Endovascular treatment of chronic ilio-femoral vein obstruction with extension below the inguinal ligament in patients with post-thrombotic syndrome

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ABSTRACT

Objective: This study aimed to evaluate postoperative outcomes of patients with chronic iliofemoral venous outflow obstruction and post-thrombotic syndrome (PTS) who underwent endovascular recanalization and stenting across the inguinal ligament.

Methods: All consecutive patients with chronic iliofemoral venous outflow obstruction and PTS were included in the analysis, from January 2018 and February 2022. Preoperative, intraoperative, and postoperative outcomes were assessed. Primary endpoints analyzed were major adverse events (MAEs) at 30 days and primary patency rate at 2 years of follow-up. Secondary endpoints assessed were secondary patency rate, target vessel revascularization, and clinical improvement evaluated with the Venous Clinical Severity Score (VCSS) classification, Villalta scale, and visual analog scale (VAS), respectively.

Results: A total of 63 patients (mean age, 48.1 ± 15.5 years; female, 61.9%) were evaluated. No intraoperative and 30-day postoperative complications were documented. The technical success rate was achieved at 100%. Overall, one in-stent occlusion and five in-stent restenosis were detected during follow-up. The primary patency rate was 93.7% (95% confidence interval [CI], 87.8%-99.9%) and 92.1% (95% CI, 85.6%-99%), at 1- and 2-year follow-up, respectively (Kaplan-Meier analysis). Target vessel revascularization was conducted in two cases, resulting in a secondary patency of 98.4% (95% CI, 95.4%-100%) at 2 years of follow-up. Stent fracture and/or migration were not observed during follow-up. A significant clinical improvement in the patient's quality of life was documented. The median improvement of VCSS and Villalta scores were 4 (interquartile range, 2-7; $P = .001$), and 3 (interquartile range, 1.5-5; $P = .001$) vs baseline at the last follow-up. Overall, pain reduction of 17 mm on the VAS scale was documented at 2 years of follow-up. At multivariate analysis, presence of trabeculation into the femoral vein and deep femoral vein (odds ratio, 1.89; 95% CI, 0.15-6.11; $P = .043$), and Villalta scale >15 points at admission (odds ratio, 1.89; 95% CI, 0.15-6.11; $P = .043$) were predictive for in-stent occlusion during the follow-up.

Conclusions: The use of a dedicated venous stent across the inguinal ligament was safe and effective for the treatment of symptomatic iliofemoral venous disease with acceptable primary and secondary patency rates at 2 years of follow-up. (J Vasc Surg Venous Lymphat Disord 2024;12:101816.)

Keywords: Dedicated venous stent; Deep vein thrombosis; Post-thrombotic syndrome

Endovenous treatment (ET) with venoplasty and stenting for chronic iliofemoral obstructions has been established as a method of choice to restore adequate venous outflow after post-thrombotic syndrome (PTS) resulting from deep vein thrombosis (DVT).[1,2] One of the main challenges of this technique is to identify nonfibrotic venous segments for stent deployment, which should be performed "from healthy to healthy" segments.[3-5] To decrease that challenge, in several cases, the stent should be deployed across the inguinal ligament into the common femoral vein (CFV) before the confluence to the deep femoral vein (DFV).

Concerns about the mechanical stent fatigue, sizing, and configuration of venous stents below the inguinal ligament have been raised regarding stent fracture and subsequently increased risk factors for worse outcomes,

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increasing the severe in-stent recurrent occlusion rate.[6,7] However, further analysis demonstrated that new dedicated stents can be safely deployed in the venous system across the inguinal ligament, without risk of stent fractures, compression, and in-stent restenosis (ISR).[4,8-11]

Our purpose was to evaluate postoperative clinical outcomes and patency rates in patients with chronic iliofemoral obstructions and PTS who underwent ET with stent deployment across the groin region throughout the 2-year follow-up.

METHODS

Study population and design. This is a single-center, retrospective, and non-randomized study including all consecutive patients treated between January 2018 and February 2022. Ninety-one patients with chronic iliofemoral obstruction and PTS were treated during the study period. Among these, 63 received an ET and a stent extension across the inguinal ligament into the CFV. The typology of the stent implanted is listed in Table I.

The study was not randomized; thus, the treatment strategies were at the discretion of the operator according to standard practice. Data were retrospectively reviewed from a prospectively maintained clinical database. Patient demographics and comorbidities are listed in Table II.

