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Endovascular Management of Chronic Disabling Ilio-caval Obstructive Lesions: Long-Term Results

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Abstract *Objective:* To report the long-term results of stenting for chronic ilio-caval obstructive lesions.
Material and methods: From January 1996 to January 2008, 89 patients (72 women, 17 men; median age 43 years) were admitted for endovascular treatment of chronic disabling non-malignant obstructive ilio-caval lesions. Patients were classified as C2 in 15 cases, C3 in 59, C4 in seven, C5 in two and C6 in six. Median preoperative venous disability score (VDS) and venous clinical severity score (VCSS) were 2 and 9, respectively. Aetiology was primary in 52 patients, secondary in 35 and congenital in two. Lesions were bilateral in seven cases, eight patients had inferior vena cava (IVC) involvement and 18 had common femoral vein (CFV) obstructive lesions. Complete occlusion was found in 30 cases.
Results: Technical success was achieved in 98%. The median hospital stay was 2 days. During a median follow-up of 38 months (range: 1–144 months), one patient died and five cases of thromboses occurred. Iterative stenting was performed for restenosis in six cases. Primary, assisted-primary and secondary patency rates, in terms of intention to treat, were 83%, 89% and 93%, respectively, at 3 and 10 years, with a median VDS of 1. Univariate analysis found that significant factors affecting patency were CFV involvement for primary patency and history of deep venous thrombosis (DVT) and CFV involvement for secondary patency.

The last 46 patients had statistically more severe lesions than the first 43 (higher VDS, more secondary lesions, more occlusions, more stented segments, higher length of stented vein), and in spite of which patency rates are not different.
Conclusion: Endovenous angioplasty, combined with stenting, is a sure, safe, effective and very minimally invasive technique which provides good long-term patency rates. Currently, it is recognised as the technique of choice for the treatment of ilio-caval obstructive lesions. Surgery should be proposed only in case of failure.

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Obstructive venous lesions represent a therapeutic challenge. Until the mid-1990s, they were treated medically or were proposed for surgical treatment. In a randomised prospective trial on patients with acute ilio-femoral deep venous thrombosis (DVT), Plate demonstrated that anticoagulation treatment does not protect against the onset of post-thrombotic disease and that 59% of patients had severe obstructive iliac lesions.[1] Different surgical techniques (such as Palma procedure and axial bypass) were used to treat them depending on the extent of the lesions. There are few reports with populations of more than 10 patients. Results were very variable and long-term patency was ranging between 44% and 85%.[2] Endovenous angioplasty, combined with stenting, has emerged as the method of choice for the treatment of ilio-caval obstructive lesions.[3–5] The goal of this study is to report our experience and to analyse the long-term results of stenting for chronic ilio-caval obstructive lesions.

Material and Methods

From January 1996 to January 2008, 89 patients were admitted (intention to treat) to our department for endovascular treatment of chronic symptomatic disabling non-malignant obstructive ilio-caval lesions. All patients remained disabled despite previous medical therapy, including compressive elastic stockings in all cases. Patients were not considered for endovascular approach if their life expectancy was limited to less than 5 years (malignant disease, severe chronic obstructive pulmonary disease, cardiac failure with forced expiratory volume (FEV) <35% and severe coronary disease). For treating chronic disease, no stenting was performed in pregnant patients.

There were 72 women and 17 men (female—male ratio, approximately 4:2) and their median age was 43 years (ranging from 16 to 79 years). They can be divided into two groups according to the date of treatment: 43 were treated more than 4 years earlier and 46 less than 4 years earlier (Table 1). Of the 72 women, 58 had a history of pregnancy with a median of two pregnancies per woman (ranging from 1 to 8). Eighteen patients had a history of varicose surgery, six of hysterectomy, two of urological procedures for retroperitoneal fibrosis, four of renal insufficiency (including one under haemodialysis), three of pelvic radiotherapy and one each of pelvic fracture and hepatectomy for hydatid cyst.

