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Research Article

Improvement of Venous Clinical Severity Score "VCSS" after Ultrasound Guided Foam Sclerotherapy "UGFS" of Incompetent Great Saphenous Vein "GSV"; 1-Year Study

Walid M Gamal[1]*, Zeinab Mohammed Askary[1], Hesham Aboloyoun[2] and Abdelraheem Fathy Mohamed[1]

[1]Department of Vascular Surgery, Qena University Hospital, South Valley University, Egypt; [2]Department of Vascular Surgery, Assiut University Hospital, Assiut University, Egypt

ABSTRACT

Background: UGFS is considered an acceptable and widely used method for management of 1ry varicose veins. The infiltration of peri-saphenous Tumescent Local Anaesthesia (TLA) decrease the procedure related pain, and compresses the saphenous vein. The VCSS added up to the CEAP classification and is very beneficial for serial assessment and patients follow up.

Aim of the work: To determine the improvement of VCSS in subjects with incompetent GSV after UGFS with the use of tumescent local anesthesia during one year follow up.

Patients and methods: Between May 2018 and May 2019, 51 subjects were recruited in this study, which attended to The Vascular Surgery Department of Qena University and Assiut University Hospitals. 58 lower extremities were thoroughly examined to evaluate severity of the venous disease using CEAP classification and VCSS. All subjects were investigated by VCSS at 1,6 months and one year for follow up.

Results: At 1 month, the VCSS score mean was 3.05 ± 1.5 ranging between (0-6), while at 6 months the score was 0.03 ± 0.18 ranging between (0-1). Statistically significant difference between the VCSS preoperatively and at 12 months follow up was determined as p value ≤ 0.05. Clinical recurrence was absent at 1 & 6 months post operatively. At 1 year follow up, 10 cases had recurrence with visible varicose veins. No considerable complications were happened except for 1 case of DVT during postoperative week that was treated successfully with catheter directed thrombolysis.

Conclusion: UGFS is considered an efficient and reliable procedure in obliterating saphenous trunks. VCSS can be applied as a perfect tool for clinical follow up of UGFS. Adding tumescent anesthesia to increase compression of GSV need further study to show its effect and benefit to improve results of UGFS.s.

Keywords: Ultrasound guided foam sclerotherapy; Great saphenous vein incompetence; VCSS; CEAP

INTRODUCTION

Incompetence of GSV is the most prevalent cause of chronic venous insufficiency of the lower limbs which conversely is considered a common disorder. Superficial vein reflux prevalence is up to 30% in the adult persons and show increase as age progresses [1].

Chronic venous insufficiency could make patients suffering from heaviness, aching and lower limb cramps. Also, it can cause complications as edema, eczema, hyperpigmentation, lipodermatosclerosis and ulceration. Venous insufficiency effects on life quality of subjects can be compared to other chronic diseases such as diabetes mellitus and cardiovascular diseases [2].

Left untreated, advancement of the condition with increasing in severity of symptoms occurs in about 58% of the patients; 4.5% of patients with CVI exhibit yearly progression [3]. Open surgery of the GSV was considered the gold standard in treating this condition but it necessitates using general or regional anesthesia, making a groin incision for surgical dissection and it may cause complications, morbidity and a late get back to casual activities [4].

Recently the use of minimally invasive procedures tremendously changed the management of GSV insufficiency [5]. Introducing duplex ultrasound into management of varicose veins increased using methods like endovenous laser ablation, radio-frequency ablation and foam sclerotherapy [6]. Among these, UGFS has

Correspondence to: Walid M Gamal, Department of Vascular Surgery, Qena University Hospital, South Valley University, Egypt; Tel: +00201005602090; E-mail: walidgamal@yahoo.com

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considered an acceptable and widely used treatment modality for primary varicose veins [7].

The infiltration of peri-saphenous Tumescent Local Anesthesia (TLA) in endovenous thermal ablation is used to minimize the venous diameter, decrease the procedure related pain, and save the peri-saphenous tissues [8].

There is significant need now to find tools that measure chronic venous morbidity and reflect improvement with treatment [9]. The VCSS added up to the CEAP classification and is very beneficial for serial assessment. It also confers a focus on significant manifestations of chronic venous disease (CEAP class 4, 6) [10].

We aim in our work to assess the improvement of VCSS in subjects with incompetent GSV after UGFS with the usage of tumescent local anesthesia during one year follow up.

PATIENTS AND METHODS

This study was conducted prospectively on 51 patients with 1ry varicose veins as a result of incompetent GSV whom presented to Vascular Surgery Departments, South Valley and Assiut University Hospitals, Egypt from May 2018 to May 2019. Patients were chosen based on the following:

Inclusion criteria

Patients with either sex, age between 20-50 years presented with incompetent GSV only, CEAP 2s-3s.

