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Recurrence of Varicose Veins Following Endovenous Laser Therapy on a Daycare Basis: Our Centre Experience

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Abstract

Background: Chronic venous insufficiency (CVI) often presents with the development of incompetent short or great saphenous veins (SSV or GSV), resulting in a condition known as varicose veins. **Material and Methods:** The present study was conducted with the aim of evaluating the outcomes and recurrence following endovenous laser therapy (EVLT) for CVI by discharging the patient on the same day following the procedure. **Results:** In this study, only 4 patients developed recurrence following varicose vein treatment out of 102 patients with EVLT on a daycare basis. An occlusion of GSV along with its branches was achieved in most of the cases with self-limiting adverse effects and very few recurrence rates in the follow-up period. **Conclusion:** Relief of symptoms and a significant improvement in the appearance of varicose veins were noted 4-6 months after initial treatment, and pain was greatly resolved in all the treated limbs.

Keywords: Varicose Veins, Chronic Venous Insufficiency, Endovenous Laser Therapy, Recurrence.

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Introduction

Chronic venous insufficiency (CVI) is a term used to describe the discomfort brought on by venous hypertension as well as lower extremity edema and skin trophic alterations.[1] Primary chronic venous insufficiency is caused by congenital abnormalities or changes in the biochemistry of the venous wall and describes the clinical presentation without a precipitating event. According to recent research, 30% of patients have secondary disease, and about 70% of patients have basic chronic venous insufficiency.[2-4] Chronic venous insufficiency-related disability results in diminished quality of life and decreased productivity at work.[5,6] A frequent ailment known as varicose veins is brought on by weak or damaged vein walls and valves. One-way valves within veins open and close to maintain blood flow toward the heart. Blood can pool and even flow backward in veins that have weak or broken walls or valves. We refer to this as reflux.[7-9]

The natural history and pathogenesis of chronic venous diseases are still unclear, possibly as a result of the disease's complex origination, which makes identifying its causal elements challenging. Varicose veins and skin trophic changes have been linked to the pathophysiology of the venous system from a hemodynamic point of view and the effects of valvular dysfunction in superficial, deep, and perforating veins.[10] Untreated CVI typically progresses and causes venous ulcers and post-phlebitis syndrome.[11-13] The patient might additionally experience pain, swelling in the legs, pruritus, and skin discoloration in addition to the cosmetic damage. Compression stocking use is the cornerstone of treatment; however, compliance rates are low.

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Most procedures for varicose veins are minimally invasive and do not require a long recovery.[14-16]

Consequently, the purpose of this study was to determine the prevalence, risk factors, and analysis of varicose veins, skin trophic changes, as well as the outcomes including recurrence of day care operations in these individuals.

Material and Methods

Study Overview: This prospective cohort study was conducted at the Department of Cardiothoracic & Vascular Surgery from November 2016 to October 2018 (2 years). The present study was conducted with the aim of evaluating the outcomes in terms of achievement of occlusion of the GSV and disappearance of the associated varicosities, complications, and recurrence rates following endovenous laser therapy (EVLT) for CVI by discharging the patient on the same day following the procedure, i.e., on a daycare basis.

During this time, a total of 102 patients (after sample size estimation) who presented to the outpatient department and met the inclusion criteria were included in the study. For this study, institutional ethics committee approval was taken from the present institute as well as from the cath lab (IEC/GSVM/LPSIC/Thesis/2016-14/CC-5802).

The study's protocols adhered to the Declaration of Helsinki's 1975 ethical criteria. Every patient gave their proper, written, informed consent. They were treated with EVLA and were followed up every week in the first month post procedure and thereafter on monthly basis till the completion of follow up visits i.e. for one year and during every visit patients were evaluated clinically and were also subjected to ultrasonography Doppler to rule out or check for recurrence following procedure.

Study Criteria: The inclusion criteria included patients with age at least 14 years, patients willing to consent (for the patients in the age groups 14-18 years consent was obtained from the parents), patients with saphenofemoral junction reflux or saphenopopliteal junction reflux with great and short saphenous vein reflux, as demonstrated by bidirectional continuous wave doppler and duplex ultrasonography, and patients ready to follow-up for 1 year after the treatment, were included in the study.

