

Medical Policy Manual

Topic: Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Pelvic congestion syndrome, also called pelvic venous incompetence, is a condition characterized by chronic pelvic pain, which is often aggravated by standing. The syndrome is thought to be associated with vascular engorgement of the uterus and the vessels of the broad ligament and lateral pelvic walls.

Embolization has been proposed as an alternative to surgical treatment for patients who fail medical therapy with analgesics. Embolization therapy involves the occlusion of blood flow through the ovarian and internal iliac veins with coils, glue, or chemical sclerosants. The internal iliac veins may be treated at the same time or a later date to prevent recurrence.

MEDICAL POLICY CRITERIA

Embolization of ovarian veins and internal iliac veins is considered **investigational** as a treatment of pelvic congestion syndrome.

SCIENTIFIC EVIDENCE

The primary beneficial outcomes of interest for treatments of pelvic pain are symptom reduction and improvement in the ability to function. These are subjective outcomes that are typically associated with a placebo effect. Therefore, data from adequately powered, randomized controlled trials (RCTs) with sufficient long-term follow-up are required to control for the placebo effect, determine its magnitude, and to determine whether any treatment effect from ovarian and internal iliac vein embolization provides a significant advantage over placebo or other treatment options.

Literature Appraisal

Systematic Reviews

In 2010, Tu and colleagues published a systematic review of literature on the diagnosis and management of pelvic congestion syndrome (PCS).^[1] The authors commented that optimal diagnostic and treatment methodologies remain controversial and vary widely across institutions. They also found that studies rarely specified explicit diagnostic criteria for PCS and that the definitions of pelvic pain varied widely among studies. Moreover, most studies did not use objective outcome measures or have consistent follow-up of outcomes. Studies on embolization for treatment of PCS were rated as poor due to lack of randomization and control groups, unclear patient selection criteria, and heterogeneous outcome measures that did not permit between-study comparison or estimates of overall treatment effects. There was 1 RCT, described below, in which embolization resulted in significantly better pain reduction than hysterectomy, but the randomization protocol was not described, and the hysterectomy patients (bilateral compared to unilateral salpingo-oophorectomy) were not blinded to their treatment allocation. Since some longer studies reported durable symptom improvement in some women, the authors recommended further studies with high quality design, comparing embolization, not just with surgical treatments, but also with hormonal therapy and other noninvasive treatments.

Randomized Controlled Trials

One RCT was found in which Chung et al. randomized 106 women with symptomatic PCS refractory to 4-6 months of medroxyprogesterone acetate to 1 of 3 groups.^[2] Group A (n=52) received ovarian vein coil embolization; Group B (n=32) underwent hysterectomy with bilateral salpingo-oophorectomy (BSO) and hormone replacement therapy; Group C (n=34) underwent hysterectomy with unilateral salpingo-oophorectomy (USO) of the affected ovary. The measured outcome was pain using the visual analog scale (VAS). Patients within each group were also classified into 3 subgroups based on stress scores from the revised social readjustment rating scale (SRRS). There was no significant difference between groups in VAS and SRRS scores at baseline. Patients were followed for 12 months after the procedure. The embolization group reported significant reduction in pain compared to baseline. The hysterectomy groups also reported pain reduction, but the changes were not statistically significant.

This preliminary RCT does not permit conclusions due to the following methodological limitations:

- It is unknown whether the randomization scheme was adequate as the randomization protocol was not reported.
- It is also unknown whether the randomization scheme was preserved since 12 women were excluded from the operative groups following randomization, 9 due to pathologic results [myoma (n=4) and adenomyosis (n=5)] and 3 in the hysterectomy with USO group because they had bilateral ovarian involvement but only received unilateral treatment.

- The small sample size limits the ability to rule out the role of chance as an explanation of study findings.
- Short-term follow-up does not permit conclusions on the durability of any beneficial effects.
- There is a discrepancy between reported outcomes in text and data tables. The text reported a significant decrease in pain scores at each follow-up visit compared with baseline in Groups A and B, but not in Group C. However, the data tables indicated significantly decreased pain only in Group A. This discrepancy could not be clarified because the p-values for each measurement were not reported.

