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Subintimal angioplasty for superficial femoral artery occlusion: poor patency in critical ischaemia

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ABSTRACT

INTRODUCTION Subintimal angioplasty has been proposed for the treatment of long segment occlusive disease and for patients with critical limb ischaemia (CLI) with significant co-morbidity. There is no consensus as to short- and long-term patency. We present our experience with this technique.

METHODS Between 1995 and 2000, 43 consecutive patients (48 limbs) underwent subintimal angioplasty for superficial femoral artery occlusions. Outcome measures were haemodynamic and/or symptomatic patency.

RESULTS Technical success was achieved in 14/17 limbs with CLI (82%) and 30/31 (97%) with intermittent claudication (IC). There were 7 complications (15%), 6 occurring in the claudicant group. The median occlusion length was 10 cm for CLI and 6 cm for IC. Patency at 12 and 36 months, on an intention-to-treat basis, was 69% and 58% for claudicants and 25% and 25% for patients with CLI ($P = 0.0005$ and $P = 0.0044$, respectively). Following only technically successful procedures, 12-month patency was 72% (IC) and 31% (CLI) ($P = 0.009$). Patients with occlusions ≥ 10 cm were more likely to re-occlude than those < 10 cm (12-month patency 60% versus 25%; $P = 0.037$).

CONCLUSIONS In this series, short- and long-term patency in patients with CLI is poor. Subintimal angioplasty in the treatment of CLI should be reserved for those patients not fit for surgical bypass.

KEYWORDS

Subintimal angioplasty – Critical ischaemia – Peripheral vascular disease – Vascular surgery

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Subintimal angioplasty has previously been described for the treatment of chronic occlusive peripheral vascular disease.[1] Its exact role has yet to be defined, but it offers an alternative to conventional percutaneous transluminal angioplasty (PTA), particularly when the latter is not technically possible. Technical failure of PTA is often attributed to long segment occlusions[2] and so subintimal angioplasty may offer the most suitable treatment for these patients. Another group who may benefit are patients with critical limb ischaemia and significant co-morbidity who are at high risk of loss to life and/or limb from surgical intervention. There are few studies illustrating long- and/or short-term patency in the treatment of femoropopliteal occlusions by this technique and those that have been published do not show consistent results. Reported cumulative patency rates vary from 58% to 51% at 6–12 months.[3,4] Patient populations within these studies were very different with critical limb ischaemia representing 11–62% of the study groups. The purpose of this study was to describe our own short- and long-term results of subintimal angioplasty for superficial femoral artery (SFA) disease.

Patients and Methods

All patients who had SFA subintimal angioplasty between November 1995 and October 2000 were studied retrospectively. Procedures were undertaken by one of two consultant radiologists using the technique described by Bolia *et al.*[1]

Decision to treat was taken by both surgeon and radiologist at weekly multidisciplinary meetings. All patients with critical ischaemia and lesions amenable to this technique were treated with subintimal angioplasty as first-line treatment. Patients with SFA disease and intermittent claudication who failed to improve using conservative measures and insisted on alternative interventional treatments were offered subintimal angioplasty if radiologically appropriate. All patients with critical ischaemia had rest pain for more than 2 weeks or ulceration or gangrene, consistent with

Fontaine stage III and IV.[5] Outcome was measured by symptomatic (ulcer healing, resolution of rest pain, increase claudication distance) and/or haemodynamic improvement (ankle brachial pressure indices [ABPI], duplex or angiography). All patients had ABPI measurements before angioplasty then 1 day and usually 6 weeks post-procedure. Follow-up patency in claudicants was then assessed on a largely symptomatic basis whereas those with CLI were assessed by a combination of ABPI and symptomatic change. Follow-up continued until return of claudication, recurrent intervention, re-occlusion or death. All vessel occlusions were confirmed by angiography. Patency rates stated are primary patency rates.

Statistical analysis of patency was carried out using the Kaplan-Meier analysis and comparisons were made with the Mantel-Haenszel log-rank test. The log-rank test was used in a univariate analysis of the effects of smoking, diabetes mellitus, length of occlusion and number of run-off vessels on patency rates. Discrete variables were analysed with the Pearson χ^2 test.

