

Perforator Management with Endovenous Laser Ablation and its Role in the Treatment of Resistant Venous Ulcers

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ABSTRACT

Introduction: Varicose vein disease can present in different patterns with pathological components being restricted to Great Saphenous Vein (GSV), Short Saphenous Vein (SSV), perforators or any combination of these. The role of perforators has been debated in the past especially for non-healing ulcers. Different methods of treatment have been used in the past for treatment of perforators with Endovenous Laser Ablation Therapy (EVL) emerging as a promising modality.

Aim: To calculate the rate of perforator closure post-EVL and to study the patient's progress using Revised Venous Clinical Severity Score (RVCS) post-treatment of incompetent perforators in resistant cases of varicose vein.

Materials and Methods: This prospective cohort longitudinal study comprised of 55 patients suffering from treatment resistant venous ulcer over a minimal period of three months with incompetent perforators even after the treatment of primary venous insufficiency. They were taken up for EVL. The

patients were followed-up for three months for healing of ulcer and improvement of symptoms using the RVCS. Statistical analysis was done using Statistical Package For Social Science (SPSS version 24.0) and paired t-test was used to calculate the p-value at three weeks and three months.

Results: Out of 55 patients, 45 consented for active perforator management. In that group of 45 patients, 75 incompetent perforators were identified and managed by EVL. Rest 10 patients opted for the conservative management. The closure of perforator was found in 100% perforators with 95% of these patients showing healing of ulcers on follow-up. With treatment of incompetent perforators, there was a significant reduction in RVCS from 9.44 to 4.16 when patients were followed-up after three months.

Conclusion: The EVL is an effective method in closure of the incompetent perforators in lower limb. The treatment of incompetent perforators is must, especially in cases of intractable/residual varicose vein disease.

Keywords: Perforator closure, Revised venous clinical severity score, Varicose veins

INTRODUCTION

Varicose veins are tortuous, dilated veins with histological presence of tunica intima hypertrophy [1]. They are most commonly seen between the age group of 30-70 years. The common clinical presentation in a case of varicose vein disease include cosmetic problems, leg pain, pruritus and skin rash. Few patients can present as thickened skin with pigmentation (lipodermatosclerosis), bleed from a varicosity or a non-healing ulcer [2]. Varicose vein disease involving the hind limbs effects the superficial component of venous system i.e., GSV, SSV and associated perforators. The concept of this disease is ancient going back into the time of Celsus and Hippocrates who gave the humoral theory of Avicenna [3]. Previously, the management of this disease mainly focussed on surgical treatment involving GSV and SSV, until Homas gave the concept of incompetent perforators management, in addition to previous treatment in 1916 [4]. Many research papers have revealed the role of incompetent perforators treatment in residual and intractable varicose vein [5,6].

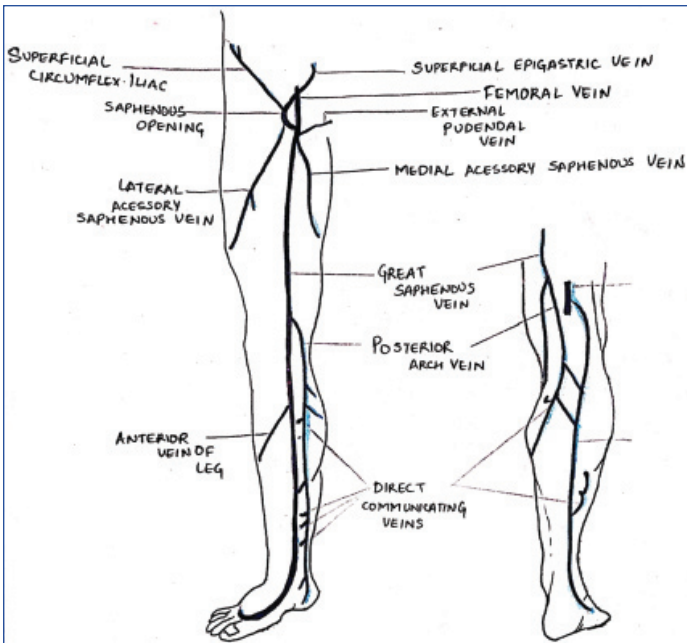
Many treatment options are available for perforator management like open ligation, subfascial endoscopic perforator surgery, coil embolisation, thermal ablation, sclerotherapy and glue embolisation [7-10]. Previously, the major focus was on the treatment of GSV and SSV with management of incompetent perforators through surgical techniques. Limited study is available which establish the role of perforator management using endovenous laser technique [11]. So in this study role of endovenous laser treatment in perforator management and healing of resistant ulcers has been studied.

