Long-term clinical outcome following lower limb arterial angioplasty

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ABSTRACT

INTRODUCTION The aim of this study was to determine the clinical outcome of lower limb arterial angioplasty in a busy district general hospital practice.

PATIENTS AND METHODS All angioplasties performed from January 1999 to December 2004 were identified and data collected included cardiovascular risk factors, indications for and complications of angioplasty, limb salvage and patient survival rates, and clinically significant re-stenoses.

RESULTS 471 interventions were performed in 385 patients (231 men, 154 women). The median age was 67.9 years (range: 39–93 years). Indications for angioplasty were critical ischaemia ($n=247$, 52%) and lifestyle-limiting intermittent claudication ($n=224$, 48%). Stenotic lesions accounted for 378 (80%) cases and occlusion for 93 (20%). Radiological success was obtained in 417 (88.5%), improving to 93.6% if only those in whom access was achieved were included. Post-angioplasty complications were observed in 42/471 (9.1%) of interventions. The actual patient survival at 1, 2, and 3 years was 87.4%, 85.1% and 83.2% respectively. Indication for angioplasty and the number of lesions present were identified as risk factors for outcome on multivariate analysis. The cumulative post-angioplasty patency rates at 1, 2 and 3 years were 86.0%, 83.1% and 81.6% respectively. The only factor associated with patency was the mode of presentation.

CONCLUSIONS Angioplasty for lower limb peripheral vascular disease can be performed safely and efficaciously with a high technical success rate and a low complication rate. The patient survival and post-angioplasty patency data reflect the progressive and multi-site nature of the underlying disease process.

KEYWORDS

Angioplasty – Peripheral vascular disease – Ischaemia – Clinical outcome – Survival

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The concept of angioplasty, first described by Dotter and Jenkins in 1964,¹ has now become the treatment of choice for arterial stenoses in most anatomical locations, with level I evidence² for the treatment of both lifestyle-limiting intermittent claudication and critical ischaemia, and the establishment of treatment guidelines for each type of lesion.^{2,3}

In an overview of the results of lower limb angioplasty, Davies *et al* reported initial radiological success rates of 90–95% for single stenotic lesions and 80–95% for occlusions of the femoropopliteal segment using a standard antegrade femoral approach⁴ with patency rates of 71%, 59%, and 53% at one, three and five years respectively.

A number of factors have been shown to compromise patency rates: lesion characteristics – location, nature of lesion (occlusion vs stenosis), length, number of lesions, multilevel disease, adequate run-off; demographics – gender, diabetes mellitus; clinical – indication (intermittent claudication vs critical ischaemia), recurrent lesions; and procedure-related – vessel dissection, radiological response.^{5–9}

There are a number of procedure-related complications associated with angioplasty with a mean overall rate of 10% reported by Davies *et al*.⁵ The prevalence of recog-

nised complications of angioplasty was summarised in the American Heart Association (AHA) guidelines and includes: severe bleeding 3.4%; false aneurysm 0.5%; arteriovenous fistula 0.1%; thrombosis 3.2%; rupture 0.3%; dissection 0.4%; embolisation 2.3%; emergency operation 2%; limb loss 0.2%; and mortality 0.2%.¹⁰

The main difficulty in interpreting much of the data in the literature is that it represents the experiences obtained in large-volume tertiary referral centres and thus there is some question regarding its applicability to non-specialist practice. With the proliferation of angioplasty and a recognition of its benefits over surgery in many patients, there has been a greatly increased demand for the service, leading to the development of treatment programmes outside the larger tertiary centres.

The aim of this study was to report outcomes of a lower limb angioplasty programme from a non-teaching hospital setting.

