



Patients Satisfaction with One-Versus Two-Stage Endovenous Laser Ablation and Tributary Veins Foam Sclerotherapy

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Abstract

Saphenous varicosities, from Great Saphenous Vein (GSV) and Saphenofemoral Junction (SFJ) are treated by surgery or Endovenous Laser Treatment (EVLT). To treat tributaries, secondary procedures (foam Sclerotherapy or multiple phlebectomy) are used concomitantly as one-stage or sequentially as two-stage procedure. However, patients' satisfaction quotient post-treatment has not been assessed till date. The present study aimed to compare patient's satisfaction with EVLT and foam Sclerotherapy as one-stage versus two-stage procedure, performed in the same patient. Patients (n=20, mean age: 38.00 ± 9.9 years, 70% females) with symptomatic bilateral GSV reflux, SFJ incompetence and prominent varicosities between March 2016 and March 2018 were included. All the patients underwent two-stage therapy (EVLT-four-week gap-foam Sclerotherapy) on one leg first and one-stage EVLT-Foam Sclerotherapy on the other after four-week gap. Post-treatment, all patients were provided with a six-point questionnaire to evaluate their satisfaction for both the procedures. Both the procedures took similar time (one-stage: 57.1 ± 3.5 (range: 47-62) minutes vs. two-stage: 47.35 ± 3.1 (range: 40-52) minutes for EVLT and 8.00 ± 1.49 (range: 5-10) minutes for foam Sclerotherapy). There was nominal median time difference between both the procedures (57.5 vs. 56 minutes). All the patients agreed that one-stage procedure is better than two-stage (strongly agreed n=18 (90%); agreed n=2 (10%). All the patients strongly agreed that one-stage procedure was better for going back to usual activities. None of them preferred two-stage procedure over one-stage procedure. The present study concluded that both the procedures were similar in terms of time consumed and overall discomfort. However, the patients were more satisfied after undergoing single-stage procedure than two-stage due to speedy recovery and higher convenience associated with concomitant therapy.

Keywords: Endovenous laser treatment; Foam Sclerotherapy; One-stage procedure for saphenous varicosity; Two-stage procedure for saphenous varicosity; Great saphenous vein varicosity; Questionnaire; Patient satisfaction

Introduction

Varicose veins, a common chronic venous disease, presents with pain, thrombus and skin ulcers [1]. It affects 15 to 40% of the total global population and 10% to 20% of the western population [2,3]. There is not much information on the prevalence of varicose veins in Middle East. A recent study by Ebrahimi et al. reported a prevalence of 47.7% in 197 female hairdressers in North East Iran which was associated with various risk factors including increasing age, family history of varicosity, hypertension, and prolonged standing [2-4]. Lower limb varicose veins are more common than upper limb varicose veins and its world-wide prevalence ranges between 10%-30% [5-7].

Saphenous varicosities, which arise from the great saphenous vein (GSV) and saphenofemoral junction (SFJ), are the most common cause of varicosity in lower limbs [8]. They are generally treated by open varicose vein surgery or Endovenous ablation using a laser (also known as Endovenous Laser Treatment, EVLT) [9]. Varicose vein surgery is associated with high recurrence rate, while EVLT is a minimally invasive, safe and an effective treatment option hence is preferred [10,11].

As EVLT manages GSV, the management of tributaries is also required. For complete elimination of varicosities, EVLT is used with secondary procedures such as foam Sclerotherapy or multiple phlebectomy [2,12,13]. Foam Sclerotherapy is usually preferred due to lower occlusion rates and high treatment accuracy [14-16].

Previous studies have reported the use of EVLT with foam Sclerotherapy concomitantly as one-stage procedure as well as sequentially (as two-stage procedure) [2,17,18]. However, none of them assessed patients' perception and satisfaction quotient post-treatment.

Therefore, the aim of this study was to compare patient's satisfaction with EVLT for GSV and foam Sclerotherapy for treating tributary varicose veins as one-stage versus two-stage procedure.

Material and Methods

Study population

Patients identified with symptomatic bilateral GSV reflux, SFJ incompetence and prominent varicosities by certified vascular ultrasound technologists between March 2016 and March 2018 were included in the study Figure 1. Study procedure was explained to them and their consent was obtained for the same. Their demographic profile and medical history were recorded.

Study procedure

All the included patients underwent one-stage EVLT-Foam Sclerotherapy on one leg and two-stage therapy on the other. Two-stage procedure was performed first on one leg, followed by one-stage on the other.

Two-stage procedure

The patients underwent EVLT for GSV first and after a four-weeks

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follow up, they underwent foam Sclerotherapy for the remaining tributaries on the same leg.

