INDICATIONS AND SHORT TERM OUTCOMES OF MAJOR LIMB AMPUTATIONS AT THE UNIVERSITY TEACHING HOSPITALS-ADULT AND EMERGENCY HOSPITAL, LUSAKA, ZAMBIA

BY

MILDRED NAKAZWE

A dissertation submitted to the University of Zambia in partial fulfilment of the requirements of the Degree of Master of Medicine in General Surgery

THE UNIVERSITY OF ZAMBIA

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DECLARATION

I, Mildred Nakazwe, hereby declare that this dissertation entitled "**Indications and Short term Outcomes of Major Limb Amputations at the University Teaching Hospital-Adult Hospital, Lusaka"** represents my work and has not been presented either wholly or in part for a diploma or degree at the University of Zambia or any other institution elsewhere.

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CERTIFICATE OF APPROVAL

This dissertation by Dr Mildred Nakazwe has been approved as partial fulfilment of the requirements for the award of Master of Medicine in General Surgery by the University of Zambia.

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ABSTRACT

Introduction: Limb amputation is the surgical removal of all or part of a limb or extremity such as an arm, leg, foot, hand, toes or fingers. A major limb amputation is performed proximal to the wrist or ankle. There are various indications and short term outcomes for major limb amputations. Limb amputations can lead to poor outcomes such as morbidity, high cost on the patients and their families and an increase in the Disability Adjusted Life Years (DALY's) and mortality. Therefore this study was aimed at assessing the indications and short term outcomes of major limb amputations at UTH-Adult hospital, Lusaka, Zambia.

Methodology: This was a cross-sectional study with a 30 days follow-up after amputation was done. A data collection tool was administered after the amputation was done to collect demographics, indications that led to the amputation, information on the operation as well as any complications that occurred. The patient was followed up on day 1, 7, 14 and 30 while in the hospital and the outpatient clinic. The data collected was analysed using STATA version 13.

Results: A total of 80 patients recruited into the study and 43(53.8%) were males and 37(46.3%) were females. The mean age of the patients was 52.2(SD, 17). The most common indication was found to be diabetic foot 36 (45%). Only 9(11.3%) were amputated due to trauma. Out of the 80 patients, 54(67.5%) developed a complication, 48 (88.9%) had local complications and 11(20.4%) had systemic complications. The most common complication was surgical site infection alone 24 (44.4%), followed by those that had multiple 13 (24.1%) then phantom limb pain (16.7%). Renal complications accounted for 6(11.1%) of those that developed a complication. The 30-day mortality rate was 18.8% with sepsis being the most common cause of death, followed by septic shock and acute kidney injury.

Conclusion: The main indication for major limb amputations at UTH was diabetic foot and trauma was amongst the least. The most common postoperative complication was surgical site infection. The 30-day mortality rate was 18.8% with sepsis being the main cause of death.

Recommendation: Formation of diabetic foot clinics in the primary health centres to diagnose and treat complications of diabetes that may lead to limb amputation.

Keywords: *Indications, short term outcomes, limb, amputations, University Teaching Hospital, Zambia*

DEDICATION

To my mother, Norma Devonish-Sikazwe and my late father, Mr Oswald Fwambo Sikazwe.

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ABBREVIATIONS AND ACRONYMS

AKA	Above Knee Amputation
AKI	Acute Kidney Injury
BKA	Below Knee Amputation
DM	Diabetes Mellitus
HIV	Human Immunodeficiency Virus
HTN	Hypertension
IV	Intravenous
NCD	Non Communicable Diseases
USA	United States of America
UTH	University Teaching Hospital

DEFINITION OF TERMS

Critical limb ischemia : the existence of rest pain or tissue loss due to severe peripheral arterial disease ("Critical Limb Ischemia: Current Trends and Future Directions,").

Surgical site infection: defined according to the Centres for Disease Prevention and Control (CDC) surgical site infection guidelines ("Complications post-amputation,")Which specifies the following:

1. Infection involves the skin, superficial and deep tissues of an incision AND

2. A patient has **at least one** of the following:

a. Purulent drainage from the incision

b. Organisms identified from the aseptically obtained specimen by culture or non-culture based testing for clinical diagnosis and treatment

c. The reopening of incision **AND** patient has **at least one** of the following signs or symptoms: pain or tenderness; localized swelling; erythema; or heat.

d. An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathological examination, or imaging test.

Haematoma: a localised collection of blood which can form in an organ, space or tissue.

American Society of Anaesthesiologists (ASA): A physical status classification system of a patient's physiological status that is used to predict operative risk. The 6 classes are as follows:

- **ASA 1**: A normal healthy patient.
- **ASA 2**: A patient with a mild systemic disease.
- **ASA 3**: A patient with a severe systemic disease that is not life-threatening.
- **ASA 4**: A patient with a severe systemic disease that is a **constant threat to life.**
- **ASA 5**: A moribund patient who is not expected to survive without the operation. The patient is not expected to survive beyond the next 24 hours without surgery.
- **ASA 6**: A brain-dead patient whose organs are being removed with the intention of transplanting them into another patient.(Doyle and Garmon, 2020)

Short Term : 30 days postoperative (Belmont, et al, 2011).

CHAPTER 1: INTRODUCTION

1.1 Background information

Amputation is the surgical removal of all or part of a limb or extremity such as an arm, leg, foot, hand, toes or fingers (Farquharson and Moran, 2005). Amputation surgery is one of the oldest surgical procedures dating back to the days of Hippocrates (Ndukwu, 2015). A major amputation is performed proximal to the wrist or ankle (Ajibade et al., 2013). There are various indications for amputation which can be put in three broad categories, the first being limb infarction, which can happen when the arterial occlusive disease is severe enough to cause infarction of macroscopic portions of tissue. The occlusion may be in a condition such as diabetes mellitus, atherosclerosis or embolic occlusion. Second, a life threatening limb such as wet gangrene, gas gangrene, spreading cellulitis and malignancy. Third would be a non-functioning limb such as severe resting pain, paralysis or contracture and major unrecoverable traumatic damage.

Peripheral arterial occlusive disease and diabetes account for more than 90% of amputations in the western world (Farquharson and Moran, 2005). The most common indications for limb amputations at UTH are trauma and diabetic-related complications followed by gangrene, infection and malignancy (Mangowela et al., 2015).

A study done in the USA stated that the most common levels of amputations for the upper limb are trans-radial (below elbow) and the trans-humeral (above elbow). Others are shoulder disarticulation, forequarter amputation and wrist disarticulation. The most common levels of amputation for the lower limb are the trans-tibial (below the knee) and

the trans-femoral (above the knee). Others are Gritti-Stokes (trans-condylar), hip disarticulation and through knee (Meier and Melton, 2014).

The surgeon must strive towards two primary goals, both of which are critical to the success of the procedure. The first goal is the removal of the diseased, damaged or dysfunctional portion of the limb. The second goal is the reconstruction of the remaining limb. Reconstruction must promote primary or secondary wound healing as well as create the most optimal sensory and motor end organ possible (Mbeckley, 2017).

Ideal outcomes are best achieved by a multidisciplinary team including physicians, nurses, physical and occupational therapists, prosthetics, psychologists, vocational counsellors and social workers (Meier and Melton, 2014). However, underlying disease state and postoperative management can result in complications.

Complications are defined as any deviation from the normal postoperative course (Dindo et al., 2004). These can either be local complications related to the surgery or systemic.

Local complications include haemorrhage, stump haematoma, infection, revision of amputation, wound dehiscence, flexion contractures. Systemic complications are mostly related to pre-existing conditions such as cardiac and pulmonary conditions. These can be acute cardiac events – arrhythmias, myocardial infarction, heart failure, pneumonia, venous thromboembolism or death (Williams et al., 2008).

For a valuable quality assessment, relevant data on outcome must be obtained in a standardized and reproducible manner to allow comparison among different centres, between different therapies and within a centre over time (Dindo et al., 2004). Therefore

the Clavein- Dindo classification of surgical outcomes will be used to classify the outcomes in this study.

This study was set out to assess the short term (30 days) outcomes of major limb amputations in adults at UTH and relate them to the indications of the procedure.

1.2 Statement of the Problem

The prevalence of non-communicable diseases (NCDs) is projected to increase by approximately 300% by the year 2030 (MOH 2008).

According to WHO, it is estimated in sub-Saharan Africa that from 2008 to 2030 deaths due to NCDs will increase from a total of 28% to 46%. WHO also projects that the total annual number of deaths from NCDs will increase to 55 million by 2030 if the current trend is not reversed (www.who.int/noncommunicable-diseases). Since NCDs such as diabetes, hypertension and cancer are risk factors for limb amputation, the rates of major limb amputations will increase as well. According to anecdotal data from UTH, more than 148 major limb amputations were carried out in 2017 alone. This number shows that the prevalence of amputations has increased from about 84 between 2013 and 2014 and this in turn potentially increases the complication rate. Limb amputations can lead to poor outcomes such as increased morbidity, high cost on the patients and their families as well as for the hospital. Furthermore, this can increase the Disability Adjusted Life Years (DALY's) and mortality.

1.3 Study Justification

Assessing indications and short term complications can enable clinicians to manage and evaluate ways to improve patient care to avoid or minimize the number of amputations and reduce post-operative complications. If indications and short term outcomes are known, they can potentially result in the reduction of length of hospital stay, reduced cost to both families and hospital, reduced morbidity and mortality. Further, the study can help in the development of protocols and standard operating procedures about management of patients with major limb amputation.

The study findings can also help policymakers for resource allocation and plan public health interventions to prevent major limb amputations.

1.4 Research Question

What are the indications and short term outcomes of major limb amputations in adults at the University Teaching Adult Hospital of Lusaka, Zambia?

1.5 Objectives

1.5.1 Main Objective

To assess the indications and short term outcomes of major limb amputations occurring in adults at UTHs-Adult and Emergency hospital, Lusaka, Zambia.

1.5.2 Specific Objectives

1. To investigate the indications in patients undergoing major limb amputations at the University Teaching Adult Hospital.
2. To determine the common short term local complications of major limb amputations.
3. To determine the common short term systemic complications of major limb amputations.
4. To determine the 30-day postoperative mortality rate and factors associated with major limb amputations at the University Teaching Hospitals- Adult and Emergency Hospital.

CHAPTER 2 LITERATURE REVIEW

Many studies have been done worldwide on the postoperative outcomes of major limb amputations.

