SCIENTIFIC ARTICLE

The outcome of diabetes mellitus-associated major lower limb amputations in a tertiary care hospital in Sri Lanka: morbidity, mortality, and rehabilitation access

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Keywords: Diabetes Mellitus, Limb amputation, Morbidity, Mortality, Rehabilitation access

Abstract

Introduction

Developing countries such as Sri Lanka are seeing an increase in the prevalence of diabetes mellitus and related complications, including major lower limb amputations. This leads to high morbidity and mortality.

Objectives

To evaluate the outcomes of diabetes mellitus-associated major lower limb amputations at a specialised tertiary care centre in Sri Lanka

Methodology

Patients who underwent major lower limb amputations due to diabetes mellitus-related complications from June 2022 to July 2023 were voluntarily recruited. Patients were followed up for a year at clinics and via telephone calls. Student's *t*-test, chi-squared test, regression models and Kaplan-Meier survival tables were used for results analysis.

Results

Of the 149 patients, the mean age was 63.7 years (SD 10.7). 30.9% (n=46) were females, and 83.9% (n=125) of the patients had undergone below-knee amputations (BKA). After one year, 28.2% (n=42) of patients were deceased and the commonest cause of death was myocardial infarction (59.6%, n=25). Of postoperative complications, surgical site infection was the commonest immediate complication (14.8%, n=22); phantom limb sensation was the commonest late-onset local complication (49.7%, n=74) and myocardial infarction was the most common late-onset systemic complication (37.6%, n=56). In multivariate analysis, binary logistic regression identified smoking (current or previous) as a significant independent predictor of one-year mortality (95% CI: 1.5–4.5, p=0.018). According to Cox regression, both smoking (95% CI: 1.8–6.0, p=0.015) and fasting blood glucose levels (95% CI: 1.0–1.3, p=0.017) significantly reduced survival time. Other risk factors were not statistically significant.

Conclusion

Diabetes-related major lower limb amputations are associated with substantial one-year mortality, largely attributable to myocardial infarction, alongside a high burden of postoperative complications. Both immediate complications, particularly surgical site infections, and late complications such as phantom limb phenomena and cardiovascular events were common. Long-term functional recovery was limited. Smoking and elevated fasting blood glucose emerged as significant predictors of reduced survival. Elevated fasting plasma glucose was significantly associated with reduced survival time in the Cox regression model, but it was not a significant predictor of one-year mortality in the binary logistic regression analysis, indicating an effect on the timing rather than the occurrence of death.

Introduction

Diabetes mellitus (DM) has become a global pandemic, placing a considerable strain on the healthcare sector, particularly in developing countries such as Sri Lanka. Historically, diabetes was confined to developed nations; however, since the 21st century, developing countries in South Asia have experienced a 151% increase in its' incidence [1].

Patients with diabetes mellitus are at a greater risk of lower limb amputation (LLA). LLA can be minor or major depending on whether the ankle joint is spared [2]. This study was based on major lower limb amputations (MLLA), characterised by above and below-knee amputations (AKA & BKA).

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https://orcid.org/0000-0002-4223-5065
Received: 11-12-2025 Accepted: 09-03-2026
DOI: https://doi.org/10.4038/sljs.v44i1.9313

MLLA carries marked postoperative morbidity and mortality, particularly in association with higher cardiovascular complications. This is evident, especially amongst those who undergo above-knee amputations (AKA) due to markedly reduced peripheral vascular resistance and the precipitation of myocardial infarction in already compromised hearts.

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Following MLLA, patients need well-designed rehabilitation programs to become functionally independent in using limb-fitting prostheses or to achieve independent wheelchair use for mobility. This has become a significant challenge, especially in developing countries like Sri Lanka, where the healthcare system struggles to deliver comprehensive rehabilitation services due to infrastructure al and policy-related constraints.

Comprehensive studies regarding diabetes-related amputations are greatly lacking from the Sri Lankan perspective. The study aims to extensively explore diabetes-related major lower limb amputations in the surgical wards of the Colombo North Teaching Hospital of Sri Lanka (CNTH). This may unearth Sri Lanka's socio-economic background and its implications in terms of the status of rehabilitation following MLLA.

