

Transcatheter Foam Sclerotherapy of Symptomatic Female Varicocele with Sodium-Tetradecyl-Sulfate Foam

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Abstract To evaluate the efficacy of transcatheter foam sclerotherapy (TCFS) in pelvic varicocele using sodium-tetradecyl-sulfate foam (STSF), we conducted a retrospective study in 38 patients (mean age, 36.9 years; range, 22–44 years) with pelvic congestion syndrome (PCS) treated between January 2000 and June 2005 by TCFS. Pelvic pain was associated with dyspareunia in 23 (60.5%) patients, urinary urgency in 9 (23.7%) patients, and worsening of pain during menstruation and at the end of a day of work in 7 (18.4%) and 38 (100%) patients, respectively. Diagnosis was made by pelvic and transvaginal color Doppler ultrasound examination, demonstrating ovarian or pelvic varices with a diameter >5 mm presenting venous reflux. TCFS was performed in all patients, using 3% STSF. Follow-up was performed by physical examination, pelvic and transvaginal Doppler ultrasound examination and by a questionnaire-based assessment of pain at 1, 3, 6, and 12 months after the procedure. Technical success was achieved in all patients (100%). In three patients a pelvic colic-like pain occurred immediately after sclerotic agent injection, disappearing spontaneously after a few minutes. No recurrent varicoceles were observed during a 12-month follow-up. A statistically significant improvement in each category of specific symptoms was observed at 1, 3, 6, and

12 months after the procedure. We conclude that TCFS of female varicocele using a 3% STSF is safe and effective for the treatment of PCS. It is associated with a significant reduction of symptoms and can be regarded as a valid alternative to other endovascular and surgical techniques.

Keywords Varicocele · Pelvic congestion syndrome · Sclerotherapy · Venous reflux · Dyspareunia · Menstrual pain

Introduction

A variety of designations, such as pelvic congestion syndrome (PCS), pelvic pain syndrome, and pelvic venous incompetence, has been used to describe the presence of ovarian and pelvic varices, also known as pelvic varicocele [1]. PCS is defined as the presence of ovarian or pelvic varices associated with noncyclic chronic pelvic pain persisting for >6 months. This disease mainly affects multiparous young women. It usually presents with dyspareunia and bladder irritability associated with pelvic pain extending to the gluteus and the posterior aspect of the thigh, which is variable in intensity and duration [2]. Most patients also present varices of the lower limbs. The etiology is not yet clear, but it is thought to be multifactorial [3, 4].

Diagnosis of PCS may be arduous. Color Doppler ultrasound (US) with transvaginal probe is performed to exclude other gynecological pathologies and to confirm the presence of ovarian and/or pelvic varices with a diameter >5 mm presenting a venous reflux [5]. As a matter of fact, differential diagnosis is very complex and a variety of pathologies, such as pelvic inflammatory diseases, endometriosis, pelvic tumors, cystitis, and inflammatory bowel diseases, needs to be considered [6, 7].

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Surgery and, more recently, the laparoscopic technique have been performed with success, but they encumber a high percentage of morbidity and aesthetic damage and require at least 2 days of hospitalization [8, 9]. Ovarian vein embolization in PCS was first described by Edwards et al. in 1993. The authors performed a bilateral ovarian vein embolization using coils in a woman with a 2-year history of chronic pelvic pain (CPP), dyspareunia, and dysmenorrhea [10]. Subsequently, the use of various sclerosing agents and metal coils has been described [11–15].

We present our experience in 38 patients with PCS treated by transcatheter foam sclerotherapy (TCFS) using a 3% sodium-tetradecyl-sulfate (STS)–air foam.

Materials and Methods

Patients

A retrospective study was conducted in 38 consecutive patients (mean age, 36.9 years; range, 22–44 years) with PCS treated by internal ovarian vein TCFS between January 2000 and June 2005 at our department. All patients referred for treatment were included in this study. The institutional review board at our institution gave full approval and waiver of informed consent for our retrospective study and approved our treatment protocol. Written patient informed consent was obtained from each patient prior to intervention.