Exclusion criteria included patients with suspected deep vein thrombosis (DVT), patients not able to ambulate, patients with poor health who are non-compliant with severe illnesses and comorbidities with non-palpable pedal pulses and females who are pregnant or planning to conceive during the course of treatment and follow-up. Patients were included after meeting the inclusion and exclusion criteria.

Study Procedure: All the patients were preoperatively assessed by colour Doppler and duplex ultrasonography, which was done by an experienced radiologist who was a member of the team prior to the instrumentation, and on subsequent follow-up visits, duplex was performed in an upright position. Reflux was defined as being antegrade and could be triggered by manual compression of the leg. Reflux was defined as a retrograde flow lasting more than 0.5 seconds with patients standing during a valsalva manoeuvre or with compression or decompression of the calf.

The pre- and post-operative diameters of SSV and GSV were measured at 3 cm distally from the Saphenopopliteal junction (SPJ)-SFJ junction. Even a slight marginal flow or reflux with largely closed veins was defined as subcutaneous varicosity of more than 3 mm in diameter in the treatment area, which occurred after initial treatment. The entire venous system was checked for any signs of DVT. Then, only patients were subjected to EVLT, as explained earlier.

Varicosity and incompetent perforators were first marked (using Henna, a dye obtained from the plant species Lawsonia inermis, was used to mark the site of the varicose vein perforators)

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as described in the methods section. Great Saphenous Vein was punctured ideally below the knee in the Trendelenburg position, as shown in [Figure 1].

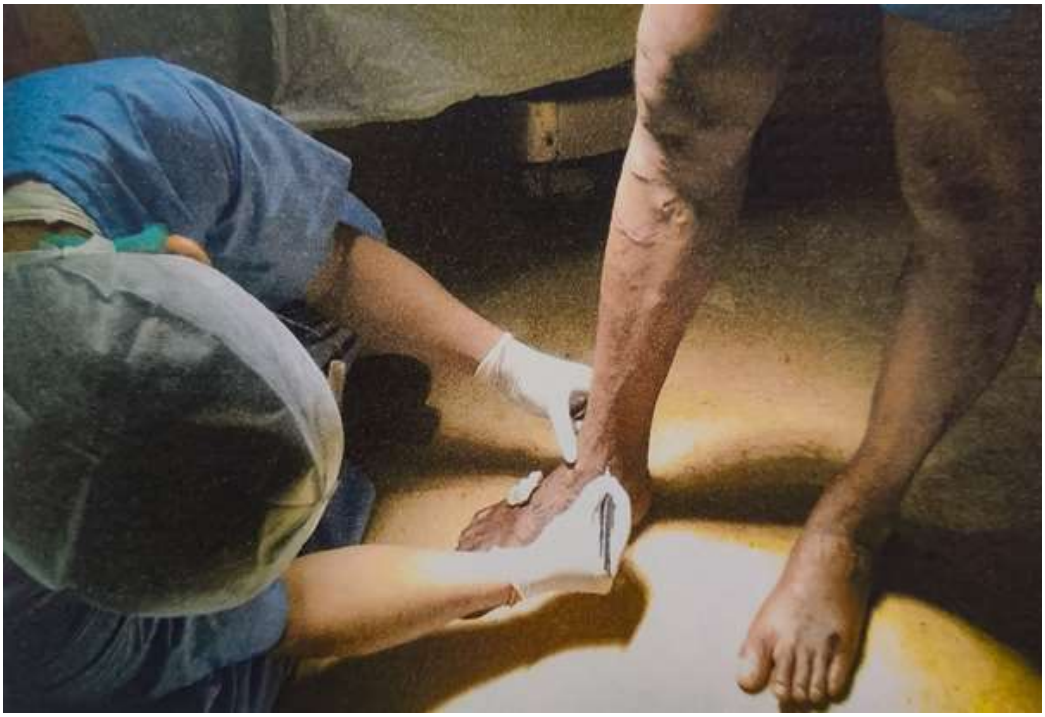

Figure 1: (A) A picture showing markings being done for perforators and varicose veins.

