Outcome of ultrasound guided foam sclerotherapy (UGFS) treatment for varicose veins: A four years retrospective study at a tertiary care hospital in north India

Singh S1, Maurya A.K.2, Singh M3, Sachdeva V4

1Dr Sanjay Singh, General Surgery, General Surgeon, 2Dr Akhilesh Kumar Maurya, Senior Resident in Department of Surgery, MLN Medical, College, Allahabad, India, 3Dr Mayurika Singh, Radiodiagnosis, Radiologist, 4Dr Vikas Sachdeva, PG Department of Surgery SRN Hospital & MLN Medical College, Allahabad, Uttar Pradesh, India.

Address for Correspondence: Dr Akhilesh Kumar Maurya, Email: dr.akhilbrd@gmail.com

Abstract

Objective: The purpose of this study was to determine the outcome and rate of recurrence for varicose veins treated with ultrasound-guided foam sclerotherapy (UGFS). Methods: Data was collected from hospital records. Patients treated with UGFS for superficial venous insufficiency were included in the study. Total 361 legs in 241 patients, out of which 121 patients with unilateral limbs and 120 patients with bilateral limbs were found to be treated by this method. Results: Out of these 361 legs great saphenous vein (GSV) varicosity was found in 88 legs, short saphenous vein (SSV) in 76, GSV & SSV both in 63, others 134. 264 legs with primary varicosity while 97 were with recurrent. In 294 legs clinical CEAP was 2-3 while in 67 legs it was 4-6. Saphenofemoral junction (SFJ) incompetence was found 60 legs, saphenopopliteal junction (SPJ) incompetence in 68, only perforator’s incompetence was in 56, SFJ with perforator’s incompetence 61, SPJ with perforator’s 29 and no incompetence was noted in 87 legs. Outcome at 6 months was 96.23% while treatment failure and recurrences were noted in 2.77 % of legs. Complications which were noted at 1 week were superficial skin necrosis in 3.04%, pain at injection sites in 15.23%, superficial thrombophlebitis in 16.62%, bruising in 12.18%, skin staining in 11.08%, superficial vein thrombosis (SVT) in 9.97% while no DVT was noted in any of the treated legs. Conclusion: On conclusion it was found that UGFS is a popular office based treatment modality, safe, effective, easy and improvement in venous signs and symptoms. Even on recurrence patients easily accepts retreatment with this method. Furthermore it is associated with lesser pain, anesthesia requirements; time off work and driving gives it additional advantages.

Keywords: Foam Sclerotherapy, Superficial Venous Insufficiency, Ultrasound Guided Sclerotherapy, UGFS Outcome, Varicose veins.

Introduction

There are two venous systems in the leg: First deep venous system; and second superficial venous system. When superficial veins under the skin become dilated, bulging and twisted then they are known as varicose veins. Ultrasound guided foam sclerotherapy (UGFS) is a well-established method for treatment of superficial venous insufficiency. First technique of foam preparation and injection was described in 1944 by Orbach[1]. The benefit of foam over liquid is that it displaces the blood and fill the vein; the foam is not diluted by blood; very small amount is needed to obtain the same effect. Once the foam reaches large veins and mixes with blood it is inactivated because blood is a strong inhibitor of sclerosants. Air from the foam is rapidly absorbed from the vein left the sclerosant for the action. Use of ultrasound guidance offers additional benefits over blind procedure is that the foam can be seen during injection and can be manipulated once injected into the veins. Without ultrasound guidance chances and quantity of foam to reach deep venous system is increased so the chances of deep vein thrombosis (DVT) are increased. Reasons behind popularity of this method are its easy availability,
simplicity, no requirement of analgesics and anesthesia, office based procedure, low cost, patient satisfaction, lesser complications and comparable efficacy with other methods[3,5]. Other common modalities which are being used for treatment of varicose veins are saphenous vein stripping (SVS), radiofrequency ablation (RFA) and endovenous laser ablation (EVLA). Requirement of anesthesia, operation theatre (OT) setup and cost of treatment are the major disadvantages of these methods[3,5].

