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Assessing UGFS+SFL as an Alternative to Conventional Surgery for Varicose Veins: Outcomes, Safety, and Economic Implications: A Comparative Study

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ABSTRACT

Objective: The aims of the study is to compare the efficacy, safety, and the cost-effectiveness of ultrasound-guided foam sclerotherapy related with the sapheno-femoral ligation (UGFS+SFL) versus conventional surgical treatment for the varicose veins.
Methods: This study was conducted over a period of 18 months. Minimum of 80 patients with primary varicose vein due to SFJ (saphenofemoral junction) incompetence were selected and randomly assigned in each arm i.e. surgical and foam sclerotherapy.
Results: Both of UGFS+SFL and the conventional surgery led to the significant improvements in CEAP and the VCSS scores. UGFS+SFL group showed the greater reduction in VCSS scores post-treatment compared to surgical group. The Early complications were fewer in UGFS+SFL group, which had no cases of deep the vein thrombosis (DVT) or saphenous nerve injury, the unlike surgical group. Cost of UGFS+SFL was Rs.255924, the significantly lower than Rs.425644 for conventional surgery. The Ultrasound follow-up revealed high rates of vein obliteration in the both groups, though UGFS+SFL group had slightly the lower rates of full obliteration at 3 months.
Conclusion: The UGFS+SFL is an effective and the cost-effective alternative to conventional surgery for treating the varicose veins. It offers the comparable clinical outcomes with fewer complications and the lower costs. These treatments achieve high rates of the vein obliteration, making UGFS+SFL a viable option for patients seeking the less invasive approach.

INTRODUCTION

A common vascular disorder characterized through enlarged, twisted veins usually appearing in legs, pose significant clinical and the aesthetic concerns for many individuals is the Varicose veins [1]. Hence, traditional surgical treatments for the varicose veins, such as vein stripping and the

ligation, have been effective but they come with notable drawbacks, including the higher costs, extended the recovery times, and potential complications [2]. The minimally invasive technical advancement, ultrasound-guided foam sclerotherapy shared with the sapheno-femoral ligation (UGFS+SFL) has emerged as a promising alternative to the conventional surgery [3].

A Randomized the controlled trial explained efficacy, safety, and the cost-effectiveness of UGFS+SFL with traditional surgical treatment for the varicose veins [4]. Another study examined various outcome measures, the including patient demographics, clinical severity (CEAP classification), the Venous Clinical Severity Score (VCSS), early post-operative complications, procedure costs, and effect of treatment on the CEAP and VCSS stratification [5]. Additionally, the ultrasound follow-up investigations evaluate obliteration rates of varicose veins at different time the points post-treatment [6].

Further study compared these two treatment modalities, trial seeks to provide the comprehensive analysis of their respective benefits and the drawbacks, ultimately guiding clinicians in the selecting most appropriate intervention for the patients with varicose veins [7]. Hence, another research presented detailed data on demographics of study the participants, clinical outcomes, complications, costs, and follow-up results, the offering insights into effectiveness and practicality of the UGFS+SFL versus traditional surgery [8].

The Early post-operative complications were monitored, the revealing comparable rates of groin infection and the unique occurrences such as skin pigmentation and the saphenous nerve injury. Costs associated with each procedure were meticulously documented, the highlighting significant differences in the expenditure between two treatment approaches [9].

The Ultrasound follow-up investigations assessed obliteration of the varicose veins at three weeks and three months' post-treatment, to providing valuable data on the long-term efficacy of UGFS+SFL compared to surgery. Study also evaluated changes in the CEAP and VCSS scores, demonstrating substantial improvements in both groups [10].

Randomized controlled trial offers an in-depth comparing to the ultrasound-guided foam sclerotherapy combined with the sapheno-femoral ligation and the traditional treatment like surgical for varicose veins [11]. Findings contribute to growing body of evidence supporting minimally invasive techniques, the guiding clinicians in making informed decisions to enhance patient care and the outcomes in varicose vein treatment [12].

