



**UNIVERSITY OF NAIROBI**

**PREVALENCE AND AETIOLOGY OF VARIOUS LEVELS OF TRAUMATIC LIMB  
AMPUTATIONS FOLLOWING TRAUMATIC INJURIES AT KENYATTA NATIONAL  
HOSPITAL**

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**H58/11520/2018**

**A dissertation submitted in partial fulfilment of requirements for the award of the degree  
of Master of Medicine in Orthopedic Surgery in the University of Nairobi**

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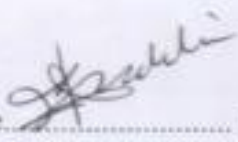
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## **ACKNOWLEDGMENT**

I would like to acknowledge and give my warmest thanks to my supervisors Dr.Vincent M. Mutiso and Dr.kasteen O. Awori whom made this work possible. Their guidance and advice carried me through all the stages of writing my dissertation.

I would also like to give special thanks to my wife Aisha and my family as a whole for their continuous support. Your prayer for me was what sustained me this far.

Finally, I would like to thank Allah, for letting me through all the difficulties.

## **DEDICATION**

I dedicate my dissertation work to my family. A special feeling of gratitude to my lovely wife Aisha, who has been a constant source of support and encouragement during the challenges of graduate school and life. I am truly thankful for having you in my life.

My brother Abdulrahman, my sister Nasra and my uncle Dr.Tahlil have never left my side and are very special

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## **ABBREVIATIONS**

MVC - Moving Vehicle Crush

TLA - Traumatic Limb Amputation

KNH - Kenyatta National hospital

UoN - University of Nairobi

ERC – Ethics and Research committee

RTA: Road Traffic Accidents

## **DEFINITION OF OPERATIONAL TERMS**

**Traumatic Limb Amputation:** severance of an extremity or its part as a result of trauma.

**Prevalence:** the proportion of a specific population affected by a medical condition at a specific period of time.

## ABSTRACT

**Background:** Traumatic limb amputation significantly contributes to morbidity among trauma patients. Due to urbanization, the incidence of traumatic limb amputations is increasing rapidly. Whereas amputations are only performed in around 1% of all trauma patients, they are linked with severe morbidity and a death rate of over 15%. Accidental traumatic amputations account for most civilian traumatic amputations linked to Moving Vehicle crashes (MVC), machinery, and gun violence. Limitations in data availability in developing countries hinder proper planning and resource mobilization toward preventing limb amputations and the care of patients with the condition.

**Objectives:** This study was to establish the prevalence and etiology of various levels of traumatic limb amputation at Kenyatta National Hospital.

**Methodology:** This study adopted a hospital-based cross-sectional study. A consecutive sampling technique was used to recruit 245 orthopedic trauma patients at Kenyatta National hospital. Data was on socio-demographics, etiology, and level of traumatic limb amputations. The outcome variable was occurrence of traumatic limb amputations. Data analysis was done using SPSS version 25. The prevalence of traumatic limb amputation was calculated as a proportion of all patients presenting with traumatic injuries and expressed in percentage. Logistic regression analysis was conducted to investigate causes of traumatic limb amputation. The level of significance was evaluated at  $p < 0.05$ .

**Results:** The median age was 34 years (IQR: 26 – 43) with 57.6 % ( n =141) of the respondents being aged between 18 to 35 years. Majority, 84.1 % ( n =206) of the patients were male. The prevalence of traumatic limb amputation was 5.3%, 95%CI: 2.9% to 8.9%. Mechanism of injury

revealed that 58.4 % (n =143) were as a result of road traffic accidents and 25.7% (n =63) were due to fall from height. Further, 58.4 % ( n =143) had closed fractures with 18.8 % ( n =46) had injuries on left and right sides, 58% ( n =142) had injury on their lower limb. The common site of injury were tibia 29.4 % (n =72), femur 26.1% (n =64) and spine 23.3% (n =57). The prevalence of traumatic limb amputation was 5.3%, 95% CI: 2.9% to 8.9%. Among those with limb amputation, 61.5% ( n =8) of patients had lower limb amputation while 38.5 % (n =5) had upper limb amputation. Those who had machinery as mechanism of injury, OR =4.24, 95% CI: 1.21 – 14.91, those presenting with open fracture, OR =8.52, 95% CI: 1.85 – 39.34, p =0.006 and those who had lower limb as location of injury, OR =3.19, 95% CI: 1.19 – 10.28, p =0.005 were more likely to have limb amputation.

**Conclusion and recommendations:** The prevalence of limb amputation is high with most of the amputation being lower limb amputations. Injuries from machinery and open fractures have been found as major causes of limb amputation. It is fundamental to incorporate better safety guidelines in handling of machinery to improve better management outcomes.

# 1: INTRODUCTION

## 1.1 Background

Traumatic limb amputation is becoming a huge health burden on medical services, as well as on families and society (1). As a result of modernity and industrialization, the rate of limb injuries has increased dramatically throughout the decades and is expected to continue to rise (2). Traumatic limb amputations are only performed in around 1% of all trauma patients, but they are linked with severe morbidity and a death rate of over 15% (3). Accidental traumatic amputations account for the bulk of civilian traumatic amputations, which are linked to Moving Vehicle crashes (MVC), machinery, and gun violence (3).

The common cause of trauma among most patients is road traffic accidents (4). Factors associated with lower extremity amputation include ulcer duration more than one month prior to hospitalization, wound infection, proteinuria, and the presence of osteomyelitis (5). The leading causes of limb amputation in Sub-Saharan Africa are tumors and trauma (4)(6).

A retrospective study conducted in the USA evaluating door-related injuries in the pediatric population concluded that (32.0%) had amputations (7). The highest proportion of traumatic amputations has been found in East Asia, South Asia, Western Europe, North Africa, and the Middle East (8). The prevalence of traumatic limb amputation in a study conducted in Kenya was 35.7% which is relatively high (9). It has also been identified that occupational injury, assault, and falls are the common causes of traumatic limb amputation (10). Other causes of traumatic limb amputation have been industrial injuries which have been commonly occurring mainly due to lack of protective gear and negligence (11). Traumatic amputations occurred in 3% of patients admitted for hand injuries (12). A study from Pakistan concluded that the phalanges were involved in the majority of traumatic amputations, followed by the middle/upper

arm (trans-radial, trans-humeral/elbow), and upper leg (trans-femoral) (13). Hand finger amputation was the most common type of amputations (76.2%) (14).

## **1.2 Statement of the Problem**

The unexpected and accidental loss of a part of an extremity (without undergoing a pre-loss adaption phase) is a catastrophic condition. People that have lost a limb may require lifelong prosthetic use, which necessitates the use of qualified prosthetists and therapists, specific equipment and materials, and a well-coordinated healthcare sector (15).

Traumatic limb amputation is a commonly occurring condition in hospitals globally and in Kenya. Due to the increased use of machines and growing industrialization, the rate of limb injuries has increased dramatically throughout the decades and is expected to continue to rise. It is prudent to undertake a study aimed at understanding the current prevalence and etiology of various levels of traumatic limb amputations in Kenya. Studies done in other settings have showed an increasing trend in traumatic limb amputation ranging from 1-35.7% (16)(14). A recent study in Kenya revealed that the prevalence of traumatic limb amputation was 35.7% (9). However, etiology and level of limb amputation among patients admitted at KNH have not been fully explored. This forms the basis of this study.

## **1.3 Study justification**

Traumatic limb amputation is a condition commonly seen at Kenyatta National Hospitals. There are only a few local studies on the prevalence and etiology of various levels of traumatic limb amputation. In developing countries, traumatic limb amputation is under documented and often under- reported. This study aimed at providing local data on the prevalence and etiology of various levels of traumatic limb amputations, emphasizing the challenges of care for the victims.

The study finding will form the basis of improving posttraumatic limb amputation care, rehabilitation, and prosthetic care.

### **1.3 Research Question**

What is the prevalence and aetiology various levels of traumatic limb amputations among patients with orthopedic related trauma admitted at Kenyatta National Hospital?

### **1.4 Study Objectives**

#### **1.4.1 Broad objective**

To determine the prevalence and aetiology of various levels of traumatic limb amputations among patients with orthopedic related trauma admitted at Kenyatta National Hospital.

