Scholars Journal of Applied Medical Sciences (SJAMS) **ISSN 2320-6691 (Online)**
Sch. J. App. Med. Sci., 2015; 3(8B):2841-2846 **ISSN 2347-954X (Print)**

(An International Publisher for Academic and Scientific Resources)
www.saspublishers.com DOI: 10.36347/sjams.2015.v03i08.020

Research Article

Randomized clinical trial on ultrasound-guided foam sclerotherapy in the treatment of venous ulcers: A prospective study from a tertiary care centre in Madhya Pradesh

Dr. Rajesh Singh Baghel[1], Dr. Bhavyashree TN[2], Dr. K. P. Ranjan[3]
[1]Assistant Professor, [2]Postgraduate student, Department of Radiodiagnosis Gajra Raja Medical College, Gwalior, Madhya Pradesh, India
[3]Assistant Professor, Department of Microbiology, Gajra Raja Medical College, Gwalior, Madhya Pradesh, India

***Corresponding author**
Dr. K.P. Ranjan
Email: drkpranjan@gmail.com

Abstract: To determine the efficacy and safety of ultrasonography (USG) guided foam sclerotherapy (UGFS) in the treatment of venous ulcer due to chronic venous insufficiency. Thirty patients with venous ulcers due to chronic venous insufficiency were treated solely by USG guided foam sclerotherapy and compression. Repeat UGFS was performed where indicated. No serious adverse outcomes were observed– specifically no thromboembolism, arterial injection, anaphylaxis or nerve damage. UGFS is safe, easy, cost effective, minimally invasive and non-surgical out- patient procedure for treating venous ulcers with 100% patient acceptance and very less morbidity compared to surgery.
Keywords: Sclerotherapy, Ultrasonography guided foam sclerotherapy, venous ulcers

INTRODUCTION

Ultrasound guided foam sclerotherapy (UGFS) is a minimally invasive, non surgical outpatient procedure for treating the varicose leg veins associated with great saphanous reflux, which were first reported in 1989 [1, 2]. There are several studies, in which it has been demonstrated the efficacy and safety of this technique with very low record of adverse events [3, 4]. Ultrasound guided foam sclerotherapy is a safe and effective procedure, with a low rate of complications, that has been primarily utilized for the treatment of lower limbs varices, offering results similar to those obtained by surgery [5]. However, ultrasound-guided foam sclerotherapy is a relatively inexpensive procedure, minimally invasive and that can be repeated many times in the case of recurrence of incompetent veins [6]. In spite of that this technique requires the standardization for the uniform acceptance all over the world and for the meaningful comparison of the results. The purpose of this study was to determine the efficacy, safety of ultrasound guided foam sclerotherapy in the treatment of venous ulcers due to chronic venous insufficiency.

MATERIALS AND METHODS

A prospective study was conducted in the Department of Radiodiagnosis, Gajra Raja Medical College, Gwalior for the period of July 2014 to June 2015. Patients who clinically diagnosed of venous ulcers were included in our study. No patients were considered unsuitable for the treatment.

Pre-treatment protocol

These patients underwent routine colour duplex ultrasound using ALOKA Prosound ALPHA-6, linear array probe with frequency 10 MHz to confirm the venous insufficiency as the cause for the venous ulcers and to know the extent of the venous disease. The patients answered the questions related to symptoms and duration of the disease. They were also assessed for the site, size and depth of the venous ulcer using digital photography and / or disposable ruler, and associated skin and limb changes. The procedure was explained to the patient in their own languages and their consent for participating in the study was taken. Fagan's method [7] of foam sclerotherapy followed by compression was the treatment procedure done on all the patients. The Tessari micro bubble method of UGFS sclerotherapy was used [8]. Polidocanol was the detergent sclerosant used in the procedure (pharmaceuticals – injection asklero 3% / 2ml, manufacturer Samarth pharma private limited. Price-Rs 85/-). The detergent sclerosant (Polidocanol) was mixed with room air to form the foam. This was done using the three way tap switch and two 5 ml disposal syringes. A 3:1 ml room air to sclerosant ratio was

