

# Venous Malformations Sclerotherapy: Outcomes, Patient Satisfaction and Predictors of Treatment Success

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## Abstract

**Purpose** To retrospectively evaluate the results of sclerotherapy for venous malformations, with emphasis on patient satisfaction, complications and predictors of positive response to treatment.

**Materials and Methods** Three hundred and nine patients were treated with ethanol sclerotherapy for venous malformations in our center between the years 2000 and 2014. All of them were sent a self-assessment questionnaire for evaluation of their satisfaction and treatment complications. In total, 153 patients (mean age 21, range 6 weeks to 67 years) responded to the questionnaire. We analyzed clinical and imaging data from the medical records of these patients.

**Results** Sixty-four (42%) patients had venous malformations in the lower extremities, 35 (23%) in head and neck regions, 33 (22%) in the trunk, 14 (9%) in the upper extremities and 5 (3%) in the buttock and genitalia. Complete relief of swelling, pain, functional and esthetic

complaints was reported in 23%, 22%, 17% and 12% of patients, respectively. Thirty-eight (25%) patients reported being very satisfied with treatment outcomes, 55 (36%) were satisfied, 49 (32%) were not satisfied and 11 (7%) were very unsatisfied. We did not find significant correlations between patient satisfaction and demographics characteristics, lesion location, lesion size, tissue involvement or total sclerosant quantity. The rate of class 3 complications was 7% and that of class 4 complications was 2%.

**Conclusion** Ethanol sclerotherapy is an effective treatment for venous malformations. Nonetheless, this treatment has a significant complication rate. Patient satisfaction is independent of lesion characteristics and is not as high as may be expected.

**Keywords** Sclerotherapy · Venous malformation · Patient satisfaction

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## Introduction

Venous malformations (VM) are the most common subtype of vascular malformation, classified as low-flow, simple vascular lesions [1]. Despite being congenital, VM may manifest at any age, with high heterogeneity in location and size [2], and have potentially major impact on quality of life. VMs tend to grow with time, sometimes as a reaction to various triggers, and cause pain, swelling, physical dysfunction and cosmetic aggravation [2, 3]. Percutaneous sclerotherapy was recognized as the first-line invasive treatment method [3, 4] as technological

development and imaging diagnosis advanced. The main goal of sclerotherapy is to cause a cascade of endothelial damaging, thrombosis and fibrosis, which in turn minimize symptoms by reducing VM structure [5]. While a variety of substances have been proven to be successful sclerosing agents [6, 7], ethanol is described as one of the most frequently used sclerosant among them. However, due to its relatively high complication rate, careful administration is recommended [1, 3, 4, 6, 8, 9].

The literature indicates no consensus regarding how to assess the effect of sclerotherapy [6, 8, 9]. While methods of measuring both imaging and clinical outcome vary among studies, only few considered the patients' overall satisfaction from therapy as a main indicator of success. Several studies have demonstrated a correlation between patients' responses to treatment, and factors such as lesion features and demographic characteristics [10–17]. Unfortunately, the existing knowledge on this subject is far from being well established and broader trials are still required. The purpose of this study was to retrospectively analyze treatment outcomes and patient satisfaction, and to identify predictors for successful sclerotherapy among patients with VM.

## Materials and Methods

### Study Design

This was a retrospective clinical study conducted at a tertiary care center between the years 2000 and 2014. Before conducting the study, institutional review board approval of the protocol was obtained. We reviewed electronic databases and imaging findings and constructed a self-assessment questionnaire aimed at analyzing assorted variables to identify predictors of positive response to sclerotherapy.

### Patients

All patients who were diagnosed with venous malformations and were treated with intra-lesional sclerotherapy in our institution between the years 2000 and 2014 were considered for this study. Exclusion criteria included patients who had no electronic medical records and patients who underwent additional treatments in another center. A total of 310 cases were systematically identified as fitting these criteria. From these were excluded 151 patients who could not be traced due to incorrect contact details or a lack thereof, four patients who refused to participate in the study and two patients who died during the follow-up period. The remaining 153 patients were included in the study after a filled-in questionnaire was provided by the

patient. In cases where the patient was under the age of 10 at the time of follow-up, the questionnaire was filled together by the patient and his parent. The demographic and clinical data were extracted from their electronic files.