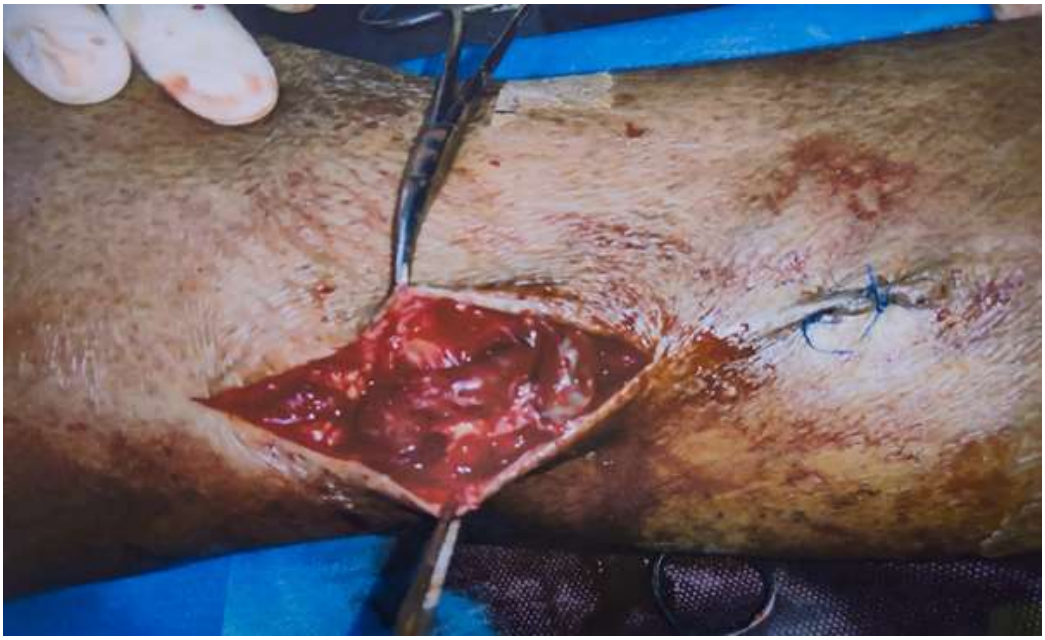

Figure 1: (B) An intraoperative picture showing perforator ligation being done.

The vein and perforators were inspected in the c-arm after injecting gadollium-based dye measuring around 50 ml into the vein. After sheath and fibre were introduced, tumescent anaesthesia was given in the perivenous plane safely with use of an intraoperative doppler (for making neighbouring tissue firm and tense for pain relief and preventing neighbouring structures from getting burned), and a laser was fired at 80 J and 8 Watts. Energy was reduced to 60 J below the knee, as shown in [Figure 2].

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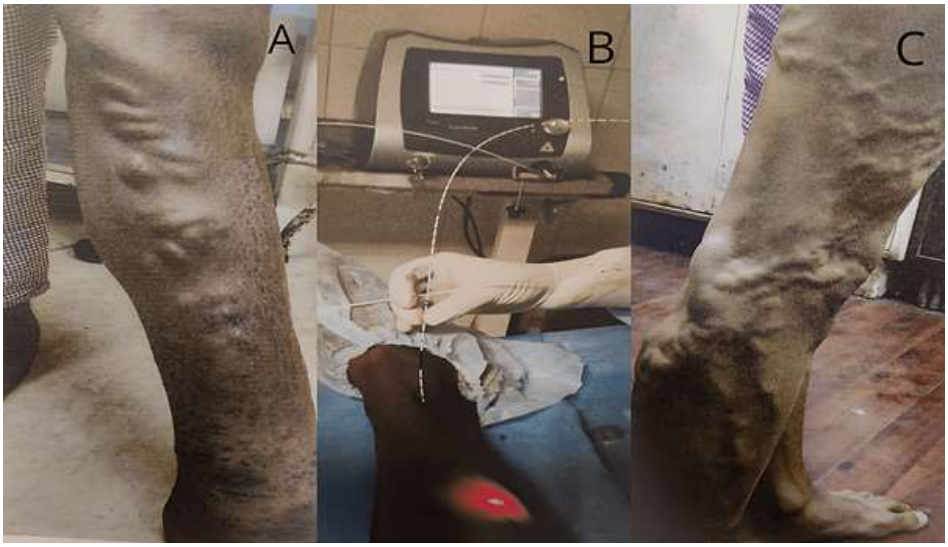

Figure 2: (A) Varicose veins with perforators in the left lower limb; (B) Endovenous laser ablation (EVLA) being done; (C) picture showing resolution of the disease in the first follow up visit.

