Compression vs No Compression After Endovenous Ablation of the Great Saphenous Vein: A Randomized Controlled trial

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Abstract

Objective
The goal of this study is to determine if compression therapy after endovenous ablation (EVA) of the great saphenous vein (GSV) improves efficacy and patient reported outcomes of pain, ecchymosis and quality of life.

Methods
This was a prospective randomized controlled trial from 2009 to 2013 comparing the use of thigh-high 30-40mmHg compression therapy for 7 days vs no compression therapy following endovenous ablation of the GSV. Severity of venous disease was measured by CEAP scale and the venous clinical severity score (VCSS). Quality of life assessments were carried out with a CIVIQ-2 questionnaire at days 1, 7, 14, 30 and 90, and the visual analog pain scale daily for the first week. Bruising score was assessed at 1 week post procedure. Post ablation venous duplex was also performed.

Results
70 patients and 85 limbs with EVA were randomized. EVA modalities included radiofrequency ablation (91%) and laser ablation (9%). CEAP class and VCSS scores were equivalent between the two groups. There was no significant difference in patient reported outcomes of post-procedural pain scores at day 1 (mean 3.0 vs. 3.12, p =0.948) and at day 7 (mean 2.11 vs 2.81, p =0.147), CIVIQ-2 scores at 1 week (mean 36.9 vs 35.1, p=0.594), at 90 days (mean 29.1 vs 22.5, p =0.367) and bruising score (mean 1.2 vs 1.4, p=0.561) in the compression vs. no compression groups respectively. Additionally, there was a 100% rate of GSV closure in both groups and no endothermal heat-induced thrombosis (eHIT) as assessed by post-ablation duplex.

Conclusion
Compression therapy does not significantly affect both patient reported and clinical outcomes after GSV ablation in patients with non-ulcerated venous insufficiency. It may be an unnecessary adjunct following GSV ablation.
Introduction

Approximately 5 to 8% of the world population suffers from venous insufficiency. In the United States alone, an estimated 2.5 million people develop lower extremity venous insufficiency. As the US population continues to age, the prevalence of venous insufficiency is on the rise as it is more common in the elderly, with a peak prevalence between 60 and 80 years of age (1-2). There is a reported female predominance of venous disease with a female-to-male ratio ranging from 1.6:1 (age-adjusted) to 10:1. The majority of venous insufficiency is attributed to venous reflux secondary to valvular incompetence (1-3). Valvular incompetence prevents normal venous blood flow from the superficial to deep venous system, resulting in increased venous pressure and hemosiderin deposition in the skin (1). This venous hypertension leads to activation of inflammatory pathways, causing further destruction of valve competency, perpetuating venous distention and may ultimately progresses to ulceration (1-3).

Great saphenous vein (GSV) valvular incompetence is the most common underlying etiology of chronic venous insufficiency. Symptomatic GSV incompetence is characterized by lower extremity fatigue, heaviness, pain, itching and may progress to skin discoloration and leg ulceration (1-3). The traditional gold standard treatment of symptomatic GSV incompetence involved surgical stripping of the vein with flush ligation at the saphenofemoral junction. However, recent advances in endovascular techniques using radiofrequency ablation (RFA) and laser ablation have been shown to be as effective and have largely supplanted GSV stripping, with less morbidity and more acceptable cosmetic outcomes (4-8). Post-procedural treatment protocols for patients after GSV ablation typically involve a compression stocking therapy with the theoretical goal of reducing edema, ecchymosis, pain and facilitating vein closure. However, there is a lack of strong clinical evidence to support their use (9-11). In addition, patients often find compression stockings to be cumbersome and uncomfortable particularly in warm climates and seasons resulting in low adherence to compression therapy (10).

The reported duration of wearing compression stockings post ablation varies greatly and there is no consensus regarding optimal length of compression therapy. Bakker et al conducted a prospective randomized trial demonstrating that wearing compression stockings for longer than 2 days after GSV ablation lead to decreased pain and improved functional status during the first week after treatment (9). Conversely, Krasznai et al showed that compression for 4 hours vs 72 hours had no significant differences in post procedure pain or leg edema, or failure rates (10).

Although duration of compression after GSV ablation has been studied, there continues to be controversy over length of treatment and the benefits of compression (9-12). To further investigate this, we performed a randomized controlled trial comparing the use of thigh high compression stockings (30-40mmHg) for 7 days vs no compression post GSV ablation.
Methods

This prospective randomized controlled trial was conducted from 2009 to 2013 at New York University Langone Medical Center. The use of thigh-high 30-40 mmHg compression therapy for 7 days vs no compression therapy (24 hours of post-procedure bandages) following endovenous ablation of the GSV was evaluated. The severity of venous disease was measured by CEAP scale. Inclusion criteria consisted of documented GSV reflux on venous duplex, CEAP (2-5) disease, and a palpable pulse or ankle brachial index (ABI) >0.9. Exclusion criteria consisted of previous ipsilateral intervention, history of DVT, hypercoagulable state, concomitant phlebectomy, or CEAP class 6 disease. CEAP 6 disease was excluded because patients with active ulcers would likely benefit from further compression therapy such as an Unna boot. All patients that met our inclusion criteria were randomized on a 1:1 basis. If a patient underwent bilateral treatment, they were done on separate occasions. If the limb was initially randomized to the compression group, then during the subsequent procedure for the contralateral limb, the patient would be assigned to the opposite group.