Methodology

All the patients who underwent major lower limb amputations as a result of diabetic complications at surgical wards of Colombo North Teaching Hospital (CNTH) between June 2022 and July 2023 were included. Major amputation was defined as above-knee amputations (AKA) and below-knee amputations (BKA). Patients presenting with acute injuries following trauma and patients whose BKA surgery led to AKA were excluded. The total sample was 149 patients.

Following the surgery, routine post-operative care was given to the patients. Upon discharge, patients were referred to the Vascular Surgery Clinic. After the initial recovery period, patients were then referred to the rehabilitation centres. Data on patient demographics, peri-operative parameters and complications (i.e., just before the surgery and during the hospital stay until discharge) were obtained both retrospectively by reviewing patients' medical records, and operative notes. Post-operative complications were divided as immediate (within one month of surgery) and late-onset, the latter subdivided into local and systemic. Data were collected by a trained data collector using a data collection pro forma. Patients' informed consent was obtained for both study participation, access to medical records and follow-up. Ethical clearance was granted by the Ethics Review Committee of the University of Kelaniya.

Data on survival were gathered at three-month intervals via telephone calls or during clinic visits for patients on regular clinic follow-up. In the event of a patient's death, family members were kindly requested to bring the relevant medical records to the clinic to determine the cause of death.

Variables such as patient's age, gender, smoking status, serum creatinine, haemoglobin, fasting blood glucose, and presence of chronic kidney disease (CKD), hypertension, dyslipidaemia and ischaemic heart disease were considered. Student's *t*-test, chi-squared test, and regression Both logistic regression and Cox proportional hazards regression were performed to evaluate different aspects of mortality. Logistic regression assessed predictors of binary one-year mortality (dead vs alive), while Cox regression analysed time-to-event data, accounting for differences in survival duration and censoring. This combined approach provides a more comprehensive evaluation of factors influencing both occurrence and timing of death.

Patients who did not experience the event or were lost to follow-up were censored at their last documented contact. The analysis assumes non-informative censoring, and numbers at risk were displayed at relevant time points in the Kaplan–Meier curves.

Models were used to analyse the association between dependent and independent variables, with a p value of <0.05 taken as statistically significant. Overall survival was analysed using the Kaplan-Meier life table method. All statistical analyses were conducted using IBM SPSS® V.22 software.

Results

Of the 149 patients with diabetes, 69.1% (n=103) were males. The mean age of the study sample was 63.7 years (SD 10.7). When considering the type of surgery, 16.1% of patients (n=24) underwent AKA while 83.9% of patients (n=125) were subjected to BKA. A total of 36.2% (n=54) of the patients had ischemic wounds, and the others (n=95, 63.8%) had non-ischemic wounds on admission. Of the entire population, 63.8% (n=95) of patients were found to have hypertension while 44.3% (n=66) of patients had ischaemic heart disease. 22.1% of patients (n=33) had dyslipidaemia and mean eGFR was approximately 47 mL/min/1.73 m², 2.7% of patients (n=4) were diagnosed with chronic kidney disease.

When evaluating the post-operative outcomes, the most common immediate complication was surgical site infection, which affected 14.8% of patients (n=22), while 11.4% of patients (n=17) developed sepsis. Other complications included myocardial infarction (n=9, 6.0%), acute kidney injury (n=8, 5.4%), necrotizing fasciitis (n=6, 4.0%), osteomyelitis (n=4, 2.7%), urinary tract infection (n=4, 2.7%), pneumonia (n=2, 1.3%), haematoma formation (n=2, 1.3%) and flap necrosis (n=2, 1.3%). A summary of the immediate complications is included in Table 1 below.

Table 1: Immediate post-operative complications

Complication	Percentage	Number (n)
Surgical site infection	14.8%	22
Sepsis	11.4%	17
Myocardial infarction	6.0%	9
AKI	5.4%	8
Necrotizing fasciitis	4.0%	6
Osteomyelitis	2.7%	4
UTI	2.7%	4
Pneumonia	1.3%	2
Hematoma formation	1.3%	2
Flap necrosis	1.3%	2

UTI – urinary tract infection, AKI – acute kidney injury

Phantom limb sensation (n=74, 49.7%) was the commonest late-onset local complication. Additionally, patients developed phantom limb pain (n=61, 40.9%), ulcerations and wounds (n=21, 14.1%), deformity of extremities (n=29, 19.5%), inability to use prosthesis (n=12, 8.1%), painful neuroma (n=5, 3.4%), bedsores (n=2, 1.3%) and contractures (n=2, 1.3%). A summary of late-onset local complications is summarised in Table 2.

