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A population-based assessment of the post-operative complications rates and 30-day mortality associated with lower limb amputations at a tertiary care center in Riyadh, Saudi Arabia

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ABSTRACT

Objectives: There is no consensus on the postoperative 30-day mortality, complication rates, and their risk factors post lower limb amputations (LLA) in the literature, especially in Saudi Arabia. To address this gap, we assessed these three parameters in our patients who underwent LLAs.

Methods: We conducted a retrospective cross-sectional study in King Abdulaziz Medical City, Riyadh, Saudi Arabia, between 2015 and 2019. Using non-probability purposive sampling, we targeted 318 adults who underwent LLA at our hospital. The primary outcome variables were postoperative 30-day mortality and complications, such as stump pain, wound infections, hemorrhage, and acute kidney injury. In addition, we collected data on demographics, comorbidities, and clinical course from electronic medical records.

Results: We assessed 318 patients (mean age = 65.7 [SD = 0.840] years), most of whom were male patients (68.6%) with endocrine and metabolic disorders (92.1%). Most amputees (87.1%) had peripheral vascular diseases as the main indication for LLA at an above-knee level (62.6%). The 30-day mortality and complication rates were 6.6% and 74%, respectively. Intermediate complications predominated (57%), with stump pain (17.3%) and phantom limb pain (15.4%) being the most common. Thirty-day mortality was significantly associated with some patient characteristics and comorbid kidneys and neurological disorders. The immediate, intermediate, and late complications were significantly related to smoking and several renal, vascular, and respiratory disorders.

Conclusion: Calculating the 30-day mortality and complication rates after LLA and mapping the associated risk factors helped identify high-risk patients, deliver better treatment, lower medical costs, and establish protective measures.

Keywords: Amputation, Lower extremity, Post-operative complications, Risk factors, Saudi Arabia

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INTRODUCTION

Amputation is an ancient surgical procedure that involves removing a necrotic or harmful limb or part of a limb, which can be due to trauma, tumors, vascular disorders, or congenital diseases.[1] In the United States (US), approximately 185,000 amputations are performed each year.[2] A Scottish study reported that non-diabetic causes of amputation were more common than diabetic ones and that minor lower limb amputations (LLAs) outnumbered major LLAs, whereas, in Germany, amputations have increased by 50% in recent years.[3,4] In the Middle East, both diabetes mellitus (DM) and war injuries are major causes of amputation.[5]

Patients with DM have a 10-fold higher risk of LLA.[6] Nowadays, almost half a billion people worldwide are living with DM, and its prevalence is projected to increase by 25–51% in 2030 and 2045, respectively.[7] By 2050, the number of individuals living with limb loss in the US will be more than double, reaching 3.6 million.[8] The annual incidence of diabetes-related LLAs in Saudi Arabia is expected to reach half a million by the next decade.[9] The burden of DM is increasing globally, which means that the rate of amputations will remain high. This makes it necessary to investigate in detail the risk of complications and mortality associated with limb removal.

Amputation carries a risk of mortality and multiple post-operative complications, the most common of which are phantom pain, stump hematoma, flexion contracture, infection, and surgical revision.[10] They also come at a high cost to health economies; in 2019, a 20-year literature review calculated this amount to be as high as 46,000 USD per patient.[11] The post-operative 30-day mortality and complications of amputations negatively impact the overall health and quality of life of amputees, decrease the workforce's productivity, and thus increase the national economic burden.

So far, Saudi research has focused on mapping the statistics of amputations but has not investigated the mortality and complications. Recognizing the 30-day mortality and post-operative complication rates of LLA along with their associated risk factors can help physicians identify high-risk patients, develop effective treatment methods, reduce costs, and establish preventive measures. Therefore, we aimed to bridge this knowledge gap by comprehensively assessing lower limb amputees' post-operative 30-day mortality and complication rates, and examining the association between possible risk factors within over 5 years at our center.

MATERIALS AND METHODS

Study design

This retrospective cross-sectional study assessed the post-operative rates of 30-day mortality and complications in 318 lower limb amputees at King Abdulaziz Medical City, Riyadh, Saudi Arabia, between January 2015 and January 2019.

