Original Article

Vascular

Vascular
2021, Vol. 29(4) 574–581

DOI: 10.1177/1708538120965081
journals.sagepub.com/home/vas
SAGE

Major lower extremity amputations in a developing country: 10-Year experience at a tertiary medical center

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Abstract

Background: Lower extremity amputation (LEA) is a major surgical procedure with a high risk of significant morbidity and mortality. The objective of this study was to describe mortality and functionality outcomes following this procedure in a developing country.

Methods: This is a retrospective study of all patients undergoing LEA for non-traumatic etiology between 2007 and 2017. Medical records were used to retrieve demographics, comorbidities, and perioperative complications of identified patients. Patients were contacted to follow-up on their medical, postoperative care, and ambulatory status. Mortality and postoperative functionality rates were analyzed.

Results: The study included 78 patients. Median follow-up duration was 24 months. Hypertension (81%) and diabetes (79%) were the most common comorbidities. Mortality rates at 30 days, 1, and 5 years were 10.3, 29.2, and 65.5%, respectively. Mortality was significantly associated with age >70 at amputation ($p=0.042$), hypertension ($p=0.003$), chronic kidney disease ($p=0.031$), and perioperative sepsis ($p=0.01$). Only 1.6% of patients were discharged into a specialized care center, and only 27% of patients were ambulatory postoperatively, although 90.5% were fitted with a prosthesis.

Conclusions: Survival following major amputation in a developing country is currently comparable to more developed regions of the world. Major discrepancy seems to exist in ambulatory status following the procedure. Discharge placement policies should be properly set, and rehabilitation centers funding should be increased. Awareness may also be warranted to educate patients and families about the value and positive impact of rehabilitation centers.

Keywords

Amputation, survival, lower extremity, functional outcomes

Introduction

Lower extremity amputation (LEA) is a radical procedure that significantly affects a patient's functional status and quality of life.[1] It is reserved as a last resort option, due to its high morbidity and mortality.[2] This operation is indicated for patients with acute limb ischemia complicated by infections or tissue necrosis, after failing to improve on medical treatments and revascularization.[3] The most common causes leading to LEA in patients are peripheral arterial disease and uncontrolled diabetes mellitus (DM), followed by trauma and malignancy.[4]

The second Trans-Atlantic Inter-Society Consensus Working Group estimated the incidence of major amputations due to peripheral artery disease to range between 12 and 50 per 100,000 individuals per year.[5] More recent studies from other middle income countries estimated the average incidence of major amputation in patients with DM to be 6.12 and 240 per

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100,000 individuals annually in Mexico and Ghana, respectively.[6,7] Despite advancement in medical management, and due to aging and increased obesity, it is estimated that the incidence of LEA will increase by 100% by the year 2050.[8]

Morbidity and mortality after an amputation are the major concerns following this procedure. Patients who had an LEA are at increased risk of having a contralateral limb amputation.[1] In addition, mortality rates at one-year post-amputation reach up to 50%.[9] In some regions like the Middle East, an area where the prevalence of diabetes exceeds 30% in some countries, the issue of LEA is bound to be one of the most concerning healthcare issues.[10] Nevertheless, scientific reports from such areas exploring characteristics of patients undergoing a LEA, mortality rates, and functional outcomes are scarce.[11]

At a tertiary care center form the Middle East region, 78 patients were admitted for major LEAs from non-traumatic causes over the last 10 years. The aim of this study is to look at a single center experience in a developing and middle to low income country describing the patients' characteristics and exploring mortality, morbidity, and functional outcomes in this population. This data can potentially assist in uncovering weaknesses in the management of this vulnerable population and support necessary reforms in their care and social integration.

