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Assessment for the Incidence of Saphenous Nerve Injury After Endovenous Laser Ablation of the Great Saphenous Vein - A Retrospective Study

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Abstract: ***Background: Endovenous laser ablation is widely used for treatment of great saphenous vein incompetence, but peripheral nerve injury remains a potential complication. Purpose: This retrospective observational study assessed the incidence and recovery pattern of saphenous nerve injury after EVLA. Methods: Eighty patients undergoing EVLA were followed for three months; demographic, clinical, and procedural variables were analysed. Results: Saphenous nerve injury occurred in 6.25 percent of patients, with complete symptom resolution within three months. Larger vein diameter was significantly associated with injury incidence, while total energy delivered showed no significant relationship. Conclusion: EVLA demonstrates a low incidence of transient nerve injury, supporting its safety profile when appropriate technique and energy modulation are used.***

Keywords: Endovenous laser ablation, Saphenous nerve injury, Great saphenous vein, Varicose veins, minimally invasive vascular surgery, Postoperative neuropathy

1. Introduction

Lower limb varicose veins are the commonest of all vascular disorders. They can impair the quality-of-life[1]. Superficial venous insufficiency of the lower limbs is a common condition, involving up to 35% of women and 15% of men [2].

The literature often quotes “Varicosity as the penalty for verticality against gravity”. Venous hypertension can lead to a broad spectrum of clinical manifestations, ranging from symptoms like cramps, itching, swelling and leg tiredness to cutaneous findings like varicose veins, reticular veins, telangiectasias, oedema, skin pigmentation and ulcerations.

Ligation and stripping of the great saphenous vein (GSV) at its junction have been the standard of care for many decades. Nerve damage with patient complaints of post-operative pain was commonly reported in between 7% and 40% but was of clinical relevance in a smaller number of patients [3].

Since the early 21st century, newer minimally invasive procedures for management of varicose veins, such as endovenous laser ablation (EVLA), radio frequency ablation (RFA) and ultrasound-guided foam sclerotherapy [4,5,6] have been widely used with a view to reduce complications, costs and post-operative recovery period.

The development of minimally invasive procedures for the treatment of varicose veins has been led by a desire to reduce operative trauma and bruising associated with standard surgical techniques. Currently the major thermal endovenous treatments available are; Endovenous Laser Ablation (EVLA) and Radiofrequency Ablation (RFA), Mechanochemical Ablation (MOCA) and VenaSeal.

In the endovenous thermal ablation techniques, there is generation of heat energy inside the lumen of the vein, which serves to damage the endothelium and cause vein spasm, leading to permanent closure of the refluxing vein lumen. The endovenous thermal procedure of the lower limb carries a small risk of peripheral nerve injury. The saphenous nerve is at risk during EVLA of the GSV.

Randomised clinical trials comparing EVLA with surgery have shown EVLA to be an equally effective treatment, while producing less pain and bruising and a significantly better quality of life[7,8,9].

Endovenous laser ablation (EVLA) as a treatment for varicose veins was first described in 2001, and involves the insertion of a laser fibre into the lumen of an incompetent truncal vein, with subsequent thermal ablation of the vein. The vast majority of patients with primary and recurrent varicose veins are suitable for EVLA, with success reported in treating the long, short and anterior saphenous veins, perforators and varicosities themselves. Percutaneous endovenous laser ablation (EVLA) of the superficial axial veins revolutionised the treatment of superficial venous insufficiency. Laser

energy delivers energy to the blood itself. Steam bubbles are generated with the laser energy, and coagulation occurs after completion of laser energy delivery. Laser energy catheters come in different wavelengths ranging from 810 nm to 1470 nm. Advantages of this technique include minimal preoperative work up, less discomfort of the patient and a more rapid recovery and can be done as a day care procedure under tumescent anaesthesia.