2.1 Global perspective (these are studies outside Africa)

In a study done to quantify global variation in the incidence of lower extremity amputations in light of the rising prevalence of diabetes mellitus, an electronic search was performed using the EMBASE and MEDLINE databases from 1989 until 2010 for the incidence of lower extremity amputation in the United Kingdom and worldwide. The results showed that the incidence of all forms of lower extremity amputation ranged from 46.1 to 9600 per 10^5 in the population with diabetes compared with 5.8–31 per 10^5 in the total population. Major amputation ranged from 5.6 to 600 per 10^5 in the population with diabetes and from 3.6 to 68.4 per 10^5 in the total population (Moxey et al., 2011).

In the USA, nearly 2 million people are living with limb loss and the main causes are vascular disease (54%) including diabetes and peripheral arterial disease, trauma (45%) and cancer are responsible for less than 2%. Approximately 185,000 amputations occur in the United States each year ("Limb Loss Statistics," n.d.).

Aulivola et al. (2004) did a retrospective study in the United States of America during a 12-year period from January 1, 1990, to December 31, 2001. The study reported that 959 major lower extremity amputations were performed on 788 patients. Most amputations were performed for indications related to ischaemia from peripheral vascular disease. Co-morbid conditions included diabetes mellitus (DM) in 635 (80.6%), hypertension in 540

(68.5%), and end-stage renal disease (ESRD) in 133 (16.9%) patients. There were 704 (73.4 %) below knee amputations (BKAs) and 255 (26.6%) above knee amputations (AKAs) done. Complications noted were cardiac (10.2%), wound infection (5.5%), and pneumonia (4.5%). Twelve (4.7%) AKA and 129 (18.4%) BKA limbs required subsequent operation. Only 66 (9.4%) BKAs required conversion to AKA. The overall 30-day mortality was 8.6%, worse for AKA (16.5%) than BKA (5.7%) patients (P<0.001).

Another retrospective study done in the USA by Nehler and colleagues (2003) from August 1, 1997, through March 2, 2002, had 154 patients (from the Veterans Affairs Medical Centre) that underwent major lower extremity amputation. At presentation, 87% of patients (n = 134) had critical limb ischemia and 13% of patients (n = 20) had complications of diabetic neuropathy. One hundred and seventy-two major lower extremity amputations were performed (78 AKA, 94 BKA; 14 BKA were initial guillotine amputations). The median hospital stay was 14 days and 34 patients had one or more complications; the most frequently occurring are decubitus ulcers 10(6.5%), pulmonary 8(5.2%), cardiac 12(7.8%), sepsis 4(2.6%), bleeding 3 (1.9%) and renal 1(0.6%). Twenty-three patients had BKA and 16 had AKAs required additional operative revision, and 18 (19%) had BKA ultimately was converted to AKA. In patients with pulmonary, cardiac, septic and renal complications, the perioperative mortality was 10.4%.

A study looking at the risk factors for the 30-day postoperative outcome of below-knee amputations was performed in 2,911 patients registered in the NSQIP (National Surgical Quality Improvement Program) database in the USA between 2005 and 2008. The most

commonly encountered medical comorbidities were history of wound infection (76.4%), peripheral vascular disease (69.8%), and diabetes (68.2%). In the first 30 days postoperatively, 205 (7.0%) patients died. In this same time period, 1,627 complications were documented in 1,013 (34.4%) patients. There were 1,156 major complications in 839 (28.8%) patients and 471 minor complications in 440 (15.1%) patients. The most common major complications were return to the operating room (15.6%), wound infection (9.3%), and postoperative sepsis (9.3%). The most common minor complications were superficial wound infection (5.3%), urinary tract infection (4.3%), and pneumonia (4.2%). Postoperative sepsis (31.7%), cardiopulmonary complications (23.9%), and return to the operating room (17.6%) were the most common complications among those who died (Belmont et al, 2011).

In Australia, Lim et al. (2006) conducted a retrospective audit of 87 cases of major lower limb amputations from January 2000 to December 2002 from the Department of Vascular Surgery at Royal Perth Hospital in Perth, Australia.. There were 51 below-knee (58.6%), 5 through-knee (5.7%) and 31 above-knee (35.6 %.) amputations. Co-morbid problems included diabetes (49.4%), smoking (81.6%), hypertension (77.0%), ischaemic heart disease (58.6%), stroke (25.3%), raised creatinine level (34.5%) and chronic airway limitation (25.3%). The main indication was critical limb ischaemia (75.9%) followed by diabetic infection (17.2%).

The overall wound infection rate was 26.4%. Revision rates were 17.6% for below-knee, 20% for through-knee and none for above-knee amputations. Twenty patients (23.0%) underwent subsequent contralateral amputation. Cumulative mortality at 30 days, was 10.1 %.

A study looking at short and long term mortality rates after lower limb amputations was conducted in all 14 hospitals of the three Northern provinces of the Netherlands. Each hospital compiled a list of all people who had an amputation at a transtibial level or proximal, in 2003 or 2004. Of 338 cases of lower limb amputations identified, 299 were due to a vascular, infection and/or diabetes related cause and were included for analysis. Twenty-two per cent of the population died within 30-days (Fortington et al., 2013).

In Bahrain, a prospective study was conducted from 1st May 2015 to 30th April 2016. A total of 45 patients were included in this study of which 47 major lower limb amputations were performed during the study period because two patients underwent bilateral amputation. Thirty-eight (84.4%) patients underwent amputations due to diabetes mellitus and its related complications, mainly due to diabetic neuropathy/infection 15 (31.9%), peripheral vascular disease with revascularization 6 (12.8%) and peripheral vascular disease without revascularization 17 (36.2%). Non-diabetic complications were acute ischaemia in 4 (8.8%), trauma in 2 (4.4%) and peripheral vascular disease with revascularization in 2 (4.4%) and without in 1 (2.2%). There were 32(68.1%) above knee, 1 (2.1 %) through knee and 14 (29.8%) below knee amputations. Seventeen (37.8%) patients had postoperative complications, surgical site wound infection (SSI) was the most common postoperative complication seen in 8 (17.8 %) patients. Other complications were phantom pain 1 (2.2%), wound infection 8 (17.8%), flexion contracture 1 (2.2%), stump necrosis 6 (13.3%), pulmonary embolism/deep vein thrombosis 1 (2.2%), respiratory complications 3 (6.7%) and cardiac complications 4 (8.9%). The overall 30-day mortality was 10.6% (AlQaseer, et al., 2017).

A retrospective study done in Iran looked at both upper and lower limb amputations. The records of patients amputated from April 2002 to December 2011 were reviewed. Of the upper limb amputations, (49) 62.8 % were major and (29)37.17 % minor. In the lower limb, 71(51.44 %) of amputations were major and 67(48.55%) minor, and this was not statistically significant (p = 0.141). The most common cause of amputations was trauma 117 (54.16%). Diabetes in 57 patients (26.38%) was the second cause of amputation; 23 (10.46%) had severe obstruction of blood vessels with or without gangrene or vascular embolism. The remainder of the amputations were due to infections (osteomyelitis or fasciitis) in 9 (4.1%), soft tissue sarcoma (1.84%), osteogenic sarcoma (1.38%), melanoma (0.46%), squamous cell carcinoma of the skin (0.46%) and congenital anomalies (0.46%). The median of hospital stay was 3 days, ranging from 1 to 54 days. Out of 216 patients, 12 (5.55%) died; 3 had a vascular cause of amputation, 3 were diabetic, 4 had trauma with other associated injuries and 2 were IV drug abusers with fasciitis. Postoperative complications occurred in 56 (25.92%) of patients. SSI was the most common postoperative complication occurring in 38 (17.59%) of patients. Amputation revisions were done for 18(8.33%) while 16 (7.4%) had wound haematoma, 10 (4.62%) phantom pain, 7 (3.24%) wound dehiscence, and 4 (1.85%) stump gangrene (Sarvestani and Azam, 2013).

2.2 Regional perspective

In Africa, a retrospective study was done in Rwanda of limb amputations done at the University Teaching Hospital in Butare (UTH-B), Rwanda, from 1st January 2009 to 31st March 2012. A total of 3466 cases were operated in the Surgery Department. Of these, 107 were limb amputations accounting for 3.08%. BKA done in 37.38% of patients was

the most frequently performed procedure and this was followed by AKA in 35.5%. The study showed that gangrene was the most common indication accounting for 43.95% especially dry gangrene with 22.43% as the most common gangrene, wet gangrene was found in 14.95%, gas gangrene accounted for 1.87% and unspecified gangrene accounted for 4.7%. The second most common indication was malignancy which accounted for 28.9%. Malignant melanoma was the most common malignancy with 7.5% followed by osteosarcoma with 6.5%. Trauma was the third leading indication with 13.08%. The study further showed that the majority (87.9%) of the patients had an uneventful recovery while 7.5% of the patients were re-operated. Infected or necrotized amputation stump was the reason for re-amputation. The postoperative mortality rate was 4.7% with sepsis being the cause of death in all the cases (Murwanashyaka et al., 2013).

A similar retrospective study of major limb amputations was conducted in Nigeria from January 2006 to December 2010. Major limb amputations were performed in 132 patients. There were 98 (74.2%) lower limb amputations and 34 (25.8%) upper limb amputations. All the amputations were unilateral. In one patient a below knee amputation was converted to above knee amputation because of ascending sepsis. The commonest indication was trauma (42.4%) followed by traditional bone setter gangrene (31.8%) and malignant tumours (12.9%). Diabetic foot gangrene accounted for only 4.5% of the amputations. The complications seen were wound infection 17(41.5%), phantom limb pain 6(14.6%), stump pain 4(9.8%), wound dehiscence 4(9.8%), stump osteomyelitis 3(7.3%), stump overgrowth 2(4.9%) and phantom limb sensation 2(4.9%). A painful bone spur, hypertrophic scar and severe depression were found in 1(2.4%) respectively. There

were 3 deaths, giving a mortality rate of 2.3%. Two deaths were caused by septicaemia while one was due to severe tetanus (Ajibade et al., 2013).