mixed with approximately 18-20 rapid exchanges which causes the turbulent flow via three way tap switch to produce micro bubble foam (Tessari micro bubble method). Typical ratios described of air to sclerosant are 3:1 to 5:1 [9]. The foam was stable for 1-2 minutes and remixing was done if reduced to froth. The maximum dose of detergent sclerosant, polidocanol that can be used per session is 12 mL of 1% (4ml of 3%) [10]. The dilated refluxing veins especially surrounding the venous ulcers are selected for the treatment. When starting treatment a basic rule for injection sclerotherapy is treat larger veins first before cutaneous veins. Injection with liquid sclerosant should proceed from proximal leg veins and progress distally. The reverse pattern, distal to proximal, is recommended with foam therapy. This change in sclerotherapy technique is because of vasospasm created with foam. The more distal veins subsequently will not be visualized if one starts proximally and hence require treatment at a later date when visible [10]. The patient was positioned to make the selected veins accessible for handling. A 22G intravenous canula (or 22G scalp vein set) is placed inside the lumen of the selected vein using ultrasound guidance and intraluminal placement is confirmed by pushing in 2 ml of normal saline. Patients limb was elevated to empty the veins and reduce the venous refilling. Tourniquet was used to prevent the higher proximal flow. Venous blood was aspirated into the syringes and fresh foam was slowly injected with gentle pressure and intraluminal distribution was confirmed using ultrasound. The treated veins were massaged manually to encourage the wide spread of the sclerosant and to promote venous occlusions. Patients were monitored for pulse, blood pressure and saturation. Immediately post procedure, direct compression with cotton balls, or dental roll was applied with a short stretch compression wrap overnight. Following this, continuous use of class-II compression stockings (30-40 mm Hg) was advised for a minimum of one week, and preferably three weeks, for achieving good results. Patients were advised to walk daily to help decrease superficial vein hypertension while in compression. In a controlled comparative study of duration of compression post sclerotherapy by Robert Weiss, MD, “three weeks of continuous compression leads to the best results, although even 3 days of compression results in greater improvement than no compression” at all [11].

Follow up surveillance duplex was performed at 7-10 days interval and patients are assessed for percentage of thrombosed or fibrosed veins and the remaining dilated refluxing veins. The patients were also assessed by questionnaires and clinical examination for

1. Any improvement in the discomfort or aching pain in the leg.
2. Any signs of ulcer healing like reduction in the oozing of the ulcer with improvement in the ulcer bed and decrease in the size or depth of the ulcer.
3. Any improvement in the skin and limb changes.

Ultrasound guided foam sclerotherapy treatment was repeated if the significant venous disease persisted with no improvement in ulcer quality. Further surveillance was done at weekly intervals until the ulcer epithelialisation and later at every three months for one year.

RESULTS

A total of 30 patients were assessed in the study which included both males and females in the age group between 30-70 years. The most frequent cases of venous ulcers in relation to age were noted in the age group of 35-40 years. We also found the relationship between venous ulcers and sex. The prevalence rate was higher in male (24) patients compared with females (06). Most of the patients had the ulcer in the lower third of leg (gaiter region) with only one patient having it anterior to medial malleoli. The average size of the ulcer around 30- 35 mm with reflux and perforators at various levels. All the patients were solely treated using ultrasound guided foam sclerotherapy treatment. The dilated refluxing veins in the leg below knee surrounding ulcer were targeted. The average total volume of foam used was 5 to 7.5 ml. Twenty three patients underwent sclerotherapy once and 7 patients required repeat sclerotherapy for the remaining dilated refluxing veins in the second session at 7-10 day interval. Symptoms such as aching pain resolved within 1- 2 days in all patients. Sings of venous ulcer healing were assessed and the data is as follows.

Assessment for signs of ulcer healing: Twenty three patients showed obvious reduction in the oozing of the ulcer with reduction in the limb oedema at first follow up (7-10 days). Seven patients without any significant reduction in the oozing of the ulcer correlated with the persisted dilated tortuous veins and required repeat Ultrasound guided foam sclerotherapy. The average time taken for the granulation tissue formation was 15 (+/-) 7 days. The average time for complete epithelialisation was 35 (+/-) 5 days. Skin changes due to chronic venous insufficiency improved over time.

Table-1: Assessment for signs of ulcer healing

No of patients (n=30)	Average ulcer size (mm)	No of treatment sessions	Average healing time (days)	Major complications
23	25-30	1	30(+/-)5	0%
7	38-42	2	40(+/-)5	0%

Fig 1: Patient presented with ulcer of size approx 25 mm above the medial malleoli of left leg associated with blackish discolouration of the surrounding skin.

