THERMOCOAGULATION OF THE GREAT SAPHENOUS VEIN WITH EVRF

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ABSTRACT

Introduction: Endovenous treatment of the great saphenous vein (GSV) is already well known and used worldwide. The last decade a lot of new treatment modalities have been introduced like different fibers for EVLA, steamablation, foamsclerosis and other treatments like Sapheon and Clarivein. A new method for ablation is thermocoagulation with the EVRF system. Previous studies have already demonstrated that this is efficient for treating small veins like telangiectasia. In this study we would like to assess the efficacy in treating the GSV insufficiency.

Materials and methods: In UZ Leuven, Belgium we did a prospective trial were we included 40 patients with insufficiency of the great saphenous vein. The endpoints were occlusion rate at 1 month and 6 months assessed with ultrasound, pain score, ecchymosis score, satisfaction score and QOL score.

Results: Ecchymosis score is 0.02, pain score (0 tot 10) at day 2 is 2.5 and at day 10 0.6. Satisfaction score is 8.9/10. QOL score (20 to 100) is diminished from 35.1 to 27. 1 paresthesia was recorded. Occlusion rate at 6 months is 92.5%.

Conclusion: We can conclude that according to these results, EVRF is a safe and efficient treatment for treating reflux of the great saphenous vein.

Key words: endovenous ablation, RFA, varicose veins

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INTRODUCTION

Varicose vein insufficiency is a very common pathology. Until recently the gold standard treatment for this superficial venous incompetence was crossectomy and stripping of the saphenous vein [1]. This treatment has some disadvantages like postoperative pain, hematoma in the stripping section, paresthesia and a high recurrence rate[2-3]. Endovenous treatment has been introduced a decade ago as a minimally invasive alternative. Since 1999 a variety of different endovenous treatments has been introduced. New products like Sapheon and Clarivein as well as steamablation and different catheters for laserablation and RFA are on the market. All endovenous treatments try to avoid the disadvantages of classical crossectomy and stripping.

Thermocoagulation with EVRF is a treatment were energy is delivered in the vein which will cause a destruction of the endothelial cells and finally a collaps of the vein. This way of delivering energy is already well known for the treatment of small veins using a pen and gives good results according to Dr Richard and Dr Chardonneau.

The purpose of this study is to see whether this thermocoagulation can also be used for the ablation of the GSV.

MATERIALS AND METHODS

Patient selection

In this prospective study 40 patients were included with a unilateral incompetence of the great saphenous vein between November 2011 and March 2012. These patients were all treated in the University Hospital of Leuven, Belgium.

All patients had a preoperative ultrasound evaluation by an independent experienced lab technician. Only patients with a unilateral GSV incompetence were included, so

patients with a concomitant incompetence of the small saphenous vein or accessory vein were excluded. Other exclusion criteria were deep vein insufficiency, hypercoagulopathy, patients on therapeutical anticoagulation and hypocoagulopathy, pregnancy, occlusive peripheral arterial disease and a wide venous diameter at the junction (more than 15mm).
The CEAP classification was determinated for each patient.
This trial was approved by the Ethical Committee of UZ Leuven.

Technical aspects

The 40 patients were treated under local, spinal or general anesthetics. A preoperative Quality of life (QOL) score was filled in by the patient. This QOL score was a CIVIQ2 score, a questionnaire with 20 questions about psychological, pain, physical and social aspects of life. This score has been used numerous times and is a valuable and reliable scale[4]. The higher the score the lower is the Quality of life.

Prior to surgery, the veins were marked and duplex evaluation was done while the patient is standing.

The patient is placed in an anti-trendelenburg position to puncture the GSV at its lowest point of incompetence. A guide wire and 6F sheath is introduced. The CR45i Catheter is placed 1.5 cm to 2 cm from the saphenofemoral junction. The patient is placed in trendelenburg. Tumescent anesthesia is given around the vein ultrasound guided, approximately 10cc/cm. We used NaHCO3 1.4% with 10cc xylocaine 2% with adrenaline. According to the diameter of the vein, 25W or 20W is delivered. The catheter is pulled back gradually, 0.5 cm every 3 beeps, as the tip of the catheter is 0.5 cm long. No extra compression is necessary.