In Tanzania, a cross-sectional descriptive study done by Chalya and others (2012) involving all patients who underwent major limb amputations at Bugando Medical Centre between March 2008 and February 2010 found a total of 162 patients underwent major limb amputations during the study period. Complications of diabetes mellitus (the majority were Wagner's classification stage 4 & 5) was the main indication for the major limb amputations in 68 (41.9%) patients followed by trauma in 62 (38.4%) patients and vascular disease in 14 (8.6%) patients. The major indications for upper limb amputations were trauma (42.3%) and malignancies (24.6%) while diabetic gangrene (45.5%) and trauma (32.2%) were the most common causes of amputation in lower limbs. Lower limbs were involved in 140 (86.4%) cases and upper limbs in 22 (13.6%) cases. There was no bilateral limb amputation. A total of 46 patients (28.4%) required additional procedures. The most common additional procedures performed were wound debridement, secondary suture and skin grafting in 42.3%, 34.5% and 23.2% respectively. Two-stage operation (e.g. initial guillotine amputation and later stump revision or change of amputation level from below to above) was required in 45.4% of patients. Post-operative complications occurred in 54 patients (33.3%) with surgical site infection (21%) being the most common, followed by amputation revision (9.9%), phantom pain (5.6%) and wound haematoma (4.3%). Others were wound dehiscence (3.1%) and stump gangrene (1.9%). The hospital stay of patients ranged from 9 to 58 days with the mean duration of 22.4 days and the mortality rate was 27 (16.7%). The main cause of deaths were complications of diabetes

in 42.8% of cases, wound sepsis in 40.5%, advanced malignancy with metastasis in 4.7% and not established in 2.8% of cases.

2.3 Local perspective

In Zambia, there has been an increase in the burden of NCDs such as Diabetes Mellitus, Hypertension and trauma. The incidence of DM has increased from 2.5 % in 2009 to 6.4% in 2011(Kasonde, 2013).

In Zambia, a prospective study was conducted by Tembo (2000) at UTH between October 1997 and April 1999.The study looked at the indications and complications of major lower limb amputations. Rays amputation was considered as a major amputation. There were 22 above knee amputations and 17 below knee amputations. The most common indications were trauma 17(33.5%), dry gangrene 12 (22%), tumours 5(9%) and diabetes mellitus 5(9%). The most common outcome out of 54 lower limb amputations done was primary healing before discharge in 21(39%) of the patients. Infection was found in 14(26%) of the patients and 8(15%) had stump revision. Other complications were haemorrhage, wound dehiscence and phantom limb pain. There were 4(7%) mortalities recorded, 2 of which were due to severe infection and the rest related to trauma and diabetes mellitus.

In a more recent study, done by (Mangowela, 2015), a total of 84 amputations were done over 24 months at UTH and the most common indication for limb amputations was trauma (29.8%) and diabetic related complications (21.4%). These were followed by gangrene, infection and malignancy.

From the above literature review, the most common indication of major limb amputation was trauma and diabetic foot complications. The common short term outcomes observed ere wound dehiscence, surgical site infection and stump revision.

In Zambia, the current anecdotal data suggested that the number of major limb amputations performed was increasing, however the indications and short term outcomes as well as 30-day mortality are not well known. Therefore, this study was set out to assess indications, short term outcomes and 30-day mortality for patients who underwent major limb amputation at the University Teaching Hospitals-Adult and Emergency Hospital, Lusaka, Zambia.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This part of the dissertation provides detailed descriptions of the methods that were used in the study. Important aspects to be described include the data collection techniques, and procedures implemented to collect and analyse the data.

3.2 Study design

This was a cross-sectional study with patients followed longitudinally. Patients were recruited into the study after the amputation was done and followed up for 30-days.

3.2.1 Study site

The study was conducted in the Department of Surgery at the Adult and Emergency Hospitals of the University Teaching Hospitals (UTH), Lusaka, Zambia

3.2.2 Study duration:

The study was conducted over 12 months.

3.2.3 Inclusion and exclusion criteria

Inclusion criteria:

- Patients aged 18 years and above scheduled for major limb amputation by the attending doctors.
- All patients consented to be part of the study.

Exclusion criteria:

- All patients below the age of 18 years.

3.2.4 Sampling

Sampling technique: The Yamane formula was used.

n = N / (1 + Ne^2)

Where

n= corrected sample size, N = population size (90), and e = Margin of error (MoE), e = 0.05

The total sample size was **80** (73 plus 10% attrition rate).

Sampling method: Consecutive sampling was used on all patients meeting the inclusion criteria.

3.3 Methodology

All patients planned for major limb amputation were managed by the admitting firm preoperatively, intraoperatively and postoperatively. The procedure was done by a registrar or consultant or senior resident medical officer. Patients were enrolled into the study after the procedure. Patients who refused to consent for inclusion in the study still received the standard treatment.

3.4 Data collection technique

A data collection sheet was used to obtain data on demographics (such as age, sex, and education level and occupation status) and clinical data (such as indications, level of

amputation, postoperative complications, length of hospital stay, 30-day mortality). Data on known co-morbid conditions such as diabetes mellitus, hypertension and HIV were also obtained.

The complications were divided as local and systemic complications and the Clavein-Dindo classification of surgical outcomes was used as a standard for determining the type and grade of complication (Dindo et al., 2004).

They were then followed up while on the wards and in the outpatient clinic for 30 days postoperatively. Follow up was done on day 1, day 7, day 14 and day 30 postoperatively. Patients that did not come for reviews, were followed up by calling the phone number entered on the data collection sheet.

The endpoint for follow up was either at the end of 30 days or the occurrence of death.

3.5 Data processing and analysis

Data Entry: The data collected was entered into an Excel spread-sheet for analysis and was only accessible by the researcher, supervisor and research ethics committee if required.

Data analysis was done using STATA version 13. Statistical significance was defined by p-value <0.05 and 95% confidence interval.

Normality of data was tested using the Shapiro- Wilk test

Continuous variables such as age and length of hospital stay were normally distributed and analysed using means and standard deviation. Duration of symptoms was not normally distributed, so median and interquartile range was used.

Categorical variables such as diabetes mellitus, HIV, smoking and association with the outcomes such as the occurrence of a complication, mortality and stump revision were analysed using Chi-square test. Indication of amputation and association with complication was analysed using the Fishers exact test.

To rule out confounders, multiple logistics regression was used.

3.6 Variables

Dependent variable – The short term outcomes Haemorrhage, Haematoma, Surgical site infection, Wound dehiscence, venous thrombosis, Pneumonia, Phantom limb pain, Stump revision and Death

Independent variable – Age, Sex, Level of education, DM, HTN, HIV, Duration of symptoms, Level of amputation, Indication for amputation, Length of hospital stay, Smoking and Alcohol

3.7 Ethical considerations

The study was conducted according to principles of research on human subjects: informed consent, beneficence, respect for anonymity and confidentiality, respect for privacy.

Risks: Apart from the standard surgical procedure of major limb amputations, there were no direct risk or injury associated with this study.

Benefits: There were no direct benefits for the patients. The patients did not receive any special treatment and financial benefits for participating in the study. All procedures, investigations and follow up were as per standard routine management.

Voluntarism: Participation in this study was completely voluntary. No coercion was used. If at any time, the patient felt inconvenienced by participation, they were free to withdraw from the study at any time without having to give a reason and there was no implication on their management.

Informed Consent: A written informed consent was obtained from each patient before their enrolment in the study.

Confidentiality: Confidentiality was strictly observed. Patient's names were not saved, codes were assigned instead. Collected data was only accessible by the researcher, and kept under lock and key. Once data had been transferred onto a soft copy, it was protected by a password only known to the researcher.

Having met the above requirements, ethical approval was sought from ERES Converge IRB (Ref: No. 2018-Oct-010). Thereafter, permission was obtained from UTH management and the Department of Surgery.

CHAPTER FOUR: RESULTS

4.1 Background

This chapter provides the findings of this study. The main objective of the study was to assess the indications and short term outcomes of major limb amputations occurring in adults at UTH-Adult and Emergency hospital. The specific objectives were to investigate the indication in patients undergoing major limb amputations, to determine the common short term local and systemic complications of major limb amputation and to establish the 30-day postoperative mortality rate in patients undergoing major limb amputations at the University Teaching Hospitals- Adult and Emergency Hospital.

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4.2 Socio-demographic characteristics of study participants

In this study, there were **80** patients and the mean age was **52.2** (SD, 17.0) years with 43(53.8%) of patients being male. Slightly over half (42) of the patients did not attain a secondary school education and about three quarters 59 (73.8%) were not in formal employment.

Majority of the patients did not smoke (60) or take alcohol (45). All patients underwent diagnostic counselling and testing for HIV, except those whose status was already known. It was found that 21 (26.3%) were positive**.** The results are shown in Table 4.1.

Table 4.1: Socio-demographic characteristics of study patients

Variable	Category	Proportion (%)
Age* (years)	52.2 (SD,17.0)	
Sex	Male	43 (53.8)
	Female	37 (46.3)
Education	Primary and below	42 (52.5)
	Secondary	29 (36.3)
	Tertiary	9 (11.3)
Employment status	Unemployed	59 (73.8)
	Employed	21 (26.3)
Smoking	No, never	60 (75)
	Stopped	10 (12.5)
	Yes, currently	10 (12.5)
Alcohol	No, never	45 (56.3)
	Stopped	18 (22.5)
	Yes, currently	17 (21.3)
HIV status	Negative	59(73.8)
	Positive	21 (26.3)

*mean and standard deviation reported; SD- Standard deviation

4.3 Clinical characteristics

The median duration of symptoms among the patients was 21days (IQR, 14-60). In this study 38(47.5%) were diabetic, 21(26.3%) hypertensive. Of the 80 patients, 57(71.3%) were managed by general surgeons (Table 4.2).

Table 4.2 Clinical characteristics

Variable	Category	Proportion (%)
Duration of symptoms* (days)	21 (IQR, 14-60)	
Diabetic	No	42 (52.5)
	Yes	38 (47.5)
Hypertensive	No	59 (73.8)
	Yes	21 (26.3)
Surgical Specialty	Orthopaedics	23 (28.8)
	General surgery	57 (71.3)
Pre-operative Hb**	9.6 (SD,2.4)	

* median and interquartile range reported; ** mean and standard deviation reported; IQR – Interquartile range; SD –Standard deviation; HB – Haemoglobin;

4.4 Operative information

It was found that about two thirds 53 (63%) of the amputations done were emergency cases and 65(81.3%) were performed by a Registrar. The most common indication for amputation was wet gangrene 20(25%), followed by diabetic foot 18(22.5%). Other indications which accounted for 17(21.3%) of the amputations included infections secondary to open tibia fractures, malignancy and burns. The most common site for amputation was the lower limbs with 38(47.5%) being above knee amputation. Sixty-eight (85%) of patients had an estimated blood loss of >100-500mls and 74(92.5%) were admitted to the general ward after the operation, with the rest being admitted to the main intensive care unit (Table 4.3).

