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The Impact of Diabetes on Current Revascularisation Practice and Clinical Outcome in Patients with Critical Lower Limb Ischaemia☆

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Objective. *To compare current revascularisation practice and outcome in diabetic and non-diabetic patients presenting with critical limb ischaemia (CLI) to a single vascular surgeon.*
Methods. *Data for 113 patients presenting with CLI were collected prospectively over a 3-year period. Forty-four (39%) were diabetic. Treatment was classified as percutaneous angioplasty, arterial reconstruction, primary major amputation, and conservative therapy. Main outcome measures were 30-day mortality, major amputation, survival, and amputation-free survival.*
Results. *Diabetic patients were more likely to present with gangrene, give a history of angina, be treated with nitrates and statins, and have lower cholesterol levels. No significant differences were found in the initial treatment options between diabetics and non-diabetics: angioplasty 39* vs *26%, surgical revascularisation 34* vs *33%, primary major amputation 9%* vs *17%, and conservative treatment 11* vs *19% (p = ns in all). There were eight deaths (7%) within 30-days. At follow-up (1–44 months, median 14 months), rates of major amputation and death for the entire population were 23 and 8%, respectively. The 12-month cumulative survival and amputation-free survival rates were 90 and 72%, respectively. When comparing diabetic to non-diabetic patients, there were no significant differences in the 30-day mortality (6.8* vs *7.2%, p = 0.4), cumulative survival (93* vs *89% at 12 months, log-rank test: 0.00, p = 0.9), amputation-free survival (71* vs *73% at 12 months, log-rank test: 0.00, p = 0.99), and major amputation rates (22.7* vs *23.1% at 12 months, p = 0.96). Similarly, there were no differences in limb salvage rates between diabetic and non-diabetic patients undergoing revascularisation procedures (78* vs *90% at 12 months, log-rank test: 2.04, p = 0.15).*
Conclusions. *In current practice, an aggressive multidisciplinary approach in diabetic patients presenting with CLI leads to similar limb salvage, amputation-free survival, mortality, and major amputation rates to those seen in non-diabetic patients. The presence of diabetes should not deter clinicians from attempting revascularisation by means of angioplasty or surgical reconstruction.*

Keywords: Diabetes; Critical limb ischaemia; Revascularisation; Amputation.

Introduction

Critical lower limb ischaemia (CLI) affects one in 2500 people in the UK annually, generating a very high total national workload.[1] The prognosis is poor and patients have a high risk of major amputation and death, the 1-year amputation rate being over 20%, and the 1- and 5-year mortality around 20 and 40–70%, respectively.[2] One-third of patients with CLI have diabetes mellitus and they are less likely to have revascularisation procedures.[3] A number of studies have examined the outcomes of surgical revascularisation in diabetic patients with CLI,[3–12] whereas others have looked at angioplasty outcomes in this group.[13,14] Only few reports have studied the group of patients with CLI as a whole and examined the impact of diabetes on clinical outcome with current practice.[15] The purpose of this study was to compare current revascularisation practice and clinical outcome in diabetic and non-diabetic

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patients presenting with CLI to a single vascular surgeon.

Patients and Methods

Over a 36-month period, from January 2001 to December 2003, a prospective study was undertaken of consecutive patients presenting with CLI to a single vascular surgeon (A.N.) based at a major university hospital. Patient details were entered into a computer database (Microsoft Excel 2000, Microsoft Limited, Reading, UK) and comprised information on patient demographics, risk factors, mode of presentation, vascular imaging and treatment. Treatment was classified as percutaneous balloon angioplasty, reconstructive surgery, primary major amputation, and conservative therapy. Outcome was recorded with emphasis on limb salvage, complications and mortality.

All patients presenting with CLI underwent non-invasive duplex scanning as first-line investigation, unless the patient had a scan performed during a recent previous admission. Angiography was only requested with a view to revascularisation by angioplasty or arterial surgery. During the study period, it was the policy of our unit to use angioplasty as a first-line treatment for patients presenting with CLI, whenever possible. Arterial reconstruction was undertaken for failed angioplasty or lesions not amenable to or deemed high risk for percutaneous treatment, a decision taken jointly by the vascular surgery and interventional radiology teams.