Table 2: Late-onset local complications following surgery

Complication	Percentage	Number (n)
Phantom limb sensation	49.7%	74
Phantom limb pain	40.9%	61
Deformities	19.5%	29
Ulceration	14.1%	21
Inability to use prosthesis	8.1%	12
Painful neuroma	3.4%	5
Bedsores	1.3%	2
Contractures	1.3%	2

When comparing the late-onset systemic complications against the total population, myocardial infarctions were the most common [37.6% of patients (n=56)]. Other recognised complications were stroke (n=6, 4.0%), orthostatic pneumonia (n=5, 3.4%), and acute kidney injury (n=14, 9.4%).

During the one-year study duration, 28.2% of the patients (n=42) were deceased, and 6.7% of the cohort (n=10) were lost to follow-up. Out of the deceased individuals, 31.0% were females (n=13) and 69.0% were males (n=29). 19 out of the 149 patients died within 30 days of surgery, yielding a 30-day mortality rate of 12.8%.

The most common cause of death was myocardial infarction, accounting for 59.6% of all deaths (n=25). Other causes of death were sepsis (n=10, 23.8%), renal failure (n=2, 4.7%), pneumonia (n=2, 4.7%), liver failure (n=1, 2.4%), and multi-organ failure (n=1, 2.4%). In one case (2.4%), the cause of death could not be confirmed, as relevant documents were not available.

The median survival time after amputation was 52 weeks (95% CI: 104.9–117.1; SE +/-3.1), No significant difference in survival was noted between AKA and BKA patients (Log-rank test χ^2 (1) =0.149, *p*=0.700). The Kaplan-Meier survival distribution is depicted in Figure 1.

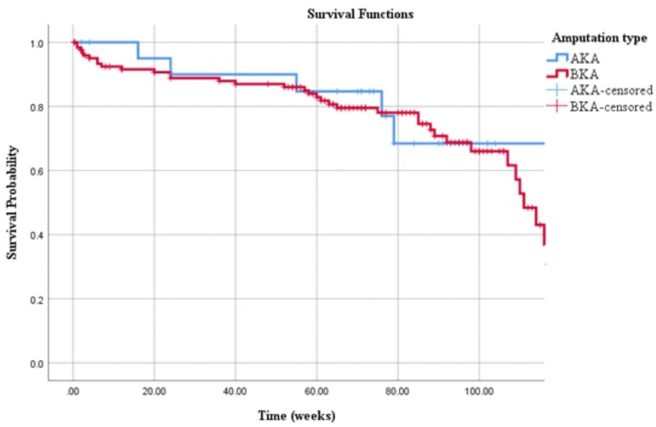

Figure 1: Kaplan-Meier distribution of survival among patients who underwent AKA vs BKA

In multivariate analysis, binary logistic regression identified smoking (current or previous) as a significant independent predictor of one-year mortality (95% CI: 1.5–4.5, *p*=0.018). According to Cox regression, both smoking (95% CI: 1.8–6.0, *p*=0.015) and fasting blood glucose levels (95% CI: 1.0–1.3, *p*=0.017) significantly reduced survival time. Other risk factors were not statistically significant. The results of both logistic and Cox regressions are presented in Table 3.

After one-year follow-up, only 14.4% of living patients (n=14) were independently mobile after receiving prosthetic limbs – 9 patients from the private sector and 5 patients from the government sector (Rheumatology and Rehabilitation Hospital, Ragama). 21.6% of patients (n=21) were ambulant

Table 3: Results of multivariate analysis – Logistic and Cox regression models

Variable	95% CI (AOR)	*p*-Logistic (Sig.)	95% CI (AHR)	*p*-Cox (Sig.)
Hypertension	0.90 – 2.34	0.349	0.25 – 1.86	0.459
IHD	0.26 – 3.54	0.963	0.49 – 3.49	0.582
Dyslipidaemia	0.09 – 1.76	0.399	0.20 – 2.93	0.696
CKD	0.38 – 14.1	0.363	0.81 – 12.10	0.098
Fasting blood glucose	0.99 – 1.01	0.835	1.01 – 1.31	0.017
Haemoglobin	0.69 – 1.46	0.973	0.81 – 1.59	0.454
Serum Creatinine	0.64 – 2.42	0.988	0.78 – 1.68	0.722
Smoking	1.48 – 4.54	0.018	1.75 – 6.03	0.015
Gender	0.99 – 1.16	0.870	0.34 – 2.94	0.989
Age	0.94 – 1.12	0.078	0.98 – 1.01	0.167

