Critical Limb Ischemia: Revascularization Options and Clinical Outcome

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Abstract

Objectives: To study the various options of revascularization, mainly the role of Percutaneous Transluminal Angioplasty (PTA) in the treatment of Critical Limb Ischemia (CLI) and to assess the clinical outcome.

Material and Methods: A retrospective study was performed involving 109 consecutive patients (75 men and 34 women; mean age 59 years, range 45-87). Fifty-nine patients were diabetic, and sixty-four smokers. Balloon angioplasty for critical limb ischemia was performed in 78 limbs, while Percutaneous Transluminal Angioplasty (PTA) and/or surgery in 34 limbs. Immediate and at one year outcome was examined by case note review to determine survival, amputation-free survival, and limb salvage.

Results: In the angioplasty, technical success was achieved in 66 (84%) out of 78 limbs, while in the combined PTA and/or surgery it was 22 limbs (65%) out of 34 limbs. The overall amputation rate was 22%. The follow-up period was 12 months. The overall in-hospital mortality was five patients (4.6%). Eighty patients (74%) had their feet spared from major amputation as a result of revascularization. Only sixty-tow patients were available for follow-up which revealed that 84% of them were doing well 12 months after their revascularizations. Patients with an initially successful angioplasty had a good outcome.

Conclusions: The results of this study justify the use of PTA as a first-line treatment for critical limb ischemia; technical failure does not preclude conventional surgery. CLI is highly prevalent among diabetes. CLI was significantly associated with diabetes, smoking, and gangrene. Educational programs and aggressive approach are highly needed to reduce the risk of amputations.

Keywords: Critical, Ischemia, Limb, angioplasty, salvage.

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Introduction

Critical ischemia of the leg develops when the perfusion pressure in the arterial system is insufficient to maintain "muscular nutrition", resulting in either severe, continuous ischemic pain or atrophic changes such as ulceration and /or gangrene.[1] Critical Limb Ischemia (CLI) was defined by the European Consensus's on CLI and more recently by the Trans Atlantic Inter-Society Consensus (TASC).[1,2] According to the TASC, "The term CLI should be used for all patients with chronic ischemic rest pain, ulcers, or gangrene attributable to objectively proven arterial occlusive disease". Evaluation of CLI objectively as per recommendations suggested pressures of either ankle pressure (<50-70mmHg) or reduced toe pressure (<30-50 mmHg) or reduced $TCPO_2$ (<30-50 mmHg). In an ageing population, this is now an increasingly common condition. It has been estimated that CLI has an annual incidence of 400 to 1000 per million among the general population[2], and represents a major workload for vascular surgeon. These patients are at increased risk for limb loss, and usually require large commitment both in medical effort and cost.[2]

The diagnosis of CLI is mainly based on clinical examination, and the treatment is often difficult in these high cardiovascular risk patients who are often elderly and frail, and tend to have a greater number of associated co-morbidities. The workload this generates also continues to increase due to an increasing availability of therapeutic techniques[3,4] mainly endovascular interventions.

All patients with severe leg ischemia should undergo limb salvage whenever feasible because it is associated with a superior quality of life, and has economic advantages over amputation.[5,6]

The optimal modern management of these high-risk patients demands a team approach combining the skills of non-invasive vascular imaging, interventional radiology and the vascular surgeon. Patient's selection for differing forms of treatment is important, and treatment of CLI requires relatively short-term objectives, especially in patients with significant co-morbidity.[7]

The aim of the present study was to evaluate the various optional treatments in patients with CLI, in terms of limb salvage and patients survival, with analysis of the effects of preoperative risk factors on outcome. To achieve this goal, we retrospectively analyze the data of patients with CLI, and were treated at King Abdullah University Hospital in northern Jordan.

Patients and Methods

The case records of 109 patients with 128 CLI during the period from July 1, 2002 to April 30, 2007 were reviewed retrospectively. In this study, CLI was defined according to the criteria of TASC recommendations,[2] with documented significant arterial disease on color duplex scanning or arteriography. Patients with an ankle pressure >50mmHg were excluded from the study.[2] However, diabetic patients with a very high ankle pressure due to incompressible tibial vessels and signs of CLI were included. Acutely ischemia limbs (symptoms for less than two weeks),[2] and neuropathic diabetic foot lesions with palpable pulses and no lesions on duplex scanning were excluded. Patients with ulcers of proved mixed etiology, involving other causes as well as peripheral arterial disease, were excluded. The majority of patients were admitted for urgent assessment of an ischemic limb with control of preoperative coexisting medical risk factors. The patient characteristics are shown in (Table 1). Ankle-brachial pressure index measurements were performed using a hand held Doppler, and when appropriate, non-invasive assessment of leg vessels was performed using duplex imaging (mapping of the aortoiliac and femeropopliteal vessels). Arteriography was performed in all patients except in a small proportion of patients with extensive gangrene and/or a functionally useless limb, and in those who were moribund and unfit for further definitive treatment. MRA and CT angiography for peripheral vessels were not performed for our patients.