In the modern era, EVLA replaced conventional surgery partly because of the common complications occurring after stripping GSV. The saphenous nerve lies close to GSV especially 2–3 cm below and medial to the tibial tuberosity and below this level the nerve and its branches are often wrapped around GSV. This fact makes it impossible to strip the vein without damaging the nerve. Supporting this, up to 50% of patients undergoing GSV stripping reports saphenous nerve damage and even stripping the vein from groin to ankle provided limited benefit[10].

A study by Murakami et al[11]. demonstrated that in the thigh the long saphenous vein rarely ran close to the saphenous nerve. In the leg however, the long saphenous vein frequently ran close to the saphenous nerve, 59.5% in the middle third of the leg and in 83.1% of cases in the lower third of the leg. Damage to the saphenous nerve usually causes sensory loss on the medial aspect of the calf, above the medial malleolus.

Abnormal sensation at the lower limb is a known complication after EVLA, which occurs infrequently but may result in substantial discomfort after surgery. According to the International Association for Study of Pain nomenclature,[12] the term paraesthesia is used to describe an abnormal sensation that is not unpleasant, whereas dysesthesia is used to describe an unpleasant abnormality. In previous EVLA reports only either one of these terms was used to report sensory loss where paraesthesia was reported to occur in 7.2 - 36.5%[13,14]and dysesthesia in 0–9% of patients. Although it has been implied that sensory loss is the manifestation of injury to the saphenous nerve or to the sural nerve which are adjacent to greater or small saphenous nerves, the issue has not been proven. This may be possibly due to the fact that paraesthesia or dysesthesia does not result in permanent disability, often resolve within 6 to 8 weeks following the procedure. In a study by Yilmaz et al [15], Thirty-five patients (mean age: 44.78 ± 8.6, male/female ratio: 16/19) who were operated on for incompetent greater saphenous veins, Dysesthesia was questioned as to whether having unpleasant abnormal sensation after the operation. Thirty-four patients were available at two-week follow-up. All patients achieved complete proximal closure. Three patients (8.8%) had dysesthesia at two weeks. Proebstle et al [16] treated 31 legs without any evidence of nerve injury. In a further series of 90 legs a single case of paraesthesia involving the medial calf was noted but had resolved at 6 weeks.[17]

We have decided to undertake this retrospective study of patients with lower limb varicose veins treated with Endovenous Laser Ablation of the great saphenous vein, with the primary aim to identify the patients suffering from saphenous nerve injury after the procedure even after using the following methods to decrease the incidence of saphenous nerve injury, such as, decreasing the energy used to ablate the lower part of the great saphenous vein where the diameter of the saphenous reduces, and its management, or by injecting sclerosant in the lower 1/3rd of the saphenous vein ;so that a standard treatment protocol can be established for the management of patients with nerve injury after EVLA at our institute.

2. Aims and Objectives

Aim:
To assess the incidence of saphenous nerve injury after endovenous laser ablation of the great saphenous vein.

Objectives:
Assessment of post-operative outcomes like-
1) Numbness- loss of sensation of feeling on the medial aspect of the lower 1/3rd of the leg around the medial malleolus of the operated leg.
2) Tingling- a stinging, prickling, or thrilling sensation
3) Burning/ shooting pain

In patients undergoing EVLA procedure for the ablation of GSV assessment of nerve injury will be seen in specific groups like
1) Age
2) Sex
3) CEAP classification

3. Materials and Methods

In this study total 80 cases of varicose veins treated with Endovenous Laser Ablation were followed up to a period of 3 months.

Study design: A retrospective Study

Ethics: The study was retrospective; therefore, previously documented data were used. Institutional ethical approval was obtained prior to data collection.

Selection of Sample Size: Sample size 80 patient is selected using the records of the general surgery department of our hospital in the past 8 months.

4. Methodology

For Patient data all standard pre anaesthesia checkup and operative steps were followed.

A 1470 nm laser system was used with radial laser fibre. Energy delivered - According to the size of the vein and was standardized at 60–100 J/cm.

Grade 2 compression stockings were worn by the patients. Patients were discharged the same or following day and were asked to follow up on OPD basis for evaluation of post-surgical outcome.

