ORIGINAL RESEARCH

Long-term mortality after lower extremity amputation: A retrospective study at a second-level government hospital in Cape Town, South Africa

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Abstract

Background
Long-term mortality after lower extremity amputation (LEA) is not well reported in low- and middle-income countries. The primary aim of this study was to report 30-day and 1-year mortality rates after LEA in South Africa. The secondary objective was to report risk factors associated with death within 1 postoperative year.

Methods
This was a retrospective study of patients who underwent LEA at New Somerset Hospital, a second-level government facility in Cape Town, South Africa, from 1 October 2015 through 31 October 2016. A medical record review was undertaken to identify comorbidities, operation details, and the perioperative mortality rate. Patient outcomes were classified as alive, dead, or lost to follow-up at 30 days and 1 year.

Results
There were 152 patients, including 90 men (59%), and the median age was 60 years. Comorbidity data were available for 137 patients (90%). One hundred eight patients (79%) had peripheral vascular disease, and 91 (66%) had diabetes mellitus. Fifty-three patients (35%) had more than 1 LEA on the same or contralateral limb. There were 183 LEAs performed on 152 patients. The most common LEA was above-knee amputation (n=104, 57%), followed by below-knee amputation (n=36, 20%). For the 30-day mortality analysis, 102 of 152 patients (67%) were traced, and 12 (12%) had died within 30 postoperative days. For the 1-year mortality analysis, 86 (57%) were traced, and 37 (43%) had died within 1 postoperative year.

Conclusions
At this second-level South African hospital, 43% of patients who underwent LEA during the investigated period were dead after 1 year. In resource-constrained settings, mortality data are necessary when considering resource allocation for LEA and essential surgical care packages.

Keywords: surgery, amputation, postoperative mortality, health systems strengthening, South Africa

Introduction

Surgical care can prevent disability and save millions of lives per year.[1] Surgical care is known to be cost-effective, and in 2015, the World Health Assembly declared that essential and emergency surgical procedures should be a part of universal health care.[2] The majority of the global surgical burden falls on low- and middle-income countries (LMICs) with limited resources available to support their health systems.[1] In these countries, high-value interventions (those that can achieve the greatest health benefits for populations with limited resources) need to be prioritized when choosing the list of procedures to be included in essential regional and national surgical packages.[3] The burden of each surgical condition, its cost-effectiveness, and its associated procedural outcomes, such as perioperative or long-term mortality, are among several factors that need to be considered.

Mortality after 30 days, or long-term mortality, is not easily measured in LMICs given the lack of systematic postoperative follow-up. However, there are data on perioperative mortality rates and in-hospital mortality in LMICs. Perioperative mortality rates in Africa are higher than the global average, especially in association with emergency procedures.[4]

In high-income countries (HICs), lower extremity amputation (LEA) is a common general surgical procedure for end-stage complications of peripheral vascular disease (PVD) and diabetes mellitus (DM), which are associated with tissue ischaemia and gangrene.[5],[6] Historically, traumatic injuries were the leading cause of LEA in LMICs[7],[8]; however, as the rates of noncommunicable diseases rise in LMICs, and infectious diseases remain prevalent, these nations face a double burden of medical indications for LEA.[9],[10] In a study conducted in Cape Town, South Africa, the most common cause of nontraumatic LEA was DM.[11]

Long-term mortality rates after LEA are high in HICs, where, according to some estimates, 30-day mortality rates range from 9%-30% and 1-year mortality rates range from 30%-54%.[12],[13] A recent meta-analysis reported a 1-year mortality rate of 48% among PVD and DM patients.[14] Risk factors for death after LEA include surgical factors, such as a higher amputation level and the need for staged procedures, increased age, and associated comorbidities, such as preoperative sepsis, DM, arteriosclerosis, coronary artery disease, cerebral vascular disease, and end-stage renal disease.[14]-[17]

In LMICs, there is a paucity of data describing long-term mortality rates after LEA and associated risk factors. A systematic review of studies conducted in Nigeria reported a perioperative mortality rate of 11%; however, intermediate- and long-term mortality data were not captured.[8] Long-term mortality after LEA in resource-limited settings has implications on the value of LEA and must be considered when planning and implementing public health surgical packages. The primary aim of this study was to report 30-day and 1-year mortality rates after LEA in South Africa, an upper middle-income country. The secondary objective was to report risk factors associated with death within 1 postoperative year.

Methods

Study design and setting

This was a retrospective study of patients who underwent LEA at New Somerset Hospital (NSH) in Cape Town, South Africa, from 1 October 2015 through 31 October 2016. NSH is a second-level government hospital that serves a catchment population of approximately 500 000 people. All patients undergoing LEA at NSH during the study period were included. We excluded patients who underwent upper extremity amputations and those who underwent other nonamputation procedures concurrently with LEA. Patients under 18 years of age were also excluded.