Fig 2: Photograph taken on day 25 post UGFS demonstrates a healed ulcer

Complications

No serious adverse effects such as deep vein thrombosis, pulmonary embolism, anaphylaxis, stroke, arterial injection, nerve damage, fatality were noted. Two patients (6.6%) experienced severe pain while injection. Three patients (10%) had skin discolouration at injection site. The most common neurologic side effect of foam sclerotherapy temporary visual

disturbance and headache was not reported in any patient in the study.

DISCUSSION

Varicose veins are dilated tortuous superficial veins, at least 3 mm in diameter, that usually affect the great (GSV) and small (SSV) saphenous veins of the lower limbs [11]. Varicose veins are caused by decreased elasticity in the vein walls and poorly functioning valves, resulting in blood pooling in the veins and vein enlargement [11]. Risk factors for people with varicose veins are unclear although prevalence increases with age and pregnancy [13]. Symptoms of varicose veins can range in severity from occasional discomfort to severe ulceration of the skin [12]. Varicosities can cause considerable disability, resulting in decreased quality of life and loss of work days [12]. If left untreated, varicose veins can progress to chronic venous insufficiency, which increases the likelihood of tissue damage and development of venous ulcers [12].

However deep vein reflux is the major and primary cause of calf muscle pump failure and has been identified in more than 90% patients with venous ulcerations [14]. Venous outflow obstruction is the pathological cause only in 5-12 % of the cases [15]. Hence by the above data correcting the root cause of the deep vein reflux is the definitive treatment for improving the calf muscle pump and important for ulcer healing. This is achieved by reconstruction of valves (valvuloplasty). There is a strong association between severe post thrombotic syndromes and venous reflux. In such cases where the veins are destroyed by thrombosis, the transplantation of veins with valves is the mainstay in management [16, 17]. Any untargeted treatment like clipping, ligation, stripping, resection of superficial veins and collaterals is useless and will fail [18]. However valvuloplasty is proposed and is effective only after the appropriate superficial and perforator therapy has failed [19]. The correction of superficial and perforator reflux could be done either by surgery or by minimally invasive technique of compression sclerotherapy. Surgery including saphanous vein ligation and stripping have traditionally been the treatment standards [20]. Surgery however is invasive and may be associated with a greater incidence of complications and slower recovery relative to newer approaches to treatments [21]. Compression sclerotherapy is a less invasive approach, by chemical means have become increasingly widespread given potentially faster recovery times, reduced resource use and greater improvement to quality of life [22]. This percutaneous technique involves the targeted chemical ablation of varicose veins. Intravenous injection of either a liquid or a foamed Sclerosing agent destroys the endothelial tissues, exposing the sub endothelial collagen fibres and irreversibly forming a fibrotic obstruction to close unwanted veins. Several sclerosant are available including sodium tetradecylsulfate, polidocanol, and chromate glycerine; each associated with varying efficacies, potencies, side effect profiles, and costs [23]. In particular, foamed preparation of Sclerosing agents (i.e., a mixture of liquid sclerosant with air and other gases) have been increasingly popular as it has been suggested to increase the surface area of exposure, thereby achieving longer and undiluted contact with the venous endothelium and permitting greater intimal damage at a lower dose [24]. Foam sclerotherapy is typically conducted under ultrasound guidance with local anaesthesia in an outpatient setting.

So, this is a short prospective study for a period of one year mainly to assess the efficacy and safety of foam sclerotherapy on venous ulcer healing using a detergent sclerosant, Polidocanol. The improvement in the symptoms such as aching pain, cramps discomfort due to ulcer was achieved 100% of patients in 1-2 days. The results of ulcer healing was also far beyond expectation and was achieved in 100 % of the patients with the average time of 35-45 days required for reepithelialisation of ulcer. A 23.3% of patients required foam sclerotherapy in two sessions to achieve this result where as remaining 76.6 % of patients required the treatment in single session. No serious adverse effects like deep vein thrombosis, pulmonary embolism, anaphylaxis, stroke, arterial injection, nerve damage, fatality were noted in the study. However minor complication like pain during injection (occurred in 6.6% of patients) and discolouration at injection site (occurred in 10% of patients) were noted. The overall cost of the procedure was expected not to exceed two hundred Indian currencies in a government set up and another important thing the patients were very happy was about no downtime following the procedure. The average time spent on doing the procedure was about 15-20 min and patients did not require the hospitalization and were able to return to their day to day routine immediately post procedure. Apart from this, there was follow up of the cases. There were no patients, which were recurrence of the ulcer.