Methods

This study was approved by the institutional review board of the medical center. Medical records of all patients who underwent an LEA at the institution between 2007 and 2017 were retrospectively reviewed. Current Procedural Terminology codes were used to identify patients. The electronic medical records were reviewed. Patients undergoing an LEA for the first time were included. Amputations for non-vascular etiologies (traumatic) were excluded. All LEA related to infections, diabetic foot, or ischemic disease are handled in the institution by the vascular surgery team. LEA included both below knee amputation (BKA) and above knee amputation (AKA). Primary major LEA (not preceded with attempted limb salvage or revascularization) is subjected first to second-opinion consultation. Efforts were made to provide patients with BKA versus above knee in the exception of immobile patients with dementia or knee contractures. Healing potential related to vascularity was evaluated by physical assessment of pulses supplemented with arterial Doppler/Duplex scan as indicated.

The data retrieved included demographic data, medical, and social history. Comorbidities at the time of the operation included DM, hypertension (HTN), peripheral vascular disease (PVD), coronary artery disease (CAD), malignancy, and chronic kidney disease (CKD). Patients were considered to have those comorbidities if diagnosis was present in the hospital records. Data on perioperative status and complications, financial coverage, and patient functional capacity on presentation were also retrieved. Medical records review was also used to provide the date of last follow-up at our institution.

Patients or responders were contacted using the available contact details found in the medical record. If there was no answer from the first attempt, each phone number was contacted up to four times at different dates for follow-up information. Data on current medical condition, status of the contralateral limb, consultation and fitting for a prosthesis, discharge disposition, and ambulatory status postoperative were collected. Patients who were autonomous or partially assisted were labeled as "ambulatory," whereas fully dependent or bedridden patients were labeled as "dependent."

Statistical analysis was performed with Statistical Package for the Social Sciences for Windows software version 25.0 (IBM SPSS, 2017). Continuous and categorical data were presented as mean (standard deviation) and number (percentage), respectively. The level of significance was set at $p < 0.05$. Univariate analysis was performed using Chi-squared or Fisher's exact test for categorical variables as appropriate. Kaplan–Meier survival graphs were used to estimate survival at 30 days, 1 year, 2 years, 3 years, and 5 years. Log-rank test was used to assess the association between mortality and the potentially associated risk factors.

Results

The study included 78 patients of which 49 underwent a BKA and 29 underwent an AKA. Median follow-up duration was 24 months. Demographic data of the population are listed in Table 1. The mean age was 70.2 ± 13.3 years. About 35.9% of patients were smokers and 85.9% were ambulatory preoperatively. Most of the patients had multiple comorbidities at the time of the operation; the most common were HTN and diabetes with 81% and 79%, respectively. PVD, CAD, and CKD followed with 68%, 60%, and 40%, respectively. In addition, 61.5% of the patients had prior vascular interventions done.

Thirty-day mortality rate was 10.3%. On follow-up, mortality rates at one, two, three, and five years were 29.2, 41.6, 55.6, and 65.5%, respectively (Figure 1). Mortality was significantly associated with age 70 and above at amputation ($p = 0.042$), HTN ($p = 0.003$), chronic kidney disease ($p = 0.031$), and perioperative sepsis ($p = 0.01$) (Figure 2). There was no significant association between mortality and type of amputation (BKA vs. AKA) or any other comorbidity.

Table 1. Baseline characteristics and discharge outcomes.

	All patients Number (%)
Number of patients	78
Age (mean ± SD)	70.2 ± 13.3
Males	50 (64.1)
Amputation location	
Below knee	49 (62.8)
Above knee	29 (37.2)
Smoker	28 (35.9)
Comorbidities	
DM	61 (79.2)
HTN	62 (80.5)
CAD	46 (59.7)
PVD	52 (67.5)
CKD	31 (40.3)
Malignancy	9 (11.7)
Prior vascular intervention	48 (61.5)
Perioperative sepsis	23 (29.5)
Surgery coverage	
Insurance	41 (52.6)
Self-payer	37 (47.4)
Preoperative mobility	
Ambulatory	67 (85.9)
Bedridden	11 (14.1)
Discharge status	
Dead	7 (10.3)
To home	69 (88.4)
To care center	1 (1.3)

After the amputation, eight patients (10.3%) died before leaving the hospital. Only one patient (1.3%) was discharged into a specialized care facility, while 69 (88.4%) patients were discharged home upon the request of the patients and/or their families. Of these 70 remaining patients, seven patients (10%) were lost to follow-up. Out of the 63 patients contacted, 57 patients were consulted and fitted for a prosthesis. Of these, 50 patients reported that they had to self-cover the fees of the prosthesis while only seven were covered by medical insurance or a third party (Figure 3).

