

**A comparative study of efficacy of simultaneous versus 6 weeks delayed sclerotherapy in patients undergoing endovenous laser therapy.**

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**Abstract**

Varicose veins are a leading cause of morbidity of the lower limbs affecting millions of people annually. Visible varicose veins in the lower limbs are estimated to affect at least a third of the population. It is usually neglected by the people initially due to trivial symptoms caused by it. This leads to late presentation when it becomes difficult to treat. Risk factors for varicose veins are unclear although prevalence rises with age and often develop during pregnancy.

Untreated varicose veins lead to development of pain, difficulty in walking, venous ulcers, deep vein thrombosis, complications associated with dvt, skin pigmentation, eczema, superficial thrombophlebitis, bleeding, loss of subcutaneous tissue, lip dermatosclerosis.

There are several options for the management of varicose veins including:

1) Advice and reassurance

2) Interventional treatments

3) Compression treatment

**Keywords:** Varicose veins, Endovenous laser therapy, Sclerotherapy

**Introduction**

Chronic venous diseases (CVDs) of the lower extremities are typical complications of venous hypertension, which is usually caused by reflux in one or more of the saphenous veins and their principal tributaries. Conservative therapy or removal of these incompetent channels utilising endovenous methods or surgery are possibilities for patients with saphenous vein incompetence. <sup>1</sup>The illustration below shows a varicose vein prior to treatment with endovenous laser therapy.



Figure 1

Varicose veins afflict 10-20% of the population, with around 2% experiencing skin abnormalities that may precede venous ulcers. Varicose veins have been known since biblical times. Compression treatment extends back to Roman times, when soldiers used tight bands to relieve pain caused by extended standing.<sup>2</sup> Our contemporary knowledge of varicose veins, however, did not emerge until the work of Brodie and Trendelenburg in the 1850s and 1890s. Trendelenburg is credited for pioneering varicose vein surgery, ushering in contemporary vascular surgery for this condition.<sup>3-4</sup>

Untreated varicose veins cause discomfort, trouble walking, varicose venous ulcers, deep vein thrombosis and problems associated with DVT, skin pigmentation, dermatitis, superficial thrombophlebitis, haemorrhage, subcutaneous tissue loss, and lip dermatosclerosis. After 6.6 years, 28.6% of individuals with obvious varicose veins but no oedema or other problems advanced to more significant venous disease, according to one research. According to other statistics on the lifetime prevalence of varicose veins, around 3-6% of persons who have varicose veins will develop venous ulcers.<sup>5-6</sup>

Surgery is still the most effective and dependable treatment option for varicose veins. High ligation, stripping, and excision/ligation of varicose veins are procedures that were introduced at the turn of the nineteenth and twentieth centuries.<sup>7</sup> Surgery, foam sclerotherapy, and endothermal ablation are examples of interventional therapies. Surgery is a classic therapy that includes surgical excision of the vein by pulling it out or ligating it. In foam sclerotherapy, sclerosant foam is injected into the vein, causing an inflammatory reaction that shuts the vein.<sup>8</sup>

Endothermal procedures are classified into two types: radiofrequency and laser ablation. These treatments heat the veins from inside, causing irreparable damage to the vein and its lining and eventually closing it off. All procedures may be conducted under general or local anaesthesia and normally do not need an overnight stay in the hospital. Reported rates of disease recurrence following treatment of superficial varicose veins vary from 7 to 65 percent. Stripping only the long saphenous vein in the thigh reduces the risk of nerve injury and recurrence by ensuring the avulsion of potential perforating veins.<sup>9</sup>

Endovenous ablation has supplanted stripping and ligation as the method of removing saphenous vein reflux. A radiofrequency-based procedure is one of the endovenous methods. In 2007, newer RF delivery technologies were established. Endovenous techniques are significantly less intrusive than surgical procedures and have a lower complication risk. Patients tolerate the treatment well, and the aesthetic outcomes are excellent.

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The present study was conducted at a tertiary healthcare center to compare the outcomes of EVLT with sclerotherapy done 6 weeks later to EVLT and sclerotherapy done in the same sitting. And hence to compare the complications against benefits associated with both. And to study the efficacy between two modalities of treatment.