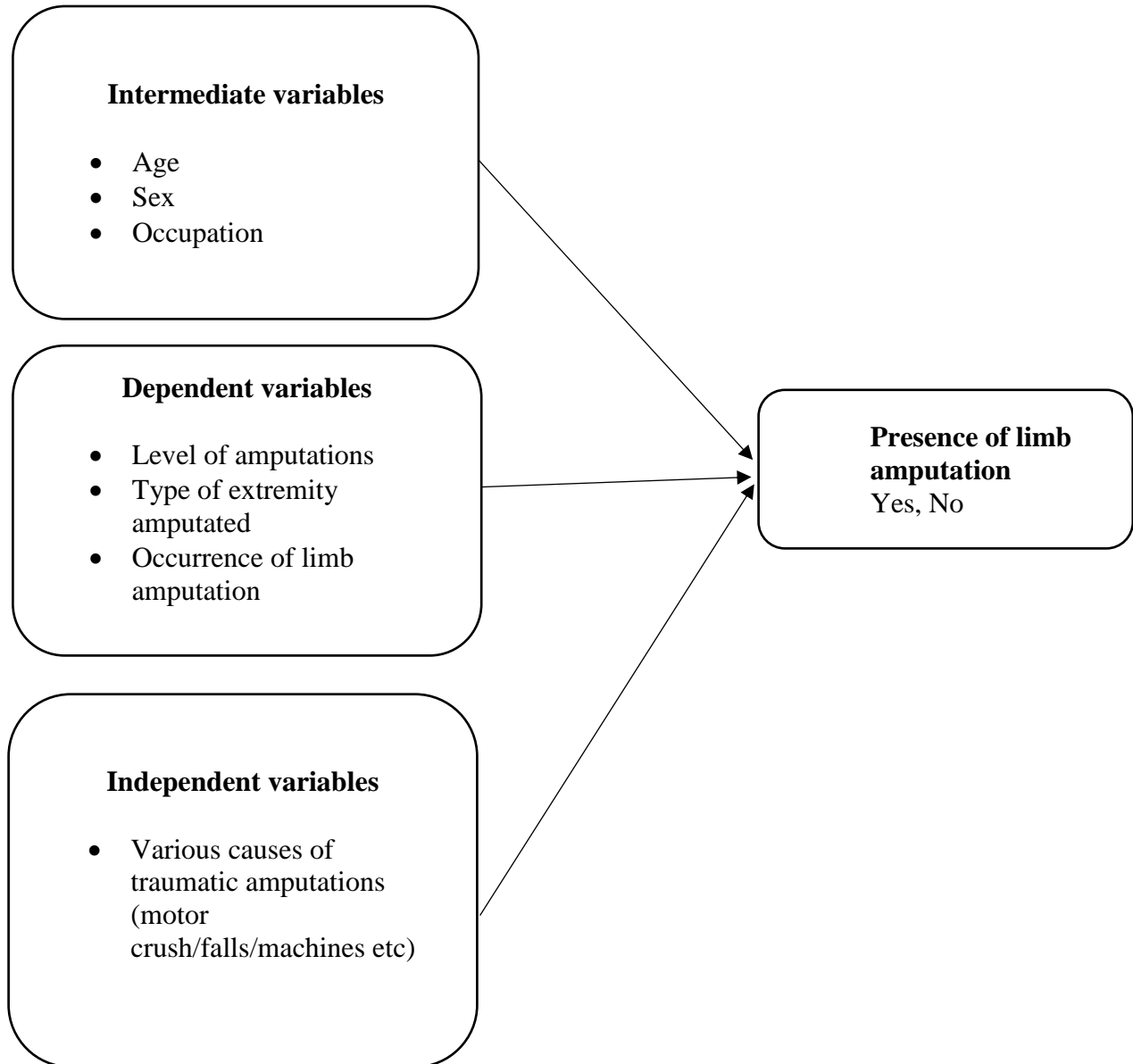
#### **1.4.2 Specific objective**

1. To determine the prevalence of traumatic limb amputations among patients with orthopedic related trauma admitted at Kenyatta National Hospital.
2. To determine the level of traumatic limb amputations among patients with orthopedic related trauma admitted at Kenyatta National Hospital.
3. To determine the causes of traumatic limb amputations among patients with orthopedic related trauma admitted at Kenyatta National Hospital.



## 1.5 Conceptual framework

The conceptual framework explains the relationship between variables included in the study.



**Figure 1: Conceptual framework**

## **2: LITERATURE REVIEW**

### **2.1 Introduction**

Limp amputation is not a new phenomenon but rather a mundane practice that has evolved in terms of an approach where circumstances mandate limb loss as the only alternative to complications such as fractures or infections of the extremities. Whilst limb loss as a result of vascular causes such as diabetes represents a predominant share of overall amputations. There are other conditions that lead to limb amputation, such as extensive limb trauma, limb malignancy, and birth anomalies on the limbs (17).

By definition, traumatic amputation refers to the immediate separation of the limb (partially or fully) from the body following severe injuries that adversely affects a patient's quality of life (18). Traumatic amputation is the second commonest etiology of limb loss and often results from a road traffic accident, machine accidents, power tools or firearms, severe limb burns, or electrocution. Trauma-related amputation is mostly common among young men but is not limited to this cohort since it can affect all persons regardless of demographic characteristics (19). As aforementioned, there is myriad mechanism of traumatic limb amputation; the categorization of the injuries is based on the severity of the injuries on the affected limb. Ideally, the severity of musculoskeletal injuries is dependent on factors such as the particular object causing the injury, the magnitude, direction, and speed of the causative agent, and the specific limb tissue or section affected by accident. Traumatic limb injuries that frequently occur include degloving, total, and partial amputations (20).

In situations the victim losses skin and adipose tissue that is more than 1 inch in surface diameter of the limb, the injury qualifies as degloving or complete avulsion. The blood loss associated with this injury is minimal due to the peripheral vasoconstriction mechanism. Despite the injuries

not seemingly being extensive and blood loss being low, degloving causes serious injuries that may need high-end surgical operations such as grafting and skin flaps (21).

Limb loss is categorized as either minor loss or major limb loss. The injuries that qualify for major limb loss include trans-humeral, trans-radial, trans-femoral, or trans-tibial amputation. Those patients who suffer an amputation of the hand, digits, toes, or mid-foot level loss are said to have had a minor limb loss (22).

In a study by Dillingham et al, that focused on assessing the prevalence of these two categories of injuries among patients being discharged from Maryland hospital for the duration starting 1979 through 1993, the majority of the amputations were minor 4.8%, while only 3.4% qualified as major limb amputations (23).

## **2.2 Prevalence of traumatic limb amputation among trauma patients**

Globally, there are significant technological advancements in the field of preventive medicine. However, these advancements have not curbed the rates of people living with limb loss, which are estimated at 1.6 million in the US and expected to increase to 3.6 million by 2050 (24).

According to estimates, there were more than 700,000 amputations induced by trauma in the United States in 2005, and this number would more than double by 2050, affecting 1,326,000 individuals. Amputation of a limb following trauma is common in the civilian population, and it is associated with severe morbidity (24).

A study was done at the level I trauma center in the USA showed that traumatic limb amputation accounts for 0.25% of all admissions (16). According to a study conducted in Iran, severe injuries involving the patient extremities were reported among 0.92 percent, who then underwent limb amputations (14). A retrospective study conducted in Ethiopia assessing major limb trauma

concluded that Fractures were (83%), amputation (6%), open wounds (5%), dislocation (4%), crush injuries (0.8%), and neurovascular injuries (1%) (25).

In Nigeria, there are 1.6 amputations of an extremity per 100,000 people, according to estimates (13). A prospective study conducted in Pakistan by Jabeen et al, established that upper limbs were more frequently affected than lower limbs. A majority of those with arm amputations were had the right arm affected. In most of them, amputations involved phalanges, the middle/upper arm, especially the trans-radial or trans-humeral/elbow sections, and the upper leg, that is, trans-femoral part (26). A retrospective study conducted by Al-Turaiki et al, found that Upper extremity amputations were most commonly caused by trauma (86.9%). Although trauma (52.9%) was the most common cause in the lower limb, 35.9% was caused by disease. Road traffic accidents, machine accidents, and falls from great heights were the most common specific causes of trauma. Trans-tibial amputations were the most common (45.2%), followed by trans-femoral (21.6%), trans-radial (7.6%), partial hand (4.8%), and trans-humeral (4.7%) (27). A study conducted by Kim et al, in Korea reported the most frequent cause of limb loss was trauma (66.7%), and peripheral vascular disease was the second most common cause (28).

In Kenya, a study conducted at Kikuyu Hospital reported trauma (35.7%), congenital defects (20.0%), and dysvascular problems (17.1%) as the main causes of limb amputations, followed by infections (14.3%) and tumors (12.8%) (9).

Several studies have provided a varied understanding of the prevalence of trauma-linked amputations (9)(29)(30)(31)(6). A retrospective study conducted in Kenya by Ogeng'o et al, investigating amputation of limb patterns in children and adolescents revealed that trauma was the most common cause (42%), followed by congenital defects (29.5%), infection (12.5%), and tumors (11.4%)(9). A prospective study conducted at Kenyatta national hospital by Awori and

Atinga et al, revealed that 18.5% of the amputation resulted from trauma (29). In another study conducted in Tanzania by Loro and Franceschi et al, in a ten-year experience of limb amputation pattern, 40% of all amputations were from trauma patients, while 17.8% were from diabetes related (30). A study done by muyembe et al, in Kenya found the prevalence of limb amputation among trauma patients was 26.5% (31).

