

ClariVein™ – One year results of mechano-chemical ablation for varicose veins in a multi-ethnic Asian population from Singapore

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Abstract

Objectives: This study assessed the effectiveness and patient experience of ClariVein for varicose veins and chronic venous insufficiency (CVI) in a multi-ethnic Asian population from Singapore.

Methods: A total of 121 patients underwent mechano-chemical ablation. Patients were reviewed at an interval of one week, and at 3, 6 and 12 months post procedure and underwent Duplex ultrasound with patient satisfaction assessment.

Results: At three months of follow-up, the great saphenous vein and short saphenous vein occlusion rates were 90.8% and 96.0%, respectively. At six months of follow-up, the GSV and short saphenous vein occlusion rates were 86.9% and 90.9%, respectively. At one year, great saphenous vein and short saphenous vein occlusion rates were 84.8% and 94.3%, respectively.

Conclusions: Early results are similar to what is described so far in the mechano-chemical ablation literature but recurrences are more than expected at one year. This is disappointing but is tempered by the fact that the majority of patients were asymptomatic and required no reintervention.

Keywords

ClariVein™, endovenous, mechano-chemical ablation, outcome

Introduction

The management of chronic venous insufficiency (CVI) and varicose veins has undergone an industrial revolution over the past decade, with endothermal ablation replacing open high tie and truncal vein stripping surgery as the “gold standard” treatment.¹ These minimally invasive endovenous techniques performed usually under local anaesthesia, have allowed a faster return to normal daily activities and a more rapid enhancement in quality of life (QoL) for the patient.² Both the National Institute of Health and Clinical Excellence and the Society for Vascular Surgery/American Venous Forum currently recommend endothermal ablation as first-line treatment for truncal vein incompetence.^{3,4} However, thermal techniques such as radiofrequency and laser ablation, require the use of tumescence as a heat sink and are associated with higher intra-procedural and post-operative discomfort⁵ as well as carrying the risk of skin and nerve damage.⁶ Non-thermal, non-tumescent (NTNT) endovenous

technologies have been introduced to obviate the need for tumescent infiltration and to enhance the patient’s experience even further both intra-procedurally and post-operatively. This focus on patient satisfaction bears importance given the fact that the decision to intervene in the majority of cases is based on symptomatology and QoL issues.

The ClariVein™ occlusion catheter system (*Vascular Insights LLC*, Quincy, MA, USA) is an example of a NTNT device that induces endovenous

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closure by a combination of mechanical damage to the endothelial cells of the vein wall and chemical injury with a liquid sclerosant infusion that causes apoptosis and vein fibrosis (mechano-chemical ablation or MOCA). It has been shown to be safe and efficacious in its initial trials^{7,8} but these studies have been limited to generally a Caucasian-based population, where the vein size, anatomy and distribution of venous incompetence can be different from their Asian counterparts.

This study assessed the effectiveness and patient experience of ClariVeinTM to target incompetent great saphenous vein (GSV) and/or short saphenous vein (SSV) incompetence from a vascular centre in the eastern part of Singapore, treating a predominantly multi-racial Asian population.

Methods and materials

Study design

A set protocol was constructed and adhered to in order to evaluate endovenous MOCA with the patented single-use, disposable ClariVeinTM system at a restructured public hospital on the East Coast of Singapore. This was a single center, single-arm study with a cohort of patients with symptomatic venous reflux disease in the GSV and/or SSV. Ethical approval was gained from the internal hospital board (CIRB ref number: 2015/2675) and data were collected both prospectively and retrospectively onto a secure computer database with a telephone questionnaire conducted if required.

Patients were either fee-paying individuals, who are partially subsidised from their Central Provident State Fund or held private health insurance. They underwent a focused history and clinical examination at the specialist vascular outpatient clinic of one of two consultant endovascular surgeons (TYT & TYK), who both have a large endovenous experience and perform MOCA regularly for CVI. TYT is also certified by *Vascular Insights LLC* as a proctor for their device in south-east Asia. Assessment included clinical signs for GSV/SSV reflux, CEAP (clinical, aetiological, anatomical and pathophysiological elements) classification and previous venous procedures.

