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Original Article

Radiology Section

Quality of Life of Patients Treated with VenaSeal™ versus Endovenous Laser Treatment for Varicose Veins: A Retrospective Cohort Study

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ABSTRACT

Introduction: Endovenous Laser Ablation (EVLT) has been considered the 'gold standard' for the treatment of varicose veins for the last two decades. The newer non thermal, Non tumescent treatment modality like VenaSeal™ has shown promising results and is now considered non inferior to thermal ablation.

Aim: To compare the Quality of Life (QoL) of patients with varicose veins treated with VenaSeal™ and EVLT.

Materials and Methods: A retrospective cohort study was carried out at the Department of Interventional Radiology of a Sahyadri Super Speciality Hospital, Pune, Maharashtra, India from January 2022 to December 2023. Adult patients (of either gender) with symptomatic venous reflux disease involving the Great Saphenous Vein (GSV) and/or Small Saphenous Vein (SSV) with associated moderate to severe varicosities (C2-C5 stages) were studied. Group I (n=30 limbs) consisted of patients who had already undergone VenaSeal™ treatment for varicose veins and group II (n=30 limbs) consisted of patients who had already undergone EVLT for varicose veins. Patients in both groups were assessed before the intervention and at one week, six weeks and six months following the procedure using the 36-item Short Form Survey (SF-36) and the Aberdeen varicose veins Questionnaire (AVVQ). Categorical variables were compared using the Chi-square test. Continuous variables were compared using unpaired t-test or Mann-Whitney U test between the two treatment groups and the Kruskal-Wallis test was used within the two treatment groups. For within-group analysis, the Friedman test was used to compare pre- and postoperative values across all time points-at enrollment, six weeks and six months. A p-value of <0.05 indicates statistical significance.

Results: The mean age was 48.70±12.62 years for group I and 50.46±13.00 years for group II. At baseline, no statistical difference was observed in all domains of SF-36 scores between the two groups. At six weeks, group I showed statistically higher scores in the domains of Physical Function (PF), Role limitations due to physical Problems (RP), Energy/Vitality (VT), Social function (SF) and Bodily Pain (BP) domains than group II. At six months again, no statistical difference was observed in all domains of SF-36 scores between the two groups. AVVQ scores were significantly better in the VenaSeal™ group at six weeks, but at six months, no statistical difference was noted between the two groups.

Conclusion: VenaSeal™ and EVLT both provide similar QoL improvements in patients with varicose veins at six months of follow-up. VenaSeal™, however, eliminates the QoL limitations experienced by patients in the immediate and early postoperative period.

Keywords: Chronic venous insufficiency, Cyanoacrylate embolisation, Endovenous laser ablation, Varicose veins surgery

INTRODUCTION

Varicose veins, a condition caused by weak or damaged vein walls and valves, affect approximately 10-20% of the general population, with a higher prevalence (40%) in women [1]. Chronic venous insufficiency due to varicose veins significantly affects the QoL, causing chronic leg pain, swelling, pigmentation and non healing ulcers. It impacts the QoL of nearly 37.25% of the Indian population [1]. Over the past two decades, the management of chronic venous disease and saphenous insufficiency has seen significant changes, with minimally invasive endovenous techniques replacing traditional surgical treatments [2]. With the advent of minimally invasive treatment, postoperative QoL has significantly improved compared to traditional surgical stripping. Endovenous thermal ablation treatments like Light Amplification by Stimulated Emission of Radiation (LASER) or Radiofrequency Ablation (RFA) have been the standard line of management for the last two decades. However, the procedure is still done under local or spinal anaesthesia with perivenous tumescence, which leads to discomfort. The newer non thermal ablation treatment modality like VenaSeal™ has the added advantage of being done under local anaesthesia without any perivenous tumescence. The Cyanoacrylate Closure (CAC) system shows better occlusion rates and shorter procedure duration with higher freedom from reopening compared to RFA [2]. Here, the authors aimed to compare the QoL between VenaSeal™ and Endovenous Laser Treatment (EVLT). Instead of using RFA, they used EVLT for comparison relative to Cyanoacrylate (VenaSeal™).

