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Endovenous Laser Ablation of the Great Saphenous Vein Using a Bare Fibre versus a Tulip Fibre: A Randomised Clinical Trial

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WHAT THIS PAPER ADDS?

- This study shows how some complications of endovenous laser ablation can be avoided. It can influence the use of endovenous laser as a treatment of saphenous vein reflux.

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ABSTRACT

Objective: This clinical trial aimed to evaluate the clinical results of the use of a tulip fibre versus the use of a bare fibre for endovenous laser ablation.
Methods: In a multicentre prospective randomised trial 174 patients were randomised for the treatment of great saphenous vein reflux. A duplex scan was scheduled 1 month, 6 months and 1 year postoperatively.
Ecchymosis was measured on the 5th postoperative day. In addition, pain, analgesics requirement, postoperative quality of life (CIVIQ 2) and patient satisfaction rate were noted.
Results: Patients treated with a tulip fibre had significantly less postoperative ecchymosis (0.04 vs. 0.21; $p < 0.001$) and pain (5th day) (1.00 vs. 2.00; $p < 0.001$) and had a better postoperative quality of life (27 vs. 32; $p = 0.023$). There was no difference in analgesic intake ($p = 0.11$) and patient satisfaction rate ($p = 0.564$). The total occlusion rate at 1 year was 97.02% and there was no significant difference between the two groups ($p = 0.309$).
Conclusion: Using a tulip fibre for EVLA of the great saphenous vein results, when compared with the use of a bare fibre, in equal occlusion rates at 1 year but causes less postoperative ecchymosis and pain and in a better postoperative quality of life.

Purpose

In this multicentre randomised prospective trial, we wished to evaluate the clinical use of a new safety fibre tip,[1] the tulip fibre.

Can the use of this safety fibre tip avoid some of the imperfections of endovenous laser ablation (EVLA)? In this clinical trial, two patient groups were compared: one in which a bare fibre was used and a second one using the tulip fibre. Primary outcome factors are the possible side effects of the treatment: the amount of used analgesics, postoperative pain, the appearance of postoperative ecchymosis, patient satisfaction rate and a postoperative quality-of-life (QoL) score (CIVIQ 2). Secondary outcomes were the occlusion rates at 1 month, 6 months and 1 year postoperatively.

Introduction

Endovenous laser ablation (EVLA) has been introduced as a minimally invasive alternative to 'stripping' in the treatment of saphenous vein reflux. Different laser wavelengths are available. This treatment results in a substantially lower morbidity, shorter periods of sick leave and less postoperative pain as compared with a classical stripping.[2–7] Nevertheless, certain problems such as postoperative ecchymosis, bruising and pain jeopardise the recovery.

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From a technical point of view, EVLA also has some adverse effects: the bare fibre used for EVLA is a rigid fibre. When this fibre is introduced in a saphenous vein, which usually has bends and areas of tortuosity, the fibre always has a tendency to straighten. As a consequence of this straightening, and since the vein is more compliant than the fibre, the fibre tip frequently hits the vessel wall.[8] Examining the fibre location on perioperative ultrasound control, we can see that the fibre tip is most frequently situated in a very eccentric position within the vein, with the tip touching the vein wall.

Tumescent anaesthesia induces compression of the vein around the fibre and can alleviate the tendency towards an eccentric position of the fibre tip.

Even then, however, particularly in larger veins, the fibre tip remains in an eccentric position. In this situation when the energy is delivered to the fibre tip, direct contact between the fibre tip and the vessel wall results in a destruction and ulceration or perforation of the vein[9,10]; other parts of the vein wall are unaffected.[1,9,10] The resulting uneven application of energy may be the cause of some of the complications of EVLA, such as postoperative ecchymosis, inflammation around the treated vein (periphlebitis) and pain.[11] A histological study showed that avoiding the direct contact between the fibre tip and the vein wall, and centring the fibre tip intraluminally, results in a more homogeneous vein wall destruction, fewer vein wall perforations and less perivenous tissue destruction.[1] The purpose of this clinical trial is to see whether the use of this tulip fibre may possibly result in fewer side effects after EVLA.

