Long-term clinical outcomes and technical factors with the Wallstent for treatment of chronic iliofemoral venous obstruction

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ABSTRACT

Background: Factors affecting long-term clinical outcome and stent patency after iliofemoral venous stenting remain complex and ill-defined. Also, consensus is lacking among clinicians regarding the continuing role for the Wallstent (Boston Scientific, Marlborough, Mass) as dedicated nitinol-based venous stents become available. We undertook this study to review our long-term results using Wallstents and to evaluate the potential role of this stent in the future.

Methods: From 2007 to 2014, there were 77 limbs in 67 consecutive patients that received Wallstents for chronic iliofemoral vein obstruction. Intravascular ultrasound (IVUS) and venography were used to assess lesion type and extent. Baseline clinical severity was assessed with Venous Clinical Severity Score (VCSS) and Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification. Clinical improvement was assessed with VCSS at 12, 24, and 36 months. VCSS change ≥4 points was considered significant improvement. Patency was assessed with duplex ultrasound. A retrospective review of patients' records and imaging was conducted to assess baseline and procedural factors associated with long-term clinical outcomes.

Results: Lesions were nonthrombotic in 42 limbs (55%) and left-sided in 48 limbs (62%). Ten patients were treated for bilateral venous disease. Patients were predominantly male (55%); median age was 63 years (range, 47-83 years). Median baseline VCSS was 9 (range, 3-23). IVUS and venography estimated equal vessel compromise length in 37 limbs (48%). IVUS estimated a longer lesion in 32 limbs (42%). Stenting correlated with venography and IVUS in 37 limbs (48%) and more closely aligned with IVUS in 35 limbs (45%). Stents extended into the common femoral vein (CFV) in 17 limbs (22%) and into the inferior vena cava in 6 limbs (8%). Sixty-five (97%) patients had available imaging follow-up (median, 50 months). At 72 months, primary patency in the overall cohort was 87%; assisted primary patency and secondary patency were both 95%. In the nonthrombotic subset, assisted primary patency and secondary patency were 100%; primary patency was 97%. In the post-thrombotic subset, primary patency was 75%; assisted primary patency and secondary patency were 88%. Three early failures occurred. Eight patients required reintervention (range, 0.5-80 months); five interventions were to maintain patency. Cox multivariate regression identified that CFV disease predicted later complications. At last VCSS follow-up per patient (median, 26 months), 52 patients (68%) showed ≥4-point VCSS improvement. None had score worsening.

Conclusions: Venous stenting with Wallstents for iliofemoral post-thrombotic or compressive obstruction proved safe and effective through long-term follow-up, with excellent patency rates. The majority of patients exhibited significant clinical improvement. CFV occlusive disease predicts increased complications. (J Vasc Surg: Venous and Lym Dis 2019;7:45-55.)

Keywords: Venous stent; Wallstent; Iliofemoral veins; Post-thrombotic; Nonthrombotic; IVUS

Venous stenting has surpassed surgical bypass as the safer and more effective treatment of chronic iliofemoral venous outflow obstruction, with fewer complications, improved patency rates, and reliable improvement of patients' quality of life. However, factors affecting clinical outcome and durable stent patency remain imperfectly understood, with widely variable results reported across centers and few commonalities,[1] apart from excellent and consistently higher patency rates observed in nonthrombotic than in post-thrombotic limbs.[1]

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In >20 years of published reports on the technical difficulties and complications associated with peripheral venous stenting—as well as an evolving debate on the optimal technique—the Wallstent (Boston Scientific, Marlborough, Mass) has been used in an overwhelming majority of cases. With the first generation of dedicated venous stents currently in trial, discussion has turned to ideal attributes for a venous stent. This conversation has also been a referendum on the Wallstent and its shortcomings—notably, less radial force at the ends and significant foreshortening. At our center, we have used the Wallstent exclusively and optimized our technique with good result. We report a 7-year experience of iliofemoral venous stenting with the Wallstent, with an aim of assessing factors associated with long-term patency and clinical outcomes.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center, retrospective cohort study
- **Take Home Message:** In 77 limbs of 67 patients treated with Wallstents for chronic iliofemoral vein obstruction, at 72 months, primary and secondary patency rates were 87% and 95%, more favorable in 42 nonthrombotic obstructions (97% and 100%) than in 35 post-thrombotic obstructions (75% and 88%). At 26 months, 68% had a ≥4-point improvement in Venous Clinical Severity Score, and none were worse. Common femoral vein occlusive disease predicted complications.
- **Recommendation:** Wallstents can be recommended as safe and effective treatment of iliofemoral venous obstructions.

METHODS

Study design. From 2007 to 2014, there were 67 consecutive patients who underwent stent placement at our center for compressive or thrombotic causes of chronic iliofemoral vein obstruction. All patients received the Wallstent endoprosthesis. Patients' records were retrospectively reviewed for baseline demographics, comorbidity profile (including history of deep venous thrombosis [DVT], phlebitis, hyperthrombophilia workup, and compression therapy), and clinical assessment. The study followed the principles of the Declaration of Helsinki and was approved by an Institutional Review Board. A waiver of informed consent was granted by the Institutional Review Board because of the retrospective nature of the study. Clinical severity of venous disease was determined by Venous Clinical Severity Score (VCSS) and Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification. Baseline venography and intravascular ultrasound (IVUS) were reviewed for lesion location and type. Stents were placed when a >50% cross-sectional area stenosis was identified by IVUS or a >50% diameter stenosis was identified by venography. Only single-view venography was performed. Procedural variables reviewed included access vessel, stent size and location, and number of stents.