Identification of study participants

We included both genders of Saudi and non-Saudi patients with above- and below-knee amputations (BKAs) who were above 14 years. We excluded upper limb amputations because of their low numbers. Applying non-probability purposive sampling, we enrolled 318 patients.

Data collection

We collected data from the patients' medical records. Data from January 2015 to December 2016 were collected from the file-based system and data from January 2017 to January 2019 were collected from the patients' electronic medical records (BestCare 2.0 for Windows, version 2). The records were accessed only by the members of the research team and access was restricted with the use of a password. The following variables were collected: Age, gender, body mass index (BMI), smoking status, comorbid disorders (such as DM, hypertension, and renal disorders), the indication of surgery (vascular, traumatic, infectious, or cancerous), level of amputation, post-operative complications (stump pain, wound infection, and hematoma, among others), the time between amputation and the manifestation of complications in days, availability of rehabilitation resources, need for surgical revision, and 30-day mortality rate.

Our primary outcome variables were the 30-day mortality and post-operative complications. We categorized the complications as immediate if they occurred postoperatively within 1 week, intermediate if they occurred within 2 weeks, and late if they occurred in more than 2 weeks. Immediate complications include cases of pneumonia and wound infection, intermediate complications include stump pain and phantom limb pain, and late complications include cases of depression and bone spurs. Possible risk factors (such as patient age and gender, smoking, DM, and renal failure) were the independent variables.

Data analysis

The data were compiled on a Microsoft Excel sheet and then uploaded into statistical software (Statistical Package for the Social Sciences, IBM version 22.0) used for data analysis. Descriptive data analysis was carried out by calculating the frequencies and percentages for categorical data (e.g., BMI) and the mean ± standard deviation (SD) for continuous data. The Chi-square or Fisher exact tests were used to test the association between qualitative data and the occurrence of 30-day mortality and complications. The results were considered statistically significant if $P \leq 0.05$ with a confidence level of 95%.

RESULTS

Of the 318 individuals included in this study, 218 (68.6%) were male and 100 (31.4%) were female. The mean age of the subjects was 65.7 years (SD = 0.84), with most being non-smokers (86.8%) with normal BMI (32.1%). The most prevalent comorbidities were endocrine and metabolic disorders (92.1%) followed by heart and vascular diseases (84.9%) [Table 1].

Our patients' need for amputation was mainly indicated by peripheral vascular disease (PVD) (87.4%), with above-knee amputations (AKAs) in 62.6% of them. The mean time between the amputation and the manifestation of the complications was 19 days (SD = 4.789) and most complications were intermediate (57%). The overall 30-day mortality and complication rates were 6.6–76.4%, respectively [Table 1 and Figure 1].

The most common immediate, intermediate, and late complications were stump pain in 55 (17.3%) patients, wound infection in 48 (15.1%) patients, and depression in 10 (3.1%) patients. Approximately half of the subjects received rehabilitation (57.2%), and more than three-fourth did not need a revision surgery (87.7%) [Tables 1 and 2]. We found that certain patient characteristics could predict the development of complications. For example, smoking was significantly associated with both immediate and late complications ($P < 0.05$), but gender and BMI were not ($P > 0.05$) [Table 3]. Kidney and neurological comorbidities were independently associated with 30-day mortality

Table 1: Characteristics and background of patients.

Demographics	*n* (%)
Age	
Mean=65.73 years	SD 0.840
Gender	
Female	100 (31.4)
Male	218 (68.6)
Comorbidities	
Endocrine and metabolic disorders	293 (92.1)
Kidney disorders	124 (39.0)
Neurological disorders	78 (24.5)
Respiratory disorders	4 (1.3)
Heart and vascular disorders	270 (84.9)
Gastrointestinal disorders	2 (0.6)
Psychiatric	3 (0.9)
Pre-operative infections	58 (18.2)
Osteoporosis	2 (0.6)
Body mass index	
Underweight	30 (9.4)
Normal	102 (32.1)
Overweight	97 (30.5)
Obese	89 (28)
Smoking	
Yes	42 (13.2)
No	276 (86.8)
Indications	
Peripheral vascular disorders	277 (87.1)
Infections	81 (25.5)
Traumas	17 (5.3)
Tumors	6 (1.9)
Level of amputation	
Above knee (major)	199 (62.6)
Below knee (minor)	119 (37.4)
Time between amputation and the manifestation of complications in days	
Mean 19.16	SD 4.789
Rehabilitation	
Received	182 (57.2)
Did not receive	136 (42.8)
Need of surgical revision	
Yes	39 (12.3)
No	279 (87.7)
30-day morality	21 (6.6)
Overall complications	243 (76.4)

Table 2: Prevalence of complications associated with amputation.