For the purpose of this study, CLI was defined as the presence of rest pain, ulceration or gangrene of greater than 2 weeks duration in the presence of an arterial lesion identified by duplex or arteriography. Ankle pressures were not measured routinely as in common with others the authors found these thresholds to be of little prognostic value.[16,17]The outcome of the patients was based on clinical status only and not on haemodynamic data. Angioplasty patients were followed-up clinically and ankle pressure and/or duplex imaging were not routinely performed unless the patient failed to improve or if further treatment was required. Of patients undergoing arterial reconstruction, only those with vein bypass grafts underwent periodic duplex scan surveillance.

Study endpoints were peri-operative mortality and morbidity, patient survival, amputation-free survival, and limb salvage. Peri-operative mortality and morbidity referred to deaths and major complications, respectively, occurring during the first 30 days following angioplasty or surgery. Systemic complications included respiratory, cardiac, renal, cerebrovascular, and gastrointestinal complications. Graft infection and all others were classified as local complications. For angioplasty procedures, treatment success was defined as initial technical success (<30% residual stenosis) combined with the absence of CLI recurrence within 30 days of the procedure. Treatment failure was defined as: (1) initial technical failure, (2) initial technical success but persistent CLI, or (3) initial technical success but CLI recurrence within 30 days. A complication following angioplasty was deemed to be major if caused death or required emergency surgery or blood transfusion. Limb salvage was defined as per the Rutherford classification[18] and has only been applied to therapeutic outcomes and to operations or other interventions that were intended to avoid an otherwise inevitable major amputation. Primary amputation was defined as that amputation without an attempt at revascularisation. Secondary amputation was defined as that performed following an attempt at revascularisation (angioplasty or surgical reconstruction). Major amputation was defined as per Rutherford classification as loss of a sufficiently functional foot remnant (to allow standing and walking) and necessitating the fitting of a prosthesis, i.e. above and below knee amputations for the purposes of this study.[18] Minor amputation constituted ray and forefoot amputations.

Statistical analysis was performed using the SPSS (version 12.0) statistical software (SPSS, Chicago, IL, USA). Chi-square test or Fischer's exact test, as appropriate, was used to compare categorical data and the unpaired *t*-test for continuous data. Non-parametric Mann–Whitney *U*-test was used to compare length of hospital stay. Patient survival, amputation-free survival and limb salvage were calculated by the Kaplan–Meier method using the log-rank test. A Cox (semi-parametric) regression model was employed to determine the combination of potential factors (i.e. cardiac, respiratory, diabetes) that affect the form of the hazard function. A stepwise selection process was used to identify the statistically significant factors. A p value <0.05 was considered to be statistically significant.

Results

There were 113 patients (113 limbs) presenting with CLI of whom 62 (55%) were male. The mean $\pm$ SD age was 69 ± 14 years. There were 44 (39%) diabetic patients of whom three (7%) were type I. Of those with type-II diabetes, five (11%) were diet-controlled,

Table 1. Patient demographics and mode of presentation

	Diabetic ($n=44$) (39%)	Non-diabetic ($n=69$) (61%)	p Value
Male/female	29 (66%)–15 (34%)	33 (48%)–36 (52%)	0.1
Age (years), mean±SD (range)	68.2±12.4 (36–95)	69.9±14.9 (33–95)	0.5
Mode of presentation			
Rest pain	32 (73%)	57 (83%)	0.2
Ulceration	24 (55%)	26 (38%)	0.1
Gangrene	20 (45%)	18 (26%)	0.03
Non-salvageable limb	3 (7%)	9 (13%)	0.2

16 (36%) were on oral hypoglycaemics, and 24 (55%) were on insulin. Patient demographic data, mode of presentation, cardiovascular risk factors, history of previous angioplasty, vascular reconstruction and amputation, and medication are summarised in Tables 1 and 2, respectively. There were no differences between the two groups other than that diabetics were more likely to present with gangrene (20/44 *vs* 18/69, $p=0.03$), give a history of angina (25/44 *vs* 20/69, $p=0.01$), be treated with antianginals (22/44 *vs* 19/69, $p=0.03$) and statins (18/44 *vs* 15/69, $p=0.03$) and have lower cholesterol levels (3.88± 1.28 *vs* 4.78±1.2 mmol/L, $p=0.01$). No differences were found between the two groups in having undergone a previous intervention (angioplasty or surgery) on either the symptomatic or the contralateral limb, or a major amputation of the contralateral limb (Table 2).

