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Pelvic Congestion Syndrome

Pelvic Congestion Syndrome (PCS)

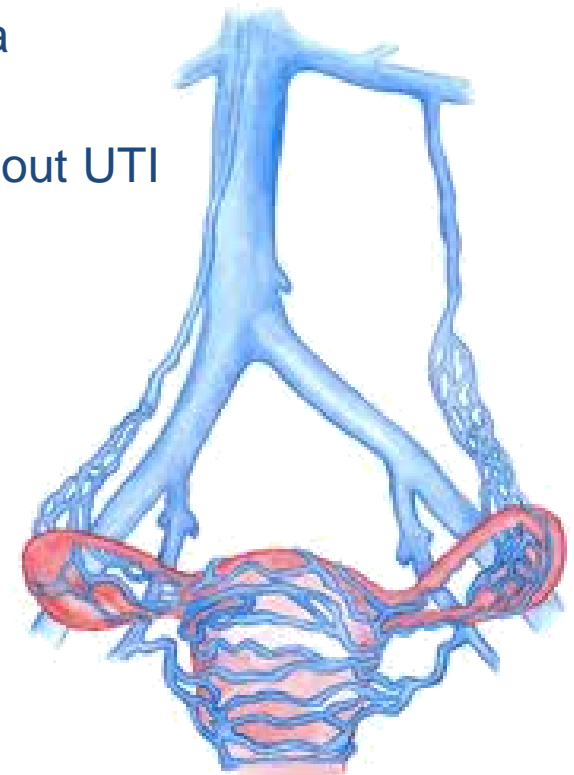
Condition and Symptom Background

Condition Overview

- Non-cyclic pelvic pain affecting 39.1% of women at some point during lifetime¹
- Typical age of onset: 20s or early 30s
- May account for ~10 – 15% of outpatient gynecological visits¹
- Dull aching pain
 - Unilateral
 - Worse with walking or postural changes

Urogynecological Symptoms²

- Dysfunctional uterine bleeding
- Dysmenorrhea
- Dyspareunia
- Dysuria without UTI



Sources:

1. Robinson JC, et al. Chronic pelvic pain. *Curr Opin Obstet Gynecol.* 1993 Dec;5(6):740-3
2. Ignacio EA., et al. Pelvic congestion syndrome: diagnosis and treatment. *Sem in Interv Radiol.* 2008; 25; 4: 361—368.
3. Image Courtesy of iVein.com: <http://www.ivein.com/venous-disease/pelvic-congestion-syndrome/>

PCS Diagnostic Testing

Diagnostic Methods and Typical Indicators of PCS

Ultrasonography^{1,2}

- Sluggish venous flow
- Pelvic venous diameters >4mm
- Tortuous pelvic vein > 6 mm in diameter
- Blood flow of 3 cm/s or reversed caudal flow
- Dilated arcuate veins in the myometrium

Magnetic Resonance Venography (MRV)^{2,3}

- Ovarian vein diameter >1.5 times the size of the contralateral vein
- Contrast in the pelvic plexus
- Tortuous hypogastric veins
- 88-100% sensitivity
- Poor specificity

Computed Tomography (CT)^{2,4,5}

- Ovarian vein diameter > 8 mm
- Four ipsilateral parauterine veins of varying caliber with one measuring > 4 mm in diameter and

Venography^{2,6}

- Ovarian vein diameter > 10 mm
- Uterine venous engorgement
- Congestion of the ovarian plexus
- Filling of the pelvic veins across the midline or filling of thigh varices

Sources:

