Treatment of Symptomatic High-Flow Female Varicocele with Balloon-occluded Retrograde Transvenous Foam Sclerotherapy (B-ORTFS) Using Sodium-tetradecyl-sulphate Foam

Poster No.: C-0800
Congress: ECR 2013
Type: Scientific Exhibit
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Keywords: Vascular, Veins / Vena cava, Genital / Reproductive system male, Fluoroscopy, CT-Angiography, Embolisation, Sclerosis, Varices
DOI: 10.1594/ecr2013/C-0800

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Purpose

Pelvic Congestion Syndrome (PCS), also known as pelvic pain syndrome and pelvic venous incompetence, is characterized by non-cyclic chronic pelvic pain with a duration of more than 6 months associated with the presence of ovarian or pelvic varices. This condition usually affects multiparous young women of childbearing age and can be potentially debilitating. The most common symptoms are pelvic pain of variable intensity and duration that can be associated with dysmenorrhea, dyspareunia, post-coital pain and bladder irritability. Pain can extend to leg and can be worsened by walking or postural changes (1). The majority of patients also present lower limb varices.

Although several theories have been put forth to explain the etiology of PCS it remains unclear and it is likely being multifactorial. Since several other pelvic disorders may present with overlapping symptoms (fibroids, adenomyosis, endometriosis, pelvic inflammatory disease, ovarian and fallopian tube diseases, pelvic tumors, cystitis, inflammatory bowel diseases and adhesions), diagnosis of PCS may be very challenging.

Computed Tomography (CT) and Magnetic Resonance (MR) imaging can reveal only large pelvic varices while laparoscopy can fail to demonstrate the presence of pelvic varices in over 80% of the cases.

Transvaginal color-Doppler US can be used to confirm the presence of ovarian and/or pelvic varices larger than 5 mm in diameter and the presence of venous reflux.

Conventional surgical options, such as hysterectomy with or without bilateral salpingo-oophorectomy and laparoscopic techniques, are burdened by high rates of recurrence rates and aesthetic damage and usually require 2-5 days of hospitalisation (1). Recently various endovascular procedures using metal coils and sclerosing agents have been described with low recurrence rates (2). Moreover, endovascular procedures may be performed in a day-hospital setting, thus not requiring hospitalization with reduction of costs and patient discomfort.

The treatment of high-flow pelvic varices with large collateral vessels communicating with the hypogastric or ovarian veins may be particularly arduous and require the placement of several coils with the potential risk of coil migration (3).

We present our experience in 12 patients with PCS presenting high-flow pelvic varices treated by balloon-occlude retrogradetransvenous foam sclerotherapy (B-ORTFS) using a 3% sodium-tetradecyl-sulphate (STS) - air foam.
Methods and Materials

Patients

A retrospective study was conducted in 12 consecutive patients (mean age: 35.2 years; range: 23-46) with PCS with atypical high-flow venous collaterals demonstrated during ovarian venography, treated at our Department by B-ORTFS between June 2005 and May 2008. Full approval and waiver of informed consent for our retrospective study was obtained by our institutional review board. Each patient gave written informed consent prior to the procedure.

Patient population

Patients were referred for treatment by gynecologists after a diagnosis of PCS had been made by physical and color-Doppler US examination and no previous surgical treatment attempts had been performed. High-flow venous collateral vessels were detected in all patients at the preliminary selective ovarian venography preceding trans-catheter foam sclerotherapy (TCFS), as previously described (4).

According to the different anatomical situations that can be observed, we classified high-flow pelvic varicoceles in:

I. non cross-pelvic varicoceles with flow through the ipsilateral hypogastric vein
II. cross-pelvic varicocele:
   1. flow through the contralateral hypogastric vein
   2. flow through both hypogastric veins
   3. flow through the contralateral ovarian vein
   4. flow through all the above venous branches

Type I high-flow venous collaterals were present in 4 (33.3%) patients, type IIa in 3 (25.0%) patients, type IIb in 4 (33.3%), type IIc in 1 (8.3%) and type IIId in 2 (16.7%). Ten (83.3%) patients presented continuous pain and dyspareunia, while 2 (16.7%) patient presented urinary urgency. A worsening of pain during menstruation was present in 5 (41.7%) patients and the coexistence of lower limb varices was observed in 5 (41.7%) patients. Two (16.7%) patients were multiparous, 3 (25.0%) were biparous, 6 (50.0%) were uniparous and one (8.3%) was nulliparous (Table 1).

