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Sclerotherapy as the Only Treatment for Varicose Veins

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Abstract

Background: Chronic venous insufficiency (CVI) is a widespread and underdiagnosed condition that affects more than 20% of the general population. The most prevalent manifestation of CVI is varicose veins (VVs), which affect up to 25% of women and 15% of males. Sclerotherapy is a minimally invasive procedure used primarily in treating telangiectasias, reticular veins, and small varicose veins. **Objectives:** This study aims to evaluate the efficacy and safety of various sclerotherapy techniques in treating varicose veins-related complications. **Methods:** We conducted a cross-sectional observational interventional study at Jordan University Hospital (JUH) from September 2022 to January 2023. The study involved patients with lower limb varicose veins, assessing their clinical response and monitoring potential treatment complications. Statistical analyses were performed using SPSS software version 21.0. **Results:** Of 567 patients with diagnosed VVs, 544 were female (95.94%), and 23 were male (4.06%). The primary complaints were pain and cosmetic concerns. Treatments included Foam Aethoxysklerol® 3% (polidocanol) and Micro-foam Aethoxysklerol® 1%. Improvement in symptoms was reported by 538 patients (94.89%). The most common adverse event was hyperpigmentation, reported in 120 patients (21.16%), followed by post-procedural pain in 104 patients (18.34%). Notably, one patient (0.18%) experienced deep vein thrombosis (DVT), one (0.18%) reported telangiectatic matting, and there were two cases (0.36%) of visual disturbances and one allergic reaction. **Conclusion:** Sclerotherapy is effective and safe for treating VVs with minimal adverse events. It is a viable standalone treatment, reducing complications linked to other methods like radiofrequency ablation and surgery.

Keywords

Chronic Venous Insufficiency, Foam Sclerotherapy, Varicose Veins,

Adverse Events

1. Introduction

Chronic venous insufficiency (CVI) is a widespread and underdiagnosed condition that affects more than 20% of the general population [1]. The most prevalent manifestation of CVI is varicose veins (VVs), which affect up to 25% of women and 15% of males [1]. Furthermore, telangiectasias (spider veins) and reticular veins affect more than 80% of men and women [2]. Females, especially those of advancing age, are more likely to develop VVs. Symptoms frequently interfere with daily tasks and result in productivity loss. In addition, VVs may be a purely cosmetic problem that will disrupt the patient's quality of life. Complications of VVs include spontaneous varix rupture with bleeding, superficial thrombophlebitis, deep vein thrombosis (DVT), and venous ulcers.

Various modes of therapy are available, ranging from simple lifestyle modifications to more invasive surgical interventions. Other methods include radiofrequency and endovascular laser ablation and sclerotherapy. Although surgical treatment of VVs is beneficial, it has fallen out of favor because of the expensive cost, time away from work, and procedural complications such as wound infection, hematoma, and nerve damage [3]. For outpatient treatment of VVs, percutaneous interventional techniques such as endovenous laser therapy (EVLT), radiofrequency ablation (RFA) followed by micro-phlebectomy, and chemical sclerotherapy using foam have recently become accessible [4] [5].

Sclerotherapy is a minimally invasive procedure used primarily in treating telangiectasias, reticular veins, and small varicose veins [6]. Patients with chronic venous disease with symptoms and signs that persist and are resistant to medical treatment are candidates for sclerotherapy. Although telangiectasias and reticular veins may be symptomatic, the majority are not, and patients frequently find cosmetic appearance distressing [6]. Although sclerotherapy is relatively safe, patients with symptoms of acute venous thrombosis (superficial or deep) are contraindicated from performing sclerotherapy. In addition, pregnant patients should postpone treatment until after delivery. Relative contraindications include diabetes, peripheral arterial disease, a history of migraine headaches, and patent foramen ovale [7]-[9].

The most common sclerotherapy agents in treating lower extremity chronic venous disease are polidocanol, hypertonic saline, sodium tetradecyl sulfate, and glycerin [10]. Although a proper selection of an agent and balancing dosage will play a significant role in the complications arising, a physician's skills and experience are still vital to successful intervention and fruitful results [11] [12].