Moreover, 44 had previous DVT, including one portal vein thrombosis and 10 of whom also had a history of pulmonary embolism. Three of these patients had interventional therapy: one isolated *in situ* thrombolysis and two venous thrombectomy with inferior vena cava (IVC) clip insertion (including one after failure of thrombolysis). Testing for thrombophylia was performed in all patients who had previous DVT. It revealed four cases of factor V mutation, one case of factor II mutation, five cases of increased factor VIII, three deficit of S protein, one deficit of factor XII and three cases of hyperhomocysteinaemia. Moreover, one patient had autoimmune thrombocytopenia and one had platelet hyperaggregability.

All patients were symptomatic. According to the CEAP clinical classification,[6] patients were classified as C_{2S} in 15 cases, C_{3S} in 59, C_{4S} in seven, C_{5S} in two and C_{6S} in six. Most of the patients ($N = 72$) had left unilateral symptoms but the symptoms were bilateral in 15 cases and were located on the right side only in two cases. Forty-five patients had venous claudication. Moreover, 26 women suffered from pelvic congestion syndrome (patients suffering from isolated pelvic congestion syndrome ($N = 14$) were classified as C_2), including five who had previous embolisation of pelvic varices (May—Thurner syndrome was not identified at this time). Median preoperative venous disability score (VDS) and venous clinical severity score (VCSS)[7] were 2 (range: 2—3) and 9 (range: 4—25), respectively.

All patients had preoperative colour Doppler ultrasonography of the lower extremities and pelvis and computed tomographic venography or magnetic resonance venography. Currently, preoperative phlebography or iliocavography is performed only in complex cases.

According to the CEAP aetiological classification,[6] 52 were classified as primary (E_P, May—Thurner syndrome), 35 secondary (E_S, post-thrombotic disease in 30 cases and retroperitoneal fibrosis in five cases) and two congenital (E_C). Venous lesions were located on the left side in 79 cases, on the right side in only two cases, while the lesions

Table 1 Patients' data.

	All patients	>4 years	<4 years	*p*
N	89	43	46	
Median age	43	42	45	0.5322
Female/male ratio	4.2	5.1	3.6	0.512
History of DVT/PE	44 (49%)	18 (42%)	26 (56%)	0.166
Clinical status				
Symptomatic	100%	100%	100%	
Bilateral symptoms	15 (17%)	9 (21%)	6 (13%)	0.320
C_2	15 (17%)	8 (19%)	7 (15%)	
C_3	59 (66%)	29 (68%)	30 (65%)	
C_4	7 (8%)	4 (9%)	3 (7%)	0.621
C_5	2 (2%)	1 (2%)	1 (2%)	
C_6	6 (7%)	1 (2%)	5 (11%)	
Venous claudication	45 (51%)	18 (42%)	27 (59%)	0.112
PCS	26 (29%)	9 (21%)	17 (37%)	0.096
Median VDS	2	2	3	0.000331
Median VCSS	9	9	9	0.3787
Aetiology				
E_P	52 (59%)	30 (70%)	22 (48%)	
E_S	35 (39%)	11 (25%)	24 (52%)	0.01290
E_C	2 (2%)	2 (5%)	0	
Anatomic lesions				
Left side only	79 (89%)	38 (89%)	41 (89%)	
Right side only	2 (2%)	1 (2%)	1 (2%)	
Bilateral + IVC	7 (8%)	4 (9%)	3 (7%)	0.9242
IVC only	1 (1%)	0	1 (2%)	
CFV	18 (20%)	6 (14%)	12 (26%)	0.154
N segment	140	60	80	0.106
Occlusion	30 (34%)	10 (23%)	20 (44%)	0.043

DVTPE: Deep venous thrombosis; PE: pulmonary embolism; PCS: pelvic congestion syndrome; VDS: venous disability score; VCSS: venous clinical severity score; IVC: inferior vena cava; CVF: common femoral vein; RPF: retroperitoneal fibrosis.

were bilateral in seven cases and in one case an isolated IVC lesion (from the infrarenal portion to the ostia of the suprahepatic veins) was present. The IVC was involved in eight cases and the common femoral vein in 18 cases (all post-thrombotic lesions). In all, 140 ilio-caval segments were involved (one to five per patient). Thirty patients had at least one totally occluded ilio-caval venous segment (23 of post-thrombotic aetiology).