Patient Population

Patients were referred to our department by gynecologists for CPP, and diagnosis of PCS was made by physical and/or color Doppler US examination. CPP was intermittent in 6 patients (15.8%) and continuous in the remaining 32 (84.2%). Dyspareunia was present in 23 (60.5%) patients, and urinary urgency in 9 (23.7%). Symptoms were usually worse at the end of an intensive working day. In 30 (78.9%) patients the coexistence of lower limb varices was also found. In seven (18.4%) patients a worsening of pain was observed during menstruation. Twenty-eight (73.7%) patients were multiparous, 5 (13.2%) were nulliparous, 3 were biparous (7.9%), and 2 (5.3%) were uniparous (Table 1).

A “homemade” quantitative measure of symptom perception before the procedure was evaluated in all patients using a Symptom Severity Score (SSS). The SSS 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.

Table 1 Patient population data

No. patients	38
Age, yr: mean (range)	36.9 (21–46)
Parity	
Biparous	3 (7.9%)
Multiparous	28 (73.7%)
Nulliparous	5 (13.1%)
Uniparous	2 (5.3%)
Pain	38
Continuous	32 (84.2%)
Intermittent	6 (15.8%)
Dyspareunia	23 (60.5%)
Worsening of symptoms	
During menstruation	7 (18.4%)
At the end of a working day	38 (100%)
Urinary urgency	9 (23.7%)

Thirty-two (84.2%) patients had bilateral ovarian varicoceles with cross-pelvic varices; 6 (15.8%) had bilateral ovarian varicoceles with non-cross-pelvic varices. There were no patients with a unilateral ovarian varicocele. Before sclerotherapy, no patient underwent laparoscopy or surgery. The majority of the patients occasionally took analgesics to reduce pelvic pain.

Pelvic Varicocele TCFS

Patients were treated in a day-hospital setting. After local anesthesia was administered with a transdermic needle using 2 ml of lidocaine, the right antecubital vein was punctured using an 18-gauge needle and a 0.035-in., J-tipped, 180-cm-long hydrophilic guidewire (Radiofocus; Terumo, Tokyo) was introduced and advanced into the innominate vein. The percutaneous access was dilated with a 5-Fr, 25-cm-long introducer sheath (Introducer II; Terumo) to avoid venous damage during subsequent manipulations of the diagnostic catheter. A 4-Fr Simmons 2 (Radiofocus Glidecath; Terumo) diagnostic catheter was used to selectively catheterize the left ovarian vein. First, the catheter was advanced into the left renal vein and, during Valsalva’s maneuver, a preliminary renal phlebography was performed to visualize the confluence of the ovarian vein. Then the ovarian vein was selectively engaged by the tip of the catheter, and a retrograde phlebography by energetic hand injection of contrast medium with a 20-ml Luer Lok syringe was carried out to assess the volume of the blood in the pelvic varices and to demonstrate their anatomy.

Two 10-ml Luer Lok syringes containing 2 ml of 3% STS (Fibrovein; STD Pharmaceuticals) and 8 ml of air,

respectively, were connected through a three-way stopcock and their contents were mixed together until a homogeneous foam was obtained. In the case of cross-pelvic varices, TCFS was only performed from the left ovarian vein using ~30 ml of STS foam (Fig. 1). In the case of non-cross-pelvic varices, ~30 ml of STS foam was selectively injected distally through the left ovarian vein into the varices (Fig. 2). A contralateral ovarian phlebography was then performed using a 4-Fr multipurpose catheter (Torcon NB Advantage; William Cook Europe ApS, Bjaeverskov, Denmark) to assess the eventual presence of right ovarian varices. When ovarian varices were found also on this side, ~20 ml of STS foam was selectively injected distally through the right ovarian vein. Foam injection was continued until no refluxing into the varices was observed after manual injection of contrast agent through the catheter.