CONCLUSION

Ultrasound guided foam sclerotherapy is safe, easy, cost effective, minimally invasive, non surgical out- patient procedure for treating venous ulcers with 100% patient acceptance and very less morbidity compared to surgery.

REFERENCES

1. Redondo P, Cabrera J; Microfoam sclerotherapy. Semin Cutan Med Surg. 2005; 24:175-83.
2. Knight RM, Vin F, Zygmunt JA; Ultrasonic guidance of injection into the superficial venous system. In: Davy A, Stemmer R, eds. Phlebologie 89'. John LibbeyEurotext Ltd, 1989:339–41

3. Cabrera J, Cabrera J Jr, Garcia-Olmedo MA; Treatment of varicose long saphenous veins with sclerosant in micro- foam form: long term outcomes. Phlebology 2000; 15:19–23
4. Kanter A, Thibault P; Saphenofemoral incompetence treated by ultrasound – guided sclerotherapy. DermSurg 1996;22:648–52
5. Morrison N; Ultrasound-guided foam sclerotherapy: safety and efficacy. Phlebology. 2009; 24: 239.
6. De Waard MM, der Kinderen DJ; Duplex ultrasonography-guided foam sclerotherapy of incompetent perforator veins in a patient with bilateral venous leg ulcers. Dermatol Surg. 2005; 31:580-3.
7. Fegan WG; Injection with compression as a treatment for varicose veins. Proc R Soc Med 1965;58:874–6
8. Tessari L; Nouvelle technique d'obtention de la sclera- mousse. Phlebologie 2000;26:705–6
9. Wollmann JC; The history of Sclerosing foams. Dermatol Surg. 2004;30:694-703
10. Perspectives in Vascular Surgery and Endovascular Therapy Volume 19 Number 3 September 2007 317-324: Charles L. Dietzek, DO, FACOS
11. Weiss RA, Sadick NS, Goldman MP, Weiss MA; Post- sclerotherapy compression: controlled comparative study of duration of compression and its effects on clinical outcome. Dermatol Surg. 1999;25:105-108
12. Raju S, Neglen P; Clinical practice. Chronic venous insufficiency and varicose veins. N Engl J Med. 2009 May 28; 360(22):2319-27.
13. Varicose veins in the legs: the diagnosis and management of varicose veins [Internet]. London: National Institute for Health and Care Excellence (UK); 2013 July.
14. Raju S venous insufficiency of lower limbs and skin ulceration: Annsurg 1983;197 688-697.
15. Raju s, Frederick R; Valve reconstruction procedures for non obstructive venous insufficiency. jvascsurg 1988;7:310-100
16. Wilson NM, Rutt DL, Browse NL; In situ valve construction. Brit j surg 1991; 78:595-600.
17. Wilson NM, Rutt DL, Browse NL; Repair and replacement of deep vein valves in the treatment of venous insufficiency .Brit j surg 1991;78:388-394
18. Thiery L; What is the medical, social and economic impact of chronic venous insufficiency (CVT). Medicographin 1994;16 (2): 7-11
19. Cheatle TR, Perrin M; Venous valve repair: early results in fifty two cases. J vascsurg 1994; 19:404-413.
20. Dwerryhouse S, Davies B, Harradine K, Earnshaw JJ; Stripping the long saphenous vein reduces the rate of reoperation for recurrent varicose veins: five-year results of a randomized trial. J Vasc Surg. 1999; 29(4):589-92.
21. Nesbitt C, Bedenis R, Bhattacharya V, Stansby G; Endogenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for great saphenous vein varies. Cochrane Database Syst Rev. 2014; 7:CD005624.
22. Bond K, Harstall C, Dennett L; Endovenous ablation interventions for symptomatic varicose veins of the legs [Internet]. Edmonton: Institute of Health Economics; 2014 Sep.[cited 2015 Jan 22]. Available from:http://www.health.alberta.ca/documents/AHTDP-Endovenous-Ablation-IHE.pdf
23. Gloviczki P, Comerota AJ, *et al.;* The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J VascSurgt. 2011 May;53(5 Suppl):2S-48S
24. Hamel-Desnos C, Desnos P, Wollmann JC, Ouvry P, Mako S, Allaert FA; Evaluation of the efficacy of polidocanol in the form of foam compared with liquid form in sclerotherapy of the greater saphenous vein: initial results. Dermatol Surg. 2003; 29(12):1170-5.