Iliac vein stent failure in community practice and results of corrective reinterventions

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ABSTRACT

Objective: The goal of endovenous stenting is to relieve venous obstruction and reduce peripheral venous hypertension by using large caliber venous stents in the presence of adequate venous inflow and outflow for the stented conduit. The aim of this report is to describe the technical reasons and outcomes for reinterventions in a subset of patients who had a history of iliac vein stenting and were now referred to us at a specialty venous clinic for further care.

Methods: From January 2016 to December 2021, records of all patients who were referred to us with a history of iliac vein stenting performed at an outside facility and who had a reoperation performed at our center were retrospectively analyzed.

Results: A total of 149 limbs underwent a deep venous reintervention after a failure of a trial of conservative therapy. The mean age of the sample was 57 ± 16 years. The ratio of non-thrombotic iliac vein lesions to post-thrombotic lesions was 1:2.5. The majority of the patients (84%) were CEAP class C4 or higher. The most common reason for reintervention was stent occlusion (74%), followed by iatrogenic stenosis (53%) and in-stent restenosis/shelving (38%). There was a trend for improvement in all clinical parameters (venous clinical severity score, visual analog scale for pain, and edema grade) after the reintervention. Poor inflow was present in 70% of limbs with stent occlusion. The median diameters of stented common femoral vein, external iliac vein, and common iliac vein prior to reintervention were 12, 12, and 13 mm, respectively. The median diameters of stented common femoral vein, external iliac vein, and common iliac vein after reintervention were 14, 15, and 16 mm, respectively. Eighty-eight percent of limbs required at least one further reintervention after initial reoperation.

Conclusions: Venous reoperations are generally infrequent and required in a small number of patients. Poor inflow appeared to be a common cause of stent occlusion. Iatrogenic stenosis is another common reason for venous reoperation and is difficult to fully rectify through current endovascular techniques and tools. Use of intravascular ultrasound planimetry routinely in every deep venous intervention and thorough knowledge of the principles of venous stenting outlined in this report may help forestall the need for reoperative deep venous surgery in some cases. (J Vasc Surg Venous Lymphat Disord 2023;■:1-7.)

Keywords: Iatrogenic stenosis; Iliac vein stent; In-stent restenosis; Intravascular ultrasound; IVUS; Poor inflow; Stent occlusion

Iliofemoral venous stenting in the management of chronic iliofemoral venous obstruction is associated with good patient outcomes and reasonable long-term stent patency. This has been demonstrated in multiple clinical studies.[1-6] Endovenous stenting has now replaced open surgery as the first line treatment of chronic iliofemoral venous obstruction. The goal of endovenous stenting is to relieve venous obstruction and reduce peripheral venous hypertension by using large caliber venous stents. Absolute cross-sectional area of iliac vein outflow has an important role in controlling venous pressure.[7-9]

In addition to rigorous and appropriate patient selection,[10,11] procedural technique is also important in optimizing outcomes from iliofemoral venous stenting. Although infrequent, some patients with iliofemoral venous stenting require reinterventions, some of which can be challenging. Stent occlusions are rare overall (<3%).[12] Reinterventions occur either due to technical factors, patient or hematologic factors (for example, compliance with anticoagulation, thrombophilia conditions, failure of anticoagulation, etc), or anatomic factors (for example, compromised inflow).[13]

The aim of this report is to describe the reasons and outcomes for reoperations in a subset of patients who had a history of iliac venous stenting and were now referred to us at a specialty venous clinic at a tertiary

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Author conflict of interest: Seshadri Raju reports United States patents for intravascular ultrasound diagnostics and iliac vein stent design.

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care hospital for further care due to recurrent or persistent venous symptoms.

METHODS

Study design and setting. From January 2016 to December 2021, records of all patients who were referred to us with a history of iliac vein stenting performed at an outside facility were retrospectively analyzed. This is a single-center study (3 venous surgeons) at a specialty venous clinic located at a tertiary care hospital. Informed consent was obtained from all patients for the procedures performed. Institutional review board permission was granted for publication of deidentified patient data from the study.