MATERIALS AND METHODS

The retrospective cohort study was conducted at the Department of Interventional Radiology of a Sahyadri Super Speciality Hospital, Pune, Maharashtra, India from January 2022 to December 2023. Institutional Ethical Committee approval was obtained.

Inclusion and Exclusion criteria: The study included adult patients (of either gender) who had undergone treatment for symptomatic venous reflux disease involving GSV and/or SSV in the form of VenaSeal™ or EVLT and were also diagnosed with moderate to severe varicosities {Clinical, Etiological, Anatomical, and Pathophysiological (CEAP) classification C2- C5)} [2]. Patients with underlying Deep Vein Thrombosis (DVT) or any other secondary cause of varicose veins (such as pregnancy or pelvic masses) were excluded from the study. Additionally, patients with CEAP C6 disease were excluded due to the possibility of reporting higher peri-operative pain scores (attributed to the presence of a venous ulcer) and therefore showing less improvement in QoL scores.

Study Procedure

The data were collected from patient records of those who had already undergone treatment for symptomatic varicose veins with either VenaSeal™ or EVLT. Group I (n=30 limbs) consisted of patients who had undergone VenaSeal™ treatment for varicose veins and group II (n=30 limbs) consisted of patients who had undergone EVLT for varicose veins. General and demographic information was retrieved from patient records. As per the protocol, preoperative lower limb baseline venous Doppler scans were performed. Sapheno-Femoral Junction (SFJ) and Sapheno-Popliteal (SPJ) incompetence were diagnosed when reflux time exceeded 500 msec and perforator incompetence was diagnosed when it exceeded 350 msec.

The primary endpoints were to evaluate immediate post-procedure complications (such as pain, paraesthesia, phlebitis, ecchymosis and DVT) at one week. The secondary endpoints aimed to evaluate changes in generic QoL scores and disease-specific QoL. The SF-36 is an instrument for objectively evaluating Health-related QoL. The scale consists of 36 questions divided into eight domains, with each domain scored from 0 to 100. Higher scores indicate better health [2,3]. QoL and overall score were calculated using an online RAND 36 calculator [3,4].

The AVVQ comprises 13 questions, with scores ranging from 0 to 100. The manikin diagram within the questionnaire can contribute up to 22 points, depending on the extent of the varicose veins. A score of 0 points indicates the best QoL for the patient [5].

Duplex Doppler Ultrasonography (USG) was performed at the time of enrollment and at the follow-ups at six weeks and six months. Anatomical closure in both groups was defined as the total occlusion of the GSV in the treated segment and any open segment exceeding 5 cm was regarded as a failure.

Details of the procedures performed for treating varicose veins:

VenaSeal™ procedure: The VenaSeal™ closure system (Medtronic, Minneapolis, Minn) procedure was performed under local anaesthesia with or without sedation. In cases of concomitant phlebectomies, spinal anaesthesia was employed. Under local anaesthesia, ultrasound-guided access was obtained into the GSV above the medial malleolus and a 7Fr sheath was placed. The guide catheter of the VenaSeal™ device was navigated 5 cm caudal to the SFJ over a 0.035" J-tip guidewire. The VenaSeal™ catheter was then loaded with 5 cc of cyanoacrylate glue in a Luer lock syringe, which was loaded onto a pistol mechanism and advanced through the guiding catheter. Under ultrasound guidance, proximal GSV compression was applied using the probe and two 0.1 mL aliquots of cyanoacrylate were administered 1 cm apart. Additional hand compression was applied to the treated segment for three minutes. Following this, 0.1 mL aliquots were administered at 3 cm intervals along the target treatment area, with compression using the ultrasound probe and hand applied for 30 seconds at each treated segment. Similarly, the short saphenous vein was treated. Perforators were treated with either sclerotherapy using 3% sodium tetradecyl sulfate or phlebectomy. A compression bandage was used postoperatively, which was removed after 48 hours.