A deep and superficial duplex ultrasound evaluation, which included colour and spectral Doppler in addition to B-mode, was performed independently by one of the dedicated vascular sonographers from the radiology department of the hospital prior to any decision for surgery. Reflux was determined at the saphenofemoral (SF)/sapheno-popliteal (SP) junction in the lying and standing position using the Valsalva manoeuvre or manual distal compression with rapid release, respectively. Reflux as documented by ultrasound was defined and considered significant as retrograde flow of >0.5 s.

Inclusion criteria were:

1. Age >21 years old and ability to give informed consent for the procedure;
2. C2-C5 varicose veins (CEAP Class 1 and 6 patients were excluded);
3. Symptomatic primary GSV and/or SSV incompetence with reflux >0.5 s on colour Duplex including one or more of the following symptoms: aching, throbbing, heaviness, fatigue, pruritus, night cramps, restlessness, generalised pain or discomfort, swelling;
4. Patients who had GSV/SSV diameters of 3–10 mm in the standing position.

Patients were consented for ClariVeinTM being a relatively new technique under study. All patients received a procedure-specific information leaflet in their native language, which explained the technique including risks and side-effects.

Patients were excluded from having this procedure if they were pregnant, lactating, allergic to sclerosant, had previous truncal varicose vein treatment, peripheral arterial disease (ABPI <0.8), history of deep venous thrombosis or hypercoagulability, previous thrombophlebitis, which had recanalised and were incompetent, anticoagulation with warfarin and if their GSV/SSV were severely tortuous. Those who underwent simultaneous radiofrequency ablation (RFA) and MOCA for concomitant GSV and SSV reflux respectively were also excluded. Patients who did not want to be treated with ClariVeinTM were routinely offered treatment with RFA, foam sclerotherapy or open surgery.

ClariVeinTM technique

The ClariVeinTM catheter has been previously described⁸ and is a FDA approved medical device. In brief, it combines two methods of action:

1. Mechanical disruption of the vessel endothelium by a high-speed rotary wire system at approximately 3500 revolutions per minute (high setting) that damages the media layer of the vein wall directly.
2. A sclerosant drug sprayed from the tip of the catheter, which penetrates deep into the media layer causing a clear inflammatory reaction and subsequent occlusion of the vein by fibrosis.

In keeping with local preference, patients were given the choice to have the procedure performed either under a regional anaesthetic (RA – generally a spinal), sedation, general (GA) or local anesthetic (LA). However, it is usual practice of the senior author (TYT) to routinely do this procedure purely

under LA with or without sedation unless concomitant phlebectomies are required in which case a RA or GA is employed. Antibiotics at induction were routinely given. The patient was positioned supine with a sand-bag under the knee to enhance access to the GSV. The SSV was treated with the patient placed either in the lateral position or prone and the foot hanging off the edge of the operating table to allow dorsiflexion and easier percutaneous venous access, depending on the surgeon's preference.

A Seldinger technique was used to introduce a micro-catheter 4F introducer sheath into either the GSV or SSV under ultrasound guidance and flushed with saline. The ClariVeinTM infusion catheter tip was inserted through the sheath and the tip of the dispersion wire positioned 20 mm distal to the SFJ or just proximal to the fascial curve for the SSV. Any venous obstructions or acute angles encountered were successfully navigated by a slight clockwise–anticlockwise rocking motion of the device whilst maintaining axial distal motion. Another helpful technique is to inject saline through the catheter to help distend the vein as the device is passed up the vein. The distal end of the dispersion wire was then unsheathed to expose the dispersion tip by connecting the 9 V battery-motorised handle unit/sclerosant syringe and positioning rechecked. The patient is placed head down to help collapse the vein onto the catheter. Wire rotation was activated for 3 s to induce spasm of the proximal vein prior to commencing pullback. With the wire continuing to rotate, infusion of the sclerosant was started simultaneously with catheter pullback only after 3 cm pullback from the junction to minimise the risk of sclerosant/sclerothrombus from spilling into the deep venous system. The activated catheter was steadily withdrawn 10 mm every 8 s. The sclerosant used was 2.0% liquid sodium tetradecyl sulphate (STS) (FibroVeinTM, STD Pharmaceutical Products Ltd, Hereford, UK) for both GSV and SSV. This was made by mixing equal volumes of 1% STS and 3% STS or diluting 4 ml 3% STS with 2 ml normal saline. The sclerosant volume used was 0.1–0.2 ml every 1 cm pullback and was determined by vein diameter and overall treatment length as per the manufacturer's guidance. Vein diameter was determined by Duplex ultrasound measurement from the widest part of the treated vein in the supine position excluding the first 2 cm of vein and any localised venous blowouts. Treatment length was calculated from the graduated markings on the catheter. Both the 65 cm and 45 cm length catheters were used depending on the length required to be ablated. The 65 cm catheter length was routinely employed for simultaneous GSV and SSV ablation as well as total GSV treatment. The 45 cm catheter system was used usually only if only the SSV were to be ablated.

