




Epidemiology and Outcome of Nontraumatic Lower Limb Amputations

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Abstract

Background: In order to create a solid evidence base for the development of improved management methods, this study was performed to describe the epidemiology and outcome of nontraumatic lower limb amputations (LLAs).

Methods: This descriptive case series was conducted over a period of 4 years. It included all patients of both sexes and all ages who underwent LLAs for nontraumatic indications.

Results: There were a total of 217 patients with 136 (62.67%) men and 81 (37.32%) women. The age range was 7 to 71 years, with a mean of 54.25 ± 11.49 years. The most common indication for amputation (41.47%) was diabetic foot gangrene. The most common level of amputation (48.29%) was below knee amputation.

Conclusion: Patients with diabetic foot gangrene, malignant tumors, and chronic neuropathic ulcers with osteomyelitis constituted the bulk of the amputees. Diabetes mellitus, obesity, and hypertension were the commonest comorbidities identified among them. Public awareness and education would ensure prompt and early health seeking at the appropriate time and help to prevent the need for major amputations in many instances. The amputees' improved reintegration into society and ability to become contributing members of society would be ensured by the provision of vigorous rehabilitation.

Keywords: Lower Limb Amputations, Lower Extremity Amputation, Complications of Diabetes Mellitus, Peripheral Artery Disease, Deadly Lower Limbs, Diabetic Foot Syndrome

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Introduction

Nontraumatic lower limb amputation (LLA) is a serious surgical undertaking that carries formidable functional impairments and lifelong psychosocial repercussions for the amputees as well as their families. Although chosen as a last surgical resort, it is often indicated either as a life-saving procedure or as a quality-of-life improving method for a potentially unreconstructable or functionally debilitating or deadly lower limb. LLA is considered a major procedure when it is performed through or above the level of the ankle. It is termed a minor procedure when it is

performed below the level of the ankle. Trauma, electric burns, frostbites, peripheral vascular disease, diabetes mellitus (DM), malignancy, congenital limb anomalies, and chronic neuropathic ulcers with refractory osteomyelitis are among the leading indications for LLAs (1-3).

In the developed world, owing to modernized health care systems and well-rooted preventive programs, the rates of nontraumatic LLAs are consistently declining and the indications are shrinking; however, the developing nations continue to be plagued by the growing menace of

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↑ What is “already known” in this topic:

- In developed countries, the rates of nontraumatic lower limb amputations (LLAs) are consistently declining because of their well-established preventive programs and modernized healthcare systems.

→ What this article adds:

- The developing nations are faced with the continuing plague of LLAs.
- Patients with diabetes mellitus have a greater likelihood of complications and mortalities. The health care team should anticipate and circumvent these issues.

LLAs (4, 5).

The goal of this study was to gather data on the prevalence and prognosis of nontraumatic LLAs at our institution in order to develop an actionable evidence foundation that would help our patients' future outcomes.

Methods

This descriptive case series was conducted over a period of 4 years from January 2017 to December 2020. Informed consent was taken from the patients. The study was performed at the National Institute of Rehabilitation Medicine, Islamabad, Pakistan. The study followed the ethical protocols as per Helsinki's Declaration-2013 revision. The anonymity of the participants was guaranteed. The design of descriptive case series was chosen as the study intended to describe the current status of nontraumatic LLAs in our population and provide systematic information about the issue under scrutiny.

The study included all patients of both sexes and all ages who underwent LLAs for nontraumatic indications. Patients in whom LLAs were performed for acute traumatic indications and those unwilling to participate in the study were excluded.

The primary diagnosis was established with history, clinical examination, and ancillary investigations. Vascular evaluation with duplex ultrasonography, computed tomography angiography, or magnetic resonance angiography was performed before undertaking amputations in patients with DM and peripheral arterial disease (PAD). The data collected included the demographic and clinical profile of the patients, frequency distribution of the indications for nontraumatic LLAs, the level of amputations, the side affected, associated comorbidities, postoperative complications, length of hospital stay (LOS) among hospitalized patients, the need for revision surgery in the form of higher level reamputations, and mortality within 1-month after amputation.