STS foam was always injected while asking the patient to perform Valsalva's maneuver in order to avoid accidental dislocation of the sclerosing agent and to maximize its effects on the endothelial surface. After the procedure, the patient was invited to maintain a moderate Valsalva's maneuver for an additional 10 min.

The patients were discharged 1 hour after the procedure with a 3-day oral anti-inflammatory (2×100 mg/day nimesulide) and a 5-day oral antibiotic (1 g/day amoxicillin) therapy. In the case of pain developing within a few days after the procedure, a 10-day intramuscular anti-inflammatory therapy was commenced (4×50 mg/day ketoprofen).

Follow-up

Follow-up was performed by questionnaire-based assessment of pain using the SSS, physical examination, and pelvic and transvaginal color Doppler US examination at 1, 3, 6, and 12 months after the procedure. The patients were asked to indicate on the SSS scale the symptoms (pelvic pain, dyspareunia, urinary urgency, and menstrual pain) perceived during the month preceding the follow-up visit.

Study Endpoints and Statistical Analysis

Study endpoints were recurrence rates of female varicocele and improvement of symptoms during a 12-month post-procedural follow-up. Recurrence was defined as the reappearance of CPP and/or return of SSS to baseline values. All data are given as mean \pm SD. Categorical data are expressed as percentages.

Statistically significant differences before and after treatment were evaluated using the paired Student's *t* test, with statistical significance established at $p < 0.05$.

Statistical analysis was performed using the SPSS version 14.0 software (SPSS, Chicago, IL). Statistical analyses were performed by two authors (M.Ch., D.K.) and a statistician.

Results

Pelvic Varicocele TCFS

The sclerotherapy procedure had a 100% technical success rate. Complications were divided into major and minor, identifying as minor those characterized by temporary and autolimiting pain, with no clinical consequence, and as major those that required a reintervention or hospitalization or that caused permanent consequences. No major complications were registered during the procedure. As a minor complication, in only three (7.9%) patients, we registered a colic-like pain after injection of the sclerosing agent, with spontaneous regression.

The mean time of fluoroscopy was 9.1 ± 2.89 min per bilateral varicocele with cross-pelvic varices and 15.3 ± 5.31 min per bilateral varicocele with non-cross-pelvic varices.

Follow-up

During the 12-month follow-up period no recurrent female varicoceles were observed. At the US Doppler control at 3, 6, and 12 months, a substantial reduction in the size of pelvic varices was observed. A statistically significant improvement in all symptom scores (pelvic pain, dyspareunia, urinary urgency, and menstrual pain) was achieved at the 1-, 3-, 6-, and 12-month follow-up visits (Student's *t* test, $p < 0.01$) (Table 2).