Patients experience sclerotherapy and tolerate it well due to its safety, excellent results in a short time, and few unfavorable side effects [13]. Providing results comparable to surgery, slightly disturbing techniques, and cost-time effectiveness have made injection sclerotherapy the most accepted and convenient method of obliterating varicose veins in a substantial group of patients.

This study aims to report safety and efficacy for treating symptomatic VVs, venous ulcerations, and venous angiomata using sclerotherapy techniques in various patients at a Jordanian tertiary center. Also, we look forward to employing injection sclerotherapy as the single intervention among patients with varicose veins of the lower limb, improving the quality of life by reducing pain and alleviating cosmetic concerns, and minimizing any complications contributable to other modes of therapy such as radiofrequency ablation and surgery.

2. Materials and Methods

2.1. Study Design, Area, and Setting

This study is a longitudinal observational interventional study evaluating people with varicose veins in their lower limbs. The observational model used in this study—conducted at the Jordan University Hospital (JUH) from September 2022 to January 2023—was to study a cohort of patients complaining of varicose veins-related complications, treating them with different sclerotherapy techniques and observe the clinical response, efficacy, patient's satisfaction, and monitor possible treatment complications. JUH is a tertiary health care center in Jubeiha, northwest of Amman. JUH serves as a general teaching and research center; it also provides referrals from other Jordanian healthcare centers, making them optimal for data collection and conducting our study.

2.2. Identification of Study Participants

The study population was planned to enroll participants of different demographics, ages, and occupations in the JUH sclerotherapy clinic from September 2022 to January 2023. The inclusion criteria were adult participants of any age who complained of lower limb varicose veins and would sign a consent form. The exclusion criterion was a refusal to sign the consent. The sample size was calculated to be 567 participants.

2.3. Data Collection Process

First, a questionnaire was used to obtain some data regarding patients' medical and surgical history, including the following variables:

1) Demographics.
2) Medical history: history of chronic diseases.
3) History of previous sclerotherapy sessions and if there was any recurrence.
4) Indications for sclerotherapy symptoms before and after treatment sessions.
5) Location of varicose veins.
6) Degree of satisfaction in the previous sessions.
7) Complications of sclerotherapy.

Accordingly, patients will be followed up in the sclerotherapy clinic by taking their history, performing a physical examination, doing a duplex ultrasound, and making mobile phone calls to assess the clinical response, degree of satisfaction, and possible development of complications.

2.4. Data Analysis

Statistical analyses are performed using Statistical Package for the Social Sciences (SPSS) software version 21.0 (IBM Corp., Armonk, NY). Descriptive statistics were used to describe the data. All continuous numerical variables will be expressed as the mean ± standard deviation (SD), whereas categorical variables will be explained in frequencies/percentages. The chi-square test or Fisher's exact test was used as appropriate to analyze the relationship between the outcome and any categorical variable. The student's t-test evaluated the relationship between the output and any continuous variable. The p-value for statistical significance was declared as 0.05. We will focus on the outcome of sclerotherapy as the only treatment for varicose veins.

2.5. Ethical Consideration

The research proposal was submitted to obtain approval from the scientific research committee and institutional review board (IRB) at JUH. In addition, patients were recruited voluntarily, and written consent was obtained from participants to ensure voluntary participation, as the researcher will inform them about the study's aim and confidentiality.

2.6. Technique

All patients underwent a duplex ultrasound study before the sclerotherapy session, either for the great saphenous and small saphenous or the targeted veins. According to the results, all patients with mild or no reflux were included in our study and underwent sclerotherapy. Large veins were treated with direct foam sclerotherapy. All patients with foam sclerotherapy were followed up with a duplex ultrasound study, which showed obliteration of varicose veins.

