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Role of Ultrasound Guided foam Sclerotherapy in Treatment of Lower Limb Varicose Vein

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ABSTRACT

Background: Veins have one-way valves which prevent blood from backing up into the legs when we stand or sit. When the valves become incompetent (or begin to have reflux), blood pools and causes an increase in pressure in the leg veins becoming enlarged and twisted.

Objective: It was to evaluate the safety and efficacy of foam sclerotherapy in the treatment of primary varicose veins.

Methodology: This study was carried out in Radiology Department of Ain Shams University Hospitals. 20 patients with sonographically proven primary varicose veins for which they had foam sclerotherapy injection.

Result: The 20 patients enrolled in this study were ranging from 24 to 52 years with mean age of 36.4 years.

Conclusion: Foam Slcerotherapy is effective & safe in treatment of primary varicose veins.

Keywords: Varicose veins (VV), Phlebograph (PHL), foam sclerosant (SCL)

INTRODUCTION

Veins have one-way valves which prevent blood from backing up into the legs when we stand or sit. When the valves become incompetent (or begin to have reflux), blood pools and causes an increase in pressure in the leg veins becoming enlarged and twisted [(1)].

This may contribute to varicose veins and causes symptoms of fatigue, heaviness, aching, burning, throbbing, itching, cramping, swelling and restlessness of the legs. Severe varicose veins can compromise the nutrition of the skin, leading to eczema, inflammation or even ulceration of the lower leg [(2)].

In general, age and gender were the most relevant risk factors for varicose veins. Male: 3.4 female 6.5. In addition in females the most frequent risk factors were oral contraception and in both gender a predominately sitting posture at work. Regarding the family history, varicose veins by the mother was most frequent compared to varicose veins by the father or both [(3)].

Sclerotherapy is the chemical ablation of abnormal veins. The modern goal of therapy is irreversible fibrotic occlusion, followed by reabsorption of the target vessel [(4)].

Sclerotherapy is an old technique that has been revolutionized by recent technological advances. Foaming detergent sclerosants offered increased potency and could be visualized by means of ultrasonography. Ultrasound guidance allowed better anatomic visualization, greater hemodynamic understanding, more precise foam targeting and delivery, and monitoring for unwanted foam passage into deep veins. With these advances, sclerotherapy has now become a competitive treatment for any type or size of vein [(5)].

Its advantages include: relatively low price, can be administered in an outpatient setting and an excellent method for treating recurrent varicose veins [(5)].

AIM OF THE WORK

The objective of this study is to evaluate the safety and efficacy of foam sclerotherapy in the treatment of primary varicose veins.

PATIENTS AND METHODS

Patients:

This is a descriptive study. During a period of 6 months duration from August 2017, twenty patients were enrolled in the study. All patients with primary varicose veins, the diagnosis was confirmed by Doppler U/S.

Inclusion criteria: Patient diagnosed by varicose veins unilateral or bilateral by U/S duplex study. No age predilection.

Exclusion criteria: Past history of DVT. Signs of superficial thrombophlebitis. Bleeding tendency. Systemic cases of varicose veins as hyperhomocysteinemia.

Ethical Considerations: Obtaining an informed consent from the patient concerning the complications of the procedure, the complication of the sclerosing material & the acceptance of the involvement in the study. The study was approved by the Ethics Board of Ain Shams University.

Study procedures: Patient preparation: stop antiplatelets drugs before the procedure by 8 hs. Patent position: Slight Trendlenberg position. Procedure duration: 30 mins. Machine used: Ultrasound device LOGIG P5 with a superficial probe of 7.5 MHZ.

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Method: The sclerosant material is injected via a fine needle directly to the incompetent perforator by U/S guidance or via a butterfly in the superficial spiders or lastly via a phlebograph in the great saphenous vein.