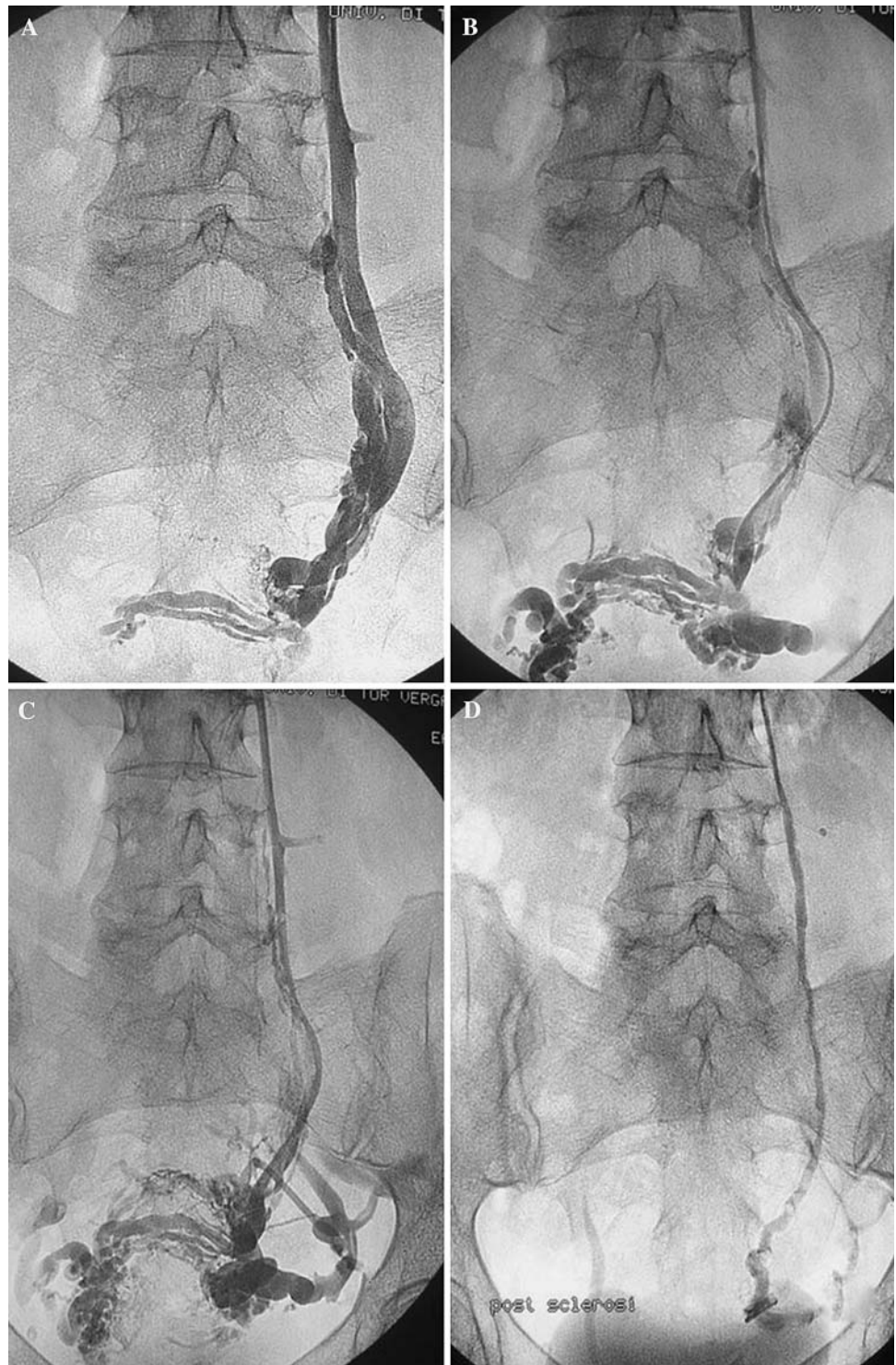
Discussion

Surgical treatment of PCS is associated with evident aesthetic alterations, significant morbidity, the use of general anesthetics, and a minimum hospitalization of 2–5 days [8, 16]. Although the recent advent of laparoscopic techniques has significantly reduced hospitalization times and aesthetic problems, it has not reduced either morbidity or costs [9].

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. Reported pain resolution rates after endovascular treatment range between 100% and 50% [10, 11, 17–23].

TCFS of female varicocele is a minimally invasive interventional procedure requiring only local anesthesia at

