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The Results of Subintimal Angioplasty in a District General Hospital

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Objectives and Design: we report a prospective study to determine if subintimal angioplasty can be performed in non-teaching centres and to establish its learning curve.

Materials and Methods: subintimal angioplasty was performed on 50 limbs in 46 patients (34 male) with a median age of 72 years (range 45–93 years). Indication was critical limb ischaemia (27 limbs) or intermittent claudication (23 limbs). Occlusions were located in the superficial femoral artery in 44 limbs, popliteal artery in 4 limbs and the peroneal artery in two limbs. At a median of 7.9 months patients had colour duplex imaging of the vessels that underwent angioplasty to assess vessel patency.

Results: primary technical success was achieved in 39 cases (78%). Primary technical success was greater in the second group of 25 consecutive limbs to undergo angioplasty at 92% (23 cases) compared with the first 25 consecutive limbs at 64% (16 cases). At 6 months the overall vessel patency rate on duplex imaging was 57%, improving to 64% in the group having a primarily successful procedure. The equivalent rate of symptomatic improvement was 59 and 66% respectively. Complications occurred in five procedures, most were minor, but a single fatality was directly attributable to the procedure.

Conclusion: subintimal angioplasty can reasonably be performed outside major teaching institutions. There is a short learning curve associated with the procedure.

Key Words: Subintimal angioplasty; Patency; Ischaemia; Intermittent claudication.

Introduction

Subintimal angioplasty is a technique practiced by Interventional Radiologists within many vascular surgical units.^{1–5} It has evolved from percutaneous transluminal angioplasty.⁶ The advantage of subintimal angioplasty is that it can be used for long occlusions, diffuse disease and in situations where the transluminal technique has already failed.^{7,8}

A few centres, mainly teaching institutions have reported good short-term results.^{3,4,6,9}

The aim of this study was to determine if this technique could be used effectively in the District General Hospital and to establish the learning curve associated with the procedure.

Patients and Methods

This was a prospective study. Two Consultant Interventional Vascular Radiologists at The

Derbyshire Royal Infirmary performed some 50 subintimal angioplasty procedures over a 7-month period. The technique used was that described by Bolia,⁷ glyceryl trinitrate (GTN) was used as the intra-arterial vasodilating agent and all patients received intra-arterial heparin (5000 IU) during the procedure.

Fifty procedures were carried out on 46 consecutive patients (34 males), with four patients undergoing bilateral procedures at separate sittings. The median age was 72 years, with a range 45–93 years. Risk factors for peripheral vascular disease included diabetes mellitus (14 patients), symptomatic ischaemic heart disease (21 patients) and hypertension (26 patients). Thirty-four patients were either current smokers or had ceased smoking within 5 years. The indication for treatment was critical limb ischaemia (27 limbs) or short distance (<100 m) intermittent claudication (23 limbs). Rest pain was present in 13 limbs, ulceration in 13 limbs and gangrene in eight limbs. Critical limb ischaemia included rest pain, ulceration and gangrene as defined by the second European consensus document on chronic critical leg ischaemia.¹⁰

The distribution of occlusive lesions showed 44 (88%) to be located predominantly in the superficial

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femoral artery, with a median length of 17.5 cm (range 7–24 cm). Four (8%) were located in the popliteal artery, median length 12.5 cm (range 7–18 cm) and two (4%) in the peroneal artery, median length 7 cm (range 5–8 cm). Twenty-six limbs had three-vessel run-off, 14 limbs had two-vessel run-off and 10 limbs had one-vessel run-off.

Primary technical success was defined as vessel recanalisation with antegrade flow upon completion angiography and <25% residual stenosis. A technical failure was defined as the inability to develop a subintimal dissection channel or the loss of such a channel at completion angiography. Arterial run-off was recorded as one, two or three-vessel run-off on completion angiography.

Unless contraindicated, all patients received aspirin at the time of the procedure and thereafter. All complications of the procedure were recorded prior to patient discharge.

Patients were followed until either a clinical endpoint was reached (additional radiological intervention, vascular surgical intervention or death) or duplex ultrasound imaging was performed to assess vessel patency for the purpose of this study. For those persons requiring no intervention duplex ultrasound studies of the limb having undergone angioplasty occurred at a median of 7.9 months (range 5.5–10.6) following the initial procedure. Duplex ultrasound assessment was performed using an Accuson 128XP ultrasound machine (Accuson, Mountain View, CA, U.S.A.) with a 5 MHz transducer. Flow velocities that showed >30% stenosis at the site of treatment was defined as recurrence of disease. Symptomatic improvement required a 50% improvement in claudication distance, relief of rest pain, healing of ulcers and the healing of minor amputations required for gangrene.

