

COLLEGE OF MEDICINE & HEALTH SCIENCES SCHOOL OF MEDICINE & PHARMACY

### **DEPARTMENT OF SURGERY**

# FACTORS AFFECTING QUALITY OF LIFE POST LOWER LIMBS AMPUTATIONS – A MULTICENTER CROSS-SECTIONAL STUDY, IN RWANDA.

Dissertation submitted as partial fulfillment of the requirements for the award of the degree of Masters of Medicine in General Surgery, School of Medicine and Pharmacy, College of Medicine and Health Sciences, University of Rwanda.

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# **Declaration**

I declare that this dissertation is the result of my own work and has not been submitted for any other degree at the University of Rwanda or any other institution.

I hereby declare that this dissertation "Factors affecting Quality of Life post lower limbs amputation – A multicenter cross-sectional study in Rwanda" except where specifically acknowledged has been checked for plagiarism and found to be compliant and this is the approved final version of the dissertation.

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### HERI Eric, MD

# **Dedication**

I first of all dedicate this work to my son HERI Ryan Livin and my wife N.NSHUTI Christine who didn't get tired in encouraging and supporting me.

In memory of my late Father, BYINGOMA M. Faustin, I dedicate this work also to my mum, MUKAMURARA Kizanye Félicité, who tirelessly supported me in achieving this work. I dedicate it also to my brothers and sister who encouraged me.

# Abstract

*Background:* Most of lower limb amputations performed are due to peripheral vascular diseases and trauma, mostly in middle and lower income countries. Quality of life post lower limb amputations as outcome is important and the cognition of what affects it is vital for its promotion.

*Objectives*: The objectives of this research are to determine the quality of life post LLA and its modifiable associated factors.

**Methodology:** Lower limbs amputees aged from 15 years and above, attending CHUK and CHUB surgical outpatient clinic and physiotherapy, were assessed, by using the health questionnaire (EQ-5D) for the measurement of quality of life, and factors associated with it were on a structured questionnaire

Study design: Cross-sectional study

**Results:** Among 126 participants, male were 72.2% (n=91) and female were 27.8% (n=35) with the mean age of 45 years. Low level of education and socio-economical status were predominant. Trauma 39.7% (50), was the leading indication of LLA followed by peripheral vascular diseases 27% (34), tumors with 11.9%(15) and diabetic foot with 8.7% (11). Major amputations, 93.7 % (118), were mostly done, and they were amongst factors influencing the QoL, particularly the mobility aspect (p-value: 0.03). Amongst all aspects of QoL, mobility aspect was the most affected. 92.9% were having problems of walking in different degree of severity, with 54.7 % (n=69) who had severe problem in walking). In usual self care, 50% (n=63) reported not to have any problem in usual self care, whereas the other half reported with problems in usual self-care in different degree of severity. The 27% reported no problem in performing usual activities whereas 73 % presented problems of doing usual activities in different levels of severity. The pain or discomfort were present in 70.6% (n=89) and 29.4% (n=37) reported not to have any pain or discomfort. 46.8% (n=59) reported to be either anxious or depressed after LLA whereas 53.2% (n=67) didn't have any anxiety or depression. Different factors like education, level of amputations, stump related problems, presence of co-morbidities, poor perception of body image, access to walking device (prosthesis, crutches and wheel chair), occupation and the economical status had significant impact at different rates in the domain of the QoL.

**Conclusion and recommendation**: The burden of LLA affect different domain of QoL and different factors play role in poor QoL after LLA. Appropriate prevention of RTA, management and control of PVD, DM and perioperative psychological support and provision of walking device would result in the diminution of amputation rate and postoperative management of LLA sequelae.

Key words: Quality of life, Lower limbs, Amputation

# List of abbreviation and Accronym

AKA: Above Knee Amputation BKA: Below Knee Amputation CHUB: Centre Hospitalier Universitaire de Butare CHUK: Centre Hospitalier Universitaire de Kigali DM: diabetes mellitus EQ-5D: Health questionnaire EQ-5D VAS: Health questionnaire visual analogue scale LEA: lower extremity amputation LL: lower limb LLA: Lower limb amputation MESS: Mangled extremity severity score NHP: Nottingham Health profile PVD: Peripheral vascular disease QOL: Quality of life Ubudehe category: Socio-economical status

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# **Chapter I. Introduction** I.1. Background

Lower limbs amputations (LLA) known as limb loss, are performed worldwide, and are followed by poor quality of life (QOL)(1). They are often associated with co-morbidities which affect profoundly the QOL. The most common pre-operative co-morbidities include diabetes mellitus (DM), hypertension, cardiovascular diseases, underlying renal disease, tobacco and alcohol abuse (2,3); while the post-operative ones include mobility related problems, stump problems, socio-economical problems and psychological problems (4). Those co-morbidities are the main factors affecting the QOL after LLA in high income countries (2). However QOL of lower limb amputees is not known in lower and middle income countries (4). In Rwanda, one study done revealed that the post lower limb amputation lifestyle is often characterized by drug and alcohol abuse; but no other aspects of QOL have been studied (5).