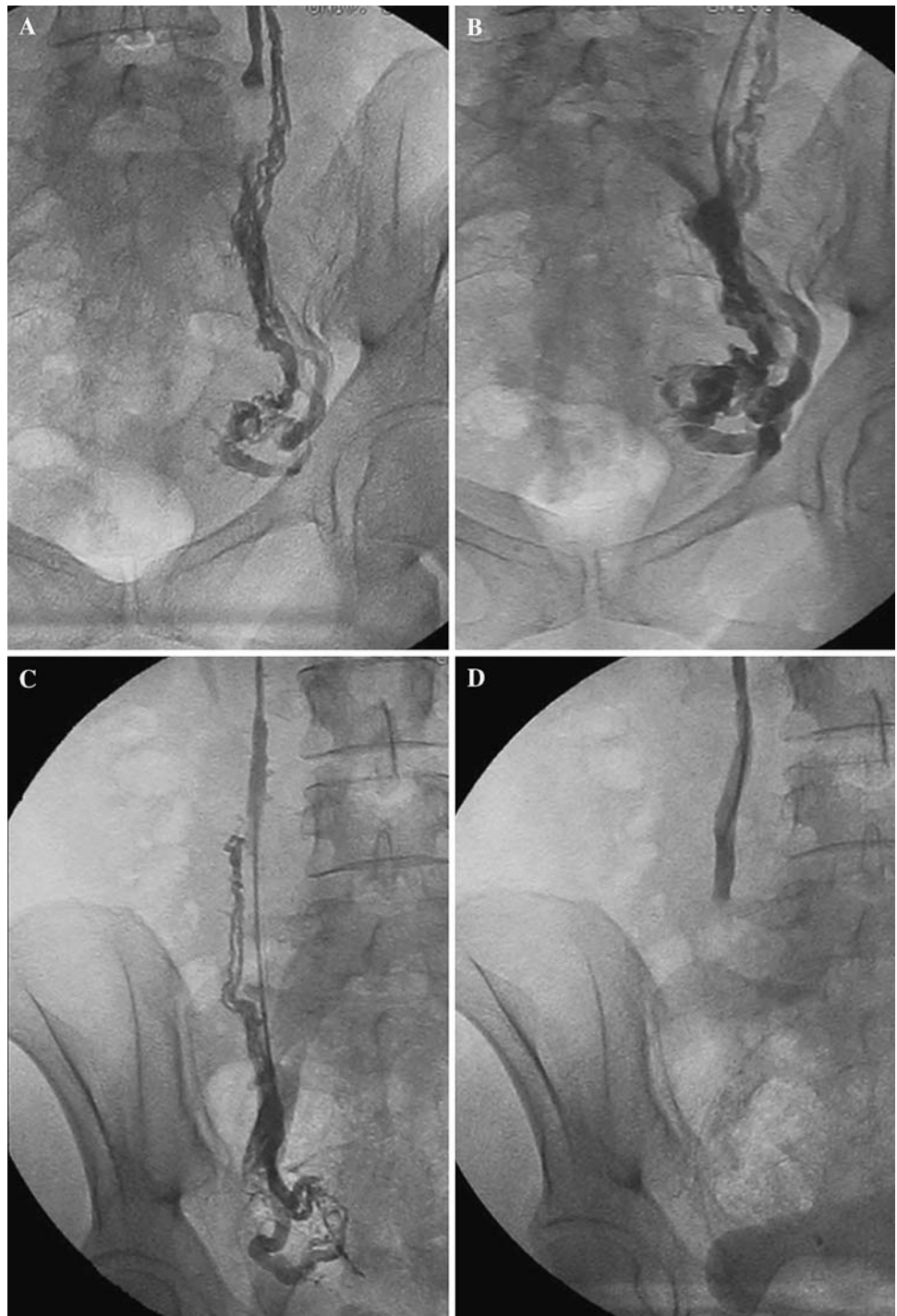
Fig. 1 A 4-Fr Simmons 2 diagnostic catheter was used to selectively catheterize the left ovarian vein, and a retrograde phlebography by energetic hand injection of contrast medium with a 20-ml Luer Lok syringe was carried out to assess the volume of the blood in the pelvic varices and to demonstrate their anatomy (**A**, **B**). In the case of cross-pelvic varices, TCFS was only performed from the left ovarian vein using ~30 ml of STS foam (**C**). Foam injection was continued until no refluxing into the varices was observed after manual injection of contrast agent through the catheter (**D**)



the puncture site and can be performed in an outpatient setting in a day hospital. In our experience, the transbrachial approach, besides allowing a feasible treatment of bilateral varicoceles with a single access and catheter, is preferable, as it is better tolerated by the patient and is associated with lower complication rates.

