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Below knee angioplasty in elderly patients: Predictors of major adverse clinical outcomes

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ABSTRACT

Aim: To determine predictors of clinical outcome following percutaneous transluminal angioplasty (PTA) in elderly patients with below knee atherosclerotic lesions causing intermittent claudication (IC) or critical limb ischaemia (CLI).
Materials and methods: Over 7.5 years, 76 patients (CLI 72%, $n = 55$) underwent below knee PTA. The composite end-point of interest was major adverse clinical outcome (MACO) of the treated limb at follow-up which was defined as clinical failure, need for subsequent endovascular or surgical revascularization or amputation. Actuarial freedom from MACO was assessed using Kaplan–Meier curves and multivariable Cox proportional hazards regression.
Results: IC was improved in 95% at mean 3.4 years (range 0.5–108 months). Successful limb salvage and ulcer healing were seen in 73% with CLI. Most failures were in the CLI group (27% CLI vs. 5% IC), with an amputation rate of 16% for CLI vs. 5% for IC and persistent ulceration in 24% of CLI. Significant independent predictors of MACO were ulceration (hazard ratio 4.02, 95% CI = 1.55–10.38) and family history of atherosclerosis (hazard ratio 2.53, 95% CI = 1.1–5.92).
Conclusion: Primary below knee PTA is a feasible therapeutic option in this elderly population. Limb ulceration and family history of atherosclerosis may be independent predictors of adverse outcome.

1. Introduction

Atherosclerosis is one of the leading causes of morbidity and mortality in the Western world at present. Peripheral arterial disease (PAD) has a prevalence of 11.4% to 33.8% in those over 60 years of age [1–3], is associated with a relative risk of 3.1 for all-cause mortality [4,5] and relative risk of 6.6 for coronary artery disease (CAD) related mortality [4]. Within this elderly population, 6–10% will have symptoms of intermittent claudication, and of these, 10–20% may develop severe limb-threatening ischaemia, requiring endovascular or surgical revascularization or even subsequent amputation [6]. Despite these facts, there are fewer studies currently in the literature focusing on PAD compared to CAD, with further trials recommended [7].

Traditionally, below knee percutaneous transluminal angioplasty (PTA) was perceived as difficult due to small vessel size, arterial spasm [8,9] and limited commercial availability of suitably sized balloon catheters, despite being first reported in 1964 [10]. Subsequent studies focused on the merits of infrageniculate PTA in achieving limb salvage in patients with critical limb ischaemia (CLI) [8,9,11,12], and intermittent claudicants (IC) [13].

The primary purpose of this study was to evaluate the mid-term clinical outcome of patients with both IC and CLI, following PTA of below knee atherosclerotic lesions. The secondary objective was to identify any patient related or lesion related predictors of major adverse clinical outcome (MACO).

2. Methods

2.1. Patients

We conducted a retrospective study of 76 consecutive patients with symptomatic PAD, either IC or CLI, who underwent PTA of a below knee arterial stenosis or occlusion, in the Interventional Radiology Department of a tertiary referral teaching hospital, over a 7.5-year period from 01/01/99 to 30/06/06. Patients were identified from the procedure logbook, and follow-up data obtained by clinical and non-invasive radiological surveillance until 31/12/07. Follow-up data were available for a maximum

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Table 1
Patient demographics.

Patient demographics (n = 76)	
Males, n, %	36, 47
Females, n, %	40, 53
Age (years)	73 (range 47–92)
Intermittent claudicants, n, %	21, 27.6
Critical limb ischaemia, n, %	55, 72.4
Rest pain (RP) only, n, % of CLI	16, 29
Ulceration +/− RP, n, % of CLI	39, 71
Cardiovascular risk factors, n, %	
Cigarette smoking	48, 63
Diabetes mellitus	30, 39
Hypercholesterolemia	44, 58
Hypertension	44, 58
Family history of atherosclerosis*	25, 33
Previous intervention, n, %	
PTA	11, 14
Surgical bypass	12, 16
Contralateral amputation (AKA)	4, 5
CABG	7, 9
Other sites atherosclerosis, n, %	36, 47
Coronary arteries	24,32
Carotid arteries	16,21
Renal arteries	3,4
Peri-procedure concomitant medication, n, %	
NS Aspirin 75 mg	50, 66
Clopidegrol	9, 12
Statin	34, 45
Warfarin	8, 11

CABG = coronary artery bypass grafting.
* First degree relative with major cardiovascular event, i.e. myocardial infarct/cerebrovascular accident/PAD.

period of nine years and a minimum period of 18 months. Hospital medical notes, including inpatient and outpatient clinic/office visits, and procedure details were reviewed. Clinical outcomes, including improvement in claudication distance/rest pain and ulcer healing/resolution, were documented prior to discharge and at subsequent outpatient visits, with repeat ankle brachial index (ABI) performed within six weeks.

