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CLINICAL INVESTIGATION — VENOUS INTERVENTIONS

Short- and Mid-Term Outcomes of Endovascular Stenting for the Treatment of Post-Thrombotic Syndrome due to Iliofemoral and Caval Occlusive Disease: A Multi-Centric Study from the French Society of Diagnostic and Interventional Cardiovascular Imaging (SFICV)

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Abstract

Purpose To assess the results of endovascular treatment in a large population of patients suffering from post-thrombotic syndrome (PTS) due to iliocaval occlusive disease.

Methods In this retrospective multi-center study, 698 patients treated by stenting for PTS in 15 French centers were analyzed. Primary, primary assisted, and secondary patency rates were assessed, and clinical efficacy was evaluated using Villalta and Chronic Venous Insufficiency Questionnaire in 20 questions (CIVIQ-20) scores. Outcomes were compared against pre-operative CT-based severity of the post-thrombotic lesions in the thigh (4 grades).

Results Technical success, defined as successful recanalization and stent deployment restoring rapid anterograde flow in the targeted vessel, was obtained in 668 (95.7%) patients with a complication rate of 3.9%. After a mean follow-up of 21.0 months, primary patency, primary assisted patency, and secondary patency were achieved in 537 (80.4%), 566 (84.7%), and 616 (92.2%) of the 668 patients, respectively. Venous patency was strongly correlated to the grade of post-thrombotic changes in the thigh, with secondary patency rates of 96.0%, 92.9%, 88.4%, and 78.9%, respectively, for grades 0 to 3 ($p = .0008$). The mean improvements of Villalta and CIVIQ-20 scores were 7.0 ± 4.7 points ($p < .0001$) and 19.1 ± 14.8 points ($p < .0001$), respectively.

Conclusion Endovascular stenting as a treatment option for PTS due to chronic iliocaval venous occlusion generates a high technical success, low morbidity, high midterm

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patency rate, and clinical improvement. Venous patency was strongly correlated to the severity of post-thrombotic lesions in the thigh.

Keywords Postthrombotic syndrome · Endovascular procedures · Stenting · Vascular patency

Introduction

Post-thrombotic syndrome (PTS) is a chronic complication of deep vein thrombosis (DVT), affecting 25–50% of patients after initial acute DVT [1, 2]. The most frequent symptoms are chronic pain and leg swelling. Severe PTS, accounting for 5–10% of cases, can be characterized by venous claudication and leg ulcers [3, 4]. PTS reduces patients' quality of life and carries a significant economic burden [5–8]. Proximal thrombosis, involving the inferior vena cava (IVC) or iliac veins, increases the risk for severe PTS because of low rate of recanalization and poorly developed collaterals [3, 9]. Percutaneous recanalization combined with endovenous angioplasty and stenting have progressively replaced open surgery as a method to treat PTS. This paradigm shift is supported by several case series findings highlighting its safety and effectiveness [9—18]. According to the meta-analysis by Qiu et al., including 489 patients from seven studies, the primary, primary assisted, and secondary patency rates at 12 and 36 months were 83.36%, 90.59%, and 94.32%, and 67.98%, 82.26%, and 86.10%, respectively [18]. Currently, percutaneous stenting is recommended by the Cardiovascular and Interventional Radiological Society of Europe, the Society for Vascular Surgery, and the American Venous Forum [19, 20]. This retrospective multicenter study was conducted to assess the results of endovascular treatment in a large population of patients suffering from PTS due to chronic iliocaval occlusive disease. The primary objective of the study was to evaluate the stent patency at the follow-up. Secondary objectives were used to determine the factors that could influence the stent patency and evaluate endovascular treatment's clinical efficacy.

Materials and Methods

Study Design and Patients

This retrospective, multicenter study was conducted in 15 French centers under the French Society of Diagnostic and Interventional Cardiovascular Imaging (SFICV) guidance. The study protocol was approved by the French data protection agencies and institutional review board (CERF-CERIM, IRB CRM-1911–057). Written consent was obtained from every patient before endovascular procedures. In accordance with French regulation for retrospective observational studies, informed consent for data collection was waived.

Patients were included in the study between January 2009 and December 2019 if they were treated for PTS due to post-thrombotic iliocaval occlusion. Each patient had functional complaints related to PTS, at least three months after acute caval or iliofemoral DVT, despite anticoagulant therapy and contention. Patients were excluded from the study if they exhibited extrinsic compression by a tumor, acute thrombosis, Budd-Chiari syndrome, non-thrombotic obstructive condition, or a venous occlusion at the dialysis catheter placement.

