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Treatment of Femoral Vein Obstruction Concomitant with Iliofemoral Stenting in Patients with Severe Post-thrombotic Syndrome

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WHAT THIS PAPER ADDS

Endovascular stenting is a common treatment for severe post-thrombotic syndrome with a chronically obstructed iliofemoral venous segment. An adequate inflow to the stent is vital for the clinical and stent outcomes after iliofemoral vein stenting. The results of this retrospective study demonstrated that concomitant femoral stenting or angioplasty of an obstructive femoral vein in the presence of a patent profunda vein does not improve the outcomes after iliofemoral stenting in this patient group.

Background: The aim was to assess the clinical and anatomical outcomes of iliofemoral stenting, with concomitant femoral stenting or balloon angioplasty alone, in patients with severe post-thrombotic syndrome (PTS) and compromised inflow.

Methods: A database of patients with severe PTS who successfully underwent endovascular iliofemoral stenting was reviewed retrospectively. Patients with impaired inflow with chronic post-thrombotic obstructive lesions in the femoral vein (FV), but patent profunda vein, were selected and divided into two groups: the FV stenting (FV-S) group and the FV angioplasty (FV-A) group. Patients in the FV-S group were treated with concomitant iliofemoral and FV stenting, and patients in the FV-A group were treated with iliofemoral stenting and balloon angioplasty alone of the obstructed femoral vein. The clinical and stent outcomes were recorded and compared in the two groups.

Results: There were 45 patients in the FV-S group and 69 patients in the FV-A group. The groups were well matched for age, gender, and diseased limbs. The pre-procedural symptoms, CEAP classifications, VCSS scores, Villalta scores, and prevalence of active ulcers were also similar between the two groups. Immediate failure (<30 days post-procedure) in the femoral segment occurred more frequently in the FV-A group (70% in FV-A group vs. 24% in FV-S group, $p < .001$); however, all treated femoral vein segments had occluded at 12 months. There was no significant difference between the FV-S and FV-A groups in cumulative primary and secondary patency rates of the iliofemoral stent at 3 years (55% vs. 52%, $p = .71$, and 77% vs. 85%, $p = .32$, respectively). Complete pain relief, swelling relief, VCSS score, Villalta score, and freedom from ulcers at a median of 22 months (1–48 months) following the procedure were similar in the two groups.

Conclusions: Stent placement to treat post-thrombotic iliofemoral obstruction with concomitant obstructed femoral vein but patent profunda vein shows cumulative patency rates and clinical outcomes similar to previous reports. Adjunctive femoral stenting or angioplasty of the obstructed femoral vein does not appear to improve clinical or stent outcomes in patients with severe PTS.

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Keywords: Post-thrombotic syndrome, Chronic post-thrombotic obstruction, Stent, Iliac vein, Femoral vein

INTRODUCTION

Endovascular stenting has become the first line revascularisation approach in many centres for patients with post-thrombotic syndrome (PTS) as a result of chronic post-thrombotic obstructions in the iliofemoral venous segments.[1–3] Many patients with severe PTS have chronic iliofemoral vein obstruction combined with femoral (FV) lesions. Given that the profunda veins and great saphenous veins are usually not involved in extensive deep venous thrombosis,[4,5] they are important inflow vessels into the iliofemoral stent. As reported before, patients with long segment stenting that extends below the inguinal ligament and those with inadequate inflow are at a high risk of occlusion.[5,6] However, whether recanalisation of an obstructive FV with stents

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improves iliofemoral inflow and therefore increases the iliofemoral stent patency rate has not been extensively examined. The aim of this study was to compare the stent and clinical outcomes of iliofemoral venous stenting extending into the FV or with FV angioplasty alone in patients suffering from severe PTS and chronic iliofemoral post-thrombotic obstruction extending into the FV, but with a patent profunda vein.

