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Research Article
How Diluted Liquid Sodium Tetradecyl Sulphate Works in Varices with Competent Superficial Valves Versus Stockings Alone

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Abstract

Background and Objective: Varicose veins are the most common complaints of referrals to vascular surgeons. Upon the cause, liquid sclerotherapy could be an efficient solution first in regard to competent main superficial valves. To find the impact of diluted liquid sclerotherapy in varices in patients with no superficial valve refluxes compare to whom wearing only stockings. **Materials and Methods:** Sclerotherapy with 0.3-0.5% liquid form of Sodium Tetradecyl Sulphate (STS) for reticular and spider varicosis, ulcers feeder veins and grade 3-4 sporadic varices were used. Patient's complaints the zone prevalence, response and satisfactoriness were detected clinically and data compared between the two injected cases and who managed by stockings alone with $\geq$1 year follow up. **Results:** Two groups (156 sclerotherapy, 76 only stockings) with three classifications for severity were obtained. Complete recovery of all varices and ulcers were almost achieved with no considerable complication. Logical regression test in unilateral to bilateral varices predict about 70% more recovery ($p = 0.048$), mild to severe 85% more ($p \leq 0.001$), moderate to severe 29% more ($p = 0.008$) and 10-15% response for severe cases. No significant difference for ages and responses between the 2 groups was existed. **Conclusion:** Diluted liquid sclerotherapy by STS was shown efficient in all ranges of varices. Stockings alone also were adequate to relief symptoms compare to sclerotherapy.

Key words: Varicose veins, sodium tetra decyl sulphate, liquid sclerotherapy, varicose elastic stockings

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Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

Varicose vein presentation is the most common complaint of referrals to vascular clinics. Individuals are involving in varices do not usually care about their problems unless they become symptomatic or being advised to refer by other physicians. Most of them have no complaint and are not aware of their underline venous valvular insufficiencies, but usually are symptomatic and confirm a discomfort with intolerance toward the restlessness feet at their activities. Symptomatic individuals are more prone as the main candidates for using stockings or undergoing sclerotherapy ablation. Successful influence of such medications on therapeutic course of venous disorders in vascular surgery, interventional radiology, gastroenterology, orthopedic, dentistry, dermatology and general practice has encouraged their free utilization as useful sclerosant manufactures. Already, numerous basic categorized drugs such as; alcohol and phenol, hypertonic saline or glucose solutions had been used, though still, they are being held in practice for extra vascular sclerosing properties in conjunction with some other drugs such as; Bleomycin, Tetracycline and less, Cephalosporins. Decision-making for sclerotherapy would be crucial and differs between the referrals depend on the varicose classification and its etiology in regard to stockings that prescribe by all physicians in first visits. Although, clinical examination is the diagnostic key, but in relation to superficial branches and communicating veins, evaluation of responsible deep and superficial veins valvular insufficiency is necessary and emphasized as a rule by ultrasound Doppler that mainly affects the recurrence and complications[1-3]. Of note, sometimes Doppler ultrasound may demonstrated no original intermediate or insufficient deep vein communications as a criterion for stem varices approach[1]. Therefore, in clinical practice, dominant visibility and the appearance of varicosity may primarily be accounted an indication for vigorous compression stockings or applying the ablative remedy. Nowadays, sclerotherapy is simply popular and feasible in the hand of all physicians. Its application could be followed by stockings[2] or occasionally without stockings[3-5] in the form of liquid or foam injections as the gold standard[6,7]. The technique requires patience and accuracy and meticulous sclerosant injection in correct doses and directions through the mother veins. Pharmaceutically now, detergent ancestry derivatives: Sodium Tetra Decyl Sulphate (STS) and Polidocanol (Macrogol lauryl ether or Dodecyl Polyethylene Glycol Ether) are the two approved and more utilizing and safe drugs than the others in venous sclerotherapy[6]. These drugs work by damaging the endothelial cell lining of the vessels and causing their thrombosis and eventually fibrosis and closed the vein, then disappear later[8,9]. Sclerotherapy is a safe and standard procedure with minimal and sporadic complication worldwide[3,6,7,10-13]. Nevertheless, as the producing pharmacies accept and have documented the probability of complications such as; the sensitivity and anaphylaxis during drug injections in the drug awareness leaflet. Thus, based on recommendation and suggestion by some STS manufacturers a small amount of diluted solutions (0.3 and 0.5 mL STS 1%, respectively) should be used in the first intra-variceal injection, which may perhaps be considered as same as the sensitivity test and the patients should be observed for an hour after the injection and before the procedure by the responsible physician for injections[14] or educated staff for testing.