The patients were evaluated for post-operative complications like numbness, tingling, burning/ shooting pain in the operated lower and were received treatment for the same and followed up serially for 3 months to observe the resolution of the symptoms.

Statistical Analysis

This is Retrospective Observational Study. Data were recorded in Microsoft Word using a standardized proforma.

Qualitative data studies like age, sex, clinical symptoms, USG findings, surgical procedure, post-operative results were recorded in Microsoft excel sheets and analysed accordingly.

The presentation of the Categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data were presented as the means ± SD and as median with 25th and 75th percentiles (interquartile range). The following statistical tests were applied for the results:

1) The comparison of the variables which were quantitative in nature were analysed using independent t test.
2) The comparison of the variables which were qualitative in nature were analysed using Fisher's exact test as at least one cell had an expected value of less than 5.

The final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 25.0. For statistical significance, p value of less than 0.05 was considered statistically significant.

Study outcomes

To study the incidence of saphenous nerve injury after EVLA of the great saphenous vein and the degree of resolution of symptoms in a 3 month follow up period in the patients with nerve injury post procedure treated with NSAIDs, multivitamin and re-assurance.

5. Results and Observations

The study was conducted in the general surgery department of a tertiary care centre. 80 patients who had undergone EVLA, aged >18 years with symptomatic Great Saphenous vein (GSV) reflux with or without associated Saphenous femoral junction (SFJ), incompetence on duplex imaging were included in the study. Saphenous nerve injury after endovenous laser ablation of the great saphenous vein was assessed and results are as follows.

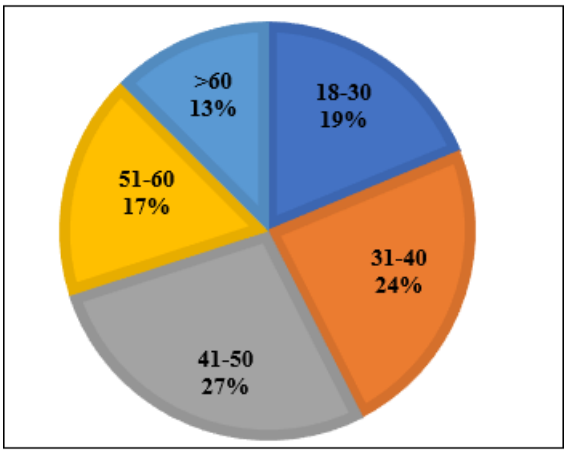

Figure 1: Distribution of age (years) of study subjects.

The age range of the total sample was from 18-74 years, with mean value of age (years) of study subjects was 43.52 ± 13.4 with median (25th-75th percentile) of 43.5 (33-54). Details of distribution of age for the study is shown in figure 1. Out of the total sample, 77.50% (n = 62) were male and 22.50% (n = 18) were female.

Table 1: Distribution of CEAP classification of study subjects

CEAP classification	Frequency	Percentage
C1 Ep Ap Pr	3	3.75%
C2 Ec AS Pr	1	1.25%
C2 Ep Ap Pr	25	31.25%
C2 Ep As Pr	10	12.50%
C3 Ep Ap Pr	13	16.25%
C4 Ep Ap Pr	25	31.25%
C4 Ep As Pr	2	2.50%
C4 Es Ap Pr	1	1.25%
Total	80	100.00%

In the majority [25(31.25%)] of patients, CEAP classification was C2 Ep Ap Pr, C4 Ep Ap Pr each followed by C3 Ep Ap Pr [13(16.25%)], C2 Ep As Pr [10(12.50%)], C1 Ep Ap Pr [3(3.75%)] and C4 Ep As Pr [2(2.50%)]. CEAP classification was C2 Ec AS Pr and C4 Es Ap Pr of only 1 out of 80 patients (1.25%) each. CEAP classification of study subjects is shown in table 1.