The tributary varicosities were marked preoperatively in standing position. The patient was placed supine, with the table in the reverse Trendelenburg position. After intradermal injection (30G; of a small amount of 1% lidocaine obtained from Mercury Pharma International Ltd, Dublin, Ireland), the incompetent GSV was punctured with an 18G needle under ultrasound guidance. An angled tip of 0.035 inch guide wire was then advanced and passed through the SFJ. The catheter was advanced over the guide wire and placed near to the junction. The guide wire was then removed and TA [lidocaine 400 mg/L (0.04%), epinephrine 1 mg/L (1: 1,000,000), and sodium bicarbonate 10 mEq/L in a physiologic saline solution were then injected by a power pump,

both along and around the vein, under ultrasound guidance. After TA, the laser fibre was inserted into the catheter and its tip was positioned several centimetres below the SFJ. Ablation (EVLT) was performed using 980-nm (A.R.C. Laser GmbH Nuremberg, Germany) or 810-nm (Angiodynamics, Queensbury, NY, USA) laser fibres giving 50–120 J/cm energy, depending on the diameter of reflux veins.

Foam Sclerotherapy was performed using Tessari-method (with 1 cc aethoxysclerol 1%: 4 cc air). The foam was injected directly into the marked tributaries. The volume of injected foam depended on the length and diameter of the tributary, with a maximum of 10 mL per procedure.

Legs were wrapped with compression bandages after the procedure. Patients were discharged after 15–20 minutes of walking under the supervision of a nurse.

One-stage procedure

Post four weeks of two-stage therapy, the same patients underwent EVLT for GSV and foam Sclerotherapy of tributaries concomitantly on the other leg. Same EVLT and Sclerotherapy procedures were followed for one-stage therapy as well.

Assessing patient satisfaction

Four weeks after the completion of both the procedures, the patients were given a short questionnaire to assess their satisfaction based on their comfort quotient and quality of life. The responses were scored based on the Likert Scale [19] namely, strongly agree, agree, not sure, disagree and strongly disagree, which had to be filled by the patients based on their experiences. The responses obtained from the patients were evaluated to compare the level of satisfaction patients felt while and after undergoing one-stage and two-stage procedures.

Results

Study population

A total of 20 patients with an average age of 38.00 ± 9.9 years (age



Figure 1: A 28 year old male with bilateral Great saphenous vein insufficiency and multiple large varicosities.

S.No.	Gender	Age (Years)	Comorbidities				Smoking	Previous pregnancies	Family history of varicosities
			DM	HTN	HL	Heart disease			
1	F	21	N	N	N	N	N	0	N
2	F	27	N	N	N	N	N	2	N
3	F	44	N	N	N	N	N	5	N
4	F	44	N	N	N	N	N	4	N
5	F	50	N	N	N	N	N	6	N
6	M	41	Y	Y	N	Y	Y	-	N
7	F	28	Y	N	N	N	N	3	N
8	F	36	N	N	N	N	N	3	N
9	F	50	N	N	N	N	N	7	N
10	F	25	N	N	N	N	N	1	N
11	M	50	N	N	Y	N	N	-	N
12	F	47	N	Y	Y	N	N	5	N
13	M	39	N	N	N	N	Y	-	N
14	M	28	N	N	N	N	Y	-	N
15	M	26	N	N	N	N	Y	-	N
16	M	39	N	N	N	N	Y	-	N
17	F	49	N	N	N	N	N	5	N
18	F	29	N	N	N	N	N	3	N
19	F	49	N	N	N	N	N	3	N
20	F	43	N	N	N	N	N	3	N

Abbreviations: F: Female; M: Male; Y: Yes; N: No; DM: Diabetes mellitus; HTN: Hypertension; HL: Hyperlipidemia

Table 1: Demographic profile of patients included in the study.

range: 21-50 years) were included in the study. Out of all, 70% (n=14; average age: 38.71 ± 10.6 years; age range: 21-50 years) of patients were females and 30% were males (n=6; average age: 37.17 ± 8.9 years; age range: 26-50 years). All the patients (n=20; 100%) had leg pain and leg swelling. The following comorbidities were found in the patients: diabetes (n=2), hypertension (n=2), hyperlipidaemia (n=2), and heart disease (n=1). Five patients were smokers (n=5). None of them had a family history of varicosities.

Of the 14 female patients, only one (7.14%) had no previous pregnancy while 13 patients (92.86%) had at least one previous pregnancy (average: 3.85 ± 1.68; range: 1-7) (Table 1).

Procedure time

On an average, one-stage EVLT+foam sclerotherapy procedure took 57.1 ± 3.5 minutes (median: 57.5 minutes, range: 47-62 minutes) in total while the two-stage procedure took 47.35 ± 3.1 minutes (median: 48 minutes, range: 40-52 minutes) for performing EVLT and 8.00 ± 1.49 minutes (median: 8 minutes, range: 5-10 minutes) for foam sclerotherapy (Table 2).

