Iliac and Femoropopliteal Vascular Occlusive Disease Treated with Flexible Tantalum Stents

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Abstract. Two hundred patients were treated with tantalum stents, 2 in the aortoiliac bifurcation, 114 in the iliac, and 84 in the femoropopliteal arteries. The indications for stenting were technically unsuccessful percutaneous transluminal angioplasty (PTA) due to arterial recoil, dissection (156 patients), or acute occlusions (15 patients). Long iliac artery occlusions (29 patients) were indications for primary stenting. Life-table analysis revealed a 3-year patency rate of 95% for stented iliac arteries, and a 1-year patency rate of 80% for stented femoropopliteal arteries. Restenosis of the stented femoropopliteal lumen was particularly frequent in stents placed for restenosis following prior PTA (7 of 12 patients), in stents placed into the distal superficial femoral and popliteal arteries (14 of 24 patients), and in stents positioned over a longer than 4-cm artery segment (9 of 16 patients). For the aortic bifurcation and iliac arteries, arterial stenting has proved to be a valuable adjunct to PTA: for femoropopliteal arteries, stenting should be restricted to acute arterial occlusions or severe residual stenosis following PTA.

Key words: Angioplasty—Flexible tantalum stents—Iliac arteries—Femoral arteries

Unsuccessful percutaneous transluminal angioplasty (PTA) is considered the main indication for vascular stenting in patients suffering from atherosclerotic disease [1-9]. In the iliac arteries this is manifested by arterial recoil, dissection, or acute reocclusion due to an intimal flap [3-5]. Recently, long occlusions of iliac arteries have been regarded as primary stent indications [10]. A relatively high incidence of stent restenoses or occlusions was reported for femoral arteries [1, 2]. While primary clinical success was mostly satisfactory, mid- and long-term results did not appear to be favorable [11]. The study presented here represents a prospective multicenter project to assess the 3-year and 1-year results of iliac and femoropopliteal stent placement, respectively.

Materials and Methods

The physical properties of the stent (Strecker Stent, Boston Scientific, Inc., Watertown, MA, USA) and the insertion technique have been described in detail before [8]. Briefly, the stent consists of a cylindrical, electropolished tantalum wire knitted (gauge 0.1 mm) and is flexible and elastic within certain limits in both the nonexpanded and expanded states. For implantation the stent is mounted on the balloon of a 5F PTA catheter (expanded dimensions of available stents: diameters, 5-11 mm; lengths, 3-8 cm). The stent is held to the balloon by 2 silicone sleeves overlapping the stent’s ends. During balloon inflation the sleeves will slide backwards from the expanding balloon, leaving the stent free for implantation. Stents mounted on a 5F PTA catheter with a width of up to 7 mm can be introduced through an 8F introducer sheath. 8-10 mm stents will need a 9F sheath and stents of 11 mm diameter will need a 10F introducer sheath.

Between May 1987 and October 1991, all 200 patients (114 men, 54 women; mean age 62; age range 37-90 years) treated with stents were included in this multicenter study (95 patients from Karlsruhe, 87 from Berlin, 18 from Frankfurt). Risk factors

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were cigarette smoking (90%), elevated serum cholesterol (81%), arterial hypertension (32%), diabetes mellitus (14%), and cigarette smoking combined with elevated serum cholesterol (68%).

During the preceding PTA procedure, 5000 IU of heparin were administered intraarterially as a bolus, and for stent implantation, an additional 2000–5000 IU were given, depending on the patient's weight, the duration of the procedure, and the length of the treated site. Immediately after stent implantation, systemic heparin was continued by intravenous infusion to maintain the partial thromboplastin time at 2 to 3 times normal. This regimen continued up to 2 days for iliac stents, up to 3 days for femoral stents, and up to 5 days for popliteal stents. Antiplatelet medication, with 325 mg of aspirin and 75 mg of dipyridamole (Asasantin, Roche, Basel, Switzerland) daily, was continued indefinitely.

Clinical symptoms before and after stent treatment were determined on the basis of Fontaine's classification (I–IV). The Doppler sonographic ankle–arm indexes (AAI) were evaluated immediately prior to treatment, 2 days and 6 months later, and at yearly intervals. Intravenous digital subtraction angiography (DSA) was performed 3 to 4 days after implantation, and 6 months later. Patients whose symptoms deteriorated after stenting received an intraarterial DSA promptly.

Iliac Arteries

One hundred sixteen patients were treated with stents in the iliac arteries, including 2 patients with atherosclerotic disease of the distal aorta extending into each common iliac artery. Indications for iliac artery stenting were immediate post-PTA restenosis over 40% due to arterial wall recoil (46 patients) or wall dissection (44 patients), occluding or severely stenosing intimal flap (7 patients) and as primary indications for stenting, occlusions of the common and/or external iliac arteries (29 patients) and the aortic bifurcation (1 occlusion) (Figs. 1 and 3). Restenoses, 1 or several months after previous balloon angioplasty (20 patients) or atherectomy (3 patients) were also treated with stents (Tables 1 and 2).

In 72 cases, the common iliac arteries, and in 42 cases, the external iliac artery, were stented. There were 29 occlusions with a mean length of 6.4 cm and a maximum length of 20 cm, and 87 stenoses with a mean length of 2.8 cm and a maximum length of 16 cm. The implanted stents had diameters ranging from 5–11 mm and lengths of 4–8 cm. In 26 cases, 2 or more stents (maximum 4 stents) were implanted consecutively, from proximally to distally, with their ends overlapping a few millimeters. In the case of iliac artery occlusions, the lesions were completely covered with stents, even if there was no residual stenosis after PTA. In primarily stenosed segments, only parts with residual stenosis post-PTA were stented.

Femoropopliteal Arteries

Eighty-four patients received stents into the femoropopliteal artery (Table 1). The indications were post-PTA acute reocclusion (8 cases), serious wall dissections (31 cases), and arterial recoil (35 cases). In the latter 2 instances, a minimum residual stenosis of 40% was required for stenting (Fig. 2). Fifteen patients had a...