1. Tu, F.F., Hahn, D., and Steege, J.F. Pelvic congestion syndrome-associated pelvic pain: a systematic review of diagnosis and management. *Obstet Gynecol Survey*. 2010; 65: 332–340
2. Moore C.J. Pelvic Congestion Syndrome Update. *Endovascular Today*. 2011; Oct: 24-31.
3. Ascianto, G., Mumme, A., Marpe, B., Koster, O., Ascianto, K.C., and Geier, B. MR venography in the detection of pelvic venous congestion. *Eur J Vasc Endovasc Surg*. 2008; 36: 491–496
4. Coakley FV, Varghese SL, and Hricak H. CT and MRI of pelvic varices in women. *J Comp Assist Tomogr* 1999;73:429-434
5. Rozenblit AM., Ricci ZJ., Tuvia J., and Amis ES. Incompetent and Dilated Ovarian veins: A Common CT Finding in Asymptomatic Parous Women. *Amer J Roent*. 2001;176: 119-122
6. Kennedy A, Hemingway A. Radiology of ovarian varices. *Br J Hosp Med*. 1990;44:38-43.

Rationale

- Intended to suppress ovarian activity via hormonal changes

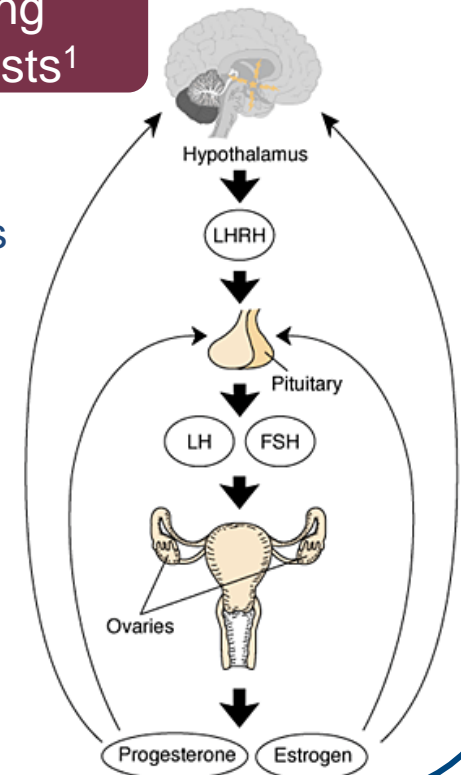
Treatment Modalities

Medroxyprogesterone¹

- Daily administration
- Visual analogue score reductions while on therapy
- Requires concomitant psychotherapy
- Side effects
 - Bloating
 - Weight gain

Gonadatropin-Releasing Hormone (GnRH) Agonists¹

- Slightly more effective
 - Pain symptoms
 - Depressive symptoms
 - Sexual function
- Side effects
 - Hot flashes
 - Night sweats
 - Vaginal dryness
 - Mood changes



Sources:

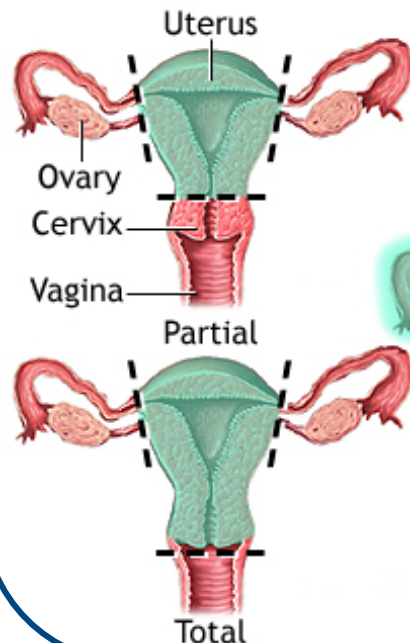
1. Tu, F.F., Hahn, D., and Steege, J.F. Pelvic congestion syndrome-associated pelvic pain: a systematic review of diagnosis and management. *Obstet Gynecol Survey*. 2010; 65: 332–340
- 4 2. Image Courtesy of Fibroid.com: <http://www.fibroid.com/lupron/>

Rationale

- Intended to suppress ovarian activity via removal of organ or obstruction of blood flow to organ

Treatment Modalities

Hysterectomy



A hysterectomy removes the uterus and may also remove the cervix (total) and ovaries, tubes, lymph nodes and upper vagina (radical)

- Efficacy is unclear

Ovarian Vein Ligation¹

- 75% of women experienced pain reduction
- Follow-up 1.0 - 5.6 years
- No complications described

ADAM.