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Endovascular Recanalization Procedures

Technical details on endovascular recanalization procedures for iliocaval occlusion are described elsewhere (23,24). The procedure was usually realized under sedation or general anesthesia, in an interventional radiology unit. Recanalization was performed using various venous approaches, depending on operator's preference. Venous occlusion was crossed with a stiff hydrophilic guidewire and a support catheter and a bolus of unfractionated heparin was injected. After progressive predilation using balloon catheters, extensive stenting was performed between two healthy landing zones. Open-cell nitinol stents were used, with diameters depending on the anatomic location: 12–28 mm for the IVC, 10 to 16 mm for the common iliac and external iliac vein, 8 to 14 mm for the common femoral vein (CFV), deep femoral vein or femoral vein, 8 to 10 mm for grand saphenous vein or popliteal vein. After the procedure, most patients received anticoagulant therapy for at least three months.

Data Collection and Outcome Measures

The demographics and clinical characteristics were obtained from the patients' files, including age, gender, mean time interval between acute DVT and recanalization, recurrent thrombosis in the ipsilateral limb, inherited thrombophilia, general DVT risk factor (such as pregnancy, post-partum, surgery, immobilization or connective tissue disease), local DVT risk factor (such as May–Thurner syndrome, congenital atresia of the IVC, postsurgical venous lesions or vena cava filter) and presence of venous leg ulcers. The clinical severity of PTS and the impact on the quality of life were evaluated using the Villalta score and the Chronic Venous Insufficiency Questionnaire in 20 questions (CIVIQ-20) [21–24]. The pre-operative morphological investigation was based on color duplex ultrasonography of the lower limb veins and computed tomography (CT) phlebography (Fig. 1). Localization and extent of post-thrombotic venous lesions in the thigh were recorded, and a CT grading for severity was established according to the four-grade scale proposed by Menez et al. [24]. This classification is based on the diameter of the veins, presence of synechia and possibility for stenting, defining four stages of increasing severity: grade 0 (no lesions in the thigh), grade 1 (minor lesions), grade 2 (significant lesions) and grade 3 (major lesions) [24]. Procedural characteristics of endovascular treatment were also recorded, including the number and the site of venous access, the number of stents, and the treated occluded venous segments. Immediate technical success was defined as successful recanalization and stent deployment restoring rapid anterograde flow in the targeted vessel. Stent patency was assessed by Doppler ultrasound (and/or CT phlebography in cases of suspicion of iliocaval stent thrombosis) before the patient was discharged from the hospital. Complications were classified as minor or major according to the Society of Interventional Radiology standards [25].

The primary, primary assisted and secondary patency rates were evaluated at 1, 6, 12, 36, and 60 months after the procedure by ultrasonography or CT phlebography (Fig. 1). Primary patency was defined as confirmed patency of the treated veins on follow-up, without occlusion, or any re-intervention. Primary assisted patency was defined as confirmed patency achieved without occlusion or reintervention, except for preemptive treatment of in-stent stenosis. Secondary patency was defined as established patency after reintervention for stent occlusion.

Villalta and CIVIQ-20 scores were evaluated immediately before intervention and during the follow-up to assess the clinical severity of PTS. The evolution of venous leg ulcers was examined and recorded at the end of follow-up using the following criteria: healed (complete and definitive epithelialization), improved, or unchanged.

Statistical Analyses

Statistical analyses were performed using R software version 3.6. Quantitative variables were expressed as medians and interquartile ranges (IQR) and qualitative variables as numbers and percentages. For variables that were not studied in all patients, the number of patients investigated was given. Cumulative primary, primary assisted, and secondary patency curves were calculated using the Kaplan–Meier method and a log-rank test was used for the comparison of patency curves between defined subgroups. Patency rates at the end of follow-up were calculated with the corresponding 95% confidence interval (CI). Comparison of two measures for quantitative variables for the same patients was performed using the Wilcoxon test. Comparisons of proportions for binary variables were performed using the chi-square test. The significance threshold was set at $p < 0.05$.