Inclusion and exclusion criteria. Inclusion criteria for this study were patients who were referred to us from an outside facility, who had a history of iliac vein stenting who had failed a trial of conservative therapy, and who underwent a deep venous system reintervention at our center. Referred patients who only had a history of superficial venous procedures, thrombolysis/thrombectomy without stenting, or inferior vena cava (IVC) filter placement without stenting were excluded from this study. Patients who did not undergo a reintervention to address iliac vein stent malfunction (ie, they were only treated conservatively) were excluded from this study. Additionally, patients with occluded venous bypasses were also excluded from this study.

Data collection. Data was collected on the following variables: age, gender, other demographics, details of initial surgery (when available), type of venous lesion on intravascular ultrasound (IVUS) (post-thrombotic or non-thrombotic), Clinical-Etiology-Anatomy-Pathophysiology (CEAP) class, clinical presentation including venous clinical severity score (VCSS), visual analog pain scale (VAS), grade of swelling, technical details of reintervention, reasons for reintervention, and technical success.

Clinical parameters. All patients underwent focused physical examination. Swelling was graded clinically from 0 to 4 (grade 0, none; grade 1, pitting but overall non-obvious; grade 2, ankle edema; grade 3, gross involving the leg below the knee; grade 4, gross involving the whole limb). Pain was computed according to the pain VAS from 0 to 10; 10 being the most severe pain, and 0 indicating the absence of pain. VCSS was also calculated for each patient.

Preoperative and operative assessment. Depending on the signs and symptoms, referred patients were assessed with the following imaging modalities: duplex ultrasound, air plethysmography, computed tomography venography, or magnetic resonance venography. During intervention, IVUS was utilized in all patients to guide endovenous therapy.[14]

ARTICLE HIGHLIGHTS

- **Type of Research**: Single-center retrospective study
- **Key Findings**: Most stent occlusions and malfunctions referred to our tertiary care regional venous center result from avoidable technical missteps.
- **Take Home Message**: Reinterventions improved clinical parameters in patients. Venous stenting should be performed correctly the first time around.

Stent failure. Stent failure was defined as failure of the stent to produce the expected decompression of peripheral venous hypertension, and hence, failure to produce improvement in symptoms. This can include both stent malfunction and stent occlusion.

Reinterventions - reasons and techniques. For the purposes of this study, technical factors for reinterventions were mainly explored. Patients were grouped into the following categories based on the reasons for the reintervention. Some patients had more than one reason for reintervention. The techniques for reintervention are also described (Table I).

1. Stent occlusion (Supplementary Fig 1, *A*, online only) - acute venous thromboembolism (VTE) with stent occlusion was treated with therapeutic anticoagulation. Thrombectomy was performed in select patients.[15] Technique for percutaneous recanalization of chronically occluded stents, including with excimer laser, has been described in detail previously.[12,16]
2. Iatrogenic stenosis — due to placement of small caliber stents (Supplementary Fig 1, *B* and *C*, online only), repeated relining of occluded stents (Supplementary Fig 1, *D*, online only), and as a complication of double-barrel stent configuration of Wallstents (Boston Scientific, Marlborough, MA). We have noted that long-term, one barrel has a larger cross-sectional area, whereas the other barrel has a smaller cross-sectional area in about 12% of patients in whom such a double-barrel configuration is utilized. This occurs due to compliance mismatch between the 2 Wallstent barrels, causing one side to have iatrogenic stenosis (Supplementary Fig 2, *A-C*, online only). Corrective technique has been described in detail previously.[17]
3. Short stent stack — leading to incomplete treatment of complete extent of venous disease (Supplementary Fig 1, *A*, online only).
4. Extension of stent stack beyond central veins (Supplementary Fig 3, *A*, online only) - If recanalization of such occluded stents was unsuccessful, endovenectomy of profunda vein and removal of common femoral vein (CFV) portion of stents was done selectively to improve inflow into the collateral channels.
5. Shelving (Supplementary Fig 3, *B*, online only) - can be prevented by avoiding landing stents at the pelvic curves.

