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Stent extension into a single inflow vessel is a valuable option after endophlebectomy

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Abstract

Background: Venous stenting with an endophlebectomy and arteriovenous fistula can be performed in patients with extensive post-thrombotic changes. However, these hybrid procedures can induce restenosis, sometimes requiring stent extension, into a single inflow vessel. This study investigates the effectiveness of stenting into a single inflow vessel.

Methods: All evaluated patients had temporary balloon occlusion of the arteriovenous fistula to evaluate venous flow into the stents. When stent inflow was deemed insufficient, AVF closure was postponed and additional stenting was performed. Patency rates and clinical outcomes were evaluated.

Results: Twenty-four (38%) of 64 patients had additional stenting. The primary, assisted primary and secondary patency were 60 %, 70% and 70% respectively. Villalta score reduced by 6.1 points ($p < 0.001$), and venous clinical severity score by 2.7 points ($p = 0.034$).

Conclusion: Stenting through the femoral confluence into a single inflow vessel is a feasible bailout option if primary hybrid intervention fails with relative high patency rates and clinical improvement.

Keywords

Chronic venous disease, endovenous technique, post-thrombotic syndrome, venous obstruction, venous thromboembolism

Introduction

Percutaneous transluminal angioplasty (PTA) with venous stenting is a procedure that is gaining increasing interest in the treatment of patients with iliofemoral deep venous obstruction.[1] This technique shows promising clinical results, excellent patency rates, and low morbidity and mortality.[2–7] However, successful endovascular treatment in patients with post thrombotic trabeculations and synechiae below the level of the femoral confluence remains a subject of debate and is not routinely performed.[8,9]

Sufficient venous inflow from infra-inguinal vessels (i.e. the femoral vein, FV, and deep femoral vein DFV) plays an important role in patency and clinical improvement. Previous literature findings show reduced patency and subsequently less favorable clinical outcome, whenever inflow is inadequate.[9,10]

However, accurate quantification of inflow and outflow at the level of the common femoral vein (CFV) is currently not possible. Therefore, patient exclusion for an endovascular procedure is usually based on signs of post-thrombotic scar tissue through the CFV confluence, identified on duplex ultrasound (DUS), magnetic

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resonance venography (MRV) or venography with or without intravascular ultrasound (IVUS).[11–14] Nevertheless, venous stenting in these patients can still be performed in combination with endophlebectomy and the creation of an arteriovenous fistula (AVF), i.e. a hybrid procedure.[14–18] Recurrent stenosis in the CFV after hybrid procedures remains an issue in maintaining long-term stent patency and clinical success. Likely, this is a multifactorial process partly due to per-operative vein wall injury, increased thrombogenicity, vein compression due to surrounding scarred tissue and AV- fistula flow. Because of recurrent restenosis, patients require re-intervention and stent extension beyond the endophlebectomy area, typically into a single inflow vessel.

Interestingly, most guidelines discourage stenting below the inguinal ligament, more specifically the femoral confluence.[8,19] This might partly be because of the presumed risk of stent related complications, i.e. fracture or kinking. Though, first experience with dedicated venous stents highlighted some favorable characteristics, which might eliminate this reason to refrain from distal stenting.[14] Moreover, after failure of primary surgical treatment, the only available option left may be distal stent extension. Thus, the aim of this study was to investigate whether secondary venous stenting into one inflow vessel caudal to the CFV is feasible and clinically effective after primary hybrid deep venous recanalization fails.

Methods

We retrospectively analyzed all patients with venous hybrid interventions performed between July 2013 and July 2015. This study included 64 limbs of 61 patients, treated primarily by a hybrid procedure at the Maastricht University Medical Centre. All patients were analyzed preoperative by DUS and MRV to locate and assess the severity of obstructions or stenosis. All patients suffered from iliofemoral deep venous obstruction with extension of post-thrombotic vein damage below the femoral confluence and significant complaints interfering with daily activities. Patients with less than 12 months postoperative follow-up were excluded.

Baseline characteristics of all patients were collected and consisted of sex, age, occurrence of deep venous thrombosis (DVT), superficial and deep venous treatment history, Venous Clinical Severity Score (VCSS), Villalta score, and the anamnestic assessment of venous claudication. Venous claudication was scored as being present or absent. Only when patients experienced onset or worsening of pain during ambulation and specifically exercise like climbing the stairs or performing sports it was scored as being present. This pain subsided during rest, especially when sitting or lifting the leg. Venous claudication was referred to as the most important complaint to treat patients.

