

# Ovarian and Internal Iliac Vein Endovascular Occlusion as a Treatment of Pelvic Congestion



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## DESCRIPTION

Pelvic congestion syndrome is characterized by chronic pelvic pain that is often aggravated by standing; diagnostic criteria for this condition are not well-defined. Endovascular occlusion (e.g., embolization, sclerotherapy) of the ovarian and internal iliac veins has been proposed as a treatment for individuals who fail medical therapy. Pelvic congestion syndrome is a chronic pelvic pain syndrome of variable location and intensity, which is associated with dyspareunia and postcoital pain and aggravated by standing. The syndrome occurs during the reproductive years, and pain is often greater before or during menses. The underlying etiology is thought to be related to varices of the ovarian veins, leading to pelvic vascular congestion. Because there are many etiologies of chronic pelvic pain, the pelvic congestion syndrome is often a diagnosis of exclusion, with the identification of varices using a variety of imaging methods, such as magnetic

resonance imaging, computed tomography, or contrast venography. However, the syndrome is still not well-defined, and it is unclear whether pelvic congestion syndrome causes chronic pelvic pain. Although venous reflux is common, not all women with this condition experience chronic pelvic pain and, conversely, chronic pelvic pain is reported by women without pelvic congestion syndrome.

Initial treatment of pelvic congestion syndrome includes psychotherapy and medical therapy (e.g., nonsteroidal anti-inflammatory drugs) and hormonal therapy. For individuals who fail initial therapy, surgical ligation of the ovarian vein may be considered. Embolization therapy and/or sclerotherapy of the ovarian and internal iliac veins has been proposed as an alternative to surgical ovarian vein ligation. Endovascular occlusion can be performed using a variety of materials including coils, vascular plugs, glue, liquid embolic agents, and gelatin sponge or powder (Gelfoam).

### **Clinical Context and Therapy Purpose**

The purpose of ovarian and/or internal iliac vein endovascular occlusion in individuals who have pelvic congestion syndrome is to provide a treatment option that is an alternative to or an improvement on existing therapies.

### **Patients**

The relevant population of interest is individuals with pelvic congestion syndrome.

### **Interventions**

The therapies being considered are ovarian and internal iliac vein endovascular occlusion.

### **Comparators**

The following therapies are currently being used to make decisions about pelvic congestion syndrome: medical therapy (e.g., analgesics, hormonal therapy) and surgical ovarian vein ligation.

### **Outcomes**

The general outcomes of interest are symptom reduction and adverse events. Procedural follow-up ranges from 1 to 3 months.

### **Comparative Studies**

(2020) Gavrilov et al. completed a single-center, retrospective cohort analysis compared the safety and efficacy of embolization with coils (N=67) and endoscopic resection (N=28) in women with pelvic congestion syndrome. Effects on pelvic venous pain, pelvic venous reflux, diameter of the pelvic veins, restoration of daily activity, and treatment safety were assessed. Clinical examinations were conducted at 1 day, 10 days, 30 days, and 36 months post-procedure. Pain reduction was observed at  $3.6 \pm 1.4$  days after embolization and  $2.5 \pm 0.8$  days after endoscopic resection ( $P=0.49$ ). At 1-month post-procedure, complete relief of pelvic pain was reported by 52 (77.6%) patients' post-embolization and by 25 (89.3%) patients post-resection ( $P>0.05$ ). Rates of valvular incompetence decreased from 85% at baseline in both groups to 3% and 0% in the

embolization and resection groups at 36 months, respectively. Postembolization syndrome was diagnosed in 13 (19.4%) patients. A 4-fold increased rate of venous thromboembolism was observed in the embolization group. The RR of this complication after embolization compared to resection was 1.4 (95% CI, 1.146 to 1.732). The time to post-embolization pain relief was statistically greater than the time calculated to postoperative pain relief (11.2±1.7 day and 4.7±0.5 days,  $P=0.0002$ ). Pelvic pain relief was achieved in 95.5% of patients in the embolization group and 100% of patients in the endoscopic resection group at 3 years. The authors note that endoscopic resection is associated with at least similar, and in some cases, superior outcomes, in terms of significantly shorter times to postprocedural pain relief and avoidance of postembolization syndrome. Evidence of selection bias through the use of differing eligibility criteria between groups limits the findings of this study.