Patients and Methods

All patients undergoing lower limb angioplasty during the period January 1999 to December 2004 were identified from

Figure 1 Patient survival according to clinical indication for operation

Figure 2 Patient survival according to number of lesions present

Table 1 Risk factors for cardiovascular disease in patients undergoing angioplasty

Risk factors	Yes	No
Smoking		80 (17%)
Smoker	220 (46.7%)	
Ex-smoker	171 (36.3%)	
Diabetes	143 (30%)	328 (70%)
Hypertension	238 (50.5%)	233 (49.5%)
Hyperlipidaemia	165 (35%)	306 (65%)
Ischaemic heart disease	159 (33.8%)	312 (66.2%)
Stroke	97 (20.6%)	374 (79.4%)
Renal failure	28 (5.9%)	443 (94.1%)

a prospectively maintained radiology database. Those undergoing primary stenting procedures were not included in this analysis.

Data collected from patient records included: indications for angioplasty; cardiovascular risk factors; location, number and nature of lesions; complications of angioplasty; limb salvage rates; and rates of clinically significant re-stenosis.

Data analysis was performed using SPSS® v15.0 (SPSS Inc, Chicago, Illinois, US). Statistical significance was assessed at the 5% level. The Kaplan–Meier method was used to assess the overall survival and post-angioplasty patency rates. A univariate analysis was performed to assess for a significant difference in factors believed to be of importance in relation to overall survival and post-angioplasty patency.

Table 2 Indications for angioplasty

Risk factors	Number
<i>Indication for angioplasty</i>	
Critical ischaemia	247 (52%)
Lifestyle-limiting intermittent claudication	224 (48%)
<i>Type of lesion</i>	
Stenosis	378 (80%)
Occlusion	93 (20%)
<i>Number of stenoses</i>	
Single	259 (68.5%)
Multiple	119 (31.5%)
<i>Number of occlusions</i>	
Single	59 (63.4%)
Multiple	34 (36.6%)

A multivariate analysis was then performed by Cox regression (stepwise forward model) on those variables identified during univariate analysis.

Results

A total of 471 angioplasties were attempted. The majority of procedures were performed in men ($n=317$, 67.3%) and the mean patient age was 67.9 years (range: 39–93 years).

The cardiovascular risk factor profiles are summarised in Table 1. As a result of patient demographics and co-morbidities, the vast majority of procedures ($n=457$, 97%) were

performed as inpatient procedures.

The indications for angioplasty are summarised in Table 2 and the distribution of lesions subjected to angioplasty in Table 3.

A good radiographic result was observed in 417 (88.5%) cases. The most common reason for failure was abandonment due to inadequate access ($n=29$). In the remaining 25 patients, angioplasty was performed but the radiological result was deemed inadequate. If only those in whom access was possible are included, the success rate improves to 363/388 (93.6%).

The complication rate was 43/471 (9.1%) (Table 4). However, it fell to 4.5% when only those considered by the AHA² were included. None of the patients required emergency operation, intervention or a blood transfusion.

There were eight (1.7%) deaths within thirty days of angioplasty. The patients in this group had a mean age of 77 years, all had critical ischaemia with ulceration as the indication for angioplasty and a history of cardiovascular disease. None of the patients experienced a complication of angioplasty and all died following a myocardial event.

Immediate radiological success rates for single and multiple stenoses were 92.1% and 91.4% respectively, whereas the initial success following angioplasty of single and multiple occlusions was 80.8% and 71.9%.

Fifty-eight patients underwent bypass surgery ($n=47$) or stenting ($n=11$) following angioplasty. Twenty-nine patients had a procedure less than three months after surgery, six of which had experienced an angioplasty-related complication (dissection [$n=2$]; extravasation [$n=1$]; perforation [$n=1$];

haematoma [$n=1$]; sub-intimal dissection [$n=1$].) In the remaining 23 patients, the angioplasty was performed as part of a management plan to dilate a stenosis in order to obtain either improved inflow or outflow prior to a surgical bypass.