The Traditional management of the varicose veins has predominantly involved the invasive the surgical techniques such as vein stripping and the ligation. The Vein stripping is a procedure that removes affected veins through the small incisions, although ligation involves tying off veins to the prevent blood flow and the redirect it through healthier veins [13]. Although these methods have been effective in the addressing symptoms and the appearance of the varicose veins, they come with notable limitations. Invasive nature of these surgeries often results in the prolonged recovery periods, the significant postoperative pain, and increased risk of the complications such as wound infections, the hematomas, and scarring [14]. Additionally, financial burden of the traditional surgical treatments can be substantial, encompassing costs related to procedure itself, hospital stays, and they follow-up care. So these factors collectively contribute to growing need for alternative, the less invasive treatment options [15].

Recent studies advancements in the medical technology have led to development of the minimally invasive techniques, which offer the promising alternative to the traditional surgery [16]. Amongst these innovations is the ultrasound-guided foam the sclerotherapy (UGFS) combined with the sapheno-femoral ligation (SFL). The UGFS involves injection of the sclerosing foam into affected veins under real-time ultrasound guidance. So this foam irritates vein walls, leading to their collapse and the subsequent reabsorption by body [17]. After used in the conjunction with the sapheno-femoral ligation, which targets main the vein where reflux occurs, the UGFS provides a more targeted and less invasive approach to the managing varicose veins. Advantages of the UGFS+SFL over traditional surgical methods include the reduced recovery times, decreased pain, and a lower incidence of the complications [18]. Minimally invasive nature of the UGFS+SFL often allows the patients to return to their normal activities more quickly, and procedure is typically performed on an outpatient basis, minimizing need for the prolonged hospital stays and the intensive

postoperative care. Furthermore, the UGFS+SFL generally involves lower overall the costs compared to the traditional surgical treatments, making it a more economically viable option for many patients [19].

To Despite promising outcomes associated with the UGFS+SFL, there remains a need for thorough, the evidence-based research to compare its efficacy, safety, and the cost-effectiveness with traditional surgical methods [20]. The Preliminary studies have indicated that the UGFS+SFL may offer several advantages; nevertheless, the comprehensive randomized controlled trials (RCTs) are essential to the validate these findings and the address any potential limitations. So this study is designed to explore the several critical questions concerning the UGFS+SFL in the comparison to the traditional surgery for varicose veins [21]. Primary, it aims to evaluate efficacy of the UGFS+SFL through examining its impact on the symptom relief and the clinical outcomes, including changes in Clinical-Etiological-Anatomical-Pathophysiological (CEAP) the classification and Venous Clinical Severity Score (VCSS) [10]. Additional, study will assess safety of the UGFS+SFL versus traditional surgery through comparing rates and types of the early postoperative complications, such as infections, the skin pigmentation changes, and the saphenous nerve injuries [22].

Our study enrolled patients aged 20-76 years, with the median age of 43 in both treatment groups. Foam of sclerotherapy group included 47% females, while surgical group had 60% females. The Patients were categorized according to the CEAP clinical classification, and their VCSS scores were recorded pre-treatment.

Significance of the Study

Outcomes of this study are anticipated to provide the valuable insights into comparative effectiveness and they practicality of the UGFS+SFL versus traditional surgical treatments. Through offering a detailed analysis of the clinical outcomes, safety profiles, and the cost implications, study aims to guide clinicians in the making informed decisions about most appropriate treatment options for the patients with varicose veins.

MATERIALS & METHODS

Study Design and Setting

The study was conducted in the department of surgery, Lahore General Hospital over a period of 18 months. All patients who presented with varicose veins were assessed based on clinical history, physical examination and duplex ultrasound and randomly assigned in each arm of the study i.e. surgical and UGFS groups fulfilling the inclusion criteria (Minimum of 40 patients in each group). All patients were informed about the intervention technique and written informed consent was taken.