All patients undergoing major amputations were admitted indoors, whereas the majority of those undergoing minor amputations were managed on daily care basis. Standard management was instituted for treating the associated conditions such as local/systemic infection, DM, PAD, or any other specific clinical condition. Prophylactic injectable antibiotics were administered before undertaking amputations. Tourniquet control was routinely employed for undertaking the amputations in a controlled fashion except in the cases of DM, PAD, and hip disarticulations.

Among adult patients who had attained skeletal maturity, the below knee amputation (BKA) was performed at a level to leave behind 12-17 cm of the tibial stump, measuring the length from the tibial tuberosity. In unfavorable circumstances, the length of the tibial stump was ensured to be no <8 cm (Figure 1, A-C). AKA was performed at a level to leave behind 25-30 cm of the femoral stump, taking the greater trochanter as the measuring landmark. Also, care was taken to resect at least 12 cm of the distal femur to provide space for a knee mechanism in the future prosthesis to be subsequently employed for rehabilitation (Figure 2, A-C). In the case of children, it was made a

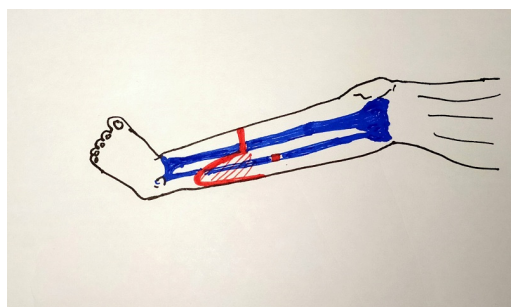
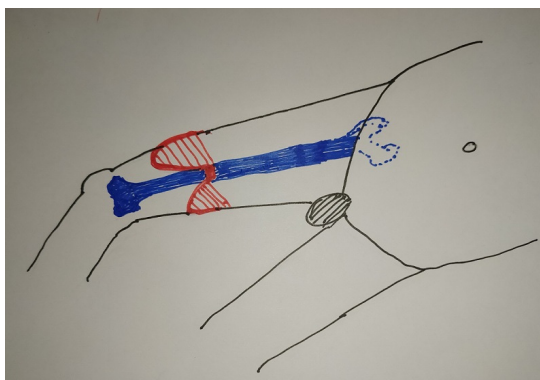


Figure 1 A-C. Below Knee Amputation (BKA). A: Schematic diagram. The BKA is performed at a level to obtain an ideal residual tibial length of 12-17 cm, measuring from the tibial tuberosity. Outlined in red color are the levels of divisions of the tibia and fibula. A long posterior musculocutaneous flap is shown in red color with hatched outline. The anterior skin incision is oriented transversely almost at the level of the intended tibial division. The fibula is divided 5 cm proximal to tibial resection level so that the subsequent axial load of the body is borne by the tibial stump. B: Characteristic immediate postoperative appearance of the BKA stump. C: Same patient as in B, showing stump appearance after removal of sutures.

priority to preserve the physis as much as possible, allowing for the growth of bones throughout the next growing years. At the outset of surgery, the musculocutaneous flaps were marked to achieve tension-free stump closure



A



B



C

Figure 2 A-C. Above Knee Amputation (AKA). A: Schematic diagram. The AKA is performed at a level to obtain an ideal residual femoral length of 25-30 cm femur, measuring from the greater trochanter. A long anterior musculocutaneous flap and a shorter posterior flap are shown in red color. B: Immediate postoperative appearance of the AKA stump. C: Same patient as in B, showing stump appearance after removal of sutures