Materials and Methods

Patient group

Between March 2010 and January 2011, 174 patients with a unilateral great saphenous vein (GSV) incompetence were treated in two hospitals: Sint-Andriesziekenhuis Tielt and the University Hospital Gasthuisberg Leuven, Belgium.

Patients who met the inclusion criteria had insufficiency of the GSV with functional and/or aesthetic inconvenience. In all patients, the diagnosis of venous insufficiency was made by clinical evaluation and Duplex studies. Only unilateral treatments were included. Patients with concomitant insufficiency of the short (SSV) and/or anterior saphenous vein (ASV) were excluded.

Other reasons for exclusion were deep venous insufficiency, patients with a venous diameter exceeding 15 mm and cross-dilatation with two or more incompetent side-branches, therapeutical anticoagulation or hypocoagulopathy, hypercoagulopathy or thrombophilia, occlusive peripheral arterial disease (ankle-brachial pressure index <0.85) and pregnancy. All included patients were a minimum age of 18 years.

Approval was obtained from the ethics committee of the University Hospitals Leuven and the local research committee of the Sint-Andries hospital (Tielt) and the research was carried out according to the guidelines set out in the Declaration of Helsinki.

A total of 215 patients met the inclusion and exclusion criteria and 174 of them were randomised after signing an informed consent form (Fig. 1, Consort flow chart). Eighty-seven patients were treated using a tulip fibre, while the remaining 87 were treated with a bare fibre. We used a 1470-nm diode laser (InterMedic°, Barcelona, Spain and Quanta Systems°, Olona Solvate Italy). Randomisation was done using numbered and sealed envelopes.

The patients were classified using the CEAP clinical classification (clinical, etiology, anatomy, pathophysiology).

Description of the tulip fibre

This safety fibre[1] consists of a bare fibre with a hollow tube, fixed at the distal end of the fibre. This tube has tulip-shaped, self-expandable blades at its distal end (around the fibre). The tube is folded into an outer guiding catheter, which permits easy access to the vein undergoing treatment. When the outer guiding catheter is withdrawn (pullback), the tulip-shaped blades at the distal end of this tube expand and push away the vein wall (Fig. 2). This expansion centres the fibre-tip intraluminal and thus avoids the direct contact between the fibre tip and the vein wall. It also prevents pushing the fibre further intraluminally into the deep system.

The tube is made of stainless steel, which has excellent mechanical and chemical resistance to high temperatures.

Technique

Prior to surgery, detailed duplex ultrasound mapping and grading of the superficial, deep venous and perforator systems was performed in the standing position, including measurement of the diameter of the incompetent saphenous vein at three reference points (2 cm distal to the saphon-femoral junction (SFJ), mid-thigh and knee). From these measurements, we calculated the average diameter of the vein. The incompetent tributaries and perforating veins were marked on the skin.

Access to the GSV was obtained by puncture under ultrasound guidance, at the most distal reflux site. The laser fibre was positioned 1.5 cm distal to the SFJ. Its position was verified by perioperative ultrasound and by visualisation of the red aiming beam through the skin, which disappears on entering the common femoral vein. Prior to laser ablation, a large quantity of tumescent anaesthetic (40 ml Lidocaine 1% diluted with 500 ml Na HCO3 1.4%) was injected around the GSV, under ultrasound control. At least 300 ml of fluid was injected around the target vein.

The majority of patients ($n = 108$) were treated with single local tumescent anaesthesia. The remaining patients received additional general ($n = 65$) or spinal ($n = 1$) anaesthesia.

All patients were treated in the Trendelenburg position and perioperative manual compression was avoided since such compression facilitates direct contact between the fibre tip and the vein wall, thus increasing the risk of perforation.

All GSV ablations were accompanied by a Muller phlebectomy. Phlebectomies were not performed in the immediate vicinity of the treated GSV, in order not to interfere with the measurement of ecchymosis resulting from the EVLA.

