Compression Stockings after Endovenous Laser Ablation of the Great Saphenous Vein: A Prospective Randomized Controlled Trial

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WHAT THIS PAPER ADDS

Currently, there is little knowledge on the optimal duration of compression stocking use after endovenous GSV ablation in terms of efficacy, but also in terms of patient satisfaction. This study demonstrates that pain is significantly reduced during the first week in the group of patients wearing the stockings for 7 days when compared with 2-day use. Also, physical function and vitality were better in the group of patients with 7-day use of stockings. No differences in results and complication rates were observed after 3 months. This study may change clinical practice as patients can be better informed on the possible counterpart of a short duration of stocking wear.

Objectives: To determine if the duration of wearing compression stockings after endovenous laser ablation (EVLA) of the great saphenous vein (GSV) has influence on pain and quality of life.

Methods: This was a prospective randomized controlled trial. Between December 2006 and February 2008, 109 consecutive patients with EVLA of the GSV were analyzed. Deep vein insufficiency, ulceration, more than one insufficient vein in one leg, and use of anticoagulants were exclusion criteria. Group A used compression stocking for 48 hours after therapy, group B for 7 days. Pain (visual analogue scale [VAS]) and quality of life (SF-36) were analyzed 48 hours, 1 week, and 6 weeks after therapy. Three months after treatment, duplex ultrasound imaging was performed to assess occlusion rates.

Results: Both groups (group A, $n = 37$; group B, $n = 32$) where comparable at baseline.
After 1 week, there was a significant difference in pain (VAS score 3.7 [$\pm$2.1] vs. 2.0 [$\pm$1.1], $p \leq .001$), and physical dysfunction (group A, 85.1 [$\pm$11.2] vs. group B, 95.7 [$\pm$10.1]; $p < .001$) as well as vitality (group A, 75 [$\pm$13.0] vs. group B, 83.7 [$\pm$13.4]; $p = .03$), all in favor of group B, which disappeared after 6 weeks. After 6 weeks, no significant differences in all endpoints were present. Duplex ultrasound imaging revealed complete GSV occlusion in all patients, while no cases of deep venous thrombosis had developed.

Conclusions: Prescribing compression stockings for longer than 2 days after endovenous GSV ablation (without simultaneous phlebectomies) leads to reduced pain and improved physical function during the first week after treatment.

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INTRODUCTION

Great saphenous vein (GSV) incompetence is the most common cause of chronic venous insufficiency. Associated symptoms range from mild conditions such as fatigue, heaviness, and itching to more serious conditions such as skin discoloration and leg ulceration. Over the last years, significant advances in GSV ablation using percutaneous techniques have emerged, including endovenous laser ablation (EVLA). EVLA has replaced surgical treatment by high ligation and stripping (HL/S) in many centers worldwide, due to greater patient satisfaction (office-based treatment, no incisions, faster recovery) and cost-effectiveness (no admission, no use of operation room facilities). The randomized controlled trials performed so far have shown equal results (at least) in terms of outcome,[1–5] even in the long term.[2,6–8] Compression stockings are frequently prescribed after HL/S in order to reduce pain and other associated symptoms.[9] It is unclear, however, whether this leads to any clinically observable benefit to the patient.[10]

In addition, the optimal duration of wearing compression stockings after HL/S or EVLA is unclear. One prospective study assessed the need to wear additional compression stockings for 4 weeks after inversion stripping of the GSV from the groin to the level of the knee.[11]