Table 2: Descriptive statistics of average vein size GSV (mm) of study subjects

Variable	Mean ± SD	Median (25th-75th percentile)	Range
Average vein size GSV (mm)	5.16 ± 1	5.1(4.57-5.82)	3.1-7.4

Mean value of average vein size GSV (mm) of study subjects was 5.16 ± 1 with median (25th-75th percentile) of 5.1(4.57-5.82). It is shown in table 2.

Table 3: Descriptive statistics of average energy used(J) of study subjects

Variable	Mean ± SD	Median (25th-75th percentile)	Range
Average energy used (J)	5.16 ± 1	5.1(4.57-5.82)	3.1-7.4

Mean value of average energy used(J) of study subjects was 3478.44 ± 434.11 with median (25th-75th percentile) of 3355(3167.5-3870). It is shown in table 3.

Table 4: Distribution of saphenous nerve injury of study subjects

Saphenous Nerve Injury	Frequency (n)	Percentage (%)
Post-operative (Day 0)		
No	80	100
Post-operative (Day 1)		
No	75	93.75
Burning	3	3.75
Numbness	2	2.50
Post-operative (1 week)		
No	75	93.75
Burning	3	3.75
Numbness	2	2.50
Post-operative 1 month		
No	78	97.50
Numbness	2	2.50
Post-operative 3 months		
No	80	100

None of the patients had saphenous nerve injury on post-operative day 0 and post-operative 3 months.

The majority [75(93.75%)] of patients did not have saphenous nerve injury in post-operative day 1. Burning was present in 3(3.75%) patients and numbness in only 2 out of 80 patients (2.50%).

The majority [75(93.75%)] of patients did not have saphenous nerve injury in post-operative 1 week. Burning was present in 3(3.75%) patients and numbness in only 2 out of 80 patients (2.50%).

The majority [78(97.50%)] of patients did not have saphenous nerve injury in post-operative 1 month. Numbness was present in only 2 out of 80 patients (2.50%). It is shown in table 4.

Table 5: Distribution of overall saphenous nerve injury of study subjects

Overall saphenous nerve injury	Frequency	Percentage
No	75	93.75%
Yes	5	6.25%
Total	80	100.00%

The majority [75(93.75%)] of patients did not have saphenous nerve injury. Saphenous nerve injury was present in only 5 out of 80 patients (6.25%) as shown in table 5. These 5 patients were also recovered in 3 months post operation. Hence the overall outcome was 100% recovery.

Table 6: Association of overall saphenous nerve injury with gender

Overall saphenous nerve injury	Female (n=18)	Male (n=62)	Total	P value
No	18 (100%)	57 (91.94%)	75 (93.75%)	0.582*
Yes	0 (0%)	5 (8.06%)	5 (6.25%)	
Total	18 (100%)	62 (100%)	80 (100%)	

Distribution of overall saphenous nerve injury was compared among female and male study subjects using Fisher's exact test. The result revealed no significant difference among both the genders as shown in table 6.

Table 7: Association of overall saphenous nerve injury with CEAP classification

Overall saphenous nerve injury	C1 Ep Ap Pr(n=3)	C2 Ec AS Pr(n=1)	C2 Ep Ap Pr(n=25)	C2 Ep As Pr(n=10)	C3 Ep Ap Pr(n=13)	C4 Ep Ap Pr(n=25)	C4 Ep As Pr(n=2)	C4 Es Ap Pr(n=1)	Total	P value
No	3 (100%)	1 (100%)	23 (92%)	9 (90%)	13 (100%)	23 (92%)	2 (100%)	1 (100%)	75 (93.75%)	0.87*
Yes	0 (0%)	0 (0%)	2 (8%)	1 (10%)	0 (0%)	2 (8%)	0 (0%)	0 (0%)	5 (6.25%)	
Total	3 (100%)	1 (100%)	25 (100%)	10 (100%)	13 (100%)	25 (100%)	2 (100%)	1 (100%)	80 (100%)	

Distribution of overall saphenous nerve injury was comparable with CEAP classification using Fisher's exact test. The test revealed no significant difference among CEAP classification {**C1 Ep Ap Pr** vs **C2 Ec AS Pr** vs **C2 Ep Ap Pr** vs **C2 Ep As Pr** vs **C3 Ep Ap Pr** vs **C4 Ep Ap Pr** vs **C4 Ep As Pr** vs **C4 Es Ap Pr**}, (0% vs 0% vs 8% vs 10% vs 0% vs 8% vs 0% vs 0% respectively) as shown in table 7.

