

The role of iliac vein stent placement in pelvic venous disorder management

Nikitha Murali, MD, Ramona Gupta, MD, and Kush R. Desai, MD, *Chicago, IL*

ABSTRACT

Pelvic venous disease (PeVD) has historically been challenging to diagnose and treat. This paper describes a comprehensive approach to the diagnosis of PeVD and reviews the role of iliac vein stent placement in treatment. Patient selection is vital for non-thrombotic iliac vein lesions (NIVLs) as only a small subset of patients with an NIVL will benefit from stent placement. There is limited, inconclusive data on optimal treatment for patients with both primary ovarian vein reflux and an NIVL. Patients with chronic post-thrombotic outflow obstruction typically have a more favorable risk/benefit ratio for intervention but require anticoagulation and close follow-up due to poorer long-term stent patency. Intravascular ultrasound is a useful tool for identifying obstructive lesions, sizing stents, and planning landing zones. More research is needed to characterize underlying pathophysiology, validate thresholds for intervention, develop reliable methods for outcomes assessment, and determine treatment response. Until this data is produced, an individualized treatment approach is warranted. (*J Vasc Surg Venous Lymphat Disord* 2024;12:101696.)

Keywords: Iliac vein stent; May-Thurner syndrome; Non-thrombotic iliac vein lesion; Pelvic pain

Chronic pelvic pain is a common clinical complaint, with up to 40% of women in outpatient gynecology clinics seeking care for this condition.¹ Approximately one-third of exploratory gynecologic laparoscopies and one-quarter of hysterectomies are performed for chronic pelvic pain.² An estimated 30% of patients with chronic pelvic pain have symptoms attributable to underlying venous dysfunction.³ For venous-origin chronic pelvic pain, venous reflux and/or obstruction are thought to be significant pain generators. Surgical interventions can be applied to treat pelvic venous disease⁴; however, data suggests endovascular therapies are more effective, with lower morbidity, less residual pain, and lower rates of symptom recurrence.⁵⁻⁷ Embolotherapy and stent placement are the mainstay endovascular therapies to address reflux and obstruction, respectively. This paper reviews the role of iliac vein stent placement in the treatment of a subset of patients with pelvic venous disease (PeVD).

There are no universally agreed upon criteria for the diagnosis and treatment of PeVD. Historically, terms such as "May-Thurner syndrome," "Nutcracker syndrome," and "pelvic congestion syndrome" were used to delineate clinical presentations within the PeVD category. These

terms problematically frame each pathology as isolated, when there is growing recognition that these conditions are related and can result in overlapping clinical presentations along a spectrum.⁸ The lack of uniformity in diagnosis and management has led to skepticism of treatment efficacy outside of the vascular specialist community. Non-venous specialists refer to a lack of data proving a causal relationship between pelvic venous insufficiency and pelvic pain.⁹ Downstream negative effects of this skepticism include delays in diagnosis and treatment and lack of complete payor coverage.

The Symptoms-Varices-Pathophysiology (SVP) instrument was created by a multidisciplinary working group supported by the American Vein and Lymphatic Society (AVLS) to precisely classify pelvic venous disorders within a comprehensive framework. The instrument describes four broad clinical presentations according to anatomic zones—left flank (left renal vein), pelvic (ovarian and iliac vein), pelvic-origin extra-pelvic (genitalia/groin), and lower extremity (Table).¹⁰ The instrument also delineates the varicosities and categorizes underlying pathophysiology of the venous dysfunction (ie, reflux or obstruction). The SVP instrument is intended to be complementary to CEAP classification in patients with lower extremity venous disease.

Two common female pelvic venous abnormalities are ovarian vein reflux and iliac vein obstruction.¹¹ One method of conceptualizing the clinical presentation is to consider whether the venous flow pattern is compensated or uncompensated, acknowledging that many patients will present in a mixed compensation pattern. Patients with uncompensated ovarian vein reflux may develop high pelvic venous pressures or venous stasis, which can lead to chronic pelvic pain, heaviness, or

From the Section of Interventional Radiology, Department of Radiology, Northwestern University.

Correspondence: Kush R. Desai, MD, 676 N St Clair St, Ste 800, Chicago, IL 60611 (e-mail: kdesai007@northwestern.edu).