Results

Patient Characteristics

From 2009 to 2019, 698 consecutive patients from 15 medical centers who underwent endovascular stenting for chronic PTS due to iliocaval occlusion were included. The median age of patients was 43 years (IQR 32–57) and 60.0% were female. Inherited thrombophilia was noted in 156 (24.3%) out of 640 patients. A general DVT risk factor was observed in 388 (59.6%) out of 651 patients and a local

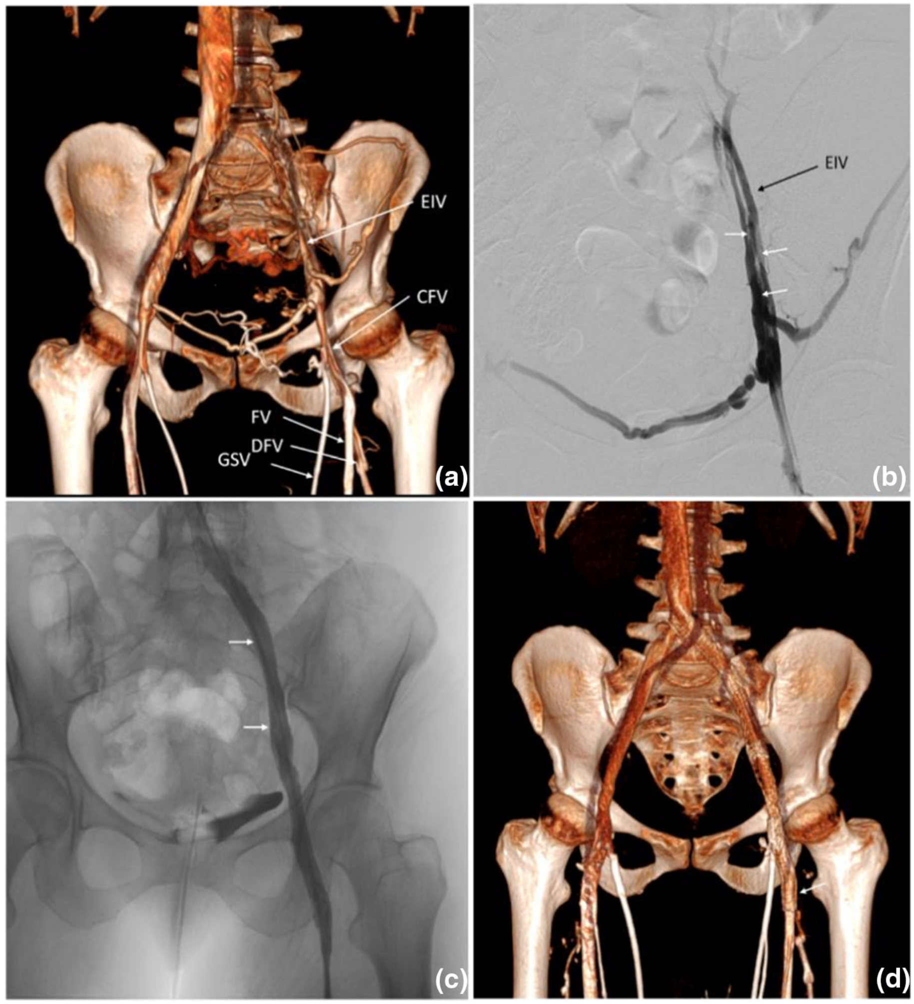


Fig. 1 Endovascular stenting in a 46-year-old woman with post-thrombotic syndrome presented a year prior with proximal acute deep venous thrombosis of the left leg. Baseline Villalta and CIVIQ-20 scores were 14 and 76, respectively. **A** Three-dimensional (3D) reconstruction of computed-tomography (CT) phlebography before treatment: occlusion of the left common iliac vein and synechia in the left external iliac vein (EIV). The left common femoral vein (CFV), femoral vein (FV), deep femoral vein (DFV), and the great saphenous vein (GSV) are patent and free of synechia. **B** Initial digital subtraction venography showing intraluminal synechia limited to the EIV (white arrows). **C** Final venography indicating stent patency and disappearance of collaterals (arrows). **D** Post-operative 3D CT phlebography highlighting the stents, with the stents' inferior edge in the CFV can be seen (arrow). At the five-year follow-up, the stents were patent. Post-procedural Villalta and CIVIQ-20 scores determined during this follow-up dropped to 0 and 21, respectively

DVT risk factor in 401 (62.0%) out of 647 patients. Baseline Villalta score was collected in 575 patients (14 centers) with a median score of 11 (IQR 8–14). Baseline CIVIQ-20 score was collected in 340 patients (7 centers), with a median score of 52 (IQR 40–65). Active chronic venous ulcers were present in 61 (9.7%) out of 627 patients. Demographic and clinical characteristics are summarized in Table 1 (and Supplement 1). Venous lesions were unilateral in 588 (84.2%) patients. CT grading of severity could be performed in 624 (89.4%) patients. Localization and severity of venous lesions are summarized in Table 2.