Endovenous Laser Treatment (EVLT): EVLT was performed under spinal anaesthesia using a 1470 nm diode laser (SmartM, Lasotronix, Poland) on pulse mode. In brief, USG-guided venous access was obtained by puncturing the GSV just above the medial malleolus with an 18 G puncture needle and a 6Fr sheath was placed in the GSV. A radial fibre was passed into the GSV through an introducer sheath with its tip placed 2.5 cm proximal to the SFJ. Tumescent fluid (normal saline) was infiltrated in the perivenous space deep to the saphenous fascia (5 mL/cm). Ablation was done at an energy setting of 8W power and energy 80 J/cm on pulse mode. The fibre was pulled out 1 cm at every 10-second interval. Similarly, the short saphenous vein was treated. Perforators were treated with either sclerotherapy using 3% sodium tetradecyl sulfate or phlebectomy. Compression bandages/Class II compression stockings were used postoperatively and this continued for at least three months.

STATISTICAL ANALYSIS

Statistical analysis was performed using MedCalc software (Version 22.0.30) and IBM Statistical Package for Social Sciences (SPSS) Statistics for Windows, Version 27.0 (IBM Corp. Released 2020, Armonk, NY: IBM Corp). Data were presented as numbers for categorical variables and mean±Standard Deviation (SD) for continuous variables. Categorical variables were compared using the Chi-square test. Continuous variables were assessed with an unpaired t-test for normally distributed data or the Mann-Whitney U test for non normally distributed data between two treatment groups. To compare values across time points (enrollment, six weeks and six months) within each treatment group, the Kruskal-Wallis test was used. For within-group analysis, the Friedman test was used to compare pre- and postoperative values across all time points - at enrollment, six weeks and six months. A p-value of less than 0.05 shows statistical significance.

RESULTS

A total of 60 patients 35 males and 25 females were studied and were equally divided into two groups. All patients (n=60) were followed-up at six weeks and six months post-procedures. The average age was 48.7 years for group I and 50.4 years for group II [Table/Fig-1]. The authors found an anatomical closure rate (total absence of GSV in the treated part) in all 30 patients in group I and 96.70% (29 patients) in group II at six months with no recurrence at six months in both groups. Both groups reported mild postoperative adverse events like pain, paraesthesia, phlebitis and ecchymosis in the first week. No serious complications like DVT were reported in either of the groups [Table/Fig-2].

Attributes		Group I VenaSeal™ (n=30)	Group II EVLT (n=30)
Age (in years); mean±SD		48.70±12.62	50.46±13.00
Gender n (%)	Male	16 (53.33%)	19 (63.33%)
	Female	14 (46.67%)	11 (36.67%)
CEAP n (%)	C2	15 (50.00%)	13 (43.33%)
	C3	8 (26.67%)	7 (23.33%)
	C4	5 (16.67%)	6 (20.00%)
	C5	2 (6.67%)	4 (13.33%)

[Table/Fig-1]: Demography of patients.

Attributes	Group I (VenaSeal™) n (%)	Group II (EVLT) n (%)	p-value Chi-square test
Postoperative pain	3 (10%)	12 (40%)	0.007
Paraesthesia	0	8 (26.67%)	-
Phlebitis	5 (16.67%)	2 (6.67%)	0.231
Ecchymosis	2 (6.67%)	8 (26.67%)	**0.039**
DVT	0	0	-

[Table/Fig-2]: Early postoperative outcomes at one week.

SF-36 results: Over the total study period of six months, QoL scores were statistically improved in both groups for PF, RP, RE, Energy/VT, SF and BP domains, except for Emotional well-being/Mental Health (MH) and General Health (GH). At baseline, no statistical difference was observed in all domains of SF-36 scores between the two groups. At six weeks, group I showed statistically higher scores in the domains of PF, RP, VT, SF and BP than group II. At six months again, no statistical difference was observed in all domains of SF-36 scores between the two groups [Table/Fig-3].

Aberdeen Varicose Vein Scoring (AVVQ): The AVVQ score of the VenaSeal™ group has improved significantly at six weeks compared to the EVLT group. At six months, no statistical difference was noted in both groups [Table/Fig-4].

