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Early and long-term comparison of endovascular treatment of iliac artery occlusions and stenosis

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Objectives: This study evaluated early and long-term results of endovascular treatment of iliac artery occlusions and compared these outcomes with those in patients treated for stenotic lesions.

Methods: During a 10-year period ending in January 2010, 223 endovascular procedures to treat aortoiliac occlusive disease (PAD) were performed. All patients were prospectively enrolled in a dedicated database. The intervention was performed for iliac occlusion in 109 patients (group 1) and for iliac stenosis in 114 (group 2). Early results were analyzed and compared by χ^2 and Fisher exact tests. Follow-up consisted of clinical examination and duplex scanning at discharge, ≤ 3 months, at 6 and 12 months, and yearly thereafter. Follow-up results were analyzed with Kaplan-Meier curves and compared with the log-rank test.

Results: The two groups had similar risk factors for atherosclerosis and comorbidities. Critical limb ischemia was more common in group 1 (20.5%) than in group 2 (8.5%; $P = .01$). Intraoperative technical details were similar, except for a higher percentage of brachial and contralateral femoral access and more frequent use of nitinol stents in group 1. Two immediate technical failures occurred, one in both groups, requiring immediate conversion to surgical bypass. Four intraoperative iliac ruptures occurred, two in each group; all were successfully treated with covered stents. An additional 10 immediate complications occurred (8 in group 1; 2 in group 2), one of which required conversion to open surgical bypass. The cumulative rate of perioperative complications was 9% in group 1 and 3.5% in group 2 ($P = .08$). Primary patency at 30 days was 97.3% and 98.7%, respectively. Mean duration of follow-up was 28.4 months; 203 patients (91%) had a regular postoperative follow-up visit. At 60 months, primary patency in group 1 vs group 2 was 82.4% vs 77.7% ($P = .9$), assisted primary patency was 90.6% vs 85.5% ($P = .4$), and estimated secondary patency was 93.1% vs 92.8% ($P = .3$). The cumulative rate of reintervention during follow-up (excluding reinterventions performed in the perioperative period) was 2.5% in group 1 and 12.5% in group 2 at 60 months ($P = .09$). Univariate analysis in group 1 failed to find any of the examined risk factors significantly affected long-term primary patency rates.

Conclusions: In our experience, endovascular treatment of iliac occlusions provides excellent early and long-term results, similar to those obtained in the treatment of stenotic lesions. (*J Vasc Surg* 2011;53:92-8.)

Percutaneous endovascular treatment has become the initial approach in patients with aortoiliac chronic occlusive disease. Even if in patients with complex unilateral or bilateral occlusive disease of the common or external iliac artery, or both (TransAtlantic InterSociety Consensus [TASC] II C and D lesions),¹ open surgery remains the recommended approach. Encouraging early and long-term results have been reported in the endovascular management of iliac artery occlusions, particularly when stenting was performed. However, reported results for technical success and long-term patency are slightly poorer than those obtained in the treatment of stenoses.² The aim of

this study was to retrospectively compare immediate and follow-up results of endovascular management of iliac artery occlusions and stenoses in a single-center experience.

MATERIAL AND METHODS

From January 2000 to January 2010, 447 consecutive endovascular procedures for peripheral arterial occlusive disease in 412 patients were performed at our institution. Data concerning these interventions were prospectively collected in a dedicated institutional database containing main anatomic, clinical, diagnostic, and technical variables. This database also contains perioperative (<30 days) results and all relevant clinical and diagnostic data collected during follow-up. A post hoc analysis of this prospective database found 223 interventions performed for aortoiliac occlusive disease in 212 patients.

Interventions were retrospectively divided into two groups: 109 interventions (group 1) performed for unilateral or bilateral occlusion of the common or external iliac artery, or both (TASC II B, C, and D lesions), and 114 interventions (group 2) performed for unilateral or bilateral stenosis of the common or external iliac artery (mainly TASC II A and B lesions).

The two groups of patients were compared by demographic data, common risk factors for atherosclerosis, and

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comorbidities. Risk factors and comorbidities included smoking habits (current and former, ≤ 5 years, smokers) arterial hypertension (defined as blood pressure $>130/80$ mm Hg or the need for antihypertensive drugs), hyperlipemia (defined as triglycerides and cholesterol values >200 mg/dL), coronary artery disease (defined as a history of myocardial infarction, angina, previous coronary revascularization), diabetes mellitus (defined as the need for specific drugs), and chronic renal failure (defined as serum creatinine values >1.5 mg/mL). The Rutherford classification³ was used to define clinical status, and TASC II guidelines¹ were used to define the anatomic characteristics of the lesions.

