

Comparative Analysis of Ultrasound-Guided Foam Sclerotherapy, Radiofrequency Ablation & Endo-Venous Laser Ablation for Management of Great Saphenous Vein Reflux at a Tertiary Care Hospital

Srinivasulu Bandam¹, Y Karthik^{2*}

¹Assistant Professor, Department of General Surgery, Narayana Medical College and Hospital, Nellore, Andhra Pradesh, India.

^{2*}Assistant Professor, Department of General Surgery, Kamineni Institute of Medical Sciences, Narketpally, Nalgonda, Telangana, India.

ABSTRACT

Introduction: Chronic venous insufficiency of lower limbs is reported to be the most common problem faced by adults. The reflux from great saphenous vein develops when the valves of the saphenous veins are irreversibly damaged or blocked. The contents of the veins travel up and down from the bottom of the leg and when the valves are weakened blood starts to pool in the leg, foot or toes. Surgical removal of those damages veins relieves the patient from signs and symptoms of chronic venous insufficiency.

Materials and Methods: The proposed study was conducted after seeking approval from the Institutional ethical committee. Patients who were reported to surgical outpatient department with GSV varicosity due to incompetent SFJ were selected on the virtue of clinical history, physical examination and duplex ultrasound and then randomly assigned in each arm i.e., duplex UGFS group and radio-frequency ablation (RFA) group by a sealed envelope technique. The inclusion criteria for the study participants include symptomatic patients based on the Clinical- Etiology- Anatomy- Pathophysiology (CEAP) classification with incompetent SFJ & Those patients between the age range of 12 and 70 years of age at the time of enrolment. All patients were informed about the intervention technique and a written informed consent was taken. Study visits took place at baseline, time of the procedure and 1 week, 1 month and 3 months following the procedure. The data was tabulated into the MS Excel sheet and was analysed using SPSS statistical software, version 16.

Results: Mean age was 30.25±8.29 in EVLA group, 32.96±6.12 in RFA group and 29.32±8.19 in UGFS group; with no significant difference among them. Females were the predominant among groups as it were distributed as 54.3% in

EVLA group, 69.2% in RFA group & 53.8% in UGFS group, while males were distributed as 46.2% in EVLA group, 30.8% in RFA group & 46.2% in UGFS group; with no significant difference among the groups regarding sex. As for BMI, the mean BMI (Kg/m²) was 21.42±1.57 in EVLA group, 22.44±0.72 in RFA group and 22.63±1.03 in UGFS group with no significant difference among the three studied groups.

Conclusion: Our study demonstrated that UGFS, EVLA & RFA are effective treatment modalities for the GSV incompetency. Observing a moderate rate of recanalization after UGFS, it appears that EVLA & RFA are superior to UGFS with respect to clinical recurrence and VCSS. Post-operative patient comfort and the outcome of EVLA & RFA in short & medium-terms are superior to those after UGFS in terms of recanalization & effective ablation.


Keywords: Sclerotherapy, Laser, Radiofrequency Ablation, Varicose Vein.

*Correspondence to:

Dr. Y Karthik,
Assistant Professor,
Department of General Surgery,
Kamineni Institute of Medical Sciences,
Narketpally, Nalgonda, Telangana, India.

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INTRODUCTION

Chronic venous insufficiency of lower limbs is reported to be the most common problem faced by adults. The reflux from great saphenous vein develops when the valves of the saphenous veins are irreversibly damaged or blocked.¹

The contents of the veins travel up and down from the bottom of the leg and when the valves are weakened blood starts to pool in the leg, foot or toes. This is the most common problem in adults affecting around every fifth or sixth men and women according to

Bonn Vein study (2003) resulting in the chronic venous insufficiency affecting the lower limbs.^{2,3} Surgical removal of those damages veins relieves the patient from signs and symptoms of chronic venous insufficiency. Surgery is the only gold standard treatment of those truncal varicose veins. The saphenous vein with an incomplete valve at the junction is usually managed by complete ligation followed by stripping that to the knee.³ Though there were high reported success rate with the surgical procedure, it is related with higher post-operative death rate and sometimes can cause a delay to return back to normality. Therefore, a minimal invasive approach has been discovered to cure the great saphenous varicose veins such as ultrasound-guided foam sclerotherapy, radio-frequency ablation (RFA) and endovenous laser therapy (EVLT), with the aim of attaining a better success rate than the conventional surgery with faster recovery and lower morbidity rate.⁴

Ultrasound-guided foam sclerotherapy (UGFS) has been invented recently, and its efficiency has been superior or it works equal to that of ultrasound-guided foam sclerotherapy.⁵ The ultrasound foam sclerotherapy technique involves injecting the varicosed sites with sclerosants in the form of foam.⁶ Radiofrequency Ablation technique uses heat (radio-frequency waves) energy waves induced total obliteration of truncal great saphenous varicose veins with extraordinary outcomes,⁷ but the drawback of the technique is expensive treatment and absence of its availability in all the hospitals. The Systematic Reviews (2014) of randomized clinical trial compared the three techniques foam sclerotherapy, radio-frequency ablation and endovenous laser therapy for the treatment of great saphenous varicose veins and concluded that all three endoluminal modalities are effective conservatively as surgery.⁸

In India, the ultrasound-guided foam sclerotherapy, especially catheter-directed, provide a significant promise not because of their availability but are relatively cheaper.