Figure 2: Endovenous Laser Fibre

### Material And Methods

It was a Single centred, observational, prospective, comparative study conducted among 50 patients in VEIN CLINIC and SURGERY WARDS at Department of General Surgery at a Government College in Mumbai during 25/6/2019 to 31/12/2021. 25 patients were given sclerotherapy after 6 weeks of EVLT, and other group of

25 patients were given sclerotherapy on the same day of undergoing EVLT. Computerised sampling method was used in this Randomised control trial. Both the groups were followed for a period of 6 months.

### Selection criteria for study subjects

**Inclusion criteria:** All male and female patients of age 18-65 yrs, admitted in general surgery ward with varicose veins were enrolled in the present study.

**Exclusion criteria:** Pregnant and lactating mothers, Patients not willing to give consent, Patients with polytrauma, Children with age less than 18yrs of age, and conservatively managed patients. Patients with serious medical illness, Recent MI, Severe Asthma, Uncontrolled HTN, Liver and Renal failure patients, Patients with DVT, Patients with leg ulcers were excluded from the present study.

**Parameters studied:** External appearance of the limb: Aching/pain in legs, Heaviness, Tiredness/fatigue. Itching/burning sensation, Leg cramping, Leg restlessness, Throbbing, Swelling, Interference with walking, Interference with sleep.

**Proposed outcome of the project:** The advantages of one treatment over the other can be compared. The working class of the population that is affected by the disease and due to which the work efficiency is decreased can be given the best possible treatment on varicose veins to improve their efficiency. Improvement in the external appearance of the affected limb (treatment modality with faster improvement in symptoms can be compared). Complications of long-standing varicose veins can be prevented.

**Statistical analysis plan:** The data was collected with the help of standard, semi-structured, pre-validated case record proforma. After collecting the data from the records, the data was entered with the help of MS- Excel

Sheet. The data was analyzed with the help of SPSS Version 22 statistical package. Descriptive statistics were derived in the form of tables and charts for frequency analysis. Appropriate statistical methods were used to analyze the data.

Group 1: EVLT with 6 weeks delayed sclerotherapy  
 Group 2: EVLT with sclerotherapy in single sitting

**Results**

**Age distribution:** In the present study we assessed Age distribution among study subjects. We observed that majority of the study subjects belonged to the age group of 36 to 45 years (28% and 24%), followed by 56 to 65 years (20% and 28%). The mean age of the study subjects in group 1 was 42.04 years, while that of in group 2 was 40.06 years.(Table 1)

Table 1: Age distribution

Age distribution	Group 1		Group 2	
	N	%	N	%
Less than 25 years	3	12	6	24
26 to 35 years	7	28	2	8
36 to 45 years	7	28	6	24
46 to 55 years	3	12	4	16
56 to 65 years	5	20	7	28
More than 65 years	0	0	0	0
Total	25	100	25	100
Mean age	42.04 years		40.06 years	

**Clinical presentation:** In the present study we assessed Clinical presentation among study subjects. We observed that pain was the commonest presentation (88% and 84% in either group), followed by swelling (36% and 16%), other symptoms were Restlessness, Fatigue, Itching, Cramps, and Pigmentation. (Table 2)

**History:** In the present study we assessed Past History among study subjects. We observed that 1 case each of diabetes, HIV seropositive was reported in group 1, while

single case of hypertension was reported in group 2.(Table 2)

Table 2: Clinical presentation and Past History

Clinical presentation and Past History		Group 1		Group 2	
		N	%	N	%
Clinical presentation	Pain	22	88	21	84
	Restlessness	2	8	2	8
	Fatigue	0	0	2	8
	Itching	3	12	2	8
	Swelling	9	36	4	16
	Cramps	1	4	2	8
	Pigmentation	3	12	1	4
Past History	Hypertension	0	0	1	4
	Diabetes mellitus	1	4	0	0
	HIV Positive	1	4	0	0

**Venous Examination:** In the present study we assessed Venous Examination among study subjects. We observed that on examination Dilated, tortuous veins (24% & 40%), Severely dilated and tortuous veins (12% & 8%), Tortuous veins (64% & 48%), Venous eczema (4% subjects in group 2). The subjects were comparable among the study groups. (Table 3)

Table 3: Venous Examination

Venous Examination	Group 1		Group 2		P-value
	N	%	N	%	
Dilated, tortuous veins	6	24	10	40	> 0.05
Severely dilated and tortuous veins	3	12	2	8	> 0.05
Tortuous veins	16	64	12	48	> 0.05
Venous eczema	0	0	1	4	NA