Table 8: Association of average vein size GSV (mm) with overall saphenous nerve injury

Average vein size GSV (mm)	With saphenous nerve injury(n=5)	Without saphenous nerve injury(n=75)	Total	P value
Mean ± SD	6.14 ± 0.84	5.09 ± 0.99	5.16 ± 1.01	*0.024†
Median (25th-75th percentile)	6.08 (5.4-6.6)	5 (4.4-5.8)	5.1 (4.575-5.825)	
Range	5.3-7.3	3.1-7.4	3.1-7.4	

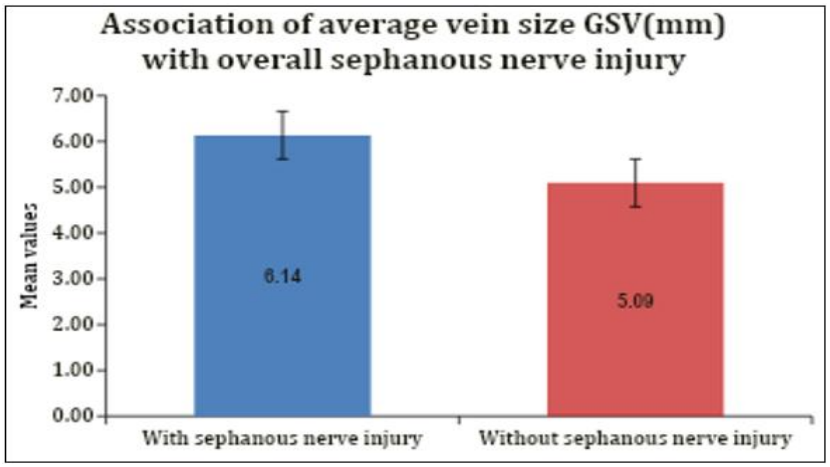

Figure 2: Association of average vein size GSV (mm) with overall saphenous nerve injury.

Using Independent t test, the mean ± SD of average vein size GSV (mm) in patients with saphenous nerve injury was 6.14 ± 0.84 which was significantly higher as compared to patients without saphenous nerve injury (5.09 ± 0.99) with a p value=0.024 as shown in table 8 and figure 2.

Table 9: Association of average energy used(J) with overall saphenous nerve injury

Average energy used (J)	With saphenous nerve injury (n=5)	Without saphenous nerve injury (n=75)	Total	P value
Mean ± SD	3490 ± 516.82	3477.67 ± 432.13	3478.44 ± 434.11	0.951†
Median (25th-75th percentile)	3290 (3180-3680)	3360 (3165-3870)	3355 (3167.5-3870)	
Range	3000-4300	2410-4500	2410-4500	

