The Biggest Challenge to Pelvic Congestion Embolization: Reimbursement

The evidence supporting embolization for chronic pelvic pain is strong.

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There is nothing better than the revelation of a double standard to stimulate a heated conversation. Such partiality has become less common in health care in the United States, but consider the care of a patient with pain resulting from gonadal vein reflux when embolization is the proposed treatment. If the patient is a man, reimbursement by a health care indemnity organization is usually as simple as entering the codes. If the patient is a woman, however, most carriers would consider the procedure investigational and deny coverage. This situation is even more frustrating because the scientific evidence to support treating women with pelvic reflux and pain with embolization is even stronger than that for treating men with painful varicoceles.

The history of this contradictory policy is an enigma. Perhaps acceptance for treatment of a symptomatic male varicocele is easier to conceptualize, as it can be felt on examination and easily seen on ultrasound. In contrast, the symptomatic varicocele in women may have little or no visible stigmata, and imaging it is more challenging and expensive.

However, the barrier that has impeded the acceptance of treating female pelvic hypertension is likely the psychologic overlay borne by the original description of the entity. Taylor first used the term "pelvic congestion-fibrosis syndrome" in 1949 when he described women with a constellation of symptoms that are now recognized as those associated with pelvic venous hypertension.[1] He was unable to explain the pathophysiology and conjectured that psychologic stress was responsible for the symptoms.

Despite our current understanding of the true pathophysiology, the stigma of Taylor's inaccurate perspective still affects the perception of this diagnosis in both the gynecologic and indemnity communities. Evidence for this includes the fact that the ICD-9 description of pelvic congestion, 625.5, includes the term "Taylor's syndrome." This prevailing misunderstanding may be the best explanation why many insurers and gynecologists have not accepted gonadal vein embolization. In this article, we briefly review the pathophysiology and various clinical presentations of pelvic congestion and detail the data that support the effectiveness of embolotherapy.

PATHOPHYSIOLOGY AND CLINICAL PRESENTATION IN WOMEN

Venous hypertension of the pelvic venous plexus can lead to chronic pelvic pain (CPP), lower extremity pain, and labial- and/or pelvic-derived lower extremity varicose veins in women. The pelvic venous plexus consists of veins in the uterus, broad ligaments, ovaries, pelvic floor, and periuterine pelvic sidewalls. These veins connect and normally drain toward both internal iliac and ovarian veins.

Venous hypertension in these veins can be caused by reflux or obstruction. Ovarian reflux is far more common than obstruction. In a study of 188 patients with pelvic reflux evaluated with venography, reflux was found more commonly in the left ovarian vein (80% alone, 10% along with right ovarian vein) and less commonly in the right (10%).[2] Other groups have found a > 10% incidence of

reflux in the right gonadal vein, but left-sided predominance is still appreciated. Reflux in the iliac veins has also been reported; however, techniques to detect reflux in the internal iliac veins are less standardized. A recent transvaginal ultrasound study found a high association of retrograde flow in the iliac veins with pelvic varicose veins.[3]

Compression of the left renal vein by the aorta (the nutcracker syndrome) can also lead to pelvic venous hypertension by directing collateral renal flow retrograde through the left ovarian vein. Compression of a common iliac vein can lead to retrograde ipsilateral internal iliac vein retrograde flow and cross-pelvic collateral flow that leads to hypertension in the pelvic venous plexus, as well. Because the treatment of these entities is not primarily embolotherapy, we will not address these further.

EMBOLIZATION TO TREAT CPP

CPP is defined as pelvic pain lasting at least 6 months. It can be caused by uterine fibroids, adenomyosis, endometriosis, hydrosalpynx/pelvic inflammatory disease, an intrauterine device, or hormonal regulatory issues affecting ovulation or ovarian cyst formation. Gastrointestinal causes, such as irritable bowel syndrome, postoperative or radiation scarring, and urinary causes such as chronic cystitis can also lead to CPP. Often, the pain can be severe, and patients have had multiple treatments, including hormones, narcotics, and psychiatric evaluations for nonstructural etiologies.

Pelvic venous hypertension (PVH) can cause CPP and is underappreciated by many physicians who care for these women. The challenge is that CPP may be very common, but the prevalence of PVH, as documented by the presence of pelvic varicosities, is also very high. Arteriography and computed tomography (CT) have documented the high incidence of pelvic varicosities in potential renal donors without CPP. In one study, ovarian vein dilation was noted on CT scan in 63% of asymptomatic parous women and in 10% of asymptomatic nonparous women.[4] Consequently, we would like to propose restricting the term "pelvic congestion syndrome" (PCS) to patients with evidence of PVH and CPP with no other identified cause.