Postoperative care and follow-up

Compression stockings (class 2) were applied for 3 weeks postoperatively. All patients were treated in an outpatient setting and were encouraged to return to normal activities as soon as possible. A prescription for Diclofenac 75 was given on discharge with the instructions only to take them if they became aware of pain or inflammation in the treated leg and then to take two capsules daily. Only patients at risk (history of deep venous thrombosis (DVT) or superficial thrombophlebitis, obesity body mass index (BMI) > 35) received DVT prophylaxis in the form of low-molecular-weight heparin (Enoxaparine 40 mg) for 10 days (thrombophilia was an exclusion criterion).

Clinical follow-up appointments were scheduled at 5 days, 1 month, 6 months and 1 year postoperatively. Several clinical scores were used: level of analgesic intake, a visual analogue pain score (VAS), a postoperative QoL score, an ecchymosis score and the patient satisfaction rate.

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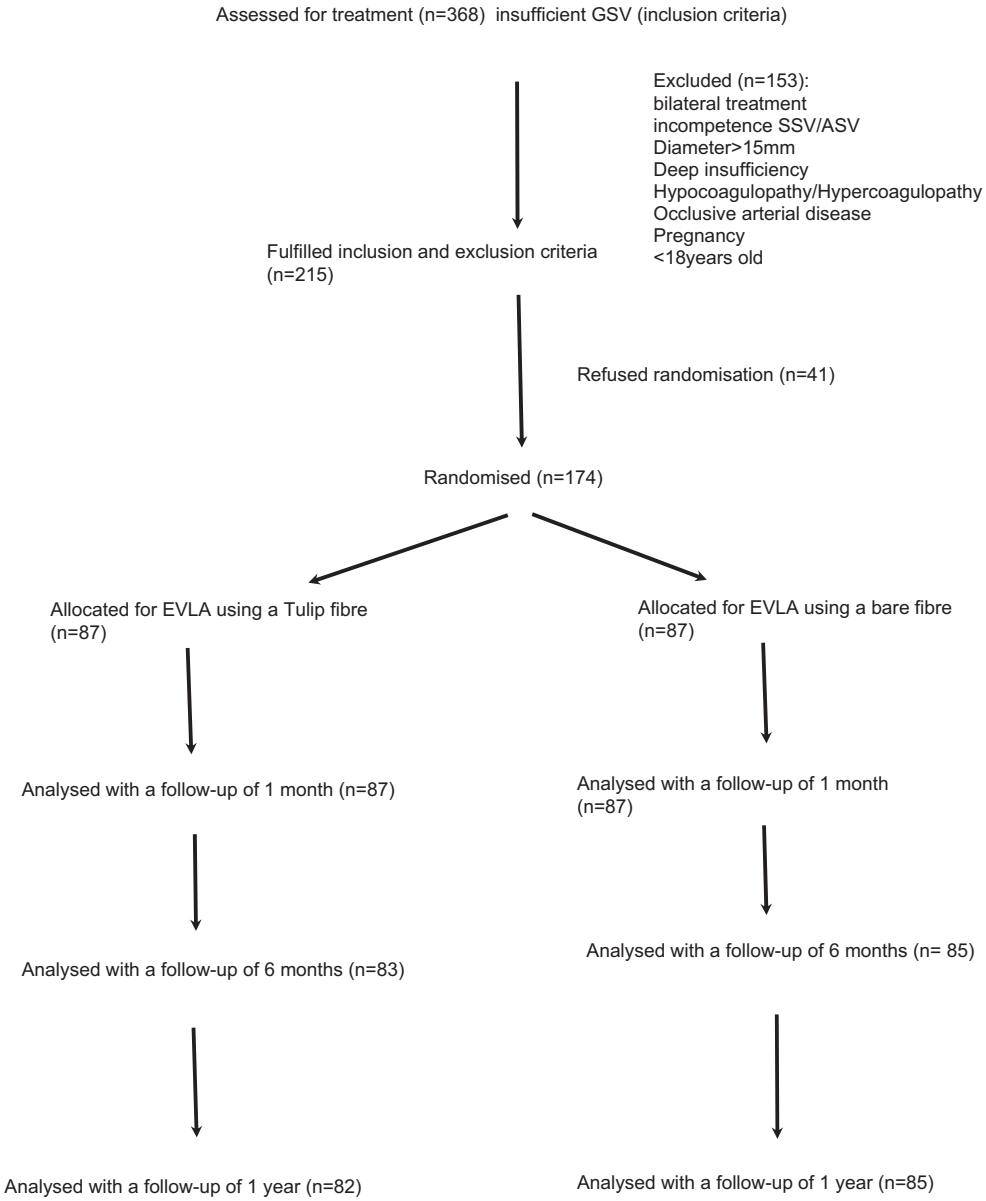

