Evaluation of transcatheter foam sclerotherapy in the treatment of pelvic and atypical lower limb varicosities

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Introduction
Chronic pelvic pain is a widely prevalent symptom ranging from mild to severe disabling intensity. Pelvic venous insufficiency is one of the causes of chronic pelvic pain, especially in females of child-bearing age. Embolotherapy is now a developing-adopted treatment method to pelvic venous insufficiency.

Patients and methods
We accomplished a prospective study on 20 females (mean age, 33.8 years; range between 20 and 45 years) with pelvic congestion syndrome treated between April 2017 and April 2018 by Trans-Cutaneus Foam Sclero- therapy (TCFS). Pelvic pain and atypical lower limb varices were associated with dyspareunia in 16 (80%) patients, urinary urgency in 12 (60%) patients, and tender ovarian point sign in 17 (70%) patients. Diagnosis depended mainly on pelvic pain analysis, detailed history taking, and clinical examination and was confirmed by transcatheter venographic findings. TCFS by 5% ethanolamine oleate was performed in all patients. Follow-up was done by estimation of pain at 1, 3, 6, and 12 months after the maneuver.

Results
The percentage of technical success was 100%. A statistically significant clinical improvement in each category of specific symptoms was noticed at 1, 3, 6, and 12 months after the procedure. Recurrence was observed in one case. Minor adverse effects were noticed after the procedure, and they were mild and responsive to medical treatment.

Conclusion
We found out that TCFS of female varicocele using a 5% ethanolamine is safe and effective to treat pelvic congestion syndrome. It is accompanied by a considerable reduction of symptoms and can be regarded as a proper alternative to other medical and surgical techniques.

Keywords:
atypical varicose veins, dyspareunia, embolization, ethanolamine, left ovarian vein, pelvic congestion syndrome, visual analog score

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Introduction

Chronic pelvic pain (CPP) is described as cyclic or non-cyclic lower abdominal and pelvic pain for more than or equal to 6 months. The pain might be of multiple factors with no evident cause, and its diagnosis and treatment may need the contribution of multiple specialties [1]. Pelvic congestion syndrome (PCS) is one of the most common causes of CPP. The expression 'venous congestion syndrome of the pelvis' was first mentioned by Taylor in 1949 to describe a collection of manifestations consisting of pelvic pain, pelvic varices, dysmenorrhea, and dyspareunia. This classical assembly of symptoms is accompanied by a typical distribution of varices such as vulval varicosities, suprapubic veins, and varices on the posterior aspect of the thigh [2].

Imaging is of a supportive role in PCS diagnosis and that means that imaging can document the distinctive pelvic venous changes, which uphold the diagnosis but do not define it [3]. Pelvi-abdominal ultrasound is the first-line imaging study. First of all, it excludes uterine conditions and pelvic masses as potential causes of pain. Then, it can evaluate and measure expanded ovarian and uterine veins [4]. Main sonography findings of PCS are dilation of the left ovarian vein (<4 mm), existence of tortuous and dilated pelvic venous connections, and changeful duplex waveform in the varicoceles during the Valsalva's maneuver (revealing valve incompetence) [5].

Treatment of PCS is one of three modalities: medical therapy, surgical intervention, and endovascular treatment, which was introduced in 1993 and has gained popularity over other treatment methods. Variable materials can be used to treat the refluxing

veins such as sclerosing agents, detachable balloons, coils, glue, and/or foam. The symptoms are usually attributed to the left ovarian or iliac vein reflux and so we treat them first; however, we can treat the right side if indicated [6].

Patients and methods

A prospective study was conducted on 20 patients with PCS managed by left ovarian vein TCFS between April 2017 and April 2018 at Vascular and Endovascular Surgery Department of Assiut University Hospitals. The institutional review board at our institution gave full approval and waiver of informed consent for our prospective study and approved our treatment protocol with IRP 17100174. Written patient informed consent was obtained from each patient before intervention. ClinicalTrial.gov identifier: NTC03652025.

Patients

The study included premenopausal women with CPP that is worse at the end of the day, related to menstruation, during or after sexual intercourse, and after long periods of standing or sitting, and relief occurs when the patients lay down. We excluded postmenopausal women and other causes of CPP (urological, gynecological, gastrointestinal, musculo-skeletal, or psychosomatic) and obstructive causes of PCS (such as May–Thurner syndrome and Nut-cracker syndrome) if appeared venographically. A quantitative estimation of symptom perception before the procedure was assessed in all patients using a visual analog score (VAS). The VAS consisted of a 0-to-10 scale evaluating the intensity of each specific symptom (pelvic pain, dyspareunia, urinary urgency, and menstrual pain), where 0 corresponds to the absence and 10 to the most severe symptom. The most repeated presentation was dyspareunia (80%) followed by urgency (60%). It was noticed that vulval varices, hemorrhoids, and dysuria were presented in eight (40%), four (20%), and 10 (50%) women, respectively, as in Table 1.