All patients underwent duplex scanning first, followed by arteriography in 88 (78%) of cases. Details of the angiographic findings appear in Table 3. There were no significant differences in the number of angiograms performed in the two groups (diabetic *vs* non-diabetic, 86 *vs* 72%, $p=0.1$). Although we expected diabetic patients to have distal vessel disease more frequently, this difference did not achieve statistical significance (82 *vs* 72%, $p=0.3$). The management options employed in the 113 patients are summarised in Fig. 1. Revascularisation was attempted in 79 patients (70%). The remaining 34 patients proceeded to primary amputation or were managed conservatively.

Overall 16 patients (14%), four of whom were diabetics, underwent primary major amputation. In the diabetic group, two patients presented with a non-salvageable limb and underwent above-knee amputation, whereas the other two had extensive medical

Table 2. Patient risk factors, history of previous angioplasty or vascular reconstruction, previous amputation in the contralateral limb and drug history

	Diabetic ($n=44$)	Non-diabetic ($n=69$)	p Value
Risk factors			
Smoking history	33 (75%)	47 (71%)	0.4
Hypertension	25 (58%)	35 (51%)	0.5
Angina	25 (58%)	20 (29%)	0.01
Cardiac failure	11 (26%)	9 (13%)	0.1
Cerebrovascular disease	12 (28%)	15 (22%)	0.5
Renal impairment*	13 (30%)	11(16%)	0.1
Respiratory disease	10 (23%)	17 (25%)	0.8
Previous angioplasty/surgery			
Symptomatic limb	7 (16%)	10 (15%)	0.8
Contralateral limb	6 (14%)	6 (9%)	0.3
Contralateral amputation			
Major	6 (14%)	5 (7%)	0.2
Minor	2 (5%)	0 (0%)	0.1
Medications			
Aspirin	20 (45%)	24 (35%)	0.3
Clopidogrel	6 (14%)	7 (10%)	0.6
Warfarin	5 (11%)	3 (4%)	0.2
Antihypertensives	21 (48%)	37 (54%)	0.5
Statins	18 (41%)	15 (22%)	0.05
Antianginals	22 (50%)	19 (28%)	0.03
Diuretics	19 (43%)	19 (28%)	0.09
Cholesterol level (mmol/L)			
Mean±SD (range)	3.88±1.28 (1.5–7)	4.78±1.2 (2.0–8.3)	0.01
Creatinine (μmol/L)			
Mean±SD (range)	118±49 (46–250)	99±31 (55–185)	0.02
Patients with raised creatinine*	13	11	0.1

* Renal impairment and raised creatinine were defined as creatinine level >130 μmol/L.

Table 3. Angiography findings

	Diabetic ($n=44$)	Non-diabetic ($n=69$)	p Value
Number of angiograms	38 (86%)	50 (72%)	0.1
Level of disease			
Suprainguinal disease	11 (29%)	24 (48%)	0.1
Infrainguinal disease	34 (90%)	42 (84%)	0.5
Infrapopliteal disease	31 (82%)	36 (72%)	0.3

co-morbidities of cardiac and renal failure and deemed medically unfit to undergo revascularisation. Both had a below-knee amputation. In the non-diabetic group (12 patients), the reasons for primary amputation were as follows: nine patients presented with a non-salvageable limb, two had disease not amenable to revascularisation, and one patient was considered medically unfit for intervention. The likelihood to undergo primary amputation was no different in diabetics when compared to non-diabetics (4/44 *vs* 12/69, $p=0.2$).

A further 18 patients with CLI, five of which were diabetic, were treated conservatively. Reasons for conservative management in diabetics were: three were medically unfit and too frail for intervention, one declined treatment, and one had disease not amenable to revascularisation; in the non-diabetic group ($n=13$), four had been admitted with acute-on-chronic ischaemia and symptoms improved after infusion of intravenous heparin, three had disease amenable only to surgical reconstruction but did not feel symptoms were severe enough to warrant surgery, five patients had severe disease not amenable to revascularisation, and one's symptoms improved after medical optimisation. The likelihood of having conservative management was statistically no different between the two groups (5/44 *vs* 13/69, $p=0.3$).