A completion Duplex was performed after the procedure to confirm the patency of the common femoral vein and the deep venous system and to ascertain whether there was any flow within the truncal vein and whether it was still compressible. The ipsilateral foot was dorsi- and plantar-flexed in order to minimise deep venous stasis at the end of the procedure. Concomitant phlebectomies were then performed as necessary using the standard Oesch hook technique. Subcutaneous heparin was routinely given after the procedure to minimise the risk of deep vein thrombosis.

A full length compression bandage (Class II; Coband liteTM) was applied to the treated limb(s) from the foot to the groin. The patient was then advised to undertake light exercise (3 × 15-min walks on the same day), once the spinal wore off or when they felt well enough to do so. Bandages were removed in 24 h and thigh-length compression stockings advised to be worn for one-week duration during the daytime only. The patients were instructed to take paracetamol and/or ibuprofen medication for discomfort and advised to return to their work and normal activities as soon as they felt capable to do so.

All patients were scheduled for a follow-up assessment at 1–2 weeks, three months, six months and one year by a vascular surgeon, including physical examination and duplex ultrasound. After three months, patients were asked to quantify their satisfaction of the treatment on a 10-point score. Patients who did not attend their follow-up clinic visits were contacted by phone to see if their symptoms had resolved and how satisfied they were.

Any post-procedural complications were documented at each visit.

The primary outcome measures were:

1. Technical success, which was defined as the ability to perform the procedure as planned and achieve immediate occlusion after the ablation.
2. Anatomical success defined as the occlusion of the treated truncal vein(s). Recurrence or treatment failure was defined arbitrarily as a re-opening of a continuous segment >5 cm in length.

The secondary outcomes included complications, patient satisfaction and post-operative pain.

Statistical analysis

Continuous variables are reported as mean and standard deviation and categorical variables as absolute number and percent, unless stated otherwise. Continuous data were compared using the Student *t* test or Mann–Whitney U test for parametric and non-parametric data, respectively. Categorical data

were compared using the Chi-square or Fisher exact tests. Statistical significance was assumed at $P < 0.05$. The statistical analyses were performed using SPSS statistical software version 19.0 (IBM Corp, Armonk, NY, USA).

Results

This study included 121 patients of whom 81 (66.9%) were females. The mean age was 52.1 ± 12.5 years. They were treated over a two-and-a-half-year period from the time the device was introduced to Singapore, and allowed at least one year follow-up. All were diagnosed with either unilateral or bilateral symptomatic GSV/SSV incompetence or a combination of unilateral GSV and SSV incompetence. Forty nine of them (40.5%) were treated for GSV incompetence alone, 16 (13.2%) for bilateral GSV, 13 (10.8%) SSV, 4 (3.3%) bilateral SSV and 39 (32.2%) combined unilateral GSV and SSV reflux (Figure 1). There were 180 truncal veins treated in 141 legs. Sixty-three of the 121 (52.1%) patients had concomitant phlebectomies.

The CEAP classification (C2:C3:C4:C5) for this cohort of patients was 61:70:32:17, respectively. There were 69 (57.0%) Chinese, 32 (26.4%) Malay, 12 (10.0%) Indian, 1 (0.8%) Caucasian and 7 (5.8%) others (all of south-east Asian descent) in terms of ethnicity.

Forty-seven of 121 (38.8%) patients had combined above and below GSV reflux, and 32 of 121 (26.4%) had some degree of suprafascial extension of their GSV during its course up the medial aspect of the leg.