Material & Methods

This study was carried out in Swaroop Rani Nehru (SRN) Hospital associated Motilal Nehru (MLN) Medical College, Allahabad, India after taking approval from ethics committee. Records of the patients treated by this modality were taken since January 2012 to February 2016. Inclusion criteria was patients aged above 18 years, clinical CEAP (clinical, etiological, anatomical, pathological elements) score above 4 or clinical CEAP score 2-4, having truncal varicose veins, great saphenous vein (GSV) (FIG. 1), small saphenous vein (SSV) (FIG. 2), anterior accessory saphenous vein (AASV) and other recurrent veins (FIG. 4), with or without incompetent deep venous connection, bleeding varicose veins, varicose ulcers and with skin complications. Exclusion criteria were patients below 18 years of age. Follow up period was 1 year.

Technique: The UGFS procedure have been described in detail elsewhere[3]. In brief UGFS consists of 4 steps: cannulation of veins; preparation of foam by Tessari’s technique[2]; injection of prepared foam into the veins; and compression bandaging.

Outcome measures: Complete occlusion of the saphenous trunk or disappearance of other varicosities from the level of incompetence between superficial and deep venous system was taken as successful treatment. If complete occlusion was not achieved or residual varicosity was noticed at 1 week then it was considered as short term treatment failure and procedure was repeated.

Results

Out of these 361 legs great saphenous vein (GSV) varicosity was found in 88 legs, small saphenous vein (SSV) in 76, GSV & SSV both in 63, others 134. 264 legs with primary varicosity while 97 were with recurrent. In 294 legs clinical CEAP was 2-3 while in 67 legs it was 4-6 (table 1). Saphenofemoral junction (SFJ) incompetence was found 60 legs, saphenopopliteal junction (SPJ) incompetence in 68, only perforator’s incompetence in 56, SFJ with perforator’s incompetence 61, SPJ with perforator’s 29 and no incompetence was noted in 87 legs (table 2). Total 241 patients were included in the study; 181 males and 60 females. 120 patients were having bilateral limbs and 121 with unilateral disease (table 3).

Table 1: Clinical details of total 361 limbs.

| Varicosities | GSV only | SSV only | GSV & SSV | Others | Primary | Recurrent | Uncomplicated (CEAP 2-3) | Complicated (CEAP 4-6) |
|-------------|----------|----------|-----------|--------|---------|-----------|--------------------------|------------------------|
| N           | 88       | 76       | 63        | 134    | 264     | 97        | 294                      | 67                     |

GSV, Great saphenous vein; SSV, Small saphenous vein; CEAP, Clinical, Etiological, Anatomical, Pathological.

Table 2: Duplex findings in 361 limbs.

| Incompetence | SFJ only | SPJ only | Perforator's only | SFJ & Perforator’s | SPJ & Perforator’s | None |
|--------------|----------|----------|-------------------|--------------------|--------------------|------|
| N            | 60       | 68       | 56                | 61                 | 29                 | 87   |

SFJ, Saphenofemoral junction; SPJ, Saphenopopliteal junction

Table 3: Patients demography.

| Variables | Total patients | Male patients | Female patients | Total limbs | Patients with Bilateral limbs | Patients with Unilateral limbs |
|-----------|----------------|---------------|-----------------|-------------|-----------------------------|-----------------------------|
| N         | 241            | 181           | 60              | 361         | 120                         | 121                         |
Table 4: Immediate complications in 361 treated limbs.

| Complications                        | N (%) |
|--------------------------------------|-------|
| Presyncope before injection          | 4 (1.1) |
| Presyncope post injection            | 7 (1.9) |
| Extravasations                       | 15 (4.1) |
| Pain in leg/at the site of injection  | 12 (3.3) |
| Minor bleeding                       | 5 (1.3) |
| Visual scotoma                       | 1 (0.2) |
| Severe headache                      | 1 (0.2) |
| Eye pain                             | 1 (0.2) |

