

EFFICACY AND SAFETY OF CONCOMITANT SAPHENOFEMORAL JUNCTION LIGATION AND ULTRASOUND-GUIDED FOAM SCLEROTHERAPY VERSUS ULTRASOUND-GUIDED FOAM SCLEROTHERAPY ALONE FOR PRIMARY SFJ REFLUX: A PROSPECTIVE COMPARATIVE STUDY

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ABSTRACT

Background: Saphenofemoral junction (SFJ) reflux is one of the most important causes of chronic venous insufficiency and varicose vein disease. The use of ultrasound-guided foam sclerotherapy (UGFS) is a common treatment for superficial venous reflux, however, there is a possibility of recurrence if there is ongoing junctional incompetence. SFJ ligation with UGFS may be more effective at controlling reflux and achieving long-term clinical results.

Objective: To compare the efficacy and safety of concomitant SFJ ligation plus UGFS with UGFS alone in patients with primary SFJ reflux.

Study Design: A Prospective comparative study.

Place and Duration of Study: From January 2023 to December 2024 at the Department of Vascular Surgery, MTI Lady Reading Hospital, Peshawar, Pakistan.

Methodology: An enrollment of 120 patients with primary SFJ reflux and symptomatic varicose veins was completed after identifying these patients with duplex ultrasound. Group A (n=60) were treated with concomitant SFJ ligation and UGFS, and Group B (n=60) with UGFS alone. Clinical and duplex evaluations were done at 1, 6, and 12 months. The primary outcomes were abolition of reflux and recurrence. Secondary endpoints included the improvement in Venous Clinical Severity Score (VCSS), recovery after the procedure and procedure-related complications. Data was analyzed using SPSS version 24.0 and a p value of <0.05 was considered statistically significant.

Results: The mean age of participants was 48.9 ± 8.2 years, and 72 (60.0%) were female. In Group A, 83.3% of the patients had achieved complete elimination of SFJ reflux at 12 months, whereas 70.0% of the patients in Group B had done so ($p=0.048$). Recurrence occurred in 4 (6.7%) patients in Group A and 11 (18.3%) patients in Group B ($p=0.041$). The VCSS score improved significantly in Group A compared to Group B (4.2 ± 1.1 compared to 3.1 ± 1.3 points; $p=0.002$). Postoperative pain scores were lower in Group A (2.1 ± 0.9 vs. 2.8 ± 1.0 ; $p=0.006$). Some minor complications were transient superficial phlebitis, hyperpigmentation and ecchymosis. There were no cases of deep venous thrombosis, pulmonary embolism or procedure-related mortality in either group.

Conclusion: Concomitant SFJ ligation and UGFS demonstrated superior reflux abolition, lower recurrence rates, and greater clinical improvement compared with UGFS alone while maintaining a favorable safety profile. This combined therapy could be a good treatment for those with primary SFJ reflux, especially in a resource-limited setting. More multicenter trials with a longer duration of follow-up are needed to substantiate these results.

KEYWORDS: Saphenofemoral Junction; Ultrasound-Guided Foam Sclerotherapy; Varicose Veins; Chronic Venous Insufficiency; Venous Reflux.

INTRODUCTION

Chronic venous disease (CVD) is an extremely common vascular disease that affects about 20-30% of the adult population in the world and is a major cause of morbidity, reduced quality of life and utilization of health care