Details of the revascularisation procedures, both angioplasty and arterial reconstruction, are presented in Table 4. Diabetics and non-diabetics were equally likely to be offered revascularisation (35/44 *vs* 44/69, $p=0.1$).

A total of 35 patients (31%), 17 diabetic and 18 non-diabetic, underwent angioplasty as a first-line treatment. There were a total of 39 angioplasty sites in 35 limbs: iliac in 13, superficial femoral/popliteal in 19, profunda femoris in one, and tibioperoneal trunk and calf vessels in six cases. None of the limbs in this patient population underwent stenting. Both diabetic and non-diabetic patients were equally likely to be offered angioplasty as a first-line revascularisation option (17/44 *vs* 18/69, $p=0.2$). Furthermore, of those patients that proceeded to revascularisation, similar numbers underwent angioplasty amongst diabetic and non-diabetic patients (17/35 *vs* 18/44, $p=0.5$). Angioplasty as a preliminary step to arterial reconstruction was performed in six additional cases. Two diabetic patients underwent femoro-femoral crossover

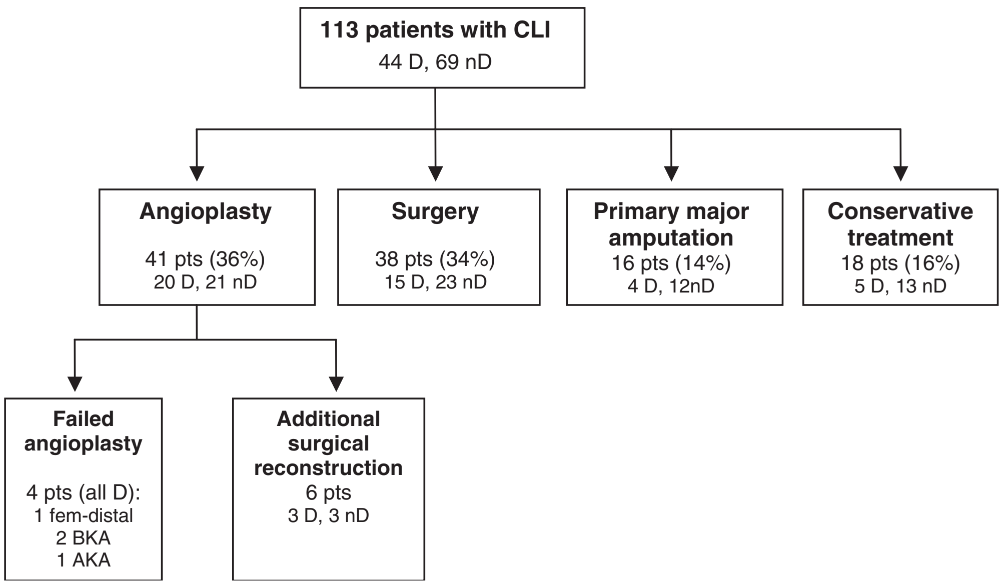


Fig. 1. Treatment in the 113 limbs with CLI. Pts, patients; CLI, critical limb ischaemia; D, diabetic; nD, non-diabetic; AxBF, axillo-bifemoral bypass graft.

Table 4. Details of angioplasty and arterial bypass procedures

	Diabetic ($n=44$)	Non-diabetic ($n=69$)	p Value
Revascularisation procedures ($n=79$)	35 (80%)	44 (64%)	0.1
Angioplasty ($n=35$)	17	18	
% of total patients	39%	26%	0.2
% of those revascularised	49%	41%	0.5
Angioplasty site:			
Iliac	3	10	
SFA/popliteal	8	11	
Profunda femoris	1	0	
TPT/calf vessels	5	1	
Arterial reconstructions ± angioplasty ($n=45$)	19 (43%)	26 (38%)	0.6
Surgical intervention alone ($n=38$)	15 (34%)	23(33%)	0.9
Operative details			
Extra-anatomic bypass	3	7	
Common femoral endarterectomy	1	3	
Femoro-popliteal bypass	6	10	
Femoro-distal bypass	7	5	
Popliteal-distal bypass	1	1	
Conduit material			
Autogenous vein	8 (42%)	11 (42%)	1
Synthetic graft	7 (37%)	12 (46%)	0.5
Composite	2	0	

SFA, superficial femoral artery; TPT, tibioperoneal trunk; extra-anatomic bypass includes, aorto-bifemoral axillo-bifemoral, ilio-iliac and femoro-femoral crossover bypass graft.

and femoro-popliteal bypass grafting, respectively, whereas in the non-diabetic group, there were two common femoral endarterectomies, one femoro-popliteal and one popliteal-distal bypass.

