Lower pain and faster treatment with mechanico-chemical endovenous ablation using ClariVein®

SV Vun, ST Rashid, NC Blest and JI Spark

Phlebology published online 8 October 2014
DOI: 10.1177/0268355514553693

Original Article

Phlebology

Phlebology
0(0) 1–5

DOI: 10.1177/0268355514553693
phl.sagepub.com
SAGE

Lower pain and faster treatment with mechanico-chemical endovenous ablation using ClariVein®

SV Vun[1,2], ST Rashid[1], NC Blest[1] and JI Spark[1,2]

Abstract

Objectives: To assess the efficacy of the ClariVein® system of mechanico-chemical ablation of superficial vein incompetence.

Method: ClariVein® treatment uses a micropuncture technique and a 4-Fr sheath to allow a catheter to be placed 1.5 cm from the saphenofemoral junction. Unlike laser (endovenous laser treatment (EVLT)) or radiofrequency ablation (RFA), no tumescence is required. The technique depends on a wire rotating at 3500 r/min causing endothelial damage whilst liquid sclerosant (1.5% sodium tetradecyl sulphate) is infused. The wire is pulled back whilst continuously infusing sclerosant along the target vessel's length. Initially, 8 mL of dilute sclerosant was used, but this was subsequently increased to 12 mL. No routine post-op analgesia was prescribed and specifically no non-steroidal anti-inflammatory drugs. Procedure times and pain scores (visual analogue scale) were recorded and compared to EVLT and RFA. All patients were invited for duplex post-procedure.

Results: Fifty-one great saphenous veins and six short saphenous veins were treated and followed up with duplex in the 10 months from July 2011. No major complications or deep vein thrombosis were reported. Duplex showed patency of three treated veins with two more veins having only a short length of occlusion, giving a technical success rate of 91%. Comparison with 50 RFA and 40 EVLT showed procedure times were significantly less for ClariVein® (23.0 ± 8.3 min) than for either RFA (37.9 ± 8.3 min) or EVLT (44.1 ± 11.4 min). Median pain scores were significantly lower for ClariVein® than RFA and EVLT (1 vs. 5 vs. 6, $p < 0.01$).

Conclusion: Mechanochemical ablation with the ClariVein® system is safe and effective. After some initial failures, the use of 12 mL of dilute sclerosant results in a very high technical success rate >90% which accords with the limited published literature. Procedure times and pain scores are significantly better than for RFA and EVLT. We await the long-term clinical outcomes.

Keywords

Endovenous technique, mechanochemical ablation, endovenous laser treatment, radiofrequency ablation, varicose veins

Background

Since the introduction of surgical techniques to treat chronic venous disease with stripping in 1907,[1,2] there has been little in the way of major improvements until the recent endovenous revolution. Traditional saphenofemoral ligation and stripping has a recurrence rate of 20–28% at five years[3–5] though this doubles if the long saphenous vein is not stripped.[6–8] There is a complication rate of 17–20%[9–11] which rises to 40% if this is for recurrent varicose veins.[12,13] Typical return-to-work times have been reported as 10–14 days with bruising lasting up to six weeks.[12,14]

Goldman[1] and Rasmussen et al.[15] first reported the use radiofrequency ablation (RFA) to treat incompetence of the saphenofemoral junction in 2000, followed a year later by Min et al.[3] and Elias and Raines[16] who

[1]Department of Vascular Surgery, Flinders Medical Centre, South Australia, Australia
[2]Department of Vascular Surgery, Flinders University, South Australia, Australia

Corresponding author:
JI Spark, Department of Vascular Surgery, Flinders University, Flinders Drive, Bedford Park SA 5007, Australia.
Email: ian.spark@health.sa.gov.au

described the use of endovenous laser treatment (EVLT) to treat truncal veins. Both techniques require tumescent anaesthesia. The endothermal techniques of RFA and EVLT have been reported to have fewer complications and acceptable recurrence rates at two years of 10–15% for RFA[6,8,12] and 7% for EVLT.[9] A Cochrane review suggested the main benefit of endothermal techniques are lower complication rates and quicker return to normal activities and work.[12]

Ultrasound-guided foam sclerotherapy (UGFS) is currently the subject of many ongoing trials comparing it to surgery and endothermal ablation. Success rates are reported as 88–93%.[14] However, failure has been reported as being higher with UGFS than other techniques.[15]

Mechanico-chemical ablation, such as ClariVein®, offers a significant advantage over the aforementioned endovenous techniques, since there is no risk of thermal injury, nor need for tumescent anaesthesia, which can be a source of procedural discomfort, as well as being the technically most challenging aspect of the technique.[16]

The aim of this study was therefore to assess the safety and efficacy of mechanico-chemical ablation using ClariVein®. In addition the total procedure time and intra-operative pain, scores were measured and compared with patients undergoing RFA and EVLT.