Table I. Reasons and techniques for reinterventions

Reason for reintervention	Reoperative technique
Stent occlusion: Due to multiple reasons including poor inflow or outflow	Involves traversing the occlusion with a glide wire supported by a catheter, followed by angioplasty of the recanalized tract.
Iatrogenic stenosis: Caused by small caliber stents, relining of occluded stents, double barrel Wallstent configuration	Corrected by balloon angioplasty. In some cases, stent fracture of previously placed small stents by high-pressure angioplasty balloons and relining with larger caliber stents was also performed.
Short stent stack: Incomplete treatment of venous disease	Extension of stent stack from healthy vein to healthy vein following angioplasty.
Extension of stent stack beyond central veins: Usually beyond femoral-profunda confluence with coverage of profunda orifice	Recanalization of occluded stented tracts.
Shelving: Leading to obstructive venous flow and development of ISR	Angioplasty and relining.
ISR: Due to other causes such as inflow-stent size mismatch.	Angioplasty.
De novo stenosis of EIV: When short stent stacks had been placed confined to the CIV.	Stent extension following angioplasty.

CIV, Common iliac vein; *EIV*, external iliac vein; *ISR*, in-stent restenosis.

6. In-stent restenosis (ISR) - correction by angioplasty or excimer laser.[18]
7. Denovo stenosis of external iliac vein (EIV) in patients in whom short stent stacks had been placed confined to the common iliac vein (CIV). This phenomenon has been described previously in detail and appears to be exclusive to the EIV.[19]

Isodilation and hyperdilation. Isodilation and hyperdilation techniques for angioplasty of the stent for iatrogenic stenosis or correction of ISR have been described in detail previously.[20,21]

Stent surveillance. Stent surveillance protocol has been described in detail previously.[3,4] Briefly, patients were followed back in the clinic at 3 weeks, 3 months, 6 months, and then 6- to 12-month intervals thereafter. Duplex ultrasound was performed to evaluate the stents at each of these clinic visits.

Reinterventions. After the initial reoperation, reinterventions were carried out for residual or recurrent symptoms such as pain, swelling, recurrent cellulitis, recurrent stasis dermatitis, or venous ulceration that were not responsive to conservative measures and that were significantly affecting the patient's quality of life.[20-22] In these patients, ultrasound surveillance usually demonstrated some signs of stent malfunction or recurrent stent occlusion.

Perioperative anticoagulation and compression protocol. Anticoagulation and compression protocol for patients has been described previously in detail.[1]

Statistical analysis. Statistical analysis was performed using a commercially available statistics program (Prism Software, Irvine, CA). Where appropriate, the χ^2 test or *t* test was used for analysis. $P < .05$ was considered as significant.

RESULTS

Demographics and CEAP class. From January 2016 to December 2021, 149 limbs had a reintervention performed at our center. The mean age of the sample was 57 ± 16 years. Other demographic details, including CEAP class, are shown in Table II. The majority of the patients (84%) were CEAP class C4 or higher.

Pre- and postoperative clinical parameters. Overall, there was a trend for improvement in all clinical parameters (VCSS, VAS pain, and edema grade) after the reinterventions (Table III).

Reinterventions. The distribution for the reasons for reinterventions is shown in Supplementary Fig 4 (online only). Some patients had more than one reason for the reintervention.

1. Stent occlusion — this was the most common reason for reintervention and was noted in 74% of patients. Poor inflow appeared to be the predominant factor that led to stent occlusion (70%). Poor outflow was less frequently encountered as a reason for stent occlusion (20%). In the remainder of patients, reasons for stent occlusions included progression of ISR, placement of small stents, or incomplete treatment of the complete extent of venous disease. The technical success of recanalization of occluded stents utilizing different techniques was 78%.
2. Iatrogenic stenosis — this was the second most common reason for reintervention and was noted in 53% of patients. For patients with iatrogenic stenosis, the mean CFV, EIV, and CIV stent diameters before and

Table II. Demographics details of patients who underwent reoperations at our center for deep venous disease (n = 149)

Demographic	Data
Age, years	57 ± 16 (26-84)
Male:female	1:2
Laterality	
Left:right:bilateral	2:1:1
NIVL:PTS	1:2.5
CEAP clinical class	
C0-2	0
C3	24 (16.2)
C4	54 (36.2)
C5	40 (26.8)
C6	31 (20.8)

CEAP, Clinical-Etiology-Anatomy-Pathophysiology; *NIVL*, non-thrombotic iliac vein lesion; *PTS*, post-thrombotic syndrome.
Data are presented as number (%), ratio, or mean ± standard deviation (range).

after reintervention are shown in Table IV. These diameters were measured with IVUS at the time of reintervention.