All patients underwent nephro-protection protocol by saline infusion 12 h preoperative and contrast allergy protection by intravenous injection of antihistaminic and rapid-acting corticosteroid just before entrance to operation room.

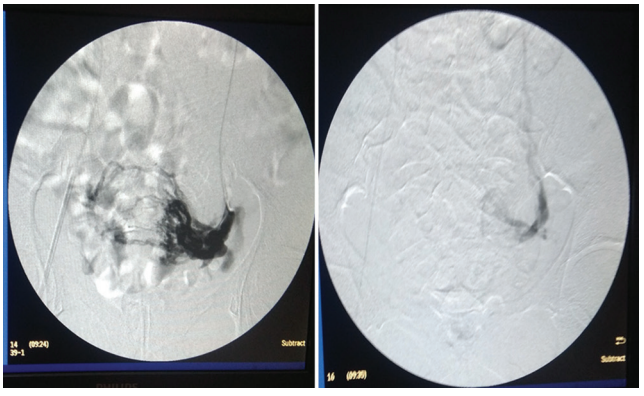
Procedure

The procedure starts with patients in a supine position on the radiological tilt table. The procedure is performed under local anesthesia with the aid of intravenous fentanyl sedation on sclerosant injection. We used bilateral femoral access in all 20 patients. Both iliac venogram is usually the first step to exclude compressive syndromes, which is done using fluoroscopic-controlled guidance through direct venogram from the bilateral 6-Fr femoral sheathes. Then we cannulated the left ovarian vein, which is a tributary of the left renal vein by using cobra catheter (Cook Medical Inc., Bloomington, Indiana, USA) and 5-Fr support catheter (TrailBlazer Support Catheter; ev3 Endovascular Inc., Plymouth, Minnesota, USA), with cross-coat hydrophilic coating. We checked for reflux in left ovarian vein and left renal vein through injection of contrast while the patient was performing Valsalva's maneuver as in Fig. 1. Refluxing ovarian veins are dilated (>6–8 mm in diameter), and the contrast generally retains in the pelvis after the injection. When an abnormal vein is encountered, treatment is usually done before evaluating the next vein. In this study, we have used ethanolamine oleate 5% 5 ml as a sclerosing agent, which was injected as distal as possible to occlude the pelvic plexus of veins. We injected 2 ml of the agent prepared by the Tessari technique with 0.2 concentration per time, and this could be repeated up to three times according to completion after each injection (the volume of injected foam was determined according to the volume of contrast needed to opacify the refluxing vein). Following ovarian vein closure, we investigated for reflux in internal iliac veins and embolized it if necessary and if it was applicable and

Table 1 Baseline clinical data of studied women

	n=20 [*n* (%)]
Vulva varices	8 (40)
Hemorrhoids	4 (20)
Dyspareunia	16 (80)
Dysuria	10 (50)
Urgency	12 (60)
Tender ovarian point	14 (70)

Figure 1



Sclerotherapy of refluxing pelvic veins of left ovarian vein.

safe. In the presence of escape points to the lower limbs or connections of internal iliac veins with lower periuterine varicose veins, selective catheterization and embolization with sclerosants should be performed as in Fig. 2. We injected left ovarian vein in all cases and left internal iliac vein tributaries in one case of this study. The patients were discharged 4–6 h after the procedure with a 3–7-day oral acetaminophen.

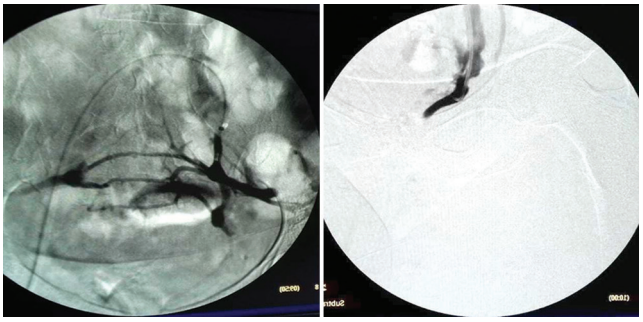
Follow-up

Follow-up was performed by questionnaire-based evaluation of pain using the VAS at 1, 3, 6, and 12 months after the maneuver. We tracked each symptom intensity after the procedure and compared with their corresponding before the procedure.