In 29 cases where surgery was performed at an interval of more than 3 months, the mean interval between angioplasty and bypass surgery/stenting was 313 days (range: 91–1,785 days). In 11 of 29 cases, stenoses were within the same arterial segment and regarded as recurrences, whereas the remaining 18 lesions were regarded as *de novo*, occurring in a different segment of artery or contralateral limb.

Eight patients underwent amputation following angioplasty. All of these initially presented with critical ischaemia and ulceration. Three amputations were performed within one month of angioplasty (18, 24 and 27 days), with angioplasty having been performed in order to optimise blood flow to the distal limb and maximise chances of stump healing. In the remaining four cases, amputation was performed at an extended interval (238, 253, 399 and 407 days) and in each case angioplasty had improved blood flow to the distal limb but was inadequate to provide healing.

One hundred and eight patients had angioplasty performed for leg ulcers. In 95 of these cases, angioplasty was the sole treatment modality and 49 (51.6%) of these healed completely.

Mean patient follow up from angioplasty to surgical intervention, patient death or end of study was 28.3 months (range: 0–80 months). To more accurately assess the role of angioplasty, procedures performed prior to elective surgery were excluded, as were those performed following previous surgery or amputation, leaving 430 angioplasties for analy-

Figure 5 Post-angioplasty patency in relation to anatomical distribution of disease.
Online version in colour.

sis.

Patient survival

Univariate analysis revealed a significant difference in survival based on the indication for angioplasty (Fig 1) (critical ischaemia vs intermittent claudication; $p<0.001$) and number of lesions present (Fig 2) (multiple vs single; $p=0.02$). The actual overall patient survival at 1, 2 and 3 years was 87.4%, 85.1% and 83.2% respectively, while the 1, 2 and 3-year overall survival rates for patients with intermittent claudication were 94.7%, 93.2% and 93.2%. For critical ischaemia the corresponding rates were 80.7%, 77.6% and 74.4%. In comparing single to multiple lesions, the overall survival rates at 1 year were 88% vs 85.6%, at 2 years they were 87.3% vs 80.1% and at 3 years 85.6% vs 78.8%. There was no difference in outcome when comparing the nature of the lesion present ($p=0.416$), radiological outcome of angioplasty ($p=0.696$) or development of complications ($p=0.938$).

Subsequent multivariate analysis revealed that presentation (risk ratio = 2.89; 95% confidence interval = 1.82–4.58) and number of lesions (risk ratio = 1.60; 95% confidence interval = 1.06–2.44) remained significant predictors for overall survival.

There was a wide distribution in outcome according to the location of the main lesion (Fig 3) with common iliac artery angioplasty superior to: popliteal ($p\leq 0.001$); superficial femoral artery ($p=0.006$); external iliac artery ($p=0.008$); and common femoral artery ($p=0.05$).

Angioplasty patency

The actual graft patency at one, two and three years was

Table 3 Distribution of lesions requiring angioplasty ($n=557$)

Site of the lesion	Number of cases
Superficial femoral artery	217
Common iliac artery	127
External iliac artery	81
Popliteal artery	80
Common femoral artery	25
Other sites	29

Table 4 Complications experienced following angioplasty ($n=43$)

Complication	Number
Small haematoma	12 (2.5%)
Dissection	9 (1.9%)
Spasm	7 (1.5%)
Sub-intimal dissection	4 (0.8%)
Thrombosis	4 (0.8%)
Pain	3 (0.6%)
Embolisation	2 (0.4%)
Extravasation	1 (0.2%)
Perforation	1 (0.2%)

86.0%, 83.1% and 81.6% respectively, with the indication for angioplasty (Fig 4) (critical ischaemia vs intermittent claudication; $p<0.001$) being the only significant factor. The one, two and three-year overall survival rates for patients with intermittent claudication were 94.2%, 92.3% and 92.3%, whereas for critical ischaemia the corresponding rates were 78.5%, 75.3% and 71.7%.

There was no difference in outcome when comparing the number of lesions ($p=0.064$), the nature of the lesion present ($p=0.437$), radiological outcome of angioplasty ($p=0.955$) or development of complications ($p=0.761$).