There have been several case series during the last 15 years that have demonstrated the benefit of pelvic embolization in patients with documented PCS. Table 1 demonstrates those series with ≥ 30 patients evaluating response of CPP to pelvic embolization using a variety of techniques.[5-11]

Several of these studies used pre- and posttreatment 10-point visual analogue scales (VAS) to evaluate patients' response to treatment (Table 2).[2,8,11-14] The preprocedural VAS scores were remarkably similar in the studies, and the improvement was significant after treatment when compared with the VAS before treatment. These improvements were durable up to 4 to 5 years of follow-up. A valid criticism of these outcome data is that there were no comparison groups. However, it is challenging to design and recruit for a study in which the control group of patients, who are in pain, receive no treatment, limited treatment, or inappropriately aggressive treatment.

Chung and Huh[2] performed a randomized trial to compare the outcomes of embolization with hysterectomy in a homogenous population. From a study population of 1,246 patients being evaluated for CPP, they identified a 13% prevalence of PCS. In this study, the authors complete an evaluation of all patients with CPP, which included ultrasound, laparoscopy, and CT or magnetic resonance imaging; ultimately, they also venographically confirmed gonadal reflux in all 164 patients diagnosed with PCS. The investigators then equally randomized the 118 patients with PCS who did not respond to medroxyprogesterone acetate (an ovarian function suppressor) therapy for pain control to ovarian vein embolization with coils, hysterectomy with bilateral salpingo-oophorectomy and hormone replacement therapy, or hysterectomy with unilateral salpingo-oophorectomy. Patients treated with embolization

TABLE 1. DATA SUPPORTING EMBOLIZATION FOR TREATING CHRONIC PELVIC PAIN

Study	No. of Women	Embolization Technique	Mean Follow-Up (mo)	Clinical Outcome
Maleux et al[5]	41	Glue	19.9	Relief: significant in 58.5%, partial in 9.7%, none in 31.8%
Venbrux et al[6]	56	Sclerosant and coils	22.1	Significant/partial relief in 96%, no relief in 4%
Pieri et al[7]	33	Sclerosant	6 and 12	Significant relief: 100%
Kim et al[8]	127	Sclerosant and coils	45	Significant relief in 85%, no relief in 12%, 3% worsened
Kwon et al[9]	67	Coils	44.8	Significant relief in 82%, no relief in 15%, 3% worsened
Gandini et al[10]	38	STS foam	12	Significant relief in 100%
Laborda et al[11]	179	Coils	60	VAS improvement 7.8–0.8

TABLE 2. VISUAL ANALOG SCALE IMPROVEMENT FOLLOWING PELVIC EMBOLIZATION

	No. of Women	Preprocedural VAS	Postprocedural VAS	Follow-Up Time
Venbrux et al[6]	56	7.8	2.7*	1 y
Chung and Huh[2]	52	7.8	3.2*	1 y
Kim et al[8]	127	7.6	2.9*	45 mo
Laborda et al[11]	179	7.3	0.8*	5 y
Nasser et al[13]	100	7.3	0.5*	1 y
Hocquelet et al[14]	33	7.4	1.4*	26 mo

**Statistically significant difference from pretreatment VAS.*

TABLE 3. VISUAL ANALOG SCALE IMPROVEMENT IN A RANDOMIZED STUDY COMPARING HYSTERECTOMY TO PELVIC EMBOLIZATION FOR CHRONIC PELVIC PAIN

	Pelvic Embolization	TAH-BSO + HRT	TAH-USO
VAS baseline	7.8 ± 1.2	7.7 ± 1.3	7.8 ± 1.2
VAS, 3 mo	4.5 ± 0.9*	5.5 ± 1	5.7 ± 1.2
VAS, 6 mo	4.3 ± 0.8*	5.3 ± 0.8	5.7 ± 1
VAS, 12 mo	3.2 ± 0.9*	4.6 ± 1.1	5.6 ± 0.8

Abbreviations: BSO, bilateral salpingo-oophorectomy; HRT, hormone replacement therapy; TAH, total abdominal hysterectomy; USO, unilateral salpingo-oophorectomy.
**Statistically significant difference from other treatment groups.*

had shorter hospital stays and made quicker returns to full function. Evaluation of VAS before and after therapy demonstrated a statistically enhanced benefit in patients who were treated with embolization when assessed at 3, 6, and 12 months (Table 3).

Some of the heterogeneity in study results may relate to differences in the techniques used, the selection of patients, and the metrics used for follow-up.[15] Most of the procedures use coils, predominantly in the ovarian veins. However, it was demonstrated in a small series that patients with reflux in the internal iliac veins and ovarian veins who are treated with only ovarian vein embolization did not respond as well.[16] Therefore, the pooled data we present may reflect outcomes in some incompletely treated patients. Increasingly, chemical ablation of the varicose pelvic venous plexus has been used with the idea that obliteration of the plexus should result in improved symptom relief and durability; completely sclerosing the varicose reservoir could obviate the need to perform internal iliac embolization, a more technically demanding procedure that, when done with coils, is more likely to result in coil misplacement.