As previously described, quantitative measure of symptom perception before the procedure was performed in all patients using a Symptom Severity Score (SSS)
evaluating the intensity of each specific symptom (pelvic pain, dyspareunia, urinary urgency and menstrual pain) on a 0 (absence) to 10 (maximum intensity) scale (4).

The majority of the patients occasionally took analgesics to reduce pelvic pain.

**Pelvic varicocele B-ORTFS**

Treatment was performed in a Day Hospital setting. As previously described, a percutaneous access was gained puncturing the right antecubital vein using a 18 Gauge needle, after a local anesthesia had been performed with 2 ml of lidocaine (4). After dilation with a 5 Fr 25-cm-long introducer sheath (Introducer II; Terumo Japan) placed over a 0.035" J tipped 180-cm-long hydrophilic guidewire (Radiofocus, Terumo, Tokyo, Japan), a 4 Fr Simmons 2 (Radiofocus Glidcath; Terumo, Tokyo, Japan) diagnostic catheter was used to selectively catheterize the left ovarian vein. A retrograde venography was then executed by an energetic hand injection of contrast medium to demonstrate the anatomy of the pelvic varices. In order to assess the eventual presence of right ovarian varices, a contralateral selective ovarian venography was also performed using a 4 Fr Multipurpose catheter (Torcon NB Advantage; William Cook Europe ApS, Bjaeverskov, Denmark).

During venography, in each patient, a rapid wash-out of contrast medium from the pelvic varices through atypical high-flow branches tributary to either the hypogastric or ovarian veins was observed.

In cases of type I high-flow pelvic varicoceles, a contralateral percutaneous common femoral vein access was gained using a 7 Fr introducer sheath (Introducer II; Terumo Japan), whereas in case of type IIa high-flow pelvic varicoceles, an ipsilateral common femoral vein access was gained. Type IIc high-flow pelvic varicoceles required a contralateral antecubital venous access as described above.

Under road mapping, the major venous vessels (hypogastric or ovarian veins) to which the high-flow collaterals were tributary were selectively catheterized using a 4 Fr Cobra 1 diagnostic catheter (Radiofocus Glidcath; Terumo, Tokyo, Japan) advanced over a 0.035" J tipped 180-cm-long hydrophilic guidewire (Radiofocus, Terumo, Tokyo, Japan). The catheter was exchanged with a 10 mm diameter balloon-catheter which was then inflated to occlude the vessel. A venographic control was then performed through the balloon catheter to confirm the retrograde opacification of the pelvic varices and to exclude the presence of other atypical high-flow venous collaterals requiring balloon-occlusion.

STS foam was prepared, as previously described, by connecting through a three-way stopcock two 10 ml Luer Lok™ syringes containing respectively 2 ml of 3% STS
(Fibrovein, STD Pharmaceuticals) and 8 ml of air and by mixing their contents together until a homogeneous foam was obtained.

After balloon-occlusion and the complete filling of the pelvic varices with contrast media, the patient was asked to perform Valsalva’s maneuver while 20-40 ml of 3% STS foam were injected until the contrast media present in the pelvic varices was completely washed-out. The absence of contrast media in the pelvic varices indicated their complete filling with 3% STS foam (figure 1).

In case of complete stagnation of contrast medium after balloon-occlusion, one of the balloon catheters was deflated creating an obliged outflow route and then re-inflated immediately after (figure 2).

The balloon-occlusion of the major veins to which the high-flow collaterals were tributary was kept for 30 minutes. After this period a control venography was performed to demonstrate the complete occlusion of the pelvic varices.

Patients were discharged 4 hours after the procedure. A 3-day oral anti-inflammatory (200 mg/day nimesulide) and a 5-day oral antibiotic (1 g/day amoxicillin) drug therapy were prescribed.

**Follow-up**

Physical examination, a pelvic and transvaginal color-Doppler US examination and a questionnaire-based assessment of pain using the SSS was performed at 1, 3, 6 and 12 months after the procedure. The SSS evaluated the presence and the entity of the specific symptoms (pelvic pain, dyspareunia, urinary urgency and menstrual pain) during the four weeks preceding the follow-up visit.

**Study Endpoints and Statistical Analysis**

Study endpoints were rates of technical success and recurrence of PCS during a 12-month follow-up period.