**Relief in symptoms:** In the present study we assessed Relief in symptoms among study subjects. We observed that relief in symptoms was comparatively

better in group 2 at the end of 3 months. However at the end of 6 month both groups achieved 100% relief. (Table 4)

Table 4: Outcome measures

Outcome measures		Group 1		Group 2	
		N	%	N	%
Relief in symptoms	15 Days	10	40	20	80
	3rd month	20	80	24	96
	6th month	25	100	25	100
Visible Reduction in Varices	Average	4	16	2	8
	Good	18	72	14	56
	Excellent	3	12	9	36
	Total	25	100	25	100
Significance		The chi-square statistic is 4.1667. The p-value is .124514. The result is not significant at $p < .05$ .			
Post procedure pain (Mild, Moderate, Severe)	+	15	60	22	88
	++	8	32	3	12
	+++	2	8	0	0
	Total	25	100	25	100
	Significance	The chi-square statistic is 5.0936. The p-value is .024015. Significant at $p < .05$ .			
Redness (Mild, Moderate, Severe)	+	23	92	23	92
	++	1	4	2	8
	+++	1	4	0	0
	Total	25	100	25	100
Complications	Ulceration after Sclerotherapy	0	0	0	0
	DVT	0	0	0	0
	Other	5	20	2	8
	Complications				

**Other Complications** include excessive burning of tissue due to laser fibre causing chronic pain and chronic discoloration of the skin due to the use of laser.

**Visible Reduction in Varices:** In the present study we assessed Visible Reduction in Varices among study subjects. We observed that group 2 subjects had shown better visible reduction in varices as compared to group 1 study subjects. However we could not get the statistical significance. (The chi-square statistic is 4.1667. The p-value is .124514. The result is not significant at  $p < .05$ .) (Table 4)

**Post procedure pain (Mild, moderate, severe):** In the present study we assessed Post procedure pain (Mild, moderate, severe) among study subjects. We observed that post procedure pain was significantly greater in group 1 as compared to group 2 (The chi-square statistic is 5.0936. The p-value is .024015. Significant at  $p < .05$ .) (Table 4)

**Redness (Mild, moderate, severe):** In the present study we assessed presence of Redness (Mild, moderate, severe) among study subjects. We observed that moderate to severe redness was observed more among group 1 subjects (4% each), as compared to group 2 subjects. (Table 4)

**Complications:** In the present study we assessed various Parameters among study subjects. We observed that we did not observe occurrence of Ulceration after Sclerotherapy and DVT among the study subjects. Other complications were observed among 20%. (Table 4)

**Number of visits:** In the present study we assessed Number of visits among study subjects. We observed that mean number of visits were significantly more among group 1 (6.28) as compared to group 2 (4.12). (The t-value is 17.00559. The p-value is  $< .00001$ . The result is significant at  $p < .05$ .) (Table 5)



Table 5: Number of visits

Parameters		Group 1	Group 2
Number of visits	Mean	6.28	4.12
	SD	0.54	0.33
	Significance	The t-value is 17.00559. The p-value is < .00001. The result is significant at p < .05.	
Quality of life (out of 4)	Mean	2.44	2.88
	SD	0.76	0.52
	Significance	The t-value is -2.36318. The p-value is .011109. The result is significant at p < .05.	

**Quality of life:** If the following symptoms relieve within 6 weeks

- 1) Back to routine activities
- 2) Ability to exercise.
- 3) Improvement in skin changes; Pigmentation + venous eczema
- 4) Swelling and oedema subsidence.

**Quality of life (score out of 4):** In the present study we assessed Quality of life (out of 4) among study subjects. We observed that the mean quality of life was significantly better in group 2 (2.88), as compared to group 1 (2.44). (The t-value is -2.36318. The p-value is .011109. The result is significant at p < .05.) (Table 5)

**Discussion**

Intra operative and post operative sclerotherapy is also used during endovascular procedures for chemical obliteration of the main trunks of the superficial veins using catheters. Several weeks after surgery, sclerotherapy is also performed to close distal segments of great and small saphenous trunks and other incompetent collateral, varicose, and perforator veins. Sclerotherapy is often applied instead of phlebectomy, which is burdened with a higher number of complications.

Sclerotherapy is also performed in the case of healing venous ulcers resulting from advanced venous insufficiencies with CEAP scores of 5 and 6 to eliminate varicose lesions and close incompetent perforator veins when more

invasive surgery poses a risk of coexisting infection.