After stent placement, patients were instructed to walk frequently during the next 5 days. Thereafter, there were no exercise limitations. Patients with persistent chronic venous insufficiency symptoms were asked to continue compression therapy (15-20 mm Hg or 20-30 mm Hg stockings). Rare patients with severe symptoms used 30 to 40 mm Hg stockings.

The typical follow-up regimen consisted of 1-, 6-, and 12-month visits and annual visits thereafter, with duplex ultrasound (DUS) of the stent at each visit and DUS of the access site leg at the first follow-up visit. Clinical improvement after stenting was determined by change in VCSS from baseline through follow-up assessment.[2] VCSS assessment was conducted at one or more follow-up visits (12-month, 24-month, or 36-month visit). For the purpose of our analysis, visit windows were defined as time point ± 6 months. VCSS improvement ≥4 points was considered significant.[3] Stent patency was assessed in follow-up using the standard definitions of primary patency (intervention-free patency), assisted primary patency (thrombosis-free patency), and secondary patency (freedom from stent abandonment).[4] Patency was determined using DUS; however, when reintervention was required (ie, severe restenosis or occlusion by DUS or clinical deterioration of chronic venous insufficiency in limb), IVUS and venography were also used.

Statistical methodology. Continuous data were presented as median (range) and categorical data as number (percentage). *P* values were calculated with paired *t*-tests for comparison of intrapatient VCSS change over time; unpaired *t*-tests and Fisher exact test were used for subset analyses. A *P* value < .05 was considered significant. Kaplan-Meier curves were generated to estimate primary, assisted primary, and secondary patency rates (all reported rates with associated standard error <10%). Survival curve analysis was conducted with SPSS version 22 (IBM Corp, Armonk, NY). Cox multivariate regression was conducted with SAS version 9.4 (SAS Institute, Cary, NC) to assess baseline and procedural variables considered possible predictors for later loss of primary patency or any event (loss of primary patency or intervention).

RESULTS

Baseline and procedural characteristics. Sixty-seven consecutive patients (77 limbs) underwent iliofemoral venous stenting at our institution from 2007 to 2014, with 10 patients receiving bilateral treatment. A majority of these patients were male (55%); median age was 63 years (range, 47-83 years). Left limb lesions were predominant (62%), as was a nonthrombotic etiology

Table I. Baseline demographics and clinical characteristics of 67 consecutive patients treated for iliofemoral venous obstruction (N = 77 limbs)

Age, years[a]	63 (47-83)
Female	30 (45)
DVT history	27 (40)
Thrombophilia	2 (3)
Phlebitis history	6/54 (11)
Diabetes	16/65 (25)
HTN	29/61 (48)
Smoking (current or prior)	32/65 (49)
Compression therapy	19 (28)
No. receiving bilateral treatment	10 (15)
Post-thrombotic	35 (45)
Nonthrombotic	42 (55)
No. of treated left limbs	48 (62)
No. of treated right limbs	29 (38)
CEAP class	
3	25 (33)
4	16 (21)
5	8 (10)
6	28 (36)
VCSS	9 (3-23)
Greater vessel involvement per IVUS	32 (42)
Greater vessel involvement per venography	8 (10)
Equal vessel involvement per venography and IVUS	37 (48)
Occlusion per IVUS	7 (9)
Occlusion per venography	11 (14)
No lesion per IVUS	0 (0)
No lesion per venography	7 (9)

CEAP, Clinical, Etiology, Anatomy, and Pathophysiology; *DVT,* deep venous thrombosis; *HTN,* hypertension; *IVUS,* intravascular ultrasound; *VCSS,* Venous Clinical Severity Score.
Continuous variables are reported as median (range). Categorical variables are reported as number (%).
[a]For demographic data, the number of patients is 67 unless indicated otherwise.

Table II. Procedural characteristics of 77 stented limbs

Access vessel[a]	
FV	40 (51)
CFV	14 (18)
PV	24 (31)
No. of stents per limb	1 (1-4)[b]
Stent location	
Isolated CIV	18 (23)
Isolated EIV	11 (14)
Isolated CFV	1 (1)
CIV/EIV	28 (36)
EIV/CFV	6 (8)
IVC/CIV/EIV	3 (4)
CIV/EIV/CFV	7 (9)
IVC/CIV/EIV/CFV	3 (4)
Lesion traversing >1 segment	47 (61)
Lesion extending into the CFV	17 (22)
Lesion extending into the IVC	6 (8)
Stenting correlated with IVUS *and* venographic assessment of lesion	37 (48)
Stenting per IVUS assessment	35 (45)
Stenting per venographic assessment	5 (6)
Stenting per modality that estimated lesser vessel involvement[c]	7 (9)
Postdilation[d]	75 (100)
Clinical follow-up, months	50 (0.25-100)
Imaging follow-up, months	50 (0-100)

CFV, Common femoral vein; *CIV,* common iliac vein; *EIV,* external iliac vein; *FV,* femoral vein; *IVC,* inferior vena cava; *IVUS,* intravascular ultrasound; *PV,* popliteal vein.
Continuous variables are reported as median (range). Categorical variables are reported as number (%).
[a]Seventy-eight access vessels were required (10 bilateral patients and 1 patient requiring multiple access vessels).
[b]A mean of 1.6 ± 0.8 stents were implanted per limb.
[c]In five limbs, stenting corresponded with IVUS estimation of the lesion, despite that IVUS estimated a shorter lesion than venography. In two limbs, stenting corresponded with venographic assessment, despite estimating a shorter lesion than IVUS.
[d]Two patients are missing postdilation data; however, the physician's standard of care was to always balloon after stent placement.