Table 4.3 Operative information for the patients

Variable	Category	Proportion (%)
Type of Operation	Elective	27 (33.8)
	Emergency	53 (66.3)
Surgeon	Registrar	65 (81.3)
	Senior registrar	8 (10)
	Consultant	2 (2.5)
	Other	5 (6.3)
Indication for amputation	Diabetic foot	18 (22.5)
	Dry gangrene	7 (8.8)
	Wet gangrene	20 (25)
	Gas gangrene	9 (11.3)
	Trauma	9 (11.3)
	Others	17 (21.3)
Level of amputation	Above Knee	38 (47.5)
	Below Knee	28 (35)
	Upper limb	7 (8.6)
	Others	7 (8.6)
Side of Operation	Left	44 (55)
	Right	35 (43.8)
	Bilateral	1 (1,3)
Blood loss(mls)	0-100	8(10)
	>100-500	68(85)
	>500-1000	4(5)
Post-operative ward	General ward	74 (92.5)
	Main Intensive Care Unit	6 (7.5)

4.5 Outcomes of the Major Limb Amputation

Out of the 80 patients, 54(67.5%) had a complication. Surgical site infection alone was noticed in 24(44.4%) of the patients, however, 13(24.1%) had multiple local complications. Surgical site infection was noted in all the patients with multiple complications. Eleven of the patients had systemic complications with 6 (11.1%) having renal complications.

Stump revision was done in 13(16.3%) of the patients. The most common indications were infected below knee amputation 4(30.1%), below knee guillotine amputation 3(23.1%) and above knee guillotine amputation 3(23.1%). Secondary suturing was done in 6(46.2%) of patients requiring stump revision and above knee amputation was done in 4(30.8%) of the patients.

The mean length of hospital stay postoperatively was 13 days (SD 10) with 31 (38.8%) mobilizing in a wheelchair. The thirty-day mortality rate was 15(18.8%) and the most common cause of death was sepsis 7(46.7%). Other causes of death were pulmonary embolism and cardiac arrest (Table 4.4)

Table 4.4 Outcomes of Major Limb Amputations

Variable	Category	Proportion
Complication	With complication	54(67.5)
	Without complication	26(32.5)
Local complications	Surgical site infection	24(44.4)
	Wound dehiscence	2(3.7)
	Phantom limb pain	9(16.7)
	Multiple	13(24.1)
Systemic complications	Renal	6(11.1)
	Respiratory	2(3.7)
	multiple	3(5.6)
Stump revision	Yes	13(16.3)
	No	67(83.8)
Procedure	Secondary suturing	6(46.2)
	Split thickness skin graft	2(15.4)
	Above knee amputation	4(30.8)
	Above elbow amputation	1(7.7)
Length of hospital stay*	13(SD,10)	
Mobility on discharge	Crutches	17(21.3)
	Wheelchair	31(38.8)
30-day mortality	Alive	65(81.3)
	Dead	15(18.8)
Cause of death	Acute Kidney Injury	2(13.3)
	Sepsis	7(46.7)
	Septic shock	2(13.3)
	Others	4(26.7)

* Mean and standard deviation (SD) reported

4.6 Association between complication and independent variables

There was no association between complication with sex, education, diabetes, the indication of the amputation and the level of the surgeon who performed the operation because the p-values were greater than 0.05 (Table 4.5). Figure 4.1 shows an association between duration of symptoms and whether a complication occurred or not

Table 4.5 Association between the complication and the variables

Variable	Complication N (%)	No Complication N (%)	P-value
Sex			
Male	28 (65.1)	15 (34.9)	0.624
Female	26 (70.3)	11 (29.73)	
Education			
Primary and below	26 (61.9)	16 (38.1)	0.509
Secondary	21 (72.4)	8 (27.6)	
Tertiary	7 (77.8)	2 (22.2)	
Employed	15(71.4)	6(28.6)	0.654
Not Employed	39(66.1)	20(33.9)	
DM*			
No	27(64.2)	15(35.7)	0.519
Yes	27(71.1)	11(28.95)	
HTN**			
No	39(66.1)	20(33.9)	0.654
Yes	15(71.4)	6(28.6)	
HIV***			
Negative	39(66.1)	20(33.9)	0.654
Positive	15(71.4)	6(28.6)	
Smoking			
No, never	43(71.7)	17(28.3)	
Stopped	6(60)	4(40)	0.345
Yes	5(50)	5(50)	
Alcohol			
No, never	33(73.3)	12(26.7)	
Stopped	10(55.6)	8(44.4)	0.381
Yes	11(64.7)	6(35.3)	
Specialty			
Orthopaedics	17(73.9)	6(26.1)	0.437
General Surgery	37(64.9)	20(35.1)	
Type of operation			
Elective	19(70.3)	8(29.6)	0.696
Emergency	35(66)	18(33.9)	

Table 4.5 Association between complication and the variables (continued)

Variable	Complication N (%)	No Complication N (%)	P-value
ASA****			
1	3(100)	0(0)	
2	34(60.7)	22(39.3)	0.226
3	13(81.2)	3(18.75)	
4	4(80)	1(20)	
Surgeon			
Registrar	44(68)	21(32.3)	
Senior registrar	6(75)	2(25)	0.408
Consultant	2(100)	0(0)	
Other	2(40)	3(60)	
Indication for amputation			
Diabetic foot	15(83.3)	3(16.7)	
Dry gangrene	4(57.1)	3(42.9)	
Wet gangrene	11(55)	9(45)	0.391
Gas gangrene	7(77.8)	2(22.2)	
Trauma	7(77.8)	2(22.2)	
Others	10(58.8)	7(41.2)	
Level of amputation			
Above Knee	25(65.8)	13(34.2)	
Below Knee	21(75)	7(25)	0.431
Upper limb	3(42.9)	4(57.1)	
Others	5(71.4)	2(28.6)	

*DM-Diabetes Mellitus, **HTN-Hypertension, ***HIV-Human Immunodeficiency Virus, ****ASA-American Society of Anaesthesiologists

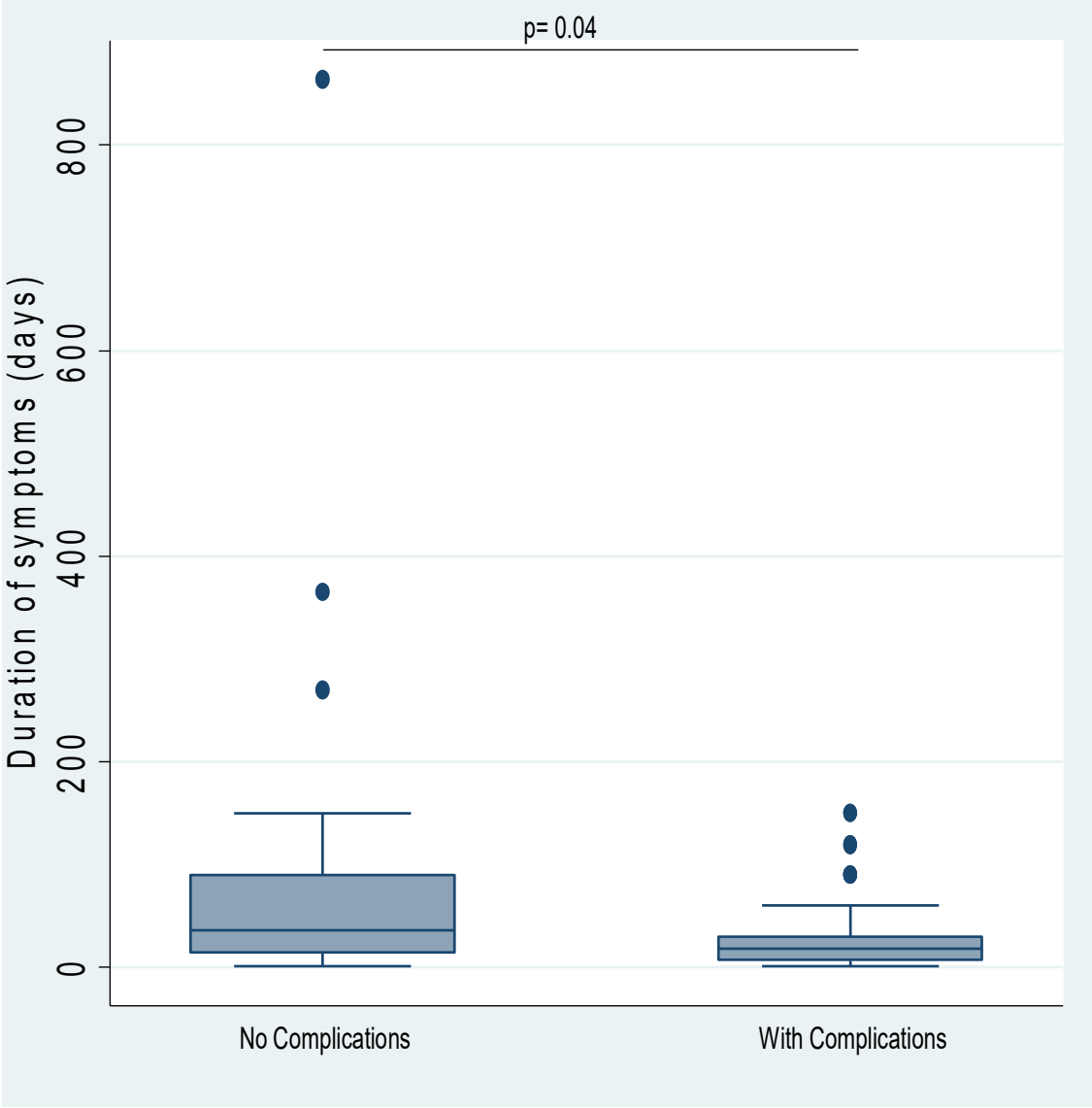

Figure 4.1: Comparison of duration of symptoms between patients with complications and those without complication