On postoperative follow-up, only 17 (27%) patients were ambulatory while 46 (73%) were dependent. Further analysis showed that postoperative mobility was significantly associated with the status of the contralateral limb (healthy or ulcerated/amputated) at the time of follow-up ($p = 0.001$); however, there was no significant association between postoperative mobility and prosthesis fitting, pre-operative mobility status, or other comorbidities (Table 2). Patients with a BKA were more likely to be ambulatory (30.2%) as compared to those with an AKA (20%); however, this did not reach statistical significance ($p = 0.316$).

Discussion

This study describes the 10-year experience in a single center of continuous series of patients with major limb

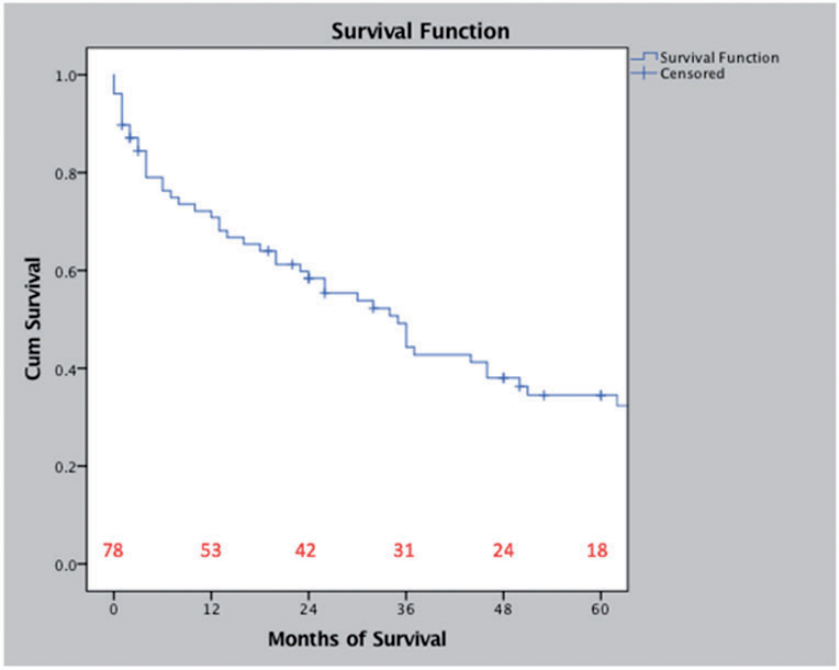

Figure 1. Five-year survival KM curve.