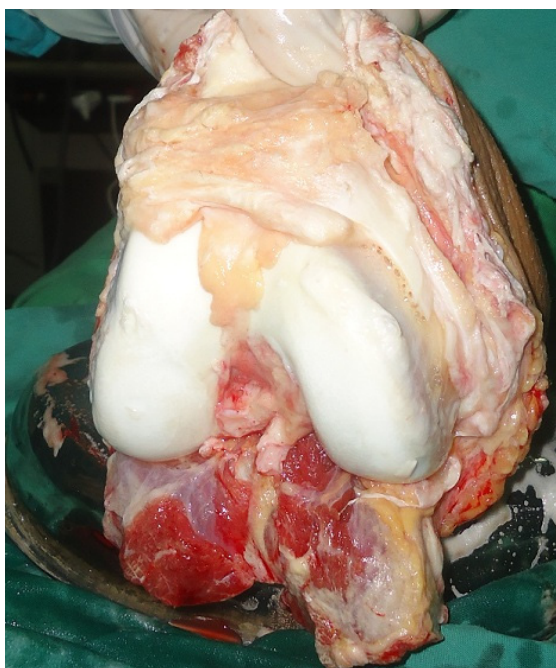
as well as ensure an appropriate stump shape for prosthesis fitting. These flaps were designed long enough to resurface the stump. In the case of BKA, a long posterior musculocutaneous flap was designed, whereas the anterior incision was oriented transverse at the level of the intended bone division. The fibula was divided 5 cm proximal to



Figure 3. Gigli saw employed for dividing the bones

the tibial resection level so that the subsequent axial load could be borne by the tibial stump. The sharp margins of the bones were made well-rounded using bone nibblers and files. Drill holes were made in the tibia and prolene 2/0 was employed to perform myodesis of the deeper muscles to the bone. The superficial muscles were repaired together using Vicryl as myoplasty to further strengthen the stump. In the case of AKA, a longer anterior musculocutaneous flap was designed. The sciatic and femoral nerves were cut as high as possible so that they retracted and buried within the muscle mass to prevent the subsequent formation of painful neuromas at the stump. The artery was doubly ligated to prevent postoperative hemorrhage. For constructing the stump, the adductor muscles were myodesed to the femur, and myoplasty of the quadriceps was performed with the hamstrings and the adductors already anchored to the femur. The bone divisions were performed with a disposable Gigli saw of 50 cm in length (Figure 3). The Gigli saw helped to divide the bone in a more controlled fashion without causing soft tissue trauma at the time of bone division. In case of knee disarticulation, a long anterior flap was designed for covering the stump. The patella was left attached to the skin flap and patellar tendon. The latter was attached to the hamstring muscles and cruciate ligaments (Figure 4, A and B). For hip disarticulation, anterior racquet design incision was employed. The handle of the incision was oriented anteriorly along the line of the femoral vessels. The medial flap was kept longer so that the final scar fell away from the perineum. At the beginning, the major vessels were ligated and divided. The anterior muscles were divided in line of incision and joint open from the front. Division of the muscles attached to the bone was continued. The sciatic nerve was divided high enough to ensure its retraction away from the stump. Disarticulation was completed by dividing the capsule and remaining muscle attachments. The flaps were trimmed to achieve adequate closure (Figure 5, A and B).

In case of ray amputations, an incision was made longitudinally on the dorsum of the foot in line with the involved metatarsal. At the metatarsophalangeal joint (MTPJ), the incision was extended along the plantar aspect in a curvilinear fashion around the joint. Amputation



A

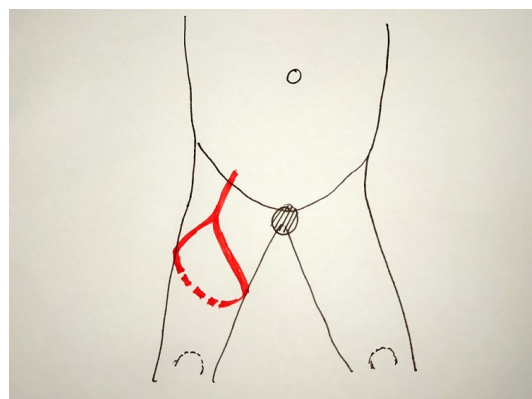


B

Figure 4 A-B. Knee disarticulation. A: Intra-operative appearance. B: Postoperative appearance of the stump. The long anterior flap included the patella and its tendon which helped with the myoplasty of the hamstrings and quadriceps muscles as well as gave better contour to the stump.

of the affected toe in continuation with the distal half of the metatarsal bone was performed. Direct closure of the wounds was undertaken. In case of MTPJ disarticulation, a longer plantar flap was designed and the incision was continued at the level of the MTPJ on the dorsal aspect. In case of transmetatarsal amputations, a longer plantar flap and shorter dorsal flap was designed. Musculofascial flaps—including the tendons and muscles—were elevated and the metatarsal bones resected from dorsal to plantar direction (6, 7).