Complications	*n* (%)
Immediate	
Stroke	11 (3.5)
Deep venous thrombosis	11 (3.5)
Acute kidney injury	7 (2.2)
Pneumonia	6 (1.9)
Sepsis	38 (11.9)
Wound dehiscence	7 (2.2)
Non-ST-elevation myocardial infarction	3 (0.9)
Cardiopulmonary arrest	2 (0.6)
Wound infection	48 (15.1)
Respiratory failure	5 (1.6)
Intermediate	
Urinary tract infection	27 (8.5)
Hemorrhage	6 (1.9)
Hematoma	11 (3.5)
Skin/muscle necrosis	16 (5.0)
Stump necrosis	17 (5.3)
Stump hematoma	2 (0.6)
Stump infection	39 (12.3)
Stump pain	55 (17.3)
Phantom limb sensation	17 (5.3)
Phantom limb pain	49 (15.4)
Ulceration	27 (8.5)
Non-healing wound	9 (2.8)
Neuroma	1 (0.3)
Necrotizing fasciitis	2 (0.6)
Osteomyelitis	5 (1.6)
Late	
Depression	10 (3.1)
Insomnia	7 (2.2)
Post-traumatic stress disorder	1 (0.3)
Anxiety	3 (0.9)
Bone spur	1 (0.3)

($P < 0.05$). Patients with comorbid kidney, neurological, and respiratory disorders were more likely to develop immediate complications ($P < 0.05$), while those with heart and PVD were more likely to develop intermediate complications ($P < 0.05$). Late complications mainly occurred in patients with metabolic, endocrine, and GI disorders ($P < 0.05$). We also found that indications of surgery were significantly associated with complications; pre-operative infections

Table 3: Association between participants' characteristics and occurrence of complications.

Variables	Complications			
	30-day mortality, *n* (%)	**Immediate, *n* (%)**	**Intermediate, *n* (%)**	**Late, *n* (%)**
Gender				
Males	14 (66.7)	66 (75.0)	96 (69.6)	13 (76.5)
Females	7 (33.3)	22 (25.0)	42 (30.4)	4 (23.5)
P-value	0.855	0.126	0.734	0.470
Body mass index				
Underweight	2 (9.5)	9 (10.2)	17 (12.3)	0
Normal	5 (23.8)	24 (27.3)	39 (28.3)	8 (47.1)
Overweight	9 (42.9)	32 (36.4)	44 (31.9)	5 (29.4)
Obese	5 (23.8)	23 (26.1)	38 (27.5)	4 (23.5)
P-value	0.632	0.480	0.330	0.379
Smoking				
Smokers	2 (9.5)	6 (6.8)	17 (12.3)	5 (29.4)
Non-smokers	19 (90.5)	82 (93.2)	121 (87.7)	12 (70.6)
P-value	0.602	0.037*	0.682	0.043*
Comorbidities				
Endocrine and metabolic disorders	20 (6.3)	80 (90.9)	126 (91.3)	12 (70.6)
P-value	0.687	0.614	0.628	0.001**
Kidney disorders	13 (4.1)	45 (51.1)	60 (43.5)	4 (23.5)
P-value	0.026*	0.006*	0.151	0.179
Neurological disorders	11 (3.5)	29 (33)	40 (29)	2 (11.8)
P-value	0.002*	0.031*	0.106	0.209
Respiratory disorders	0	3 (3.4)	0	0
P-value	0.593	0.033*	0.078	0.632
Heart and vascular disease	20 (6.3)	79 (89.8)	124 (89.8)	14 (82.4)
P-value	0.171	0.134	0.031*	0.763
Gastrointestinal disorders	0	1 (1.1)	2 (1.4)	1 (5.9)
P-value	0.706	0.479	0.1875	0.005*
Psychiatric	0	1 (1.1)	0	0
P-value	0.644	0.826	0.128	0.679
Osteoporosis	0	1 (1.1)	2 (1.4)	0
P-value	0.706	0.479	0.105	0.736
Pre-operative infections	5 (1.6)	23 (26.1)	37 (26.8)	4 (23.5)
P-value	0.494	0.024*	0.001**	0.562
Indications				
Peripheral vascular disease	17 (5.3)	72 (81.8)	120 (87)	11 (64.7)
P-value	0.355	0.082	0.944	0.005*
Infection	8 (2.5)	22 (25)	37 (26.8)	4 (23.5)
P-value	0.169	0.905	0.631	0.850
Trauma	1 (0.3)	8 (9.1)	7 (5.1)	4 (23.5)
P-value	0.854	0.066	0.849	0.001**
Tumor	1 (0.3)	2 (2.3)	1 (0.7)	1 (5.9)
P-value	0.408	0.754	0.182	0.213
Level of amputation				
Above knee	17 (81)	63 (71.6)	88 (63.8)	10 (58.8)
Below knee	4 (19)	25 (28.4)	50 (36.2)	7 (41.2)
P-value	0.070	0.040*	0.701	0.742

