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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

Tristan Lane[1,2,3], Roshan Bootun[1,2], Brahman Dharmarajah[1,2,3], Chung S Lim[1,2,3], Mojahid Najem[3], Sophie Renton[3], Kaji Sritharan[1,2] and Alun H Davies[1,2]

Abstract

Background: Endovenous thermal ablation has revolutionised varicose vein treatment. New non-thermal techniques such as mechanical occlusion chemically assisted endovenous ablation (MOCA) allow treatment of entire trunks with single anaesthetic injections. Previous non-randomised work has shown reduced pain post-operatively with MOCA. This study presents a multi-centre randomised controlled trial assessing the difference in pain during truncal ablation using MOCA and radiofrequency endovenous ablation (RFA) with six months' follow-up.

Methods: Patients undergoing local anaesthetic endovenous ablation for primary varicose veins were randomised to either MOCA or RFA. Pain scores using Visual Analogue Scale and number scale (0–10) during truncal ablation were recorded. Adjunctive procedures were completed subsequently. Pain after phlebectomy was not assessed. Patients were reviewed at one and six months with clinical scores, quality of life scores and duplex ultrasound assessment of the treated leg.

Results: A total of 170 patients were recruited over a 21-month period from 240 screened. Patients in the MOCA group experienced significantly less maximum pain during the procedure by Visual Analogue Scale (MOCA median 15 mm (interquartile range 7–36 mm) versus RFA 34 mm (interquartile range 16–53 mm), $p = 0.003$) and number scale (MOCA median 3 (interquartile range 1–5) versus RFA 4 mm (interquartile range 3–6.5), $p = 0.002$). '*Average*' pain scores were also significantly less in the MOCA group; 74% underwent simultaneous phlebectomy. Occlusion rates, clinical severity scores, disease specific and generic quality of life scores were similar between groups at one and six months. There were two deep vein thromboses, one in each group.

Conclusion: Pain secondary to truncal ablation is less painful with MOCA than RFA with similar short-term technical, quality of life and safety outcomes.

Keywords

Varicose veins, randomised controlled trial, endovenous ablation, mechanical occlusion chemically assisted ablation, radiofrequency ablation, pain

[1]Section of Vascular Surgery, Department of Surgery and Cancer, Imperial College London, London, UK
[2]Department of Vascular Surgery, Imperial College Healthcare NHS Trust, London, UK
[3]Department of Vascular Surgery, London North West Hospitals NHS Trust, London, UK

Previously Presented: Preliminary results have been presented at the Royal Society of Medicine Venous Forum, Charing Cross Symposium, Society for Academic and Research Surgery, the Controversies and Updates in Vascular Surgery Meeting and the American Venous Forum. A short report of early results has been published in Phlebology.

Corresponding author:
Tristan Lane, Section of Vascular Surgery, Department of Surgery and Cancer, Imperial College London, London, UK.
Email: Tristan.lane@imperial.ac.uk

Introduction

Varicose veins are a common condition worldwide and cause significant quality of life impairments with consequent healthcare costs.[1] Symptomatology is varied, as is progression to ulceration.[2,3] Endovenous ablation with catheter-based technology, using radiofrequency energy or laser energy to cause thermal damage to the vein leading to fibrosis and occlusion, has revolutionised modern varicose vein treatment. Now any superficial vein navigable by a soft hydrophilic guidewire can be treated in this manner. These developments have led to endovenous thermal ablation being recommended as first line treatment by the National Institute for Health and Care Excellence.[4,5] The aforementioned techniques, however, require the use of tumescent anaesthesia which involves multiple needle injections.[6] In the past few years, new techniques have been developed and older techniques extended to alleviate the need for tumescent anaesthesia and improve the patient experience. One of the new techniques is mechanical occlusion chemically assisted endovenous ablation (MOCA), which uses a hybrid system of physical damage to the vein wall and liquid sclerotherapy to lead to scarring and fibrosis without the need for tumescent anaesthesia.[7,8] The lack of requirement for multiple needle injections should in theory lead to reduced intra-operative and peri-operative pain. Recent work in a non-randomised study comparing RFA and MOCA has shown a reduced pain experience post-operatively for those patients undergoing MOCA.[9] This study was designed to compare the pain levels encountered during the procedure between RFA (using the Medtronic Venefit RFA segmental catheter; Medtronic, Santa Rosa, CA, USA) and MOCA (using the Vascular Insights Clarivein catheter; Vascular Insights, Quincy, MA, USA), with MOCA hypothesised to be less painful. Initial results of this study have previously been published.[10]

Methods

The trial protocol and methodology have previously been reported[10] and is described in full below. The trial was registered with Current Controlled Trials and the ISRCTN registry (http://www.isrctn.com) (ISRCTN06552809). The trial protocol, inclusion and exclusion criteria are freely available at http://www.isrctn.com/ISRCTN06552809. Ethical approval was obtained from the United Kingdom National Research Ethics Service, London – Chelsea Committee (Research Ethics Committee Reference: 12/LO/0570). Imperial College London were the trial sponsors (reference number JRCOHH0431).