All procedures were performed in the operating room. After percutaneous venous access, an iliocavography was performed through a 5Fr sheath (Figs. 1A and 2A). If there was venous segment(s) occlusion, re-canalisation was performed using a 0.035 hydrophylic guidewire and a vertebral angiographic catheter (Fig. 2B). Then a larger sheath (9F in most of the cases) was inserted and unfractionated heparin 50 UI kg^{-1}, 500 mg of aspirin and cefamandole for infection prophylaxis were given intravenously. Balloon angioplasty was performed before deployment of self-expanding metallic stents (Wallstent, Boston Scientific-Schneider, Minneapolis, MN, USA) (Figs. 1B and 2C). If multiple stents were used, an overlapping of at least 20 mm was performed. After completion iliocavography, the sheath was retrieved and elastic stockings were applied. Postoperatively, patients received subcutaneous low-molecular-weight heparin therapy (LMWH). The treatment at discharge was initially fluindion for 6 months; since 2003, patients suffering from May—Thurner syndrome have been discharged on LMWH for 15 days, and anti-platelet drugs but those with complex lesions (post-thrombotic and re-canalisation mainly) were treated by oral anticoagulation for at least 12 months.

Follow-up

Clinical examination and duplex scanning were scheduled at 1, 3, 6 and 12 months and then annually. VCSS and VDS[7] were evaluated before surgery and during the follow-up to assess clinical results. In case of clinical recurrence of the symptoms or of restenosis at colour Doppler ultrasonography (>50% of in-stent restenosis with inflow obstruction was considered significant),[4,5] transfemoral venography was performed.

Statistical analysis

Primary, assisted-primary and secondary patency rates were calculated by using survival analysis with the life-table method. Continuous variables were analysed by Student's *t*-test and the Fisher's exact test for categorical data when comparing the two groups of patients. The log-rank test was used to compare cumulative curves. Univariate analysis of patient characteristics or technical variables was performed with Fisher's exact test or chi-square test (qualitative variables). Any variables found to be significant in univariate analysis with $p < 0.10$ were used for multivariate analysis and the measure of association was the adjusted odds ratio (OR). All statistical calculations were performed with the SPSS software package, version 15.1 (SPSS Software Inc., Chicago, IL, USA).

Results

The results are summarised in Table 2. Procedures were performed under general anaesthesia in 49 cases, local anaesthesia in 20 cases and local anaesthesia plus intravenous sedation (midazolam and sufentanyl) in 20 cases. The access was performed percutaneously in 83 patients (93%) through the femoral vein in 81 cases, the popliteal vein in one case and the obturator vein in one case. All seven patients with bi-ilio-caval lesions had bilateral femoral vein access. Surgical access was performed in six cases (Table 2). Technical success rate was 98% (93% for patients needing re-canalisation) due to re-canalisation failure in two cases (one hypoplasia and one post-thrombotic lesion with CVF involvement). In one case external iliac vein re-canalisation failed, but the common iliac vein was re-canalised by ipsilateral obturator vein access. In another case with bi-ilio-caval thrombosis, the IVC was re-canalised from the left side but performing complete re-canalisation of the right common iliac vein proved to be impossible. The right ascending lumbar vein which was dilated with multiple stenoses was stented up to the right renal vein. In all, 121 stents (12—16 mm in diameter and 40—90 mm in length) were used and the mean number of stents for treating the lesions

