ORIGINAL ARTICLE

Bypass surgery or percutaneous transluminal angioplasty to treat critical lower limb ischaemia due to infrainguinal arterial occlusive disease?

CME

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Objectives To define the role of bypass surgery and percutaneous transluminal angioplasty to manage critical limb ischaemia due to infrainguinal arterial occlusive disease.

Design Retrospective review.

Setting Regional hospital, Hong Kong.

Patients Consecutive patients treated for critical limb ischaemia, for whom data were prospectively collected in those who underwent: (i) infrainguinal percutaneous transluminal angioplasty first, or (ii) infrainguinal bypass surgery.

Results Among patients with critical lower limb ischaemia, 364 consecutive individuals having infrainguinal bypass operations and 100 having percutaneous transluminal angioplasty first were compared. The latter patients were older (77 vs 74 years, P=0.014) and had more co-morbidities but higher ankle pressure than those having bypass surgery. In the angioplasty-first group, 74% had favourable lesions (classified as TransAtlantic Inter-Society Consensus A/B). In the bypass group, operative mortality was higher (4% vs 1%, P=0.03) than that in the angioplasty-first group. Hospital mortality was comparable (8% vs 3%, P=0.15). In the bypass group, median hospital stay was longer than that in the angioplasty-first group (24 vs 4 days, P<0.001), and postoperatively they also had a higher median ankle-brachial index (0.92 vs 0.70, P<0.001) and superior long-term patency. In the bypass group, American Society of Anesthesiologists class 4 patients suffered very high operative and hospital mortality (15% and 31%, respectively). Long-term patency of percutaneous transluminal angioplasty depended on the TransAtlantic Inter-Society Consensus class of the treated lesion. Limb salvage rates at 3 years were 89% and 78% for percutaneous transluminal angioplasty first and surgical bypass, respectively (P=0.046). Long-term survival was poorer in the percutaneous transluminal angioplasty–first group (21% vs 51% at 5 years, P=0.04).

Conclusion Infrainguinal bypass and percutaneous transluminal angioplasty are complementary. For TransAtlantic Inter-Society Consensus A and B lesions, percutaneous transluminal angioplasty should be offered first. For American Society of Anesthesiologists class 4 patients, percutaneous transluminal angioplasty should be considered first, regardless of the TransAtlantic Inter-Society Consensus class.

Key words
Angioplasty, balloon; Arterial occlusive diseases; Ischemia; Leg

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Introduction

Critical lower limb ischaemia, which is characterised by rest pain with or without tissue loss (ulcer, gangrene) is a substantial health burden in the ageing population, and in many developed countries it is associated with an increased prevalence of diabetes. The goals of treatment are: to provide pain relief, promote wound healing, and preserve limb function, whilst minimising overall cardiovascular risks. These goals help maintain independence and quality of life. They are best attained by limb revascularisation whenever possible, as the risk of limb loss within 1 year is estimated to be 70% in the presence of rest pain and 95% if there is tissue loss.[1] Two such treatments are widely available—bypass surgery and

使用繞道手術或經皮血管腔內成形術醫治因下腹股溝動脈閉塞症引致的下肢嚴重缺血病

目的 探討繞道手術或經皮血管腔內成形術，在醫治因下腹股溝動脈閉塞引致的下肢嚴重缺血的情況。

設計 回顧研究。

安排 香港一所地區醫院。

患者 所有因下肢嚴重缺血而要先接受下腹股溝經皮血管腔內成形術（血管成形術組），或接受下腹股溝繞道手術的病人（繞道術組）。

結果 下肢嚴重缺血的病人中，把連續364位接受下腹股溝繞道手術及100位接受經皮血管腔內成形術的數據作比較。與繞道術組比較，血管成形術組年紀較大（77歲比74歲，P=0.014）、有較多相關疾病，但有較高踝壓。先接受血管成形術的病人中，74%有良好病變（即按泛大西洋協作組織共識[TASC]分為A或B級的）。繞道術組的術中死亡率較高（4%比1%；P=0.03），兩組的醫院死亡率卻相約（8%比3%；P=0.15）。繞道術組的留院時間較長（中位數：24天比4天；P<0.001），並有較高的術後踝臂指數（中位數：0.92比0.70；P<0.001），及較好的遠期動脈橋通暢性。繞道術組中屬美國麻醉醫師協會（ASA）第4級的病人有相當高的術中及醫院死亡率，依次為15%及31%。血管成形術組的長期動脈橋通暢性視乎TASC級別。3年保肢率方面，血管成形術組89%，繞道術組78%（P=0.046）。血管成形術組的遠期（5年）生存率較低（21%比51%；P=0.04）。