Procedural Data

Single venous access was used in 408 (58.5%) patients, involving a single (or combined) jugular vein access in 550 (78.8%) patients. A median number of 3 (IQR 2–4) stents were used. Out of 694 patients, 656 (94.5%) had at least one stent implanted into an iliac vein. Moreover, 123 (17.7%) IVCs were stented and an extension below the CFV was performed in 216 (31.1%) patients. Procedural data are summarized in Table 3.

Outcomes

Immediate technical success was obtained in 668 (95.7%) patients, requiring single-stage intervention during index hospitalization in 551 (78.9%) patients (Table 4). No procedural-related death occurred during or within one month after the intervention. Nine patients (0.9%) died during the follow-up period, without any death related to the venous disease (Table 4). Five major complications were reported (0.7%), which included a hip prosthesis infection, a pneumonia with pulmonary embolism, an arteriovenous fistula at the puncture site, an IVC rupture requiring surveillance in intensive care unit, and one case of chronic inguinal pain requiring long-term analgesic use. Twenty-two minor complications were also noted (3.2%, [Table 4]). At the end of the mean follow-up (21.0 ± 19.1 months), in the setting of initial technical success (668 patients), the primary, primary-assisted and secondary patency were

Table 1 Baseline characteristics

Demographics and clinical characteristics	
Age–years	43 [32–57]
Gender	
Female	419 (60.0)
Delay before treatment—years	3 [1–3]
Recurrent thrombosis	169/623 (27.1)
Inherited thrombophilia	156/640 (24.3)
General DVT risk factor	388/651 (59.6)
Pregnancy/post-partum	109 (16.7)
Hormonal treatment	66 (10.1)
Surgery	53 (8.1)
Immobilization	51 (7.8)
Traumatism	32 (4.9)
Other	77 (11.8)
Local DVT risk factor	401/647 (62.0)
May–Thurner	269 (41.6)
Congenital atresia of the IVC	50 (7.7)
Postsurgical venous lesions	24 (3.7)
Vena cava filter or clip	20 (3.1)
Other	48 (7.4)
Baseline Villalta score (575 patients)	11 [8–14]
Score < 5	31 (5.4)
Score 5–14	402 (69.9)
Score > 14	142 (24.7)
Baseline CIVIQ-20 score (340 patients)	52 [40–65]
Score < 30	23 (6.8)
Score 30–59	199 (58.5)
Score > 60–100	118 (34.7)
Active leg venous ulcers	61 (9.7)

DVT, deep vein thrombosis; IVC, inferior vena cava

Data are expressed as numbers (with percentages) or median [interquartile range]

Table 2 Venous lesions

Venous lesions	
Laterality	
Both legs	110 (15.8)
Left leg	479 (68.6)
Right leg	109 (15.6)
Venous occlusion	
IVC	121 (17.3)
CIV	571 (81.8)
EIV	649 (93.0)
CFV	560 (80.2)
Post-thrombotic sequelae caudal to the CFV	376 (53.9)
Grade	624 patients
Grade 0	232 (37.2)
Grade 1	143 (22.9)
Grade 2	201 (32.2)
Grade 3	48 (7.7)

IVC, inferior vena cava; CIV, common iliac vein; EIV, external iliac vein;CFV, common femoral vein

Data are expressed as numbers (with percentages)

achieved in 537 patients (80.4%; 95%CI: 77.4–83.4), 566 patients (84.7%; 95%CI: 82.0–87.5) and 616 patients (92.2%; 95%CI: 90.2–94.3), respectively. In intention to treat (including technical failures) primary, primary assisted, and secondary patency rates were 76.9% (95%CI: 73.8–80.1), 81.1% (95%CI: 78.2–84.0), and 89.0% (95%CI: 86.6–91.3), respectively. Results of venous patency are summarized in Fig. 2 (and Supplement 2).