Statistical analysis: Data were coded and entered using the statistical package SPSS (Statistical Package for the Social Sciences) version 23. Data were summarized using mean, standard deviation, median, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Comparisons between quantitative variables were done using the non-parametric Kruskal-Wallis and Mann-Whitney tests. P-values less than 0.05 were considered as statistically significant.

RESULTS

The 20 patients enrolled in this study were ranging from 24 to 52 years with mean age of 36.4 years.

Table (1): Demonstrating the complain & duration of the symptoms.

		Number of patients	Percentage
Complain	Disfigurement	9	45.0%
	Heaviness	5	25.0%
	Pain	6	30.0%
Duration	More than 3years	5	25.0%
	1-3 years	13	65.0%
	Less than 1 year	2	10.0%

Complain of the patient were categorized in three categories as shown in the previous table, skin disfigurement represented 45 %, heaviness and pain representing 55 %.

Table (2): Demonstrating the relation between the category of the disease in relation to the age & sex.

		Superficial spiders	GSV varicosities	GSV varicosities with incompetent perforators	Test value	P-value	Sig.
		No.= 5	No.= 3	No.= 12			
Sex	Female	1 (20.0%)	1 (33.3%)	10 (83.3%)	6.944*	0.031	S
	Male	4 (80.0%)	2 (66.7%)	2 (16.7%)			
Age	Mean ± SD	31.60 ± 9.42	35.00 ± 7.55	38.83 ± 8.85	1.227•	0.318	NS
	Range	24 – 46	27 – 42	26 – 52			

NS: Non significant, S: Significant

The U/S findings of the patients was categorized into three categories, superficial spiders where GSV was found to be patent, free with no tortuous course, the second category was GSV tortuous course with no perforators detected and the third category (the severest) GSV tortuous course with multiple incompetent perforators that increase the venous pressure on the great saphenous vein.

In the previous table regarding the gender of the patients, the P-value showed a significant relationship between the grading of the disease and the gender of the patient, where the female sex acts as a risk factor for the severity of the disease, however the age of the patients doesn't represent a significant value that's owed to the small sample size.

Table (3): Demonstrating the category of the disease in relation to the complain and duration.

		Superficial spiders		GSV varicosities		GSV varicosities with incompetent perforators		Test value*	P-value	Sig.
		No	%	No	%	No	%			
Complain	Disfigurement	5	100.0%	2	66.7%	2	16.7%	11.204	0.024	S
	Heaviness	0	0.0%	0	0.0%	5	41.7%			
	Pain	0	0.0%	1	33.3%	5	41.7%			
Duration	Long	1	20.0%	0	0.0%	4	33.3%	3.621	0.460	NS
	Med	4	80.0%	3	100.0%	6	50.0%			
	Short	0	0.0%	0	0.0%	2	16.7%			

NS: Non significant, S: Significant

The previous table showed that cases presented with superficial spiders, complained of skin disfigurement, another cases of skin disfigurement owed to tortuous course of the great spahenous vein with no reflux of the perforators, however pain was the most distressing complain for cases presented by great saphenous vein tortosuity and incompetent perforators and thus the P -value was significant concerning the relation of the severity of the disease to the category of the complain

Table (4): Demonstrating the category of the disease in relation to the procedure, complications.

		Superficial spiders		GSV varicosities		GSV varicosities with incompetent perforators		Test value*	P-value	Sig.
		No	%	No	%	No	%			
Procedure	Butterfly	5	100.0%	0	0.0%	0	0.0%	40.000	0.000	HS
	Direct	0	0.0%	0	0.0%	5	41.7%			
	Phlebograph	0	0.0%	3	100.0%	0	0.0%			
	Phlebograph & direct	0	0.0%	0	0.0%	7	58.3%			
Complications	Nothing	3	60.0%	1	33.3%	5	41.7%	6.093	0.192	NS
	Pain	0	0.0%	2	66.7%	6	50.0%			
	S.thromophlebitis	2	40.0%	0	0.0%	1	8.3%			

NS: Non significant, S: Significant

The previous table shows the procedure done for the different categories of the patients in our study, for cases with superficial spiders, direct injection of the foam scleosant was done via butterfly, cases presented by GSV varcioisties with competent perforators were injected through using phlebograph, lastly cases presented by GSV varciosites and incompetent perforators were

injected by phelbograph accompanied by direct injection of the incompetent perforators in a trial to lower down the high venous pressure load affecting the great saphenous vein.

