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The Increasing Role of Percutaneous Transluminal Angioplasty in the Primary Management of Critical Limb Ischaemia

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Objective: *to review the current role and results of angioplasty in the management of critical limb ischaemia (CLI) in a single institution.*
Methods: *data on 526 patients with 608 ischaemic limbs, treated between January 1994 and December 1999 was collected prospectively and analysed retrospectively. Patients were divided into 3 groups according to the date of presentation: group 1 (1994–95), group 2 (1996–97) and group 3 (1998–99). The groups were comparable in terms of demographics, mode of presentation and level of disease.*
Results: *Revascularisation was attempted in 87%, 81% and 91% for groups 1, 2 and 3 respectively (NS). Primary percutaneous transluminal angioplasty (PTA) rates increased from 44% (1994–95) to 69% (1998–99)* ($p < 0.001$)*, and surgical revascularisation rates decreased correspondingly* ($p < 0.01$)*. Overall cumulative patient survival and limb salvage rates were 82% and 89% for 1 year and 45% and 87% for 5 years, respectively. No statistically significant difference existed between the three groups regarding patient survival, limb salvage rates and mean hospital stay (19, 12 and 12 days, respectively).*
Conclusion: *PTA is increasingly replacing bypass surgery in the treatment of CLI, without compromising patient survival or limb salvage rates.*

Key Words: Critical limb ischaemia; Percutaneous transluminal angioplasty; Bypass surgery.

Introduction

The Audit Committee of the Vascular Surgical Society of Great Britain and Ireland defined Critical limb ischaemia (CLI) as chronic or acute on chronic ischaemia that endangers the whole or part of a leg.[1] CLI is a common problem. Its incidence is estimated to be between 50–100 cases per 100 000 population per year.[2] The second European consensus document on CLI estimated that only 66% of critically ischaemic limbs undergo revascularisation versus 16% which undergo primary major amputation, 10% which require medical or minor surgical treatment, and 8% which receive symptomatic relief only.[2] The refinement of bypass surgery and endovascular procedures has led many to argue that revascularisation should be attempted in more patients.[3]

CLI was previously considered as a primary indication for bypass surgery, and percutaneous transluminal angioplasty (PTA) only considered if the patient was at high risk for surgery or if autogenous bypass material was not available.[4,5] In 1991, only about 20% of limbs with critical ischaemia were considered suitable for PTA.[6] Recent studies have shown a trend towards more utilisation of PTA as a first line treatment for CLI from 23% to 46%.[7–11] This study reviews the role of PTA in the management of CLI in our institution over a 6-year period, and assess the results of an aggressive policy towards revascularisation, where PTA was used as a first line treatment, and surgical bypass was reserved for those where angioplasty was either inappropriate or unsuccessful.

Patients and Methods

Patients

A total of 526 patients with 608 chronic critically ischaemic limbs admitted to the vascular unit at the Royal United Hospital Bath between January 1994 and December 1999 are included. CLI was defined by the clinical definition of the Audit Committee of the

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Vascular Surgical Society of Great Britain and Ireland, (the presence of rest pain for at least two weeks or tissue necrosis). Patients were grouped into three groups according to the date of presentation. Group 1 (185 patients with 222 ischaemic limbs) presented during 1994 and 1995. Group 2 (180 patients with 204 ischaemic limbs) presented during 1996 and 1997 and group 3 (161 patients with 182 ischaemic limbs) presented during 1998 and 1999.

Management

An active revascularisation policy was used except in cases where it was deemed that the limb was clinically unsalvageable or the patient unfit for revascularisation (e.g. wheelchair bound or severely demented patients). Patients considered for revascularisation were assessed with colour Duplex scanning and then angiography with a view to proceed to PTA if possible. Bypass surgery was reserved for patients either unsuitable for PTA, according to the surgeon and radiologist judgement, or in whom PTA had failed (according to angiographic morphology, post-procedure ABPI, or persistence of symptoms). All patients were then started on antiplatelet therapy (low dose aspirin or clopidogrel where aspirin was contraindicated).

Follow-up

All patients who had a surgical bypass were followed-up in a clinical and duplex graft surveillance programme and reviewed at 6 weeks, 3 months, 6 months, 12 months and then annually. PTA patients were followed-up clinically at the vascular clinic until their rest pain, ulcers or gangrene had healed, then they were discharged from follow-up, unless their symptoms recurred in which case they were seen urgently in a one-stop vascular and duplex clinic (patients were encouraged to contact the vascular department directly on recurrence of symptoms).