Where the amputation stump was infected, only deeper layers were closed and the skin and subcutaneous layers were left open. Vacuum assisted closure (VAC) was employed to obtain healthy granulating wound, which was



A



B

Figure 5 A-B. Hip disarticulation. A: Schematic diagram. The characteristic racquet shaped incision is demonstrated in red color. The handle of the racquet is oriented anteriorly along the line of the femoral vessels which are controlled and ligated at the outset of the procedure. The medial flap is kept longer so that the final scar falls away from the perineum. The dotted line shows the extension of incisions on the posterior aspect of the thigh. B: Immediate postoperative appearance of the stump of a hip disarticulation. The long medial flap helps to keep the suture line away from perineum and hence avoid its contamination from the urine and stool. The genitals are camouflaged with the white color circle.

later closed using the delayed primary closure technique (8). The Redivac suction drain was employed in the patients who underwent hip disarticulation.

Bulky absorbent dressings were applied and limb elevation ensured in the immediate postoperative phase. The first change of the dressing was performed 5 days after surgery. Removal of stitches was performed at days 10 to 14 after surgery. Prosthesis management was initiated at 6-] weeks postoperatively. Stump rehabilitation with massages and muscle contraction exercises were started and attention was paid to prevent joint contractures. Patients who had such issues as neuromuscular disorders and body balance were left without prosthesis. One-year follow up was done.

The data were subjected to statistical analysis using IBM-SPSS for Windows Version 21. Numerical data, such as age were expressed as mean \pm standard deviation. Categorical data such as sex and the side affected were expressed as frequencies and percentages. The patients were stratified into DM group and non-DM group to carry out subgroup analysis of the outcome measures. The

percentages of different variables were compared by employing the fisher exact test and $P < 0.05$ was considered statistically significant.

Results

There was a total of 217 patients, with 136 (62.67%) men and 81(37.32%) women. The age of patients ranged from 7 years to 71 years, with a mean age of 54.25 ± 11.49 years.

The indications for amputations are summarized in Figure 6. Various comorbidities observed among the patients included DM ($n = 90$; 41.47%), obesity ($n = 55$; 25.34%), hypertension ($n = 45$; 20.73%), ischemic heart disease ($n = 17$; 7.83%), smoking ($n = 13$; 5.99%) and Buerger disease ($n = 3$; 1.38%).

The side of involvement was the right side ($n = 129$; 59.45%) followed by the left side ($n = 78$; 35.94%) and bilateral involvement among 27 (12.44%) patients. Also, 162 (74.65%) patients were admitted, whereas 55 (25.34%) were managed on day care basis.

Various amputations performed among the patients are indicated in Figure 7. Secondary procedures performed included delayed primary closure of the superficial wound layers ($n = 21$; 9.97%), use of VAC ($n = 15$; 6.41%), and reamputation at a higher level (BKA) ($n = 17$; 7.83%).

The share of complications included wound infection/wound breakdown ($n = 27$; 12.53%), stump edema ($n = 14$; 6.46%), Phantom limb pain ($n = 9$; 4.15%), bursa formation at the stump ($n = 4$; 1.84%), knee joint contracture ($n = 1$; 0.46%), and osseous overgrowth ($n = 1$; 0.46%).