Figure 1. Consort flow chart.

A QoL questionnaire (CIVIQ), originally designed to analyse changes in QoL caused by venous insufficiency, was used to analyse the 2-week postoperative morbidity caused by the treatment. This 20-item questionnaire (CIVIQ2) provides a profile on four QoL dimensions (psychological, pain, physical and social) specific to venous disorders in the lower limb. The CIVIQ2 has been demonstrated to be a valid, reliable, stable and sensitive scale.[12,13] The QoL questionnaire had to be completed on the 14th postoperative day and to be returned at the 1 month postoperative check-up.

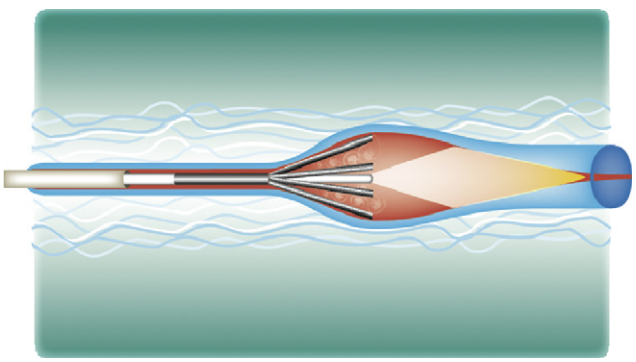

Figure 2. The tulip fibre.

In order to evaluate ecchymosis, we developed a scale in which the postoperative ecchymosis around the ablated vein was measured in square centimetres (cm^2), and this measured surface was divided by the length of the treated vein. Measurement of ecchymosis was performed at the 5th postoperative day. The patients fulfilled a visual analogue pain score (0–10) at the first clinical control (5th postoperative day). Another visual analogue pain score was filled in to accompany the QoL questionnaire. This second VAS measured average pain intensity for the first 2 postoperative weeks. The patients' satisfaction rate was measured using a VAS (0–10) and included the written questionnaire. Patients were blinded concerning which fibre was used and filled in the questionnaires in the absence of the treating consultant.

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A duplex scan was scheduled at 1 month, 6 months and 1 year. We used the Groupe d' Évaluation des Lasers et de l'Échographie Vasculaire (GELEV) score (Table 3) to interpret the occlusion rate. In this score the diameter of the treated vein is compared to the diameter measured in the preoperative duplex mapping.[14] For this purpose, we used the proximal measured diameter of the treated vein, which is located 2 cm distal to the SFJ. This diameter was compared at the various outpatient reviews, and the veins were classified using the GELEV score. These duplex controls were carried out by independent, blinded radiologists.

Data analyses were done by a study nurse and an independent registrar.

Calculation of energy deposits

We use the term linear endovenous energy density (LEED)[15] to refer to the amount of energy in Joules divided by the treated vein length in centimetres. The term endovenous fluence (EF)[8] is used to describe the quotient of the energy in Joules delivered to the approximated inner vessel surface (calculated using the mean diameter of the three reference diameters measured preoperatively with the patient in the standing position). The advantage of using EF is that it makes it easy to compare energy used in treated veins with various diameters, since the diameter is included in the calculation of fluence.