MATERIALS AND METHODS

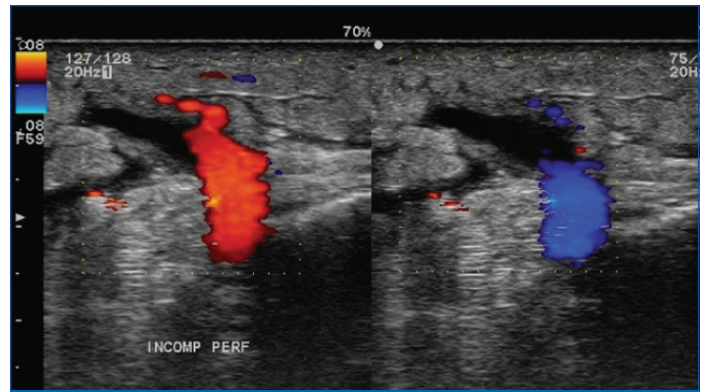
This was a prospective cohort longitudinal study carried out over a period of one year from June 2019 to June 2020 after obtaining

approval from the Institutional Review Board (IRB) Ethical number DM/IEC/2019-20/195. The study included patients referred to the Radiology Department with chief complaint of non-healing ulcer even three months after surgical/EVL of GSV/SSV and having incompetent perforators. All procedures performed in this study involving human participants were according to the Ethical standards of the Institutional and/or National Research Committee. Fifty five patients presented during the study period, who fulfilled this inclusion criteria were taken up for the study. Those cases having underlying Deep Vein Thrombosis (DVT) or reflux in the deep vein, overlapping arterial disease were excluded from the study.

The venous anatomy of the lower limb consists of superficial and deep veins. Superficial venous system consists of the Common Femoral Vein (CFV) which begins at the level of the inguinal ligament as the continuation of the external iliac vein and extends caudally to the bifurcation into the Femoral Vein (FV) and the profunda femoris vein, which lie medial to the adjacent artery. The Popliteal Vein (PV) represents the continuation of the FV after its exit from the adductor canal in the posterior caudal thigh. The paired anterior tibial veins arise from the PV and course laterally along the anterior calf to the dorsum of the foot. The tibioperoneal trunk originates from the PV slightly caudal to the anterior tibial veins and bifurcates into the paired posterior tibial veins and peroneal veins. GSV and SSV and their branches comprise the superficial venous system of the lower extremities. The GSV empties into the medial aspect of the CFV. The normal GSV typically is 1 to 3 mm in diameter at the level of the ankle and 3 to 5 mm in diameter at the saphenofemoral junction. The SSV measures 1 to 2 mm in diameter inferiorly and 2 to 4 mm at the saphenopopliteal junction [Table/Fig-1].



[Table/Fig-1]: Venous anatomy of the lower extremity.

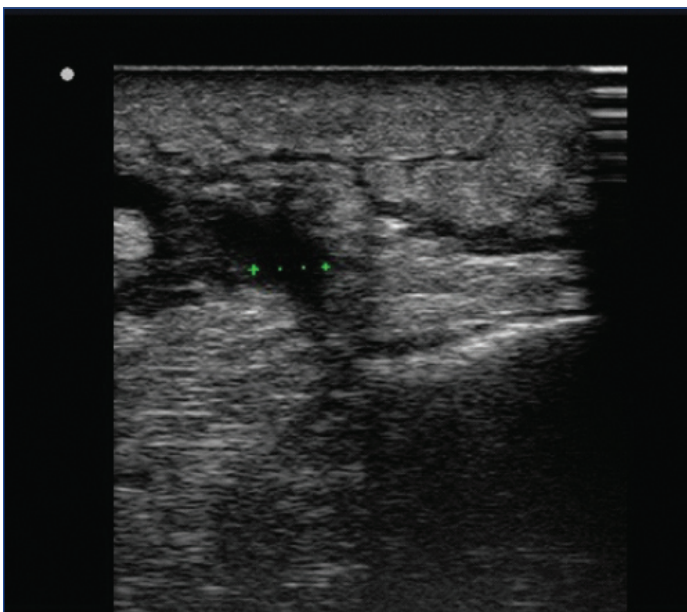


[Table/Fig-3]: Reflux is seen on distal augmentation.