Table 1: Summary of leading causes of limb amputation in some African countries

Author	Sample	Main Factors				
		Trauma	Tumor	Congenital defects	Diabetic	Non-diabetic
Ogeng'o JA (9).	140 patients from Kenya	32%		20%	11.40%	5.70%
Awori and Atinga (29)	77 patients from Kenya	18.90%	24.40%		17.50%	38.70%
Loro and Franceschi (30)	241 patients from Tanzania	40%			17.80%	
Muyembe and Muhinga (31).	102 patients from Kenya	26.50%	26.50%		26.50%	14.70%
Thanni and Tade(6)	1642 patients from Nigeria	34%	14.50%		12.3%	9.3%

Source: Ogeng'o et al. (9)

### 2.3 Level of traumatic limb amputation in trauma patients

Limb amputation has an adverse influence on individual mental well-being, especially depending on the level of amputation. Amputation can be done in both the lower and upper parts of the body. A study in 2015 by McDonald et al, estimated a total of 1.2 million people sustained major limb amputation due to traumatic causes. Among those with major limb amputations secondary to trauma, 84.7% (N =10) were unilateral for legs, and bilateral lower limbs accounted for 0.6%. In addition, 7.5% of the major traumatic limb amputations were upper limbs, while bilateral arm

amputations accounted for 7.2%. In a descriptive study that utilized a secondary database assessing the global prevalence of traumatic non-fatal limb amputations in 2017, the data showed that 57.7 million people across the globe were living with limb amputations. On the causes of these limb losses, the main contributors were falls accounting for 36.2%, followed by road accidents accounting for 15.7%. Other transportation-related injuries accounted for 11.2%, with mechanical force injuries contributing to 10.4% of these limb losses (8). In a retrospective study conducted by Livingston et al, among 42 patients who had sustained traumatic limb amputation, it was found that the majority of them, 53.2% had an amputation below the knee, 19.2% had an amputation below the elbow, 17% had amputation above the knee, and 10.6% had limb amputation above the elbow (32). Another study conducted in the United States investigating traumatic amputations in children by Loder et al, established that among the 256 amputations in 235 children, 165 involved the lower extremity, 38% of the patients had below the knee amputation, 13.2% had above the knee amputation, and 2.1% had knee disarticulation. Further, the findings established that 12.4% had below elbow amputation and 3% had above elbow amputation (33).

A cross-sectional study conducted among Palestinians in the Gaza strip by Heszlein-Lossius et al, established that 85% of the cases were recorded as major amputations. The major amputations affected the lower limbs while a huge proportion of minor amputations were concentrated on the upper limbs. Those with unilateral above-knee amputations accounted for 35% while 11% were classified as having bilateral amputations above the knee and lastly 7% with bilateral amputations below the knee. Upper limb amputations were majorly affecting the distal sections. The percentage of the study sample with a section of both arm and leg amputated was 8% (34).

A retrospective study conducted in Western Nigeria by Nwosu et al, investigating major limb amputations revealed that 45.5% had above the knee amputation, 39.3% had an amputation below the knee while 13.4% had amputation above the elbow while 1.8% had below elbow amputation (15). Lower limb amputations were performed more than upper limb amputations. This is probably due to the fact that the lower limb is more involved in trauma, complications of diabetes mellitus, and peripheral vascular disease (15).

A 10 years retrospective conducted in France by G. Pomares et al, found that in the population admitted for hand-related injuries, the annual incidence of traumatic amputations was 3%. The left upper limb was more frequently injured than the right one (12). An assessment of the pattern of limb amputations carried out over a period of five years in Liberia by Weyhee al, revealed that the different levels of amputation were as follows: below the knee (47 percent), above the knee (45 percent), below the elbow (2 percent), above the elbow (2 percent), knee disarticulation (2%) and big toe amputation (2 percent) (35).

A retrospective study conducted by Al-Turaiki et al, found that trans-tibial amputations were the most common (45.2%), followed by trans-femoral (21.6%), trans-radial (7.6%), partial hand (4.8%), and trans-humeral (4.7%)(27). A retrospective study in Nigeria revealed that trauma contributed to a majority of the limb loss at 42.8%. Amputations of the lower limb affected 71.4% while upper extremity cases were 28.6%. The amputation of the lower extremity below the knee was the most common type of lower limb amputation, accounting for 62.8% of the 35 lower limb amputations that were performed (4). A retrospective study in Kenya concluded that 92.2%of the amputations were done on the lower extremity while 7.8% were on the upper extremity (31).

## **2.4 Etiology of traumatic limb amputation**

Traumatic etiologies contribute to the worldwide prevalence of limb amputation and associated disability. Despite traumatic limb amputations occurring in roughly 10 out of every 1000 trauma patients, they lead to significant morbidities and mortalities of nearly 15% (36).

By distributions, the percentage of the etiological causes of these traumatic limb amputation indicated that falls (36.2%) had the highest prevalence, followed by road traffic injuries road 15.7% while 11.2% were from other injuries associated with transportation, and just 10.4% resulting from mechanical forces (8).

Available evidence portrays a contrasting trend in the factors associated with traumatic limb amputation between developed countries and developing countries. In developed countries, the main etiological factors in order of prevalence are diabetic vasculopathy, peripheral vascular disease, trauma, and neoplasia (36). Different from those in developing countries, which are mainly traumas related or peripheral vascular diseases? The difference in these trends is explained by the differences in population distribution by age, given that the majority of the population in developing countries is young compared to those in developed countries (23).

In the adult population, the foremost common etiology of traumatic amputations is blunt injury. Motor vehicle accidents have the largest proportion of these blunt injury amputations, while other accidents such as machinery-involved industrial accidents, motorcycle accidents, and other mechanisms (3). In terms of demographics, most of those involved in these amputations are males aged 15 years to 40 years. In reference to the part affected by these amputations, 60-80% affect the digits, while lower limbs are more affected than the upper limbs (24) (3). When upper extremity amputations occur, there is a higher likelihood that they result from penetrating high



velocity with associated vascular injuries. On the other hand, lower extremity amputations are observed to involve the bone shafts mostly as opposed to joints and occur mainly at the upper third of the tibia (37). Having multiple limb amputations increases the odds of mortality, as shown in a study where mortality was 23.2% in multiple amputations in comparison to 15% for overall amputations (3). These injuries tend to happen in the workplace for the young population.

Among the pediatric population, traumatic amputations occur at a rate of 6.1%, featuring a bimodal distribution and mainly involving the fingers and toes. In most cases, traumatic amputation in pediatrics is associated with caught-between injuries, e.g., doors. Other causative factors include machinery, which is associated with 15.6%, while motor vehicle accidents account for 8% (7).

A study conducted in Nigeria by Onyemaechi et al, established that the average age of trauma patients was 40.9 years ranging between 2 to 85 years. In 39.3% of patients, diabetic foot gangrene was the primary contributor to the need for amputation of a limb. Amputation above the knee was the most prevalent level of amputation, accounting for 48.2% of all cases. The most prevalent problem that arose was an infection of the wound (12.5%). Only four patients, which is 7.1% of the total, wore prostheses, and the mortality rate was 8.9% (38).

## **2.5 Determinants of limb amputation among trauma patients**

Limb amputation is associated with diverse factors which need to be effectively assessed to improve outcomes among trauma patients. In a retrospective study conducted in China by Kim et al. investigating predictors of limb amputation, it was found that injury severity score (ISS), mangled extremity severity score (MESS), and age of the patients were significant predictors of limb amputation. Patients with higher ISS scores were more likely to have their limbs amputated.

Similarly, those with higher MESS and older age were associated with increased limb amputation among the patients (39).

Another study conducted in Karachi by Soomro et al, established that the diabetic status of the patient, socioeconomic status, and education level was significantly associated with increased limb amputation (40). These findings have established that patients with diabetes were more likely to have limb amputation. Further low socio-economic status has a negative influence on an individual ability to afford restorative limb procedures (40).

According to the findings of another prospective study that was carried out in Nigeria by Adegbingbe et al, the following factors were found to be independent predictors of limb amputation among trauma patients: age, sex, occupation, limb ischemia, gangrene, severe open fracture, source or nature of the injury, presence of shock, delay in hospital presentation, and MESS. As a result of these findings, we now know that the patient and their family consider an early amputation to be a consequence of the accident, whereas a delayed amputation is regarded as an indication that the therapy was ineffective. The identification of risk factors for primary amputation will lead to a reduction in the morbidity and mortality associated with trauma(41).