Statistical analysis and study end points

Study end points were determined according to recurrence rates and tracking the symptoms through the year after the procedure. Recurrence was defined as return of the VAS measures as they were before the TCFS. Data were collected and analyzed using SPSS (Statistical Package for the Social Science, version 20; IBM, Armonk, New York, USA). Continuous data were expressed in form of mean ± SD or median (range), whereas nominal data were expressed in the form of frequency (percentage). Intensity of pain (pelvic pain, leg pain, dyspareunia, and pain with menses) at different times of follow-up was compared with baseline data by Wilcoxon test was used. Level of confidence was kept at 95% and hence, *P* value was significant if less than 0.05, in Figs. 3-7.

Figure 2



Sclerotherapy of pelvic tributaries and leakage points to lower limb of internal iliac vein.

Results

It was noticed that 17 (85%) of them were multiparous, and only three women were uniparous, with a mean parity of 3.05. A statistically significant reduction in all symptom scores (pelvic pain, dyspareunia, dysmenorrhea) was achieved at 1, 3, 6, and 12 months of follow-up (Table 2).

Moreover, we observed improvement and diminution in size of atypical lower limb varices after the procedure in 12 (60%) patients, whereas eight (40%) showed no improvement. There were minor complications in three (15%) patients, and these complications were transient and responded to medical treatment as in Table 3.

The sclerotherapy procedure had a 100% technical success rate and a 95% primary clinical success rate, as there was one case with recurrence during the 12-month follow-up duration.

Figure 3

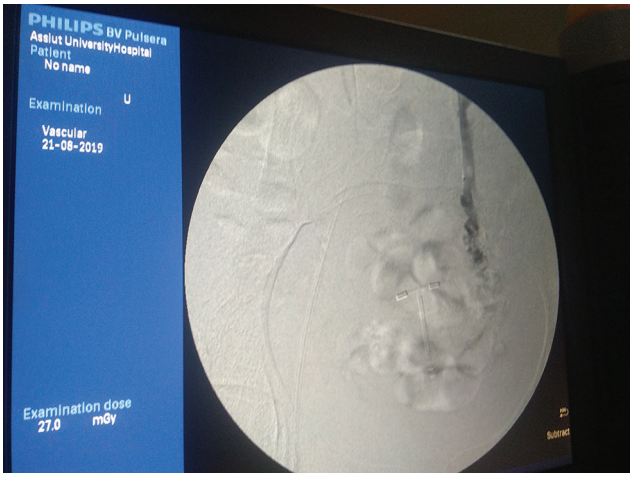
Stagnation of the dye in pelvic veins through selective catheterization of left 0varian vein.

Table 2 Data expressed as mean±SD

	Baseline	1 month later	3 months later	6 months later	1 year later
Pelvic pain					
Lying pain	1.05±0.80	0.48±0.35	0.35±0.11*	0.30±0.13*	0.30±0.11*
Standing	4.45±1.46	2.05±1.43*	1.55±0.68	1.50±0.15*	1.30±0.13*
Leg pain					
Lying pain	1.20±0.69	0.95±0.39	1.11±0.34*	0.94±0.14*	0.90±0.10*
Standing	4.55±1.27	3.45±1.53*	2.86±0.22*	1.80±0.24*	1.77±0.21*
Dyspareunia	5.90±1.80	2.90±1.48*	2.11±1.22*	1.98±1.98*	1.80±1.01*
Pain with menses	5.65±1.53	2.75±1.55*	2.65±1.78*	2.11±1.88*	1.90±1.22*

*Statistically significant change from baseline value (Wilcoxon test).

Figure 4

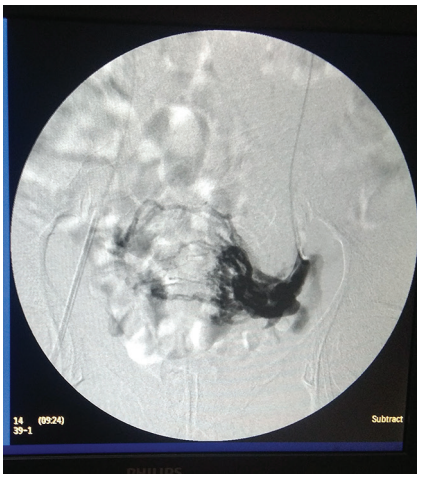


Post injection of figure3 noticing obliteration of pelvic veins.

Figure 5

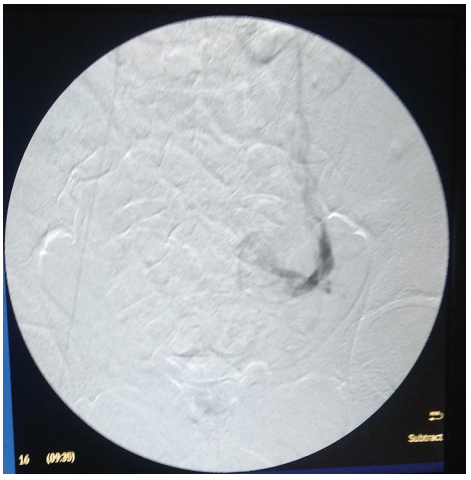
Pelvic veins reflux through selective catheterization of left internal iliac vein.

