



A comparative study of duplex guided Foam sclerotherapy and liquid sclerotherapy for the treatment of lower extremity varicose veins

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Abstract

Objective: Injection sclerotherapy is an important primary and adjunctive therapy in the spectrum of care for superficial venous insufficiency. Aim of this study is to compare the preliminary outcomes between duplex-guided foam sclerotherapy and duplex-guided liquid sclerotherapy. The sclerosing foam was produced by Tessari's method. At a minimum, the injected sclerosant must remain in contact with the vessel wall (dwell time) long enough to have the desired effect on the endothelium. Ideally, a sclerosant should stay in the target vessel until that vessel has fibrosed or should wash out from the vessel after a dwell time sufficient to damage the target without damaging any vessels into which it subsequently comes in contact.

Method: It is an institutional based prospective comparative observational study carried out in Midnapore medical college and hospital between March 2021 – August 2021. Total 60 patients are selected by simple random sampling and using proper exclusion criteria. These selected patients are finally divided into two groups of 30 patients each. First group undergone foam sclerotherapy using 1% and 3% sodium tetradecyl sulphate (STS). Second group undergone liquid sclerotherapy using 1%,3% STS. Data is recorded and analysed using SPSS software.

Result: Foam sclerotherapy is more likely than liquid sclerotherapy in occluding superficial varicose veins after 4 weeks [$X^2 (1, N=60) = 21.6964, p < 0.00001$]. Recurrence following Foam sclerotherapy is less likely than liquid sclerotherapy after 6 months [$X^2 (1, N=39) = 19.5, p = 0.00001$].

Occlusion following Foam sclerotherapy is more likely than liquid sclerotherapy after 6 months [$X^2 (1, N=60) = 32.8507, p < 0.00001$].

Conclusion: Foam sclerotherapy is far better than liquid sclerotherapy (p value < 0.00001) in occluding the superficial varicose veins and also recurrence is very less in foam sclerotherapy (p value $= 0.00001$).

Keywords: Foam sclerotherapy, liquid sclerotherapy, varicose veins.

Introduction

Sclerotherapy is the targeted chemical ablation of a varicose vein by intravenous injection of a liquid

or foam sclerosant^[1,2]. Intradermal, subcutaneous and/or trans fascial (perforator) veins can be treated by this method, as well as epi-, supra- and

subfascial vessels with venous malformations. The sclerosant destroys the endothelium of the vein and possibly other regions of the vein wall, and is deactivated by blood components and circulating cells^[1,2]. After successful sclerotherapy the varicose vein is transformed in the long term into a string of connecting tissue, in a process known as sclerosis^[3,4,5,6]. The objective of sclerotherapy is not thrombosis of the vein, since re-channelling may occur after this process, but its transformation into a string of connecting tissue. Re-channelling of this is impossible, so the functional outcome is equivalent to removal of the vein or endovenous thermal ablation. Duplex ultrasound examination is carried out with the patient standing, and is particularly good for identifying incompetent saphenous veins, subcutaneous veins (tributaries) and connections to the deep vein system, for clarifying post-thrombotic alterations, and for planning treatment. Duplex ultrasound should also always be used to show incompetent terminal and/or pre-terminal valves. Duplex ultrasound offers substantial advantages over Doppler ultrasound for pre-therapeutic evaluation of saphenous vein incompetence, including measuring vein diameters. Sodium tetradecyl sulphate i.e. STS is composed of sodium 1-isobutyl-4-ethyloctyl sulphate plus benzoyl alcohol 2% (as an anaesthetic agent) and phosphate buffered to a pH of 7.6. It is recommended that solutions be protected from light. It is a long-chain fatty acid salt of an alkali metal with the properties of soap. The solution is clear, non-viscous, has a low surface tension and is readily miscible with blood, leading to a uniform distribution after injection.¹⁰⁸ It primarily acts on the endothelium of the vein, because, if diluted with blood, the molecules attach to the surface of RBCs, causing hemolysis.

Material and Methods

Institutional based prospective comparative observational study carried out at Midnapore medical college and hospital, Midnapore between march 2021 and august 2021. Selection of patients

done by simple random sampling and divided into two groups.

Each group is assigned with one mode of treatment either by duplex guided foam sclerotherapy using STS or by duplex guided liquid sclerotherapy using STS. Foam is created by Tessari's method. Follow up is done at 1,3,6 month post procedure.

Exclusion Criteria

1. Age above 60 years and below 20 years.
2. Co-morbidities like heart disease, history of DVT, history of stroke, CAD, CVA.
3. Pregnancy

Inclusion Criteria

1. Age between 20-60 years
2. Primary varicose veins.
3. CEAP SCORE C above 2, E-Primary, A-GSV/SSV, P-Reflux

Study Design: prospective comparative observation study.

Study Tool: 3 way canula, syringes, compression hosiery, duplex ultrasound, Excel, Turnitin, SPSS software, computer etc.

Study Technique

Total 60 patients are selected by simple random sampling and following proper exclusion and inclusion criteria. Proper patient consent and ethical committee clearance is taken. All the selected patients are matched according to basic socio economic status, age and geographical area and divide into two groups of 30 patients each. First group undergone duplex guided foam sclerotherapy using 1% and 3% STS after creating foam by Tessari's method. Second group undergone duplex guided liquid sclerotherapy using 1% and 3% STS.