Table (1): Characteristics of 109 patients with CLI.

Variable	*No. Patients (109 patients) (%)*
Gender	
Male	*75 (69%)*
Female	*34 (31%)*
Age	*59 years (range 45 to 87)*
Risk Factors	
Diabetes	*59 (54%)*
Ischemic heart disease	*48 (44%)*
Hypertension	*38 (35%)*
Cerebrovascular disease	*22 (20%)*
Smoking	*64 (59%)*
Clinical presentation (128 limbs)	
Ischemic ulcers	*47 (37%)*
Ischemic rest pain	*40 (31%)*
Gangrene	*41 (32%)*

Angioplasty was performed in the presence of amenable arterial lesions and whenever possible with stenting, irrespective of the surgical risk. The decision was always made after close consultation between the vascular surgeon and the interventional radiologist. The technique of subintimal angioplasty was performed in 8 limbs. If percutaneous transluminal angioplasty (PTA) failed or was technically impossible, surgical reconstruction was considered, if possible. Treatment was classified as PTA, combined PTA and surgery, reconstructive surgery, and primary amputation (minor foot amputation excluded) (Table 3). Patients that were confined to a wheelchair had extensive necrosis and/or infection or joint contractures, which prevented walking, and were treated with major amputation.

Limb salvage was defined as the preservation of a functional limb, including at least part of the forefoot, without requiring prosthesis. A successful outcome was defined as the relief of symptoms (mainly pain), and a complete healing of any existing ulcers or gangrenous lesions (even with the help of minor surgery). Minor amputations or debridement were done for localized area of gangrene.

Patients were followed up in the outpatient clinic to assess their revascularization, by hand held Doppler and/or Duplex scan, the state of their healing wounds, and arteriography if needed. The risk factors evaluated in this study were diabetes mellitus, smoking, and the presenting clinical features with analysis of their effects on outcome. Statistical analysis was done using SPSS statistical package.

Results

During the 58-month period, 109 patients with 128 CLI were reviewed retrospectively. There were 75 men (68.8%) and 34 (31.2%) women and the mean age was 59 years (range 45 to 87). Fifty-nine patients (54.1%) were diabetic, and 64 (58.7%) were active smokers. Ischemic rest pain was the presenting feature in 38 limbs (29.7%), and tissue necrosis (ulceration and/or gangrene) in 78 limbs (60.9%), and partially healed ulcer in 12 limbs (9.3%). The limbs fulfilled the TASC criteria for CLI with an ankle systolic pressure of 50 mm Hg or less. Non-invasive duplex scanning was the first line of investigation in 38 patients (34.8%). Angiography was performed in 93 patients (85.3%), after an initial duplex scanning in 31 patients (28.4%), and primarily in 62 patients (56.8%). The distributions of the lesions are summarized in (Table 2). No diagnostic procedures were performed in 9 patients. The methods of treatment adopted based on these investigations are shown in (Table 3). Angioplasty was performed in 78 limbs (60.9%). The angiography performed at the time of PTA confirmed the duplex findings in 90% of the cases with minor discrepancies in the remaining cases that did not change the planned approach to PTA. Stents were placed in 32 limbs (25%), all in the suprainguinal arteries.

Table (2): Distribution of lesions (128 limbs).

Arterial segments	*No. limbs (%)*
Suprainguinal	*42 (33%)*
Infrainguinal	*48 (37%)*
Extensive lesions	*38 (39%)*

A combination of PTA and surgery was performed in 18 limbs (14%). In the remaining limbs, duplex scan and/or angiographic findings were judged unsuitable for PTA, and these patients were treated with surgery in 16 limbs (12.5%), and primary amputation in 16 limbs (12.5%).

Eighty-seven percent of the PTA procedures were performed as elective sessions. The levels of vessels dilated by PTA are summarized in Table (4).

The overall in-hospital outcomes were; in the PTA group, a technical success was achieved in 66 limbs (84.6%), 8 limbs (10.2%) referred for surgery due to distal embolization, and 4 limbs (5.1%) experienced failed procedures with subsequent amputation. In the surgical group, there were five in-hospital deaths, 8 limbs (19%) experienced failed procedures with subsequent amputations.

Primary amputations were performed in 16 limbs (12.5%); for extensive necrosis (12), functionally useless limb (2), unfit for reconstruction and PTA not possible (2). The remaining amputations were secondary; following initial PTA (4), and surgery (8). The overall amputation rate was 28 limbs (21.8%). There were 4 limbs above knee and 24 limbs below knee amputations, two patients had bilateral amputations. Limb salvage was achieved in 100 limbs (78.2%).