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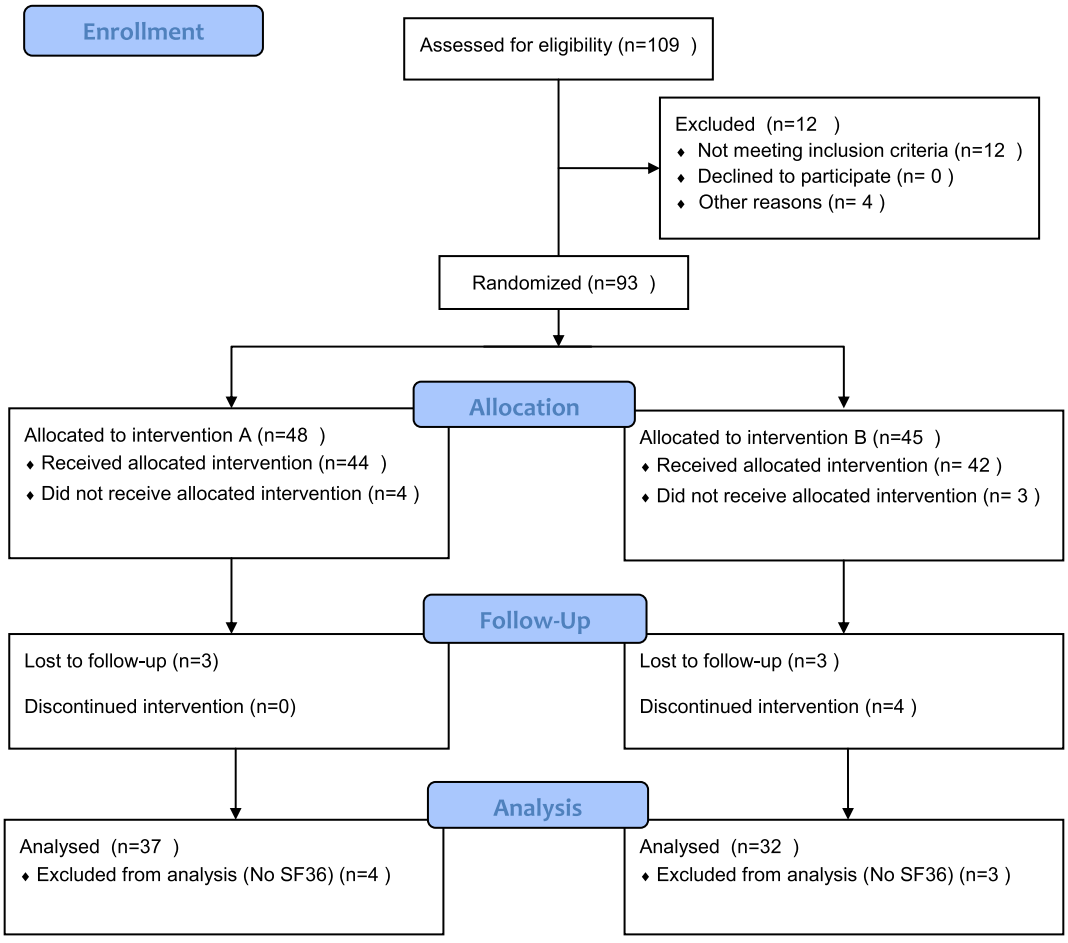

Figure 1. Flowchart of patient enrolment.

It showed that wearing a compression stocking has no additional benefit following elastic bandaging for 3 days in postoperative care after stripping of the GSV as assessed by control of limb edema, pain, complications, and time to return to work.

In patients treated with EVLA, no studies on the duration of wearing compression stockings have been performed so far.[12] One study prospectively evaluated the effect of eccentric compression applied by a crossed-tape technique on procedure-related pain occurrence after EVLA of the GSV. It showed that the intensity of postoperative pain was significantly reduced in the eccentric compression group compared with the non-compression one.[10]

It was our observation that many patients experience inconvenience when wearing compression stockings for a longer period of time. Therefore, our aim was to investigate whether shortening the duration of wearing compression stockings after EVLA had any influence on outcome in terms of pain and quality of life. We therefore conducted a prospective, randomized controlled trial, in which patients were randomized to wear compression stockings postoperatively for 2 or 7 days. In addition, all patients underwent duplex ultrasound imaging of the GSV 3 months after treatment to study the definitive occlusion rate in both groups to confirm that the period of compression had no influence on the occlusion rate after EVLA.

MATERIALS AND METHODS

Patients

This prospective randomized controlled trial took place from December 2006 until February 2008. A total of 109 consecutive patients were included. All patients were treated at the Center of Phlebology Emmen, a specialized outpatient clinic for treatment of lower limb venous disease. Patients were considered eligible for inclusion if they were between 18 and 65 years of age with symptomatic varicose veins due to GSV insufficiency. Exclusion criteria were deep venous insufficiency, coexistence of an ulcus cruris, use of anticoagulants or antiplatelet therapy, presence of more than one potentially treatable insufficient vein. After discussion with the institutional review board, ethical approval was not considered necessary as no additional invasive or other medical treatments were applied to the intervention group. Still, written informed consent was obtained from all patients.

