Randomized Controlled Trial of Compression After Endovenous Thermal Ablation of Varicose Veins (COMETA Trial)

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Background: The 21st century has witnessed a rise in the use of endovenous thermal ablation. Being highly clinically and cost-effective and improving the quality of life of patients, they are now considered to be the “gold-standard” treatment for varicose veins. Postintervention management, especially in terms of postoperative compression; however, remains unclear. As a result, a randomized study was undertaken to investigate the effects of wearing compression stockings after varicose vein treatment.

Method: Patients with saphenous vein reflux undergoing treatment with endothermal ablation (with or without concurrent phlebotomies) were randomized to receive either 7 days of compression stockings or no stockings. The primary outcome measure for this study was the pain score over the first 10 postoperative days. The pain scores, clinical score, time to return to normal activities, and ecchymosis were assessed. Patients were followed-up at 2 weeks and 6 months post-ablation.

Results: In total, 206 patients were randomized, 49% of them to the compression group. The mean age was 49.7 (±16) years and approximately 51% of the population was male. The median pain score in the compression group using a visual analog scale was significantly lower on days 2–5, compared to the no compression group. Those having concurrent phlebotomies and compression stockings also had significantly better pain scores on days 1–3, day 5, and day 7. Improvement in the median venous clinical severity score was noted at 6-month follow-up, but this was not significant. No difference in the generic- or disease-specific quality of life was observed and the time to return to activities was similar. There were no differences in the degree of ecchymosis between the 2 groups and both groups had similar occlusion rates.

Conclusions: These results indicate that wearing compression stockings after endothermal ablation is advantageous in the first few days after treatment and is especially beneficial for those having concurrent phlebotomies.

Keywords: compression, varicose veins

VARICOUS VEINS

Varicose veins disease is an important condition affecting approximately a third of the general population. As it becomes more chronic, it can give rise to a variety of symptoms ranging from achiness and limb swelling to skin pigmentation and ulceration. The presence of the disease is also associated with depression and adversely impacts the quality of life (QoL) of patients, which, in turn, is improved by treating the condition.

The beginning of the 21st century has witnessed a paradigm shift with regards to management of varicose veins with surgical ligation and stripping of saphenous veins becoming less popular as newer endovenous technologies were being introduced. These methods, notably endovenous laser treatment and radiofrequency ablation (RFA), have been deemed to be as clinically effective, but also probably more cost-effective compared to surgical procedures, especially when performed in an outpatient or “office-based” setting. They are now considered the “gold-standard” in the treatment of varicose vein disease.

A common post-intervention practice is the use of compression stockings. Edwards et al (2009) found that 82% of respondents in their survey of the members of the Vascular Society of Great Britain and Ireland were using some form of bandaging immediately post-procedure, and approximately 3 quarters of them would change to stockings after a period of time. The length of time the bandages or stockings were worn was inconsistent.

A systematic review looking at the use of compression after treatment of varicose veins found that the evidence available was limited and could not point to the best method and duration of postintervention compression.

In the United Kingdom, the National Institute of Health and Care Excellence recommends the use of compression (either bandaging or hosiery) for no more than 7 days after interventional treatment for varicose veins. However, due to current uncertainty of compression compared to no compression after the treatment of varicose veins, the National Institute of Health and Care Excellence Guideline Development Group have advocated further research to evaluate the clinical and cost-effectiveness of this postprocedure method and looking at its duration.

Hence, this trial was conducted to examine the effects of compression after varicose vein treatment.

METHODS

This was a single center prospective randomized controlled trial (RCT) investigating the use of compression therapy in patients receiving endovenous thermal treatment for refluxing truncal saphenous veins using either RFA or endovenous laser ablation (EVLA).

Patient Selection

Adult patients with symptomatic great saphenous vein or small saphenous vein incompetence on color duplex scan and attending for endothermal ablation were invited to participate in the study.