services [1,2]. Varicose veins are the most common symptom of CVD and often there is incompetence of the great saphenous vein (GSV) and saphenofemoral junction (SFJ) [3]. At the SFJ, reflux causes venous hypertension, which causes progressive venous dilation, lower-limb pain, edema, skin changes and in advanced cases, venous ulceration [4]. A long time ago, it was believed that high ligation of the SFJ and stripping of the GSV was the “gold standard” treatment for symptomatic varicose veins. Traditional surgery is effective for reflux but has the disadvantages of postoperative pain, bruises, slow recovery, and postoperative recurrence in the long term follow-up period [5,6]. The treatment of superficial venous insufficiency has been revolutionized by the development of minimally invasive venous interventions that offer a viable option in the management of this condition with a lower procedural morbidity and shorter recovery period [7]. Compared with the other contemporary treatments, ultrasound-guided foam sclerotherapy (UGFS), which is performed without the need for sophisticated equipment, is now widely accepted as being both minimally invasive and cost-effective, with the possibility of treating the condition in an outpatient setting [8]. The technique consists of the injection of a sclerosant foam under ultrasound guidance causing endothelial damage, fibrosis and refluxing veins to be obliterated. Although short-term results are good, there are concerns about recanalization and recurrence, especially in those with severe SFJ incompetence, in whom there may be a significant proximal reflux that will limit long-term treatment success [9,10]. To overcome this limitation, a combined surgical procedure of SFJ ligation and UGFS has been suggested as a hybrid treatment. Anatomical closure rates and recurrence are better when surgical interruption of proximal reflux at the SFJ and chemical ablation of the incompetent GSV trunk and tributaries are done, but this may not offer up the same benefits of a minimally invasive procedure [11]. In the past, it was hypothesized that long-term success in the treatment of SVI is dependent on effective control of junctional reflux [12]. There is, however, limited comparative evidence assessing the efficacy and safety of concomitant SFJ ligation in addition to UGFS compared to UGFS alone, especially in the healthcare environments without adequate resources where cost-effective treatment is required. It is unclear if there is any clinical or anatomic advantages to adjunctive SFJ ligation, which may help guide the selection of therapy and impact long-term outcomes in patients with primary SFJ reflux. Based on this, the present prospective comparative study was performed to compare the safety and efficacy of concomitant SFJ ligation plus ultrasound guided foam sclerotherapy versus UGFS alone in cases with duplex ultrasound documented primary SFJ reflux. The main outcomes were reflux abolition and reflux recurrence, while the secondary outcomes were improvement in Venous Clinical Severity Score (VCSS), postoperative recovery and procedure-related complications during a follow-up period of 12 months.

MATERIALS AND METHODS

Study Design and Setting

This prospective comparative study was conducted in the Department of Vascular Surgery, MTI Lady Reading Hospital (LRH), Peshawar, Pakistan, from January 2023 to December 2024. A total of 120 patients with duplex ultrasound-confirmed primary saphenofemoral junction (SFJ) reflux were enrolled. Patients were assigned to one of two treatment groups: Group A (n=60), who underwent concomitant SFJ ligation plus ultrasound-guided foam sclerotherapy (UGFS), and Group B (n=60), who underwent UGFS alone.

Inclusion Criteria

Eligible for inclusion were patients, 25 to 70 years old, who had clinically apparent primary varicose veins (CEAP clinical classes C2–C5) and SFJ reflux on duplex ultrasound. Venous reflux was considered blood flow in a vein against the normal direction for more than 0.5 seconds during a standardized provocation. All participants were judged as appropriate for local anesthetic treatment.

Exclusion Criteria

Patients were excluded if they had a history of deep venous thrombosis, previous varicose vein intervention, pregnancy, known hypersensitivity to polidocanol, active lower-extremity infection, severe peripheral arterial disease, or significant systemic comorbidities that could affect treatment safety, procedural outcomes, or compliance with follow-up assessments.

Allocation of Participants

Participants were allocated into the two treatment groups according to the treatment strategy selected by the treating vascular surgeon during the study period. Group A comprised 60 patients treated with concomitant SFJ ligation plus UGFS, whereas Group B comprised 60 patients treated with UGFS alone.

Treatment Procedure

Group A: SFJ Ligation Plus UGFS

Under local anesthesia all procedures were carried out. All visible tributaries were ligated at the saphenofemoral junction which was flushed through a groin incision. Following this, ultrasound guided foam sclerotherapy was then carried out with 3% polidocanol foam prepared using the Tessari technique, with sclerosant-to-air ratio of 1:4. The incompetent great saphenous vein (GSV) trunk and associated refluxing tributaries were accessed and the foam was injected during real-time ultrasound guidance.