Technical success was defined as the complete occlusion of pelvic varices at post-procedural venography with no evidence of venous flow observed at color-Doppler US.

The appearance of pelvic varices and/or return of SSS to baseline values was considered as a recurrence of PCS.

All data are given as means ± SD. Categorical data are expressed as percentages.
The paired Student's $t$ test was used to assess statistical significance of differences before and after treatment ($P$-value < 0.05). All statistical analyses were performed using the Epi Info 3.5.1 software (CDC, Atlanta USA).
Fig. 1: Figure 1: Selectively left ovarian venography demonstrating a type II d pelvic varicocele (a). Selective catheterization and balloon-occlusion of the ipsilateral and contralateral hypogastric veins (b-d). Left ovarian venography after injection of 3% STS foam showing complete occlusion of the pelvic varices (e, f).

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Fig. 2: Figure 2: Right ovarian venography demonstrating a type IIa pelvic varicocele (a). Selective catheterization and balloon-occlusion of the ipsilateral hypogastric vein (b-c). Right ovarian venography showing a high-flow venous collateral to the contralateral hypogastric vein (type II b pelvic varicocele) (d). Selective catheterization and balloon-occlusion of the contralateral hypogastric vein (e-g). Right ovarian venography demonstrating a rapid out-flow of contrast medium through the right ovarian vein (h). Balloon-occlusion of the right ovarian vein and control right ovarian venography showing no further high-flow venous collateral vessels with stagnation of contrast-medium in the pelvic varices (i, j). Injection of 3% STS foam during temporary deflation of the balloon-catheter in the right ovarian vein to create an obliged contrast-medium out-flow route (k). Left ovarian venography showing complete occlusion of the pelvic varices (l).
Fig. 3: Figure 3: Selectively left ovarian venography demonstrating a type I high-flow pelvic varicocele (a). Selective catheterization and balloon-occlusion of the ipsilateral hypogastric vein (b, c) and control venography demonstrating a type II b high-flow pelvic varicocele (d). Selective catheterization and balloon-occlusion also of the contralateral hypogastric veins (e). Left ovarian venography after injection of 3% STS foam showing complete occlusion of the pelvic varices (f).
Table 1: Table 1. Patient population.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic Pain</td>
<td>12 (100)</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>10 (83.3)</td>
</tr>
<tr>
<td>Urinary Urgency</td>
<td>2 (16.7)</td>
</tr>
<tr>
<td>Menstrual Pain</td>
<td>5 (41.7)</td>
</tr>
<tr>
<td>Nulliparous</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>Uniparous</td>
<td>6 (50.0)</td>
</tr>
<tr>
<td>Biparous</td>
<td>3 (25.0)</td>
</tr>
<tr>
<td>Multiparous</td>
<td>2 (16.7)</td>
</tr>
<tr>
<td>I</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>IIa</td>
<td>3 (25.0)</td>
</tr>
<tr>
<td>IIb</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>IIc</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>IIId</td>
<td>2 (16.7)</td>
</tr>
</tbody>
</table>

Table 2: Table 2. Symptom Severity Score changes during the 12 month post-procedural follow-up period.

<table>
<thead>
<tr>
<th>Follow-up (months)</th>
<th>Pelvic Pain</th>
<th>Dyspareunia</th>
<th>Urinary Urgency</th>
<th>Menstrual Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>8.2 ± 0.7</td>
<td>6.3 ± 1.7</td>
<td>1.1 ± 2.4</td>
<td>2.9 ± 3.3</td>
</tr>
<tr>
<td>1</td>
<td>4.2 ± 1.1†</td>
<td>2.1 ± 1.3†</td>
<td>0.4 ± 0.9†</td>
<td>0.8 ± 1.1†</td>
</tr>
<tr>
<td>3</td>
<td>3.3 ± 1.3†</td>
<td>1.5 ± 1.4†</td>
<td>0.2 ± 0.6†</td>
<td>0.6 ± 1.2†</td>
</tr>
<tr>
<td>6</td>
<td>2.9 ± 0.9†</td>
<td>1.4 ± 1.6†</td>
<td>0.2 ± 0.4†</td>
<td>0.5 ± 0.9†</td>
</tr>
<tr>
<td>12</td>
<td>2.8 ± 1.0†</td>
<td>1.4 ± 1.5†</td>
<td>0.3 ± 0.7†</td>
<td>0.6 ± 1.1†</td>
</tr>
</tbody>
</table>

Symptom Severity Score

Table 2: Table 2. Symptom Severity Score changes during the 12 month post-procedural follow-up period.
Results

Pelvic varicocele B-ORTFS

A technical success was achieved in all patients.