Patients

Patients with symptomatic primary varicose veins with either great saphenous vein (GSV) or small saphenous vein (SSV) incompetence (>0.5 s reflux on colour duplex ultrasound), presenting to Charing Cross Hospital (Imperial College Healthcare NHS Trust) or Northwick Park Hospital (London North West Healthcare NHS Trust) in London, UK, were assessed clinically by independent clinicians and listed for treatment. Clinical stage and symptom scores were recorded. Once listed for treatment they were screened trial inclusion and invited to participate in the Venefit Versus Clarivein for Varicose Veins trial. Patients with recurrent varicose veins, current deep vein thrombosis, arterial disease (ankle brachial pressure index <0.8), veins <3 mm in diameter or hypercoagulability were excluded from participation. Additionally, patients unable or unwilling to complete questionnaires or to participate were also excluded. Consenting participants were then randomised on the day of treatment to either MOCA (group one) or RFA (group two), using an online computerised randomisation software (SealedEnvelope, London, UK).In patients with bilateral disease, the most symptomatic side was entered into the study. Patients completed generic and disease specific questionnaires prior to intervention.

Interventions

All procedures were carried out by trained vascular surgeons who were experienced in both techniques of endovenous ablation. No peri-operative analgesia or sedation was used. Standard distraction techniques were utilised with music and verbal distraction. Ultrasound guidance and local anaesthetic (and tumescent anaesthesia in the RFA group) were used in all procedures. Initial vein access (GSV or SSV) was performed under ultrasound guidance after injection of local anaesthetic (1% Lidocaine using a standard 3 cm length 23 Gauge needle), targeting the most distal point of venous reflux where cannulation was possible. A standard 7Fr vascular sheath was placed (Medtronic, USA).The treatment catheter tip was positioned 2 cm distal to the saphenofemoral junction or sapheno-popliteal junction, assessed in both longitudinal and transverse views on ultrasound.

The standard method was used for RFA (Venefit, Medtronic, USA) as described before.[11] Concisely, cooled tumescent anaesthesia (either 360 ml Normal Saline with 40 ml 1% lignocaine with 1:200,000 adrenaline; or 500 ml normal saline with 20 ml 1% lignocaine and 5 ml 8.4% sodium bicarbonate, dependent on local protocol) was injected using a standard 4 cm length, 21 Gauge needle into the saphenous sheath using a Klein pump at 400 ml per minute to create a "1 cm halo" of tumescent along the vein to be treated (approximately 10 ml per cm). Then, RF segmental ablation was completed, with 20 s per treatment zone (7 cm or 3 cm dependent on catheter tip), and double treatment for the first segment.

MOCA (Clarivein, Vascular Insights, USA) was performed as previously described[9,10] using 2% sodium tetradecyl sulphate (STS) (Fibrovein™, STD Pharmaceutical Products Ltd., Hereford, UK) (made by mixing equal volumes of 1% STS and 3% STS). Concisely, following cannulation and tip positioning under ultrasound guidance, the treatment tip was unsheathed and positioning rechecked. The sclerosant syringe was then attached. The device motor was engaged for 1–2 s to induce proximal vein spasm. Then, the activated catheter with rotating tip was steadily withdrawn by 1 cm every 7 s, whilst injecting sclerosant at a constant rate dependent on length of vein to be treated and volume of sclerosant. This sclerosant injection rates were calculated as per the manufacturer's guidance.

Immediately after completion of the endovenous ablation, patients were asked to report their pain experience on a 0–100 mm Visual Analogue Scale (VAS) and a 0–10 number scale.

If required (if symptomatic visible varicosities) and with patient consent, concomitant phlebectomies were then performed using standard Oesch hook technique with local tumescent anaesthesia.[12,13]

All patients received a single prophylactic dose of low molecular weight heparin at the completion of the procedure. Use of prophylactic antibiotics was left to the discretion of the treating surgeon.

Stockings were worn for two weeks post-procedure, and patients were advised to return to their work and normal activities as soon as they felt able to.

Patients were reviewed at one month and six months post-procedure with clinical assessment, duplex ultrasound and asked to complete a questionnaire.