Telangiectasias, reticular veins, spider veins, and small varicosities (<6 mm) are treated using a liquid polidocanol 1%, whereas more prominent veins (≥6 mm) are treated using a foam polidocanol 3%. Medium and large-sized veins are injected with foam polidocanol 3% under ultrasound guidance. The patient is placed in a prone or supine position; some patients need to be placed in the Trendelenburg position, which helps empty the veins from the blood and approximate the vein walls from each other. We identified the targeted veins using a very light illuminator. The skin over the vein is cleaned with alcohol, and a small needle (27- or 30-gauge) is inserted into the vein. A syringe containing polidocanol solution or foam is attached to the needle, and the sclerosant is injected into the vein. The amount and concentration of polidocanol depend on the size and location of the vein. The needle is withdrawn, and pressure is applied to the injection site to prevent bleeding. A bandage or compression stocking may be applied to the treated area. The procedure is repeated for other veins as needed. The whole session usually takes 15 to 30 minutes.

3. Results

A total of 567 patients with a known diagnosis of VVs underwent injection sclero-

therapy, including 544 female patients (95.94%) and 23 male patients (4.06%). The mean age was 44.5 years (SD = 12.74). Regarding comorbidities, 81 (14.29%) patients were known to have hypertension, 56 (9.88%) were diabetic, 25 (4.4%) had been diagnosed with dyslipidemia, and 10 (1.76%) were asthmatic. Additionally, 19 (3.35%) patients had a previous history of deep vein thrombosis (DVT). The most common location of VVs was in the great saphenous vein in 515 (90.83%) patients. Patients with a family history of VVs were found to be 229 (40.39%), and the other 338 (59.61%) did not report a family history of VVs. The patients' occupation was studied, and it yielded that most patients were either teachers, nurses, or housewives, either retired or on top of their work. They were represented by 167 (29.45%) teachers, 120 (21.16%) nurses, and 80 (14.10%) housewives. The two main complaints necessitating sclerotherapy among our sample were pain, especially with prolonged standing, and cosmetic concerns. Pain accounted for 191 (33.69%) and cosmetic concerns for 221 (38.98%) patients. Patients treated using Foam Aethoxysklerol®3% (polidocanol) were 337 (59.44%), whereas 230 (40.56%) patients underwent Micro-foam Aethoxysklerol® 1% treatment, with a median number of sclerotherapy injection frequencies of 4 times (Table 1).

Table 1. Variables of the study sample (N = 567). The mean age of 44.51 years (SD = 12.74). The median number of injection frequency = 4.

Variable	Frequency	%
Gender		
Female	544	95.94%
Male	23	4.06%
Comorbidity		
Hypertension	81	14.29%
Diabetes mellitus	56	9.88%
Dyslipidemia	25	4.4%
Asthma	10	1.76%
History of DVT		
No	548	96.65%
Yes	19	3.35%
Location of VV		
Great saphenous vein	515	90.83%
Great and small saphenous vein	38	6.7%
Small saphenous vein	14	2.47%
Symptoms before treatment		
Cosmetic concerns	221	38.98%
Pain	191	33.69%
Pain and cosmetic concerns	145	25.57%
Discomfort	10	1.76%

Continued

Use of compression therapy		
No	483	85.19%
Yes (after treatment)	83	14.64%
Yes (before treatment)	1	0.18%
Type of agent used		
Foam Aethoxysklerol® 3%	337	59.44%
Micro-foam Aethoxysklerol® 1%	230	40.56%
Family history of VV		
No	338	59.61%
Yes	229	40.39%
Occupation		
Teacher	225	39.67%
Nurse	120	21.16%
Housewife	80	14.10%
Government employee	36	6.35%
Student	30	5.29%
Bank employee	18	3.17%
Freelance	16	2.82%
Accountant	14	2.47%
Doctor	9	1.59%
Dietitian	5	0.90%
Dentist	4	0.71%
Engineer	4	0.71%
Personal trainer	3	0.53%
Information technology	3	0.53%

VV: varicose veins; DVT: deep vein thrombosis; Aethoxysklerol®: polidocanol.

The number of patients reporting symptom improvement was 538 (94.89%); pain and tightness upon standing were the most reported symptom improvement. However, minimal adverse events (AE) were associated with the sclerotherapy procedure. One hundred and twenty (21.16%) patients reported hyperpigmentation near/at the injection site, making it the most reported adverse event. This is followed by pain after the procedure, which accounted for 104 (18.34%) patients. Ninety-one (87.5%) patients did not require any analgesic medication, and 13 (12.5%) patients required over-the-counter analgesia. In addition, only one patient (0.18%) reported an episode of DVT after the initial session, another one (0.18%) reported telangiectatic matting, and two (0.36%) reported visual disturbances. Moreover, one allergic reaction event was reported (Table 2).