The overall in-hospital mortality was 5 patients (4.6%), although none was directly attributable to the procedure; 3 patients developed myocardial infarction, and 2 patients developed cerebrovascular accident. Eighty patients (74%) had their feet spared from major amputation as a result of revascularization. Only sixty-two patients were available for follow-up which revealed that 86% of the whole sample were doing well 12 months after their revascularizations. Presentation with rest pain was associated with a better limb salvage rate than ulceration and gangrene (p=0.0.3).

Diabetes was the only independent risk factor to be associated significantly with amputation (p=0.0.2). The overall limb salvage rate in diabetics was 69% compared with 86% in non-diabetics. The significance of diabetes on limb salvage was lost, however, when an aggressive treatment was applied. Death was associated with multiple risk factors. The overall median hospital stay was 9 days (range 1-38).

Table (3): Method of treatment of 109 patients with CLI (128 limbs).

Treatment	***No. limbs (%)***
PTA	*78 (61%)*
Combination PTA and surgery	*18 (14%)*
Surgical revascularization	*16 (13%)*
Primary amputation	*16 (13%)*
Secondary amputation	*12 (11)*

Table (4): Level of revascularization of treated limbs by PTA and/or Surgery (112 limbs).

Arterial segment	***PTA***	***PTA and/or Surgery***
Suprainguinal	*54*	*8*
Supragenicular	*14*	*12*
Infragenicular	*16*	*8*

Discussion

Patients with CLI are typically afflicted with generalized atherosclerotic disease characterized predominantly by males, advanced age, multiple associated diseases, and a strong history of cigarette smoking resulting in a relative high incidence of perioperative complications.[8,9] Unfortunately, most of them have multi-segment occlusive disease.[1] In addition, it is well-recognized that CLI patients suffer diagnostic delays and poor risk factors modification, which, in part, contributes to limb loss and poor survival.[2]

The management of patients with CLI is a multidisciplinary, and has usually been discouraging as limb loss was often necessary after minor ablative surgery for gangrene in view of the poor blood supply and retarded wound healing. In these patients, revascularization procedure has a better quality of life than

amputation. Amputee's patients, especially elderly, do not rehabilitate well with their prostheses and become dependent on their families or support services. Many become depressed as a result of the major amputation and a significant number (up to 30%) would also lose the other leg within 3 years from atherosclerotic disease.[9,10] Our patient cohort is different from those reported in Western literature with a lower mean age of 59, with 58.7% smokers, and 54,1% diabetics. This has important implications for the management of these patients as 13.4% of the population in Jordan are diabetics[11] and 58.4% will have foot problems at some stage, being mainly associated with ischemia[12], which may be amenable to revascularization. The prevalence of amputation in diabetic patients is (5%) and correlates mainly with the duration of diabetes, smoking, and peripheral vascular disease. Age and gender were not found to have any impact on the prevalence of amputation.[13]

However, diabetics have exactly the same ischemic problems as non-diabetics except for the more frequent distal distribution of their atherosclerotic disease affecting mainly the calf vessels and they present at a younger age and should be treated in the same way by revascularization if possible.[14]

This study was based on a clinical level supported by duplex and mainly angiographic demonstration of arterial disease in the vast majority of cases. Angiography remains the "golden standard" for the assessment of severe leg ischemia, and the role of PTA in the management of lower-limb peripheral arterial disease is increasing, because it is a less invasive and an inexpensive alternative to surgical revascularization procedures.[7,8] Most of the patients (85%) in the present series were admitted for arteriography and underwent treatment within 2-3 days of admission. More lesions are suitable for PTA, if PTA fails or is not possible; the leg may be salvaged with reconstructive vascular surgery .[7,8,10]

PTA was performed in (61%) of the limbs. The advantages of PTA are well-established for the high-risk elderly vascular patient with shorter hospital stay, which reduces hospital costs.[10,14,15] A deliberate policy at our hospital to use PTA as first-line treatment whenever possible has resulted in a significant increase in the proportion of patients treated by angioplasty. Angioplasty has been shown to be effective in 88% of patients with CLI, the estimated secondary patency rate was 72% at 3 years, and can produce a limb salvage rate of 60% at 3 years.[16] PTA has been proposed not only as a good alternative to surgical revascularization procedures in high-risk patients, but also as the first-line treatment for treating CLI, however, if angioplasty fails, surgical intervention is undertaken in nearly all patients.[7,8,10,15-17] In our study, 66 of the 78 attempted endovascular procedures were considered as technically successful, giving an overall 84% success rate to our patients. Whatever the technical success and overall patency rates are, what matters in patients with CLI is the clinical outcome in terms of clinical improvement, limb salvage, and survival. The initial results of PTA and surgery were comparable and in some reports PTA is superior to surgery, and PTA is a durable procedure.[8-10,15-17] PTA was associated with a complication rate (requiring surgery) in 6% of this study, which is higher than other reported series.[15,17] Surgery was associated with a 4% mortality rate (directly attributable to the procedure) and a 10% rate of serious complications (graft infection) which needed further surgery. The mortality rate in this study is similar to the rate reported by other authors.[15,16]