Outcome measures

The primary outcome of the study was the degree of pain experience during endovenous ablation using a validated patient reported VAS and 0–10 number scale, prior to completion of any phlebectomies. Patients were also asked to describe the duration of the pain as lasting seconds, minutes or several minutes. The secondary outcomes were improvement in patient-reported quality of life, both disease specific (Aberdeen Varicose Vein Questionnaire – AVVQ)[14] and generic (Euroqol 5 Domain 3 Level – EQ-5D-3 L and EuroQol VAS)[15], clinical scores (Venous Clinical Severity Score – VCSS, Venous Disability Score – VDS and Clinical Etiology Anatomy Pathology score)[16,17] and time taken to return to normal activities and work. The primary outcome measure was assessed at the time of intervention. The secondary outcomes were assessed at one month and six months' post-operative follow-up. Technical success was also assessed at one month and six months with validated, blinded venous duplex ultrasound scanning. There were four possible scan classifications: complete occlusion of the saphenous vein, proximal occlusion (>5 cm proximally occluded, with >5 cm open distally), distal occlusion (>5 cm distally occluded, with >5 cm open proximally) and open. Patency in the first 3 cm of the GSV was considered normal.[18]

Power calculations

Power calculations were based on the primary outcome of pain during the truncal ablation procedure as assessed by VAS. Detection of a 20-mm difference in maximum pain score with a standard deviation of pain score of 20 mm was considered a significant difference. The minimum target size was calculated to be 94 patients (47 per group) at 90% power and 5% significance. Allowing for loss to follow-up or protocol violations, an overall target recruitment of 170 legs (85 per group) was estimated.

Statistical analysis

Data were recorded prospectively on a bespoke database and analysed using SPSS version 23 (IBM, Armonk, USA), STATA version 14 SE (Statscorp, College Station, Texas, USA), Wizard Pro version 1.7.14 (Evan Miller, Chicago, IL, USA) and Prism version 6 (GraphPad, La Jolla, California, USA). Data were analysed using parametric and non-parametric statistical tests as dictated by the distribution of data. Normally distributed data are reported as mean and standard deviation, non-normal distributions are reported as median and interquartile range (IQR).

Results

A total of 170 patients were recruited between January 2013 and September 2014 from a potential 240 screened patients; 41% were male, 86% were GSV and 14% SSV. Baseline data are presented in Table 1, there were no significant differences between groups. A total of 87 were randomised to receive MOCA and 83 to RFA; 83 of the 87 MOCA cases underwent MOCA and 82 of the 83 RFA cases underwent RFA. There was one crossover in each group. Analysis was performed on an intention to treat basis. Treatment data are presented in Table 2, there were no significant differences between procedural details, including number of patients having concomitant phlebectomies and number of phlebectomies performed. See Figure 1 for the Trial Consort Diagram. Proportion of patients completing follow-up at one month was 76% (n = 129) and at six months was 71% (n = 121).

Table 1. Patient demographics – mechanochemical ablation group (MOCA) and radiofrequency ablation (RFA).

	Total	MOCA	RFA	Difference
n	170	87	83	ns
Male	70 (41.2%)	37 (42.5%)	33 (39.8)	ns (0.714)
Age_{Median}	50	54.5	48	ns (0.099)
GSV	147 (86.5%)	77 (88.5%)	70 (84.3%)	ns (0.427)
BMI >30	20 (13.4%)	13 (16.7%)	7 (9.9%)	ns (0.223)
$CEAP_{Median}$	4	4	4	ns (0.627)
$VCSS_{Median}$	5	6	5	ns (0.112)
VDS_{Median}	1	1	1	ns (0.135)
AVVQ	19.303	19.546	18.888	ns (0.592)
EQ5D QOL_{Median}	0.761	0.761	0.730	ns (0.989)
EQ5D VAS_{Median}	81.0	84.5	80.0	ns (0.050)

GSV: great saphenous vein; BMI: body mass index; CEAP: clinical etiology anatomy pathology; VCSS: venous clinical severity score; VDS: venous disability score; AVVQ: Aberdeen varicose vein questionnaire; VAS: visual analogue scale.

Table 2. Treatment characteristics.

	Total	MOCA	RFA	Difference
N	165	83	82	ns
Length of vein treated (GSV) (mm)	364	359	373	ns
Length of vein treated (SSV) (mm)	205	227	166	ns
Concomitant avulsions	74%	68%	76%	ns
Median number of avulsions	4	4	4	ns
Median vein diameter (mm)	7	7	7	ns

GSV: great saphenous vein; SSV: small saphenous vein; MOCA: mechanochemical ablation group; RFA: radiofrequency ablation.