There was no deviation of the protocol. All GSV and SSV were successfully punctured percutaneously. There were no device-related complications and the ClariVein™ catheter was delivered without incident to the intended position in the truncal vein in all cases (100% technical success). All patients had immediate on-table completion duplex ultrasound to document successful obliteration of either GSV/SSV in the treated segment and lack of deep vein thrombosis as shown by the squeeze and compressibility in the common femoral or popliteal vein.

No major adverse events were observed, i.e. pulmonary embolism, transient ischaemic attack, migraines, nerve injury, skin necrosis, infection or pigmentation except for one case of clot found in the external iliac vein in a single GSV-treated patient. This clot was likely some spillover from the SFJ as the GSV was completely occluded. The patient was asymptomatic in terms of leg swelling at one week follow-up and was prescribed a three-month course of Rivoroxaban (Xarelto™). A follow-up ultrasound at three months showed that the external iliac vein was patent and the clot had resolved. The patient was also asymptomatic. Transient superficial phlebitis was reported in 10 of 141 (7.1%) legs. Seven cases came from those who had a unilateral or bilateral GSV procedure, and two cases from a combined GSV/SSV ablation – the phlebitis developing along the line of the above knee GSV. Most of the phlebitis was noted along the line of the treated GSV rather than its tributaries. There was one reported case from a unilateral SSV MOCA. In all cases, this was mild and self-limiting and responded

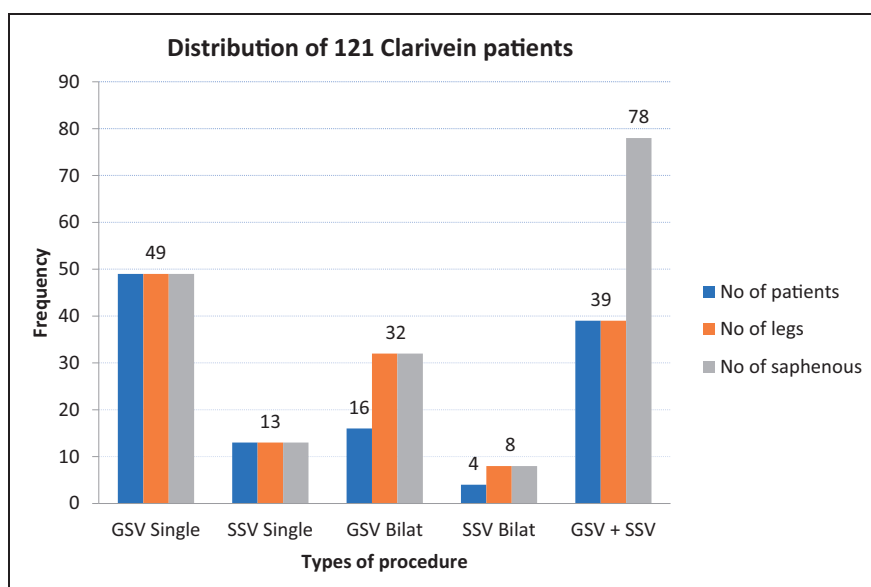


Figure 1. Distribution of truncal endovenous ablation in CGH cohort.

to several days of over the counter paracetamol and non-steroidal anti-inflammatory tablets (ibuprofen). At three-month follow-up, these cases had fully resolved. Ecchymosis from the puncture site was reported in 12/141 legs (8.5%). Six cases from a unilateral GSV puncture, two cases from a bilateral SSV ablation and four cases from a combined GSV and SSV MOCA case. The complication rate per patient had no significant association ($p=0.187$) between unilateral (12/62, 19.4%) and bilateral or combined GSV/SSV (9/79, 11.4%).

The mean length of GSV obliterated was 47.9 ± 10.1 cm compared to 29.8 ± 5.4 cm for a SSV (mean difference = 18.1 cm, 95% CI 15.3–20.9 cm, $p < 0.001$). A mean volume of 7.4 ± 2.1 mL of sclerosant was used per GSV treated and 4.5 ± 1.3 mL per SSV treated (mean difference = 2.9 mL, 95% CI 2.4 to 3.5 mL, $p < 0.001$). The mean volume used in a bilateral GSV procedure was 13.0 ± 1.3 mL, bilateral SSV procedure was 9.5 ± 2.3 mL and combined unilateral GSV and SSV was 11.3 ± 1.5 mL ($p < 0.001$, Bonferroni post-hoc test). We used more sclerosant in a bilateral GSV compared to a bilateral SSV procedure (mean difference = 3.5 mL; $p < 0.001$). The average diameter of GSV and SSV treated was 5.6 ± 1.0 mm and 4.2 ± 1.2 mm, respectively (mean difference = 1.4 mm, 95% CI 1.1 to 1.7 mm, $p < 0.001$).