Statistical evaluation

Statistical analysis was performed using SPSS 19.0 (Statistical Package for the Social Sciences). For correlation analysis, we used the Spearman correlation test. Inter-group variances for unpaired continuous and ordinal data (patient data) were evaluated non-parametrically using the Student's *t*-test. We used the Mann–Whitney *U* test to evaluate the clinical results. An α-level of significance of 0.05 was used. A linear regression model was used to correct the influence of a different patient parameter (LEED and BMI) on the side effects. To compare the occlusion rates (primary outcome factor), non-inferiority was investigated using Newcombe's 95% CI for the difference of two independent proportions (Altman et al., 2000). Calculations were based on the 'scoreci' function from the 'PropsCIs' library (Scherer, 2010) in R 2.14.1 (The R Foundation for Statistical Computing, 2011).

Results

In total, 368 patients were assessed for treatment of an incompetent GSV. One hundred and fifty-three patients were excluded according to the protocol. Another 41 patients refused to be randomised.

The mean age was 51.4 years (SD: 13.3) and the female predominance was 75.8%.

The CEAP classification showed that the vast majority of the treated veins were uncomplicated and there was no difference between the two groups: 61 C2, 20 C3, 3 C4, 0 C5, 3 C6 (bare fibre); 68 C2, 8 C3, 7 C4, 1 C5, 3 C6; the median was C2 for both.

The two patient cohorts were similar (Table 1) except for LEED and BMI.

The average energy used in patients treated with a bare fibre was on average 63.4 J cm^{-1} and 59.6 J cm^{-1} in patients treated with a tulip fibre. This difference was statistically significant ($p = 0.007$). Nevertheless, no statistically significant difference could be found when comparing the EF in the two groups ($p = 0.3$). The average BMI figures were 26.8 and 25.3 in the bare-fibre group and the tulip-fibre group, respectively ($p = 0.04$).

Postoperative 'ecchymosis' is mainly due to vein wall perforations. Patients treated with a bare fibre had significantly more ecchymosis compared to patients treated with a tulip fibre (0.21 vs. 0.04, $p < 0.001$). These patients also had a significantly higher pain score measured on the 5th postoperative day (median 2.00 vs. 1.00, $p < 0.001$). There was no difference in the average 'pain' during the first 2 postoperative weeks. Patients treated with a bare fibre, as compared to those treated with a tulip fibre, needed somewhat more 'analgesics' (number of tablets respectively: median 1.0 vs. 0.0, $p = 0.11$) and for a longer period (respective median number of days: 1.0 vs. 0.0; $p = 0.11$) but this difference was not statistically significant (Table 2).

Table 1
Patients characteristics.

	Tulp fibre	Bare fibre	
n	87	87	
Average age	51.41 (SD:13,4)	52.29 (SD:13,2)	$p = 0.66$
BMI	25.36 (SD:3.7)	26.81 (SD:5.06)	$p = 0.038$
Max diameter	7.4 mm (SD:2.7)	7.5 (SD:2.8)	$P = 0.73$
Mean diameter	5.7 mm (SD:1.8)	5.9 mm (SD:2.1)	$p = 0.50$
Length	36.3 cm (SD:8.4)	34.16 cm (SD:10.9)	$p = 0.14$
LEED	59.6 J/cm (SD:8.04)	63.4 J/cm (SD:9.92)	$p = 0.007$
Fluence	36 J/cm^2(SD:10.3)	37.8 J/cm^2 (SD:12.5)	$p = 0.30$
Gender (female)	78%	73%	$p = 0.50$

Student *T*-Test.

The QoL score (CIVIQ2 Questionnaire) allowed us to rate postoperative morbidity (including pain) after EVLA. This postoperative morbidity was significantly lower in the group treated with a tulip fibre ($p = 0.023$) (Table 2).

At the 1 month clinical check-up the 'patient' satisfaction rate' was measured using a VAS (0–10). This was part of the questionnaire. The median scores were 9.5 and 10 for the tulip group and the bare fibre group, respectively. There was statistically no significant difference ($p = 0.56$) between the two cohorts.

'Ultrasound scans' were performed at 1 month, 6 months and 1 year postoperatively.