Fibre was withdrawn slowly at the rate of 1mm per second. Perforators were ligated and divided, and dressing was done along with Crepe bandage was applied post procedure followed by compression stocking advised ranging from 2 to 4 weeks post procedure following the hospital discharge based on the follow up visits. During follow-up, duplex USG was done at one month, three months, six months, and yearly thereafter to assess treatment efficiency and adverse effects associated with the procedure. Patients with recurrence were treated with redo surgery. The follow-up period ranged from 30 days to 1 year.

Study Assessment: The patients were followed up every week in the first month post procedure and thereafter on monthly basis till the completion of follow up visits i.e. for 1 year and during every visit patients were evaluated clinically and were also subjected to ultrasonography Doppler to rule out or check for recurrence following procedure.

Sample Size & Statistical Analysis: Our estimated sample size was based on the study of the role of EVLT in the management of CVI by M.A. Sharif et al.[15] Thus, a sample size of 102 provided 90% power at a 95% confidence level. A total of 102 patients were included from the outpatient department who met the inclusion criteria and who met the criteria as shown in [Table 1].

Table 1: A table showing the inclusion and exclusion criteria for the patients.

Inclusion Criteria	Exclusion Criteria
SFJ or SPJ with GSV or SSV as demonstrated by bidirectional continuous wave doppler and duplex ultrasonography.	In women, pregnancy or plans to conceive during the course of treatment and follow-up.
Age at least 14 years.	Deep Vein Thrombosis (DVT)
Patients willing to consent.	Inability to ambulate.
Ready for follow-up for 1 year after EVLT.	General poor health with non-palpable pedal pulses.

The total number of 102 patients who presented to outpatient department of Cardiothoracic & Vascular Surgery within the study duration i.e., from November 2016 to October 2018 (2 years) and met the inclusion criteria were admitted and treated by these methods after obtaining the informed consent. For testing the significance of proportion, we used the Fisher-Z test to

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declare that the aim or hypothesis is significant or not at p <0.05 (significant) or p >0.05 (non-significant) at different degrees of freedom and the tabulated value of Z.

Results

In our study, a total of 102 patients have undergone treatment for varicose veins. The maximum number of patients (34.3%) were found in the 41-50-year-old age group, followed by the 18-30-year-old age group, i.e., 32.3%, and the male prevalence was 82.4% higher when compared to the female prevalence (p = 0.021), i.e., 17.6%. Most of the patients presented with complaints of dilated veins (88.0%) (p = 0.032), followed by pain (41.0%). The demographic profile and disease characteristics of the patients have been shown in Table 2.

Table 1: A table showing the demographic profile and disease characteristics of the patients included in the present study.

Age Distribution of Patients (102 patients)		
Age Group	**Number of Patients**	**Percentage**
18-30	33	32.3
31-40	17	16.6
41-50	35	34.3
51-60	11	10.7
61-70	06	05.8
Sex Distribution of Patients (102 patients)		
Sex	**Number of Patients**	**Percentage**
Male	84	82.4
Female	18	17.6
History of Presenting Complaints (102 patients)		
Complaints	**Number of Patients**	**Percentage**
Pain	42	41.0
Dilated veins	90	88.0
Edema	20	19.6
Pigmentation	38	37.2
Ulcers and ulcer scars	32	31.3
Venous claudication	22	21.5
Risk Factor Distributions in Patients (102 patients)		
Risk Factor	**Number of Patients**	**Percentage**
Male	84	82.3
Female	18	17.6
Prolonged smoking	76	74.5
Hereditary	06	05.8
Obesity	25	24.5
Venous Segment Involved in Patients (102 Patients)		
Segment Involved	**Number of Limbs**	**Percentage**
GSV	30	29.4
SSV	05	04.9
Associated Veins (including perforators)	05	04.9
Combined	62	60.7

In our study, there was male preponderance and the most prevalent risk factor contributing to this condition was prolonged standing at 74.5% (p = 0.043), followed by obesity, i.e., 24.5% observed during the clinical assessment.

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The majority of the patients had combined segment involvement of 60.7% (p = 0.046), followed by GSV involvement of 29.4% as shown in Table 3.

Table 3: A table showing the limb involvement etiology, anatomical variation and pathology leading to varicose veins.