Finally, 69 of the 109 included patients were analyzed. Forty patients were excluded because of incomplete informed consent ($n = 12$), no proper treatment ($n = 7$), early release of stockings ($n = 4$), incomplete SF-36 ($n = 7$), lost to follow-up ($n = 6$), other ($n = 4$). The flowchart according to the CONSORT statement is shown in Fig. 1.

Methods

After informed consent was obtained, patients were randomized into two groups before the start of treatment. Patients received a numbered sealed envelope at the day of treatment stating to which group they were allocated. This numbered envelope was blindly provided by one of the research nurses. At follow-up after 48 hours, 1 week, and 6 weeks of treatment, providers were still blinded. Both groups (A, $n = 37$; B, $n = 32$) were equal in baseline patient characteristics (age, sex, surgeon, clinical [part C of the Clinical, Etiologic, Anatomic, and Pathophysiologic] classification, and length of the insufficient GSV) (Table 1).

Group A (intervention group) wore compression stockings for 48 hours after treatment, while group B (control group) wore compression stockings for 7 days after treatment.

All patients were followed for 3 months after initial treatment. The visual analogue scale (VAS) for pain was recorded at 48 hours, 1 week, and 6 weeks. The SF-36[13] was scored, and physical examination was done at 1 week and 6 weeks. The physician assistant performing the follow-up was blinded to which group the patients were allocated. Occlusion rates were assessed at 3 months to see if there was any suggestion that the duration of compression might influence occlusion rates.

Treatment

Patients were treated in the supine position. The usual puncture site was 5–10 cm below the knee. The entire procedure was performed under duplex ultrasound guidance (Philips iU22 ultrasound system, Philips medical systems, The Netherlands). All patients were treated with a 810-nm diode laser with a bare-tip fiber (Diomed delta 15W; Andover, MA, USA), continuous mode, 14 W, delivering 70 J/cm. Perivascular local tumescent anesthesia (500 mL of NaCl 0.9%, 33 mL of lidocaine 1% with epinephrine (adrenaline) 1:200.000 and 1 mL of $NaHCO_3$ 8.4%) was used for the GSV. Additional sclerotherapy or phlebectomies were not performed simultaneously.

After treatment, the circumference of the ankle, the lower leg, the knee, and the upper leg was measured in order to estimate the size of the compression stocking (Mediven Struva®, AG hip, 35 mmHg) the patient should wear. They were fitted directly after treatment by the same person (RGB), and worn continually day and night until removal. Patients were advised to walk regularly (at least 3 times daily for 20 minutes) and prescribed standard Diclofenac (50 mg 3 times a day) during 10 days post-procedure. Pharmacological prophylaxis for deep venous thrombosis was not provided.

Table 1. Patient characteristics.

	Group A	SD	Group B	SD	*p* Value
Age (years)	49.5	12.7	51.3	11.1	NS
Weight (kg)	78.4	11.1	81.6	13.6	NS
Length (cm)	173	7.8	169	7.7	NS
GSV length (cm)	45.6	10.3	48.1	10.6	NS
C of CEAP	2.3	0.65	2.4	0.94	NS

CEAP = Clinical, Etiologic, Anatomic, and Pathophysiologic; GSV = great saphenous vein.

Endpoints

Primary outcome measures were quality of life as measured by the SF-36 questionnaire and pain (VAS score) at each visit. In addition, an ultrasound was performed 3 months after treatment to check occlusion of the treated GSV and the deep venous system. Also, postoperative morbidity (hematoma, occurrence of thrombophlebitis, edema) was assessed.

Statistics

Continuous variables were expressed as mean with standard deviation or median with range, and categorical variables as counts and percentages. The Shapiro–Wilk test, together with normality plots were used to assess normal distribution of the continuous variables. Differences between groups were evaluated by the Student *t* test or Mann–Whitney *U* test for continuous data and by the Fisher exact test or χ^2 test for categorical data. A post hoc power analysis with $\alpha = .05$ was performed to identify whether enough patents had been enrolled to show any significant differences in the primary outcome measures. A two-tailed $p < .05$ was considered to indicate statistical significance. All analyses were performed using SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

Quality of life (SF-36)

At 1-week follow-up, physical function (group A 85.1 [±11.2] vs. group B 95.7 [±10.1]; $p \leq .001$) and vitality (group A 75 [±13.0] vs. group B 83.7 [±13.4]; $p = .03$) were both significantly better in group B. A post hoc power analysis for these outcome variables showed a power of 98.5 and 77.8%, respectively. At 48 hours and 6 weeks postoperatively, no significant differences were observed between both groups (Tables 2 and 3).

