

Surgical Venous Ablation in Varicose Veins Lower Extremity under Sonographic Guidance

Deepak Tolia¹, Jitesh Tolia²

¹Associate Professor, Department of Radiology, Shantabaa Medical College, Amreli, Gujarat,

²Assistant Professor, Department of Surgery, People's College Of Medical Sciences & Research Centre, Bhopal, Madhya Pradesh.

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Abstract

Introduction: The EVLA method can be applied in approximately 70% of the patients with complaints of varices. The aim of this study is to assess the efficacy of the EVLA procedure in treatment of saphenous venous insufficiency and the resultant varicose veins.

Materials & Method: Total of 100 patients were include in the study. The EVLA procedure was done using a 1470 nm laser diode by the Interventional Radiologist. The patients were evaluated clinically and by using colour Doppler before the procedure, two months and five months after the procedure.

Results: The decrease in Venous clinical severity score and Venous disability score from the pre-procedural score to the second and fifth month scores (post procedure) was found to be statistically significant ($p < 0.05$). Decrease in saphenous vein diameters from the pre-procedure measurement to the second and fifth month diameters (post procedure) at various levels as described was found to be statistically significant ($p < 0.05$). Significant decrease in the number of patients with venous reflux was noted on fifth month follow-up after the procedure.

Discussion & Conclusion: EVLA is a minimally invasive technique. EVLA results in irreversible damage to the vein which is ablated. The venous occlusion is mainly due to progressive fibrosis which causes obliteration of the vein rather than thrombotic occlusion. As this is a new technique, data regarding the long-term outcome of EVLA is required to confirm the durability of the procedure.

Keywords: EVLA, Saphenous vein, Venous insufficiency; varicose veins

Introduction

Venous disease is a common health problem encountered by many people. The effects of this in terms of disability and health care costs are

considerable. Etiology is multifactorial ranging from thrombotic obstruction, loss of vein wall elasticity, to valve incompetence. The most common cause of chronic venous insufficiency and varicose veins is saphenous vein insufficiency.^{1,2} Refluxing venous

Corresponding Author: Jitesh Tolia, Assistant Professor, Department of Surgery, People's College Of Medical Sciences & Research Centre, Bhopal, Madhya Pradesh.

E-mail: jiteshtolia@hotmail.com

Phone: 99242 32730

blood leads to venous hypertension. This results in venous reflux due to poorly functioning or incompetent venous valves. Distension of the vein as well as endothelial activation can be seen which promotes leukocyte extravasation. The resulting inflammatory state in the superficial dermis and in the vein wall itself causes a range of symptoms and physiologic changes including pain, edema, varicosities, stasis dermatitis, and ulceration.³

Symptoms of superficial venous disease include telangiectasia, varicose veins, edema or skin changes. Skin or venous ulceration can also be present in severe cases. The prevalence of chronic venous disease in adults is usually indicated by the presence of varicose veins. This has been noted to vary between 5% and 65% of the population.⁴ The prevalence of chronic venous disease is noted to be higher in the western countries than in the developing countries. However, an international, observational, prospective study called the vein consult program which consisted of about 90,000 patients across different regions of the globe showed that the prevalence of chronic venous disease was mostly the same across the globe.⁵

Though some studies have shown that varicose veins and chronic venous disease are more commonly reported in females than in males, the established risk factors for development of chronic venous disease are increasing age and previous pregnancy.

Some of the lesser risk factors are noted to be female sex alone (without previous pregnancy), high BMI (Body mass index), work which involves prolonged standing throughout the day or prolonged sitting throughout the day. Symptomatic chronic venous disease patients usually face a measurable decrease in the quality of their lives. QOL is used to denote quality of life. The symptoms can cause hinderance to the social life of the patient and can limit the physical or occupational activities of the patient. This can even lead to financial consequences due to disability resulting from the disease causing loss of work time or loss of the ability to continue the present occupation.⁶

Treatment options for varicose veins include conservative methods, minimal invasive procedures and surgery. Conservative treatment options include the avoidance of prolonged standing and straining,

elevation of the affected leg, exercise, external compression, medical therapies, and weight loss.⁷ External compression therapies with bandages or support stockings have been recommended as the initial therapy for varicose veins. Conservative therapies may relieve the patient's discomfort and slow the progression of the disease but cannot cure it.⁸

In surgical treatment, the most common operation is ligation and stripping. However, disadvantages include requirement of general anaesthesia, postoperative pain and cut scar. In addition, recurrence is observed in approximately half of the patients in the first 5 years after treatment.⁹

Endovenous Laser Ablation (EVLA) is one of the best minimally invasive techniques for the treatment of varicose veins. Laser therapy for varicose veins was described in 1985 but the current technique of EVLA was first used by Dr Bone in 1999, and subsequently reported in large series by Dr Luis Navarro and Dr Robert J. Min.¹⁰ The most important advantages of this method include performance under local anesthesia, absence of pain, absence of wound or scar and mobilization of the patient immediately after the procedure. The EVLA method can be applied in approximately 70% of the patients with complaints of varices. The aim of this study is to assess the efficacy of the EVLA procedure in treatment of saphenous venous insufficiency and the resultant varicose veins.¹¹