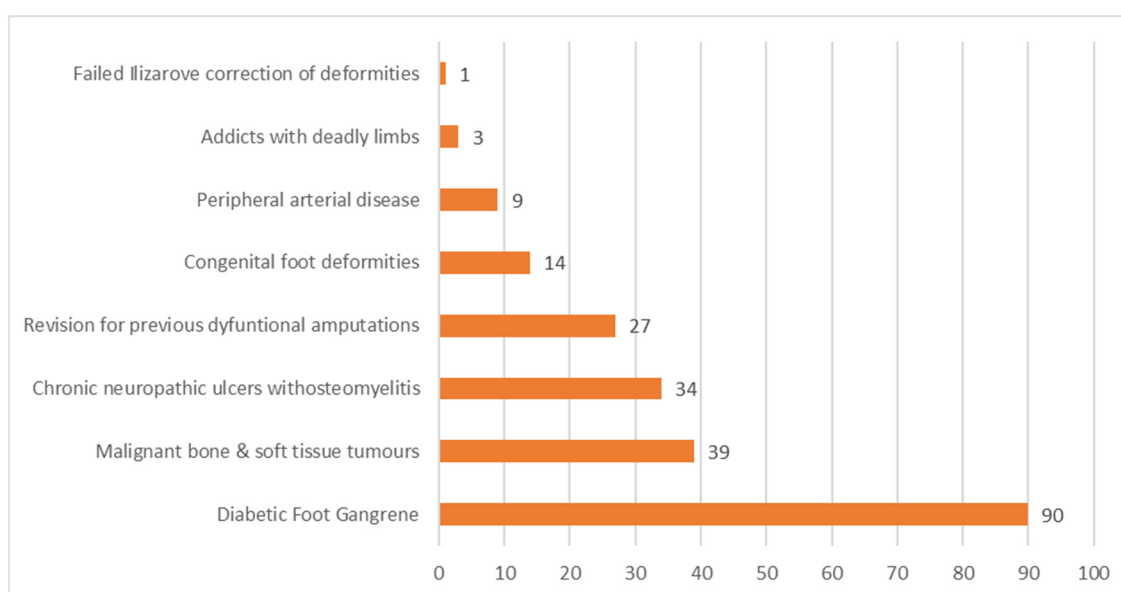


Figure 6. Various indications for amputations among the included patients ($n=217$)

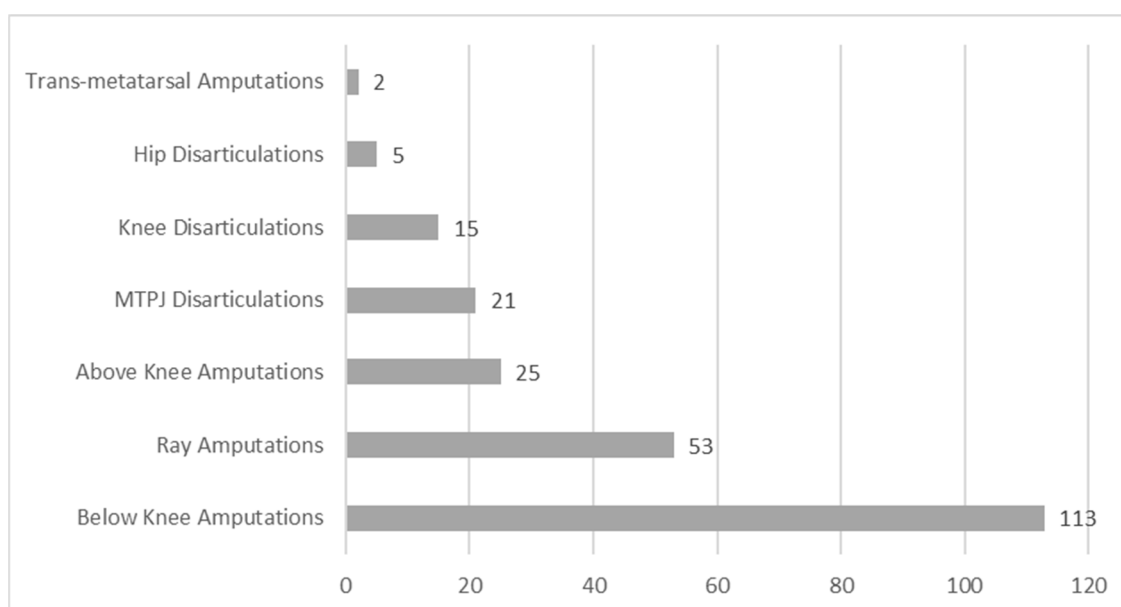


Figure 7. The various amputations performed among the patients ($n=234$)