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Table. Symptoms-Varices-Pathophysiology (SVP) clinical subtypes

Anatomic zone	Descriptor	Clinical symptoms (S)
1	Left renal vein	S ₁ – renal symptoms of venous origin (left flank pain, hematuria)
2	Gonadal and internal iliac vein with pelvic venous plexuses	S ₂ – chronic pelvic pain of venous origin
3	Pelvic origin extra-pelvic veins	S _{3a} – localized symptoms of external genitalia (pain, discomfort, tenderness, itching, bleeding, superficial thrombosis of the vulva or scrotum) S _{3b} – Localized symptoms associated with pelvic origin non-saphenous veins of the leg (pain, discomfort, tenderness, itching, bleeding, superficial thrombosis, paresthesias)
4	Lower extremity deep and superficial veins	S _{3c} – Venous claudication

Note to the editor: this table is a combination of Fig 1 and Table II from the cited JVS:VL 2021 paper Meissner et al (<https://doi.org/10.1016/j.jvsv.2020.12.084>). The journal may wish to republish those original figures/tables which are more complete rather than this table. This table summarizes the anatomic zones and clinical symptoms of patients as classified by the Symptom-Varices-Pathophysiology (SVP) instrument.

dyspareunia. In compensated ovarian vein reflux, venous blood will redistribute into connected venous reservoirs, which can result in symptomatic varices in the perineal, inguinal, vulvar, gluteal, and saphenous lower extremity distributions. Patients with uncompensated iliac vein obstruction may have leg pain and edema. Compensated iliac obstruction may pressurize parametrial veins, which can result in pelvic pain. Symptoms can vary in a mixed compensation state, such as the presence of pelvic pain and genital varicosities.

DIAGNOSIS: CLINICAL EVALUATION

What follows is an approach to the clinical evaluation of the patient with suspected pelvic venous disease, beginning with a complete history and physical exam (Fig 1). A common descriptor of venous etiology pelvic pain is a dull ache that worsens with standing.¹² The combination of postcoital ache and ovarian point tenderness (one-third of the way between the umbilicus and the anterior superior iliac spine) on physical exam is reportedly 94% sensitive and 77% specific for venous origin pelvic pain.¹³ Of note, these symptoms are classically associated with reflux-related PeVD, and obstructive etiology PeVD may present differently. For example, patients with iliac vein obstruction may describe lower extremity dominant symptoms. The patient may report lower extremity edema, pruritus, or skin changes such as wounds.¹⁴ Perineal, posterior labial, and vulvar varices (V_{3a}) may be observed after having the patient stand for approximately 10 minutes prior to examination. Atypical extremity varicosity patterns such as sciatic and/or superficial medial/posterior thigh varices (V_{3b}) should raise suspicion for venous reflux transmitting through pelvic escape points.¹⁵

Due to the nonspecific nature of chronic pelvic pain, it is important to evaluate for non-venous etiologies of the

patient's symptoms. The primary gynecologic differential consideration is pelvic floor myalgia. Other common gynecologic causes of pelvic pain include fibroids and adenomyosis. If a patient describes pain during intercourse, endometriosis should be considered. Unlike PeVD, endometriosis pain is cyclic and generally has a pain-free interval each month. Consider gastrointestinal etiologies if the symptoms relate to food intake, are sensitive to dietary changes, or are associated with bowel movements. Lower extremity swelling from underlying venous disease must be distinguished from lymphedema, lipedema, and medical comorbidities that can result in volume overload such as congestive heart failure. Some degree of asymmetry in lower extremity edema is highly likely to relate to venous/lymphatic disease rather than systemic disorders. A thorough medication reconciliation will also help identify common pharmacologic sources of swelling, such as calcium channel blockers.