MATERIALS AND METHODOLOGY

Patients who were reported to surgical outpatient department with GSV varicosity due to incompetent SFJ were selected on the virtue of clinical history, physical examination and duplex ultrasound and then randomly assigned in each arm i.e., duplex UGFS group and radio-frequency ablation (RFA) group by a sealed envelope technique. The inclusion criteria for the study participants include symptomatic patients based on the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification with incompetent SFJ & Those patients between the age range of 12 and 70 years of age at the time of enrolment. Patients belonging to C_{0,1,6} of CEAP classification and those with a history of deep venous thrombosis & Pregnant ladies & those who are allergic to polidocanol or anaesthetic agent & Greatly tortuous GSV & Peripheral arterial insufficiency & Locoregional infection & Immobility & Severe co-morbidities & History of previous treatment for varicose vein & Patent foramen ovale examined on echocardiography were excluded from the study. All patients were informed about the intervention technique and a written informed consent was taken. Study visits took place at baseline, time of the procedure and 1 week, 1 month and 3 months following the procedure.

The data was tabulated into the MS Excel sheet and was analysed using SPSS statistical software, version 16. Categorical variables were presented as numbers and continuous data was presented as mean \pm standard deviation or median (min-max) as necessary. The comparison between qualitative data of each group was determined by using chi-square or Fischer's exact test. The continuous data was compared by Student's t test/Mann-Whitney U test when required. The comparison over a period of time was done by applying the Friedman test followed by the post hoc comparison by the Wilcoxon signed-rank test after minor tweaking of the probability. A P value less than 0.05 was considered as statistically significant.

Table 1: Demographic data of the three studied groups (age, BMI and sex distribution).

Variant	EVLA	RFA	UGFS	Chi – square	P – value
Age	30.25 \pm 8.29	32.96 \pm 6.12	29.32 \pm 8.19	0.833	0.443
BMI	21.42 \pm 1.57	22.44 \pm 0.72	22.63 \pm 1.03	1.465	0.245
Sex					
Female					
N (%)	8 (53.3%)	9 (60%)	8 (53.3%)	0.85	0.65
Male					
N (%)	7 (46.6%)	6 (40%)	7 (46.6%)		
Total					
N (%)	15 (100%)	15 (100%)	15 (100%)	-	-

Table 2: Lesion laterality among the three studied groups.

Variant	EVLA	RFA	UGFS	Total	Chi – square	P – value
Bilateral						
N (%)	6 (40%)	4 (26.6%)	5 (33.33%)	15 (33.3%)		
Left						
N (%)	5 (33.33%)	5 (33.33%)	6 (40%)	16 (35.6%)	1.27	0.89
Right						
N (%)	4 (26.6%)	6 (40%)	4 (26.6%)	14 (31.1%)		
Total						
N (%)	15 (100%)	15 (100%)	15 (100%)	45 (100%)	-	-

Table 3: Clinical (CEAP) classification between the three studied groups.

Variant (CEAP)	EVLA	RFA	UGFS	Total	Chi – square	P – value
C2 N (%)	0 (0%)	0 (0%)	1 (6.6%)	1 (2.2%)	3.24	0.523
C3 N (%)	4 (26.6%)	5 (33.3%)	5 (33.3%)	14 (31.2%)		
C4 N (%)	11 (73.3%)	10 (66.6%)	9 (60%)	30 (66.6%)		
Total N (%)	15 (100%)	15 (100%)	15 (100%)	45 (100%)	-	-

Table 4: Pre-operative valve closure time distribution among the three groups

Variant	EVLA	RFA	UGFS	Friedman	P - value
Valve closure time	0.75±0.18	0.66±0.19	0.62±0.11	4.621	0.023

Table 5: Return to work between the three studied groups.

Variant	EVLA	RFA	UGFS	Friedman	P - value
Return to work	9.23±2.83	8.99±2.15	15.65±5.25	13.977	0.00

RESULTS

In the study, Table - 1 depicted the mean age was 30.25±8.29 in EVLA group, 32.96±6.12 in RFA group and 29.32±8.19 in UGFS group; with no significant difference among them. Females were the predominant among groups as it were distributed as 54.3% in EVLA group, 69.2% in RFA group & 53.8% in UGFS group, while males were distributed as 46.2% in EVLA group, 30.8% in RFA group & 46.2% in UGFS group; with no significant difference among the groups regarding sex. As for BMI, the mean BMI (Kg/m²) was 21.42±1.57 in EVLA group, 22.44±0.72 in RFA group and 22.63±1.03 in UGFS group with no significant difference among the three studied groups. (Table 1)

There was non-significant difference whether the lesion was unilateral or bilateral between the three groups. Most of RFA group patients were affected unilateral as shown in table 2. There was non-significant difference in distribution of CEAP classification among the three studied groups. Majority of cases were in C4 category as seen in Table 3. Table – 4 shows that the valve closure time was non-significant among the three studied groups; although p-value was < 0.05.