Ethical considerations

Phone numbers for study patients were obtained from medical records. A surgical nurse working at the hospital but not involved in the study contacted each of the patients (or their next of kin) by telephone to explain the study objectives and ask if study investigators could contact them. All patients or next of kin who were successfully contacted agreed to telephone interviews. During the telephone interviews with study investigators, telephonic consent was obtained by the first author (S.R.H.) before any study questions were asked. Ethical approval was granted by the University of Cape Town Human Ethics Committee. The data were deidentified before analysis, and all databases were password protected.

Data collection

NSH's electronic database of surgical procedures, used for routine monitoring and evaluation, was reviewed to identify eligible patients and operative characteristics. A medical record review was undertaken to identify comorbidities and compile long-term mortality data. The following patient demographic and clinical variables were captured: age, gender, PVD status, DM status, hypertension status, smoking status, and history of previous LEA on the contralateral limb. Surgical variables included the type of LEA, traumatic or nontraumatic indication for LEA, and multiple LEA status. A patient was designated as having had multiple LEAs if multiple amputations were performed on the same limb during the study period or if an LEA was previously performed on the contralateral limb. LEA types included toe, transmetatarsal, supramalleolar (guillotine), below-knee, and above-knee amputations.

In terms of final outcome, patients were designated as alive, dead, or lost to follow-up. The final outcome status for each patient was obtained from 1 of 3 possible sources. First, patients or their next of kin were traced telephonically after providing verbal consent during 2 tracing periods: March to April 2017 and August 2018. During each tracing period, 3 attempts were made to contact each patient or next of kin. Second, a search for deaths at Western Cape government hospitals using a centralized computerized administration system (CLINICOM)[18] was undertaken. Third, deaths of patients with South African identification numbers (through 16 March 2018) were identified using the National Population Register. Patients not traced and not confirmed dead were considered lost to follow-up. Thirty-day mortality was defined as death within 30 days of LEA. If more than 1 LEA was performed during the study period, mortality was calculated from the last procedure. One-year mortality was defined as death within 365 days of the last LEA.

Statistical analysis

Descriptive statistics were used to describe patient-level and operative characteristics. Univariate and multivariate logistic regression analyses were performed to determine variables associated with 1-year mortality. Age and gender were included a priori, and all other variables with a *P* value <0.2 in the univariate analysis were included in the multivariate

Table 1. Characteristics of patients who underwent lower extremity amputations at a second-level government hospital in Cape Town, South Africa, October 2015 through October 2016 (N=152)

Characteristic	Statistic
Median age, years (interquartile range)	60 (54-67)
Males	90 (59)
Comorbidities and smoking history (n=137)	
Peripheral vascular disease	108 (79)
Hypertension	95 (69)
Diabetes mellitus	91 (66)
Smoking	70 (51)
≥1 factor	136 (99)
Operative indications (n=139)	
Gangrene	135 (97)
Wet gangrene	67 (48)
Dry gangrene	68 (49)
Trauma	4 (3)
Multiple lower extremity amputations[a]	53 (35)

Values are n (%) unless otherwise indicated.
[a]More than 1 amputation on the same or contralateral limb

Table 2. Types of lower extremity amputations performed at a second-level government hospital in Cape Town, South Africa, October 2015 through October 2016

Procedure	n (%)
Above-knee amputation	104 (57)
Below-knee amputation	36 (20)
Toe amputation	19 (10)
Supramalleolar amputation	18 (10)
Transmetatarsal amputation	6 (3)
Total	183

analysis. Previous and multiple LEA were combined into 1 variable. All analyses were performed using Stata 13 (StataCorp, College Station, TX, USA).

Results

There were 152 patients, including 90 men (59%), and the median age was 60 years (interquartile range, 54-67 years). Comorbidity data were available for 137 patients (90%), among whom 136 (99%) were smokers or had hypertension, PVD, or DM. Specifically, 108 (79%) had PVD, and 91 (66%) had DM. Operartive indication data were available for 139 patients (91%), the majority of whom had gangrene (97%)—half with wet gangrene and the other half with dry gangrene. Fifty-three patients (35%) had more than 1 LEA on the same or contralateral limb. Only 4 LEAs (3%) were performed for traumatic injuries. Patient demographics are shown in Table 1.

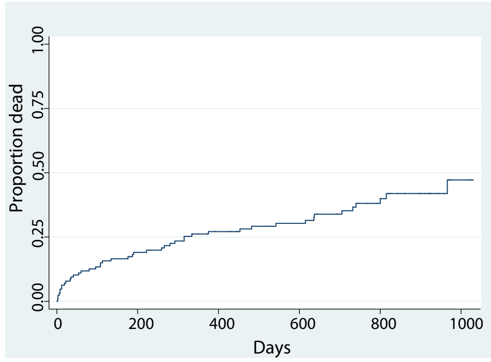

Figure. Kaplan–Meier curve showing deaths over time after lower extremity amputation at a second-level hospital in Cape Town, South Africa, October 2015 through October 2016

Operative characteristics

There were 183 LEAs performed on 152 patients; above-knee amputations (n=104, 57%) were the most common, followed by below-knee amputations (n=36, 20%) (Table 2).