METHODS

Study design

A prospectively maintained database registry of patients with severe PTS that underwent endovascular iliofemoral stenting between January 2012 and December 2015 was retrospectively reviewed (Fig. 1). According to the checklists for PTS in the institution, duplex ultrasound was conducted to map the patency of the great saphenous vein and deep veins in the lower extremity. Ascending venography or venous computed tomography (CT) angiography was also performed when obtaining adequate imaging of the iliac vein and inferior vena cava was difficult with duplex ultrasound alone. Images were reviewed with particular focus on assessing the peripheral inflow into the common FV. Patients with iliofemoral vein obstruction without extension into the inferior vena cava were chosen, and among those only patients with obstructive FV disease and patent profunda vein were included in the study. The excluded patients are presented in Fig. 1, including clinical severity and access points. Patients with an occluded popliteal vein stented through the profunda FV, and patients with occluded profunda FV stented through the great saphenous vein were excluded from the present study. For each included patient the demographics, symptoms, Villalta score,[7] VCSS (Venous Clinical Severity Score), and clinical stage of the CEAP classification (Clinical Etiology Anatomy Pathophysiology classification)[8] were identified and recorded. All patients provided written informed consent before

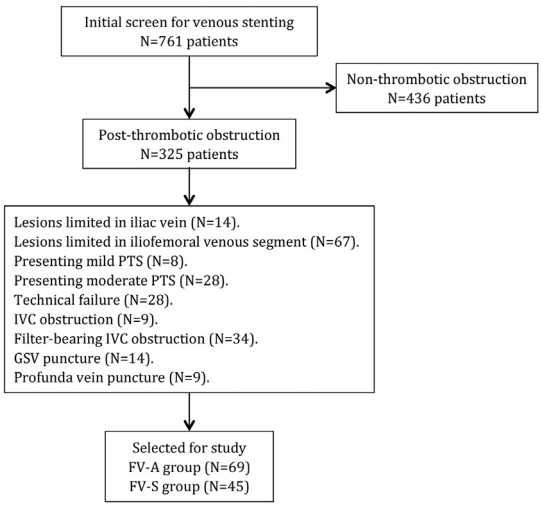

Figure 1. Study algorithm for selection of patients. FV = femoral vein; GSV = great saphenous vein; IVC = inferior vena cava; PTS = post-thrombotic syndrome.

procedures, and the Institutional Review Board of the hospital approved the study protocol for this retrospective analysis.

Stenting procedure

After ipsilateral popliteal vein puncture under ultrasound guidance was achieved, heparin sodium 80 IU/kg was administered to achieve an activated clotting time of 250—300 s in all patients. Antegrade venography from the introducer sheath was obtained to define the existing venous anatomical features (Radifocus Introducer II; Terumo, Tokyo, Japan). Details of the balloon angioplasty and stenting procedure have been described in detail previously.[6,7] Briefly, a stiff straight .035 inch hydrophilic guidewire (Terumo Medical Corporation, Somerset, NJ, USA) was directed through the FV obstruction under the guidance of a matched multipurpose catheter or angled tip catheter (MP A1; Cordis Corporation, Miami Lakes, FL, USA; Trailblazer; ev3 Endovascular, Inc., Plymouth, MN, USA). The guidewire was then used to centrally track along the iliofemoral venous segment until the obstruction had been crossed. The progress of recanalisation by the guidewire and catheter was checked by intermittent oblique images and venography to ensure that the guidewire followed the iliofemoral venous segment anatomically through the pelvis. The guidewire was removed after the catheter was successfully advanced through the lesion, and venography was performed to ensure that the catheter tip was located within the lumen of the inferior vena cava.

