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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☆

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Endovenous laser ablation;
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Abstract *Objectives:* The aim of this study is to compare efficacy, early postoperative morbidity and patient comfort of two laser wavelengths and fibre types in treatment of great saphenous vein (GSV) incompetence resulting in varicosities of the lower limb.
Design: Prospective randomised clinical trial.
Materials and Methods: Sixty patients (106 limbs) were randomised into two groups. They were treated with bare-tip fibres and a 980 nm laser in group 1 and radial fibres and 1470 nm laser in group 2 in order to ablate the GSV. Local pain, ecchymosis, induration and paraesthesia in treated regions, distance from skin, vein diameter, treated vein length, tumescent anaesthesia volume, delivered energy and patient satisfaction were recorded. Follow-up visits were planned on the 2nd postoperative day, 7th day, 1st, 2nd, 3rd and 6th months.
Results: Mean GSV diameters at saphenofemoral junction and knee levels were 12.1 S.D. 4.3 mm and 8.2 S.D. 2.4 mm, and 11.8 S.D. 4.1 mm and 7.9 S.D. 2.6 mm respectively in groups 1 and 2. There were 14 patients with induration, 13 with ecchymosis and nine minimal paraesthesia in group 1 and no or minimal local pain, minimum ecchymosis or induration in group 2. Duration of pain and need for analgesia was also lower in group 2 ($p < 0.05$). There was significant difference on postoperative day 2, day 7 and 1st month control in favour of group 2 in venous clinical severity scores (VCSS).
Conclusion: Treatment of the GSV by endovenous laser ablation using a 1470 nm laser and a radial fibre resulted in less postoperative pain and better VCSS scores in the first month than treatment with a 980 nm laser and a bare-tip fibre.

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Varicose veins are a common disorder and occurs in about 40% of men and 32% of women.[1] The effect of venous insufficiency on patients' quality of life is comparable with other common chronic diseases such as arthritis, diabetes and cardiovascular disease.[2]

Traditional treatment of great saphenous vein (GSV) varicosities includes ligation of the saphenofemoral junction (SFJ) combined with GSV stripping. However, the associated morbidity and patient dissatisfaction associated with this treatment have led to the development of alternative techniques.[3] Endovenous treatment modalities (laser ablation, radiofrequency ablation and foam sclerotherapy) have been readily accepted by both patients and doctors. Puglisi[4] first described endovenous laser ablation of the GSV in 1989 and the first successful results were reported by Navarro[5] in 2001. Many studies have been published subsequently concerning this treatment. Semiconductor (diode) lasers have been the main laser type employed for this treatment, although some reports have mentioned the neodymium: yttrium-aluminium-garnet (Nd:YAG) laser. Laser wavelengths reported include 810 nm, 940 nm, 980 nm, 1064 nm, 1320 nm and 1470 nm.[3,6] However, the most appropriate wavelength is still the subject of debate.

There is no scientific evidence that wavelength has any effect on long-term outcome, although short-term differences have been found for some side effects.[7] Clinical trial experience with diode lasers has produced extremely low rates of deep vein thrombosis (DVT) and paraesthesia, a low risk of skin burns and no documented cases of pulmonary embolism; both paraesthesia and skin burns have been associated with 1064 nm laser treatment. The most common side effects seen with all laser types are bruising, localised pain, induration and discomfort along the treated vein and superficial phlebitis.[8] Results after endovenous laser ablation (EVLA) with 1320 nm laser light showed good occlusion rates, and less bruising and pain. Longer wavelengths ($>$1000 nm) show greater water absorption but are overall less strongly absorbed in blood than shorter wavelengths and may have some advantages for endovenous laser ablation.[9–11] The 1470 nm diode laser operates at a relatively new wavelength for this treatment and has been in use since 2006. The first successful results have been published by Pannier et al.[6] However no published data have compared this laser wavelength with other commonly used wavelengths. There has also been progress in the field of laser fibres. Recently, new fibre tips (jacket-tip fibres, glass, metal, ceramic, diffusion and radial) were developed.[12,13]

The aim of the current prospective study was to compare the efficacy, early postoperative morbidity, patient comfort and effects on venous clinical severity score (VCSS) of two different laser wavelengths (1470 nm and 980 nm diode lasers) and fibres (bare-tip fibre and radial fibres) in the treatment of GSV reflux.

