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Long-term Results of Percutaneous Transluminal Angioplasty for Symptomatic Iliac In-stent Stenosis

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Objective. *This study describes the long-term results of endoluminal therapy for iliac in-stent obstructions.*
Design. *This is a retrospective study.*
Materials and methods. *From 1992 to 2005, 68 patients (22 women), with a mean age of 61 ± 13 years and 16 bi-iliac in-stent obstructions, underwent 84 endovascular interventions for focal iliac in-stent stenoses (n = 61) or occlusions (n = 23). Primarily, only uncovered stents were placed. All patients were symptomatic: 70% had disabling intermittent claudication, 23% had resting pain, and 7% had trophic changes. All had in-stent diameter reduction exceeding 50% that was confirmed by duplex scanning and angiography. Procedures were performed under local anesthesia via the femoral route.*
Results. *All interventions were initially technically successful, with a minor complication of pneumonia in one patient (2%). Initial clinical success was achieved in 86% of patients. PTA alone was used to treat 72 (86%) in-stent obstructions, the other 12 (14%) had PTA and renewed stent placement. The 30-day mortality rate was 0%. Mean follow-up was 35 months (range, 3 months to 10 years) and included duplex scanning. Primary clinical patency was 88% at 1 year, 62% at 3 years, and 38% at 5 years follow-up. During follow-up, 28 (33%) of 84 extremities required secondary reinterventions because of symptomatic renewed in-stent stenosis, and 11 were treated successfully with repeated endovascular interventions. Secondary patency at 1 year was 94%, 78% at 3 years, and 63% at 5 years. Surgical intervention was eventually needed in 17 (20%) of the 84 extremities.*
Conclusions. *Endoluminal therapy for iliac focal in-stent obstructive disease seems to be a safe technique with acceptable long-term outcome and therefore a true alternative to primary surgical reconstruction.*

Keywords: Percutaneous transluminal angioplasty; Iliac artery; In-stent obstruction.

Introduction

During the past decades, a major shift has occurred in the treatment of obstructive iliac disease from open reconstructions (desobstruction or bypass surgery) to endovascular techniques. The surplus value of additional stents in iliac endoluminal therapy has been studied thoroughly. Originally, additional stents were indicated to treat periprocedural complications of percutaneous transluminal angioplasty (PTA).[1,2] Selective use of stents was advocated in a later randomized study, with similar outcome, and appeared to be cost-effective compared with routine use of additional stents.[3] In daily practice, routine stent placement is still attempted on a large scale to prevent recurrent disease; however, the long-term outcome of iliac stenting shows restenosis in up to 25%.[4,5] Little is known so far about the initial success and long-term outcome of endovascular treatment of these iliac in-stent obstructions, which is the aim of this study.

Methods

Patients

Between January 1992 and July 2005, 1086 patients underwent primary endoluminal treatment for aortoiliac atherosclerotic obstructive disease in our hospital. During this time, 129 patients were treated for symptomatic iliac artery reobstructions, of which 45 appeared after primary PTA alone or were located

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outside an iliac stent. The remaining 84 iliac reobstructions were located in-stent and are the subject of this study. Primarily, an uncovered stent was placed in all patients.

Preprocedural evaluation included physical examination with additional ankle-brachial index (ABI) measurement and duplex scanning. All patients underwent digital subtraction angiography in at least two planes to confirm the obstructive iliac in-stent lesion. Aspirin (80 mg daily) was given to all patients at least 2 weeks before treatment of the in-stent obstruction and was continued for at least 3 months after the procedure.

Methods

All procedures were performed under local anesthesia in the angiography suite of the Interventional Radiology Department. Angioplasty procedures were performed by the three staff interventional radiologists, with use of the Seldinger technique. For in-stent stenosis just distal to the aortic bifurcation, a bifemoral route with ''kissing balloon'' technique was used; otherwise, a single balloon was used. After crossing the in-stent obstruction with a guidewire and subsequent PTA, a control angiogram was obtained to measure the trans-lesion pressure gradient. A persistent transstenotic mean pressure gradient of 10 mm Hg or more during pharmacologically induced vasodilatation was an indication for selective renewed stent placement. Other criteria for additional stent placement were occlusive in-stent lesions, residual in-stent stenosis of 30% or more after PTA, or dissection. In case of renewed stent placement, balloon-expandable stents (Palmaz, Cordis, Johnson & Johnson, Warren, NJ) and self-expendable stents (Wallstent; Boston Scientific, Schneider, Bullach, Switzerland) were used. A bolus of 5000 IU of heparin was given before angioplasty.

Most of the femoral access sites were closed with a percutaneous femoral artery closure device. Patients were discharged from the hospital on the first postoperative day.

Follow-up

ABI at rest was measured before discharge. Postprocedural follow-up was at 3, 6, and 12 months, and yearly thereafter. It consisted of clinical examination, ABI measurements, and duplex scanning. In case of clinical deterioration in combination with more than 50% recurrent stenosis as measured by duplex scanning, digital subtraction angiography was performed, eventually in combination with reintervention.

Definitions

Initial technical failure was defined as impossibility to cross the in-stent obstruction or an angiographic residual stenosis exceeding 20%, with a mean pressure gradient of more than 10 mm Hg across the treated in-stent obstruction. During follow-up, primary and secondary patency rates were defined according to the standards for evaluating and reporting the results of percutaneous interventions for peripheral arterial disease.[6] Clinical success was determined by using the definitions of the Society for Vascular Surgery (SVS) and the Interventional Society for Cardiovascular Surgery (ISCVS) (an upward shift by at least one clinical category plus a change in ABI >0.10).[7]

Statistical analysis

Standard descriptive statistics were used. Patency rates were computed using the Kaplan-Meier method and compared with the log-rank test. For comparison of means, the Student's t test was used. The analysis was performed using SAS 8.2 (SAS Inc., Cary, NC).

Results

During the study period, 68 patients (22 women), with a mean age of 61 ± 13 years, underwent 84 endoluminal interventions (16 bilateral obstructions) for symptomatic iliac in-stent stenosis of at least 50% ($n = 61$) or occlusion ($n = 23$). The in-stent obstructions were located in the common iliac artery in 69% ($n = 58$), and the remaining 31% were in the external iliac artery. Indications for treatment of in-stent obstructions were disabling intermittent claudication (SVS/ISCVS category 2 and 3) in 70%, rest pain (category 4) in 23%, and trophic changes (category 5) in 7%. Patient preprocedural vascular risk factors are listed in Table 1. The mean preprocedural ABI at rest was 0.68 ± 0.26 and $0.53 \pm .23$ after exertion.

Table 1. Pre-procedural patient's vascular risk factors

Risk factor	Total ($n = 68$) (%)
Coronary heart disease	22 (32)
Cerebrovascular accident	8 (12)
Hypertension	23 (34)
Hyperlipidemia	54 (79)
Renal insufficiency	2 (3)
Diabetes mellitus	18 (26)
Familiar history	30 (44)
Smoking	52 (76)