3. ISR and shelving – this was the third most common reason for reintervention and was noted in 38% of patients. There were several patients in whom the stent wall was not completely apposed to the vein wall (Supplementary Fig 5, *A*, online only), leading to development of ISR in the stent column as the stent appeared to act as a flow divider. In these patients, generally angioplasty with a high-pressure balloon was sufficient to expand the stent snugly against the vein walls. In one particular patient, who has been described previously,[23] the stent was not apposed to the iliac vein wall and was noted to be thrombosed (Supplementary Fig 5, *B*, online only). It was crushed to the side with a high-pressure balloon, and a new Wallstent was deployed in the iliac vein with good clinical result.[23] ISR rarely progressed to complete stent occlusion (<10%).
4. Short stent stack or denovo stenosis of EIV – this was seen in 31% of patients. Often the short stent stack had been relined with multiple stents. When occluded, these stents were difficult to recannalize.
5. Extension of stent stack beyond central veins - several patients (2%) had occlusion of their stents that extended below the profunda-femoral junction that reoccluded in the long-term despite recanalization. In one particular patient, the stents extended from the IVC all the way to the popliteal vein. In this patient, multiple recanalization attempts were made, but the recanalized stent did not stay patent due to severely compromised inflow. In this patient, endovenectomy of profunda vein and removal of common femoral vein (CFV) portion of stent to improve inflow into collaterals was done along with an exercise regimen – this resulted in clinical improvement.

Table III. Comparison of clinical outcomes before and after reintervention (n = 149)

Clinical parameter	Pre-intervention value (median, mean ± SD)	Post-intervention value (median, mean ± SD)	*P*-value
VCSS	8, 8 ± 5	6, 7 ± 4	**<.0001**
GOS	3, 2 ± 1	2, 2 ± 1	**<.0001**
VAS	8, 6 ± 3	4, 4 ± 3	**<.0001**

GOS, Grade of swelling; *SD*, standard deviation; *VAS*, visual analog scale for pain; *VCSS*, venous clinical severity score.
Boldface *P*-value indicates statistical significance.

Table IV. Common femoral vein (*CFV*), external iliac vein (*EIV*), and common iliac vein (*CIV*) stent diameters before and after reintervention for patients with iatrogenic stenosis

Venous segment	Pre-reintervention (Median, mean ± SD)	Post-reintervention (Median, mean ± SD)	*P*-value
CFV	12, 12 ± 3	14, 14 ± 2	**<.0001**
EIV	12, 11 ± 3	15, 15 ± 2	**<.0001**
CIV	13, 13 ± 4	16, 16 ± 2	**<.0001**

SD, Standard deviation.
Boldface *P*-value indicates statistical significance.

Patients with CEAP 6. Thirty-one patients (21%) had CEAP C6 in this data set. Of these 31 patients, 25 (81%) had stent occlusion. Recanalization of stent occlusions in these 25 patients resulted in an ulcer healing rate of 70%.

Reinterventions following reoperative surgery. Overall, the rate of reinterventions in this group of patients was high. All but 18 limbs (88%) required at least one further reintervention to sustain patency and/or clinical improvement in symptoms. The mean duration to reintervention was 6 ± 2 months. Details of reintervention are shown in Table V.

Follow-up. The mean follow-up was 52 ± 8 months (range, 6-62 months).

DISCUSSION

This study showed that the most common reason for reoperation after iliac vein stenting was stent occlusion followed by iatrogenic stenosis. Reinterventions were required to sustain clinical improvements in most of these patients. Generally, a reintervention rate of about 15% to 20% has been reported in our past venous experience[21] and remains the bane of current stent technology. Chronic venous disease is not a threat to limb or

Table V. Number of reinterventions listed according to the reason for reintervention

Reason for reintervention	Mean ± SD	Median
Stent occlusion	2 ± 1	2
Iatrogenic stenosis	3 ± 3	2
ISR or shelving	2 ± 1	1
Short stent stack or denovo stenosis of EIV	2 ± 1	2

EIV, External iliac vein; *ISR*, in-stent restenosis; *SD*, standard deviation.

life, and surgery is undertaken with the goal of improving the patient's quality of life. Therefore, intervention is inherently conservative initially. There is no role for venous intervention in asymptomatic individuals.[24]

