

Sclerotherapy versus surgical excision in treatment of primary varicose veins: an experience from Duhok, Kurdistan, Iraq

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ABSTRACT

INTRODUCTION: varicose vein is one of the commonest vascular diseases of lower limbs affecting usually young adults, with wide range of clinical presentation and complications. Many modalities of treatment are now available although our commonest practice was only in surgical excision new practice developed by using foam sclerotherapy.

OBJECTIVE: comparison between the two methods of treatment of varicose veins.

METHODS: prospective comparative non randomized study between two groups of one hundred patients complained from varicose veins. Fifty treated by Sclerotherapy and compared to fifty patients had been treated by surgery, Diagnosis done on clinical base, evaluation and follow up include full clinical examination, duplex ultrasound scanning of the deep and superficial veins.

RESULTS: The patients who underwent surgery all had some form of anesthesia (local, spinal or general anesthesia). While in the sclerotherapy group did not receive any form of anesthesia is needed. Recurrence and complications rate were less in surgery group (6% recurrence and 22% complications) in comparison to sclerotherapy group (12% recurrence and 40% complications). Although the morbidity were more in patients treated by surgery because of the nature of complications. All patients treated by sclerotherapy returned to daily activity within 24 hours while three quarter of patients of surgery groups need five days or more to return to daily activity. There was better post-procedure pain and oedema in patients treated by sclerotherapy.

CONCLUSION: As in many countries foam sclerotherapy is increasing in popularity (including our locality) as an option of treatment of varicose veins where the results and complications are comparable to surgery and its advantage to be done with no anaesthesia, as an outpatient, less morbidity, more cosmetically accepted and easy repeatability.

Key words: varicose veins, foam sclerotherapy, venous insufficiency

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INTRODUCTION

Varicose veins can be defined as dilated, tortuous and superficial veins of the lower limb. It's the commonest cause of venous insufficiency. Majority of the patients had primary varices (95%), while secondary varices develop mainly due to deep veins thrombosis.¹

Incidence of varicose veins ranges from 40 to 60% of women and 15 to 30% of men. Risk factors of varicose veins includes: hereditary, pregnancy, increase body weight, low exercise, occupation with long time standing, smoking, prolong chair sitting, oral contraceptives, and low-fiber diet with constipation. Clinical examination is adequate to make the diagnosis but sometimes it may not identify those varicosi-

ties that lie deep or are not prominent.² Cough impulse over the sapheno-femoral junction, disappearance of varicose veins with a tourniquet applied to the upper thigh (Trendelenburg's test) indicate reflux (incompetence of sapheno-femoral junction valve) causing varices of the long saphenous vein. Short saphenous vein reflux may present with varicosities over the posterior and lateral leg and control of varicosities only with a tourniquet applied below the knee. Other test, Perthes', is done by applying a tourniquet below the knee and let the patient to walk. Venous pain indicates deep venous obstruction.³

Venous Duplex Ultrasound is the standard tool for evaluation of venous function it can be

Table 1: Revised Venous Clinical Severity Score

Attribute	Absent = 0	Mild = 1	Moderate = 2	Severe = 3
Pain	None	Occasional not restricting activity	Daily, interfering but not preventing daily activity	Daily limits most daily activity
Varicose veins	None	Few isolated branch varices or clusters	Confined to calf or thigh includes ankle flare	Involves calf and thigh
Venous oedema	None	Limited to foot and ankle	Extends above the ankle but below knee	Extends to knee and above

used to evaluate reflux in individual venous segments targeting diseased areas. It performed with the patient in the standing position and the examined leg non-weight bearing. The common femoral, femoral, popliteal, posterior tibial, great saphenous and small saphenous vein, are evaluated in a complete examination.⁴

For standardization and description of the chronic venous disease, a classification scheme was developed known as CEAP classification. It based on clinical signs of venous disease (C), etiology (E), anatomy (A), and underlying pathophysiology (P). Clinical class include no varicose veins (C0), telangiectasia or reticular veins (C1), varicose veins (C2), edema (C3), skin changes like pigmentation or eczema (C4a) or lipodermatosclerosis or atrophic blanche (C4a), healed ulcer (C5) or active ulcer (C6). Etiology can be congenital (Ec), primary (Ep), secondary (Es) or no venous cause identified (En). The anatomic classifications separates superficial (As), perforator (Ap) or involvement of deep veins (Ad) or no venous location identified (An). Pathophysiology of the disease can be reflux (Pr), obstruction (Po) or both and (Pn) if no venous pathophysiology identified. Severity of disease and outcome of treatment are assessed by using revised Venous Clinical Severity Score (VCSS) which is recommended by Society for Vascular Surgery and American Venous Forum that is based on assessment of ten descriptors including pain, oedema, presence of varicose veins, signs of venous reflux and venous ulcer.⁵