AOR – Adjusted Odds Ratio, AHR – Adjusted Hazard Ratio, CI – Confidence Interval, Sig. – significance

using only crutches, 7.2% (n=7) were using moving walkers and 15.5% (n=15) were using wheelchairs independently. 28.9% of patients (n=28) were dependent on wheelchairs and 12.4% (n=12) were completely bedbound.

Discussion

At the end of one-year follow-up of 149 patients, 28.2% were deceased. The majority of patients also suffered a multitude of post-operative complications, which had short-term and long-term implications. Additionally, rehabilitation following amputations was found to be severely inadequate. Our study found that there was a significant mortality associated with diabetic-related major amputations, which aligned with results from international studies, the 30-day mortality rate of 12.8% in the current study is comparable to the 12.4% reported in a study carried out in the UK (median survival time 34 months, 95% CI=25.5-42.5 months, which is approximately equivalent to 1034 days) [4]. However, the Turkish study focused solely on diabetic patients while the UK study included all causes of amputation, thus showing that non-diabetic patients may also face comparable risks. This aspect is worth investigating further in a study.

In our study, fasting blood glucose (FBG) was not significantly associated with one-year mortality in the logistic regression model (95% CI: 0.99–1.01; $p = 0.835$), but it was significantly associated with reduced survival time in the Cox regression model (95% CI: 1.01–1.31; $p = 0.017$). This indicates that elevated FBG may not increase the absolute likelihood of death within one year, but it may accelerate the timing of mortality. Clinically, this underscores the importance of glycemic control in potentially delaying adverse outcomes after major lower limb amputation.

Our study found no significant association between age, gender, and mortality, while various international studies had reported similar mortality rates for both genders. However, unlike our findings, these aforementioned studies identified old age as a key risk factor associated with mortality [5–7]. On the other hand, the male gender has often been associated with a higher risk of amputation due to higher diabetes prevalence, an aspect we did not find in our analysis [2,8,9].

The Kaplan-Meier analysis did not indicate any statistical difference in survival between BKA and AKA. This result contradicts the findings of a study in the UK which reported worse outcomes for trans-femoral (above-knee) amputations with a notable increase in mortality of 4-9% compared to trans-tibial amputations [7]. However, 83.9% of patients in our study had undergone BKA, resulting in a skewed sample. This may be because BKA is often preferred as it preserves knee joint function with lesser physiological burden and energy expenditure than AKA. On the other hand, attempts to salvage marginally viable limbs may have increased the risk of wound dehiscence, delayed healing, or stump infection, ultimately escalating BKA-related mortality. We suggest that future studies on this topic should ensure a balanced sample to improve the quality of the research.

Our study identified myocardial infarction as the commonest cause of death (59.6%), reflecting the high cardiovascular risk in diabetic patients with major amputations. The study conducted in the UK yielded similar results, hence proving the burden of cardiovascular disease, as 88% of the patients who had died at the end of five years in that study had cardiovascular risks (p=0.008) [10]. The presence of diabetes invariably increases the cardiovascular risk [11] by contributing to both macrovascular and microvascular complications. Other risk factors and co-morbidities may have also contributed to MI-associated deaths. This is supported by our multivariate analysis, which identified smoking and blood glucose levels as predictors of mortality and survival time. Amputation of extremities contributes to high-output heart failure, as the circulation of blood volume places excessive strain on the heart. Hence, it is crucial to manage the cardiovascular risk factors before and after the surgery as this will significantly reduce morbidity and mortality. These patients need to be closely followed up by a multidisciplinary team including cardiologists, physicians, and surgeons to provide optimum care [12].

Upon analysis of 23.8% of deaths, sepsis was the second most common cause, which was attributable to the immune deficiency status in diabetes, delayed wound healing, and surgical site infections. Another Sri Lankan study identified sepsis to be the main cause of death in the cohort of patients following major amputations [13]; however, that study included patients with all causes leading to amputations and considered in-hospital mortality only. This signifies the impact of sepsis-related mortality among such patients.