Comparison with our experience. In our own experience, we have noted a stent occlusion rate of 3%. Most of these occlusions (69%) were chronic. Compromised inflow led to the occlusion in >60% of patients with acute or chronic occlusions. Recanalization was successful in 84% of patients with occlusions in whom a reintervention was attempted.[12] For nonocclusive stent malfunction, reinterventions were performed in 13% of patients. These reinterventions included stent extension proximally or distally for missed venous lesions and angioplasty for ISR and stent compression.[19]

Adequate venous stent sizing. As in the arterial system, adequate stent sizing is important in the venous system. In the venous system, undersizing stents will likely lead to stent failure. As mentioned earlier, the caliber (absolute cross-sectional area) of iliac venous outflow is an important factor in controlling peripheral venous pressure.[25] We have previously described the optimum sizing for iliac venous stents based on data derived from flow equations, IVUS planimetry, and Poiseuille equation in non-diseased venous segments in healthy volunteers. These stent diameters are: CIV, 16 to 18 mm (area, 200 mm^2); EIV, 14 mm (area, 150 mm^2); and CFV, 12 mm (area, 125 mm^2). Use of large caliber stents is recommended in the venous system to emulate normal venous anatomy.[25] Undersizing stents will cause residual symptoms despite stent patency demonstrated on imaging studies such as venography.

Use of IVUS. IVUS should be used to guide deep venous interventions because it is more sensitive than multiplanar venography and other multidimensional contrast modalities.[26-28] Venography is an important adjunct as it provides a panoramic view and also gives information about venous anatomic variants. In this study, data was not available on whether IVUS had been utilized at the time of initial deep venous intervention. A recent study found that IVUS examination before iliofemoral venous stent deployment significantly protected against reinterventions when compared with multiplanar venography.[29] Other general principles to consider are to stent from healthy vein to healthy vein, avoiding the use of short length stents, avoiding shelving when landing stents, and generously overlapping stents. The general principles are not to jail the ipsilateral profunda orifice or the contralateral iliac orifice.[30] A recent study found that the stent length was not a risk factor for stent thrombosis.[31]

Other factors. Particular care should be exercised in stenting patients with extensive post-thrombotic iliofemoral venous obstruction as patency is poorer than stenting for non-thrombotic iliac vein lesions. Such patients, once stented, may require multiple reinterventions to maintain stent patency. Therefore, the decision to stent such patients should be made after a thorough consideration of anatomic, judgment, technical, and patient factors. Inflow and outflow should be adequate to support a stented conduit.[32] Inflow remains a difficult parameter to assess, despite preoperative imaging, particularly in borderline cases. Washout of contrast is a crude way to assess this, but it may be affected by obstructive sheath and other factors. In our experience, about 50% of patients with poor washout occlude their stents. Inguinal and pelvic collaterals do work in the remaining 50% of patients to provide adequate inflow to maintain stent patency. One hypothesis is that stenting improves the outflow; this invariably recruits more inflow through the collaterals; hence, about 50% stents with poor inflow remain patent due to this inflow recruitment phenomenon. We have previously demonstrated that the extension of an iliac vein stent into the profunda femoris vein is a useful, but rarely required, procedure for stent salvage and symptom relief.[33]

Endophlebectomy and adjunctive arteriovenous fistula formation. Endophlebectomy and arteriovenous fistula (AVF) remain as adjunct options[34] in select patients with compromised inflow to improve stent patency, but the benefits should be carefully weighed against the risks of an open operation with several potential complications.[35] The role of temporary AVF is relatively well-established after an extensive acute DVT. However, it remains less clear after chronic stent occlusions. In our experience, we have had mixed results with endophlebectomy. It appears to work well for focal/localized trabeculations. There appears to be a minimal role for veno-venous bypass currently. For salvage purposes, an occasional role may exist for iliac vein-profunda vein bypass.