Assessing patient satisfaction

A six-point questionnaire was provided to all the patients. All the responses obtained from the questionnaire favored one-stage procedure.

All the patients agreed that one-stage procedure is better than two-stage (n=18 [90%] strongly agreed; n=2 [10%] agreed). All the patients (n=20 [100%] strongly agreed) reported that one-stage procedure was better for going back to usual activities and would advise one-stage procedure as compared to two-stage. All the patients (n=19 [95%] strongly agreed; n=1 [5%], agreed) found one-stage procedure more convenient than two-stage. All patients agreed that both the procedures had same degree of post-operative discomfort (n=16 [80%] strongly agreed; n=4 [20%] agreed). None of the patients preferred two-stage

procedure over one-stage procedure. All the patients except one felt that procedures time, including pre and post-operative, was almost the same for one versus two-stage (n=16 [80%] strongly agreed; n=3 [15%] agreed). Only one (5%) patient was not sure whether one- and two-stage procedures took similar time or not (Table 3).

Discussion

Varicose veins lead to substantial disease and economic burden on society. Its incidence is associated with various risk factors such as family history of varicosities and age in both genders, and the number of pregnancies in females [20]. In the present study, 92.86% (n=13) of the females had at least one pregnancy in lifetime (range 1-7 pregnancies) which is in concordance with the previous studies [20]. However, none of the patients, neither male nor female, had a family history of varicose veins. In the present study, five patients were smokers and a correlation has also been reported between tobacco smoking and venous insufficiency by previous studies [21].

Various techniques are used to treat varicose veins; however, none of them is a gold standard method [22]. EVLT is more accepted as an alternative to surgery for treatment of GSV due to its association with decreased pain, speedy recovery, improved patient satisfaction and improved quality of life [23-25]. Moreover, it is a minimally invasive ablation procedure [26]. According to Min et al., EVLT is less complicated and does not require general anaesthesia, while Wallace and his co-workers (2018) reported EVLT more effective, as compared to surgery, in preventing recurrence of varicosity of GSV even after five years of treatment [17,27]. One of the studies highlighted the role of EVLT in treating varicose veins. Of the 86 extremities included in the study, 76 were treated with EVLT. Out of 76, complete eradication was reported in 36 extremities (41.8%) while the reduction in size was observed in 48 extremities (55.8%). However, 2 extremities (2.3%) did not show any improvement and 36 out of 86 (41.8%) extremities, were required to undergo a secondary procedure. Studies by Kokkosis et al. also reported the necessity of undergoing secondary procedure in patients with prominent varicosities [28]. As the patients included in the present study also had prominent varicosities, it was essential to undergo a secondary procedure to improve patient outcome.

The remaining tributaries are generally treated with secondary procedures such as phlebectomy and sclerotherapy [17,29]. Sclerotherapy can be performed using a liquid or a foam sclerosant. Foam Sclerotherapy is preferred over liquid Sclerotherapy due to higher

S. No.	One-stage procedure	Two-stage procedure	
	EVLT with foam sclerotherapy (Minutes)	EVLT Only (Minutes)	Foam sclerotherapy only (Minutes)
1	47	40	7
2	52	45	8
3	56	48	7
4	55	48	9
5	57	49	5
6	58	50	8
7	54	43	8
8	55	47	9
9	59	48	10
10	60	51	7
11	62	52	5
12	57	48	6
13	58	47	8
14	60	50	8
15	61	49	9
16	61	50	9
17	60	50	10
18	57	45	10
19	58	44	9
20	55	43	8

EVLT: Endovenous Laser Treatment

Table 2: Time taken to perform Endovenous laser treatment and foam sclerotherapy as one-stage and two-stage procedure.

Item	Score				
	Strongly Agree	Agree	Not Sure	Disagree	Strongly disagree
One-stage is better than two-stage	18	2	0	0	0
Procedures time was almost the same including pre and post-operative	16	3	1	0	0
Both procedures had same degree of post-operative discomfort	16	4	0	0	0
One-stage is better for going back to usual activities	20	0	0	0	0
One-stage is more convenient overall	19	1	0	0	0
I would advise for one-stage procedure than tow stage	20	0	0	0	0

Table 3: Responses to questionnaire or patient satisfaction assessment sheet.

efficacy in eliminating tributary varicosities. Foam Sclerotherapy is also associated with lower occlusion rates and high treatment accuracy, due to which foam Sclerotherapy was used in the present study [14-16].