Table 2. Adverse events.

Adverse events	Frequency	%
Hyperpigmentation	120	21.16%
Pain after the procedure	104	18.34%
Not require analgesia	91	87.5%
Require analgesia	13	12.5%
Neurological/Visual disturbance	2	0.36%
Deep vein thrombosis	1	0.18%
Telangiectatic matting	1	0.18%
Allergic reaction	1	0.18%
Ulceration	0	0
Thrombophlebitis	0	0

When investigating hyperpigmentation and the type of agent used, no difference was found as 40 (7.12%) of patients and 32 (5.65%) of patients developed hyperpigmentation after foam 3% and micro-foam 1% treatment, respectively (p-value = 0.6013).

Moreover, no association was found between age and hyperpigmentation development (p-value = 0.385). Finally, 560 (98.8%) patients denied any varicose veins recurrence at the same injection site.

4. Discussion

In this study, our findings pretend that the sclerotherapy procedure effectively obliterates symptomatic VVs in the outpatient clinic. Overall, effective obliteration of VVs and symptomatic improvement were achieved in 94.89% of patients after the initial session. These results were observed and evidenced by the physical examination and duplex ultrasonography one week after the initial session. Patients concerned about cosmetic issues and pain with long-standing were significantly satisfied, as proved by using a satisfaction survey. These results concord with Nael's study, which showed 99% complete obliteration of VVs and symptomatic improvement in 93% of patients after the initial sclerotherapy session [14] [15]. A meta-analysis conducted by Rathbun proved that the great saphenous, small saphenous, and tributary veins were all treated with foam sclerotherapy, with an occlusion rate of 85%. Eighty-two to 90% of patients reported cosmetic improvement and symptom relief [16]. Our patients were followed up for any recurrence of varicosities, and 98.8% of them denied any recurrence at the same injection site. In contrast, Jia discovered that 96 studies of treating venous disorders revealed an 8.1% recurrence rate and an overall occlusion rate of 87.5% [17]. Thus, foam sclerotherapy exhibits great results that rival surgery and other methods. In addition, another meta-analysis conducted by Rathbun did a comprehensive and extensive search of the literature in multiple databases to further investigate foam sclerotherapy's safety and effectiveness profile. Over 90% of cases had

relief of symptoms as reported, with an 85% occlusion rate of varicosities, which would compete with laser treatment results [18]. More recently, a comparative meta-analysis compared surgery and endovascular approaches, suggesting low-quality data implies that surgery and endovascular techniques are on the same level in treating varicose veins and that surgery caused more dysfunction and pain [19]. Considering the previous reviews, the Society for Vascular Surgery and American Venous Forum approved sclerotherapy to treat reticular veins, varicose veins, and telangiectasias. It subtracted surgery advice to treat varicose veins originally accompanied by axial reflux [20]. On the other hand, we found that patients with a family history of VVs have an increased incidence of development of VVs that require sclerotherapy compared with the normal population. Also, we observed a higher recurrence rate after treatment sessions among these patients. These results concorded with Seyam and AlBader's studies [15] [21]-[25]. Although most patients in our study did not have a previous history of DVT, we found that 19 (3.35%) patients had secondary VVs due to CVI caused by previous DVT. Consequently, this will increase the incidence of recurrent VVs even after treatment sessions. Baylis concluded that race also appears to influence the risk of acquiring VVs, with the Black population having the greatest rates of VTE, followed by the White, Hispanic, and Asian populations in that order [25]. Interestingly, during observation, we found that people with darker skin have a higher tendency to develop hyperpigmentation after sclerotherapy sessions. Moreover, occupations that require prolonged standing, such as teachers and nurses, are found to be more predisposed to develop VVs that require sclerotherapy of various indications. The results of the Busbai study and others conducted on teachers and nurses support our findings [21] [22] [26] [27].