Primary outcome

Maximum pain experienced during truncal ablation (Figure 2). Overall median maximum pain via VAS was 24 mm (IQR 10–45) and 4 mm (2–5) by 0–10 number scale. Maximum pain experienced during endovenous ablation as measured on VAS was significantly less in the MOCA group with a median of 15 mm (IQR 7–36 mm) versus 34 mm (16–53 mm), $p = 0.003$ (Mann–Whitney). As measured on a number scale of 0–10, median maximum pain experienced was also significantly less in the MOCA group – 3 (1–5) versus 4 (3–6.5), $p = 0.002$ (Mann–Whitney). Post hoc power analysis demonstrated 91% power at 0.05% significance for the VAS and 94% power at 0.05% significance for the number scale. VAS and number scale showed a very strong correlation (Pearson's $r = 0.96$, $p < 0.001$).

Eighty-six percent of patients described the maximum pain as lasting seconds, and there was no difference in estimated duration of maximal pain duration between groups (90% seconds in MOCA group versus 82% seconds in RFA group, $p = 0.169$).

'Average' pain experienced during truncal ablation (Figure 3). Overall median '*average*' pain experienced was 15 mm (6–32) and 2.5 (1–4) by 0–10 number scale. '*Average*' pain experienced during endovenous ablation was also significantly less in the MOCA group with both VAS – median of 10 mm (3–25 mm) versus 19.5 mm (9–38 mm), $p = 0.003$ (Mann–Whitney); and number scale – median of 2 (0.5–4) versus 3 (2–5), $p = 0.004$ (Mann–Whitney). Post hoc power analysis demonstrated 55% power at 0.05% significance for the VAS and 74% power at 0.05% significance for the number scale. VAS and number scale showed a very strong correlation (Pearson's $r = 0.94$, $p < 0.001$).

Sixty-eight percent of patients described the 'average' pain as lasting seconds, and there was a significant difference in estimated duration of "average" pain duration (76% seconds in MOCA versus 60% seconds in RFA group, $p = 0.021$).

Secondary outcomes

Disease specific quality of life – AVVQ (Figure 4). Overall AVVQ significantly improved from baseline to one month post treatment (19.3 (13.2–28.7) to 12.8 (7.3–20.7), $p < 0.001$), and this continued to be significant at six months (10.8 (4.3–20.5), $p < 0.001$ (Friedman)). Between groups, there was no significant difference at baseline, one month or six month – 12.1 (7.3–21.2) for MOCA versus 12.9 (6.6–20.4) for RFA at one month ($p = 0.799$); and 11.8 (7.2–20.5) for MOCA versus 9.4 (3.6–21.4) for RFA at six months ($p = 0.511$), Figure 4.

General quality of life - EQ-5D QOL and EQ-5D VAS. Overall, EQ-5D QOL and EQ-5D VAS showed no significant change from baseline to six months (Median 0.761 (0.690–0.796) at baseline, 0.761 (0.690–1.000) at one month and 0.761 (0.659–1.000) at six months, $p = 0.060$, Friedman). Between groups, there was no significant difference in EQ-5D QOL at one month (MOCA – 0.761 (0.659–1.000) versus RFA – 0.761 (0.690–1), $p = 0.939$) or at six months (MOCA 0.761 (0.690–1.000) versus RFA 0.761 (0.486–1.000), $p = 0.125$).

EQ-5D VAS was also not significantly different at either timepoint – at one month 85 (60–95) for MOCA versus 87 (80–90) for RFA ($p = 0.227$) and at six months 85 (60–93) versus 89 (70–95) ($p = 0.302$).