Methods

Patients

The study was approved by our institutional ethics committee and an informed written consent was obtained from patients. Between October 2008 and February 2009, 71 patients presenting with symptomatic varicose veins were considered for inclusion in the study which was undertaken at Gulhane Military Academy of Medicine Department of Cardiovascular Surgery. All patients were examined clinically and with duplex ultrasound (US) imaging using a LOGIC Book XP (GE Healthcare, Buckinghamshire, UK) system to assess the deep and superficial veins of both lower limbs to allow the Clinical Etiological Anatomical Pathological (CEAP)[14] classification to be assessed for each patient. Venous clinical severity scores (VCSS) were recorded. Duplex examination was performed with patients in the upright position. Reflux was defined as retrograde flow with a duration of 0.5 s or greater duration after a Valsalva manoeuvre, in the proximal part of the vein or manual compression and decompression of the calf to assess the distal part of the vein. The diameter of the GSV was measured at the level of the SFJ and at the knee, the distance of the GSV from skin was also measured.

Patients with a history of previous DVT, concomitant peripheral arterial disease (ABPI $<$ 0.8), difficulty in ambulation, pregnant or breast-feeding, recurrent varicose veins and those who had reflux in other axial veins, (anterior accessory great saphenous vein, small saphenous vein) or perforators were excluded from the study. Patient progress through this study is shown in a CONSORT diagram (Fig. 1).

Eleven patients were excluded from the study. Of these, two were pregnant, three had a history of previous DVT, one had additional peripheral arterial disease, three had additional reflux in other venous segments detailed ahead and two declined to undergo the randomisation process (these two patients were treated with the 1470 nm laser). The remaining 60 patients (106 limbs) were randomised into two groups according to a computer-generated randomisation list. Group 1 ($n = 30$) was treated with the 980 nm diode laser (Biolitec AG, Germany) and bare-tip laser fibre (ElvesPlus, Biolitec AG, Germany). Group 2 ($n = 30$) was treated with the 1470 nm diode laser (Biolitec AG, Germany) and radial laser fibre (Elves radial, Bolitec AG, Bonn, Germany).

Primary outcomes of the study were to compare early postoperative morbidity assessed by the extent of ecchymosis, paraesthesia, postoperative pain, induration and VCSS scores. Secondary outcome measures were patient satisfaction and comfort related with both procedures.

EVLA procedure

All patients underwent the EVLA procedure under intravenous midazolam sedation with oxygen supplementation. All GSVs were cannulated percutaneously with a 16-gauge needle under US control at the knee level with the patient in a reverse Trendelenburg position to maximise vein diameter. Then a guide-wire inserted through the needle and a 6-F introducer sheath (INPUT® Intraducer sheath, Medronic Ireland Parkmore Business Park West, Galway, Ireland) was placed over the guide-wire into the GSV in group 2. In group 1, a long guide-wire was inserted through the needle and a long sheath positioned over the guide-wire 2 cm below the SFJ. A bare-tip 600-μm-diameter laser fibre was inserted into the long sheath and locked. In group 2, a radial catheter was directly inserted through the sheath. In both groups, the tip of the laser fibre was positioned 1–2 cm below the SFJ under

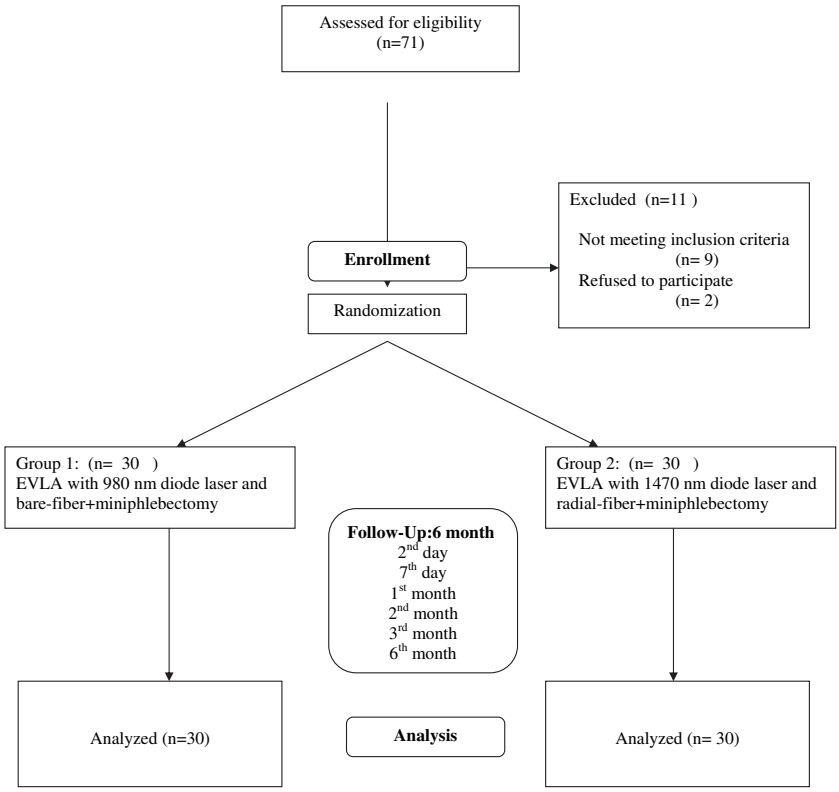

Figure 1 Consort flow diagram of the study.

