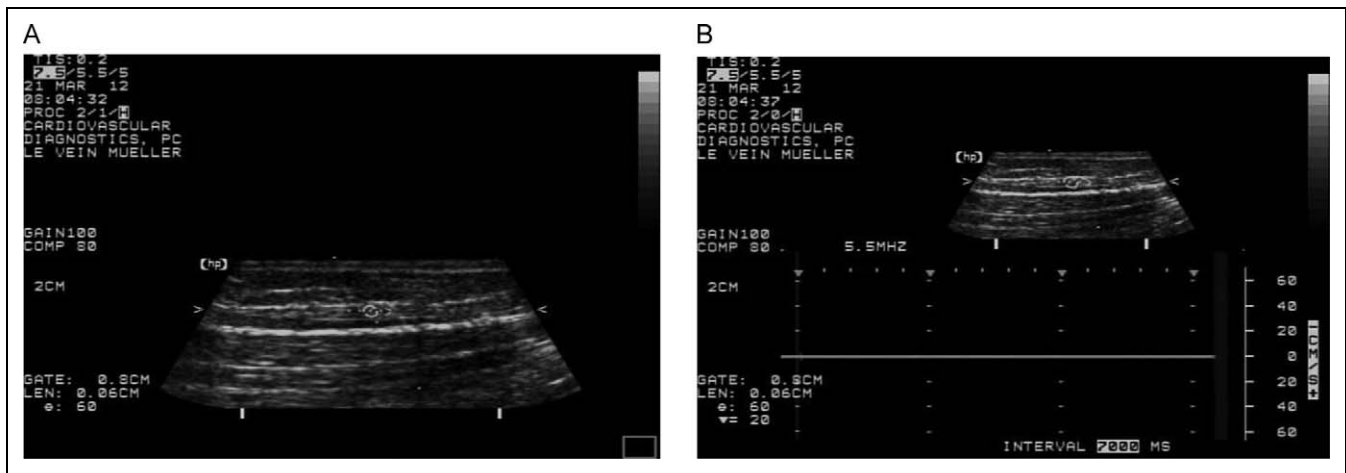


Figure 9. A and B, Two-dimensional and PW Doppler images of GSV immediately postprocedure, revealing no venous flow. In this case, the streaky gray scale hyperechogenicity is similar to thermal ablation, but there is often early hypoechogenicity (Copyright © 2012 Richard L. Mueller, MD, PC). PW indicates pulse wave; GSV, great saphenous vein.

Traditional prepping of the entire leg and use of split drapes, as is done for thermal ablation where numerous tumescent anesthetic injections must be performed in sterile fashion, is redundant for ClariVein because a single-access skin puncture is the only site requiring sterile preparation. Care is taken not to place the ultrasound transducer over the access site once it has moved out of the sterile skin zone.

Dosing. Pullback speed is constant for all vessels and all vessel sizes at 1.5 mm/s, or 6 to 7 (6.67) s/cm.^{3,4} We use a digital metronome to help time the pullback, with a backbeat chime every 7 seconds. Keep the catheter moving to avoid wire snagging, including when the wire is first activated for 3 seconds without rotation and injection. The catheter should never be bent acutely.

Liquid rather than foamed sclerosant is advised by the company, largely due to lack of FDA approval for foamed sclerosants as well as excellent short-term closure rates without resorting to foam that has more side effects. Both the US and Dutch studies used liquid sclerosants.^{3,4}

As an alternative sclerosant, Dr Karsten Hartmann of Germany has used 1% POLI foam in the proximal 5 cm of the GSV (3-mL volume), then 2% POLI liquid for the remainder of the vein in approximately 50 legs, with excellent results and no side effects (personal communication). A clinical trial is registered in the Netherlands comparing liquid POLI 2% and 3% as well as 1% foam.⁵ Despite meticulous air purging of the sclerosant syringe and 3-way stopcock, a small amount of bubbles are noted within the rotating wire field during treatment, such that a mild in situ foaming effect cannot be excluded.

