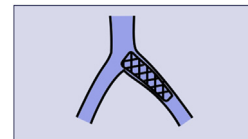


# Society of Interventional Radiology Position Statement on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents



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## ABSTRACT

**Purpose:** To state the position of the Society of Interventional Radiology (SIR) on the endovascular management of chronic iliofemoral venous obstruction with metallic stents.

**Materials and Methods:** A multidisciplinary writing group with expertise in treating venous disease was convened by SIR. A comprehensive literature search was conducted to identify studies on the topic of interest. Recommendations were drafted and graded according to the updated SIR evidence grading system. A modified Delphi technique was used to achieve consensus agreement on the recommendation statements.

**Results:** A total of 41 studies, including randomized trials, systematic reviews and meta-analyses, prospective single-arm studies, and retrospective studies were identified. The expert writing group developed 15 recommendations on the use of endovascular stent placement.

**Conclusions:** SIR considers the use of endovascular stent placement for chronic iliofemoral venous obstruction to be likely to help selected patients, but the risks and benefits have not been fully quantified in well-designed randomized studies. SIR recommends urgent completion of such studies. In the meantime, careful patient selection and optimization of conservative therapy are recommended prior to stent placement, with attention to appropriate stent sizing and quality procedural technique. The use of multiplanar venography with intravascular ultrasound is suggested in diagnosing and characterizing obstructive iliac vein lesions and in guiding stent therapy. After stent placement, SIR recommends close patient follow-up to ensure optimal antithrombotic therapy, durable symptom response, and early identification of adverse events.

## ABBREVIATIONS

BEST = Best Endovenous Treatment, Including Stenting, Versus Best Non-Endovenous Treatment in Chronic Proximal Deep Venous Disease, CEAP = Clinical-Etiological-Anatomic-Pathophysiologic, CI = confidence interval, CIVIQ-20 = Chronic Venous Insufficiency Quality of Life Questionnaire, C-TRACT = Chronic Venous Thrombosis: Relief with Adjunctive Catheter-Directed Therapy, DVT = deep vein thrombosis, FDA = Food and Drug Administration, IVC = inferior vena cava, NIVL = nonthrombotic iliac vein lesion, OR = odds ratio, PTS = postthrombotic syndrome, QOL = quality of life, US = ultrasound, VAS = Visual Analog Scale, VCSS = Venous Clinical Severity Score, VEINES = Venous Insufficiency Epidemiological and Economic Study, VTE = venous thromboembolism

## INTRODUCTION

Chronic iliofemoral venous obstruction often plays a central role in the pathophysiology of chronic venous disease (1). Either alone or in combination with venous valvular reflux and other factors, chronic iliofemoral venous obstruction can

contribute to ambulatory venous hypertension, which leads to limb swelling, pain, calf pump dysfunction, and pathological skin changes including ulceration (2–4). Many affected patients experience substantial impairment of ambulatory capacity and symptoms that reduce their health-related quality of life (QOL) (1–4).

Appendixes A–C can be found by accessing the online version of this article on [www.jvir.org](http://www.jvir.org) and selecting the Supplemental Material tab.  
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Endovascular stent placement has been used to manage patients with chronic iliofemoral venous obstruction for many years (5–7). Stents have been used to treat venous occlusions and venous stenoses, either of which can stem from external venous compression, internal fibrotic changes, and/or residual organized thrombus from previous deep vein thrombosis (DVT). In recent years, the field has evolved with additional clinical experience, improvements in venous imaging, the approval of dedicated venous stents for iliac vein use by the U.S. Food and Drug Administration (FDA), and subsequent awareness of unanticipated post-marketing safety issues that prompted device recalls and changes to instructions for use for some stent brands. This article provides an updated review of the published literature and documents the current position of the Society of Interventional Radiology (SIR) on the use of stents for the management of chronic iliofemoral venous obstruction.

## MATERIALS AND METHODS

### Panel Formation

Under the direction of SIR, a multidisciplinary group of experts from interventional radiology, vascular medicine, and vascular surgery was convened to review the current literature on the endovascular management of chronic iliofemoral venous obstruction.

### Literature Review

A comprehensive literature search was conducted in MEDLINE via PubMed in November 2020 using a combination of search terms, including “venous thrombosis,” “venous insufficiency,” “venous obstruction,” “thrombosis,” “post-thrombotic syndrome,” “iliofemoral,” “iliac,” “inferior vena cava,” “vein,” “venous,” “endovascular,” and “stent.” The full details of the search are shown in [Appendix A](#) (available online on the article’s [Supplemental Material](#) page at [www.jvir.org](http://www.jvir.org)). Searches were limited to the English language from 2013 to present, with 2013 representing the last search date from the previous version of the SIR quality improvement guidelines. The literature search did not focus on nonendovascular therapies. Although limited, the evidence on medical, compressive, and ulcer therapies is summarized below to provide clinical context for recommendations relating to stent placement.

### Recommendation Development and Consensus

Recommendations were drafted and graded according to the updated SIR evidence grading system ([Appendix B](#), available online at [www.jvir.org](http://www.jvir.org)). A modified Delphi technique was used to achieve consensus agreement on the recommendation statements. Consensus is reached when 80% of the panelists agree with each statement. All recommendation statements in this document achieved the 80% agreement threshold.

## STUDY DETAILS

**Study type:** Systematic review and Guidelines

**Level of evidence:** 2 (SIR-B)

### Definitions

Even with quality imaging, the etiology of a venous obstructive lesion often cannot be known with certainty—it may have been caused by previous DVT, an intrinsic non-thrombotic iliac vein lesion (NIVL), external compression of the vein, or a combination of these factors. However, a known history of DVT or external venous compression (especially when due to a malignant tumor) is a factor that likely influences disease prognosis, treatment, and outcome. Hence, in contemporary studies of the endovascular treatment of patients with symptomatic chronic venous disease, the outcomes of patients with previous DVT (ie, being treated for established postthrombotic syndrome [PTS]) have often been reported separately from those of patients with no DVT history (ie, being treated for an NIVL). This document addresses both the overall evidence on stent placement and issues that are specific to either subpopulation. In this document, the term NIVL includes intrinsic lesions and lesions that are related to vascular or osseous compression syndromes (eg, left iliac vein compression syndrome) but not lesions that are associated with an adjacent external compressive mass lesion because clinical priorities, the mechanical performance of stents, and their appropriateness and sequencing relative to other therapies may differ substantially. Patients with malignant venous obstruction have distinct clinical considerations and were excluded from prospective stent studies. Patients with benign compressive mass lesions are sometimes eligible for therapies that are targeted to the specific lesion type (eg, uterine fibroids and hematomas). Of note, stent placement in patients who have undergone recent endovascular thrombus removal to treat acute DVT is not discussed here but is addressed in a separate SIR position statement (8).

Across studies, there has been substantial variability in the methods of stent placement, types of stents utilized, outcome definitions, and levels of reporting detail and completeness. The committee did not attempt to reconcile these differences via patient-level analyses and did not undertake formal statistical meta-analyses to summarize treatment effects. Rather, the following recommendations reflect insights from collective analysis of the best individual studies.

## RESULTS

### Iliac Vein Stent Placement

The best available evidence on the use of endovascular stent placement for the treatment of chronic iliofemoral venous obstruction is summarized in the following sections, grouped by study design. The search retrieved a number of

studies ([Appendix C](#), available online at [www.jvir.org](http://www.jvir.org)); however, few well-designed, high-quality studies have objectively assessed the effects of stent placement for chronic venous disease. Many studies provided limited information on important cointerventions such as concomitant medical therapy and management of superficial venous reflux. Because the methodological quality of nearly all published studies is low, the recommendations here reflect a combination of the evidence and expert consensus opinion on how to optimize patient outcomes despite ongoing uncertainty about many issues pertinent to the safety and effectiveness of iliac vein stent placement.

**Randomized Controlled Trials.** In a single-center, double-blind, randomized controlled trial, 51 limbs with moderate or severe chronic venous disease (Clinical-Etiological-Anatomic-Pathophysiologic [CEAP] clinical classes 3–6, with a venous clinical severity score [VCSS] of  $\geq 10$  or visual analog scale [VAS] pain score of  $> 2$ ) and iliac vein obstruction (occlusion or  $> 50\%$  area stenosis) were randomized to receive, or not receive, placement of iliac vein Wallstents (Boston Scientific, Marlborough, Massachusetts) guided by venography and intravascular ultrasound (US) (9). The study (9) included patients whose disease extended into the inferior vena cava (IVC) but excluded patients with common femoral vein occlusions. Initial iliac vein recanalization with  $< 20\%$  residual obstruction was achieved in all patients in the stent arm. Primary and secondary stent patency rates were 92% and 100%, respectively, at a median follow-up duration of 11.8 months. Greater improvement in mean VAS pain score and VCSS (for both scales, change of 6.5 points in stent arm vs 1.0 point in no-stent arm;  $P < .001$ ) and QOL (Short Form-36 Health Survey, multiple domains,  $P < .001$ ) was seen in the patients with stent placement compared with patients without stent placement. Limitations included the small sample size, single-center performance, mixing of data from patients with PTS and NIVL, and baseline imbalances (limbs allocated to stent placement had higher baseline VAS scores and VCSSs and less valvular reflux in the deep and perforator veins). It is not known if these imbalances occurred due to random chance or if they reflected a problem with the processes for randomization and/or allocation concealment.

**Ongoing Randomized Controlled Trials.** The Chronic Venous Thrombosis: Relief with Adjunctive Catheter-Directed Therapy (C-TRACT) clinical trial is an ongoing multicenter, open-label, assessor-blinded, randomized controlled trial sponsored by the U.S. National Institutes of Health (National Heart, Lung, and Blood Institute) (NCT03250247 at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)) (10). This study (10) aims to randomize 374 patients with moderate or severe PTS and iliac vein obstruction (with or without extension into the IVC or common femoral vein) to receive, or not receive, iliac vein stent placement (multiple brands) guided by venography and

intravascular US. Patients in both arms receive active efforts to improve PTS using medical, compressive, and ulcer therapies. The primary outcome is the 6-month VCSS, blindly assessed and adjusted for baseline; 24-month follow-up includes evaluation of PTS severity, QOL, safety, cost effectiveness, stent patency, and valvular reflux.