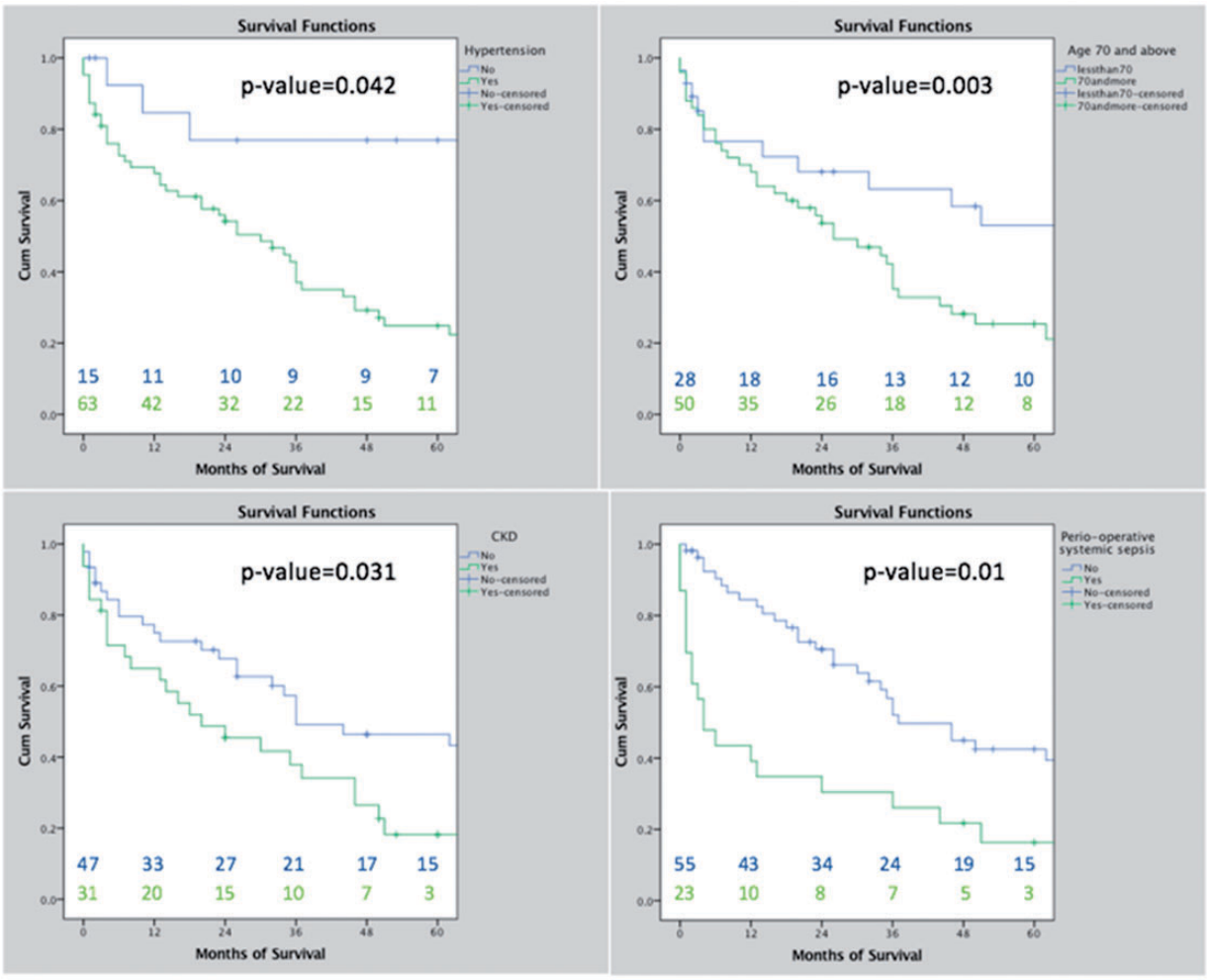

Figure 2. KM curve factoring HTN, age, CKD, and sepsis.

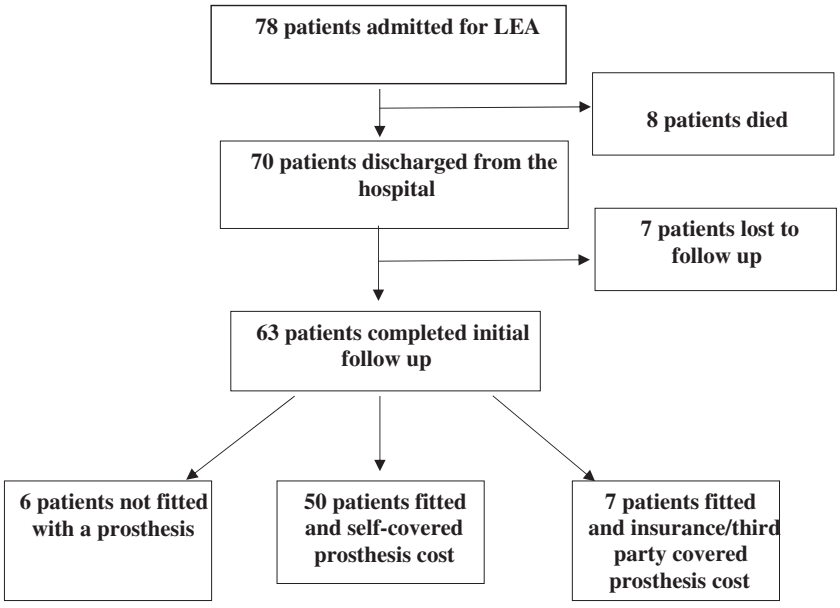

Figure 3. Patient initial follow up and prosthesis fitting.