The company advises using STS 1.5% for GSV, 1% for SSV, and 2% POLI for GSV and SSV. The Elias pivotal study used STS 1.5% for GSV; other veins were not studied.³ The Dutch pivotal study used POLI 1.5% for GSV, and had a few cases of proximal GSV nonclosure, leading them to transition to using 2% POLI for the proximal third of the GSV.⁴

This is not surprising, as STS is 2 to 3 times more potent than POLI. An equivalent POLI concentration to STS is significant weaker sclerosant. Of note, unless one uses compounded drug, POLI is not available in the United States at concentrations higher than 1%, nor is it FDA approved for vessels larger than reticular veins. Neither sclerosant is approved in foamed form in the United States.

Sclerosant dosage and infusion rate are obtained from a unique interactive MOCA dosing chart supplied by Vascular Insights, LLC. One inputs the vein treatment length, vein diameter, and patient weight into an Excel spreadsheet (Microsoft Corporation, Redmond, Washington), and the spreadsheet calculates and displays sclerosant volume and infusion rate in milliliter/minute. Weight only affects the maximal sclerosant volume and the infusion rate for GSV treatment with POLI. Recently the European version of the table has added 0.6 mL to sclerosant volume to compensate for the catheter's saline dead space, though one could use saline flush of 0.7 to 1 mL at the end of delivery of the calculated sclerosant volume.

Rather than accessing this chart online and inputting values for each treatment when mixing sclerosant, we have created our own table of infusion rates and volumes for the GSV and SSV at various vein diameters and vein lengths for quick reference. I also converted the spreadsheet infusion rate of milliliter/minute into the more practical milliliter/centimeter of catheter pullback, using the pullback rate for conversion. Linking infusion rates to catheter pullback unifies timing of the simultaneous left- and right-hand tasks during the procedure: catheter pullback and sclerosant infusion. The European version of the dosing table has recently added the milliliter/centimeter infusion rate I have proposed. The maximum volume of STS is given as 10 mL for the GSV and 4 mL for the SSV (8-10 mL for a large Giacomini/SSV vein complex is advised by the company), whereas the maximum volume of POLI is weight dependent for GSV (2 mg/kg) and 4 mL for the SSV. Minimum volumes for small, short vein segments are 0.2 mL. An

approximate rule of thumb is 1 mL of STS per millimeter diameter “full” GSV treatment. Of note, the dose of STS for the GSV in the Elias study was 12 mL for all patients by protocol, regardless of vein length, diameter, or patient size, with no significant complications. Regarding infusion rates, the smallest marked increments on the 5 mL syringe are 0.2 mL; infusion rates range from 0.04 to 0.38 mL/cm.

Bilateral long truncal vein ablations are not advised, given the dose limitations of sclerosant. Foam sclerotherapy treatment of short-segment recanalizations is advised, when clinically indicated (many recanalized segments do not reflux and may have no clinical relevance). Longer recanalized segments can be treated with thermal ablation.

As noted, the company provides an optional 1-way luer duckbill check valve as an alternate interface to the 3-way stopcock between the catheter cartridge’s luer port and the sclerosant syringe. This check valve has less slippage, but the author notes more resistance to flow.

Smaller syringes than the standard 5-mL syringe can be used in order to provide more precise control and more even flow of sclerosant flow, by increasing injection pressure. The risk of venoarteriolar reflex-mediated necrosis with higher injection pressures is a consideration.⁶

Low-resistance syringes such as reusable sterilized 5 mL glass syringes, or Epilor (BD, Franklin Lakes, New Jersey) 7-mL or similar disposable plastic loss of resistance (LOR) anesthesia syringes with special low-resistance plungers can be used to provide smoother flow of sclerosant. Borosilicate glass syringe barrels have a very low coefficient of friction with their plungers and can be autoclaved.