At one week follow-up, the GSV was completely occluded in 114/118 (96.6%) veins and SSV completely closed in 58/59 (98.3%) veins. At three months of follow-up, the GSV was occluded in 89/98 (90.8%) veins and SSV completely closed in 48/50 (96.0%) veins. At six months of follow-up, the GSV was

completely occluded in 93/107 (86.9%) veins and SSV completely closed in 50/55 (90.9%) veins. At one year, GSV and SSV occlusion rates were 78/92 (84.8%) and 50/53 (94.3%) (Figure 2). There was no significant difference in recurrence rates in either the GSV or SSV system when ethnicity was considered. Over that time period only 5/180 (2.8%) legs (3 GSV and 2 SSV) required re-intervention for recurrent or worsening lower limb swelling. All were completely obliterated with one course of ultrasound guided foam sclerotherapy with no complications. No additional complications were observed either clinically or detected with duplex ultrasonography.

The majority of the GSVs that had recanalised were noted to have done so within the first 10 cm from the sapheno-femoral junction or around the knee region. There was no relationship between the initial diameter of the veins and recanalisation.

All procedures were very well tolerated with a mean pain score of 0.8 (range 0–4) on a 10-point scale, documented on the morning afterwards.

After three months, median patient satisfaction of the treatment was 9 (IQR 9–10). Overall, 78/84 (94%) patients were either somewhat satisfied or very satisfied with their treatment. Seventy-three of 84 (87%) patients expressed that their symptoms had either somewhat improved or were much improved. Nine of 84 (11%) patients said their symptoms remained unchanged with 2/84 (2%) saying their symptoms were somewhat worse. Seventy-five of 84 (89%) patients indicated that they would choose this procedure again if given the choice.

One of the common complaints patients made during follow-up was the week long use of compression

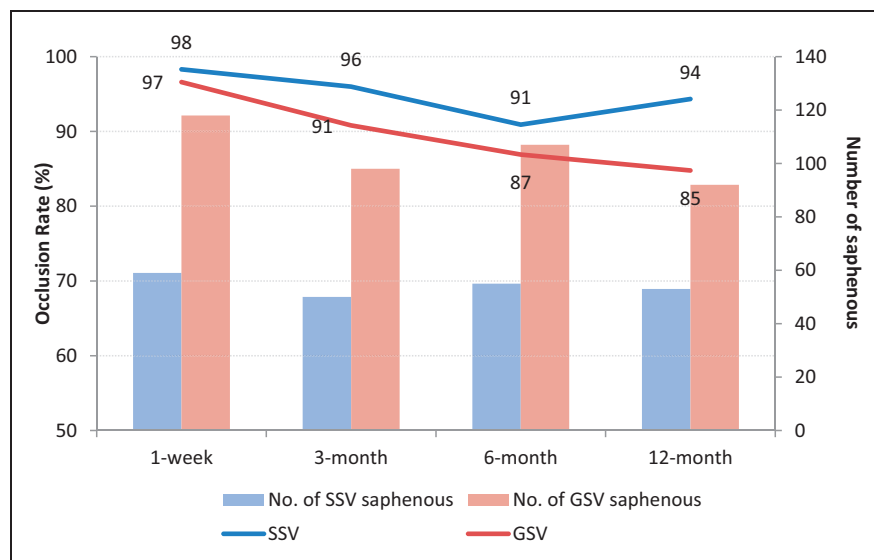


Figure 2. Truncal vein occlusion outcomes.

stockings post-operatively especially in the older age groups. They complained of discomfort and tightness, pruritus, contact dermatitis and difficulty in putting the stockings on especially for the more elderly patients. A significant number admitted that they were non compliant for the full week compression course (>50%). However, this did not correlate with the patients who had re-opening of their veins.