Outcomes

For the 30-day mortality analysis, 102 of 152 patients (67%) were traced, among whom 12 (12%) had died within 30 postoperative days. For the 1-year mortality analysis, 86 (57%) were traced, among whom 37 (43%) had died within 1 postoperative year. At the end of the study, there was a median follow-up duration of 522 days (interquartile range, 190-801 days) (Figure).

Associations with 1-year mortality

Univariate analysis identified age ≥75 years, male gender, and above-knee amputation as associated with 1-year mortality, and these factors were included in the multivariate analysis (Table 3). Multivariate analysis revealed an association between age ≥75 years and death within 1 postoperative year (odds ratio, 7.81; 95% confidence interval, 1.45-42.20; P=0.02).

Discussion

To our knowledge, this was the first study conducted in South Africa confirming a high long-term mortality rate after LEA, with 43% of patients dead within 1 year of the procedure and older age as a risk factor. The high long-term mortality is consistent with reported data from several HICs.[12],[14],[19]-[21] Multivariate analysis identified age ≥75 years as the only independent risk factor for death within 1 year after LEA; advanced age has been reported as risk factor elsewhere.[12],[16],[22] Given the increasing life expectancy in South Africa,[23] LEA will continue to be a high-risk procedure in our population.

Table 3. Risk factors for death within 1 year after lower extremity amputation at a second-level hospital in Cape Town, South Africa, October 2015 through October 2016

Variable	Univariate analysis			Multivariate analysis		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Demographics						
Age ≥75 years	6.43	1.29-32.05	0.02	7.81	1.45-42.20	0.02
Male gender	1.89	0.76-4.74	0.17	2.15	0.80-5.77	0.13
Comorbidities and smoking history						
Peripheral vascular disease	1.32	0.39-4.48	0.66			
Hypertension	1.33	0.49-3.62	0.57			
Diabetes mellitus	0.97	0.38-2.51	0.95			
Smoking	1.23	0.49-3.09	0.65			
Operative indications						
Wet gangrene	1.30	0.51-3.28	0.58			
Trauma	2.34	0.20-26.95	0.49			
Operation						
Above-knee amputation	2.14	0.75-6.08	0.15	2.35	0.77-7.20	0.13
Below-knee amputation	0.44	0.12-1.59	0.21			
Toe amputation	1.00					
Supramalleolar amputation	1.00					
Transmetatarsal amputation	1.14	0.15-8.54	0.90			
Multiple lower extremity amputations[a]	0.54	0.21-1.41	0.21			

Risk factors with $P<0.2$ in the univariate analysis were included in the multivariate analysis.
[a]More than 1 lower extremity amputation on the same or contralateral limb; CI, confidence interval; OR, odds ratio

In our study, most LEA patients had a prior history of hypertension, PVD, DM, or smoking. The results of this study indicate the risk of long-term mortality was not significantly impacted by these factors. The published evidence is inconsistent regarding the associations between these factors and long-term mortality after LEA, with some studies reporting an association between post-LEA mortality and DM or heart disease[19],[20] and others failing to support such associations.[19],[21] Larger multicentre or national cohort studies are need to clarify these associations.

South Africa, an upper middle-income country, is rolling out a National Health Insurance plan—a funding system for essential health coverage—and will likely include a package of surgical procedures covered for South African citizens and long-term residents.[24] Given the resource limitations in LMICs, each surgical procedure needs to be evaluated to determine if it is a high-value intervention.[1]-[3] This study is significant in that it demonstrates that long-term mortality rates after LEA can be high and, therefore, may impact the consideration of LEA as a high-value intervention under universal health coverage for South Africa. Further studies are needed to evaluate other considerations, such as the burden of each associated disease, the cost-effectiveness of the intervention, quality-adjusted life years gained, indirect and direct costs to the health system and patient, postoperative outcomes associated with each procedure, minimization of suffering, and respect and dignity afforded to patients.[3],[25]

One limitation of this study was that one-third of patients were lost to follow-up at 30 days, and more than 40% were lost to follow-up by 1 year. It is likely that a large proportion of patients lost to follow-up were actually alive, given they were not recorded as dead in our mortality databases. Therefore, the 30-day mortality rate may have been as low as 8% and the 1-year mortality rate as low as 24% if all patients lost to follow-up were considered alive. This was a retrospective manual review of secondary data. There are additional factors and comorbidities that may be important considerations for risk factor analysis but were unavailable at the time of data collection. Traumatic indications for LEA were included. However, cases of major extremity trauma were referred to a nearby third-level hospital. Therefore, trauma cases were likely to be underrepresented in this study. Furthermore, the sample size was relatively small and may have been insufficient to capture true associations between nontraumatic comorbidities and mortality. A longer study period would have likely resulted in a larger sample size and increased statistical power.

Conclusions

At NSH in Cape Town, South Africa, up to 43% of patients were dead at 1 year after LEAs performed between 1 October 2015 and 31 October 2016. Long-term mortality needs to be considered when deciding which surgical procedures should be considered in universal health coverage in national surgical planning.

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