Treatment should result in removal, ablation, or ligation of the refluxing venous segment this can be done by high ligation with or without stripping and stab phlebectomy may be applied as needed to the great saphenous vein, short saphenous vein, tributary veins, and perforating veins.⁶ Endovenous ablation can be done also by using LAZER, Radio-frequency or sclerotherapy. Sclerotherapy is made by injecting sclerosants that destroy the target vein by aggregating on the endothelial wall, disrupting

the cell surface membrane, and causing thrombosis. The advantages of foaming are stability and longevity and when it is injected, blood is displaced, allowing the agent to make contact with the endothelium. Sometimes repeated sessions are required to complete the process.⁷ Aim of treatment is abolishing the sources of reflux and removing the affected segment of vein.⁸ Although there is no level one evidence, the superiority of foam sclerotherapy to traditional surgery is becoming well established and widely accepted in the vascular surgical community.⁹ Sclerotherapy can also be used as supplementary therapy with the surgery for improving the results and for better overall outcome.¹⁰ Minimal invasive technologies like radiofrequency, laser and sclerotherapy have largely replaced classical open surgery. The guidelines recommended by the Society for Vascular surgery and American Venous Forum includes sclerotherapy as line of management of varicose veins tributaries and for incompetent saphenous vein.¹¹

As the sclerotherapy is an emerging method for treatment of varicose veins, less well established in Iraq and it regards as an option for patients for treatment the varicose veins in this study we aimed at comparing the effectiveness and safety profile of sclerotherapy to that of traditional surgical excision in the treatment of varicose veins. By reviewing and analyzing the results and all advantages and disadvantages of this type of therapy in our locality and comparing it to the results of surgical excision and with other international studies.

METHODS

Setting and design: A comparative, non-randomized clinical study was conducted by comparing the data prospectively collected from patients with varicose veins treated with sclerotherapy to the recorded data of those who had been treated by conventional surgical intervention.

The study was conducted at the vascular department at Azadi Teaching Hospital in Duhok Directorate of Health from 1st of June 2014 to 1st of December 2015. Azadi Teaching Hospital in the main hospital in governorate of Duhok, Kurdistan, Iraq. The research protocol was approved by the scientific unit of the College of Medicine in Duhok University and the committee of ethics at scientific research division of Duhok Directorate General of Health. A written consent was obtained from the patients enrolled in the sclerotherapy group after explaining the nature of the study.

The comparison was made between two groups; the first group included patients who were diagnosed as varicose veins and treated with foam sclerotherapy, we called it sclerotherapy group. Patients in this group were followed prospectively. The second group, surgery group, included patients who had varicose veins and underwent surgical excision of the varicose veins. Data of patients who were included in the second group were taken from the records of the same hospital.

Definition of the cases: In both groups, we define varicose veins as dilated, tortuous and superficial veins of the lower limbs.¹ Doppler ultrasonography was used to support the diagnosis of varicose veins and to exclude deep vein thrombosis as a potential cause for it. This definition was used to diagnosis all cases enrolled in the sclerotherapy group and it was used also in our centre for the diagnosis of patients received conventional surgical treatment.

Selection of patients in the first group (sclerotherapy group): Any patients who has attended the outpatient clinic of Azadi teaching hospital on every Tuesday during the studied period and fulfilling the definition criteria of varicose veins and have met the inclusion criteria listed below were included in this study. Those patients have undergone full clinical evaluation (history and physical examination) and pre-therapy assessment using Duplex ultrasound examination of varicose vein, perforators, long and short saphenous systems, accessory dilated and deep veins to exclude deep vein thrombosis (DVT).