This paper reports the results and responses for performing sclerotherapy by using half or less quantity of 1% diluted liquid STS defined as sub-standard manufactured volume and dose per session for symptomatic patients compare to cases who have used continuous stockings alone in various selected varices and producing feeder veins for venous ulcers which were followed about one year in our institution.

MATERIALS AND METHODS

This was a prospective, cohort clinical study had been performed on 156 symptomatic patients who accepted sclerotherapy for their lower extremity varices as they were mostly not keen to wear stockings and the other 76 cases of symptomatic varices who did not accept sclerotherapy performance and preferred to use only elastic stockings. The study was carried out at vascular clinic of Surgery Department of Golestan Hospital affiliated to Jundishapur University of Medical Science, Ahwaz, Iran, from October, 2014-December, 2017, with one year follow up. The study had programmed on the base of: (1) Observational judgment by a depicted and graphical sheet of anatomic category for sclerotherapy cases that was obtained from electronic site: www.oscarcanada.org graphical-eform (Fig. 1), (2) A provided questionnaire for coverage of all important and related items of patient's demography and medical history and determining the results and outcome satisfaction after treatment for both groups. A formal file consent paper which was signed by all the participants, based on our hospital sheet and ethical approval conform to the guidelines of 1975 declaration of Helsinki was provided. The study was already accepted and approved by the ethical and research projects committee of the university institution No: P.8.20.1722 and faculty registration No:A.88.60. Inclusion criteria were: Varices (Spider, reticular and

