

Treatment of male varicoceles by transcatheter ethanolamine oleate 5% foam sclerotherapy

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Objective

The authors report the experience with foam sclerotherapy with no additional coils, evaluating clinical success, patients' satisfaction, and complications.

Patients and methods

The authors conducted a retrospective study of 71 patients with 76 varicoceles (mean age: 29.3 years; range: 13–60 years) who underwent foam sclerotherapy with ethanolamine oleate 5% (range: 2–12 ml) in an outpatient setting between October 2016 and September 2018. For the follow-up, interviews with the patients were conducted (mean follow-up time: 6.4 months, with SD: 5.17 months).

Results

The technical success rate was 84.2%. There was a 100% response rate to the patient interviews. Follow-up revealed a clinical success rate of 83.9% and a persistence or relapse rate of 16.1%. Of the patients, 85.9% were absolutely satisfied with the outcome. In 94.9% of cases, pain or discomfort resolution was reported, and in 97% of cases, aesthetic issues were no longer a problem. Of partners, 63.2% achieved pregnancy, and in 50% of patients with preprocedural testicular atrophy, catch-up growth was observed. One patient with pampiniform plexus phlebitis received inpatient treatment with no long-term damage recorded.

Conclusion

Ethanolamine oleate 5% foam varicocele sclerotherapy is a safe and effective procedure, with a high rate of patients' satisfaction, clinical and technical success, and considerable catch-up growth and pregnancy achievement.

Keywords:

ethanolamine oleate 5%, sclerotherapy, varicocele

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Introduction

Varicocele, the most common correctable cause of male infertility [1], can be treated in multiple ways. First, there are the endovascular methods, which include embolization using coils, detachable balloons, *N*-butylcyanoacrylate (NBCA) or *N*-butylcyanoacrylate + methacryloxysulfolane (NBCA-MS), hot contrast material, gelatin sponges or Amplatzer vascular plugs, foam or liquid sclerotherapy using sclerosing agents (e.g. polidocanol, sodium tetradecyl sulfate, sodium morrhuate, or ethanolamine oleate), and scleroembolization, which uses sclerosants in combination with coils and/or balloons.

Second, varicocele can also be treated with a spectrum of surgical techniques comprising open varicocelectomy [2,3], laparoscopic ligation [3], and microscopic varicocelectomy [4,5].

Because of the different symptoms patients with varicocele may present, clinical follow-up evaluating patients' satisfaction is necessary.

The aim of this study was to analyze the outcome of sclerotherapy using isolated transcatheter

ethanolamine oleate 5% injection regarding the following study end points: varicocele recurrence, pain resolution, pregnancy achievement, testicular swelling resolution, catch-up growth, and assessment of procedure-related complications. Moreover, we reviewed the literature of the past 10 years on sclerotherapy and alternative techniques, and also compared our method to both endovascular and surgical approaches.

Patients and methods

Patients

We conducted a retrospective study of 71 patients with 76 varicoceles who underwent percutaneous sclerotherapy between October 2016 and September 2018 in Vascular and Endovascular Surgery Department, Assiut University Hospitals, Assiut. Patient demographics, imaging data, periprocedural parameters and complications, technical aspects,

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history of previous varicocele repair, and clinical grading of the varicoceles were recorded. Clinical grading was determined according to the Dubin and Amelar classification [6]; no subclinical varicoceles were considered. Patients' characteristics are listed in Table 1.

Indications for treatment included testicular pain and/or discomfort, infertility, testicular atrophy, testicular or inguinal swelling, palpable 'bag of worms,' and prophylactic treatment. Institutional Review Board approval was obtained. Written informed consent was obtained from all participants in this study.