(55%). Baseline demographics and clinical assessment are presented in Table I.

Local anesthesia with conscious sedation (midazolam, fentanyl, or diphenhydramine) was used in all cases. Intravenous unfractionated heparin, 3000-5000 units, or maintenance of existing anticoagulation was used during the procedure. Access was most commonly attained through the femoral vein (51%). Stenting correlated with both IVUS and venographic findings in 37 limbs (48%). When findings differed, stenting was per IVUS estimation of the lesion in 35 limbs (45%) and per venographic assessment in 5 limbs (6%; Table II). Seventeen limbs (22%) had stents placed in the common femoral vein (CFV). Of the 17 limbs (in 17 patients) with stents placed in the CFV, 6 of 17 limbs presented with occlusions by one or both imaging modalities (with 2 of 6 occlusions occurring in the CFV segment). Twelve of 17 limbs with CFV involvement were post-thrombotic.

Deployed Wallstents (n = 126) ranged in diameter from 10 to 22 mm and in length from 40 to 90 mm; 82% of the Wallstents were 14- to 18-mm diameters, whereas 18% were smaller or larger (10 mm, n = 1; 12 mm, n = 6; 20 mm, n = 9; 22 mm, n = 7). Left iliofemoral vein occlusive disease was identified and treated with stents (80/126 [63%]) twice as frequently as right iliofemoral vein disease (46/126 [37%]). All patients received procedural anticoagulation. After the procedure, nonthrombotic patients were prescribed lifelong antiplatelet therapy (clopidogrel [Plavix] 75 mg/day, if already prescribed, or aspirin 81 mg/day). Post-thrombotic patients were prescribed 6 to 12 months of anticoagulant therapy,

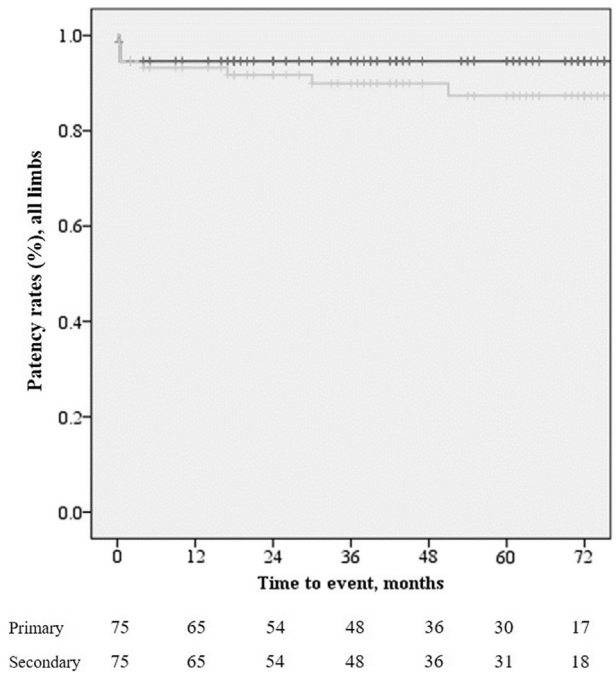

Fig 1. At 72 months, primary patency and secondary patency were 87% and 95%, respectively (assisted primary and secondary patency rates were identical). The standard error was <10% at all intervals. Two patients did not have imaging follow-up available for Kaplan-Meier analysis.

with duration dependent on the extent of scarring in the deep venous system, or lifelong anticoagulation if they had a history of recurrent DVT, per contemporary guidelines.[5] The median clinical and imaging follow-up was 50 months. All patients had at least one clinical follow-up visit; however, two patients had no follow-up imaging. Compression therapy noncompliance after stent placement was noted in 31 of 67 (46%) patients, with 23 of these patients having ongoing symptoms (VCSS >4). Eight patients died during follow-up from causes unrelated to venous disease and the stent or procedure; an additional 12 patients were lost to follow-up.

Patency. At 12 months, primary, primary assisted, and secondary patency rates were 93%, 95%, and 95%, respectively (Fig 1). Primary, primary assisted, and secondary patency rates at 72 months were 87%, 95%, and 95%, respectively. Patency rates were also assessed in the post-thrombotic and nonthrombotic limb subsets (n = 33 and n = 42, respectively). Patency rates at 12 months were lower in the post-thrombotic subset, with primary patency of 85% and primary assisted and secondary patency of 88%. Primary assisted and secondary patency remained the same through 72-month follow-up, whereas primary patency decreased to 75% (Fig 2). In nonthrombotic limbs, 12-month primary, assisted primary, and secondary patency rates were 100% (Fig 2). Secondary and assisted primary patency remained at 100% through 72 months. Primary patency was 97% at 72 months.

Early failures. Three patients (four limbs) experienced stent closure, all occurring within 30 days of the index procedure. The Wallstents placed were 14 to 18 mm in diameter. All three patients had a history of DVT, with residual post-thrombotic disease. The first patient, an 82-year-old woman with chronic post-thrombotic scar (popliteal vein to common iliac vein [CIV]), was implanted with two stents in the CIV and external iliac vein, which closed at 1 week. The patient refused reintervention and died of unknown causes remote to the intervention. The second patient was a 50-year-old man with bilateral post-thrombotic occlusive scar (inferior vena cava [IVC] to CFVs bilaterally). The patient received four stents in each limb, with all eight stents closing at 2 weeks, probably because of the severity of occlusive disease and inadequate lumen gain with stenting. Further revascularization was not attempted. In the third patient, a 59-year-old man with protein C deficiency and right leg post-thrombotic stenosis and scarring (popliteal vein-CIV), two stents were implanted from the CIV to the CFV. The stents were occluded 2 weeks later. The patient declined reintervention and was lost to follow-up after 4 weeks.

