

Conventional Surgery and Foam Sclerotherapy for Great Saphenous Varicose Veins-A Comparative Study

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Abstract

Original Research Article

Varicose veins are defined as dilated, tortuous, subcutaneous veins ≥ 3 mm in diameter measured in the upright position with demonstrable reflux. They do not threaten life and are seldom disabling, but it causes a considerable demand on medical care. It is the cause of morbidity and loss of precious work hours and a significant financial burden on the health-care system. The aim of this study was to evaluate clinical profile and compare two treatment modalities like, conventional surgery (CS) and ultrasound-guided foam sclerotherapy (UGFS). This study was conducted at Department of surgery, Kakatiya medical college, Warangal after obtaining permission from hospital ethics committee. Hundred adult patients with a symptomatic primary incompetent great saphenous vein (GSV) in which 70 were males and 30 were females. Maximum patients were in age group of 40 to 50 years. The majority of the patients were overweight and obese, had a history of prolonged standing. Most of patients had unilateral lower limb varicose veins with C2 and C3 clinical classification. After 1 year, the occlusion rate of UGFS was significantly lower than CS. In both groups, the C of the CEAP-classification decreased significantly after treatment, and there was no difference between groups. After 1 year, the anatomic success rate was highest for CS and UGFS. The complication rate was low and comparable between treatment groups. This study concludes that both the conventional surgery and ultrasound guided foam sclerotherapy were good for varicose veins. Anatomic success was more in conventional surgery.

Keywords: Varicose veins, saphenous vein, conventional surgery, ultrasound guided foam sclerotherapy, clinical outcome.

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INTRODUCTION

Superficial venous insufficiency (SVI) is a very common cause of disease. Symptomatic varicose veins affect up to half of the adult population [1] and have been shown to have a significant detrimental effect upon physical elements of quality of life [2]. Treatment is associated with significant improvement [3]. There is also emerging evidence that without treatment, the disease severity tends to progress over time. Most of this evidence is based on treatment of the most common pattern of SVI, insufficiency of the great saphenous vein (GSV).

Varicose veins of the legs affect approximately 25% of the population and may have a substantial impact on patient's health-related quality of life. The treatment of varicose veins and its complications consume a relatively large proportion of the limited health care resources [4]. Until recently, conventional surgery (CS) of the great saphenous vein (GSV), consisting of high ligation at the saphenofemoral junction (SFJ) and stripping of the above knee GSV,

was the standard of care. In the last decade, minimally invasive techniques such as endovenous laser ablation (EVLA), radiofrequency ablation (RFA), and ultrasound-guided foam sclerotherapy (UGFS) have challenged the position of CS for primary varicose veins [5]. These techniques are effective and safe. CS associates stripping of the refluxing GSV trunk with high ligation at the SFJ, and this may induce neovascularisation

In the last few years, several important random clinical trials comparing two different treatment modalities for varicose veins show that the minimally invasive techniques are at least as effective as CS and that they result in faster recovery time and less postoperative pain, and they are preferred by patients [6, 7].

Various predisposing factors of varicose veins have been implicated such as pregnancy, prolonged standing, obesity, old age, chronic rise in intra-abdominal pressure, and athletics. Heredity also

plays an important role [8]. The aim of this study was to evaluate clinical profile and compare two treatment modalities like, conventional surgery (CS) of the great saphenous vein (GSV), consisting of high ligation at the saphenofemoral junction (SFJ) and stripping of the above knee GSV, was the standard of care and ultrasound-guided foam sclerotherapy (UGFS).

MATERIALS AND METHODS

This study was conducted at Department of surgery, Kakatiya medical college, Warangal after obtaining permission from hospital ethics committee. Hundred adult patients with a symptomatic primary incompetent GSV at least above the knee with a diameter of 0.5 cm and with an incompetent SFJ were included in this study. The incompetence of the GSV was defined as reflux of 0.5 seconds at color duplex ultrasound (HDI 4500, 10-MHz probe; Philips, Andover, Mass). Exclusion criteria were previous treatment of the ipsilateral GSV, deep venous incompetence or obstruction, agenesis of the deep system, vascular malformations, use of anticoagulation, pregnancy, heart failure, contra indication for one of the treatments, immobility, and arterial insufficiency. In this study, only the GSV in the thigh from just below or above knee level in most cases was treated.