Ethical Review Statement

The study protocol was approved by the Institutional Review Board (IRB) of the participating hospital, ensuring compliance with ethical standards for research involving human subjects. Informed consent was obtained from all participants before enrollment in the study.

Participants

Participants aged 20-76 years with symptomatic varicose veins classified as CEAP clinical class 2-6 were enrolled in the study.

Inclusion Criteria

Inclusion criteria required patients to have documented saphenous vein reflux, age 20-76 years, CEAP clinical class 2-6.

Exclusion Criteria

To ensure a homogenous study population and reduce the risk of confounding factors, patients with previous varicose vein surgery, deep vein thrombosis (DVT), pregnancy, or those unable to provide informed consent were excluded.

Interventions

- **UGFS+SFL Group:** Patients in this group underwent sapheno-femoral ligation followed by ultrasound-guided foam sclerotherapy. The sapheno-femoral junction was ligated under local anesthesia. Foam sclerotherapy was performed using a sclerosant (sodium tetradecyl sulfate) mixed with air to create foam, which was injected into affected veins under ultrasound guidance.
- **Conventional Surgical Treatment:** Patients in the surgical group underwent traditional varicose vein surgery, including high ligation and stripping of the saphenous

vein. This procedure was performed under general or regional anesthesia.

Study Duration and Follow-Up

The study was conducted over a period of 18 months, with each participant followed up for three months after the procedure to assess the primary and secondary outcomes.

Sampling Method

Participants were assessed by comparing pre- and post-treatment CEAP classifications and VCSS scores. Follow-up ultrasound investigations were conducted at three weeks and three months post-treatment to evaluate the obliteration rates of treated veins. The ultrasound grading system used included:

- Grade 1: Full obliteration
- Grade 2a: Partial obliteration without reflux
- Grade 2b: Partial obliteration with reflux
- Grade 3: No obliteration

Variables

The primary outcome variable was the obliteration rate of treated veins. Secondary outcomes included post-operative complications, cost analysis, and changes in CEAP and VCSS scores.

Methods and Equipment

Ultrasound machines with high-resolution probes were used for guiding foam sclerotherapy and assessing vein obliteration. Sodium tetradecyl sulfate was used as the sclerosant for foam sclerotherapy. Conventional surgical instruments were employed for varicose vein surgery.

Data Analysis

Data were analyzed using the Mann–Whitney U-test for continuous variables and chi-square tests for categorical variables. Changes in CEAP and VCSS scores were evaluated using the Wilcoxon signed-rank test. A p-value of less than 0.05 was considered statistically significant.

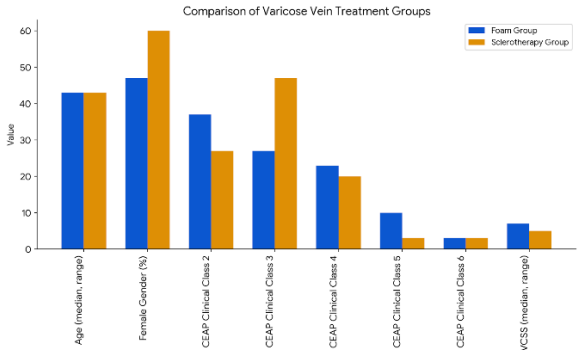
RESULTS

Participant Demographics and Baseline Characteristics

Study enrolled a total of 80 participants, with 40 in the UGFS+SFL group and 40 in conventional surgery group. Demographics and the reference line characteristics are summarized in Table 1.

Table 1. Demographics, CEAP, and VCSS before Treatment

Characteristic	Foam Sclerotherapy Group	Surgical Group	p Value
Age (median, range)	43 (21–72)	43 (20–76)	NS
Female Gender (%)	47%	60%	NS
CEAP Clinical Class 2	37%	27%	NS
CEAP Clinical Class 3	27%	47%	NS
CEAP Clinical Class 4	23%	20%	NS
CEAP Clinical Class 5	10%	3%	NS
CEAP Clinical Class 6	3%	3%	NS
VCSS (median, range)	7 (2–13)	5 (2–16)	NS



Early Post-Operative Complications

The Early post-operative complications are the summarized in Table 2.UGFS+SFL group and surgical group had different profiles of complications.