Complications and reinterventions. Jailing of the right (ie, contralateral) CIV occurred in five patients during follow-up; in three of five patients, jailing led to subsequent contralateral DVT (one within 1 month of the index procedure). Additional contralateral stent placement resolved jailing in three patients; the other two patients died or are currently under observation. Long-term follow-up is available for all five patients with jailing (median follow-up, 72 months [range, 40-93 months]). Fourteen patients (21%) had new or recurrent ulceration during follow-up; another three patients (5%) had other leg wound issues. Of 14 patients with recurrent ulceration, 3 were related to an acute DVT episode (1 of which was subsequent to right CIV jailing). Recurrent ulcers or sores were observed in three of five patients (60%) with jailed CIVs.

Twenty-one patients (31%) underwent ipsilateral superficial vein ablation procedures during follow-up. Eight patients (12%) required vascular reintervention during follow-up (range, 0.5-92 months), with one early reintervention. Five of eight interventions were to maintain stent patency. Details on all reinterventions are presented in Table III. Reinterventions consisted of placement of additional Wallstents in all but one case.

VCSS and CEAP outcomes. All patients underwent follow-up VCSS assessment within 36 months after the index procedure, with 36 limbs (32 patients) undergoing multiple VCSS assessments. Median VCSS and VCSS change at the 12-, 24-, and 36-month visit windows are presented in Table IV. At each visit window, a majority exhibited significant clinical improvement of 4 points or

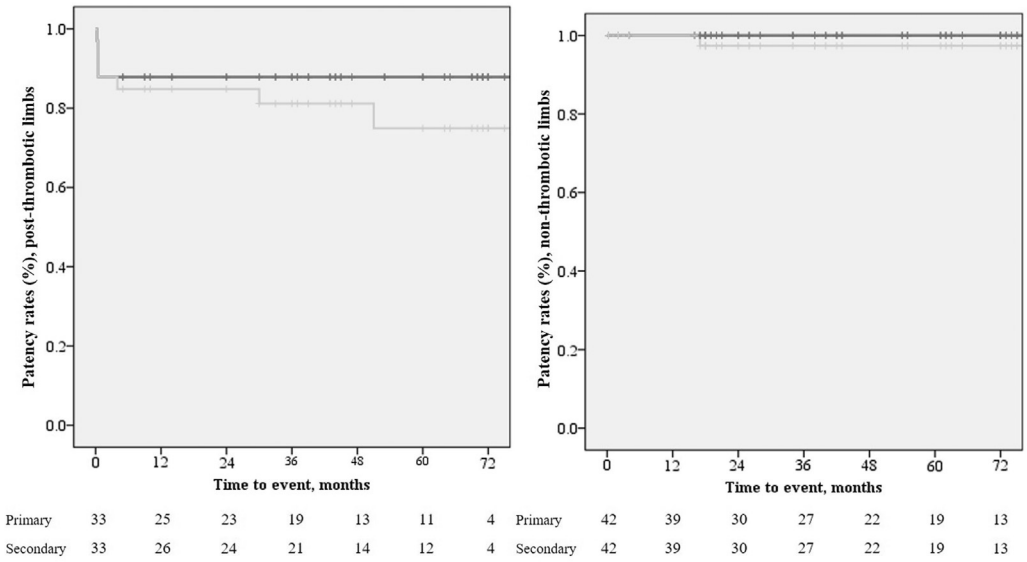

Fig 2. Patency rates for post-thrombotic limbs (n = 33) and nonthrombotic limbs (n = 42) through 72 months. The standard error was <10% at all intervals.

more (75%, 62%, and 66%, respectively). Only one patient (1%) exhibited score worsening during follow-up, which resolved by a subsequent visit. Table IV also presents the score change from baseline to the latest available VCSS follow-up for all patients, which occurred at a median of 26 months. The median VCSS change at last available VCSS follow-up was 5 points improvement (range, 0-17 points improvement). At last follow-up, 52 patients (68%) were observed with VCSS improvement ≥4 points. Seven patients (9%) exhibited no score change. No patients had score worsening. VCSS at each follow-up window and VCSS at last available follow-up were significantly lower than baseline VCSS ($P < .001$) for all comparisons.

CEAP C3 (venous edema) patients had the least predictable response to iliofemoral venous stenting. There were 25 CEAP clinical class 3 limbs; 15 (60%) had index leg pain and 15 (60%) wore compression garments before stent placement. After stent placement, venous edema had resolved in 11 of 25 (44%) limbs, and pain remained in only 2 of 25 (8%) limbs. Venous edema

Table III. Reinterventions during all follow-up (N = 8)

Months from index procedure	Reintervention	Indication
0.5	Right stent implantation, angioplasty	Acute DVT of contralateral (right) limb and subsequent jailing of right CIV
4	Thrombolysis and additional left stent	Developed acute DVT in left limb; stents showed nonocclusive thrombus
5	Left femoral-popliteal arterial bypass with ipsilateral GSV	Left leg ulcer never healed
17	Additional left stent	Onset of new symptoms, morbid obesity; compression observed in EIV
30	Two additional left stents	Original stent stenosed and fractured, probably because of ending stent at inguinal ligament and tissue fibrosis from radiation treatment in pelvis for prostate cancer[a]
50	Two additional right stents	Original stent patent but exhibited narrowing and proximal scarring; compression noted proximal to the stent
72	Right stent placed through left stent to return flow	Right CIV jailed because of left stent implanted high in IVC
92	Two additional right stents	Left stents were compressing right limb (also previously stented), jailing right CIV

CIV, Common iliac vein; *DVT*, deep venous thrombosis; *EIV*, external iliac vein; *GSV*, great saphenous vein; *IVC*, inferior vena cava.
All additional stents implanted were Wallstents.
[a]The fracture was at the caudal end of the stent under the inguinal ligament.