At 1 month, 173 patients were checked (Fig. 1 Consort flow chart). At 6 months and 1 year respectively 168 and 167 patients were checked. The 'occlusion rates' at 1 year were 96.4% and 98.7% respectively for the veins treated with a bare fibre and a tulip fibre (calculations based on the group of patients checked) (Table 3). Some non-closed veins at 6 months postoperative closed spontaneously in the following months. A significant degree of shrinkage of the veins was noted. At 1 year for 89.4% (bare fibre) and 85.3% (tulip fibre) of the patients checked, the vein had evolved into a fibrotic cord. We were unable to find any significant differences between the two cohorts in terms of occlusion rate and vein shrinkage.

At 1 year, new incompetence of the anterior accessory saphenous vein (ASV) was noted in 12 patients (7.1%).

Discussion

Some of the side effects of EVLA can be explained by the use of a bare fibre. The direct contact between the fibre tip and the vein

Table 2
Patients data.

Factor	Bare			Tulip			Sig
	25%	Median	75%	25%	Median	75%	
Echymosis Score	0.08	0.21	0.66	0.00	0.04	0.14	0.000
Painscore d5-	1.00	2.00	3.50	0.00	1.00	2.00	0.000
Painscore 2 weeks	1.00	2.00	3.00	1.00	2.00	3.00	0.180
Analgetics, days	0.00	1.00	2.00	0.00	0.00	1.00	0.111
Analgetics, total number	0.00	1.00	2.50	0.00	0.00	2.00	0.119
QoL (0–100)	24	32	40	23	27	34	0.023
Satisfaction	9.00	10.00	10.00	8.00	9.50	10.00	0.564

Mann Whitney-*U* test.

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Table 3
Occlusion rates.

	1 Month		6 Months		1 Year	
	Bare fibre	Tulip fibre	Bare fibre	Tulip fibre	Bare fibre	Tulip fibre
Lev 0	0	0	0	0	0	0
Lev 1a	0	2	0	1	2	0
Lev 1b	1	1	3	6	1	1
Lev 2a	56	50	2	2	0	0
Lev 2b	19	24	7	9	0	0
Lev 3	10	9	22	22	6	11
Lev 4	1	0	51	43	76	70
Not-controlled	0	1	2	4	2	5
Total	87	87	87	87	87	87
Occlusion rate	86/87 (98.8%)	83/86 (96.5%)	82/85 (96.4%)	76/83 (91.6%)	82/85 (96.4%)	81/82 (98.7%)

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.
This scoring was introduced by GELEV(Groupe d' Évaluation des Lasers et de l'Échographie Vasculaire, part of the " Société Française d'Angéiologie").

wall results in ulceration and perforation of the vein wall. More perivenous tissue destruction can be noticed at this point of direct contact.[1,10] The use of a tulip fibre avoids this direct contact since the fibre tip is centred intraluminally (Fig. 2). This results in a more even energy distribution to the vein wall. Patients treated with a bare fibre did receive somewhat more energy than those treated with a tulip fibre (LEED respectively 63.4 J cm^{-1} vs. 59.6 J cm^{-1}, $p = 0.007$). A linear regression model was used to model the mean of the measured ecchymosis, pain score and QoL score to adjust for the differences in LEED. After this correction, it was possible to prevent the energy difference influencing the outcome factors.

Avoiding vein wall perforations clearly reduces the incidence of ecchymosis. Less perivenous tissue destruction can minimise the postoperative inflammatory reactions and pain. In fact, we also found a strong correlation between the measured ecchymosis and the postoperative pain score (VAS, 5th day) (Pearson correlation $r = 0.274$, $p = 0.000$). The differences in side effects only encompassed the immediate postoperative period; the score for the average pain during the 2 weeks postoperatively no longer showed any difference.