DISCUSSION

Endovenous thermal modalities, including EVLA and RFA, are reported to be effective in treating symptomatic superficial truncal

Characteristics	Group	At enrollment mean±SD	Six weeks follow-up mean±SD	Six months follow-up mean±SD	p-value (across all time)
Physical Function (PF)	Group I- VenaSeal™	49.67±14.74	76.83±5.94	81.33±8.70	**<0.00001**
	Group II- EVLT	50.17±14.53	68.17±11.02	78.83±11.12	**<0.00001**
	p-value	0.895	0.001	0.336	
Role limitation due to Physical Problems (RP)	Group I- VenaSeal™	56.33±11.52	81±7.70	91.5±5.59	**<0.00001**
	Group II- EVLT	57.67±11.65	73.17±8.15	88.5±6.84	**<0.00001**
	p-value	0.657	**0.0003**	0.0681	
Role limitation due to Emotional problem (RE)	Group I- VenaSeal™	70.83±5.58	82.37±4.44	91.5±5.11	**<0.00001**
	Group II- EVLT	71±5.63	82.5±6.12	92.33±4.3	**<0.00001**
	p-value	0.909	0.923	0.497	
Energy/Vitality (VT)	Group I- VenaSeal™	60.67±9.8	78±10.64	80±10.42	**<0.00001**
	Group II- EVLT	60±8.71	72±11.86	76.67±10.77	**<0.00001**
	p-value	0.782	0.043	0.228	
Emotional well-being/ Mental Health (MH)	Group I- VenaSeal™	68.67±6.56	70.33±7.54	71.5±7.45	0.054
	Group II- EVLT	69.83±6.49	71.67±6.48	72.33±6.26	0.115
	p-value	0.491	0.465	0.641	
Social Function (SF)	Group I- VenaSeal™	65.5±4.22	84.83±5.94	89.17±4.75	**<0.00001**
	Group II- EVLT	66.67±4.22	79.83±8.66	87±4.84	**<0.00001**
	p-value	0.289	0.011	0.085	
Bodily Pain (BP)	Group I- VenaSeal™	46.33±11.52	78.33±9.41	83.67±8.30	**<0.00001**
	Group II- EVLT	48.67±11.29	72.17±11.27	84±7.81	**<0.00001**
	p-value	0.431	0.025	0.873	
General Health (GH)	Group I- VenaSeal™	78.16±7.36	79.5±6.48	80.83±7.08	0.097
	Group II- EVLT	78.5±12.04	79±11.99	80.33±8.50	0.897
	p-value	0.897	0.841	0.805	

[Table/Fig-3]: Comparison of Quality of Life (QoL) domain scores.
Test used: Friedman test and Unpaired t-test. p-value <0.05* considered as statistically significant

Groups	At enrollment mean±SD	6 weeks mean±SD	6 months mean±SD	p-value mean±SD
Group I- VenaSeal™	15.00±1.68	3.57±1.31	3.17±1.26	<0.001*
Group II- EVLT	15.87±2.19	6.73±1.70	3.37±1.33	<0.001*
p-value	†0.091	<0.001*	0.544	

[Table/Fig-4]: Comparison of Aberdeen Varicose Vein Questionnaire (AVVQ) scores.
Values represented are mean±SD. Test used: Two sample t-test1 or Mann-Whitney U test for inter-group analysis (group I and group II) and independent-sample t-test and Kruskal-Wallis test for intra-group analysis (Across different time points). p-value <0.05* is considered statistically significant

saphenous vein incompetence and are considered 'the gold standards' of care [6,7]. Despite the administration of tumescent anaesthesia, thermal-related complications such as skin burns, nerve injury and endothermal heat-induced thrombosis still occur. Post-procedural pain and bruising are commonly associated with thermal therapies [8,9].

The newer non thermal non tumescent techniques that do not require tumescent anaesthesia include Mechanochemical Endovenous Ablation (MOCA), Proprietary polidocanol endovenous microfoam 1% - Varithena and Cyanoacrylate glue - VenaSeal™. Both microfoam and MOCA have limitations of dose constraints and treating more than one saphenous vein in a single session is not possible. Furthermore, it requires patients to wear medical compression stockings after undergoing either treatment modality [10]. The VenaSeal™ Closure System (Medtronic, Minneapolis, MN, USA) uses cyanoacrylate glue for the closure of lower extremity superficial truncal veins [11].