Methods and materials

Patient sample

All patients with duplex-proven, symptomatic saphenous vein incompetence were offered the option of conventional surgery or compression hosiery; those suitable for endovenous ablation were additionally offered this.

Duplex criteria for incompetence of the saphenofemoral, saphenopoliteal, great saphenous vein (GSV) and short saphenous vein (SSV) used were defined as >1.0 s reflux with pulsed wave Doppler using a 7.5–10-MHz linear array transducer.

Those patients with non-tortuous veins between 3 and 10 mm who opted for endovenous ablation were offered a choice of ClariVein®, RFA and EVLT – no attempt at randomisation was made.

Techniques

ClariVein® (Vascular Insights, Madison, USA) requires local anaesthetic for the superficial skin at the entry site of the catheter to allow skin puncture and advancement of the catheter. The tip of the wire is placed 1.5 cm below the saphenofemoral junction (confirmed with ultrasound) and rotated at 3500 r/min causing endothelial damage. After 2–3 s, the device is pulled back at 1 cm per 5 s whilst constantly infusing a sclerosant (1.5% sodium tetradecyl sulphate) as the angled wire rotates. Initially, 4 mL of sclerosant diluted to 8 mL with saline was used in total, but this was subsequently increased to 6 mL (diluted to 12 mL).

RFA and EVLT were used as per the standard protocol. In brief, after local anaesthetic infiltration of the skin and puncture of the vein, the catheter was advanced into position 1.5–2 cm below the saphenofemoral junction. The whole of the saphenous vein is then bathed in tumescent anaesthesia (500 mL normal saline with 10 mL 1% Xylocaine and adrenaline 100:200,000). For RFA (VNUS Closure RFG2, VNUS Medical Technologies Inc., San Jose, USA), the first section nearest the junction has two ablation cycles, and then the device is pulled back in 7 cm increments with single ablation cycles. For EVLT (Ceralas E, Biolitec AG, Bonn, Germany), the device is pulled back at 1 cm per 5 s.

At the end, a steristrip was placed over the puncture site, and a thin foam compressive dressing over the treated vein and compression bandaging (Swisslastic, Swisslastic AG, St Gallen, Switzerland) was applied for 24 h. After this, the patients wore TED stockings for six weeks until they were reviewed in outpatients.

No routine post-op analgesia was prescribed and specifically no non-steroidal anti-inflammatory drugs for ClariVein® patients. RFA and EVLT patients were given two days of routine non-steroidal anti-inflammatory agents (diclofenac 50 mg tds prn) for analgesia. Pain scores (visual analogue scale) were recorded post-procedure in the recovery area for all three techniques. The visual analogue scale was introduced by the recovery nurse who was blinded to the intervention performed to minimise bias.

Procedure times were documented from the time of entry into theatre until they left theatre.

All patients were invited for duplex post-procedure at 4–6 weeks and reviewed in outpatients at six weeks and as appropriate thereafter – any problems were noted. A vein was considered occluded if it was incompressible and free from blood flow on colour Doppler.

Statistical analysis

Statistical analysis was performed using the GraphPad Prism 6.00 for OS X (GraphPad Software, La Jolla California USA). Non-parametric data were assessed using the Kruskal–Wallis test to compare medians. If there was a significant difference between the groups, post hoc multiple comparisons were performed using Dunn's tests. Continuous data are presented as median ± interquartile range (IQR). A p value of less than 0.05 was considered significant for differences between groups.

Results

Between July 2011 and April 2012, a total of 127 patients were treated. Following its introduction in July 2011, 65 patients were consented for ClariVein® treatment as described above. One patient was deemed unsuitable on the day due to tortuosity. Sixty-four patients were treated, but nine did not attend for a follow-up duplex. Of the 55 patients treated and duplexed, 51 had GSVs and six SSVs with two patients having both veins treated. Table 1 shows the patient demographics.

Duplex showed patency of three treated veins with two more veins having only a short length of occlusion, giving a technical success rate of 91%.

This compares with a technical success rate of 93% for the other techniques (EVLT and RFA).[17]

During the study period, 50 RFA and 40 EVLT were compared for procedure times and pain.

Procedure times (Figure 1) were significantly less ($p < 0.0001$) for ClariVein® (23.0 ± 8.3 min) than for either RFA (37.9 ± 8.3 min) or EVLT (44.1 ± 11.4 min).

Table 1. Patient demographics.