In terms of occlusion rates we were unable to find any difference between the patient cohorts (non-inferiority using Newcombe's 95% CI, estimated difference: −2.3 [−8.7; 3.5]). At 6 months postoperatively we found some cases of proximal recanalisation of the treated veins ($n = 10$, no significant differences between the two groups). We defined a recanalisation as a vein with an open lumen and intraluminal flow at a distance of more than 2 cm distal to the SFJ. These non-closed veins were mostly short proximal stumps with a filliform lumen and a thickened vein wall. At the 1-year check, however, most of these non-occluded veins had closed spontaneously. This reopening and subsequent reclosing of treated veins can be explained by the healing process: the infiltration of the vein wall with necro-inflammatory tissue will lead to a fibrotic process resulting in shrinking of the vein and will end in a fibrotic cord if the thermal destruction has been sufficient.[1,10] The intraluminal thrombus, however, which causes the thrombotic occlusion of the vein in the immediate postoperative period, resolves during the postoperative period. If this thrombus dissolves more quickly than the fibrotic process closes the veins, especially at the proximal end where the vein diameter is larger and nearer to the central circulation, the result will be temporary recanalisation. All those patients stayed asymptomatic. Later these proximal stumps will continue to shrink and evolve into a fibrotic cord.[14,16–18] After 6 months postoperatively, no newly formed recanalisations could be found.

At 1 year, respective occlusion rates were noted of 96.4% and 98.7% (bare fibre vs. tulip fibre). To interpret the occlusion rates, we used the GELEV score (Table 3). This score makes it possible to evaluate the morphological evolution of the treated veins. The marked shrinkage of the treated veins due to fibrotic organisation can guarantee very good long-term results.

We did not, however, use the Kaplan–Meier survival curve, which is very often used in clinical trials, specially to look for a specific event or end point (recanalisation in this trial).[19] The control intervals in this trial are too irregular and too long. If we notice a recanalisation at 6 months postoperatively, this 'event' may have happened several months previously.

Some of the recanalised veins also re-close spontaneously some months later. This 'new event' cannot be included in a Kaplan–Meier life table.

The advantage of using a tulip fibre is that by avoiding the direct contact between the fibre tip and the vein wall, some possible adverse effects of EVLA could be avoided. This tulip fibre was previously tested in an animal model.[1] EVLA using a tulip fibre avoids ulceration and perforation of the vein associated with treatment using a bare fibre. It also results in more even circumferential vein wall necrosis and less pervious tissue destruction.

Other new laser fibre designs are the NeverTouch VenaCure laser fibre (AngioDynamics, Queensbury, NY, USA) and the radial fibre (Cereals E, Biolitec). A retrospective chart review[20] showed a fivefold increase in the failure rates (recanalisations) for vein segments treated with EVLA using the NeverTouch gold-tip fibre compared with standard bare-tip fibres. Promising results have been published using the radial fibre.[21] EVLA of the GSV with radially emitting laser fibre by using a 1470-nm diode laser is safe and efficient. The cost of a radial fibre is about double of a that of a tulip fibre. These prices can vary from country to country.

At 1 year postoperatively, we found cumulative newly formed incompetence of the anterior accessory saphenous vein in 12 patients (7.1%). This incompetence may be the cause of a clinical recurrence of varicose veins. One of the advantages of endovenous thermal ablation techniques is the avoidance of a crossectomy. The inguinal dissection and ligature of the SFJ and side branches can induce neovascularisation, which is a common cause of recurrent varicose veins after surgical treatment of saphenous vein reflux.[22,23] Neovascularisation can be seen more frequently, although statistically not significantly different, following crossectomy/stripping as compared to endovenous thermal ablation.[24] Since it has been shown that extended SFJ ligation may add little to effective GSV obliteration, crossectomy is no longer performed.[25] The occurrence of new incompetence of the ASV after EVLA may, however, contribute to the discussion about the role of SFJ ligation in the treatment of saphenous vein incompetence. Further clinical trials are necessary to evaluate this new ASV incompetence on the long-term clinical results of endovenous thermal techniques.

Conclusion

Using a tulip fibre for EVLA of the GSV results, as compared with the use of a bare fibre, in equal occlusion rates at 1 year postoperatively, but in less postoperative ecchymosis and pain. Patients treated with a tulip fibre seem to have a better postoperative QoL.

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