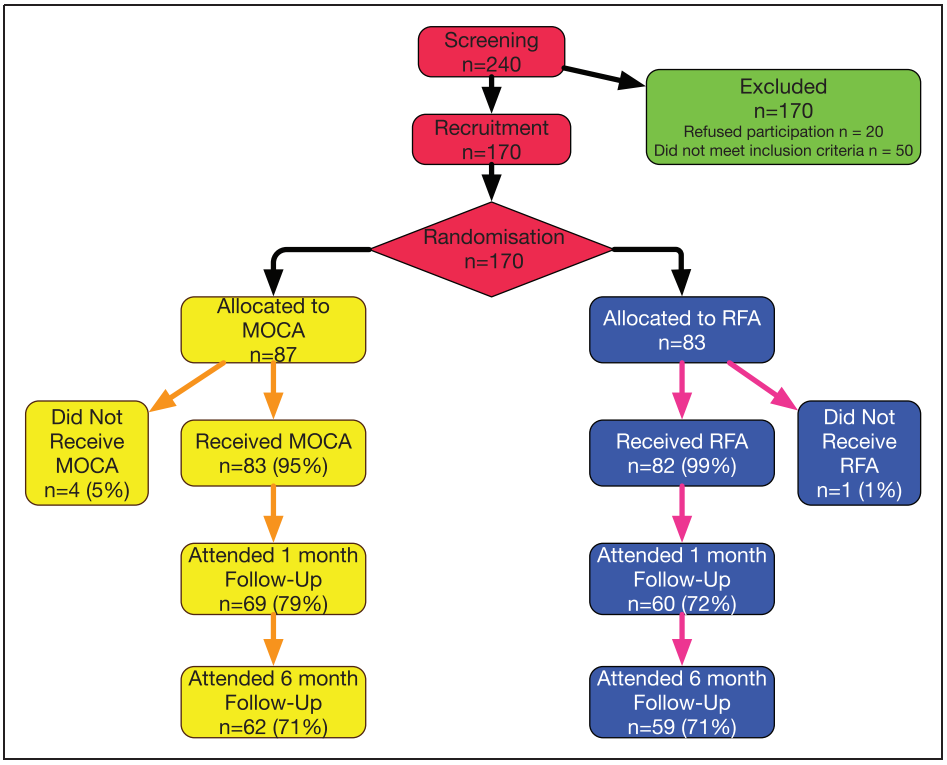

Figure 1. Venefit versus Clarivein for varicose veins consort diagram.

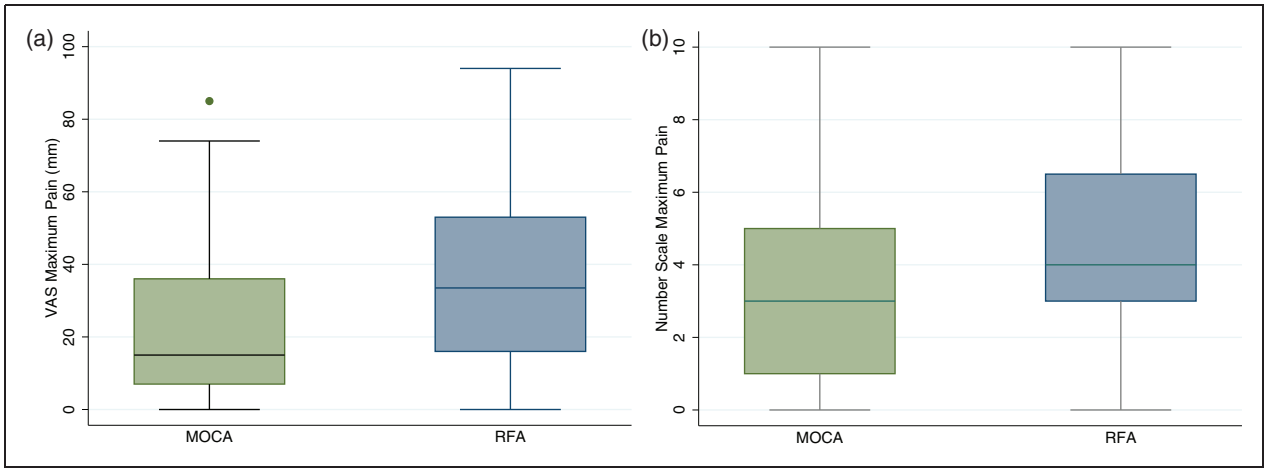

Figure 2. Maximum pain score during procedure for mechanochemical ablation group (MOCA) and radiofrequency ablation (RFA) (a) – visual analogue scale and (b) – number scale.

Clinical severity scoring – VCSS and VDS (Figure 5). Overall, VCSS significantly improved from baseline to one month (5 (4–7) versus 2 (1–5)) as did VDS (1 (1–2) versus 0 (0–1)), and both VCSS and VDS preserved this change at six months ($p < 0.001$, Friedman). Between groups, there was no significant difference for VCSS at either one month (MOCA 2 (1–4) versus RFA 3 (1–5), $p = 0.096$) or six months (MOCA 2 (1–4) versus RFA 2 (1–5), $p = 0.536$) (Figure 5).

VDS also showed no significant difference between groups at one month or six months.

Return to work and return to normal activities. Overall, participants returned to work at a median of two days