Exclusion criteria included patients with peripheral arterial disease (ankle-brachial pressure index <0.8), presence of C6 disease, small vein diameter (<3 mm), current deep vein thrombosis (DVT), unwillingness to participate, and inability/unwillingness to complete the trial questionnaires.

Randomization

Eligible patients attending the outpatient clinic were provided with a participant information sheet when they were added to the waiting list for treatment. On the day of their treatment and after providing their informed consent, patients were randomized to either the compression group (group A) or the no compression group (group B) using an online randomization service (Sealed Envelope, London, UK).
Treatment
The thermal method of treatment was at the discretion of the treating physician. Following standard endovenous ablation with either EVLA (VenaCure endovenous laser treatment system; Angiodynamics, Albany, NY) or RFA (ClosureFast; Medtronic, MN), patients with symptomatic varicose tributaries were treated with ambulatory phlebectomies or foam sclerotherapy.

Intervention
Following varicose vein treatment, patients randomized to the compression group (A) received an initial 24 hours of compression using elastic bandages (Bastos Viegas, Penafiel, Portugal) followed by 7 days of thigh-length class 2 compression stockings (Crededalst, Credenhill Limited, Derbyshire, UK).

The advice provided was for the patients to wear the stockings for 24 hours every day for the full 7 days. Compliance was assessed by asking them how many days they were wearing the stockings.

Patients randomized to the no compression group (B) received 24 hours of bandaging only.

Objectives
The primary outcome measure of the study was the pain score for the first 10 postoperative days using a validated 100 mm visual analog scale (VAS). Patients were followed up at 2 weeks and 6 months.

The secondary outcome measures included the change in clinical score, QoL, degree of bruising and phlebitis, compliance with compression, time to return to usual activities, and occlusion rate at 6 months.

At baseline, patients’ characteristics, clinical scores [using the venous clinical severity score (VCSS)] and QoL scores were recorded. The instruments used to measure generic QoL change were the EuroQol’s EQ-VAS and EQ-5D whereas disease-specific QoL questionnaires used were the Aberdeen varicose veins questionnaire (AVVQ) and the chronic venous insufficiency quality of life questionnaire (CIVIQ-14).

On discharge after their varicose vein intervention, patients were provided with a diary to record their post-procedural pain every day for 10 days using a validated 100 mm VAS.

At 2 weeks, the diary was collected and patients were assessed for any bruising or phlebitis because of their procedure. Patients randomized to group A were also asked about their compliance with compression. The clinical scores, QoL scores and their time to return to normal activities were recorded. The degree of ecchymosis was based on the scoring system used by Almeida et al (2013). At the 6 months follow-up, patients had their VCSS, EQ-VAS, EQ-5D, AVVQ, and the CIVIQ scores documented. A venous Duplex scan was also performed to determine occlusion of the treated vein.

Sample Size and Study Duration
A power calculation was carried out to determine the sample size. The mean difference in the VAS score between group A and group B was estimated to be 20 mm with a standard deviation of 20 mm.

The power calculation targeted power of 90% and 5% significance equivalence, which lead to a target recruitment of 128 participants (64 per group) would be needed. Allowing for potential loss to follow-up rate of 40%, the target recruitment was 124 patients.

The trial period ran from May 2015 to June 2018.

Settings
The study was conducted at the Imperial College Healthcare NHS Trust, with patients recruited at the Charing Cross Hospital and St Mary’s Hospital.

Ethics and Registration
Ethical approval was sought and obtained from the National Research Ethics Service Committee London – Fulham (REC Reference: 15/LO/0181). The trial is registered on the ClinicalTrials.gov website and bears registration number NCT02522845.

Statistical Analysis
All data was anonymized and entered onto a database on IBM SPSS Statistics for Macintosh version 22.0 (IBM Corp., Armonk, NY). Statistical analysis was performed using SPSS Statistics version 25.0, Stata for Mac version 14.2 (StataCorp., College Station, TX) and Wizard Pro v1.9.31 (Evan Miller, Chicago, IL). Graphical representation was carried out on Stata for Mac (version 14.2) and Microsoft Excel for Mac 2011 version 14.7.4 (Microsoft Corp., Redmond, Washington).