4.7 Comparison between the length of stay between those who died and those did not

The median length of hospital stay for patients that died was 4(IQR, 2-8) and for those who were alive at the end of 30 days was 11 (IQR, 7-28) as shown in figure 4.2

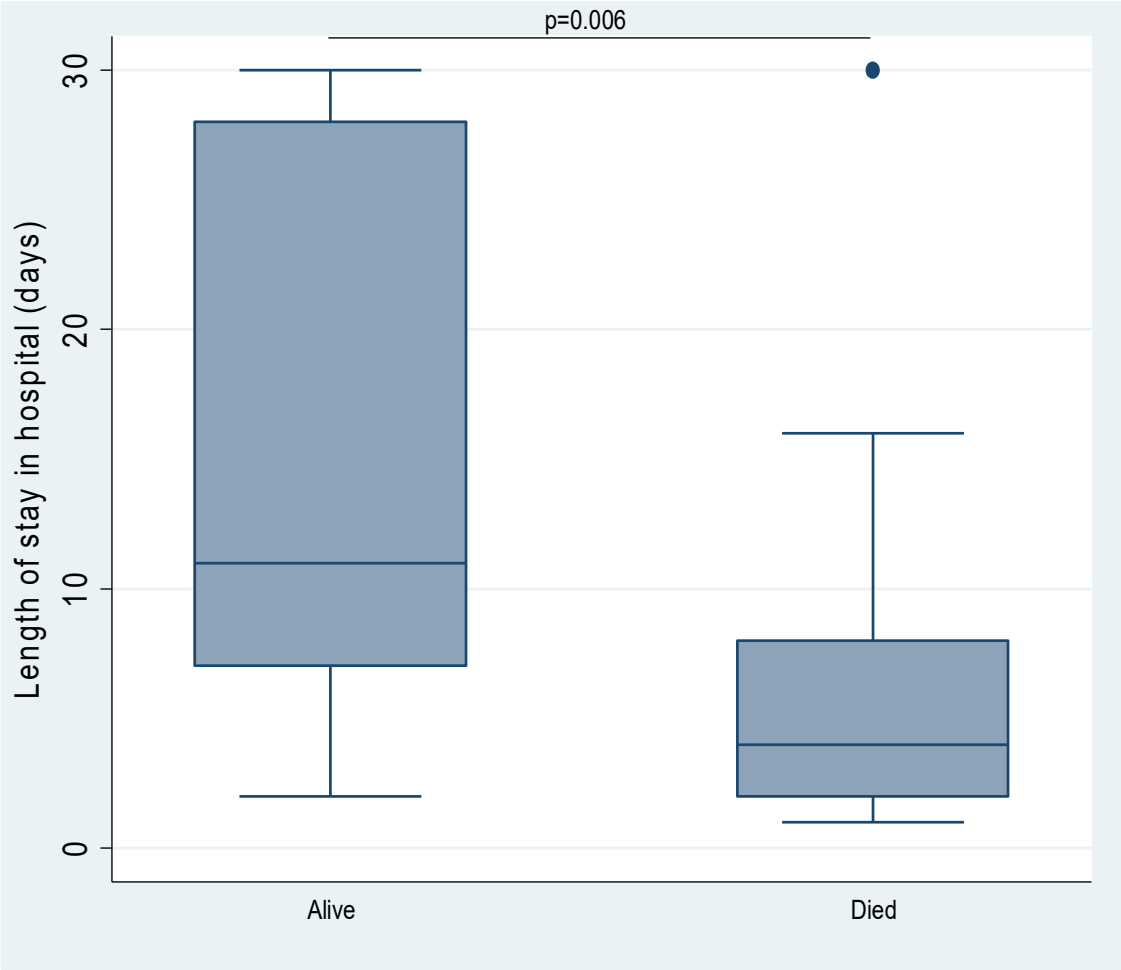

Figure 4.2: Comparison of length of stay between the length of stay and mortality

4.8 Association between mortality and independent variables

There was no significant association between diabetes mellitus (p=0.282) and HIV (p=0.207) with mortality, however, 9 of the patients who died were diabetic and only 2 were HIV positive. The ASA status had a significant association with mortality (p=0.001) and showed that the percentage of patients who died increased as the ASA status increased. Amongst the participants managed by general surgeons, 14(24.6%) died and only 1(4.4%) under orthopaedics died.

Though no significance was found between indication and mortality (p=0.292), 4(44.4%) of the patients with gas gangrene died, 4(20%) with wet gangrene and 3 (16.7%) with diabetic foot died. However, no trauma patients died (Table 4.6)

Table 4.6 Association between Mortality and independent variables

Variable	Dead N (%)	Alive N (%)	p-value
Diabetes Mellitus			
Diabetic	9(23.4)	29(76.3)	0.282
Not Diabetic	6(14.29)	36(85.7)	
HIV*			
Positive	2(9.5)	19(90.5)	0.207
Negative	13(22)	46(78)	
ASA**			
1	0(0)	3(100)	
2	6(10.7)	50(89.3)	0.001
3	5(31.3)	11(68.6)	
4	4(80)	1(20)	
Specialty			
General Surgery	14(24.6)	43(75.4)	0.036
Orthopaedics	1(4.4)	22(95.7)	
Indication			
Diabetic foot	3(16.7)	15(83.3)	
Dry gangrene	1(14.3)	6(85.7)	0.292
Wet gangrene	4(20)	16(80)	
Gas gangrene	4(44.4)	5(55.6)	
Trauma	0(0)	9(100)	
Others	3(17.7)	14(82.4)	

*HIV –Human Immunodeficiency Virus, ***ASA – American Association of Anaesthesiologists)

4.9 Association between Diabetes Mellitus and the indications for amputation

None of the patients with dry gangrene and trauma was diabetic, however, 11(55%) of the patients with wet gangrene and 7(77.8%) of the patients with gas gangrene were diabetic (Table 4.7).

Table 4.7 Association between Diabetes Mellitus and indications for amputation

Variable	Diabetic N (%)	Non Diabetic N (%0	p-value
Indications			
Diabetic foot	18(100)	0(0)	
Dry gangrene	0(0)	7(100)	0.000
Wet gangrene	11(55)	9(45)	
Gas gangrene	7(77.8)	2(22.2)	
Trauma	0(0)	9(0)	
Other	2(11.8)	15(88.2)	

4.10 Association between HIV and the indications for amputation

The association between HIV and the indication for amputations was significant (p=0.016). Amongst those with dry gangrene, 3(42.9%) were HIV positive as well as 8 (40%) of the patients with wet gangrene (table 4.8).

Table 4.8 Association between HIV and the indications for amputation

Variable	HIV positive N (%)	HIV negative N (%)	p-value
Indications			
Diabetic foot	3(16.7)	15(83.3)	
Dry gangrene	3(42.9)	4(57.1)	
Wet gangrene	8(40.0)	12(60.0)	0.016
Gas gangrene	2(22.2)	7(77.8)	
Trauma	5(55.6)	4(44.4)	
Other	0(0.0)	17(100.0)	

4.11 Multiple logistic regression analysis of complication with independent variables

Though not significant (p=0.624), females are 27% more likely to develop a complication compared to males. The odds of hypertensives developing a complication post-amputation is 3.25 higher than non-hypertensives, however, it is not significant. Those with trauma were 99% less likely to develop complications compared to those with diabetic foot and this was found to be significant (OR-0.01, [CI-0.0-0.26], p=0.08). Another significant finding was that those with wet gangrene were 89% less likely to develop a complication compared to those with diabetic foot (OR-0.11, [CI0.02-0.77], p=0.026). Those that underwent BKA were 56% more likely to develop a complication compared to those that

had AKA done, though this was not statistically significant (OR-1, 56, [CI-0.53-4.62], p=0.423) as shown in Table 4.9.

Table 4.9. Multiple logistic regression analysis of complications with independent variables

Variable	OR	95% CI	p-value
Age(years)	0.96	0.90-1.02	0.203
Sex			
Male	Ref		
female	1.27	0.49-3.25	0.624
Duration of symptoms(days)	0.99	0.90-1.02	0.105
DM*			
Not diabetic	Ref		
Diabetic	0.98	0.15-6.22	0.984
Hypertension			
Not hypertensive	Ref		
Hypertensive	3.25	0.46-23.15	0.239
HIV**			
Negative	Ref		
Positive	2.85	0.53-15.5	0.224
Indication			
Diabetic foot	Ref		
Dry gangrene	0.33	0.02-5.98	0.453
Wet gangrene	0.11	0.02-0.77	0.026
Gas gangrene	0.22	0.02-3.06	0.264
Trauma	0.01	0.00-0.26	0.008
Others	0.23	0.02-2.45	0.223
Length of stay(days)	1.17	1.04-1.32	0.009
Level of amputation			
Above knee			
Below knee	Ref	0.53-4.62	0.423
Upper limb	1.56	0.08-2.01	0.260
Others	0.39	0.22-7.64	0.772
	1.3		

*DM-Diabetes Mellitus, **HIV-Human Immunodeficiency Virus

4.12 Multiple logistic regression analysis of mortality with independent variables

Females were 42% more likely to die compared to males. Diabetics were 86% more likely to die than non-diabetics, however, this was not significant. The odds of hypertensive dying was 3.19 more than non-hypertensive and this was found to be significant (p=0.053). Though not significant, the odds of those with gas gangrene dying compared to those with diabetic foot was 4. One significant finding was that those who underwent BKA were 82% less like to die compared to those who had AKA

Table 4.10. Multiple logistic regression analysis of mortality with independent variables

Variable	OR	95% CI	p-value
Age(years)	1.02	0.99-1.06	0.180
Sex			
Male	Ref		
female	1.42	0.46-4.37	0.543
Duration of symptoms(days)	0.99	0.98-1.01	0.323
DM*			
Not diabetic	Ref		
Diabetic	1.86	0.59-5.84	0.286
Hypertension			
Not hypertensive	Ref		
Hypertensive	3.19	0.98-10.31	0.053
HIV**			
Negative	Ref		
Positive	0.37	0.07-1.81	0.221
Indication			
Diabetic foot	Ref		
Dry gangrene	0.83	0.07-9.69	0.884
Wet gangrene	1.25	0.24-6.54	0.792
Gas gangrene	4	0.66-24.37	0.133
Trauma	1		
Others	1.07	0.18-6.22	0.939
Level of amputation			
Above knee	Ref		
Below knee	0.12	0.01-1.01	0.051
Upper limb	1		
Others	8.06	1.33-48.85	0.023

