ORIGINAL RESEARCH

Surgical management and outcomes of acute limb ischaemia at 2 referral hospitals in Addis Ababa, Ethiopia: A 3-month prospective study

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Abstract

Background
We sought to evaluate risk factors and outcomes for patients undergoing surgical procedures for treatment of acute limb ischaemia (ALI) in Ethiopia.

Methods
We conducted a hospital-based prospective cohort study of consecutive patients undergoing surgical treatment for ALI at Tikur Anbessa Specialized Hospital and Teklehaimanot General Hospital in Addis Ababa, Ethiopia from 1 January through 31 December 2018. ALI diagnoses were made using Doppler ultrasound or computed tomography angiography and intraoperative findings. Patients were followed for 3 months postoperatively. Logistic regression modelling was conducted to assess the associations of sociodemographic and clinical variables with amputation, postoperative complications, and mortality.

Results
Data were analysed for 102 of 116 patients who underwent surgical procedures for ALI (mean age, 54 years; 67.6% male). Patients presented to hospital after an average of 9 days (range, 1-15 days) after symptom onset. The primary surgical procedures performed were thrombectomy (n=51, 47.2%), primary amputation (n=24, 22.2%), bypass or interposition vascular grafts (n=10, 9.2%), embolectomy (n=10, 9.2%), primary vascular repair (n=7, 6.4%), and femorofemoral graft (n=6, 5.5%). Local and systemic complications occurred in 35.3% and 17.6%, respectively. Amputation after revascularization surgery was conducted in 33 patients (32.4%). The 30-day amputation and mortality rates were 52.9% and 9.8%, respectively. Variables significantly associated with complications (such as amputation) or death were age greater than 60 years (OR, 3.8; 95% CI, 1.3-11.1; *P*=0.02), presentation later than 9 days after symptom onset (OR, 4.2; 95% CI, 1.4-13.1; *P*=0.01), hypertension alone (OR, 2.8; 95% CI, 1.1-6.3; *P*=0.03), hypertension in combination with diabetes mellitus (OR, 10.2; 95% CI, 1.3-80.1; *P*=0.03), and other cardiac risk factors (OR, 5.3; 95% CI, 1.1-25.4; *P*=0.04).

Conclusions
High rates of amputation and postoperative complications occurred among patients surgically treated for ALI at 2 tertiary hospitals in Addis Ababa, Ethiopia. Timely detection of ALI and treatment of comorbidities are essential for improving outcomes for patients with surgically treated ALI in this setting.

Keywords: acute limb ischaemia, thrombosis, embolism, revascularization, Ethiopia

Introduction

Acute limb ischaemia (ALI) is a medical emergency characterized by a sudden decrease in limb perfusion within 2 weeks of acute onset.[1] ALI can threaten limb viability and is responsible for a high proportion of the morbidity and mortality attributable to cardiovascular disease.[1] Even with urgent revascularization with thrombolytic, endovascular, or open vascular surgery, 1-year amputation and mortality rates are high, ranging from 15% to 20% and 15% to 40%, respectively.[2] In the United States, ALI affects 1.28% of adults aged 40 years and older.[3],[4] There are few population-based estimates of ALI incidence in low- and middle-income countries, like Ethiopia. However, data from the Global Burden of Diseases programme and a systematic review of prevalence surveys showed that the

rate of increase of ALI prevalence between 1990 and 2010 was faster in low- and middle-income countries than in developed nations.[3]-[8]

Ethiopia has a young population: the median age is 19.8 years, 60% of the population is less than 24 years old, and only 3% of the population is over 65 years old. Despite this age distribution, Ethiopia has a large burden of ageing-related diseases. Noncommunicable diseases, such as cardiovascular disease, diabetes mellitus, and cancer were the leading causes of in-hospital death in Ethiopia in 2015.[8]

In Ethiopia, surgical services to treat ALI have only become available in the last 5 years and only at a few hospitals in the country. Experience in the surgical management of ALI in the country is limited. To date, few published articles report on surgical management of ALI in sub-Saharan Africa, and to our knowledge no study has investigated this topic in Ethiopia. Therefore, our study evaluated outcomes among patients undergoing surgical management of ALI at 2 tertiary care hospitals in Addis Ababa, Ethiopia.

Methods

We conducted a hospital-based, prospective cohort study of patients undergoing surgical treatment for ALI at Tikur Anbessa Specialized Hospital (TASH) and Teklehaimanot General Hospital (TGH) in Addis Ababa, Ethiopia, from 1 January through 31 December 2018. All patients with ALI due to thrombosis, emboli, or trauma who were referred from regional hospitals or presented directly to TASH or TGH were included in the study. ALI diagnoses were made using a combination of clinical imaging by Doppler ultrasound or computed tomography angiography and intraoperative findings. Patients with peripheral arterial disease without ischaemia, who self-discharged before undergoing a surgical procedure, or who refused surgery, were excluded.