### **Randomized Studies**

(2018) Guirola et al. noted in a randomized, prospective trial compared the safety and efficacy of embolization with vascular plugs (VPs) or fibered platinum coils (FPCs) in women with pelvic congestion syndrome. Patients were enrolled (N=100) and randomly assigned to each treatment group via block randomization (N=50). Diagnosis of pelvic congestion syndrome was accomplished through a symptom screening questionnaire followed by an ultrasound study. Patients with 3 or more positive symptom responses advanced to the ultrasound screening, and patients with pelvic veins >6 mm in diameter and/or venous reflux or dilated midline communicating veins were advanced to randomization. Follow-up screening occurred at 1, 3, 6, and 12 months. The primary outcome was clinical success assessed subjectively through patient responses regarding relief of symptoms and pain scores assessed with the visual analog scale. Clinical success was achieved in 89.7% of the FPC group and 90.6% of the VP group ( $P=0.760$ ). Improvement in visual analog scale pain scores at the end of 12 months was 90.2% overall and improvement was seen in 95.9% of the FPC group and 96% of the VP group ( $P>0.999$ ). A total of 11 (22%) complications were seen in the FPC group and 5 (10%) in the VP group ( $P=0.059$ ). Minor adverse events included access site hematoma and ovarian vein extravasation. Device migrations were considered major complications. A major limitation in the study is the significant difference in age ( $P=0.004$ ) and pre-treatment visual analog scale pain score between groups ( $P=0.004$ ), both of which were higher in the VP group despite randomization.

### **Systematic Reviews**

(2021) Senechal et al. completed a review on the study population included 327 consecutively recruited patients referred to the interventional radiology unit from January 2014 to December 2019 due to chronic pelvic congestion (91; 27.83%), lower limb varices (15; 4.59%), or a combination of both the symptoms (221; 67.58%). Preprocedural pelvic, transvaginal Doppler ultrasound (US), and MRI were conducted in all the patients and revealed anatomical varicosities and incompetent pelvic veins in 312 patients. In all the patients, selective catheterization demonstrated uterine venous engorgement, ovarian plexus congestion, or pelvic vein filling. Retrograde flow was detected on catheter venography in the left ovarian vein (250; 78%), the right ovarian

vein (85; 26%), the left internal iliac vein (222; 68%), and the right internal iliac vein (185; 57%). Patients were followed-up at 1, 6, and 12 months, and years thereafter systematically by the referring angiologist and the interventional radiologist of center. They were contacted by telephone in November and December 2020 to assess pain perception and quality of life by using the visual analog scales from 0 to 10 with assessments made at the baseline and last follow-up. Of the 327 patients (mean age, 42 ± 12 years), 312 patients were suffering from pelvic congestion syndrome and 236 patients was suffering from lower limb varices. All underwent embolization by using ethylene vinyl alcohol copolymer (Onyx®). Eighty-five right ovarian veins, 249 left ovarian veins, 510 tributaries of the right internal iliac vein, and 624 tributaries of the left internal iliac vein were embolized. A cohort of patients also underwent nutcracker syndrome angioplasty (6.7%) and May–Thurner syndrome angioplasty (14%) with a stent placement. The initial technical success rate was 80.9% for embolization of pathological veins and 100% for stenting of stenoses. Overall, 307 patients attended 12-month follow-up visits and 288 (82%) patients completed the telephone survey at mean 39 (±18)-month postintervention. Main pelvic pain significantly improved from 6.9 (±2.4) pre- to 2.0 (±2.4) postembolization ( $p < 0.001$ ), as did specific symptoms in each category. Improvement or disappearance of pain was achieved in 266/288 (92.36%) patients with improved quality of life in 276/288 (95.8%) patients. There were 16 minor and 4 major adverse events reported on the follow-up.

Several limitations of this study must be highlighted. The major limitation of study is its retrospective, non-randomized study design, with the lack of a control group. Secondly, US evaluation criteria were not predefined prior to the study initiation, which may have contributed to some inconsistency in US assessments. We used the VAS scale to evaluate QoL, an applicable questionnaire of QoL assessments would have been more relevant. Lastly, of the 327 patients, only 288 patients attended the last follow-up telephonic interview. This may have somewhat biased the outcome data. Prospective randomized studies are needed to confirm these encouraging results.

(2018) Brown et al. evaluated patient outcomes following percutaneous treatment of pelvic congestion syndrome (N=828). Study inclusion criteria required symptom(s) of pelvic congestion syndrome and the presence of pelvic venous incompetence on catheter-based venography criteria which were not specified or defined. This review also includes a randomized trial published by Chung and Huh that evaluated the efficacy of various treatments for pelvic congestion syndrome that had failed 4-6 months of treatment with medroxyprogesterone acetate (N=106). However, this study compared ovarian vein coil embolization to hysterectomy with bilateral or unilateral oophorectomy and was therefore not assessed separately as evidence.