Data collection and analysis

Patients details were entered into a computerised database which was updated regularly with the details of outpatient visits, hospital admissions and mortality. General practitioners were contacted or the patients were contacted directly if they did not re-attend or were discharged from follow-up to determine eventual outcome; all patients were accounted for. The study endpoints were mortality and/or major amputations.

Statistics

Statistical analysis was performed through a computerised software package 'StatsDirect, CamCode, U.K.'. Cumulative patient survival and limb salvage rates were calculated by the Kaplan–Meier method with Cox regression. Discrete variables were analysed with the Chi-squared test. Continuous variables are expressed as medians (interquartile range). Statistical significance was taken at p values ≤ 0.05.

Results

Patients

Patients demographics and mode of presentation are presented in Table 1. There was no statistical difference between the groups in terms of age, gender, or mode of presentation. Distribution of the site of the disease was not statistically different between the three groups.

Management

Table 2 shows the primary management for the all groups. Revascularisation was attempted in 87%, 81% and 91% for groups 1, 2 and 3 respectively (NS). Primary major amputation rates were not statistically

Table 1. Patients demographics and mode of presentation.

	Group 1	Group 2	Group 3	Total	p value
Patients	185	180	161	526	–
Median age (years)	75 (67–81)	78 (70–84)	76 (69–82)	77 (70–84)	NS
Females	87 (47)	91 (50)	86 (53)	264 (50)	NS
Diabetics	45 (24)	43 (24)	52 (32)	140 (27)	NS
Limbs	222	204	182	608	–
Necrosis	129 (58)	116 (57)	111 (61)	356 (59)	NS
Rest Pain	93 (42)	88 (43)	71 (49)	252 (41)	NS

Values between parentheses are percentages, except for median age (interquartile range). NS = not significant.

different between the groups at 7%, 10% and 6% respectively. The percentage of limbs treated by PTA as the sole treatment increased from 44% for group 1, to 56% for group 2, and 69% for group 3 ($p < 0.001$). Bypass surgery rates decreased from 36% to 21% and 18% respectively ($p = 0.003$).

Table 3 shows the changing role of PTA in the management of CLI according to the site of the disease at presentation. These data demonstrate that the role of PTA has significantly increased in the treatment of aortoiliac ($p < 0.0001$) and femoropopliteal disease ($p = 0.002$). Although our data showed an increase of PTA in the treatment of crural disease it was not statistically significant ($p = 0.2$). The rate of repeat (same site) or additional (different site) PTA (due to restenosis, reocclusion, or new lesion as detected by re-investigation after recurrence of symptoms), decreased from 39% for group 1 to 21% for group 2 and 12% for group 3 ($p = 0.0005$).

Patient survival and limb salvage

Actuarial 30-day mortality rates were 1.5% for PTA and 5% for bypass surgery (NS) for all patients. There was no difference in 30-day mortality between the 3 groups. Cumulative patient survival and limb salvage rates for all patients were 82% and 89% for 1 year, 63% and 87% for 3 years and 45% and 87% for 5 years respectively. Cumulative patient survival and limb salvage rates were not statistically different between the three groups at mid-term follow up (up to 2 years, Figures 1 and 2 respectively).

Mean hospital stay was not statistically different between the three groups (19, 12 and 12 days respectively). Diabetes did not influence patient survival in this series. Limb salvage rate was not influenced by the presence/absence of diabetes, site of the disease or mode of presentation.

Table 2. Primary management.

	Group 1	Group 2	Group 3
Limbs	222	204	182
Revascularisation:	193 (87)	165 (81)	166 (91)
PTA	97 (44)	116 (56)	125 (69)
Surgery	80 (36)	43 (21)	33 (18)
Combined	16 (7)	6 (4)	8 (4)
Major amputation	16 (7)	20 (10)	11 (6)
Conservative	13 (6)	19 (9)	5 (3)

Values between parenthesis are percentages of the total number of limbs. PTA: percutaneous transluminal angioplasty, Combined: PTA and surgery for multiple iesions, Major amputation: above or below knee amputation, Conservative: symptomatic treatment or minor amputation (toes or forefoot amputation).