Table IV. Venous Clinical Severity Score (*VCSS*) in 77 stented limbs, all follow-up assessments

	Baseline (N = 77)	12 Months (n = 52)[a]	24 Months (n = 29)[b]	36 Months (n = 32)[c]	Last follow-up (N = 77)[d]
VCSS	9 (3-23)	3 (0-16)	4 (0-16)	4.5 (0-17)	4 (0-17)
VCSS change		5 (0-14)	4 (-1-12)	5 (0-13)	5 (0-14)
No. with ≥4-point improvement		39 (75)	18 (62)	21 (66)	52 (68)
No. with no change		2 (4)	1 (3)	4 (13)	7 (9)
No. with score worsening		0 (0)	1 (3)	0 (0)	0 (0)

Continuous variables are reported as median (range). Categorical variables are reported as number (%).
[a]Median follow-up of the 52 limbs (46 patients) at this interval was 12 months (range, 0.25-20 months).
[b]Median follow-up of the 29 limbs (25 patients) in this window was 24 months (range, 18-29 months).
[c]Median follow-up of the 32 limbs (29 patients) in this window was 36 months (range, 32-42 months).
[d]The final follow-up assessment for each patient occurred at a median 26 months (range, 0.25-42 months). Thirty-six limbs in 32 patients had multiple VCSS assessments in follow-up.

had decreased (21/25 [84%]) or stayed the same (4/25 [16%]) in all patients. Of the 15 of the 25 (60%) patients who did not wear compression therapy after stenting, 8 of 15 (53%) had no venous edema or pain.

Most and least improved subset analyses. All limbs with score change ≥7 points improvement at their last VCSS assessment (top quartile) were considered the most improved subset (Table V). All limbs with <3 points improvement (bottom quartile) were considered the least improved. Patients in the least improved subset presented with less severe venous disease, with a substantially higher proportion classified as C3 compared with the most improved subset (44% vs 13%; $P = .11$). Stent diameter did not appear to distinguish the least or most improved C3 patients, with 16- to 20-mm stents

Table V. Most and least improved limbs, subset analyses

	Most improved (n = 15 limbs)	Least improved (n = 16 limbs)	*P* value
Age, years	58 (36-68)	64.5 (49-82)	.05
Female	6 (43)[a]	5 (31)	.71
Smoking	5 (36)[a]	11 (69)	.14
Bilateral patient	4 (29)[a]	1 (6)	.16
Nonthrombotic	11 (73)	10 (63)	.70
Left limb	12 (80)	10 (63)	.43
Occlusion	1 (7)	1 (6)	>.99
CFV involvement	3 (20)	3 (19)	>.99
IVC involvement	1 (7)	1 (6)	>.99
CEAP class			
C3	2 (13)	8 (50)	.05
C4	2 (13)	2 (13)	.99
C5	2 (13)	2 (13)	.99
C6	9 (60)	5 (31)	.16
No. of stents	2 (1-3)	1 (1-3)	.16
Median follow-up, months	29 (10-40)	33 (9-42)	.70
Baseline VCSS	14 (7-23)	8.5 (3-17)	.003
Intervention required[b]	3 (20)	3 (19)	.99

CEAP, Clinical, Etiology, Anatomy, and Pathophysiology; *CFV,* common femoral vein; *IVC,* inferior vena cava; *VCSS,* Venous Clinical Severity Score.
Continuous variables are reported as median (range). Categorical variables are reported as number (%).
P values were calculated with Fisher exact test or unpaired *t*-test.
Limbs with ≥7-point improvement on VCSS (top quartile) were considered the most improved. This represented 15 limbs in 14 patients (1 bilateral patient had 10-point VCSS improvement in both limbs). Limbs with ≤2-point improvement (bottom quartile) were considered the least improved. This represented 16 limbs in 16 patients. Limbs were excised from the subset analysis if VCSS follow-up assessment occurred <6 months after the index procedure or if stents were no longer patent at the time of last VCSS follow-up.
[a]Fourteen patients (one of the four bilaterally treated patients stratified into the most improved subset had both limbs qualify as most improved).
[b]Reintervention was required in three patients in each subset. In the most improved subset, reintervention occurred before VCSS assessment in two of three cases and never constituted a loss of primary patency (two were to resolve early or late contralateral jailing, one arterial bypass). In the least improved subset, all three interventions constituted a loss of primary patency, and two of three occurred after VCSS assessment. All reinterventions were due to onset compression of the treated vessel (two cases) or contralateral limb (one case).