Inclusion and exclusion criteria: We included only patients who were diagnosed as primary varicose veins and designated as C2-4Ep As&p Pr According to CEAP classification varicose veins. Patients who have reticular veins only, venous ulcer, or his or her varicose veins were sec-

ondary to DVT were excluded from this study. Diagnosis DVT was based on history (previous positive history of DVT) and clinical examination looking for swelling, skin changes (mainly over medial malleolus), oedema and was proved by Doppler ultrasound examination. Pregnant ladies and patients who chose or shifted to other form of therapy were also excluded from this study. (Shifting the modality of therapy was due to either cost, the need for more than three sessions, or due to patients desire).

Selection of patients in the second group (surgical group): patients of this group were those who had varicose veins and treated by surgical intervention at the same hospital since January 2013. Data of those patients were collected from the records of the hospital retrospectively. In this group we depended on the same defining criteria of the diagnosis of varicose veins and the same inclusion and exclusion criteria; in addition, we have excluded patients with missing data in their records.

Primary and secondary outcomes: In both groups, we searched for improvement and development of complications at the end of first week after therapy and then one month later on. This assessment was made through physical examination and examination by ultrasonography. Assessment of clinical improvement was made through studying the effect of the intervention on post-operative pain, oedema, and appearance of varicose veins. (table 1) We used venous clinical severity score VCSS to assess clinical improvement. Safety of the intervention was assessed by searching for development of the following complications: infection, phlebitis, skin pigmentation and haematoma. Recurrence of varicose veins was also searched for up to a month after the procedure. It is worth emphasizing that the follow up was made prospectively in the sclerotherapy group and retrospectively, though searching records of the patients, in conventional surgical intervention.

Procedure: Surgical treatment was done as in patients under (general, spinal or local anesthesia) in operating room, if great saphenous or short saphenous veins involved stripping done and any varicose vein not in their course separately ligated and excised, if varicosity affecting below knee multiple ligations and excision done alone without stripping.

Sclerotherapy was performed in an outpatient clinic with no anesthesia. Foam is made by Tes-

sari's method* (mixing air and the sclerosant by using two syringes connected to three way stop-cock to produce foam) from polidocanol (Aethoxysklerol®) (**Aethoxysklerol is a registered trademark of Kreussler pharma, Wiesbaden, Germany.) In concentrations 0.5%, 1%, 3% according to the size of the varicosity, foam formed 1:4 (sclerosants: air), doses (ml per session) but not more than 10 ml of foam had been given in one session and sessions repeated accordingly (no more than three sessions and at least one week between each session), compression bandages or elastic stocks applied after finishing the session of sclerotherapy.

Statistical analysis: Data were analysed using the Statistical Package for Social Sciences (SPSS, version 19). Chi square test of association was used to compare between proportions. When the expected count of more than 20% of the cells of the table was less than 5, Fisher's exact test was used. Mann-Whitney test was used to compare the differences of the outcome scores of the two groups. Wilcoxon signed ranks test was used to compare the outcome score before and after management in each group. A p value of ≤ 0.05 was considered statistically significant.

RESULTS

Of 100 patients fifty treated by surgery 26 was female and 24 male, sclerotherapy group 34 female and 16 male.

Veins affected by varicosity in surgery group mainly was affecting long saphenous vein (78%), short saphenous vein affected in 10% of patients, both long and short saphenous vein affected in 6% while accessory veins was affected in 6% only. In patients treated by sclerotherapy 50% have varicosity in long saphenous vein, short saphenous vein affected in 18% of patients, combined lesion in long and short saphenous affect 14% and accessory veins in 18% of patients.

Clinical presentation or assessment of the patients according to CEAP classification showed in. (Table 1) Anatomical assessment of varicose veins revealed that group treated by surgery 18% had defect in superficial veins only, 44% the defect was in perforator veins and 38% had defect in both superficial and perforator veins. While in sclerotherapy group 12% the defect was in superficial veins only, 66% had defect in perforator veins only and 22% had defect in both superficial and perforators.

Surgical technique used in treating patient include stripping only in 22% of patients, 40% by multiple ligation and 38% stripping and multiple ligation was used. The type of anaesthesia used was 34% general anaesthesia, 58% spinal and 8% local anaesthesia. We should mention here that no anaesthesia used in any patient treating by sclerotherapy.