Post procedural compression hosiery is given in all patients for 4 weeks.

Follow up is done in all the patients at 4 weeks, 3 months and 6 months using duplex scan.

Data is recorded by excel software using 2 factors i.e occlusion of target vein at 4 weeks, recurrence after 6 months. Analysis is done using SPSS software and results are concluded.

Ethics: Proper ethical committee clearance is taken.

Statistical Analysis: Statistical analysis is done using SPSS software.

Patient Consent: Proper informed patient consent taken.

Table 1

Type of sclerotherapy	Partial occlusion of varicose veins 4 week after therapy.	Complete occlusion of varicose veins 4 week after therapy.	No occlusion 4 week after therapy.
Foam	2 (6.66%)	25 (83.33%)	3 (10%)
Liquid	5 (16.66%)	7 (23.33%)	18 (60%)

Table 2

Type of sclerotherapy	Recurrent varicose veins 6 months after therapy.
Foam	3 (10%)
Liquid	10 (33.33%)

Table 3

Type of sclerotherapy	Total Occlusion achieved 4 week after therapy.	Total Occlusion not achieved 4 week after therapy.	Total
Foam	25 (16) [5.06]	5 (14) [5.79]	30
Liquid	7 (16) [5.06]	23 (14) [5.79]	30
Total	32	28	60

The chi-square statistic is 21.6964. The *p*-value is < 0.00001. Significant at *p* < .05.

The chi-square statistic with Yates correction is 19.3527. The *p*-value is < 0.00001. Significant at *p* < .05.

Table 4

Type of sclerotherapy	Recurrence present 6 month after therapy.	Recurrence absent 6 months after therapy. (including partial and total occlusion)	Total
Foam	3 (9) [4]	24 (18) [2]	27
liquid	10 (4) [9]	2 (8) [4.5]	12
Total	13	26	39

The chi-square statistic is 19.5. The *p*-value is .00001. Significant at *p* < .05.

The chi-square statistic with Yates correction is 16.3854. The *p*-value is .000052. Significant at *p* < .05.

Table 5

Type of sclerotherapy	Effective occlusion at the end of 6 months excluding the recurrent cases.	No occlusion at the end of 6 months including the recurrent cases.	Total
Foam	24 (13) [9.31]	6 (17) [7.12]	30
Liquid	2 (13) [9.31]	28 (17) [7.12]	30
Total	26	34	60

The chi-square statistic is 32.8507. The *p*-value is < 0.00001. Significant at *p* < .05.

The chi-square statistic with Yates correction is 29.9321. The *p*-value is < 0.00001. Significant at *p* < .05.

Results

- 1) Partial occlusion of varicose veins after 4 weeks of therapy take place in 6.66% patients in case of foam sclerotherapy and 16.66% patients in case of liquid sclerotherapy.
Whereas complete occlusion of superficial varicose veins 4 week following therapy take place in 83.33% patients in case of foam sclerotherapy and 23.33% patients in case of liquid sclerotherapy.
- 2) Recurrence after 6 month post procedural duplex scan observed in 10% patients who undergone foam sclerotherapy and 33.33% patients who undergone liquid sclerotherapy.
- 3) A chi square test of independence was performed to examine the relation between type of sclerotherapy used and occlusion achieved at the end of 4 weeks. The relation between these variables was significant, $X^2 (1, N=60) = 21.6964$, $p < 0.00001$. Foam sclerotherapy is more likely than liquid sclerotherapy in occluding superficial varicose veins after 4 weeks.
- 4) A chi square test of independence was performed to examine the relation between type of sclerotherapy used and recurrence after 6 months post procedural confirmed by duplex scan. The relation between these variables was significant, $X^2 (1, N=39) = 19.5$, $p = 0.00001$. Recurrence following Foam sclerotherapy is less likely than liquid sclerotherapy after 6 months.
- 5) A chi square test of independence was performed to examine the relation between type of sclerotherapy used and effective occlusion excluding the recurrent cases after 6 months post procedural confirmed by duplex scan. The relation between these variables was significant, $X^2 (1, N=60) = 32.8507$, $p < 0.00001$. Occlusion following Foam sclerotherapy is more likely than liquid sclerotherapy after 6 months.

Discussion

This 6 month follow-up outcomes confirm early results e.g. foam sclerosant is more effective as the liquid despite containing 5 times less sclerosing agent. The rate of immediate success in the foam group (83.33%) is relatively low when compared to the literature^[1,2,3,4]. This is probably due to the fact that in this study, treatment consisted of *only a small volume* whatever the immediate result. The goal, however, was not to measure the efficacy of foam sclerotherapy, but to compare foam to liquid. Spasm at the time of injection was predictive of immediate success but the absence of spasm was a poor negative predictor.

A follow-up period of 6 months might appear short when the goal of treatment is improvement measured in tens of years. This is true for treatments such as surgery, which are meant to be definitive and where recurrences are difficult to treat. Where sclerotherapy is concerned, this thinking must be put into context. In the presence of recanalisation, diameter has decreased and the dosage used to achieve that result years earlier is known. Thus, treatment has every chance of being quick and effective and re-treatment is generally easier.

Conclusion

Foam sclerotherapy is far better than liquid sclerotherapy (p value < 0.00001) in occluding the superficial varicose veins and recurrence is way less in foam sclerotherapy as compared to liquid sclerotherapy (p value = 0.00001).

Conflict of Interest: None

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