The laser ablations were all 890nm at 7watts for total of 60-80 Joules/cm delivery. Radiofrequency ablation (RFA) was performed using the Covidien Closure FAST™ endovenous RFA catheter. The catheter was introduced in standard fashion through a 7-Fr sheath under ultrasound guidance. The initial trigger of the ablative catheter was performed at least 2cm peripheral to the saphenofemoral junction with two fires of the device and then one fire of the ablation at subsequent treatment levels for the entire GSV segment treated. The compression group was prescribed 30-40 mm Hg thigh high compression stockings for 24 hours after the procedure and then daily during waking hours for the remainder of the first seven days after the procedure.

Our primary endpoints were overall improvement in quality of life (QOL) on two scales, the venous clinical severity score (VCSS) and chronic venous insufficiency questionnaire (CIVIQ-2) at days 1, 7, 14, 30 and 90 post-procedure. Secondary endpoints were post procedure pain and bruising score. Pain was assessed using the visual analog pain scale daily for the first week. The pain scale score was categorized as mild pain 1-3, moderate pain 4-6, and severe pain 7-10. Bruising was calculated on a scale from 0 to 5. The scale was defined as no bruising=0, mild=1, moderate 2-3, and severe=4-5. Bruising score was evaluated by assessing photographs of the treated leg obtained one week post procedure. A blinded clinical research staff member that did not perform the procedure and was not involved in direct care of the patient made the final assessment of the bruising score based on photography. The photographs were taken with a digital single lens reflex camera in high definition in JPEG format with no compression allowing for the highest quality image to be produced for study. In order to determine the accuracy of the assessment there would have to be a gold standard measurement of bruising to which we could compare photography to clinical assessment, however this has not been done previously reported in the literature. This bruising model shown in this study allows for further refinement and qualitative analysis in future studies to allow for better assessment of this clinical finding. Procedural success was defined as a closed GSV with no flow by Doppler on follow up post ablation venous duplex.

Statistical analysis
Descriptive and comparative analyses of demographic and clinical characteristics between the post-procedural compression therapy and no compression therapy groups were performed using chi-square tests for categorical variables and t-test for continuous variables. All reported p-values are two sided and p<0.05 was considered statistically significant. Analyses were performed in SPSS version 20.0 (IBM SPSS Statistics, 2011).

**Results**

70 patients and 85 limbs were treated with EVA. 46 were randomized to compression and 39 to no compression therapy after ablation treatment (P=0.89). Baseline characteristics were similar for both groups. Gender distribution between the two groups were similar with a higher number of female patients in both groups, 77% women vs 76% women in the compression group and no compression groups respectively. The mean age of treated patients was also similar at 52 vs. 49 (years) in the compression and no compression group (P=0.928). The majority of patients were treated using RFA in 91% of the cases, whereas laser ablation was only used in 9% of patients. The distribution of CEAP class pre-procedure was similar between the two groups (p=0.77) (table 1).

With regard to primary outcomes, there was no significant difference in quality of life measures between the two groups. Both groups showed an improvement in overall symptoms on both VCSS and CIVIQ-2 QOL scales. However, there was no statistically significant difference in the VCSS scores pre-procedure (mean 5.69 vs. 5.61, p=0.89) and post procedure (mean 3.12 vs. 4.35, p=0.491) in the compression therapy and no compression therapy group respectively (table 1). CIVIQ-2 scores at 1 week (mean 36.9 vs 35.1, p=0.594) and at 90 days (mean 29.1 vs 22.5, p =0.367) were not statistically significant. This improvement in QOL was maintained at ninety day QOL follow up of 20% of patients included in the study with lower mean CIVIQ-2 scores (figure 1).

There were no significant differences in secondary outcomes of pain and bruising post-procedurally. Pain scores at day 1(mean 3.0 vs. 3.12, p =0.948) and at day 7(mean 2.11 vs 2.81,p =0.147) were not significantly different in the compression and no compression therapy groups respectively (Figure 2). The mean bruising score at 7 days post-procedure was (1.2 vs. 1.4, p=0.561) in the compression vs. no compression groups were equivalent. There was a 100% rate of GSV closure and no evidence of e-HIT as assessed by post-ablation duplex (table 1).