Sources:

1. Tu, F.F., Hahn, D., and Steege, J.F. Pelvic congestion syndrome-associated pelvic pain: a systematic review of diagnosis and management. *Obstet Gynecol Survey*. 2010; 65: 332–340
- 5 2. Image courtesy of National Institute of Health. <http://www.nlm.nih.gov/medlineplus/ency/imagepages/17073.htm>

Rationale

- Intended to suppress ovarian activity via obstruction of blood flow to organ

Treatment Modalities

Embolotherapy¹

- 12 relevant studies
- Few explicit criteria
- 40-100% of patients with improvement in symptoms
- VAS improvement
 - 7.2 - 7.9 pretreatment
 - 2.5 – 5.6 post-treatment
- Potential complications^{1,2}:
 - Perforation of the ovarian vein
 - Coil migration into pulmonary vasculature
 - Stent migration
 - Flank pain
 - Fevers
 - Venipuncture site hematoma



Sources:

1. Kim, HS. et al. . Embolotherapy for pelvic congestion syndrome: long-term results. *J Vasc Interv Radiol.* 2006; 17: 289–297
2. Tu, F.F., Hahn, D., and Steege, J.F. Pelvic congestion syndrome-associated pelvic pain: a systematic review of diagnosis and management. *Obstet Gynecol Survey.* 2010; 65: 332–340

PCS Percutaneous Embolotherapy

Single-Center Protocol: The Moore Method^{1,2}

1

Site of Entry

2

Diagnostic
Imaging

3

Access
Target
Vessel

4

Embolization

Site of Entry

- A. The right common femoral vein is cannulated using the Seldinger technique
- B. Place a 6-French sheath in the right common femoral vein

Access Left Renal Vein

- A. Perform a venogram of the inferior vena cava from the sheath to identify the level of the renal veins
- B. Insert a wire into the vena cava above the level of the renal veins
- C. Select an appropriately sized 6-French guiding sheath and insert it over the wire above the level of the left renal vein
- D. Retract the guidewire to the edge of the guiding sheath
- E. With the guiding sheath directed at the left wall of the vena cava, slowly retract it until it engages the left renal vein

Sources:

1. Moore CJ. Pelvic Congestion Syndrome. Presentation at TheVeins. 2012.
- 7 2. Moore CJ. Pelvic Congestion Syndrome Update. Endovascular Today. 2011; Oct: 24-31.

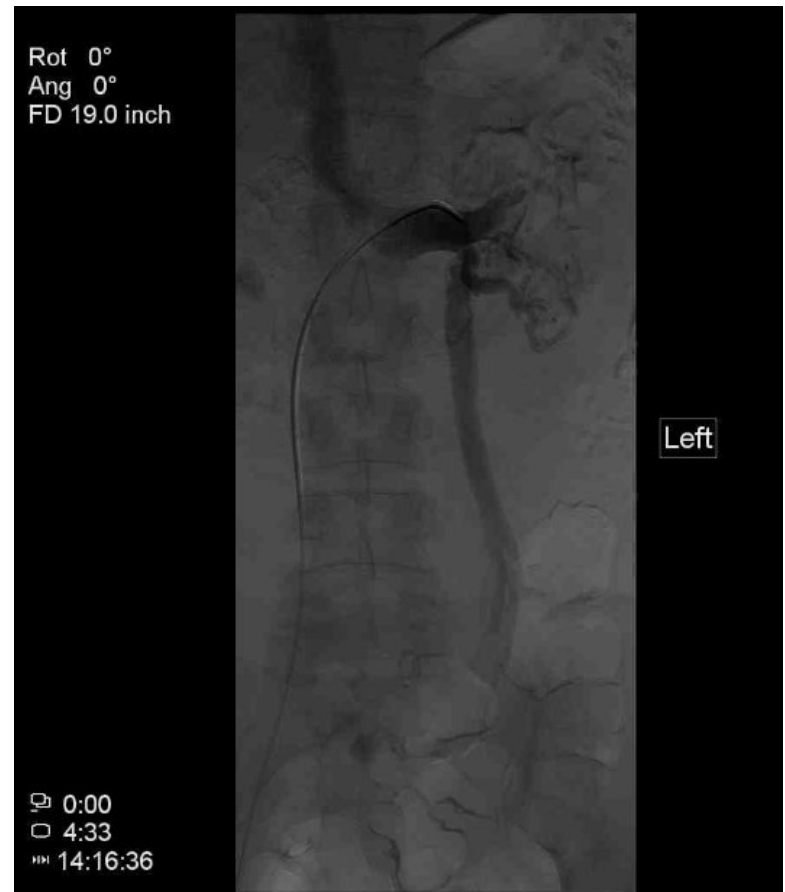
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Single-Center Protocol: The Moore Method