A balloon catheter (EverCross, ev3 Endovascular, Inc, Plymouth, MN, USA; ReeKross, ClearStream Technologies, Wexford, Ireland; PowerFlex P3, Cordis Corporation Milpitas, CA; Mustang, Boston Scientific Corporation, Natick, MA, USA), with a diameter of 4—16 mm and a length of 60—220 mm, was used for serial dilation from the FV to the common FV, the external iliac vein and the common iliac vein. After balloon angioplasty, self expanding stents (Wallstent, Boston Scientific Corporation; Luminexx; Bard, Austin, TX, USA) with a diameter of 10—16 mm and a length of 60—150 mm were implanted. In the FV-S group (Fig. 2), the stents were deployed in the iliac vein and the common FV, and covered the obstructed FV (all the femoral stents were contiguous with the iliofemoral stents and jailed the inflow of the profunda vein). In the FV-A group (Fig. 3), the stents were limited to deployment in the iliac vein and the common FV just above the inflow from the profunda vein. Usually after the deployment of all stents, post-stent dilation was required because of the common occurrence of severe recoil. The optimum calibre of the stents in the FV, common FV, and iliac vein ranged from 10 mm to 12 mm, from 12 mm to 14 mm and from 14 mm to 16 mm, respectively. In the FV-A group, to achieve the best angiographic result in the FV, a prolonged (at least 180 s) dilatation was performed repeatedly in cases with residual stenosis or recoil. At the end of the procedure, venography was performed from the sheath to assess the success of the procedure and to identify potential recoil, stenosis, and thrombosis.