結論 兩種手術可以互保不足。病人如屬TASC中A或B級病變，應先用經皮血管腔內成形術。而屬ASA第4級的病人，無論屬於TASC哪一級別，也應先考慮經皮血管腔內成形術。

percutaneous transluminal angioplasty (PTA). Often, however, there is no clear choice, particularly in the presence of infrainguinal occlusive disease, as the procedure amounts to a compromise between saving a limb versus risking a life. Bypass surgery achieves superior long-term patency and possibly superior limb salvage rates, but at the cost of higher initial morbidity and possibly higher mortality. By contrast, balloon angioplasty carries the potential advantages of lower procedural morbidity and mortality, and shorter hospital stay. Moreover, it is repeatable, a suitable vein is not required, and does not seem to jeopardise subsequent surgery.[2-4] Nevertheless, its benefits seem less durable. Over the years, there has been much discussion on which of these two modalities should be first-line treatment for patients with critical limb ischaemia (CLI). In reality though, the treatment offered often depends on the available expertise in a particular institution, personal biases, and the results of uncontrolled observational studies.

The best study defining the role of these two modalities to-date (known as BASIL) clearly shows that bypass surgery is more expensive and confers higher morbidity in the short term, but beyond 2 years it is associated with reduced risk of limb loss and death.[5] In the real world, patients suffering from CLI may not be suitable candidates for both of these treatments at the same time, as was described in that trial. To develop a suitable treatment strategy for our patients presenting with CLI, the present study aimed to analyse our results of bypass surgery versus PTA first.

Methods

The clinical data pertaining to all patients who underwent infrainguinal bypass for CLI over a 13-year period were examined. Bypass surgery was introduced first. Percutaneous transluminal angioplasty became available much later, and only procedures performed over the 6 years from 2001 to 2006 were included in the analysis. All the latter procedures were performed for category-4 and -5 CLI.[6] We did not have a PTA-first policy, but this was performed first for lesions judged suitable for this procedure by the vascular surgeon and interventional radiologist.

Clinical findings, demographic data, and co-morbidity were all prospectively recorded. In patients undergoing angioplasty, the TransAtlantic Inter-Society Consensus (TASC) classification status[7] of the occlusive disease (based on arteriography) was also recorded. The TASC classification status of arterial occlusive disease in patients undergoing bypass could not be recorded, as many patients were treated before year 2001. Primary and secondary graft patency was defined according to SVS/ISCVS (Society for Vascular Surgery/International Society for CardioVascular Surgery) criteria.[5] The data were analysed using the Statistical Package for the Social Sciences (SPSS; Windows version 8.0; SPSS Inc, Chicago [IL], US). The endpoints included: peri-procedural mortality, morbidity, graft patency, limb salvage rate, and long-term survival. Chi squared tests were used for comparing proportions. The Kaplan-Meier method was used to produce survival curves and comparisons of survival curves were carried out using the log rank test.

Results

There were 364 surgical bypass operations performed for 163 (52%) male and 151 (48%) female patients. Their median age was 74 years; 86% endured tissue loss (ulcer or gangrene) and the remaining 14% had rest pain only. For patients with diabetes, the median ankle-brachial index (ABI) was 0.40 (range, 0-1.01) and the median toe pressure was 0 mm Hg. Co-morbidities included: hypertension, diabetes mellitus, cigarette

smoking, coronary heart disease, impaired renal function, and past cerebrovascular accident (Table 1). Secondary bypass for recurrent CLI accounted for 39 (11%) of their operations.

The bypass operations included above-knee (n=97, 27%) and below-knee (n=77, 21%) femoropopliteal bypass, infrapopliteal bypass to tibial/peroneal artery (n=141, 39%), and bypass to a foot artery (n=49, 13%). Inadequate inflow due to aorto-iliac occlusive disease was present in 60 limbs that were treated by PTA (n=25), additional proximal bypass surgery (n=21), and endarterectomy (n=14).

In this surgical bypass group, overall 30-day operative mortality was 4.4% (n=16), the causes being: myocardial infarction (n=8), congestive heart failure (n=4), cerebrovascular accident (n=1), pneumonia (n=2), and mesenteric infarction (n=1). Whilst the operative and in-hospital mortality for American Society of Anesthesiologists (ASA) class 2 and 3 patients (n=330) were 3.3% and 5.5%, respectively; a small number of ASA class 4 patients (n=34) suffered very high operative mortality (15%) and in-hospital mortality (31%). In patients undergoing bypass, the early limb salvage rate (within 30 days) was 94% and their median postoperative hospital stay was 24 days.