Table 2. Early Post-Operative Complications

Complications	Foam sclerotherapy group	Surgery group
Groin infection	2	2
Skin pigmentation	2	1 (skin ulcer)
Superficial thrombophlebitis	3	-
Allergy	-	-
DVT	-	-
Saphenous nerve injury	-	2
Other	-	2 (hematoma, retention)

Expenditure of the Procedure

The Cost analysis is detailed in Table 3.

UGFS+SFL procedure was significantly less expensive than conventional surgical treatment.

Table 3. Expenditure of the Procedure

Category	Conventional surgery (Rs)	Foam sclerotherapy (Rs)
Surgeon	35568	15579
Assistant	14896	6517
Anesthetist	35568	0
Nursing	20672	9044
Anesthetic	3174	1078
Anesthetic assistant	7600	0
Consumables	3249	1783
Anti-embolism stockings	2660	6650
Sterile supplies	30612	30612
Subtotal A	154000	71047
Theater recovery	31667	15200
Ward time	186233	98167
Ultrasound	8892	19000
Medical attendance	3021	3021
Capital and overhead	53740	27306
Subtotal B	271479	184838
Grand Total	425644	255924

Effect on CEAP and VCSS

The Changes in CEAP and VCSS scores before and after treatment are shown in the Table 4. Both of the treatment modalities resulted in significant improvements in clinical outcomes.

Table 4. Effect of Procedure on CEAP and VCSS Stratification

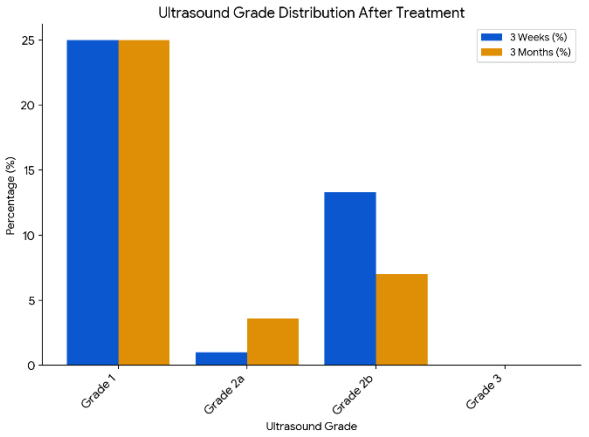
Measure	Foam Sclerotherapy (Pre)	Foam Sclerotherapy (Post)	Surgery (Pre)	Surgery (Post)	p Value (Wilcoxon)
CEAP (Median, Range)	4 (2–6)	1 (0–5)	4 (2–6)	1 (0–5)	<0.001
VCSS (Median, Range)	5 (2–13)	1 (0–5)	7 (2–16)	3 (0–4)	<0.001

Ultrasound Follow-Up Investigation

The Ultrasound follow-up results are summarized in Table 5. Both of the treatment groups showed varying degrees of vein obliteration at 3 weeks and 3 months.

Table 5. Ultrasound Follow-Up Investigation

Ultrasound Grade	3 Weeks (%)	3 Months (%)
	Foam Sclerotherapy	Surgery
Grade 1 (Full Obliteration)	25	25.0
Grade 2a (Partial Obliteration without Reflux)	1	3.6
Grade 2b (Partial Obliteration with Reflux)	13.3	7.0
Grade 3 (No Obliteration)	0	0



Summary of Results

UGFS+SFL group exhibited the comparable or better outcomes in the terms of cost-effectiveness and the clinical improvement compared to conventional surgery group. Both of the methods resulted in significant reductions in the CEAP and VCSS scores, they indicating clinical benefit. UGFS+SFL group had the lower complication rate and the overall cost, while both groups demonstrated effective vein obliteration at follow-up.