US guidance and confirmed by direct visualisation of the red aiming beam through the skin. Perivenous tumescent local anaesthesia (TLA) (1000 ml saline 0.9%, 50 ml lidocaine 2%, 1 ml Epinenephrine 1:1000, 10 mEq $NaHCO_3$) was given under US control. Laser energy was applied using the laser's continuous mode and a constant pullback with a rate corresponding to 90 J cm^{-1} linear endovenous energy density (LEED). In both groups, laser power was set to 15 W power and total laser energy was recorded. After removing the fibre, closure of the GSV was confirmed by US. Concomitant phlebectomies were performed in both groups and a compression bandage was applied over the course of the treated vein for 24 h. Patients then wore graduated compression stockings (20—30 mmHg, knee-high) continuously during the following 7 days. After the first week, they continued to wear stockings during the day. Prophylactic low-molecular-weight heparin was not used in either group. Patients were advised to walk regularly during recovery from treatment and diclofenac 75 mg twice daily as required was prescribed for analgesia.

Follow-up

Patients were re-examined on the 2nd and 7th postoperative day, and at months 1, 2, 3 and 6 after the procedure. Clinical examination and duplex US were undertaken to assess efficacy of treatment including ultrasound assessment of the GSV to detect patent or incompetent veins. VCSS, postoperative pain, patient satisfaction, side effects, adverse events and recurrence rates were evaluated and recorded at each visit.

Patient satisfaction was assessed on a scale ranging from 0 to 4. The questions were 'Are you satisfied with the method being used?' (0 = very satisfied; 1 = satisfied; 2 = fairly satisfied; 3 = not satisfied; 4 = extremely unsatisfied) and 'would you choose endovenous laser therapy again?' (0 = definitely; 1 = probably; 2 = don't know; 3 = probably not; 4 = definitely not).

Local pain, duration of pain, duration of requirement for analgesia, return to daily activities, ecchymosis, skin burn, skin necrosis, induration and paraesthesia over treated parts of legs were also recorded at postoperative follow-up visits. These parameters were recorded in a written form by the patients during the follow-up visits. Ecchymosis and paraesthesia were recorded in regions of the limb adjacent to the ablated vein segments. The areas of ecchymosis and paraesthesia were not measured. These outcome measures were recorded as present or absent.

Statistical analysis

Recurrence, postoperative complications, morbidity and side-effect rates were compared between groups using Fisher's exact test. Patient satisfaction in the two groups was compared using a Mann—Whitney *U* test. A p value of <0.05 was considered significant. All analyses were performed using the statistical package SPSS® for Windows version 15.0 (SPSS, Chicago, IL, USA).

Results

Successful percutaneous access and endovenous placement of the laser fibre were achieved in all patients and were well tolerated. A total of 52 limbs of 30 patients in group 1

Table 1 Preoperative patient demographics.

Parameters	Group 1 ($N = 30$) 980 nm Bare-tip fibre	Group 2 ($N = 30$) 1470 nm Radial fibre
Number of treated legs	52	54
Gender (M/F)	16/14	19/11
Mean age (years)	35 S.D. 9.2	36 S.D. 7.6
Mean GSV diameter (mm)		
SFJ level	12.1 S.D. 4.3	11.8 S.D. 4.1
Knee level	8.2 S.D. 2.4	7.9 S.D. 2.6
Mean reflux duration at SFJ (s)	6.5 S.D. 1.7	6.8 S.D. 1.3
GSV distance from the skin (cm)	3.7 S.D. 1.8	3.4 S.D. 1.9
CEAP classification/limb		
C2	16	16
C3	29	30
C4	7	8
Ep	52	54

M: Male, F: Female, GSV: Great saphenous vein, SFJ: Saphenofemoral junction.

and 54 limbs of 30 patients in group 2 were treated. Demographic details and results of preoperative clinical and US examinations are shown in Table 1. The two groups of patients are very similar.

Operative data are shown in Table 2. Our aim was to achieve a LEED of 90 J cm^{-1} and this appears to have been achieved in both groups. Similar amounts of TLA were used in both groups and the volume was approximately 10 ml per treated centimetre, which we consider to be optimum in minimising postoperative ecchymosis and paraesthesia.