Longer-term primary graft patency rates at 1, 12, 36, and 60 months were 92%, 65%, 48%, and 40%, respectively (Fig 1). Eighty (22%) patients underwent secondary intervention or further surgery in the presence of ischaemic symptoms due to graft failure. Of these, 34 underwent balloon angioplasty with or without prior intra-arterial thrombolysis. Subsequent secondary graft patency rates at 1, 12, 36 and 60 months were 95%, 74%, 58%, and 54%, respectively. Long-term limb salvage rates were 82%, 78%, 76% at 1, 3, and 5 years, respectively. Patient survival rates were 82%, 66%, and 51% at 1, 3, and 5 years, respectively.

In the PTA group, angioplasty was performed for 100 limbs as the first-line treatment for CLI in 47 males and 45 females. Tissue loss and rest pain were the indications in 84 and 16 procedures, respectively, for which PTA was the routine technique employed in our hospital. Compared to the bypass surgery group, the median age of these patients was significantly greater (77 years), a higher percentage had renal impairment and ASA class 3 and 4 disease (P=0.001). The median ABI was 0.45 (range, 0-1.43) which was higher than that in the bypass group (P=0.02). Percutaneous transluminal angioplasty was performed for lesions in the superficial femoral artery (SFA, n=79), above-knee popliteal artery (n=44), below-knee popliteal artery (n=5), and tibial artery (n=8). In terms of the TASC classification, there were 20, 54, 16 and 10 class A, B, C, and D lesions, respectively.

Overall, 30-day mortality in those having PTA (n=1, 1%; P=0.03) was lower than that of the surgical group, but the 3% hospital mortality was

TABLE 1. Demographic data of patients first undergoing bypass surgery or percutaneous transluminal angioplasty (PTA)

Demographic data*	Bypass (n=364)	PTA first (n=100)	P value
Median age (years)	74	77	0.014
Coronary heart disease	44%	48%	0.51
Diabetes mellitus	66%	75%	0.41
Hypertension	71%	88%	0.002
Cerebrovascular accident	21%	28%	0.30
Cigarette smoking	62%	70%	0.14
Renal impairment	21%	32%	0.002
Presence of tissue loss	86%	82%	0.74
Median preoperative ABI	0.40	0.45	0.02
ASA			
Class 2	135 (37%)	20 (20%)	0.001
Class 3	190 (52%)	58 (58%)	
Class 4	39 (11%)	22 (22%)	

* ABI denotes ankle-brachial index, and ASA American Society of Anesthesiologists

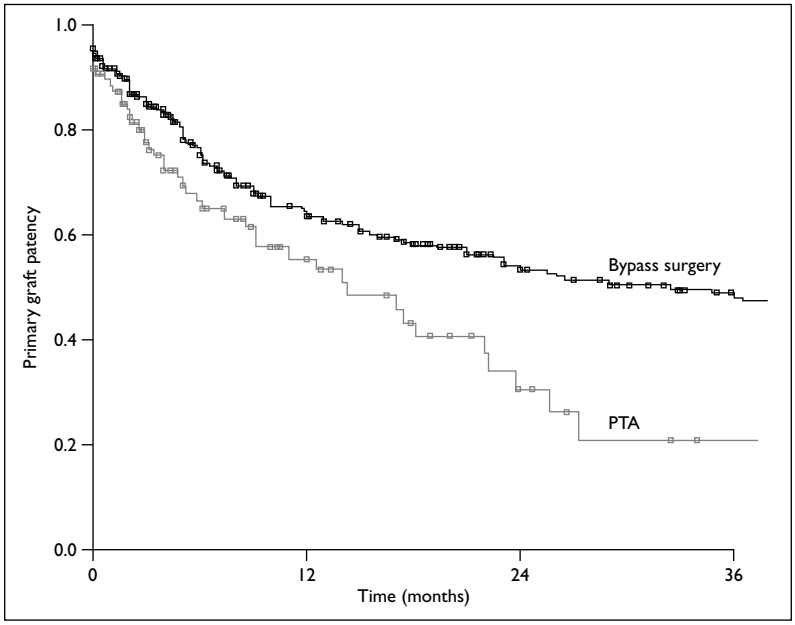

FIG 1. Primary graft patency following bypass surgery was significantly better (P=0.016) than after percutaneous transluminal angioplasty (PTA)

TABLE 2. Early outcomes of patients first undergoing surgery or percutaneous transluminal angioplasty (PTA)