Technique

Intentional subintimal SFA angioplasty was performed from either an antegrade ipsilateral femoral approach or an ipsilateral retrograde popliteal approach. For the antegrade approach, the common femoral artery was punctured below the inguinal ligament using fluoroscopic guidance. A standard 0.0035 inch 1.5 mm J guide-wire (Cook, Bjaeverskov, Denmark) and either a 6Fr sheath or 5Fr Van Andel catheter (Cook) was introduced. For the retrograde approach, the popliteal artery was punctured at the level of the knee joint using the Smart Doppler ultrasound needle (Cardiovascular Dynamics, CA, USA), usually from a posteromedial position. A standard J guide-wire and a 5f Van Andel catheter were introduced. The rest of the procedure was similar for the two approaches. Angiographic images were obtained and 2000 units of heparin given intra-arterially. Using 'roadmapping', the occlusion was crossed using the technique of Bolia *et al.*[1] The subintimal plane was entered using the Van Andel catheter and angled hydrophilic guide-wire (Terumo, Tokyo, Japan). Care was taken to avoid the origin of any collateral vessels. The guide-wire was formed into a loop and together with the catheter was advanced beyond the occlusion. The loop was then shortened and the lumen re-entered. The intraluminal position was confirmed with contrast. The catheter was then removed and replaced with an appropriate size balloon (usually a 4,5 or 6 mm × 40 mm) of various makes. The balloon was the inflated twice for 30 s along the length of the occlusion. A completion angiogram was performed and any residual stenosis (greater than 30%) was re-dilated. Technical success was defined as restored patency with no stenosis greater than 30%. Aspirin 75 mg was routinely started post-procedure and continued indefinitely.

Table 1 Details of all patients who underwent subintimal angioplasty

	Critical ischaemia	Intermittent claudication	*P* value
Number of limbs	17	31	
Median age (range) years	79 (50–92)	72 (49–88)	
Men	4 (24%)	20 (65%)	0.12
Smoking	9 (53%)	21 (68%)	0.91
Hypertension	9 (53%)	13 (42%)	0.97
Diabetes	4 (24%)	6 (19%)	0.99
Hyperlipidaemia	0	5 (16%)	0.55
Ischaemic heart disease	6 (35%)	19 (61%)	0.56
Cerebrovascular accident	2 (12%)	2 (6%)	0.98

P values calculated using the Pearson χ^2 test.

Results

During the time of the study, 43 consecutive patients (48 limbs) were identified as having undergone subintimal angioplasty. There were 21 women (23 limbs) and 22 men (25 limbs) with a median age of 73 years (range, 49–92 years). Seventeen limbs were critically ischaemic. The remaining patients (31 limbs), had intermittent claudication at distances between 5 and 500 yards. The clinical details of the patients are shown in Table 1.

The median number of risk factors (smoking, hypertension, diabetes, hyperlipidaemia, ischaemic heart disease and cerebrovascular accident) for patients with CLI and intermittent claudication was 2 for each group. The median number of run-off vessels was 2 and 3 for those with CLI and intermittent claudication, respectively. The median occlusion length for claudicants and those with CLI was 6 cm and 10 cm, respectively.

Technical success was achieved in 44/48 (92%) limbs in total, 14/17 limbs with CLI (82%) and 30/31 (97%) with intermittent claudication ($P = 0.56$). There were seven complications (15%), five distal embolisations and two thromboses; six occurred in patients with claudication. Three patients received 24-h intravenous heparin and one patient underwent thrombolysis; two patients required no further intervention due to only small debris emboli and good run-off. One patient subsequently had an endarterectomy but no patient suffered limb loss as a direct result of the procedure. The 30-day mortality was 6% (3 deaths) all occurring in the critically ischaemic group. No patient died as a direct complication of the procedure. One patient died the following day from an acute myocardial infarction, the remaining two patients both died shortly after acute vessel occlusions occurring 1 and 3 weeks after subintimal angioplasty. No attempt was made to salvage or amputate the affected limbs in these patients.

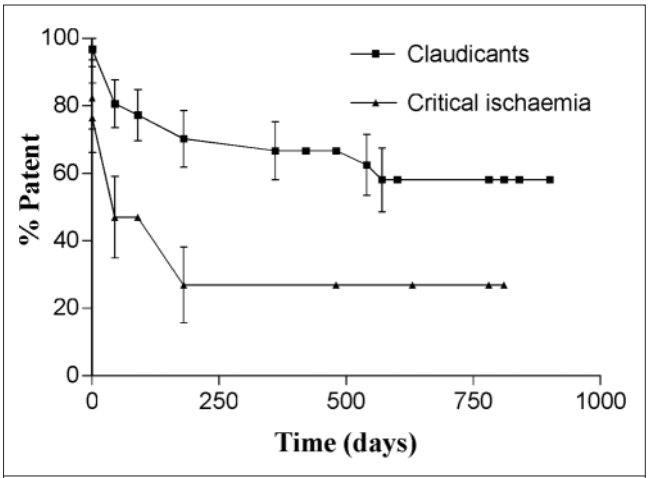

Figure 1 Kaplan-Meier plot illustrating patency rates following subintimal angioplasty on the basis of intention to treat.