Table 2. Ambulation outcomes associations.

	Dependent *N* (%)	Ambulatory *N* (%)	*p*-Value
Amputation level			
BKA	29 (63.0)	13 (76.5)	0.316
AKA	17 (37.0)	4 (23.5)	
Age			
<70	16 (34.8)	6 (35.3)	0.97
70 and above	30 (65.2)	11 (64.7)	
Preoperative mobility			
Ambulatory	42 (91.3)	15 (88.2)	0.713
Dependent	4 (8.7)	2 (11.8)	
Status of contralateral limb			
Ulcerated/amputated	15 (32.6)	0 (0)	**0.001**
Healthy	31 (67.4)	17 (100)	
Fitted with prosthesis			
No	6 (13.0)	0 (0)	0.066
Yes	40 (87.0)	17 (100)	

The bold value is significant.

amputations. The cohort included 49 patients with BKA and 29 patients with AKA as per the Peripheral Academic Research Consortium definition.[12] In addition to exploring the survival outcomes and risk factors associated with mortality in our population, the aim was to uncover the functional outcomes of such morbid surgery in a developing country with limited resources.

Mortality outcomes

Major LEAs are known to be followed by elevated mortality rates.[13] These rates vary with different reports. The difference in mortality between studies could be attributed to the heterogeneity of patients' risk factors in each study; risk factors such as heart failure, cancer, renal disease, and chronic obstructive pulmonary disease have been associated with increased mortality rates.[13] In a recent VASCUNET report, 30-day mortality rates between the years 2010 and 2014 ranged from a minimum of 6.12% in Finland reaching up to 20.88% in Hungary.[14] In this cohort, the 30-day mortality was 10.3%. This is comparable to 30-day mortality rates reported in developed countries like the USA (6.5–12.8%) and New Zealand (11.1%) as well as developing countries like Sri Lanka (9.4%), Nigeria (11.8%), and Tanzania (16.7%).[15–19]

Reported long-term mortality rates are also variable. A meta-analysis of 16 articles published in 2017 estimated mortality rates to be 47.9 and 62.2% at one and five-year follow-up, respectively.[9] In our cohort, mortality rates are comparable with 29.2 and 65.5% at one and five years, respectively. One-year mortality rate is similar to rates reported in Jordan (30.7%) and another country in the Eastern Mediterranean region.[11] Rates were also comparable to outcomes from North America and Australia and better than outcomes reported in other developed countries like the Netherlands with mortality rates reaching 44 and 77% at one and five years, respectively.[20–24] In a more recent report from a single center in the US, the one-year-mortality rate was at 17%, reaching as low as 10% in ambulatory patients.[25] However, it is important to note that the cohort's mean age was 62.5 years as compared to 70 years in this cohort. Hence, the data from this cohort can suggest that concerning mortality, outcomes seem to be comparable across continents and between developed and developing regions of the world. Further contemporary and larger series are warranted to make sure that no divergence is occurring in favor of developed communities.

In consistence with relevant literature, risk factors such as CKD, HTN, and sepsis were found to be associated with higher mortality rates.[9,26] However, types of amputation (BKA vs. AKA), cancer, CAD, or diabetes were not associated with worse outcomes.[13] This could be due to the relatively small cohort size in this study. Also along the same line, insurance coverage in a society with limited resources was not found to be associated with difference in medical outcomes.