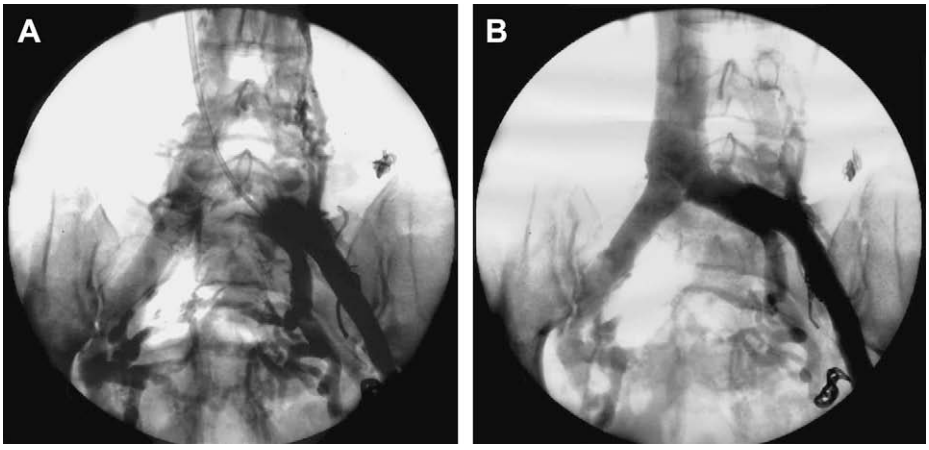

Figure 1 Angiographic view of May—Thurner syndrome. A: before stenting: important transversal and ascending collateral pathways. B: after stenting.

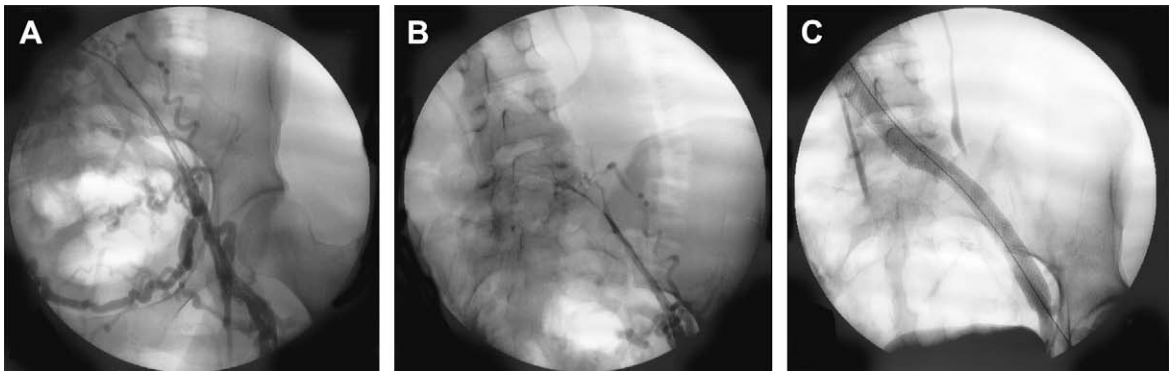

Figure 2 Left femoro-iliac re-canalisation of post-thrombotic lesions. A: after re-canalisation of the external iliac vein. B: common iliac vein occlusion. C: result after re-canalisation and stenting.

per patient was 1.3 (range: 1—5). The mean length of stented vein was 91 mm (range: 40—350 mm).

Concomitant procedures were performed in 13 patients: six left renal vein phlebography with reno-caval pull-back gradient measurement, three left ovarian vein embolisation, one IVC clip resection, two left great saphenous vein high resections (one iterative), one left great saphenous vein stripping, one left lesser saphenous vein high resection, one left medial gastrocnemian vein resection and one skin grafting (the patient had an active ulcer). Five procedural complications occurred: two stent migrations,[3] one superficial femoral artery tear which was treated percutaneously by a covered stent (Viabahn, W. L. Gore and Associates, Flagstaff, AZ, USA) and contrast extravasation in two cases of re-canalisation.

Neither perioperative death nor pulmonary embolism occurred. Five postoperative complications occurred: two thromboses after left iliac vein re-canalisation for post-thrombotic disease (both with common femoral vein involvement) treated by successful surgical thrombectomy in one case, one right hemothorax needing drainage and 2 haematomas at access site (none needed surgical treatment). The median length of hospital stay was 2 days (range: 1—14 days). Fifty-two patients were discharged with oral anticoagulation for at least 6 months and 37 were discharged with LMWH for 2—3 weeks and anti-platelet drugs for at least 1 year. Primary and secondary patency rates were respectively 96% and 97% at 30 days.