Concomitant phlebectomies were performed in almost all cases, but were not performed around the GSV tract in the thigh.

After treatment a compression stocking (class 2) was applied for 4 weeks, the first 10 days day and night. There was no pain medication prescribed, but if necessary Ibuprofen or paracetamol could be taken and needed to be noted. Low molecular weight heparine was only given in a prophylactic dose when a risk factor as previous DVT or obesitas was present.

There was a clinical follow-up after 1 week, 1 month and 6 months. At 1 week the ecchymosis score was noted. This is a score were the ecchymosis is measured and divided by the total length of the treated vein. A QOL questionnaire was filled in as well as the patient satisfaction score (0-10). Pain score was a VAS scale (0-10) and noted at day 2, 5, 7 and 10.

At 1 month and 6 month a duplex evaluation was performed. A GELEV (Groupe d' Evaluation des Lasers et de l'Echographie Vasculaire) scale was used to measure the grade of occlusion. This score not only gives you the occlusion rate but also the difference in diameter compared with preoperative measurements.

Statistics

Data are presented as frequencies and percentages for categorical variables, or mean for continuous variables.

Differences between time points with respect to occlusion and quality of life were analyzed using linear models, where correlations between repeated measurements were accounted for by modeling an unstructured residual covariance matrix. Bonferroni step-down correction was applied to account for multiple testing resulting from multiple pairwise tests between time points and testing occlusion at various specific locations.

RESULTS:

Between November 2011 and March 2012, 40 patients were treated. The mean age was 50 years. Of this 40, 28 patients were female. The mean BMI was 25.2. 22/40 patients had a standing profession.

The CEAP classification showed a predominance for C2, 34/40, 1 C1, 3 C4, 1 C5 and 1 C6.

General anesthesia was used in 30/40 patients, 2 under spinal and 8 under local anesthesia. Preoperative mean diameter was 6.5 mm.

The total energy delivered was measured and the mean was 7365.8 J. The average treated vein length was 37.2 cm. Postoperative LMWH was given to 11 patients.

Analgesia was recorded at 1 week and 1 month. Total analgesia taken was 0.7 and mean of 0.9 days. The ecchymosis score was noted at the clinical follow-up at 1

week and was 0.02 with a maximum score of 0.13. Pain score was at day 2 2.5, at day 5 2.0, at day 7 1.6 and at day 10 0.6..

Incapacity to work was recorded and there was a mean of 10.2 days. 1 patient had a paresthesia of the saphenous nerve, and there was a mean of 1.1 days of periphlebitis.

The patient satisfaction score was 8.9/10.

The QOL questionnaire was filled in three times by the patient. There was a mean score of 35.2 preoperative, 38.5 at 7days and 27 at 1 month.

The occlusion rate was measured at 1 month and at 6 months postoperative according to the GELEV score. At 1 month all veins were occluded with 34 2a scores and 6 2b scores. At 6 months, 92.5% of the GSV's were occluded with 4 veins with a diameter reduction of >30% (2b), 23 veins had a diameter reduction of >50% (3) and 10 veins were only a fibrotic cord (4). The three veins which were not occluded were 1 score 0 and 2 score 1b, where only a narrow lumen was le.

DISCUSSION

Endovenous ablation of the greater saphenous veins is a safe and efficient treatment used worldwide. Several ways to deliver the right amount of energy into the vessel have been suggested. In this pilot study we evaluated the efficacy of the thermocoagulation with EVRF. This way of energy delivery is already know and has proven already its benefit for the treatment of teleangiectasia. It can also be used for the treatment of GSV with a long catheter with a 0.5 cm tip (CR 45i catheter).

Occlusion rate was 92,5% which is comparable with other endovenous treatments on the market. Of the veins which were not occluded, 1 was still open and with reflux. Probably this was a technical failure. The other two veins were only partial occluded, but not refluxing. We expect that after another 6 months these two veins will be occluded.

The complication rate were very low with 1 paresthesia, 1.1 days of periphlebitis. There was no DVT or thrombophlebitis noted. There was a very low ecchymosis score and a low painscore. The QOL diminished from 35.2 to 27.