No patient was lost from this series during the 6-month follow-up period. No evidence of residual flow or venous reflux was found on US imaging at any time during follow-up. VCSS scores improved significantly in both groups at each follow-up visit (Table 3). However improvements of VCSS for the second day, seventh day and the first month were significantly better in group 2 than in group 1. After the first month, there was no difference at the recorded parameters.

Table 4 summarises the side effects and other assessments of the outcome of this clinical trial. The most frequent side effects in both groups were ecchymosis, induration and minor paraesthesia, all of which were more common in group 1. Severe complications such as DVT, pulmonary embolism, skin burns, motor nerve lesions or the formation of arteriovenous fistula did not occur in any limb. Assessments of postoperative pain included duration of pain and need for analgesia, both of which were less in group 1 patients. Ecchymosis was also less frequently seen in patients from group 2. However, in those patients in whom ecchymosis developed, the mean duration was almost 2 weeks in both groups. Subcutaneous induration along the treated veins after EVLA resembling either a palpable cord or the feeling of a shortened muscle at the medial part of the thigh were noticed in 14 limbs in group 1 and 3 limbs in group 2 ($p < 0.001$). This lasted for a mean of 8 weeks in group 1 and less than 3 weeks in group 2. Paraesthesia in the region of treated veins was more common in group 1 but overall symptoms were of minor severity and the mean duration was not longer than 4 weeks in both groups.

Patient satisfaction

Subjective assessment of the treatment by patients at the sixth-month visit demonstrated that most of the patients were very satisfied with the treatment. In group 1, 10 patients were very satisfied with the method, nine were satisfied, nine were fairly satisfied and two were not satisfied. The mean score for group 1 was 1.1. In group 2, 15 patients were very satisfied, 12 patients were satisfied and three were fairly satisfied. The mean for group 2 was 0.6.

Table 2 Operative data.

Parameters	Group 1 ($N = 30$) 980 nm Bare-tip fibre	Group 2 ($N = 30$) 1470 nm Radial fibre
Mean treated GSV length (cm)	39.2 S.D. 6.2	40.6 S.D. 7.1
Used laser power (W)	15	15
LEED (J/cm)	90	90
Mean total energy/limb (J)	3548 S.D. 564	3696 S.D. 642
Mean TLA volume/limb (ml)	310 S.D. 76	296 S.D. 83
Mean procedure duration/limb (min) (EVLA + Miniphlebectomy)	35 S.D. 9.4	34 S.D. 10
Number of phlebectomies/limb	5.2 S.D. 1.7	4.9 S.D. 1.5
Immediate postoperative closure rate (%)	100	100

GSV: Great saphenous vein, W: Watt, LEED: Linear endovenous energy density, J: Joule, TLA: Tumescent local anaesthesia, EVLA: Endovenous laser ablation.

Table 3 Changes in venous clinical severity score.

Time point	Group 1 ($N = 30$) 980 nm Bare-tip fibre	Group 2 ($N = 30$) 1470 nm Radial fibre	P value
Preoperative	8.6 S.D. 3.2	8.4 S.D. 2.9	N.S.
PO second day	5.3 S.D. 2.5	4.6 S.D. 2.4	$P < 0.05$
PO seventh day	5.0 S.D. 2.2	4.2 S.D. 2.0	$P < 0.05$
PO first month	4.2 S.D. 2.1	3.7 S.D. 1.9	$P < 0.05$
PO second month	3.5 S.D. 1.9	3.1 S.D. 1.6	N.S.
PO third month	3.2 S.D. 1.7	2.9 S.D. 1.5	N.S.
PO sixth-month	2.2 S.D. 0.9	2.0 S.D. 0.7	N.S.

PO: postoperative.

The difference between the groups was statistically significant ($p < 0.05$).

The response to the question 'Would you choose endovenous laser therapy again?' was 'definitely' in eight patients, 'probably yes' in nine, 'do not know' in nine and 'probably would not' in four patients in group 1. The mean score for group 1 was 1.3. In group 2, 16 patients replied 'definitely', 10 'probably yes', three 'do not know' and one patient replied 'probably would not'. The mean for group 2 was 0.5. The difference between the groups was statistically significant ($p < 0.05$).

Compression stockings were worn for similar periods in the two patient groups. Return to daily activities was slightly earlier in group 2 than in group 1 (Table 4).