After the clinical diagnosis of nontraumatic ALI, the primary treatment strategy was determined according to the clinical assessment of limb viability. Patients were managed surgically by a consultant who performed either a revascularization or amputation procedure. Before undergoing the surgical procedure, patients were initially given 5000 units of unfractionated heparin administered intravenously, followed by 17 500 units of unfractionated heparin administered subcutaneously for 2 to 3 days. Later, this was switched to oral warfarin. Patients with a history of atherosclerosis and in situ thrombosis were given an oral dose of aspirin 81 mg once daily or clopidogrel 75 mg once daily. Patients were followed up at months 1 and 3 following the surgical procedure.

Data management and statistical analysis

General surgery residents who were trained on study procedures collected patient data using a structured, paper-based questionnaire; data were collected at the patients' initial presentations and on follow-up visits at months 1 and 3 after the surgical intervention. The study's principal investigator reviewed and validated all completed questionnaires prior to data entry. Independent variables assessed included age, sex, duration of acute limb pain, cardiovascular risk factors (like hypertension, ischaemic heart disease, and dyslipidaemia), and comorbidities. Amputation, local or systemic complications, and mortality were treated as dependent variables. The primary outcomes were composite variables defined as the occurrence of amputation, systemic or local complications, or death at 1 month and 3 months after the surgical intervention. Individual event types were treated separately as secondary outcomes. Data were entered into a dedicated study database; all data management and analyses were conducted using IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Aramonk, NY, USA). Univariate analysis was conducted using frequencies and percentages. Associations between independent and dependent variables were evaluated using 2-sided *t* tests; a *P* value <0.05 was used to define statistical significance. Logistic regression modelling was used to evaluate relationships between independent variables and binary study outcomes in terms of amputation status, systemic or local complications, and mortality.

Results

From 1 January through 31 December 2018, 124 patients presented with ALI at TASH and TGH. Surgical interventions were performed on 116 patients; 8 patients refused surgery. In total, 102 patients met the study eligibility criteria and were included in the analysis; 14 patients were not included in the analysis because they lacked postoperative follow-up data.

Patient characteristics

In total, 69 study patients (67.6%) were men, the mean age at presentation was 54 years (range, 23-95 years), and the mean duration of symptoms before presentation was 9 days (range, 1-15 days).

The main causes of ALI in the cohort were thrombosis (n=77, 75.5%), embolism (n=14, 13.7%), and trauma (n=11, 10.8%). The most common risk factors for ALI were hypertension (n=40, 39.2%), diabetes mellitus (n=32, 31.4%), or a combination of hypertension and diabetes mellitus (n=20, 19.6%) (Table 1). Less common risk factors for ALI included smoking (n=7, 6.9%), dyslipidaemia (n=4, 3.9%), and ischaemic heart disease (n=4, 3.9%). Ischaemia affected the lower limb more frequently than the upper limb (86.3% vs 13.7%); bilateral lower limb ischaemia was observed in only 5 patients (4.9%). At the initial presentation, 47 patients (45.9%) had gangrene and 58 (56.9%) had neurologic deficits of the affected limb. Among patients presenting with gangrene, 43 (42.2%) were treated with amputation (24 with primary amputation and 19 with secondary amputation); 4 patients (3.9%) had digital gangrene, which was sloughed off after the revascularization procedure.

Surgical procedures

In total, 108 surgical procedures were conducted on 102 patients. Thrombectomy (n=51, 47.2%) was the most frequently conducted procedure, followed by primary major amputation (n=23, 21.3), and embolectomy (n=10, 9.2%) (Table 2). Primary vascular repair and reverse great saphen-

Table 1. Amputation rates according to demographic characteristics and associated factors among patients with acute limb ischaemia