Baseline Characteristics
Between May 2015 and June 2018, 206 patients attending for their varicose veins procedures at the Charing Cross Hospital and St Mary’s Hospital were recruited. The trial CONSORT diagram is illustrated below (Fig. 2). The most common reasons for declining participation was preference for compression (58%), preference for no compression (10%), and inability to attend follow-up appointments (10%).

Two patients were randomized in error (not meeting criteria to be part of trial) and were excluded from the final analysis. Six patients received EVLA, whereas the rest underwent RFA. 65% of patients attended the follow-up at 2 weeks and 44% attended at 6 months.

Baseline Characteristics
The baseline characteristics are shown in Table 1. Overall, 51.4% of the patients were males (58.6% in group A vs 44.2% in group B; P = 0.041), with a mean age of 49.7 years (standard deviation: ±16 years). The mean body mass index was 27.1 kg/m² and 22% of the total participants had a body mass index greater than 30 kg/m² (obese).

In the compression group, 67% of patients were in clinical-etiological-anatomical-pathophysiological classification (CEAP) class C2-C3 and 33% were in CEAP class C4-5. The baseline clinical CEAP classification for the no compression group was C2-3 76% and C4-5 24% (Chi-squared, P = 0.062).

Pain Score
The median pain score using a validated 100 mm VAS for the first 10 postoperative days in group A was 17.9 mm (interquartile range (IQR): 6.27–33.8) compared to 26.5 mm (IQR: 10.1–42.1) in group B (Mann-Whitney U-test, P = 0.133).

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These were also examined for the first 5 post-ablation days and for days 6–10. This showed that the median pain score for the first 5 postoperative days in the compression group was significantly better in group A at 18.7 mm (IQR: 7.58–36.9) compared to 27.8 mm (IQR: 13.0–53.6) in group B (Mann-Whitney U-test, \( P = 0.045 \)). The median pain score for the subsequent few days was 9.80 mm (IQR: 0.95–35.1) in group A compared to 16.8 mm (IQR: 0.70–39.7) in the no compression group (Mann-Whitney U-test, \( P = 0.436 \)).

Median pain scores recorded on days 2–5 in group A compared to group B were significantly less (Fig. 3). The median pain score on day 2 was 15.5 mm (IQR: 2.0–37.0) in the compression group versus 37.0 mm (IQR: 11.5–60.0) \( (P = 0.008) \), day 3 [14.5 mm (IQR: 1.0–34.0) vs 30.0 mm (IQR: 7.5–58.0); \( P = 0.018 \)], day 4 [12.5 mm (IQR: 3.0–36.0) vs 27.0 mm (IQR: 7.5–49.5); \( P = 0.038 \)], and day 5 [9.5 mm (IQR: 2.0–34.0) vs 28.0 mm (IQR: 5.0–49.0); \( P = 0.022 \)].

**VCSS**

The median VCSS score at recruitment was 5 (IQR: 4–7) in group A and 4 (IQR: 3–6) in group B (Mann-Whitney U-test, \( P = 0.026 \)). The median VCSS observed after 2 weeks was 3 (IQR: 2–5) in the compression group versus 2 (IQR: 1–3) in group B (\( P = 0.014 \)).
FIGURE 2. CONSORT diagram.