Median follow-up was 38 months (1—144) and no patient was lost. Late complications included one death at 16 months (peritoneal carcinosis caused by colic cancer) and three late thromboses (all occurred on patients with history of DVT): one at 1.5 months (successfully treated by venous thrombectomy, CVF endophlebectomy, iterative common iliac vein re-canalisation and arteriovenous (AV) fistula), one at 15 months (treated by successful Palma procedure) and one at 28 months (successfully treated by venous thrombectomy, iterative stenting and AV fistula). Restenosis occurred in six patients after a median delay of 9 months (range, 1—27 months). In five cases (all in patients with more than 4-year follow-up) restenosis were due to an underestimation of the length of vein to be stented. In one case it was due to a very short overlapping between two stents. All were successfully treated by iterative stenting. One patient had a Palma procedure 3 months later for iterative restenosis.

All patients with technical success had clinical improvement and median VDS decreased from 2

Table 2 Results.

	All patients	>4 years	<4 years	*p*
N	89	43	46	
Percutaneous access	83 (93%)	37 (86%)	46 (100%)	0.01
Technical success	87 (98%)	41 (95%)	46 (100%)	0.23
Mean stent number	1.3	1	1.4	0.303
Mean stented segments	1.3	1.1	1.5	0.027
Mean stented vein length	91 mm	72 mm	106 mm	0.004183
Stented CFV (%)	8	1	7	0.0593
Median length of stay	2 days	3 days	2 days	0.067
Median follow-up	38 M	68 M	20 M	<0.0001
Re-thrombosis	5 (6%)	2 (5%)	3 (7%)	0.99
Restenosis	6 (7%)	5 (12%)	1 (2%)	0.10
Median VDS	1	0	1	0.15
Primary patency	83% at 120 M	78% at 120 M	86% at 42 M	0.239
Assisted-primary patency	89% at 120 M	88% at 120 M	88% at 42 M	0.610
Secondary patency	93% at 120 M	90% at 120 M	97% at 42 M	0.212

VDS: venous disability score; M: months.

preoperatively to 1 (range: 0—3) at the end of the follow-up. One patient had healing of his ulcer at 1 month but the ulcer re-opened when he had thrombosis at 1.5 months; it healed after re-intervention. All other C6 patients had healing of their ulcers without recurrence. Of the 45 patients with preoperative venous claudication, all but two (one had technical failure, one re-thrombosed at day 3 and was not re-operated) showed improvement, including 31 without residual claudication. Of the 26 patients who suffered preoperatively from pelvic congestion syndrome, one had technical failure and another, despite a patent stent, showed no improvement and 23 had improvement including 15 who became asymptomatic (one poorly improved patient had subsequently left renal vein stenting for nutcracker syndrome).[8]

Primary, assisted-primary and secondary patency rates in intention to treat were 89%, 94% and 96%, respectively, at 1 year and 83%, 89% and 93% at 3 and 10 years (Fig. 3). Of the 89 patients, 43 were treated more than 4 years ago. With a median 68 months follow-up (49—144), primary, assisted-primary and secondary patency rates in intention to treat were, respectively, 86%, 93% and 95% at 1 year and 78%, 88% and 90% at 3 and 10 years. For the remaining 46 patients (less than 4 years after treatment), median follow-up was 20 months (range: 1—43 months). Primary, assisted-primary and secondary patency rates were, respectively, 93%, 95% and 97% at 1 year and 86%, 88% and 97% at 3 years. Univariate analysis performed on 22 variables found that CFV involvement was significant for primary patency although secondary patency was related to history of DVT and CFV involvement (Table 3). Multivariate analysis did not indicate any factor associated with decreased primary or secondary patency but there was a trend for CFV involvement for primary patency ($p = 0.15$, OR 7.4, 95% CI 0.47—116.7).

Table 3 Univariate analysis.