The Best Endovenous Treatment, Including Stenting, Versus Best Non-Endovenous Treatment in Chronic Proximal Deep Venous Disease (BEST) Trial is a multicenter, open-label, assessor-blinded, randomized controlled trial sponsored by the British Heart Foundation. This study plans to randomize 328 patients with chronic venous disease and iliac vein disease (unlike C-TRACT clinical trial, the BEST trial includes patients with PTS and those with NIVLs and no DVT history) to receive, or not receive, endovenous stent reconstruction guided by venography and intravascular US. Patients in both arms will receive optimal medical therapy including compression therapy with or without antithrombotic medications. The primary outcome was VCSS at 6 months, blindly assessed. Follow-up will extend to 12 months with evaluation of PTS severity, symptom resolution, QOL, safety, cost effectiveness, and stent patency.

**Systematic Reviews.** Only 2 systematic reviews were identified that specifically addressed iliac stent placement for treatment of chronic venous disease and iliac vein obstruction (11,12). Both are limited by significant heterogeneity and poor quality of included studies. A recent systematic review by Seager et al (11) reviewed the available data regarding the efficiency and safety of venous stent placement. A total of 16 studies ( $n = 2,431$  patients) were included, and among these studies, stent placement was attempted in 2,649 limbs with initial procedural success in 2,586 limbs (97.6%). Formal meta-analysis was not performed because of significant heterogeneity. Five included studies ( $n = 295$  patients) reported reduction in venous disease severity (CEAP, venous disability score, Villalta PTS scale, or VCSS scale) after stent placement. Three studies reported statistically significant improvements in venous disease-specific QOL scores (Chronic Venous Insufficiency Quality of Life Questionnaire [CIVIQ-20] or Venous Insufficiency Epidemiological and Economic Study [VEINES]-QOL measure) after stent placement. In the 14 studies ( $n = 2,410$  limbs) that reported on stent patency between 6 and 48 months, primary patency rates ranged from 32% to 99%, and secondary patency rates ranged from 66% to 96%.

Another systematic review pooled data from 22 studies ( $n = 2,240$  patients, including 1,118 patients with PTS and 1,122 patients with NIVLs) in which iliac vein stents were placed to treat chronic venous disease (12). Pooled technical success in placing stents was 95%. Complete relief of pain, edema, and ulcers was observed in 69%, 63%, and 70% of patients with PTS, respectively, and in 81%, 68%, and 81% of patients with NIVLs. Primary patency rates at 1 year were 79% for patients with PTS and 96% for patients with NIVLs.

The secondary patency rates at 1 year were 94% for patients with PTS and 99% for patients with NIVLs.

**Observational Studies.** Prospective multicenter studies examining the safety and efficacy of 4 nitinol stents designed for venous use have been completed, with the results of 3 studies published as of this writing (13–16). These studies were similarly designed to evaluate the use of stents to treat iliac vein obstruction (generally defined as total occlusion or stenosis causing  $\geq 50\%$  reduction of venous lumen caliber) but varied in the specific populations they studied. These studies excluded patients with IVC disease or malignant venous obstruction. Major limitations to these studies include the lack of control groups for patients without stent placement; thus, they are unable to provide insight into whether and to what degree stent placement may offer benefits that exceed what is achieved with conservative treatment.

In the VERNACULAR study (13), the Venovo Venous Stent (Becton Dickinson, Franklin Lakes, New Jersey) was placed in 170 patients with symptomatic chronic venous disease (93 PTS and 71 NIVL cases) and iliofemoral venous outflow obstruction (CEAP clinical class  $\geq 3$  or VCSS pain item  $\geq 2$ ). Only 9% of patients had common femoral vein disease. The primary patency at 1 year was 88.6% (81.8% for PTS and 97.1% for NIVL). Changes in the VCSS pain item (before stent placement, 2.3 [2.1–2.4], vs after stent placement, 0.6 [0.5–0.7]) and QOL (CIVIQ-20, before stent placement, 49.3 [46.5–52.0], vs after stent placement, 33.6 [31.0–36.2]) scores were also observed ( $P < .001$ ). At 36 months of follow-up, the primary patency was 79.5% (70.0% for PTS and 93.6% for NIVL).

In the VIRTUS: An Evaluation of the Vici Venous Stent System in Patients with Chronic Iliofemoral Venous Outflow Obstruction study (14,15), the VICI venous stent (Boston Scientific) was placed in 170 patients with symptomatic chronic venous disease (127 PTS and 43 NIVL cases) and iliofemoral venous outflow obstruction (total occlusion or  $\geq 50\%$  diameter stenosis, with CEAP clinical class  $\geq 3$  or VCSS pain item  $\geq 2$ ). Approximately 37% of the patients had common femoral vein disease needing stent placement. The primary patency at 1 year in the 125 patients who underwent venography was 83.2% (79.8% for PTS and 96.2% for NIVL). Secondary patency at 1 year was 98.4%. Changes in VCSS (before stent placement,  $10.0 \pm 5.1$ , vs after stent placement,  $5.6 \pm 4.1$ ), VAS pain score (before stent placement,  $45.9 \pm 29.1$ , vs after stent placement,  $23.1 \pm 26.2$ ), and QOL score (CIVIQ-20, before stent placement,  $55.4 \pm 19.4$ , vs after stent placement,  $41.7 \pm 20.0$ ) over 12 months were also observed compared with the baseline scores ( $P < .001$  for all aforementioned comparisons).

In the ABRE study (16), the Abre Venous Self-Expanding Stent System (Medtronic, Minneapolis, Minnesota) was placed in 167 patients with symptomatic chronic venous disease and iliofemoral venous outflow obstruction (95 PTS and 72 NIVL cases). Patients were required to have a CEAP clinical class of  $\geq 3$  or VCSS pain item of  $\geq 2$  and a total

occlusion, 50% diameter stenosis on venography, or 50% area stenosis on intravascular US of the iliac vein. Approximately 44% of patients had stents extended into the common femoral vein. At 12 months of follow-up, the primary patency was 88.2% (79.8% for PTS and 98.6% for NIVL), and the secondary patency was 94.1% (89.3% for PTS and 100% for NIVL). In the patients treated for PTS, the point estimates for the mean VCSS and venous QOL scores 12 months after stent placement were lower than the baseline scores (VCSS, before stent placement,  $8.8 \pm 0.5$ , vs after stent placement,  $5.0 \pm 0.4$ ; VEINES-QOL, before stent placement,  $49.1 \pm 2.5$ , vs after stent placement,  $69.0 \pm 2.6$ ). The same was true for the patients treated for NIVLs (VCSS, before stent placement,  $9.0 \pm 0.5$ , vs after stent placement,  $4.3 \pm 0.4$ ; VEINES-QOL, before stent placement,  $46.8 \pm 3.0$ , vs after stent placement,  $71.8 \pm 3.1$ ).

At the time of writing, the full-cohort results of the VIVO study (17), which evaluated the safety and efficacy of the Zilver Vena Stent (Cook Medical, Bloomington, Indiana) for the management of symptomatic iliofemoral venous obstruction, had not been published.

**Other Studies of Interest.** Additional studies have reported outcomes in patients who underwent iliac vein stent placement for treatment of chronic venous disease. Below we summarize the results of a few available older prospective studies and large observational series. Because these studies suffer from important methodological limitations including small sample size, lack of blinding, and lack of suitable control groups, they cannot serve as definitive assessments of stent outcomes. However, the supplementary data in these studies, perhaps especially the physiological correlations, provide useful context to the overall understanding of the effects of venous stent placement.

Four prospective single-arm, single-center studies (18–21) were identified. Delis et al (18) evaluated venous physiological function in 23 limbs with chronic venous disease (CEAP clinical classes 3–6) and iliofemoral venous obstruction using strain gauge plethysmography. Stent placement was successfully achieved in all treated patients. At a mean follow-up duration of 8.4 months after stent placement, improvement was documented in venous outflow fraction, calf muscle pump function (increased ejection fraction), with a reduction in residual vein fraction ( $P < .001$  for comparisons). Venous claudication was eliminated in all 15 limbs that presented with this symptom. In a study by Rosales et al (19), 34 patients with chronic venous disease (CEAP clinical class 3 [ $n = 27$ ] or 6 [ $n = 7$ ]) and iliac vein obstruction underwent attempted Wallstent placement (successful in 32 patients, 94%). Changes in the VCSSs from baseline to 3 months after stent placement occurred in the C3 patients (median scores, before stent placement, 9 [5–12] vs 1 [0–11];  $P = .0001$ ) and C6 patients (median scores, before stent placement, 21 [18–29] vs 7 [6–14];  $P = .002$ ). Another study (20) of 52 patients with PTS and iliofemoral venous occlusion or stenosis with stent placement reported changes in the VCSSs (median, before stent placement, 14, vs after stent placement, 5), Villalta score (median, before stent



placement, 18, vs after stent placement, 8), CIVIQ-20 venous QOL score (mean increase, 15.6 points  $\pm$  12.5), calf circumference (mean reduction, 12 mm in right legs and 20 mm in left legs), and thigh circumference (mean reduction, 23 mm in right lower extremities and 33 mm in left lower extremities) ( $P < .001$  for all comparisons). Finally, in a study of 61 patients by Catarinella et al (21), improvements in venous symptoms (VEINES-Symptoms,  $P < .001$ ), venous disease-specific QOL (VEINES-QOL,  $P < .001$ ), and general QOL (Short Form-36 Health Survey,  $P < .01$ ) were observed at 3 and 12 months after iliac vein stent placement (multiple brands, sometimes with thromboendovenectomy to enhance inflow).