ISR. About 25% of ISR is common in most venous stents when carefully surveyed. However, ISR rarely leads to complete occlusion (<10%). Slightly oversizing Wallstents is a technique that can somewhat compensate for future development of ISR while also allowing more aggressive

balloon dilatation in the future, if needed. We have previously shown that ISR is affected by 2 main factors: a stent inflow area <125 mm^2 and shear rate >100 s^{-1}.[20]

Removal of Wallstent. The removal technique of Wallstent has been described previously.[36] A limited transverse venotomy is created with steady pull on the strands of the stent under fluoroscopy, resulting in serial removal of braids.[36]

Stent surveillance. Stent surveillance should be instituted to detect stent malfunction in a timely manner so that intervention may be considered in the correct clinical context. We do not advocate intervention for asymptomatic "failing stents" — this refers to ISR in the absence of symptoms because ISR by itself rarely leads to stent occlusion (<10%). Many of the patients in this study were initially stented, but then lost to follow-up with their interventionists (up to 50%). They were then referred to us by their primary care physicians when signs and symptoms of recurrent or residual chronic venous insufficiency were appropriately recognized.

Study limitations. The main limitations of the study include retrospective nature and small but heterogeneous sample. Data such as usage of IVUS at the time of initial venous intervention was not available. For iatrogenic stenosis, it was difficult to decipher the impact of stent compression separately. Nevertheless, all the stent measurements reported were made with IVUS at the time of the reinterventions. It is acknowledged that the high rate of reinterventions following reoperations may be a reflection of the severity of the underlying disease.

CONCLUSION

Venous reoperations are generally infrequent and required in a small number of patients. Poor inflow was a common cause, leading to stent occlusion. Iatrogenic stenosis is another common reason for venous reoperation and is difficult to fully rectify through current endovascular techniques and tools. Use of IVUS planimetry routinely in every deep venous intervention and thorough knowledge of the principles of venous stenting outlined above may help forestall the need for deep venous reintervention in some cases.

AUTHOR CONTRIBUTIONS

Conception and design: TS, SR
Analysis and interpretation: TS, OB, DT, HP, SR
Data collection: OB, DT, HP
Writing the article: TS, OB, DT, HP, SR
Critical revision of the article: TS, SR
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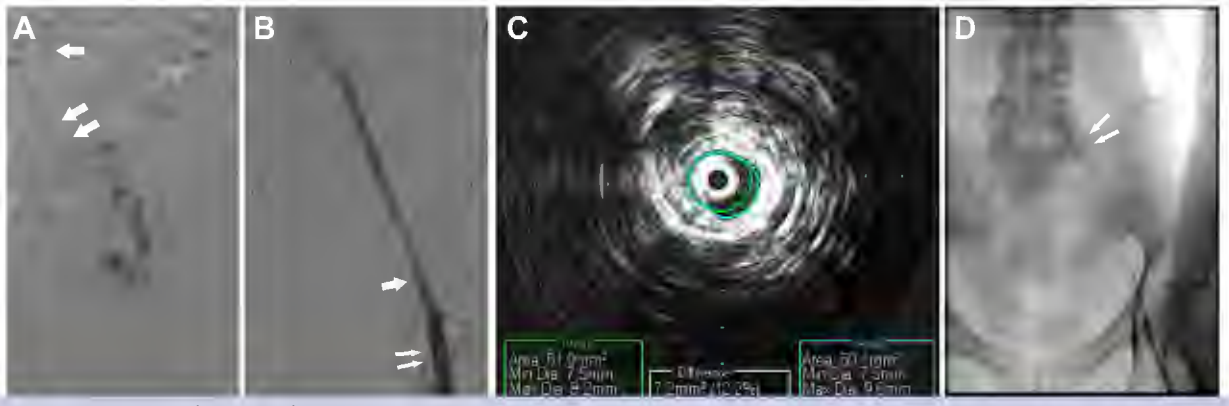
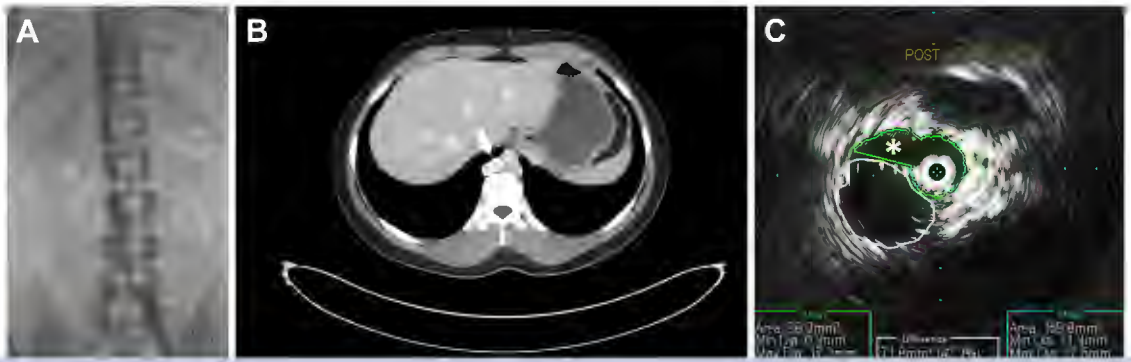
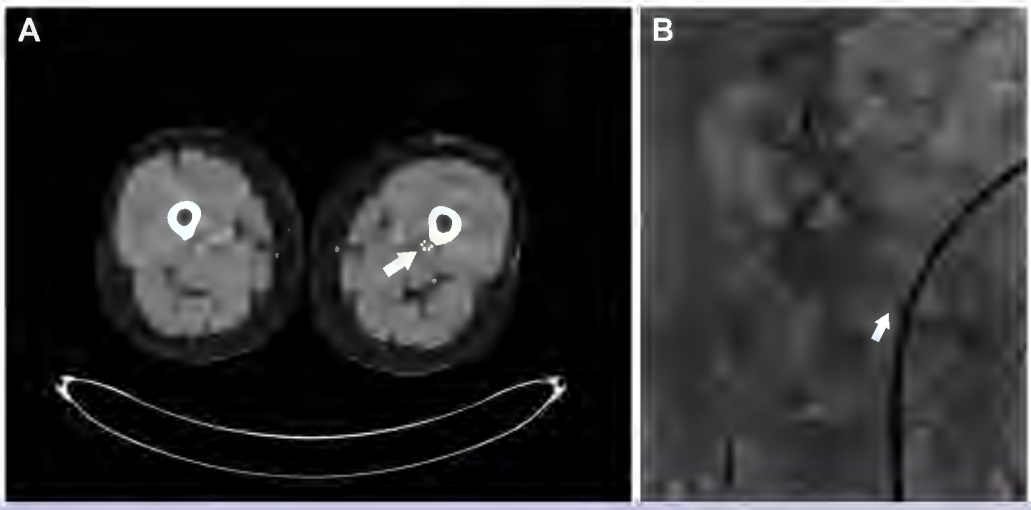