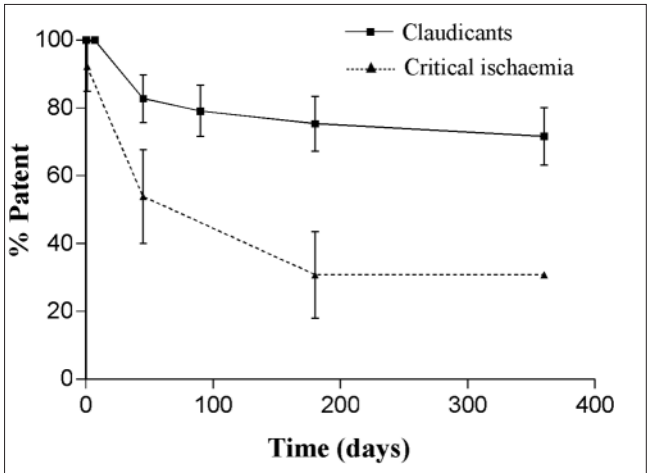

Figure 2 Kaplan-Meier plot illustrating patency rates following subintimal angioplasty on the basis of technically successful procedures only.

The cumulative short-term patency rates at 6 and 12 months were 57% and 53%, respectively. On an intention-to-treat basis, the patency rates were 73% and 69% for claudicants and 25% and 25% for patients with CLI at 6 and 12 months, respectively. The difference being statistically significant between the two groups at 12 months' follow-up (P = 0.0005; Fig. 1). When we analysed patency on the basis of only the technically successful procedures, the patency rates were 75% and 72% for claudicants and 31% and 31% for CLI patients at 6 and 12 months, respectively. Once again, the difference between the two groups was statistically significant at 12 months (P = 0.009; Fig. 2).

Patency at 12 months for all patients was also analysed with regard to smoking (smokers versus non-smokers, P = 0.66), number of run-off vessels (1 versus 2, P = 0.55; 1 versus 3, P = 0.94; 2 versus 3, P = 0.25), diabetes mellitus and length of occlusion. The difference in occlusion length was significant in relation to patency, < 10 cm compared with ≥ 10 cm (P = 0.037; Fig. 3) as was the presence of diabetes (P = 0.041). In a further sub-analysis, patients with CLI and occlusions ≥ 10 cm had 13% patency at 12 months (1/8 patients) compared with 33% (3/9 patients) in those with lesions < 10 cm (P = 0.52).

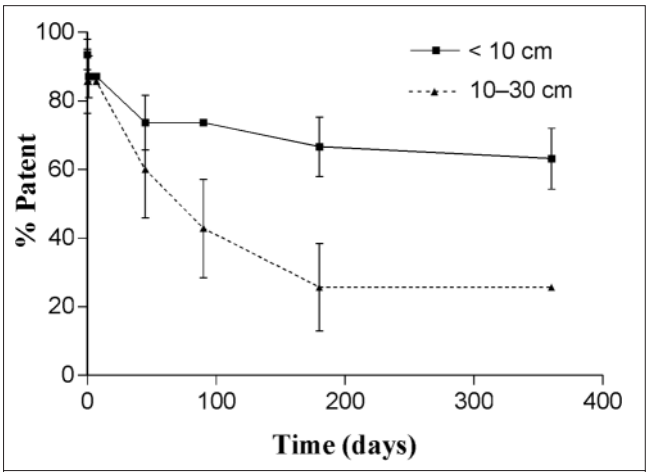

Figure 3 Kaplan-Meier plot illustrating patency rates in relation to length of occlusion following subintimal angioplasty on the basis of intention to treat.

There were more women in the critical ischaemic group but no statistically significant difference was found in patency comparing men and women across both groups (P = 0.24) or claudicants alone (P = 0.54). Meaningful statistical analysis of patients within the CLI group was not possible due to the small number of male patients.

Patients were followed up for up to 5 years (median, 20 months). The cumulative patency at 20 months was 46% on an intention-to-treat basis. Similarly, patency within the claudicant group and those with CLI was 58% and 25%, respectively. Patency rates remained the same from 3 years onwards the last occlusion occurring at 19 months (Fig. 1).