Sclerosing agents can be classified into detergents, chemical irritants, and osmotic agents. The usual techniques for treating VVs are liquid, foam, and microfoam sclerotherapy. Our study used foam polidocanol (Aethoxysklerol®) 1% and 3%. Multicenter research compared Polidocanol 0.5% and 1.0% to placebo. The VVSymQ score was used to assess patient improvement in symptoms at 4 and 8 weeks, and it showed distinguishable improvements in patients receiving 0.5% and 1.0% polidocanol compared to placebo. Regarding total symptom burden, there was a 64% reduction in patients undergoing polidocanol treatment, in contrast to a 22% reduction in the placebo group. Moreover, this symptom improvement was noticeable regardless of the use of intensity or duration scales to measure symptom relief. Cosmetically, polidocanol remains superior to a placebo, as evidenced by patients and physicians reporting improved appearance [28]. When comparing liquid and foam sclerotherapy, foam is a better technique. In two trials involving 75 or more patients, the obliteration rate for foam-treated patients was 94.4%, and approximately 70% of patients had a successful treatment; liquid sclerotherapy, on the other hand, had an obliteration rate of 53%, and only 27% of patients had a successful course of treatment [29] [30].

Although sclerotherapy is considered a safe and effective procedure, it has some

local and systemic adverse events (AE). In our experience, dermal pigmentation is the most common AE observed after sclerotherapy sessions, accounting for 120 (21.16%) patients. This is concorded with Coyne and Yiannakopoulou, in which the incidence of transient hyperpigmentation ranges from 0.3 to 30%. Post-sclerosis hyperpigmentation appears along the course of varicose veins treated with sclerotherapy. It can be temporary or permanent. Even though hyperpigmentation may persist for several months, 70% of patients revealed spontaneous resolution within 6 months and with 99% of resolution occurring in 1 year. Persistence of staining after 1 year is considered permanent hyperpigmentation, which affects around 1% - 2% of patients [4] [31].

The second most common AE reported was the pain that developed after the procedure, which accounted for 104 (18.34%) patients. Most of them did not require any analgesia, and a minority of patients used over-the-counter analgesics. Polidocanol (Aethoxysklerol®) is the agent that causes the least pain upon injection, as shown by a review by Tisi [32]. Additionally, we observed in our study that patients experienced mild pain that spontaneously resolved after a short period. On the other hand, the most painful sclerosant agents are hypertonic saline and glycerin, particularly if they are used without local anesthetic [33]. Pain at the injection site is frequently reported after sclerotherapy treatment sessions [4] [13] [31] [34] [35]. Palm proved that around 25.6% of patients experienced post-procedural pain. Patient-reported pain was typically mild and probably due to the phlebitic reaction of sclerotherapy agents, especially with hypertonic saline; thus, it is usually used with a local anesthetic to reduce the pain [4] [13].

Telangiectatic matting or post-sclerotherapy neovascularization refers to the small red telangiectasias around the sclerosed vein. Only one patient (0.18%) reported this local AE, which arises in about 15% - 20% of patients treated with sclerotherapy. Matting is composed of an unpredictable individual reaction of the patient that appears after the surgical removal of the vein [36]. The cause of matting remains unclear. It has been suggested that this represents either dilating preexisting subclinical vessels or angiogenesis due to inflammatory processes and vascular obstruction. It appears as a patchy pigmentation with onset 4 - 6 weeks posttreatment. Technique-related precautions include utilizing the lowest sclerosant concentration, minimal volumes, and low pressure while treating a vein. Telangiectatic matting is temporary and disappears 3 - 12 months after treatment [37]. Nevertheless, matting can also be permanent. The initial step in treating matting is to look for untreated proximal reflux from saphenous veins, perforators, tributaries, or reticular veins [37]. Glycerin, however, has a low risk for telangiectatic matting [37].