Hybrid procedure

Patients were recanalized, received one or multiple stents, an endophlebectomy and an AVF. This procedure has been described in detail before but will be explained briefly.[10,20] All hybrid procedures were performed under general anesthesia and full anticoagulation. Venous access was acquired through ultrasound-guided puncture of the ipsilateral femoral vein and/or right jugular vein. After successful guidewire and balloon-recanalization, the common femoral vein was opened longitudinal and the intraluminal synechiae were carefully removed. The venotomy was closed by primary closure or patch-plasty and a 6 mm polytertafluoroethylene AVF was created between the common femoral vein and common femoral artery to reduce the risk of early stent thrombosis.

Hemodynamic evaluation and endovascular stent extension

The long-term changes caused by an AVF are still unknown. Possible complications might be intimal hyperplasia due to shear stress or cardiac overload.[21,22] Therefore, all patients were planned for endovascular occlusion of the AVF six weeks to three months after the intervention. Temporary balloon occlusion of the AVF was performed to evaluate venous outflow of the leg. After contralateral common femoral artery (CFA) access, a 5F 55 cm sheath was positioned into the ipsilateral CFA, thereafter the AVF loop was catheterized and a 6×20 mm non-compliant balloon (Powerflex, Cardinal Health/Cordis, USA) was positioned inside the AVF. With the balloon occluding the AVF, an angiography was performed through the balloon-catheter lumen. In case spontaneous venous flow was deemed sufficient, the AVF was closed with an Amplatzer plug (St. Jude Medical, Plymouth, MN, USA). Based on our six-year experience, sufficient inflow was scored as an arbitrary cutoff of contrast washout of 4 seconds. When flow was deemed insufficient, the AVF was not closed. An ascending venography, with contrast administration from the foot veins, was performed to identify the major outflow veins and possible alternative routes via collaterals. Additional stenting with a dedicated venous stent (Sinus Venous, Optimed, Optimed GmbH) was performed into the vessel below the sapheno-femoral junction with highest quality and flow, i.e. the dominant inflow vessel and the AVF was not closed. This dominant inflow vessel was referred to as the 'target vessel' (Figure 1). Patency, complications,

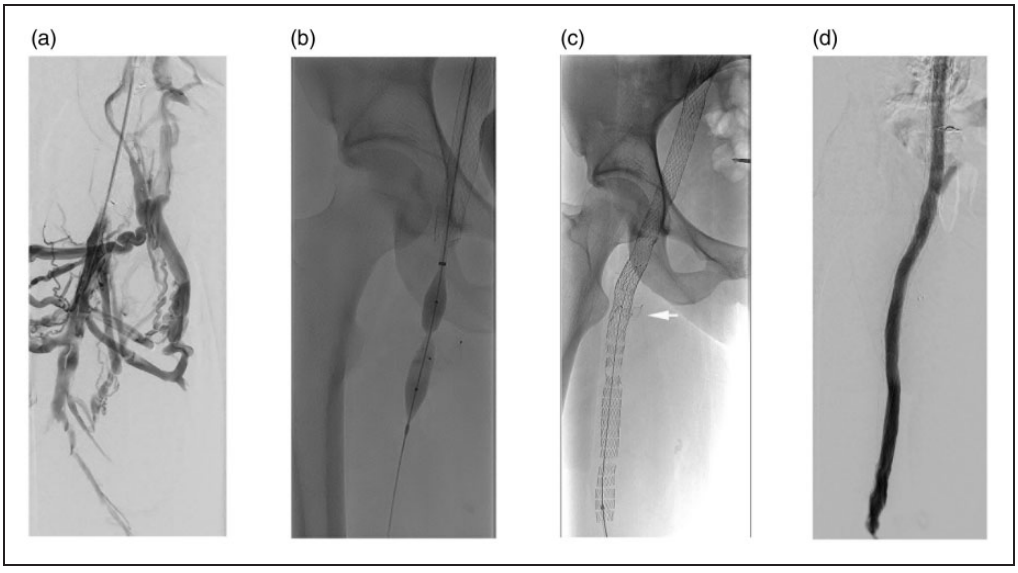

Figure 1. Example of recanalization, balloon occlusion and plug occlusion of AV-fistula. (a). After retrograde recanalization from jugular access angiography from the profunda femoral vein shows occlusion of the CFV and an extensive collateral venous network. (b). High-pressure PTA (up to 30 Atm.) with a diameter of 12 mm was necessary to provide enough space for the stent to deployed. (c). Spot image showing a 12x150 mm sinus Venous stent (Optimed GmbH, Ettlingen, Germany) in position. The 8 mm Amplatzer plug (arrow) placed during an earlier procedure occludes the AV-fistula. Notice the two gaps in the distal stent segment, caused by suboptimal deployment from the jugular approach. (d) However, no residual stenosis was seen and flow was deemed excellent on completion angiography.