	Bypass (n=364)	PTA first (n=100)	P value
Operative mortality	4%	1%	0.03
Hospital mortality	8%	3%	0.15
Early failure (30 days)	8%	12%	0.49
Myocardial infarction	10%	3%	0.095
Wound complications	29%	8%	<0.001
Median postoperative ABI*	0.92	0.70	<0.001
Median hospital stay	24 days	4 days	<0.001

* ABI denotes ankle-brachial index

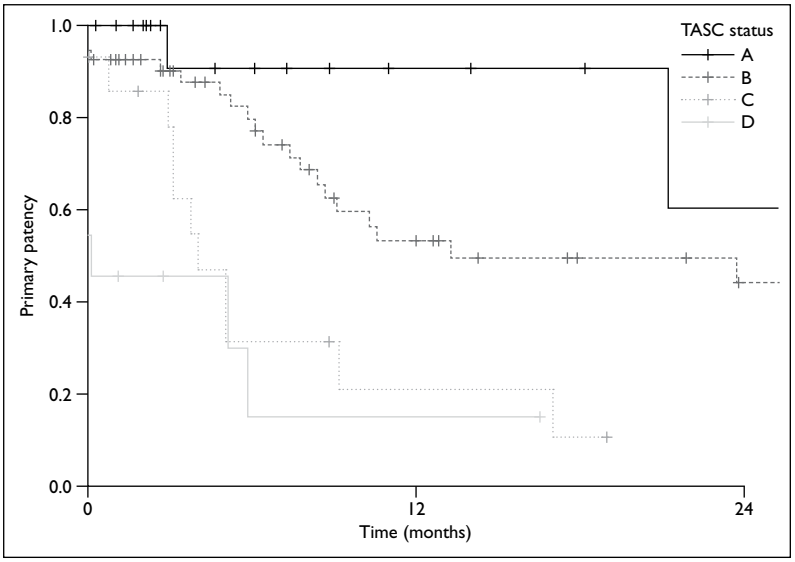

FIG 2. Primary patency following percutaneous transluminal angioplasty stratified according to TransAtlantic Inter-Society Consensus (TASC) status of treated lesions

comparable (n=3; P=0.15). The median hospital stay (4 days) was shorter than that for the surgical bypass group (P<0.001) [Table 2]. Complications included myocardial infarction (n=3), wound haematoma (n=4), and pseudoaneurysm (n=4). Thromboembolic complications occurred in five patients with symptomatic deterioration. One patient with extensive thromboembolic complications was considered suitable for above-knee femoropopliteal bypass before angioplasty, but due to extensive clogging of distal arteries, subsequent attempts at thrombolysis, embolectomy and then bypass surgery all failed. This patient underwent a major amputation.

When PTA was offered as the first-line treatment for CLI, technical success was achieved in 91% of the procedures. Stents were deployed in only five (5%) patients due to a limited budget. At 1, 12, and 36 months, primary patency was 88%, 48%, and 27%, respectively (Fig 1). This was significantly lower than that of bypass surgery (P=0.016) even though majority (74%) of treated lesions were TASC A and B. Secondary patency improved to 88%, 61% and 31%, respectively over the same period. Long-term patency and technical success rates very much depend on the TASC classification status of the occlusive disease (Fig 2).

After PTA, 61% of the treated limbs required no further procedure; 30% of patients without clinical improvement underwent bypass surgery. Their persistent ischaemia was due to multi-segment occlusive disease distal to the target lesions that were deemed unsuitable for PTA. Repeated PTA was performed for one (1%) patient, whilst severe multiple co-morbidities or absence of run-off arteries precluded bypass surgery in the remaining 8%. Median postoperative hospital stay was 4 days which was significantly shorter than in the bypass surgery group (P<0.001). With PTA as the first approach, supplemented by bypass surgery and secondary angioplasty, the overall limb salvage rate was 93%, 89% and 77% at 1, 3, and 5 years, respectively. This was significantly better than that for bypass surgery (P=0.046) up to 3 years. However, long-term survival was poorer than in the bypass group, being 80%, 59% and 21% at 1, 3, and 5 years, respectively (P=0.04).