All patients had a conventional digital subtraction angiogram performed for diagnosis and characterisation of the lesions, before PTA. Initial MRA was not standard practice in our department at that time. Prior to PTA, all patients had a full vascular assessment, including clinical history, physical examination, ABI, risk factor profile and serum creatinine. On the basis of this assessment patients were then categorised as IC or CLI, with IC being defined as lower limb (calf, thigh or buttock) pain brought on by exertion and relieved by rest, and with CLI being defined as rest pain, arterial ulceration and/or gangrene. Appropriate medical management was commenced, along with risk factor modification (Table 1).

2.2. Study inclusion and exclusion criteria

Patients with treated atherosclerotic lesions at or below the mid popliteal artery (arterial segments below the knee joint) were included. Patients who had co-existing proximal lesions treated on the same occasion were also included. Intermittent claudicants and patients with CLI were included. Exclusion criteria included patients who had lesions treated proximal to the mid-popliteal arterial segment.

2.3. Procedure details

Angiographic information regarding diseased segment location, length and degree of stenosis or occlusion, and extent of distal run-off was available on all patients prior to angioplasty. Arterial location was divided into two regions, mid-popliteal (MP) if the lesion was located within the mid section of the popliteal artery, and distal popliteal (DP) if the lesion was within the distal popliteal, tibioperoneal trunk or any of the three run-off vessels (anterior/posterior tibial/peroneal arteries). The atherosclerotic lesion was compared to that of the proximal non-diseased arterial segment to determine degree of stenosis, measured as a percentage. Following informed consent, ipsilateral antegrade femoral arterial puncture was performed in 91% of patients (n = 69). A crossover technique was used in the remainder (n = 7). All patients received 3000–5000 IU intra-arterial heparin prior to balloon angioplasty. The angioplasty balloon diameter was determined from the diameter of the proximal non-diseased arterial segment (mean diameter = 4.8 mm, range 3–6 mm). The balloon was inflated to 8–10 atmospheres for 30–60 s with a mechanical inflator. Following deflation, routine angiography was performed with the guide-wire remaining across the lesion and procedure outcome was recorded. (Figs. 1–3) A number of patients required subintimal angioplasty (n = 9, 12%) due to lesion length and occlusion. The subintimal angioplasty followed Bolia's previously described techniques [14].

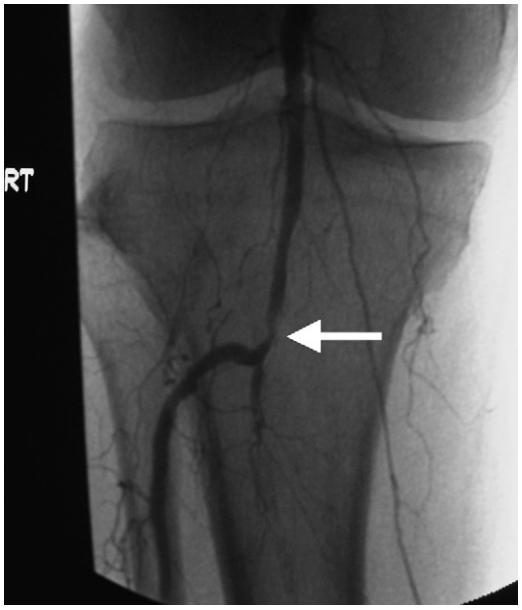

Fig. 1. Seventy-two-year old male who presented with 150 m intermittent claudication. Digital subtraction right lower limb angiogram showing a tibio-peroneal trunk stenosis (arrow).

2.4. Definition of study end-point and follow-up

The composite end-point of interest was major adverse clinical outcome (MACO) of the treated limb at follow-up, which was defined as clinical failure, the need for subsequent endovascular or surgical revascularization, need for above or below knee amputation. Clinical follow-up data were collected at each clinic visit. Surviving patients remained on this annual surveillance protocol. The survival and freedom from MACO commenced at the time of angioplasty and ended at the time of death/MACO event or at last follow-up (censoring).

2.5. Statistical methods

Patients were grouped according to whether they had experienced MACO of the treated limb at follow-up (Table 2). Continuous variables were presented as means ± standard deviation (SD) or