All patients in this study had an episode of DVT more than 6 months before stent placement. Only symptomatic patients with a Villalta score ≥8 points and Venous Clinical Severity Score (VCSS) ≥10 points, were considered for ET. Patients with acute iliofemoral DVT, with non-thrombotic disease, or those with previous surgical or endovascular intervention at the target vessels were excluded from the analysis.

Preoperative color Doppler ultrasound (CDUS) examination of inflow and outflow vessels and computed-tomography venography (CTV) or magnetic resonance venography (MRV) were performed before ET. The anatomical features and the types of lesions (trabeculation and/or scarring) were analyzed for each patient and recorded in a dedicated database.

Venography and intravascular ultrasound (IVUS, Volcano Philips) were used to evaluate baseline stenosis/occlusion length and vessel diameters, to define the size and length of stent implantation, and to assess residual stenosis after stent deployment.

Details on technical strategies and implantation of stents in chronically obstructed veins are published elsewhere.[12] In our clinical practice, the stent is deployed in the CFV area that exhibits the best anatomical characteristics and in absence of disease following the IVUS evaluation. Therefore, when necessary, it is also placed beyond the femoral saphenous junction.

At the end of the procedure, a CDUS control was performed to evaluate the patency, type of inflow, and absence of access complication.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center, retrospective, non-randomized cohort study
- **Key Findings:** Poor inflow and Villalta scale >15 points at admission were predictive for in-stent occlusion over the follow-up. Proper inflow ensures the patency of the treated iliac axis.
- **Take Home Message:** The use of a dedicated venous stent across the inguinal ligament is feasible and safe, with acceptable primary and secondary patency rates and a low rate of complications in the early and medium terms.

This study followed the principles outlined in the Declaration of Helsinki and used only information obtained from the review of medical records. Patients gave consent for the anonymous collection of their data on the standard consent form provided by our institution. Ethical committee approval was waived according to Italian laws.

Study endpoints. The primary endpoints assessed were technical success, major adverse events (MAEs) at 30 days, and primary patency at 2 years of follow-up. The technical success was defined as adequate stent deployment into the CFV. The efficacy of the treatment was defined as the stent patency and residual stenosis <30% after ET. The MAEs were defined as the onset of complication at 30 days after the intervention including bleeding at the access site or target vessel segment, stent or procedure-related DVT, pulmonary embolism (PE), stent migration, target limb amputation, or death. The primary patency was defined as freedom from target lesion revascularization (TLR) without reintervention or stenosis >50% measured by CDUS.

The secondary endpoint assessed were: secondary patency defined as freedom from TLR at the time of follow-up visit after reintervention in case of restenosis or occlusion; target vessel revascularization (TVR) defined as any clinically driven surgical or percutaneous revascularization of the target vessel; clinical outcomes evaluated by the VCSS score, Villalta scale, and visual analog pain score (VAS).[13] The clinical improvement was considered significant when it decreased at least 30% vs the baseline for the VCSS and Villalta scale score over the follow-up.

CEAP classification and stent integrity or migration were reported during the follow-up.

Follow-up assessment. After the intervention, all patients were discharged with compression stocking and anticoagulant therapy using direct-acting oral anticoagulants (DOACs) for at least 1 year. The postoperative imaging follow-up protocol consisted of CDUS

Table I. Type of venous stents used below the inguinal ligament

Stent name, factory	Cell design	No
Blueflow, Plus Medica, GmbH & Co, Germany	Braided	26
Vici, Boston Scientific, Irving, CA, USA	Closed cell	4
Venovo, Bard Inc, AZ, USA	Open cell	16
Abre, Medtronic, CA, USA	Open cell	12
Wallstent, Boston Scientific, Marlborough, Mass	Braided	5

examination before discharge, at 1, 3, and 6 months, 1-year post-intervention, and yearly thereafter. Follow-up CDUS was performed by vascular specialists, who analyzed the in-stent deposits and flow velocities (vein velocity ratio >2.5).[8] An additional treatment was performed in case of worsening of clinical symptoms and stenosis >50% documented with venography examination and IVUS.

Statistical analysis. The collected data were expressed as means ± standard deviation (SDs) or median + inter-quartile ranges (IQRs or 25%-75%) and percentages. A logistic regression model used stepwise selection and identified predictors of the primary endpoint.

Data were entered into the model if they had a univariate *P*-value of less than .1. Collinearity and overfitting were assessed using a stepwise regression model and the Pearson correlation test. In the univariate model, all preoperative, intraoperative, and postoperative variables that were hypothesized to have a possible effect on the development of in-stent occlusion were tested. Variables that showed an association (cutoff value $P < .05$) with in-stent occlusion at univariate analysis were entered in the multivariable model. For multivariate analysis, the binary logistic regression model was applied, and the results are presented as the odds ratios (ORs) with 95% confidence intervals (CIs).