### Pre-treatment Status and Evaluation

The diagnosis of all participating patients was based on clinical findings along with noninvasive imaging modalities such as ultrasound and MR imaging [1, 2, 4]. The VM's location was categorized as either head/neck, lower extremities, upper extremities, trunk or buttocks/genital area. All clinical findings and pretreatment imaging results were retrieved from patients' records and radiologic archives. Lesions were assessed by MRI for their size, demarcation and infiltration to proximal structures, and were classified as either subcutaneous, intramuscular or involving bone structure demarcation of the VM was categorized as either well-defined or ill-defined.

### Procedure

The decision to use sclerotherapy treatment was based on assessing the severity of symptoms and the risks of intervention. The option of subsequent procedures after each session was discussed jointly by the patient and the interventional radiologist, taking into consideration the goals and the patients' response to previous treatment. Patients who turned with recurrences of worsening in symptoms were treated according to the severity and intensity of the clinical symptoms, regardless of its cause. All treatments were conducted after informed, written consent was provided by the patient or their parent. Sclerotherapy was administered in all patients under general anesthesia and by an interventional radiologist who specializes in the field of vascular malformations sclerotherapy. Rather than adhering to a uniform protocol, the treatment was personalized and tailored to each lesion according to the variability of each VM manifestation. Prior to sclerotherapy administration, direct puncture contrast material fluoroscopy was used to evaluate the VM's volume and to characterize the venous drainage from the lesions. Lesions were defined, according to the angiographic examination, as having immediate or late visualization of the drainage vein. One or more direct punctures of the lesion were performed using a 21 g needle, and 96% ethanol (Concept-Rx, Kfar-Saba' Israel) was injected under fluoroscopy guidance. In certain patients, and at the acting physician's discretion, additional substances such as a 3% Atossisclerol (Lauromacrogol 400, Kreussler & Co, Como, Italy) solution and/or bleomycin were added. The total volume of injected substance was based on the lesion's volume and location and on the patients' weight. The amount of ethanol never exceeded

1 ml/kg and was usually less than 0.5 ml/kg. After sclerotherapy, analgesic was used as needed. Patients were examined on the following day. If infection had developed at the site of injection, an antibiotic was prescribed.

### Outcome Assessment

Treatment complications were described upon their occurrence and were categorized according to the CIRSE classification system [18]. All patients received an informative letter via postal mail with a notification regarding our intent to contact them. The letter was followed by a telephone call obtaining verbal consent from patients or their parents, and a self-assessment questionnaire was administered. In keeping with the literature, the questionnaire was based on the same grading principles used by Van der Linden [19], and others [15, 20]. Patients were requested to answer whether they had specific symptoms of pain, swelling, functional limitations, cosmetic disfigurements or any additional symptoms before receiving sclerotherapy treatment. The improvement of each symptom was assessed using a four categories grading scale: significantly improved, slightly improved, did not change and worsened. Additionally, patients were asked to indicate whether they were significantly satisfied, slightly satisfied, unsatisfied or significantly dissatisfied from their treatment. For the purposes of this study, patients who gave one of the two former responses were categorized as the “satisfied group” and those who gave one of the two latter responses were categorized as the “dissatisfied group”. Lastly, patients were asked to describe any other complications that occurred after therapy and whether there was any permanent damage. Findings were arranged according to these symptoms’ prevalence.

### Statistical Tools

Statistical analysis was performed using IBM’s SPSS Statistics 21.0 for Windows. A value of  $p < .05$  was considered as statistically significant. To determine the predictors of positive response to sclerotherapy treatment, analyses were conducted using demographic, clinical and treatment variables. Continuous variables were analyzed via student’s  $t$  tests that compared the “satisfied group” and the “dissatisfied group”. Pearson’s Chi-squared or the Fisher’s exact test were used to analyze categorical variables.