Age median (IQR)	50 years (31–82)
Sex	17 men, 33 women
Vein diameter median (IQR)	9 mm (4–12 mm)
Segments treated	GSV 47, SSV 8
CEAP classification	2–6

IQR: interquartile range; GSV: great saphenous veins; SSV: short saphenous veins.

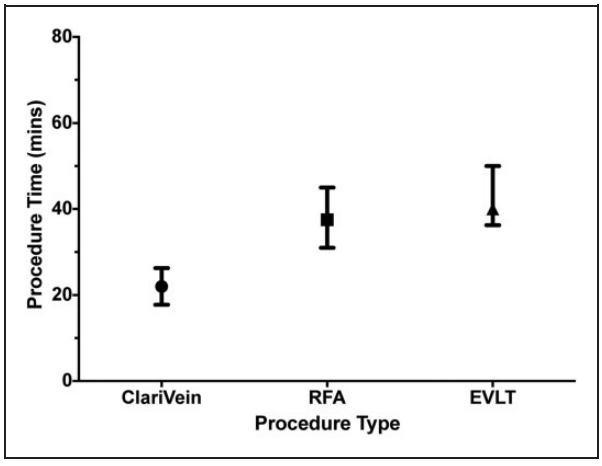

Figure 1. Procedure duration between the three groups (median ± IQR). Kruskall–Wallis test, $p = 0.0001$. Dunn's post hoc multiple comparisons: ClariVein® versus RFA, $p < 0.05$; ClariVein® versus EVLT, $p < 0.05$; RFA versus EVLT, ns. RFA: radiofrequency ablation; EVLT: endovenous laser treatment.

There was no significant difference between RFA and EVLT.

Median pain scores were significantly lower for ClariVein® than RFA and EVLT (1 vs. 5 vs. 6, $p < 0.01$).

Discussion

In the long term, treatment for varicose veins should primarily be guided by efficacy and recurrence rates. There is little data that goes out to five years or more comparing surgery to endovenous techniques, but a recent Cochrane review found that up to two to three years, both RFA and EVLT seem to have equivalent efficacy to surgery with perhaps higher re-canalisation rates but less neovascularisation.[12] Foam sclerotherapy has not been evaluated to the same degree, but there is evidence to suggest it may have a higher technical failure rate[15] although proponents may argue it can easily be repeated.

The next major issue is patient comfort and impact on their life, and there is somewhat mixed evidence, but certainly a trend towards endovenous therapies resulting in a quicker return to normal activities and less time off work.[12] However, recent trial evidence suggests that if rather than a general anaesthetic, surgery is performed under tumescent anaesthesia with light sedation, then the return to work and normal activities can be almost as good as endovenous techniques.[15]

The results of mechanico-chemical ablation using ClariVein® described here are early but promising. A primary occlusion rate of 91% is acceptable in the early learning phase of a new technique and consistent with other studies.[16,18] Furthermore, modifications have been made to improve efficacy such as increasing the amount of sclerosant used, to a total of 6 mL of 3% solution diluted to 1.5%, which is below the manufacturers' recommended total maximum dose of 10 mL of 3% solution.[19] Reassuringly, except for one superficial wound infection, the technique appears to be safe.

The main theoretical advantage for ClariVein® was the avoidance of thermal energy, which would allow a tumescence-free technique. The concern was that despite this, the procedure would be too painful. However, despite avoidance of any routine analgesics, pain scores were very low indeed and much lower than the endothermal techniques.

The avoidance of tumescence also had a great benefit in speed of the procedure with an approximate halving of the time required. This has major financial implications as one could theoretically double the number of patients treated in a session. In addition to this, the technique does not require any fixed equipment – the device comes as a disposable pack allowing a greater degree of flexibility in where the procedure can be done, especially in relation to EVLT, which requires laser safety certification and an appropriate room.

This study is limited by the lack of randomisation and is not powered to detect whether ClariVein® is equally efficacious as the endothermal techniques. Furthermore, we need to have longer follow-up to see the extent of recanalisation ideally at three years. Ultimately, trials should be undertaken and powered to see clinical outcomes in terms of clinically relevant recurrence rates at five years. One other point to note is that we have not treated varicosities at the same time although there is some evidence to suggest the benefit of this.[20] It would be interesting to investigate formally whether the use of the foam with ClariVein® reduces the subsequent need for sclerotherapy in outpatients for residual varicosities.