DISCUSSION

This study provide the important insights into efficacy, safety, and cost-effectiveness of the ultrasound-guided foam sclerotherapy combined with sapheno-femoral ligation (UGFS+SFL) compared to conventional surgical treatment for the varicose veins. Both of the treatment modalities resulted in significant clinical improvements, but notable differences in the outcomes were observed, particularly in the terms of cost-effectiveness and the complication rates.

Both of UGFS+SFL and the conventional surgery

demonstrated significant improvements in the clinical outcomes, as evidenced by reduction in the CEAP and VCSS scores. Median of CEAP and VCSS scores improved the substantially post-treatment in the both groups (Table 4), highlighting effectiveness of both interventions in the alleviating symptoms and improving quality of life for the patients with varicose veins. They Aligns with the existing literature, which indicates that both the treatments are effective in reducing clinical severity of varicose veins. Nevertheless, UGFS+SFL had slightly better post-treatment VCSS scores, suggesting the marginally superior impact on the venous clinical severity.

This ultrasound follow-up investigations revealed that both treatments achieved the effective vein obliteration, with the full obliteration observed in the significant portion of patients in both groups at 3 weeks and 3 months post-treatment (Table 5). UGFS+SFL group showed the slightly higher percentage of full obliteration at earlier follow-up points, indicating the potential advantage in the achieving rapid treatment success. Finding is consistent with the previous studies suggesting that foam sclerotherapy can lead to the quicker initial vein closure due to its minimally invasive nature and direct application of sclerosant foam.

The most compelling findings were lower complication rate in UGFS+SFL group compared to conventional surgery group. They minimally invasive nature of the UGFS+SFL likely contributes to this reduced risk of the complications, as traditional surgical procedures involve more extensive tissue dissection and are associated with the higher rates of the surgical complications such as infections and the hematoma formation.So this advantage of the UGFS+SFL is particularly relevant for the patients seeking effective yet low-risk treatment options for the varicose veins.

The Cost-effectiveness is the critical consideration in selection of the treatment modalities, particularly in the healthcare systems with limited resources. UGFS+SFL group demonstrated the superior cost-effectiveness, with the lower overall treatment costs compared to the conventional surgery. Reduced costs are primarily attributed to the shorter procedure times, use of local anesthesia, and fewer post-operative complications requiring medical intervention. So this economic advantage positions the UGFS+SFL as the highly attractive option for the healthcare providers and patients alike, especially in the settings where financial constraints are a concern.

Limitations

To Despite promising findings, this study has several limitations. They relatively small sample size may limit generalizability of results to broader populations. Furthermore, the follow-up period of three months, while the sufficient to assess initial treatment outcomes, may not capture long-term recurrence rates or late-onset complications. Additional studies with larger sample sizes and extended follow-up durations are warranted to the confirm these findings and to explore long-term durability of UGFS+SFL.

CONCLUSION

In the conclusion, the UGFS+SFL offers a safe, effective, and the cost-efficient alternative to conventional surgical treatment for varicose veins. The advantages in the reducing complication rates and the overall treatment costs, combined with comparable efficacy in the clinical outcomes, make it the viable option for patients and the healthcare systems aiming to optimize the management of varicose veins. Findings of this study contribute valuable data to growing body of the evidence supporting the use of minimally invasive techniques in the vascular surgery and highlight the need for continued research into innovative treatments that enhance patient care and resource utilization.

UGFS+SFL and the conventional surgery are both effective treatments for the varicose veins, with significant improvements in CEAP and the VCSS scores. The UGFS+SFL offers a cost-effective alternative with the fewer complications, although both methods are effective in the achieving vein obliteration. Choice between these treatments should be guided by the individual patient characteristics, preferences, and available resources, considering both the clinical and economic factors. For Further research will be crucial in confirming these findings and the optimizing treatment strategies for varicose veins.

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