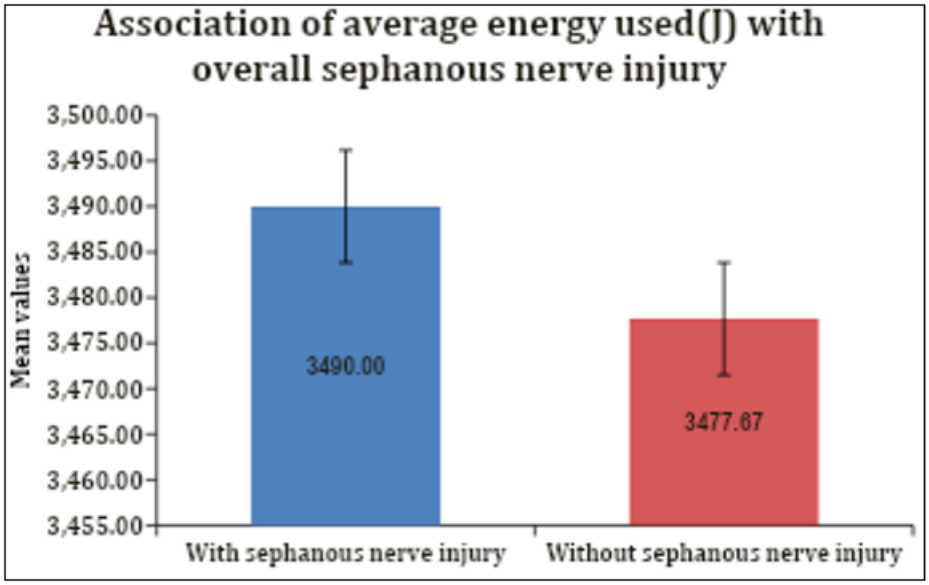

Figure 3: Association of average energy used(J) with overall saphenous nerve injury

Mean energy (J) delivered in patients with saphenous nerve injury was 3490 ± 516.82 and in patients without saphenous nerve injury was 3477.67 ± 432.13 (mean 3483). On using independent t test, there was no significant association between them (p value=0.951) as shown in table 9 and figure 3.

Table 10: Comparison of average energy used(J) between female and male

Average energy used (J)	Female(n=18)	Male(n=62)	Total	P value
Mean ± SD	3171.11 ± 371.26	3567.66 ± 411.92	3478.44 ± 434.11	0.0004†
Median (25th-75th percentile)	3135 (2992.5-3270)	3495 (3222.5-3938.75)	3355 (3167.5-3870)	
Range	2410-4100	2760-4500	2410-4500	

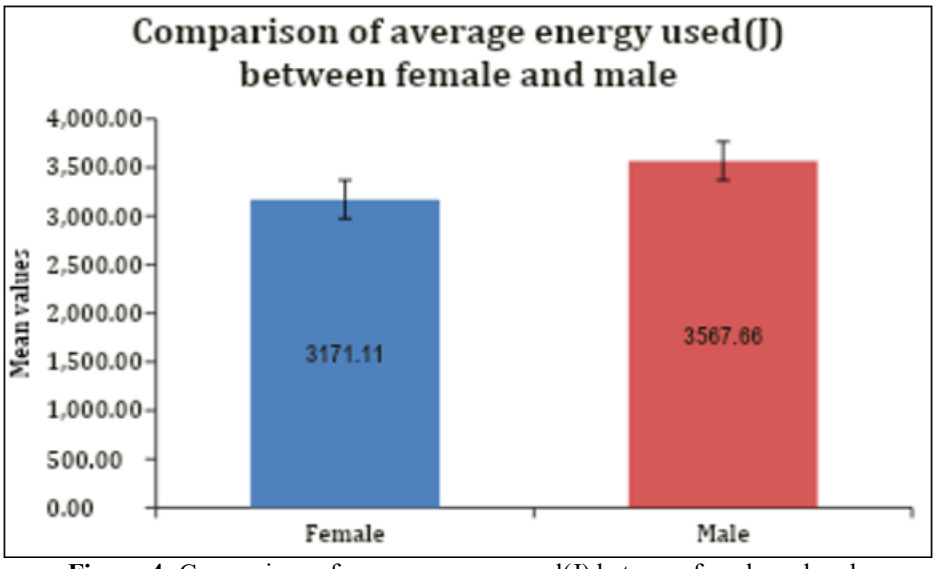

Figure 4: Comparison of average energy used(J) between female and male

Mean ± SD of average energy used(J) in male was 3567.66 ± 411.92 which was significantly (p value=0.0004) higher as compared to females (3171.11 ± 371.26) according to independent t test. It is shown in table 10 and figure 4.