Discussion

In recently published studies, high success rates after EVLA have been reported.[3,9,15] These have been based mainly on duplex US assessment of the treated veins. In our study, we found 100% ablation of veins in both treatment groups at 6 months. Laser systems with emission wavelengths of 1320 nm and 1470 nm have their main absorption in water[10,11] but the effect of these wavelengths on the vein wall is still under discussion. Good efficacy of a 1320 nm Nd: Yag system with reduced post-treatment pain and bruising compared to shorter wavelength lasers has been reported.[10,16] Successful endovenous ablation using a 1470 nm laser has been reported by Pannier et al.,[6] but no study has compared this with other commonly used laser systems.

In this prospective randomised study, we found that side effects such as pain, induration, ecchymosis and paraesthesia were significantly reduced with the 1470 nm laser and radial catheter system compared to the 980 mm bare-tip laser fibre. Pannier[6] reported phlebitic reactions in three cases and 9.5% paraesthesia in treated legs at the six-month follow-up in their study group. However, it is not clear whether they used a bare-tip fibre or radial fibre. Side effects were also more common in patients treated with a LEED of >100 J cm^{-1}. In our study, in group 2 (1470 nm), we experienced only a few minor complications of this type. This may be the result of limiting the LEED to 90 J cm^{-1} and the use of radial laser fibres.

Table 4 Postoperative data.

Parameters	Group 1 ($N = 30$) 980 nm Bare-tip fibre	Group 2 ($N = 30$) 1470 nm Radial fibre	P value
Pain duration (day)	3.2 S.D. 4.1	2.2 S.D.3.4	$P < 0.05$
Duration of analgesia need (day)	7.1 S.D.3.9	5.8 S.D.2.7	$P < 0.05$
Induration (number of limbs)	14	3	$P < 0.001$
Ecchymosis (number of limbs)	13	2	$P < 0.001$
Skin necrosis (number of limbs)	0	0	NS
Skin burn (number of limbs)	0	0	NS
Paraesthesia (number of limbs)	9	1	$P < 0.001$
Deep vein thrombosis	0	0	NS
Pulmonary Embolus	0	0	NS
Return to daily activity (day)	2.3 S.D. 2.1	1.6 S.D. 1.8	$P < 0.05$
Duration of compression stockings (day)	56 S.D. 17	60 S.D. 20	NS
Patient satisfaction (median)	1.1 S.D.0.95 (1)	0.6 S.D.0.67 (0.5)	$P < 0.05$
Willing to undergo EVLA again (median)	1.3 S.D.1.02 (1)	0.5 S.D.0.8 (0)	$P < 0.05$
6th month closure rate (%)	100	100	NS

EVLA: Endovenous laser ablation.
Patient satisfaction: 0 = very satisfied; 1 = satisfied; 2 = fairly satisfied; 3 = not satisfied; 4 = extremely unsatisfied.
Willing to undergo EVLA again:0 = definitely; 1 = probably; 2 = don't know; 3 = probably not; 4 = definitely not.

In a study by Almeida et al.[11] 1470 nm laser and radial fibres were used with low LEED levels (20–30 J cm^{-1}). This was not a randomised study but the authors concluded that in comparison to 980 nm wavelength systems (their past experience) there was a marked reduction in postoperative pain and ecchymosis. They attributed this finding to reduced vein-wall perforations with this system. Our findings are similar to those reported in this study with reduced postoperative pain, although we used higher LEED levels.

The design of the fibre tip probably has a substantial effect on the early postoperative course. Kabnick et al. concluded that a jacket-tip laser fibre produces a more tolerable procedure, with less ecchymosis and postoperative pain.[12] The use of radial fibres in our study almost certainly had a large effect on the outcome.

Desmyttère et al.[17] have reported their long-term result with a 980-nm diode laser. In this study, 500 patients were treated. They reported 60% ecchymosis and 7% transient paraesthesia following treatment. In our study, the outcome in group 1 is comparable with Desmyttère's study, although far fewer complications were seen in group 2.

In general, patients report high levels of satisfaction following laser ablation of saphenous veins, according to a number of studies. Our study confirms that patients were satisfied with the outcome of treatment and that a high proportion of patients would be content to undergo further treatment using endovenous ablation. We observed higher levels of satisfaction and agreement to undergo further treatment in group 2 patients, consistent with our other outcome measures. VCSS scores also show that during the first postoperative month symptoms were fewer in group 2 than in group 1. However, following this there was no difference.

In conclusion, 1470- and 980-nm diode lasers and both laser fibre types are effective in the treatment of GSV varicosities by endovenous laser ablation. However, early postoperative patient comfort, patient satisfaction and acceptability of the procedure are higher in 1470 nm laser and radial fibre group which showed fewer side effects. A limitation of this study is that we cannot identify whether these results are attributable solely to the laser frequency, the fibre tip or a combination of both factors.

Conflict of Interest

None.

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