### TABLE 1. Baseline Characteristics of Patients

<table>
<thead>
<tr>
<th></th>
<th>Overall (n = 204)</th>
<th>Compression Group (n = 100)</th>
<th>No Compression Group (n = 104)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>51.2</td>
<td>58.6</td>
<td>44.2</td>
<td>0.041</td>
</tr>
<tr>
<td>Age (±SD) (yr)</td>
<td>49.7 (±16)</td>
<td>49.7 (±17)</td>
<td>49.6 (±15)</td>
<td>0.968</td>
</tr>
<tr>
<td>BMI (±SD) (kg/m²)</td>
<td>27.1 (±6)</td>
<td>27.3 (±5)</td>
<td>27.0 (±7)</td>
<td>0.780</td>
</tr>
<tr>
<td>BMI &gt;30 (%)</td>
<td>22</td>
<td>23</td>
<td>21</td>
<td>0.739</td>
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<tr>
<td>Clinical CEAP class (%)</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>C2–3</td>
<td>71.5</td>
<td>67.0</td>
<td>76.1</td>
<td>0.062</td>
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<tr>
<td>C4–5</td>
<td>28.5</td>
<td>33.0</td>
<td>23.9</td>
<td></td>
</tr>
<tr>
<td>VCSS (median) (IQR)</td>
<td>5 (3–6)</td>
<td>5 (4–7)</td>
<td>4 (3–6)</td>
<td>0.026</td>
</tr>
<tr>
<td>EQ-VAS (median) (IQR)</td>
<td>80 (70–90)</td>
<td>80 (70–90)</td>
<td>80 (70–90)</td>
<td>0.492</td>
</tr>
<tr>
<td>EQ-SD (median) (IQR)</td>
<td>0.761 (0.659–1.0)</td>
<td>0.761 (0.659–0.891)</td>
<td>0.761 (0.659–1.0)</td>
<td>0.700</td>
</tr>
<tr>
<td>AVVQ (median) (IQR)</td>
<td>16.0 (10.8–22.6)</td>
<td>16.7 (10.0–25.2)</td>
<td>15.0 (11.4–21.8)</td>
<td>0.792</td>
</tr>
<tr>
<td>CIVIQ-14 (median) (IQR)</td>
<td>19.6 (8.9–42.9)</td>
<td>17.9 (8.9–47.3)</td>
<td>21.4 (8.8–37.5)</td>
<td>0.830</td>
</tr>
</tbody>
</table>

AVVQ indicates Aberdeen varicose vein questionnaire; BMI, body mass index; CEAP, clinical-etiological-anatomical-pathophysiological classification; CIVIQ-14, chronic venous insufficiency quality of life questionnaire; EQ-VAS, EuroQol’s visual analog scale; IQR, interquartile range; SD, standard deviation.
After 6 months, the combined median VCSS was 1.5 (IQR: 1.0–3.0; Wilcoxon Signed Rank Test, $P < 0.001$). At that point, the median VCSS in the compression group was 2 (IQR: 1–4) compared to 1 (IQR: 1–3) in the no compression group ($P = 0.687$).

**QoL**

There was no significant improvement in the overall median EQ-VAS (80 mm at baseline (IQR: 70–90) and 80 mm at 6 months (IQR: 75–90); Wilcoxon Signed Rank Test, $P = 0.65$) and statistically significant improvement in the overall median EQ-5D (0.659–1.0) and 0.772 at 6 months (IQR: 0.696–1.0, $P = 0.001$).

Similarly, there was significant improvement in the disease-specific QoL (AVVQ and CIVIQ-14) at 6 months after intervention. The combined median AVVQ at baseline was 16.0 (IQR: 10.8–22.6) and 8.7 at 6 months (IQR: 2.5–16.4) ($P < 0.001$), and the overall median CIVIQ-14 was 19.6 at baseline (IQR: 8.9–42.9) and 7.1 at 6 months (IQR: 1.8–18.8) ($P < 0.001$).

However, there were no statistically significant differences between the 2 groups in either the generic and disease-specific QoL at baseline, 2 weeks and 6 months (see Table 2).

**Time to Usual Activities**

Both groups returned to their normal activities and went back to work at a median of 2 days (Mann-Whitney $U$-test, $P = 0.224$) and 3 days ($P = 0.955$), respectively.

**Compliance**

The median time for patients in the compression group to stop wearing their compression stockings was 7 days (IQR: 7–9 days).