Primary and secondary patency rates were reported using the Kaplan-Meier method. Curves were displayed up to a value of standard error (SE) < 0.10, with a 95% CI. All analyses were performed using R version 3.3.0 (open-source software, R Foundation for Statistical Computing).

RESULTS

A total of 63 consecutive patients (mean age, 48.1 ± 15.5 years; female, 61.9%) with PTS due to chronic iliofemoral obstruction that involved the CFV and PTS were analyzed. Six patients (9.5%) had hypertension, 16 (25.4%) were current smokers, and four (6.3%) had diabetes. All patients had a clinical history of DVT, and four (6.3%) had previous PE. Fifteen patients (24%) were wearing compression stockings before the intervention.

Table II. Baseline characteristics of 63 patients that underwent to endovascular treatment of iliofemoral vein obstruction with dedicated venous stent across the inguinal ligament

Variables	Overall population (n = 63)
Age, years	49.7±14.4
Gender	
Female	39 (61.9)
Male	24 (38.1)
Hypertension	6 (9.5)
Diabetes	4 (6.3)
BMI, kg/m^2	25.6 ± 1.8
Smoking	16 (25.4)
Chronic renal insufficiency	4 (6.3)
Cardiac disease	6 (9.5)
Pulmonary disease	3 (4.7)
Thrombophilia	12 (19.2)
Previous PE	4 (6.3)
Cancer	4 (6.3)
Stenosis (mean) ± SD	82.3 ± 2.4
Total occlusion	35 (55.5)
Mean lesion length (cm) ± SD	10.1 ± 6.4
Lesion localization	
CIV	60 (95.2)
EIV	63 (100)
CFV	63 (100)
Inflow characteristics	
DFV patency	62 (98.4)
DFV involved by trabeculation	6 (9.5)
FV patency	57 (90.5)
FV involved by trabeculation	15 (24)
PV patency	55 (83.4)
PV involved by trabeculation	11 (17.4)
Follow-up, months	19.1 ± 7.4

BMI, Body mass index; *CFV*, common femoral vein; *CIV*, common iliac vein; *DFV*, deep femoral vein; *EIV*, external iliac vein; *FV*, femoral vein; *PE*, pulmonary embolism; *PV*, popliteal vein.
Results are expressed as mean (± standard deviation) or number (%).

Four patients (6.3%) had previous cancer, with negative follow-up >5 years, and 12 (19%) had thrombophilia disorders. The median VCSS score and Villalta scale at baseline were 17 (IQR, 10-21) and 16 (IQR, 11-19), respectively. The median CEAP class was 4 (IQR, 3-5). Overall, 6 patients (9.5%) presented with leg ulcers, and almost all patients (81%) had varicose veins.

Overall, mean baseline diameter stenosis was 82%, and 56% of patients had complete occlusion of the target vessel. The mean lesion length was 10.1 ± 6.4 cm (range, 5-16 cm). Other baseline patient details are listed in Table II.

Table III. Overall intraoperative details

Variables	Overall population N = 63
Technical success	63 (100)
Mid femoral access	30 (47.6)
Popliteal access	22 (35)
IJV access	11 (17.4)
Total duration of procedure, minutes	67.2 ± 28.8
Total fluoroscopy time, minutes	31.1 ± 16.9
Total contrast administration, mL	49.1 ± 18.1
Double barrel	12 (19)
Stents per limb	2.1 ± 0.9
Pre-dilatation	63 (100)
Post-dilatation	63 (100)
Segment stented	
IVC	2 (3.2)
CIV	60 (95.2)
EIV	63 (100)
CFV and/or cephalad to it	63 (100)
DFV	2 (3.2)
FV	0
MAEs	0 (0)
Lumbar pain	35 (55)

CFV, Common femoral vein; *CIV*, common iliac vein; *DFV*, deep femoral vein; *EIV*, external iliac vein; *FV*, femoral vein; *IGV*, internal giugular vein; *IVC*, inferior vein cava; *MAE*, major adverse event; *RIGV*, right internal jugular vein.
MAEs included bleeding at the access site or target vessel segment, stent- or procedure-related deep vein thrombosis, pulmonary embolism, device migration, target limb amputation, or death.
Results are expressed as mean ± standard deviation, and number (%).