Another study that was carried out in Turkey looked into the factors that were effective in traumatic amputations occurring after road accidents. The findings showed that 66.7% of the amputations resulted from accidents from automobile. For these injuries, 59.3% affected the lower limbs with 51.9% involving the right side-extremities, and mainly the below the elbow/knee levels. Accidents involving passengers seated in the driver or front seats affected the lower limbs mostly, and especially the direction of oncoming cars (42).

A case-control study conducted in Indonesia investigating risk factors for limb amputation established that levels of HbA1c  $\geq 8\%$ , presence of peripheral arterial disease (PAD),

hypertriglyceridemia, and hypertension as the independent risk factors associated with subsequent lower limb extremity amputation (43).

## **2.6 Summary**

The findings from prior research have established that limb amputation is common, with trauma being the common etiology. Traumatic limb amputation (TLA) has far-reaching implications, both direct and indirect, in terms of personal health, economic capabilities, and psychological. Available evidence points to a continuing struggle among amputee patients with pain management postoperatively. There are available techniques that can be used towards improving pain management, such as targeted muscle reinnervation (TMR), but there is a gap in evidence that can allow a full understanding of the magnitude, levels, and predictors of limb amputation. Even though the research was conducted in Kenya at Moi Teaching and Referral Hospital by Kogoss et al. on the characteristics and outcome of lower extremity amputation, they recommended future scholars assess the discharge destination and uptake of prosthesis services (44). In summary, there is a notable paucity of knowledge related to traumatic limb amputation in Kenya. In addressing this gap, the current study proposes to evaluate the prevalence and etiology of various levels of traumatic limb amputations for a better understanding of the problem and possible evidence-based planning.

### **3: PATIENTS AND METHODS**

#### **3.1 Study design**

This was a cross-sectional hospital-based study. The study sought to determine the prevalence of limb amputation among trauma patients at Kenyatta National Hospital. This design was appropriate considering that it provides an understanding of the magnitude of limb amputation related to trauma, etiology, and level of amputation.

#### **3.2 Study Site**

This study was conducted at Kenyatta National Hospital, Department of Orthopedic surgery. Kenyatta National Hospital is the largest referral hospital in the country, with a 1,800-bed capacity. The institution also houses the University Of Nairobi Faculty Of Health Sciences. KNH has 50 inpatient wards and various outpatient and specialized units and clinics. The Orthopedic Surgery department offers both inpatient and outpatient services. In the outpatient clinics 40 patients attend in each of the three days of the week. Patients with traumatic limb amputation are first seen at the accident and emergency department where preliminary investigations are done. All patients with traumatic limb amputation are then transferred into the Orthopedic wards where they are admitted for surgical procedures.

#### **3.3 Study population**

The study population included all adult patients with orthopedic-related traumatic injuries admitted to KNH during the study period.

### 3.4 Eligibility Criteria

#### 3.4.1 Inclusion criteria

- i. The study included adult patients aged  $\geq 18$  years.
- ii. All patients with orthopedic-related trauma were admitted to KNH during the study duration.
- iii. Patients who consented to the study.

#### 3.4.2 Exclusion Criteria

- i. Critically ill patients who are unable to communicate.

### 3.5 Sample Size Determination

The sample size for the study was determined by applying Cochran's formula. The parameters to be used in the formula are adopted from a study conducted in Ethiopia by Dessie et al. (2009), which reported a prevalence of 6% for traumatic limb amputation in major limb injuries (25).

The formula is;  $N = \frac{P(1-P)Z^2}{e^2}$  where;

N is the sample size

Z is Z-scores for converted confidence level at 95%, equivalent to 1.96

P is an estimate of the prevalence, mainly from a previous study, that is 0.06.

e is the margin of error, for this study is 3%

Therefore, the sample size was

$$\begin{aligned}n &= (1.96)^2 (0.06 \cdot 0.94) / 0.03^2 \\&= 0.2167 / 0.0009 \\&= 241\end{aligned}$$

Thus, a minimum sample size of 241 was targeted in this study. A total of 245 participants were enrolled in the study. This was done to increase the statistical power of the study and allow the detection of smaller effects with greater confidence.

### **3.6 Sampling Procedure**

A probability sampling method based on consecutive patients seen. The approach involved enrolling each patient who met the eligibility criteria. The enrolment process entailed signing the consent forms.

### **3.7 Variables**

#### **3.7.1 Intermediate variables**

- Age
- Sex
- Education
- Income

#### **3.7.2 Dependent variables**

- Occurrence of traumatic limb amputation
- Type of extremity amputated
- Level of limb amputation

#### **3.7.3 Independent variables**

- Various causes of traumatic limb amputations (car crash, fall from height, machines, and ETC).

### **3.8 Data collection tool**

Data collection was done using structured data forms. The principal investigator or research assistant administered the questionnaires.

### **3.9 Recruitment of research assistants**

The researcher recruited two research assistants who assisted in the data collection process. The research assistants had a minimum diploma certificate in any medical field or level 6 undergraduate medical students and have experience in data collection with Kenyatta National Hospital. The research assistants were trained to ensure that they understand the purpose of the study and how to approach patients.

### **3.10 Data collection procedure**

The data collection process began after KNH-UoN Ethics and research committee approval and permission to collect data from the KNH administration. The researcher, with the two research assistants, approached patients in the orthopedic wards to identify patients who met the inclusion criteria. They explained the purpose of the study and administered the consent. Once consent was granted, the patients were required to provide their demographic details. They were assisted by the research assistant in filling out the questionnaires effectively.

### **3.11 Quality control measures**

A pre-test was conducted at the Kenyatta National Hospital orthopedic wards. The Pretest emphasized on ensuring that the research instrument selected contains all the necessary questions that could help in attaining better outcomes in improving research validity. All identified issues in the data collection tool was revised prior to commencing of actual data collection. A statistician reviewed the data collection tool to ensure that it met the underlying research goals.

### **3.12 Quality assurance**

In compliance with quality research standards, the data was collected by qualified nurses with at least a diploma certification. The research assistants were adequately trained on research protocol and ethics before the data collection commenced. The principle investigator had the

mandate to train the research assistants, supervise the data collection, and appraise the data collected for completeness before each case was marked as completed. The completed data collection for each case/file was then transferred into the password protected EPI database before sharing it with the statistician. The statistician was then sourced and mandated with the role of cleaning and analyzing the data as per the study objectives.

### **3.13 Data management and analysis**

#### **3.13.1 Data cleaning and entry**

The raw data were cleaned and coded for ease of analysis into Epi-data 3.1. Each of the responses were serialized to ensure that they were accurately entered and could be traced as well.

The collected data were entered into SPSS version 25 for analysis.

#### **3.13.2 Data storage and archival**

The data confidentiality, security and privacy were enhanced by ensuring that the filled questionnaires were stored in a secure cabinet, which was locked at all times and only accessible to the Principal Investigator. The data back-up in softcopy was stored in password protected disk accessible to principal investigator, statistician, or study supervisors. The data will be stored for five years before it is destroyed by shredding the questionnaires and formatting the hard disk with backup files.

### **3.14 Data Analysis**

The Statistical Package for the Social Sciences version 25 was used in analyzing the data. P values  $<0.05$  was considered statistically significant. Descriptive statistics with standard deviations and medians are used to describe the characteristics of the study participants. Categorical data were analyzed using frequencies and percentages. For hypothesis testing in the



bivariate analysis, logistic regression analysis was used. Findings obtained through regression analysis are presented by highlighting the odds ratio and the confidence intervals range. Data are presented using bar charts, pie charts, and tables.

### **3.15 Data dissemination**

Once data are analyzed and the manuscript developed, study findings will be disseminated in conferences presentations. The manuscript shall also be published in a peer-reviewed journal.

### **3.16 Ethical Consideration**

Ethical approval was sought from the KNH/UON-Ethical and Research Committee. The study adhered strictly to the written down codes of conduct of researchers by the ethical committee. An approved written consent form, in both English and Kiswahili, was administered and explained to all study participants. All precautions were undertaken to ensure patients' confidentiality and integrity are honored.

## 4: RESULTS

A total of 245 patients were met the inclusion criteria and they were included into the study and completed the study questionnaire representing 100% response rate.

### 4.1.Characteristics of patients with orthopedic related trauma admitted at Kenyatta National Hospital.

#### 4.1.1. Demographic characteristics of patients

The median age was 34 years (IQR: 26 – 43) of the respondents being aged between 18 to 35 years. Majority of the respondents were male, whom majority were residing within Nairobi, While 41.6 %( n =102) of the patients were self-employed (Table 2).