*DM-Diabetes Mellitus, **HIV-Human Immunodeficiency Virus

4.13 Clavein-Dindo Classification of the Local and Systemic Complications

Most of the patients who developed SSI had a Clavein–Dindo grade of 1 (44.4%) and thus required the release of sutures on the ward, however, 47.7% required surgical intervention with a grade of 3. Amongst those that developed wound dehiscence, 50 % had a Clavein-Dindo grade of 3 and required surgical intervention. All the patients that had phantom limb pain (17) did not require any pharmacological intervention. Only one participant developed a cardiovascular complication of grade 4 and thus required MICU admission. Seven patients (87.5%) developed deranged creatinine values only at a grade of 1. There were 2(40%) patients who had a grade 4 respiratory complication (Table 14.11)

Table 4.11 Clavein-Dindo Classification of the Complications

Grade	*SSI N (%)	Wound dehiscence N (%)	Phantom limb pain N (%)	Cardiovascular system N (%)	Renal N (%)	Respiratory N (%)
1	16(44.4)	3(30.0)	17(100.0)	0(0)	7(87.5)	1(20.0)
2	5(13.9)	2(20.0)	0(0)	0(0)	1(12.5)	1(20.0)
3	15(41.7)	5(50.0)	0(0)	0(0)	0(0)	1(20.0)
4	0(0)	0(0)	0(0)	1(100)	0(0)	2(40.0)

*SSI-Surgical Site Infection

4.14Association between Surgical Site Infection (SSI) and diabetes mellitus

Half (8) of the patients who developed grade 1 SSI were diabetic, 60 %(3) of those with grade 2 SSI and 60%(9) of those with grade 3 SSI were also diabetic. This is seen in table 4.12

Table 4.12 Association between DM and SSI

	*SSI Clavein-Dindo grade			
	1	**2**	**3**	**P value**
Non Diabetic	8 (50)	2(12.5)	6(37.5)	0.8.35
Diabetic	8(40)	3(15)	9(45)	

*SSI- Surgical Site Infection

CHAPTER 5: DISCUSSION

This study has shown that the common indications for major limb amputation at the UTH are wet gangrene and diabetic foot. The common short term complications are surgical site infection alone and phantom limb pain. About a quarter of the patients had more than one local complications. Renal complications were the most common systemic complications. The 30-day mortality was 18.8%, with sepsis being the most common cause of death. According to the Clavein-Dindo grading of complications, the most common grade for all complications noted was grade 1. The factors associated with short term outcomes were the length of hospital stay and the presence of severe infection.

In Zambia, the incidence of major limb amputations appears to be increasing. In a previous study done looking at indications of major limb amputations 19 years ago, a total number of 54 amputations were done over a period of 18 months giving an incidence of 3 amputations per month (Tembo, 2000). In another study done 4 years ago, a total number of 84 major limb amputations were done over a period of 24 months, giving an incidence of 7 amputations per month (Mangowela, 2015).

5.1 Socio-economic demographics

The mean age of the patients recruited into the study was 52.2years which is comparable with other studies, 59.2 years (Unnikrishman et al., 2017), however in Tanzania (Chalya et al., 2012) and Zambia (Tembo, 2000), the mean age was lower. This difference in age can be explained by the variation in the main causes of the major limb amputations that were found in these studies. Similar to previous studies done in Zambia, the majority of

patients were male, however, the ratio has reduced over the years, from 3:1 (Tembo, 2000) to 1.16:1 in this study. This is a similar finding in other studies (Kayssi et al., 2016; Nwosu et al., 2017). There has been no explanation found for the male preponderance, other than the fact that males are said to be more active and most likely to be involved in trauma compared to women. However, with the growing increase of NCDs, the ratio is reducing.

The median duration of symptoms prior to the amputation was 21 days. This long duration could be attributed to poor health seeking behaviour, delays in the referral system and no established diabetic foot clinics as well as poverty. It was found that almost three-quarters of the patients were unemployed. Education is another factor that contributes to the early seeking of healthcare, slightly over half the patients have either not been to school or only went up to primary school level. These were similar to a study done in Tanzania (Chalya et al., 2012)

5.2 Clinical characteristics

In this study, close to half of the patients were diabetic and slightly about a quarter were hypertensive, contrary to a study done in Canada that found 96% of patients were diabetic and 33% were hypertensive (Kayssi et al., 2016). However, all trauma patients were excluded from the study. This difference can be explained by a study done by Saeedi and colleagues (2019) looking at the global and regional prevalence of diabetes found that the prevalence of diabetes is higher in high income countries (10.4%) than low income countries (4.0%) hence it is expected to have a higher number of diabetics in Canada as compared to Zambia. Diabetics have a 28 times greater lifetime risk of having an amputation than non-diabetics (Calle-Pascual et al., 1997). Another study done in South Africa showed that 53.7% of the patients that underwent lower limb amputation were

diabetic and 56.7% were hypertensive (Khan et al., 2020). It can be seen that Non-communicable diseases are a health issue of high income countries but are now becoming a huge health problem in sub-Saharan Africa. A 2010 report by WHO suggests that NCDs are overtaking infectious diseases in terms of global mortality rates, and deaths from NCDs are forecast to exceed mortality from infectious, maternal, and child diseases even in sub-Saharan Africa by 2030 (Phiri, 2017). In the most recent study done in Zambia, the prevalence of hypertension was 34.8% (38.0% of males and 33.3% of females (Goma et al., 2011). Another study estimated prevalence for diabetes mellitus was 3.5% in Zambian communities (Bailey et al., 2016) however, recent WHO reports show that NCDs in 2016 contributed to 33% of deaths for all ages in Zambia (WHO, 2016) as compared to 23% in 2014 (WHO, 2014). Among the patients, 26.3% were HIV positive, which is higher than the national prevalence of 12.3% amongst those between the ages of 15 and 59 years (ZAMPHIA 2016). The association between HIV and indication for amputations in the study was significant, which correlates with findings from another study that have shown that HIV alone is a risk factor for peripheral vascular disease, which can lead to amputation (Ye et al., 2010). Similar to developed countries (Kayssi et al., 2016), the majority of amputations were done by general surgeons. This is because trauma accounted for only 11.3% of the amputations done. Most of the amputations were done as an emergency and performed by a Registrar (81.3%).

5.3 Indication for amputation

The most common indication for major limb amputation was wet gangrene followed by diabetic foot. However, the association between diabetes mellitus and indication for

amputation showed that slightly over half of the patients that presented with wet gangrene were diabetic and more than three-quarters of the patients that presented with gas gangrene were diabetic. According to the WHO and the International Working Group on the Diabetic Foot (Newrick, 2000), diabetic foot is defined as the foot of diabetic patients with ulceration, infection and/or destruction of the deep tissues, associated with neurological abnormalities and various degrees of peripheral vascular disease in the lower limb. The group developed a classification system for research purposes known as the PEDIS system in which all foot ulcers are classified according to five categories: perfusion, extent/size, depth/tissue loss, infection and sensation (Schaper, 2004). Thus according to the above definition and the PEDIS system, wet and gas gangrene in a diabetic patient are grade 3/4.

Therefore diabetic foot can be said to be the most common cause of major limb amputations at the UTH (45%). Others which included infected open fractures (6), 4 of which were open tibia fractures; infected BKA stump (1); malignancies (Ewing's sarcoma, osteosarcoma and malignant melanoma); burns and chronic ulcers accounted for 21.3% of the amputations done. Trauma and dry gangrene accounted for 9% and 8% respectively. These findings are contrary to what was found in the two previous studies done in Zambia that showed trauma as the major contributor to major limb amputations (Mangowela, 2015; Tembo, 2000). The prevalence of NCDs such as diabetes mellitus and hypertension has been increasing over the years ("WHO | Diabetes country profiles 2016," .), thus we are seeing a change in the disease pattern and their complications. Others studies done in Iran (Sabzi Sarvestani and Taheri Azam, 2013) and Nigeria (Ajibade et al., 2013; Nwosu et al., 2017) also showed trauma as the main indication for major limb amputations. This could be as a result of the patients in these studies being younger than

those in this study and hence the amputations more likely to be due to trauma than diabetic foot. Also, variations in cause and pattern of amputation occur within different regions and also cities of the same country. On the contrary, another study done in a different part of Nigeria stated that diabetic related complications were a major contributor to major limb amputations (Ndukwu, 2015a). However, studies done in the Western world (Aulivola et al., 2004; Kayssi et al., 2016) had similar findings as this study, as well as studies done in Tanzania (Chalya et al., 2012) and South Africa (Khan et al., 2020)

5.4. Level of Amputation

In keeping with literature (Chalya et al., 2012; Mangowela, 2015; Unnikrishman et al., 2017), the most common site for amputation was the lower limb. This is because the main cause of amputation found was diabetic foot, which affects the lower limbs and most trauma has been shown to occur in the lower limbs than upper limbs (Sabzi Sarvestani and Taheri Azam, 2013). In contrast to literature from Nigeria (Ndukwu, 2015), Rwanda (Murwanashyaka et al., 2013) and South Africa (Khan et al., 2020), the most common level of amputation in this study was above knee amputation, followed by below knee amputation. Studies done in Zambia (Tembo, 2000) and (Mangowela, 2015) had similar findings. This is an indication of the late presentation of the disease. Apart from peripheral vascular disease and peripheral neuropathy, other risk factors for diabetic foot ulcers are inappropriate footwear, poor foot hygiene and delay in seeking medical attention (Abbas and Archibald, 2007)

The other levels of amputation done were shoulder disarticulation in an HIV positive participant who developed gas gangrene secondary to trauma. The other indication was

severe burns. Hip disarticulation, through elbow and above elbow amputation were the other types of amputation done.

Most amputations were unilateral and done on the left side. The reason for this may be explained by studies that showed that the dominant foot is subjected to greater shearing or mechanical stresses or might be more susceptible to injury by accident as it is the one that is used most for starting or stopping movement (Coxon and Gallen, 1999; Friedman et al., 2020) . However, in this study, leg dominance was not assessed. One bilateral amputation was done in a trauma patient who was run over by a train.