Exclusion criteria

Patients with history of deep vein thrombosis, presence of inter-atrial or inter-ventricular communication, peripheral arterial ischemia with an ankle brachial index <0.8, known allergy to the sclerosing agent, acute superficial or deep venous system thrombosis, severe systemic illness, pregnancy, bronchial asthma, local infection, previous surgery/management for varicose veins, immobility or bedridden, diabetic foot (peripheral neuropathy or ulceration).

All patients have given informed consent before allocation to the study, which was approved by the ethical committee of Qena Faculty of Medicine, South Valley University.

Pretreatment, all subjects were thoroughly examined to evaluate severity of the venous disease using CEAP classification and VCSS and all data were recorded. All patients have undergone routine duplex ultrasonography to confirm presence of venous reflux and to assess extent of venous disease.

PROCEDURE

At the start of treatment, patients were first evaluated in the standing position using a duplex ultrasound technique to map the GSV (Figure 1). The limb was scrubbed with povidone-iodine solution; veins were then cannulated under ultrasound "US" guidance with 18 G, 20 G, and 22 G cannulas, depending on the target vein size and its distance from skin. The foam was made using a three-way cannula (stopcock) and two 5 mL syringes by mixing 1 mL of ethanolamine oleate with 4 mL of air according to Tessari method.

Tumescent local anesthesia "TLA" solution was also prepared, it is composed of 500 mL physiological saline, 25 mL 2% lidocaine, 10 mL 8.4% sodium bicarbonate, and 1 mL 1:1000 epinephrine. The volume of tumescence solution used was sufficient to fully collapse the GSV trunk for the full targeted length, with a maximum of 500 mL.

The lower extremity was then placed at an angle of 45° in supine position to empty the GSV. Tumescent local anesthesia was infused precisely into the saphenous compartment along the target vein using a spinal anesthesia needle under DUS guidance, to obtain a fully compressed GSV.

After completion of TLA infusion, foam was injected under ultrasound guidance. Foam was injected as a bolus and its advancement along the GSV was observed by duplex (Figure 2). The saphenofemoral junction "SFJ" was protected by manual compression using the ulnar border of patient's own hand during high truncal injections, to prevent proximal flow.

During injection of foam, the patient was asked to plantar and dorsi-flex the ankle to increase the deep veins blood flow and to neutralize excess foam that may pass into the deep system. A maximum of 20 mL of foam were used per treatment session. Treated veins were observed for 3 to 5 min to confirm spasm.

After completion of the injections, the cannulae were taken away and crepe bandage was applied. The patients were instructed to walk for 15 min before discharge.

The compression was kept for 5-7 days then removed and patients examined for any remaining varicosities or complications. Class 2 elastic stockings were advised for the next 3-6 weeks during walking and standing with limb elevation during sleeping.

Follow up

The 1ry outcome measure evaluated in our work was the VCSS at

Figure 1: Shows mapping of GSV before foam sclerotherapy injection.

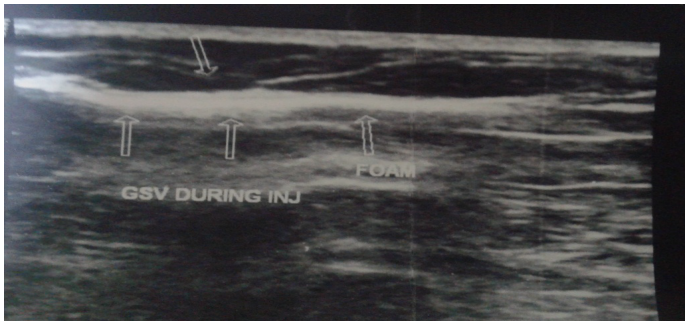

Figure 2: Shows foam sclerotherapy inside incompetent GSV.

1 month, 6 months and 1 year after the injection. The scores were determined at each follow-up visit after clinical examination of the patient. Secondary outcome measures were anatomical success defined as complete obliteration of the injected segment of the GSV assessed by duplex ultrasound "DUS" and the existence of any post-procedural complications as pain, inflammation, ecchymosis, and induration.

DUS was carried out either 1 week or 1 year after the procedure to assess effectiveness of treatment. Success was assigned to one of the four grades [11]: (1) Total occlusion; (2) Partial recanalization without reflux; (3) Partial recanalization with reflux; and (4) Total recanalization. The procedure was believed to be successful in cases of total occlusion or partial recanalization without reflux; the two remaining categories were deemed a treatment failure. Patients with recanalization had no further venous interventions during follow-up.

Statistical analysis

It was carried out using SPSS 21.0 (SPSS Inc, Chicago, IL, USA). Demographic data and GSV diameters were descriptively presented as mean ± standard deviation (SD).Wilcoxon signed rank test was utilized to compare VCSS results preoperatively and after 12 months. Statistical significance was determined at p value ≤ 0.05.