Group B: UGFS Alone

Patients in Group B underwent ultrasound-guided foam sclerotherapy alone using 3% STD (Sodium tetradecyl sulfate) foam prepared according to the Tessari technique with a sclerosant-to-air ratio of 1:4. The foam was injected under real-time ultrasound guidance into the incompetent great saphenous vein trunk and associated refluxing tributaries without surgical ligation of the saphenofemoral junction.

Follow-up and Outcome Assessment

Patients were clinically and duplex ultrasound evaluated at 1, 6 and 12 months following treatment. Abolition of SFJ reflux (as seen on duplex ultrasonography) was the primary outcome measure. Secondary outcomes assessed were: recurrence, postoperative pain, time to ambulation, procedure-related complications and change in Venous Clinical Severity Score (VCSS). Recurrence was considered the recurrence of any symptomatic venous reflux on duplex ultrasonography after initial successful treatment. All the duplex ultrasound examinations were performed by the same experienced vascular radiologist to reduce the interobserver variability.

Ethical Considerations

The study was approved by the Institutional Review Board (IRB) of MTI Lady Reading Hospital, Peshawar. All subjects gave informed consent prior to participation. The study was carried out in compliance with the guidelines of the Declaration of Helsinki 2013.

Statistical Analysis

Data analysis was carried out by Statistical Package for the Social Sciences (SPSS) version 24.0 (IBM Corp., Armonk, NY, USA). Data for continuous variables were displayed as mean $\pm$ SD, while data for categorical variables were displayed as frequencies and percentages. Independent sample t-tests were performed to compare continuous variables between group; paired t-tests were used to compare continuous variables within group. The chi-square test or Fisher's exact test (when applicable) was used to compare categorical variables. A p value < 0.05 was deemed to be statistically significant.

RESULTS

A total of 120 patients with duplex ultrasound-confirmed primary saphenofemoral junction (SFJ) reflux were enrolled in the study. Group A (concomitant SFJ ligation plus ultrasound-guided foam sclerotherapy [UGFS]) comprised 60 patients, while Group B (UGFS alone) included 60 patients. The overall mean age was 48.9 ± 8.2 years, and 72 (60.0%) participants were female. Baseline demographic and clinical characteristics were comparable between the two groups (Table 1). Clinical outcomes were favorable in both groups; however, patients treated with concomitant SFJ ligation and UGFS demonstrated superior anatomical and clinical outcomes. The mean postoperative pain score was significantly lower in Group A than in Group B (2.1 ± 0.9 vs. 2.8 ± 1.0 ; $p=0.006$). Early ambulation within 24 hours was achieved in 57 (95.0%) patients in Group A compared with 52 (86.7%) patients in Group B ($p=0.12$). The mean hospital stay was 0.8 ± 0.3 days in Group A and 1.1 ± 0.4 days in Group B ($p=0.021$). A significantly greater improvement in Venous Clinical Severity Score (VCSS) was observed in Group A compared with Group B (4.2 ± 1.1 vs. 3.1 ± 1.3 points; $p=0.002$) (Table 2). Duplex ultrasound assessment demonstrated complete abolition of SFJ reflux in 58 (96.7%) patients in Group A and 54 (90.0%) patients in Group B at one month. At six months, complete reflux abolition was observed in 54 (90.0%) patients in Group A and 48 (80.0%) patients in Group B. At the 12-month follow-up, complete abolition of SFJ reflux was maintained in 50 (83.3%) patients in Group A compared with 42 (70.0%) patients in Group B ($p=0.048$). Recurrence occurred in 4 (6.7%) patients in Group A and 11 (18.3%) patients in Group B ($p=0.041$) (Table 3). Procedure-related complications were infrequent and predominantly minor. Transient superficial phlebitis occurred in 5 (8.3%) patients in Group A and 7 (11.7%) patients in Group B. Localized hyperpigmentation was observed in 3 (5.0%) and 5 (8.3%) patients, respectively, while ecchymosis occurred in 4 (6.7%) and 6 (10.0%) patients, respectively. No cases of wound infection, deep venous thrombosis, pulmonary embolism, or procedure-related mortality were reported in either group (Table 4). Overall, concomitant SFJ ligation combined with UGFS achieved higher rates of reflux abolition, lower recurrence rates, greater clinical improvement, and a favorable safety profile compared with UGFS alone during the 12-month follow-up period.