Discussion

Varicose veins are common and are known to affect at least one-third of the population.⁹ CVI has been shown to have a negative impact on patients' QoL and treatment of varicose veins has been demonstrated to lead to improvement.¹⁰ Over the past decade, new endovenous techniques have been introduced and these are felt to be cost-effective.¹¹ Recently, clinicians have sought to enhance the patient's experience further during truncal ablation by removing the tumescent aspect of endothermal therapy and looking for the finer percentage point benefits such as reduced pain intra- and post-operatively and minimal ecchymosis and haematoma formation at the puncture sites and along the vein track.

The reported complications of MOCA are minimal; deep vein thrombosis occurs in less than 0.5% of cases, temporary paraesthesiae in less than 0.2% cases and no permanent skin injury has been reported.¹²

The primary objective of the study was to determine technical success of the ClariVein[®] procedure in a multi-ethnic population of patients with varicose veins or CVI. This was 100% and there was immediate truncal vein occlusion in all cases. From the results, there were a significant number of patients (>25%) who had their GSV come out of its fascial envelope during its course (supra-fascial extension) and traversing up to the skin surface. It can also be noted from the anatomical findings that there was a significant number of patients with total (AK and BK) GSV reflux and concomitant SSV reflux. The occlusion catheter has been shown to be flexible enough to traverse this venous bend from fascia to the surface of the skin (4Fr system) and the advantage of a NTNT device would be to obviate the need to push the GSV off the skin surface during the tumescence process to avoid cutaneous burns. Furthermore, dealing with below knee venous reflux using a device not requiring thermal energy would prevent saphenous nerve injury. Owing to the proximity of the GSV and saphenous nerve below the knee, most vein specialists do not routinely use endothermal ablation in this anatomical region. Also minimising the use of tumescence below the knee for below knee GSV and SSV reflux, especially with poor quality skin in CEAP 4b/5/6 CVI, is an obvious advantage. This cohort of patients is unique from

previous studies in that it contains patients treated for advanced CVI (CEAP 4a/b and 5). MOCA also has the advantage in that a venous puncture can be performed retrogradely, i.e. at the knee, and the catheter can be passed distally to under an ulcer bed and injected directly into the veins, which feed the ulcer or unhealthy area of skin. We have found that making the venous puncture at the knee is easier technically than at the ankle where the skin and surrounding tissue are desmoplastic and tougher to cannulate the vein and the experience is that you can get right under the ulcer bed if you are approaching it from a retrograde position. Another group has shown that this technique can expedite wound healing in the venous ulcer setting.¹³

Our experience in this cohort of Asian patients with CVI is that a higher percentage of patients underwent concomitant phlebectomies (more of a real life registry) compared to the published superficial venous ablation trials using a NTNT device. The patients had average GSV and SSV diameters of 5.6 mm and 4.2 mm, respectively. The average diameters of the GSV and SSV from a recent review of the western literature of over 1200 MOCA cases were 6.4 mm and 5.6 mm, respectively.¹⁴ Our experience is that Asian veins tend to be smaller in diameter and may well lend itself nicely for MOCA to allow easier vein closure with a more minimally invasive technique compared to EVLA or RFA.

This study is the largest reported single centre Asian experience to date with the ClariVein[™] occlusion catheter system. Our results are comparable (initial occlusion rate 100% with 90–96% completely sealed at 1 and 12 weeks follow-up, respectively) to the literature from Caucasian cohorts.^{15–17} The 6- and 12-month follow-up duplex scans show higher recurrence rates in terms of anatomical re-opening (10–15%) than the literature but this may reflect how we define anatomical recurrence. Anatomical failure in this study was defined as the presence of flow and reflux in a recanalised segment with a length ≥ 5 cm. This is a stricter definition than the previous trials^{2,12} have used (length ≥ 10 cm). Unfortunately, there is heterogeneity in the definition of recurrence among the previous ClariVein studies,^{9–11} which is a major problem in comparing the results between them and emphasises the need for standardisation and consensus on outcome measures in any future MOCA trial. Perhaps a percentage of recanalisation of the length of treated vein could be a better outcome parameter since there is a wide variation in lengths of vein treated with this device. Our data suggest that we have safely treated longer GSV and SSV segments (mean GSV treatment length = 48 cm; SSV = 30 cm) compared to 38 cm and 21 cm, respectively, in the literature¹⁴ and with comparable complication rates such as phlebitis and bruising.