CONCLUSION

EVRF is a safe and efficient treatment for treating GSV incompetence with a low painscore, no ecchymosis, high quality of life and an occlusion rate at six month of 92.5%.

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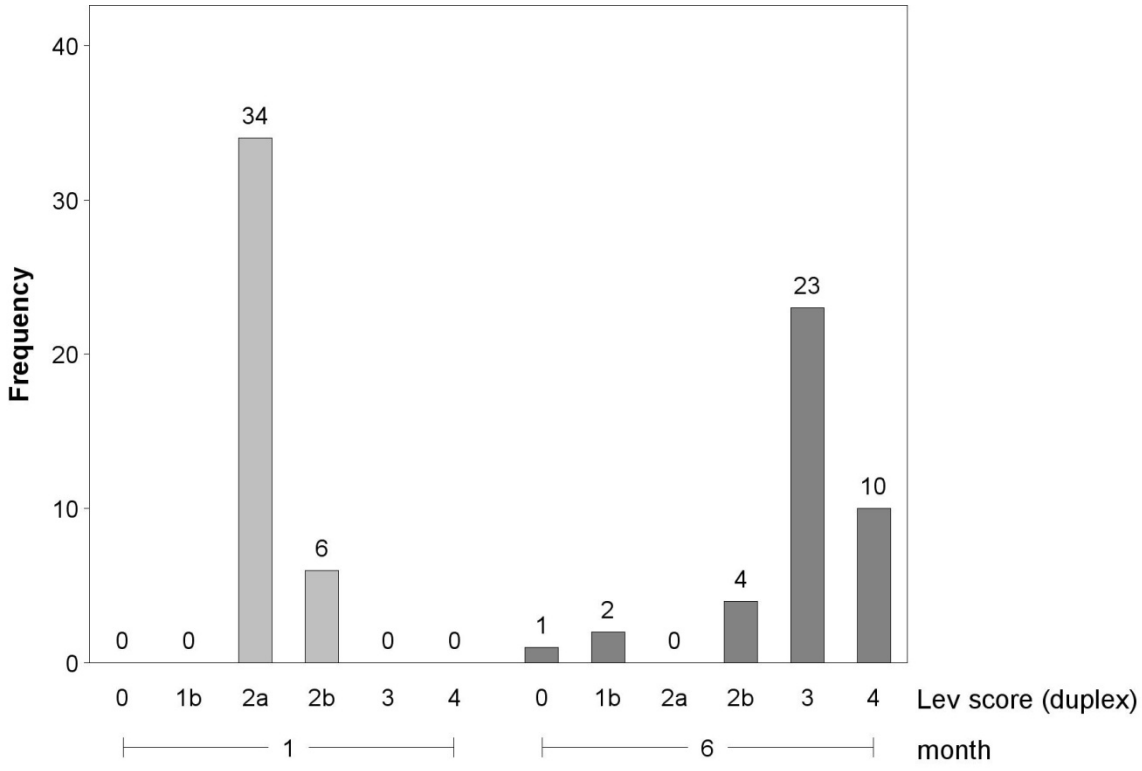
TABLES:

Table

	Statistics					
variable	**N**	**mean**	**std**	**median**	**min**	**max**
age	40	50.1	14.9	50.5	19.0	84.0
CEAP (1-6)	40	2.3	0.9	2.0	1.0	6.0
BMI	40	25.2	4.5	24.9	17.6	38.2
Total Joules	40	7365.8	2258.6	7607.5	3025.0	12350.0

	1 Month		6 Month	
Lev score (duplex)	N	Percentage	N	Percentage
0	0	0.0	1	2.5
1b	0	0.0	2	5.0
2a	34	85.0	0	0.0
2b	6	15.0	4	10.0
3	0	0.0	23	57.5
4	0	0.0	10	25.0



GELEV score

- **Lev 0: no occlusion, refluxing vein, unchanged vein**
- **Lev 1a: partial occlusion with proximal reflux**

- **Lev 1b: partial occlusion without reflux**
- **Lev 2a: complete occlusion with unchanged or larger diameter**
- **Lev 2b: complete occlusion with diameter reduction >30%**
- **Lev 3: complete occlusion with diameter reduction >50%**
- **Lev 4: fibrotic cord, vein not visible**