The final issue that needs to be considered is the financial impact of the treatments especially in a world where healthcare finances are under increasing scrutiny and varicose veins are an easy target for restriction by healthcare funders despite evidence to support intervention as a cost-effective treatment.[20,21] In this regard, not just the re-imbursement, direct procedure and social costs need to be considered but also the speed of therapy and theatre throughput should be factored in – if turnaround times can be reduced, then the number of patients treated in a fixed theatre allocation session time can be increased. For this, there needs to be a consistent and comparable policy on the treatment of varicosities as some do this routinely at the time of surgery but not endovenous ablation. If sclerotherapy is done for residual varicosities, then this cost also needs to be factored in.

Conclusion

ClariVein® is a safe and well-tolerated viable alternative to RFA and EVLT for the treatment of superficial venous incompetence. It is associated with significantly lower pain scores and shorter treatment times and eliminates the need for tumescent anaesthesia. Further work in the form of a randomised controlled trial should be undertaken to assess the long-term success and cost effectiveness of ClariVein®.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest

None declared.

References

1. Goldman MP. Closure of the greater saphenous vein with endoluminal radiofrequency thermal heating of the vein wall in combination with ambulatory phlebectomy: preliminary 6-month follow-up. *Dermatol Surg* 2000; 26: 452–456.
2. Babcock WW. A new operation for the extirpation of varicose veins of the leg. *NY Med J* 1907; 86: 153–156.
3. Min RJ, Zimmet SE, Isaacs MN, et al. Endovenous laser treatment of the incompetent greater saphenous vein. *J Vasc Surg* 2001; 12: 1167–1171.
4. Darke SG. The morphology of recurrent varicose veins. *Eur J Vasc Surg* 1992; 6: 512–517.
5. Fischer R, Linde N, Duff C, et al. Late recurrent saphenofemoral junction reflux after ligation and stripping of the greater saphenous vein. *J Vasc Surg* 2001; 34: 236–240.
6. Merchant RF, DePalma RG and Kabnick LS. Endovascular obliteration of saphenous reflux: a multicenter study. *J Vasc Surg* 2002; 35: 1190–1196.
7. Sarin S, Scurr JH and Coleridge Smith PD. Assessment of stripping the long saphenous vein in the treatment of primary varicose veins. *Br J Surg* 1992; 79: 889–893.
8. Pichot O, Kabnick LS, Creton D, et al. Duplex ultrasound scan findings two years after great saphenous vein radiofrequency endovenous obliteration. *J Vasc Surg* 2004; 39: 189–195.
9. Min RJ, Khilnani N and Zimmet SE. Endovenous laser treatment of saphenous vein reflux: long-term results. *J Vasc Surg* 2003; 14: 991–996.
10. Critchley G, Handa A, Maw A, et al. Complications of varicose vein surgery. *Ann R Coll Surg Engl* 1997; 79: 105–110.
11. Wigger P. [Surgical therapy of primary varicose veins]. *Schweiz Med Wochenschr* 1998; 128: 1781–1788.
12. Nesbitt C, Eifell RK, Coyne P, et al. Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus conventional surgery for great saphenous vein varices. *Cochrane Database Syst Rev (Online)* 2011; 10: CD005624.
13. Hayden A and Holdsworth J. Complications following re-exploration of the groin for recurrent varicose veins. *Ann R Coll Surg Engl* 2001; 83: 272–273.
14. Frullini A and Cavezzi A. Sclerosing foam in the treatment of varicose veins and telangiectases: history and analysis of safety and complications. *Dermatol Surg* 2002; 28: 11–15.
15. Rasmussen LH, Lawaetz M, Bjoern L, et al. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. *Br J Surg* 2011; 98: 1079–1087.
16. Elias S and Raines JK. Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial. *Phlebology* 2012; 27: 67–72.
17. Delaney CL, Russell DA, Iannos J, et al. Is endovenous laser ablation possible while taking warfarin? *Phlebology* 2014; 27: 231–234.
18. Boersma D, van Eekeren RRJP, Werson DAB, et al. Mechanochemical endovenous ablation of small saphenous vein insufficiency using the ClariVein(®) device: one-year results of a prospective series. *Eur J Vasc Endovasc Surg* 2013; 45: 299–303.

19. AngioDynamics Inc. *Tetradecyl hydrogen sulfate (ester) injection solution prescribing information*. Queensbury, NY: AngioDynamics Inc, 2008.
20. Carradice D, Mekako AI, Hatfield J, et al. Randomized clinical trial of concomitant or sequential phlebectomy after endovenous laser therapy for varicose veins. *Br J Surg* 2009; 96: 369–375.
21. Michaels JA, Brazier JE, Campbell WB, et al. Randomized clinical trial comparing surgery with conservative treatment for uncomplicated varicose veins. *Br J Surg* 2006; 93: 175–181.