Preoperative diagnostic assessment consisted of ankle-brachial index (ABI) measurement and duplex scanning in all patients. Duplex examinations were performed in our validated vascular laboratory by First Level Italian Society for Vascular Investigations certified physicians. Computed tomography angiography (CTA) of the aorta and iliofemoral axis was performed in patients with multilevel disease and in those with extremely calcified lesions at duplex scanning.

In patients presenting with recent (<14 days) worsening of symptoms or Rutherford class upgrade and the evidence of iliac thrombosis, preoperative catheter-directed thrombolysis with urokinase (Urochinas Crinos, Crinos SPA, Milan, Italy) was attempted. Thrombolytic treatment was administered in a bolus of 100,000 IU, followed by continuous infusion with a delivery rate of 70,000 IU/h. All patients were administered 1000 to 1500 IU/h of sodium heparin through the same catheter to maintain activated partial thromboplastin time values two times higher than normal.

Angiographic controls were performed daily or more, when necessary, and the lytic infusion lasted until patency of iliac vessels was achieved, or for a maximum of 3 days when unsuccessful. Thrombolysis was defined as successful in the presence of restored patency of the targeted vessel, even in the presence of significant residual stenosis, which was routinely treated at the end of thrombolytic treatment. Owing to the presence of underlying stenosis, these patients were all categorized as group 2.

All the interventions were performed by vascular surgeons in the operating room in the first period of the experience and then in the angiographic suite, under local anaesthesia, supplemented with intravenous sedation or analgesia when required.

Stenotic lesions were normally crossed from an ipsilateral approach, with a combination of soft-tip guidewire or hydrophilic wire and a vertebral 4F catheter. Occlusive lesions were initially negotiated from an ipsilateral approach, and if this approach failed, contralateral access was performed and recanalization of the occlusion was attempted. In patients with short or no proximal iliac stump, left brachial access was performed.

In patients with complex lesions involving the femoral bifurcation, a hybrid approach was performed in which a surgical femoral endarterectomy, with or without patch

angioplasty, was followed by endovascular treatment of the iliac lesion.

After the introducer sheath was placed, administration of 5000 IU of intravenous sodium heparin was performed in all cases.

Arterial recanalization in patients in group 1 was achieved in most cases with a subintimal technique. Balloon-expandable stents were used preferentially for focal, ostial, and severely calcified lesions; in case of involvement of aortic bifurcation, a kissing balloon or kissing stents technique was done. Self-expanding stents were usually placed for long-segment diseased or tortuous arteries.

Intraoperative and perioperative data included type of access, procedure performed (isolated percutaneous transluminal angioplasty [PTA] or stenting), type, number, and length of stents, associated surgical and endovascular procedures, concomitant treatment of outflow vessels, and postoperative medical treatment with single- or dual-antiplatelet therapy or oral anticoagulants. The choice for dual- or single-antiplatelet therapy was not standardized but was at the surgeon's discretion and also according to the patient's socioeconomic status. Oral anticoagulants were prescribed only to patients who already had undergone this treatment for comorbidities.

Early (intraoperative and <30 days) results were analyzed for technical success (defined as a $<20\%$ residual stenosis at completion angiography), conversion to open surgery (defined as technical failure, followed by immediate surgical repair), primary patency (defined as uninterrupted patency without procedures performed on or at the margin of the treated segment), secondary patency (defined as restored patency through the original treated segment), and for patients with critical limb ischemia, limb salvage (defined as the avoidance of above or below knee amputation).

The postoperative follow-up program consisted of clinical examination and duplex scanning with ABI measurement ≤ 3 months, at 6 and 12 months, and yearly thereafter. All ultrasound studies were performed using an Acuson Sequoia 512 Ultrasound System (Acuson Corp, Mountain View, Calif).

Loss of primary patency was diagnosed when ABI deterioration $>20\%$ was associated with duplex evidence of significant ($>50\%$) restenosis, requiring or not a secondary intervention to maintain arterial patency or thrombolysis of the treated segment. In the presence of flow-limiting lesions associated with recurrence or impairment of symptoms, patients underwent digital subtraction angiography for the endovascular treatment.

Follow-up results were analyzed for survival, primary and secondary patency, assisted primary patency (defined as the success of procedures done on a still patent segment to prevent its thrombolysis), and for patients with critical ischemia, limb salvage.