Cyanoacrylate glue has been used previously in treating vascular diseases, arteriovenous malformations [12,13], occluding esophageal varices in portal hypertension [14,15] and treating pelvic varicosities [16,17]. VenaSeal™, a proprietary n-butyl cyanoacrylate glue, possesses characteristics of rapid polymerisation upon contact with blood and high viscosity, preventing embolisation. Additionally, once solidified, VenaSeal™ is capable of allowing for flexion and torsion [18].

In an initial preclinical feasibility study evaluating the use of the VenaSeal™ procedure in 38 patients, the catheter tip was positioned 1.5 to 2 cm away from the SFJ and the first two aliquots of cyanoacrylate glue were injected simultaneously. Glue extension into the common femoral vein was observed in eight patients (21.1%) [19]. The technique was further modified in subsequent trials by changing the position of the catheter tip 5 cm away from the SFJ and by injecting the first two aliquots of the cyanoacrylate glue 1 cm apart, rather than simultaneously [20]. In the present study, the authors have used the modified technique.

The single-arm multicentre European Sapheon Closure System Observational Prospective (eSCOPE) trial demonstrated the anatomical and clinical effectiveness of VenaSeal™ Cyanoacrylate Embolisation (CAE) at 12 months, with an extended follow-up to 36 months. The closure rates at 6, 12, 24 and 36 months were 91.4%, 90.0%, 88.5% and 88.5%, respectively. The AVVQ score improved significantly from 16.3 at baseline to 6.7 at 12 months (p<0.0001). Phlebitis was observed in 8 cases (11.4%) [21].

The VenaSeal™ Sapheon Closure System Pivotal Study (VeClose) was a randomised trial comparing CAC and RFA and has demonstrated continued non inferiority of CAC to RFA at five-year follow-up [2]. Along with CAC, sustained improvements were also reported in symptoms and QoL, lower CEAP class and a high level of patient satisfaction without serious adverse events between 36 and 60 months. In a similar trial, at day 3, less ecchymosis was noticed after CAE in the treated region compared with RFA treatment (p<0.01). At 12 months, the complete occlusion rates were nearly identical in both groups [2]. AVVQ score declined (improved) by 50% at the end of six months for both groups and by 55% and 67% at the end of five years for CAC and RFA, respectively [2]. The closure rate in our study was also similar for VenaSeal™ and for EVLT at the end of six months (100% vs. 97%).

In the Lake Washington Vascular VenaSeal™ Post-market Evaluation Study (WAVES), one-year results demonstrated the safety and efficacy of CAC for treating GSVs up to 20 mm in diameter, as well

as SSVs and accessory saphenous veins, with an occlusion rate of 98% across all treated veins [22].

In a recent meta-analysis by Amshar M et al., comparing CAE and EVLA for treating saphenous vein insufficiency, it was found that venous closure rates and Venous Clinical Severity Scores (VCSS) did not significantly differ between the two groups in terms of efficacy. However, from a safety perspective, the pooled data revealed that the CAE group experienced significantly less peri-procedural pain ($p<0.001$), lower rates of skin pigmentation (0.60% vs. 4.46%; $p=0.008$) and reduced nerve damage (0% vs. 3.94%; $p=0.007$). Rates of phlebitis, DVT and ecchymosis were not significantly different between the two groups [23]. These findings are consistent with the present study.

Neuropathy in the form of paraesthesia developed in 8 (26.67%) patients in the EVLT group in the present study and none in the VenaSeal™ group. This could be due to avoiding heating the perivenous tissue and obviating tumescent anaesthesia. The incidence of phlebitis was higher in the VenaSeal™ group, but overall no statistically significant difference was observed in both groups. These postoperative outcomes are consistent with the literature.

Minimally invasive treatments have early recovery compared to open surgical treatments. Hence, in the late postoperative period, the long-term effects due to those factors plateau with time.

Limitation(s)

The treatment method applied to patients was determined based on patient preference and cost considerations, preventing the use of a randomised methodology in the present study. As a result, aspects such as the use of spinal anaesthesia and the choice of ablation method could not be randomised.

CONCLUSION(S)

It is evident from the present study that both VenaSeal™ and EVLT procedures for the treatment of varicose veins improved QoL. In the early post-intervention period, VenaSeal™ offers a QoL advantage over EVLT. Although this advantage diminishes over time, it may have significant implications for an early return to normal lifestyle and activities.

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