Despite the slighter higher recurrence rate reported here in this Asian series, the reintervention rate is low (5/180 legs for recurrent leg swelling). This may well reflect that patients remain asymptomatic clinically because the sclerosant used has permeated to the side branches or varicosities off the main truncal vein and has kept them closed during this period of time, a theory originally put forward in a recent publication by Witte et al.¹⁸ This shows that anatomical recurrence does not equate to clinical recurrence. The few anatomical recurrences that were reported in this cohort occurred within the GSV truncal vein around the proximal thigh and knee regions. We suspect that this may be a consequence of the repeated flexion/extension motion of the hip and knee joints, respectively, which may aid re-opening of the vein mechanically and we have subsequently modified our technique to include slower pullback of the catheter around these regions to allow maximal vein scouring with injection of more sclerosant to expedite vein occlusion.

Transient phlebitis was the only common minor complication to have been noted (7%) – patients should be warned about the risk of phlebitis in advance and advised of the measures to treat it, i.e. compression and NSAIDs. This is a higher incidence rate compared to after EVLT, but comparable to RFA and lower than if foam or liquid sclerotherapy was used.^{9–11}

The satisfaction score at eight weeks is high and very few patients complained of pain immediately post procedure. This did not matter whether it was a unilateral or bilateral ablation. Van Eekeren's group showed similar degree of patient satisfaction and very low pain scores in their pioneering MOCA manuscript,⁶ which was reiterated by Tang et al. in their large series from the UK.¹⁷ Reasons for this are that MOCA is performed without tumescent anaesthesia and requires only one injection with local anaesthesia at the injection site where only a 4Fr microcatheter sheath is inserted. Furthermore, there is no potential risk of thermal related injuries to surrounding nerves or tissues. On the flip side, scaling back on the anaesthesia (no tumescence) introduces a risk to the heart of minimally invasive treatment namely peri-procedural or post-operative pain. This was not borne out in this study and the level of pain experienced was lower than that experienced after EVLT and RFA.¹³ One of the key steps using MOCA is the continuous pullback of the catheter at a steady rate. The more times you stop the device and perform intermittent pullback, the more chance that the device gets caught in valves, which can cause pain. In this scenario, it is important to recognise this and stop rotating the wire and disengage it from the valve by pushing forward and rotating the catheter away from it. The benefit of MOCA though may well be the elimination of pain during the

tumescent process itself, which is known to be higher than during the treatment itself.¹⁴ MOCA is associated with significantly less post-operative pain, faster recovery and earlier work resumption compared with RFA in the treatment of GSV incompetence.^{5,14} Limitations of the study include the fact that this is a single centre series with a limited follow-up period (12 months), albeit large, multi-ethnic and mostly Asian. Collection of data was both prospective and retrospective in nature, which may have biased some of the outcomes measured. This study also did not include pre- and post-op CEAP and VCSS¹⁹ scores for comparison, which would have strengthened the study. Randomised trials with a prolonged follow-up protocol are clearly indicated to compare closure rates directly with other endovenous modalities, especially as most recanalizations are seen to occur during the second and third year after treatment.^{2,18} These trials should look at other aspects such as cost savings associated with the use of the ClariVeinTM device, which are not yet reported but will definitely play an important role in acceptance of this new technology as a treatment option especially in the current economic climate in Singapore and large-scale healthcare reimbursement schemes. There is no hardware to buy, loan or upkeep and the technique can be performed on an outpatient basis if required, thereby reducing overhead and procedural costs. Another aspect of the study that was not formally looked at was change in quality of life scores and VCSS¹⁹ at the different follow-up periods using validated questionnaires. The real question is how these NTNT techniques will hold up in terms of clinical and anatomical recurrences at medium- to long-term follow-up (5–10 years) and whether the rate of reinterventions will dramatically increase at these timepoints.