**Discussion**

The optimal duration and benefit of compression therapy following EVA remains controversial. Elderman et al conducted a randomized controlled trial (RCT) comparing 24h of post procedure bandages vs 1 weeks of compressive therapy. In this study, there was a small but significant reduction in post procedure pain during the first week and a decreased use of analgesics (11). Krasznai et al also conducted a recent RCT comparing compression for 4h vs 72 and showed no difference in leg edema or pain (10). Furthermore, the
shorter compression duration was associated with fewer complications such as blistering and skin irritation. Although there is no consensus on the therapeutic benefit of post ablation compression, most of the existing data has shown little to no benefit for duration of compression over two weeks and that the potential benefits of compression such as decreased pain, swelling, ecchymosis are small for non-ulceration venous disease (12).

In our current study, we compared compression therapy for one-week post ablation vs no compression to further investigate this controversial area in the treatment of venous insufficiency in patients without ulceration. Our results demonstrate that there was no significant difference in VCSS scores, CIVIQ-2 score, bruising, or pain score with or without compression therapy. Although not statistically significant, there was a trend toward better pain control during the first week post procedure in the compression group. This is a finding that is compatible with previous studies that demonstrated a tendency towards better pain control with compression, but the questionnaires used to score pain are different in these studies making it difficult to ascertain a true benefit (9-10). We do not believe that this finding is the result of a sample error. The sample size of our study was powered for the primary outcome, which was overall improvement in quality of life using the VCSS and CIVIQ-2 as outcome measures. Therefore, a sample error with respect to the study is not present as it was not powered for the secondary endpoint of post-procedure pain. Our report of a trend towards less pain with compression that was not statistically significant is an interesting finding that will need corroboration with a larger study powered to find a meaningful difference between the two management strategies with respect to pain as the primary outcome.

There were a small number of patients that underwent laser ablation (9%). Laser and RF endothermal techniques have been shown to be equal in regards to efficacy. The lower wavelength laser ablative devices used in the past had a reported difference in the postoperative pain with laser having worse pain scores than RF. However, in the advent of the higher wavelength laser ablative devices used contemporaneously and exclusively in this study, there is now randomized clinical trial data in the literature that suggests that lasers that are higher in frequency may have slightly less post operative pain and are equivalent in this regard to RF(16). The 890nm laser used in our study is supported in the existing literature comparing the VNUS ClosureFast system to laser ablation with similar outcomes in post-procedure discomfort. Therefore we included the small number of patients that underwent laser ablation as the endothermal venous ablation technique. The results should be generalizable to endothermal venous ablation procedures with the available existing technology that utilizes these higher frequency lasers and RF devices.

In regards to concomitant phlebectomies, our study specifically excluded patients with stab phlebectomies to avoid conflating the outcomes and creating a bias during the follow-up period. Subsequent to the study and follow up period, only 4 patients underwent a microphlebectomy after QOL evaluations had been completed. Therefore, the effect of stab phlebectomies on QOL was not measured in this study.

The rationale behind compression therapy resulting in less pain, ecchymosis, and better functional outcomes is not well founded and may be even less significant in the modern era of endovascular ablative treatments in comparison to traditional venous stripping. Our trial shows that there is a lack of significant evidence to support the routine use of compression therapy post ablation. This study supports previous trials that show very little, if any benefit of compression post procedure. The strengths of our study are that it is a
A randomized trial that assessed several outcome parameters (VESS, CIVIQ-2, pain, ecchymosis) relating to quality of life and patient satisfaction (13-15). Our inclusion criteria was objectively selected with pre-procedure documented reflux and documented CEAP 2-5 venous disease. Also, given that 100% of patients in both groups had documented GSV closure and no evidence of eHIT on post procedure duplex demonstrates that our venous treatments were highly effective without significant complications.

A limitation of this study is that it was not a blinded study which may introduce bias in these outcomes that are mostly subjective. In addition our long-term follow up was limited, and therefore post-procedure assessments of outcomes particularly the VCSS and CIVIQ-2 cannot be extrapolated from this data. Despite several attempts to contact patients to have them return for follow up or mail back the completed questionnaires, our 90 day follow up was 20% in both groups. However, given that the rate of follow up was equivalent in both groups, one can infer that it was not related to the treatment arm. Another limitation is that we did not strictly assess the post-procedural doses of pain medicine and compliance of stocking use in the compression group which may have influenced our outcome measures. However, this mimics real world experience with prescription of compression stockings and counseling on post-procedure pain control with medication in that adherence to physician recommendations is typically not strictly followed on an outpatient basis making these results more generalizable.

In conclusion, patients may derive a minimal benefit from better pain control during the first week post procedure with compression therapy. However, compression therapy does not significantly affect clinical or patient reported outcomes and may be an unnecessary adjunct following GSV ablation.

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<th>Compression</th>
<th>No Compression</th>
<th>P value (&lt;0.05)</th>
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<tr>
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<td>1.4</td>
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