*Significant at 5% **Significant at 1%

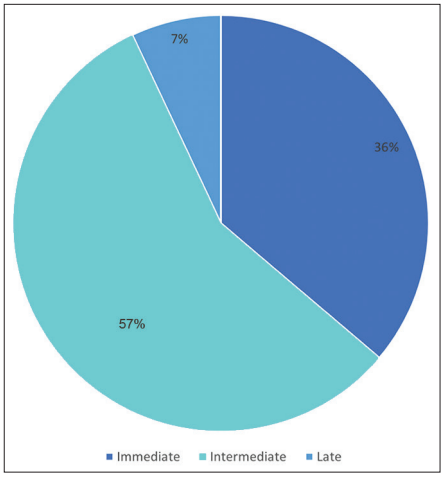

Figure 1: Prevalence of different types of complications among patients.

indicating amputation were significantly associated with both immediate and intermediate complications ($P < 0.05$), whereas amputations indicated by PVD, and trauma mostly resulted in late complications ($P < 0.05$). The level of amputation, above or below knee (major or minor), was also significantly associated with immediate complications ($P < 0.05$) [Table 3].

DISCUSSION

Sufficient evidence-based data on the short- and long-term post-operative complications of LLA along with their associated risk factors can help physicians identify high-risk patients, take measures to avoid them, and improve their quality of life by establishing better treatment protocols, shortening hospital stays, and reducing health expenses. LLA's most common indications have been adequately studied, but there is limited evidence on the prevalence of postoperative complications.[12]

There is a considerable global variation in the reported incidences of the level of amputation. Most studies found BKA more common, while others reported a higher incidence of AKA.[13-17] Moreover, AKA was reported to be 6 times higher in the diabetic population.[14] We found a greater number of AKA in our patient population, which can be attributed to their characteristics, as the majority had comorbid endocrine disorders.

We observed that most amputations were indicated by PVD and infectious disorders. Amputation has several intersectional indications that can differ between countries based on income level and economic development. For example, surgeons in the US and UK commonly perform amputations due to DM and PVD, whereas trauma is the most common indication in Nigeria and Liberia.[13-16] Saudi Arabia has seen a shift in the causes of amputation over the years, from trauma to DM and PVD.[17-19] Most patients in this study had PVD as the main indication for surgery.