Table 1. Presentation and outcome data of the included patients (n = 217)

Characteristic	Number of Patients (%)
Age	
Mean age was 54.25±11.49 with a range of 7-71 years.	
Gender:	
Female	136 (62.67%)
Male	81 (37.32%)
Indications for amputations:	
Diabetic foot gangrene	90 (41.47%)
Malignant bone/ soft tissue tumors	39 (17.97%)
Chronic neuropathic ulcers with osteomyelitis	34 (15.66%)
Revision for previously performed dysfunctional amputations	27 (12.44%)
Congenital foot deformities	14 (6.45%)
PAD	9 (4.14%)
Addicts with chronically infected deadly lower limbs	3 (1.38%)
Failed Ilizarov correction of deformed ankle	1 (0.46%)
Comorbidities and Associated conditions:	
Diabetes mellitus	90 (41.47%)
Obesity	55 (25.34%)
Hypertension	45 (20.73%)
Ischemic heart disease	17 (7.83%)
Smoking	13 (5.99%)
Buerger's disease	3 (1.38%)
Side affected:	
Right	129 (55.12%)
Left	78 (33.33%)
Bilateral	27 (11.53%)
Hospitalization:	
Indoor admission	162 (74.65%)
Day care basis Management	55 (25.34%)
Type/ Level of amputation:	
BKA	113 (48.29%)
Ray amputations	53 (22.64%)
AKA	25 (10.68%)
MTPJ-disarticulation	21 (8.67%)
Knee disarticulation	15 (6.41%)
Hip disarticulation	5 (2.13%)
Trans-metatarsal amputations	2 (0.85%)
Secondary procedures:	
Delayed primary closure	21 (9.97%)
VAC	15 (6.41%)
Revision as BKA	17 (7.83%)
Postoperative complications observed:	
Wound infection/ wound breakdown	27 (11.53%)
Stump edema	14 (5.98%)
Phantom limb pain	9 (3.84%)
Bursa formation at the stump	4 (1.70%)
Knee joint contracture	1 (0.42%)
Osseous overgrowth	1 (0.42%)
Outcomes:	
Length of hospital stay (LOS)	Mean 9.72±4.50 (range 7-28) days
Mortalities	9(4.68%)

The LOS among hospitalized patients (n = 162) ranged from 7 to 28 days, with a mean of 9.72 ± 4.50 days. The hospitalized patients' death rate was 4.68% and there were 9 fatalities among them, all of whom had uncontrolled diabetes when they were admitted. Table 1 summarizes the presentation and outcome data of the included patients.

Table 2 shows the comparison of outcome measures between the patients of the DM group and non-DM group. The post hoc power analysis for the study data showed the power to be 70% (Table 2).

Discussion

Our institute deals with the rehabilitation of disabled patients as well as the surgical candidates for various amputations. These patients are referred from across the coun-

try. The present prospective study is the first of its kind that aimed to establish the demographic and clinical profile of nontraumatic LLAs managed at our institute.

In this study, over half of the study participants were constituted by patients aged 50 to 63 years. Several published studies have reported variable age group involvement among the amputees of nontraumatic LLAs. For instance, Kayssi et al from Canada reported a mean age of 67 ± 13 years (1).