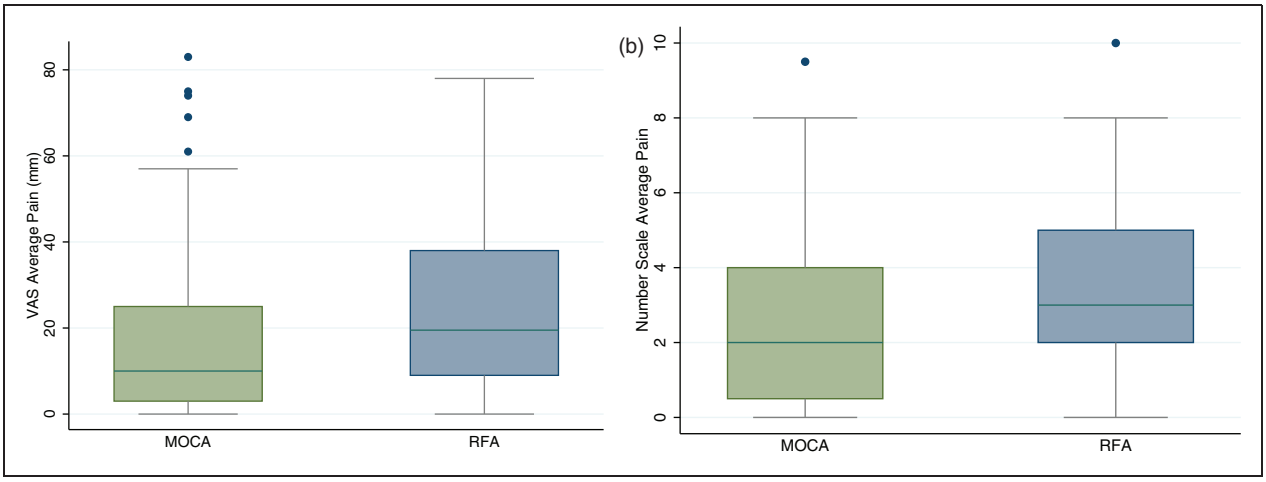

Figure 3. Average pain score during procedure for mechanochemical ablation group (MOCA) and radiofrequency ablation (RFA) (a) – visual analogue scale and (b) – number scale.

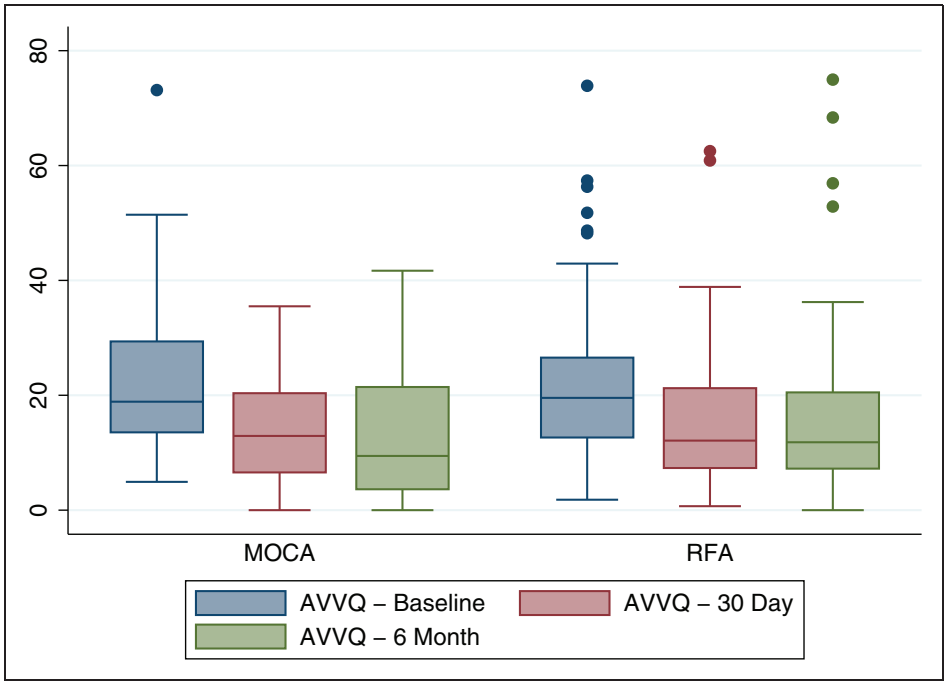

Figure 4. Aberdeen varicose vein questionnaire scores at baseline, one month and six months follow-up – by treatment group – mechanochemical ablation group (MOCA) and radiofrequency ablation (RFA).

(IQR 2–7) and to normal activities at a median of two days (IQR 1–6). There was no significant difference between groups for either return to work (MOCA Median 3, IQR 1–7 versus RFA Median 2, IQR 2–7, ns) or return to normal activities (MOCA Median 2, IQR 1–4 versus RFA Median 2, IQR 1–7, ns).

Technical success of truncal ablation. Overall complete or proximal occlusion rates were 92% at one month and 90% at six months. MOCA showed 93% complete or proximal occlusion at one month, compared to 92% in RFA. At six months, the rates were 87% for MOCA versus 93% for RFA. There was no significant difference in occlusion rates at one month or six months ($p = 0.403$ and $p = 0.483$). Occlusion status had no significant effect on clinical or quality of life scores.