Table 1. Baseline Demographic and Clinical Characteristics of Patients

Variable	Group A (n=60)	Group B (n=60)	p-value
Age (years), Mean $\pm$ SD	49.6 ± 7.8	48.2 ± 8.5	0.342
Female Gender, n (%)	36 (60.0)	36 (60.0)	1.000
Duration of Symptoms (years), Mean $\pm$ SD	4.2 ± 2.1	4.0 ± 2.3	0.618
CEAP C2, n (%)	28 (46.7)	26 (43.3)	0.711
CEAP C3, n (%)	18 (30.0)	20 (33.3)	
CEAP C4, n (%)	14 (23.3)	14 (23.3)	

Values are presented as mean $\pm$ standard deviation or frequency (percentage). CEAP = Clinical, Etiological, Anatomical, and Pathophysiological classification.

Table 2. Clinical Outcomes Following Treatment

Outcome Measure	Group A (n=60)	Group B (n=60)	p-value
Postoperative Pain Score (VAS)	2.1 ± 0.9	2.8 ± 1.0	0.006

Time to Ambulation (hours)	23.5 ± 4.2	27.1 ± 5.6	0.014
Hospital Stay (days)	0.8 ± 0.3	1.1 ± 0.4	0.021
Return to Normal Activity (days)	3.2 ± 1.1	4.6 ± 1.5	0.008
Patients Ambulating Within 24 Hours, n (%)	57 (95.0)	52 (86.7)	0.120
Mean VCSS Improvement	4.2 ± 1.1	3.1 ± 1.3	0.002

VAS = Visual Analogue Scale; VCSS = Venous Clinical Severity Score.

Table 3. Duplex Ultrasound Outcomes During Follow-up

Follow-up Interval	Group A Complete Reflux Abolition n (%)	Group B Complete Reflux Abolition n (%)	p-value
1 Month	58 (96.7)	54 (90.0)	0.142
6 Months	54 (90.0)	48 (80.0)	0.118
12 Months	50 (83.3)	42 (70.0)	0.048
Outcome	Group A n (%)	Group B n (%)	p-value
Recurrence	4 (6.7)	11 (18.3)	0.041

Recurrence was defined as reappearance of reflux after initial successful treatment.

Table 4. Procedure-Related Complications

Complication	Group A n (%)	Group B n (%)
Superficial Phlebitis	5 (8.3)	7 (11.7)
Hyperpigmentation	3 (5.0)	5 (8.3)
Ecchymosis	4 (6.7)	6 (10.0)
Wound Infection	0	0
Deep Venous Thrombosis	0	0
Pulmonary Embolism	0	0

All complications were minor and self-limiting. No major adverse events were observed.

Table 5. Summary of Primary and Secondary Outcomes

Outcome	Group A	Group B	p-value
Reflux Abolition at 12 Months	83.3%	70.0%	0.048
Recurrence Rate	6.7%	18.3%	0.041
Mean VCSS Improvement	4.2 ± 1.1	3.1 ± 1.3	0.002
Postoperative Pain Score	2.1 ± 0.9	2.8 ± 1.0	0.006