Existing literature also supports the use of combination of therapies for treating major varicose vein and its tributaries together, thereby exhibiting better results [2]. Combination therapies can be given concomitantly as one-stage procedure or in two stages [2,17,18]. Use of EVLT along with foam Sclerotherapy is highly recommended in previous studies as it avoids nerves from getting injured [22].

A study by Yilmaz et al. evaluated the concomitant use of EVLT and foam Sclerotherapy in 504 patients with chronic venous insufficiency for a 6-year period and reported the therapy feasible, successful, effective and less complicated. Only 1.4% of treated legs experienced major complications. The concomitant procedure was also associated with reduced recanalization rate of laser-ablated vessels [30]. Wasim et al. also assessed the possibility of performing EVLT along with foam Sclerotherapy in 250 patients aged 31-40 years and reported the median operating time for performing one procedure as 35 minutes with few post-procedure adverse effects including pain (n=25), ecchymosis (n=30), neuralgia (n=45), pain (n=35) and deep vein thrombosis (n=1). According to the authors, the concomitant use of both the procedures was easy, safe and durable [22].

Literature also reports the use of foam Sclerotherapy for treating varicose tributaries followed by EVLT which is the reverse of the procedure followed in the present study. The study included 312 patients (411 limbs) presented with varicose veins and 99% (410/411) of total limbs were technically successfully treated with no serious complications. This sequence of procedure was safe, effective and reduced the requirement of additional Sclerotherapy and technical failure [31]. Given that success of EVLT followed by foam Sclerotherapy sequence used in the present study, it is reasonable to say both the sequences were safe and effective.

EVLT+ phlebectomy could be more time consuming as compared to EVLT+foam Sclerotherapy when given concomitantly. Carradice et al. also compared the concomitant and sequential use of EVLT and phlebectomy for treating varicose veins in 50 patients and reported that the concomitant procedure took more time (median (interquartile range, i.q.r.) 65 minutes (range: 50–70 minutes) as compared to the time taken for EVLT alone in sequential (median (i.q.r.) 45 minutes (range: 40–55 minutes); $p=0.002$) with an average difference of 20 minutes [13]. In our study, one-stage EVLT+foam Sclerotherapy procedure took an average 57.5 minutes in total which was less than the time taken for EVLT+ phlebectomy (65 minutes) in the study by Carradice et al. Moreover, in the present study there was nominal median time difference between the two procedures (one-stage: 57.5 minutes vs. two-stage: 48 minutes+8 minutes= 56 minutes). In the study by Carradice et al, though the combined procedure took more time, it reduced the requirement of secondary treatment procedures [13].

The present study focused on the assessment of patients' satisfaction with GSV-EVLT and tributary veins foam Sclerotherapy for the treatment of varicose veins as one- vs. two-stage procedure. Since every patient underwent both, one-stage (on one leg) and two-stage procedure (on other leg), therefore they could compare the results of both the procedures more effectively. As per results, one-stage procedure was considered superior to other (strongly agree: 18; agree: 2) due to almost same procedure time (strongly agree: 16; agree: 3; not sure: 1) and post-operative discomfort (strongly agree: 16; agree:

4). Moreover, one-stage was more convenient (strongly agree: 19; agree: 1) and required lesser time for recovery (strongly agree: 20). Existing literature focuses on the patients' satisfaction and perception on treatment of varicose veins which reported improvement in quality of life, and anxiety or depression post-treatment [32]. Another study by Santiago et al. evaluated patients' self-perception of cosmetic improvement before and after sclerotherapy using pre- and post-procedure photographs. The study reported improvement in patient satisfaction ($p < 0.0028$) using photographs as a simple intervention [33]. However, none of the previous studies compared the EVLT-foam sclerotherapy one-stage and two-stage procedures in terms of patients' satisfaction. Therefore, to the best of our knowledge, the present study is not only the first to assess the same, but it is also the only study that compared both the procedures on one patient, thereby making the comparison bias free.

However, our study had a few limitations. One limitation is a small sample size of just 20 patients. Another is that EVLT and foam sclerotherapy was not compared with any other combination or sequential procedures. Third limitation is that patient satisfaction was measured just after eight weeks of two-stage procedure and four weeks of one-stage procedure. Hence, larger longitudinal and comparative studies are required before the results of this study can be extrapolated to a larger population.

Conclusion

EVLT and foam sclerotherapy are highly recommended procedures for treating varicose veins. The present study concluded that both the procedures were similar in terms of time consumed and overall discomfort. However, the patients were more satisfied after undergoing single-stage procedure than two-stage due to speedy recovery and higher convenience associated with concomitant therapy. However, larger longitudinal comparative studies are required to understand the impact of one-stage versus two-stage EVLT and foam sclerotherapy procedures.

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