In the largest published single-center study (22) of ilio-femoral venous stent placement for chronic venous disease ( $n = 982$  patients, including 518 patients with NIVLs and 464 patients with PTS), improvements from baseline in severe limb pain (VAS score of  $>5$ , before stent placement, 54%, to after stent placement, 11%), severe edema (Grade 3, before stent placement, 44%, to after stent placement, 18%), and QOL (multiple CIVIQ-20 subscales) were reported in predominantly retrospective analyses; however, statistical comparisons were not presented. In this study (22), Wall-stents were used in 98% of patients. Over 6 years of follow-up, the primary patency was 67% (79% for NIVL and 57% for PTS), and the secondary patency was 95% (100% for NIVL and 86% for PTS). **Additional observations made over the course of multiple analyses of this experience found that the patency rates were substantially worse for stent placement of total venous occlusions than for that of venous stenoses, treatment was usually successful even when stents needed to be extended into the common femoral vein** (although with slightly lower patency rates), treatment was usually successful when surgical or endovenous treatment of saphenous reflux was concomitantly delivered, and the presence of untreated deep valvular reflux did not preclude a successful clinical outcome after stent placement (22–25). As noted above, each of the above studies had methodological limitations that created substantial potential for bias in estimating the actual treatment efficacy of stent placement.

## Postthrombotic versus Nonthrombotic Lesions

A common observation that has emerged from clinical experiences and published studies is that while many challenges of using stents in patients with chronic venous disease apply to both subpopulations, there are major substantive differences between the PTS and NIVL subpopulations that should be considered in pursuing optimal treatment practices.

**Patients with PTS are more likely to experience loss of stent patency due to thrombus deposition after stent placement than patients treated for NIVLs. Iliac vein lesions in patients with PTS often extend over long venous segments, are densely fibrotic, and involve critical inflow and/or outflow veins, in contrast to many NIVLs that are isolated in the iliac vein and constituted of internal webs or more**

**focal stenoses that relate solely to external vascular compression** (eg, iliac vein compression [May-Thurner] lesions). **Therefore, in patients with PTS, it is important to ensure that there is quality inflow to the common femoral vein from the femoral or deep femoral vein and quality outflow through the IVC. Extension of stents across the inguinal ligament into a diseased common femoral vein is often necessary to enable adequate inflow and a reasonable expectation of patency.** Although stent fractures can occur in this location, they have been rarely documented with available stents and may tend to be less consequential than in the arterial system. **Because superficial veins (eg, great saphenous vein) are not supported by surrounding muscle, they do not tend to serve well as primary inflow to iliac vein stents.** In centers with specialized surgical expertise, open thromboendovenectomy has been reported as another means to optimize inflow to the common femoral vein, although rigorous studies describing outcomes with this method are lacking (26,27). **In treating PTS, it is important to robustly predilate the target vein to ensure adequate stent expansion and use antithrombotic therapy more aggressively in the postintervention period. In some patients, balloon inflation causes pain that can deter the physician from pursuing full predilatation; hence, preprocedural planning should include consideration of whether general anesthesia would be optimal, especially if treatment of a long-segment occlusion is planned.**

In contrast, in patients with NIVLs, stents are likely to stay open but the following issues are more pronounced: (a) because they are often subtle to appreciate, the diagnosis of NIVLs can be challenging to make and often requires invasive imaging, and (b) because limited information is available on what morphological characteristics determine clinically meaningful manifestations and because symptoms (eg, pain and swelling) often have nonvenous or multifactorial etiologies, it can be difficult to predict which patients will benefit after stent placement across NIVLs. This creates a substantial risk of overtreating normally functioning veins—for example, in some retrospective studies (28,29), the use of a 50% area stenosis threshold did not predict the degree of clinical improvement with stent placement, and the degree of stenosis did not predict stent patency. Even asymptomatic patients can exhibit imaging features of iliac vein compression, and it is not entirely clear why some patients experience symptoms, whereas others do not (30,31). Therefore, although clinical severity is a relevant consideration, a causal relationship should not be automatically inferred from the concomitant presence of lower extremity symptoms and an anatomic stenosis. (c) Because NIVLs are often short, elliptical (often with preserved luminal caliber of much of the vein), and less fibrotic, these veins can exhibit greater dynamic variability with changes in intraluminal pressure and intravascular volume. These characteristics can impair stent fixation and create greater potential for stent migration. Consequently, for NIVLs, extreme care is essential during patient selection, imaging evaluation of stenosis, and stent sizing and deployment.

## Adjunctive Elements of Endovascular Care

**Intravascular US.** Various imaging modalities are used to evaluate the iliac venous system, each with its own strengths and limitations (32). Multiplanar venography enables assessment of the size and morphology of the venous lumen and visual estimation of dynamic blood flow but does not enable detailed evaluation of the vein wall architecture and more subtle internal abnormalities. In recent years, intravascular US has been used with increasing frequency to supplement venographic assessment of iliac vein lesions in clinical practice. Intravascular US has been evaluated in several observational studies for its ability to enhance iliac vein lesion diagnosis, characterization, and treatment. The VIDIO study (33), a multicenter prospective cohort study that evaluated the addition of intravascular US to multiplanar venography in 100 patients with severe chronic venous disease (CEAP clinical classes 4–6) and suspected iliac vein obstruction, showed that intravascular US was found to identify iliac vein lesions ( $\geq 50\%$  stenosis) not detected by venography in 26% of patients. Treatment plans frequently (57%) changed after performance of intravascular US—in particular, the addition of intravascular US often led to decisions to place stents and to place a larger number of stents. Intravascular US venous area measurements were more predictive of clinical (VCSS) improvement with stent placement than the degree of stenosis on multiplanar venography. NIVLs were more often eccentric than PTS lesions, often with substantial differences in vein diameter between the anteroposterior and transverse planes, arguing for care in estimating diameter with venography alone.

The correlative analyses in this study (33) suggested that clinical improvement with stent placement was best predicted when a stenosis measured at least 54% area reduction on intravascular US; however, for NIVLs, clinical improvement was best predicted by an intravascular US diameter stenosis of at least 61% (34). On the other hand, even when venography, intravascular US diameter, and intravascular US area measurements concurrently demonstrated a  $\geq 50\%$  stenosis, significant clinical improvement with stent placement (defined as reduction in the VCSS by  $>4$  points in this study) occurred in only 52% of treated patients. Although intravascular US information enhanced the assessment of the iliac vein, the predictive value of intravascular US measurements was not high enough to claim excellent diagnostic efficacy. Thus, it is important that information from clinical assessment, patient history, and other venous morphological indicators should be used along with intravascular US and venography to determine the appropriate treatment strategy for patients with severe chronic venous disease.

In another retrospective study (35) of 155 limbs with chronic venous disease, multiplanar venography often underestimated the degree of stenosis on

intravascular US and was often unable to localize the intravascular US–determined point of maximal stenosis, iliac vein confluence, and optimal distal stent landing zone.

In a recent study (36) of 41 patients with pelvic venous disorders, the intravascular US–measured cross-sectional iliac vein area was significantly lower with patients in the supine position than in the left decubitus position; the supine position resulted in characterization of many more patients as having significant iliac vein stenosis. Hence, care should be exercised in relying on supine intravascular US assessments as the sole method of evaluating iliac vein lesions.

Limitations of these studies included the small sample sizes (overall and for the PTS and NIVL subgroups), lack of a true gold standard against which to compare imaging assessments for several parameters (including what constitutes a “significant” iliac vein stenosis), use of a binary cutpoint to define clinical improvement in the VIDIO study, and lack of assessment of whether intravascular US led to improved long-term outcomes and was cost-effective. A randomized trial (the IGuideU study) is ongoing to evaluate if early intravascular US leads to enhanced venous ulcer healing compared with deferred intravascular US ([www.clinicaltrials.gov](http://www.clinicaltrials.gov), NCT04696354).

**Antithrombotic Therapy.** Four retrospective cohort studies (37–40) were identified that assessed use of antithrombotic therapy. In a study by Arendt et al (37), no differences were seen in thrombotic complications or patient-reported symptom improvement between patients who had received fully therapeutic anticoagulation ( $n = 26$ ) and those who had received no or subtherapeutic anticoagulation ( $n = 25$ ). In a retrospective study (38) ( $n = 106$ ) with stent placement in patients with PTS and total iliac vein occlusions, the presence of multiple occluded venous outflow segments (odds ratio [OR], 4.596; 95% confidence interval [CI], 1.424–18.109), a hypercoagulable state (OR, 3.835; 95% CI, 1.207–12.871), and the type of anticoagulation used were independently associated with a higher rate of early ( $<3$  months) stent thrombosis. Specifically, the use of low-molecular-weight heparin for  $>10$  days after the procedure was associated with significantly lower odds of reocclusion (OR, 0.012; 95% CI, 0.001–0.130). In another single-center retrospective study (39) ( $n = 87$ ), the use of triple therapy (anticoagulation, aspirin, and a thienopyridine antiplatelet agent) appeared to be more effective in preventing recurrent thrombosis after stent placement than dual antiplatelet therapy (OR, 0.07;  $P = .01$ ). Additionally, Endo et al (40) found that the use of adjunctive antiplatelet therapy (in addition to anticoagulation) was associated with improved primary patency (hazard ratio, 0.28;  $P = .022$ ) in patients who had undergone ilio caval venous stent placement. Published articles describing prospective randomized or nonrandomized comparisons of different antithrombotic

treatment strategies for use during or after iliac vein stent placement could not be identified. The importance of conducting such studies was recognized by a SIR Foundation Research Consensus Panel (41).

Clinical practice continues to exhibit substantial variability in the use of antithrombotic therapy following iliofemoral venous stent placement (42,43). Populations of patients undergoing endovascular therapy tend to be substantially younger than those in traditional DVT anticoagulation studies, and the midterm stent patency rates clearly show room for improvement in patients with PTS. Hence, the individualized assessment of risk and benefit will often favor longer and more intense antithrombotic therapy in stented patients with PTS, especially during the early weeks and months after the procedure. For patients with NIVLs, stent patency rates have been extremely high, and the available literature does not support the use of routine antithrombotic therapy.

## Safety Considerations

Complications of venous stent placement can occur during the endovascular procedure, in the early postprocedural period, or during later follow-up and can include issues with the following: (a) stent deployment, initial stability, and local irritation; (b) thrombosis, bleeding, or vascular injury; (c) mechanical problems; (d) biological compatibility; or (e) other procedure elements including sedation/anesthesia and iodinated contrast administration. In considering published reports, prospective studies may be more likely to have reported all events that occurred. On the other hand, systematic reviews that include retrospective studies may offer larger sample sizes.