Typical disposable plastic syringes yield a stepwise infusion of sclerosant due to their high plunger resistance. However, this stepwise instillation has not compromised occlusion rates in the author’s experience and in many ways make the simultaneous infusion of sclerosant and catheter pullback easier by transforming it into small alternating tasks. Rather than having 2 hands perform separate tasks at separate rates, the catheter pullback takes the lead, and a small aliquot of sclerosant can easily be injected after each centimeter of catheter pullback.

Ultrasound. Attention to meticulous ultrasound technique is essential, including preprocedure planning, as well as intraprocedural guidance. In addition to the standard ablation guidance steps of guiding access, catheter passage, and positioning, ultrasound is key to monitoring for any potential abrasion wire malfunction, snagging, or vessel perforation, guiding delivery of slower pullback, second catheter pass, and/or higher infusion rate at sites of target perforators or tributaries, as well as for identifying the rare visible arteriovenous fistula in the region of the target vein.

While catheter-assisted sclerotherapy using ultrasound guidance is considered by many to be the safest form of sclerotherapy due to the high confidence level of intravenous injection, rare catastrophic complications such as amputation related to injection near or into an AVF have been documented.⁷ Excessive injection pressure, rates, and volumes should be avoided,

at least in the SSV, due to the potential for tissue ischemia or necrosis due to inciting venoarteriolar reflex.⁶

The frequent partial compressibility early after ClariVein therapy augments the value of color and PW Doppler over gray scale ultrasound. Furthermore, vein contraction may take a full year. One unique finding we have noted is a diffuse echogenic halo (perivenous edema and infiltration) surrounding inflamed vein segments.

Vein Sizes. The maximum treated vein diameter reported to date is 19 mm.⁸ The company advises manual ultrasound probe compression for veins larger than 10 mm diameter. The abrasion wire will still provide at least partial endothelial contact in veins larger than its centerline of rotation, due to drift and wobble of the wire caused by its rapid rotation.

Manual compression will enhance circumferential wire endothelial contact. Larger veins can also theoretically be treated with application of tumescent anesthesia or saline prior to treatment to enhance results. Extremely superficial veins, including those in patients with HIV lipodystrophy, may occasionally require tumescent anesthesia.

Mild to moderate pain in the absence of wire snagging can also occur in small caliber veins. If pain occurs in superficial or small veins, especially at the knee area, motor speed can be reduced to 3000 rpm or less.

Phlebectomy. Concomitant phlebectomy has been performed either just prior to or just after ClariVein ablation. Rationale for performing phlebectomy first would be to avoid a long time for the patient on the table with sclerosant in the leg (foot flaps can be performed to mitigate this thrombotic risk). Rationale for ClariVein ablation first is to decompress the tributary varicosities and minimize their bleeding. Reassuringly, despite the high likelihood of sclerosant extravasation with either strategy, no cases of tissue necrosis have been reported.

Complications. We have not experienced any mechanical catheter/handle failures that have compromised any treatments. Though they are clearly theoretically possible, their potential for having to abort a case is far lower than with thermal ablation using complex energy generator sources. Given the disposable nature of the equipment, it seems the worst-case scenario would involve replacing a catheter or handle intraprocedure. We have encountered cases of detachment of handle and catheter after they have been locked into the second position, but this has not compromised procedural success. We have also had cases of a very high pitched, screaming noise emanating from the catheter, with shuddering of the wire on ultrasound, and eventual loss of motor function. However, the procedure was successful and necessitated only exchange of the handle, which detached from the catheter due to loss of washer function at their interface. One strategy is to stop the motor, resheath the wire, and then unsheathe again to try to stabilize the washer function and eliminate the vibration. Even if this fails to correct the problem, treatment can continue.

Especially in small veins, the motor sound will change to a higher frequency and the wire may appear on ultrasound to rotate more slowly, suggesting a snagging of the wire. The catheter should be gently slid proximally and distally a few centimeter to check for free movement, which would indicate no snagging. Instead, this “pseudo-snagging” may be a small caliber vein restricting full wire tip angle of rotation. In this case, treatment can proceed without interruption.