Materials and Method

The source of data for this study will be patients referred to the Department of Radio Diagnosis, in the Medical College and Hospital, for the treatment of saphenous vein insufficiency. The study was conducted for the period of two years. The ethical committee of the institute was informed about the study and the ethical clearance certificate was obtained. The inclusion and exclusion criteria of the study were as below:

Inclusion Criteria

1. Patients diagnosed with symptomatic saphenous vein insufficiency.

Exclusion Criteria

1. Patients diagnosed with deep vein thrombosis (DVT).

2. Patients diagnosed with severe arterial insufficiency.
3. Pregnant or breast feeding patients.
4. Patients with past history of allergy against local anaesthetics.

All patients referred to the Department of Radio Diagnosis, in Medical College and Hospital, for the treatment of saphenous vein insufficiency were the source of the data. Total of 100 patients were included in the study. All the patients included were informed about the procedure and purpose of the study. Written informed consent was obtained from all the included patients. Those who did not provide the consent were excluded from the study. The detail history was recorded.

Before the EVLA procedure is done, the condition of patients would be evaluated by the following measures:

Presence of venous reflux would be assessed using colour Doppler ultrasonography, in case of venous insufficiency of the long saphenous vein; the diameter of the vein would be measured along the course at the following sites using ultrasonography:

- a. 3 cm distal to Saphenofemoral junction.
- b. 1 cm above knee.
- c. 1 cm below knee.
- d. 1 cm above medial malleolus.

In case of venous insufficiency of the short saphenous vein, the diameter of the vein would be measured along the course at the following sites using ultrasonography:

- a. 1 cm below knee.
- b. 1 cm above lateral malleolus.

The EVLA procedure is done by the interventional radiologist in the department using a 1470 nm laser diode. The outcome of the EVLA procedure would be assessed by follow-up of the patient and evaluation by:

- Venous clinical Severity Score,
- Venous disability score,
- Presence or absence of venous reflux,

- Measurement of the diameter of saphenous veins at the above mentioned sites.

All statistical analyses were performed via Statistical Package for the Social Sciences (SPSS).

Results

The present study was performed with an aim of evaluating the early efficacy of Endovenous Laser Ablation treatment in Saphenous vein insufficiency. Our findings were tabulated using Microsoft Excel and have been provided within the Annexure.

A total of 100 patients were included in the study. All the patients were diagnosed with great saphenous vein insufficiency. The data was recorded, compiled and analyzed. Of the 100 included patients, there were 46 males and 54 females.

Sonography assessment of saphenous vein diameters pre- procedure and during followup:

Pre-procedure:

The mean diameter of GSV 3 cm below SFJ was noted to be 6.23 ± 0.67 mm.

The mean diameter of GSV 1 cm above knee was noted to be 6.02 ± 0.43 mm.

The mean diameter of GSV 1 cm below knee was noted to be 6.01 ± 0.94 mm.

The mean diameter of GSV 1 cm above ankle was noted to be 5.84 ± 0.82 mm.

Two months after the procedure:

The mean diameter of GSV 3 cm below SFJ was noted to be 3.21 ± 0.56 mm.

The mean diameter of GSV 1 cm above knee was noted to be 3.02 ± 0.86 mm.

The mean diameter of GSV 1 cm below knee was noted to be 2.86 ± 0.39 mm.

The mean diameter of GSV 1 cm above ankle was noted to be 2.11 ± 0.69 mm.

Five months after the procedure:

The mean diameter of GSV 3 cm below SFJ was noted to be 1.11 ± 0.02 mm.

The mean diameter of GSV 1 cm above knee was noted to be 1.21 ± 0.16 mm.

The mean diameter of GSV 1 cm below knee was noted to be 1.12 ± 0.12 mm.

The mean diameter of GSV 1 cm above ankle was noted to be 0.64 ± 0.01 mm.

The decrease in saphenous vein diameters from the pre-procedure measurement to the second and fifth month diameters (post procedure) at various levels as described were found to be statistically significant ($p < 0.05$).

Venous clinical severity score pre- procedure and during followup

The mean Venous Clinical Severity Score pre-procedure was 19.2 ± 4.2 .

The mean Venous Clinical Severity Score two month after procedure was 11.25 ± 3.1 .

The mean Venous Clinical Severity Score five month after procedure was 1.86 ± 0.9 .

The decrease in Venous clinical severity score from the pre-procedural score to the second and fifth month scores (post procedure) was found to be statistically significant ($p < 0.05$).

Venous Disability Score Pre-Procedure and During Follow-Up

The mean venous disability score pre procedure was 1.4 ± 0.23 . The mean venous disability score one month after procedure was 1.1 ± 0.32 . The mean venous disability score three months after procedure was 0.82 ± 0 . All patients were noted to have a venous disability score of 0 six months after the procedure. The decrease in Venous disability Score from the pre-procedural score to the first, third and sixth month scores (post procedure) was found to be statistically significant ($p < 0.05$).