A second study was done to identify the presence of a learning curve to the procedure. The outcome of the first 25 limbs was therefore compared with that of the second 25 limbs.

Statistical analysis of the results was done using the Fishers exact test for discrete variables. Continuous variables were analysed by the Mann–Whitney *U*-test. Patency of the vessel having undergone angioplasty was determined by Kaplan–Meier life-table analysis (SPSS 11.0, SPSS, Chicago, IL, U.S.A.). *p*-values of less than 0.05 were considered significant.

Results

Subintimal angioplasty was performed on 50 limbs in 46 patients. Forty-six limbs in 43 patients were

available to follow-up. Three patients who had four angioplasty procedures were not available to follow-up. One patient was diagnosed with hepatocellular carcinoma; a second with lymphoma and the third patient withdrew from follow-up.

Technical success

Primary technical success was achieved in 39 of 50 procedures (78%) and was significantly associated with a greater number of run-off vessels. Patients with three-vessel run-off were significantly more likely to have a successful angioplasty than those with two-vessel run-off (*p* = 0.01). Primary technical success was independent of age, co-morbidity and size (length) of occlusion. See Table 1.

Outcome and patency

In the group with a primary technical success, at 6 months 23 limbs were symptomatically improved, 21 with no recurrent disease seen on duplex assessment and in two the vessels had occluded but required no further treatment. In these 23 limbs, the initial presentation was intermittent claudication in 12 limbs and critical ischaemia in 11 limbs. Three limbs required amputation and two limbs needed arterial reconstruction, all of these initially presented with critical ischaemia. Five patients (seven angioplasty procedures) were dead at 6 months, in all of these cases the presentation was that of critical ischaemia.

In the group with a primary technical failure there were seven limbs presenting with intermittent claudication and 4 limbs with critical ischaemia. At 6 months six limbs were either improved or no worse, with none of these requiring further interventions. Two of these six limbs presented with critical ischaemia. Four limbs deteriorated, two required amputations and two

Table 1. Comparison of technically successful with unsuccessful procedures.

	Successful <i>n</i> = 39	Failed <i>n</i> = 11	<i>p</i>
Median age (range)	73 (45–89)	72 (49–93)	0.47†
Diabetes mellitus	10 (26%)	4 (36%)	0.47*
Hypertension	19 (49%)	7 (63%)	0.5*
Smoking	28 (72%)	6 (55%)	0.3*
Ischaemic heart disease	14 (36%)	7 (63%)	0.17*
Median occlusion length (range)	15 cm (5–25)	15 cm (5–20)	0.67†

* Fisher's exact test.

† Mann–Whitney *U*-test.

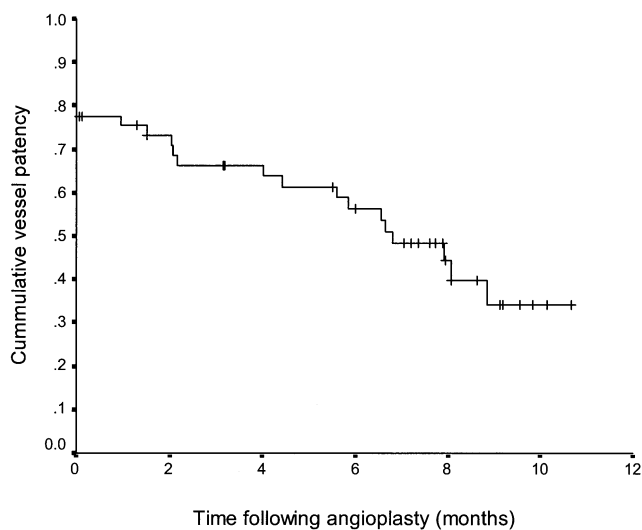


Fig. 1. Kaplan-Meier curve showing the duration of arterial patency following subintimal angioplasty.

required arterial reconstructions. One patient had died by 6 months having presented with critical lower limb ischaemia.

On an intention to treat basis the patency rate at 6 months was 57% (Fig. 1) with symptomatic improvement in 59%. The patency of the vessels with a successful procedure was 64 and 66% of patients had improved symptoms.