We have had a case where the target SSV was nearly adjacent to a large gastrocnemius vein as well as the popliteal vein. Because of the 6.5 mm diameter for rotation of the wire tip, visible stretching of the smaller GSV was noted on ultrasound, along with deformation of the anterior wall of the gastrocnemius vein. No thrombus was detected in either deep vein postprocedure.

Short or Superficial Veins and Perforators. Theoretically, the shortest effective treatment length is likely to be 4 cm of catheter within the vein and 5 to 7 cm within the leg, including 1 cm of angled catheter from skin to the plane of the vein, which is typically 0.2 to 2 cm deep to the skin, for a total of 1 to 3 cm of catheter outside the vein within the leg.

The proximal 2 cm of wire is providing treatment locally for that distance, with the distal 1 cm of catheter within the vein as a safety margin, and one more centimeter of catheter in the vein to be pulled back, and a minimum of 1 to 3 cm of catheter exposed outside the leg proximal to the white mark, indicating the point at which the catheter should not be pulled back any further and should be withdrawn from the leg.

The wire is rotated in place for 3 seconds to induce spasm, a slow instillation of an amount of sclerosant equal to the catheter's saline dead space volume is advised, 1 cm is pulled back, and the wire is rotated in place without further injection, before removing the catheter. This would provide a short “spot welding” treatment with just 1 cm of pullback, treating approximately 3 cm of vein.

Incompetent perforators can be treated with direct access, although the perforator would have to have a minimum length of several centimeters. A more practical option is described by Rick Bernstein, MD (personal communication), employing retrograde access down a truncal vein and positioning the angled catheter tip in the orifice of the perforator.

Unique Mechanistic Advantages. These points are speculative as mechanistic studies have not been published, but the intense vasospasm created by the abrasion wire may augment procedural safety and efficacy. Safety may be enhanced by a zipper type effect of the advancing wave front of vein spasm proceeding distally. This might limit sclerosant flow into the junction and deep veins as well as limit sclerosant, bubble, and even endothelin delivery to the systemic circulation, potentially reducing the risk of DVT and/or neurologic toxicity. Efficacy might be enhanced by retention of higher concentration of sclerosant with much greater contact with the intimal endothelium of the treated segment due to this zipping effect, which may displace blood via the wire-induced vortex as well as by reducing

vessel volume. Intense and long lasting spasm and lumen filling with denuded intima might not only displace blood from the lumen and allow more higher concentration of sclerosant at the intimal surface but also prevent refilling with blood posttreatment, which would limit plasma proteins such as albumin from inactivating sclerosant, improving potency, limiting treatment failure, and preventing the trapped blood that can lead to a superficial vein becoming a tender, pigmented cord. At the same time, efficacy is maintained in the proximal treated segment, despite the initial vortex being composed of saline, due to a bidirectional milking effect of the vortex spasm wave front extruding sclerosant proximally as well as the conveyor belt effect of antegrade residual sclerosant-laden blood flow before the vein “cures” after treatment and flow ceases in a time-dependent fashion. Mechanical denudation of intima may fill the lumen with debris, providing a unique additional mechanism for vessel collapse. An increase in intimal surface area as a substrate for sclerosant activity is also possible beyond the increase in surface area proportional to vessel volume induced by venospasm.

For those familiar with thermal ablation techniques, the learning curve for ClariVein is short, as most steps are similar. The hardest part of the ClariVein learning curve is the manual and multitasking challenge of a simultaneous catheter pullback, motor activation, and sclerosant injection, with differential speeds of pullback and infusion.

Discussion

To date, there have been 2 pivotal studies published. The author through personal communication with the investigators and presentations at venous symposia has updated the published material.