Because of central pain sensitization, patients may have more than one source of pain; this scenario necessitates a strong therapeutic alliance between physician and patient and a sequential treatment approach to achieve meaningful symptom improvement.⁸ A multidisciplinary approach with early involvement of pain specialists can be helpful in the treatment of patients with refractory symptoms. Cognitive behavioral therapy and the use of medications such as selective serotonin reuptake inhibitors (SSRIs) may be of value in these cases, and mental health providers should be included in the multidisciplinary care of these patients.⁸

One factor contributing to the clinical ambiguity of PeVD is the absence of a validated assessment tool to quantify symptoms in a comprehensive and reproducible manner. This makes the decision to intervene and assessment of treatment success a subjective endeavor

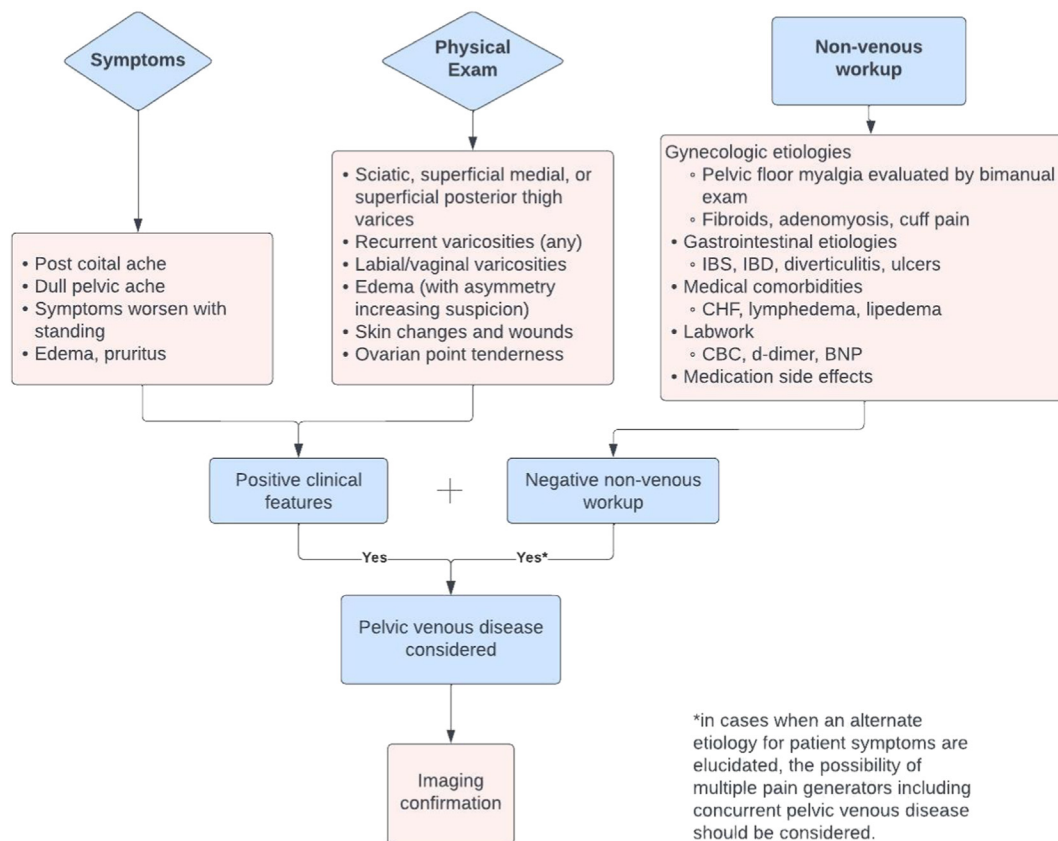


Fig 1. Systematic clinical evaluation of pelvic venous disorder (PeVD). This algorithm is a simplified general approach for evaluating patients with potential PeVD. *BNP*, Brain natriuretic peptide; *CBC*, complete blood count; *CHF*, congestive heart failure; *IBD*, inflammatory bowel disease; *IBS*, irritable bowel syndrome.

in clinical practice. Although visual analog pain scores are commonly employed in current practice, a more detailed outcome assessment tool is needed to effectively compare patients and treatments in research efforts. A clinical instrument analogous to the revised Venous Clinical Severity Score (rVCSS) and complementary to the SVP classification is needed to add clarity to the management of patients with PeVD.