Out of the 80 participants enrolled in the study, 6 (7.5%) were admitted to MICU postoperatively and it was noted that these participants had an ASA status of ≥3 which means that they had severe systemic disease.

5.5 Outcomes

Postoperative complications were seen in 67.5%. This has increased since the last study was done over 10 years ago at UTH (Tembo, 2000). This could be attributed to the increasing number of NCDs. The complication rate was found to be higher than what was found in India (Unnikrishman et al., 2017) and Tanzania (Chalya et al., 2012). Among the diabetics, 71.1% had a complication and 71.4% of the hypertensive patients also had a complication. Statistically, these were not significant but can be explained clinically especially if diabetic control was not obtained. Studies have shown that high postoperative peripheral blood glucose is one of the main risk factors for postoperative adverse events in diabetic patients (Wang et al., 2019). Diabetes mellitus and hypertension are risk factors for peripheral arterial disease which can affect wound healing and lead to postoperative

complications. It was found that over four-fifths of the patients with diabetic foot, slightly over three-quarters of participants with gas gangrene and trauma had complications. Among those with wet gangrene, slightly above half had complications. Although this was not statistically significant could be possibly explained by the presence of infection in the limb prior to amputation as a predictor of postoperative complications, as was found in a study that assessed risk factors for 30-day postoperative complications after BKA (Belmont, et al, 2011). For the trauma patients, factors such as the cause of trauma and duration from the time of injury to operation can lead to post-operative complications (Josten and Schmidt, 2009). Out of the complications that occurred, the majority were local complications and few systemic complications. The most common local complication, similar to other studies (Chalya et al., 2012; Khan et al., 2020; Tembo, 2000), was surgical site infection alone. Out of the patients who developed surgical site infection, slightly over half were diabetic. This is expected because in this study the indication for amputation in the majority of the diabetics was diabetic foot, including gas and wet gangrene, and this in keeping with studies elsewhere which have shown that the presence of pre-existing infection is a predictor of postoperative complications (Belmont, et al, 2011; Wang et al., 2019). The multiple logistic regression showed that those with trauma were 99% less likely to develop complications than those with diabetic foot. This is because diabetic foot ulcers present as infected wounds, as compared to traumatic wounds. Also, duplex sonography is not routinely done to directly visualize vessels and determine patency prior to amputation and thus the level of amputation is only determined clinically which could lead to an amputation being done at a level where the vessels are diseased and thus leading to complications in wound healing.

Amongst those that developed SSI, 15 had a Clavein-Dindo grade of 3 and thus had to be surgically treated.

Phantom limb pain, often described as a burning or throbbing pain, was the second most common short term complication noted in this study. In contrast to this, studies report that it occurs in 80% of amputees (Pascale and Potter, 2014; Richardson et al., 2006). It ranges from mild to intolerable pain, however, all the patients in the study had a Clavein-Dindo grade of 1, hence was tolerable and no pharmacological treatment was required. Multiple local complications were seen in less than one-fifth of the patients.

Renal complications, in particular, Acute Kidney Injury (AKI) was the most common systemic complication observed in this study. Most, except 1 had a Clavein-Dindo grade of 1 which is a transient rise in serum creatinine level and did not require dialysis. This was found to be higher than another study done in the region (Khan et al., 2020). Diabetes mellitus and sepsis are known to be some of the risk factors for AKI, in this study, most of the patients that developed AKI were diabetic and had diabetic foot gangrene, wet and gas gangrene. This could explain why the numbers were high.

Stump revision was done in slightly less than one-fifth of the participants. In this study, any patient that required secondary suturing of the wound, skin graft and a higher level amputation to be done were considered under stump revision. The most common indication for stump revision was infected BKA stump, followed by above knee guillotine and below knee guillotine. Other indications were infected below elbow amputation, above elbow guillotine and shoulder disarticulation (guillotine). Close to half of the participants underwent secondary suturing and slightly less than one-third underwent

above knee amputation. All the patients with infected BKA stump underwent AKA and the patients with infected below elbow amputation, had above elbow amputation done. This is explained in the regression that showed that patients with below knee amputation were more likely to develop a complication than those that had AKA done. Though not statistically significant, it can explain why those with the most common indication for stump revision was infected BKA stump. In our setting, we are unable to carry out specific tests such as magnetic resonance angiogram (MRA), duplex sonography and transcutaneous partial pressure of oxygen (TcPO2) in an emergency due to inaccessibility and unavailability. These tests can help in assessing the blood vessels in the limb as well as predict wound healing. Thus an appropriate decision on the level of amputation can be made and complications reduced. Secondary suturing was done in 2 patients who had below knee guillotine amputation, 2 above knee guillotine amputation and 1 above elbow guillotine amputation. These cases were done as a 2 staged procedure. Two staged approach to amputation is done in a setting of extremity sepsis due to high risk of stump infection.

The mean length of hospital stay was almost two weeks and showed a significant association with complications. There was a significant difference in the length of hospital stay between those who died and those who survived up to day 30. This difference could suggest that the condition of those that died was severe. In other studies, the length of stay was almost twice as more than this study (Chalya et al., 2012), because the number of patients requiring stump revision was higher, which leads to a longer hospital stay

It was noted that amongst the patients with lower limb amputation, some were able to use crutches on discharge, however, over a third were discharged on a wheelchair. This could

be attributed to the fact that the mean age of the patients was over 50 years and thus the older patients were more comfortable using a wheelchair than crutches. This is contrary to what Tembo and others (2000) noted that the mean age of the patients was 41years and the majority of the patients were discharged on crutches.

The 30-day mortality rate was close to one-fifth and this was higher than studies done in the region (Chalya et al., 2012; Khan et al., 2020; Tembo, 2000). The most common cause of death was sepsis which is similar to a study done in Ivory Coast (Sié Essoh et al., 2009). In contrast, other studies found diabetic foot complications as the main cause of mortality, followed by wound infection (Chalya et al., 2012; Ndukwu, 2015). Diabetics were more likely to die than non-diabetics, though not statistically significant, the findings are in keeping with other studies(Chalya et al., 2012; Ndukwu, 2015) that as stated above had diabetic foot complications as the main cause of death. This was attributed to late presentation to the hospital and delayed consent for amputation. These studies had more patients presenting with diabetic foot than in this study. This study showed that 60% that died were diabetic and participants with gas gangrene were more likely to die than those with diabetic foot. Though it was not statistically significant, however, the patients with gas gangrene, at the time of presentation to the hospital, were already septic, which was the possible reason for mortality in this study.

The association between ASA and mortality was significant and showed that the percentage of those who died increased as the ASA status increased. ASA physical status classification looks at the patient's physiological status preoperatively. Patients with a higher ASA classification had a poorer clinical picture, and it is known that poor ASA

status is associated with poor postoperative outcome and higher mortality (Doyle and Garmon, 2020). Therefore, the higher the ASA status, the higher the mortality.

Majority of the amputations were done by general surgeons because the main indications found were managed by general surgeons, therefore 93% of the mortalities were operated on by general surgeons and thus the association between specialty and mortality was significant.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusion

1. The main indication for major limb amputations done at UTH, Adult hospital is diabetic foot sepsis. In this study, trauma was amongst the least indications listed for major limb amputations.

2. The main short term local complications were surgical site infection followed by phantom limb pain.

3. The main short term systemic complication was renal complications.

4. The 30-day mortality rate was 18.8% with sepsis being the most common cause of death.

Therefore most of the indications are preventable and the mortality rate can be lowered.

6.2 Recommendations

With diabetes being a major risk factor for amputations, there is a need for a more multi-disciplinary approach to the management of these patients. Once the patients are noted to have peripheral neuropathies and peripheral arterial disease by physicians, podiatrists, vascular and general surgeons respectively need to be incorporated into the management to prevent the progression to diabetic foot.

Diabetic foot clinics should be established within the communities at the primary health level to detect and treat any complications early and thus reducing the rate of amputations, as per international recommendations.

Hence further studies can be done to determine factors that lead to late presentation of patients with diabetic foot ulcers.

HIV was found to be a major factor in this study, hence a study looking at risk factors for amputation in HIV positive patients can be done, which may include vasculitis, and viral load.

The functional outcome of patients who undergo major limb amputations can be further studied with a longer period of follow up.

6. 3 Limitations

The limitations in this study were the sample size which may have affected statistical significance. Amongst those with diabetes, doing the glycated haemoglobin (Hb1Ac) would have established whether there was good diabetic control and hence further explained the outcomes.

HIV was found to be a risk factor for amputations and hence further investigations such as CD4 count and viral load could have been done to establish the status of immunity.

6.4 Contributions to the body of Knowledge

This study has shown that there has been a change in the trend in the indications for major limb amputation. Moving from trauma to diabetes mellitus.

It has also established that HIV, in the Zambian setting is a risk factor to major limb amputations.

6.5 Implications for the Public

There is a need to educate the public on regular medical check-ups to detect NCDs early and establish control to prevent complications from occurring or progressing.

Those already with NCDs should have regular clinic visits to maintain control.

Major limb amputations have cost implications to both the patient and those caring for the patients due to the long length of hospital stay and increased Disability-adjusted life years (DALYs)

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APPENDICES

Appendix A: Participant information sheet

INDICATIONS AND SHORT TERM OUTCOMES OF MAJOR LIMB AMPUTATIONS AT THE UNIVERSITY TEACHING HOSPITALS- ADULT HOSPITAL

Code No _____

Consent to participate in the study of Indications and Short term outcomes of Major Limb Amputations at the University Teaching Hospitals, Lusaka, Zambia.

Introduction:

I am Dr Mildred Nakazwe a postgraduate student at The University of Zambia, School of Medicine, in the Department of Surgery.

The purpose of the study:

Trauma, Diabetes Mellitus and Hypertension are significant risk factors for major limb amputations and have been projected to increase in number by WHO. The number of amputations being done at this hospital have been seen to increase from previous studies done.

This study explores the causes and short term results of major limb amputations in order to improve the management of these patients as well as reduce morbidity and mortality.

What participation involves?

Once you consent to participate in this study, you will need to answer a five (5) minute questionnaire (when stable and fit enough to do so). You will then be followed up for a total of 30 days while on the ward and in the outpatient clinic, specifically on day 1, 7, 14 and day 30 postoperative. Should your appointment days not coincide with the above days or you miss your appointment, you will be contacted via phone using the phone number entered in the data collection sheet.