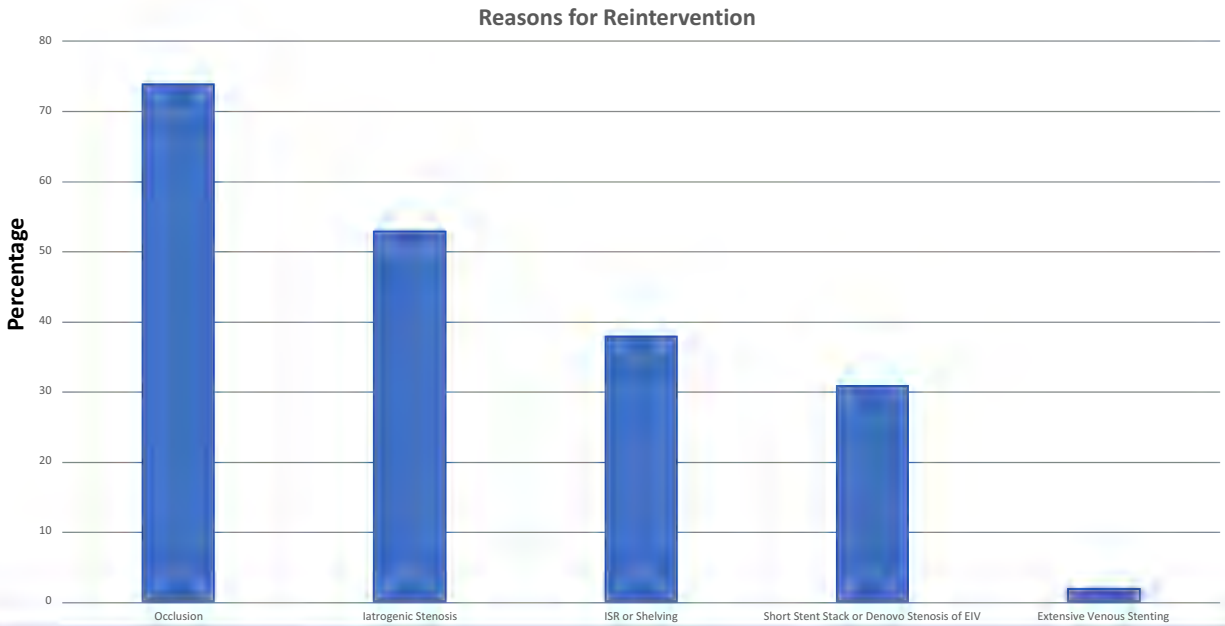
Supplementary Fig 1 (online only). Iliofemoral venous stents should mirror normal venous anatomy. **A**, Venogram showing chronic iliac venous stent occlusion with collaterals. Note that the stent stack is short (*double arrows*), confined to the common iliac vein (CIV) only. Also seen is an inferior vena cava (IVC) filter (*marked by a single arrow*). The IVC was patent at the level of the filter. **B**, Insertion of an 8-mm stent led to stent failure and persistence of symptoms despite patency. Note the size incongruity between the femoral venous inflow and the stent itself (*shown by arrows*). **C**, Intravascular ultrasound shows an 8-mm diameter stent further narrowed by some element of in-stent restenosis (ISR). **D**, Repeated relining reduces the effective cross-sectional area of the stents (*shown by arrows*). *EIV,* External iliac vein.