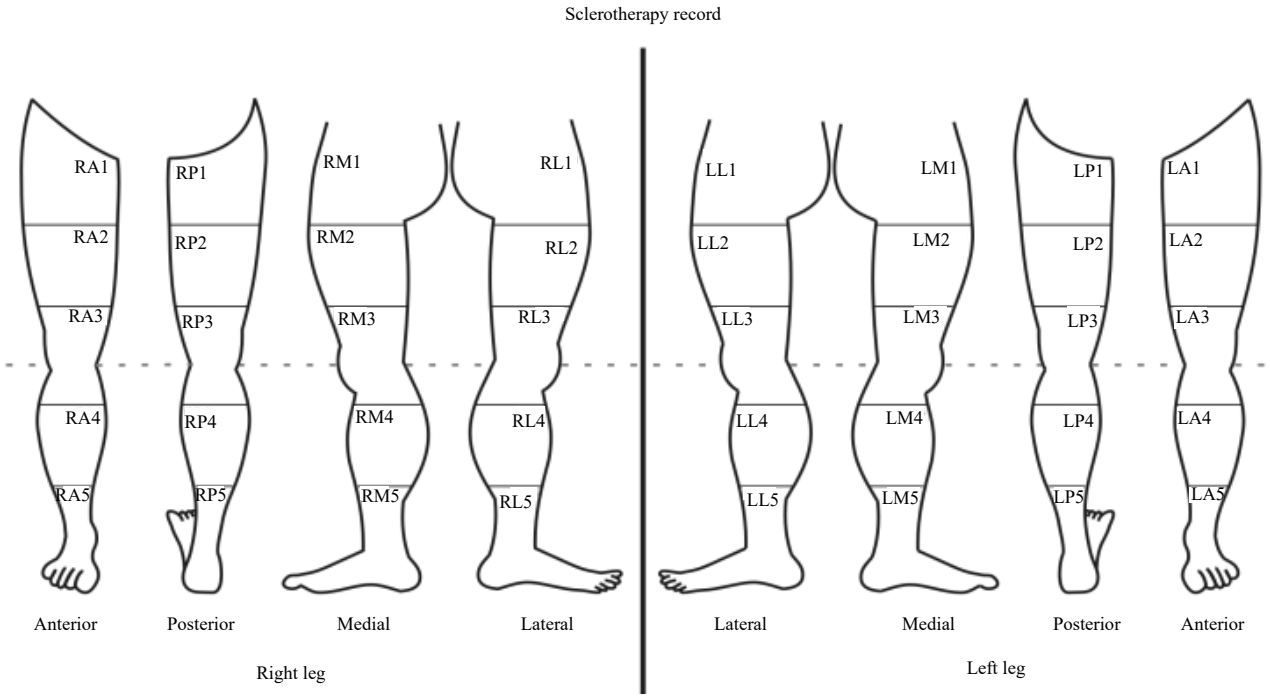

Fig. 1: Sclerotherapy record sheet

sporadic regional grade III-IV varicosity) and varicose ulcers. Exclusion criteria were: patients with saphenofemoral and saphenopopliteal valve insufficiency, history of unknown drug sensitivity, active allergy, blood factor hyper-coagulopathy and previous DVT.

Sclerotherapy (Group 1): Patients, who were candidate for sclerotherapy at first were completely explained for the drug, procedure and probabilities. It was used diluted form of liquid solution of European manufactured (Fibro-vein, UK) 2 mL 1% vial of Sodium Tetra Decyl Sulphate (STS) in sub-standard volume and doses which were optimal in drug manufactured leaflet for either avoiding or simultaneous determining complications. A concentration of 0.3-0.5% diluted STS was injected firstly as the test by very fine insulin needles and followed the procedure about 1-2 h next with uneventful result. Totally, every session up to 1-2 vials of 2 mL (1% = 20-40 mg, 1/3 of permitted dose by manufacture company) was used. About 0.3-0.5% for thread and reticular veins (<1,1-3 mm vein diameter) and for >3 mm vein diameter, 0.7-1% diluted or non-diluted liquid based on the veins by butterfly needles (scalp vein set) were injected so that in <3 mm veins 20-30°, for >5 mm 45° foot elevation was accomplished after needle insertion and before drug injections. Compressing round cotton balls or dental round cotton rolls were used at once after injection on the injected site through the course of the veins. Up to 20 injections per extremity depends on the patient tolerance for needle sticks and the maximum two vials were performed. At the end, the extremities were covered with one layer cross over elastic bandages or prepared stockings after minutes of total elevation and were held in elevated position for half an hour and then the patient discharged with prescribed commentaries.

Stockings users (Group 2): For patients who did not accept to have injection sclerotherapy, standard optimal pressure elastic stockings SIGVARIS kind/Switzerland, pressure class 2-3, cotton 222-223 and traditional 503-504, AD-AG had been prescribed and follow up was fulfilled in the manner of renewing the stockings every three months after full wearing and in order to account them as the second group for comparison with injected patients regarding the response, success, complications and outcome satisfaction that was related to their symptoms and achieved results.

Analysis: It was compared and analyzed the two groups based on the results by statistic comparing of demographic features, groups, severity, bilaterally and accurate prediction of probable response by ordinal logistic regression test through the Excel and SPSS software, version 14 with 95% confidence interval.