*Table 2: Demographic characteristics of patients*

	Frequency	Percent
<b>Age, Median (IQR)</b>	<b>34(IQR:26 – 43)</b>	
18 - 35 years	141	57.6
36 - 50 years	67	27.3
Above 50 years	37	15.1
<b>Gender</b>		
Female	39	15.9
Male	206	84.1
<b>Residence</b>		
Within Nairobi	132	53.9
Outside Nairobi	113	46.1
<b>Occupation</b>		
Employed salaried	32	13.1
Employed self	102	41.6
Casual	64	26.1
Unemployed	47	19.2

#### 4.1.2. Injury related characteristics of patients

The majority of injuries were as a result of motor vehicle crash, followed by fall from height. Further, most of patients had closed fractures with bilateral injuries. Larger number of patients had injury on their lower limb. The commonest sites of injuries were tibia, followed by femur than spine (Table 3).

Table 3: Injury related characteristics of patients

	Frequency	Percent
<b>Mechanism of injury</b>		
Gunshot and blast	3	1.2
Burn	1	0.4
Fall from height	63	25.7
Human/animal bite	9	3.7
Machine and tools	26	10.6
RTA	143	58.4
<b>Type of fracture</b>		
Closed fracture	143	58.4
Open fracture	102	41.6
<b>Site of injury</b>		
Bilateral	46	18.8
Left	69	28.2
Right	72	29.4
Missing	58	23.7
<b>Anatomic Location of injury</b>		
Upper limb	43	17.6
Lower limb	142	58.0
Spine	58	23.7
Pelvis	28	11.4
<b>Site of limb fracture</b>		
Femur	64	26.1
Tibia	72	29.4
Ankle	12	4.9
Spine	57	23.3
Pelvis	20	8.2
Foot	6	2.4
Clavicle	5	2.0
Radius	7	2.9
Wrist	4	1.6

#### 4.2. The prevalence of traumatic limb amputations

The findings established that the prevalence of traumatic limb amputation was 5.3%, 95% CI: 2.9% to 8.9% as shown in Figure 2.

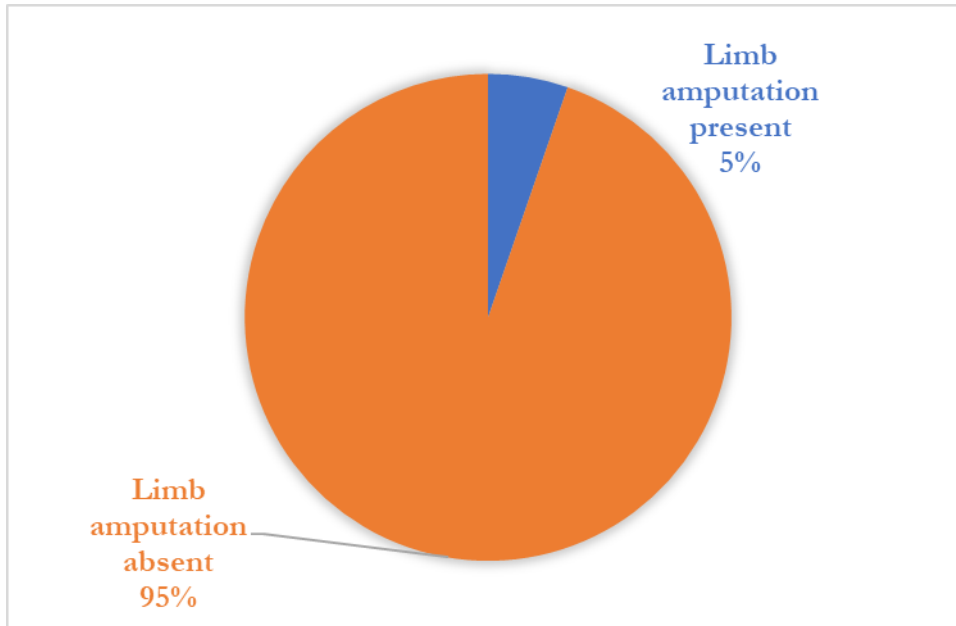


Figure 2: The prevalence of traumatic limb amputations

#### 4.3. The level of traumatic limb amputations

The findings established that 61.5 % ( n =8) of patients had lower limb amputation while 38.5 % ( n =5) had upper limb amputation as shown in Figure 3.

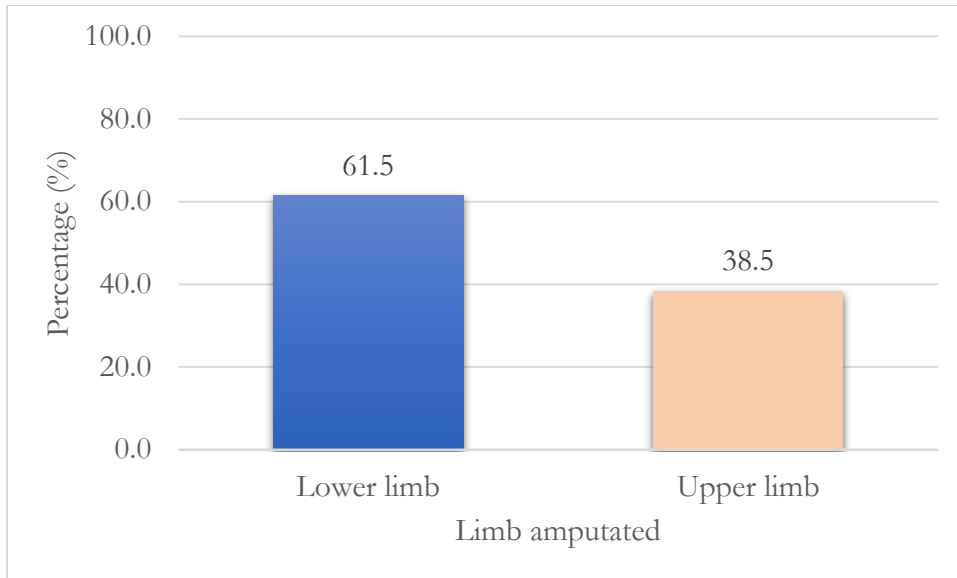


Figure 3: The level of traumatic limb amputations

#### 4.3.1. Level of upper limb amputations

The findings showed that out of five upper limb amputations, 60 % ( n =3) were digits, 20 % ( n =1) were Metacarpal and 20 % ( n =1) had amputation on trans-metacarpal as shown in Figure 3.

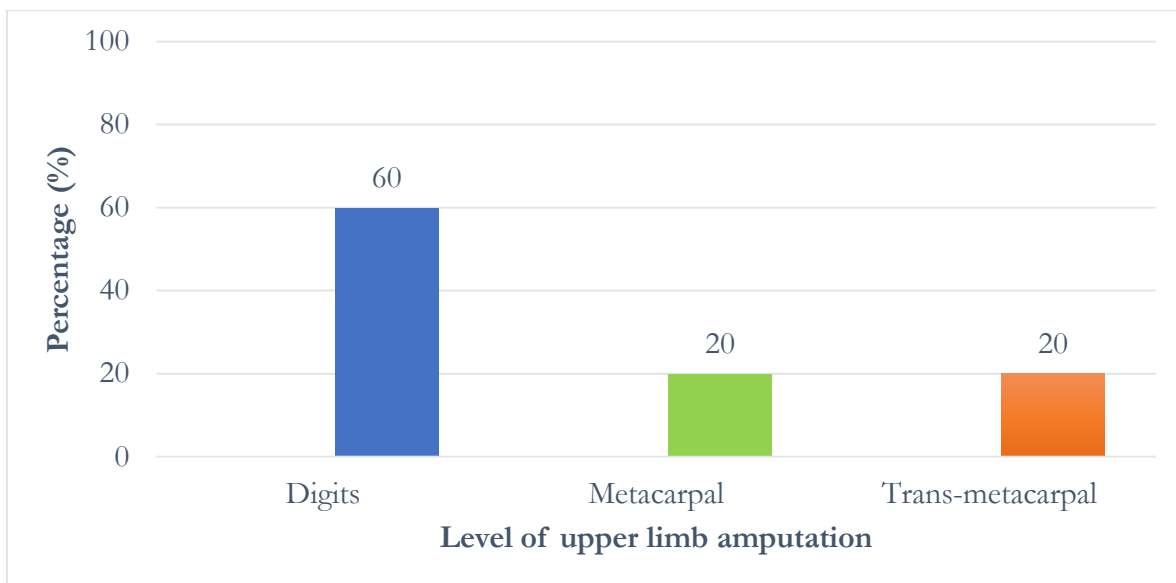


Figure 4: Level of upper limb amputations

### 4.3.2. Level of lower limb amputations

In investigating level of lower limb amputation among patients with orthopaedic related trauma, 37.5%(n =3) had their toes amputated, 25%(n =2) were amputated below knee, 25%(n =2) were amputated midfoot while 12.5%(n =1) were amputated at trans metatarsal level as shown in Figure 5.