Correlations between patency rate and the severity of post-thrombotic lesions are shown in Fig. 3 (and Supplement 3). For patients with no or minor distal lesions (grades 0 and 1), secondary patency rates at the end of follow-up were 96.0% and 92.9%, respectively. However, patency fell to 88.4% for patients with severe lesions (grade 2) and to 78.9% for patients with major lesions (grade 3, $p = 0.0008$). There were no significant differences in cumulative secondary patency at the end of follow-up for patients with and without inherited thrombophilia, for patients with and without a history of recurrent thrombosis, or for patients treated within three years after the initial thrombosis or after three years (Supplement 3). No significant differences in patency rates between patients with or without extension of stenting caudal to the CFV for equivalent grades of severity, or between patients treated by IVC reconstruction versus patients treated by iliofemoral stenting alone for equivalent grades of severity (Supplement 3). For the 537 patients for whom both baseline and post-procedural Villalta scores were available, the mean improvement was 7.0 ± 4.7 points ($p < 0.0001$). From 297 patients, a baseline and a post-procedural CIVIQ-20 score showed a mean improvement of 19.1 ± 14.8 points ($p < 0.0001$). Of the active leg ulcers detected in 61 patients, 32 (52.5%) patients healed, 22 (36.1%) improved, and seven (11.5%) remained unchanged. Clinical outcomes are summarized in Table 5.

Discussion

Our results confirm venous stenting's efficacy and safety in short- and mid-term follow-up in the largest multi-centric cohort of post-thrombotic iliocaval occlusions to date. We report here a near two-year follow-up secondary patency of

Table 3 Procedural data

Venous access	
Single	408 (58.5)
Jugular vein	261 (37.4)
Femoral vein	104 (14.9)
Popliteal vein	39 (5.6)
Other	4 (0.6)
Double	242 (34.7)
Triple	42 (6.0)
Quadruple	5 (0.7)
Involvement of jugular vein	550 (78.8)
Venous stents (694 patients)	
Number of stents	3 [2–4]
Segments stented	
IVC	123 (17.7)
CIV-EIV	656 (94.5)
CFV	349 (50.3)
Caudal to the CFV	216 (31.1)
Deep FV	94 (13.5)
FV	129 (18.6)
Popliteal vein	5 (0.7)
Great saphenous vein	6 (0.9)
Stents diameter (mm)	
IVC	20 [16–22]
CIV-EIV	12 [12–14]
CFV	12 [12–14]
Caudal to the CFV	
Deep FV	12 [10–12]
FV	12 [10–12]
Popliteal vein	10 [8–10]
Great saphenous vein	8 [8, 9]

Data are presented as n (%) or median [IQR]. IVC = inferior vena cava; CIV = common iliac vein; EIV = external iliac vein; CFV = common femoral vein; FV = femoral vein

Table 4 Immediate outcomes and complications

Technical success	668 (95.7)
Number of interventions during index hospitalization	
1	551 (78.9)
2	142 (20.3)
3	5 (0.7)
Deaths	9 (0.9)
Concomitant cancer	3 (0.4)
Concomitant cardiopulmonary disease	2 (0.3)
Acute antiphospholipid syndrome	1 (0.1)
Road accident	1 (0.1)
Unknown cause	2 (0.3)
Complications	27 (3.9)
Major	5 (0.7)
Hip prosthesis infection	1 (0.1)
Pneumonia with pulmonary embolism	1 (0.1)
Arteriovenous fistula at the puncture site	1 (0.1)
IVC rupture	1 (0.1)
Chronic inguinal pain	1 (0.1)
Minor	22 (3.2)
Hematoma at the puncture site	10 (1.4)
Sepsis	3 (0.4)
Chronic pain	6 (0.9)
Protrusion of the stent in the IVC wall	1 (0.1)
Venous rupture	1 (0.1)
Psoas hematoma under anticoagulation	1 (0.1)