Nonrandomized Trials

The remainder of the published literature regarding the clinical outcomes of embolization therapy consists of case series and retrospective reviews.^[3-22] Collectively, conclusions concerning safety and effectiveness cannot be reached from these studies due to significant limitations in the data, including:

- Lack of established diagnostic criteria for pelvic congestion syndrome
Without consistent criteria for patient selection, it is unknown which patients are most likely to benefit — or not — from treatment. It is unknown how results from the various case series can be applied to the overall population of patients with this condition.
- Lack of randomization and comparison groups
Failure to randomize patients to different treatment groups may introduce bias on the part of both the study participant and researchers in favor of the new technology. As noted above, for pain treatments, a comparator (preferably sham treatment) is necessary, in order to guard against this bias and to distinguish treatment from placebo effects.
- Retrospective design and failure to control for other treatments
Retrospective study designs do not allow for control of co-treatments or confounding factors that may influence results. This design may also introduce bias to interpretation of results. Control for additional factors, such as other medical therapies, is necessary to isolate treatment response to embolization therapy.
- Failure to define relevant study endpoints
Bias may also be introduced by failure to define study endpoints and treatment success prior to commencement of the study.

Adverse Effects

The following adverse effects associated with embolization of the uterine and internal iliac veins, though uncommon, have been reported in the literature.^[3,11]

- Embolization of coils to the pulmonary circulation
- Embolization of coils to the renal circulation
- Accidental embolization of glue fragments
- Perforations of the ovarian vein with extravasation of contrast
- Transient cardiac arrhythmia

Clinical Practice Guidelines

American Congress of Obstetricians and Gynecologists (ACOG)

No relevant policy positions on embolization for treating pelvic congestion syndrome were identified on the organization's website.

Society for Vascular Surgery (SVS) and the American Venous Forum (AVF)

The SVS/AVS guidelines for the care of patients with varicose veins and associated chronic venous diseases provided a Grade 2B recommendation in favor of coil embolization, plugs, or transcatheter sclerotherapy for treatment of PCS. A Grade 2B recommendation is defined as a weak recommendation based on medium quality evidence.^[23]

Summary

The current evidence does not permit conclusions concerning the effect of ovarian and internal iliac vein embolization on pelvic congestion syndrome; therefore the use of this intervention is considered **investigational** in this patient population. Additional randomized controlled studies using well-defined diagnostic criteria are required to establish the efficacy and safety of this procedure.

REFERENCES

1. Tu, FF, Hahn, D, Steege, JF. Pelvic congestion syndrome-associated pelvic pain: a systematic review of diagnosis and management. *Obstet Gynecol Surv.* 2010 May;65(5):332-40. PMID: 20591203
2. Chung, MH, Huh, CY. Comparison of treatments for pelvic congestion syndrome. *Tohoku J Exp Med.* 2003 Nov;201(3):131-8. PMID: 14649734
3. Maleux, G, Stockx, L, Wilms, G, Marchal, G. Ovarian vein embolization for the treatment of pelvic congestion syndrome: long-term technical and clinical results. *J Vasc Interv Radiol.* 2000 Jul-Aug;11(7):859-64. PMID: 10928522
4. Venbrux, AC, Chang, AH, Kim, HS, et al. Pelvic congestion syndrome (pelvic venous incompetence): impact of ovarian and internal iliac vein embolotherapy on menstrual cycle and chronic pelvic pain. *J Vasc Interv Radiol.* 2002 Feb;13(2 Pt 1):171-8. PMID: 11830623
5. Sichlau, MJ, Yao, JS, Vogelzang, RL. Transcatheter embolotherapy for the treatment of pelvic congestion syndrome. *Obstet Gynecol.* 1994 May;83(5 Pt 2):892-6. PMID: 8159389
6. Venbrux, AC, Lambert, DL. Embolization of the ovarian veins as a treatment for patients with chronic pelvic pain caused by pelvic venous incompetence (pelvic congestion syndrome). *Curr Opin Obstet Gynecol.* 1999 Aug;11(4):395-9. PMID: 10498026
7. Tarazov, PG, Prozorovskij, KV, Ryzhkov, VK. Pelvic pain syndrome caused by ovarian varices. Treatment by transcatheter embolization. *Acta Radiol.* 1997 Nov;38(6):1023-5. PMID: 9394662
8. Cordts, PR, Eclavea, A, Buckley, PJ, DeMaiores, CA, Cockerill, ML, Yeager, TD. Pelvic congestion syndrome: early clinical results after transcatheter ovarian vein embolization. *J Vasc Surg.* 1998 Nov;28(5):862-8. PMID: 9808854
9. Kim, HS, Malhotra, AD, Rowe, PC, Lee, JM, Venbrux, AC. Embolotherapy for pelvic congestion syndrome: long-term results. *J Vasc Interv Radiol.* 2006 Feb;17(2 Pt 1):289-97. PMID: 16517774
10. Kwon, SH, Oh, JH, Ko, KR, Park, HC, Huh, JY. Transcatheter ovarian vein embolization using coils for the treatment of pelvic congestion syndrome. *Cardiovasc Intervent Radiol.* 2007 Jul-Aug;30(4):655-61. PMID: 17468903