Discussion

The findings of a large prospective cohort study of 1560 patients confirm the poor prognosis of CLI. The overall mortality rate at 12 months (19.1%) indicates that the prognosis is similar to that of myocardial infarction and stroke. The suitability and practicability of revascularisation profoundly affected the prognosis of the patients. Compared with patients for whom revascularisation was deemed unnecessary, the risk of dying within six or 12 months was double among patients considered unsuitable for intervention.[12]

The management of CLI is a major part of the workload in any vascular unit. With continuing improvements in endovascular technology and expertise, an increasing proportion of patients with CLI can he treated by PTA. Successful angioplasty or surgical intervention lead to a similar degree of quality of life improvement in CLL.[13] A deliberate policy in this unit to use PTA as a first-line treatment whenever possible has resulted in a significant increase in the proportion of patients treated by angioplasty compared to other studies (see Fig. 3).

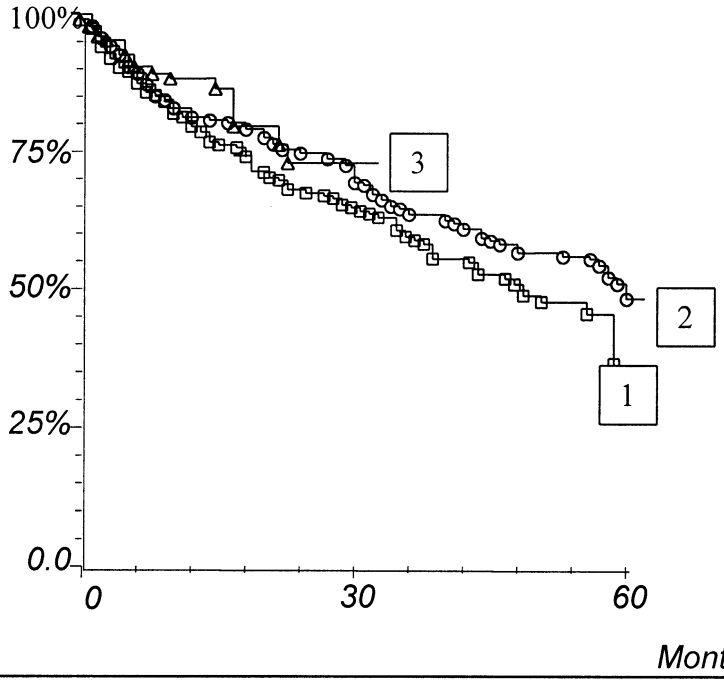
Patient survival and limb salvage

Our one-year cumulative patient survival and limb salvage rates of 82 and 89% respectively, compare

Table 3. Revascularisation procedures, according to the site of disease.

	Group 1 (193 limbs)			Group 2 (165 limbs)			Group 3 (166 limbs)		
	PTA	Surg.	Comb.	PTA	Surg.	Comb.	PTA	Surg.	Comb.
Aortoiliac	10 (29)	22 (63)	3 (8)	26 (66)	13 (33)	1 (1)	36 (77)	7 (16)	3 (7)
Femoro-popliteal	81 (59)	47 (34)	10 (7)	75 (77)	18 (18)	5 (5)	76 (79)	18 (19)	2 (2)
Crural	6 (31)	11 (54)	3 (15)	15 (55)	12 (45)	0 (0)	13 (54)	8 (33)	3 (13)
Total	97 (50)	80 (42)	16 (8)	116 (70)	43 (26)	6 (4)	125 (75)	33 (20)	8 (5)

Values between parenthesis are percentages. PTA: percutaneous transluminal angioplasty, Surg.: bypass surgery, Comb.: combined PTA and bypass surgery.



Months	0	12	36	60
No at risk				
Group 1	185	154	120	91
Group 2	180	145	107	15
Group 3	161	109	1	0

Fig. 1. Cumulative patient survival rates according to groups.

favourably with previous studies where the percentages of primary PTA were much lower, ranging from 20% to 46%. Beside the higher rate of primary PTA in our series, the rate of revascularisation (averaging 86% during the 6-year period) is much higher than other series and of that of the second European consensus document on CLI.[2,6–11] This high rate of revascularisation was probably the reason for the good limb salvage rate.