Variable	*p* value
For primary patency	
-history of DVT	0.144
-CFV involvement	0.035
-stented CFV	0.06
For secondary patency	
-history of DVT	0.023
-CFV involvement	0.049
-stented CFV	0.325

Discussion

Since its introduction in the mid-1990s, the concept of the endovascular approach for ilio-caval obstructive disease had become popular, thanks to its low invasiveness and promising initial results. Short- and mid-term efficiencies were demonstrated for patients with acute DVT as an adjunct to thrombolysis[9,10] or venous thrombectomy.[11,12]

Chronic obstructive lesions can schematically be divided into two groups: non-thrombotic iliac vein lesions (mainly May—Thurner syndrome) and post-thrombotic lesions. If both populations are treated for symptomatic and invalidating impact of the obstruction, the extension and the severity of the lesions are quite different.[13] In this report, in fact, post-thrombotic lesions represent 77% of the occlusions and all cases of common femoral vein involvement are caused by these lesions. Treatment of C2 patients can appear excessive but 14 were suffering from invalidating pelvic congestion syndrome and one had varicose recurrence after left great saphenous vein stripping.

We and others have shown that certain technical rules have to be followed in order to avoid complications and to obtain good results.[3—5,13—16] Ultrasound-guided puncture is absolutely needed for patients with lesions involving the external iliac vein and/or the common femoral vein to allow access through the femoral vein. In case of limited lesions, such as the May—Thurner syndrome, access is performed through the common femoral vein and ultrasound guidance is recommended. Treatment requires the systematic use of large (14—16 mm) and long (6 cm at least) self-expanding metallic rather than nitinol stents, protruding into the IVC with large overlapping (at least

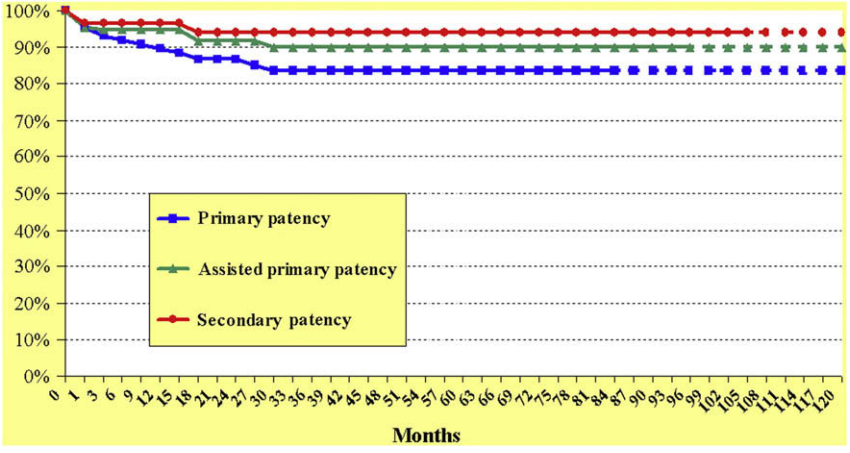

Figure 3 Cumulative primary, assisted-primary and secondary patency rates of 89 patients admitted for endovascular treatment of chronic ilio-caval occlusive disease (intention to treat). The curves are represented as dotted lines when SEM is >10%.

Table 4 Results of the published series of endovascular treatment for chronic ilio-caval occlusive disease.

	N	Post DVT	Technical success	FU	Late PP	Late SP
Nazarian et al.[19]	56		92%	NS	50% at 48 M	75% at 48 M
Blatter and Blatter[20]	14		85%	15 M	79% at 15 M	79% at 15 M
Razavi et al.*[21]	17		88%	19 M	80%	87%
O'Sullivan et al.[22]	20	0%				93.9% at 12 M
Hood and Alexander[23]	7	NS	100%	19 M	100%	100%
Te Riele et al.*[24]	9	NS	100%	9 M	78% at 9 M	
Raju et al.*[25]	104		93%	11 M	58% at 24 M	82% at 24 M
Knipp et al.[26]	58	90%	100%	NS	38% at 60 M	73% at 60 M
Oguzkurt et al.[27]	16	100%	94%	NS	72% at 48 M	75% at 48 M
Neglen et al.[15]	982	47%	NS	22 M	67% at 72 M	93% at 72 M
Hartung	89	33%	97%	38 M	83% at 120 M	93% at 120 M
>4 years	43	20%	95%	68 M	78% at 120 M	90% at 120 M
<4 years	46	45%	100%	20 M	86% at 42 M	97% at 42 M

FU: follow-up; PP: primary patency rate; SP: secondary patency rate; M: months; NS: not specified; *: Inferior vena cava involvement in all patients.