**Systematic Reviews.** Two systematic reviews retrieved in the authors' search reported on complications of venous stent placement during endovascular procedures. Seager et al (11) reported major bleeds occurring in 0.6% of treated patients (n = 16 studies, 2,431 patients), symptomatic PE occurring in 0.3% of treated patients, and mortality occurring in 0.2%. Razavi et al (12) reported 25 major complications (approximately 1% of patients); this included 9 stent migrations (0.004% of treated patients).

**Randomized Controlled Trials.** In a study by Rossi et al (9), there were no deaths, device fractures, or recurrent venous thromboembolism (VTE) after stent placement. Two minor access site hematomas (4%) and 1 distal stent migration that resulted in persistence of symptoms and required an additional procedure were reported. Approximately 25% of patients experienced transient back pain after stent implantation.

**Observational Studies.** The complication rates are similar across observational studies reporting on stent placement. In the VERNACULAR study (13) (Venovo Stent), freedom from major adverse events through 30

days was 93.5%. There were no procedure-related deaths or stent fractures, embolizations, or migrations (13). However, in early 2021, a temporary recall of this device was issued because of stent maldeployment events that were subsequently attributed to the deployment catheter (44,45). After this issue was addressed by the manufacturer, this stent underwent FDA regulatory review and was returned to the U.S. marketplace in the summer of 2022.

In the VIRTUS: An Evaluation of the Vici Venous Stent System in Patients with Chronic Iliofemoral Venous Outflow Obstruction study (14,15) (VICI Stent), freedom from major adverse events through 30 days was 98.8%. There were no deaths or bleeding events through 12 months of follow-up. However, 3.6% of stents placed were observed to have fractured on 12-month radiographs (no clinical sequelae); 9 of the 10 fractures occurred in stents placed in the common femoral vein (14,15). This stent was permanently recalled from the marketplace in late 2021 after reports of additional stent migrations, of which some involved major clinical sequelae (46). In the ABRE stent study (16), freedom from major adverse events through 30 days was 97.6%. There were 2 deaths (unrelated to procedure/device), 1 major bleed, 1 symptomatic PE, and no cases of stent migration or fracture within 12 months (16).

Overall, the risk of periprocedural complications is not likely to deter endovascular therapy for most patients who have a compelling clinical indication for stent placement. Although published data are insufficient for rigorous analysis of patient-specific factors, careful individualized assessment is prudent to identify patients with characteristics that may connote a particularly high risk of bleeding, vascular injury (eg, radiation injury, chronic steroid use, and some types of cancer therapy), or complications of sedation/anesthesia.

## Cost and Cost Effectiveness

Quality studies that compared the cost effectiveness of stent placement with that of no stent placement or that compared the economic impact of different devices could not be identified. The assessment of cost effectiveness is incorporated into the ongoing C-TRACT and BEST trials.

## Special Populations

**Pregnant Women.** In pregnant patients, although some cases are feasible to perform with minimal exposure to radiation and iodinated contrast, procedural radiation exposure is a significant limiting factor in the application of venous stent placement. Procedure-related complications, although uncommon, also hold the potential to complicate pregnancy care. Moreover, because venous symptoms can improve to a variable degree during the months after delivery, there is rarely a need to incur these risks by expediting the treatment of chronic venous obstruction. Hence, stent placement during pregnancy should be rare;



when deemed necessary, an “as low as reasonably achievable” approach to radiation exposure should be utilized.

The degree to which a gravid uterus is likely to compress an existing stent and predispose to occlusion or fracture is unknown. Limited observations suggest that stent compression infrequently occurs during pregnancy and that meaningful negative sequelae are rare (47,48). Nevertheless, given the uncertainty, this possibility may be worth discussing with women with future childbearing potential who are considering stent placement and can be a reason to defer the procedure, especially if the current impact of venous symptoms on life activities is not compelling. For stented patients who become pregnant, collaboration with the patient’s obstetrician around the optimal antithrombotic strategy is advised.

**Children and Adolescents.** Although children and adolescents exhibit a robust capacity for clinical improvement and venous collateral formation, they can develop severe chronic venous disease. In general, conservative therapies should be employed before considering alternatives. Data on stent placement in children and adolescents in the chronic setting are very limited (49). Although achievement of technical success may be feasible, stent placement will usually not be judicious because of the potential for catheter manipulation to cause endothelial damage and the uncertainties around stent sizing and durability. These concerns are particularly important in children and younger adolescents because their vessels are expected to grow over time.

## Recent Societal Guidelines

Several national health organizations and medical specialty societies have developed evidence-based recommendations on endovascular stent placement for chronic iliofemoral venous obstruction (50–55) (Table). The 2014 guidelines from the Cardiovascular and Interventional Radiological Society of Europe suggest consideration of endovascular therapy including stent placement in patients of CEAP clinical classes 3–6 who have chronic venous outflow obstruction (thrombotic or nonthrombotic) (55). For C3 patients, a trial of compression therapy first is recommended. Specifically, the 2014 clinical practice guidelines on the management of venous leg ulcers from the Society for Vascular Surgery and American Venous Forum recommend that balloon angioplasty and stent placement be considered for patients with nonhealing venous ulcers and ilio caval obstruction after failure of conservative and superficial venous reflux treatments (50). A 2014 scientific statement on the prevention, diagnosis, and treatment of PTS from the American Heart Association suggests that percutaneous endovascular recanalization (eg, stent and balloon angioplasty) is considered for severely symptomatic patients with PTS and iliac vein or vena cava occlusion (51). A 2016 Medicare Evidence Development and Coverage Advisory

Committee reviewed the available evidence on the management of chronic venous disease, including endovascular interventions, and did not find sufficient evidence to support a claim of efficacy for any therapy (52). The Committee noted the low overall evidence quality and lack of randomized trials. The recent Appropriate Use Criteria of the American Venous Forum, American Vein and Lymphatic Society, Society for Vascular Surgery, and SIR indicated appropriate use of stent placement in specific patient scenarios (Table) (53). Most recently, the 2022 guidelines of the European Society for Vascular Surgery suggest that patients with iliac vein outflow obstruction should be managed by a multidisciplinary team that includes an interventional radiologist, vascular surgeon, and hematologist (54). They recommend that when there are severe symptoms/signs, first-line endovascular treatment should be considered, ideally with use of intravascular US to guide treatment. For selected patients with recalcitrant venous ulcer, severe PTS, or disabling venous claudication, surgical or hybrid endovascular-surgical venous reconstruction may be considered when endovascular options alone are not appropriate (eg, because of poor inflow to the common femoral vein). After endovascular or surgical intervention, duplex US surveillance at 1 day and 2 weeks and at regular intervals thereafter is recommended.

## CONCLUSION

SIR considers the use of endovascular stent placement for chronic iliofemoral venous obstruction to be likely to help selected patients, but the risks and benefits have not been fully quantified in well-designed, high-quality studies. Careful patient selection and optimization of conservative therapy are currently recommended prior to stent placement, with attention to appropriate stent sizing and quality procedural technique. The use of multiplanar venography with intravascular US is suggested in diagnosing and characterizing obstructive iliac vein lesions and in guiding stent therapy. As further research proceeds, SIR believes that adherence to the following recommendations will enable judicious use of endovascular therapy in a manner that optimizes benefit and minimizes harm.

## RECOMMENDATIONS

1. **Clinical Suspicion:** In patients with symptoms or signs of advanced chronic venous disease, the possibility that iliofemoral venous obstruction could be a contributing factor should be considered and evaluated when supported by the medical history, symptoms, physical examination, and prior imaging studies (Level of Evidence E, Strength of Recommendation Strong).

*Comment: Findings that can suggest the presence of iliofemoral venous obstruction include a history of*



**Table.** Current Societal Clinical Practice Guidelines on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents (50,51,53,54)

Society	Recommendation
Society for Vascular Surgery and American Venous Forum, 2014 (50)	In a patient with IVC or iliac vein chronic total occlusion or severe stenosis, with or without lower extremity deep venous reflux disease, that is associated with skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we recommend venous angioplasty and stent recanalization in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence (GRADE -1; Level of Evidence C).
American Heart Association, 2014 (51)	For the severely symptomatic patient with iliac vein or vena cava occlusion, surgery (eg, femorofemoral or femorocaval bypass) (Class IIb; Level of Evidence C) or percutaneous endovenous recanalization (eg, stent and balloon angioplasty) (Class IIb, Level of Evidence B) may be considered.
American Venous Forum, Society for Vascular Surgery, American Vein and Lymphatic Society, and Society of Interventional Radiology, 2020 (53)	<ul style="list-style-type: none"> <li>• Iliac vein or IVC stent placement for obstructive disease without superficial truncal reflux as the first-line treatment in a symptomatic patient with skin or subcutaneous changes and healed or active ulcers (CEAP classes 4–6) (Appropriate).</li> <li>• Iliac vein or IVC stent placement for obstructive disease with or without superficial truncal reflux as the first-line therapy in a symptomatic patient with edema due to venous disease (CEAP class 3), provided that careful clinical judgment is exercised because of the potential for a wide range of coexisting nonvenous causes of edema (May be appropriate).</li> <li>• Iliac vein or IVC stent placement for obstructive disease in an asymptomatic patient for iliac vein compression, such as May-Thurner compression, for incidental finding by imaging or telangiectasia (Never appropriate).</li> </ul>
European Society for Vascular Surgery, 2022 (54)	<ul style="list-style-type: none"> <li>• For patients with iliac vein outflow obstruction and severe symptoms/signs, endovascular treatment should be considered as the first choice treatment (Class IIa, Level B).</li> <li>• For patients with iliac vein outflow obstruction undergoing endovascular treatment, the use of intravascular ultrasound should be considered to guide treatment (Class IIa, Level C).</li> <li>• For patients with iliac vein outflow obstruction with a recalcitrant venous ulcer, severe postthrombotic syndrome, or disabling venous claudication, surgical or hybrid deep venous reconstruction may be considered when endovascular options alone are not appropriate (Class IIb, Level C).</li> <li>• For patients with iliac vein outflow obstruction, without severe symptoms, neither endovascular nor surgical interventions are recommended (Class III, Level C).</li> <li>• For patients undergoing either endovascular or surgical reconstruction of iliac vein outflow obstruction, duplex ultrasound surveillance is recommended 1 day and 2 weeks after (Class I, Level C).</li> <li>• For patients with iliac vein outflow obstruction, management by a multidisciplinary team is recommended (Class I, Level C).</li> </ul>

CEAP = Clinical-Etiological-Anatomic-Pathophysiological; IVC = inferior vena cava.