Table VI. Predictive factors for primary patency and all events

Variables	HR (95% CI)	*P* value
Primary patency		
PT vs NT	6.9 (4.8-9.0)	.07
CFV involvement	4.4 (2.9-5.8)	.04
All events		
PT vs NT	3.3 (1.9-4.7)	.12
CFV involvement	2.7 (1.5-3.9)	.08

CFV, Common femoral vein; *CI,* confidence interval; *HR,* hazard ratio; *NT,* nonthrombotic; *PT,* post-thrombotic.
Loss of primary patency occurred in nine limbs (eight patients): three early technical failures and six interventions to maintain stent patency. All events includes primary patency events as well as 3 interventions unrelated to primary patency (1 arterial bypass, 2 for contralateral jailing), for a total of 12 limbs in 11 patients. All variables assessed were categorical. Variables not found to be predictive were inferior vena cava involvement, target limb, and degree of obstruction (occlusion vs stenosis). Cox regression analysis was performed using a backward stepwise model in SAS version 9.4.

preferred in both groups. Conversely, the most improved subset was primarily composed of C6 patients (60% vs 31%; $P = .16$). These patients were also significantly younger than patients in the least improved subset (58 vs 65 years; $P = .05$).

Cox multivariate regression. Cox modeling was performed to assess the predictive value of several baseline and procedural variables on primary patency and all events (loss of primary patency or intervention) during all follow-up (median, 50 months). These were lesion etiology (post-thrombotic vs nonthrombotic), degree of obstruction (occlusion vs stenotic lesion), target limb, stent placement in the CFV, and stent placement in the IVC. Regression analysis found only CFV involvement to be a predictive factor for loss of primary patency (Table VI). Patients with stenting in the CFV were 4.4 times more likely to experience later loss of primary patency ($P = .04$). Post-thrombotic lesion etiology was also predictive (although not significantly) and associated with a 6.9 times increased likelihood of loss of primary patency ($P = .07$). Post-thrombotic lesions and stenting into the CFV were also predictors for all events, although neither factor was significantly predictive.

DISCUSSION

Our experience found that stenting of chronic iliofemoral venous obstruction resulted in excellent long-term patency rates and significant clinical improvement for a majority of patients. Although the Wallstent presents certain technical challenges—critically, foreshortening and lessened radial force at the ends when not restrained—we have optimized our technique to work through these challenges to good result.

The optimal landing site for the Wallstent has been a source of debate. If the highest proximal landing site is 3 to 5 cm into the IVC, as suggested by Neglen and Raju et al,[6,7] contralateral jailing is a risk, although this was rare in their experience.[8] Positioning lower risks caudal migration and loss of efficacy. Furthermore, the radial force of the Wallstent is weakest at its ends. Sufficient anchoring is therefore critical. To address this concern, Raju et al[9] modified their original technique with the Wallstent, using a Gianturco Z-stent atop the Wallstent. This increased radial force at the confluence, and secondary patency improved after this modification. Our approach differs and is as follows.

We originally landed the cranial end of the stent as high as 4 to 5 cm into the IVC (Fig 3, *A*). However, we observed a few cases of contralateral jailing with the stent extended this far beyond the confluence. This prompted a change at our center to a more caudal central landing site; we now recommend stenting no higher than 2 to 3 cm above the CIV confluence (Fig 3, *B*). Since then, we have not observed any acute contralateral jailing. We have also observed that stent sizing is instrumental in avoiding contralateral jailing. We found that an 18-mm-diameter stent in an 18-mm IVC will result in jailing, as there is no room for blood to flow around the stent from the contralateral CIV. We therefore size iliac vein Wallstents with the IVC IVUS-measured size in mind; we would implant a 16-mm iliac vein stent extending into an 18-mm IVC.

One concern with stent undersizing in the veins is that this will lead to migration of the stent. We have only one instance of late foreshortening and caudal stent migration with this approach, which ultimately required telescoping a stent into the IVC to treat a recurrent vein compression. We have seen no cranial migration. This success may largely reflect our method of anchoring the stent. In a case of May-Thurner compression in the CIV, significant dilation often occurs just peripheral to a tight stenosis (ie, prestenosis dilation). The tendency is to size the stent for the largest diameter CIV; however, we advocate against this as a routine approach. If the stent is sized for a significantly dilated CIV and extended into a normal or small IVC, the IVC will be overfilled or "plugged" by the stent, and contralateral iliac vein jailing is likely to occur. We have found the best approach is to use the external iliac vein to anchor a stent that may be undersized for the dilated CIV. This smaller stent still opens up the stenosis in the CIV adequately, and contralateral jailing is less likely to occur because of "too much" stent in the IVC.

In post-thrombotic cases, our approach differs. Wallstents, because of their unique construction, provide a challenge to obtaining adequate radial force in post-thrombotic iliofemoral vein occlusions (Fig 4, *A*). In arteries, the common practice is to stent across the entire lesion, placing stent ends in normal, disease-free lumens. If both ends of the Wallstent do not "fix" in the normal vein, often because of size discrepancies in the normal vein at the end of the post-thrombotic diseased segment