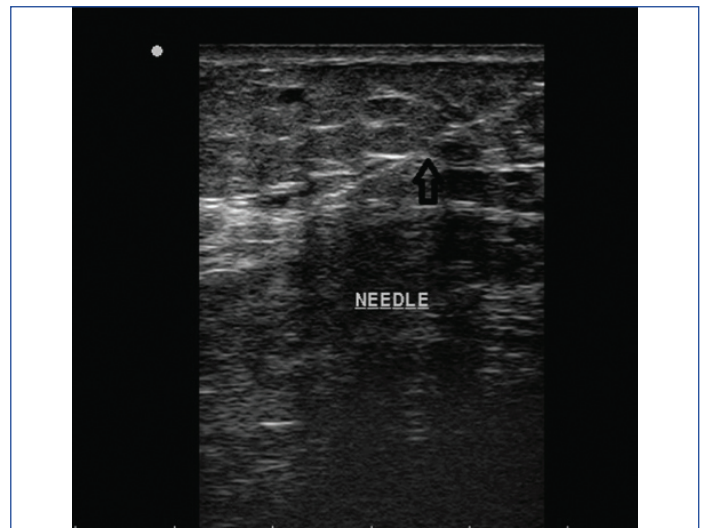
The cases which fulfilled the aforementioned criteria underwent complete physical examination for any venous pathology. The evaluation was performed and graded according to the RVCSS which was given by American Venous Forum [12]. The various parameters included in evaluation were skin pigmentation, pain, venous oedema, inflammation, number and size of active ulcers and were graded according to the scoring pattern mentioned in the RVCSS. The similar repeat examination after procedure was performed after three weeks and at three months post-treatment. The scoring was done independently by two radiologists blinded to each other's observation to limit the bias.

The positive cases were assessed with hind limb venous doppler examination to identify the perforators which are incompetent. The examination was done in lying down and standing position. The doppler was performed using high frequency probe (7-12Mhz) for better resolution imaging. The criteria to label the perforator as incompetent was reflux for more than 0.5 second and diameter more than 3.5 mm [Table/Fig-2,3] [13,14]. After the identification of the incompetent perforators, endovenous laser was used to ablate them.

of the Ultrasound (USG) probe and the puncture site with 2% chlorhexidine solution, 5 mL 2% lignocaine was injected for local anaesthesia. The perforator vein was accessed using the 18-gauge needle under USG guidance. The position of the needle was confirmed by USG guidance and blood extravasation through needle [Table/Fig-4]. No tumescent was given in this procedure. Under USG guidance, needle tip was positioned at the fascial level. Furthermore, the positioning of the laser fibre was kept such that the fibre tip was 1 cm distal to the tip of the needle. Under laser energy, the perforator vein ablation was done, using 940-nm diode, 1,320 nm Nd:YAG and 1,470-nm microfibers [15]. The perforator occlusion was ensured using USG in the follow-up [Table/Fig-5]. The steps of EVLT are shown in the schematic diagram [Table/Fig-6].



[Table/Fig-2]: Incompetent perforator with closure procedure.

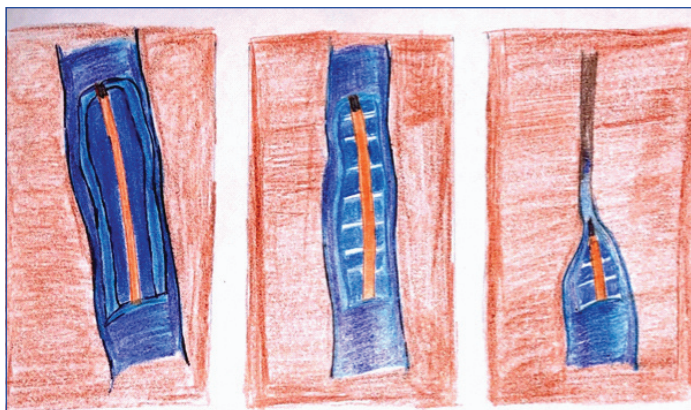


[Table/Fig-4]: EVLT procedure done with needle placement at fascial level (black arrow).



[Table/Fig-5]: Postprocedure doppler image showing obliterated perforator with no flow.

The ablation was carried out under asepsis in accordance with a strict protocol [13]. The patient position was set as prone/supine according to the site of the perforator. After adequate preparation



[Table/Fig-6]: Fiberoptic laser is inserted into the diseased vein. Laser energy causes vein to collapse. Laser is slowly withdrawn and vein closes. Vein becomes harmless fibrous tissue and is gradually absorbed.

STATISTICAL ANALYSIS

Statistical analysis was done using SPSS version 24.0 and paired t-test was used to calculate the p-value at three weeks and three months.

RESULTS

A total of 55 patients (18 female and 37 male) were taken up in this study with average age of 48.50 ± 11.86 (25-75 years). A total of 55 ulcers were present in 55 patients. Out of the 55 patients, only 45 agreed for the laser ablation of the incompetent perforators. Rest 10 patients opted for the conservative management. In the evaluated 45 patients, there were 75 incompetent perforators which were successfully treated through laser ablation. The most common site for the perforators was medial aspect of ankle with average diameter of 4.5 mm.

The patients were followed-up for healing of ulcer and improvement of symptoms using the RVCSS after three weeks and at interval of three months after procedure. There was a significant mean reduction in the RVCSS (5.28 ± 1.52 , p -value < 0.001) among the patients with the perforator closure in comparison to the patient with non-closure. Detailed follow-up RVCSS for the patients and ulcer healing are given in the [Table/Fig-7].