VCSS and Villalta score were analyzed 12 months after additional stenting.

Statistics

All normally distributed continuous data are presented as average with their standard deviation. Non-normally distributed data are presented as median values with inter quartile ranges. Categorical data are shown as frequencies and percentages. A $p \leq .05$ was considered statistical significant.

Paired *T*-tests were used to analyze the difference in clinical scoring before and after treatment. Kaplan–Meier survival estimation was used to calculate patency rates. Statistical analysis was performed with IBM SPSS version 23.0 software for Windows (IBM Corporation, Armonk, NY, USA), survival analysis was performed with Graph Pad Prism 5.01 (GraphPad Software, Inc. La Jolla, USA).

Results

Demographics

In total, 64 limbs were treated by PTA, stenting and endophlebectomy. In 38 limbs (59.4%), the balloon occlusion test showed insufficient spontaneous venous inflow. Six out of these 38 limbs did not experience any clinical complaints, while eight had no adequate calibre target vessel suitable for stent extension. In all of them, a conservative management, i.e. compressive stockings and anticoagulation, was maintained. Twenty-four patients (38%) did experience complaints of heaviness or leg swelling and had one dominant inflow vessel at venography. Additional stenting in the target vessel was successfully performed in all of them.

Four of these patients were lost to follow-up and were excluded from further analysis. A total of 20 limbs in 20 patients could be included. Median follow up was 14 months (IQ range 12–21). Demographics of the included patients are shown in Table 1. Of all included patients with a median age of 41 years (IQR 26–55), 70% were female. In 10 patients (50%), thrombophilia testing was performed of which 60% had a positive result, mainly indicating Factor V Leiden. Since most patients were already on coumadin therapy when presenting at our outpatient clinic, it was not possible to receive reliable results regarding thrombophilia tests. Moreover, it is not proven that those patients with positive thrombophilia test have higher DVT recurrence rates and as a result no additional tests were performed.[23]

A median stent length of 4.5 cm (2.25–10 cm) was deployed in the additional procedure.

Clinical scoring

Tables 1 and 2 show clinical scoring before first intervention and after treatment. Statistically significant

Table 1. Demographics of patients.

Demographics			Percentage	Based on no. of patients
Age (year) (median IQR)		41 (26-55)		20
Females (*N*)		14	70	20
DVT	left	14	70	20
	right	1	5	20
	Bilateral	5	25	20
Trombophilia positive		6	60	10
VC		18	90	20
VCSS score (Mean ± SD (min-max)		8.5 ± 3,2 (3–16)		13
Villalta score (Mean ± SD (min–max)		11 ± 3.9 (4–18)		13
Abdominal collateral		17	85	20
CEAP highest C				20
C0		2	10	
C1		5	25	
C2		2	10	
C3		3	15	
C4		7	35	
C5		0	0	
C6		1	5	

Yr: year, N: number, DVT: deep venous thrombosis, VC: venous claudication, VCSS: venous clinical severity score.

Table 2. Post-interventional scores.

	Outcome		Based on number of patients	*p* Value
Side (*N*, %)	Left	17 (85%)	20	
	Right	3 (15%)		
	Bilateral	0		
VC		1	19	
VCSS (Mean ± SD (min–max)		5.8 ± 3.2 (0–11)	13	$p = 0.034$
Villalta (Mean ± SD (min–max)		4.9 ± 2.6 (1–12)	13	$p < 0.001$
Complication (*N*,%)	Minor	3 (15%)	20	
	Major	7 (35%)		
Reintervention (*N*, %)		5 (25%)	20	

Note: VCSS and Villalta post interventional scores are compared to pre interventional scores. A *p*-value of ≤ .05 was considered statistical significant. *N*: number, VC: venous claudication, VCSS: venous clinical severity score.

improvement was seen in Villalta scores and VCSS scores. VCSS was analyzed pre- and post-treatment in 13 patients and showed a mean decrease of 2.7 points ($p = 0.034$). Villalta was scored pre- and postoperative in 13 patients and showed a significant mean decrease of 6.1 points ($p < 0.001$).