(2016) Mahmoud et al. identified 20 case series (total N=1081 patients) assessing endovascular treatment for pelvic congestion syndrome. Reviewers did not require any particular diagnostic criteria for pelvic congestion syndrome. Only a single study used a comparison group, but patients in it received conservative treatment because they were ineligible for vein embolization therapy; as a result, outcomes following the 2

interventions cannot be compared. The authors included a quality assessment for the included studies which were deemed to be of poor quality.

### **UptoDate**

(Literature review current through: Apr 2022. Topic last updated: 2019) Johnson et al. reports for individuals with PCS without vulvar varices — Although the data supporting medical management of PCS are limited, we suggest a trial of medical therapy as first-line treatment. The risks of medical therapy are low, particularly when compared with the risks of invasive procedures. Supporting data come from three small, randomized trials that reported improved pain scores and improved venography scores in women treated with goserelin (3.6 mg per month), medroxyprogesterone acetate (30 to 50 mg per day), or etonogestrel implant. Additionally, women treated with medroxyprogesterone acetate reported rapid return of pain after cessation of treatment, which further suggests that hormonal therapy suppressed pain. Limitations of these studies include small size and lack of a placebo group.

Women who do not respond to medical therapy can pursue invasive treatment, but the optimal procedure is not known, as randomized trials have not been performed. Reported procedures include embolization or sclerotherapy of the ovarian veins with or without the internal iliac veins, laparoscopic or open ligation of the ovarian veins and hysterectomy with bilateral salpingo-oophorectomy (BSO) for women who have completed childbearing. The existing studies are difficult to compare because they use different diagnostic criteria for PCS; lack control groups; involve different venography, embolization, and surgical techniques; fail to provide standardized evaluation of symptoms before and after treatment; and have variable durations of follow-up.

### **Section Summary**

Regarding the treatment of pelvic congestion syndrome, the evidence consists of systematic reviews, randomized studies, comparative studies, and case series. A retrospective analysis comparing coil embolization to endoscopic resection determined that resection is associated with significantly shorter times to postprocedural pain relief and avoidance of postembolization syndrome. Moreover, definitions of pelvic congestion syndrome vary, making it difficult to define a patient population with symptoms arising from pelvic congestion. RCTs with well-defined eligibility criteria and relevant comparators are needed.

### **Summary of Evidence**

For individuals who have pelvic congestion syndrome who receive ovarian and/or internal iliac vein endovascular occlusion, the evidence includes randomized studies, comparative studies, case series and systematic reviews. In a randomized trial of embolization with vascular plugs or coils in individuals with pelvic congestion syndrome, adverse events were reported in 22% and 10% of individuals, respectively. A retrospective analysis comparing coil embolization to endoscopic resection determined that resection is associated with significantly shorter times to postprocedural pain relief and avoidance of postembolization syndrome. Moreover, definitions of pelvic congestion

syndrome vary, making it challenging to define a patient population with symptoms arising from pelvic congestion. Randomized controlled trials using well-defined eligibility criteria and relevant comparators are needed. The evidence is insufficient to determine the effects of the technology on net health outcomes.

### **Practice Guidelines and Position Statements**

Currently, there are no official practice guideline or position statements addressing the treatment of pelvic congestion.

### **Regulatory Status**

Ovarian and internal iliac vein embolization are surgical procedures and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

Various products (e.g., coils, vascular plugs, glue, liquid embolic agents, Gelfoam) and/or delivery-assist devices would be used to embolize the vein(s), and they would be subject to FDA regulation. Several products have been cleared for marketing by the FDA through the 510(k) process for uterine fibroid embolization (e.g., Embosphere® Microspheres, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles) and/or embolization of hypervascular tumors and arteriovenous malformations (e.g., Contour® Emboli PVA). Several embolization delivery systems have also been cleared via the 510(k) process for arterial and venous embolization in the peripheral vasculature featuring vascular plugs (e.g., ArtVentive Medical Group, Inc. Endoluminal Occlusion System [EOS™]) or coils (e.g., Cook Incorporated MReye® Flipper®).

## **PRIOR APPROVAL**

Not applicable

## **POLICY**

Endovascular occlusion of the ovarian vein and/or internal iliac veins are considered **investigational** as a treatment of pelvic congestion syndrome because the evidence is insufficient to determine the effects of the technology on net health outcomes.