Statistical analysis was performed by means of SPSS 15.0 software (SPSS Inc, Chicago, Ill). Early results were analyzed with χ^2 test and Fisher exact test, when necessary. Univariate and multivariate analysis (stepwise logistic re-

Table I. Demographic data, risk factors, and comorbidities

Variable	Group 1	Group 2	P
Interventions, No.	109	114	
Female sex, No. (%)	22 (20)	31 (27)	.2
Median age, years (range)	66.3 (37-87)	65.7 (34-84)	.2
History of smoking, No. (%)	87 (80)	89 (78)	.09
Hyperlipemia, No. (%)	66 (60)	60 (53)	.06
Arterial hypertension, No. (%)	80 (73)	87 (76)	.08
Diabetes mellitus, No. (%)	20 (18)	25 (22)	.06
Coronary artery disease, No. (%)	32 (29)	33 (29)	.08
Chronic renal failure, No. (%)	6 (5)	2 (2)	.09

Table II. Clinical and anatomic status

Classification	Group 1 (n = 109) No. (%)	Group 2 (n = 114) No. (%)	P
Rutherford			
Class 3	86 (79.5)	104 (91.5)	.05
Class 4	14 (13)	3 (2.5)	.003
Class 5	9 (7.5)	6 (5)	.5
Class 6	...	1 (1)	.1
TASC II			
Type A	...	112 (98)	<.001
Type B	52 (48.5)	1 (1)	<.001
Type C	25 (22)	...	<.001
Type D	32 (29.5)	1 (1)	<.001

TASC, TransAtlantic InterSociety Consensus.

gression) of the factors affecting early complication rate in group 1 were performed. Statistical significance was defined as a value of $P < .05$.

Follow-up data were analyzed by Kaplan-Meier life-table analysis, and results in the two groups were compared by means of the log-rank test. Univariate and multivariate analysis (Cox's regression) of the factors affecting late results in patients of group 1 were performed.

RESULTS

Demographic data and clinical and anatomic status.

There were no differences between the two groups in sex, age, risk factors for atherosclerosis, and comorbidities (Table I). Intervention was performed for critical limb ischemia in 23 patients (20.5%) in group 1 and in 10 patients (8.5%) in group 2 ($P = .01$). The remaining patients had severe intermittent claudication. The Rutherford classification in both groups is reported in Table II. The preoperative mean ABI was 0.50 ± 0.26 and was significantly lower in group 1 (0.44 ± 0.25) than in group 2 (0.57 ± 0.27 ; $P = .001$).

In 58 group 1 patients, the targeted vessels had TASC II C and D lesions; in group 2, only 1 patient had a type D lesion, and type A or B disease was present in the remaining patients. TASC II classification in both groups is reported in Table II.

Operative details. In the entire study group, percutaneous ipsilateral femoral access was used in 109 interven-

tions, percutaneous contralateral femoral access was used in 50 interventions, and percutaneous brachial access was used in 38 interventions. An ipsilateral open surgical femoral approach was used in 28 interventions. Patients in group 1 had more frequent contralateral and brachial access than patients in group 2; whereas in patients in group 2, targeted lesions were more frequently approached using an ipsilateral percutaneous puncture (Table III).

The lesions were successfully crossed in all but one patient. Isolated percutaneous transluminal angioplasty was performed in 12 in group 1 (11%) and in 13 in group 2 (11.5%; $P = .9$). One or more stents were placed in the remaining cases. The mean number of placed stents was 1.9 ± 1 in group 1 and 1.1 ± 0.5 in group 2 ($P < .001$). The mean length of treated arterial segments was 126.7 ± 71 mm in group 1 and 52.1 ± 35.1 mm in group 2 ($P < .001$).

Twenty different types of commercially available stents were used. A nitinol stent was used in 106 patients, a steel stent was used in 84, and a covered stent was placed in the rest. The distribution of the stent type in the two groups is listed in Table III. In group 1, nitinol stents were more commonly used, whereas in group 2, steel stents were more frequently implanted. The kissing stent technique was used in 24 cases in group 1 (22%) and in 10 cases in group 2 (8.5%; $P = .05$).

Intra-arterial thrombolysis with urokinase was performed in nine patients with recent symptoms, impairment, and angiographic evidence of iliac occlusion. Mean duration of thrombolytic treatment was 48 hours (range, 24-72 hours). Thrombolysis was successful in all but one patient, unmasking the presence of a stenotic lesions, which were treated with PTA, with or without stenting, ≤ 24 hours from the cessation of urokinase administration. As a consequence, these nine patients were categorized in group 2.