11. Creton, D, Hennequin, L, Kohler, F, Allaert, FA. Embolisation of symptomatic pelvic veins in women presenting with non-saphenous varicose veins of pelvic origin - three-year follow-up. *Eur J Vasc Endovasc Surg.* 2007 Jul;34(1):112-7. PMID: 17336555
12. Gandini, R, Chiocchi, M, Konda, D, Pampana, E, Fabiano, S, Simonetti, G. Transcatheter foam sclerotherapy of symptomatic female varicocele with sodium-tetradecyl-sulfate foam. *Cardiovasc Intervent Radiol.* 2008 Jul-Aug;31(4):778-84. PMID: 18172712
13. Tropeano, G, Di Stasi, C, Amoroso, S, Cina, A, Scambia, G. Ovarian vein incompetence: a potential cause of chronic pelvic pain in women. *Eur J Obstet Gynecol Reprod Biol.* 2008 Aug;139(2):215-21. PMID: 18313828
14. Pieri, S, Agresti, P, Morucci, M, de' Medici, L. Percutaneous treatment of pelvic congestion syndrome. *Radiol Med.* 2003 Jan-Feb;105(1-2):76-82. PMID: 12700549
15. Capasso, P, Simons, C, Trotteur, G, Dondelinger, RF, Henroteaux, D, Gaspard, U. Treatment of symptomatic pelvic varices by ovarian vein embolization. *Cardiovasc Intervent Radiol.* 1997 Mar-Apr;20(2):107-11. PMID: 9030500
16. Ascutto, G, Ascutto, KC, Mumme, A, Geier, B. Pelvic venous incompetence: reflux patterns and treatment results. *Eur J Vasc Endovasc Surg.* 2009 Sep;38(3):381-6. PMID: 19574069
17. van der Vleuten, CJ, van Kempen, JA, Schultze-Kool, LJ. Embolization to treat pelvic congestion syndrome and vulval varicose veins. *Int J Gynaecol Obstet.* 2012 Sep;118(3):227-30. PMID: 22727416
18. Edo Prades, MA, Ferrer Puchol, MD, Esteban Hernandez, E, Ferrero Asensi, M. Pelvic congestion syndrome: outcome after embolization with coils. *Radiologia.* 2012 May 24. PMID: 22633116
19. Meneses, L, Fava, M, Diaz, P, et al. Embolization of incompetent pelvic veins for the treatment of recurrent varicose veins in lower limbs and pelvic congestion syndrome. *Cardiovasc Intervent Radiol.* 2013 Feb;36(1):128-32. PMID: 22547030
20. Laborda, A, Medrano, J, de Blas, I, Urriaga, I, Carnevale, FC, de Gregorio, MA. Endovascular treatment of pelvic congestion syndrome: visual analog scale (VAS) long-term follow-up clinical evaluation in 202 patients. *Cardiovasc Intervent Radiol.* 2013 Aug;36(4):1006-14. PMID: 23456353
21. Nasser, F, Cavalcante, RN, Affonso, BB, Messina, ML, Carnevale, FC, de Gregorio, MA. Safety, efficacy, and prognostic factors in endovascular treatment of pelvic congestion syndrome. *Int J Gynaecol Obstet.* 2014 Apr;125(1):65-8. PMID: 24486124
22. Hocquelet, A, Le Bras, Y, Balian, E, et al. Evaluation of the efficacy of endovascular treatment of pelvic congestion syndrome. *Diagnostic and interventional imaging.* 2014 Mar;95(3):301-6. PMID: 24183954
23. Gloviczki, P, Comerota, AJ, Dalsing, MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg.* 2011 May;53(5 Suppl):2S-48S. PMID: 21536172
24. Bluecross BlueShield Association Medical Policy Reference Manual "Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome." Policy No. 4.01.18

CROSS REFERENCES

[Varicose Vein Treatment](#), Surgery, Policy No. 104

CODES	NUMBER	DESCRIPTION
There are no specific codes for ovarian and internal iliac vein embolization; however, the following codes may be used:		
CPT	36012	Selective catheter placement, venous system: second order or more selective, branch (eg, left adrenal vein, petrosal sinus)
	37204	Transcatheter occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck (Deleted 1/1/14)
	37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)
	75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation
HCPCS	None	