When the first 25 consecutive patients were compared with the second 25 consecutive patients there were no significant differences between the demographic, clinical or radiological factors identified. Arterial run-off below the popliteal artery was the same in both groups. Primary technical success was achieved in 16 of the first 25 patients (64%), compared with 23 of the second 25 patients (92%). This difference was significant ($p=0.004$). In those patients undergoing duplex assessment a patency rate of 47% was found in the first patient group, compared to 65% in the second patient group ($p=0.09$).

Complications

There were five complications (10%). Distal embolisation occurred in two cases, on both occasions this was recognised at the time of angioplasty and the embolus was evacuated using an aspiration catheter without clinical sequelae. A peroneal artery was ruptured on one occasion, this required no intervention but discharge was delayed by the need for neurovascular observations of the limb. Retroperitoneal haemorrhage occurred in two patients. The first case resolved spontaneously. The second patient required surgical

exploration of the arterial puncture site with repair of the damaged vessel. Despite this the patient developed multiple organ dysfunction syndrome (MODS) and died 3 days later. The 30-day mortality was two patients (4%), as one further patient died, at home from a myocardial infarction 9 days after the procedure.

Discussion

This study shows that subintimal angioplasty can be performed in centres other than teaching institutions, and that there is a short learning curve associated with this procedure.

The primary technical success rate is 78% in this study. This compares well with those published by other vascular units.^{3-6,11}

There is little published data looking at the patency of the vessels that underwent angioplasty by direct means.^{11,12} Most studies have used indirect measures of vessel patency such as the ankle-brachial pressure index (ABPI). This study uses duplex ultrasound to view the arterial tree with particular reference to the vessels that had undergone angioplasty. While this is probably better than ABPI measurement in the assessment of vessel patency it is inferior to invasive arterial angiography, however it is hard to justify the use of angiography for routine follow-up. In addition it should be remembered that this study is a short-term follow-up study in a heterogeneous group of patients. The six-month patency rate for successful procedures of 64% is comparable with the few centres that have published results.^{3,4,9} On an intention-to-treat basis the patency rate on duplex ultrasound was 57% at 6 months, but with a higher symptomatic improvement rate of 59%. These results are disappointing, but are similar to those of other published studies.^{3-5,9} It is, however, difficult to draw direct comparisons between the published series, the case mix in all the published studies is quite different. The study from London *et al.* have 11% of patients with critical limb ischaemia, from McCarthy *et al.* this figure was 62%, and in this study critical limb ischaemia was the indication for angioplasty in 54% of cases.

Subintimal angioplasty is a relatively new technique. This study shows that a learning curve is demonstrable, but that it appears to be short. This study shows a significantly better primary technical success rate in the second 25 consecutive patients to undergo angioplasty. The technical success rate in this group of 92% is the highest reported in the literature. In addition the learning curve shown represents that of two radiologists. We can expect the figures to remain high

as further experience is gained and patient selection for this type of procedure improves. We showed a trend towards better vessel patency at 6 months in the second group of 25 patients at 65% compared to 47% for the first group, but this did not reach statistical significance ($p=0.09$).

We confirmed the findings of other studies in showing the importance of the number of run-off vessels to the technical success of the procedure^{3,4} Having three-vessel run-off increased the chances of primary technical success when compared to two-vessel run-off ($p=0.01$). There were probably too few patients with one-vessel run-off to demonstrate a difference, but it appeared that there was a trend towards significance ($p=0.19$).

Subintimal angioplasty is associated with some complications.¹³ This study shows a complication rate of 10%, with a single fatality directly attributable to the procedure. Haemorrhage is a well-recognized complication of arterial puncture, but it is not confined to subintimal angioplasty. Recent National Confidential Enquiry into Peri-operative Deaths (NCEPOD) recommendations suggests that supra-inguinal approaches to the femoral artery are avoided to limit the risk of retroperitoneal haemorrhage.² All arterial punctures in this study were infra inguinal. It should however be noted that we have included distal embolisation that was recognized and easily treated at the time of angioplasty by aspiration as a complication. Many Radiologists would not consider this event a complication.

The 6 month patency of subintimal angioplasty is not the same as with surgical bypass procedures. Angioplasty has the advantage when compared to surgery as appearing to be less of an insult to a group of patients who generally are frail. Subintimal angioplasty does not seem to limit the potential for further surgical reconstruction^{5,14} and therefore it is a reasonable first-line procedure, although McCarthy *et al.*⁴ have reported a case of run-off loss following angioplasty. Further studies to assess the effectiveness

of subintimal angioplasty are required, especially to establish which patients would benefit most from this new technique.

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