Concomitant open surgical intervention was performed in 26 patients (15 in group 1 and 11 in group 2; $P = .4$). Associated open interventions were performed in all but five patients who had surgical femoral access, in two patients who had brachial access, and in one patient who had percutaneous contralateral femoral access. The associ-

Table III. Technical details

Variable	Group 1 (n = 109) No. (%)	Group 2 (n = 114) No. (%)	P
Vascular access			
Percutaneous			
Ipsilateral femoral	29 (26.5)	80 (70)	<.001
Contralateral femoral	31 (28.5)	17 (15)	.05
Brachial	33 (30)	5 (4.5)	<.001
Surgical ipsilateral femoral	16 (14.5)	12 (10.5)	.3
	(n = 97)	(n = 101)	
Type of stent			
Nitinol	68 (70)	38 (37.5)	<.001
Steel	24 (25)	60 (59.5)	<.001
Covered stent	5 (5)	3 (3)	.1

Table IV. Associated open and endovascular procedures and postoperative medical treatment in both groups

Variable	Group 1 (n = 109) No. (%)	Group 2 (n = 114) No. (%)	P
Associated open procedures			
Femoral endarterectomy	14 (13)	4 (3.5)	.05
Femoral-femoral bypass	1 (1)	3 (2.5)	.5
Femoral-popliteal bypass	...	4 (3.5)	.07
Associated endovascular procedures			
Ipsilateral SFA PTA	6 (5.5)	4 (3.5)	.3
Ipsilateral SFA stenting	1 (1)	3 (2.5)	.07
Ipsilateral tibial PTA	...	1 (1)	.3
Contralateral SFA PTA	...	2 (1.8)	.2
Renal stenting	1 (1)3
Postoperative treatment			
Single antiplatelet	23 (21)	17 (15)	.4
Dual antiplatelet	81 (74)	93 (81)	.4
Oral anticoagulant	5 (5)	4 (4)	.1

PTA, Percutaneous transluminal angioplasty; SFA, superficial femoral artery.

ated open interventions are listed in Table IV. An associated endovascular procedure of the femoropopliteal axis was performed in 18 patients (8 in group 1 and 10 in group 2, $P = .7$). The associated endovascular interventions are listed in Table IV.

Postoperative medical treatment consisted of lifelong dual-antiplatelet therapy in 174 patients and single-antiplatelet therapy in 40. In nine patients who took oral anticoagulants before the procedure, the therapeutic regimen was continued after discharge. There were no differences between the two groups in postoperative medical treatment (Table IV).

Perioperative and early (<30 days) results. Technical success was 98.9%. Two procedures failed: In one patient of group 1, treated for left common iliac occlusion and stenosis of the contralateral common iliac artery, the iliac occlusion could not be crossed and immediate conversion to aortobifemoral bypass was necessary. The other patient, treated for common iliac stenosis, required conversion to aortobifemoral bypass because of an immediate stent migration in the abdominal aorta.

Four intraoperative iliac ruptures occurred, two in each group, and all were successfully treated with a covered stent. An additional 10 immediate complications occurred, 8 in group 1 and 2 in group 2 (Table V), of which one conversion to open surgical bypass was required. The cumulative rate of perioperative complications was 9% in group 1 and 3.5% in group 2 ($P = .08$), whereas the rate of conversion to open surgery was 1.8% and 0.9%, respectively, without differences between the groups.

The mean postoperative ABI was 0.88 ± 0.17 , with a significant improvement compared with preoperative values ($P < .001$) in group 1 (0.87 ± 0.19 ; $P = .001$) and in group 2 (0.89 ± 0.15 ; $P < .001$).

At 30 days, no deaths or major cardiovascular complications occurred. No new thrombosis or significant restenosis

was noted at the early postoperative follow-up visit. Primary patency at 30 days was 97.3% and secondary patency was 98.7%, without differences between the two groups.

At univariate analysis for the risk of perioperative complications in group 1, only postoperative treatment with oral anticoagulants was significantly associated with an increased risk (odds ratio, 4.8; 95% confidence interval; 0.9-15.7; $P = .04$), but this was not seen on multivariate analysis.

Follow-up results. Median duration of follow-up was 18 months (interquartile range, 9-36 months) and was significantly longer in group 2 (30 months) than in group 1 (12 months, $P < .001$). A total of 203 patients (91%) had regular postoperative follow-up visits.

During follow-up, 12 deaths occurred, 5 in group 1 and 7 in group 2. The cause of death was cardiac in 4 patients, cancer in 5, acute accidental overdose of psychotropic drugs in 1 patient, and was unknown in the remaining 2 patients. Estimated 60-month survival rates were 82.5% (standard error [SE], 0.1) in group 1 and 86.3% (SE, 0.05) in group 2 ($P = .7$; log-rank, 0.09).

Significant restenosis of the treated vessel occurred in 14 patients in the whole study group, 4 in group 1 and 10 in group 2. In all but 2 patients the restenosis was successfully treated—in 11 with a new endovascular procedure (5 stent placements, 2 new PTA, 3 cutting-balloon procedures, and 1 combined PTA and femoral endarterectomy) and in 1 with an iliofemoral endarterectomy. Restenosis in the remaining patients was asymptomatic, and they were medically managed, without developing occlusion or clinical impairment during follow-up.