Conclusions

MOCA is a safe and efficacious modality to ablate the great and short saphenous veins in Asian patients in the short term (one year). The procedure can be expanded to bilateral procedures and multiple truncal veins in the same leg, which are well tolerated. There is a high satisfaction rate and peri-procedural pain is low. Furthermore, the distribution of truncal venous reflux in the Asian patient may lend favourably to the use of ClariVeinTM for their CVI. Early results are promising but further evaluation and longer term follow-up are required in the form of randomised controlled and cost-effectiveness studies.

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Declaration of Conflicting Interests

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Ethical approval

Changi General Hospital Internal Hospital Board (CIRB ref number: 2015/2675).

Guarantor

TYT.

Contributorship

SNK and LJ had researched literature, gaining ethical approval, patient recruitment and data analysis. TYT was involved in protocol development. SNK wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the definitive version of the manuscript.

References

1. Kanwar A, Hansrani M, Lees T, et al. Trends in varicose vein therapy in England: radical changes in the last decade. *Ann R Coll Surg Engl* 2010; 92: 341–346.
2. 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.
3. Marsden G, Perry M, Kelley K, et al. Diagnosis and management of varicose veins in the legs: summary of NICE guidance. *BMJ* 2013; 347: f4279.
4. Gloviczki P, Comerota AJ, Dalsing MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg* 2011; 53: 2S–48S.
5. Lane T, Bootun R, Dharmarajah B, et al. A multi-centre randomised controlled trial comparing radiofrequency and mechanical occlusion chemically assisted ablation of varicose veins – final results of the Venefit versus ClariVein for varicose veins trial. *Phlebology* 2017; 32: 89–98.
6. van Eekeren RR, Boersma D, Konijn V, et al. Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins. *J Vasc Surg* 2013; 57: 445–450.
7. van Eekeren RR, Boersma D, Elias S, et al. Endovenous mechanochemical ablation of great saphenous vein incompetence using the ClariVein device: a safety study. *J Endovasc Ther* 2011; 18: 328–334.
8. Elias S and Raines JK. Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial. *Phlebology* 2012; 27: 67–72.
9. Robertson L, Evans C and Fowkes FG. Epidemiology of chronic venous disease. *Phlebology* 2008; 23: 103–111.
10. Lee AJ, Evans CJ, Allan PL, et al. Lifestyle factors and the risk of varicose veins: Edinburgh Vein Study. *J Clin Epidemiol* 2003; 56: 171–179.
11. Shepherd AC, Ortega-Ortega M, Gohel MS, et al. Cost-effectiveness of radiofrequency ablation versus laser for varicose veins. *Int J Technol Assess Health Care* 2015; 31: 289–296.
12. Witte ME, Zeebregts CJ, de Borst GJ, et al. Mechanochemical endovenous ablation of saphenous veins using the ClariVein: a systematic review. *Phlebology* 2017; 32: 649–657.
13. Sullivan LP, Quach G and Chapman T. Retrograde mechanochemical endovenous ablation of infrageniculate great saphenous vein for persistent venous stasis ulcers. *Phlebology* 2014; 29: 654–657.
14. Sun JJ, Chowdhury MM, Sadat U, et al. Mechanochemical Ablation (MOCA) for treatment of truncal venous insufficiency: a review of the current literature. *J Vasc Interv Radiol* 2017; 28: 1422–1431.
15. Bishawi M, Bernstein R, Boter M, et al. Mechanochemical ablation in patients with chronic venous disease: a prospective multicenter report. *Phlebology* 2014; 29: 397–400.
16. Deijen CL, Schreve MA, Bosma J, et al. ClariVein mechanochemical ablation of the great and small saphenous vein: early treatment outcomes of two hospitals. *Phlebology* 2016; 31: 192–197.
17. Tang TY, Kam JW and Gaunt ME. ClariVein(R) – early results from a large single-centre series of mechanochemical endovenous ablation for varicose veins. *Phlebology* 2017; 32: 6–12.
18. Witte ME, Holewijn S, van Eekeren RR, et al. Midterm outcome of mechanochemical endovenous ablation for the treatment of great saphenous vein insufficiency. *J Endovasc Ther* 2017; 24: 149–155.
19. Rutherford RB, Padberg FT Jr, Comerota AJ, et al. Venous severity scoring: an adjunct to venous outcome assessment. *J Vasc Surg* 2000; 31: 1307–1312.