20 mm) in case of use of multiple stents. Intravascular ultrasound guidance is also recommended[5,17] and although we do not have access to this technology our results are comparable to those of the literature (Table 3). The use of this device is quite expensive but its use could have avoided some cases of restenoses in our early experience due to the underestimation of lesion length.[3]

We had previously reported treating 20 patients suffering from May—Thurner syndrome under local anaesthesia,[3] but we discontinued because they experienced very intense back pain. On the other hand, general anaesthesia is not necessary in all patients. This gave us a good reason to develop the use of local anaesthesia plus sedation (midazolam and sufentanyl). Percutaneous access, iliocavography, catheterism of the lesion and even re-canalisation, when needed, can be performed under local anaesthesia. If the lesion is significant and catheterism (and re-canalisation) is successful, sedation or general anaesthesia is given according to the extent and to the complexity of the lesions. Re-canalisation is a painless procedure and can be performed under local anaesthesia, thus helping to prevent complications (vein perforation is painful due to the course of the guidewire through the venous wall into the retroperitoneal space).

One of the main issues is postoperative treatment and there are no recommendations about it. Neglen[18] recommended the use of anti-platelet drugs exclusively. As these drugs were not shown do be efficient in preventing DVT, we prefer to use it in association with low-molecular-weight heparin for 2 weeks for non-thrombotic lesions; however, in case of re-canalisation or post-thrombotic disease, all patients were discharged under oral anticoagulation for at least 1 year. Accordingly, we had only three cases of re-thrombosis at 12 months, including two within the first week and all occurred in patients with post-thrombotic lesions with common femoral vein involvement.

Many authors have published good mid-term results in term of patency (Table 4)[15,19—27] and our long-term results show that this treatment is durable. Clinical results are also satisfactory in terms of ulcer healing (100% on six patients in this report and 58% on 148 limbs for Neglen),[15] venous claudication (95% improvement including 68% without residual claudication) and also pain and swelling, according to Neglen et al.[15] Moreover, 88% of our patients suffering from pelvic congestion syndrome were improved. Stenting had become the first-line treatment as stated at the International Summit of the 5th Pacific Vascular Symposium.[5] In our experience, median delay for restenosis or re-thrombosis was 8.2 months (range 3 days—28 months). All thromboses occurred in patients with post-thrombotic disease or history of DVT and all restenoses are due to technical errors.

We had to treat 18 patients with lesions extending down to the inguinal ligament. Of these, eight had stenting and no thrombosis occurred during the follow-up. On the other hand, 10 diseased CFV were not stented and three had re-thrombosis. Even if this is not significant ($p = 0.22$) we think that stenting of diseased CFV should be performed. According to Neglen et al.,[16] stent can be safely positioned down to the inguinal ligament without the risk of fracture or effect on patency and the result is dependent upon the aetiology and the presence or not of an occlusion.

So far, none of our patients experienced contralateral iliac vein occlusion despite all patients but nine had a left common iliac vein stent protruding into the IVC. This complication occurred in 1% of the patients in the study by Neglen et al.[15] It must be emphasised that in cases of left common iliac stent re-thrombosis, the right common iliac vein stayed patent with blood flowing through the cells of the distal part of the stent.

During the last 4 years, we had to treat patients with more complex lesions (higher preoperative VDS, more secondary disease, more occlusions, longer length of stented vein and more segment stented) and this was performed percutaneously in all patients. Despite this, patency rates are not different. This is certainly linked with the increase of our experience that leads us to use ultrasound-guided puncture in order to facilitate percutaneous venous access and to deploy longer stents to avoid restenosis.

Conclusion

Stenting has turned out to be the technique of reference for the treatment of femoro-ilio-caval obstructive lesions and provides good long-term patency with low complication

rates. Despite this, several issues like postoperative therapy are not resolved and should be evaluated in order to optimise the results.

Conflict of Interest/Funding

None.

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