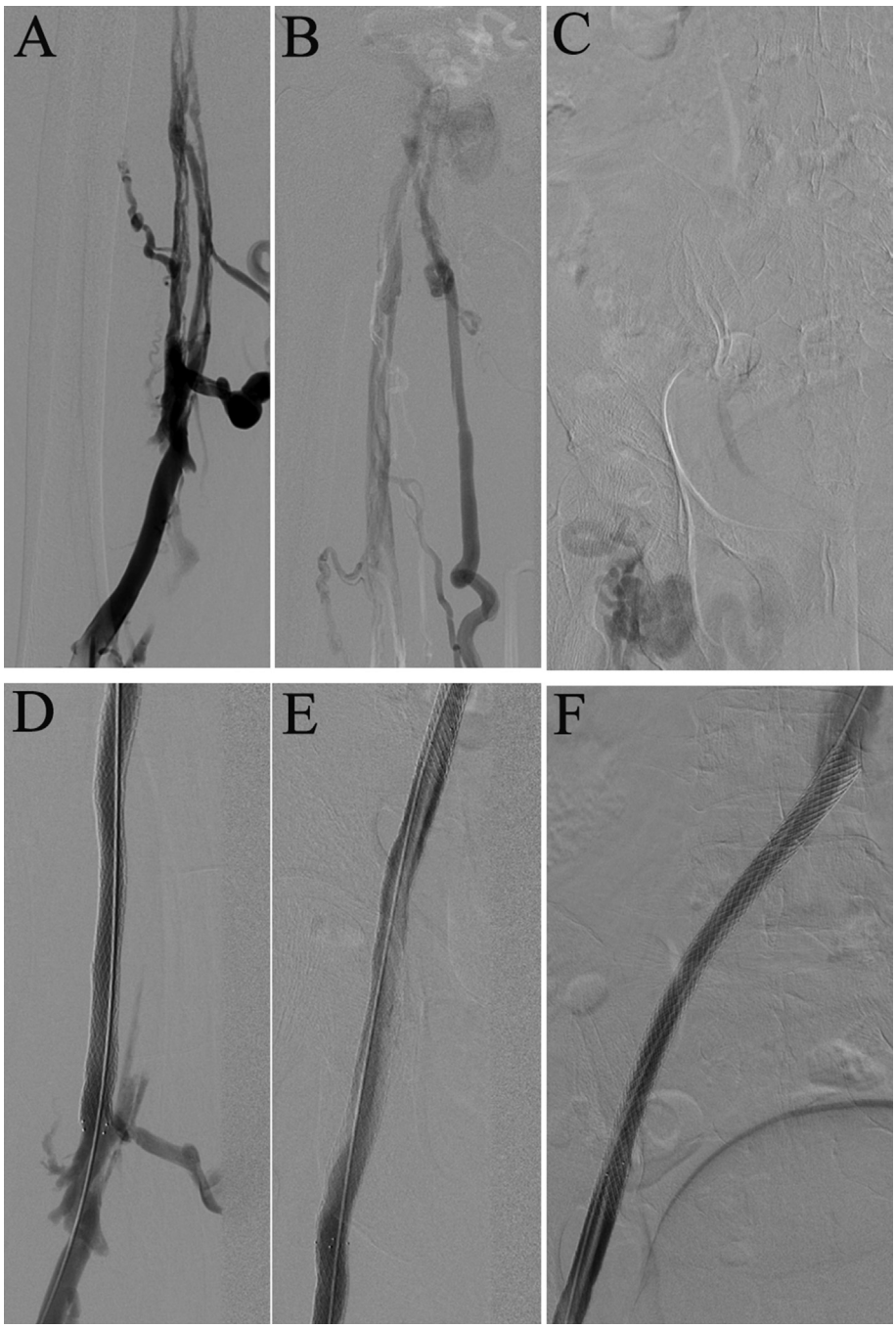

Figure 2. A 44 year old patient with an active ulcer in the left lower extremity was treated by endovascular stenting. The venogram shows the thrombotic lesion in the femoral vein (A,B) and the chronic post-thrombotic obstruction of iliofemoral venous segment (C). The stents were deployed in the femoral vein (D), the common femoral vein (E) and the iliac vein (F).

After the stenting procedure, all patients received 4100 IU nadroparin (Fraxiparine, GlaxoSmithKline, Brentford, UK) every 12 h for 3—5 days and a therapeutic dosage of warfarin (international normalised ratio 2—3) for at least 6 months after discharge from the hospital. Long-term warfarin was indicated for patients with thrombophilia according to the current guidelines.[9] All patients wore graduated compression stockings (30—40 mmHg) for at least 3 months.

Study definitions and follow-up visits

All patients were routinely followed up within 30 days of the procedure and were scheduled to return every 3 months during the first year after treatment and annually thereafter. Follow-up imaging was primarily performed using duplex ultrasound scanning, but some patients (approximately 20% of patients after stenting) underwent venous CT angiography or venography because the

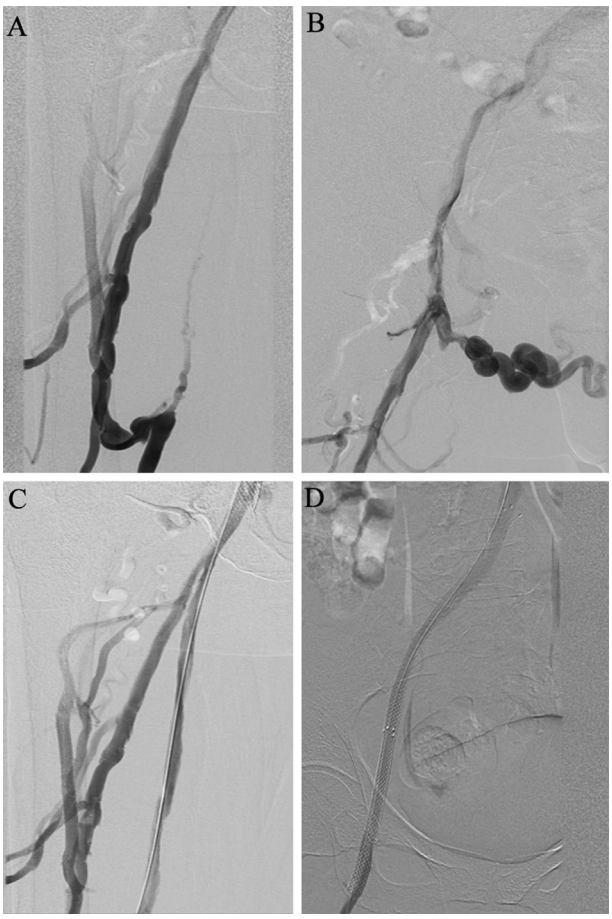

Figure 3. A 55 year old patient with severe post-thrombotic syndrome in the left lower extremity was treated by endovascular stenting. The venogram shows that the chronic post-thrombotic obstruction involved the femoral vein (A) and the iliofemoral venous segment (B). The femoral vein was recanalised by balloon angioplasty (C), and the stents were limited to deployment in the iliac vein and the common femoral vein just above the inflow from the profunda vein (C,D).