Limb Involvement in Patients (102 Patients)		
Side Involved	**Number of Patients**	**Percentage**
Right	20	19.7
Left	47	46.0
Both	35	34.3
Etiology of Varicose Veins in Patients (102 Patients)		
Etiology	**Number of Patients**	**Percentage**
Primary	102	100
Secondary	00	00
Anatomical Variation in Patients (102 Patients)		
Anatomy	**Number of Patients**	**Percentage**
Superficial veins	102	100
Deep veins	00	00
Pathology leading to Varicose Veins in Patients (102 Patients)		
Pathology	**Number of Patients**	**Percentage**
Reflux	78	76.4
Arteriovenous Fistula/Venous Malformation	24	23.5

As per the above-mentioned table, the left limb was most frequently involved (46.0%) (p = 0.029), followed by bilateral lower limb involvement (34.3%), and all the patients had primary aetiology and superficial vein involvement pertaining to chronic venous insufficiency in our study.

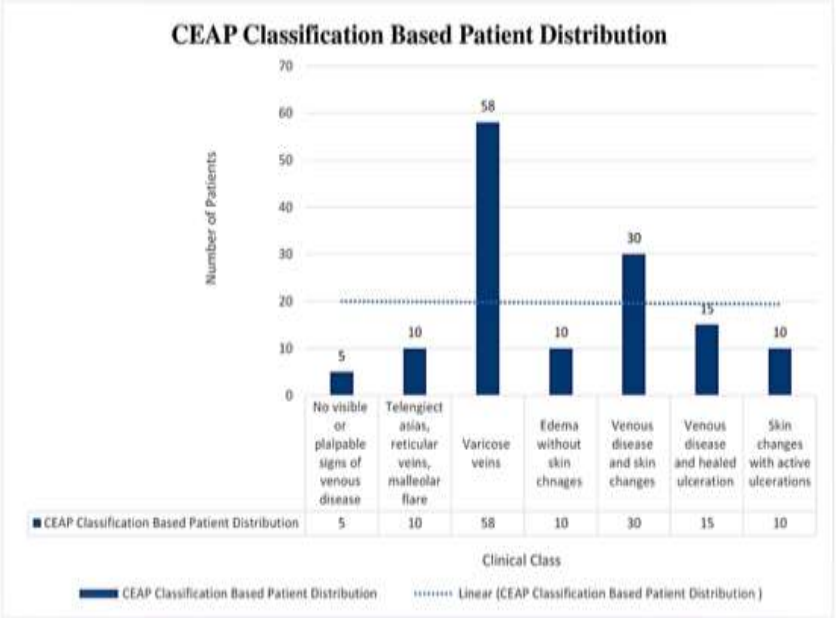

Figure 3: A figure showing Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P) CEAP classification-based patient distribution in our study.

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The pathology associated with the disease was reflux in 76.4% (p = 0.016) and arteriovenous fistula/venous malformation in 23.5% of cases. As per the below-mentioned chart, most of the patients fell into clinical class II (varicose veins) (P ≤ 0.016), followed by clinical class IV (skin changes with varicose veins) (p = 0.019), as shown in [Figure 3].

The GSV diameter range between 5-21.4 mm (mean 1.31, S.D. 3.2) (p = 0.022) measured 3 cm below the SFJ whereas the SSV diameter ranged between 6-9 mm (mean 7, S.D. 1.2) measured 3 cm below popliteal crease. Total length of GSV treated range from 55-70 cm (mean 61, S.D. 2.6) and that of SSV was 15-22 cm (mean 18, S.D. 1.9). In 35 (34.3%) subjects the involvement was bilateral in the rest 67 (65.7%) (p = 0.028) of the subjects, it was unilateral. Overall we treated 47 (46%) left limbs and 20 (19.7%) right limbs.

We used an average linear endovenous energy density (LEED) for GSV of 72.2 J/cm vein with a minimum of 60J/cm (50 to 80 J/cm). The dilated tributaries of GSV and SSV were also ablated with laser using multiple punctures.

In our study, the most common complication was pain and tightness in the lower limbs in 30 patients (29.4%) (p = 0.039), paraesthesia in 20 patients (19.6%), skin burn in 10 patients (9.8%), and infections in 2 patients (1.9%) after undergoing EVLT at our centre, as shown in [Figure 4].