General anesthesia was performed on all patients. During venography, a careful examination of inflow from the CFV confluence was performed. Specifically, all except six patients exhibited good inflow. Among these patients, five had evident trabeculations on the DFV, whereas one patient, despite lacking fibrotic septa, had a slender appearance of the DFV. In all patients studied, fibrotic septa involving the CFV were present. In 78% of cases, the lesion extended into the proximal segment of the CFV, whereas in other cases, the CFV was involved by trabeculations, and the thrombus extended up to the distal segment of the external iliac vein. Femoral vein (FV) was involved by trabeculation in 15 cases (24%) and popliteal vein in 11 cases (17.4%) (Table I).

Technical success was achieved in 100% of cases. The diameter and length of the deployed stents into the CFV were sized according to multiplanar venography and IVUS imaging. Overall, a median of 2.1 ± 1.1 stents were placed per limb. Vici Venous Stent (Boston Scientific), Venovo (Bard Inc), or Abre venous stent (Medtronic) were deployed proximally from the CIV up to the external iliac vein above the inguinal ligament. All stents deployed into the CFV had 2 cm of overlapping with the proximal one (Table I). Intraoperative details are listed in Table III. No endophlebectomy was performed.

Early outcome. The mean in-hospital stay was 3 ± 0.5 days. No perioperative complications were registered. Six patients had lumbar pain that was treated with medical therapy. No symptomatic PE, stent migration, or target limb amputation was documented. No target limb DVT or death occurred. Lumbar pain was detected in 35 patients (55%) after intervention, and it was treated with analgesic medication.

Before discharge, all patients underwent a DUS examination that showed improvement in the venous flow through the ilio-femoral axis and the patency of the implanted stent. After the intervention, the patients admitted without any anticoagulant therapy were anticoagulated with low molecular weight heparin for 2 weeks followed by extended DOACs for at least 1 year. The patients who were already under oral anticoagulant therapy continued their previous therapy. All patients were discharged with compression therapy.

Midterm outcomes. All patients completed 2 years of follow-up, with a median follow-up time of 29 months (IQR, 24-36 months). Five patients experienced lower back pain in the 3 months following the surgery, with symptom resolution in four cases. One patient continues to exhibit lumbar pain symptoms due to the coexistence of lumbosacral neurological disease. At the last follow-up, only 66% of the patients were wearing the compression stocking leg. No death occurred during this period. No stent migration and fracture were reported over the follow-up.

The primary patency rate was 93.7% (95% CI, 87.8%-99.9%) and 92.1% (95% CI, 85.6%-99%), at 1 and 2 years of follow-up, respectively (Fig 1). After TVR in two patients, secondary patency was 98.4% (95% CI, 95.4%-100%) at 2 years of follow-up (Fig 2).

Stent fracture and/or migration were not observed during follow-up. Six patients (9.5%) had a worsening of symptoms over the follow-up (Supplementary Table, online only). These patients underwent clinical and CDUS examination, which documented the presence of intrastent restenosis in five patients and occlusion in one. Consequently, the patients were hospitalized and subjected to venography and IVUS examination that confirmed the diagnosis. A prevalent localization of the lesion was observed at the point of stent overlap, particularly at the curvature and just before the iliac-femoral junction in 67% of cases. In one case (patient ID 12) (Supplementary Table, online only), the lesion was focal and located at the CIV in the midsegment without

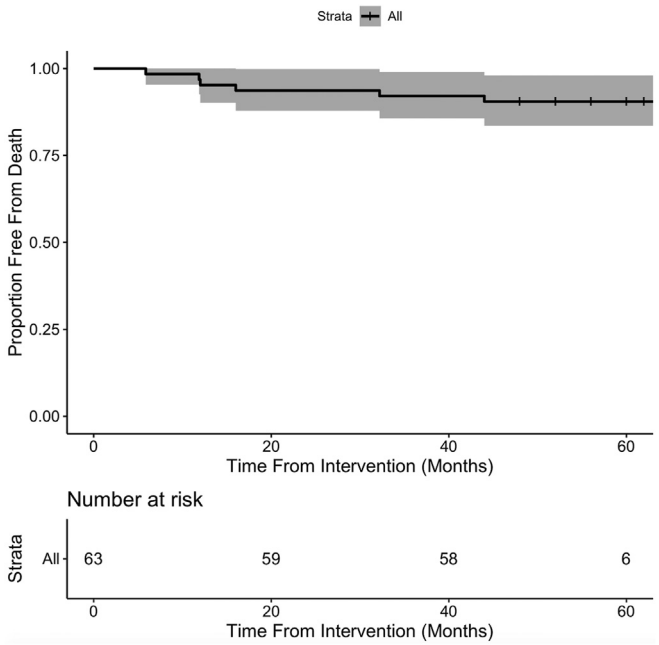

Fig 1. Kaplan-Meier estimates primary patency rate (and 95% confidence bands).