DIAGNOSIS: IMAGING

Imaging should be guided by the patient's dominant symptoms. For S₁ (left flank pain), an abdominal ultrasound is a cost-effective initial study when performed by experienced sonographers. For S₂ (pelvic), an extended pelvic ultrasound is the initial exam of choice to evaluate for ovarian vein reflux. Ovarian vein diameter of 6 mm or greater is frequently associated with ovarian reflux.¹⁶ The presence of four or more ipsilateral tortuous para-uterine veins measuring 4 mm or more in diameter is another reported sign of ovarian reflux.^{17,18} Experienced sonographers can also reliably image the iliac vein in most scenarios. For S₃ patients, a lower extremity and pelvic ultrasound are the initial imaging choice to map varicosities and segments of reflux. Ultrasound is the mainstay

diagnostic imaging modality in many practices but is heavily dependent on local sonographer expertise. Axial imaging in the form of computed tomography venography or magnetic resonance venography can be obtained when intervention is being considered to delineate anatomy and help with procedural planning. Magnetic resonance venography is particularly helpful in cases of proximal occlusion (such as ilio-caval obstruction) and atypical or extensive collateralization and has the added benefit of evaluating for non-venous etiologies for symptoms.

TREATMENT: MEDICAL

Once symptoms are confirmed as venous in origin, patients should be counseled on conservative measures, including weight loss, exercise, and avoiding prolonged sitting or standing. Lifestyle modification has been primarily supported by studies of patients with lower extremity venous disease.^{12,19} However, based on described pathophysiology of obesity and sedentary related pro-inflammatory states resulting in worsening venous disease, it has been inferred that these lifestyle measures may also help patients with pelvic venous disease.¹² Leg elevation and compression stockings are

SVP clinical presentation	S1 Left flank pain	S2 Chronic pelvic pain	S3 Pelvic origin extra-pelvic and/or leg symptoms
Common imaging findings	Left renal vein obstruction Renal hilar varices	Ovarian vein reflux Iliac vein obstruction	Escape point/atypical extremity varicosities Labial/vaginal varicosities Iliac vein obstruction Lower extremity reflux
Endovascular interventions considered	Left renal vein venoplasty and/or stent Renal hilar variceal embolization	Reservoir embolization (Ovarian vein and internal iliac vein) Iliac vein stent	Localized treatment of symptomatic varicosities (thermal or nonthermal) Reservoir embolization (Ovarian vein and internal iliac vein) Iliac vein stent

Fig 2. Locally directed interventions for pelvic venous disorder (PeVD). This figure summarizes potential endovascular interventions considered for PeVD based on the clinical presentation and imaging findings. SVP, Symptoms-Varices-Pathophysiology.

recommended for patients with S₃ and some S₂ category symptoms. A trial of venoactive drugs such as flavonoids could be considered, although these drugs are not widely prescribed in the United States. In patients with severe symptoms or those failing conservative measures, localized interventions can be pursued (Fig 2). Ultimately, a subset of S₂ (ie S_{2,P_{CIV,O,NT}} and S_{2,P_{CIV,O,T}}) and S₃ (S_{3c} and likely S_{3a}) patients may benefit from iliac vein stent placement.^{15,20,21}

TREATMENT: INTERVENTIONAL

Correction of isolated chronic iliofemoral venous obstruction. Patients with chronic iliofemoral venous obstruction (CIVO) may present with pelvic pain, lower extremity symptoms, or both depending on the degree of compensation and the presence of other concurrent venous pathology. CIVO can be thrombotic (eg, P_{CIV, O, T}) or non-thrombotic (eg, P_{CIV, O, NT}) in etiology.

Only a subset of patients with non-thrombotic iliac vein lesions (NIVLs) will benefit from stent placement, making patient selection critical in this population. This is because anatomic compressions are frequently identified in up to 70% of asymptomatic individuals, which implies that an NIVL can be an incidental noncontributory finding in a symptomatic patient.²¹⁻²³ However, NIVLs contribute to symptoms in many patients with PeVD, and failure to treat this subset of patients could result

in a suboptimal or failed clinical response.²⁴ Therefore, the challenge is determining what constitutes a clinically significant NIVL and excluding other causes of pathology.

Iliac vein stenoses are typically identified during initial imaging workup of a patient with PeVD, and it is important to recognize the limitations of diagnostic imaging. For example, obesity or dehydration can falsely exaggerate the degree of stenosis on cross-sectional imaging; the false positive rate of magnetic resonance venography has been reported as high as 41.5%.²⁵ Ultrasound is a useful pre-intervention screening modality for iliac stenoses; recent data has demonstrated that normalized ultrasound diameter measurements combined with velocity measurements of stenoses correlate with intravascular ultrasound (IVUS)-derived area reductions.^{26,27} However, the reliability of ultrasound measurements depend on sonographer variability and experience. Venography can be helpful when collateral pathways are present to suggest hemodynamic significance; however, it can also miss lesions. IVUS is a more sensitive and precise tool than venography for identifying iliofemoral venous obstruction.²⁸ We suggest evaluating iliac obstructive lesions by both venography and IVUS routinely before placing a stent.