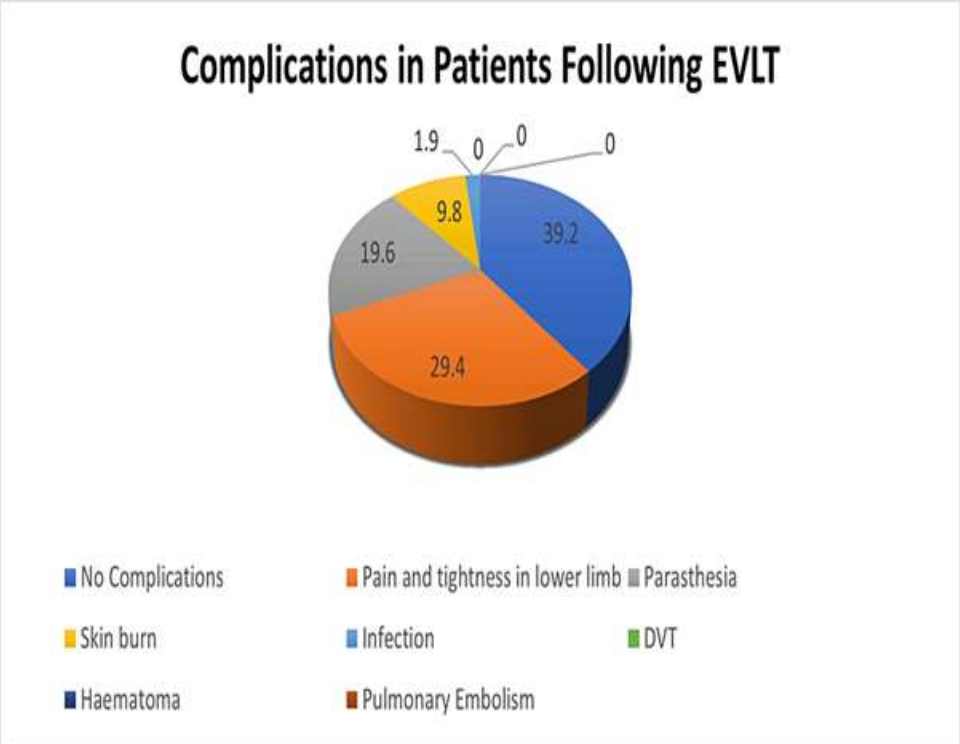

Figure 4: A figure showing complications in the patients following endovenous laser ablation therapy (EVLT) in our study.

EVLT: Endo Venous Laser Therapy

DVT: Deep Vein Thrombosis

In the present study, all the patients completed follow up protocols. The mean follow up duration was 1 year. Clinical examination correlated well with duplex USG findings. All patients showed improvement in the appearance of the limb with disappearance in the sizer and number of visible varicosities, one month after EVLT, relief of symptoms and significant improvement in the appearance of varicose veins was noted by 4-6 months after the initial treatment, pain was greatly improved or resolved in all treated limbs. Only 4 patients developed recurrence following varicose vein treatment out of 102 patients with EVLT on a daycare basis as shown in Figure 5.

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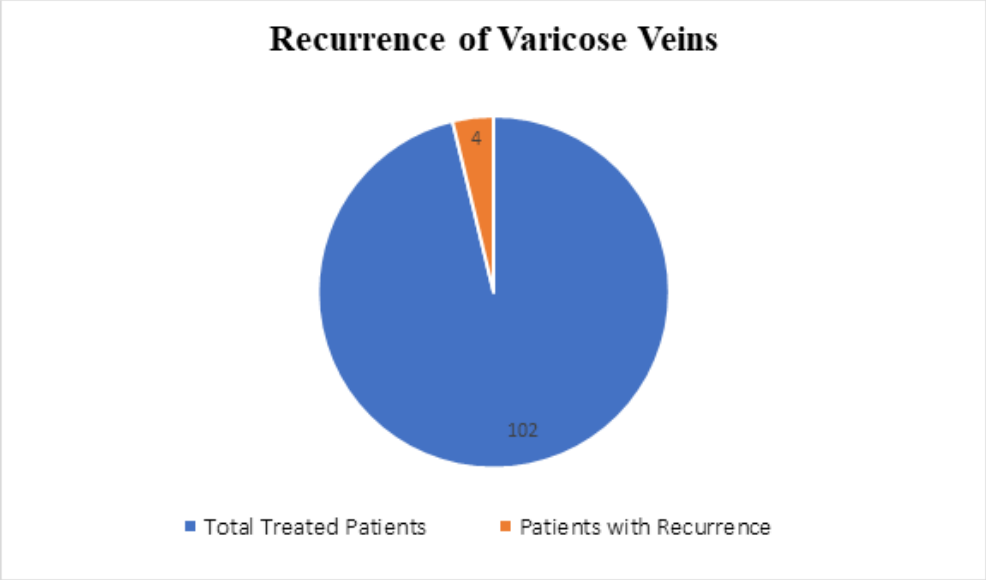