RESULTS

This research was conducted on 58 lower limbs in 51 patients. The average age of the examined population was 35.6 ± 13.13 years, with 26 males and 25 females. According to CEAP classification, 48 patients have presented with $C2_s$ and the remaining 3 presented with $C3_s$. The mean diameter of the GSV was 7.9 ± 1.4 mm (6-9.8 mm).

Regarding primary ablation

Technical success was achievable in all cases. Follow up of subjects at 1, 6 and 12 months showed a primary ablation rate of 100%, 93.8%, and 84.5 % respectively as shown in Figure 3.

Venous clinical severity score (VCSS): Follow up of the VCSS was done at 1, 6, and 12 months. Changes in VCSS during follow up are summarized in Figure 4. At one month, the score mean was 3.05 ± 1.5 ranging between (0-6), while at 6 months the score was 0.03 ± 0.18 ranging between (0-1).We found statistically significant difference between the VCSS preoperatively and at 12 months (p=0.00) as shown in Table 1.

Recurrence: Clinical recurrence in the form of visible varicose veins along the course of GSV or due to neovascularization at the Sapheno-Femoral junction was absent at 1, and 6 months post operatively. At 1 year follow up visits, 10 cases were presented with recurrence of visible varicose veins. Six cases as a result of recanalization of the GSV and four cases were 2ry to neovascularization as detected by duplex ultrasound (Figure 5).

Complications

No significant complications were detected except for 1 case of DVT during post-intervention week that was treated successfully with catheter directed thrombolysis. Other minor side effects were found as follows: five cases of thrombophlebitis, treated successfully with low molecular weight heparin and $NSAID_s$, and 5 cases with persistent pain at the injection site which resolved within 1 week.

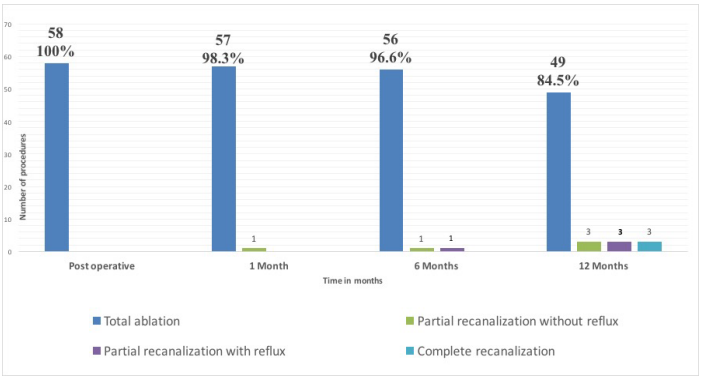

Figure 3: Primary ablation using Duplex ultrasound.

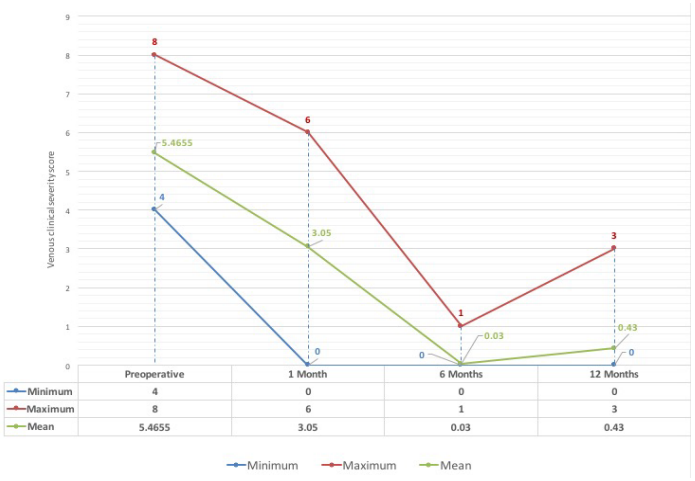

Figure 4: Shows the changes in VCSS during follow up period.

Table 1: Showing follow up of Venous Clinical Severity Score (VCSS).

VCSS	Range	Mean	Std. Deviation	Significance
Preoperative	4 – 8	5.4655	0.95908	0.000
1 Year follow up	0 – 3	0.43	0.975	

Tested with Wilcoxon Signed Rank test.

p value ≤ 0.05 is considered significant.