Interventional treatments include surgery, foam sclerotherapy and endothermal ablation. Surgery is a traditional treatment that involves surgical removal by stripping out the vein or ligation. In foam sclerotherapy sclerosant foam is injected into the vein to cause an inflammatory response which consequently closes it.

There are 2 main endothermal methods: radiofrequency and laser ablation. These methods heat the veins from inside causing irreversible damage to the vein and it's lining and closes it off. All treatments can be performed under general or local anaesthesia and do not usually require an overnight stay in hospital.

A review of the data from the trials of interventional procedures indicates that the rate of clinical recurrence of varicose veins at 3 years after treatment is likely to be between 10 and 30 %. There is no clear simple system to identify which people benefit the most from interventional therapy and currently there is no established framework for the diagnosis and management of varicose veins. This has led to considerable regional variation in the management of varicose veins. By comparing 2 modalities of treatment the aim is to conclude if EVLT and sclerotherapy done on the same day is more beneficial to the patients as compared to EVLT and a 6 weeks delayed sclerotherapy in terms of time, cost and efficacy.

In the present study we assessed Age distribution among study subjects. We observed that majority of the study subjects belonged to the age group of 36 to 45 years (28%

and 24%), followed by 56 to 65 years (20% and 28%). The mean age of the study subjects in group 1 was 42.04 years, while that of in group 2 was 40.06 years. **Sulaiman S Shoab et al** in their study observed that mean age of 54  $\pm$  16 (standard deviation) years.<sup>11</sup>

In the present study we assessed Clinical presentation among study subjects. We observed that pain was the commonest presentation (88% and 84% in either group), followed by swelling (36% and 16%), other symptoms were Restlessness, Fatigue, Itching, Cramps, and Pigmentation. In the present study we assessed Past History among study subjects. We observed that 1 case each of diabetes, HIV seropositive was reported in group 1, while single case of hypertension was reported in group 2.

In the present study we assessed Venous Examination among study subjects. We observed that on examination Dilated, tortuous veins (24% % 40%), Severely dilated and tortuous veins (12% & 8%), Tortuous veins (64% & 48%), Venous eczema (4% subjects in group 2). The subjects were comparable among the study groups.

**Outcomes:** In the present study we assessed Relief in symptoms among study subjects. We observed that relief in symptoms was comparatively better in group 2 at the end of 3 months. However, at the end of 6 month both groups achieved 100% relief. Chi square test applied. The result is significant at 15 days(0.004),not significant at 3 months(0.082).

Group 2 subjects had shown better visible reduction in varices as compared to group 1 study subjects. However, we could not get the statistical significance. (The chi-square statistic is 4.1667. The p-value is .124514. The result is not significant at  $p < .05$ ). The post procedure pain was significantly greater in group 1 as compared to

group 2 (The chi-square statistic is 5.0936. The p-value is .024015. Significant at  $p < .05$ .)

In the present study we observed that moderate to severe redness was observed more among group 1 subjects (4% each), as compared to group 2 subjects. In the present study we assessed various Parameters among study subjects. We observed that we did not observe occurrence of Ulceration after Sclerotherapy and DVT among the study subjects. Other complications were observed among 20% in Group 1 and 8 % in Group 2.

In the present study we assessed Number of visits among study subjects. We observed that mean number of visits were significantly more among group 1 (6.28) as compared to group 2 (4. 12). (The t-value is 17.00559. The p-value is  $< .00001$ . The result is significant at  $p < .05$ ). We observed that the mean quality of life was significantly better in group 2 (2.88), as compared to group 1 (2.44). (The t-value is -2.36318. The p-value is .011109. The result is significant at  $p < .05$ .)

**Ji-Chang Wang et al**<sup>12</sup> in their study recruited 418 patients (542 legs) with diagnosed varicose veins. Patients in the EVLA/FS group (255 patients, 327 legs) received concomitant FS for the tributaries with truncal lasering. For the EVLA-alone group (163 patients, 215 legs), tributaries (8W) were ablated with EVLA in addition to the GSV trunk (14W). Except for ecchymosis, incidence of other complications was not significantly different between both groups at 6 months. Pain NRS scores of the EVLA/FS group were remarkably elevated at 4 weeks and then, at 6 months, declined to a level similar to the EVLA-alone group. The EVLA/FS group exhibited more significant improvement in both AVVQ and EQ-5D scales than the EVLA group at 6 months, while exhibiting poor improvement at 4 weeks. The EVLA/FS group had a significantly lower rate

of residual varicosities than the EVLA group, thus reducing the need for the staged FS. These results confirm the feasibility and safety of simultaneous tributary EVLA and FS. In addition, they indicate better early quality-of-life improvement and a reduced reoperation rate of simultaneously combined truncal EVLA and tributary FS.