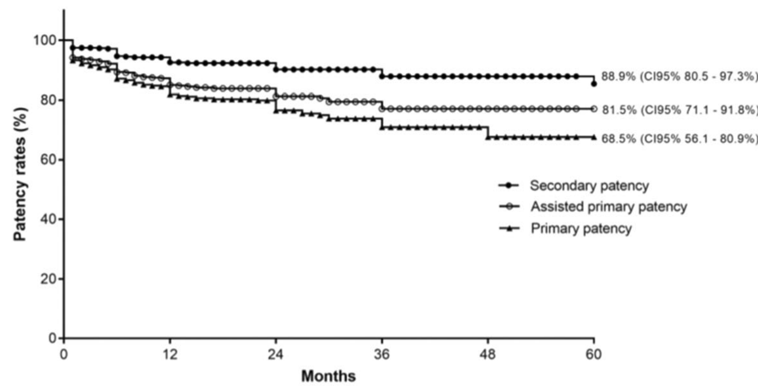
Data are presented as *n* (%). IVC = inferior vena cava

92.2%. Our results are comparable with previous reports, particularly those included in a meta-analysis published by Qiu et al. involving post-thrombotic venous occlusions, thus excluding non-thrombotic iliac vein lesions [18]. However, a closer analysis of this meta-analysis revealed that nearly all the lesions were treated without stent extension below the CFV, suggesting that almost all treated lesions were of low grade of severity. Indeed, only the study from Nayak et al. included 7 out of 44 patients (16%) treated for iliac lesions with stents implanted caudal to the CFV [12]. This is well below the rate of 31% of stenting extension caudal to CFV reported in our series. Consequently, our data suggest that in experienced radiological centers, patency rates remain high, despite supposedly more severe treated lesions.

Immediate technical success was achieved in 668 (95.7%) of the 698 patients, similar to the 95% rate reported in the meta-analysis by Qiu et al. [18]. In our opinion, this high technical success rate fully justifies an exclusive endovascular approach, even for patients with very severe post-thrombotic venous lesions. A low rate of complications (3.9%) observed within this study was found similar to other publications [18, 23, 24] attesting to the safety of this intervention. The retrospective nature of the study may however explain the relatively low morbidity rate.

Regarding the long-term patency of venous stenting, we reported up to 68.5% primary patency and 88.9% secondary patency at five years, similar to previously reported data [10–18]. By comparison, Qiu et al., in their meta-analysis, reported a five-year primary and secondary patency rate of 63.4% and 81.9% [18]. The Kaplan–Meier curves analysis showed that primary patency slightly decreased over time, whereas secondary patency remained

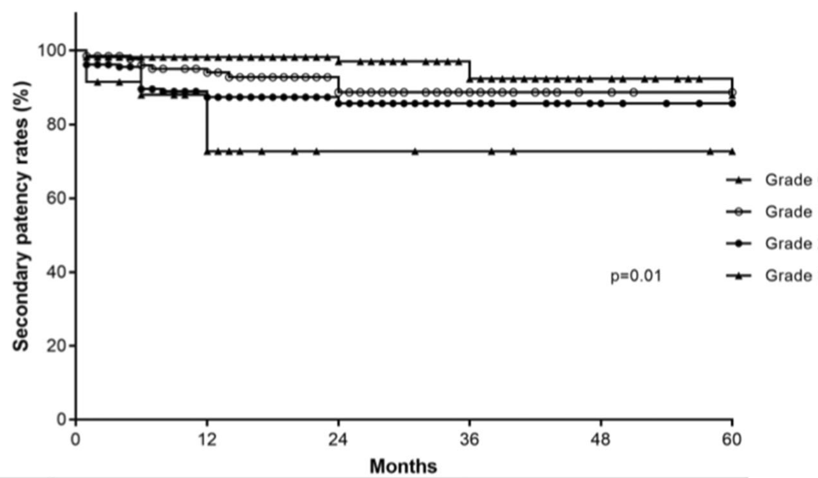
Fig. 2 Cumulative primary, primary assisted and secondary patency rates of endovascular venous stenting). The lower numbers represent patient risk at each time interval. Standard error was < 10% for all data points shown



Primary patency	668	399	191	102	43	25
Assisted primary patency	668	399	191	102	43	25
Secondary patency	668	443	218	119	52	35

Patients at risk

Fig. 3 Cumulative secondary patency rates stratified by CT-based severity of post-thrombotic venous lesions ($p = 0.01$, Log rank test). The lower numbers represent patient risk at each time interval. Standard error was < 10% for all data points shown



Grade 0	225	149	85	62	29	21
Grade 1	141	90	46	24	9	7
Grade 2	190	119	52	22	8	5
Grade 3	38	23	8	5	3	2