In 1999, Tessari et al. first described the preparation and use of STS in foam for the treatment of varicose veins [15]. STS causes endothelial surface damage which in turn induces an inflammatory reaction leading to vessel sclerotization. The use of STS in the form of foam is associated with several advantages. The foam spreads on the

Fig. 2 In the case of non-cross-pelvic varices, ~30 ml of STS foam was selectively injected into the varices through the left ovarian vein (**A, B**). A contralateral ovarian phlebography was then performed using a 4-Fr multipurpose catheter to assess the eventual presence of right ovarian varices. When ovarian varices were found also on this side, ~20 ml of STS foam was selectively injected through the right ovarian vein (**C**). Foam injection was continued until no refluxing into the varices was observed after manual injection of contrast agent through the catheter (**D**)



endothelium with a larger surface contact, thus inducing more effective sclerotization. The foam's malleability allows complete filling of the varices through the ovarian veins, without the need for selective catheterization and embolization of eventual collaterals draining into the internal iliac veins. Contrary to other reported series, thanks to this feature of the STS foam, in our experience a selective internal iliac sclerotization never had to be

performed. Differently from other endovascular procedures that use coils, TCFS using STS foam does not involve the insertion of extraneous bodies and, therefore, is less invasive.

On the other hand, although coils are effective in the occlusion of the ovarian veins [13, 14], varicocele may recur due to recanalization of the embolized vessel through endogenous thrombolysis or coil erosion or to development

Table 2 Changes in Symptom Severity Score (SSS) during the 12-month postprocedural follow-up period. SSS evaluating the intensity of four symptoms: 0 corresponds to no evidence of the symptom and 10 to the most severe symptom

Symptom	Baseline	1 mo	3 mo	6 mo	12 mo
Pelvic pain	7.8 ± 1.8	4.4 ± 1.8*	4.2 ± 1.9*	3.8 ± 0.9*	2.7 ± 2.8*
Dyspareunia	3.3 ± 3.7	2.0 ± 2.3*	1.8 ± 2.0*	1.6 ± 1.8*	1.5 ± 2.7*
Urinary urgency	3.5 ± 3.9	2.1 ± 1.9*	1.9 ± 2.1*	1.7 ± 1.9*	1.5 ± 3.0*
Menstrual pain	4.9 ± 4.2	2.7 ± 2.0*	2.6 ± 2.2*	2.4 ± 2.0*	2.2 ± 3.1*

* Statistically significant change from baseline value (Student's *t* test, $p < 0.05$)

of collaterals, as described for embolization with metallic coils of the internal spermatic vein in the treatment of male varicocele [24, 25].

Compared to other endovascular procedures using sclerosing agents, the increased viscosity of STS foam allows the use of smaller amounts of sclerosing agent and is associated with a lower risk of extravasation, systemic dispersion, and adverse reactions. Furthermore, the increased feasibility of this procedure allows a substantial reduction in the duration of fluoroscopy.

In our series we observed no recurrent varicoceles during a 12-month follow-up period. A significant improvement of symptoms (pelvic pain, dyspareunia, menstrual pain, and urinary urgency) was obtained at 1, 3, 6, and 12 months after the procedure (Student's *t* test, $p < 0.05$).

To our knowledge, this is the first reported large series of patients affected by female varicoceles treated with TCFS using STS foam. Multicenter studies including larger patient populations with longer follow-up periods are necessary to confirm our data. TCFS using STS foam in the treatment of PCS is a safe and effective therapeutic option, associated with a low recurrence rate and a significant reduction of symptoms.

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