There were four treatment failures following angioplasty, all in the diabetic group; one underwent femoro-distal bypass, two had a below-knee amputation due to non-reconstructable run-off disease, and one had an above-knee amputation due to extensive medical co-morbidities. The latter eventually died on the third post-operative day due to myocardial infarction. There were no angioplasty failures in the non-diabetic group. Therefore, treatment success was achieved in 31 (89%) of the 35 patients who had angioplasty as a first-line treatment. Angioplasty was less likely to be successful in diabetics (13/17 *vs* 18/18, $p=0.04$).

Finally, a total of 45 patients underwent arterial reconstruction; 38 had surgery alone, six had combined angioplasty and surgery, whereas one was operated upon after a failed angioplasty. Details of the surgical procedures performed in the two groups appear in Table 4. The likelihood to undergo arterial reconstruction was no different in diabetics when compared to non-diabetics, either when considering the total population (15/44 *vs* 23/69, $p=0.9$) or only those who proceeded to revascularisation (19/35 *vs* 26/44, $p=0.6$). There were no differences in the choice of bypass graft material between the two groups.

Five patients in the surgery group, three of whom were non-diabetic, died during the first 30 days (30-day operative mortality of 11%). Four patients (two diabetic) died following an axillo-femoral bypass, two from cardiac causes, one from pneumonia and the last from multi-organ dysfunction syndrome. Finally, one non-diabetic died following a femoro-popliteal bypass due to cardiac causes. Diabetics had no higher 30-day operative mortality rate than non-diabetics (1/19 *vs* 4/26, $p=0.3$).

A total of 27 complications, both systemic and local, were encountered in 20 patients in the surgery group during the first 30 days (20/45, 44%). Eight of these patients were diabetic. There were 13 systemic and 14 local complications. Systemic included eight cardiac, two respiratory and three renal complications. Local complications were 13 wound infections and one graft infection. There were no differences in the 30-day overall, systemic, and local complication rates between diabetic and non-diabetic patients (8/19 *vs* 12/26, $p=0.79$, patients with all complications; 4/19 *vs* 9/26, $p=0.26$, systemic; and 7/19 *vs* 7/26, $p=0.48$, local, respectively). There was only one graft occlusion in a non-diabetic patient who had undergone femoro-distal bypass.

Thirty-day outcome

Details of the mortality and morbidity within the first 30 days for the entire group are summarised in Table 5. Diabetic and non-diabetic patients had similar length of hospital stay, i.e. median 19 days (range 1–87) *vs* 13 days (range 1–111), $p=0.2$. The 30-day mortality of all patients presenting with CLI during the study

Table 5. Mortality and morbidity within the first 30 days in the 113 patients irrespective of the method of treatment

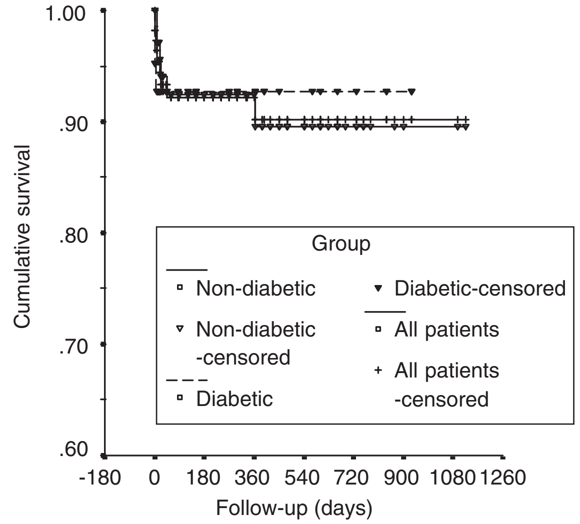
30-day outcome	Diabetic ($n=44$)	Non-diabetic ($n=69$)	p Value
30-day mortality	3	5	0.6
Causes of death			
Cardiac	3	2	
Respiratory	0	1	
Sepsis	0	1	
MODS	0	1	
Complications (any)*	22	31	
Pts with complications (any)	14 (32%)	20 (29%)	0.7
Systemic complications*	12	20	
Cardiac	6	10	
Respiratory	4	7	
Gastrointestinal	1	1	
Renal	1	2	
Local complications*	10	11	
Wound infection	10	9	
Graft infection	0	2	