Concerning the complications, 45% of the cases experienced no complications after the procedure, however 8 cases complained of pain that lasts for one to two weeks with good response to analgesics. It's to be considered that 50 % of cases that had foam sclerotherapy injection in GSV via the phlebograph complained of pain. Only 3 cases complained of superficial thrombophleibits in the form of pain, redness and swelling at the site of injection with good response to medical treatment, with no further complications. No major complications occurred.

Table (5): Demonstrating the category of the disease in relation to the U/S follow up & patient response.

		Superficial spiders		GSV varicosities		GSV varicosities with incompetent perforators		Test value*	P-value	Sig.
		No	%	No	%	No	%			
U/S findings follow up	Med	0	0.0%	0	0.0%	4	33.3%	4.444	0.349	NS
	Perfect	4	80%	3	100.0%	7	58.3%			
	Poor	1	20%	0	0.0%	1	8.3%			
Patient response	Med	2	40.0%	0	0.0%	4	33.3%	2.444	0.655	NS
	Perfect	3	60.0%	3	100.0%	7	58.3%			
	Poor	0	0.0%	0	0.0%	1	8.3%			

NS: Non significant, S: Significant

Concerning one month follow up, 7 cases out of 12 done via combined injection of the sclerosant via the phlebograph and direct in the incompetent perforators revealed total occlusion of the injected veins with perfect outcome of the patient complain, 4 cases out of 12 U/S follow up revealed recanalized perforators, with total occlusion of the GSV.

Two cases with poor outcome, a case of superficial spiders, that come for follow up after one month, however no significant changes are noted, another case with phlebography injection of the sclerosant revealed recanalized segments of the Great saphenous vein.

DISCUSSION

A) Safety:

In the 20 case treated with sclerosing foam we had no serious complications (in particular, no pulmonary embolism, no DVT or nerve injury). Phlebitis which was a sequela of excessive inflammatory reaction of the sclerosing foam had-occurred in 15 % of patients (three cases), while ***Frullini and Cavezzi*** [6] and ***Rabee et al.***[7] reported only 1% of phlebitis. No skin necrosis, sclerosant induced ulcer, wound infection ornerve injury was reported. This study demonstrated a high patient satisfaction with improvement of the quality of life and a high rate of closure of the saphenous trunks and visible varicosities with foam therapy.

Results achieved in this study were comparable with otherstudies [8-11]. But in the VEDICO trial comparing the treatment of varicose veins using several techniques including sclerotherapy, surgery and foam sclerotherapy, the study demonstrated the elimination of reflux in all patients with 10 year follow up [12]. The incidence of passage of the foam to the deep system is eliminated by direct compression on the saphenofemroal junction localized by Doppler study.

A study conducted by ***Barrett et al.***[13] showed similar results to our study. They used the same technique to obtain high success with low incidence of complication.

b) Efficacy:

Compared with classic liquid sclerotherapy, foam sclerotherapy was about four times more effective because of increased contact time with the venous wall, increased surface area of the venous wall, and venous spasm [1].

After one UGFS session, 75% of the truncal varicosities were occluded (15 case out of 20) several large case series and one multicenter study have been published. UGFS in 1411 limbs showed occlusion in 88% of GSVs after a mean follow-up of 11 months [17–19]. Few studies showed 69% complete sclerosis in 99 limbs after 24 months of follow-up,12 44% occlusion in 211 limbs after 5 years of follow-up, 13 and 88% occlusion in 143 limbs after 6 weeks of follow-up.14 A small prospective randomized trial suggested that SFJ ligation and one session of UGFS was less effective in the short term, but significantly less costly and time-consuming than stripping, and multiple avulsions.