### Results

A total of 403 sclerotherapy sessions were performed on 153 patients (Seventy-eight women and 75 men). Patients’ mean age upon treatment onset was 21 years, with a range

of 0.1–67 years. The mean follow-up period was 44 months, with a range of 4–122 months. Demographic and clinical data are presented in Table 1. Most of the lesions were located in the extremities (65%) and only a third was distributed over the remainder of the body’s surface. One patient had a venous malformation that involved both groin and hip, and one had multiple lesions, located both in upper and lower extremities. One hundred and thirty patients (85%) had pre-procedural MR imaging records. The other twenty-three patients (15%) were evaluated using ultrasound imaging, as they all had small, superficial lesions. Forty-five of the 153 patients (28%) required over two sclerotherapy sessions. Details regarding sclerotherapy procedures for VM patients are displayed in Table 2.

Local symptoms immediately after treatment were common as expected [6, 20] and included pain ( $n = 50$ ), swelling ( $n = 50$ ), hematoma ( $n = 24$ ), stiffness ( $n = 24$ ) and neurologic complaints ( $n = 14$ ) in the injection site. Mostly, these issues were temporary and faded gradually

**Table 1** Demographics and clinical data of VM patients

Variables	$n = 153$ patients (%)
Gender	
Women	78 (51%)
Men	75 (49%)
Location of VM*	
Head and neck	35 (23%)
Lower extremities	66 (43%)
Upper extremity	34 (22%)
Trunk	14 (9%)
Buttocks and genital area	6 (4%)
VM’s size before treatment	
< 5 cm	61 (40%)
> 5 cm	92 (60%)
Tissue infiltration	
Subcutaneous only	32 (21%)
Muscle involvement	57 (37%)
Bone or joint involvement	46 (30%)
Not reported	18 (12%)
Demarcation of the VMs	
Well-defined	63 (41%)
Ill-defined	71 (46%)
Not reported	19 (13%)
Drainage vein visualization	
Immediate	86 (56%)
Delayed	64 (42%)
Not reported	3 (2%)

\*One patient had a venous malformation that involved both groin and hip, and one had multiple lesions, located both in upper and lower extremities

**Table 2** Details of percutaneous ethanol sclerotherapy for VM patients

Variables	<i>n</i> = 153 patients (%)
Total volume of injected ethanol, mean, in mL	34 (1–783), SD 76
Number of sessions/patient, mean	2.63 (1–20), SD 2.9
1–2 sessions	111 (73)
3–9 sessions	35 (23)
≥ 10 sessions	7 (5)
Sclerosing agent used	
Only ethanol	128 (84)
Ethanol with atosisclerol	22 (14)
Ethanol with bleomycin	2 (1.3)
Ethanol with atosisclerol and bleomycin	1 (0.65)

without intervention during the following days to weeks (complication grade 1). Three patients had a local infection which required systemic antibiotic administration: one had recurrent secretions, one patient's wound required draining and one case resulted in an extensive wound that required plastic surgical intervention (complication grade 3). Nine patients had a permanent scar at the site of injection (complication grade 4) out of which two had also systemic, life threatening complications: one patient with large chest wall and mediastinal lesion suffered from acute pulmonary hypertension after 55 ml of ethanol injection (weight 65 kg). Another patient with large pedunculated VM located in the buttock suffered from treatment-related septicemia after the fifth sclerotherapy, where ethanol + polideconol were used. Both cases required a 24-h stay in an intensive care unit. One patient with a 17 cm lesion involving the groin and hip suffered from a sensorial injury that was only resolved a year afterward, and another patient with lower limb VM was caused permanent nerve damage that resulted in atrophy of the leg (Complication grade 4). In both patients, the lesion involved the muscle and less than 20 ml of ethanol was used. Neither anesthesia-related complications nor death related to therapy was observed in our series.

Symptoms experienced prior to treatment and their change following sclerotherapy as reported in the self-assessment questionnaire are summarized in Table 3. Pain and swelling were the most common symptoms. Functional limitation and cosmetic disfigurement were both reported by over half of the patients.