MODS, multiple organ dysfunction syndrome.
* Patients may have developed more than one complication.

period, irrespective of method of treatment, was 7% (eight deaths). This was no different amongst the two groups (4/44 *vs* 4/69, $p=0.4$). On multivariable analysis, neither diabetes nor any other risk factors were found to be statistically significant predictors of 30-day mortality. Complications were encountered in 34 patients (30%), again no different in diabetics when compared to non-diabetic patients (14/44 *vs* 20/69, $p=0.7$). Limb salvage was achieved in 70 out of the 79 patients undergoing revascularisation (89%), again with no difference between the two groups (diabetic *vs* non-diabetic, 30/35 *vs* 40/44, $p=0.5$).

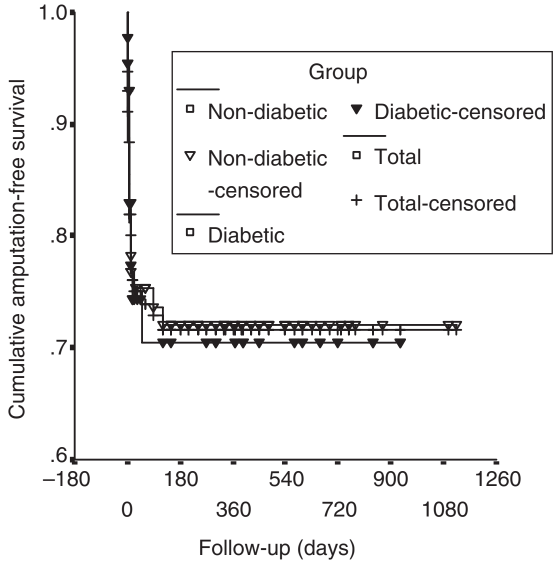
Follow-up

The median follow-up was 14 months (range 1–44); 15 months (range 2–44) for diabetic and 13 months (range 1–37) for non-diabetic patients ($p=0.15$). Eleven patients were lost to follow-up, five and six patients in the diabetic and non-diabetic groups, respectively. There was one further death during follow-up. This was an elderly, non-diabetic patient who died 12 months later from cardiac causes. Therefore, the 12-month survival for the entire population was 92%. Patient cumulative survival is presented graphically in Fig. 2 by means of Kaplan–Meier curves. The 12-month cumulative survival was 93% in diabetic and 89% in non-diabetic patients (log-rank test: 0.00, $p=0.9$). Amputation-free survival for the entire patient sample is also presented graphically in Fig. 3. The 12-month cumulative amputation-free survival rates were 71 and 73%, respectively. Similarly, no differences were seen between the two groups (log-rank test: 0.00, $p=0.99$). Finally, amongst the 79 patients who



Numbers at risk				
Days	0	365	730	1095
Total	113	45	14	1
DM	44	14	6	0
Non-DM	69	31	8	1

Fig. 2. Cumulative patient survival rates according to groups (Kaplan–Meier curves). There is no statistically significant difference in the survival between diabetic and non-diabetic patients (log-rank test: 0.00, $p=0.985$).