The first-in-man study by Elias reported 30 limbs treated at one center (Englewood Hospital, NJ), with mean venous clinical severity score (VCSS) of 4.5 and CEAP class 2 to 4 (80% class 2). Only the GSV was treated, all with 12 mL of 1.5% STS; review of vein diameters were 5.5 to 13 mm.³ Wire tip was 2 cm distal to the SFJ, with stationary rotation for 2 to 3 seconds, followed by 1 to 2 mm/s pullback and injection, 1 day of compression bandage, and 12 days of compression stockings. 97% total occlusion of the treated vein segments was noted at 6 months (mean follow-up 260 days). This compares very favorably to occlusion rates after Endovenous Laser Ablation (EVLA) (94% at 3 years⁹ in one meta-analysis; 96% at mid-term follow up in another¹⁰) and are superior numerically to occlusion rates after radiofrequency ablation (RF) ablation (84% at 3 years⁹) as well after foam and liquid sclerotherapy (approximately 75% for foam sclerosants 55-80% after 1-3 years of follow up¹¹; 77% long term in a meta-analysis¹²; 77% at 3 years in another meta-analysis⁹, with generally accepted higher side effect profile than for liquid sclerosant. Long term (6 months – 10 years, typically 1 year) occlusion rates are only approximately 40% for liquid sclerosants¹²).

The only recanalized vein was in the initial patient (occurring between the 1-week and 1-month follow-up), without

reflux; this patient was later retreated with RF ablation (S. Elias, personal communication). Mean total procedure time was 14 minutes, distributed with 9 minutes of ablation time and 5 minutes in the active treatment mode. No patient had pain during the procedure, 3 had ecchymoses, and no other side effects. Any vein occluded at 1 month remained occluded throughout follow-up. One year follow-up revealed 22 (100%) of 22 evaluated GSVs totally occluded⁸ and 2-year follow-up revealed 27 (96%) of 28 total occlusion.¹³

The second pivotal study, was by van Eekeren et al.⁴ A pilot safety study at 2 centers (Rijnstate & St. Antonius Hospitals; Dutch study #1), it reported initial technical success of 100% in 30 limbs' GSV (4-12 mm diameter; mean 6 mm near the SFJ). The patients had CEAP scores of 2 to 4 (72% CEAP 2). Liquid POLI 1.5% was used; mean dosage was 6.8 mL, and was based on vein diameter (1 mL/mm). Wire tip was 2 cm distal to the SFJ, with stationary rotation for a few seconds, followed by infusion and pullback rate of 2 mm/s. Average procedure duration was 20 minutes; compression was used for 24 hours continuously, then during daytime for remainder of 2 weeks. There were no major adverse events; 30% had mild ecchymoses at entry site, and 13% had phlebitis. At 6-week follow-up, 87% complete occlusion occurred and 97% had partial + complete occlusion. One patient had complete recanalization (and was successfully retreated); 3 had >4 cm length partial recanalization (2 in the proximal and 1 in the distal GSV). Eighty-eight percent patient satisfaction was recorded, in addition to significant improvement in VCSS (3.0-1.0), even in those with partial recanalization. Pain was 2 to 9/100 visual analog scale within the first week.

Drs Reijnen and DeVries, from the same 2 Dutch institutions have reported in presentation form an unpublished Efficacy/Pivotal Study (Dutch study #2)¹⁴ which included 97 patients/limbs, including GSV, SSV, and accessory GSV. Initial occlusion rate was 100%; 6-week follow-up revealed 97% occlusion (3 patients had greater than 4 cm length of partial recanalized in proximal GSV segments).

There were no major adverse events; 27% had minor hematoma, 22% had indurations, and 13% had pain had pain for greater than 1 week.

Reijnen and deVries have also presented an unpublished registry study (Dutch study #3)¹⁵ of 64 treated GSV limbs. Occlusion rates were 94% at 6 weeks (62 of 64 totally occluded; 2 open GSV, 2 proximal recanalized veins) and 91% at 6 months (21 of 22 totally occluded; 1 open GSV and 1 proximal recanalized vein). There were no major complications; 6% of patients had hematoma and 6% had induration. Finally, the same group has presented an unpublished summary of their clinical series,¹⁶ including 210 GSV, 44 SSV, and 14 anterolateral GSV accessory veins treated. Vein diameters ranged from 2.5 to 13 mm, with C1-C5/6 disease represented (mainly C2-4). Occlusion rates for the GSV, SSV, and accessory were 98%, 100%, and 100% at 6 weeks, and 93%, 94%, and 100% at 6 months.