After taking written informed consent, eligible patients were randomized using a computerized list. Each 50 Patients were allocated to two treatments of conventional surgery (CS) and ultrasound guided foam sclerotherapy (UGFS) were performed by surgeons with more than 5 years of experience. Ultrasound-guided foam sclerotherapy was performed as reported previously. The Tessari-method [9] was used to prepare foam (1 cc aethoxysclerol 3%: 3 cc air), which was injected directly under ultrasound guidance in the GSV with the patient in a horizontal position. The volume of injected foam depended on the length and diameter of the vessel, with a maximum of 10 mL per session (as suggested by the Second European Consensus). After injection, the patient remained in a prone position for at least 5 minutes [10]. If considered necessary, UGFS of the included GSV could be repeated after 3 months. In conventional surgery method High ligation with short (above knee) stripping was performed under spinal or general anaesthesia. Flush SFJ ligation was followed by ligation of all tributaries back to the second branch and

invaginating stripping of the GSV to knee level. The cribriform fascia, superficial fascia, and skin were closed.

After all treatments, an ambulatory compressive bandage was applied for 48 hours, followed by therapeutic compression stockings for 2 weeks post procedure. All patients were observed for at least one-half of an hour in the clinic after treatment. No specific analgesics were prescribed. Patients were encouraged to mobilize and to resume their usual activities as soon as possible.

Patients were evaluated at 3 and 12 months for clinical examination and duplex ultrasound. The primary outcome was anatomic success according to duplex ultrasound evaluation. For UGFS, this was defined as complete obliteration, without flow or reflux, of the GSV at the level of the mid-thigh. For CS, success was defined as absence of the GSV in the saphenous compartment at thigh level. We differentiated between obliteration, partial, or complete patency of the treated vein, with or without reflux. Postoperative neovascularization was assessed at the level of the SFJ using the classification described by De Maeseneer *et al.* [11] They state that "The degree of neovascularisation was determined as 'grade 1 neovascularization' (tiny new vein(s) up to 3 mm diameter, not connecting with any superficial vein) and 'grade 2 neovascularization' (tortuous new vein[s] with a diameter 4 mm, with pathological reflux and connecting with thigh varicose veins)."

The collected data were analyzed using Chi-square test and IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. (IBM Corp, Armonk, NY).

RESULTS

This study was conducted at Department of surgery, Kakatiya medical college, Warangal after obtaining permission from hospital ethics committee. This study includes 118 patients and 17 people were not continued follow up and one was died. Total study includes 100 patients only in which 70 were males and 30 were females.

Table-1: The distribution of baseline characteristics

Parameter	UGFS No of patients	CS No of patients
Age	42.69	43.25
Sex male/female	34/16	36/14
Side effected		
Left	24	23
Right	26	27
Unilateral	46	47
Bilateral	4	3
Mean GSV diameter		
Left	0.58	0.61
Right	0.61	0.59

Table-2: Age wise distribution

Age in years	UGFS No of patients	CS No of patients
<20	2	3
20-30	8	7
30-40	10	12
40-50	12	14
50-60	10	10
>60	8	6

Table-3: BMI of patients

BMI	UGFS No of patients	CS No of patients
16-18.5	6	5
18.6 -25	23	23
26-30	22	25
>30	9	7

Table-4: Clinical classification

CEEP	UGFS No of patients	CS No of patients
C1	0	0
C2	22	25
C3	18	19
C4	16	6
C5	4	1
C6	0	0

Table-5: Comparison between incompetent saphenofemoral junction on clinical tests and colour Doppler

Incompetent SFJ	UGFS No of patients	CS No of patients
Clinical examination	38	36
Colour Doppler	48	47

Table-6: Location of incompetent perforators on clinical tests

Location of perforator	UGFS No of patients	CS No of patients
Mid-thigh perforators	6	7
Knee	15	18
Mid-calf	13	14
Ankle	10	12