RESULTS

About 232 cases (205 females and 27 males, 19-62 year old) were recruited in 2 groups. First group 156 patients (10 male, 146 female, 19-61 year old [mean = 33.7]) who accepted to have sclerotherapy. Second group, 76 cases (17 male, 59 female, 22-67 year old [mean = 41.58]) who did not accept the sclerotherapy, used only stockings and had completed the follow up. We achieved observational models of severity to be classified as 3 types of mild, moderate and severe which were related to the common characteristics and complaints in 89 (38.4%) unilateral and 143 (61.6%) bilateral cases (Table 1, 2). The data in Table 1 shows common features in two groups that present varices directions were towards the dominancy of bilateral then right side prevalence and complaint of heaviness then sign of static foot, respectively with 70-100% cure responses. The Table 2 presents the correlation of symptoms and signs with the severity and incidence of classifications that directly are parallel to the clinical and the obtained analytic responses. For total 156 sclerotherapy cases, 223 sessions (1-7 session/case [mean = 1.44]) were injected as 113 cases of spider and reticular varices, 32 confined and sporadic regions of type III-IV varicose veins due to perforator insufficiencies and 11 cases of resistant venous ulcers with peri-ulcer feeding varices. Females and bilateral features were found obviously dominant with interestingly right side prevalence in the study. Injections had been performed most commonly on all aspects of medial mid-calf zone 4, then posterior side of zone 3 (popliteal region) and anterior tight 2 middle zone (Table 3). Thread veins were most commonly seen on the anterior thigh and spider and reticular veins on calves with clear prevalence of right side. There was no considerable or unsafe complication, but, one 61 year old man with probable test reaction who produced throat and pharynx itching sensation, uneventful 26 cases of some burning sensation around the injection sites immediately, one case of small blisters around the big pooling site injection for ulcer after 24 h, 4 cases of pigmented blemishes after 2 weeks, 3 cases of telangiectatic matting one month later, one deep anterior tibial vein thrombosis with mild dorsum foot swelling 2 weeks past from injections were found. There were no superficial thrombophlebitis or ecchymosis post injections. Almost 111 cases (98%) of spider and reticular, all 32 confined regions of varices and all eleven peri-malleoli ulcers were healed and disappeared (100%). Excellent level of satisfaction 94% for mild, 68% for moderate and 52% in severe varices has expressed by patients during follow up on questionnaires. In severe cases satisfaction of sclerotherapy overall was obtained in more than 2 third (70%) of patients in consideration with their expectations and prediction of responses clinically. For second group who used stockings, almost all were satisfied

Table 1: Groups and related complaints and end responses

									Clinical response		
Patients	Rt	Lt	Bilateral	Sole pain	Static foot	Restlessness foot	Heaviness	Edema	Pb*	Vb**	Cr***
Group 1 (156 Pts)	32	23	101	19	45	18	68	7	14	44	98
Mild varies 89 (24-45 year old)	20	13	56	3	9	3	27	-	1	18	70
Moderate 47 (21-38 year old)	9	7	31	5	21	5	23	4 (1+)	7	14	26
Severe 20 (43-56 year old)	3	3	14	11	15	10	18	3 (1,2+)	6	12	2
Group 2 (76 Pts)	21	13	42	9	16	7	53	8	10	25	41
Mild varices 36 (28-41 year old)	9	3	24	1	1	-	6	1 (1+)	7	8	21
Moderate 25 (27-51 year old)	7	7	11	4	5	1	17	3 (1+)	2	10	13
Severe 15 (33-51 year old)	5	3	7	4	10	6	9	4 (2,3+)	1	7	7

No response = 0. *Pretty better $\leq$50%, **Very better $\geq$70%, No pain, No heaviness. ***Completely relief, 100%, No complaint

Table 2: Achieved varicose classification, characteristics and symptoms

Classifications	Characteristics	Symptoms and signs
Mild (125, 53.9% cases)	Thread-reticular varices 1-3 zones, few $\leq$3 mm medial varices	End day restlessness foot, some plantar ache in long standing and inconvenient sole, immediate comfort in elevation
Moderate (72, 31% cases)	Mixed thread-reticular-spider varices $\geq$3 zones, sporadic multiple long 3-4 mm varices, confined skin pigmentations	Mid day restlessness foot, continuous sole pain, static foot, occasional muscular cramps with long standing, needs multiple rests
Severe (35, 15.1% cases)	Mixed scattered thread-reticular-spider varices $\pm$ pulling of mother vein, scattered multiple long 3-4 mm varices, sporadic pulling veins, grooved varices, diffused medial pigmentation or confined liposclerosis, $\pm$ ulcers	Persistent restlessness foot, purple static foot, immediate sole and toes inconvenience, nocturnal muscular cramps per week, inevitable avoidance of continuous standing, $\pm$ dermatolipo-sclerosis, $\pm$ painful ulcers, agonized status