The overall 30-day mortality and complication rates were 6.6–76.4%, respectively, with stump pain, phantom limb pain, wound infection, and stump infection being the most common complications. Smoking habits, comorbidities, indications for surgery, and level of amputation were all significantly associated with 30-day mortality and post-operative complications. Regardless of the etiology, LLA has a high rate of probable and overt mortality and complications. While the 30-day mortality rate of 6.6% in our study was consistent with international averages, our patients' rate of developing complications (76.4%) was higher than previously reported.[13] This high percentage can be attributed to the difference in the scope of previous studies; they primarily focused on wound-related complications, whereas our study examined a more comprehensive list of possible complications.[20]

Post-amputation neuropathic pain, such as phantom limb pain or stump pain, is common and negatively affects patients' overall physical health.[21-25] The prevalence of phantom limb pain is as high as 85% (with recent studies showing higher percentages) while the stump (residual limb) pain is 92%; its persistence is due to infection, wound breakdown, and surgical site hematoma.[25,26] In our patients, stump and phantom limb pain were the most common complications followed by wound and stump infections, which mirrors what has been previously reported. In contrast, cardiac, pulmonary, and renal complications have been reported at higher frequencies as compared to what was observed in this study.[27-30] The slightly lower percentages we presented might be because we conducted our study in a single tertiary care center, while others were multicenter studies. The high prevalence of neuropathic pain in our study population and the fact that the intensity of stump and phantom limb pain can determine the amputees' quality of life is evidence that it is essential to timely recognize and treat these complications.

Whether or not various risk factors are associated with increased mortality and morbidity rates after LLA remains to be elucidated because there is no consensus on this in the literature.[31,32] In our study, amputees with pre-existing infections and renal, neurological, respiratory, cardiac, vascular, endocrine, and gastrointestinal disorders were significantly associated with higher 30-day mortality and rate of complications. Moreover, patients with continuous tobacco smoking habits, a major level of amputation, and PVD or trauma as the primary indication for surgery had higher rates of complications and consequently worse outcomes; this finding is in line with published studies.[27-32] Female patients and obese patients are thought to be at a higher risk of 30-day mortality and complications.[29,33-35] However, our data did not demonstrate such an association, which might be due to

the small percentage of females and obese individuals in our sample.

To the bets of our knowledge, this study is the first to investigate the prevalence of post-operative 30-days mortality and morbidity in LLA patients in Saudi Arabia, while also examining its associated risk factors. Our results may help in developing a Saudi national database for amputees and will further enrich international repositories. We acknowledge the potential limitations of this study, including its retrospective, cross-sectional, and single-center nature. In addition, we were unable to show a temporal sequence because we described the trends of postoperative mortality and morbidity without investigating their mechanisms, that is, we described "what but not why."

CONCLUSION

Wound infection, stump pain, and phantom pain are the most reported complications post-amputation. Moreover, patients' comorbidities, smoking habits, level of amputation, and PVD as a primary indication for surgery are significantly associated with a higher risk of 30-day mortality and post-amputation complications.

RECOMMENDATIONS

We recommend an increased clinical emphasis on wound care along with identifying and treating stump and phantom pain. We also recommend calculating the 30-day mortality and complication rates after amputation and mapping the associated risk factors to help identify high-risk patients, deliver better treatment, lower medical costs, and establish protective measures.

Further prospective studies from multiple centers worldwide with a higher level of evidence (e.g., case-control) are needed to evaluate 30-day and 1-year mortality, causes of death, the occurrence of post-amputation complications, and their degree of severity. In addition, we recommend other potential risk factors be examined to check for the development of post-operative complications, such as the impact of rehabilitation, surgical revision and its causes, and history of previous vascular procedures in the amputated leg. We also recommend prospective studies using validated outcomes measure tools (e.g., the visual analog scale) to help surgeons understand the patient-reported results of their operations.

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AUTHORS' CONTRIBUTIONS

NSA conceptualized and designed the study. SMA[a], SMA[b], SAA, SHA, and RSA conducted research, provided research material, collected and organized data, and wrote the initial draft of the article. YC analyzed and interpreted data. SMA[a] wrote the final draft of the article. All authors have critically reviewed and approved the final draft and are responsible for the manuscript's content and similarity index.

ETHICAL APPROVAL

The study was approved in April 16, 2019, by the Institutional Review Board of King Abdullah International Medical Research Center (KAIMRC), Riyadh, Saudi Arabia, under the protocol number SP19/076/R.

Declaration of patient consent

The authors certify that they have obtained all appropriate patients consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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