The positioning of the patient during imaging will affect the degree of stenosis on venography and ultrasound. Stenoses found in patients while supine often disappear when the patient is repositioned to left side down or

standing.²⁹ Reverse Trendelenburg is considered the optimal positioning for venography.³⁰ True venous stenoses will persist despite repositioning and remain fixed despite exam maneuvers such as Valsalva.²⁹

Determining the severity of an iliac vein stenosis is important when evaluating whether an NIVL is likely to be clinically meaningful. Historically, thresholds ranging from 20% to 50% area stenosis were used as the minimum stenosis warranting treatment.²¹ Some continue to advocate for lower thresholds for intervention in NIVLs for patients with quality of life-impairing symptoms who have failed conservative treatment.³¹ Validation of such thresholds is necessary in multicenter, bias-limited cohorts. The Venogram vs intravascular ultrasound (IVUS) for Diagnosing Iliac Vein Obstruction (VIDIO) trial prospectively evaluated iliofemoral obstruction in 45 patients with C4-C6 venous disease; their analysis suggested treatment of $\geq 61\%$ diameter, 86% area stenosis (by IVUS) in patients with NIVL yielded positive results in their patient cohort.²⁸ The external validity of the results has been questioned, given that the studied patient population was limited to those with C4-C6 disease.²⁶ Peak vein velocity ratio >2.5 in the area of stenosis is a reported ultrasound criterion for identifying a significant NIVL.²⁶ Reversal of flow in the internal iliac vein, balloon pullback test, and the presence of collaterals have been anecdotally reported as helpful signs of a significant NIVL.³²

Patients with post-thrombotic iliac vein obstruction generally present with symptoms of post-thrombotic syndrome in addition to pelvic symptoms. Treatment of the specific symptom of pelvic pain in post-thrombotic iliac vein obstruction is not well-studied, as existing literature focuses on lower extremity symptoms. In our experience, patients with chronic pelvic pain and post-thrombotic iliac obstruction can present with an asymmetrically higher burden of lower extremity symptoms in addition to pelvic pain. We tend to have a lower threshold to treat these patients given the favorable risk/benefit ratio of intervention when compared with NIVLs; not only are the etiology of symptoms clearer, the degree of lower extremity symptoms is often more debilitating. In cases of chronic post-thrombotic outflow obstruction, the patient's anatomy must be individually assessed to ensure that adequate inflow is present to support durable stent patency and symptom improvement.³³

Correction of chronic iliofemoral venous obstruction with concurrent ovarian vein reflux.

Once an iliac vein obstruction has been determined as significant, the next decision is when to stent if the patient has concurrent ovarian vein reflux, a common clinical scenario.¹¹ The topic is controversial and without conclusive evidence. Although some advocate for the treatment of ovarian reflux first when present, others support initial treatment

of the NIVL. Available data is confounded by lack of control arms, inhomogeneous patient populations, varying criteria for defining an obstructing lesion, and heterogeneous treatment protocols. The treatment decision should also factor in whether the ovarian vein reflux is primary ($S_2 V_2 P_{BCV,R,NT}$) or secondary to left renal vein compression ($S_2 V_{1,2} P_{LRV,O,NT; LCV,R,NT}$). In secondary ovarian vein reflux, where there are clinical features of a pressurized renal reservoir (hematuria, flank pain), treatment of renal vein compression may be necessary. There are two approaches: endovascular stent placement and renal/ovarian transposition. Although large series are not present to suggest the best course of treatment, we favor operative intervention at centers with experience in renal/ovarian transposition. If stent placement is considered, there should be an extensive review of sizing prior to implantation, given the known risk of migration. The patient should be counseled on the risks and potential benefits of all approaches prior to potential treatment.