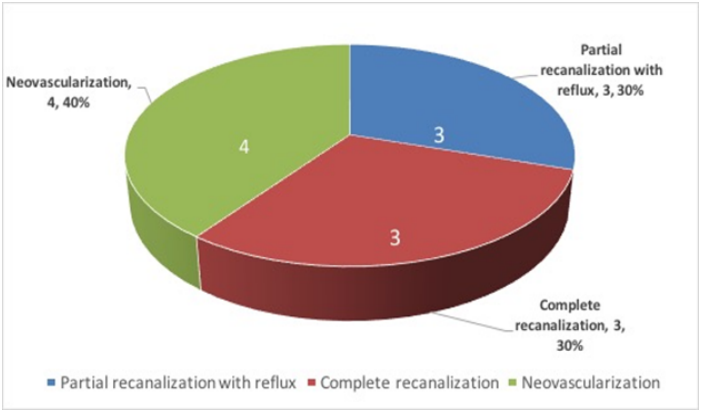

Figure 5: Shows duplex ultrasound of clinically recurrent cases at 1 year.

DISCUSSION

Lower limb varicose veins affect nearly 15% of adult men and 25% of adult women [12]. Incompetence of the "SFJ" with insufficiency of the (GSV) is often the leading cause of 1ry varicose veins in most of the patients [13].

Reflux combined with symptoms is considered to be the most relevant measurement because it best reflects clinical practice,

where patients are treated only if they exhibit both venous reflux and symptoms [14,15].

Our prospective study was conducted on 51 patients presented with primary lower limb varicose veins due to incompetent GSV. We tried to evaluate VCSS improvement in subjects with incompetent GSV after UGFS with the use of tumescent local anesthesia in one year duration.

This study showed that primary ablation rate was 100%, 93.8%, and 84.5% at 1, 6, and 12 months respectively. This was similar to Hamel-Desnos et al. [16] who reported that 100% of cases showed total occlusion and absence of reflux of the treated veins at the 28th day. The target vein in his work was either GSV or SSV. Also, a clinical series explained the outcomes of 459 limbs with chronic venous insufficiency related to greater saphenous vessel incompetence treated by means of ultrasound-guided sclerotherapy has indicated that 88% of the veins still occluded six months or longer after the treatment [17].

As well, Wael et al. [18] had conducted his study on subjects with isolated GSV reflux associated with SFJ incompetence showed complete occlusion in 87.7% of the subjects after two weeks.

In another study done by Ohare et al. [19] reported that the target vein occlusion was 93% by duplex at 2 weeks follow up and 74% at six months follow up. Their study included subjects with varicose veins due to incompetent great saphenous vein, small saphenous vein, Anterior Accessory Saphenous Vein (AASV) or other recurrent veins with considerable proximal incompetent deep venous connection. VCSS has been presented shortly after the year 2004, therefore only few studies available compare the outcomes following treatment using this scoring system [20]. In our work the treatment was directly evaluated using VCSS score at 1 month, 6 months and 1 year after intervention. Mean VCSS pre-intervention was (5.4655) and after 1 year follow up was improved to (0.43) (p=0.000). This indicated that UGFS for main GSV reflux has been validated to be highly effective for the short and midterm results. This was in line with Figueiredo et al. who made a comparison between results of foam sclerotherapy versus surgery on the basis of VCSS and determined improvement in both groups in VCSS at 1 month and 6 month duration of follow up [21]. As well, in a research by Masuda et al. they found that the median score of VCSS changed from 8 to 2 after foam injection (75% change in score) [22].

In a study by Wael, et al. [18] he reported that there was significant improvement of VCSS 2 weeks following the UGFS (p value <0.0001) in comparison to pre-intervention VCSS. Another study showed pre-procedure VCSS score of 49 subjects, ranged between 3.0-19.0 (Mean=10.7) and post injection VCSS was between 2-16 (Mean=7.6), which is statistically significant (p=0.01) [23]. This shows that our result is comparable to results of previous studies.

No significant complications were detected in our work except for 1 case of DVT "1.9%" during the first post-intervention week, which was treated successfully with catheter directed thrombolysis. Other minor side effects were found as follows: five cases of thrombophlebitis "9.8%", treated successfully with low molecular weight heparin and NSAIDs, and 5 cases "9.8%" with persistent pain at the injection site which disappeared within 1 week.

This is in accordance with a research of 116 patients by Thomasset et al. [24] detected that superficial thrombophlebitis occurred in (18%), skin staining in (28%), pain in (14%) and DVT in (1%) of cases. While Partsch, et al. [25] reported thrombophlebitis and hyperpigmentation to be the most common complications associated with foam sclerotherapy.

LIMITATIONS OF THE STUDY

Few patients assessed and the short period of follow-up was the main limitations of the present work. Finally, the follow-up period was quite not long enough so it could not sufficiently clarify the long term efficiency of UGFS for incompetent GSV, so further long term prospective studies should be recommended.

CONCLUSION

UGFS is considered an efficient and reliable method in obliterating saphenous trunks. VCSS can be utilized as a perfect tool for clinical follow up of UGFS. Adding tumescent anesthesia to increase compression of GSV need further study to show its effect and benefit to improve result of UGFS.

CONFLICT OF INTEREST

There is no conflict of interest.

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