Complications in both group (table 2) revealed that the commonest complications in patients treated by surgery were haematoma and swelling, while in sclerotherapy group was phlebitis followed by pigmentation, one patients developed abscess at site of injection.

Recurrence rate of varicose veins in patients treated by sclerotherapy diagnosed in six patients (12%) and it was more than in patients treated by surgery three patients only (6%). (Figure 1)

Return to full activity was assessed in both groups with significantly difference where sclerotherapy group all patients returned to full activity within 24 hours from therapy, while in surgery group about 75% need more than 5 days to return to full activity.

Pain, oedema, varicose veins which included in revised venous severity score was evaluated in this study pre and post treatment. (Table 3) Comparison of the outcome between the two groups evaluated table 4. Pain is significantly less in patients treated with sclerotherapy, no difference in oedema and the varicose vein were better in patients treated by surgery.

DISCUSSION

Percentage of female underwent sclerotherapy was more 68% (mainly was the cosmetic issue). Surgical procedures like ligation, ligation and stripping, endovenous thermal ablation, sclerotherapy, and ambulatory phlebectomy have a role in the treatment of patients with symptomatic varicose veins.^{6,8,9} Although combination of more than one modality had been practiced and assessed and showed superiority to single form of treatment (like surgery combined with sclerotherapy);¹⁰ however, surgery is still the commonest type of treatment for varicose veins in many countries.^{9, 12,13} In our locality, surgery (stripping and/or multiple ligations) is the commonest and the standard procedure for treating varicose veins. In Iraq, we didn't

Table 1: clinical presentation of patients

Group	C2 (%)	C3 (%)	C4a (%)	C4b (%)	Total (%)
Surgery	40 (80)	6 (12)	2 (4)	2 (4)	50 (100)
Sclerotherapy	41 (82)	3 (6)	4 (8)	2 (4)	50 (100)

Table 2 complications of treatment

Complications		Group		P value
		Surgery	Sclerotherapy	
Complications	None	39 (78%)	30 (60%)	0.052
	Infection	2 (4%)	1 (2%)	
	Haematoma	5 (10%)	0 (0%)	
	Swelling	4 (8%)	2 (4%)	
	Pigmentation	0 (0%)	7 (14%)	
	Phlebitis	0 (0%)	10 (20%)	
Total		50 (100%)	50 (100%)	

find any published article comparing new and old modalities of treating varicose veins. However, our personal communication with many vascular surgeons practising in Iraq has shown that new modalities like sclerotherapy is still under used in our daily practise.

In our study, rate of recurrence and failure after one month from the last session of sclerotherapy or surgery was more in patients treated

by sclerotherapy, 6 patients (12%), than in those treated by surgery, 3 patients (6%). Recurrence and failure rate was defined as re-canalization of varicose veins diagnosed either clinically or ultrasonographically. Many studies have shown comparable results,^{12,13,14,15,16,17} while others have revealed no statistical difference in rate of recurrence, Nesbitt et al¹⁸ and Murad in his meta-analysis,¹⁹ or even higher rate in patients treated by surgery like Kastan et al.²⁰ Kastan has explained this result by development of new vascularisation, presence of residual veins due to uncompleted resection, or presence of complex pattern of varicosity.

Treatment of varicose veins is not exempted from major complications like deep venous thrombosis (DVT) and pulmonary embolism which are recorded in many studies.^{8,17,21} Fortunately (in both methods of treatment) no major complication had been recorded in our study. Absence of such complications in our series may be due to small sample size and our dependence on clinical assessment only in detection of DVT and pulmonary embolism and this might lead to miss many subclinical or asymptomatic DVT or pulmonary embolism. Other complications (table 2) are within accepted limits comparing to other studies.^{8,12} The majority of complica-

Table 3: Mean score of pain, oedema, and varicose veins as assessed by Revised Venous Clinical Severity Score in both groups before treatment, one week, and one month thereafter.