Figure 5: A figure showing recurrence of varicose veins in treated patients with EVLT.

Discussion

The development of minimally invasive endovascular procedures within the past ten years has resulted in a significant shift in the guidelines for treating symptomatic varicose veins.[16] In terms of occlusion rate and recovery time, radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) are equally safe and effective.[17] Dr. Carlos Bone first presented EVLA at the 1999 International Union of Phlebology as a treatment for varicose veins. After inserting the laser fibre into the intended vein, a heat generator produces laser energy. The thermal light that the fibre tip generates causes localised thermal injury to the veins, which causes venous fibrosis, blood thrombosis, and vein constriction. Patients with inadequate saphenous veins seemed to respond well to EVLA therapy. For patients with symptomatic varicose veins, endovenous thermal ablation is advised as a first-line treatment and has replaced surgery to occlude and destroy the veins by employing heat.[18]

In a comparative study conducted, ninety percent of patients in both treatment groups i.e EVLT and radiofrequency ablation groups reported symptom improvement following the operations, indicating that the primary clinical outcomes were similar for the two groups. In the limbs treated with laser therapy, ecchymosis, soreness, and intra- and post-procedural pain were somewhat but not significantly more common. At eight hours, twenty-four hours, one week, six months, and twelve months, there was statistically similarity between the two groups for all pain and tenderness levels. There were no serious issues, although the EVLA group saw a higher frequency of minor complications ($p = 0.0210$). Every follow-up visit, we also computed the AVVSS score for every patient and compared the outcomes.[19-21]

During the past decade, increased interest in venous disorders and the development of new non-invasive diagnostic tests and minimally invasive treatment options have led to tremendous advancements in the understanding and management of varicose veins.[18] EVL ablation was introduced as an alternative to ligation and stripping and has rapidly become the treatment of choice for treating saphenous vein insufficiency.[22,23]

When it came to the time it took for a patient to resume work, endovenous laser treatment was helpful, but the difference was only 1.4 days, and the recovery period of 10 days was greater than what was predicted by the literature.[16,17] However, because recovery is a highly variable parameter that depends on a number of variables (such as the number of varicose veins and the number of phlebectomies performed simultaneously), the published studies are completely non-comparable due to the variety of methodologies and study populations used.[23] Varicose

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veins have been treated extensively with EVLT. For the treatment of varicosity of the GSV, EVLT is at least as successful as surgical procedures, despite the fact that different approaches yield varying outcomes. When it came to primary failure and recurrence, EVLT and surgery did not differ appreciably. EVLT is safe, and despite using more energy, the rate of complications has not increased.

Although few of the patients required additional complimentary procedures i.e. perforator ligation for residual varicosities starting one month after the discharge from the hospital, while most of the patients were discharged within 24 hours of the procedure.

Limitations of the Study: Further prospective research on this subject would be beneficial, taking into consideration aspects like the Visual Analogue Score (VAS) pain score, the impact of compression stockings post-procedure, and the use of pre-procedure anaesthesia to determine its impact on complications and results and with a long follow up period as in the present study we excluded those patients who didn't follow up for a period of 1 year.

Conclusion

In this study, only 4 patients developed recurrence following varicose vein treatment out of 102 patients with EVLT on a daycare basis. An occlusion of GSV along with its branches was achieved in most of the cases with self-limiting adverse effects and very few recurrence rates in the follow-up period. Relief of symptoms and a significant improvement in the appearance of varicose veins were noted 4-6 months after initial treatment, and pain was greatly resolved in all the treated limbs.

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