Retrograde inversion stripping as a complication of the ClariVein[®] mechanochemical venous ablation procedure

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ABSTRACT

The endovenous revolution has accelerated the development of new techniques and devices for the treatment of varicose veins. The ClariVein[®] mechanochemical ablation device offers tumescentless treatment with a rotating ablation tip that can theoretically become stuck in tissue. We present the first report of retrograde stripping of the small saphenous vein without anaesthesia following attempted use of the ClariVein[®] device, without adverse sequelae.

KEYWORDS

Varicose veins – Venous insufficiency – Percutaneous catheter ablation – Sclerotherapy

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The management of varicose veins has changed significantly in the past decade with increasing evidence of the significance of the disease arising in tandem with advancements in medical devices. The rise of endovenous ablation techniques for truncal veins using radiofrequency or laser energy to cause thermal ablation has opened the door for almost all comers to the venous clinic to be suitable for treatment. These techniques show excellent occlusion rates and symptomatic improvements with minimal complications and an excellent pain profile.¹

The desire for a better device with even fewer side effects as well as less complex procedures has led to the development of non-thermal treatments such as the mechanochemical ClariVein[®] system (Vascular Insights, Madison, CT, US).² The principle of the ClariVein[®] mechanochemical ablation device is to use a rotating tip and inject a sclerosant to ablate the vein. This has been shown to be safe and efficacious for both the GSV and SSV.^{2–4} Such new devices may have exciting potential but they also only have a limited safety experience. We present a rare complication of mechanochemical ablation of which clinicians should be aware with increased use of the ClariVein[®] device.

Case History

A 70-year-old man presented with symptomatic chronic venous disease (CEAP [(Clinical, Etiological, Anatomical and Pathophysiological] class C4) to the venous outpatients department at Charing Cross Hospital, London. His venous clinical severity score (VCSS) was 5, his Aberdeen varicose

vein questionnaire (AVVQ) score was 19.90, his EQ-5D-5L score was 0.531 and his EQ VAS score was 60.⁵

Duplex ultrasonography of the venous tree showed an incompetent and refluxing small saphenous vein (SSV) with a maximum vein diameter of 6.6mm (at the saphenopopliteal junction) as well as an incompetent and refluxing great saphenous vein (GSV) measuring 5.3mm. The patient was counselled regarding treatment and opted to undergo endovenous ablation with the ClariVein[®] device. He was taking warfarin for atrial fibrillation, which was continued during the procedure.

The procedure was performed according to the manufacturer's instructions for use and as described by Elias *et al.*² Briefly, the patient was treated in the prone position, local anaesthetic was injected and the SSV cannulated at the distal calf under ultrasonography guidance, and a 4Fr sheath was placed. The ClariVein[®] catheter was advanced to the fascial curve of the SSV, 2cm distal to the saphenopopliteal junction. The treatment wire was unsheathed and safe placement confirmed on ultrasonography. The device was tested for 0.1 seconds to demonstrate the feeling of the treatment to the patient.

The planned treatment length of SSV was 20cm and the average diameter was 6mm. Consequently, 4ml of liquid 2% sodium tetradecyl sulfate (equal parts 1% and 3% sclerosant solution) was prepared. As per the standard treatment protocol, the first 5 seconds of pullback was treated with mechanical ablation only to create venospasm (no sclerosant). However, after the first 1cm, the catheter would no longer withdraw and the motor slowed. This is a known occurrence when the tip catches a valve leaflet.

Figure 1 Vein being retracted with the device in situ

Figure 3 Close-up of catching point of vein and tip of catheter

The motor was therefore shut off (to prevent shearing and damage) and a short jerking pull was given to the catheter in an attempt to free it of the obstruction. This did not free the catheter tip and no further movement was possible. No obvious obstruction or misalignment was seen on

ultrasonography, nor were any significant tributaries or perforating veins. A further pull was used to free the catheter, which was retracted gently for assessment. No sclerosant was injected.

On retrieval via the original cannulation site, the entirety of the SSV was also extracted, having been inversion stripped (Figs 1–5). No bleeding occurred at the entry site and there was no bruising or haematoma at the popliteal fossa. On duplex ultrasonography, no SSV could be seen throughout the calf (Fig 6) and the popliteal vein was intact with no demonstrable bleeding. Despite the absence of objective evidence of bleeding, pressure was applied for ten minutes during inspection of the catheter and stripped vein. The entry site wound was closed with one 6/0 Prolene® suture (Ethicon, Somerville, NJ, US) and the patient

Figure 2 Vein being retracted with the device removed

Figure 4 Vein attached to catheter ex vivo showing 16cm length

Figure 5 Vein detached from catheter ex vivo showing 16cm length

Figure 6 Duplex ultrasonography of calf showing empty short saphenous vein fascia

was turned over for treatment of the GSV in the supine position, using a standard technique. This was uneventful; 35cm of the GSV was treated using 6ml of the 2% sodium tetradecyl sulfate. The wound was again closed with one 6/0 Prolene® suture.

The patient was placed in European class 2 compression hosiery and observed for bleeding for one hour. He remained pain free throughout the duration of the procedure after the initial entry site local anaesthesia and his only reported sensation during the inversion stripping was of a 'pulling sensation'.

The vein and device combination was dissected, and the tip was found to be affixed to a small calcified tributary. The only successful method of disconnection was with a scalpel (Fig 5). No nerve injury was detected and the patient walked out of the clinic.

At the six-week and six-month follow-up appointments, the patient was asymptomatic and pain free with no abnormal neurology and no cutaneous numbness. His VCSS at six weeks was 3, his AVVQ was 8.09, his EQ-5D-5L was 0.531 and his EQ VAS was 80. At six months, his VCSS was 1, his AVVQ was 22.94 owing to development of contralateral (left) leg symptoms, his EQ-5D-5L was 0.746 and his EQ VAS was 80. There was no recurrence or neovascularisation clinically or on duplex ultrasonography at six weeks or six months for either the GSV or SSV.

Conclusions

We present the first report of a rare complication of mechanochemical endovenous ablation using the ClariVein®

device. This case illustrates the possibility of adverse events in even routine elective procedures. However, it also shows that such complications can produce a 'satisfactory' clinical result. The patient suffered no recurrence, no sign of revascularisation and no neurological compromise.

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