Venography and transcatheter sclerotherapy

Sclerotherapy was performed in an outpatient setting. We placed a lead testicle pouch over the testes to limit gonadal radiation exposure. With the patient in the supine position, the right femoral vein was punctured under local anesthesia. Using the Seldinger technique, a 0.035-inch (0.89 mm) angled hydrophilic guide wire (Radifocus; Terumo, Tokyo, Japan) and a 4-Fr Cobra C2 catheter (Radifocus Optitorque; Terumo) were introduced and advanced under fluoroscopic guidance into the left renal vein. The internal spermatic vein (ISV) was then superselectively catheterized, and contrast medium was injected at the level of the orifice while the patient performed the Valsalva maneuver to determine venous reflux and valve incompetence. If the orifice of the ISV could not be catheterized, a renal venography was performed to visualize the insertion of the refluxing vein and to identify unusual anatomy. In some cases, we encountered difficulties with the stiffness of the standard Cobra catheter, and we subsequently used a 4-Fr GlideCath hydrophilic coated catheter (Terumo), which allowed for a smoother passage and a more

flexible navigation of tortuous veins. Sheath placement was, therefore, not necessary, as the GlideCath catheter alone was flexible enough to prevent vein lesion and allow cannulation.

In one case though, we experienced difficulty even with the GlideCath catheter because of unusual venous anatomy (Baehren type 2), and as a result, we successfully used a Progreat co-axial microcatheter (Terumo), additionally to the GlideCath catheter, also without using a sheath.

In the case of the right-sided and five bilateral varicoceles, the right ISV was selectively catheterized using a 4-Fr Simmons 1 sidewinder catheter (Radifocus Opti torque; Terumo).

Varicocele anatomy was determined according to the classification by Baehren *et al.* [7] for the left side (Table 2) and by Siegel *et al.* [8] for the right side. Of the right-sided varicoceles, two were classified as Siegel type 1 and two as Siegel type 2 and 3, correspondingly.

To perform sclerotherapy, one syringe containing ethanolamine oleate at 5% (range: 2–12 ml; mean: 6.022 ml; median: 6 ml; SD: 1.86 ml; inter quartile range: 2 ml) was mixed through a three-way stopcock with another syringe containing unfiltered room air (1 : 4 ratio) to create foam sclerosant. Before administering the foam sclerosant, we injected ~0.5-ml air bubble that could be visualized under fluoroscopy. The foam was then administered under fluoroscopic guidance through the catheter that was placed, in most of the cases, at the level of the sacroiliac joint. In the presence of further collateral vein origins below the

Table 1 Patient characteristics

Number of patients (total)	71 (total)
	65 (adult)
	6 (adolescent)
Number of varicoceles	76
Affected side	65 (91.6%) left-sided
	1 (1.4%) right-sided
	5 (7%) bilateral
Age range	13–60 years (mean: 29.3 years; median: 27 years)
Grade	62 (81.6%) grade III
	12 (15.8%) grade II
	2 (2.6%) grade I
Number of recurrent varicoceles included in the study	8 (5.5%)
Mean ISV diameter	5.2 mm (range: 1.9–9 mm)

ISV, internal spermatic vein.

Table 2 Venographic anatomy

Baehren anatomic type	Features	n (%)
0	Single ISV with sufficient valves and no evidence of venous reflux	4 (5.6)
1	Reflux into a single ISV without duplication	23 (32.4)
2	Reflux into a single ISV that communicates with collaterals to Vv. Lumbales and/or V. cava inferior (Fig. 2a)	6 (8.5)
3	Reflux into an ISV showing two or more parallel collaterals that eventually coalesce into a single trunk (Fig. 1a)	35 (49.3)
4	Reflux into a single ISV that communicates with renal and perirenal collaterals	2 (2.8)
5	Renal vein anomaly (bifurcation of the renal vein, circumaortic renal vein)	1 (1.4)

ISV, internal spermatic vein.

sacroiliac joint, the catheter was positioned at the level of these origins to allow for extensive sclerotherapy of all collaterals. During ethanolamine oleate injection, the patient performed the Valsalva maneuver once again to prevent reflux of the sclerosing agent into the renal vein, whereas the interventional endovascular surgeon compressed manually the inguinal ring for 1 min to prevent sclerosant from passing in the pampiniform plexus, which would lead to a thrombophlebitis of the pampiniform plexus. During Valsalva, the position of the air bubble that we previously injected was monitored, to determine how intensely the maneuver was to be performed by the patient. As no contrast medium was added to the foam, we could not, however, absolutely rule out reflux of the sclerosant into the renal vein.