Pain

At the first measurement, 48 hours postoperatively, no statistically significant differences were observed between the VAS scores in both groups. After 1 week, though, the VAS score in group A (2 days of stocking wear) was significantly higher than patients in group B (VAS score 3.7 [±2.1] vs. 2.0 [±1.1]; $p \leq .001$, Table 2). A post hoc power analysis showed a power of 98.5% ($\alpha = 0.05$) for this outcome

Table 2. Visual analogue scale score (pain).

Time	Group A	SD	Group B	SD	*p* Value
48 h	3.2	1.6	3.4	2.1	NS
1 week	3.7	2.1	2.0	2.0	<.001
6 weeks	1.6	1.3	1.9	2.0	NS

Table 3. Quality of life after 1 week and 6 weeks (SF-36).

Quality of life (SF-36)	Group	1 week			6 weeks		
		Mean	SD	*p* Value	Mean	SD	*p* Value
Physical function	A	85	11.21	<.001	97	6.38	NS
	B	96	10.06		96	9.92	
Social function	A	84	16.51	NS	99	3.12	NS
	B	94	17.08		99	3.12	
Role physical	A	73	37.44	NS	95	13.57	NS
	B	88	29.25		86	31.04	
Role emotional	A	86	30.89	NS	98	11.97	NS
	B	96	13.87		94	17.79	
Mental health	A	88	8.76	NS	91	7.15	NS
	B	92	8.36		91	8.33	
Vitality	A	75	13.30	.03	82	12.95	NS
	B	83	13.36		82	13.53	
Pain	A	66	21.19	<.001	87	12.30	NS
	B	86	17.98		84	20.04	
General health	A	79	11.00	NS	82	12.01	NS
	B	84	14.36		84	14.25	

variable. These differences were no longer present at 6 weeks' follow-up.

After 3 months, 100% occlusion of the GSV in both groups was seen by duplex ultrasound imaging, while none of the patients developed deep vein thrombosis in both groups.

Morbidity

The morbidity rate was comparable in both groups at all times: 22 patients (61.1%) in group A suffered from postoperative morbidity after 1 week (only hematoma), compared with 14 patients (50.0%) in group B ($p = .36$).

DISCUSSION

As GSV incompetence is a commonly observed medical problem all over the world, many physicians are faced by this problem. Although treatment strategies have evolved over the last decades, with the introduction of effective minimal invasive percutaneous techniques such as EVLA, postoperative care is still not standardized due to a lack of feasible studies. In this prospective randomized trial it is clearly demonstrated that wearing elastic stockings after EVLA for more than 2 days does not lead to any clinically observable benefit after 6 weeks while occlusion rates as measured by duplex ultrasound imaging are comparable. Also, complication rates are comparable.

However, postoperative pain is significantly reduced when measured 1 week after treatment and also the physical function and vitality (as measured by the SF-36) is significantly better in the group of patients wearing the stockings for 1 week. To the best of our knowledge this is the first study directly comparing the duration of wearing compression stockings after EVLA.

Some study limitations have to be mentioned. It is clear that the present results only apply to patients in whom GSV incompetence is treated by EVLA. It is important to recognize that this was a feasibility study and that results in terms of efficacy cannot be provided as the present study is underpowered. For such a study, given a 95.0% efficacy rate of EVLA (occlusion after 3 months, yes/no), and detecting an absolute difference of 5.0% in efficacy, a minimal of 868 patients should have been enrolled. The duplex ultrasound at 3 months' follow-up was performed to assess the safety of the different patient categories, not to analyze superiority of one of the protocols in terms of efficacy. Also, it is obvious that our results cannot be generalized to other treatment options for GSV incompetence such as phlebectomies or sclerotherapy. Also, if phlebectomies are to be performed simultaneously, our results might not be applicable. Another limitation is the loss of 40 patients after randomization due to a variety of reasons. As the number of patients included is relatively small, we cannot exclude that different results may have shown up without the loss of follow-up of these patients. In addition, four patients in the control group (group B, stockings for 7 days) discontinued stocking wear early. These patients were not analyzed. However, if these patients had been analyzed on an intention to treat base, this might have influenced the results. Patient adherence to prescribed postoperative medication was not assessed regularly, as such we cannot exclude that this might also influence results in terms of pain. Another issue that needs to be addressed is the kind of laser and tip used. It would be interesting to know whether newer laser generations or the use of another tip another tip[14] might have led to other results. Further research is warranted in this area.