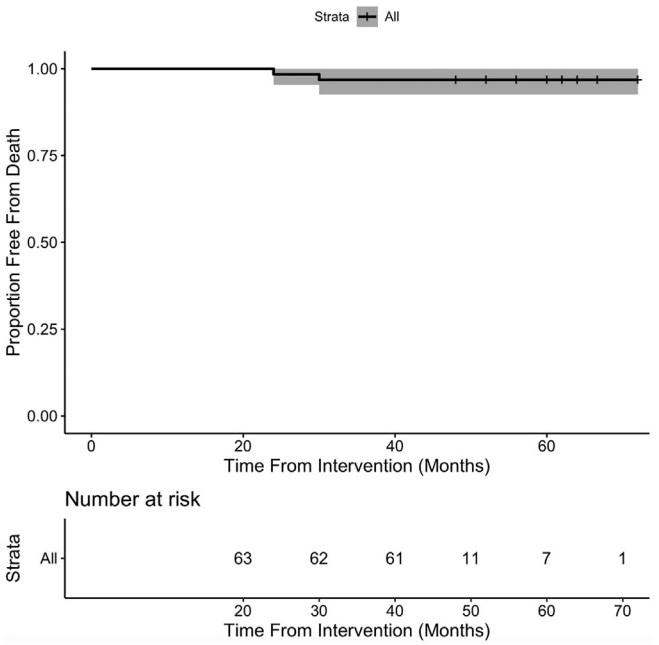

Fig 2. Kaplan-Meier estimates the secondary patency rate of two groups (and 95% confidence bands, log-rank).

compromising the outflow. The patient with stent occlusion (patient ID 102) (Supplementary Table, online only) had previously undergone pelvic surgical reconstruction after a polytrauma. He had a lesion that encompassed part of the stent just below the inguinal ligament up to the common iliac vein in the midsegment. Color duplex ultrasound showed poor inflow with severe trabeculation into the DFV and occlusion of the FV. He underwent recanalization with thrombectomy and additional venoplasty. Despite this, after 3 weeks, he had in-stent re-occlusion, and he was discharged with anticoagulant therapy and stocking leg compression. All patients with restenosis exhibited trabeculation in the segment of the FV and DFV but had a good inflow from the DFV and no residual lesions in the segment of CFV not covered by the stent. Among these, two patients required an angioplasty, and an additional stent was implanted (Supplementary Table, online only). Two patients, although they had worsening symptoms, did not show restenosis at venography (<50%) and did not require additional treatment.

Among six patients who presented with a chronic venous ulcer before the intervention, two had ulcers healing after 6 months from ET, and four improved over the follow-up.

Overall, at 24 months, VCSS score had decreased a median of 4 (IQR, 2-7) points from baseline ($P = .001$) (Fig 3, *A*). The Villalta score had decreased by a median of 3 (IQR, 1.5-5) points from baseline ($P = .001$) (Fig 3, *B*). Overall, the median VAS score change was a pain reduction of 17 mm. It decreased from a median baseline classification of moderate pain (58 mm) to mild pain at 12 months (18 mm). The CEAP class had decreased a median of 1 (IQR, 1-2) point from baseline ($P = .01$) (Fig 3, *C*).

Univariate analysis showed that smoking, thrombophilia, trabeculation into the FV with or without involvement of the DFV, and high Villalta scores were potential risk factors for in-stent occlusion (ISO) or ISR rate >50% (ISR) (Table IV). However, only the association with the presence of trabeculation into the FV and DFV (OR, 2.41; 95% CI, 0.56-7.12; $P = .037$), and Villalta score >15 at admission (OR, 1.89; 95% CI, 0.15-6.11; $P = .043$) reached statistical significance in multivariate analysis (Table IV).