**Ecchymosis**

The extent of ecchymosis was recorded according to the same scale as Almeida et al (2013) and was recorded at the 2 weeks’ follow-up. The degree of ecchymosis was arbitrarily categorized into 2 groups using a cut-off of 25% (<25% and ≥25%). Using this dichotomization, approximately 85% of patients in group A had an area less than 25% covered in ecchymosis compared to about 80% in group B [analysis of variance (ANOVA), $P = 0.507$].

**Concurrent Varicosity Treatment**

Two patients from the compression group (and none from the no compression group) also received additional foam treatment to their varicosities. No separate statistical analysis was possible for

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**TABLE 2. Median of Generic- and Disease-specific Quality of Life at Baseline, 2 wk and 6 mo**

<table>
<thead>
<tr>
<th></th>
<th>Compression</th>
<th>No Compression</th>
<th>$P$-value</th>
<th>Compression</th>
<th>No Compression</th>
<th>$P$-value</th>
<th>Compression</th>
<th>No Compression</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EQ-VAS</td>
<td>80 (70–90)</td>
<td>80 (70–90)</td>
<td>0.492</td>
<td>90 (73.5–90)</td>
<td>85.5 (75–95)</td>
<td>0.880</td>
<td>85 (75–90)</td>
<td>80 (71–90)</td>
<td>0.309</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>0.761 (0.659–0.891)</td>
<td>0.761 (0.659–1.0)</td>
<td>0.700</td>
<td>0.761 (0.730–1.0)</td>
<td>0.761 (0.698–1.0)</td>
<td>0.914</td>
<td>0.761 (0.690–1.0)</td>
<td>0.891 (0.722–1.0)</td>
<td>0.400</td>
</tr>
<tr>
<td>AVVQ</td>
<td>16.7 (10.0–25.2)</td>
<td>15.0 (11.4–21.8)</td>
<td>0.792</td>
<td>11.7 (7.5–23.1)</td>
<td>14.2 (8.8–21.7)</td>
<td>0.894</td>
<td>7.3 (3.0–16.3)</td>
<td>10.1 (2.5–16.7)</td>
<td>0.576</td>
</tr>
<tr>
<td>CIVIQ-14</td>
<td>17.9 (8.9–47.3)</td>
<td>21.4 (8.8–37.5)</td>
<td>0.830</td>
<td>17.9 (7.1–33.9)</td>
<td>19.6 (7.1–37.5)</td>
<td>0.641</td>
<td>7.1 (1.8–20.5)</td>
<td>5.4 (1.8–16.1)</td>
<td>0.695</td>
</tr>
</tbody>
</table>

Values in parentheses are interquartile ranges. Mann-Whitney $U$-test used to calculate $P$-values. $P < 0.05$ considered significant.

AVVQ indicates Aberdeen varicose vein questionnaire; CIVIQ-14, chronic venous insufficiency quality of life questionnaire; EQ-VAS, EuroQol’s visual analog scale.

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them and they were instead included in the group receiving endothermal ablation only. Forty-five percent of patients in group A received concurrent phlebectomies after endothermal ablation compared to 59% in group B (P = 0.147). For those patients in the compression group, the median pain score over the first 10 days was 27.6 mm (IQR: 1.6–39) compared to 38.5 mm (IQR: 27.0–63.6) in the no compression group (Mann-Whitney U-test, P = 0.268). Patients in the compression group had significantly better median pain scores on days 1–3, day 5, and day 7 (Fig. 4). No such finding was observed when looking at those having thermal ablation only with a median pain score for first 10 postoperative days of 17.7 mm (IQR: 7.3–23.8) in group A compared to 13.9 mm (IQR: 1.3–45.9) in the no compression group (P = 0.979).

Interestingly, the VCSS in those having phlebectomies was significantly better in the no compression group (group B) at baseline (2.5 compared to 6; P = 0.001) and at 2 weeks (3.5 compared to 4; P = 0.040). There was no statistically significant difference noted at 6 months though (1 compared to 2.5; P = 0.808).