Venous claudication was scored pre- and postoperative for all patients and was present in 18 (90%)

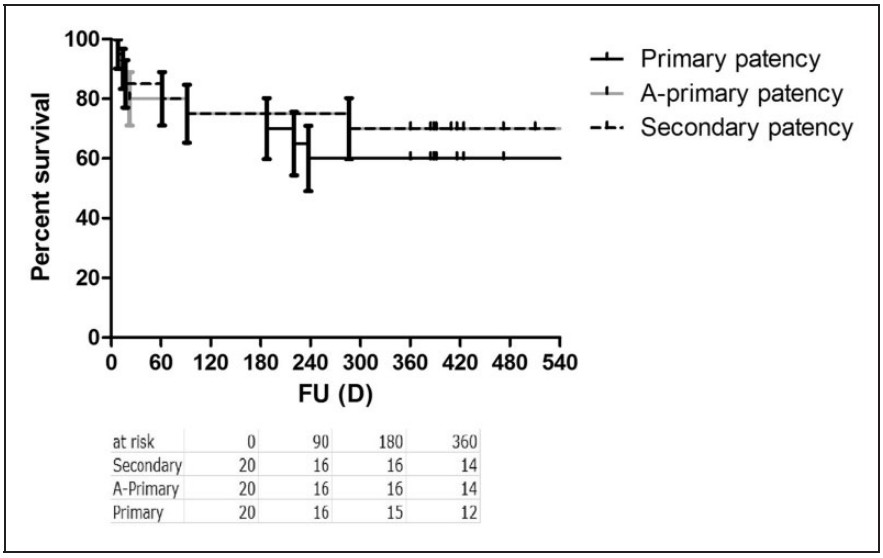

Figure 2. Kalpan–Meier survival analysis.

subjects before treatment. After treatment, there was absence of claudication in 17 (90%) patients.

Outcome

Figure 2 shows the Kaplan–Meier estimation graph of all treated patients. Patency rates were calculated starting from stenting into the target vessel. Seven (35%) patients received additional stenting into the FV and 13 (65%) patients into the DFV.

Primary patency of the entire stented tract at 12-month follow-up was 60%. Assisted primary patency and secondary patency were 70% at 12-month follow-up. Five patients (25%) had additional interventions after stenting into the target vessel. Primary patency was lost in four of them due to stenosis of the iliac tract. Two patients (10%) were only treated by PTA and two subjects (10%) received new stents of their previously stented iliac tract. One patient (5%) presented with loss of primary patency due to acute occlusion of the stents for which thrombolysis was started; however, this ultimately did not result in long-term patency.

Seven additional patients (35%) presented with occlusion of the targeted stented tract which resulted in loss of secondary patency and was scored as a major complication. However, the iliac stents were patent in all of them and thus did not result in loss of secondary patency of the whole stented tract.

One patient (5%) experienced fever due to superficial cutaneous infection of the puncture location for which oral antibiotic treatment was given, related to as minor complication. Whenever a PTA was deemed necessary, this was defined as minor complication as well. In six patients (30%), the AVF closed spontaneously, in six patients (30%) the AVF remained patent so far but will be closed in the follow-up period. In the remaining eight (40%) patients, the AVF was closed after a median of 160 days.

Discussion

In this study, we describe the results of bailout stent extension after failed primary hybrid recanalization of chronic iliofemoral obstructions. The moderate to good outcome of this "single inflow vein stenting" might nuance the debate about stenting below the CFV. Although some guidelines mention that stenting below the inguinal ligament should be avoided, general experience described in recent literature supports stenting into the CFV when necessary, since the main goal is to completely treat all diseased vein segments proximal to the CFV confluence. In contrast, primary stenting into one inflow vessel distal to the CFV confluence, i.e. DFV or FV, is currently not supported in the literature. Therefore, we usually offer a hybrid procedure to patients with post-thrombotic trabeculation distal to the level of the CFV confluence (Figure 1). This hybrid procedure, including percutaneous stenting and additional endophlebectomy, has shown favourable secondary patency between 72% and 90% and clinical decrease of Villalta with a median of 7 points.[16,17,20,24] However, patient selection for this procedure remains an important topic since complications like lymphorrhoea and wound infections can occur in an amount of subjects. This should be thoroughly discussed with a patient before the first intervention in which benefits of the intervention and morbidity after intervention should be weighted against each other. Moreover, in patients with hybrid interventions,

recurrent obstruction at the level of the CFV is an issue in which the only valuable option to maintain stent patency is to perform stent extension into an adequate inflow vein. We demonstrated that stenting into such a target vessel below the femoral confluence resulted in a secondary patency of 70% after 12 months. This seems surprisingly high for a bailout procedure in patients in which the primary hybrid intervention failed, which in fact, shows a lower overall patency.