A Japanese study found that low serum albumin worsened survival outcomes (p=0.03) [14], although this was not incorporated into our study. A study conducted in Turkey reported that renal disease and haemodialysis were associated with increased mortality, but not serum creatinine levels [3]. In comparison, our study did not reveal a statistically significant association with serum creatinine levels (p=0.722). A notable shortcoming was the absence of follow-up tests since the amputation, as the most recent measurements would likely have provided the most accurate reflection of the association.

Surgical site infection was the commonest of short-term postoperative complications, being related to multiple factors such as diabetes-related immune deficiency, poor surgical techniques of tissue approximation and handling, amputation stump haematoma, etc.

Affecting nearly half of the population, phantom limb sensation was the most common long-term complication, followed by phantom limb pain. A Swedish study remarked that 69% of the patients were affected by phantom limb pain, and it reduced with time with proper surgical techniques and pain management [15].

Rehabilitation following the amputation showed poor results, with only 14 patients receiving prostheses while many remained on waiting lists even after one year. Some were bedbound, illustrating the poor quality of life endured by the patients. This resonates with a study done in Southeast Asia, which remarked that patients with major amputations have a poorer quality of life compared to those with minor amputations [16]. In contrast, a South African study illustrated more favourable rehabilitation outcomes following amputations [17]. Although overall compliance was poor, the study found that patients who did attend physiotherapy achieved better mobility. Similarly, several studies highlight the benefits of incorporating aggressive lifestyle and medical interventions into post-surgical rehabilitation plans, which should be adopted as standard practice [12,18]. This requires close collaboration between the surgical, medical, and rehabilitation teams.

The rehabilitation efforts are hindered in Sri Lanka and the broader South Asian region mainly due to limited infrastructure, poor accessibility, financial constraints, and weak health policy frameworks [19]. Despite having free healthcare, rehabilitation programs are mostly confined to a few dedicated Rheumatology and Rehabilitation Institutes. As the centres are located in urban areas of the country, accessibility becomes a major barrier, particularly for rural communities. Additional hurdles include shortage of trained rehabilitation professionals, inadequate continuity of care, poor health literacy and awareness among patients, as well as delayed patient presentations.

To overcome these limitations, proper government policies should be implemented; such as integration into national noncommunicable disease (NCD) action plans, decentralising services, workforce development, financial support schemes, and strengthening of community-based rehabilitation programs.

Limitations

Several methodological constraints should be acknowledged. It was conducted as a single-centre study involving only one hospital, which may have introduced potential selection bias and affected the generalisability of the results. As previously mentioned, there was a notable imbalance in the sample sizes of AKA and BKA. Most components of the study relied on existing medical records, which may have limitations in completeness and accuracy, and it also heavily depended on patients' compliance with follow-up. Investigation parameters were based on single-time measurements and lacked continuity. The study could have been further improved by including additional parameters such as ejection fraction, serum albumin levels, and white cell counts, etc. Cause of death determination depended on the provision of relevant documents by the family. Rehabilitation data relied solely on patients' self-reports, highlighting the need for more objectively documented evidence.

Conclusion

In conclusion, diabetes-related major lower limb amputations in the Sri Lankan healthcare setting are associated with significant morbidity and mortality. Key factors such as high plasma glucose levels and cigarette smoking were found to influence survival times, with smoking being an independent predictor of mortality. However, variables such as age, gender, and pre-operative serum creatinine and haemoglobin levels were not identified as significant contributors.

Common post-operative complications included surgical site infections and phantom limb sensation–the former typically occurring in the immediate post-operative period, and the latter presenting as a delayed-onset local complication. Myocardial infarction was frequently observed as a late-onset systemic complication. Among patients who died within one year, the majority succumbed to complications related to ischemic heart disease.

Additionally, the inadequate rehabilitation process and long waiting lists for prosthetic devices for amputees underscore a critical gap in the Sri Lankan healthcare system that requires urgent attention and improvement.

Acknowledgements

None

Competing interests

The author(s) declare that they have no conflicts of interest.

Data accessibility

Due to patient confidentiality and ethical restrictions, the data are not publicly available and are stored on a password-protected computer, accessible only to the investigators. However, the data may be shared upon formal request and approval by the Ethics Review Committee.

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