One retrospective study of 227 women compared visual analog pain scores (VAS) after patients were treated with ovarian vein embolization ($n = 39$), staged embolization and iliac stent ($n = 94$), simultaneous embolization and stent ($n = 30$), and stent alone ($n = 50$).³⁴ Eleven patients were treated with ovarian vein embolization with venoplasty or venoplasty alone. Within this patient population, 80% of patients had an iliac vein obstruction as defined by $>50\%$ area iliac vein stenosis by IVUS. In the staged group, only nine of 94 patients reported significant VAS decrease with embolization alone. After staged stent placement, a significant decrease in VAS from 8.6 to 1.3 was reported. Simultaneous stent and ovarian vein embolization also achieved a VAS reduction, although the post treatment pain scores were slightly higher than the staged approach (VAS of 2.4). There was a short interval of 2 to 4 weeks between embolization and stent placement. Additionally, only the left ovarian vein was treated in all patients. These aspects of the study design may explain why embolization alone did not result in a better clinical response.

Another retrospective study by Lakhanpal et al examined patients with iliac vein stenosis and concurrent ovarian vein reflux treated with only iliac vein stent placement. A threshold of $>50\%$ area iliac vein stenosis by IVUS was set as the inclusion criteria, with an average area reduction of 74.1% in their patient population. The authors concluded that stent placement alone could achieve symptom resolution in a majority of patients.³⁵ However, many of these patients (44%) had an untreated pelvic reservoir, and the long-term durability of their reported symptom response is unclear, given that patients were only followed 6 months post treatment.

In the absence of conclusive evidence, we typically offer ovarian embolization first for patients with primary ovarian vein reflux and an NIVL presenting with pelvic pain.³⁶⁻³⁸ If symptoms resolve, the patient is spared

potential risks associated with iliac stent placement. If symptoms persist at 3 to 6 months, an iliac vein stent is then placed in a staged approach. When treating a combination of iliac vein obstruction and ovarian reflux where the presenting complaints are dominant in the lower extremity or back pain secondary to large paravertebral collaterals, we suggest individualized treatment based on what symptoms most impact the patient; initial iliac vein stent placement may be reasonable here. A stent-first approach may also be sensible if the degree of iliac obstruction is severe and ovarian reflux appears very mild; however, there are no validated criteria to grade severity of ovarian reflux.

ILIAC VEIN STENT PLACEMENT: PROCEDURAL CONSIDERATIONS, RISKS, AND CONTRAINDICATIONS

Although stent placement in an NIVL is usually technically straightforward, the procedure is not without risks. Back pain after iliac vein stent placement is reported in up to 66% of patients at 1 week and usually resolves by 1 month.³⁹ Although rare, there have been anecdotal reports of persistent and chronic back pain after stent placement.¹⁶ The development of persistent back pain may relate to stent oversizing, although this is debated, with one retrospective study demonstrating no correlation with pain and stent size.⁴⁰

There is also the rare but devastating risk of stent migration, reported as high as 6.25% and likely under-reported in the literature.⁴¹ Stent migration can necessitate open heart surgery for retrieval and tricuspid valve repair. Stent migration is thought to be more likely with NIVLs than post-thrombotic lesions. This may be due to decreased stent adherence to the relatively undamaged vein wall, making adequate stent length and sizing of vital importance.

IVUS can serve as a useful intraprocedural tool for stent sizing and planning landing zones in this context. IVUS is helpful for determining the length of disease segment and location of inflow (profunda) and outflow (iliac venous confluence). The stent length and diameter must account for pre-stenotic dilatation as measured by IVUS. A review of venous stent migration by Sayed et al noted that a vast majority of migrated stents were short (<90 mm) and small diameter (<14 mm).⁴² To mitigate the risk of migration, we recommend longer stents anchored in the mid external iliac vein, with stent lengths typically >120 mm. Stents should extend beyond the posterior turn in the pelvis, which is verified by steep oblique venography. Coverage of the internal iliac vein is typically not of clinical concern given that the risk of migration is of utmost importance to mitigate; subsequent internal iliac catheterization is frequently possible through stent interstices.

General contraindications to stent placement include active infection, unmanaged coagulopathy, medical

comorbidities that markedly increase sedation risk, and anticipated poor compliance with anticoagulation and follow-up. Another important consideration is nickel hypersensitivity, the most common metal allergy found in up to 17% of women.⁴³ Studies of coronary and intracranial stents have failed to demonstrate that nickel in nitinol stents constitutes a significant exposure.^{44,45} There is no meaningful data studying hypersensitivity response following placement of larger iliac venous stents. Although rare, case reports exist of nickel-mediated allergy following iliac vein stent placement that ultimately required surgical excision.⁴⁶ The topic requires a risk/benefit discussion with the patient. We generally consider a known severe nickel allergy as an absolute contraindication for iliac vein stent placement.