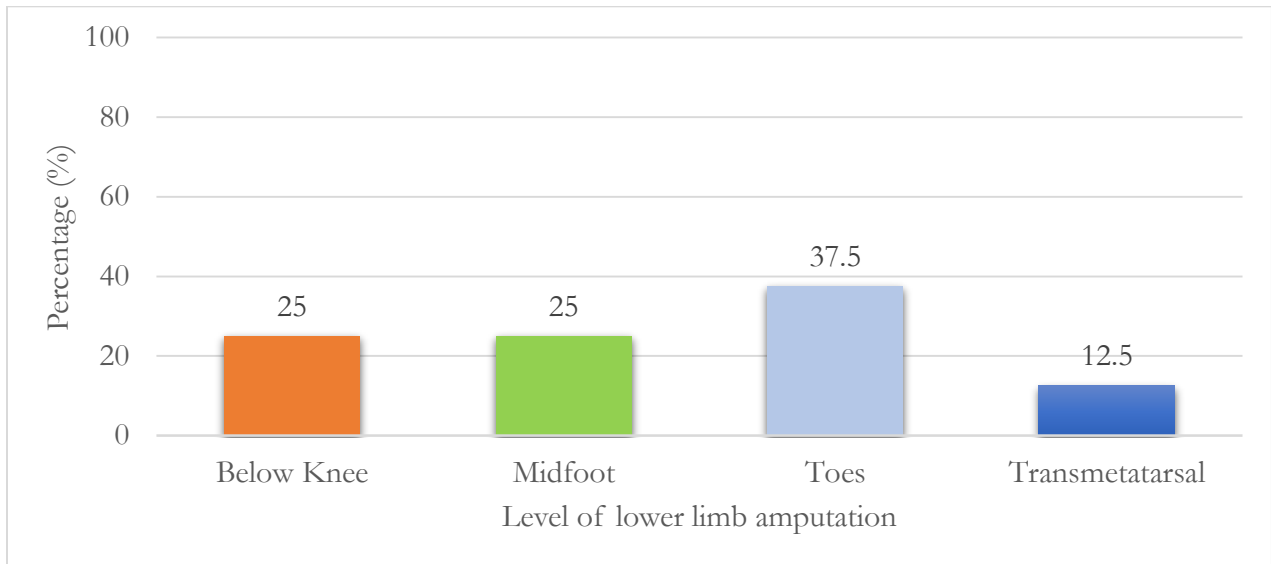


Figure 5: Level of lower limb amputation

### 4.4. The causes of traumatic limb amputations

The findings established that patients who had mechanism of injury as machine operating and tools were 4.2 times more likely to have limb amputation compared to other mechanisms of injury, OR =4.24, 95%CI:1.21 – 14.91. Patients who had open fractures were 8.5 times more likely to have limb amputation compared to those who had closed fractures, OR =8.52, 95%CI: 1.85 – 39.34, p =0.006. further, those who had lower limb as location of injury were 3.2 times more likely to have limb amputation compared to other anatomic location of injury, OR =3.19, 95%CI:1.19 – 10.28, p =0.005 (Table 4).

Table 4: The causes of traumatic limb amputations

Characteristics	Presence of limb amputation		OR(95%CI)	P-value
	Yes n (%)	No n (%)		
<b>Age</b>				
18 - 35 years	6(4.3)	135(95.7)	2.73(0.73 - 10.22)	0.137
36 - 50 years	3(4.5)	64(95.5)	2.59(0.55 - 12.24)	0.231
Above 50 years	4(10.8)	33(89.2)	Ref	
<b>Gender</b>				
Female	2(5.1)	37(94.9)	0.96(0.20 - 4.50)	0.658
Male	11(5.3)	195(94.7)	Ref	
<b>Residence</b>				
Within Nairobi	10(7.6)	122(92.4)	3.01(0.81 - 11.20)	0.151
Outside Nairobi	3(2.7)	110(97.3)	Ref	
<b>Mechanism of injury</b>				
Fall	1(1.6)	62(98.4)	0.23(0.03 - 1.77)	0.193
RTA	7(4.9)	135(95.1)	0.84(0.27 - 2.57)	0.779
Machinery	4(15.4)	22(84.6)	4.24(1.21 - 14.91)	<b>0.037</b>
Human or animal bite	1(11.1)	8(88.9)	2.33(0.27 - 20.20)	0.393
Bullet	0	4(100)		
<b>Type of injury</b>				
Closed fracture	2(1.4)	141(98.6)	Ref	
Open fracture	11(10.8)	91(89.2)	8.52(1.85 - 39.34)	<b>0.006</b>
<b>Anatomic Location of injury</b>				
Upper limb	5(11.6)	38(88.4)	1.17(0.37 - 3.69)	0.514
Lower limb	8(5.6)	134(94.4)	<b>3.19(1.97 - 10.28)</b>	<b>0.005</b>
Spine	0	58(100)		
Pelvic	0	28(100)		
<b>Type of injury</b>				
Dislocation	0	11(100)		
Fracture	13(5.7)	216(94.3)		
Soft tissue injury	0	5(100)		

## 5: DISCUSSION

Traumatic limb amputation is a condition commonly seen at Kenyatta National Hospitals. There are only a few local studies on the prevalence and etiology of various levels of traumatic limb amputation. In developing countries, traumatic limb amputation is under documented and often under- reported. This study aimed at providing local data on the prevalence and etiology of various levels of traumatic limb amputations

The present findings have showed that the average age of patients with orthopaedic related trauma were 34 years with majority of them being aged between 18 to 35 years. These findings are comparable to a study in India which found that the average age of limb amputees was 35.6 years (45). Nwosu et al. in a study in Nigeria also established that the mean age of orthopaedic trauma patients was 32 years (15). This could be due to the level of physical activity and behaviour. Young people tend to be more active and participate in sports and other physical activities that put them at risk of injury. For instance, contact sports such as football, basketball, and soccer are associated with a high risk of musculoskeletal injuries. Similarly, individuals who engage in extreme sports such as skateboarding, snowboarding, and mountain biking are also at risk of orthopaedic trauma. These activities often involve high speed driving, falls from construction site or during crop harvesting and machine and tools operations, which can result in fractures, dislocations, and other injuries.

The present findings further established that majority of patients were male (84%) which is comparable to most of previous studies. A study conducted in India by Dhillon et al. established that 84% of the patients with orthopaedic trauma were male (45). Similarly, another study conducted by Ndukwu et al. in Nigeria revealed that majority of trauma patients were males (46). This shows that the pattern of trauma occurrence is consistently high among males than female.



The higher proportion of male with trauma injuries could be as a result of higher likelihood of involvement in riskier behaviours. Males are more likely to participate in contact sports, engage in high-speed activities such as motorcycling, and take part in physically demanding occupations such as construction work. These activities can put males at a higher risk of sustaining orthopaedic injuries, which can lead to a higher number of male patients seeking orthopedic trauma treatment.

The findings also revealed that most patients resided within Nairobi (53.9%), while 46.1% were outside Nairobi. These findings are comparable to Awori et al. in a study conducted at Kenyatta national hospital, which established that most patients with traumatic limb injuries were from within Nairobi (29). The accessibility of the facility is a major factor in determining the nature of patients who present at the facility. A further higher number of patients outside Nairobi could be explained by the fact that Kenyatta National Hospital is majorly a referral facility with a wide array of experts who can manage these referral cases.

The current study also revealed that almost half of the patients were self-employed (41.1%), while 26.1% were casual. This could be explained by the assertion that in Kenya, many self-employed and casual workers in Kenya work in industries such as construction, agriculture, and transportation, which are often associated with high rates of workplace injuries. Without strong workplace safety regulations and enforcement, these workers may be more vulnerable to accidents and injuries. These findings are comparable to those from Muyembe et al. in Kenya, which found that the majority of patients with trauma injuries were self-employed (31).

The present findings showed that the prevalence of 5.3% which lower compared to most of previous studies (13)(14)(16). These findings are comparable to a study in Ethiopia by Dessie et al which revealed that the prevalence of limb amputation was 6% (25). Similarly, Dillingham et al, established that 4.8% of limb amputations were minor while 3.4% of the cases qualified as major limb amputation (23).

Further, some studies have also revealed a lower prevalence of limb amputation. A study in India which revealed that the hospital-based prevalence of traumatic limb amputation was 2.5% (45). A study conducted in Pakistan established that the prevalence of traumatic limb amputation was 0.011% (13). The lower prevalence of TLA in this study could be explained by the nature of the study where in their study, they utilized a prospective door to door survey which could have limited the number of patients with trauma and resulting in traumatic limb amputation. Further, another study in the United States revealed that the prevalence of traumatic limb amputation was 0.25% of all trauma admissions (16).