The total time of radiation exposure range from 15 to 20 min.

After the desired result of vein obstruction was attained, the catheter was withdrawn and the puncture site was compressed manually for 5–10 min, followed by compression with a sandbag for 2 h after sterile wound dressing. Patients were ordered to stay in bed for 2 h, during which they were closely monitored. In addition, they were advised to avoid strenuous exercise and heavy lifting for 5 days and also to avoid hot showers for a day. Immediately preoperatively, all patients were given antihistaminic and low-dose corticosteroids through an intravenous line to avoid dye hypersensitivity. In case of postprocedural pain, patients were given three doses of 400 mg/day of ibuprofen.

Follow-up

For the follow-up, we used patients' medical records and conducted interviews with the patients with scrotal duplex examination in each visit every 3 months for 1 year, requesting information concerning postinterventional visits in outpatient clinic, indication for treatment, history of previous varicocele repair, partial or complete varicocele resolution, complications, pain or discomfort related to the procedure, varicocele recurrence or persistence, symptom resolution, postprocedural varicocele repair, and patients' satisfaction. Depending on the initial indication, we asked in addition, in cases of infertility, whether pregnancy was achieved, and in cases of testicular atrophy, whether catch-up growth was observed. Catch-up growth was observed by patients themselves and documented in the telephone follow-up.

Mean and median follow-up times were 5.6 and 7 months, respectively (range: 3–12 months; SD: 5.17 months; interquartile range: 6 months).

We graded patients' satisfaction on a scale from 1 to 5, with 1 signifying 'absolutely satisfied' and 5 signifying 'absolutely unsatisfied.' Preprocedural pain, as well as pain related to the procedure, was assessed using the quantitative pain scale (0–10).

Statistical analysis

Descriptive statistical analysis was performed using IBM SPSS Statistics version 22 (IBM, New York, USA).

Results

Technical success

Of the 76 varicocele sclerotherapy attempts, 64 sclerotherapies in 71 patients were technically feasible (84.2% technical success rate). The 12 technical failures occurred in the following cases: three varicoceles were recurrent and the vein could not be venographically identified owing to prior endovascular treatment; four varicoceles had sufficient valves, making the catheterization of the vein impossible; and two varicoceles had a difficult venous anatomy (Baehren type 2), leading to failure. In another three cases, the origin of the ISV could not be selectively catheterized, a renal venography was made, and no orifice could be found (Figs 1–4).

Clinical success

We contacted the 71 patients, in whom the sclerotherapy proved feasible, and all of them responded to the interview questions (100% response rate). The 71 patients are the group the clinical results

Figure 1



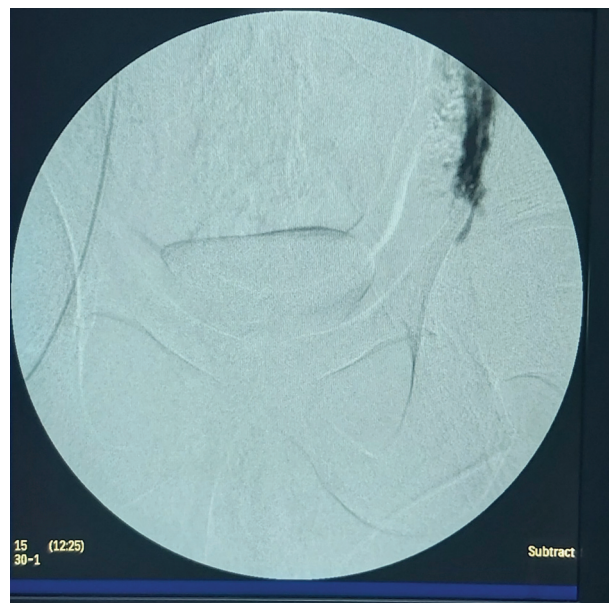
Diagnostic venography showing reflux of the left gonadal vein.