Seven new thromboses were recorded during follow-up, four in group 1 and three in group 2. In group 1, a new

Table V. Intraoperative results

Variable	Group 1 (n = 109) No. (%)	Group 2 (n = 114) No. (%)	P
Technical failure	1 (0.9)	1 (0.8)	.99
Intraoperative complications			
Rupture	2 (1.8)	2 (1.5)	.99
Immediate complications			
Arterial dissection	...	1 ^a	
Iliac thrombosis	1 ^b	1 ^c	
Femoral thrombosis	2 ^d	...	
Brachial thrombosis	3 ^e	...	
Femoral pseudoaneurysm	1 ^f	...	
Distal embolization	1 ^g	...	
Cumulative intra-op complications	10 (9)	4 (3.5)	.08

NS, Not significant.

^aTreated with stent placement.

^bTreated with conversion to aortobifemoral bypass.

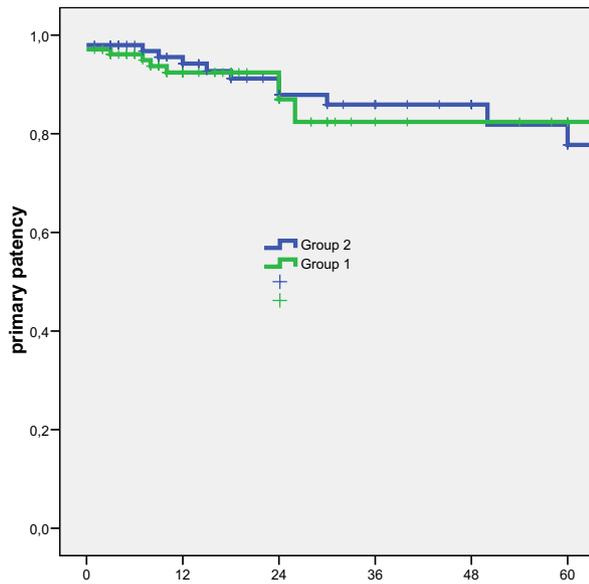
^cTreated with surgical thrombectomy and femoral patching.

^dOne patient was treated with thromboaspiration and one with surgical thrombectomy and femoral patching.

^eAll treated with brachial thrombectomy.

^fTreated with open repair.

^gTreated with thrombolysis and distal percutaneous transluminal angioplasty.



Months	0	12	24	48	60
Group 1 (n. at risk)	103	65	33	8	5
Group 2 (n. at risk)	98	71	54	31	19

Fig 1. Kaplan-Meier curve for primary patency during follow-up is shown for groups 1 and 2, with numbers of patients at risk.

thrombosis developed at 5 months in a patient who had been treated in the perioperative period with a femoral thrombectomy and patching for acute thrombosis, and conversion was required to open aortobifemoral bypass. Another patient presented a thrombosis in postoperative month 7 and was treated with thrombolysis and kissing stent of the aortic bifurcation. The same patient showed a new acute thrombosis at 30 months and underwent conversion to aortobifemoral bypass. An additional patient sustained thrombosis at 8 months and was successfully treated with intra-arterial thrombolysis and restenting. The remaining patient, showing an occlusion at 24 months with mild claudication, was managed medically.

In group 2, one acute thrombosis occurred at 24 months and required conversion to aortobifemoral bypass; another patient had recurrent stenting for thrombosis at 30 months, whereas in the remaining occlusion, occurring at 50 months, medical management due to the presence of mild claudication was chosen. No amputation was recorded.

Primary patency rates at 60 months were 82.4% (SE, 0.06) in group 1 and 77.7% (SE, 0.06) in group 2 ($P = .9$, log-rank 0.05; Fig 1). The corresponding rates of assisted primary patency were 90.6% (SE, 0.04) and 85.5% (SE, 0.06), respectively ($P = .4$; log-rank, 0.6).

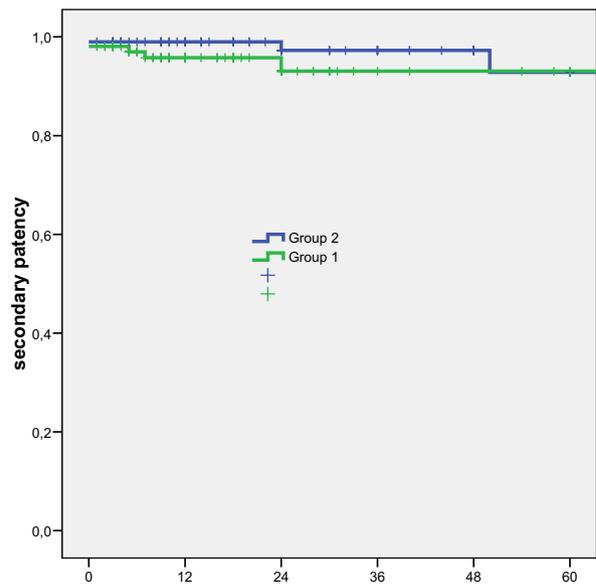
Estimated secondary patency rates at 60 months were 93.1% (SE, 0.03) in group 1 and 92.8% (SE, 0.05) in group 2 ($P = .3$; log-rank, 1; Fig 2). At the same time interval, freedom from conversion to open surgery was 89.5% (SE,