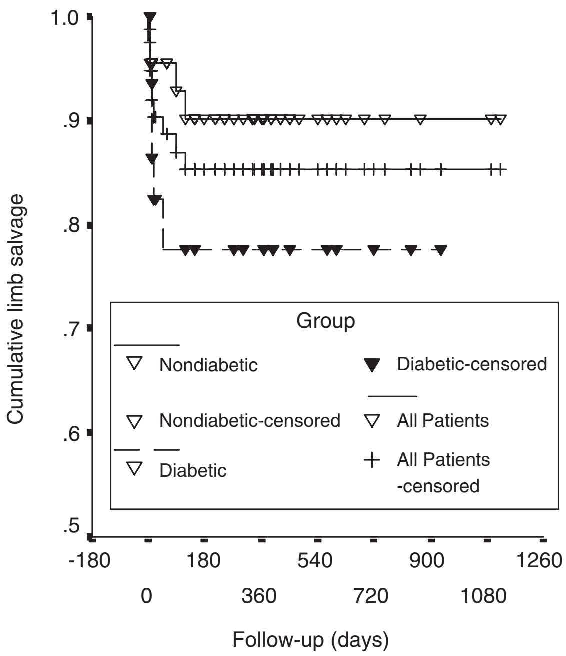


Numbers at risk				
Days	0	365	730	1095
Total	113	39	11	1
DM	44	12	4	0
Non-DM	69	27	7	1

Fig. 3. Cumulative amputation-free survival (Kaplan–Meier curves) for the entire patient sample (113 patients). No difference was seen between diabetic and non-diabetic patients (log-rank test: 0.00, $p=0.99$).

underwent revascularisation procedures, there was no difference between the two groups, the 12-month cumulative limb salvage rates for the entire group, diabetic, and non-diabetic patients being 85, 78, and 90%, respectively (Fig. 4, log-rank test: 2.04, $p=0.15$). The overall limb salvage rates following angioplasty and arterial reconstruction at the end of follow-up was 89 and 87%, respectively, no different amongst diabetic and non-diabetic patients (angioplasty 13/17 *vs* 18/18, $p=0.07$, surgery 17/19 *vs* 22/26, $p=0.5$). When Cox regression analysis was performed, diabetes was not found to be a statistically significant predictor of survival, amputation free-survival, or limb salvage. The only significant variables for survival was the presence of cardiac (hazard ratio 8.991 [95% CI: 1.115–72.498; $p=0.039$]) and respiratory disease (hazard ratio 5.765 [95% CI; 1.429–23.255; $p=0.014$]).

To completion of the study, major amputation (both primary and secondary) and death rates were 23 and 8%, respectively. The overall major amputation rates were similar amongst diabetics and non-diabetics (10/44 *vs* 16/69, $p=0.96$).



Numbers at risk				
Months	0	365	730	1095
Total	79	30	8	1
DM	35	11	4	0
Non-DM	44	19	4	1

Fig. 4. Cumulative limb salvage (Kaplan–Meier curves) in diabetic and non-diabetic patients that underwent revascularisation. No difference was seen between diabetic and non-diabetic patients (log-rank test: 2.04, $p=0.15$).

Discussion

Diabetic patients comprise a significant proportion of those presenting with CLI. Previous studies have shown the clinical results following arterial reconstruction to be worse in diabetics with an increased mortality[4–8] and inferior limb salvage rates.[3,7,9] Similarly, it has been shown that presence of diabetes correlates with worse clinical outcomes following percutaneous angioplasty.[13] As a result, some remain sceptical about whether diabetics really profit from revascularisation.[6] A number of recent series, however, have challenged these results demonstrating that, with an aggressive approach, diabetic patients can achieve similar outcomes to non-diabetics.[6,10–12,14,19]

One area that is infrequently addressed in reports dealing with CLI is the outcome of the entire population presenting to the vascular surgeon and not only of those being offered revascularisation. The majority of the reports focus on the outcome of patients undergoing either revascularisation as a whole, or specific surgical and endovascular procedures, such as femoro-distal bypass or balloon angioplasty. A national survey in the UK found that 60% of patients were suitable for revascularisation while a further 20% needed a primary amputation.[1] In our study, revascularisation was attempted in 70% of all patients (80% in diabetic and 64% in non-diabetic patients) while 14% needed a primary amputation. These figures are comparable, if not somewhat better than those reported by others who looked at outcomes of CLI. The percentages of revascularisation and primary amputations in the reported series ranged from 48 to 74%, and 8 to 35%, respectively.[1,3,15,20–24] Finally, there are a number of patients with CLI that are being treated conservatively. Some may be too unwell or too frail to undergo further investigation and treatment, and, therefore, conservative management and palliation is the only option.[15] Others may decline further intervention or may be wheel chair or bed bound with no prospect of mobilisation. Eighteen patients (16%) were treated conservatively in our series. This contrasts with the 52% of patients being treated conservatively in a contemporary series from a British District General Hospital.[15] Overall, diabetic and non-diabetic patients were equally likely to be offered revascularisation by means of surgery or angioplasty, primary amputation, or conservative treatment in our series.

