Evaluation of the efficacy of duplex-guided foam sclerotherapy in the management of low-flow vascular malformation

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Objectives
The main objective of this prospective study was to clarify the therapeutic efficacy and tolerance of duplex-guided polidocanol foam injection in the treatment of low-flow venous malformations (LFVM), residual symptomatic hemangiomas after medical treatment, and Klippel-Trenaunay syndrome (KTS) performed at Vascular Surgery Department at Zagazig University Hospitals.
Patients and methods
This prospective study included 36 patients divided into three groups: 17 cases with LFVM, 11 cases with vascular tumors (hemangiomas), and eight cases with KTS. All cases were treated by duplex-guided polidocanol foam sclerotherapy.
Results
The study included 20 (56%) males. The mean age of the patients was 15.19 years. The final outcome was good response regarding the decrease in size and symptoms in 13 cases of LFVM, six cases of hemangiomas, and six cases of KTS. The remaining four cases of LFVM, five cases of hemangiomas, and two cases of KTS had fair or poor results after sclerotherapy (unfavorable outcome), for which surgical excision was done. There was no statistically significant difference among the three different types of patients regarding outcome or occurrence of complications.
Conclusion
Duplex-guided polidocanol foam sclerotherapy is easy to perform and is a safe procedure that provides excellent outcome for venous malformations and good outcome for infantile hemangiomas and KTS.

Keywords:
hemangiomas, low-flow vascular malformation, sclerotherapy

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Introduction

Maldevelopment of the venous system during early stages of embryogenesis is the cause of vascular malformation, which present early or later in the patient's life [1–4].

The diagnosis of venous malformation (VM) is based on history taking, clinical examination, and imaging represented by duplex ultrasound, MRI with gadolinium enhancement, or computerized tomography angiography, when needed [4,5].

Conditions requiring urgent interventions include hemorrhage either spontaneous or traumatic, high-flow types causing either cardiac output failure, or steal phenomenon causing ischemia in a diseased limb [6].

Complexity in structure with microinvasion into different tissue planes makes radical complete surgical excision of vascular malformation extremely difficult and carries the risk of severe morbidity, as there is risk of massive hemorrhage during surgery and high recurrence rates owing to unavailability to remove all the lesions [7].

Duplex-guided sclerotherapy has evolved as an effective treatment option for low-flow malformations using various materials including polidocanol foam [8–10].

Patients and methods

A prospective observational study was conducted that included 36 patients from Zagazig University hospitals between January 2016 and June 2017.

According to International Society for the Study of Vascular Anomalies which conducted a standard classification of vascular anomalies on 1996 into

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vascular malformations and proliferative vascular (lesions) and was recently updated by the Society's Scientific Committee and Board at Melbourne, Australia, 2014 to incorporate the recent changes based on genetic bases [11].

We included three groups of patients in our study, which were as follows: 17 cases with low-flow venous malformations (LFVM), 11 cases with vascular tumors (hemangiomas), and eight cases with Klippel-Trenaunay syndrome (KTS).

Exclusion criteria were lesions around the eye (due to direct communications between this area with the cavernous sinus via the superior and inferior ophthalmic veins), patients with atrial septal defects and patients with previous interventions.

Treatment was mainly duplex-guided foam sclerotherapy sessions separated by 4-week interval; during the follow-up, we evaluated symptomatic improvement regarding the decrease in pain and lesion size and obliteration of vascular channels on imaging. The end point was successful reduction in size or complete obliteration of vascular channels. Surgery may be needed as a final stage.

Polidocanol was used at a concentration of 1–3% according to the size and depth of vascular channels, and acted as a sclerosing agent inducing damage of vascular endothelial cells, with formation of dense platelet aggregation, and lastly, the vessels were replaced by fibrous connective tissue.

The patients were re-evaluated after 7 days, and the next session was arranged after 3 weeks depending on the remaining lesions. The final outcome at 6-month follow-up (clinical and duplex evaluation) after the last sclerotherapy session was taken as end point for our study (Tables 1 and 2).

Table 1 Demographic criteria of the different study cases

	n (%)
Sex (male)	20 (56)
Age (mean±SD)	15.19±7.9
Types of lesion	
LFVM	17 (47)
Hemangiomas	11 (31)
KTS	8 (22)
Size of the lesions	
Small (<5 cm)	9 (25)
Medium (5–10 cm)	10 (28)
Large (>10 cm)	17 (47)
Anatomical site	
Upper extremities	7 (19.4)
Lower extremities	11 (30.6)
Trunk	8 (22.2)
Head and neck	4 (11.1)
Multiple locations	6 (16.7)

KTS, Klippel-Trenaunay syndrome; LFVM, low-flow venous malformations.