acquisition of adequate images of the iliofemoral stents was difficult with ultrasound alone. Patency was defined as recanalisation with cranial flow and <50% diameter reduction. If the patient showed recurring or worsening symptoms, venous CT angiography or venography was performed to assess the patency of the iliofemoral stents. Immediate failure was defined as an in stent thrombosis or the occlusion of the treated vein within 30 days of the intervention. Pre- and post-operative evaluations were performed including the VCSS and Villalta scores.[7,8] The degree of pain was assessed using a visual analogue scale (VAS) ranging from 0 to 10, and a VAS > 5 was defined as severe pain.[10] Local ulcer care methods that were in use pre-operatively were continued after stenting until the completion of healing. Ulcer healing was defined as the complete epithelialisation of the ulcer. The clinical severity of the swelling was scored as none (0), evening oedema in the ankle only (1), afternoon oedema above the ankle (2), or morning oedema above the ankle requiring activity change (3).[8] The patency outcome was measured per intervention related to a specific vein, since the patency rates of the iliofemoral and femoral venous segments were analysed separately. The same evaluation was performed post-operatively during each follow-up visit. The most recently completed questionnaire for each patient was used to assess the clinical outcome.

Data collection and statistical analyses

At each patient visit, all clinical data and clinical outcomes were entered into a time stamped database for subsequent analysis. Individual data were reported as the median with range (continued data) or as a proportion (categorical data). The differences between the two groups were compared using the Student *t* test for continuous variables and the Fisher test for categorical variables. The primary and secondary patency rates and the cumulative rate of ulcer healing were estimated using the Kaplan—Meier method, and the log-rank test was used to discriminate between the Kaplan—Meier curves. SPSS version 22.0 (SPSS, Inc., Chicago, IL, USA) was used for the statistical analyses. A p value $< .05$ was considered statistically significant.

RESULTS

Patient population

During the study period, 761 patients underwent attempted endovascular stenting of the iliofemoral venous segment, and a total of 114 limbs in 114 patients with severe PTS were including in the present study (Fig. 1). In the FV-S group, 45 limbs were treated with combined iliofemoral stenting and femoral stenting. In the FV-A group, 69 limbs were treated with iliofemoral stenting and balloon angioplasty in the femoral segment. The presented symptoms, demographics, clinical stage of CEAP classifications, VCSS score, and Villalta score were similar between the groups (Table 1). All patients in the present study had a patent

Table 1. Baseline patient demographics and pre-operative clinical characteristics in the two groups.

Characteristic	FV-S group (45 patients)	FV-A group (69 patients)	*p*
No. of limbs	45	69	—
Left side, n (%)	40 (89%)	57 (83%)	.36
Male, n (%)	26 (58%)	41 (59%)	.86
Age, median, years	47 (31—80)	50 (28—79)	.45
DVT history, median (years)	8.3 (2—12)	7.1 (2—11)	.12
BMI, median (range)	22.6 (17.1—26.6)	21.3 (18.6—28.2)	.23
Pain score, median (range)	4 (1—8)	4 (1—7)	.13
Severe pain, limbs n (%)	16 (36%)	28 (41%)	.59
Swelling score, median, range	3 (1—3)	3 (1—3)	.24
Severe swelling, limbs n (%)	33 (73%)	54 (78%)	.55
GSV occlusion, limbs n (%)	4 (9%)	4 (6%)	.71
VCSS, median (range)	21 (5—32)	19 (4—29)	.11
Villalta score, median (range)	18 (4—30)	19 (3—28)	.48
Clinical classification			
C4	13 (29%)	21 (30%)	.23
C5	9 (20%)	12 (18%)	.73
C6	23 (51%)	36 (52%)	.91

BMI = body mass index; DVT = deep vein thrombosis; SD = standard deviation; VCSS = Venous Clinical Severity Score.

profunda vein, but 9% (4/45) and 6% (4/69) of patients had an occluded great saphenous vein in FV-S and FV-A groups ($p = .71$), respectively.