Figure 2



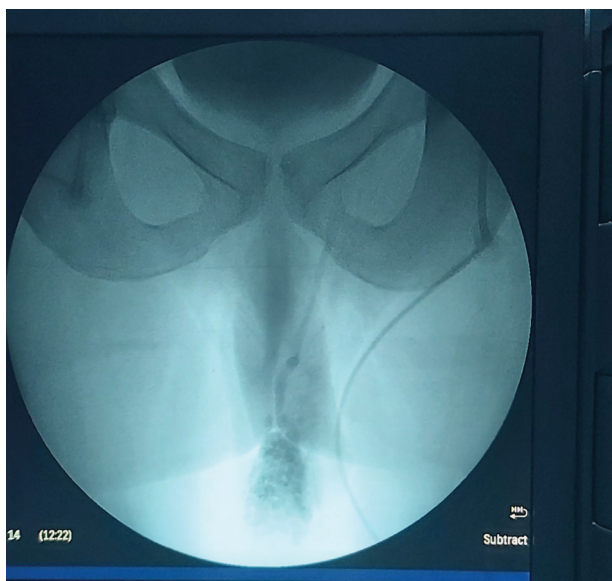
Diagnostic venography showing reflux of the pampiniform plexus of veins.

Figure 3



Completion venogram (postembolization) demonstrating total occlusion of the left gonadal vein.

Figure 4



Postembolization venogram showing occlusion of the pampiniform plexus of veins.

are mainly based on. We defined clinical success as the complete resolution of varicocele.

We achieved a clinical success rate of 85.9%; a complete resolution of the disease was documented by the referring physician in 61 of 71 patients (10 patients did not complete a follow-up visit after the procedure). One case of persistence, three cases of relapse, and six cases of partial resolution were noted, with a resulting persistence and relapse rate of 16.1%.

In 37 (94.9%) of 39 cases, a complete resolution of pain or discomfort was recorded; in one case, there was no change in pain or discomfort and in another, the pain worsened after the procedure (the median pain before sclerotherapy was 5 of 10 on the quantitative pain scale).

In 32 of 33 cases (97%) of testicular swelling or palpable 'bag of worms,' the symptoms resolved. In one case, there was no change in swelling or appearance.

Of six cases of testicular atrophy, three (50%) showed postprocedural catch-up growth, two cases showed no change, whereas in one case, the atrophy worsened.

Of 19 patients who desired pregnancy, 12 achieved pregnancy with a resulting pregnancy achievement rate of 63.2%.

Concerning patients' satisfaction, of the 71 patients, 58 (81.7%) were absolutely satisfied with the outcome, six (8.5%) were satisfied, one (1.4%) was neutral, three could not give an answer (4.2%), and another three were not satisfied (4.2%). No patient was absolutely unsatisfied. The three cases of unsatisfied patients comprised a case with varicocele persistence and 45 days of lasting flank pain and two cases with varicocele relapse.

Complications and periprocedural pain or discomfort

We encountered the following periprocedural complications: one case of vein lesion with contrast

agent extravasation, two cases of perioral and lingual paresthesia, one case of acute nausea, one case of pruritus and erythema, and one case of hypotensive reaction with 110/80 mmHg.

The one case of vein lesion with contrast agent extravasation did not require treatment and the patient had no clinical sequelae, as it proved to be self-limiting. We interpreted the two cases of perioral and lingual paresthesia, as well as the case of acute nausea, as allergic reactions to contrast agent. Therefore, two ampoules of cimetidine and dimetindene, respectively, were administered in each case, after which symptoms resolved. The patient with pruritus and erythema was treated with two ampoules of cimetidine and dimetindene, correspondingly, and 1000 mg prednisolone. The case of hypotensive reaction resolved spontaneously after 10 min, not requiring further treatment.