Majority of the TLA were on lower limb (61.5%). These findings are comparable to a study in Nigeria by Nwosu et al. which established that most of the TLA were in lower limb (84.8%) compared to 15.2% in upper limb which is comparable to present study where the proportion of upper limb amputation was 38.5% (15). Comparable findings were also obtained in a study conducted in Kenya which revealed that 94% of patients with TLA had lower limb amputation (31). The lower limbs are more exposed than the upper limbs, making them more vulnerable to injury in accidents such as car crashes, motorcycle accidents, and pedestrian accidents. Further, the lower limbs bear the weight of the body and are subjected to high forces during activities such as running and jumping, which can increase the risk of injury.

The most common amputation in lower limb were toes and below knee amputation while among the patients who had upper limb amputation, 60% of them were digits. This could be explained by the nature of the injury where in present study, 15.4% of the TLA were due to machinery and tools which increase the risk of amputation in digits and toes. These findings however are inconsistent with those from a study conducted in Liberia which established that below the knee (47 percent), above the knee (45 percent), below the elbow (2 percent), above the elbow (2 percent), knee disarticulation (2%) and big toe amputation (2 percent) were the common levels of amputation (35). The difference could be explained by the fact that in their study most of the TLA were caused by RTA which increases the risk of amputation below and above knee as well as below and above the elbow.

Similarly, a study conducted in Palestine also established that lower limb amputations were the most common major amputations, while upper extremity amputations were the most common minor amputations. Unilateral above-knee amputations were the most common among patients (35%). Bilateral amputations above the knees were most common (11%), while bilateral amputations below the knees occurred in 7% of cases. The most prevalent amputation in patients with upper limb amputations occurred distally in the arm and hand, while 8% had both upper and lower limb amputations (34). The population of interest in their study was soldiers which could explain the existing difference.

The findings from the present study found that who had mechanism of injury as machinery were 4.2 times more likely to have limb amputation compared to other mechanisms of injury. These findings are comparable to a study in Pakistan which established that agriculture tools were the leading cause of traumatic limb amputation (13). Similarly, McDonald et al found that majority of limb amputations were from falls accounting for 36.2%, road injuries (15.7 percent), other

transportation injuries (11.2 percent), and mechanical forces (10.4 percent) (8). Machinery is a leading cause of traumatic limb amputation because it involves the use of heavy equipment, sharp blades, and powerful moving parts that can cause severe injuries.

These injuries can occur when workers come into contact with machines that are in operation or when machines malfunction. The high speed and force of these machines can cause devastating injuries that can result in the loss of limbs or even death. In some cases, workers may become trapped in machinery or caught in between moving parts, leading to traumatic amputations. Most of the patients recruited in the present study were casual laborers who are highly involved in construction hence more likely to operate machinery without the necessary gear.

However, these findings are not in line with majority of the studies which have found that RTA has been the leading cause of traumatic limb amputation. A study conducted in Turkey revealed that road traffic accidents was the fundamental mechanism contributing to traumatic limb amputation (42). Reckless driving has been a major problem especially in developing countries leading to high trauma injuries where in some cases the severity of these injuries requires amputation. A study conducted by Ndukwu in Nigeria established that road traffic accidents were the leading causes of traumatic limb amputation (46).

The present study also established that patients who had open fractures were more likely to suffer amputations. These findings are in line with other previous studies which established similar findings (47)(48). Patients who have open fractures are more likely to be amputated because open fractures can cause extensive damage to the surrounding tissues, blood vessels, and nerves. Open fractures occur when a broken bone penetrates through the skin, creating an open wound that exposes the bone to the outside environment (48). The risk of infection is high with open fractures, and if left untreated or improperly treated, the infection can spread to the bone

and surrounding tissues, leading to severe complications. In some cases, the extent of the damage caused by the open fracture and subsequent infection may be so severe that amputation is the only viable treatment option (49).

The present findings also showed that patients who had lower limb injuries were more likely to suffer amputation. Comparable findings were obtained in a study conducted in Sweden by Tampe et al. (2014) who found that the risk of traumatic limb amputation was higher among patients who had injuries in lower limb (48). In addition, a study conducted in Sub-Saharan Africa investigating etiological and clinical profiles of major limb amputation also revealed that majority of traumatic limb amputation were lower limb injuries (50). Patients who have lower limb injuries are more likely to be amputated because the lower limbs, including the legs and feet, are often subjected to high levels of stress and are more prone to injury. Injuries to the lower limbs can result from various causes, including accidents, falls, sports injuries, and work-related incidents.

## **6: CONCLUSION AND RECOMMENDATIONS**

### **6.1. Conclusion**

The prevalence of traumatic limb amputations among patients with orthopedic related trauma was found to be 5.3%. Most common cause of traumatic limb amputations were machines and tools operations, affecting mainly those with open fractures

Most of the traumatic limb amputations (61.5%) were lower limb amputation while 38.5% had upper limb amputation. In the upper limb amputation, 60% of them were digits while majority of amputations in lower limb were toes (37.5%).

### **6.2. Recommendations**

Create awareness on the need the availability and strictly adherence to use personal protective gears among individuals who work with machine and tools in their workplace.

Prompt transfer of patients with open fractures to the centres with personnel and equipment to manage such injuries.

Patients presenting with open fractures and lower limb injuries should be effectively targeted for fracture stabilization such as immobilization with a splint.

Open wounds should be managed promptly with wound irrigation, debridement, and appropriate dressings to prevent infection.

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## APPENDICES

### Appendix A: Questionnaire/data tool

**TITLE: PREVALENCE AND AETIOLOGY OF VARIOUS LEVELS OF  
TRAUMATIC LIMB AMPUTATIONS FOLLOWING TRAUMATIC INJURIES  
AT KENYATTA NATIONAL HOSPITAL**

Serial Number:

IP number:

1. Age \_\_\_\_\_ years
2. Sex: Male / Female
3. Residence -----
4. Occupation -----
5. Mechanism of injury
  - a. RTA
  - b. Machine injury
  - c. machine and Tools
  - d. Fall from height
  - e. Blast and Gunshot
  - f. Human /animal bite
  - g. Electrical injury
6. Site of injury
  - a. Right
  - b. Left
  - c. bilateral

7. Anatomic Location of injury

- a. Upper limb
- b. Lower limb
- c. Spine
- d. Pelvic

8. Type of the injury

- a. Fracture
- b. Dislocation
- c. Soft tissue injury

9. Site of limb fracture

- a. Femur
- b. Tibia
- c. Ankle
- d. Foot
- e. Clavicle and scapula
- f. Humerus
- g. Radius and ulnar
- h. Wrist
- i. Hand

10. Presence of limb amputation

- a. Yes
- b. No

11. Limb amputated

- a. Upper limb
- b. Lower limb

12. Level of upper limb amputation

- a. Digits
- b. Trans-metacarpal
- c. Wrist
- d. Below elbow
- e. Elbow disarticulation
- f. Above elbow

13. Level of lower limb amputation

- a. Toes
- b. Mid-foot
- c. Hind foot
- d. Ankle
- e. Below knee
- f. Knee disarticulation
- g. Above knee

14. Management received

- a. Debridement and stump refashioning
- b. Re-implantation
- c. Debridement and fixations

## **Appendix B: Informed consent English version**

### **PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY**

This Informed Consent form is for patients undergoing treatment due to trauma at KNH. It will be administered to eligible patients. We are requesting you to participate in this research project whose title is (prevalence and etiology of various levels of traumatic limb amputations in orthopedic injuries seen at KNH).

**Principal Investigator:** Dr. ABDI ABDIRAZAK ALI

**Institution:** faculty of health science, University of Nairobi.

Department of surgery

This Informed Consent Form has three parts:

- I. Information Sheet (informs you in a brief overview about the research with you).
- II. Certificate of Consent (for you to sign if you agree to take part).
- III. Statement by the researcher/person taking consent.

A copy of the informed consent form will be provided.

#### **PART I: Information Sheet**

##### **Introduction**

My name is Dr. Abdi Abdirazak Ali , a postgraduate student in orthopedic surgery at the University of Nairobi. I am carrying out research to prevalence and pattern of traumatic limb



amputation among orthopedic injuries in patients seeking treatment at the Kenyatta national hospital.

### **Purpose of the research**

I will provide information and invite you to be a participant in this research. There may be some words that you don't comprehend. Please ask me to explain as we go through the information and I will explain. After receiving the information concerning the study, you are encouraged to seek clarification in case of any doubt. The study will also aim to justify the establishment of appropriate management protocols on accidental limb loss.

### **Type of Research Intervention**

This research will involve use of questionnaires and medical records with your doctor's permission [or their representative], imaging and laboratory investigation results.

### **Voluntary participation/right to refuse or withdraw**

It is your decision to participate or not. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change. If you decide against participating, you will be offered the treatment that is routinely provided in this hospital for your condition. You have a choice to refuse or withdraw your participation in this study at any point.