Results

The study included 20 (56%) male, mean age was 15.19±7.9 years; Table 1 summarized the demographic criteria of all patients, while Table 2 summarized the details of sessions of sclerotherapy in the 3 different patients groups

Final outcome of sclerotherapy

The final results were considered excellent when there was a decrease in the size of the lesion from 75 to 100%, good when there was a reduction in the size from 50 to 75%, fair when there was a decrease in lesion size from 25 to 50%, and poor results when the reduction in the size was less than 25% (Table 3). The results of the 3 different patient groups were summarized in Table 3 and Figure 7.

Using χ^2-test, there was no statistically significant difference among the three different groups of patients regarding occurrence of complications, with *P* value 0.391, or regarding the outcome, with *P* value 0.794, by Fisher's exact test (Figs 1–8).

The fate of unfavorable outcome

The remaining four cases of LFVM, five cases of hemangiomas, and two cases of KTS had fair or poor results after sclerotherapy (unfavorable outcome), for which surgical excision was done as described in Table 4 and Figure 8.

Table 2 Sessions of sclerotherapy in the three different patient groups

	LFVM	Hemangiomas	KTS
Mean number of sessions	2.705 (1–5)	1.909 (1–3)	3.125 (2–4)
Mean amount of polidocanol per session (ml)	3.3 (1.5–6)	2.2 (1.5–4)	4.2 (3–6)
Mean total dose of polidocanol injected (ml for every patient)	9.8 (1.5–24)	4.2 (2–6)	13.8 (6–22)

KTS, Klippel-Trenaunay syndrome; LFVM, low-flow venous malformations.

Table 3 Final outcome in the three different treatment groups

Type of the lesions	Final outcome			
	Excellent	Good	Fair	Poor
Low-flow venous malformation	7	6	2	2
Hemangiomas	4	2	4	1
Klippel-Trenaunay	3	3	1	1

Figure 1

Low flow venous malformation of the hand before injection.

Figure 2

Low flow venous malformation of the hand after 3 sessions of injection.

Discussion

In the present study, the type of lesion had no correlation with the incidence of complications.

The relation of the size of the lesion and efficacy of foam sclerotherapy for vascular malformations was more with the opinion that well-circumscribed lesions of less than 10 cm in diameter had a better response of treatment, which may be attributed to the longer contact time between the sclerosant and the vascular walls, as described by some authors [12].

Duplex guidance helped us to achieve a proper needle deployment and facilitated avoiding escaping of the polidocanol foam into the nearby tissues and reaching beyond the draining veins to the normal circulation [13,14]. It is particularly beneficial for penetrating lesions but remains highly helpful even for superficial ones. In our study, we used duplex guidance alone, but Zheng *et al*. [14] stated that fluoroscopy and digital subtraction angiography can be used by injecting the dye into the lesion to outline

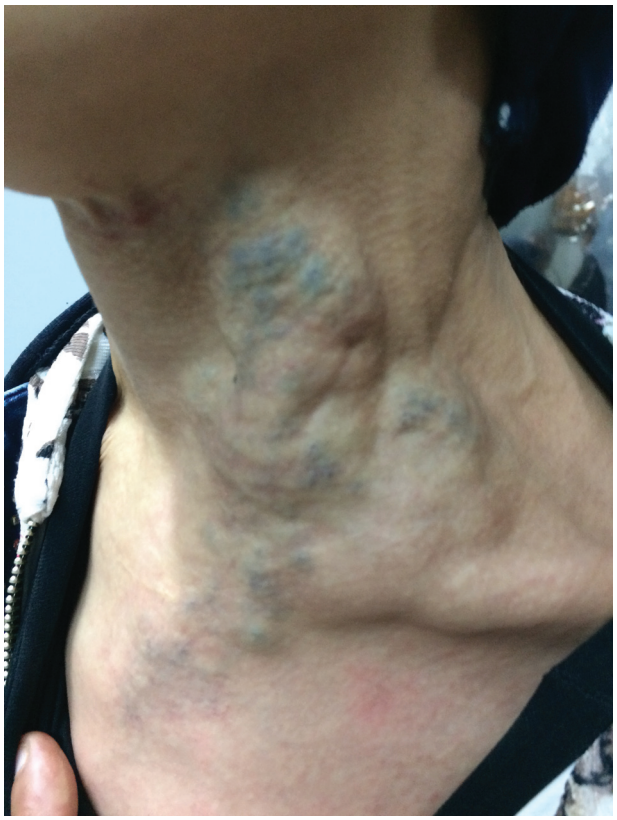
Figure 3

Hemangioma of the face before injection.

