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 condition of chronic pelvic pain 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 congestion. As 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 (MRI), computed tomography (CT) scanning, or contrast venography. For those who fail medical therapy with analgesics, surgical ligation of the ovarian vein has been considered. More recently, embolization therapy of the ovarian and internal iliac veins has been proposed. 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 have been published comparing embolization therapy for pelvic congestion syndrome to an alternative or sham/placebo treatment. Randomized controlled trials 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. Case series have been discussed in several review articles, most recently in 2012. (1-3)

A summary table of the largest case series reporting the proportion of patients with improvement in symptoms (4-8) is as follows:

<table>
<thead>
<tr>
<th>Study</th>
<th>Location</th>
<th>No. of patients</th>
<th>Mean follow-up (months)</th>
<th>Clinical outcome (improvement in symptoms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kim et al., 2006</td>
<td>U.S.</td>
<td>127</td>
<td>45</td>
<td>Significant: 83%</td>
</tr>
<tr>
<td>Kwon et al., 2007</td>
<td>Korea</td>
<td>67</td>
<td>~44.8</td>
<td>Significant or partial: 82%</td>
</tr>
<tr>
<td>Gandini et al., 2008</td>
<td>Italy</td>
<td>38</td>
<td>12</td>
<td>Significant: 100%</td>
</tr>
<tr>
<td>Nasser et al., 2014</td>
<td>Brazil</td>
<td>113</td>
<td>12</td>
<td>100% (53% complete, 47% partial)</td>
</tr>
<tr>
<td>Hocquelet et al., 2014</td>
<td>France</td>
<td>33</td>
<td>26</td>
<td>94% (61% complete, 33% partial)</td>
</tr>
</tbody>
</table>

Longer-term outcomes after coil embolization for pelvic congestion syndrome were reported by Laborda and colleagues in 2013. (9) The study included patients who were referred by a vascular surgeon. There were no clearly defined diagnostic criteria. A total of 179 of 202 women (89%) completed a 5-year follow-up. Mean age at baseline was 43.5 years. The primary outcomes were pain improvement and patient satisfaction. Pain improvement was measured on a 10-point visual analog scale (VAS) with 0 defined as no pain at all and 10 defined as the worst pain imaginable. At baseline, mean VAS was 7.34 (standard deviation [SD]: 0.7) and at 5 years mean VAS was 0.78 (SD: 1.2). The decrease in the VAS score over time was statistically significant (p<0.0001). Mean patient satisfaction was 7.39 (SD: 1.5) on a 0 to 9 scale. There were 4 cases of coil migration (2%) and these were considered major complications. As with the other case series discussed above, this study is limited by the lack a control group with which to compare outcomes.
Another limitation in the literature on embolization therapy for the treatment of pelvic congestion syndrome is lack of standardization regarding diagnostic criteria. In 2010, Tu and colleagues published a systematic review of literature on the diagnosis and management of pelvic congestion syndrome. (10) The authors commented 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 2012 review article by Ball and colleagues stated that the issue of whether pelvic congestion syndrome causes chronic pelvic pain is still a matter of debate. (11) The authors noted that although venous reflux is common, not all women with this condition experience chronic pelvic pain and, additionally, chronic pelvic pain is reported by women without pelvic congestion syndrome.

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. (12)

American College of Obstetricians and Gynecologists (ACOG): No relevant policy positions on embolization for treating pelvic congestion syndrome were identified on the organization’s website.

U.S. Preventive Services Task Force Recommendations:
Not applicable.

Summary

Randomized controlled studies using well-defined diagnostic criteria are required to establish the safety and efficacy of this procedure. The available literature regarding embolization therapy for the treatment of pelvic congestion syndrome consists of case series and is inadequate to draw clinical conclusions; thus the treatment is considered investigational.

Medicare National Coverage

No national coverage determination

References


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<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy reviewed with literature search, policy statement unchanged.</td>
</tr>
<tr>
<td>December 2012</td>
<td>Update Policy</td>
<td>References updated.</td>
</tr>
<tr>
<td>September 2013</td>
<td>Update Policy</td>
<td>Policy reviewed with literature search, Reference 2 and 10 added, others reordered, Policy statement unchanged.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Update Policy</td>
<td>Policy reviewed with literature search, adding references 5 and 8. Policy statement is unchanged.</td>
</tr>
</tbody>
</table>

**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 18, 2015 and is effective October 15, 2015.

Signature on file
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