Regence

Medical Policy Manual Surgery, Policy No. 147

Ovarian, Internal Iliac, and Gonadal Vein Embolization, Ablation, and Sclerotherapy

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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

Embolization involves occlusion of blood flow through the ovarian, internal iliac, and gonadal veins with coils, foam, or a chemical sclerosant as a treatment of pelvic congestion syndrome or varicoceles.

MEDICAL POLICY CRITERIA

Note: This policy does not address surgical ligation of the spermatic vein(s) or uterine artery embolization.

Embolization, ablation, and sclerotherapy of ovarian veins, internal iliac veins, or gonadal veins is considered **investigational** for the treatment of pelvic congestion syndrome and varicoceles.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Varicose Vein Treatment, Surgery, Policy No. 104

BACKGROUND

Enlarged ovarian and internal iliac veins can lead to pelvic congestion syndrome in women, and enlarged gonadal and internal iliac veins can lead to a varicoceles in men. Each are discussed separately below.

PELVIC CONGESTION SYNDROME

Pelvic congestion syndrome (PCS), also called pelvic venous incompetence, is a rare condition characterized by chronic pelvic pain. Although this condition is primarily found in women it can also be found in men. PCS is often aggravated by standing for long periods of time, and often manifests during or after pregnancy. The syndrome is thought to be associated with dilated and refluxing incompetent pelvic veins, similar to what happens in varicose veins of the legs. However, the cause of PCS is unclear. Furthermore, there are no definitive diagnostic criteria for PCS. Instead, the diagnosis is generally based on a combination of symptoms, tenderness on physical exam, and documentation of pelvic vein dilation or incompetence after excluding all other causes for the nonspecific findings. Although imaging may show vein dilation or incompetence, these findings are common nonspecific findings and therefore no diagnostic.

There is no standard treatment approach for PCS, and the optimum treatment is unknown. Instead, therapy is individualized and based on symptoms. Medical therapy is generally the first line of treatment, as it is low risk and non-invasive. Other methods, such as 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.

VARICOCELES

A varicocele is the dilation of the pampiniform plexus of the gonadal veins. Varicoceles are present in 15 to 20% of post-pubertal males, and generally get larger over time. Most varicoceles occur in the left hemiscrotum because the left gonadal vein is one of the longest veins in the body and it enters the left renal vein at a perpendicular angle increasing pressure which can dilate the veins and cause incompetence of the valves, similar to varicose veins of the legs. Although varicoceles on the left are more common, bilateral varicoceles can occur; however, this could be caused by a possible underlying pathology warranting more investigation. Symptoms of a varicocele include dull, aching, left scrotal pain, which is often aggravated by standing for long periods of time, testicular atrophy, and decreased fertility. Although there are no clear guidelines regarding the established treatment for varicoceles, surgical ligation is the preferred first-line treatment.

EVIDENCE SUMMARY

The primary beneficial outcomes of interest for treatments of pelvic pain in both men and woman 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 provides a significant advantage over placebo or other treatment options.

TREATMENT FOR PELVIC CONGESTION SYNDROME

Health Technology Assessments

In 2016, Champaneria published a health technology assessment from the National Institute for Health Research that examined the diagnosis and treatment of pelvic vein incompetence and chronic pelvic pain in women.[1] Forty studies were included in the review; six association studies, ten studies involving ultrasound, two studies involving magnetic resonance venography, 21 case series, and one poor-quality randomized trial of embolization. The authors found that there were no consistent diagnostic criteria for pelvic congestion syndrome (PCS). Although the studies have showed associations between chronic pelvic pain (CPP) and pelvic vein incompetence (PVI), the prevalence of PVI ranged widely. The authors identified that transvaginal ultrasound with doppler and magnetic resonance venography are both useful screening methods; however, there is limited data on the accuracy of these methods for PCS. Finally, although the research showed embolization provides symptomatic relief in the majority of women, these studies were small case series. The authors concluded that more research is needed to determine what the diagnostic criteria for PCS are, and the efficacy of embolization as a treatment for PCS.

Systematic Reviews

Sutanto (2022) published a systematic review to study the efficacy and safety of the use of percutaneous coil embolization (CE) in isolation for pelvic venous reflux (PVR).[2] A total of 970 patients (range 3 to 218, 100% female) undergoing isolated ovarian vein or mixed veins embolization from 20 studies were included. Pooled analysis revealed mean improvements of 5.47 points (95% CI 4.77 to 6.16) on the visual analogue scale. Common symptoms such as urinary urgency and dyspareunia reported significant improvements of 78% to 100% and 60% to 89.5% respectively. Two randomized controlled trials revealed improved clinical outcomes with CE as compared with vascular plugs and hysterectomy. While this data suggests that isolated CE is technically effective and can result in clinical improvement among patients with PVR, further trials are required to ascertain the long-term effects.

A 2016 systematic review by Mahmoud identified 20 case series (total of 1,081 patients) who underwent vein embolization for pelvic congestion syndrome.[3] The authors did not require any particular diagnostic criteria for pelvic congestion syndrome. The length of follow-up in the studies ranged from one month to six 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 one study used a comparison group, but patients in it received conservative treatment because they were ineligible for vein embolization therapy, so outcomes after the two interventions cannot be compared.

A systematic review by Daniels (2016) assessed the effectiveness of sclerotherapy or embolization for the treatment of chronic pelvic pain.[4] The review included 21 case series and one poor-quality randomized trial. Due to the overall low quality and heterogeneity of the studies, a meta-analysis was not performed. However, the authors reported that approximately 75% of women who underwent embolization experienced early pain relief. Adverse events noted included, transient pain following foam embolization and a small (<2%) risk of coil migration.