Renal Vein, Ovarian Vein Venography^{1,2}

- A. Must be performed in supine position
- B. Ovarian vein venography is performed via cannulation of the left renal vein and remains the gold standard test for diagnosis of ovarian vein reflux and PCS
- C. Selective venography performed during a Valsalva maneuver or with the table in the reverse Trendelenburg position
- D. Reflux can also be exacerbated by tilting the table into a semi-upright position



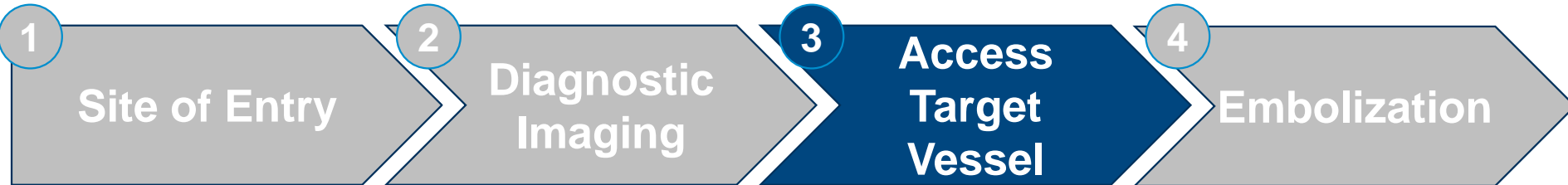
Results from case studies are not necessarily indicative of results in other cases. Results in other cases may vary.

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2. Moore CJ. Pelvic Congestion Syndrome Update. Endovascular Today. 2011; Oct: 24-31.

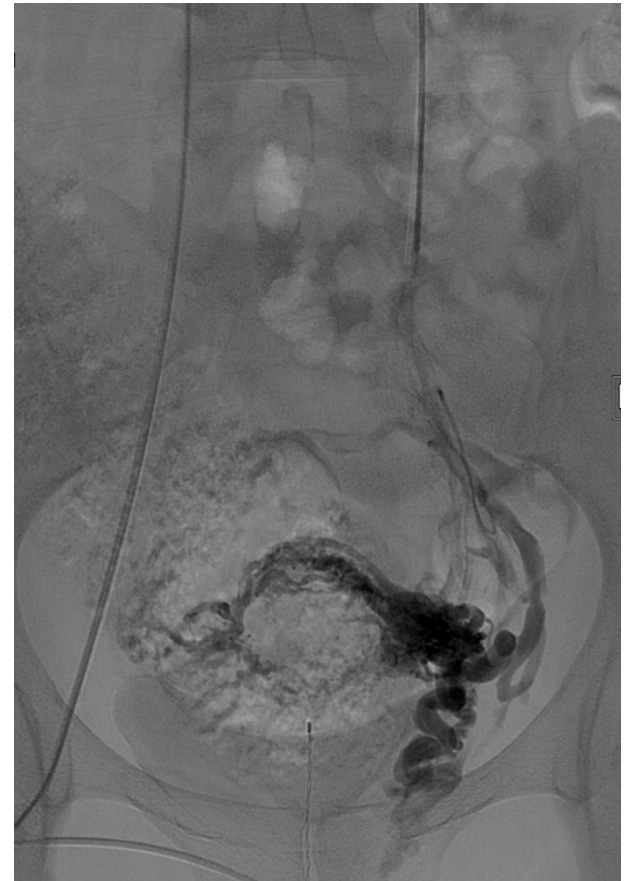
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Single-Center Protocol: The Moore Method