Immediate outcomes

The immediate outcomes, including acute in stent thrombosis, are shown in Table 2. In the FV-S group, there were 11 limbs and seven limbs with acute in stent thrombosis occurring in the femoral and iliofemoral venous segments, respectively. In the FV-A group the numbers were 48 limbs and eight limbs, respectively. All limbs with in stent thrombosis were successfully treated by catheter directed thrombolysis in both groups. The rate of immediate failure of the stented iliofemoral vein was similar in the FV-S and FV-A groups (16% vs. 12%, respectively, $p = .54$), but patients in the FV-S group had experienced a lower rate of immediate failure in the femoral segments (24% in FV-S group vs. 70% in FV-A group, respectively, $p < .001$).

Stent patency

During the median follow-up of 22 months (1–48 months), loss of patency in the iliofemoral stent occurred in 34 limbs. Occlusion occurred in 15 limbs and 19 limbs in the FV-S and FV-A groups, respectively. The frequency of occlusion in the iliofemoral venous segment was similar between groups (33% in the FV-S group vs. 28% in the FV-A group, $p = .54$). Kaplan–Meier survival curves showed that the two groups had a similar cumulative primary iliofemoral stent patency rate at one year (82% in the FV-S group vs. 87% in the FV-A group, $p = .77$) and at three years (55% in the FV-S group vs. 52% in the FV-A group, $p = .71$) (Fig. 4). The cumulative secondary patency rate of the iliofemoral stents at the 3 year follow-up visit in the FV-A group (85%) was not significantly greater than that in the FV-A group (77%, $p = .32$).

In the FV-S group, the incidence of occlusion on the femoral stents at 3 months and 6 months was 69%, and 89%, respectively, while in the FV-A group, 97% of all FV segments recanalised by balloon angioplasty occluded within 6 months of the procedure. All treated femoral segments in both groups were occluded within 1 year.

Table 2. Immediate results within 30 days post-operatively in the two groups.

Characteristic	FV-S group (45 limbs)	FV-A group (69 limbs)	*p*
IFV in stent thrombosis, n (%)	7 (16%)	8 (12%)	.54
FV occlusion, n (%)	11 (24%)	48 (70%)	<.001
Complete relief of severe pain, n (%)	7 (44%)	12 (43%)	.95
Pain score, median, (range)	2 (1–5)	2 (1–5)	.44
Complete relief of severe swelling, n (%)	11 (33%)	17 (32%)	.86
Swelling score, median (range)	2 (1–3)	2 (1–3)	.46
Ulcer healing, n (%)	11 (48%)	14 (39%)	.50
VCSS, median (range)	14 (6–20)	15 (7–19)	.29
Villalta score, median (range)	16 (4–28)	14 (3–26)	.28

FV = femoral vein; IFV = iliofemoral vein; VCSS = Venous Clinical Severity Score.

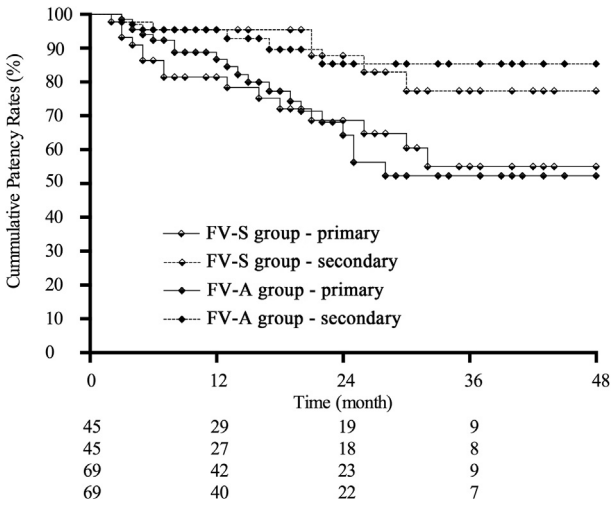

Figure 4. Cumulative primary and secondary patency rates of the iliofemoral stent in the FV-S (n = 45 limbs) and FV-A groups (n = 69 limbs). The lower numbers represent the limbs at risk at each time interval (all standard errors of the means were <10%).