Complications. There were three cases of minor phlebitis along the treated vein in the MOCA group and two in the RFA group. Two deep vein thromboses (DVTs)

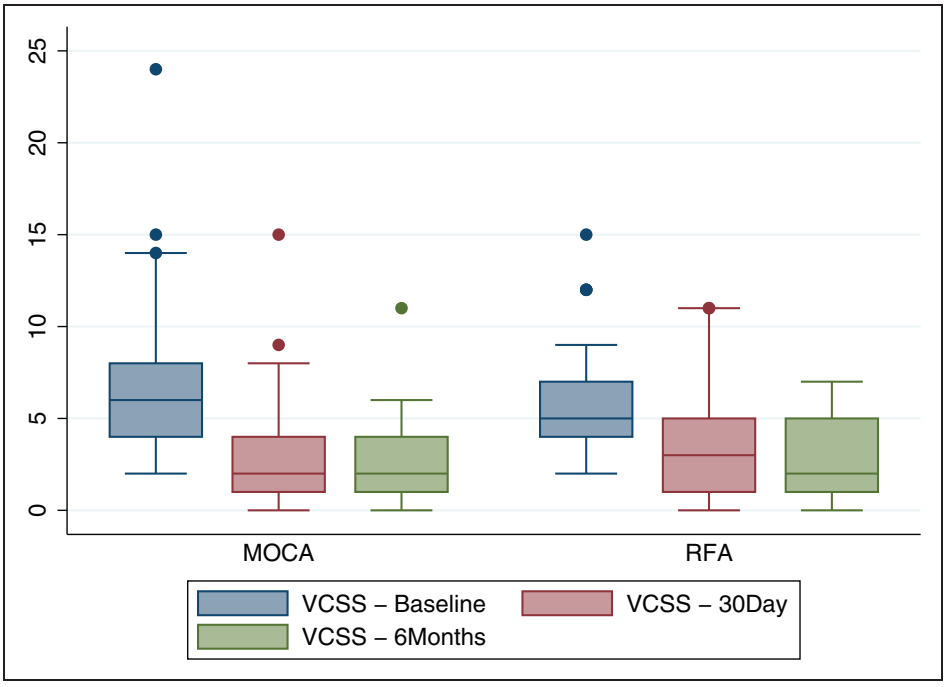

Figure 5. VCSS scores at baseline, one month and six months follow-up – by treatment group – mechanochemical ablation group (MOCA) and radiofrequency ablation (RFA).

occurred (1.2%) – one in each group. The MOCA DVT was a tongue of thrombus into the common femoral vein occluding <50% of the vein diameter (corresponding to Endovascular Treatment Induced Thrombosis stage 2[19]), and the RFA DVT was a calf vein thrombus. Neither DVT had had avulsions performed. There were no patient-reported cases of sensory disturbance at either clinical follow-up. No further procedures were required after initial treatment at six months of follow-up. No difference in cosmetic appearance or satisfaction was reported by patients at clinical follow-up. There were no significant differences in complications between groups.

Discussion

Varicose veins and chronic venous disease is a benign but progressive and pervasive disease. The treatment options have been transformed with endovenous ablation, allowing movement from the operating theatre to the outpatient suite. Recently, clinicians have begun searching for fine point percentage benefits in treatment.[20]

This study shows that tumescentless treatment using MOCA for truncal veins has a reduced pain profile for truncal procedure, whilst retaining similar six-month occlusion rates, as compared to RFA. Patients improved similarly in both groups with respect to disease specific clinical scoring and disease specific quality of life values at all time points. The MOCA group did show a significantly larger improvement in AVVQ from baseline to six months, despite no significant difference in baseline or six-month follow-up group values. This difference of 3.3 AVVQ points falls below the clinically significant threshold of five points used for previous studies.[11,12] On simple group comparison, patients in the MOCA group also had an improved generic quality of life outcomes (EQ-5D QOL) at six months, despite similar post-operative complication rates. However, once corrected via linear regression for baseline differences there was no significant difference. No significant improvement was found from baseline to six months due to multiple testing correction (six month data were significantly improved from baseline when assessed directly) and loss to follow-up. This study was not prospectively powered to assess generic or disease QOL. It may also be possible that due to the severity of disease treated in this cohort, the reversibility of QOL detriment is limited.[21]

The occlusion rates at six months are equivalent for both modalities; however, both the RFA and MOCA groups had lower rates of occlusion than expected from the published literature. In the most recent study of long-term follow-up, a total or proximal occlusion rate of 92.7% at five years post RFA has been reported.[18] However, a recent study comparing open surgery to endovenous laser ablation found a 41% recurrence rate at five years.[22] The findings of this study may be secondary to detailed and independent post-operative duplex scanning or it may represent real world efficacy of these treatment types. The vascular scientists

performing the follow-up scans were experienced in the post-operative appearances of both techniques. It is unlikely that these rates are due to poor technique, due to extensive experience in all operators prior to commencement of the study (there was no "roll-in" period). Longer follow-up is needed to give detailed evidence of the robustness of the techniques. The total number of patients without successful occlusion at one month was 11 and at six months was 12, which limits the inferences that can be drawn from such occlusion rates.