EMBOLIZATION TO TREAT PELVIC-DERIVED LOWER EXTREMITY VARICOSE VEINS

Pelvic-derived lower extremity varicose veins are found in up to 20% of women with varicose veins.[17,18] The prevalence might be even higher in populations with persistent or recurrent varicose veins after previous treatment.[19] Pelvic-derived lower extremity varicose veins result from PVH that escapes to the legs through one of four common points. The most common escape point is the perineal or P point, where the internal and external pudendal veins connect in the urogenital triangle. These can lead to inner thigh and posterior labial varicose veins. The next most common escape point is the inguinal or I point. At this location, pelvic venous plexus-derived reflux passes through the external inguinal ring via a recanalized vein of the round ligament, emerging in the groin medial to the common femoral vein. This can lead to groin and labial varicose veins. Other less commonly discussed escape points include the gluteal points and varicose veins traveling along the sciatic nerve.

Data for treating pelvic-derived lower extremity varicose veins with pelvic embolization are not as strong as those for the treatment of PCS. Ratnam et al followed 219 patients with pelvic reflux documented by leg and transvaginal ultrasound and lower extremity veins after coil embolization of the ovarian vein and internal iliac vein as needed.[20] They noted a significant reduction in reflux found on transvaginal ultrasound but did not comment on the change in the leg veins or the patients' symptoms.

A few of the studies combined pelvic embolization with superficial vein surgery that confounds interpretation of the outcome after embolization for recurrent varicose veins after previous surgery.[19,21] One of these studies reported on the treatment of 643 female patients with recurrent varicose veins after surgery.[19] The investigators estimated that 46% of patients had recurrence as a consequence of pelvic venous reflux. In this group, 215 patients were treated with gonadal vein embolization, with 50.2% having complete resolution of symptoms and 39.7% having partial relief. Unfortunately for the strength of this work, as mentioned previously, the investigators also performed surgical procedures to eliminate infrainguinal reflux and varicose veins in an unspecified number of these patients.

Castenmiller et al reported that in 43 women undergoing only ovarian vein embolization, 12% had resolution of leg varicose veins, and 23% had no response.[22] The remaining 63% of patients had additional leg vein treatments, again confounding the interpretation of the outcome after embolotherapy. They did note that in 24 patients with vulvar varicose veins as a part of their problem, 88% of them had vein disappearance after embolization of refluxing veins.

From these studies, it is clear that recurrent or persistent symptomatic varicose veins are often pelvic derived. What is not clear is how effective pelvic vein embolization is in eliminating symptoms in the lower extremity. Studies suggest some effectiveness, but complete control may be dependent on the technique used and patient selection. It is apparent that adjunctive infrainguinal procedures in the leg are needed to fully treat these patients' symptoms. This is analogous to the use of microphlebectomy and sclerotherapy after great saphenous vein ablation; after only great saphenous vein ablation, many patients' symptoms only partially improve. Additional studies are needed to determine which embolization technique is most effective and when adjunctive procedures are needed.

CONCLUSIONS

Data supporting the use of pelvic embolization to treat CPP without another cause are moderately strong, based on a number of nonrandomized studies and one high-quality randomized study utilizing VAS as the metric for outcome assessment. The Society for Vascular Surgery guidelines give pelvic embolization a 2B recommendation for treatment of PVH in general but did not consider all of the studies listed in this review, including the randomized study by Chung and Huh.[2] It is our interpretation of the literature that in patients with CPP and PVH and no other cause for pain, embolization is likely to have great benefit and should be used.

In patients with lower extremity pelvic-derived varicose veins, the value of pelvic embolization is less clear. In these patients, in addition to the use of standard techniques such as saphenous ablation, microphlebectomy, and sclerotherapy, direct treatment of the varicose veins beginning at their pelvic escape points with either visual or, if needed, image-guided chemical ablation is recommended to control these varicosities. These approaches are inexpensive and, in our experience, are very effective. If the patients' varicose veins or leg symptoms are difficult to eliminate or recur on short follow-up, then pelvic embolization should be considered. Based on the impressive results from one study, pelvic embolization may be useful in patients with varicose veins primarily found on the labia when the varicosities are substantial in number or size or when antecedent direct injection of a sclerosant is either not successful or not technically possible.

We conclude that the evidence supporting the use of pelvic embolization for CPP is strong, and we hope that insurers will recognize its utility and offer coverage. The vast majority of patients with varicose veins with lower extremity varicose veins can be managed with procedures directed at the lower extremities. Further study is needed to understand the role of embolization for patients with lower extremity varicose veins; we know some patients will benefit but determining which patients at this point is not clear. ■

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