Table-7: Location of incompetent perforators on colour Doppler

Location of perforator	UGFS	CS
	No of patients	No of patients
Mid-thigh perforators	36	35
Knee	16	15
Mid-calf	20	24
Ankle	25	20

Table-8: Complications at 3 and 12 months after therapy

3 months	UGFS	CS
	No of patients	No of patients
Hyperpigmentation	1	0
Paresthesia	1	4
Superficial vein thrombosis	1	4
Wound infection	0	3
DVT	0	0
12 months		
Hyperpigmentation	1	0
Paresthesia	1	1

Age of the patients ranged from 15 to 70 years. Maximum patients were in age group of 40 to 50 years. The majority of the patients were overweight and obese, had a history of prolonged standing. Most of patients had unilateral lower limb varicose veins while some patients had bilateral lower limbs. The groups were well matched for the demographic data, CEAP classification, and GSV diameter.

In the CS group, 6 of patients had grade 1 neovascularization at ultrasound examination of the groin. After 1 year, the occlusion rate of UGFS was significantly lower than CS. Twelve patients (24%) of the UGFS group had partial obliteration with reflux. In 5 of these patients, initial treatment resulted in complete relief of complaints despite persisting reflux after 1-year follow-up, and therefore they did not undergo any additional treatment. In both groups, the C of the CEAP-classification decreased significantly after treatment, and there was no difference between groups. An improvement of the C score was seen in 80% of all treated patients at 3 months. After 12 months, 42% of all patients showed improvement of at least two categories. However, the mean improvement in C score was not significantly different between the two groups.

DISCUSSION

Varicose veins are more common in the Western countries as compared to India [12] which results in considerable morbidity and costs to the health services. Age of the patients ranged from 15 to 70 years. Maximum patients were in age group of 40–50 years (21.67%). The finding is in accordance with Edinburgh Vein Study [13]. In our study, 70% of patients were males and 30% patients were females. Our findings are in accordance with the study of Vashist *et al.* which showed 64% of males and 36% of females [14]. Our study showed that majority of patients was either overweight or obese. Our findings

correlate with the findings of Kröger *et al.* which showed that increase in BMI was one of the most important determinants of the development of varicose veins [15]. A study by Selçuk Kapisız *et al.* showed that obesity and lack of exercise are one of the contributory factors in the development of varicose veins [16]. These minimal invasive interventions are increasingly used as an alternative to CS for treating saphenous veins [17].

The results of this UGFS are strikingly similar to other clinical studies that included UGFS increasing the validity of the findings [3, 11, 18, 19]. One year after treatment, remaining (segmental) flow with reflux was observed in more than one-quarter of the patients treated with UGFS, which is in line with other observational studies. Neovascularization occurs in 10% of the patients in the CS group 1 year postoperatively, which corresponds with results of a previous study focusing on the effect of closing the cribriform fascia to contain postoperative neovascularisation at the SFJ [11].

In a meta-analysis [20] for the comparison UGFS versus surgery, the findings may have indicated no difference in the rate of recurrences in the surgical group when measured by clinicians, and no difference between the groups for symptomatic recurrence. Recanalisation at < 4 months had an OR of 0.66 (95% CI 0.20 to 2.12), recanalisation > 4 months an OR of 5.05 (95% CI 1.67 to 15.28) and for neovascularisation an OR of 0.05 (95% CI 0.00 to 0.94). There was no difference in the rate of technical failure between the two groups (OR 0.44, 95% CI 0.12 to 1.57).

In a study by Biemann *et al.* [17] more than 80% of the study population was classified as C2 or C3 venous disease. After 1 year, the anatomic success rate was highest after EVLA (88.5%), followed by CS (88.2%) and UGFS (72.2%) (P < .001). The complication rate was low and comparable between

treatment groups. All groups showed significant ($P < .001$) improvement of EuroQol 5 and Chronic Venous Insufficiency Quality-of-Life Questionnaire scores after therapy; 84.3% of all treated patients showed an improvement of the “C” of the CEAP classification.

This study concludes that both the conventional surgery and ultrasound guided foam sclerotherapy were good for varicose veins. Anatomic success was more in conventional surgery.

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