Endovascular laser treatment of incompetent saphenous veins using the 1470 nm diode laser and radial fiber

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ABSTRACT

Objectives: To assess the technical success, complications, and patients' quality of life (QoL) after treatment of chronic venous disease (CVD) using the 1470 nm radial fiber laser.

Methods: A total of 170 patients with chronic venous disease, classified as C2 to C4 according to CEAP classification, were treated for incompetent greater (GSV) and small (SSV) saphenous veins, using the 1470 nm radial fiber laser and application of tumescent anesthesia. Additional phlebectomies were performed through stab microincisions, while 11 patients further underwent sclerotherapy intraoperatively. Patients' QoL was recorded using a CIVIQ-20 questionnaire pre and post-operatively.

Results: Technical success regarding GSV vein occlusion was recorded at 100% and 98% during 12 and 24 month follow up respectively. SSV occlusion rates were recorded at 100% for the same period. 55% of patients were classified as C2. Mean laser application time was 401.1 ± 92.6 s and 169.4 ± 56.8 s, while an average of 3986.6 ± 934.9 and 1643.5 ± 534.1 J were applied during ablation of GSV and SSV respectively. Three incidents of postoperative pain were recorded. Two patients exhibited partial proximal GSV recanalization, while two patients reported mild post-operative temporal paresthesia. No major complications were observed post-operatively. A significant improvement in patients' QoL was demonstrated through the CIVIQ-20 questionnaires. Mean pre-operative CIVIQ-20 total score was recorded at 77 ± 3.9, with a total score of 32.8 ± 2.8 being observed during 12 month follow-up.

Conclusions: Endovascular laser treatment using the 1470 nm radial fiber laser constitutes an effective and safe modality for treatment of CVD.

1. Introduction

Chronic venous disease refers to the peripheral veins' inability of adequate blood regulation. CVD of the lower extremities can present with various clinical signs, the most common being symptomatic varicosities [1]. The etiology, anatomic location, and pathology of the incompetence have led to the development of a classification system known as CEAP [1]. Classification of patients with CVD is essential in decision making regarding treatment management. Duplex colour scan is the basis for the assessment of CVD, with incompetence of the greater and small saphenous veins (GSV – SSV) being the commonest finding [1–3].

A number of therapeutic modalities have been introduced for treatment of CVD. Non-operative methods include compression therapy and pharmacological products [1,3,4] while ligation and stripping of incompetent saphenous veins along with varicosities excision, has been the gold standard surgical approach until the 21st century [5]. In the last 15 years, improvements in knowledge of venous pathology and circulation have led to the introduction of minimal invasive therapeutic options, demonstrating excellent technical success rates, and less complications and discomfort for the patient compared to open surgery. Such modalities include endovascular laser treatment (EVLT), radiofrequency ablation (RFA) and liquid/foam sclerotherapy [1,6–8].

This study aims to evaluate the outcome and complications of 170 patients who underwent EVLT for treatment of CVD, using the 1470 nm diode laser and radial fiber.

2. Methods and materials

A retrospective data analysis was performed in our center.
C2–C4 according to CEAP classifying either GSV/SSV incompetence, or both. Patients eligible for surgery were examined annually. Physical examination and colour duplex scan of the treated extremity were performed for the assessment of recurrent varicosities, GSV/SSV occlusion and possible reflux and recanalization. Patients were asked to complete a CIVIQ questionnaire at 1 and 12 months postoperatively, defined as pre-CIVIQ, to complete prior to the operation. Data collection, analysis and calculations were performed using IBM SPSS statistics 23.0.

All procedures were performed by the main author, an experienced vascular surgeon, with an additional established experience in RF ablation and EVLT. Patients were operated under general or local anesthesia with mild sedation in supine or prone position, depending on GSV or SSV incompetence. With the patient in reverse Trendelenburg position, U/S guided percutaneous access of the GSV was achieved approximately 5–10 cm below the knee according to the Seldinger technique, followed by insertion of a 5 Fr sheath inside the GSV lumen. A 1470 nm radial optic fiber (Laser ELVeS Painless 1470 nm, Boliotec-Endotech, Athens) was inserted through the sheath with its tip advancing 2 cm distal from the saphenofemoral junction (SFJ) (Fig. 1). In Trendelenburg position under ultrasound guidance, patients were administered tumescent anesthesia (500 ml N/S 0.9%, 20 ml xylocaine 2%, 10 ml bicarbonate 4%) within the fascial sheath of the GSV. For the SSV, access was obtained in the middle third of the calf, with advancement of the laser fiber as close as 2.5 cm from the saphenopopliteal junction (SPJ) and perivenous administration of tumescent anesthetic under ultrasound guidance. With the power set at 9–10 W at thigh level combined with manual compression and 6–7 W at knee level, the laser fiber was withdrawn at a rate of approximately 0.2 cm/s with the help of audio feedback from the laser device. Withdrawal of the sheath was performed as the laser tip came in close proximity, treating the overlapping vein as well (Fig. 2). Ablation stopped approximately 1 cm proximal to the puncture site. Incompetent perforator veins were ligated, and marked varicosities were excised through stab microincisions closed with steri strips. All patients received low molecular weight heparin in a prophylactic dose during the first postoperative week. An elastic compression bandage was applied on the treated extremity and kept for 2 days, after which a class II graduated compression stocking was used for a length of approximately 1 month.