*ipsilateral DVT involving the iliac or common femoral vein; thigh swelling or pain during a previous DVT episode or as a chronic ongoing daily symptom; venous claudication; visible collateral veins on the lower body wall, groins, or perineum; entire-limb edema; previous imaging demonstrating an abnormal iliac or common femoral vein; a history of abdominal/pelvic malignancy; and loss of Doppler waveform phasicity in the ipsilateral common femoral vein on US examination. Imaging of the iliac vein should be considered in patients with one or more of these clinical features who have a lower extremity skin ulcer or severe symptoms. Imaging can be performed using noninvasive (eg, Duplex US, computed tomographic venography, and magnetic resonance venography) or invasive (eg, catheter venography and intravascular US) modalities. The optimal noninvasive imaging method varies based on local expertise/resources. Active collaboration among endovascular proceduralists and diagnostic radiologists is helpful in optimizing technical imaging factors and ensuring dedicated attention to venous findings, which includes visualization of the entirety of the iliofemoral and ilio caval venous segments. In patients with particularly severe clinical manifestations of venous disease in whom noninvasive*

*imaging is nondiagnostic or negative, invasive imaging may be performed.*

2. **Clinical Evaluation:** A thorough clinical evaluation of the patient's self-reported symptoms, objective clinical signs of venous disease, and their impact on life activities should be performed and documented before undertaking any endovascular treatment for chronic iliofemoral venous obstruction (**Level of Evidence E, Strength of Recommendation Strong**).

*Comment: Elements of clinical assessment include a medical history, physical examination, and imaging evaluation for venous obstruction and valvular reflux. It should be recognized that even within a particular descriptive CEAP category (especially CEAP clinical class 3), there is broad diversity in disease severity and life consequences. Hence, emphasis should be placed on understanding the life impact of symptoms and disability and the degree to which they are due to venous disease versus other conditions (eg, peripheral arterial disease, lymphedema/phlebolymphedema, cardiovascular conditions that can cause swelling, and musculoskeletal and neurological conditions that can cause pain). The patient's previous use of, and response to,*

conservative therapies should be documented. The clinical assessment will help establish baseline status and appropriate expectations for treatment. Routine use of standardized venous assessment tools is recommended—this may include the Revised CEAP System to descriptively classify the condition and assessment scales (eg, Villalta or revised VCSS) to follow disease severity longitudinally over time and evaluate the impact of therapy (56–58).

3. **Conservative Therapy:** In patients with chronic iliofemoral venous obstruction, efforts to alleviate symptoms and optimize limb function using conservative means should be made before placing stents (**Level of Evidence E, Strength of Recommendation Strong**).

*Comment:* Patients should be educated about venous disease and efforts made to counter misperceptions. For example, some patients may be motivated to pursue more aggressive treatments because of fears of progression to severe limb complications (unlikely) or to prevent recurrent DVT (unproven) and, therefore, enable cessation of anticoagulation. Notwithstanding the lack of data to support these practices as therapeutic interventions for chronic venous disease, smoking cessation, weight loss, and achievement of optimal glucose control are advisable in applicable patients with tobacco use history, obesity, and diabetes, respectively. Efforts to address nonvenous causes of symptoms should be made. Ongoing risk factors for DVT recurrence should be reviewed, and appropriate antithrombotic therapy should be provided (59). Collaboration with the patient's other healthcare providers is recommended; consultation with hematology or vascular medicine colleagues will often be helpful. Patients with symptoms of chronic venous disease (especially limb swelling or heaviness) should be encouraged to utilize compression therapy unless it is contraindicated (eg, severe peripheral arterial disease and severe contact allergies). Compression therapy is more likely to be effective with active efforts to size garments properly, provide donning devices (if needed), make periodic adjustments to ensure comfort and compliance (eg, open toe vs closed toe, knee-high vs thigh-high, and ankle pressure), and try different modes of compression (graduated elastic compression stockings, wraps, pneumatic compression devices, and venous return assist devices). For stockings, compliance may be aided by starting with garments of lower strength (eg, 20–30 mm Hg) and increasing as dictated by residual symptoms and patient tolerance. Although large definitive trials of these therapies have not been completed, oral diosmin and supervised exercise therapy may also reduce symptoms in selected patients (50,60,61). In patients with benign compressive mass lesions, it may be reasonable to consider treatments targeted to the specific lesion (eg, embolization for uterine fibroids) to relieve the venous

obstruction and related symptoms prior to undertaking venous stent placement.

4. **Venous Ulcers:** Patients with venous ulcers should receive compression therapy and close active follow-up, ideally in a specialized wound care facility that follows published clinical practice guidelines (**Level of Evidence A, Strength of Recommendation Strong**).

*Comment:* Whether or not the endovascular physician is the primary provider of ulcer care, they should verify that key elements of care are being delivered (52): (a) compression therapy (ideally high-strength inelastic compression but because many patients with ulcers experience pain with compression, provider willingness to tailor therapy will enhance compliance and promote overall effectiveness) (62); (b) wound bed preparation via use of absorptive dressings; (c) oral pentoxifylline (63); (d) antibiotics for wound infections or severe bacterial colonization, guided by quantitative wound cultures; and (e) wound debridement, as needed. Depending on the clinical assessment of the relative contributions of valvular reflux in the superficial or perforator veins versus iliac vein obstruction to the venous hypertension, early ablation of refluxing saphenous veins or treatment of large refluxing perforator veins with high outward flow that appears to be directed toward an active ulcer bed (with or without also addressing venous obstruction) may be considered, if present (53,55,64,65). Poor ulcer healing response to compression therapy and wound care or increased pain with application of compression can suggest the presence of venous outflow obstruction that should be evaluated.

5. **Patient Selection for Stent Placement:** Venous stent placement may be appropriate in highly selected symptomatic patients with chronic iliac vein obstruction but should be avoided in most patients who do not have the following: (a) life interference (symptoms or functional disability) of at least moderate severity, with a high probability that it is attributable to the venous disease; (b) anatomic evidence of significant venous obstruction in the IVC, iliac vein, or common femoral vein; (c) good inflow to the common femoral vein from a patent femoral and/or deep femoral vein; and (d), for patients with an individualized risk profile that portends a substantial risk of stent thrombosis, the ability to receive long-term anticoagulation (**Level of Evidence C, Strength of Recommendation Weak**).

*Comment:* The risk-benefit ratio of iliac vein stent placement has not been evaluated in well-designed multicenter randomized trials. Because currently available stents are permanent implants, it is important to avoid stent placements that do not provide durable patency and clinical benefits. In many patients, the attribution of limb symptoms to venous obstruction is uncertain; available diagnostic

testing is limited in its ability to establish the presence of clinically meaningful venous obstruction. Functional venous obstruction can be measured with air plethysmography; if unavailable, obstruction can be suggested by anatomic imaging demonstrating complete occlusion, tight stenosis (visualization of luminal narrowing and/or internal webbing), and/or collateral veins. Although prospective stent studies have included patients with  $\geq 50\%$  stenosis, caution is urged in using this or any other threshold for diameter/area stenosis as a sole criterion for obstruction. Based on the VIDIO study, a higher threshold should be used for stent placement of patients with NIVLs (than that for stent placement of patients with PTS). Preprocedural and intraprocedural imaging assessment should include careful review of the full extent of venous obstruction (ie, inflow and outflow) and the presence of any superimposed acute thrombus. Specific venous inflow criteria have not been shown to predict stent patency—although this is a critical knowledge gap, experience to date suggests that the lack of at least 1 deep vein tributary to the common femoral vein of good caliber should prompt reconsideration of stent placement. If venous outflow appears inadequate, extension of stents into the IVC may be needed. Additional removal or recanalization of occluded IVC filters should be considered as well as the strategy for optimal reconstruction of the iliac confluence that may require bilateral kissing stents. The need for, and importance of compliance with, post-procedural antithrombotic therapy should be discussed in advance with the patient to gain buy-in and, therefore, enhance the potential to achieve long-term patency. In patients at moderate-to-high risk of rethrombosis who demonstrate reluctance or inability to receive antithrombotic therapy, stent placement should be reconsidered. Patients with refractory or recurrent venous obstruction may be susceptible to additional risks that argue for procedure postponement or modification. For example, caution should be applied when performing repeated prolonged procedures within a short time period (to avoid radiation injury) and when using sharp recanalization methods (to avoid local vascular injury). The latter risks may be particularly high in patients on chronic steroid therapy or with a history of pelvic radiation therapy, connective tissue disease, or prior surgical procedures. For patients with suspected allergy or hypersensitivity to metallic stent components, consultation with an allergy/immunology specialist may help in understanding the risks of stent implantation.

**6. Intravascular US:** The addition of intravascular US is encouraged when catheter venography is performed to evaluate for chronic iliac venous obstruction (Level of Evidence C, Strength of Recommendation Moderate).

*Comment:* The recommendation reflects the demonstration of the enhanced accuracy of intravascular US with multiplanar venography for identifying and characterizing iliac vein lesions (compared with multiplanar

venography alone) in the VIDIO trial and in other retrospective studies. Intravascular US is helpful in evaluating the full extent of venous disease, properly sizing stents, evaluating stent apposition and expansion, and identifying thrombus. However, especially for non-thrombotic lesions, technical and patient factors can artificially influence venous lumen caliber estimation on intravascular US; therefore, caution is urged in relying upon it as a sole modality to diagnose venous stenosis. Intravascular US may be most accurate with patient prehydration (to avoid diagnosis of stenosis that simply reflects low volume status), positional maneuvers (with Valsalva maneuver or in the left lateral decubitus position, the lumen may expand, which may sometimes argue against stent placement), visualization of dynamic changes in lumen caliber during the cardiorespiratory cycle, and venographic correlation.