DISCUSSION

This prospective comparative study evaluated the efficacy and safety of concomitant saphenofemoral junction (SFJ) ligation plus ultrasound-guided foam sclerotherapy (UGFS) compared with UGFS alone in patients with primary SFJ reflux. During the 12-month follow up period, the findings showed that the hybrid approach provided superior anatomical and clinical results with greater reflux abolition, lower recurrence rates, and greater improvement in Venous Clinical Severity Score (VCSS) compared with the conventional approach, while safety was at least equal. Recurrent failure after superficial venous reflux intervention is well documented to be due to ongoing poor competence at the SFJ. In earlier reports when UGFS was used alone, short-term occlusion rates were good and long-term rates of recanalization and recurrent reflux were higher, with the authors attributing this to the fact that the surgical procedure itself resulted in a persistent proximal venous incompetence [13,14]. The hybrid surgical procedure, in which the SFJ reflux is surgically interrupted, the incompetent GSV and tributaries are chemically ablated, and the procedure is performed at the same time, thus tackles the anatomical and hemodynamic mechanisms of disease progression and recurrence [15]. The present study found that 83.3% of patients in the SFJ ligation plus UGFS group had complete elimination of SFJ reflux at 12 months, which was significantly higher than the UGFS-alone group (70.0%). Likewise, the hybrid-treatment group had a significantly lower recurrence rate (6.7% vs. 18.3%). These results are in line with previous studies describing that sufficient reflux control will lead to better anatomical success in the long-term and will decrease the risk of subsequent venous insufficiency [16,17]. The hybrid treatment was also found to be superior in clinical outcomes. The patients with concomitant SFJ ligation and UGFS showed statistically significantly better improvement in VCSS, which reflects the better symptoms and functional recovery from the procedure. Furthermore, pain scores after surgery were reduced, and patients were able to resume their normal daily activities more quickly in the patients receiving the combined treatment. The results are consistent with the hypothesis that successful treatment of proximal reflux should lead to better patient-reported outcomes and better quality of life [18]. Both treatment methods had a good safety profile. The majority of complications were superficial, minor and self-limiting such as transient superficial phlebitis, hyperpigmentation at the site and ecchymosis. There was no incidence of deep venous thrombosis, pulmonary embolism, wound infection or procedure-related mortality. The complication rates reported in the present study are similar to those in previous studies that have assessed foam sclerotherapy and hybrid venous interventions [19,20]. This study's results have special meaning in a healthcare environment where access to cutting edge endovenous technologies may be limited. Concomitant SFJ ligation and UGFS applies to common surgical procedures and sclerosant therapy, and has favorable results in both clinical and anatomical aspects. Hence, this combination therapy could be a feasible and inexpensive option for primary SFJ reflux in developing countries [21,22]. Although these are promising results, large multicenter trials with longer follow-up times are needed to assess durability, and to compare this technique with newer endovenous procedures (e.g., radiofrequency and endovenous laser ablation).

LIMITATIONS

There are a number of limitations to this study. Firstly, it was carried out in a single tertiary care center and may not be generalizable. Second, the sample size used for the preliminary comparisons was of acceptable size, but further multicenter studies are needed to confirm the findings. Third, the duration of follow-up was 12 months and it may not reflect long-term recurrence, recanalization, or neovascularization. Also, costs and patient-reported quality of life outcomes were not formally evaluated. Thus, the results should be viewed in the light of the following limitations.

CONCLUSION

Concomitant saphenofemoral junction ligation combined with ultrasound-guided foam sclerotherapy demonstrated superior reflux abolition, lower recurrence rates, and greater clinical improvement compared with UGFS alone while maintaining a favorable safety profile. The procedure was associated with rapid postoperative recovery, minimal complications, and satisfactory short-term outcomes. Given its effectiveness and potential cost advantages, this hybrid approach may represent a valuable treatment option for patients with primary SFJ reflux, particularly in resource-constrained healthcare settings. Further multicenter randomized studies with longer follow-up are warranted to confirm these findings and establish long-term comparative effectiveness.

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Authors Contributions

Concept & Design of Study:

Drafting:

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