All patients had a follow up check at 1, 6, 12 months and then annually. Preoperative workup included physical examination for the evaluation and extent of varicosities. A colour duplex scan was performed in all patients for the assessment of retrograde blood flow in the GSV or SSV and identification of incompetent perforating veins. Venous incompetence was defined as retrograde blood flow > 0.5s, after manual compression of the calf, followed by sudden release. Incompetent varicosities and perforator veins were marked with the patient in standing position. Written informed consent was taken from all patients, while they were also given a chronic venous insufficiency questionnaire (CIVIQ), defined as pre-CIVIQ, to complete prior to the operation. Data collection, analysis and calculations were performed using IBM SPSS statistics 23.0.

### Table 1

| Inclusion Criteria | Exclusion Criteria |
|--------------------|--------------------|
| Patients with incompetent saphenous veins (reflux > 0.5 s) | Patients with hypercoagulable disorders |
| Patients with symptomatic varicosities in the calf | Presence of tortuous veins |
| Patients whose saphenous vein diameter was ≤ 2 cm | Patients undergoing previous varicose surgery |
| Patients who were CEAP classified as C2 to C4 | Patients with a history of deep vein thrombosis or superficial thrombophlebitis |

Concerning patients who underwent EVLT for treatment of CVD of the lower extremities at a private clinic from 2013 to 2015, under the supervision of the main author. Patients eligible for surgery were exhibiting either GSV/SSV incompetence, or both and were classified as C2–C4 according to CEAP classification. Inclusion and exclusion criteria are summarized in Table 1.

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All procedures were performed by the main author, an experienced vascular surgeon, with an additional established experience in RF ablation and EVLT. Patients were operated under general or local anesthesia with mild sedation in supine or prone position, depending on GSV or SSV incompetence. With the patient in reverse Trendelenburg position, U/S guided percutaneous access of the GSV was achieved approximately 5–10 cm below the knee according to the Seldinger technique, followed by insertion of a 5 Fr sheath inside the GSV lumen. A 1470 nm radial optic fiber (Laser ELVeS Painless 1470 nm, Boliotec-Endotech, Athens) was inserted through the sheath with its tip advancing 2 cm distal from the saphenofemoral junction (SFJ) (Fig. 1). In Trendelenburg position under ultrasound guidance, patients were administered tumescent anesthesia (500 ml N/S 0.9%, 20 ml xylocaine 2%, 10 ml bicarbonate 4%) within the fascial sheath of the GSV. For the SSV, access was obtained in the middle third of the calf, with advancement of the laser fiber as close as 2.5 cm from the saphenopopliteal junction (SPJ) and perivenous administration of tumescent anesthetic under ultrasound guidance. With the power set at 9–10 W at thigh level combined with manual compression and 6–7 W at knee level, the laser fiber was withdrawn at a rate of approximately 0.2 cm/s with the help of audio feedback from the laser device. Withdrawal of the sheath was performed as the laser tip came in close proximity, treating the overlapping vein as well (Fig. 2). Ablation stopped approximately 1 cm proximal to the puncture site. Incompetent perforator veins were ligated, and marked varicosities were excised through stab microincisions closed with steri strips. All patients received low molecular weight heparin in a prophylactic dose during the first postoperative week. An elastic compression bandage was applied on the treated extremity and kept for 2 days, after which a class II graduated compression stocking was used for a length of approximately 1 month.

All patients had a follow up check at 1, 6, 12 months and then annually. Preoperative workup included physical examination for the evaluation and extent of varicosities. A colour duplex scan was performed in all patients for the assessment of retrograde blood flow in the GSV or SSV and identification of incompetent perforating veins. Venous incompetence was defined as retrograde blood flow > 0.5s, after manual compression of the calf, followed by sudden release. Incompetent varicosities and perforator veins were marked with the patient in standing position. Written informed consent was taken from all patients, while they were also given a chronic venous insufficiency questionnaire (CIVIQ), defined as pre-CIVIQ, to complete prior to the operation. Data collection, analysis and calculations were performed using IBM SPSS statistics 23.0.