**7. Clinical Trial Enrollment:** Enrollment of study-eligible patients with chronic iliofemoral venous obstruction in rigorous randomized controlled clinical trials that evaluate the effectiveness and safety of endovascular therapies including stent placement is strongly recommended (Level of Evidence E, Strength of Recommendation Strong).

*Comment:* SIR strongly endorses the National Institutes of Health–sponsored C-TRACT Trial and encourages physicians to enroll their patients with moderate or severe PTS and iliac vein obstruction. Although single-arm studies can document clinical change, they cannot confidently attribute clinical change to stents absent a control group. Clinical trials can benefit participating patients via close monitoring, independent safety oversight, use of expert-endorsed consensus treatment protocols, and provision of free patient care items/services. SIR also encourages patient referral to other clinical studies that compare endovascular and medical treatment strategies for chronic venous disease, assess posttreatment surveillance and strategies to maintain stent patency, and evaluate the durability of stents and clinical responses.

**8. Patients with Cancer:** In patients with malignant iliofemoral venous obstruction, application of a palliative care framework is suggested to ensure that patient selection for stent placement is appropriate, considering the multifactorial etiology of symptoms, cancer treatment goals, and palliative goals (Level of Evidence E, Strength of Recommendation Moderate).

*Comment:* In many patients with cancer, concomitant lymphedema and other comorbidities may reduce the benefits achieved with relief of venous obstruction. Patients with cancer with VTE experience higher rates of major bleeding and recurrent VTE than those without cancer, which may influence outcomes and care during and after stent procedures. The veins obstructed by a tumor may be



less amenable to durable expansion with stents or may be susceptible to tumor ingrowth; in some patients, preprocedural imaging may help in predicting treatment efficacy and guiding the technical approach. Although prospective comparative studies have not been performed to determine if stent outcomes differ in patients with versus without cancer, preprocedural evaluation should include open discussion with the patient about the procedure's likelihood of reducing symptoms given the patient's life expectancy, cancer treatment, and palliative goals, ideally in collaboration with the patient's oncologist and palliative care team.

9. **Pregnant Women:** For most pregnant women with chronic iliofemoral venous obstruction, deferral of consideration of stent placement to the postpartum period is suggested (Level of Evidence D, Strength of Recommendation Moderate).

*Comment:* Lower extremity venous symptoms often spontaneously improve after delivery. Therefore, pregnancy is often a poor time to assess if long-term stent implantation will truly be necessary for a given patient. Stent placement can unnecessarily complicate pregnancy management by influencing the need, type, and intensity of ongoing antithrombotic therapy; creating the potential for acute thrombosis or other complications that require additional management; and exposing the fetus to procedural radiation.

10. **Children and Younger Adolescents:** For children and younger adolescents with chronic iliofemoral venous obstruction, stent placement should not be routinely performed (Level of Evidence D, Strength of Recommendation Moderate).

*Comment:* Children and younger adolescents exhibit a strong capacity for venous collateral development that can yield substantial symptom improvement. In early life, it often cannot be known if functional limitations will persist into adulthood and to what degree. The biological effects and long-term clinical consequences of stent placement in growing vessels are poorly understood. Hence, conservative management is recommended, with follow-up to assess progress over time and reassessment of the need for stent placement in early adulthood. The panel acknowledged that this recommendation reflects the extreme paucity of published data on the outcomes of stent placement in children and younger adolescents and places high value on avoidance of long-term stent complications in this population pending further evidence.

11. **Choice of Stent Device:** For iliac vein placement, the use of self-expandable, noncovered stents with longitudinal flexibility and high radial strength is suggested; however, the optimal device to use is uncertain (Level of Evidence C, Strength of Recommendation Moderate).

*Comment:* In prospective multicenter single-arm studies, several self-expandable nitinol stents demonstrated early

safety and immediate anatomic efficacy in the management of patients with iliofemoral venous obstruction, resulting in FDA approval for iliac vein use. In addition, an elgiloy stent that has been used extensively over many years, with results documented mostly in retrospective studies, has also received FDA approval for iliac vein use. However, prospective comparative studies have not been performed to determine which stent performs best in different clinical situations. Rigorous studies have not evaluated covered stents in this setting, so their use is strongly discouraged beyond exceptional situations (eg, refractory malignant occlusions that appear to be related to tumor ingrowth and venous rupture). The use of balloon-expandable stents should be rare and limited to venous segments with severe refractory narrowing and limited flexion.

12. **Stent Sizing and Deployment:** When iliac vein stent placement is performed, careful attention should be given to ensuring appropriate stent sizing to enable durable venous patency, freedom from chronic pain, and freedom from stent migration (Level of Evidence C, Strength of Recommendation Strong).

*Comment:* Persistent postimplantation pain, device migration, and loss of patency have been observed after iliac vein implantation of various stent brands and may often be avoided with the selection of optimally sized stents. Although stent migration events appear to occur at low frequencies, they can have severe consequences and, therefore, deserve extra attention for prevention. The risk of stent migration is likely higher in treating NIVLs than in treating fibrotic postthrombotic lesions; hence, slight oversizing may be optimal for NIVLs. The risk of stent migration is likely to be higher with use of smaller-diameter and shorter-length stents (66). In the iliac vein, the placement of stents with a diameter of <12 mm should be performed rarely, if ever. Iliac vein stents should routinely be post-dilated, usually to their nominal diameters. Careful attention should be paid to anchoring/centering the devices in venous segments with adequate friction seal, avoiding disruption of implanted stents during balloon/catheter passage/withdrawal, and optimally managing the iliac vein confluence (because there are no FDA-approved stents that were expressly designed for this target location). Routine predilatation of venous lesions before stent placement is recommended to facilitate accurate craniocaudal centering and maximal expansion of the stents. When multiple stents are placed, there should be longitudinal overlap per the manufacturer's instructions for use (typically at least 2–3 cm)—in areas of curvature, more overlap is ideal. If confidence in the ability to securely anchor a stent in a common iliac vein lesion is not strong, then either avoidance of stent placement or extension of a longer stent into the external iliac vein (beyond the steep natural curve of the vein) to enhance fixation may be considered. Venous stent placement differs in important respects from arterial stent placement—physicians who have had limited training in



venous stent placement or the specific device they intend to use are encouraged to pursue opportunities for focused education, consult knowledgeable colleagues, or use proctoring during their initial experiences.

13. **Anticoagulant Therapy after Stent Placement:** After iliac vein stent placement, anticoagulant therapy is recommended for at least several months in most patients with a history of DVT/PTS but may not be needed for most patients with nonthrombotic disease (Level of Evidence D, Strength of Recommendation Moderate).

*Comment:* The recommendation is based on the observed patency rates of iliac vein stents in observational studies, which suggest higher risk of patency loss in patients with a history of venous thrombosis. Decisions on use of anticoagulation after stent placement should be individualized, with consideration of the anatomic result obtained and patient's DVT history—patients with a poor anatomic result, ongoing risk factors for DVT recurrence, or unprovoked DVT should continue anticoagulation. Patients being treated for anatomically extensive venous obstruction may benefit from more aggressive antithrombotic therapy, especially during the early postoperative period.

14. **Antiplatelet Therapy after Stent Placement:** After iliac vein stent placement, the addition of antiplatelet therapy to anticoagulation for at least several months is appropriate for most patients being treated for PTS who have a low projected risk of bleeding. It is uncertain whether patients receiving stents for NIVLs should receive antiplatelet therapy (Level of Evidence D, Strength of Recommendation Weak).

*Comment:* The recommendation is based on observed differences in patency rates of iliac vein stents between the PTS and NIVL populations and the very low rates of bleeding observed with use of antiplatelet drug therapy (often in conjunction with anticoagulant therapy) in prospective and retrospective studies. The type of antiplatelet therapy to use has not been rigorously studied; therefore, individualized assessment is advised, with consideration of clinical factors that suggest a high risk of rethrombosis (eg, severe hypercoagulable state, history of in-stent thrombosis, poor venous inflow, and poor technical result) or bleeding (eg, advanced age and thrombocytopenia). The incremental bleeding risks of aspirin versus thienopyridine, and dual antiplatelet therapy versus either, should be weighed in selecting a regimen.

15. **Follow-up:** After iliac vein stent placement, close clinical follow-up should be performed to ensure that the patient is compliant with antithrombotic therapy and anticoagulation is fully therapeutic, to monitor for bleeding and symptom response, to enable timely reintervention to restore patency in patients who develop recurrent symptoms, and to

monitor for late stent complications (Level of Evidence C, Strength of Recommendation Strong).

*Comment:* Device-specific complications should be reported into central registries (eg, MAUDE database) to ensure appropriate surveillance of implanted devices. Use of standardized assessment scales may aid in gauging clinical change over time. Patients with residual symptoms after stent placement should continue to have their venous disease actively managed with the conservative therapies noted above (especially compression therapy) and, if appropriate, with management of superficial venous valvular reflux. The importance of strict compliance with antithrombotic therapy recommendations should be reinforced with patients on the procedure day and at subsequent follow-up visits. Patients should be educated on, and encouraged to report, symptoms that may prompt suspicion for bleeding, recurrent VTE (including stent occlusion), and device-related complications. The utility of routine surveillance imaging versus clinically driven imaging is unclear.