Clinical outcomes

During the follow-up period, the median Villalta score decreased from 18 and 19 pre-procedure to 8 and 7 post procedure in the FV-S and FV-A groups, respectively (see Table 3). There were 16 limbs and 28 limbs with severe pain in the FV-S and FV-A groups, respectively, and the cumulative rate of complete relief was 81% and 81% (see Table 3). The median VAS score decreased from 4 pre-procedure to 2 post procedure in both groups (see Table 3). Severe swelling (Grade 3) was present in 33 limbs in the FV-S group and in 54 limbs in the FV-A group, and the cumulative relief rate was 67% and 70% in the FV-S and FV-A groups, respectively (see Table 3). Active ulcers were present in 23 limbs (FV-S group) and 36 limbs (FV-A group), and the cumulative recurrence free ulcer healing rates were 76% and 83% at 1 year and 61% and 61% at 3 years in the FV-S and FV-A groups, respectively (Fig. 5). All of these clinical outcomes were similar between the two groups.

DISCUSSION

This study has demonstrated that iliofemoral stenting, with either concomitant femoral stenting or balloon angioplasty

Table 3. Clinical outcomes at a median of 22 months (1–48 months) of follow up in the two groups.

Characteristic	FV-S group (45 limbs)	FV-A group (69 limbs)	*p*
Complete relief of severe pain, n, %	13 (81%)	25 (81%)	.46
Pain score, median (range)	2 (1–5)	2 (1–5)	.41
Complete relief of severe swelling, n, %	22 (67%)	38 (70%)	.56
Swelling score, median (range)	1 (1–3)	1 (1–3)	.56
Ulcer healing, n (%)	17 (74%)	29 (81%)	.55
VCSS, median (range)	10 (2–20)	9 (3–17)	.18
Villalta score, median (range)	8 (2–14)	7 (2–12)	.24

VCSS = Venous Clinical Severity Score.

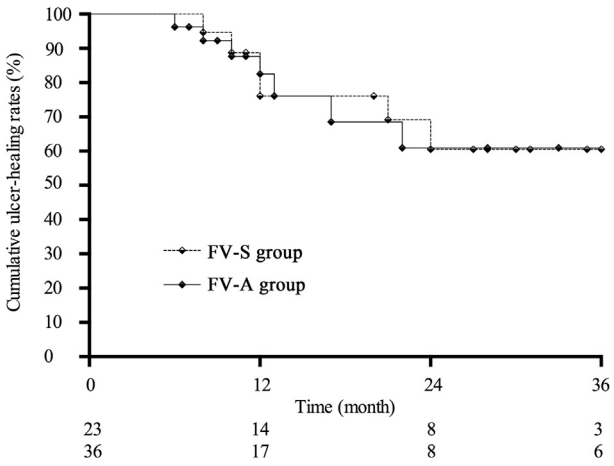

Figure 5. Cumulative ulcer healing rates in patients with venous ulcers after stenting in the FV-S (n = 23 limbs) and FV-A groups (n = 36 limbs). The lower numbers represent the limbs at risk at each time interval (all standard errors of the means were <10%).

alone, in patients with severe PTS has a high level of improvement in clinical symptoms with acceptable short-term patency rates for the iliofemoral stent. Both approaches provide equivalent measures of immediate symptom relief and short-term stent outcomes after treatment. However, ulcer free survival and other objective metrics, such as complete pain relief and the Villalta score, are not improved by combining iliofemoral stenting with femoral stenting compared with iliofemoral stenting with femoral balloon angioplasty alone.