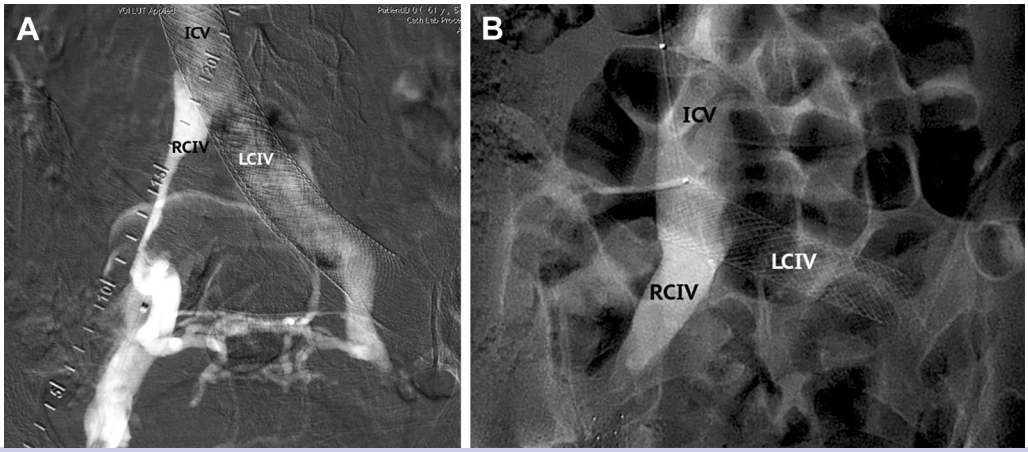

Fig 3. Wallstent placed too high **(A)** in inferior vena cava (*IVC*), "jailing" contralateral iliac vein with subsequent contralateral deep venous thrombosis (DVT). **B,** Recommended left common iliac vein (*LCIV*) stent placement. *RCIV,* Right common iliac vein.

with one end of the stent not "oversized" to the vein lumen, the stent may not be fixed, and even after post-stent dilation, the Wallstent may not achieve adequate lumen size because of reversible shortening and then elongation of the stent (Fig 4, *B*). Inadequate lumen gain could affect stent patency. We have found the following method to be reliable and effective for addressing this challenge. If stenting a 70-mm-long post-thrombotic occlusion, we select a 60-mm Wallstent as the primary stent. We then bury the stent ends in the scar tissue (Fig 4, *C*). This effectively anchors the device and provides good radial force at the ends. The stent should keep its size and not foreshorten significantly. We then use additional appropriately sized stents and extend to normal vein cranial and caudal (Fig 4, *D*). We have no data to support this, but with this method, we have found a successful workaround to the related issues of radial strength and foreshortening.

We have found the Wallstent to be a good solution for long-term pelvic venous stenting, despite its shortcomings, in part because of its excellent crush resistance and flexibility. Given the unrelenting compression in this region as well as the risk for flexion point fracture under the inguinal ligament and in the CFV, this is key. Fracture observed in our series has been limited to one patient, who experienced stent stenoses and fracture. He had pelvic radiation treatment and post-DVT tissue fibrosis, and the caudal end of the Wallstent landed at the inguinal ligament. Rigid fixation of the weakest part of the Wallstent at the ligament likely facilitated the fracture at the caudal end. Having adjusted our technique to have the caudal end of Wallstents crossing the inguinal ligament always ending at least in the mid-CFV, we have seen no further fractures.

In a comparison of outcomes in 177 limbs with stenting across the inguinal ligament and 316 limbs with stents landed above the inguinal ligament, Neglen et al[10] found that secondary patency at 54 months was lowered in patients with stents extending beyond the inguinal ligament. However, the authors found that other factors were more significant for later stent occlusion or restenosis in the iliofemoral tract, namely, post-thrombotic lesion etiology and degree of obstruction. The authors further noted that if the lesion does extend distally into the CFV, failure to cross the inguinal ligament to stent the entirety of the lesion poses a far greater risk for later treatment failure. Cox regression analysis for possible predictive variables in our series also identified stenting into the CFV as the sole significant predictor for later loss of primary patency. Post-thrombotic lesions were found to be predictive for later loss of primary patency in our series as well, but not to a significant degree.

The higher likelihood of stent occlusion with CFV involvement does not appear associated with the mechanical stress associated with the inguinal ligament flexion point itself, as evidenced by the historically low rate of fracture observed in this region with stainless steel stents. Stenting in the CFV despite insufficient inflow from peripheral veins may pose the greater risk. All early failures in our series had post-thrombotic scar involving long segments of the deep venous system extending peripheral to the CFV. Although determination of sufficient inflow is subjective and correction of insufficient inflow is not always possible, wherever feasible, poor inflow should be addressed before stent treatment to prevent acute stent occlusion.[11-13] In 755 patients implanted with the Wallstent with caval extension, Murphy et al[14] found that the two primary causes of later ipsilateral DVT were failure to visualize and to stent distal lesions and poor inflow. The authors found that IVUS was a critical adjunct for accurate visualization of both the optimal distal landing zone and the iliocaval confluence.

Stenting at our institution correlated with both venographic and IVUS assessment of vessel involvement in