0.07) in group 1 and 97.2% (SE, 0.03) in group 2 ($P = .4$; log-rank, 0.6). At 60 months of follow-up, the cumulative rate of reintervention (excluding reinterventions performed in the intraoperative and immediate perioperative period) was 2.5% (SE, 0.02) in group 1 and 12.5% (SE, 0.05) in group 2 ($P = .09$, log-rank 2.7; Fig 3).

Univariate analysis in group 1 failed to find that any of the examined risk factors significantly affected primary patency rates (Table VI).

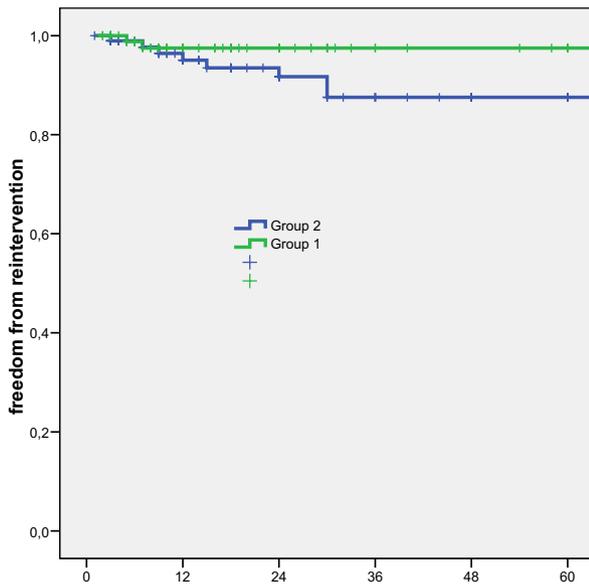
DISCUSSION

Endovascular surgery has become the initial therapeutic option for aortoiliac occlusive disease due to the substantial risk of perioperative complications during open surgery⁴ and the significant improvement in endovascular techniques and materials. Endovascular treatment has been proven to be safe and effective, particularly in focal iliac artery stenosis, with high rates of technical success and excellent long-term patency rates.^{1,5} Although TASC guidelines still recommend surgical treatment in the case of complex, multifocal or totally occluded segments of iliac arteries (TASC II types C and D iliac lesions), the recent advancements in endovascular techniques have led to an extension of the indications to more extensive aortoiliac occlusive disease, with satisfactory early and long-term results.^{6,7} A recent literature review² reported overall slightly better results in the treatment of iliac stenosis than iliac occlusions in immediate success and long-term patency. However,



Months	0	12	24	48	60
Group 1 (n. at risk)	103	66	34	8	5
Group 2 (n. at risk)	98	72	42	32	20

Fig 2. Kaplan-Meier curve for secondary patency during follow-up is shown for groups 1 and 2, with numbers of patients at risk.



Months	0	12	24	48	60
Group 1 (n. at risk)	82	61	33	8	5
Group 2 (n. at risk)	92	69	52	37	19

Fig 3. Kaplan-Meier curve for freedom from new reinterventions (excluding reinterventions performed in the intraoperative and immediate perioperative period) during follow-up is shown for groups 1 and 2, with numbers of patients at risk.

Table VI. Univariate analysis for factors affecting follow-up primary patency in group 1

Factor	Log-rank	OR	95% CI	P
Female sex	2.8	2.8	0.8-10	.09
Diabetes	0.5	0.6	0.1-2.3	.4
Critical limb ischemia	1.7	2.4	0.6-9.7	.2
TASC C/D lesions	0.5	1.6	0.4-5.7	.4
Isolated PTA	0.02	1	0.1-8.3	.9
Arterial access	1.5	1.2	0.6-2.2	.7
Hybrid procedure	0.01	1.1	0.1-8.9	.9
Stent type	1.9	1.9	0.7-4.9	.4
Post-op drug therapy	2.8	1.1	0.1-10.7	.2

CI, Confidence interval; OR, odds ratio; PTA, percutaneous transluminal angioplasty; TASC, TransAtlantic InterSociety Consensus.

the range of results was significant, with primary patency of 54% to 92% at 5 years for stenoses and 48% to 85% at 3 years for occlusions, and only a limited number of studies directly compared results in occlusions and stenoses.⁸

The paucity of data concerning this comparison may be because most studies categorize and analyze patients by the TASC classification,^{9,10} which often includes in the same class a wide range of different lesions, both occlusions and stenoses.