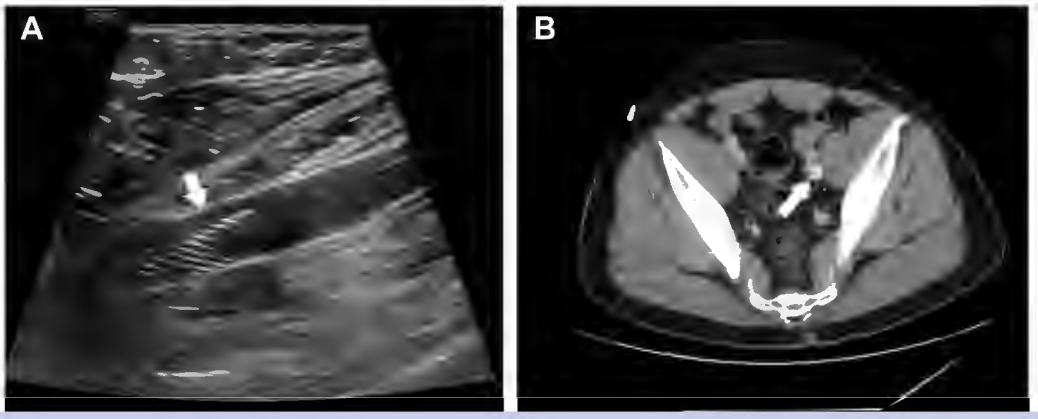
Supplementary Fig 2 (online only). **A**, Extensive double-barrel stenting using Wallstents. **B**, Computed tomography scan showing cranial extent of the double-barrel Wallstents near the diaphragmatic hiatus. **C**, Compliance mismatch causes one of the barrels to be larger and the other to be smaller, introducing a source of iatrogenic stenosis with this technique. The intravascular ultrasound (IVUS) is in the smaller barrel; marked by an *asterisk*. *IVC,* Inferior vena cava.



Supplementary Fig 3 (online only). A, Distal extent of the stent is seen in the popliteal vein in the proximity of the knee joint of the left leg. The proximal extent of the stent was in the infrarenal inferior vena cava (IVC) in this patient. **B**, Shelving seen in iliac venous stent at the level of pelvic venous curvature (*arrow*).



Supplementary Fig 4 (online only). Distribution of reinterventions among 149 limbs. Some patients had more than one reason for reintervention. *EIV*, External iliac vein; *ISR*, in-stent restenosis.



Supplementary Fig 5 (online only). A, Ultrasound image showing Wallstent not completely apposed to the wall of the common femoral vein (CFV) (*arrow*). **B**, Computed tomography scan showing thrombosed iliac vein stent that is not completely apposed to the venous wall (*arrow*).