Table 5: Early complications in 361 treated limbs.

| Complications                        | N (%) |
|--------------------------------------|-------|
| Superficial skin necrosis            | 11 (3.0) |
| Pain at injection sites              | 55 (15.2) |
| Superficial thrombophlebitis         | 60 (16.6) |
| Bruising                             | 44 (12.2) |
| Skin staining                        | 40 (11.1) |
| Deep vein thrombosis (DVT)           | 0 |
| Superficial vein thrombosis (SVT)    | 36 (10.0) |
| Treatment failures & recurrences     | 10 (2.8) |

Table 6: Anaphylactic reactions with UGFS.

| Studies                         | Bradbury et al.\textsuperscript{[10]} | Scurr et al.\textsuperscript{[18]} | Brzoza et al.\textsuperscript{[19]} | Guex et al.\textsuperscript{[20]} | Jia X et al.\textsuperscript{[11]} |
|--------------------------------|--------------------------------------|----------------------------------|----------------------------------|---------------------------------|----------------------------------|
| N                              | 1/1252                               | 1                                | 1                                | 1                               | 0/6856                           |

UGFS, Ultrasound Guided Foam Sclerotherapy

Fig 1: Great saphenous vein varicosity

Fig 2: Small saphenous vein varicosity

Outcome at 6 months was 96.2% while treatment failure and recurrences were noted in 2.8% of legs. Immediate adverse effects were self-limiting and shown in table 4. Complications which were noted at 1 week were superficial skin necrosis (FIG. 3) in 3.0%, pain at injection sites in 15.2%, superficial thrombophlebitis in 16.6%, bruising in 12.2%, skin staining in 11.1%, superficial vein thrombosis (SVT) in 10.0% while no DVT was noted in any of the treated legs (table 5). All of these complications resolved without any treatment.
Discussion

This article shows the experience of our centre in treating 361 limbs with varicose veins by this method. Success rate was 97.2% at a median follow up period of one year. Many papers have described particular problems in the management of varicose veins out of which neovascularization is a common problem and leading cause of poor outcome in surgically treated patients for recurrent varices[4].

Table 7: Incidence of different complications with UGFS in different studies

| Studies                     | Superficial skin necrosis | Pain at injection sites | Superficial thrombophlebitis | Bruising & pigmentation | Skin staining | DVT | SVT | Treatment failures & recurrences |
|-----------------------------|---------------------------|-------------------------|-------------------------------|-------------------------|---------------|-----|-----|----------------------------------|
| Present study               | 3.0                       | 15.2                    | 16.6                          | 12.2                    | 11.1          | 0   | 10.0| 2.8                              |
| Chapman Smith P et. Al[6]   | -                         | 3                       | 10.3                          | -                       | 3.9           | 1   | -   | 23.43                            |
| Jia X et. Al[11]            | 0-1.3                     | 0.3-4.2                 | 0.05-9.2                      | 19.8-31.6               | 7.8-55.1      | 0.02-0.7 | 0.1-8.8 | 0.5-5.9                          |
| Brunken A et. Al[7]         | -                         | -                       | 14.9                          | -                       | -             | 0   | -   | 20                               |
| Blaise S et. Al[22]         | -                         | -                       | 6-9                           | -                       | -             | -   | -   | -                                |
| Figueiredo M et. Al[17]     | -                         | -                       | 37.1                          | 28.6                    | 14.3          | -   | 54.2                        |
| Evi Kalodiki et. Al[27]     | -                         | -                       | 7.7                           | 15                      | 1.5           | -   | -   | -                                |
| Shadid N et. Al[28]         | -                         | 2.6                     | 7.4                           | 0                       | 5.6           | 0.4 | -   | 19.3                              |
| Bradbury AW et. Al[10]      | -                         | 0.24                    | -                             | -                       | -             | 0.24 | -   | 12.9                              |
| Myers KA et. Al[29]         | -                         | -                       | -                             | -                       | -             | -   | -   | 47.6-23.2                        |
| Gillet JL et. Al[30]        | -                         | -                       | -                             | -                       | -             | .98 | 9.7                          |
| Hamahata A et.al[31]        | -                         | -                       | -                             | -                       | -             | -   | -   | 34                               |
| Myers KA et. Al[32]         | -                         | -                       | -                             | -                       | -             | 1.45 | -   | -                                |
| Hamel-Desnos C et. Al[33]   | -                         | -                       | -                             | -                       | -             | -   | -   | 23.2                              |
| Maurya AK et. Al[34]        | 2.7                       | 14.18                   | 14.18                         | 12.16                   | 8.78          | 0   | 6.75 | 0                                |