Table 4 summarizes the univariate analyses of predictors for patients' satisfaction rates after sclerotherapy treatment. No significant difference was found based on any of the variables describing the lesions or the patients' features. Neurological or permanent damage caused by therapy was found to be negative predictors for patient satisfaction ( $p < .018$ ). No other tested variables were significantly identified as having predictive value for patients' satisfaction from therapy. Patients treated with over 15 ml ethanol

tended to develop more complications that resulted in permanent damage (35%) than those treated with less than 15 ml ethanol (11%;  $p < .001$ ). No other variables were found to be significantly associated with complications.

## Discussion

Percutaneous sclerotherapy is considered to be a very effective treatment for VM. Nevertheless, its outcomes have been evaluated differently among studies in the literature, who used varying methods of assessment [4, 6, 8, 9, 20, 21]. While the definition of sclerotherapy success is still vague, this study uses the subjective evaluation of ethanol sclerotherapy from the patient viewpoint. Our sample includes a relatively large number of patients and distributed lesion sites, such as the neck, buttocks and genital locations which may be challenging to treat. In our results, 25% of the patients reported being "significantly satisfied" and 36% reported being "satisfied". These rates correspond to the results obtained by Linden [19], in which 53% of patients reported being satisfied, while Nakamura's results [15] pointed to an 80% satisfaction rate from VM therapy in the extremities. In the analysis of Horbach [17] which was based on patient-reported outcomes following bleomycin sclerotherapy, the satisfaction with the treatment procedure received a median rating of 7 in a 0–10 scale.

Information regarding factors that may predict the patients' responses to treatment may help identify the candidates who stand to benefit the most from treatment, as well as establish its limitations. Puig [22] and Yun [16] described the VM's draining vein visualization using venography, as a tool for predicting complication rates during sclerotherapy. Some studies suggested that smaller lesions tend to respond better to therapy [10, 14, 15, 23]. Osseous infiltration of the VM was associated with symptom recurrence [12] and with patient dissatisfaction [15]. Berenguer [13] reported that the higher the number of sessions, the better the response, while the results of Nakamura [15] suggest the opposite. The

**Table 3** Clinical outcomes and degree of satisfaction after sclerotherapy assessed by questionnaire

Symptom	Significantly improved (%)	Slightly improve in symptom (%)	No change in symptom (%)	Symptom worsening (%)	Total prevalence before the treatment (%)
Pain	32 (28)	43 (38)	30 (34)	8 (7)	113 (74)
Swelling	36 (30)	49 (40)	29 (24)	8 (6.5)	122 (80)
Cosmetic disfigurement	19 (22)	37 (42)	28 (32)	7 (8)	88 (58)
Functional limitation	27 (34)	20 (25)	27 (34)	5 (6)	79 (52)
	Significantly satisfied	Slightly satisfied	Unsatisfied	Significantly dissatisfied	
Patient satisfaction	38 (25)	55 (36)	49 (32)	11 (7)	

**Table 4** Variables tested in univariate analysis to predict the patient satisfaction rates after sclerotherapy treatment

Variables	<i>p</i> value	OR	95% CI for odds	
			Lower	Upper
Gender	0.321	1.456	0.758	2.798
VM location	0.208	0.532	0.222	1.276
VM's size before treatment	0.595	1.000	0.998	1.001
VM demarcation	0.725	1.139	0.566	2.289
Tissue involvement	0.613	0.825	0.339	2.005
Draining vein	0.063	0.509	0.257	1.008
No. of sessions	0.438	0.949	0.436	2.062
Total ethanol injected	0.827	1.218	0.635	2.336
Permanent damage after therapy	0.018	2.567	1.187	5.548

characteristics of lesion margins in MRI [10, 14–16, 23] have also been shown to have a predictive value. In our research, we did not find a significant correlation between patient satisfaction from therapy and any of the following variables: age, gender, VM size and site, tissue involvement, number of sessions or amount of injected sclerosing agent.

Complication rates in this sample are consistent with those reported in the literature. Grade 3 complication rate was 2% ( $n = 3$ ), and grade 4 complication rate was 7% ( $n = 11$ ). We also noticed that after sclerotherapy, a temporary symptom of swelling was found to occur significantly more often in patients whose malformations were located in the head and neck areas. The correlation between the amount of injected ethanol and treatment complications was also demonstrated.