A colic-like pain occurred after the injection of sclerosing agent with spontaneous resolution after 5 minutes in two (40%) patients.

No other complications were observed.

Mean fluoroscopy time was 23.4 minutes ± 3.91.

Follow-up

No recurrences of PCS were observed during the 12 month follow-up period.

A substantial reduction in size of the pelvic varices with no signs of blood flow was observed at the 3, 6 and 12-month control color-Doppler US.

SSS assessed at 1, 3, 6 and 12 months revealed a significant improvement of symptoms (Student’s $t$ test $P<0.01$). (Table 2).

DISCUSSION

Conventional surgical and laparoscopic techniques are associated to reported rates of residual pain of 33% and recurrence of 20%. Although laparoscopic techniques have reduced aesthetic damage and hospitalization times, they have failed to significantly affect morbidity and costs.

The first successful endovascular treatment of pelvic varicocele was described in 1993 by Edwards et al using metal coils (2). Subsequently embolization with various glues and sclerosing agents has been described with reported pain resolution rates ranging between 60-100% (2, 3, 4). Contrarily to surgical techniques, endovascular techniques are minimally invasive and may be performed in a Day-Hospital setting, thus further reducing costs and patient discomfort.
The preparation and use of STS foam was first described in 1999 by Tessari for the sclerotherapy of varicous veins. We have previously reported our experience with Transcatheter Foam Sclerotherapy using 3% STS foam in male and female varicocele (4). In our experience, the benefits of using this sclerosing agent in the form of foam are an increased contact with the endothelial surface, the malleability of the foam allowing the complete filling of the varices through the ovarian veins without the need of selectively catheterizing low-flow collaterals and the need for smaller volumes of sclerosing agent reducing toxic effects and risk of embolization. Furthermore, the use of STS can be considered less invasive as it does not involve the positioning of extraneous bodies such as metal coils that may be associated to re-canalisation, coil erosion, varicocele recurrence through unembolised low-flow collaterals and migration (3).

The use of balloon-occluded retrograde transvenous embolization (B-RTO) was first described by Kanagawa et al for the treatment of large gastric fundal varices with a spontaneous splenorenal shunt. This technique is also used for the treatment of refractory portosystemic encephalopathy caused by a large splenorenal shunt.

Balloon-occluded retrograde transvenous embolization from the hypogastric veins has been previously described as a completion of pelvic varicocele embolization with residual low-flow collaterals tributary to the hypogastric vein (1). As previously described, thanks to the characteristics of the 3% STS foam, TCFS with this sclerosing agent is sufficient to completely fill and occlude pelvic varices in case of low-flow collaterals to the hypogastric arteries or contralateral ovarian vein (4). Differently, we performed B-ORTFS in case of atypical high-flow venous collaterals. The identification of all high-flow collaterals and the simultaneous balloon-occlusion of the major venous vessels to which they are tributary enables the complete opacification of the pelvic varices with contrast agent and the exclusion of further atypical high-flow collaterals. The sclerosing agent successively injected through the ipsilateral ovarian vein replaces the contrast medium. This enables to determine when the pelvic varices are completely filled with the sclerosing agent, thus optimizing the amount of 3% STS foam required and avoiding its systemic dispersion. In case of stagnation of the contrast medium in the pelvic varices after balloon-occlusion, one of the balloon catheters needs to be momentarily deflated in order to allow the outflow of the contrast medium and re-inflated immediately after. The balloon-occlusion kept for 30 minutes is sufficient to determine an endothelial damage leading to complete sclerotization of the pelvic varices.

During the follow-up period, no recurring pelvic varices were detected and a significant and persistent improvement of symptoms (pelvic pain, dyspareunia, menstrual pain and urinary urgency) was observed (Student's t test; P<0.05).
Conclusion

To our knowledge, this is the first reported series of pelvic varicocele with high-flow collaterals treated by B-ORTFS.

Our preliminary results need to be confirmed by studies including larger patient populations.

Treatment of PCS with high-flow venous collaterals by B-ORTFS is a safe and effective and should be taken in consideration as an alternative to other endovascular and surgical options.
References