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**Appendix A. Literature Search**

1	thrombosis.mp.
2	postthrombo* syndrom*.mp.
3	post-thrombo* syndrom*.mp.
4	exp postthrombotic syndrome/
5	exp Venous Insufficiency/
6	(venous adj1 obstruction).mp.
7	venous thrombosis.mp.
8	(venous adj1 occlusi*).mp.
9	Chronic venous insufficiency.mp.
10	Postphlebotic syndrome/
11	femoral vein.mp.
12	iliac vein.mp.
13	exp Vena Cava, Inferior/
14	iliofemoral.mp.
15	endovascular.mp.
16	stent*.mp.
17	exp Angioplasty/
18	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
19	11 or 12 or 13 or 14
20	15 or 16 or 17
21	18 and 19 and 20



**Appendix B. Level of Evidence and Recommendation Classification System (1–3)**

**LEVEL OF EVIDENCE**

<b>A HIGH QUALITY EVIDENCE</b>	
<b>Types of Evidence</b> Multiple RCTs Systematic reviews or meta-analyses of high-quality RCTs RCT data supported by high-quality registry studies	<b>Characteristics of Evidence</b> Homogeneity of RCT study population Intention-to-treat principle maintained Appropriate blinding Precision of data (narrow CIs) Appropriate follow-up (consider duration and patients lost to follow-up) Appropriate statistical design
<b>B MODERATE QUALITY EVIDENCE—Randomized Study Design</b>	
<b>Types of Evidence</b> ≥ 1 RCTs Systematic reviews or meta-analyses of moderate-quality RCTs	<b>Characteristics of Evidence</b> RCTs with limitations (eg, < 80% follow-up, heterogeneity of patient population, bias, etc) Imprecision of data (small sample size, wide CIs)
<b>C MODERATE QUALITY EVIDENCE—Nonrandomized Study Design</b>	
<b>Types of Evidence</b> Nonrandomized trials Observational or registry studies Systematic reviews or meta-analyses of moderate quality studies	<b>Characteristics of Evidence</b> Nonrandomized controlled cohort study Observational study with dramatic effect Outcomes research Ecological study
<b>D LIMITED QUALITY EVIDENCE</b>	
<b>Types of Evidence</b> Observational or registry studies with limited design and execution Systematic reviews or meta-analyses of studies limited by design and execution	<b>Characteristics of Evidence</b> Case series Case-control studies Historically controlled studies
<b>E EXPERT OPINION</b>	
<b>Types of Evidence</b> Expert consensus based on clinical practice	<b>Characteristics of Evidence</b> Expert opinion without explicit critical appraisal or based on physiology, bench research, or “first principles”

**STRENGTH OF RECOMMENDATION**

<b>Strong Recommendation</b> Supported by high quality evidence for or against recommendation	<b>Moderate Recommendation</b> Supported by moderate quality evidence for or against recommendation; new research may be able to provide additional context	<b>Weak Recommendation</b> Supported by weak quality evidence for or against recommendation; new research likely to provide additional context	<b>No Recommendation</b> Insufficient evidence in the literature to support or refute recommendation
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CI = confidence interval; RCT = randomized controlled trial.

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## Appendix C. Society of Interventional Radiology Position Statement on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents

Reference	Study design	No. of patients*	Objective	Key results	Level of evidence
Rossi FH, Kambara AM, Izukawa NM, et al. Randomized double-blinded study comparing medical treatment versus iliac vein stenting in chronic venous disease. <i>J Vasc Surg Venous Lymphat Disord</i> 2018; 6:183–191.	Randomized controlled trial	51 (limbs)	To compare medical and endovascular treatment results in symptomatic patients with CVD with significant IVO documented by intravascular US	Iliac vein stent placement was successful in 100% of stented patients. At 6 mo of follow-up, mean VAS pain score improved, VCSS dropped, and QOL (SF-36) improved with stent placement.	B
Seager MJ, Busuttill A, Dharmarajah B, Davies AH. Editor's choice— a systematic review of endovenous stenting in chronic venous disease secondary to iliac vein obstruction. <i>Eur J Vasc Endovasc Surg</i> 2016; 51:100–120.	Systematic review	16 studies (n = 2,586 patients)	To conduct a systematic review on the available evidence on deep endovenous stent placement to relieve CVD secondary to postthrombotic or nonthrombotic IVO	The primary and secondary stent patency rates ranged from 32% to 98.7% and from 66% to 96%, respectively. The major complication rate ranged from 0 to 8.7% per stented limb. Significant improvements in validated measures of the severity of CVD and venous disease-specific QOL.	B
Razavi MK, Jaff MR, Miller LE. Safety and effectiveness of stent placement for iliofemoral venous outflow obstruction: systematic review and meta-analysis. <i>Circ Cardiovasc Interv</i> 2015; 8:e002772.	Systematic review/meta-analysis	37 studies (n = 2,869 patients)	To determine the safety and effectiveness of venous stent placement in patients with iliofemoral venous outflow obstruction	Technical success in placing stents was 95%. Complete relief of pain, edema, and ulcers was observed in 69%, 63%, and 70% of patients with PTS, respectively, and in 81%, 68%, and 81% of patients with NIVLs. The primary patency rates at 1 y were 79% for patients with PTS and 96% for patients with NIVLs. The secondary patency rates at 1 y were 94% for patients with PTS and 99% for patients with NIVLs.	B
Dake MD, O'Sullivan G, Shammass NW, Lichtenberg M, Mwiapatayi BP, Settlege RA. Three-year results from the Venovo Venous Stent Study for the treatment of iliac and femoral vein obstruction. <i>Cardiovasc Intervent Radiol</i> 2021; 44:1918–1929.	Observational study	170	To assess the safety and patency of the Venovo Venous Stent for the treatment of iliofemoral vein obstruction	The primary patency at 12 mo was 88.6%. The mean QOL measures were statistically improved compared with the baseline values at 12 mo ( $P < .0001$ ). The primary patency at 36 mo was 84%.	C
Razavi MK, Black S, Gagne P, Chiacchierini R, Nicolini P, Marston W. Pivotal study of endovenous stent placement for symptomatic iliofemoral venous obstruction. <i>Circ Cardiovasc Interv</i> 2019; 12:e008268.	Observational study	170	To determine the safety and effectiveness of a dedicated endovenous stent for symptomatic iliofemoral venous obstruction	The 1-y primary patency rate for the entire group was 84%. At 12 mo, 64% of patients demonstrated at least a 3-point reduction in the VCSS.	C
Razavi M, Marston W, Black S, Bentley D, Neglén P. The initial report on 1-year outcomes of the feasibility study of the VENITI VICI VENOUS STENT in symptomatic iliofemoral venous obstruction. <i>J Vasc Surg Venous Lymphat Disord</i> 2018; 6:192–200.	Observational study	30	To assess the safety and efficacy of the VICI venous stent for the treatment of symptomatic iliofemoral venous outflow obstruction	12 mo of follow-up, the primary, primary-assisted, and secondary patency rates were 93%, 96%, and 100%, respectively. Symptomatic improvement of $\geq 2$ points on the VCSS was observed in 23 patients (85%) at 12 mo.	D
Murphy E, Gibson K, Sapoval M, et al. Pivotal study evaluating the safety and effectiveness of the Abre Venous Self-Expanding Stent System in patients with symptomatic iliofemoral venous outflow obstruction. <i>Circ Cardiovasc Interv</i> 2022; 15:e010960.	Observational study	200	To evaluate the safety and effectiveness of the Abre Venous Self-Expanding Stent System for the treatment of symptomatic iliofemoral venous outflow obstruction	The primary patency at 12 mo was 88%. The major adverse event rate was 2% within 30 days. The 12-mo primary-assisted and secondary patency rates were 91.8% and 92.9%, respectively.	C
O'Sullivan GJ, Karunanithy N, Binkert CA, Ortega MR, Lichtenberg M, McCann-Brown JA. One year outcomes of the VIVO-EU study	Observational study	35	To evaluate the performance of the Zilver Vena Venous Stent in the treatment of patients with symptomatic iliofemoral outflow obstruction	The rate of freedom from occlusion at 6 and 12 mo was 88.2%. The rates of qualitative	D

continued

**Appendix C. Society of Interventional Radiology Position Statement on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents (continued)**

Reference	Study design	No. of patients*	Objective	Key results	Level of evidence
of treatment of symptomatic iliofemoral outflow obstruction with the Zilver Vena Venous Self-Expanding Stent. <i>Cardiovasc Intervent Radiol</i> 2021; 44:1930–1936.				patency were 88.2% at 6 mo and 85.2% at 12 mo.	
Delis KT, Bjarnason H, Wennberg PW, Rooke TW, Gloviczki P. Successful iliac vein and inferior vena cava stenting ameliorates venous claudication and improves venous outflow, calf muscle pump function, and clinical status in post-thrombotic syndrome. <i>Ann Surg</i> 2007; 245:130–139.	Observational study	16	To determine the effects of technically successful stent placement in consecutive patients with advanced CVD	At 8.4 mo (IQR, 3–11.8 mo) after successful stent placement, both venous outflow (OF1, OF4) and calf muscle pump function (EF) had improved.	D
Rosales A, Sandbaek G, Jørgensen JJ. Stenting for chronic post-thrombotic vena cava and iliofemoral venous occlusions: mid-term patency and clinical outcome. <i>Eur J Vasc Endovasc Surg</i> 2010; 40:234–240.	Observational study	34	To determine the midterm patency and clinical outcome after stent placement of chronic occluded caval and iliofemoral venous segments	The 2-y primary, primary-assisted, and secondary patency rates were 67%, 76%, and 90%, respectively.	D
Sarici IS, Yanar F, Agcaoglu O, et al. Our early experience with iliofemoral vein stenting in patients with post-thrombotic syndrome. <i>Phlebology</i> 2014; 29:298–303.	Observational study	52	To the 1-y outcome and efficacy of balloon angioplasty and stent placement for the treatment of PTS in iliofemoral vein segments	Technical success of stent placement was 100%; the VCSS, Villalta scale score, and CIVIQ-20 score showed a significant decrease in the severity of PTS signs and symptoms ( $P < .001$ ). The calf and middle thigh circumferences significantly decreased on both sides ( $P < .001$ ).	D
Catarinella F, Nieman F, de Wolf M, Wittens C. Short-term follow-up of quality-of-life in interventional treated patients with post-thrombotic syndrome after deep venous occlusion. <i>Phlebology</i> 2014; 29:104–111.	Observational study	61	To assess the short-term QOL effects of treated patients with PTS after deep venous occlusion	VEINES-QOL and VEINES-Symptoms scores improved after 3 mo (17.5 points for QOL [ $P \leq .001$ ] and 21.4 points for symptoms [ $P \leq .001$ ]) and 12 mo (18.8 points for QOL [ $P = .004$ ] and 21.3 points for symptoms [ $P = .003$ ]).	D
Neglén P, Hollis KC, Olivier J, Raju S. Stenting of the venous outflow in chronic venous disease: long-term stent-related outcome, clinical, and hemodynamic result. <i>J Vasc Surg</i> 2007; 46:979–990.	Observational study	982	To perform long-term analysis of stent-related outcome and clinical and hemodynamic results	At 72 mo, the primary, primary-assisted, and secondary cumulative patency rates were 79%, 100%, and 100% in nonthrombotic disease and 57%, 80%, and 86% in thrombotic disease, respectively. Severe in-stent restenosis occurred in 5% of the limbs at 72 mo (10% in the thrombotic limbs and 1% in the nonthrombotic limbs).	D
Raju S, Neglén P. Percutaneous recanalization of total occlusions of the iliac vein. <i>J Vasc Surg</i> 2009; 50:360–368.	Observational study	159 (n = 167 limbs)	To assess the stent patency and clinical outcomes of percutaneous recanalization of the iliac vein	The secondary stent patency rate at 4 y was 66%. The rates of cumulative marked relief of pain and swelling at 3 y were 79% and 66%, respectively.	C
Neglén P, Hollis KC, Raju S. Combined saphenous ablation and iliac stent placement for complex severe chronic venous disease. <i>J Vasc Surg</i> 2006; 44:828–833.	Observational study	96 (n = 99 limbs)	To describe the results after combined interventions to correct outflow obstruction and superficial reflux, even in the presence of deep venous reflux	The primary, primary-assisted, and secondary stent patency rates at 4 y were 83%, 97%, and 97%, respectively.	C
Raju S, Darcey R, Neglén P. Unexpected major role for venous stenting in deep reflux disease. <i>J Vasc Surg</i> 2010; 51:401–408.	Observational study	504 (n = 528 limbs)	To assess stent-related and clinical outcomes after treatment by iliac venous stent placement	The secondary stent patency was 88% at 5 y; no-stent occlusions occurred in nonthrombotic limbs.	D

