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Clinical paper review for Health care professionals

"Embolization of ovarian vein for pelvic congestion syndrome with ethylene vinyl alcohol copolymer (Onyx[™])" Marcelin C. et al. 2017



Highlights:

- 1. 17 consecutive patients
- 2. Embolization with Onyx[™] and metallic coils
- 3. Mean follow-up 24.2 months

- 4. 76.4% clinical efficacy as resolution of the symptoms after the embolization
- 5. 94.1% clinical efficacy as resolution of the symptoms at the end of the follow-up

Background

- Pelvic Congestion Syndrome (PCS), which has recently been redefined as Pelvic Venous Disorder (PeVD), presents with anatomical varicosities and incompetent parametrial veins and is one of the main causes of chronic pelvic pain.
- Endovascular treatment of PCS/PVD is challenging and requires occlusion of incompetent pelvic veins.
- Most authors reported the use of metallic coils and sclerotherapy for pelvic embolization procedure in treating PCS/PVD. However, coils convey a risk of migration or further recanalization and sclerotherapy does not allow a monitoring with fluoroscopy.
- The Onyx[™] Liquid Embolic System (LES) is an ethylene vinyl alcohol copolymer that allows easy fluoroscopic monitoring and control with less risk than coils and glue of additional migration or recanalization.

Study objective

To evaluate the safety and efficacy of Pelvic Venous Embolization using ethylene vinyl alcohol copolymer (Onyx[™]) for PCS/PeVD.

Materials and methods

- Seventeen consecutive women with PCS/PeVD, which were treated using pelvic venous embolization with Onyx[™] 18 between January 2012 and July 2016, were retrieved.
- PCS/PeVD was initially diagnosed by clinical examination and the results of transvaginal Doppler ultrasound and further confirmed by pelvic venography.
- Embolization was proposed as a first-line treatment after a discussion by a multidisciplinary committee comprised of gynecologists, vascular surgeons, and radiologists.

Patients' characteristics	Mean [range]
Age (year)	44.7 [34–71]
Parity	2.6 [0-7]
Gravidity	2.2 [0-4]
Symptoms	
 Chronic pelvic pain 	17
• Dyspareunia	10
 Vulvoperineal varicosities 	3
 Painful defecation, mictional urgency 	3
 Painful menstruation, dysmenorrhea 	6
 Lower limb varices 	11
Medical history	
 Essure[®] placement for birth control 	1
 Intern iliac vein thrombosis 	1
 Laparoscopic surgery for endometriosis 	1
 Negative laparoscopy for pelvic pain 	1

- For the embolization, ethylene vinyl alcohol copolymer (Onyx[™] 18) and metallic coils (Concerto[™], Ev3, or IDC[™], Boston Scientific) were used. Coils were employed first when the pelvic varicosities were widely dilated with an anastomosis of the internal iliac vein to reduce blood flow velocity and diminish the risk of non-target embolization of Onyx[™].
- After embolization, in case of persistent symptoms, a second intervention was planned two months late
- Prospective clinical follow-up was performed until September 2016 via telephone interviews.
- Primary and secondary clinical efficacy was defined respectively by the resolution of the symptoms after the embolization and at the end of the follow-up irrespective of the number of embolization.

Results

1 0 7 Technical efficacy

Complications

94.1% Clinical efficacy (resolution of the symptoms at the end of the follow-up) Mean Onyx[™] volume used: 5.2 mL 2.2 SD

Coils (with Onyx[™]) were used: in 47% of patients (n=8)

• Mean follow-up time was 24.2 months

• (range: 6–69 months).

0%

- During the follow-up, 5/17 women (29%) had recurrent symptoms 21 months after their embolization (range: 7–42 months).
- Four women (24%) had a second embolization of pelvic varicosities 1-3 months later.
- One woman underwent a third embolization at four months.

Procedure outcomes	
Mean time between diagnosis and embolization	2 months (range 1-6 months)
Patients with left gonadal vein embolization (n)	17/17
left obturator vein embolization (n)	8/17
pudental vein embolization (n)	6/17
ischiatic vein embolization (n)	3/17
ischiatic vein embolization (n)	1/17

Conclusions

Pelvic embolization using Onyx[™] is a feasible and safe treatment for PCS/PeVD, allowing complete embolization of pelvic varicosities through an ovarian vein, without the risk of the migration of embolic material.

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See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

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Reference

Marcelin C et al. "Embolization of ovarian vein for pelvic congestion syndrome with ethylene vinyl alcohol copolymer (Onyx[®])". Diagnostic and Interventional Imaging. 2017, 98:12.