DISCUSSION

Restoration of venous outflow in case of chronic iliofemoral venous occlusion is crucial to improve the patient's quality of life (QoL) and avoid further PTS-related complications.[12,14-16] Percutaneous transluminal venoplasty (PTV) and stenting of ilio-caval lesions have been already well-established as effective treatments to recanalize obstructions and to restore adequate venous return.[1,2] The most recent guideline issued by the European Society for Vascular Surgery has recommended that, in cases of severe symptoms stemming from iliofemoral venous obstruction, endovascular intervention should be prioritized as the initial treatment option.[2] This recommendation is supported by Level B evidence and holds a Class IIa recommendation. However, in the case of lesions that extend across the inguinal ligament involving CFV, stent placement is still a matter of debate. Some investigations discovered a

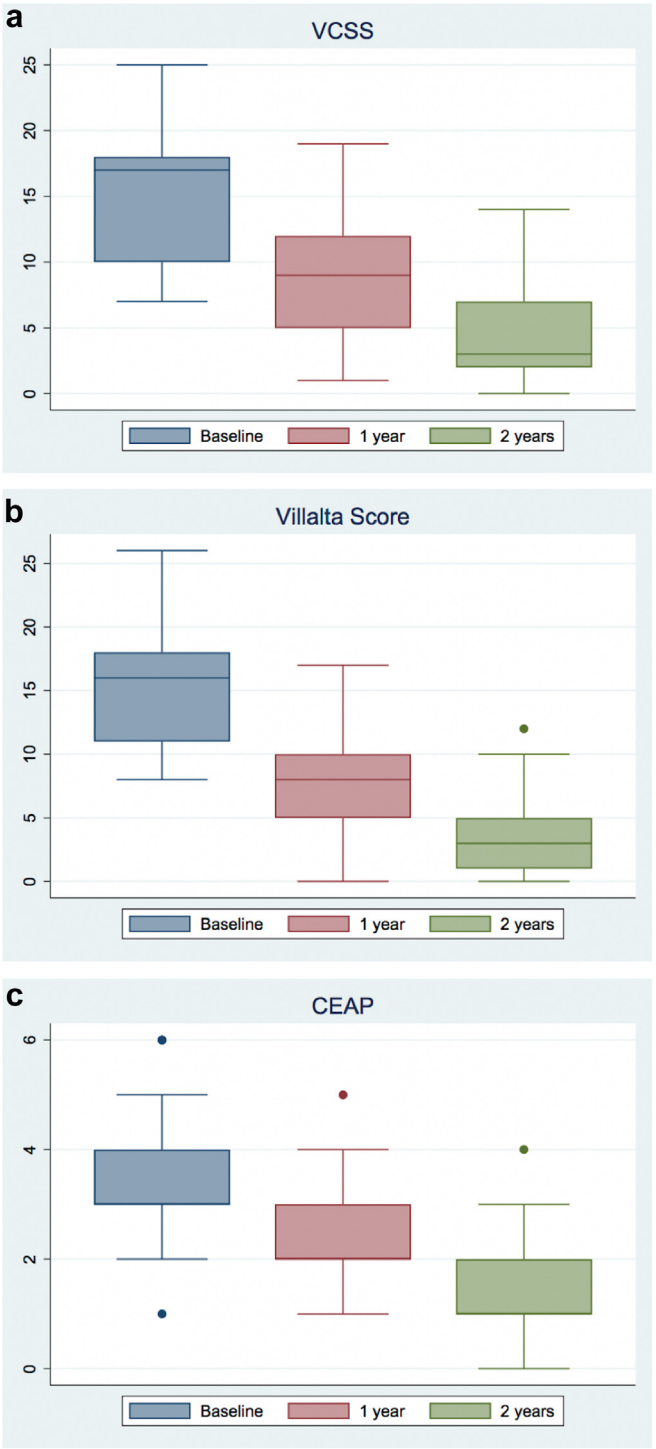

Fig 3. Venous Clinical Severity Score (*VCSS*) **(A)**, Villalta **(B)**, and CEAP **(C)** classes before and after endovascular treatment of chronic ilio-femoral vein obstruction with extension below the inguinal ligament in patients with post-thrombotic syndrome (PTS). The median (*line within the box*) and range (*error bar*), excluding outliers (*circles*), are shown.

correlation between stenting beneath the inguinal ligament and inferior patency rates.[17,18] whereas others reported that venous stents can be safely placed across the inguinal ligament without affecting mid- and long-term patency.[19,20]

These outcomes raise a question about how the inguinal ligament interacts with the iliofemoral venous segment biomechanically. Cheng et al[7] studied the biomechanical impact of the hip movement on iliofemoral venous anatomy and stenting for DVT, and interestingly, showed that the CFV is not compressed by the inguinal ligament during hip flexion, but rather by the pubis during hip extension. The authors observed that the variation of the stent minor diameter over point-to-point change during hip flexion was much less than over the stent total length. As venous stents are not tapered, they are manufactured like a tube with the same diameter, the authors suggested that the stent's mean cross-section strain overcomes the dynamic tension due to hip flexion. Studies that analyzed cobalt-chromium and nitinol stent fatigue and durability reported that changing dynamic movement stress and tension affect device fatigue much more than mean stress and strain.[21,22] In the face of these facts, other mechanisms behind venous ISR should be discussed.