Among patients who suffered from pain, swelling, cosmetic disfigurement and functional limitations before treatment, 28%, 30%, 22% and 24%, respectively, reported of symptom alleviation. In comparison with previous studies that used similar evaluation techniques, these rates are lower than those in Linden's [19], Nakamura's [15] and Horbach's [17] reports, but comparable to those reported in Yun's [16] study, which was conducted on 158 patients.

This study has important limitations. Firstly, it was conducted retrospectively, and data reported by patients carry the disadvantage of recall bias. Secondly, in this work we did not consider potential triggers for recurrence of worsening, such as hormonal changes or trauma, which might influence the natural history of the malformation and consequently the patient symptoms and satisfaction in the long term. Furthermore, patient satisfaction from treatment may be influenced by subjective experiences that were not measured in this study, such as inter-personal interactions between the patient and the medical staff and sometimes the patients' complex characters.

In conclusion, sclerotherapy will be the treatment of first choice for most patient with Venous Malformations, but with a noteworthy failure rate from the patient point of view. Ethanol sclerotherapy alleviates at least some of the symptoms in the majority of patients, and both temporary and permanent complications are common. Taking this work together with previous studies, it is still difficult to predict which VM lesions or patients will respond better to sclerotherapy based on measured parameters. Creating realistic expectations both for patient and the medical team is crucial for patient satisfaction from therapy and the appropriate patient selection.

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#### Compliance with Ethical Standards

**Conflict of interest** On behalf of all authors, the corresponding author states that there is no conflict of interest.

**Ethical Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

**Informed Consent** For this type of study formal consent is not required, as individual patients indirectly consent to participate in the study when completing the questionnaire.

## Questionnaire

Date \_\_\_\_\_ Name \_\_\_\_\_ ID number \_\_\_\_\_

1. This questionnaire is being filled in by

- The patient
- A patient's parent or legal guardian (in the case of children under 16)

2. Have you suffered from one or more of the following symptoms prior to treatment?

- Pain
- Swelling
- Functional limitations
- Cosmetic complaints
- If you experienced any further symptoms, please describe them:  
\_\_\_\_\_

3. If you experienced one or more of the mentioned symptoms, what was the nature of your experience with this symptom after treatment?

- |                               |  |   |                                 |                                |
|-------------------------------|--|---|---------------------------------|--------------------------------|
| <b>Pain</b>                   | <input type="radio"/> Significantly improved | <input type="radio"/> Slightly improved | <input type="radio"/> No change | <input type="radio"/> Worsened |
| <b>Swelling</b>               | <input type="radio"/> Significantly improved | <input type="radio"/> Slightly improved | <input type="radio"/> No change | <input type="radio"/> Worsened |
| <b>Functional limitations</b> | <input type="radio"/> Significantly improved | <input type="radio"/> Slightly improved | <input type="radio"/> No change | <input type="radio"/> Worsened |
| <b>Cosmetic complaints</b>    | <input type="radio"/> Significantly improved | <input type="radio"/> Slightly improved | <input type="radio"/> No change | <input type="radio"/> worsened |
| <b>Other</b>                  | <input type="radio"/> Significantly improved | <input type="radio"/> Slightly improved | <input type="radio"/> No change | <input type="radio"/> worsened |

4. How long after treatment did you notice improvement, if at all?

After \_\_\_\_\_ treatments/ After \_\_\_\_\_ weeks

5. If relapse occurred, how long after treatment did the symptoms return?

\_\_\_\_\_

6. Were you generally satisfied with the effects of the treatment?

- Significantly satisfied
- Slightly satisfied
- Slightly dissatisfied
- Unsatisfied

7. Have you suffered from one or more of the following side effects and/or complications after treatment?

- Pain
- Swelling
- Functional limitations
- Scar / wound / necrosis / cosmetic changes of the skin
- Neurological complaints
- Hematoma
- Other:  
\_\_\_\_\_

8. For how long after the treatment did you suffer from side effects?

\_\_\_\_\_

9. Please indicate whether you underwent any treatment for complications

\_\_\_\_\_

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