In this study, men underwent amputations at a higher rate compared with women. Male sex has been reported to be an independent risk factor for LLAs, particularly among patients with DM and peripheral vascular disease. Hormonal variables and men's height have been implicated in the cause of the main male ailment, albeit the exact

Table 2. Comparison of outcomes between the diabetes mellitus group and non-diabetes Mellitus group (n = 217)

Outcome Measures	DM group n=90	Non-DM group n=127	P-value
Complications encountered:			
Wound infection/ breakdown	21(23.33%)	6(4.72%)	<0.001*
Stump edema	5(3.93%)	9(7.08%)	0.782
Phantom limb pain	4(4.44%)	5(5.55%)	1
Bursa formation at the stump	1(1.11%)	3(2.36%)	0.643
Knee joint contracture	0(%)	1(0.42%)	1
Osseous overgrowth	0(%)	1(0.42%)	1
Need for additional interventions:			
Delayed primary closure	15(16.66%)	6(4.72%)	<0.004*
VAC	7(7.77%)	8(6.29%)	0.787
Revision as BKA	17(18.88%)	0(%)	<0.001*
Mortalities observed:			
	9(4.68%)	0(0%)	<0.001*

<0.05* Significant P-value

>0.05 Insignificant P-value

cause is still unknown (1, 9-11).

In the present study, 41.47% of the patients needing LLAs presented with complications of uncontrolled or poorly controlled DM. Uncontrolled DM constitutes one of the leading causes of nontraumatic LLAs worldwide. Globally, the share of diabetic complications contributing to LLAs ranges between 25% to 90%. The risk of LLAs among DM patients is 10 times greater than those without DM. Patients with DM may develop local foot infection, chronic trophic ulcers, osteomyelitis and systemic sepsis that ultimately culminate in a variety of minor and major amputations (12-14).

In this study, reamputation at a higher level (BKA) was observed among 17 patients. Liu et al recently published a systematic review and meta-analysis on the risk of reamputations among the diabetic patients. They found an overall reamputation rate of 19% within 1 year, whereas this rate was 37.1% at 5 years after the first amputation. They observed that the reamputation rates and trends have remained consistent over the last 2 decades (15). The level of initial amputation is primarily based on the vascular status and sepsis free tissue planes of the limb. However, owing to the poor vascularity and advancing infection, the need for revision or reamputation at a higher anatomic level may arise in a certain percentage of the diabetic patients. Therefore, the initial counselling of these patients should include clear explanation of the possible need for such secondary procedures.

In developed countries, commendable success has been achieved in declining the rates of LLAs among DM patients owing to a host of interventions. Strong public awareness campaigns aimed at primary prevention, improved glycemic control in patients who have been diagnosed, multidisciplinary foot care clinics, and improved management of the associated modifiable risk factors like high blood pressure and abnormal lipid profiles among DM patients are a few examples. With high-quality outpatient management of DM and more frequent medical and surgical revascularizations, limb salvage rates are reported to be increased and the postamputation readmission rates are reduced (14, 16, 17). The developing nations like ours should learn from the experiences of developed countries

to reduce the incidence of DM-related amputations.

In the present study, 4.14% of the LLAs were performed for complications of PAD. Kayssi et al from Canada reported 6% share of PAD in their series of LLAs, however, in the United States PAD is reported to be the leading indication for LLA. The published literature has highlighted the fact that 50% of the patients with PAD have DM, whereas the remaining 50% are nondiabetics. Many unavoidable reasons for performing amputations on patients with PAD have been mentioned in the published studies; for instance, stubborn instances of soft tissue infections with or without an underlying osteomyelitis. Additionally, relentless disease with progressive soft tissue necrosis and persistent ischemic pain that fails to respond to conservative therapies constitutes indications for such amputations. Among the patients with PAD, a variety of nonsurgical interventions, such as the use of statins, are initially instituted to avoid amputations (1, 6, 18, 19).

In the current study, 15.66% of LLAs were done for lower limb amputations due to osteomyelitis caused by chronic neuropathic ulcers. These patients presented with various neuropathic disorders such as spina bifida/myelomeningocele (MMC), post-poliomyelitis paralysis, and paraplegic of different etiologies. There is scarcity of published literature regarding amputations among such patients. Roach et al from the United States retrospectively reviewed 84 adult individuals with MMC and analyzed the social, cognitive, and physical disabilities they encountered. Of them, 54% developed pressure sores that necessitated four major LLAs. These included a hemipelvectomy (n = 1), hip disarticulation (n = 1), Symes amputation (n = 1), and 3 ray resections (20).