Variable	n (%)	Amputation rate (%)	*P* value	Odds ratio
Male sex	69 (67.6)	38.2	0.60	1.2
Age, years				3.8
>60	34 (33.3)	19.6	0.02	3.0
40-60	40 (39.2)	26.5	0.03	
Hypertension	40 (39.2)	29.4	0.03	2.8
Diabetes mellitus	32 (31.4)	17.6	0.16	2.1
Hypertension and diabetes mellitus	20 (19.6)	13.7	0.03	10.2
Smoking	7 (6.9)	3.9	0.48	1.8
Dyslipidaemia	4 (3.9)	1.9	>0.99	1.1
Ischaemic heart disease	4 (3.9)	2.9	0.37	0.6
Atrial fibrillation	3 (2.9)	1.9	0.34	2.2
Ischaemic heart disease and atrial fibrillation	2 (1.9)	1.9	0.76	1.6
Rheumatic valvular heart disease and atrial fibrillation	3 (2.9)	1.9	0.50	0.8
Rheumatic valvular heart disease	1 (0.9)	0.9	0.70	0.5
Dilated cardiomyopathy	1(0.9)	0.9	0.70	0.5

Table 2. Types of surgical procedures performed for acute limb ischaemia and subsequent amputation rates at 3 months' follow-up

Primary surgical procedure	n (%)
Thrombectomy	51 (47.2)
Primary major amputation	23 (21.3)
Embolectomy	10 (9.2)
Primary vascular repair	7 (6.4)
Extra-anatomic crossover Femorofemoral graft (polytetrafluoroethylene)	6 (5.5)
Interposition graft (reversed greater saphenous vein)	5 (4.6)
Bypass graft (reversed greater saphenous vein)	5 (4.6)
Primary minor amputation	1 (0.9)
Total	108 (100)

Six patients underwent repeat operations.

ous vein graft (RGSV) interposition grafting were conducted on patients with traumatic injuries; these procedures were conducted on 7 (6.4%) and 5 (4.6%) patients, respectively.

Short-term predictors of amputation and death

Bivariate logistic regression modelling identified several variables that were significantly associated with increased risk of amputation: age >60 years vs 20 to 40 years (OR, 3.8; 95% CI, 1.3-11.1), having both hypertension and diabetes mellitus vs having neither (OR, 10.2; 95% CI, 1.3-80.1), and having hypertension vs not having been diagnosed with hypertension (OR, 2.8; 95% CI, 1.1-6.3). Presentation to hospital more than 9 days after symptom onset (i.e., the average interval in the study sample) was significantly associated with an increased risk of amputation compared with an interval of 3 days or less (OR, 4.2; 95% CI, 1.4-13.1).

An increased risk of death was significantly associated with older age (>60 years vs 20-40 years; OR, 9.7; 95% CI, 1.2-82.3) and the presence of ischaemic heart disease (OR, 5.3; 95% CI, 1.1-25.4). Diabetes mellitus in the absence of hypertension, smoking, dyslipidaemia, and cardiac risk factors other than ischaemic heart disease was not significantly associated with amputation or with death according to bivariate logistic analysis.

Table 3. Local and systemic complications of acute limb ischaemia at 30 days and 3 months of follow-up

Category	Follow-up interval	
	30 days	3 months
Systemic complications		
Acute coronary syndrome	6 (5.9)	6 (5.9)
Acute kidney injury	5 (4.9)	5 (4.9)
Sepsis	3 (2.9)	3 (2.9)
Cerebrovascular attack	3 (2.9)	4 (3.9)
Acute respiratory insufficiency	1 (0.9)	1 (0.9)
Local complications		
Rethrombosis of native vessels	15 (14.7)	20 (19.6)
Surgical site infection	13 (12.6)	15 (14.7)
Graft failure	6 (5.9)	6 (5.9)
Others	2 (1.9)	2 (1.9)
No complications	48 (47.1)	40 (39.2)
Total	102 (100)	102 (100)

Values are n (%)

Outcomes of surgical intervention

In total, 57 patients (55.9%) underwent amputation, most (n=54) following their initial admission to hospital (Table 3). Amputation after an attempt to conduct revascularization was performed on 33 patients (32.4%), including 3 patients who underwent amputation after readmission following their initial procedures. Procedure-related local complications developed in 36 patients (35.3%), including 15 patients (14.7%) in whom rethrombosis of native vessels occurred and 13 patients (12.6%) who had surgical site infections. Within 3 postoperative months, systemic complications occurred in 18 patients (17.6%), the most common of which were acute coronary syndrome (n=6, 5.9%) and acute kidney injury (n=5, 4.9%). Eleven patients (10.8%) died, including 10 deaths that occurred within 30 days following the initial surgical intervention and 1 death that occurred during the 3-month follow-up period. The causes of death within 30 postoperative days were acute coronary syndrome (n=6, 5.9%), sepsis (n=3, 2.9%), and acute respiratory insufficiency (n=1, 0.9%). Within 3 postoperative months, 1 patient died of overwhelming sepsis secondary to surgical site infection.

