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

Description

Pelvic congestion syndrome is characterized by chronic pelvic pain that often is aggravated by standing; diagnostic criteria are not well defined. Embolization of the ovarian and internal iliac veins has been proposed as a treatment for patients who fail medical therapy with analgesics.

Background

Pelvic congestion syndrome is a chronic pelvic pain syndrome of variable location and intensity, which is associated with dyspareunia and post coital 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 scanning, 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 (eg, nonsteroidal anti-inflammatory drugs) and hormonal therapy. For patients who fail initial therapy, surgical ligation of the ovarian vein may be considered. Embolization therapy of the ovarian and internal iliac veins has been proposed as an alternative to surgical ovarian vein ligation. Vein embolization can be performed using a variety of materials including coils, glue, and gel foam.

Regulatory Status

Ovarian and internal iliac vein embolization is a surgical procedure and as such is not subject to regulation by FDA.
A variety of materials including coils, glue, and gel foam would be used to embolize the vein(s), and those would be subject to FDA regulation. Several of these products have 510(k) marketing clearance for uterine fibroid embolization (eg, Embosphere® Microspheres, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles) and/or embolization of hypervascular tumors and arteriovenous malformations (eg, Contour® Emboli PVA).

Related Policies

4.01.11 Occlusion of Uterine Arteries Using Transcatheter Embolization

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

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

Rationale

No randomized controlled trials (RCTs) have been published comparing embolization therapy for pelvic congestion syndrome to an alternative or sham/placebo treatment. RCTs are especially needed in situations such as this where the primary symptom is pain, a subjective outcome for which a placebo response to treatment is likely. The published studies consist of case series, most of which were retrospective and conducted outside of the United States. A limitation of the literature on embolization therapy for the treatment of pelvic congestion syndrome is lack of standardized diagnostic criteria. In 2010, Tu et al published a systematic review of literature on the diagnosis and management of pelvic congestion syndrome. The authors observed that studies have rarely specified explicit diagnostic criteria for pelvic congestion syndrome and that definitions of pelvic pain have varied widely among studies. Moreover, most studies have not used objective outcome measures.

A 2016 systematic review by Mahmoud et al identified 20 case series (total N=1081 patients) who underwent vein embolization for pelvic congestion syndrome. The authors did not require any particular diagnostic criteria for pelvic congestion syndrome. The length of follow-up in the studies ranged from 1 month to 6 years. Seventeen studies (n=648 patients) reported the proportion of patients who reported symptom relief. Overall, 571 (88.1%) patients reported short-term symptom relief and 77 (11.9%) reported little or no relief. Seventeen studies (n=721 patients) reported symptom relief at 12 months. A total of 88.6% had symptom improvement and 13.4% reported little or no relief. Only 1 study used a comparison group, but patients in it received conservative treatment because they were ineligible for vein embolization therapy, so outcomes after the 2 interventions cannot be compared.

Table 1 summarizes larger case series published in the last 10 years that have reported symptom improvement in patients with pelvic congestion syndrome treated with vein embolization.
Study | Location | No. of Patients | Mean Follow-Up, mo | Clinical Outcome (at Least Substantial Improvement in Symptoms)
---|---|---|---|---
Kim et al (2006) | U.S. | 127 | 45 | 83%
Nasser et al (2014) | Brazil | 113 | 12 | 100% (53% complete, 47% partial)
Kwon et al (2007) | Korea | 67 | 45 | 82%
Gandini et al (2008) | Italy | 38 | 12 | 100%
Hocquelet et al (2014) | France | 33 | 26 | 94% (61% complete, 33% partial)

Laborda et al in (2013) reported pain outcomes on 202 patients who underwent coil embolization for pelvic congestion syndrome. There were no clearly defined diagnostic criteria; patients were referred by a vascular surgeon. A total of 179 (89%) of 202 women completed 5-year follow-up. Pain was measured on a 10-point visual analog scale (VAS). At baseline, mean VAS (SD) was 7.34 (0.7), and at 5 years mean VAS was 0.78 (1.2). The decrease in mean VAS score over time was statistically significant (p<0.001). There were 4 (2%) cases of coil migration, and they were considered major complications. As with the other case series previously reported, this study lacked a control group with which to compare outcomes.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td>Ongoing</td>
<td>Pelvic Embolisation to Reduce Recurrent Varicose Veins - Recurrent</td>
<td>270</td>
<td>Dec 2018</td>
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</tbody>
</table>

NCT: national clinical trial.

### Practice Guidelines and Position Statements

Society of Interventional Radiology (SIR): A fact sheet on chronic pelvic pain in women endorsed coil embolization as an effective treatment option for pelvic congestion syndrome.

### U.S. Preventive Services Task Force Recommendations:

Not applicable.

### Summary of Evidence

For individuals who have pelvic congestion syndrome who receive ovarian and/or internal iliac vein embolization, the evidence includes case series and a systematic review. Relevant outcomes are symptoms and treatment-related morbidity. According to a systematic review of case series data, approximately 80% of patients have reported some degree of symptom relief 12 months after ovarian and/or internal iliac vein embolization. It is difficult to draw conclusions from these data because of a lack of a placebo control or comparative data from alternative interventions. Moreover, definitions of pelvic congestion syndrome vary, making it challenging to clearly define a patient population with symptoms arising from pelvic congestion. Randomized controlled trials using well-defined eligibility criteria are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.
Medicare National Coverage

No national coverage determination.

References


Policy History

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<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy reviewed with literature search, policy statement unchanged, References updated.</td>
</tr>
<tr>
<td>December 2012</td>
<td>Update Policy</td>
<td>Policy reviewed with literature search, Reference 2 and 10 added, others reordered, Policy statement unchanged.</td>
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<tr>
<td>September 2013</td>
<td>Update Policy</td>
<td>Policy reviewed with literature search, adding references 5 and 8. Policy statement is unchanged.</td>
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Keywords

Embolization Therapy, Ovarian Vein, for Pelvic Congestion Syndrome
Pelvic Congestion Syndrome, Embolization Therapy
Chronic Pain, Ovarian
Varices, Ovarian
Venography

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 16, 2016 and is effective October 15, 2016.

Signature on file
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