The postprocedural complications are based on the 71 patients who responded to the interviews. A pampiniform plexus phlebitis was diagnosed in one patient who developed severe swelling with pain after sclerotherapy and received inpatient treatment for 5 days. There were no long-term complications, such as testes loss. Other postprocedural complications include four cases of temporary inguinal/scrotal swelling, four cases of temporary minimal groin hematoma, and two cases of temporary pain in the flanks.

Twenty-four of the 72 interviewed patients (33.3%) reported pain or discomfort during the procedure. The median pain or discomfort during the procedure was 3.5 on the quantitative pain scale with a range of 1–10.

Postsclerotherapy pain or discomfort related to the procedure was reported by 30 of 72 patients (41.7%). The median postprocedural pain or discomfort was three on the quantitative pain scale with a range of 1–8 and a median duration of 20 days (maximum: 45 days; minimum: 1 day).

Discussion

Percutaneous sclerotherapy versus surgery

Percutaneous varicocele sclerotherapy is a rapid and minimally invasive procedure, usually performed in an outpatient setting and not requiring general anesthesia.

Radiologic treatment offers the advantages of less patient discomfort and rapid recovery in comparison with the more invasive approach of varicocelectomy

[9]. In addition, surgery does not provide the possibility to visualize the exact varicocele anatomy.

Concerning open varicocelectomy techniques – Palomo (high retroperitoneal ligation of the spermatic vein) and Ivanissevich (ligation within the inguinal canal) – high recurrence and complication rates have been reported, with complications ranging from hydrocele formation, testicular artery injury, epididymitis, to vas deferens occlusion, which are rarely seen with sclerotherapy [10].

Laparoscopic varicocelectomy can preserve the testicular artery and in some cases also the lymphatics, lowering the risk of artery injury or hydrocele [11]. Disadvantages include the high cost, the need for an experienced surgeon, and the long operating times [10].

The microscopic inguinal or subinguinal varicocelectomy spare the testicular artery and the lymphatics, which accounts for lower recurrence rates. Hydrocele also hardly occurs. Another advantage is its possible outpatient setting as local anesthesia is feasible [10,11].

In 2009, Cayan *et al.* [12] compared the outcomes of various studies on open, laparoscopic, microscopic, and radiologic embolization treatment and found that the best results (lowest overall postoperative recurrence rate and hydrocele formation rate, as well as the highest overall spontaneous pregnancy rates) occurred with microscopic varicocelectomy, whereas the Palomo technique showed the highest recurrence and hydrocele formation rates.

Table 3 offers a comparison regarding persistence or recurrence rates, pregnancy rates, and hydrocele formation between our data and studies on the Palomo technique, laparoscopy, and microsurgery, correspondingly.

The table shows that in comparison to these techniques, we achieved the highest pregnancy rate of 63.2%. Our method did not lead to any hydrocele formation either, as with percutaneous sclerotherapy, the testicular artery and the lymphatics are not at risk of injury.

The lowest recurrence rates and a low hydrocele formation rate were recorded with the microsurgical methods, explained by the good identification of distended plexus pampiniformis veins and lymphatics, correspondingly, during surgery. The