Primary amputation is considered only in those who have extensive tissue necrosis of the weight-bearing area of the foot, sever foot infections, and who have severe fixed contractures or who have no prospect of walking again.[18,19] The in-hospital amputation rate of 22% in this study was similar to the amputation rate of other reported series.[1,18,19]

Previous studies have shown that age and poor practical condition should not be considered

reasons for preferring amputation to revascularization.[20,21] Age and gender were not found to have an impact on the prevalence of amputation.[13]

It is essential to treat preexisting medical disease before definitive therapy of severe leg ischemia. Tissue necrosis is often considered to be associated with a worse outcome than rest pain alone with amputation rate 16% and 31%, respectively.[22] The results of the present study do not support this and similar findings were reported.[15-17] Revascularization is therefore worthwhile despite tissue necrosis, provided weight-bearing area of the foot remains unaffected.

Diabetic patients are five times more likely to develop critical leg ischemia, and operative mortality for major amputation is 10% to 15% for diabetic gangrene[10] and late mortality is 25%, consistent with the poor life expectancy of these patients as a whole (50% in 5 years).

The results of the present study suggest that, with aggressive treatment, limb salvage and mortality rates are the same for diabetic and non-diabetic patients. Similar findings have been reported by others.[2,22] The durability of these revascularization procedures requires further follow-up, but the initial in-hospital outcomes, 10% mortality rate and 78% limb salvage, were similar to those in previous studies. Even after successful revascularization, multidisciplinary cooperation with plastic and orthopedic surgery for partial amputation and muscular cutaneous flaps as well as rehabilitation is essential. Psychological support will also be required.

Conclusions

With an aging population and improved medical care that has increased life expectancy, more patients with severe systemic disease are presenting with CLI. Patients with CLI should be promptly admitted for an early non-invasive assessment, with color duplex scanning and angiography allowing efficient selection of patients for PTA or surgery.

An increasing proportion can be treated by PTA rather than by surgery, an important benefit for elderly, high-risk patients, and regardless of their diabetic status, age, and tissue necrosis. Patient education with regard to the early symptoms and signs of this condition will greatly assist in limb salvage before it is too late. The medical community on its part should constantly be alert to ensure early diagnosis and treatment.

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نقص توعية الطرف الحرجة (التوعّي، النتائج)

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الملخص

الهدف: مقارنة الخيارات المتاحة لإعادة التوعّي، بشكل أساسي رأب الوعاء عبر الجلد (PTA) في معالجة نقص توعية الطرف الحرجة (CLI).

الطريقة: في دراسة استيعادية اجريت على (109) مرضى (75 ذكراً، 34 أنثى، العمر الوسطي (59) سنة، المدى 45–87). 50% من المرضى لديهم داء السكري و 64% من المدخنين. رأب الوعاء أجري في (78) طرفاً لديهم نقص توعية الطرف الحرجة (CLI) وأجري في(34) طرفاً رأب الوعاء عن طريق الجلد و/أو جراحة.

النتائج أخذت فوراً وبعد سنة و بفحص النتائج بدراسة الحالة لتحديدِ إنقاذ الطرف، وإنقاذ الطرف دون بتر وبتر الطرف.

النتيجة: في رأب الوعاء نجاح تقني حقق في 66 طرفا (84%) من أصل (78) طرفا في حين PTA/جراحة كانت في (22) طرفا (65%) و34 بتر طرف حيث تشكل 22%.

فترة المراقبة كانت 12شهراً . الوفيات داخل المستشفى 5 مرضى (4.6%). 80 طرفاً (74%)، بإعادة التوعي تجنبوا بتر الطرف. فقط 62 مريضاً تبقوا للمتابعة و أن 84% كانت أمورهم جيدة خلال 12 شهراً بعد إعادة التوعي.

رأب الوعاء يؤدي إلى نتائج جيدة لاحقا.

خاتمة: هي تبرير استعمال رأب الوعاء عبر الجلد كخط معالجة أول في CLI، الفشل للبعض لا يبرر عدم اللجوء للجراحة التقليدية. CLI يحدث بنسبة عالية عند مرضى داء السكري ، المدخنين والمصابين بتعفن القدم. لتقليل نسبة بتر الأطراف مطلوب برامج تعليمية للمعنين ومعالجة حثيثة لتجنب نسبة البتر.

الكلمات الدالة: ضعف، تروية، حرج ،توعّي، رأب ، وعاء.