Significant reductions in VCSS were documented, along with visual analog pain scores posttreatment of <1 during week 1. Deep vein thrombosis was found in 1 (<0.5%) of 268

patients, the first reported DVT with ClariVein, as well as ecchymosis, phlebitis, and discomfort longer than 1 week in 26%, 21%, and 16% of patients.

A poster presentation from Veith Symposium 2011 by Bishawi et al¹⁷ is notable because it is the largest series of patients (419) treated to date. This multicenter observational study had only very short term (2-7 day) follow up. The majority of veins treated were GSV, but SSV, accessory GSV, and other veins were also treated. Mean vein diameter was 7 mm, mean sclerosant volume 7 ml; most were treated with STS at 1.5%, some with POLI 3%. Occlusion rate was 97%, with no univariate predictors of treatment failure.

The Dutch group added two publications in 2012. The first compared postoperative pain and short term quality of life and return to work in a prospective, observational study of 68 patients with GSV reflux treated with ClariVein vs. radiofrequency ablation¹⁸. Patients treated with ClariVein (POLI 2 ml of 2% liquid for the proximal 10-15 cm, then 1.5% for the remainder) had statistically significant reduced post operative pain (5 vs. 19/100 at a mean of 14 days), earlier return to normal activities (1.2 vs. 2.4 days) and to work (3.3 vs. 5.6 days). There were no serious side effects with ClariVein and no significant difference in hematoma, phlebitis, induration, or pigmentation between modalities, both of which improved quality of life at 6 weeks. Occlusion rates were not reported. The other publication was a prospective, non controlled, observational study of 50 consecutive SSV reflux patients¹⁹. The SSV was treated in the first third of patients with 1.5% POLI, then the protocol was changed to 2 ml of 2% POLI for the proximal 10-15 cm, then 1.5% for the remainder. Occlusion rates were 100% initially and at 6 weeks, and 94% overall at 1 year (87% at the lower concentration, 97% at the higher concentration [NS]). Mean pain visual analog score was 2/10 during the procedure and mean satisfaction score was 8/10 at 6 weeks. Mean VCSS dropped from 3 to 1 at 6 weeks and at 1 year. There were 3 recanalized veins (1 at the higher dose) longer than 10 cm (2 complete, 1 partial), all with reflux. Two patients were retreated with thermal ablation. There were no major complications; 12% of patients had ecchymosis or induration at the access site, while 14% had phlebitis (10% incidence of lasting more than one week). There were no additional complications at 6 weeks or at 1 year.

Conclusions

ClariVein is an exciting addition to the phlebologist's toolbox. The method has the potential to be a first-line treatment, addressing several of the deficiencies of thermal ablation by reducing side effects, streamlining the procedure, and broadening applications.

Late recanalization appears unlikely, given a very high occlusion rate at 2 years. However, further studies addressing the following issues are needed: randomized clinical trials versus thermal ablation, both mechanical (pullback parameters) and chemical dose ranging (sclerosant dosing volumes, concentrations, and foamed agents), analysis of the components of closure, pathologic mechanistic studies of vein closure (including endothelin release patterns), and longer periods of

follow-up and larger patient numbers (more patient-years). Currently, patient numbers are using and follow-up is now mid-term. An 840 patient, 5-year Dutch randomized trial of ClariVein versus radiofrequency ablation was launched in 2012.²⁰

As with all therapies, careful patient selection and informed explanation of therapeutic options are paramount. ClariVein fills several therapeutic gaps seen with thermal ablation.

Declaration of Conflicting Interests

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