The risks of implanting a permanent stent should not be understated in patients with an NIVL, who are typically young to early middle-aged women with bothersome, potentially debilitating, but non-life-threatening symptoms. The same level of caution should be applied to patients with overlapping symptoms and multiple anatomic locations of venous disease—a conservative staged approach can help reduce the number of permanent devices required and associated long-term risks.

ILIAC VEIN STENT PLACEMENT: POSTPROCEDURAL CARE

The use of antithrombotic therapy after iliac vein stent placement remains controversial. Stents placed for NIVLs generally have excellent patency, upwards of 95% in reported studies.⁴⁷ One retrospective study concluded that perioperative stent thrombosis in this setting is very uncommon.⁴⁸ Based on this, we typically do not anticoagulate patients with stents placed for NIVLs even in the short term and caution against prolonged anticoagulation in the absence of data supporting its efficacy.

For post-thrombotic etiology iliac vein lesion stents, long-term patency is generally poorer.^{47,49} Anticoagulation plays an important role in post-thrombotic stent patency, but there are a wide range of anticoagulation protocols employed in practice. Our practice for thrombotic etiology iliac stents is to anticoagulate with a short-term course of low molecular weight heparin, which is selected in part due to its anti-inflammatory effects and has been shown to reduce odds of early reocclusion.^{50,51} After approximately 4 weeks, the patient is bridged to a direct-acting oral anticoagulant. Because most direct-acting oral anticoagulants do not have a recommended prophylactic dose, we prescribe a full dose. The duration of anticoagulation in post-thrombotic patients is largely guided by whether the thrombosis is provoked or unprovoked, initial or subsequent, and the extent of anatomy involved. For those with recurrent or unprovoked thrombosis, indefinite antithrombotic therapy is generally favored. Antiplatelet therapy is

controversial; we usually elect for monotherapy over dual agent therapy given insufficient evidence validating antiplatelet use and increased bleeding risk.⁵²

Establishing clinical follow-up is important to identify the minority of patients who develop significant in stent stenosis (up to 5% of all patients at 72 months; 10% in post-thrombotic occlusions and 1% NIVL); early reintervention in these cases is more likely to be successful.^{53,54} Ultrasound or cross-sectional imaging at regular intervals is suggested, particularly for thrombotic lesions. There is no conclusive data to inform a surveillance timeline at present. We suggest ultrasound, or if not visible, CT at 1, 3, 6, and 12 months and subsequently annually for post-thrombotic occlusions. A more infrequent surveillance schedule would be reasonable for patients with NIVL.

CONCLUSIONS

Pelvic venous disease is common but has historically been challenging to diagnose and treat. The SVP classification can help specify the clinical presentation and serve as a reporting standard for population comparison studies in research. Although non-thrombotic iliac vein lesions are a significant contributive factor in many patient's PeVD, only a subset of patients with an NIVL will benefit from a venous stent. Many patients will have both ovarian vein reflux and an NIVL; however, data on the optimal treatment approach in this population is limited.

There is a need for more robust research in nearly every aspect of PeVD. Randomized controlled trials are needed to better understand the relationship of symptoms and pathophysiology, validate thresholds for reflux and stenoses, and determine clinical response to treatment with minimization of bias. In the absence of conclusive evidence, exercising careful clinical judgement and treating each patient individually is prudent.

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Analysis and interpretation: Not applicable

Data collection: Not applicable

Writing the article: KD, RG, NM

Critical revision of the article: KD, RG, NM

Final approval of the article: KD, RG, NM

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Overall responsibility: KD

DISCLOSURE

K.D. has served as a paid consultant and is on the speaker's bureau for the following companies: Cook Medical, Boston Scientific, Becton Dickinson/CR Bard, Medtronic, Penumbra, Tactile Medical, and Philips; and has served as a paid consultant for W.L Gore, Shockwave Medical, Asahi Intecc, Veryan, Cordis, and Surmodics.

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