No differences were observed between phlebectomy or no phlebectomy groups in the generic QoL. (EQ-VAS: P = 0.804 at 2 weeks and P = 0.673 at 6 months; EQ-5D: P = 0.271 at 2 weeks and P = 0.272 at 6 months) or disease-specific QoL (AVVQ: P = 0.481 at 2 weeks and P = 0.503 at 6 months; CIVIQ: P = 0.180 at 2 weeks and P = 0.573 at 6 months).

Approximately 87.5% of patients having endothermal ablation and phlebectomies had <25% of their limbs covered in bruising compared to 97.4% in those having endothermal ablation only (ANOVA, P = 0.127).

**Occlusion Rates**

At 6 months, 87.5% of patients in the compression group had complete occlusion of their saphenous vein compared to 92.1% of patients in the no compression group (ANOVA, P = 0.121).

**Complications**

One patient had a symptomatic DVT (gastrocnemius DVT) noted in a 68-year-old lady who did not receive any compression.

**DISCUSSION**

The main findings of this randomized clinical trial is the use of compression stockings leads to significantly better pain scores for the first 5 days after endothermal ablation of saphenous veins. However, no associated difference was noted in the clinical scores and QoL scores by the 6-month point. There was also no additional advantage in time to resumption of normal activities or in occlusion rates.

Patients in the compression group receiving concurrent phlebectomies had significantly better pain scores in the early days after treatment as well. It is possible that these above noted differences are bringing about the corresponding better pain scores in all the patients in the combined compression group. This has important implications for the management of varicose veins as the recommended management of varicose vein tributaries is for treating them concurrently.9,21,22

This study suggests a potential in terms of pain control in patients undergoing phlebectomies as an adjuvant to endothermal truncal ablation and provided with compression stockings for their post-operative period. However, in those patients only having endothermal ablation wearing compression stockings did not seem to confer any additional benefit, but this RCT is not sufficiently powered to be able to verify this.

Similar previous RCTs have provided mixed results. Bakker et al (2013) investigated the wearing of compression stockings after EVLA by conducting a RCT recruiting 109 patients.23 None of the patients had simultaneous tributary treatment. Analysis; however, was on 69 patients (40 patients were excluded for various reasons) and found that, at 1 week, the VAS was significantly better in those patients having compression for 7 days compared to those wearing stockings for only 48 hours (VAS score: 2.0 vs 3.7; P ≤ 0.001).

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**FIGURE 4.** Median pain score using a VAS in the first 10 days postintervention in patients receiving concurrent phlebectomies. Significantly lower VAS scores were recorded on days 1–3, 5, and 7 in the compression group. VAS indicates visual analog scale.
Similarly, Elderman et al (2014) and Ye et al (2016) found less pain in those wearing compression stockings. Ayo et al (2016) indicated a trend for less pain in those wearing compression stockings post-ablation, although this was only a secondary outcome and the sample size calculation did not look at the number needed to demonstrate a significant difference. For their part, Krasznai et al (2016) found no significant differences in leg volume or pain scores in their RCT of 101 patients receiving either 4 hours or 72 hours of compression stockings after RFA. Both disease-specific and generic QoL also showed mixed results.

In their review of compression after endothermal ablation, Al Shakarchi et al (2018) concluded that there was no advantage in having extended compression (defined as wearing compression stockings 3–15 days post-ablation) and suggested that compression stockings should not be used for longer than 2 days. None of the included studies had conducted simultaneous tributary treatment.

In their 2019 Clinical Practice Guidelines, the American Venous Forum, Society for Vascular Surgery, American College of Phlebology, Society for Vascular Medicine, and International Union of Phlebology recommend the use of compression (Grade 2C evidence: weak recommendation, low-quality, or very low-quality evidence) providing pressures of more than 20 mm Hg after thermal ablation (Grade 2B: weak recommendation, moderate quality evidence). The guidelines were, however, unable to provide guidance with regards to the duration of this post-ablation treatment and suggested using a “best practice” approach to determining the length of time to use compression. Therefore, it is possible that this present study might be able to add strength to these recommendations.