Percutaneous balloon angioplasty has been central to improving outcomes in CLI and in many institutions has increasingly become the first-line treatment for such patients.[14,19,24–29] Some of the advantages of angioplasty are that it is minimally-invasive, it is performed under local anaesthesia, and it is well-tolerated. Furthermore, it is ideally suited to elderly and frail patients deemed at high risk for arterial reconstructive surgery. The latter may be associated with significant morbidity and carries the risks of graft occlusion and soft tissue or graft infection, including MRSA, a particular problem in diabetics with tissue loss. In this context, angioplasty is preferred to bypass surgery as the peri-procedure morbidity and mortality rates, even in this group, are low. Finally, angioplasty and surgery are not mutually exclusive, and, in most cases, the former does not preclude the latter.[25] Of course, conventional transluminal angioplasty has limitations as it is not suitable for long stenoses or occlusions, a problem, however, now overcome with the advent of subintimal angioplasty.[26–30] Hynes *et al.* have recently reported the number of attempted revascularisations to have doubled since the introduction of the subintimal angioplasty.[23] In our patients, the subintimal technique was routinely employed in all femoropopliteal occlusions, whereas stenoses were usually treated intraluminally. Others have adopted a much more aggressive policy using the subintimal recanalisation as a first-line option in the majority of cases.[14,23–30] A total of 35 patients (31%) underwent angioplasty in this series. This comprised 44% of those amenable to revascularisation, as opposed to 16–69% quoted by others.[15,19,20,23–30]

The overall limb salvage rate following angioplasty at the end of follow-up in our study was 89%. There were no differences detected between the diabetic and non-diabetic groups. This is in accordance with previous studies which have demonstrated similar limb salvage rates with angioplasty between diabetic and non-diabetic patients.[8,14,19] Close liaison between surgeon and interventional radiologist regarding case selection and suitability for angioplasty has ensured a high technical success rate of 89%, a figure similar to the 78–89% reported by others.[14,27,30] It is of note that all the technical failures in this series occurred in the diabetic group, a finding which has been demonstrated by others.[14,30]

In the present series, 56% of patients amenable to revascularisation had reconstructive surgery, a figure similar to those reported in two recent prospective studies examining outcomes in CLI in the UK.[15,20] A similar proportion of diabetic and non-diabetic patients underwent surgical reconstruction (51 *vs* 59%) and the limb salvage rate at end of follow-up overall, in diabetics, and non-diabetics was 87, 89.5 and 85%, respectively. The high success rate of surgical revascularisations in diabetics is encouraging and, again, emphasises in common with other studies[6,10,12] that there is a role for surgery in these patients despite the perceived poorer outcome.[4–9]

A limitation of our study is the small numbers. Although both univariate and multivariable analysis suggest that diabetes has no effect on any of the outcomes examined, it may be that statistically significant differences could not be detected because of the small sample size.

In conclusion, diabetes seems to have no significant impact on the current revascularisation practice in patients with CLI, as it influences neither the type of treatment being offered, nor the clinical outcome of these patients. Given a similar limb salvage rate in those undergoing revascularisation procedures, diabetics should not be prejudiced against and the decision to amputate or treat conservatively rather than revascularise should be based on suitability for revascularisation, appropriate anatomy, and the presence of medical conditions other than diabetes. It is clear that the modern management of CLI has evolved. The increase in technical expertise and the advent of balloon angioplasty, and in particular the subintimal technique, have revolutionised the treatment of CLI in patients who previously would have been deemed too high risk to undergo surgical revascularisation. The modern management of co-morbidities, such as hypertension, coronary artery disease, diabetes, and hypercholesterolaemia, is also likely to have contributed to the improved outcomes in diabetics presenting with CLI. This prospective study has shown that by advocating an aggressive approach to revascularisation, equally good results, in terms of survival and limb salvage, can be achieved in both diabetic and non-diabetic patients, despite the presence of increased medical co-morbidity in the former. Careful pre-operative optimisation of risk factors, close liaison between vascular surgeon and interventional radiologist, liberal use of revascularisation procedures and offering angioplasty as a first-line treatment in selected patients, are all equally important factors that need to be addressed if a favourable outcome is to be achieved.

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