Table 3: Injection numbers per zone based on the sheet

Zones	Thigh 1 upper zone	Thigh 2 middle zone	Knee 3 above/lower	Mid calf 4	Lower calf and feet 5
Anterior	Rarely some threads	5-7	-	5-7	1-2
Posterior	-	2-3	5-7	4-8	-
Medial	-	1-2	1-2	5-10	3-8
Lateral	-	-	1-2	3-7	1-2

(93%) with removal symptoms. In observations, sclerotherapy was shown superior appearance compare to the second group. In statistic comparing between the two groups there were no meaningful significant differences for response ($p = 0.586$) and ages ($p = 0.628$). Based on positive variable co-efficient in the Logit link, for comparing of unilateral to bilateral varices in sclerotherapy group, unilateral varices were shown about 70% = 1.7 times more improvement (Odd = 0.32, interval = 0.027-1.178, 95% confidence interval, $p = 0.048$), mild to severe 85% = >6 times more (Odd = 0.29, interval: 1.066-2.645, $p = <0.001$), moderate to severe 29% = 3 times more (Odd = 0.36, interval: 0.291-1.933, $p = 0.008$) and success of 10-15% for severe cases.

DISCUSSION

A century has passed from performance of sclerotherapy. Patients, who are not fit for surgery when there is valvular or perforator insufficiencies, also benefit from this modality. Today, its efficacy for all medical purposes has been standardized and progressed in European countries[12] and USA[6]. Overall sclerotherapy safety and pharmaceutical approvals have provided its utility in conjunction with ultrasonography even in high grade varices as a rival to surgery. Relevantly, varicose veins, especially spider and reticular varices and superficial venous abnormalities have been shown that are responding well to ablative drugs such as 1% STS[1-5]. Histochemically, its effectiveness and preference among the other sclerosants have been postulated for years. For STS foam, regarding *in vitro* clinical studies, endothelial cell damage and tissue loss to the depth of media layer of veins is significantly greater with 3% and has happened faster in the first 100 sec[8]. *In vivo* assessment of 3% foam of STS also has confirmed mentioned rapid 2 min complete cell damage and edema with progressive separation of intima from media in following 15-30 min[15]. The least effective dose was shown to be 0.15% for STS, considering that effective histologic changes were determined with 0.2% of it[16]. In this regard, high diluted liquid form of STS for performance with high security was chosen in the study. Whereas, it was also considered that drug complication specially the sensitivity cannot be neglected and has to be avoided in all cases. That was because of a broad list of experienced complications were postulated by many trials such as; dermatitis, urticaria, erythema, skin pigmentation or matting, phlebitis, migrainous headache, deep vein thrombosis, thromboembolism, nerve damage, scintillating scotomas and anaphylaxis[7,11,17]. Besides, other reports of serious type of these sequels even death due to pulmonary emboli by many British and Irish vascular surgeons were existed who had favorably responded back to European questionnaires. Thus reasonably, it had been accepted that any un-explained symptom which be produced at once after the primary test injection in the study, being construed as a probable sensitivity to stop the procedure. Two separate cases during the project had been experienced in these regards. A 60 years old male with leg ulcer who developed progressive itching of his larynx after the test and urgently handled by corticosteroids uneventfully. Second, a case of single vein ankle DVT with minimal transient side effects even in one–third diluted quantity of the drug that was also managed uneventfully. The issue of anaphylaxis has brought out from probable impurity of pharmacy manufactures. Existence of the contaminant poisonous materials such as 'Carbitol' which was presented in some compounds of pharmacies of 3% STS is the example. Perhaps, it is due to adding industrial detergent solutions that are not manufactured for use in humans for dilution[18]. Regarding the issue, three turning points should probably be considered in prevention of life-threatening accidents. First is decreasing the injection concentration of drugs to the lower point of their efficiency concomitant with correct case selection as performed in the project. Second is to raise the knowledge of expecting rapid deactivation of drug by blood protein attenuation mechanism in patient's blood circulation[19]. Third is avoidance of rapid injection of high volume and high concentration of the drug. Deactivation ability of blood proteins has been postulated and documented by Watkins in bovine blood samples of albumin and erythrocytes and mixture of them. Researcher has shown that a very low volume of whole blood approximately 0.5 mL, deactivate 1 mL of 3% STS sulphate by titration method[19]. But nevertheless, supposing that the other noxious roots may still be existed and remain in circulation and may continue promoting the reaction. Hence, the paper insisted on using the lowermost effective limits and intermittent continuous slow injections to surrender the serious side effects. Which selected form of drug is preferred for injection?