Confidentiality:

All data collected on questionnaires will be entered into a personal computer with a code number. The questionnaires will be handled with great privacy in order to maintain confidentiality throughout the study.

Risks:

All the procedures done are part of the standard surgical care for patients with this condition. Complications may arise because of the magnitude of the condition and the major operation. However, there is no additional risk associated with this study.

Right to withdraw:

Participating in this study is entirely voluntary. You are free to withdraw from the study at any time and skip questions which may be too personal for you to answer. If you choose not to participate in the study or withdraw, you will continue to receive all services that you would normally get from the hospital.

Benefits:

The study does not have any direct benefits. The findings of the study will help to improve the health care delivery and follow up of patient who have undergone major limb amputations.

Who to contact?

A committee that works to protect your rights and welfare reviews all research. If you have questions or concerns about your rights as a research participant or comments regarding the conduct of this research, you may contact:

Dr Mildred Nakazwe Registrar Surgeon Principal Investigator Department of Surgery University Teaching Hospital Lusaka Zambia +260966727309 mildred.z.nakazwe@gmail.com	Dr David Linyama Consultant Surgeon Department of Surgery University Teaching Hospitals Lusaka Zambia +260977207082 dmlinyama@yahoo.co.uk	The Chairperson ERES Converge IRB 33 Joseph Mwilwa Road Rhodes Park Lusaka Zambia +260955155633/4 eresconverge@yahoo.co.uk

Appendix B: Informed Consent form

INDICATIONS AND SHORT TERM OUTCOMES OF MAJOR LIMB AMPUTATIONS AT THE UNIVERSITY TEACHING HOSPITALS- ADULT HOSPITAL, LUSAKA.

Signature:

I …… have read the content of this form. All my questions have been answered; I have been told I can ask questions at any time during the course of the study and can skip questions that I feel may be too personal. I am free to withdraw from the study at any stage. I, therefore, agree to participate in this study.

Signature or thumbprint of participant ……...

Signature or thumbprint of witness ……

Date of signed consent …….....

Participant agrees / Participant does NOT agree

Appendix C: Data Collection Sheet

INDICATIONS AND SHORT TERM OUTCOMES OF MAJOR LIMB AMPUTATIONS AT THE UNIVERSITY TEACHING HOSPITALS- ADULT HOSPITAL

Patient ID: _____ Mobile number: 1)
_____

2) _____

1.0 SOCIO-DEMOGRAPHICS

1.1 AGE _____ (years)

1.2. SEX: 1.2.1 M

1.2.2 F

1.3. EDUCATION LEVEL

1.3.1 PRIMARY /1.3.2 SECONDARY / 1.3.4 TERTIARY

1.4 OCCUPATION

1.4.1 EMPLOYED / 1.4.2 NOT EMPLOYED

2.0 CLINICAL INFORMATION

2.1. DATE OF FIRST CONTACT _____/_____/_____ (DD/MM/YYYY)

2.2 DATE OF ADMISSION _____/_____/_____ (DD/MM/YYYY)

2.3 DURATION OF SYMPTOMS _____

2.4.0 COMORBID CONDITIONS

2.4.1 DIABETES MELLITUS A) YES DURATION _____ MEDICATION
_____

B) NO

2.4.2 HYPERTENSION A) YES DURATION _____ MEDICATION
_____

B) NO

2.4.3 RVD STATUS NEGATIVE / POSITIVE / UNKNOWN

3.0. SMOKING NO, NEVER / STOPPED / YES

4.0 ALCOHOL NO, NEVER / STOPPED / YES

5.0 PREOPERATIVE INFORMATION

5.1 PRE-OP HB_____g/dl

5.2 ASA 1 / 2 / 3 / 4 / 5 / UNKNOWN

6.0 OPERATIVE DATA

6.1 DATE OF OPERATION _____/_____/_____ (DD/MM/YYYY)

6.2 TYPE OF OPERATION

ELECTIVE / EMERGENCY

6.3 SURGEON: REGISTRAR / SENIOR REGISTRAR / CONSULTANT / OTHER

_____

6.4 INDICATION FOR AMPUTATION

6.4.1 Diabetic foot ☐

6.4.2 Dry gangrene ☐

6.4.3 Wet gangrene ☐

6.4.4 Gas gangrene ☐

6.4.5 Burns ☐

6.4.6 Trauma ☐

6.4.7 Malignancy ☐

6.4.8 OTHER _____

6.5.0. LEVEL OF AMPUTATION

6.5.1 ABOVE KNEE ☐

6.5.2 BELOW KNEE ☐

6.5.3 THROUGH KNEE ☐

6.5.4 ABOVE ELBOW ☐

6.5.5 BELOW ELBOW ☐

6.5.6 OTHER_____

6.6 BLOOD LOSS

0-100mls / >100 -500mls / > 500 -1000mls /> 1000

7.0 POSTOPERATIVE INFORMATION

7.1 POSTOPERATIVE WARD

GENERAL WARD/ MAIN INTENSIVE CARE UNIT

7.1 OUTCOMES

LOCAL

COMPLICATION	DAY 1	DAY 7	DAY 14	DAY 30
HEMORRHAGE	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5
HEMATOMA	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5
SURGICAL SITE INFECTION	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5
WOUND DEHISCENCE	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5
PHANTOM LIMB PAIN				

SYSTEMIC

COMPLICATION	DAY 1	DAY 7	DAY 14	DAY 30
CARDIOVASCULAR	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5
RENAL	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5
RESPIRATORY	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5
VENOUS THROMBOEMBOLISM	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5	0 / 1 / 2 / 3 / 4 / 5

KEY 0, NO

1, YES, CLAVEIN DINDO 1

2, YES, CLAVEIN DINDO 2

3, YES, CLAVEIN DINDO 3

4, YES, CLAVEIN DINDO 4

5, YES, CLAVEIN DINDO 5

7.2 STUMP REVISION: YES

NO

IF YES, INDICATION _____

PROCEDURE_____

LENGTH OF HOSPITAL STAY _____DAYS (FIRST DAY AFTER SURGERY = 1)

DATE OF DISCHARGE _____/_____/_____ (DD/MM/YYYY)

7.3 Mobility on Discharge

7.3.1 Zema frame ☐

7.3.2 Crutches ☐

7.3.3 Wheelchair ☐

7.4 30 DAY MORTALITY: ALIVE/ DEAD / UNKNOWN

DATE OF DEATH _____/_____/_____ (DD/MM/YYYY)

CAUSE _____ (ACCORDING TO DEATH CERTIFICATE)

UNKNOWN ☐

Appendix D: Ethical Approval

ERES CONVERGE

33 Joseph Mwilwa Road
Rhodes Park, Lusaka
Tel: +260 955 155 633
+260 955 155 634
Cell: +260 966 765 503
Email: eresconverge@yahoo.co.uk

I.R.B. No. 00005948
F.W.A. No. 00011697

29th November, 2018

Ref: No. 2018-Oct-010

The Principal Investigator
Dr. Mildred Nakazwe
The University of Zambia
School of Medicine
P.O. Box 50110,
LUSAKA.

Dear Ds. Nakazwe,

RE: INDICATORS AND SHORTTERM OUTCOMES OF MAJOR LIMB AMPUTATIONS AT THE UNIVERSITY TEACHING HOSPITAL-ADULT HOSPITAL, LUSAKA.

Reference is made to your corrections dated 20th November, 2018. The IRB resolved to approve this study and your participation as Principal Investigator for a period of one year.

Review Type	**Ordinary**	Approval No. **2018-Oct-010**
Approval and Expiry Date	Approval Date: 29th November, 2018	Expiry Date: 28th November, 2019
Protocol Version and Date	Version - Nil.	28th November, 2019
Information Sheet, Consent Forms and Dates	• English, Nyanja.	28th November, 2019
Consent form ID and Date	Version - Nil	28th November, 2019
Recruitment Materials	Nil	28th November, 2019
Other Study Documents	Data Collection Sheets.	28th November, 2019
Number of participants approved for study	80	28th November, 2019

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- A reprint of this letter shall be done at a fee.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,
ERES CONVERGE IRB

Prof. E. Munalula-Nkandu
BSc (Hons), MSc, MA Bioethics, PgD R/Ethics, PhD
CHAIRPERSON

Appendix E: GPPF Clearance

UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

Telephone : +260211252641
Telegram: UNZA, Lusaka
Telex: UNZALU ZA 44370
Email: assistantdeanpgmedicine@unza.zm

P.O Box 50110
Lusaka, Zambia

4 October 2018

Dr. Mildred Nakazwe
Department of Surgery
University of Zambia
LUSAKA

Dear Dr. Nakazwe

RE: GRADUATE PROPOSAL PRESENTATION FORUM

Following the presentation of your proposal entitled **"Indications and Short Term Outcomes of Major Limb Amputations at the University Teaching Hospital"** your supervisor has confirmed that the necessary corrections to your research proposal have been done.

You can proceed and present to the Research Ethics.

Yours Sincerely

Dr. Lavina Prashar
Assistant Dean, Postgraduate

cc: HOD – Surgery
Supervisor

UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE
- 4 OCT 2018
ASSISTANT DEAN (PG)
P.O. BOX 50110, LUSAKA.

Appendix F: UTH Permission letter

Dr. Mildred Nakazwe
University of Zambia
School of Medicine
P.O.Box 50110
Lusaka
Zambia

01st October, 2018.

Senior Medical Superintendent
University Teaching Hospitals
Adult Hospitals
P/Bag RW 1X
Lusaka
Zambia

UFS: Head of Department
Department of Surgery
University teaching Hospitals
Lusaka

Dear Sir,

RE: APPLICATION FOR AUTHORISATION TO CONDUCT A RESEARCH FOR MMED DISSERTATION.

The above subject refers.

I am a General Surgery Specialist Registrar under the University of Zambia, School of Medicine, in the third year of study. As a requirement for the MMED degree award, I would like to conduct a research study entitled **"Indications and Short Term Outcomes of Major Limb Amputations at the University Teaching Adult Hospital, Lusaka, Zambia."** The study proposal has been approved by the Department of Surgery and the Graduate Proposal Presentation Forum.
The study runs for a duration of 12 months in the Department of Surgery.

Your prompt response would be greatly appreciated.

Yours Sincerely,

Dr Mildred Nakazwe
MMED General Surgery Trainee
University Teaching Hospitals
Lusaka