The incidence of superficial thrombophlebitis after sclerotherapy varies, ranging from 0.1% - 1.2% [13] and 4% - 7.5% [4], and occurs mainly after treating large varicose veins. It usually develops after a few weeks of treatment sessions and involves various segments of the treated vein proximal and distal to the injection site. Uurto showed that the incidence of superficial thrombophlebitis would

increase with a high concentration of sclerosant agent and short-term bandage application after the treatment session. Thus, recommendations suggest using the minimum effective concentration of sclerosant agents and encouraging patients to wear the initial bandage for 3 days and nights, after which 2 to 3 weeks of compression hosiery or bandage. On the other hand, ulceration is extremely rare to develop after lower limb varicose vein treatment with sclerotherapy, even with a high concentration of sclerosant agents [13].

Applying long-time compression after a sclerotherapy session is unnecessary for 85.19% of our patients. This is supported by other studies that compared patient satisfaction and recovery following sclerotherapy with and applying external compression [38].

Additionally, our findings showed that two (0.36%) patients reported visual disturbances after the initial sclerotherapy session. Transient visual disturbance is the most reported adverse event of clinical significance [4] [39]-[42]. Their incidence varies among different studies in literature and ranges between 1.4% - 14% of patients and is probably dose-related [4] [40]. It occurs after liquid and foam sclerotherapy but is more common with foam preparations [40] [41]. Uurto evidenced that the most frequent complication after foam sclerotherapy is visual disturbances, estimated at 0.5 - 1 per 100 treatment sessions [11] [34]. In addition, quadrantanopia, hemianopsia with a Moire effect, and scintillating scotomas are more frequent than other visual defects [13] [40].

Severe thromboembolic events (proximal deep vein thrombosis (DVT), pulmonary embolism (PE)) extremely infrequently take place [43] [44]. The frequency of DVT varies depending on the practitioner, the procedure, and the patient's medical history, specifically whether they smoke or have thrombophilia. For example, after receiving polidocanol treatment, the frequency of DVT has been reported to range from 0% to 0.14% in large groups [45]. Also, it is described in Jia and Dermody's meta-analyses as 0.6%, while the overall frequency of thromboembolic events is less than 1%, and distal DVT is shown to be predominant [17] [46]. Interestingly, these results are concorded with ours in which only one case (0.18%) of DVT was recorded and discovered by clinical suspicion and ultrasound findings. Many patients are asymptomatic and are found during normal follow-up examinations using duplex ultrasonography [11] [40] [46]. The risk of thrombosis increases with the injection of high volumes of sclerosant, particularly foam sclerosants [42]. Also, people with a family history of thromboembolism or thrombophilia have additional risk [47]. A thorough risk-benefit analysis must be done for patients with these risk factors, and extra safety measures should be adopted. Additionally, consideration should also be given to other risk factors, such as obesity or a lack of mobility.

Allergic reactions associated with sclerotherapy rarely occurred. One case of non-fatal allergic response was observed after the injection of polidocanol. Yiannakopoulou concluded that 7 cases of non-fatal anaphylactic shock were reported after polidocanol exposure. Two of them had taken the drug for the first time [4].

However, four cases of anaphylactic shock resulting in death have been reported in patients who received STS. One of them had a history of asthma, which precludes the administration of STS [4].

5. Conclusion

Sclerotherapy has proven to be an effective and safe treatment for varicose veins, demonstrating a high rate of symptom relief and minimal adverse events. With an impressive improvement rate of 94.89% among patients, this minimally invasive procedure offers a compelling alternative to more invasive interventions such as surgery and radiofrequency ablation. The findings underscore the viability of sclerotherapy as a standalone treatment, capable of addressing both functional and cosmetic concerns related to varicose veins, thereby enhancing patients' quality of life while minimizing complications. Further research may reinforce these findings and explore long-term outcomes, solidifying sclerotherapy's role in managing chronic venous insufficiency.

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The Ethics Statement

The Institutional Review Board (IRB) approval:

The Institutional Review Board (IRB) at the Jordan University Hospital, the University of Jordan (IRB-JUH) convened on July 2, 2023. It evaluated the research proposal presented by Dr. Moaath Alsmady, which was entitled Sclerotherapy as the only treatment of varicose veins.

Decision No. (64/2023).

The ethics approval reference/number: 10/2023/4134.

Date: 15/2/2023.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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