### **Confidentiality**

The information obtained in this study will be treated with confidentiality and only be available to the principal investigator and the study team. Your name will not be used. Any personal information will have a number on it instead of your name. We will not be sharing the identity of those participating in this research.

### **Study procedure**

After agreeing and consenting to participate in the study, you will answer questionnaires and physical examination will be carry out.

### **Sharing the results**

The knowledge obtained from this study will be shared with the policymakers in KNH and doctors through publications and conferences. Confidential information will not be shared.

### **Benefits**

The benefits of joining the study include:

- Contribution to the advancement of patient management.
- Improvement in the management of pregnant women with sickle cell trait.

### **Risks**

There will be no risk involved by enlisting for this study

### **Cost and compensation**

There will be no extra cost incurred for participating in this study nor is there compensation offered.

This research proposal has been reviewed and approved by the UoN/KNH Ethics and Research Committee, which is a Committee whose task is to make sure that research participants are protected from harm.

### **Communication**

Incase of any queries or clarifications, feel free to consult principal investigator, Abdi Adbirazak Ali on 0715013341 or email through [suufi995@gmail.com](mailto:suufi995@gmail.com), my supervisor Kirsteen Awori on phone number; + 254 722 812 499 or email through [kawori@uonbi.ac.ke](mailto:kawori@uonbi.ac.ke) or the

Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research  
Committee Telephone No. 2726300 Ext. 44102 email [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke).

**PART II: Certificate of Consent**

I have read and understood the above information/the above information has been read out to me.  
I have had the opportunity to ask questions and the questions that I have asked have been  
answered satisfactorily. I voluntarily agree and consent to participate in this research.

Name \_\_\_\_\_

Signature \_\_\_\_\_

Date\_\_\_\_\_

If illiterate:

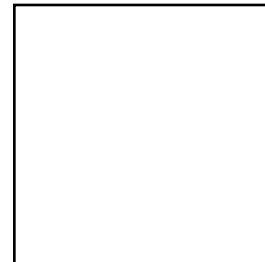
I have witnessed the reading of the consent form to the potential participant, and the individual  
has had the opportunity to ask questions. I can confirm that the individual has given consent  
voluntarily.

Print Name of witness\_\_\_\_\_

Thumb print of participant

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_



**PART III: Statement by the researcher**

I have read out the information sheet to the participant, and made sure that the participant  
understands that the following will be done:

A decision to refuse to participate or withdrawal from the study will not in any way compromise  
the care of treatment.

All information given will be handled with confidentiality.

The results of this study might be published to facilitate research and improved clinical guidelines. I can confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the approval has been given voluntarily.

A copy of the Informed Consent Form has been provided to the participant.

Name of researcher/person taking consent \_\_\_\_\_

Signature of researcher/person taking consent\_\_\_\_\_

Date\_\_\_\_\_

## Appendix C: Informed Consent Swahili version

### Fomu Ya Makubaliano Ya Kujiunga Na Utafiti

#### Fomu ya makubaliano

Nimeelezwa utafiti huu kwa kina. Nakubali kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Jina la Mshiriki \_\_\_\_\_

Sahihi ya mshiriki \_\_\_\_\_

Tarehe \_\_\_\_\_

#### **Kwa wasioweza kusoma na kuandika:**

Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki. Mshiriki amepewa nafasi ya kuuliza maswali. Nathibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi \_\_\_\_\_

Alama ya kidole cha mshiriki

Sahihi la shahidi \_\_\_\_\_



Tarehe \_\_\_\_\_

#### **Ujumbe kutoka kwa mtafiti**

Nimemsomea mshiriki ujumbe kiwango ninavyoweza na kuhakikisha kuwa mshiriki amefahamu yafuatayo:

Kutoshiriki au kujitoka kwenye utafiti huu hautadhuru kupata kwake kwa matibabu. Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.

Matokeo ya utafiti huu yanaweza chapishwa ili kuwezesha kuzuia na kutibu matatizo yanayosababishwa na prostate biopsy.

Ninathibitisha kuwa mshiriki alipewa nafasi ya kuuliza maswali na yote yakajibiwa vilivyo.

Ninahakikisha kuwa mshiriki alitoa ruhusa bila ya kulazimishwa.

Mshiriki amepewa nakala ya hii fomu ya makubaliano.


Jina la mtafiti \_\_\_\_\_

Sahihi ya Mtafiti \_\_\_\_\_

Tarehe \_\_\_\_\_

**Appendix D: Letter to collaborating institution seeking permission to conduct study.**

KNH/R&P/FORM/01



**KENYATTA NATIONAL HOSPITAL**  
P.O. Box 20723-00202 Nairobi


Tel.: 2726300/2726450/2726565  
Research & Programs: Ext. 44705  
Fax: 2725272  
Email: knhresearch@gmail.com

**Study Registration Certificate**

1. Name of the Principal Investigator/Researcher  
Abdi Abdirazak Ali
2. Email address: Sun.F.995@jamaika.com Tel No. 0715013341
3. Contact person (if different from PI).....
4. Email address: ..... Tel No. ....
5. Study Title  
Prevalance and aetiology of various level of Traumatic Limb amputations following traumatic injuries at KNH.
6. Department where the study will be conducted Orthopaedics  
(Please attach copy of Abstract)
7. Endorsed by Research Coordinator of Department where study will be conducted.  
Name: ..... Signature ..... Date .....
8. Endorsed by KNH Head of Department where study will be conducted  
Name: NDEUYA B.M. Ag HOD Signature [Signature] Date 10/03/2023
9. KNH UoN Ethics Research Committee approved study number 1022  
(Please attach copy of ERC approval)
10. I Abdi Abdirazak Ali commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research.  
Signature [Signature] Date 29/3/2023
11. Study Registration number (Dept/Number/Year) Orthopaedics / 47 / 2023  
(To be completed by Medical Research Department)
12. Research and Program Stamp


All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Medical Research and investigators **must commit** to share results with the hospital.

## Appendix E: UoN/KNH ERC approval



**UNIVERSITY OF NAIROBI**  
FACULTY OF HEALTH SCIENCES  
P O BOX 19676 Code 00202  
Telegrams: varsity  
Tel: (254-020) 2726300 Ext 44355

**KNH-UoN ERC**  
Email: [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke)  
Website: <http://www.erc.uonbi.ac.ke>  
Facebook: <https://www.facebook.com/uonknh.erc>  
Twitter: [@UONKNH\\_ERC](https://twitter.com/UONKNH_ERC) [https://twitter.com/UONKNH\\_ERC](https://twitter.com/UONKNH_ERC)




**KENYATTA NATIONAL HOSPITAL**  
P O BOX 20723 Code 00202  
Tel: 726300-9  
Fax: 725272  
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/43

Dr. Abdirazak Ali Abdi  
Reg. No. H58/11520/2018  
Dept. of Orthopaedic Surgery  
Faculty of Health Sciences  
University of Nairobi

Dear Dr. Abdi,



**RESEARCH PROPOSAL: PREVALENCE AND AETIOLOGY OF VARIOUS LEVELS OF TRAUMATIC LIMB AMPUTATIONS FOLLOWING TRAUMATIC INJURIES AT KENYATTA NATIONAL HOSPITAL (P776/10/2022)**

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P776/10/2022**. The approval period is 30<sup>th</sup> January 2023 – 29<sup>th</sup> January 2024.

This approval is subject to compliance with the following requirements;


- i. Only approved documents including (informed consents, study instruments, MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
- v. Clearance for export of biological specimens must be obtained from relevant institutions.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Protect to discover



Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) <https://research-portal.nacosti.go.ke> and also obtain other clearances needed.

Yours sincerely,

  
**DR. BEATRICE K.M. AMUGUNE**  
**SECRETARY, KNH-UoN ERC**


c.c.     The Dean, Faculty of Health Sciences, UoN  
          The Senior Director, CS, KNH  
          The Assistant Director, Health Information Dept., KNH  
          The Chairperson, KNH- UoN ERC  
          The Chair, Dept. of Orthopaedic Surgery, UoN  
Supervisors: Dr. Vincent Muoki Mutiso, Dept. of Orthopaedic Surgery, UoN  
              Dr. Kirsteen O. Awori, Dept. of Human Anatomy and Physiology, UoN

Appendix F: NACOSTI Research License

REPUBLIC OF KENYA  
MAMAMBE  
NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION

Ref No: 438241

**RESEARCH LICENSE**




This is to Certify that Dr.. Abdirazak Ali Abdi of University of Nairobi, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Nairobi on the topic: prevalence and aetiology of various levels of traumatic limb amputations following traumatic injuries atKenyatta National Hospital for the period ending : 01/March/2024.

License No: NACOSTI/P/23/23552

438241  
Applicant Identification Number

Wadhwanji  
Director General  
NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION

Verification QR Code



NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions

## Appendix G: Similarity report