Patients at risk

Table 5 Clinical outcomes

Post-procedural Villalta score (547 patients)	3 [1–6]	$p < .0001$*
Score < 5	341 (62.3)	
Score 5–14	181 (33.1)	
Score > 14	25 (4.6)	
Post-procedural CIVIQ-20 (314 patients)	28 [22–40]	$p < .0001$*
Score < 30	176 (56.1)	
Score 30–59	107 (34.1)	
Score > 60–100	31 (9.9)	
Active leg venous ulcers (61 patients)		
Healed	32 (52.5)	
Improved	22 (36.1)	
Unchanged	7 (11.5)	

*p value of difference between post-procedural and baseline median scores

relatively stable (Figs. 2 and 3). A strict follow-up, by duplex sonography or CT phlebography is recommended, in order to detect early in-stent restenoses and thromboses and systematically treat them to maintain long-term patency.

In the present study, patency rates were correlated with the CT-based severity of post-thrombotic lesions in the thigh. For patients with no distal lesion (grade 0), the secondary patency rate at the end of follow-up was 96.0%, falling to 78.9% for patients with major lesions (grade 3), confirming that the severity of post-thrombotic changes impacts the inflow through the stent and thus the long-term patency. These results are in line with those previously reported, highlighting the importance of a pre-operative assessment of these post-thrombotic lesions to predict the inflow's quality through the future venous stents [24, 26].

In our study, there was no significant difference in patency rates between patients with or without extension of stenting caudal to the CFV for equivalent grades of severity. Currently, the effect of stenting extension caudal to the CFV on patency rates remains controversial. Several authors recommend stenting below the inguinal ligament in case of obstructive lesions caudal to the CFV, suggesting that the patency rate depends on the etiology of the obstruction and whether or not this obstruction is occlusive [26–28]. Conversely, other authors discourage distal stent placement, putting forth the argument that the CFV stenting could compromise the venous inflow from deep femoral vein and collaterals, thus jeopardizing stent patency [29–32]. Hence, hybrid surgical techniques were developed, combining iliac vein stenting with endophlebectomy [33–35]. There is no evidence that these techniques can achieve better patency rates or improve clinical symptomatology and reported complication rates are higher than using a pure endovascular approach [29, 30].

While the presence of inherited thrombophilia may be a high-risk factor for thrombosis, it was not statistically associated with stent occlusion in our series, corroborating with the literature [9, 35]. The history of recurrent thrombosis and the delay before endovascular treatment did not influence stent outcome, highlighting that endovascular treatment remains an interesting option for most patients, regardless of the number and age of preoperative thrombotic events.

Our results confirm the significant impact of endovascular treatment on symptoms and quality of life. Median Villalta and CIVIQ-20 scores significantly decreased from 11 and 52, respectively, to 3 and 28, in accordance with the literature [10, 15, 23]. This study has some limitations, especially as a result of missing data due to its retrospective nature. Thus, Villalta and CIVIQ-20 scores and the degree of pain were not systematically documented and would have strengthened the evaluation of clinical efficacy. Prospective randomized comparative studies are planned to confirm the superiority of endovascular treatment compared to conservative medical treatment. We could also not differentiate between the outcomes of using different stents (size and length) or determine the optimal protocol to give anticoagulant or antiplatelet medication peri- or post-operatively. Finally, superficial venous disease was not considered, when it might play a role in the clinical severity of PTS and ulcers. Future studies will be needed to reach these objectives.

Our study confirmed the feasibility and safety of percutaneous recanalization and stent placement as a treatment option for PTS due to chronic iliocaval occlusion, based on a large population of patients treated in expert centers specialized in vascular interventional radiology. In France, this treatment can be performed with high technical success, low morbidity, high midterm patency rates, and midterm clinical improvement. Our results showed a strong correlation between the decreased venous patency and increased severity of post-thrombotic lesions in the thigh. The pre-operative evaluation of these lesions is thus crucial to plan appropriate intervention.

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Declarations

Conflict of interest Dr Espitia reports honoraria from Boston and Optimed. Dr Douane reports honoraria from Optimed. The other authors report no conflicts.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required. The study protocol was approved by the French data protection agencies and institutional review board (CERF-CERIM, IRB CRM-1911–057).

Informed Consent This study has obtained IRB approval from (CERF-CERIM, IRB CRM-1911–057) and the need for informed consent was waived.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

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