Table 3 Surgical varicocele repair vs our data

References	Number of patients	Technique	Persistence/recurrence	Pregnancy rates	Hydrocele formation
This study	71	Sclerotherapy with ethanolamine oleate	14.1% (10/71)	63.2% (12/19)	0% (0/71)
Cayan <i>et al.</i> [13]	232	Palomo technique	15.51% (36/232)	33.57% (47/140)	9.09% (12/132)
Watanabe <i>et al.</i> (2005) [27]	50	Palomo technique	12% (6/50)	35.8% (18/50)	10% (5/50)
Watanabe <i>et al.</i> (2005) [27]	33	Laparoscopy	6.1% (2/33)	40.4% (12/30)	3.3% (1/33)
Marmar and Kim (1994) [28]	466	Microscopic subinguinal varicocelectomy	0.82% (4/606)	35.6% (186/466)	0.2% (1/466)
Cayan <i>et al.</i> [13]	236	Microscopic inguinal varicocelectomy	2.11% (5/236)	42.85% (57/133)	0.69% (1/143)

complication rates in the literature are also low, between 0 and 2%, making microsurgery the most favorable in outcome among surgical options [10].

In conclusion, sclerotherapy with ethanolamine oleate 5% can achieve higher pregnancy rates than surgical treatment options and has the advantage of no hydrocele formation. Regarding recurrence, however, microsurgery proves to be more effective.

Percutaneous sclerotherapy versus other endovascular treatment options

In the interventional radiology literature, technical and clinical success rates of 80–100% [14–17] in both sclerotherapy and embolization have been reported, which are consistent with our technical and clinical success rates of 91.8 and 83.9%, respectively. We observed a slightly higher persistence and relapse rate (16.1%) than those of 0–16% described in the literature [14,15,18,19], possibly owing to the longer follow-up time. Kim *et al.* [16] likewise describe a comparatively high persistence and relapse rate of 20% in a study using coils alone or coils combined with 3% Sodium Tetradecyl Sulfate (STS) foam.

Although varicocele sclerotherapy is generally safe and well tolerated with minimal complication rates [18], complications may appear, as with any other medical procedure. The most common complication associated with varicocele sclerotherapy is the pampiniform plexus thrombophlebitis, which occurs as a result of insufficient manual compression of the inguinal ring during polidocanol injection, allowing the sclerosant to pass in the pampiniform plexus. It is usually treated with oral corticosteroids, antibiotics, and pain medication [1]. We observed one such case. As polidocanol induces an inflammatory reaction resulting in endothelial necrosis and secondary phlebitis with thrombosis and fibrosis of the vein [14,20–22], transitory pain in the flanks during and

after injection is also commonly observed. Other complications include groin hematomas owing to inadequate compression of the puncture site, vessel lesion with contrast agent extravasation, testicular swelling, and allergic reactions. Possible complications that were not seen in our study population include pulmonary embolism, venous spasms, edema of the scrotum, and intra-arterial puncture.

Sclerotherapy has been proven to improve not only testicular function and seminal parameters, increasing sperm density, motility, and morphology, and serum inhibin B levels but also pregnancy rates. In a study using STS foam sclerotherapy, Gandini and colleagues achieved improvement of sperm density, motility, and morphology, as well as a pregnancy rate of 39%. In the present study, we achieved a higher pregnancy rate of 63.2%, explicable by the longer follow-up time.

An important aspect is the achievement of the therapeutic goal, which may be different for each patient, pregnancy achievement, pain resolution, catch-up growth, or testicular swelling resolution. In the age of patient-centered care, patients' satisfaction is, of course, the central element. However, the individual study of these end points is limited in the literature and focuses almost exclusively on the resolution of pain, without considering catch-up growth or aesthetic goals. We took all these aspects into account, achieving a catch-up growth rate of 50% and a swelling resolution rate of 97%. We also recorded a high patients' satisfaction rate.

Concerning painful varicoceles, Puche-Sanz *et al.* [24] reported significant differences in pain after coil embolization and Gandini and colleagues described pain resolution in 96.5% of cases after STS foam sclerotherapy, comparable to our pain and discomfort resolution rate of 94.9%. We did not

differentiate between pain and discomfort after seeing that patients had difficulties differentiating the two.

Among the endovascular methods, coils are the most commonly used. Coils obliterate the lumen, either mechanically, in the case of hydrogel-coated coils, or by inducing thrombosis, in the case of fibered coils [20]. A disadvantage of coils is that they are not as effective in the presence of collateral vessels, which may lead to the recanalization of the varicocele. Sclerosing agents also occlude collaterals [10], preventing recurrence. Coils, as well as occlusive balloons, are also more expensive than sclerosants [23].