6. Discussion

Mean age and gender distribution

In our study, the mean age of the study sample was 43.52 ± 13.4 years, which was reported to be younger when compared to the studies by Agus GB et al[19] (54.5 years) and Kim et al[22](57 years). Similarity in the mean age of study sample was seen in research done by Yilmaz et al[15] (44.78 ± 8.6) , Ahmad Raza Jawaid Mughal et al[20](45.2 ± 10.1) and Albricker et al [21] (45.7years)

Gender Distribution: A significant male predominance {m-62,f-18,n=80} was recorded in our study but it contrasts with all other studies (Yilmaz et al.{m-16,f-19, n=35} [15], Agus GB et al{m-241,f-809,n=1050}[19], Ahmad Raza Jawaid Mughal et al{m-24,f-36,n=60} [20], Albricker et al{m-81,f-341,n=422} [21], and Kim et al{m-166,f-239,n=405}[22] , where a female predominance was reported.

CEAP Classification

All studies include study samples having CEPA classification with C2, C3, C4 while , Oguzkurt L[18] Kathleen D. Gibson etal[23] Boersma, Doeke[25] also included C5 C6.

Mean size of GSV in mm

In our study, we found that mean size of GSV (mm) with saphenous nerve injury is higher than without nerve injury that is 6.14 and 5.09.

Saphenous Nerve Injury rate

Our study reports five cases of saphenous nerve injury out of 80 patients. It aligns with studies reported by Yilmaz et al [15] who reported 3 cases out of 34, but contrasts with Proebstle et al{n=31}[16] and Min RJ [17].

Energy utilised mean and range

The amount of energy used (likely as EVLA energy or Linear Endovenous Energy Density, LEED) is a critical variable:

- Our study's mean energy utilized is 3483 J (total energy).
- In comparison, other studies report energy in different metrics (total energy in Joules, J or energy density in Joules per centimetre J/cm).
- Comparing total energy: in our study, mean total energy of 3483J is higher than N.Nwaejike et al[24]. mean of 955 J but significantly lower than Beale RJ[27] 15,240J.
- Whereas, Rasmussen LH etal[9] energy utilize during surgery is in range of 73.5 J/cm & 57-95 J/cm and with Doganci S[26] it is 90J/cm.
- The combination of zero nerve injuries and a mean total energy of 3483 J suggests that the energy delivery protocol used in our study was both safe and effective for the treated patient group.

Our study has been conducted for the first time in a public hospital. Routinely entry of radial fibre for EVLA is done from below the knee, but in our patients, we enter just near to medial malleolus. It helps in obliteration of all the leg perforators causing reducing the possibility of recurrence of varicosities. Patients therefore give better clinical outcomes with reduction of symptoms.

In 7 patients out of 80 who were very thin having nerves in the superficial layer and had very thin subcutaneous GSV, we injected sclerotherapy from ankle joint to mid leg to avoid saphenous nerve injury. Patients who were non diabetic and had no evidence of venous ulcer were included in our study.

In our study, we have taken the GSV size as an average of 5 readings that is the sum total average of the total of the upper thigh, mid-thigh, knee, upper calf and ankle.

All the symptoms are subjective but they were objectivized with visual Analogue scale for better collaboration to objectivize the results. The patients had features of hypoesthesia such as numbness and hyperesthesia such a burning pain too. The injury rate incidence in our study was 6.25%. To decrease the injury to the saphenous nerve, we used radial fiber with 640 nm frequency and also reduce the amount of energy in lower 1/3rd of leg. All cases were done under spinal anaesthesia which gives good analgesia and easy access to GSV for ablation as it causes vasodilatation of the superficial veins of the lower limbs.

In case of saphenous nerve injury, reassurance given to the patients and tablet pregabalin with methyl cobalamin as a part of management to improve sensations in the area of paraesthesia, are given as the treatment, and the nerve injury is transient and usually recovers within one month to maximum three months.

7. Conclusion

This retrospective analysis demonstrates a low incidence of transient saphenous nerve injury following EVLA, with complete recovery observed within three months. Larger vein diameter was associated with increased risk, while total delivered energy showed no significant effect. These findings support EVLA as a safe minimally invasive option when procedural parameters are carefully optimized.

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