An increasing number of patients with multi-segment venous disease and more complicated venous lesions are currently being treated, ranging from the FV to the iliac vein and the inferior vena cava.[1–3,11–13] Endovascular stenting was reported to be favourable in treating chronic post-thrombotic obstructive lesions, with a high technical success rate, effective symptom relief, low rate of procedure related adverse events, and acceptable patency rates.[1–3] These results support the increasing role of endovascular stenting as a first line modality to treat severe PTS.[4] The iliofemoral venous segment is the common outflow tract of the lower extremity. Owing to the poor collateral potential in this venous segment, chronic post-thrombotic obstruction results in more severe symptoms and a higher prevalence of PTS than lower segmental obstructions, such as that in the FV, popliteal vein, and tibial veins.[14] Therefore, most studies only report the results of stenting for the iliofemoral venous segment.[6,15–19] Unlike the present study, few have evaluated the potential impact of the addition of femoral stenting or angioplasty of an obstructed FV to improve inflow to the iliofemoral stent.

Sufficient inflow into the iliofemoral stent system is essential for preventing early in stent thrombosis and may subsequently play an important role in preserving stent patency in the long-term.[20,21] Therefore, it was presumed that stent placement or angioplasty of an obstructive FV would improve the patency rate of the iliofemoral stent. However, comparing the results described in previous reviews,[2,3,22] the concomitant FV disobliteration in the present study did not significantly affect the primary and secondary patency rates of the iliofemoral stents. The primary and secondary patency rates at 3 years were 55% and 77%, and 52% and 85% in FV-A and FV-S groups, respectively. The patency rates after successful iliofemoral vein stenting have been reported to be worse in patients with post-thrombotic obstruction in both the FV and profunda vein.[6,23] As shown in this study, the FV appears not to be decisive in determining stent outcome after iliofemoral stenting in patients with extensive iliofemoral and femoral obstruction with a patent profunda vein, which appears to be a more important source of inflow into the stented common FV. Additional inflow may also arise from axial collaterals not visualised appropriately. In this situation, the obstructed FV should not be treated.[24] Neglén et al.[25] also thought that the blood flow from a patent profunda vein appeared to provide sufficient inflow into the iliofemoral stent, and the iliofemoral stent could be placed into the profunda vein if the FV was occluded.

As previously reported, balloon angioplasty alone has been shown to be insufficient in the venous system.[26] In the present study, patients with FV angioplasty alone had more frequent early occlusion than those with femoral stent placement (70% vs. 24%, respectively, $p < .001$). This observation supports the known fact that balloon angioplasty alone frequently fails and stenting of a venous obstruction is mandatory.

Iliofemoral stenting below the femoral confluence into the FV jailed the profunda vein inflow, which would be expected to lead to a worse patency rate of iliofemoral stent. However, this was not observed in the present study. As recently reported,[27] endophlebectomy of the common FV may have to be combined with iliofemoral stenting in cases with obstructed inflow from the femoral and profunda veins. However, these hybrid procedures were reported to have lower long-term stent patency, a high rate of complications, and frequent re-interventions. The main causes and mechanisms of venous stent occlusion are not yet known. Venous stent occlusion appears to be caused by a recurrent thrombotic event rather than slowly developing stenosis in the stent.[28] Fortunately the profunda vein stayed patent despite being jailed and provided inflow into the iliofemoral stent, despite occlusion of the FV. One explanation is that deep venous thrombosis rarely occurs in the profunda FV.[29]

There are limitations to the study. It is a retrospective study of single institution registry data from two relatively small groups of patients. The clinical results may be affected by lower limb reflux, which was not identified or assessed haemodynamically. The study mainly examined femoral and profunda vein patency as an inflow source to the stent system; however, axial and other collaterals may contribute. There is presently no method to adequately measure the outflow of the lower limb into the common FV segment.

Treatment of FV obstruction during stent placement of post-thrombotic iliofemoral vein obstruction may be considered to improve the inflow to the stent system. However, adjunctive contiguous femoral stenting or

angioplasty of the obstructed FV with a patent profunda vein does not appear to improve clinical and iliofemoral stent outcomes in patients with severe PTS. In this situation, extended stenting peripheral to the femoral confluence cannot be recommended.

CONFLICT OF INTEREST

None.

FUNDING

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