Nevertheless, there is no accurate data to which our results can be compared, since primary stenting into a single vein below the CFV confluence has not been described before. Therefore, our intention was to describe the technical aspects of this endovascular solution and assess feasibility and effectiveness treating recurrent obstruction after endophlebectomy of the CFV.

We critically evaluated the cases in which patency was lost after stent extension. In all of them, stent-related complications were ruled out. The possibility of kinking, residual or recurrent stent compression was eliminated by evaluating the duplex images. The fact that dedicated venous stents were used with high flexibility and radial forces might be beneficial in this case. Postoperative anticoagulation might have been a critical factor. Although we have a standard postoperative regimen of six months coumadin therapy with a target INR level of 3–4, anticoagulation therapy is monitored and regulated by a separate National institution and it cannot be completely ruled out that suboptimal anticoagulation therapy influenced primary and secondary patency.

Another reason for stent occlusion might be impaired flow through the stented segments, caused by insufficient size or quality of the inflow vessel. In many patients with extended post-thrombotic disease, significant blood volume is forced through multiple competitive collateral veins. Therefore, less blood is reaching the CFV through the diseased FV and DFV segments. Subsequently, this altered venous outflow tract is not reaching the stents, reducing the amount of blood flow needed to maintain stent patency.

The main reason patients undergo deep venous reconstruction is the relief of complaints. The clinical success of treatment is specifically evaluated by comparing VCSS, Villalta and venous claudication scores before and after treatment. Villalta scale and venous claudication significantly improved after stent extension into a single inflow vein. More importantly, patients with stent re-occlusion did not experience worsening of their complaints compared to the situation before stent extension, expressed in Villalta and VCSS scores and more specifically the venous claudication score. This might be explained by the pre-existent collateral network, which is unlikely to be harmed by stent extension. Moreover, did all patients with stent occlusion have a patent iliac stent tract. In our experience, occlusion of the iliac tract can result in more debilitating complaints than occlusion in the distal part of the leg. This could have been found due to the lesser capability of collateral formation in the more central veins compared to the veins in the lower extremity.

As a possible limitation of this study it should be mentioned that the follow-up period is relatively short which could result in lower patency rates on the long term. With the current possibility of IVUS imaging, this could, however, provide benefit in detecting stenosis at an earlier term. With a follow-up protocol of 10 years minimum, long-term results can be provided in future research.

Future discussions might further address whether primary stenting into a single inflow vein could be a first choice treatment instead of an endophlebectomy. Apart from patency, the main advantage of this endovascular strategy would be the reduction of surgery related complications like wound infections and lymphorroea. Previous research from our group demonstrated the occurrence of lymphorroea or wound infections in about one-third of all patients with endophlebectomy and AV fistula. Due to this high possible morbidity, it would be a great advantage to opt for primary stent placement into a target vessel in a selected group of patients. Nevertheless, it seems unlikely that all patients can be treated without an endophlebectomy, since stenting into a relatively clean vein segment is a very important factor in the management of deep venous obstructions.[8,9] In patients with extensive post-thrombotic changes in all potential target vessels, endophlebectomy might remain the best option. Furthermore, the high success rate of stent extension as a bailout procedure cannot be extrapolated to primary stenting into one inflow vein. The iliofemoral stents placed during the hybrid procedure are more or less incorporated in the vein wall at the time of stent extension. This might have an effect on thrombogenicity compared to primary stenting. Primary stenting into a dominant inflow vessel may have a higher thrombosis risk due to a relatively low flow rate and an extremely long stent length. Beyond assumptions, it would be sensible to prospectively compare the best possible endovascular option with a hybrid intervention in selected comparable patients.

Conclusion

Stenting below the femoral confluence into a single inflow vessel is a feasible bailout option if primary hybrid intervention fails. Future research should determine if a sole endovascular procedure, with primary stenting into a single inflow vessel below the femoral

confluence might be a valuable alternative for CFV endophlebectomy.

Declaration of Conflicting Interests

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Ethical approval

This study was approved by the medical ethical committee of Maastricht University (reference number METC 16-4-126).

Authors' contribution

TV took part in the study design, ethical approval, data collection, data analysis, and writing; RK and MW contributed to the study design, data analysis, and critical review in writing; JL took part in critical review, data analysis and writing; CW and RG contributed to the study design, data collection, critical review, data analysis and writing. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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