Superficial Venous Reflux Pre-Procedure and During Follow-Up:

Reflux was noted to be present in 72 out of the total 100 Great Saphenous veins. These veins did not show reflux in the USG examinations done at 2nd month and 5th months post-procedure. All

100 patients of the Great saphenous veins who were ablated showed occlusion at end of 2nd months and 5th months post procedure. Recanalization of GSV was not found in any of the 100 Great saphenous veins 5th months after the procedure.

Discussion

Endovenous laser ablation provides a minimally invasive, very effective and safe treatment option for varicose veins. Laser diodes of varying wavelengths (810 - 1470 nm) can be used to perform the venous ablation. In our study, the 1470 nm laser diode along with radial fibre is used.¹² This diode produces light energy which is primarily absorbed by the water molecules in the vein. The light energy produced by the laser diodes of lower wavelength are preferentially absorbed by the haemoglobin in the vein. Use of a radial fibre along with a laser diode of 1470 nm wavelength results in significant reduction in the power required to achieve the venous ablation. This method also reduces the discomfort of the patient after the treatment.^{12, 13}

In a study performed by Desmyttere et. al. in 500 patients (436 women, 64 men, treatment with EVLA was performed and occlusion with a rate of 98% was obtained immediately after the procedure. In the one-year follow-up visit, the LSV was mostly not visualized or was seen as a fibrous cord.¹⁴ Even when the patients were followed up after 4 years, the venous occlusion rate was found to be 97.1%. In our study, all 100 of the ablated Great saphenous veins were noted to be occluded at 2nd month and 5th months.

EVLA treatment was found to be successful in 85.5% of patients in a study done by Sharif et. al.¹⁵ The procedure was performed in 145 limbs of 136 patients who had Great saphenous vein insufficiency. A complete occlusion rate of 89.7% and a partial occlusion rate of 7.7 % were observed at a 2 month follow-up visit. At the 12-month follow-up visit, complete occlusion was observed with a rate of 76% and partial occlusion was found with a rate of 18%. In our study, all 100 of the ablated Great saphenous veins were noted to be occluded at 2nd month and 5th months.

In a study performed by M Beyazal et. al. using

a 980 nm diode laser, the mean diameter of the saphenous veins pre-procedure was 4.9 ± 0.8 mm. After months post-procedure, the mean diameter of the saphenous veins was 1.8 ± 0.2 mm. The pre-procedure VCSS score in this study was 5.91 ± 1.2 mm. The VCSS score 5th month post-procedure in this study was 0.8 ± 0.6 mm.

In our study, 1470 nm diode laser has been used. The mean diameter of saphenous vein pre-procedure and 5th month post-procedure measures 3 cm below SFJ were found to be 6.23 ± 0.67 mm and 1.11 ± 0.02 mm respectively. The mean Venous Clinical Severity Score pre-procedure was 19.2 ± 4.2 . The mean Venous Clinical Severity Score six month after procedure was 1.86 ± 0.9 . There is a larger mean difference in Saphenous vein diameter and VCSS score in our study and can be due to the usage of 1470 nm laser diode with radial tip fibre.

In a study performed by Rathod et. al. EVLA was performed on 108 veins on 76 limbs using 1470 nm diode laser and were followed up on day 2, 1 month, 6 months, and 12 months post-procedurally. The venous occlusion rate at the end of 1 year follow-up was 98.61%. The pre-procedure clinical grade and the venous disability score also showed significant improvement.

In a study performed by Mundy et. al., rate of closure of GSV has been reported as 88-100%. Relief in symptoms along with reduction in superficial varicosities has been observed. Separate treatment of individual varicosities is not needed initially. Any varicosities which are remaining 6 weeks after the EVLA procedure can be treated using delayed sclerotherapy.

In our study, we found that there was a significant progressive reduction in the Saphenous vein diameter at various levels.

When the pre-procedure value and the postprocedure values after 2nd month and 5th month were compared ($p < 0.05$). We also found that there was a significant reduction in the VCSS and VDS scores when the pre-procedure values and the post-procedure values after 2nd month and 5th months were compared ($p < 0.05$). Greenhouse-Geisser correction was used to calculate the p value and thus

evaluate the significance of the progressive reduction in saphenous vein diameters along with the VCSS and VDS scores. No evidence of venous reflux nor recanalization was noted in any of the 50 Great saphenous veins which were ablated.

Conclusion

EVLA is a minimally invasive technique. Cannulation of the vein is done using a needle and the further procedure is performed through this site. Few injections are given surrounding the superficial vein while injecting the local anaesthetic. This also provides excellent cosmesis. EVLA results in irreversible damage to the vein which is ablated. The venous occlusion is mainly due to progressive fibrosis which causes obliteration of the vein rather than thrombotic occlusion. As this is a new technique, data regarding the long-term outcome of EVLA is required to confirm the durability of the procedure.

Ethical approval was taken from the institutional ethical committee and written informed consent was taken from all the participants.

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Conflict of Interest: None declared

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