ELSEVIER

Value of Cutting Balloon Angioplasty for Limb Salvage in Patients with Obstruction of Popliteal and Distal Arteries

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Popliteal-to-distal bypass is still the gold standard for limb salvage. However, some patients, especially elderly or diabetic patients, are not eligible for such treatment; and problems may arise, including poor healing of distal surgical wounds, delayed resumption of ambulation, and prolonged hospitalization. This prospective multicenter study carried out on an intent-to-treat basis includes 53 extremities in 48 patients presenting critical ischemia due to infrageniculate arterial lesions with no proximal lesions. Two populations were isolated: diabetic patients (56.6%) and elderly patients over 80 years (45%). In 82% of cases the arterial lesions were long, i.e., more than 1 cm. The limb salvage rate at 1 year was 81%. Postoperative mortality was 9%, and mortality at 1 year was 22.6%. These results show that cutting balloon angioplasty can be proposed as primary treatment in patients with critical ischemia due to popliteal and distal artery lesions.

INTRODUCTION

Surgical bypass using the great saphenous vein remains the gold standard for distal revascularization.[1-5] Endovascular techniques have been described in recent reports, but findings have been contradictory for clinical and anatomic indications involving popliteal and distal artery lesions.[6-13] The main purpose of this prospective multicenter study carried out on an intent-to-treat basis was to determine the limb salvage rate at 1 year after treatment using a new type of balloon angioplasty catheter, i.e., the ''cutting balloon'' (Boston Scientific, Watertown, MA), in critical ischemia patients with infrageniculate arterial lesions. The secondary purpose was to determine patency by postoperative Doppler ultrasound at 6 months and 1 year.

PATIENTS AND METHODS

This study included all patients presenting Rutherford grade 4, 5, and 6 critical ischemia associated with short or long arterial stenosis or occlusion located on the middle or distal popliteal artery and/or on distal arteries. If measurable, residual pressure index (RPI) had to be <0.6 for inclusion. Patients who had benefited from proximal surgical or endovascular revascularization within 3 weeks, patients with lesions showing an embolic aspect on arteriography, patients with acute ischemia, and patients requiring immediate major amputation were excluded from study.

Criteria for success were based on clinical and Doppler ultrasound findings on postoperative day 1 and at 1 month, 6 months, and 1 year. Clinical success was defined as limb salvage without amputation greater than transmetatarsal amputation with disappearance of resting pain and healing of ischemic lesions and/or of the distal amputation. Patency

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was evaluated at the angioplasty site by color Doppler ultrasound, and ABI was measured.

Since cutting balloon angioplasty is a transluminal angioplasty technique, it can be performed under local anesthesia using the ipsilateral percutaneous femoral route. It requires a 6-7F introducer and a 0.014-inch guidewire. The special feature of the cutting balloon is to have four longitudinally mounted microsurgical blades that are exposed when the balloon is inflated (Fig. 1). Incision of the atheromatous plaque by these blades followed by compression during balloon dilatation packs the plaque into the wall without major dissection in the same way as with a conventional angioplasty balloon. This technique avoids the need for stent placement to stabilize dissection. The main advantage of endovascular treatment is to allow immediate resumption of ambulation, a factor that is of vital importance in elderly patients.

From December 2003 to December 2004, a total of 53 extremities in 48 patients (five bilateral) were treated at six vascular surgery centers by vascular surgeons with training in endovascular techniques (Table I). All procedures were carried out in the operating room. All patients underwent preoperative arteriography. There were 28 men and 20 women, 45% of whom were over 80 years old. Even in the diabetic group, many patients were over 80 years: 27 patients had diabetes (56%), but 48% of diabetic patients were over 80 years old (Fig. 2).

Critical ischemia in 53 exposed members was classified as Fontaine grade III or Rutherford grade 4 (19%) or as Fontaine grade IV (81%) divided into Rutherford grade 5 (56%) and Rutherford grade 6 (25%).

All arteries treated were located below the midline of the knee. Treatment involved one artery in 39 cases (74%) and two arteries in 14 cases (26%) (Table II).

The length of the lesion (stenosis or occlusion) was <1 cm in 18% of cases, 1-4 cm in 52%, and >4 cm in 30%.

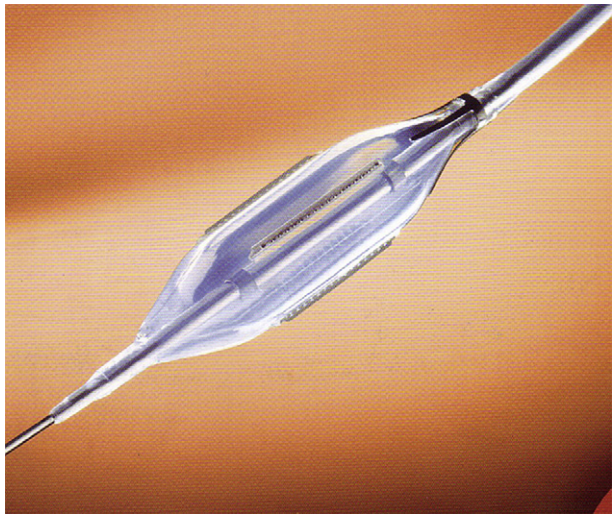

Fig. 1. Inflated cutting balloon catheter. Microsurgical blades are exposed.

Table I. Distribution according to treatment center of 53 members in 48 patients treated using cutting balloon angioplasty

	Patients	Bilateral lesions	Extremities treated
Hôpital Privé Les Franciscaines, Nîmes	24	4	28
CHU Sud, Rennes	12	1	13
Clinique Montréal, Lille	6	0	6
Hôpital St. Joseph, Marseille	3	0	3
Clinique Montréal, Carcassonne	2	0	2
Clinique Millénaire, Montpellier	1	0	1

RESULTS

The procedure was a technical success in 51 cases (96%). The two cases in which it was not possible to pass through the lesion involved long occlusion (>4 cm). Both technical failures led to amputation at the thigh level since bypass was considered unfeasible. One of the two patients died following amputation.

Stenting was not required since results in all 51 cases were considered satisfactory, with no residual lesion >30% and no imaging evidence of major dissection.

Twenty-five associated distal amputations were performed during or immediately after revascularization, i.e., six transmetatarsal amputations, 10 metatarsophalangeal amputations removing at least two segments, and nine isolated toe amputations. There were seven immediate failures in the first month. One 45-year-old patient underwent successful distal bypass. In the other six patients bypass was considered unfeasible, and amputation was performed above the knee in four cases and below the knee in two. In the first month five patients died, including two despite success based on both clinical and Doppler ultrasound findings in patients without resting pain who had resumed ambulation (day 6