Access Left Ovarian Vein^{1,2}

- A. Advance diagnostic catheter into the distal ovarian vein

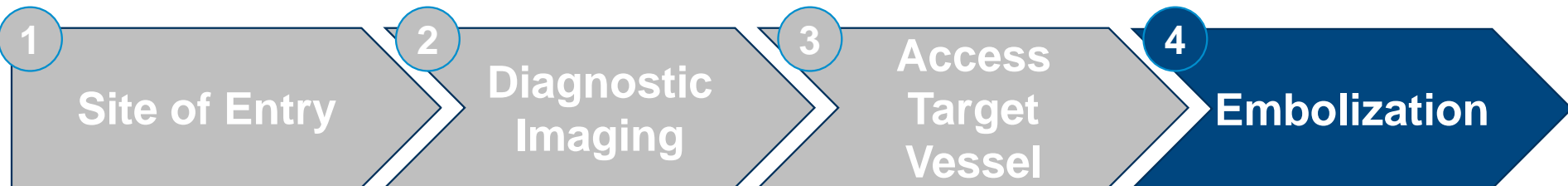


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PCS Percutaneous Embolotherapy

Single-Center Protocol: The Moore Method



Dual-Device Approach:

① Vascular Plug: Amplatzer¹

② Embolization Coils: InterlockTM-35 Fibered IDC Occlusion System^{1,2}

- A. Although any 0.035" coil can be used, the number of coils required to successfully occlude the entirety of this dilated ovarian vein has led [this center] to primarily use InterlockTM-35 coils
- B. Coils come in much larger diameters and in lengths up to 40cm, which are more appropriate for this indication
- C. Interlock coils have the ability to be recaptured until 95% deployed, allowing for optimal placement, especially near the confluence of the ovarian and renal veins



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Single-Center Protocol: The Moore Method

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Embolization



- Transcatheter therapy for PCS given grade 2B recommendation by AVF and SVS²
- 75% - 80% of women report an improvement of symptoms within the first 2 weeks after embolization²

In this study, use of Interlock™ embolization coils resulted in the need for fewer coils and superior packing into desired vessel¹

Results from case studies are not necessarily indicative of results in other cases. Results in other cases may vary.

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1. Moore CJ. Pelvic Congestion Syndrome. Presentation at TheVeins. 2012.
2. Moore CJ. Pelvic Congestion Syndrome Update. Endovascular Today. 2011; Oct: 24-31.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

INTENDED USE/INDICATIONS FOR USE

The Interlock - 35 Fibered IDC Occlusion System is indicated for obstructing or reducing blood flow in the peripheral vasculature during embolization procedures. This device is not intended for neurovascular use.

CONTRAINDICATIONS

None known.

PRECAUTIONS

Do not attempt to use the Interlock - 35 Fibered IDC Occlusion System with a soft-walled delivery catheter. Do not advance the Interlock - 35 Fibered IDC Occlusion System if it becomes lodged within the catheter. Determine the cause of the resistance and replace the catheter and coil if necessary.

ADVERSE EVENTS

The complications that may result from a peripheral embolization procedure include, but are not limited to:

- Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, nerve and vessel dissection or perforation, etc.)
- Pain
- Hemorrhage
- Infection necessitating medical intervention
- Foreign body reactions necessitating medical intervention
- Emboli
- Ischemia
- Vasospasm
- Tissue necrosis
- Undesirable clot formation of the vasculature
- Recanalization
- Death
- Temporary neurological deficit