Figure 4

Hemangioma of the face after 4 sessions of injection.

Figure 5

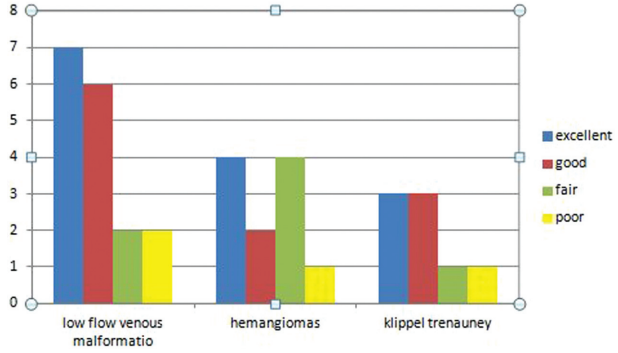


Low flow vascular malformation of the neck.

Figure 6

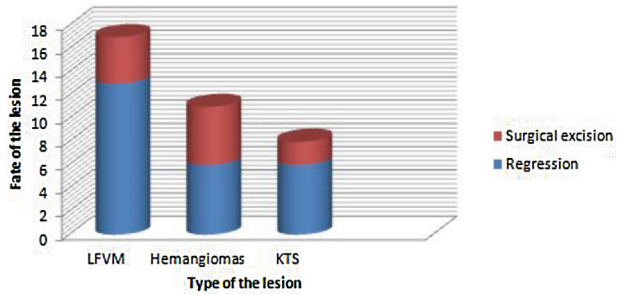
Low flow vascular malformation of the neck after 3 sessions of injection.

Figure 7



Final outcome in the 3 different patients groups.

Figure 8



Final fate of all types of lesions.

Table 4 Fate of the total cases of different three types of lesions

Type of the lesion	Sclerotherapy regression [*n* (%)]	Surgical excision [*n* (%)]
LFVM	13 (36.1)	4 (11.1)
hemangiomas	6 (16.7)	5 (13.8)
KTS	6 (16.7)	2 (5.5)

KTS, Klippel-Trenaunay syndrome; LFVM, low-flow venous malformations.

the vascular spaces and then under roadmap, inject the foam to fill the lesion while replacing the dye.

Kadhum and Abdul Lateef [15] included 17 patients, where 11 (64.7%) had VMs whereas six (35.29%) had infantile hemangiomas; only two (11.7%) cases of hemangiomas had favorable outcome compared with 10 (58.8%) cases of VM.

Different types of complications occurred in all types of patients were described in Table 5. The 11 cases of hemangiomas included in this study were six recurrent cases after propranolol treatment and five cases with partial regression after propranolol treatment, of which six from the 11 cases had favorable outcome and five cases needed surgical excision.

Table 5 Incidence of each type of complications

Complications	*n* (%)
Skin necrosis	3 (8.3)
Infection	2 (5.5)
Thrombus formation and swelling	3 (8.3)

One of the biggest series on managing LFVM of KTS with surgery is from the Mayo clinic, which gave detailed ideas about surgical outcomes in KTS. It included 252 consecutive cases seen between 1956 and 1995, and only 145 (57.5%) patients could have a surgical option. Of these treated cases, the early success rate for each type of surgery is as follows: ligation and stripping (40%), excision of malformation (60%), and debulking (65%). Almost all the procedures had a high recurrence rate during the follow-up [16]. Thus, the investigators recommended that the treatment approach to KTS should be primarily nonoperative, as the absence of clarity and unpredictable communications in vascular malformations of KTS make them refractory to stripping and excision operations [17]. McDonagh *et al.* [18] included 11 cases of KTSs, and eight of them completed the therapeutic plan, with 75% of them showing excellent to good results with good quality of life during the follow-up period.In the present study, we included eight cases of KTSs with venous insufficiency owing to the presence of VMs, but, strictly speaking, their symptoms regarding pain and swelling were refractory to conservative management, with profound reduction of treated abnormal venous channels after foam sclerotherapy in six (16.7%) cases, with subsequent surgical treatment in these cases.

Conclusion

We included three groups of patients in this study for the evaluation of the outcome and complications of duplex-guided sclerotherapy for hemangiomas remained after propranolol treatment, patients with KTS as well as those with LFVM, and we found that it is a safe and effective and less invasive method of treatment.

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Conflicts of interest

There are no conflicts of interest.

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