Subintimal Angioplasty of Supra- and Infrageniculate Arteries

F. Aarts, MD,[1] J. D. Blankensteijn, MD, PhD,[1] J. A. van der Vliet, PhD, MD,[1] and L. J. Schultze Kool, PhD, MD,[2] Nijmegen, The Netherlands

We retrospectively reviewed our experience with subintimal angioplasty for chronic limb ischemia. Hospital records and films of all subintimal angioplasty procedures performed between October 2002 and December 2004 were reviewed and analyzed for demographic data, clinical data, and comorbid condition status. Thirty-nine subintimal angioplasties were performed in 37 patients (65% male, 35% female), with a median age of 73 years. Median follow-up was 9 months. The 30-day mortality rate was 8%. All-cause mortality was 33% after 24 months. In 23 cases (59%), a subintimal angioplasty of the superficial femoral artery (SFA) alone was performed. Both the SFA and popliteal/crural vessels were used in nine limbs (23%), the popliteal artery alone in three limbs (8%), and the crural arteries alone in four limbs (10%). Initial technical and clinical success rates were 67% and 49%, respectively. The complication rate was 28%. Twenty-four additional surgical interventions were performed after the initial angioplasty procedure, of which 12 were major amputations. Amputation-free survival (limb-salvage rate) was 69% at 12 months [95% confidence interval (CI) 52-85%], and overall survival was 69% (95% CI 52-85%) at 12 months. In patients with critical limb ischemia, subintimal angioplasty is feasible and in most cases technically successful. In these high-risk patients, often with combined cardiac, pulmonary, and diabetic risk and considered unfit for bypass surgery, subintimal angioplasty offers a safe and effective alternative.

INTRODUCTION

Patients with chronic limb ischemia (CLI) have a poor prognosis with regard to limb salvage and survival compared to the general population and at the same time are at increased risk for perioperative complications from major vascular surgery.[1-4] Subintimal angioplasty or percutaneous intentional extraluminal recanalization (PIER) is a percutaneous, endovascular technique for recanalization of occluded arteries. Its minimally invasive nature may allow for treatment of CLI with reduced periprocedural risks.[5-8] Since its inception in the late 1980s, conflicting results have been published for various indications (intermittent claudication versus critical ischemia),[9,10] comorbid conditions (diabetes mellitus and renal insufficiency),[11] and arteries (superficial femoral versus tibial). Consequently, the exact role of subintimal angioplasty in CLI is still unclear. We therefore retrospectively reviewed our experience with subintimal angioplasty for CLI.

PATIENTS AND METHODS

All subintimal angioplasty procedures performed between October 2002 and December 2004 were recorded on an intention-to-treat basis. Bypass surgery is the treatment of choice for peripheral arterial disease. Patient selection for PIER was therefore based on both anatomical and comorbidity status, meaning that patients were considered eligible for PIER only when they were thought to have no surgical reconstructive options or an

[1]*Department of Vascular Surgery, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands.*

[2]*Department of Radiology, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands.*

Correspondence to: F. Aarts, MD, Department of Vascular Surgery, Radboud University Nijmegen Medical Centre, PO Box 9101 6500 HB Nijmegen, The Netherlands, E-mail: f.aarts@chir.umcn.nl

Ann Vasc Surg 2006; 20: 620–624
DOI: 10.1007/s10016-006-9105-0

Published online: June 27, 2006

unacceptably high operative risk. Hospital records and films were reviewed. Follow-up consisted of routine outpatient department visits with clinical evaluation, color Doppler ultrasound scans, and in most cases ankle-brachial index measurement, and colour Doppler ultrasound scans.

Technical success was defined as arterial runoff directly after the procedure. Clinical success was defined as resolution of pain and/or healing of ulcers. Primary failure was defined as the inability to achieve recanalization at the time of the initial procedure. The 30-day mortality rate was defined as death occurring within 30 days of the procedure or during the same hospital admission. Small inguinal hematoma and peripheral arterial perforation were referred to as minor complications. Major complications were those that required immediate reintervention or those that were directly related to the cause of death. Limb salvage was defined as the retention of a functional foot, allowing amputations at and beyond the transmetatarsal level.

Cumulative overall survival, amputation-free survival (limb salvage), and freedom from reintervention (intervention-free survival) were calculated using the Kaplan-Meier method. Categorical data were compared using the Pearson chi-squared and Fisher's exact tests, and continuous variables were compared using the independent samples *t*-test, with $p < 0.05$ considered statistically significant.

Subintimal Angioplasty Technique

The technique has been extensively described in the literature. In short, an antegrade puncture of the common femoral artery was performed. Access to the subintimal space was obtained with a 5-French Terumo (Tokyo, Japan) Cobra catheter and a 0.035-inch Terumo guidewire. After reentry to the true distal lumen, a dilatation of the subintimal channel with a 3-6 mm balloon was performed (3 mm for the lower limb vessels, 6 mm for popliteal and superficial femoral arteries). Additional procedures like stenting were performed only in case of outflow obstruction following the recanalization.

RESULTS

The group consisted of 37 patients (65% male, 35% female) with a median age of 73 years (range 25-75%, interquartile range 65-82%), in whom 39 subintimal angioplasties were performed.

Median preprocedural ankle-brachial index was 34% (range 25-75%, interquartile range 25-45%). One patient had undergone a bifurcated aortoiliac bypass, and four patients had previously undergone vascular bypass surgery in the contralateral limb. Baseline demographics and comorbid conditions are summarized in Table I.

Subintimal angioplasty of the superficial femoral artery (SFA) alone was performed in 23 cases (59%). A procedure of both SFA and popliteal/crural vessels was performed in nine limbs (23%). A procedure of the popliteal artery alone was performed in three limbs (8%) and one of the crural arteries alone in four limbs (10%). Additional procedures to improve in- and outflow were undertaken in seven patients prior to the PIER procedure, consisting of two percutaneous transluminal angioplasty (PTA) procedures of the SFA (in one case with additional stenting) and, in five cases, PTA with additional stenting of the external iliac artery in three cases. In three cases, an additional PTA procedure of the vessel distant to the PIER vessel was performed.

The initial technical success rate was 67% and the clinical success rate was 49%. Of the 13 cases in which subintimal angioplasty failed, eight amputations and one bypass were ultimately required. A wait-and-see policy was undertaken in four cases, two of whom died within 3 months of the initial subintimal angioplasty. A repeat subintimal angioplasty was undertaken in five limbs (13%) and, of these, two procedures failed (one of which was complicated by arterial perforation). One patient was planned to undergo a repeat subintimal angioplasty but died before it was undertaken.

Complications occurred in 11 (28%) of the procedures, three of which were major complications (two acute arterial occlusions that both needed reintervention and one retroperitoneal hematoma). One of the patients with acute arterial occlusion died after undergoing a lower limb amputation due to infection of the bypass, which was undertaken after the occlusion.

Median follow-up was 9 months (interquartile range 0-24). The 30-day mortality rate was 8% ($n = 3$). All-cause mortality was 33% after 24 months.

After the subintimal angioplasty procedure, 28 surgical interventions were performed. These additional surgical procedures consisted of six intended femoropopliteal bypasses, five intended femorocrural bypasses, and one femoropedal bypass. A total of 12 major amputations were performed: three above-knee amputations, two through-knee amputations, and seven below-knee amputations. Digital amputation was performed in two patients. In three patients, although initially thought to have