UGFS, Ultrasound Guided Foam Sclerotherapy; DVT, Deep Vein Thrombosis; SVT, Superficial Vein Thrombosis
Most common immediate complication noticed in this study was extravasation of foam during injection (4.1%), which is similar to other studies[5]. Superficial thrombophlebitis incidence in this study was 16.6% which was similar to different studies[6,7,8] except one who shows its incidence 39%[9]. Other adverse effects in this study were superficial skin necrosis, pain at injection sites, bruising & pigmentation, skin staining and SVT. The incidences of these adverse events in different studies have been described in table 7 and table 8. Rasmussen LH et. Al[16] reported one case of DVT with SVS in their RCT. Most of these complications were found to be self-limiting and minor so UGFS can be considered as a safe procedure. Systemic complications of foam sclerotherapy like Photopsia, Transient blurring of vision, Transient ischemic attack, Headache, Chest tightness & dry cough seen with both liquid and foam sclerotherapy has been reported in less than 1% of the patients[6,10,11,12]. A study came with comparison of carbon dioxide foam with air foam. Use of CO2 foam was associated with substantial reduction these systemic complications[21].

Table 8: Incidence of different complications with SVS, RFA and EVLA in different studies.

| Complications                  | SVS                | RFA                | EVLA               |
|-------------------------------|--------------------|--------------------|--------------------|
| Lurie F et. Al[23]            | Subramonia S et. Al[24] | Lurie F et. Al[23] | Lurie F et. Al[23]|
| Bruising & pigmentation       | 0                  | 93.54              | 4.6                |
| DVT                           | 0                  | -                  | -                  |
| Superficial thrombophlebitis  | -                  | -                  | 0                  |
| Pain at injection sites/leg   | 25.0               | -                  | 0                  |
| Paraesthesia                  | 5.6                | 8                  | 3                  |
| Groin infection               | 5.6                | 2                  | 2                  |
| Hematoma                      | 38.9               | -                  | 1                  |

SVS, Saphenous Vein Striping; RFA, Radiofrequency Ablation; EVLA, Endovenous Laser Ablation; DVT, Deep Vein Thrombosis

Recurrences associated with treatment of varicose veins is a common problem and its rate varies from 4.9% to 40% in different studies [6,13,14,15,16]. One study shows 57%[17] failure rate while another study shows only 2%[6]. Our study noted 2.8% failure rate and recurrence. Neovascularization should be kept in mind for these failures and recurrences.

Anaphylactic reactions mostly seen with liquid sclerotherapy but can be seen with foam also. Table 6 shows incidence of this complication in different reports. No case of anaphylactic reaction seen in this study.

**Conclusion**

On conclusion it was found that UGFS is a popular office based treatment modality, safe, effective, easy and improvement in venous signs and symptoms. Even on recurrence patients easily accepts retreatment with this method. Furthermore it is associated with lesser pain, anesthesia requirements, time off work and driving gives it additional advantages.

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**Conflicts of interest**

Authors hereby declare that there are no conflicts of interest in present study.

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