In the present study, 6.45% of the patients needing LLAs presented with congenital lower limb deformities, deficiencies, or malformations; for instance, long neglected cases of hemimelia, constriction ring syndrome with deadly limb, and neglected congenital talipes equino varus. The LLAs are indicated among cases of congenitally deficient lower limbs in order to restore function with use of appropriate prostheses. Such deficiencies are anatomically classified as longitudinal deficiencies (ie, hemimelias), transverse deficiencies (ie, absent part in a transverse

fashion), or intercalary deficiencies (ie, absent intervening segment of the lower limb). There could be tibial or fibular deficiencies. These situations are evaluated on an individual basis and initially an attempt is made to make them functional without amputations; for instance, with orthotic management or limb reconstruction. When these steps are ineffective, amputation is scheduled at a level that will improve the amputee's functional status compared to his current physical impairment (6, 21).

In the present study, BKA constituted the most frequent level of amputation, accounting for 48.29% of the LLAs performed. Johannesson et al also reported transtibial (74%) amputations as the commonest in their series. Kayssi et al similarly reported BKA (61%) as the commonest, followed by AKA in 22%, and a foot amputation in 14% of reamputation patients (1, 22).

The level of amputation has significant bearing on the energy expenditure of ambulation (EEA). As a rule of thumb, the higher the level of a LLAs, the greater the EEA. The amount of energy and oxygen used when walking will increase with the degree of amputation. Also, the walking speed will reduce accordingly with the higher level of amputation. In case of BKA, the extra energy (above baseline) consumed for walking with a short transtibial amputation, average transtibial amputation, and long transtibial amputation is 40%, 25%, and 10%, respectively. In case of AKA, there is 50% to 65% greater energy consumption than the baseline (6, 23).

In the present study, phantom limb pain was observed among 3.84% of patients. On average, it resolved over a period of 6 months with the use of various treatment modalities, including nonsteroidal anti-inflammatory drugs, amitriptyline, stump massage, transcutaneous nerve stimulation, and encouraging the patients to regularly wear the prosthesis. Our observations conform to several published studies (24).

In the present study, 9 patients were younger than 16 years. Krajbich I has summarized the principles for amputations among children as follows: (1) preserve the limb length as much as possible; (2) preserve important growth plates; (3) perform disarticulation rather than transosseous amputations whenever possible; (4) preserve the knee joint whenever possible; (5) stabilize and normalize the proximal portion of the limb; and (6) be prepared to deal with issues in addition to limb deficiency in children with other clinically important conditions (25).

LLAs among children pose special challenges in the form of osseous overgrowth, which can lead to skin perforation, pressure ulcers, and difficulty with prosthesis fitting. Consequently, numerous surgical revisions may be required to address such issues from time to time (26).

Hospital mortality was found to be 4.68% in the current study. Between 4% and 22% of LLA patients die within the first year after surgery (27).

Strengths and limitations

The current study has certain strengths as well as some limitations. The first strength is that it is focused on the descriptive epidemiology of nontraumatic LLAs in clinical setting. Second, it provides valuable information by

comparing the demographic and clinical characteristics of diabetics and nondiabetic patients presenting for amputations. One limitation of the study is that it does not seek to demonstrate a relationship between the results of preoperative imaging and the level of amputations that the patients ultimately received. The author would suggest a future well- designed study to address this research gap. This would be useful in establishing the predictive role of preoperative imaging studies among diabetic patients in predicting the final level of amputation.

Conclusion

Patients with diabetic foot gangrene, malignant tumors, and chronic neuropathic ulcers with osteomyelitis constituted the bulk of the amputees. DM, obesity, and hypertension were the commonest comorbidities identified among them. Public awareness and education would ensure prompt and early health seeking at the appropriate time and help to prevent the need for major amputations in many instances. Provision of robust rehabilitation to the amputees would help to ensure their better reintegration in the society, rendering them productive members of the society.

Acknowledgement

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Author's Contributions

M.S. designed the study and wrote the manuscript. He performed data collection, analyzed the results, and approved the manuscript.

Conflict of Interests

The authors declare that they have no competing interests.

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