In this study, we have retrospectively analyzed our early and long-term results of endovascular treatment of occlusive aortoiliac disease, comparing patients treated for iso-

lated or multiple stenoses and patients treated for occlusions. Even if patients in group 1 were more likely than patients in group 2 to have critical limb ischemia, most patients in both groups had severe intermittent claudication, a common finding in most published series, where the percentage of claudicants is between 50% and 100%.²

Percutaneous femoral access was performed in most cases; however, as expected, patients in group 1 more frequently underwent contralateral femoral and brachial access. Surprisingly, we found no difference between the two groups in the percentage of ipsilateral femoral surgical access, probably due to the procedures performed for stenotic lesions early in our experience, when we had a more cautious approach to the common femoral artery. Moreover, we preferred surgical access whenever significant femoral lesions were present. Currently in our practice, the femoral surgical approach is reserved for complex occlusive lesions, similarly to what is reported in most published studies.^{11,12}

Our policy in iliac occlusion is to attempt to endoluminally cross the lesion; this was impossible in many cases, and a subintimal route was used. We prefer in these cases an anterograde access to reduce, in case of no re-entry, the possible retrograde dissection of the aorta; in addition, we have more pushability of the system and easier control of the guidewire. By adopting this strategy, we have achieved a high rate of technical success.

One or more stents were placed in most patients in both groups. As expected in group 1, a significantly higher number of stents were placed covering a longer arterial segment, confirming what is generally accepted in clinical practice,¹³ that it is better to perform a direct or primary stenting in patients with chronic occlusion. The high number of placed stents also in group 2 can be possibly related to the influence of the randomized trials published in the late 1990s^{14,15} on our early and intermediate experience.

The choice of the type of stent in our series reflects the current opinions and guidelines²: we preferred steel stents in patients with short, calcified ostial stenoses, whereas self-expandable nitinol stents were commonly used in patients with longer occlusions. Covered stents were used only to bail out the procedure (ruptures) and in rare cases of very complex lesions when complications could be expected.

Perioperative and early results were satisfactory, with an excellent rate of technical success and significant hemodynamic improvement in both groups. Several intraoperative and immediate complications were recorded, however, with a threefold increased risk of complications in group 1 that only approached significance, probably due to the low number of cases (type II statistical error). Similarly, Ozkan et al¹⁶ reported in their large series concerning early and late results of endovascular treatment of chronic iliac occlusion a complication rate of 19%, successfully treated in most cases with an endovascular procedure. A pooled analysis of 38 studies of iliac PTA and of 18 studies of stenting² reported a complication rate of 2.7% and 6%, respectively; however, the results were not separately analyzed between stenoses and occlusions. Interestingly, we did not find any association between clinical, anatomic, and technical factors, and the occurrence of periop-

erative complications in patients with occlusions. The status of the run-off, the length of occlusive lesions, and the type of approach to the treated vessels have all been found, in different studies,^{2,6,16} to significantly affect the rate of complications. These factors were not significant in our series; however, the low number of events could have influenced this finding. A combination of open and endovascular procedures was used to treat our immediate complications. Once the complication was treated, the risk of further adverse events was minimal, with a 30-day patency rate >97% in both groups.

Follow-up results demonstrated satisfactory primary, assisted primary, and secondary patency rates, with no difference between the groups. The main limit in the analysis and interpretation of follow-up data is represented by the significantly different duration of surveillance between the two groups. We did find a higher percentage of significant restenosis in group 2 patients, even if not statistically significant. The explanation for this finding is uncertain; apart from the mentioned difference in follow-up duration, we believe it could be also related to the more "focal" treatment of lesions in the stenosis group (ie, a lower number of placed stents and shorter covered arterial segments). A wider use of covered stents in the future probably could answer some questions regarding the rate of in-stent restenosis that still remains substantial with the bare stent. In most cases, however, restenosis was successfully treated with an endovascular approach, confirming the effectiveness of such a strategy.¹⁷

The percentage of conversion to open repair was higher in group 1 patients than in group 2 patients, probably influenced by a perioperatively higher rate of surgical conversion in patients treated for iliac occlusion. During follow-up, however, the rate of conversion in the two groups was similarly low. Furthermore, when excluding the need for reinterventions in the perioperative and immediate postoperative period, we found a trend toward higher percentages of reinterventions in group 2, suggesting the need for prolonged surveillance during follow-up in patients treated for stenotic lesions and also confirming the good durability of endovascular treatment of chronic iliac occlusions.