Require comparison of liquid and foam utility to find their differences that has not been apparently clear. To allude, as reported[7], also disclosed the transient migraine headache was produced by using foam STS and was not presented in liquid type utility[7], the study results also did not find any complaint of migraine type or simple headache to be experienced by the patients after injections. To physician duty and ethically, for preventing complications, all have to be aware of pharmaceutical properties of sclerosing components besides indications and contraindications. However, indications are defined and determined by the practitioners related to their experience and presentation of causes and consent of the patients for performance. Contraindications include the history of DVT, hypercoagulopathy, pregnancy, cardiomyopathy, migraine, serious systemic disease, immobility with dependent edema, hypersensitivity, corticosteroid dependency, distal limb arterial disease and chronic diabetes[11]. Today, apart from varicosis, there are numerous other indicative reports for sclerotherapy in other features of involvements. Intra oral, tongue hemangiomas may efficiently cure by STS injection to decrease the risk of bleeding and insidious growth[20]. Even selected intra-oral pyogenic granulomas as hyper-vascular tumoral lesions are prone effectively to elimination by non-surgical method of STS sclerotherapy[21]. To avoid ethanol injection complications, intra-osseous vertebral hemangiomas with significant epidural extension and radiculopathy due to cord compression that require decompression surgery has also been improved by highly reducing intra-operative bleeding due to concomitant embolization with STS sclerotherapy[22]. Moreover, treatment of low flow vascular malformations of buccal mucosa[23] and in children lymphatic vascular malformations with 84.3% therapeutic benefit and excellent results have also been reported[24]. In further instance, treatment of disseminated cutaneous glomuvenous malformations was postulated as well[25], though, it was by polidocanol usage but as mentioned before it is completely adjustable to STS ablation[8]. Improvement of numerous anal lesions such as; grade II-IV hemorrhoids through flexible endoscopy with foam sclerotherapy[26] and a series of perianal fistulas by direct intra-canal liquid injection of 1% STS intermittently with Metronidazole and Ceftazidime are the other examples[27]. In this way, long term urologic experiences for epididymal cysts and hydroceles treatments by STS has been offered too; a cost effective and promising outpatient method [28]. For the role of elastic bandage or stockings, this study[2] in comparison between the two groups was shown that elastic stockings alone have the same satisfactory capability of management of varices ($p = 0.576$) even in defined severe varicose types in two-third of the patients. Unilateral cases were more responding versus bilateral varices ($p = 0.048$), the result that achieved in conformity with "Aberdeen varicose vein questionnaire protocol" that explained bilateral and unilateral importance for C2 disease and predicted a better quality of life in unilateral involvement[29]. Stockings of medium pressure (25-30 mmHg) may handle all susceptible patients as an expecting, acceptable therapeutic modality; though, it did not compare with or without stocking support effects.

CONCLUSION

Diluted liquid types of STS in non-being saphenofemoral and saphenopopliteal refluxes presented the least complicating, safe and effective. Complying and standing in the less than 50% of authorized pharmaceutical dose of STS per session as a novel suggestion has shown practical. Extremity elevation concomitant by few seconds intervals and intermittent injections are the technical keys. Optimal elastic stockings also were respond comparable to sclerotherapy; though, from aesthetic view, sclerotherapy is more apparent, but as economic and safety, stockings are.

SIGNIFICANCE STATEMENT

This study presents highly effectiveness of diluted STS in sub-authorized dose for varices variety with non-being main superficial refluxes and has defined the technique. Also, finds the novel comparable response of varicose stockings with sclerotherapy and because of economy and safety, it may consequently, rule out its popular ablative indications as the first treatment step. Findings open and support a new sight of challenging for non-symptomatic cases with aesthetic enthusiasm towards avoidance of hazards of sclerotherapy.

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