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All patients had a follow up check at 1, 6, 12 months and then annually. Physical examination and colour duplex scan of the treated extremity were performed for the assessment of recurrent varicosities, GSV/SSV occlusion and possible reflux and recanalization. Patients were asked to complete a CIVIQ questionnaire at 1 and 12 months postoperatively, defined as pre-CIVIQ-1 and post-CIVIQ-2 respectively.

The chronic venous insufficiency questionnaire (CIVIQ) is used to assess a person's quality of life (QoL) through 20 items, categorized in four dimensions (pain, physical, psychological, social). Scores range from 1 to 5. Minimum total score is 20, referring to an excellent QoL. While maximum score is 100, reflecting a very poor QoL. It is a useful tool for the evaluation of patients' clinical status and symptoms, prior to lower extremity venous surgery [9].

### 3. Results

A total number of 170 patients underwent EVLT for treatment of CVI, involving 193 lower extremities. 94 (48%) right extremities and 99 (52%) left extremities with incompetence were treated, with bilateral
insufficiency being observed in 23 (13%) patients. Ablation was performed in 176 and 24, GSVs and SSVs respectively. Mean age was 52.9 ± 11.2, with a ratio of women to men approximately 2.9. Most patients were CEAP classified as C2, with a percentage of 55%. Preoperative CIVIQ questionnaire showed an average score of 77 ± 3.9, demonstrating a rather low QoL (Table 2).

General anesthesia was applied only in 8 (5%) procedures as patient preference, while the remaining were performed under local anesthesia and mild sedation. Mean laser application time was 401.1 ± 92.6 s and 169.4 ± 56.8 s, while an average of 3986.6 ± 934.9 and 1643.5 ± 534.1 J were applied during ablation of GSV and SSV respectively. Phlebectomies were performed in all patients, while 11 patients underwent additional intraoperative sclerotherapy using polidocanol for treatment of telangiectasias and reticular veins. All operations have been met with technical success with no intraoperative complications (Table 3).

All patients were discharged home the day of operation. No postsurgical complications where observed such as ecchymosis, and skin burn. Eight incidents of local bruising due to phlebectomies or tumescent anesthetic were observed, while three incidents of postoperative pain were recorded. Complete follow up was performed in 160 (94%) patients. At 1 month follow up, three patients reported temporary mild tenderness, while two reported paresthesia. No thrombotic complications were reported throughout the follow up. Complete occlusion of GSV was recorded at 100% during 1, 6 and 12 month follow up and 98% during 24 month follow up respectively, as demonstrated with duplex scan. Two patients had a partial proximal (< 20 cm) GSV re-canalization and reflux without symptoms. SSV occlusion rate was recorded at 100%, for the same follow up visits. No recurrent varicosities were observed (Fig. 3a and b).

Average pre-CIVIQ questionnaire score was 77 ± 3.9. Post-CIVIQ-1 average score of 36.3 ± 3, and post-CIVIQ-2 average score of 32.8 ± 2.8, reflect a significant increase in patients QoL after treatment. Most significant score differences were noted in the ‘pain’ dimension, with the pre-CIVQ ‘pain’ score being 17.4 ± 1.3, while the same score was recorded as 6.7 ± 1.2 and 6 ± 1.1 in post-CIVIQ-1 and post-CIVIQ-2 questionnaires respectively (Table 4).
complications were reported during the follow-up period. Tumescent anesthesia as was observed in our study.

Cases of paresthesia after EVLT were observed, with similar rates compared to EVLT, with patients resuming earlier their normal activities. Postoperative thrombophlebitis following treatment with RFA [10,19].

In conclusion, EVLT offers an excellent modality for treatment of chronic venous disease. While its efficacy demonstrates similar results compared to other treatment options such as open surgery and RFA, its intraoperative safety and lower rates of postoperative complications render it a viable treatment option. Higher wavelength lasers such as the 1470 nm should be preferred over first generation, low wavelength lasers, while bare tip fibers should be avoided, since they account for a number of postoperative complications. Tumescent anesthesia is also of major importance regarding technical success and avoidance of adverse effects, with its application depending solely on surgical experience and expertise. Further studies should be conducted with different wavelength lasers and laser tips in order to evaluate and compare their outcome.

Ethical approval

This was a retrospective data analysis, so ethical approval was not required.

Funding

Nothing to declare.

Conflicts of interest

All authors declare that they have no conflict of interest.

Consent

Written consent was obtained from all patients prior to the operation.

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References

[1] R.T. Eberhardt, J.D. Raffetto, Chronic venous insufficiency, Circulation 130 (4) (2014) 323–346.

[2] W.A. Marston, PPG, APG, duplex: which noninvasive tests are most appropriate for...
the management of patients with chronic venous insufficiency? Semin. Vasc. Surg. 15 (1) (2002) 13–20.