Neglén et al[6] observed ISR in 7% of the limbs at the site of the inguinal ligament, but all less than 50%. Raju[23] studied the causes of ISR in venous stents placed in the lower extremity venous outflow tract and reported a high rate of ISR over the follow-up. They observed that the presence of thrombotic disease and positive thrombophilia appear to be major risk factors for ISR and concluded that the mechanism behind the ISR in venous stents could be probably due to a novel thrombotic event with acute stent thrombosis. Neglen et al conducted an additional examination of their dataset,[4] which indicated that patency is not associated with the extension over the inguinal ligament. Instead, it appears to be linked to the underlying cause, with better patency rates observed for non-occlusive lesions compared to chronic total occlusions and for non-thrombotic iliac vein lesions (NIVLs) compared with PTS. This finding is reinforced by the notably high patency rates documented in studies exclusively focused on stenting NIVLs, whereas studies with a substantial proportion of chronic total occlusion PTS cases often reported less favorable patency outcomes Therefore, following this analysis, the importance of achieving adequate inflow become more vital to maintain adequate venous outflow and satisfactory patency rates.

To improve venous in- and outflow, the characteristics of the stent do not appear to be a significant feature. Recently, we reported satisfactory outcomes at 1-year follow-up in terms of stent patency in a cohort of patients submitted to nitinol-braided dedicated venous stent implantation across the inguinal ligament.[24] A bigger series was reported by Lichtenberg et al,[25] who observed also a favorable clinical improvement over the mid-term follow-up. Other studies with different types of venous stents implanted below the ligament also

Table IV. Univariate and multivariate analysis to identify predictors of in-stent occlusion (ISO) or restenosis (ISR) in patients with ilio-femoral vein obstruction and post-thrombotic syndrome (PTS) that underwent to endovascular treatment and stent extension below the inguinal ligament

	Univariate			Multivariate		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Smoke	1.05	−0.22 to 0.30	.029	—	—	ns
Thrombophilia	1.41	−0.54 to 2.32	.041	—	—	ns
Trabeculation into FV	0.95	0.28-4.11	.031	—	—	ns
Trabeculation into FV and DFV	2.34	0.84-8.23	.001	2.41	0.56-7.12	.037
Villata >15	1.78	0.19-5.23	.001	1.89	0.15-6.11	.043

CI, Confidence interval; *DFV*, deep femoral vein; *FV*, femoral vein; *OR*, odds ratio.

demonstrated satisfactory primary and secondary patency rates.[8-11]

The present study showed that venous stent implantation across the inguinal ligament is safe and effective at midterm follow-up, regardless of the stent material. We corroborate the idea that proper inflow ensures the patency of the treated iliac axis. Before conducting a recanalization procedure, a thorough assessment of femoral confluence, profunda, and its collateral circulations is mandatory. A meticulous preoperative and intraoperative evaluation of venous femoral confluence by CDUS or CT/MRI examinations and by intraoperative venography and IVUS examination is mandatory for a correct inflow evaluation. As evidenced by our outcomes, one patient experienced ISO, whereas five had ISRs. All these patients had residual fibrotic septa involving the femoral confluence, DFV, and FV. Specifically, the patient who suffered ISO presented with hypertrophic collateral circulations in the groin region, with occluded femoral and popliteal veins, and a filiform aspect of the DFV. In multivariate analysis, it has been revealed that the presence of fibrotic septa involving the confluence, the FV, and the DFV constitutes a potential risk factor for ISO and ISR during the follow-up period (OR, 2.41; 95% CI, 0.56-7.12; $P = .037$). Analyzing further results, no MAE complications occurred, which is advantageous as it can be considered a highly safe procedure according to the literature.[26,27] Fifty-five patients (35%) developed postoperative lower back pain with almost complete resolution of symptoms over the follow-up. Additionally, we observed a progressive healing of ulcers, with two patients experiencing complete healing, whereas four showed a significant reduction in diameter. Substantial enhancement in the patients' overall QoL was observed. In this study, the median improvement in VCSS and Villalta scores was 4 (IQR, 2-7; $P = .001$) and 3 (IQR, 1.5-5; $P = .001$), respectively, when compared with the baseline. Moreover, at multivariate analysis, Villalta scale >15 points at admission was predictive for ISO and ISR during the follow-up (OR, 1.89; 95% CI, 0.15-6.11; $P = .043$). In aggregate, a decrease of 17 mm in pain intensity on the VAS score was documented over the follow-up period.