	Preprocedure		Postprocedure (three weeks)		Postprocedure (three months)	
	RVCSS	Ulcer healing	RVCSS	Ulcer healing	RVCSS	Ulcer Healing
Perforators closed	9.44 ± 1.11	0	6.01 ± 1.01	20	4.16 ± 1.1	43
Perforators not closed	10.21 ± 1.21	0	9.15 ± 1.19	1	8.29 ± 1.02	2

[Table/Fig-7]: Showing RVCSS score and ulcer healing in preprocedure and follow-up to three months; (RVCSS-Revised Venous Clinical Severity Score).

No major complications were found in this study. However, on subsequent follow-up post-treatment; 20% patients complained of pain and redness due to persistent inflammation with few of them showing small areas of burn around ablation.

DISCUSSION

The study was carried in two aspects to evaluate the success rate of perforator closure in EVLT procedures and its impact on ulcer healing in resistant non-healing ulcers. Closure rate of the perforators in the study was 100%. Its corresponding impact on ulcer healing was favourable with comparison of pre and postprocedure RVCSS showing significant postprocedure reduction. Perforator occlusion in the management of the venous ulcer has always been a debatable issue in the past. Some studies have shown positive results for the closure of incompetent perforators [16,17], while some of them have advocated contrary to this [18,19]. Many studies have shown that incompetency of perforators can be attributed to change in the haemodynamics in the lower limb post saphenous vein occlusion

and these incompetent perforators play an important role in recurrent venous ulcer [20]. Evaluation of incompetent perforators is done using the duplex doppler. Various criteria have been used to evaluate the incompetent perforators. The most widely accepted criteria for the incompetency of the perforators is diameter > 3.5 mm and reflux > 0.5 second [13,14]. Various methods are available for the management of the incompetent perforators including surgical method, using cyanoacrylate glue, coil embolisation and endovenous laser management. This study was intended to study the efficacy of the endovenous laser treatment of the incompetent perforators and its impact on the clinical profile of the patient.

The perforator occlusion success rate in this study was 100%. The available literature also shows a similar high success rate achieved for perforator closure using laser ablation. Zerweck C et al., in a similar study achieved an occlusion rate of 95.6% [21]. Dumantepe M et al., had a occlusion rate of about 86% in their study [22]. Similar results were also observed by Hissink RJ et al., and Lawrence PF et al., [23,24]. The symptom relief in the patients of chronic venous insufficiency was calculated using RVCSS and by separately evaluating the ulcer healing. RVCSS was calculated in the preprocedure phase and during follow-up to three months. The average reduction in the RVCSS post-ablation of the perforators was 5.28 ± 1.52 which was significant statically (p -value < 0.001). Similar results are also found in the literature. Most studies have revealed favourable reduction in the RVCSS postperforator closure. Prasad Bp K et al., studied the RVCSS after perforator management in chronic residual and recurrent varicose vein [25]. A significant reduction in score was evident i.e., from 8.18 ± 3.60 to 4.30 ± 2.48 after three months which decreased even further to 2.42 ± 1.52 after six months and significant statistical result. Dumantepe M et al., also showed similar results in their study [22]. Amongst the cases with perforator treatment, the ulcers were healed in 95% of the cases in three months, however there was no significant improvement in patients who opted for conservative treatment. Lawrence PF et al., also illustrated ulcer cure in 90% of their patients [24]. Similarly Prasad Bp K et al., also gave about 100% cure in the patients with ulcer post-treatment of incompetent perforator [25].

The laser management of the perforators offers multiple advantages. It has high success rate which is most novel method of management of varicose veins. However, it is not universally available and is expensive treatment modality for varicose vein and perforator management. Endovenous laser management produces successful results in treatment of patients with incompetent perforators. Treatment of incompetent perforators produces significant symptomatic improvement in the form of decrease in the RVCSS and improved ulcer healing. The laser ablation has its associated complications. In 20% of patients in the study there was persistent inflammation with few of them shows small areas of burn around ablation.

Limitation(s)

Firstly, it was carried in a short sample size. Secondly, perforator closure was studied in specific set of patients who had already undergone primary treatment of GSV/SSV stripping/ablation. The generalisation of the results to full set of population has to be done with caution. Thirdly, study was done with short time of follow-up limited to three months. The delayed complications/effects of perforator closure and its impact on ulcer healing was not done after three months.

CONCLUSION(S)

The EVLT is a relatively safe procedure producing no major complications in the patients. It is a very good method in closure of the incompetent perforators in lower limb, producing 100% success rate in present study. It produces statistically significant mean reduction in the RVCSS in comparison to the patient with non-closure.

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