continued

## Appendix C. Society of Interventional Radiology Position Statement on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents (continued)

Reference	Study design	No. of patients*	Objective	Key results	Level of evidence
			alone in the limbs with a combination of IVO and deep venous reflux		
Gagne PJ, Tahara RW, Fastabend CP, et al. Venography versus intravascular ultrasound for diagnosing and treating iliofemoral vein obstruction. <i>J Vasc Surg Venous Lymphat Disord</i> 2017; 5:678–687.	Observational study	100	To compare the diagnostic efficacy of intravascular US with multiplanar venography for iliofemoral vein obstruction	Venography identified stenotic lesions in 51 of 100 subjects, whereas intravascular US-identified lesions in 81 of 100 subjects; intravascular US-identified significant lesions not detected with 3-view venography in 26.3% of patients.	C
Gagne PJ, Gasparis A, Black S, et al. Analysis of threshold stenosis by multiplanar venogram and intravascular ultrasound examination for predicting clinical improvement after iliofemoral vein stenting in the VIDIO trial. <i>J Vasc Surg Venous Lymphat Disord</i> 2018; 6:48–56.	Observational study	100	To compare the diagnostic efficacy of intravascular US with multiplanar venography for iliofemoral vein obstruction	Clinical improvement after stent placement was best predicted by the intravascular US baseline measurement of area stenosis (AUC, 0.64; $P = .04$ ).	C
Montminy ML, Thomasson JD, Tanaka GJ, Lamanilao LM, Crim W, Raju S. A comparison between intravascular ultrasound and venography in identifying key parameters essential for iliac vein stenting. <i>J Vasc Surg Venous Lymphat Disord</i> 2019; 7:801–807.	Observational study	152 (n = 155 limbs)	To compare the accuracy of venography compared with that of intravascular US in determining key parameters essential for iliac vein stent placement	Venographic correlation with intravascular US for the anatomic location of maximal stenosis was present in only 32% of the limbs.	C
Krzanowski M, Partyka L, Drelicharz L, et al. Posture commonly and considerably modifies stenosis of left common iliac and left renal veins in women diagnosed with pelvic venous disorder. <i>J Vasc Surg Venous Lymphat Disord</i> 2019; 7:845–852.e2.	Observational study	41	To test the hypothesis that postural changes may significantly affect the CSA of the LRV and LCIV	Significant stenosis of the LCIV was observed in 26 patients (63.4%) in the supine position, 8 patients (19.5%) lying on the left side, and 10 patients (24.4%) standing.	D
Arendt VA, Mabud TS, Kuo WT, et al. Comparison of anticoagulation regimens following stent placement for nonthrombotic lower extremity venous disease. <i>J Vasc Interv Radiol</i> 2021; 32:1584–1590.	Observational study	51	To determine whether subtherapeutic anticoagulation regimens are noninferior to therapeutic anticoagulation regimens after stent placement for nonthrombotic lower extremity venous disease	No thrombotic adverse events or luminal obstructions due to in-stent restenosis were reported in either group.	D
Marston WA, Browder SE, Iles K, Griffith A, McGinagle KL. Early thrombosis after iliac stenting for venous outflow occlusion is related to disease severity and type of anticoagulation. <i>J Vasc Surg Venous Lymphat Disord</i> 2021; 9:1399–1407.	Observational study	106	To assess the variables associated with early post-stent placement thrombosis to identify opportunities to reduce its incidence	The presence of a hypercoagulable state, type IV obstruction, and type of anticoagulation used after stent placement were associated with early stent thrombosis.	D
Lin C, Martin KA, Wang M, Stein BL, Desai KR. Long-term antithrombotic therapy after venous stent placement. <i>Phlebology</i> 2020; 35:402–408.	Observational study	87	To examine the prescribing patterns and outcomes of antithrombotic regimens after venous stent placement	In-stent restenosis and stent thrombosis events were reported in 21% of patients. Major bleeding events were noted in 7% of patients. Triple therapy reduced the odds of in-stent restenosis/stent thrombosis compared with dual antiplatelet therapy (OR, 0.07; $P = .01$ ).	D
Endo M, Jahangiri Y, Horikawa M, et al. Antiplatelet therapy is associated with stent patency after ilio caval venous stenting.	Observational study	62	To examine the effectiveness of antithrombotic medications to prevent venous stent malfunction for ilio caval occlusive disease	The primary and secondary cumulative patency rates at 12 mo were 70.0% and 92.4%, respectively. Poststent placement	D

continued



**Appendix C. Society of Interventional Radiology Position Statement on the Management of Chronic Iliofemoral Venous Obstruction with Endovascular Placement of Metallic Stents (continued)**

Reference	Study design	No. of patients*	Objective	Key results	Level of evidence
Cardiovasc Intervent Radiol 2018; 41:1691–1698.				antiplatelet use was significantly associated with primary stent patency (HR, 0.28; $P = .022$ ).	
Eijgenraam P, ten Cate H, ten Cate-Hoek AJ. Venous stenting after deep venous thrombosis and antithrombotic therapy: a systematic review. <i>Rev Vasc Med</i> 2014; 2:88–97.	Systematic review	64 studies	To summarize the literature on antithrombotic therapy after (post)thrombotic venous stent placement	The mean primary patency rate of 82.3% was observed 1 y after the intervention.	B
Milinis K, Thapar A, Shalhoub J, Davies AH. Antithrombotic therapy following venous stenting: international Delphi consensus. <i>Eur J Vasc Endovasc Surg</i> 2018; 55:537–544.	Consensus document	n/a	To determine the most commonly used antithrombotic regimens and facilitate global consensus	Anticoagulation was the preferred treatment during the first 6–12 mo after venous stent placement for a compressive iliac vein lesion. Low-molecular-weight heparin was the antithrombotic agent of choice during the first 2–6 wk. Lifelong anticoagulation was recommended after multiple DVTs.	n/a
Hartung O, Barthelemy P, Arnoux D, Boufi M, Alimi YS. Management of pregnancy in women with previous left ilio-caval stenting. <i>J Vasc Surg</i> 2009; 50:355–359.	Observational study	6	To report experience of pregnancy in women who have a history of ilio-caval stent placement	No DVT or symptomatic pulmonary embolism occurred during pregnancy, delivery, or the postpartum period.	D
Dasari M, Avgerinos E, Raju S, Tahara R, Chaer RA. Outcomes of iliac vein stents after pregnancy. <i>J Vasc Surg Venous Lymphat Disord</i> 2017; 5:353–357.	Observational study	12	To evaluate ilio-caval stent patency during and after pregnancy in women of reproductive age who became pregnant after stent placement	At the mean follow-up duration of 61 mo $\pm$ 56, all patients had patent stents with no US-identified structural damage or thrombosis.	D
Avila L, Cullinan N, White M, et al. Pediatric May-Thurner syndrome-systematic review and individual patient data meta-analysis. <i>J Thromb Haemost</i> 2021; 19:1283–1293.	Systematic review/meta-analysis	28 studies (n = 109 cases)	To describe the outcomes of children with MTS presenting with DVT	Recurrent thrombosis (aOR, 3.36; 95% CI, 1.28–8.82). DVT management strategies predicted vessel patency (aOR, 2.10; 95% CI, 1.43–3.08). The lack of complete vessel patency predicted recurrent DVT (aOR, 2.70; 95% CI, 1.09–6.67).	B

\*Unless otherwise indicated. aOR = adjusted odds ratio; AUC = area under the curve; CI = confidence interval; CSA = cross-sectional area; CVD = chronic venous disease; DVT = deep vein thrombosis; HR = hazard ratio; IQR = interquartile range; IV = intravenous; IVO = iliac vein obstruction; LCIV = left common iliac vein; LRV = left renal vein; MTS = May-Thurner syndrome; n/a = not available; OR = odds ratio; PTS = postthrombotic syndrome; QOL = quality of life; SF-36 = Short Form-36; US = ultrasound; VAS = visual analog scale; VCSS = venous clinical severity score; VEINES = Venous Insufficiency Epidemiological and Economic Study.