Tissue adhesives, introduced by M. Kunnen in 1980 [24], are nowadays represented by NBCA and NBCA-MS, a co-polymer of NBCA with a lower temperature of polymerization. The endothelium of the vessel is damaged as a result of the exothermic heat, activated by the polymerization of the glue [14]. However, both coil and glue embolization have been shown to lead to several complications: coil migration and corrosion, causing pulmonary embolism and late varicocele recurrence; lipiodol pneumonia; and glued catheter [10]. Furthermore, coils may prevent further selective catheterization of the ISV, in case the embolization was insufficient [13].

Hot contrast material is also used, its effect being explained by the damage to the vessel endothelium caused by the thermic injury. However, it has been reported to be painful [10].

In the present study, we used isolated ethanolamine oleate 5% foam sclerotherapy, which presents various advantages: its extensive effect on collaterals, the steadier and more controlled distribution in the veins in comparison with liquid sclerotherapy, the decreased dilution by blood, the improved adherence to the vein, and the increase in contact time compared with liquid agents, leading to more effective results. Foam also allows the use of lower doses of sclerosant, minimizing the adverse effects [23]. We performed the sclerotherapy mostly at the sacroiliac joint level and in the presence of collateral origins below this level; we also applied sclerosant at the level of these origins. This is a further technical advantage over coil embolization, as coils mostly need to be placed far distally with a resulting higher risk of vein damage.

We offer an overview of the studies on sclerotherapy and the aforementioned alternative techniques with the highest number of patients included in the past 10

years, reviewing technique, technical and clinical success, relapse rates, and complications. The overview highlights the good results of endovascular options, with the highest technical and clinical success rate, and therefore, the lowest relapse rate having been achieved by Jargiello *et al.* [15] using 3% aethoxysklerol with fibered coils. The highest relapse rates were seen in the study of Puche-Sanz *et al.* [25] and Wunsch and Efinger [26] when using fibered coils alone and aethoxysklerol alone in various concentrations, respectively. Similarly, our relapse rate was 14.1% and although we had a longer follow-up time, which allows for a more thorough relapse identification, the following question arises: does a combination of sclerotherapy and embolization provide better results? Kwak and Siegel [20] describe in their 2014 review on interventional therapy for varicoceles the so-called sandwich technique, involving the placement of a nest of coils at the level of the inguinal canal before sclerotherapy. This would prevent sclerosant reflux into the plexus pampiniformis and, simultaneously, occlude the small collaterals that otherwise would not be embolized with coils alone. The question could be answered via a prospective, randomized controlled study comparing sclerotherapy with scleroembolization. However, although there are a few studies comparing surgery to endovascular techniques, one cannot help but notice the lack of studies comparing the two endovascular techniques with each other.

We also show that complications after endovascular techniques are less serious than with surgery, as hydrocele formation was only observed by Puche-Sanz and colleagues using fibered coils, and in the sclerotherapy studies, including ours, no hydrocele or arterial or vas deferens injury was observed.

Conclusion

Treatment of male varicocele via transcatheter ethanolamine oleate 5% foam injection proves to be a safe and effective procedure, easily feasible in an outpatient setting, with high clinical and technical success rates. It shows a high rate of patients' satisfaction and symptom resolution, with considerable catch-up growth and pregnancy achievement.

Surgery-related complications, such as testicular necrosis or hydrocele formation, did not occur in any case with ethanolamine oleate 5% sclerotherapy. Moreover, there is no need for general anesthesia, making sclerotherapy a quick and comfortable outpatient treatment.

To compare sclerotherapy further with other endovascular treatments, such as coil or glue embolization or scleroembolization, prospective, randomized controlled studies are needed.

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Conflicts of interest

There are no conflicts of interest.

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