Discussion

Following subintimal angioplasty for occlusive femoropopliteal disease, the cumulative vessel patency reported will depend largely on the relative numbers of patients with IC and CLI. London *et al.*[5] reported a cumulative vessel patency of 56–58% at 12 months. Subsequent studies have reported cumulative patencies of 51–60% at 6 months[4] and 43% and 37% at 6 and 12 months, respectively.[6] Our own figures of 57% and 53% at 6 and 12 months appear consistent with others. However, the case mix between studies varies greatly.

There does appear to be some agreement as to the success of subintimal angioplasty in the treatment of femoropopliteal disease for intermittent claudication. We

report vessel patency of 69% at 12 months, for patients with IC, on an intention-to-treat basis. McCarthy *et al.*[4] recorded that 65% of patients were improved at 6 months on the same basis. When only technically successful procedures are considered, vessel patency has been demonstrated at around 73% at 12 months,[5] this figure matching our own of 72%. In each of these results reported by London *et al.*,[5] a small percentage of patients (11%) with CLI are included; consequently, the figures of London *et al.*[5] for IC may be slightly better than stated above.

The rate of occlusion appears to slow from 12 months onwards with 58% still being patent at 3 years (Fig. 1). Vessel patency appears to be significantly related to the length of the occlusion and the presence of diabetes mellitus, in agreement with others.[5,6] We found no correlation with outcome and number of run-off vessels or smoking, the latter possibly due to the unreliability of patient information. Patients with short segment occlusions appear to have superior results with patency of 77% at 12 months comparing favourably with traditional PTA.[7,8]

London *et al.*[5] demonstrated vessel patency of 60% at 12 months in patients with CLI following subintimal angioplasty for femoropopliteal occlusions. Our experience with this group of patients is not as good. In a comparable analysis, when excluding failed procedures, our vessel patency was only 31% whilst on an intention-to-treat basis, patency at 12 months within the CLI group was 25%. These results are similar to those described by Tisi *et al.*[9] and Laxdal *et al.*[6] Our patency rate at 12 months for claudicants is comparable to that described by the Leicester group and so the disparity in patency rates between patients with CLI is unlikely to be accounted for by technical differences alone. McCarthy *et al.*[4] demonstrated a 6-month limb salvage rate of 49% in patients with CLI on an intention-to-treat basis. That is, 21/43 patients, who were still alive at 6 months following subintimal angioplasty, required no further intervention up to that point in time. A more recent publication demonstrated above-knee femoropopliteal patency of 24% for patients with CLI at 6 months.[6]

There appears to be little consensus as to patency following subintimal angioplasty for CLI. Patient numbers are small, particularly so in the Leicester series with the best results. Although our series also has small numbers, the combination of the two largest studies by McCarthy *et al.*[4] and Laxdal *et al.*[6] have demonstrated 6-month patency/limb salvage in 89 limbs at 24–49%. There may be a degree of sampling error accounting for the differences between our study and that of the Leicester group. This combined with differences across the study populations, variation in anatomy of the lesions, variation in technique and learning curves, may all contribute to differences. Within our study population, the median occlusion length in CLI was equal to that of previous studies. Patients with critical ischaemia and long occlusions appear to have very low patency rates with only 1/8 vessels (13%) patent at 12 months compared with 3/9 (33%) of those with CLI and occlusions < 10 cm. Patient numbers are too small within this subgroup, however, for meaningful statistical analysis.

Unlike intermittent claudication, patients with critical limb ischaemia are more likely to require interventional procedures for limb salvage. The choice of the most appropriate procedure will depend on many factors including risk factors, co-morbidity, mobility, quality of life and anatomy of the disease. Patency using traditional PTA appears inferior to bypass surgery[10–12] although there are no randomised trials to support this.[13,14] The subintimal technique proposed is yet to be proven as a successful alternative to surgical bypass and appears to have poor patency in the short term. Although not all patients with occlusion following subintimal angioplasty will necessarily lose their legs, they may well remain symptomatic with rest pain and ulceration. Patients with CLI represent a high-risk population: up to 40% may die within 6 months[15] and when considered for surgical bypass have a high postoperative mortality with patency rates of 60–90% at 12 months[16,17] and up to 75% at 5 years.[18]

General practitioners seem reluctant to refer patients with CLI for a specialist vascular opinion.[19,20] As a result, patients with CLI are often waiting many weeks before referral.[21]

Conclusions

In the absence of a randomised controlled trial of subintimal angioplasty versus surgical bypass in CLI and based on the current data available, a pragmatic approach to the management of CLI is required. We suggest that subintimal angioplasty should be first-line treatment for those with critical limb ischaemia who are not fit to undergo surgical bypass, those with a high peri-operative mortality risk or those with CLI and occlusions < 10 cm. Surgical bypass may be the preferred treatment for those patients fit enough to undergo the procedure.

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