Discussion

We prospectively followed a pragmatic cohort of patients who received surgical treatment for ALI at 2 large tertiary hospitals in Ethiopia, finding that patients frequently presented late with irreversible limb ischaemia and tissue loss. In most patients, ischaemia affected the lower limbs, a finding that accords with other studies[10],[14] and which may reflect the unequal distribution of atherosclerotic occlusive diseases affecting the limbs.[22] Over half of the study patients underwent amputation, reflecting the advanced stage of disease progression at which many of the patients presented. Ideally, interventions for ALI should be performed within 6 hours of onset; beyond this time frame, outcomes depend the on the presence of collateral circulation and the degree of vascular occlusion. Similar rates of amputation in patients with ALI have been reported elsewhere in Africa.[22],[26]

Table 4. Limb salvage and amputation rates according to symptom duration

Symptom duration, days	Limb salvage	Amputations	Total
<4	12 (66.7)	6 (33.3)	18 (17.7)
4-9	8 (22.9)	27 (77.1)	35 (34.3)
>9	14 (28.6)	35 (71.4)	49 (48)
Total	34 (33.3)	68 (66.7)	102 (100)

Values are n (%)

Presentation to hospital following initial symptoms of ALI was significantly delayed in the study cohort and contributed to poorer patient outcomes. In contrast to trends seen in developed countries,[8],[23] all study patients presented at least 24 hours after symptom onset at which time many of them had either neurologic deficits or gangrene. Patients who presented at least 9 days after acute symptom onset—the average in the study cohort—had a 5-fold increased risk of limb loss compared with those who presented within 3 days of symptom onset. Thus, late presentation contributed to the high amputation rate of 55.9%, a rate 2 to 3 times higher than that reported in similar studies from developed countries.[23] The rate of limb loss following a revascularization procedure was also higher in our study cohort (32.4%) than in cohorts from developed countries.[24],[25],[27] Hypertension, particularly in combination with diabetes mellitus, was also associated with amputation in the study cohort, a finding that accords with those of other studies.[21],[24] Notably, in the study cohort, primary vascular repair and RGSV interposition grafting conducted for vascular injury was associated with a better limb salvage rate than other procedures. The younger ages and earlier presentations, overall, among patients who underwent primary vascular repair and RGSV may, in part, account for these better outcomes.

Delayed presentation to hospital may also have contributed to the high rates of postoperative complications in the cohort. Bivariate analysis showed that age >60 years was associated with a 3-fold increase in limb loss and a 9-fold increase in mortality relative to age between 20 and 40 years. Similarly high rates of limb loss and death have been reported by other studies.[15],[18],[19]

The rates of systemic and procedure-related complications in study patients were 17.6% and 35.3%, respectively, which are considerably higher than rates reported for a

similar patient group in South Africa.[25] In contrast, the 3-month mortality rate from ALI in this study was 10.8%, which was lower than reports of ALI mortality from research conducted in Côte d'Ivoire[26] but similar to reports from Iran[22] and Lithuania.[27] In our study, older age and previous ischaemic heart disease were associated with increased risk of death; however, ALI mortality was not associated several other common cardiovascular risk factors, including diabetes mellitus in the absence of hypertension, smoking, and dyslipidaemia. Compared with findings from elsewhere,[7]-[10] the lack of association of these cardiovascular disease factors is unusual.

The predominance of older men among patients in this study is consistent with other reports of ALI patients.[9]-[11],[19],[22],[27] Previous studies have reported that smoking is the most common predisposing factor for ALI[19],[22],[25] and that this risk is compounded by the presence of hypertension. However, in this study, only 6.7% of patients smoked, highlighting the contributions of other risk factors, such as hypertension, to the ALI incidence in Ethiopia. Given the association between hypertension and ALI, the current guideline for hypertensive diseases with peripheral arterial disease supports aggressive treatment with a target blood pressure of 130/80 mmHg.[17],[18],[20],[21]

This study had several limitations. The analysis of clinical records was conducted at only 2 centres in Addis Ababa; therefore, findings may not be generalizable to other areas of the country, particularly rural areas. In total, 14 patients were excluded from the analysis due to loss to follow-up or incomplete follow-up data, which may have influenced the study findings. Finally, follow-up was limited to 3 months, and thus we were unable to evaluate long-term outcomes.

Conclusions

High rates of amputation and postoperative complications occurred among patients surgically treated for ALI at 2 large tertiary hospitals in Addis Ababa, Ethiopia. Late presentation, older age, and the presence of cardiovascular comorbidities were strongly associated with increased risk of postoperative morbidity and mortality in this patient population. The timely detection of ALI and the treatment of comorbidities are essential for improving outcomes among surgically treated ALI patients in this setting.

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