UGFS group was significantly bit longer procedure regarding duration to return to work than EVLA and RFA group which both had non-significant difference between them which is given in table 5. All patients had reported improvement in VAS after the three procedures with significant Improvement in EVLA & RFA groups than UGFS group within the 1st week and after one-month post-operative than the pre-operative periods.

DISCUSSION

The diagnosis of varicose vein is most often missed identity disease because of the under-appreciation of the magnitude and impact of the problem. In the Vein Consult Program, more than 91,000 subjects reported from the various geographic regions were evaluated and worldwide prevalence of clinically significant chronic venous insufficiency of lower limb was roughly around 60%. Prevalence was higher in developed countries when compared with developing countries.¹⁰ According to a study conducted in the western area, approximately 23% of U.S adults reported to have varicose veins, a disease being commoner in women and older adults of age range between 40–80 years.¹¹ However, in the latest *Edinburgh Vein Study* (2014), there was no age or sex difference when a large population size was followed up for 13 years for the incidence of venous reflux.¹²

In our study, mean age was 30.25±8.29 in EVLA group, 32.96±6.12 in RFA group and 29.32±8.19 in UGFS group with a male preponderance. Though there seems to be no clear explanation for this finding, this might well be attributed by the fact that most of the patients suffering from the disease were involved either in strenuous labour or standing long time or walk for long periods in their job nature, as more males are involved in heavy work. Also, females mostly seek delayed help and probably dependent on males for their medical care in a hospital especially those belonging lower socioeconomic background.

The classical presenting complains include visible dilated veins of the lower limb, heaviness in the leg, swelling around the ankle, hyperpigmentation and recurrent/non-healing ulcers in the calf muscle area. A duplex study of the venous system explains about patency of deep veins; incompetency of the SFJ, SPJ, and perforators, if any; and diameter of GSV at the mid-thigh level. The present study compared the outcome of GSV truncal obliteration using the two minimally invasive methods: RFA and ultrasound-guided, endo-venous laser ablation. Anatomical success rate was reported to be high and statistically comparable in both the study groups which were maintained over the 90-day follow-up (100 % in the RFA group and 93.3 % in the UGFS group). The most important observation was that GSVs with a mid-thigh diameter up to 10 mm were successfully obliterated in a single session while higher diameters required multiple sessions of sclerotherapy to attain the stipulated goal. Studies have already proven the high occlusion rates of RFA maintained in short and middle terms.^{13, 14} But there are relatively fewer studies on ultrasound-guided sclerotherapy of varicose veins; however, they prove it to be safer and more efficacious when compared with the standard ultrasound-guided foam sclerotherapy.¹⁵ Studies on ultrasound-guided foam sclerotherapy have reported around 75 % success rate at 1 year^{16,17} and 65 % at 5 years¹⁸ in managing the truncal occlusion when assessed sonologically, and while on clinical assessment, the result was almost comparable to that of endothermal modalities followed in certain studies.¹⁸ The improvement in subjective complaints, as assessed by the VCSS and VDS, was significant and comparable at every visit, suggesting excellent clinical results and increased patient satisfaction. Post-operative complications such as post-procedural pain, ecchymosis and persistent cannulation site numbness of the skin were reported in some patients of the RFA treatment group of the study which seemed inherent to heat-based therapies.¹⁹

Sclerotherapy group subjects had self-limiting mild post-procedural pain and cord-like induration along the GSV with slightly higher incidences of thrombophlebitis as observed in previous studies.¹³ Deep vein thrombosis, pulmonary embolism and anaphylaxis have been reported to be the serious complications of these endoluminal treatment modalities²⁰⁻²² but none of the study participants in our study groups developed these complications. This study is not devoid of any limitations, and they are like small sample size and short duration of follow-up. But still, the results are very encouraging especially with ultrasound-guided, radiofrequency ablation and endovenous laser ablation. A longer follow-up with quite larger number of patients will definitely help in establishing it as a treatment of choice in developing countries.

CONCLUSION

Our study demonstrated that UGFS, EVLA & RFA are effective treatment modalities for the GSV incompetency. Observing a moderate rate of recanalization after UGFS, it appears that EVLA & RFA are superior to UGFS with respect to clinical recurrence and VCSS. Post-operative patient comfort and the outcome of EVLA & RFA in short & medium-terms are superior to those after UGFS in terms of recanalization & effective ablation. Using of high wavelength laser (1470nm) with modified fiber tip (radial emission) with tumescent solution play a unique role in attaining the best results and greatly reducing the adverse effects. This allows a homogeneous destruction of the vein wall exclusively, without any risk of damage to the surrounding tissues and also providing successful ablation of larger sized vein diameter.

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