## **PROCEDURE CODES AND BILLING GUIDELINES**

To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 37241 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g., congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)

## SELECTED REFERENCES

- Brown CL, Rizer M, Alexander R, et al. Pelvic Congestion Syndrome: Systematic Review of Treatment Success. *Semin Intervent Radiol.* Mar 2018; 35(1): 35-40. PMID 29628614
- Mahmoud O, Vikatmaa P, Aho P, et al. Efficacy of endovascular treatment for pelvic congestion syndrome. *J Vasc Surg Venous Lymphat Disord.* Jul 2016; 4(3): 355-70. PMID 27318059
- Guirola JA, Sanchez-Ballestin M, Sierre S, et al. A Randomized Trial of Endovascular Embolization Treatment in Pelvic Congestion Syndrome: Fibered Platinum Coils versus Vascular Plugs with 1-Year Clinical Outcomes. *J Vasc Interv Radiol.* Jan 2018; 29(1): 45-53. PMID 29174618
- Gavrilov SG, Sazhin A, Krasavin G, et al. Comparative analysis of the efficacy and safety of endovascular and endoscopic interventions on the gonadal veins in the treatment of pelvic congestion syndrome. *J Vasc Surg Venous Lymphat Disord.* May 25, 2020. PMID 32464289
- Liu J, Han L, Han X. The Effect of a Subsequent Pregnancy After Ovarian Vein Embolization in Patients with Infertility Caused by Pelvic Congestion Syndrome. *Acad Radiol.* Oct 2019; 26(10): 1373-1377. PMID 30660471
- Ball E, Khan KS, Meads C. Does pelvic venous congestion syndrome exist and can it be treated?. *Acta Obstet Gynecol Scand.* May 2012; 91(5): 525-8. PMID 22268663
- Tu FF, Hahn D, Steege JF. Pelvic congestion syndrome-associated pelvic pain: a systematic review of diagnosis and management. *Obstet Gynecol Surv.* May 2010; 65(5): 332-40. PMID 20591203
- Chung MH, Huh CY. Comparison of treatments for pelvic congestion syndrome. *Tohoku J Exp Med.* Nov 2003; 201(3): 131-8. PMID 14649734
- Hocquelet A, Le Bras Y, Balian E, et al. Evaluation of the efficacy of endovascular treatment of pelvic congestion syndrome. *Diagn Interv Imaging.* Mar 2014; 95(3): 301-6. PMID 24183954
- Nasser F, Cavalcante RN, Affonso BB, et al. Safety, efficacy, and prognostic factors in endovascular treatment of pelvic congestion syndrome. *Int J Gynaecol Obstet.* Apr 2014; 125(1): 65-8. PMID 24486124
- Laborda A, Medrano J, de Blas I, et al. Endovascular treatment of pelvic congestion syndrome: visual analog scale (VAS) long-term follow-up clinical evaluation in 202 patients. *Cardiovasc Intervent Radiol.* Aug 2013; 36(4): 1006-14. PMID 23456353
- Kwon SH, Oh JH, Ko KR, et al. Transcatheter ovarian vein embolization using coils for the treatment of pelvic congestion syndrome. *Cardiovasc Intervent Radiol.* Jul-Aug 2007; 30(4): 655-61. PMID 17468903
- Kim HS, Malhotra AD, Rowe PC, et al. Embolotherapy for pelvic congestion syndrome: long-term results. *J Vasc Interv Radiol.* Feb 2006; 17(2 Pt 1): 289-97. PMID 16517774
- Society of Interventional Radiology (SIR). Diseases and conditions: Chronic pelvic pain (pelvic congestion syndrome) [Patient Center]. n.d.;

- Senechal, Quentin et al. “Endovascular Treatment of Pelvic Congestion Syndrome: Visual Analog Scale Follow-Up.” *Frontiers in cardiovascular medicine* vol. 8 751178. 17 Nov. 2021, doi:10.3389/fcvm.2021.751178
- UptoDate. Johnson N.R., Barbieri R.L., Eidt J.F., et al., Vulvovaginal varicosities and pelvic congestion syndrome. Literature review current through: Apr 2022. | This topic last updated: Nov 18, 2019. Available at: <https://www.uptodate.com/>.
- Society for Women’s Health Research. Chronic Pelvic Pain: Hope for a Solution. Updated January 19, 2022. Accessed May 2022. Available at <https://swhr.org/chronic-pelvic-pain-hope-for-a-solution/>

<b>POLICY HISTORY</b>		
<b>Date</b>	<b>Reason</b>	<b>Action</b>
May 2022	Annual Review	Policy Revised
May 2021		New Medical Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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