All sizes of GSVs over all CEAP classes were shown to be safely and effectively treated. Patients enjoyed an immediate return to activity, avoiding the cost of time off work. The technique of UGFS was well accepted by all patients, who felt strongly that UGFS was effective in treating their varicose veins, would recommend it to a

friend, and would have UGFS repeated in the future if required.

Although most of the patients who needed further treatment were during the first 3 months of follow up, we believed that the 6 month follow up provides a sufficient time to assess the development of early recanalization. ***Barrett et al.*** [13] had reported that, a 3 month follow up was enough but others [8,13] did not accept that because this period was too short for establishment of alternative venous pathway. Surgery carries a risk of general anesthesia and the time of work off. Surgery is not more effective than foam sclerotherapy for primary truncal saphenous vein treatment [14]. So we believed that, it was difficult to justify a procedure that has increased patient morbidity and mortality and no increase in safety.

CONCLUSION

We believed that foam sclerotherapy is a safe and effective treatment for varicose veins without serious side effects. It can be used for varicosities due to saphenous trunk reflux. Patient safety is a prime indication for foam therapy (no general anesthesia and low risk of DVT). Foam has added the benefit of high patient satisfaction, less hospital stay and early return to the daily work.

REFERENCES

1. **Emory Healthcare (2015):** Varicose Veins: Description & Causes. Emory Health care j., 333(7562): 287–292.
2. **Evans CJ, Fowkes FGR, Ruckley CV *et al.* (1999):** Prevalence of varicose veins and chronic venous insufficiency in men and women in the general population: Edinburgh Vein Study. J Epidemiol Community Health, 53: 149–153.
3. **Callam MJ (1994):** Epidemiology of varicose veins. Br J Surg., 81: 167–173.
4. **Orsini C and Brotto M (2007):** Immediate pathologic effects on the vein wall of foam sclerotherapy. Dermatol Surg., 33(10):1250-4.
5. **Sarvananthan T, Shepherd AC, Willenberg T *et al.* (2012):** Neurological complications of sclerotherapy for varicose veins. J Vasc Surg,, 55:243–251.
6. **Frullini A, Cavezzi A (2002):** Sclerosing foam in the treatment of varicose veins and telangiectasia. Dermatol Surg., 28: 11–5.
7. **Rabee E, Fisher P, Gerlach A *et al.* (2004):** Guidelines for sclerotherapy of varicose veins. Dermatol Surg., 30:687–93.
8. **Barrett LM, Frazegp C, Allen B *et al.* (2004):** Guidelines of sclerotherapy. Dermatol Surg., 82:1291–301.
9. **Rybak Z (2003):** Foam obliteration of insufficient perforating veins in patients suffering from leg ulcers. Phlebolymphology, 42: 20.
10. **Wright D (2006):** Safety of intra venous foamed sclerosants. Phlebolymphology, 44:155–9.
11. **Hamel- Desnos, Philipe D, Jan CW *et al.* (2003):** Evaluation of the efficacy of Polidocanol in the form of foam compared with liquid form in sclerotherapy of the greater saphenous vein. Surg., 29: 1170–5.
12. **Belcaro G, Cesatrone MR, Di Renzo A *et al.* (2003):** Foam-sclerotherapy surgery, sclerotherapy and combined for varicose: 10-year, prospective study, randomised, control, trial (VEDICO trial). Angiology, 54: 307–15.
13. **Barrett LM, Allen B, Ockelford A *et al.* (2004):** Microfoam ultrasound guided sclerotherapy treatment for varicose veins in a subgroup with diameter of 10 mm or greater versus a subgroup of less than 10 mm. Dermatol Surg., 30: 1386–90.
14. **Geroulakos G (2005):** Foam therapy for those with varicose vein. Dermatol Surg., 50: 89–94.