The distribution of outcome in relation to the location of the main lesion is shown in Figure 5 and is similar to that seen for overall survival. The patency rates were highest in those undergoing angioplasty of the common iliac artery and worst for patients with infragenicular stenoses ($p\leq 0.001$).

Symptomatic outcome

The majority ($n=262$, 60.9%) of patients reported that their claudication distances improved, with 123 (28.6%) patients experiencing no change and 15 (3.5%) reporting a deterioration. Data were absent for 30 patients (7.0%). When the data were re-examined including only those with a successful radiological result, the improvement rate increased to 69.6% and the 'no improvement' rate fell to 3.7%, leaving 26.7% unchanged.

Discussion

The primary finding of this study is that angioplasty can be performed with acceptable periprocedural morbidity and good long-term outcome in a non-tertiary centre setting.

The proportion of patients undergoing angioplasty for critical ischaemia in the current study (52%) was greater than in reported meta-analyses of angioplasty for iliac¹¹ and femoropopliteal disease.^{12,15}

The majority of angioplasties were performed for stenotic lesions, this being the case in most of the published literature.^{11–14} However, almost a third of those with stenoses had more than one lesion treated by angioplasty. Furthermore, even though occlusive lesions accounted for only 20% of cases, a third had more than one occlusion.

Davies *et al* indicated that the overall complication rate of angioplasty should be less than 10%, while in recent meta-analyses only major complications were included.^{11–14} The prevalence of major complications in the current series at 4.5% is in keeping with these meta-analyses where rates were 4.3–8.1%.

The 30-day mortality appears high at 1.7%. However, the proportions of critically ischaemic patients was higher and the major complication rates favourable, suggesting patient rather than technical factors as the cause of the increased mortality. Moreover, demographic and co-morbidity data were missing from the other series, thus adding further obstacles to a fair comparison of the series.

The fact that overall survival and patency rates were very similar and that the number of patients requiring bypass surgery or amputation were small suggests that the main factor determining outcome is the extent of the atherosclerotic cardiovascular disease. It is well recognised that patients with peripheral vascular disease have a high prevalence of cardiovascular disease and that the majority of claudicants (in excess of 80%) die of cardiovascular causes.^{15–19} Indeed, the mortality of individuals with claudication is four times greater than an otherwise comparable population.²⁰ This also implies that patients with peripheral vascular disease, even in the absence of symptomatic cardiovascular disease, require treatment of cardiovascular risk factors.²¹

The patency rates in this series were superior to those in the meta-analyses for iliac¹¹ and femoropopliteal disease.^{12,15} In the current series, the only factor associated with a poorer post-angioplasty patency was the indication for angioplasty, with critical ischaemia being associated with a poorer outcome.

Although a formal quality-of-life assessment tool was not used, 70% undergoing a technically successful procedure reported a significantly improved claudication distance following angioplasty. There are limited published data looking at the quality of life following angioplasty for lower limb vascular disease but the data that do exist suggest an improved quality of life following angioplasty.^{22,23}

Conclusions

This study has demonstrated that angioplasty for peripheral vascular disease may be performed safely and efficaciously

in a non-tertiary referral centre setting. The results of angioplasty in this series are comparable to those obtained from larger specialist vascular units in terms of complication rates and graft patency, with low rates of recurrence and a minimal requirement for further treatment (be it stenting, surgical bypass or amputation). Furthermore, our long-term survival appears to be better than expected and this may be related to our careful follow up of a local population.