[3] P. Gloviczki, A.J. Comerota, M.C. Dalsing, et al., The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum, J. Vasc. Surg. 53 (5 Suppl) (2011) 25–48S.

[4] A.N. Nicolaides, From symptoms to leg edema: efficacy of Daflon 500 mg, Angiology 54 (Suppl 1) (2003) S33–S44.

[5] R.K. MacKenzie, P.L. Allan, C.V. Ruckley, et al., The effect of long saphenous vein stripping on deep venous reflux, Eur. J. Vasc. Endovasc. Surg. 28 (1) (2004) 104–107.

[6] B. Kahle, K. Leng, Efficacy of sclerotherapy in varicose veins–prospective, blinded, placebo-controlled study, Dermatol. Surg. 30 (5) (2004) 723–728.

[7] R.F. Merchant, R.G. DePalma, L.S. Kabnick, Endovascular obliteration of saphenous reflux: a multicenter study, J. Vasc. Surg. 35 (6) (2002) 1190–1196.

[8] F. Lurie, D. Creton, B. Eklof, et al., Prospective randomised study of endovenous radiofrequency obliteration (closure) versus ligation and vein stripping (EVOLVE): two-year follow-up, Eur. J. Vasc. Endovasc. Surg. 29 (1) (2005) 67–73.

[9] R. Launois, A. Mansilha, G. Jantet, International psychometric validation of the chronic venous disease quality of life questionnaire (CIVIQ-20), Eur. J. Vasc. Endovasc. Surg. 40 (6) (2010) 783–789.

[10] B. Siribumrungwong, P. Noorit, C. Wilasrusmee, et al., A systematic review and meta-analysis of randomised controlled trials comparing endovenous ablation and surgical intervention in patients with varicose vein, Eur. J. Vasc. Endovasc. Surg. 44 (2) (2012) 214–223.

[11] B.C. Disselho , D.J. Der Kinderen, J.C. Kelder, et al., Five-year results of a randomised clinical trial of endovenous laser ablation of the great saphenous vein with and without ligation of the saphenofemoral junction, Eur. J. Vasc. Endovasc. Surg. 41 (5) (2011) 685–690.

[12] G. Galanopoulos, C. Lalandis, Minimally invasive treatment of varicose veins: endovenous laser ablation (EVLA), Int. J. Surg. 10 (3) (2012) 134–139.

[13] J.I. Almeida, J.K. Raines, Laser ablation of cutaneous leg veins, Perspect. Vasc. Surg. Endovasc. Ther. 20 (4) (2008) 358–366.

[14] R.R. Van Den Bos, P.W. Van Ruijven, C.W. Van Der Geld, et al., Endovenous simulated laser experiments at 940 nm and 1470 nm suggest wavelength-independent temperature profiles, Eur. J. Vasc. Endovasc. Surg. 44 (1) (2012) 77–81.

[15] S. Saha, A. Tiwari, C. Hunns, J. Refson, A. Abidia, Efficacy of topical local anaesthesia to reduce perioperative pain for endovenous laser ablation of varicose veins: a double-blind randomized controlled trial, Ther. Adv. Cardiovasc. Dis. 10 (4) (2016) 251–255.

[16] L. Van Groenendael, J.A. Van Der Vliet, L. Flinkenflugel, et al., Treatment of recurrent varicose veins of the great saphenous vein by conventional surgery and endovenous laser ablation, J. Vasc. Surg. 50 (5) (2009) 1106–1113.

[17] M. Hirokawa, T. Ogawa, H. Sugawara, et al., Comparison of 1470 nm laser and radial 2ring fiber with 980 nm laser and bare-tip fiber in endovenous laser ablation of saphenous varicose veins: a multicenter, prospective, randomized, non-blind study, Ann. Vasc. Dis. 8 (4) (2015) 282–289.

[18] M.E. Vuyksteke, S. Thomis, P. Mahieu, et al., Endovenous laser ablation of the great saphenous vein using a bare fibre versus a tulip fibre: a randomised clinical trial, Eur. J. Vasc. Endovasc. Surg. 44 (6) (2012) 587–592.

[19] S.D. Goode, A. Chowdhury, M. Crockett, et al., Laser and radiofrequency ablation study (LARA study): a randomised study comparing radiofrequency ablation and endovenous laser ablation (810 nm), Eur. J. Vasc. Endovasc. Surg. 40 (2) (2010) 246–253.

[20] R.A. Agha, A.J. Fowler, S. Rammohan, I. Barai, Orgill DP and the process group. The process statement: preferred reporting of case series in surgery, Int. J. Surg. 36 (Pt A) (2016) 319–323.