Hansrani (2015) published a systematic review that evaluated the effectiveness of trans-venous occlusion as a treatment of chronic pelvic pain.[5] Thirteen studies were included comprising 866 women. The authors noted that all 13 studies were of poor methodological quality, and 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 one RCT included in the review, in which embolization resulted in significantly better pain reduction than hysterectomy, but the study also had significant limitations, including but not limited to, the randomization protocol was not described, and the hysterectomy patients (bilateral compared to unilateral salpingo-oophorectomy) were not blinded to their treatment allocation, small sample size limits the ability to rule out the role of chance as an explanation of study findings, and a discrepancy between reported outcomes in text and data tables. The authors recommended that more high-quality studies are needed that compare embolization, with other treatments, including surgical treatments, hormonal therapy, and other noninvasive treatments.

Randomized Controlled Trials

Emad el din (2023) published a randomized trial comparing surgical ovarian vein ligation under spinal or general anesthesia (n=25) with endovascular coil embolization under spinal or local anesthesia (n=25) in patients with pelvic congestion syndrome (criteria included chronic pelvic pain with an ovarian vein diameter >6 mm and moderate to severe congestion of the ovarian plexus) who had not experienced improvement with unspecified (non-surgical/embolization) medical management.[6] Patients who were nulliparous, more than 55 years old, or deemed unfit for surgery were excluded. Outcomes including VAS pain score (possible responses ranging from 0 to 10) and ultrasound assessment of varicosities and reflux were evaluated. No differences between groups in baseline characteristics were reported; median VAS pain score at pre-operative baseline was 9 in both groups (range 7 to 10 in the surgical group, 8 to 10 in the embolization group, p=0.71). At one week post-operatively, median VAS pain score was reduced to 2 in the surgical group and 1 in the embolization group ($p \leq 0.001$ for within-group pre-post comparison; p=0.006 for between-group comparison). However, although patients were followed for three months, subsequent clinical outcomes and complication rates were not reported; the authors stated that no procedural complications were recorded.

A randomized, prospective trial by Guirola (2018) compared the safety and efficacy of embolization with vascular plugs (VP) or fibered platinum coils (FPC) in women with pelvic congestion syndrome.[7] 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 three 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 one, three, six, 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. 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. A total of 11 (22%) complications were seen in the FPC group and five (10%) in the VP group. 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 and pre-treatment visual analog scale pain score between groups, both of which were higher in the VP group despite randomization.

Nonrandomized Studies

The remainder of the published literature regarding the clinical outcomes of embolization therapy consists of nonrandomized studies, case series, and retrospective reviews.[8-31] Collectively, conclusions concerning safety and effectiveness cannot be reached from these studies due to significant limitations in the data, including but not limited to:

- Lack of established diagnostic criteria for pelvic congestion syndrome. Without consistent criteria for patient selection, it is unclear which patients are most likely to benefit, or not benefit, from treatment. Furthermore, 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.[8, 16]

- 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

Treatment of Varicoceles

Systematic Reviews

A Cochrane systematic review by Persad (2021) evaluated surgical or radiological treatment for varicoceles for subfertility.[32] A total of 48 RCTs were included in the analysis, including seven studies comparing surgical treatment with radiological treatment (embolization or sclerotherapy). The authors reported that the certainty of the available evidence ranged from moderate to very low, depending on outcome, and that conclusions could not be made regarding the effectiveness of radiological treatment compared with surgical treatment on live birth, pregnancy rate, varicocele recurrence, and hydrocele formation.

Belczak (2021) published a systematic review regarding semen parameter improvement after varicocele coil embolization.[33] There were six retrospective studies and two observational studies included involving 701 patients where semen concentration and motility were the primary outcomes. The authors concluded that semen concentration was improved significantly in all five studies using that outcome and semen motility was significantly improved in seven studies. This review is limited by a small number of studies and no randomized or comparative studies being included.

Kroese (2012) published results from a systematic review and meta-analysis that examined the effect of treatment, surgery or embolization, for varicoceles in subfertile men.[34] Ten studies were included in the review, which comprised 894 men. The authors concluded that there is evidence to suggest treatment improves a couple's chance of pregnancy; however, findings are inconclusive. Furthermore, the available evidence is of low quality and limited to men from couples with subfertility problems. Therefore, further research is needed to determine the efficacy of treatment, surgery or embolization, for the treatment of varicoceles.

Randomized-Controlled Trials

No randomized controlled trials comparing embolization to other techniques published since the Cochrane review by Persad (2021), discussed above, were identified.

Nonrandomized studies

The remainder of the published literature regarding the clinical outcomes of embolization therapy consists of case series and retrospective reviews.[35-52] Collectively, conclusions concerning safety and effectiveness cannot be reached from these studies due to significant limitations in the data.

PRACTICE GUIDELINE SUMMARY

PELVIC CONGESTION SYNDROME

American Congress of Obstetricians and Gynecologists

No relevant policy positions on embolization for treating pelvic congestion syndrome were identified on the American Congress of Obstetricians and Gynecologists (ACOG) website.[53]

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

The 2011 Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) 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.[54]

SUMMARY

There is not enough research to show that embolization, ablation, or sclerotherapy improves long term health outcomes for people with pelvic congestion syndrome or varicoceles, compared to other forms of therapy. Therefore, embolization, ablation, or sclerotherapy of

ovarian veins, internal iliac veins, or gonadal veins are considered investigational for the treatment of pelvic congestion syndrome or varicoceles.

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CODES

NOTE: There are no specific codes for ovarian and internal iliac vein embolization; however, the following codes may be used:

Codes	Number	Description
CPT	36012	Selective catheter placement, venous system: second order or more selective, branch (eg, left adrenal vein, petrosal sinus)
	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	

Date of Origin: *October 2005*