Nevertheless, in our opinion, the results of the present study are important for patients and their physicians. From a medical point of view, compression stockings do not have to be prescribed for more than 2 days, as clinical results and morbidity rates seem to be comparable in both groups. Pain and quality of life are among the most important parameters when it comes to patient satisfaction, however. We can therefore not ignore the observation that 7-day use of compression stockings leads to better results in terms of these parameters. We therefore suggest the following algorithm: the patient should wear compression stockings after EVLA for at least 48 hours after treatment. After careful informed consent, in which the patient is informed on the possible consequences, the patient

is then free to decide whether the inconvenience of wearing the stockings outweighs the potential possible pain and reduced physical functioning.

FUNDING

None.

CONFLICT OF INTEREST

None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.ejvs.2013.08.001.

REFERENCES

1 Johnson CM, McLafferty RB. Endovenous laser ablation of varicose veins: review of current technologies and clinical outcome. *Vascular* 2007;**15**:250–4.
2 Christenson JT, Gueddi S, Gemayel G, Bounameaux H. Prospective randomized trial comparing endovenous laser ablation and surgery for treatment of primary great saphenous varicose veins with a 2-year follow-up. *J Vasc Surg* 2010;**52**:1234–41.
3 Disselhoff BC, der Kinderen DJ, Moll FL. Is there recanalization of the great saphenous vein 2 years after endovenous laser treatment? *J Endovasc Ther* 2005;**12**:731–8.
4 Disselhoff BC, der Kinderen DJ, Kelder JC, Moll FL. Randomized clinical trial comparing endovenous laser ablation of the great Saphenous vein with and without ligation of the sapheno-femoral junction: 2-year results. *Eur J Vasc Endovasc Surg* 2008;**36**:713–8.
5 Rasmussen LH, Bjoern L, Lawaetz M, Blemings A, Lawaetz B, Eklof B. Randomized trial comparing endovenous laser ablation of the great saphenous vein with high ligation and stripping in patients with varicose veins: short-term results. *J Vasc Surg* 2007;**46**:308–15.
6 Carradice D, Mekako AI, Mazari FA, Samuel N, Hatfield J, Chetter IC. Clinical and technical outcomes from a randomized clinical trial of endovenous laser ablation compared with conventional surgery for great saphenous varicose veins. *Br J Surg* 2011;**98**:1117–23.
7 Darwood RJ, Theivacumar N, Dellagrammaticas D, Mavor AI, Gough MJ. Randomized clinical trial comparing endovenous laser ablation with surgery for the treatment of primary great saphenous varicose veins. *Br J Surg* 2008;**95**:294–301.
8 Spreafico G, Kabnick L, Berland TL, Cayne NS, Maldonado TS, Jacobowitz GS, et al. MA. Laser saphenous ablations in more than 1,000 limbs with long-term duplex examination follow-up. *Ann Vasc Surg* 2011;**25**:71–8.
9 Biswas S, Clark A, Shields DA. Randomised clinical trial of the duration of compression therapy after varicose vein surgery. *Eur J Vasc Endovasc Surg* 2007;**33**:631–7.
10 Lugli M, Cogo A, Guerzoni S, Petti A, Maleti O. Effects of eccentric compression by a crossed-tape technique after endovenous laser ablation of the great saphenous vein: a randomized study. *Phlebology* 2009;**24**:151–6.
11 Houtermans-Auckel JP, van Rossum E, Teijink JA, Dahlmans AA, Eussen EF, Nicolai SP, et al. To wear or not to wear compression stockings after varicose vein stripping: a randomised controlled trial. *Eur J Vasc Endovasc Surg* 2009;**38**:387–91.
12 Mosti G. Post-treatment compression: duration and techniques. *Phlebology* 2013;**28**(Suppl. 1):21–4.
13 Ware Jr JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;**30**:473–83.
14 Doganci S, Demirkilic U. Comparison of 980 nm laser and bare-tip fibre with 1470 nm laser and radial fibre in the treatment of great saphenous vein varicosities: a prospective randomised clinical trial. *Eur J Vasc Endovasc Surg* 2010;**40**:254–9.