Analyzing the reasons not to participate in the trial, it seems that a large proportion of patients have a preference for compression stockings. The exact origin for this choice is unclear, especially as studies have so far produced mixed results. Clinical advice from their own GP may be a factor because many prescribe stockings when patients first present to them with varicose vein symptoms. It is also possible that there is an element of peer/family influence or personal beliefs. Moreover, there may be the effect of the marketing industry encouraging patients to wear stockings for a variety of reasons including a need to wear compression postintervention. However, only patients happy to be randomized (and therefore, had equipoise) were included in the study. Hence, it can be argued that this reduced bias and made the findings of the study more generalizable.

The clinical scores at baseline and 2 weeks were significantly better in the group not receiving any compression stockings, however, by 6 months there was no significant difference. It is unclear whether this represents an improved response in the compression group.

On the whole, there was enhancement in the disease-specific QoL of patients, without significant differences observed when comparing the 2 groups. This confirms that treatment of varicose veins is indeed beneficial, but also indicates that the wearing or not of compression stockings does not lead to noticeable differences between these 2 groups.

There was only 1 incidence of DVT noted in our study population which does not allow any comments to be made with regards to the protective effect of compression after endovenous treatment. It does, however, provide evidence that the rate of DVT after thermal ablation is likely to be less than 1%, similar to a recently published meta-analysis.

**Limitations**

There are a few limitations to this study. First, after ethical approval, the power of the study was decreased from 90% to 80%. This was mainly because as the trial started, it became evident that recruitment was slow and there was a lack of success in engaging other trial sites. Hence, the target recruitment had to be lowered from 350 patients to 214 patients (allowing for loss to follow-up). Indeed, a greater number of patients may have demonstrated significant differences in the secondary outcome measures and enabled more robust conclusions to be drawn from this study. Although it can be argued that this reduces the strength of our study findings, practically, this has allowed successful completion of the RCT within a time frame of just over 3 years with a robust result for the primary outcome measure, despite slow recruitment.

Another limitation was that the use of analgesia was not recorded so that it is unclear whether the pain score observed was with or without analgesia. This seems to be highly pertinent and accounting for analgesia use; therefore, would be a necessary prerequisite in any future trial designs looking at pain as an outcome measure.

The study did use arbitrary end-points (eg, in the expression of ecchymosis), although these have been used in the literature before. This highlights the gaps in knowledge in venous disease (eg, how much ecchymosis is relevant enough to be affecting QoL) and calls for improved guidance as to the most appropriate outcome measures.

Follow-up for the study was limited to 6-months and does not allow for extrapolation of the findings beyond that point, especially with respect to clinical scores, QoL, and occlusion rates. Extended follow-up would be helpful to clarify how these end-points change with time, but this can be difficult in a mobile population in a large geographical area.

Also, both groups were assessed twice post-procedure, and it can be argued that more frequent follow-up might have facilitated the detection of earlier differences between the groups. Although this might have been feasible, it runs the risk of alienating the study cohort from attending any further follow-ups, questionnaire fatigue and could potentially have impacted on follow-up rates.

Moreover, this study was designed to assess the effects of compression stockings after endothermal ablation, but it is possible that the inclusion of those having phlebectomies have distorted our final results.

The utilization of concurrent phlebectomies was recorded, however, this did not include the number of phlebectomies carried out or their locations. Hence, the appropriate recording of these additional details in studies with patients having phlebectomies seems justified.

**CONCLUSIONS**

This study suggests that the use of compression after varicose treatment by endothermal ablation with or without phlebectomy reduces postoperative pain in the first 5 days after treatment, and maybe more important in patients undergoing concurrent phlebectomy. This finding is not; however, associated with any short-term gains in QoL or occlusion rates compared to no compression postoperatively.

**REFERENCES**


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