Group	Score	Pre-treatment (mean)	1 week post treatment (mean)	P value	1 month post treatment (mean)	P value
Surgery	Pain	1.7	1.06	<0.001	0.2	<0.001
	Oedema	0.36	0.28	<0.285	0.2	<0.002
	Varicose veins	2.56	0.2	<0.001	0.6	<0.001
Sclerotherapy	Pain	1.94	0.36	<0.001	0.04	<0.001
	Oedema	0.28	0.18	<0.025	0.06	<0.009
	Varicose veins	2.34	0.18	<0.001	0.18	<0.001

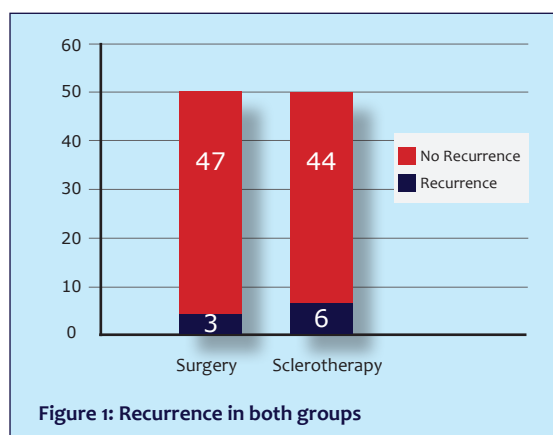
Table 4: Difference in mean score of pain, oedema, and varicose veins after a week and a month to the pretreatment means in both groups.*

	Surgery	Sclerotherapy	P value
Difference in mean of pain score after a week †	35.15	65.85	<0.001
Difference in mean of pain score after a month ‡	43.19	57.81	<0.005
Difference in mean of oedema score after a week †	49.75	51.25	<0.685
Difference in mean of oedema score after a month ‡	52.49	48.51	<0.325
Difference in mean of varicose veins score after a week †	58.89	42.11	<0.001
Difference in mean of varicose veins score after a month ‡	58.15	42.85	<0.004

* Assessment was made according to the Revised Venous Clinical Severity Score

† Difference between mean after a week to pretreatment state.

‡ Difference between mean after a month to pretreatment state.



tions arising from sclerotherapy can be considered minor in severity and are often transient.⁷ Apparently the complication rate was more in patients with sclerotherapy group (40%) in comparison to surgery group (22%), but this difference has not shown a statistical significance due probably to a small sample size. Scrutinizing the nature of the complications showed an interesting results; the major two complications in sclerotherapy group were phlebitis and pigmentation which were not or minimally affect the activity and quality of life of the patients comparing to the complications resulted from surgery ,haematoma and swelling, which carried more morbidity to the patients. This notice has been reflected in our study by the presence of significant difference ,in favour of sclerotherapy, in the time needed to return to work after the procedures. This fact has also been shown by many other studies.^{8,9,16,17,18}

For assessing the outcomes of treatment between the two groups, we compared the mean differences in scores of some elements of revised venous clinical severity score.⁵ Improvement of pain and varicose veins post therapy where statistically significant after one week and one month from the procedure in patients treated with sclerotherapy and this goes with many studies.^{11,12,17,19} In an intervention review, Nesbitt et al¹⁸ has revealed that patients treated by foam sclerotherapy have performed better in the short term for the domains bodily pain and physical functioning with no difference in long term improvement of venous clinical severity score. Interestingly a study by Brittenden et al has concluded that quality of life is slightly worse in patient treated by foam sclerotherapy.¹⁵

We think that foam sclerotherapy may be more convenient for many patients and it gains more popularity than surgery because it is an out-patient procedure, feasible, does not need anaesthesia, has minimal post procedural pain, has a fast recovery, comparable results and complications with surgery, scar free (more cosmetic) and less work off time.^{8,9,11,12,13,16,17,18,19} Recurrence rate which is the worse disadvantage of sclerotherapy, can be overcome by easy repeatability of the procedure to decrease the burden of this issue and good selection of patients. The overlapping of the wide spectrum of varicose veins, indications, complications, success rate, and patient preference make the standardization of procedure debatable. For reaching a better conclusion we need more experimental studies recruiting more patients to compare the effectiveness and safety of sclerotherapy in comparison to the conventional surgery and to measure its cost effectiveness in treating varicose veins.

CONCLUSIONS

Sclerotherapy is a low morbidity procedure and can be done as an out-patient procedure for treatment of varicose veins. It has a comparable safety profile to the conventional surgery with a shorter recovery time; however, high recurrence rate is its main disadvantage.

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Abbreviation list: Clinical Aetiologic Anatomic Pathologic (CEAP), Venous Clinical Severity Score (VCSS), Deep Venous Thrombosis (DVT).

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