Functional outcomes

Preoperative factors associated with improved functional outcomes and quality of life in patients having LEA have been explored by looking at indicators such as independence and ambulation after the procedure.[22] Studies have shown that ambulation before

amputation, BKA as opposed to AKA, early referral, and young age are factors associated with improved outcomes. On the other hand, dialysis, dementia, homebound ambulatory status, and CAD are factors associated with worse functional outcomes.[27–30] In more recent studies, higher BMI and increased frailty index (mFI) were found to be predictive of non-ambulatory status after LEA.[25] In this study, the majority of patients (85.3%) were ambulatory prior to the operation. However, contrary to what is expected, their status did not correlate with functionality after the amputation. Age below 70 was also not associated with higher ambulation rates.

Although 90.5% of the patients were fitted with a prosthesis, only 27% of them were ambulatory postoperatively, a low percentage compared to 46.1% reported in current literature.[25] To understand the factors behind this discrepancy, post-procedural management was explored. Post-amputation patient care strategies and their effect on functional outcomes have been an area of recent research. In a prospective study from the US, patients receiving post-acute care rehabilitation in an inpatient rehabilitation facility had improved functional outcomes as compared to patients receiving care in a skilled nursing facility or at home.[31] In our cohort, only one patient was discharged to a care facility with rehabilitation services. The 69 other patients were discharged back home. These patients were receiving a limited number of home visits at best from physical therapists who are often not experts in post-amputation rehabilitation. This is probably the most reveling data from the study and the most diverging outcome as compared to developed countries where studies show that only 17–24% of patients are discharged home.[25,31]

Reported data show that patients who received a prescription for a prosthetic limb within a year after major amputation have a higher three-year survival rate than patients who did not receive a prosthetic limb post-major amputation.[32] This highlights the importance of the optimal utilization of prosthesis post-amputation, as that would not only provide patients with improved functionality but also improve their survival. This part seems to be the Achilles heel in our system.

In this region, different factors feed into the suboptimal postoperative care. First, the cultural stigma of sending a family member to a care facility renders a family preferring to live with them or providing a private care giver who is not specialized in providing rehabilitation care. In addition, there is a possible wrongful association between rehabilitation centers and chronic care facilities or nursing homes. Data from developing countries like Nigeria, Bangladesh, and South Africa show that lack of patient education and knowledge are a major contributor to suboptimal pre-and-post-amputation care including the under-utilization of rehabilitation services.[33–35] Hence, according to our result of poor ambulation despite high rate of prosthetic fitting, we recommend that the physicians emphasize the importance of disposition to a specialized facility, clearing any misconceptions on this issue. Moreover, third-party payers including governmental funds either do not cover or require a substantial copay for expenses at these centers, which further limits the ability of patients and their families to get this service. Financial constraint was also reported as a barrier to postoperative rehabilitation in South Africa.[34] Therefore, we will recommend that governments and principal stakeholders depending on the country should consider increasing the financial support for better post-procedural coverage and not only hospital costs. This will have direct implications not only on the degree of autonomy but also on the survival of patients.[32]

To our knowledge, this is the first study of its kind, looking not only at long-term mortality but also at functional outcomes from this part of the world. The study was limited by its retrospective nature and relatively small sample size, limiting the availability of all patients' variables and affecting the power and significance of the statistical analysis. Knowing that a number of patients treated in this tertiary medical center are referred from other countries, losing those patients to follow-up was another limitation. In addition, as a single institution experience, the results, although reflecting what's happening in the country, may not be generalizable elsewhere.

Conclusion

Survival outcomes after major amputation do not seem to differ in a developing country when compared to other parts of the World. Major discrepancy seems to exist in functional outcomes, with significantly less patients being ambulatory following those procedures. This represents a call for reform in the placement policies following discharge and in prioritizing funding in rehabilitation centers to render them available and accessible for the general population. Awareness may also be warranted to educate patients and families about the value of specialized rehabilitation units. Continued monitoring of medical outcomes is important to make sure that those variables also improve in parallel to trends in more developed countries.

Authors' contribution

We would like to acknowledge that the first and second authors had equal contribution in this manuscript.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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