Figure 6



Pooling of contrast in pelvic veins and crossing to the other side.

Figure 7



Post injection picture of the same patient in figure 6 noticing obliteration of the pelvic veins.

Table 3 Postprocedural complications in studied women

Complications	*n* (%)
Contrast allergy	1 (5)
Postprocedural pain	2 (10)

Discussion

Since its first description in 1993 using coils, several materials such as glue and sclerosing agents have been described for the endovascular management of PCS. TCFS of female varices is a minimally invasive interventional procedure requiring only local anesthesia at the puncture site and can be performed in a day hospital. In 1999, preparation and application of foam was first described by Tessari *et al.* [7]. Foam damages the vein's endothelium and triggers inflammatory mediators that sclerotize the vein. The use of ethanolamine in the form of foam is associated with several advantages. The foam covers a larger surface contact of endothelium, thus triggering more effective sclerotization. The foam's malleability guarantees complete filling of the varices through the ovarian veins. Differently from other endovascular procedures that use coils, TCFS using ethanolamine foam is less invasive than insertion of metallic coils in to the body. The majority of our patients (85%) were multiparous, with 3.05 as a mean parity, agreeing with other studies such as Chung and Huh[8] study, who documented a mean parity of 2.1, and Laborda *et al.* [9], who reported 2.86, reflecting hormonal and multiparity influence in developing PCS. Regarding the embolization materials, we used ethanolamine oleate 5% 5 ml as the sole embolizing agent in the consistency of foam, which was prepared by Tessari technique in all of our cases. Moreover, in other studies, sclerosing agents without coils were the sole embolizing agents, as in Pieri *et al.*[10] and Gandini *et al.* [11], who used sodium-tetradecyl-sulfate foam. Creton *et al.*[12] used both coiling and foam to occlude the refluxing pelvic veins. However, in other studies, coils were the sole embolizing agent, such as

Table 4 Results of pelvic embolization in this study and other studies

References	Number of patients	Treatment	Technical success rate (%)	Primary clinical success rate (%)	Follow up (month)	Results
Laborda *et al*. [9]	202	Coil embolization	100	93.85	60	(VAS) relief from baseline 7.34 to 0.78
Gandini *et al*. [11]	38	Foam sclerotherapy	100	100	12	(VAS) significant relief of all symptoms
Venbrux *et al*. [13]	56	Coil embolization	100	96	22	(VAS) mean pain from 7.8 to 2.7 at end of first year then no significant change
Pieri *et al*. [10]	33	Foam sclerotherapy	100	60.6	12	Duplex follow up partial reduction in size of refluxing veins
Creton *et al*. [12]	24	Coil embolization	100	95.4	36	Maintained significant relief of all symptoms
Kwon *et al*. [14]	67	Coil embolization	100	82	44.8	Significant pain relief 2 coil migration
Maleux *et al*. [15]	41	Glue embolization	98	58.5	20	No significant clinical difference between unilateral and bilateral embolization
Our study	20	Foam sclerotherapy	100	95	12	(VAS) significant relief of all symptoms + Decrease of atypical lower limb varices in 60% of patients

VAS, visual analog score.

in Kwon and colleagues and Laborda *et al*. [9]. In our study, embolization was unilateral in all cases for the left ovarian vein. The study by Maleux *et al*.[15] on 41 patients discovered insignificant difference between bilateral and unilateral embolization, with a *P* value of 0.35, on the scale of clinical improvement. Other studies like Gandini *et al*.[16] targeted bilateral ovarian veins for embolization. We used VAS to assess our clinical success at 1, 3, 6, and 12 months, and there was significant relief in pelvic and leg pain, dysmenorrhea, and dyspareunia. This improvement is observed from the first month after the procedure and continued till the end of our follow-up. Dyspareuneal pain intensity decreased by 66.4% after 1 year, and also dysmenorrheal pain intensity decreased by 61% after 1 year. Standing pelvic pain improvement was by 65% after 1 year, and improvement of standing leg pain occurred by 59% after 1 year. We summarize our results relative to other studies in Table 4.

It is of value to mention that there was improvement in the lower limb atypical veins in 12 (60%) patients, which became less prominent. Similar to these results, the study by Abdelsalam[17] on 11 patients documented an improvement of thigh and leg varices in 66.7% of patients.

Conclusion

Transcatheter ethanolamine foam embolization is an effective and safe method to treat pelvic and atypical lower limb varices.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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