Hospital stay, cost implications and resources allocation

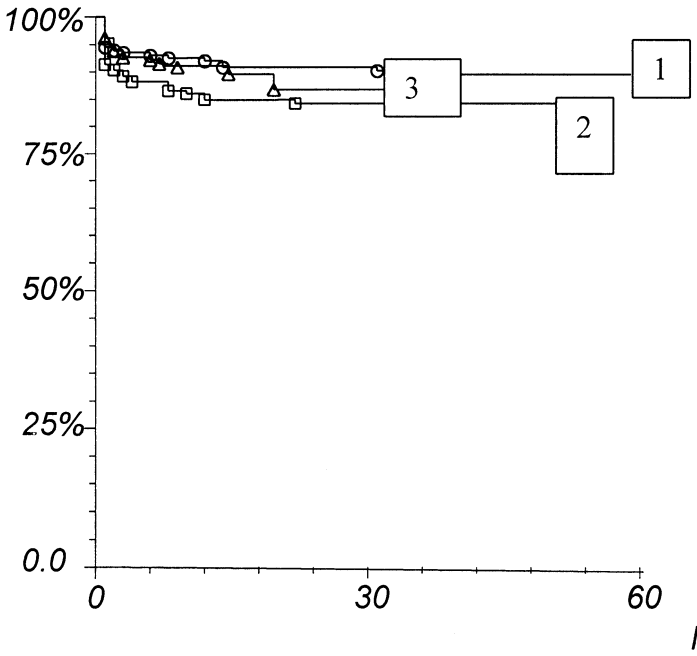
Despite earlier reports of shorter hospital stay for PTA, we have found no significant difference in mean hospital stay (which is the major contributor to the cost of management) between the three groups.[11,14,15]This was probably due to the similar degree of ischaemia and tissue loss suffered by the patients whose duration of inpatient stay and rehabilitation needs were comparable.

Our results show an increase in PTA utilisation, especially for aortoiliac and femoropopliteal disease, 77% and 79% respectively and even for crural disease (55%), this is in line with other studies which showed that infrapopliteal PTA is a feasible primary treatment for CLI with angiographic and clinical success and a cumulative limb salvage rate comparable to that of surgical revascularisation.[16]

The increase in PTA utilisation and the corresponding decrease in surgical revascularisation should call for a change in vascular surgical and radiological resources allocation. It also raises the question of the need for a review of vascular training with more emphasis on endovascular training for vascular surgery trainees.

Conclusions

Although we did not demonstrate any statistically significant difference in favour of either treatment,



Months	0	12	36	60
Limbs at risk				
Group 1	222	167	129	99
Group 2	204	149	111	19
Group 3	182	131	2	0

Fig. 2. Cumulative limb salvage rates according to groups.

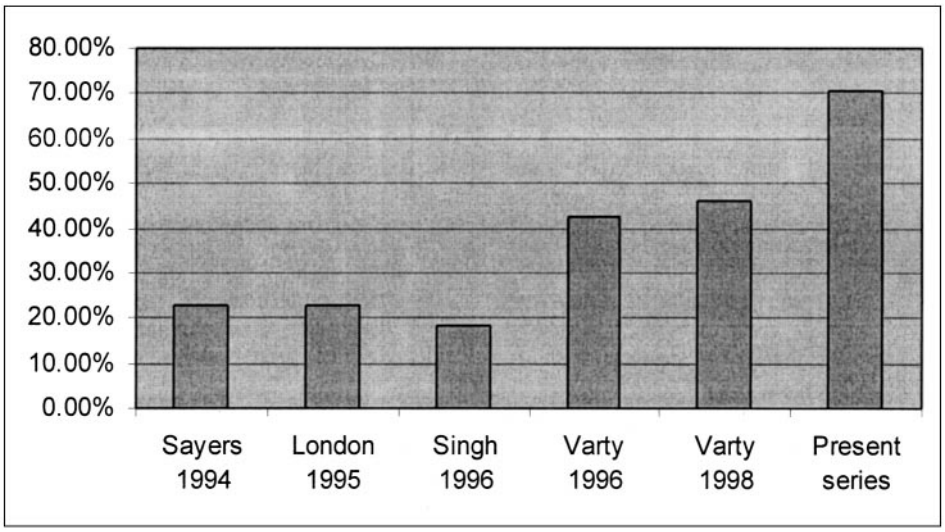


Fig. 3. PTA as a sole intervention for CLI.

the clinical advantages of PTA are well established for the high-risk, elderly vascularly compromised patient.[8] The present study suggests that PTA should increasingly replace revascularisation surgery in the primary management of CLI, emphasising that teamwork between vascular surgeons and radiologists is essential for good vascular practice. The increase in revascularisation for CLI should be supported by adequate funding for surgical and radiological services. Finally the high rate of mortality reflects co-existent morbidity and calls for an integrated approach to treatment of the patient's other medical conditions.

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