Thus, this study supports the hypothesis that MOCA is an effective treatment for truncal vein incompetence and subjects the patient to a less painful ablative procedure. Additionally, this study provides evidence that MOCA with simultaneous phlebectomy is safe and effective in the short term.

The study was powered at 90% power and 5% significance to detect a 20 mm difference in mean pain scores on VAS, with the observed difference in medians found being 19 mm. This protocol power calculation required 47 patients per treatment group. However, target recruitment was inflated to 170 patients to compensate for expected 50% loss to follow-up; 121 patients (71%) attended six-month follow-up. The study treated 165 patients, and post hoc power calculations with these data show that for pain scores, the study had 91% power at 0.05% significance criterion.

The use of both VAS and number scale has provided evidence of their equivalence. The full study showed no significant reduction in pain scores from the initial report[10] suggesting that there was no time dependent decrease in pain score to indicate a learning curve during the study.

This study was limited by lack of treatment blinding for the patients and interventional clinicians. This was due to the technical differences between devices, i.e. tumescent injections in the RFA group and device vibration in the MOCA group. Follow-up appointments and ultrasound scanning were treatment blind.

A further limitation of this study is the lack of long-term follow-up – only short-term occlusion rates are assessed in this study, with the primary outcome obtained at the time of procedure. Operating time was not recorded in this study; however, all cases were performed in standardised theatre sessions in single slots with one surgeon performing all tasks, and 74% of patients also underwent simultaneous phlebectomy.

A major limitation of all tumescentless techniques is how to treat varicosities left after truncal ablation, with level one evidence now supporting combined treatment with phlebectomies.[12,13] This study was designed and commenced prior to the completion of latest trial, but took into consideration the fact that phlebectomies cause pain, and so pain scores taken after truncal ablation but before any phlebectomies were completed. This, therefore, represents a significant limitation to the outcomes of this trial, as the pain scores reported above do not assess the complete treatment, except for those patients who did not undergo phlebectomy.

However, similar number of patients underwent phlebectomies in both treatment groups. In the context of tumescentless truncal ablation, the use of phlebectomies requires the use of additional local or tumescent anaesthesia, so further injections are not avoided. Indeed, the phlebectomies may be the over-riding cause of pain. However, tumescentless techniques still obviate the need for injections in the proximal thigh and groin, which may be more painful than distal injection in the leg. This would require further study to delineate. Additionally, volume of tumescent anaesthesia used was not formally documented.

This study did not assess pain scores after phlebectomy or after the periprocedural period.

Treatment of the varicosities with foam sclerotherapy in combination with truncal ablation is an alternative technique but has yet to be assessed formally in an appropriately powered randomised study; however, previous work has supported its use in principle.[23] MOCA presents a dilemma due to sclerosant dose limitations, with European consensus guidelines advocating a maximum dose of 10 ml of <3% concentration liquid STS sclerosant or 2 mg/kg polidocanol sclerosant and 10 ml of foam sclerosant.[24] Additionally, the treatment techniques leads to a variable dosage of scleroant per centimetre treated, dependent on vein diameter, and governed by the Vascular Insights MOCA sclerosant guidance and instructions for use. Alternative tumescentless devices do not have such dose limitations, but published data are lacking. Studies examining volume limits would be beneficial to help guide both MOCA and pure sclerotherapy techniques.

Further studies examining pain experienced during combined phlebectomy and truncal ablation procedures would be of great benefit to ascertain the difference treatment devices make in simultaneous therapy – for the assessment of the whole treatment.

Conclusion

Mechanochemical truncal ablation offers patients reduced intra-procedural pain with equivalent technical success compared to radiofrequency truncal ablation at six months. Patients have equivalent disease specific quality of life and clinical outcomes, and returned to work and normal activities at similar times.

Further work with larger studies and extended follow-up is needed to assess long-term outcomes and recurrence rates.

Author contributions

TRAL and AHD conceived and setup the study. TRAL, RB, BD, CSL, MN, SR, KS and AHD performed the procedures and collated the data. TRAL and RB performed the data-analysis. TRAL wrote the first draft of the manuscript. TRAL, RB, BD, CSL, MN, SR, KS and AHD critically appraised, edited and approved the final manuscript. AHD is the guarantor.

Declaration of conflicting interests

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