These data are consistent with those reported in the literature. Recently Jalaie et al showed in an randomized clinical trial that patients experiencing symptoms related to DVT who underwent dedicated venous stenting demonstrated notably elevated VEINES-QoL/Sym scores after 12 months when juxtaposed with the control cohort.[28] However, the intergroup disparity fell below the pre-defined clinically significant QoL threshold of at least 14 points. Moreover, the authors demonstrated a statistically significant reduction in VCSS in the stent group compared with the control group. In another randomized trial conducted by Rossi et al, 30 limbs from a cohort of 50 patients with iliofemoral deep vein obstruction were treated.[29] Their findings indicated that the utilization of non-dedicated venous stenting yielded substantial enhancements in VCSS, VAS pain scores, and SF-36 scores after a 6-month follow-up period. As demonstrated, even when non-dedicated stents were employed, Rossi et al achieved an improvement in the QoL. This underscores that the specific type of stent used may not be of particular significance, but, based on our experience, the type of pathology (non-thrombotic iliac vein lesions or occlusive) and its extent play a crucial role. The involvement of venous confluence and improper inflow are responsible for the procedure outcome and stent patency duration. Accordingly, Neglén et al[4] observed worse secondary patency rates in limbs stented below the inguinal ligament treated for thrombotic occlusion than in non-thrombotic obstructions. However, the association between venous inflow, venous disease, and stent thrombosis should be further assessed.

Currently, additional procedures involving ilio-femoral and popliteal veins are being employed to enhance inflow. In the ACCESS PTS study[30] (Accelerated Thrombolysis for Post-Thrombotic Syndrome Using the Acoustic Pulse Thrombolysis Ekosonic Endovascular System), the researchers observed that, in cases of patients suffering from PTS due to chronic venous obstruction, a

combination of percutaneous transluminal venoplasty and ultrasound-accelerated thrombolysis interventions led to enhancements in clinical PTS outcomes. These improvements were quantified using the Villalta scale and VCSS, and they were accompanied by the preservation of venous patency over time. However, there is limited literature data to conclusively demonstrate their real effectiveness in the midterm period.

Limitations of this study are the small number of patients and its retrospective fashion. Furthermore, this study did not aim to compare different typologies of the stent or to examine the combined effect of stenting with medical adjunctive management. The lack of homogenous anticoagulation protocols receiving venous stents across the inguinal ligament may have had implications for the outcomes. Longer follow-up is required to ensure long-term patency and safety. Further, in asymptomatic patients, X-rays were not routinely performed, and a stent fracture could have potentially been missed in the CDUS exam.

CONCLUSIONS

The use of dedicated venous stents across the inguinal ligament seems to be safe and effective for the treatment of symptomatic iliofemoral venous disease with encouraging primary and secondary patency rates at 2 years of follow-up. The involvement of the venous confluence, especially when it leads to inadequate inflow, could be responsible for reduced intrastent patency and worsening of symptoms over the follow-up. However, further analysis regarding the venous disease etiology and adequate assessment of venous in and outflow are warranted.

AUTHOR CONTRIBUTIONS

Conception and design: VA, NG, DB
Analysis and interpretation: VA, RL
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Supplementary Table (online only). Characteristics of patients with in-stent restenosis (*ISR*) or occlusion (*ISO*)

ID patient	Time (day)	Type	Treatment	Anticoagulation
34	660	Symptomatic IISR at external iliac vein (VICI) and common femoral vein (Blueflow)	IVUS showed restenosis 62% - PTA intrastent	Apixaban
52	180	ISR at common iliac vein (Venovo), external and common femoral vein (Blueflow)	IVUS showed restenosis 57% - PTA intrastent	Apixaban
102	240	ISO at common (VICI) external iliac and common femoral vein (Venovo)	Thrombectomy – PTA – stent	Sulodexide
82	178	Symptomatic ISR at external iliac vein (VICI) and common femoral vein (Blueflow)	IVUS showed restenosis 51% - PTA intrastent	Apixaban
26	88	Symptomatic ISR at common and external iliac vein (VICI) and common femoral vein (Venovo)	IVUS showed restenosis 70% - PTA intrastent	Dabigatran
12	483	Symptomatic ISR at common and external iliac vein (VICI) and common femoral vein (Abre)	IVUS showed restenosis 83% - PTA intrastent	Apixaban

IVUS, Intravascular ultrasound; *PTA*, percutaneous transluminal angioplasty.