Discussion

In the treatment of CLI, the main aim was to provide adequate revascularisation with minimal cardiovascular risk. It was therefore necessary to consider patient fitness, the anatomy of the occlusive disease, the TASC category of the target lesions, and the quality of run-off. The availability of expertise was also a decisive factor. Percutaneous intervention was an excellent modality, given the appropriate patient and the fast-evolving technology. The procedure was recommended based on guidelines to treat TASC A and B lesions, but is increasingly used as first-line therapy regardless of the TASC status.[8,9] Patients with CLI often present with multi-segment occlusive disease. To effectively treat these multi-segments, bypass surgery remains the most effective modality. It can bypass the most extensive occlusive disease provided there is an adequate inflow, suitable vein/conduit and an adequate run-off artery at or beyond the ankle. For common pathology, such as complete SFA occlusion, above-knee femoropopliteal bypass is a simple procedure that can be performed expeditiously and is associated with durable patency even with a prosthetic conduit.[10,11] Conversely, PTA is often followed by disappointingly low patency, even in claudicants treated with drug-eluting stents.[12,13] When the two techniques were compared in a randomised study, SFA occlusion treated with bypass surgery attained significantly better primary patency than balloon dilatation.[14] A meta-analysis also revealed poor patency following femoropopliteal balloon angioplasty for critical ischaemia especially with totally occlusive lesions.[15] Poor patency can be attributed to the presence of CLI with a long occlusion, diabetes mellitus (75%), and poor run-off (from a blind segment fed by collaterals or up to one tibial/peroneal run-off artery, 86%).[16] Therefore, for ASA class 2 and 3 patients with long SFA occlusions that start from the origin, an above-knee femoropopliteal bypass remains the treatment of choice. However, more than half of the patients undergoing bypass surgery have diffuse tibial disease. These patients require lengthy femorodistal bypass operations and may lack adequate autogenous vein grafts, which are crucial for durable success. Long-term graft patency may be inferior to more proximal femoropopliteal bypass procedures, and wound complications are

common. The potential gain from a successful tibial PTA is obvious, even if repeated procedures are needed. In our experience, however, the results of PTA for infrapopliteal arteries have been disappointing, even for less extensive lesions, but this may change as coronary technology can be increasingly applied to the treatment of below-knee disease. Nevertheless, successful PTA for SFA (mainly for TASC A and B lesions) did reduce the magnitude of subsequent distal bypass procedures, resulting in shorter wounds and requirement of shorter vein lengths.

In our practice, patients offered angioplasty as first-line therapy tended to have more co-morbidities with a higher percentage of ASA class 3 and 4 lesions. They also had more favourable (mostly TASC A and B) lesions in the more proximal SFA. They may also have less severe arterial disease as suggested by the higher preoperative ABI. Despite these features, the primary patency rate was poor. Fortunately, inferior patency was not followed by inferior limb salvage and the outcome of patients having bypass operations after PTA did not differ from those who underwent surgery first. Surgical revascularisation is highly effective but there is a very high operative mortality, especially in ASA class 4 patients, almost a third of whom did not leave the hospital alive. Wound complications are common following bypass operations and result in long hospital stays and increased costs.

Percutaneous transluminal angioplasty on the other hand offers good short-term success with minimal trauma, but suffers from lack of sustainability of this initial success. This shortcoming probably explains the wide variety of alternative options that have developed. These include: atherectomy, cryoplasty, brachytherapy, cutting balloon angioplasty, excimer laser, subintimal angioplasty, and plain and drug-eluting stents. However, successful PTA provided improved perfusion, symptomatic relief and/or wound healing in more than half of our patients, though CLI persisted in 40% of them. It was also associated with lower peri-operative mortality and morbidity and shorter hospital stays. Success rate was closely related to the TASC class of the lesions. In patients with anatomically favourable lesions (TASC A and B), the technical success and patency rates were relatively high. In our experience, the technical failure rate was very high with TASC D lesions, which may have been related to limited experience with this difficult lesion. Long-term patency was also low in this patient group. Overall long-term patency was significantly lower than that following surgical bypass, despite the majority of treated lesions being TASC class A and B. However, the procedures can be repeated or surgical bypass can be offered as appropriate. Notably, PTA rarely jeopardises subsequent surgery. In our experience, in only one patient surgical bypass was no longer feasible after PTA.

In conclusion, bypass surgery and PTA are complementary in the treatment of severe peripheral arterial disease. Percutaneous transluminal angioplasty can also be a useful preoperative adjunct as well as an intervention to manage graft failure. The appropriate treatment modality depends on the patient's general condition, the distribution of occlusive disease, the TASC characteristics of the occlusive disease, and the available expertise. In our opinion, for TASC A and B lesions PTA should be used first. For ASA class 4 patients, PTA should also be offered first whenever possible, regardless of the TASC status of the arterial lesion. By contrast, surgery should be offered for fitter patients with long occlusive lesion (TASC D), and especially those with diffuse infrapopliteal occlusive disease. In the future, it will certainly be beneficial for vascular surgeons and other interventional colleagues to increase their capacity to provide endovascular treatment of below-knee occlusive disease causing CLI.

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