**Watanabe et al<sup>13</sup>** combined endovascular therapy with sclerotherapy under ultrasound guidance for the comprehensive treatment of varicose veins of the lower extremities. EVLA was performed in one group, while EVLA/TLFS (transluminal injection of foam sclerotherapy) was performed in the other. After three months of follow-up, ultrasound showed abolition of reflux in GSVs in all patients. However, additional second-stage sclerotherapy was needed in the group treated with EVLA (n = 33, 66%) compared to the group treated with EVLA/TLFS (n = 2, 3%). The researchers concluded that TLFS combined with EVLA could be an easy, safe, and effective procedure with acceptable complications compared to EVLA alone and limits additional second-stage interventions.

**Zhang et al<sup>14</sup>** compared the short- and medium-term efficacy, postoperative morbidity, and patient satisfaction of 1470 nm EVLA combined with foam sclerotherapy in one-day surgery, with 810 nm EVLA with high ligation combined with foam sclerotherapy in-hospital surgery in the case of GSV failure. A single-center cohort study of 194 patients was conducted at the Ninth People's Hospital in Shanghai, China. A group of 97 patients underwent 1470 nm EVLA combined with foam sclerotherapy in a one-day surgery (the 1470 nm group). In contrast, 97 patients underwent 810 nm EVLA with high saphenous vein ligation with foam sclerotherapy in guideline-recommended hospital surgery

(the 810-nm group). There was no significant difference between the 1470 nm group and 810 nm group in terms of GSV occlusion rate (both 100%), incidence of complications, or recurrence rate (8.2% vs. 11.3%, respectively) at 1- 12 months after surgery.

Severe complications in patients who underwent 1470 nm laser treatment and 810 nm laser treatment were 0% and 1.0%, respectively. Minor complications in the group of patients who underwent 1470 nm laser treatment and 810 nm laser treatment were petechiae in 20.6% and 18.6%, edema in 69.1% and 63.9%, and paresthesia around the ankle in 0% and 3.1%, respectively. The advantage of the group undergoing the 1470 nm treatment over the group undergoing the 810 nm treatment was statistically significant in perioperative patient comfort and economic costs. Treatment with 1470 nm EVLA in combination with foam sclerotherapy in one-day surgery was found to have similar efficacy to 810 nm EVLA with high ligation in combination with foam sclerotherapy in-hospital surgery for GSV failure and to be more comfortable with minor incision, hospitalization procedure, and medical cost. This combined procedure may be a new option for patients afraid of hospitalization or who cannot be hospitalized. Theivacumar et al showed that EVLA alone resulted in 93% GSV obstruction, while the primary determinant of successful GSV ablation after EVLA was laser energy. A subsequent study found the need for additional sclerotherapy after EVLA for 42% of patients six weeks after the procedure due to residual varicose lesions. After EVLA laser ablation, 40-50% of patients with residual varicose veins required foam sclerotherapy.<sup>15-16</sup>

### Conclusions

The mean age of the study subjects in group 1 was 42.04 years, while that of in group 2 was 40.06 years. Pain was



the commonest, followed by swelling. Relief in symptoms was comparatively better in EVLT with sclerotherapy in single sitting at the end of 3 months. However at the end of 6 month both groups achieved 100% relief.

We observed that EVLT with sclerotherapy in single sitting subjects had shown comparatively better visible reduction in varices as compared to EVLT with sclerotherapy after 6 weeks study subjects.

We observed that post procedure pain was significantly greater in EVLT with sclerotherapy after 6 weeks as compared to single sitting. Moderate to severe redness was observed more among group 1 subjects (4% each), as compared to group 2 subjects. We did not observe occurrence of ulceration after sclerotherapy and DVT among the study subjects. Other complications were observed among 20% in group 1 and 8% in group 2. Other complications include excessive burning of tissue due to laser fibre causing chronic pain and chronic discoloration of the skin due to the use of laser.

Mean number of visits were significantly more among EVLT with sclerotherapy after 6 weeks as compared to single sitting. Mean quality of life was significantly better in EVLT with sclerotherapy in single sitting, as compared to EVLT with sclerotherapy after 6 weeks.

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