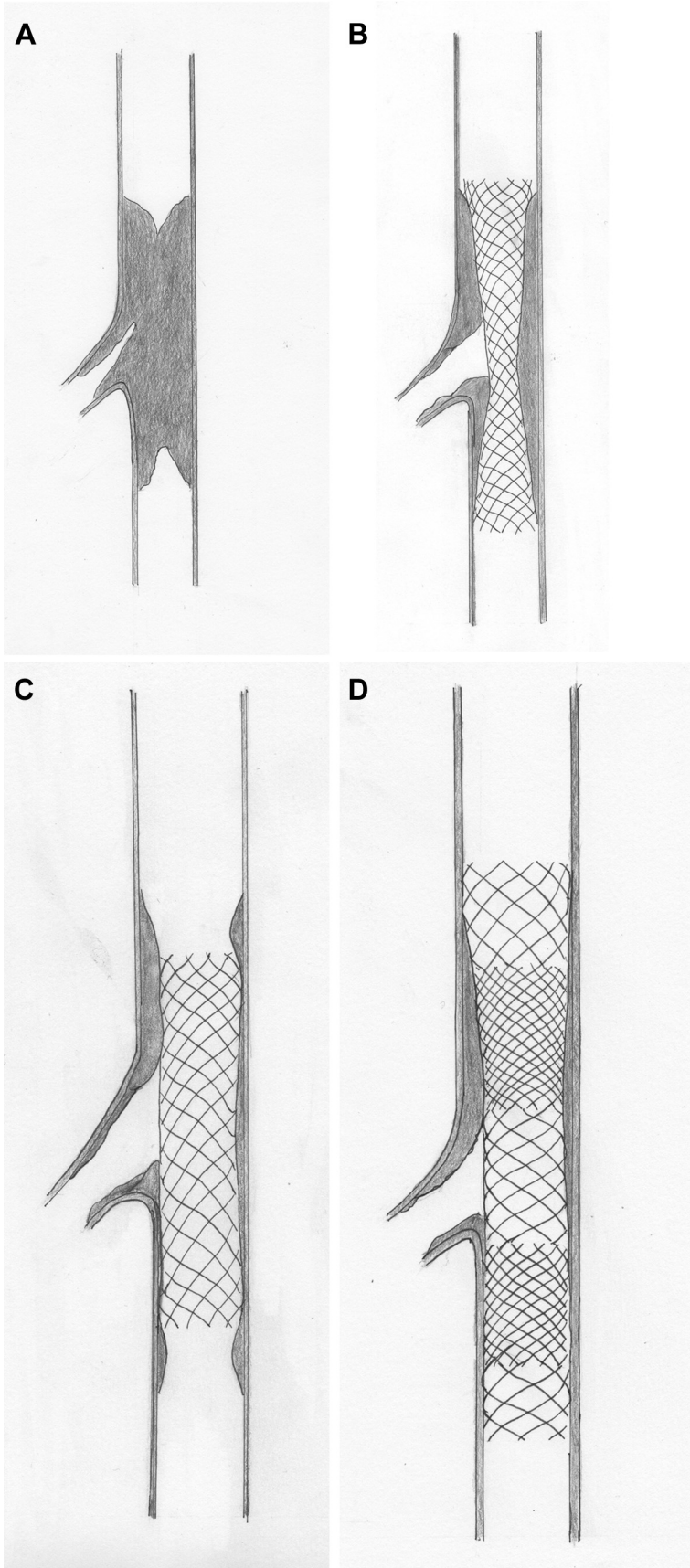

Fig 4. Wallstent placed at iliac vein-inferior vena cava (IVC) confluence appropriately. **A,** Chronic occluded vein at external, internal, and common iliac vein confluence; **B,** Stent incompletely expanded; **C,** Stent ends anchored and full stent expansion; **D,** Complete stenting of diseased vein.

nearly half of treated limbs (48%). When IVUS and venographic findings did not concur on the extent of the lesion, we erred with IVUS in 45% of cases and venography in 6%. Stenting in this series did not correspond with the imaging modality that estimated the longer lesion in seven cases. Of those seven limbs, four were included in the least improved subset. Three of four limbs were stented per venographic assessment of vessel involvement, despite that IVUS estimated a longer lesion. In the fourth limb, stenting was per IVUS despite that venography assessed greater vessel involvement. Three of these four limbs were implanted with a single stent in one vessel. Conversely, none of the limbs in the most improved subset were stented per imaging modality that estimated a shorter lesion.

This points to the importance of attaining measurements with both venography and IVUS and erring with whichever modality estimates a longer lesion. In the majority of cases, this will be IVUS, as was observed in our experience, because of its increased sensitivity for venous lesions, particularly of irregular or nonthrombotic origin.[15-17] Ultimately, it is preferential to overstent rather than to understent a lesion. Failure to stent the full length of venous disease, including peripheral webbing and scars, is likely to result in insufficient inflow to the stented lumen and subsequent treatment failure.

The analysis of most and least improved limbs also found that improved outcomes were observed in patients who presented with more severe venous disease. The most improved subset was disproportionally composed of C6 patients, whereas one-third of the C3 patients treated in the overall series were among the least improved. Unpredictable clinical response after stenting of C3 patients with "significant" venous stenosis has been identified previously and suggests that the criteria for intervention in these patients require further study and refinement.[7] The most improved subset also presented with a significantly higher baseline VCSS than the least improved subset or even the overall study population of patients, at a median 14 points. Apart from most improved patients being significantly younger, severity of venous disease on presentation was the only other significant differentiator observed between these subsets. Interestingly, 4 of 10 patients who received bilateral treatment in our series were stratified into the most improved subset, indicating the long-term benefit of iliofemoral stenting even in cases of widespread venous disease.

Limitations. We are limited by the small size and retrospective nature of this single-center study. All statistical analyses conducted were post hoc and exploratory, and the low number of events precluded a robust analysis of predictive factors for primary patency. We are further limited by a lack of available data on certain baseline and procedural characteristics, some of which were not collected (eg, percentage degree stenosis) and some that were not collected in all patients.

CONCLUSIONS

We report excellent long-term patency and clinical improvement using the Wallstent in chronic venous obstruction of the iliofemoral tract. Stenting into the CFV is associated with a higher risk of loss of primary patency through late follow-up.

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AUTHOR CONTRIBUTIONS

Conception and design: PG
Analysis and interpretation: PG, TK, DB
Data collection: PG, NG, MT
Writing the article: DB
Critical revision of the article: PG, NG, TK, MT, DB
Final approval of the article: PG, NG, TK, MT, DB
Statistical analysis: DB
Obtained funding: PG
Overall responsibility: PG

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