CONCLUSIONS

In our experience, endovascular treatment of iliac occlusions provides excellent early and long-term results, similar to those obtained in the treatment of stenotic lesion. The rate of perioperative complications is higher in the treatment of occlusive lesions; however, most of these can be managed endovascularly. The use of hybrid procedures of the femoral artery may improve outcomes with complex iliac lesions. These data support our current practice of an initial endovascular approach to manage iliac occlusions.

AUTHOR CONTRIBUTIONS

Conception and design: RP, WD, CP
Analysis and interpretation: RP, WD
Data collection: AF, GP, AI

Writing the article: WD, JM, RP
Critical revision of the article: RP, JM
Final approval of the article: CP, RP
Statistical analysis: WD, RP
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REFERENCES

- Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg* 2007;45 (suppl S):S5-67.
- Tsetis D, Uberoi R. Quality improvement guidelines for endovascular treatment of iliac artery occlusive disease. *Cardiovasc Intervent Radiol* 2008;31:238-45.
- Rutherford RB, Becker GJ. Standards for evaluating and reporting the results of surgical and percutaneous therapy for peripheral arterial disease. *Radiology* 1991;181:277-81.
- De Vries SO, Hunink MGM. Results of aortic bifurcation grafts for aorto-iliac occlusive disease: a meta-analysis. *J Vasc Surg* 1997;26:558-69.
- Schurmann K, Mahnken A, Meyer J, Haage P, Chalabi K, Peters I, et al. Long-term results 10 years after iliac arterial stent placement. *Radiology* 2002;224:731-8.
- Timaran CH, Prault TL, Stevens SL, Freeman MB, Goldman MH. Iliac artery stenting versus surgical reconstruction for TASC type B and type C iliac lesions. *J Vasc Surg* 2003;38:272-8.
- Leville CD, Kashyap VS, Clair DG, Bena JF, Lyden SP, Greenberg RK, et al. Endovascular management of iliac artery occlusions: extending treatment to Trans Atlantic Inter-Society Consensus class C and D patients. *J Vasc Surg* 2006;33:32-9.
- Murphy TP, Webb MS, Lambiase RE, Haas RA, Dorfman GS, Carney WI, et al. Percutaneous revascularization of complex iliac artery stenoses and occlusions with use of Wallstent: three-year experience. *J Vasc Interv Radiol* 1996;7:21-7.
- Hans SS, DeSantis D, Siddiqui R, Khoury M. Results of endovascular therapy and aortobifemoral grafting for Transatlantic Inter-Society type C and D aortoiliac occlusive disease. *Surgery* 2008;144:583-9.
- Sixt S, Alawied AK, Rastan A, Schwarzwalder U, Kleim M, Noory E, et al. Acute and long-term outcome of endovascular therapy for aortoiliac occlusive lesions stratified according to the TASC classification: a single-center experience. *J Endovasc Ther* 2008;15:408-16.
- Nelson PR, Powell PJ, Schermerhorn ML, Fillinger MF, Zwolak RM, Walsh DB, et al. Early results of external iliac stenting combined with common femoral artery endarterectomy. *J Vasc Surg* 2002;35:1107-13.
- Mousa AY, Beauford RB, Flores L, Faries PL, Patel P, Fogler R. Endovascular treatment of iliac occlusive disease: review and update. *Vascular* 2007;15:5-11.
- Onal B, Ilgit ET, Yücel C, Ozbek E, Vural M, Akpek S. Primary stenting for complex atherosclerotic plaques in aortic and iliac stenoses. *Cardiovasc Intervent Radiol* 1998;21:386-92.
- Richter GM, Roeren T, Brado M. Arterial stenting: randomized trial between primary iliac stenting vs PTA in iliac artery stenosis and obstruction. *Eur Radiol* 1995;5:103-9.
- Tetteroo E, van Der Graaf Y, Bosch JL, van Engelen AD, Hunink MG, Eikelboom BC, et al. Randomised comparison of primary stent placement versus primary angioplasty followed by selective stent placement in patients with iliac artery occlusive disease. *Lancet* 1998;351:1553-9.
- Ozkan U, Oguzkurt L, Tercan F. Technique, complication, and long-term outcome for endovascular treatment of iliac artery occlusion. *Cardiovasc Intervent Radiol* 2010;33:18-24.
- Schurmann K, Mahnken A, Meyer J, Haage P, Chalabi K, Peters I, et al. Long-term results 10 years after iliac artery stent placement. *Radiology* 2002;224:731-8.

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