References

- Dotter CT, Judkins MP. Transluminal treatment of arteriosclerotic obstruction. *Circulation* 1964; **30**: 654–670.
- Hirsch AT, Haskal ZJ, Hertzner NR *et al*. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): executive summary. *J Am Coll Cardiol* 2006; **47**: 1,239–1,312.
- Norgren L, Hiatt WR, Dormandy JA *et al*. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg* 2007; **45** (Suppl): S5–S67.
- Davies MG, Waldman DL, Pearson TA. Comprehensive endovascular therapy for femoropopliteal arterial atherosclerotic occlusive disease. *J Am Coll Surg* 2005; **201**: 275–296.
- Capek P, McLean GK, Berkowitz HD. Femoropopliteal angioplasty. Factors influencing long-term success. *Circulation* 1991; **83**(2 Suppl): 70–80.
- Johnston KW. Femoral and popliteal arteries: reanalysis of results of balloon angioplasty. *Radiology* 1992; **183**: 767–771.
- Huinink MG, Donaldson MC, Meyerovitz MF *et al*. Risks and benefits of femoropopliteal percutaneous balloon angioplasty. *J Vasc Surg* 1993; **17**: 183–192.
- Becquemin JP, Cavillon A, Haiduc F. Surgical transluminal femoropopliteal angioplasty: multivariate analysis outcome. *J Vasc Surg* 1994; **19**: 495–502.
- Clark TW, Groffsky JL, Soulen MC. Predictors of long-term patency after femoropopliteal angioplasty: results from the STAR registry. *J Vasc Interv Radiol* 2001; **12**: 923–933.
- Pentecost MJ, Criqui MH, Dorros G *et al*. Guidelines for peripheral percutaneous transluminal angioplasty of the aorta and lower extremity vessels. *Circulation* 1994; **89**: 511–531.
- Bosch JL, Huinink MG. Meta-analysis of the results of percutaneous transluminal angioplasty and stent placement for aortoiliac occlusive disease. *Radiology* 1997; **204**: 87–96.
- Huinink MG, Wong JB, Donaldson MC *et al*. Patency results of percutaneous and surgical revascularization for femoropopliteal arterial disease. *Med Decis Making* 1994; **14**: 71–81.
- Huinink MG, Wong JB, Donaldson MC *et al*. Revascularization for femoropopliteal disease. A decision and cost-effectiveness analysis. *JAMA* 1995; **274**: 165–171.
- Nicoloff AD, Taylor LM Jr, McLafferty RB *et al*. Patient recovery after infrainguinal bypass grafting for limb salvage. *J Vasc Surg* 1998; **27**: 256–263.
- Imparato AM, Kim GE, Davidson T, Crowley JG. Intermittent claudication: its natural course. *Surgery* 1975; **78**: 795–799.
- McAllister FF. The fate of patients with intermittent claudication managed nonoperatively. *Am J Surg* 1976; **132**: 593–595.
- Cronenwett JL, Warner KG, Zelenock GB *et al*. Intermittent claudication. Current results of non-operative management. *Arch Surg* 1984; **119**: 430–436.
- Leng GC, Fowkes FGR. The epidemiology of peripheral vascular disease. *Vasc Med Rev* 1993; **4**: 5–18.
- Walsh DB, Gilbertson JJ, Zwolak RM *et al*. The natural history of superficial femoral artery stenoses. *J Vasc Surg* 1991; **14**: 299–304.
- Smith GD, Shipley MJ, Rose G. Intermittent claudication, heart disease risk factors, and mortality. The Whitehall Study. *Circulation* 1990; **82**: 1,925–1,931.
- D'Souza J, Patel NN, Rocker M *et al*. Management of cardiovascular risk factors by primary care physicians in patients with peripheral arterial disease. *Surgeon* 2008; **6**: 140–147.
- Klevsgård R, Hallberg IR, Risberg B, Thomsen MB. The effects of successful intervention on quality of life in patients with varying degrees of lower-limb ischaemia. *Eur J Vasc Endovasc Surg* 2000; **19**: 238–245.
- Kalbaugh CA, Taylor SM, Blackhurst DW *et al*. One-year prospective quality-of-life outcomes in patients treated with angioplasty for symptomatic peripheral arterial disease. *J Vasc Surg* 2006; **44**: 296–302.