Epidemiological figures about lower limbs amputations vary from one country to another. (6). The risk of LLA in diabetic patients is 15 times comparing to non diabetic patients. LLA increase with age and they are more common in male than female(7–9). In high income countries, peripheral vascular disease (PVD) and black race have been found to be the major risk factors(10,11) whilst in middle income countries like Nigeria, the prevalence of LLA is 1.6 per 100,000(12). In lower income countries, the available data are based on only hospital based studies, mainly about indications and in hospital complications of LLA with the paucity of data about the quality of life post LLA. In our region, hospital based studies done in Tanzania, Kenya and Ethiopia have shown the rate of LLA to be ranging between 58.6% and 86.4% of all limb amputations performed (13–15).

In Rwanda, few studies done have shown that LLA are indicated for different causes including PVD, diabetic foot, trauma, malignancy and soft tissues infections represent 3.087% of all surgeries done in referral hospitals and among them only 6.5% have access to prosthesis (16).

## I.2 Problem statement

Lower limb amputation is one of the most performed procedure in lower and middle income countries as well as in developed countries for a wide variety of reasons and associated with a wide range of complications affecting quality of life of amputees. Satisfaction with prosthesis and physiotherapy is associated with significant improved QOL in terms of mobility and body image perception(17–19).

The quality of life post LLA is poor in developed countries in terms of occupational, psychological and social lifestyle(20). The situation is deemed to be worse in middle and lower income countries with relatively low level of treatment modalities and socioeconomic status compared to the high income countries counterparts. However there is scarcity of data regarding QOL of lower limb amputees. The knowledge from this study might contribute to preoperative risk stratification and enhanced postoperative follow up for improved post amputation welfare of these needy patients.

## I.3. Justification of the study

The majority of LLA are commonly procedures done in elderly, retired, and mostly with comorbidities(20–22).

In Rwanda, the frequency of LLA was 50 and 45 of theatre procedures in CHUB and CHUK respectively in 2020, in which 9 % were due trauma in CHUK. The only study done in 2012 was solely demonstrating about different types of amputations, indications and in hospital complications (16).To our knowledge, there is no data about QOL in lower limb amputees in Rwanda.

Therefore, we conducted this study which aimed at assessing the QOL of patients who underwent LLA and factors associated, in the aim to raise awareness about the burden of LLA. It will also provide with evidenced information to the health care providers for pre-operative patient's risk stratification and improve post operative follow up plan to decrease of post LLA morbidity, and to health sector decision makers to provide sustainable medical, psycho-socioeconomical supports to the lower limbs amputees.

# I.4.Research question

What are the factors influencing the QOL post lower limb amputation in Rwanda?

## I.5. Study objective

## I.5.1 Main objective

To assess patients' quality of life in contribution to an improved patients welfare post lower limbs amputation.

## I.5.2 Specific objectives

1. To assess the quality of life post lower limb amputation

2. To identify the modifiable factors associated with poor quality of life post lower limb amputation.

## I.5.3.Outcome

The primary outcome of this study is the QOL post LLA

The secondary outcome is the determinants of QOL post LLA.

# **Chapter. II. Literature review**

## II.1. Pattern of lower limb amputation

### II.1.1. Definition of lower limb amputations

Lower limb amputation consists of complete loss in the transverse anatomical plane of any part of the lower limb due to any pathology(7), and it is either minor or major by considering different levels at which it is done.

### II.1.2.Levels of amputations

### II.1.2.1 Minor amputation

Minor amputation is any limb loss distal to the ankle joint(7). They are often done in order to prevent major amputation by limiting proximal disease progression (7). These include toes amputation or disarticulation which are performed through the phalanges or interphalangeal joints; disarticulation at metatarso-phalangeal joints ); transmetatarsal amputation ( done at the level of the shaft of the metatarsals); mid-tarsal (Chopart) amputation ( done through the tarsal bones) and Lisfranc amputation which is done at tarso-metatarsal joint(1,23).

### II.1.2.2. Major amputation

An amputation is considered major when it is done through or above the ankle joint(7). Major amputations are associated with decrease in future functional status(7). Major LLA include ankle (Symes) disarticulation, below-knee amputation which is done at 11 to 12 cm distal to the knee; knee disarticulation, Gritti-Stokes (femoral condyles) amputation performed at the supracondylar femoral level and fixation of the patella to the distal part of the femur; mid-thigh (Above knee) amputation which is done through the femur , at 12 cm above knee. Hip disarticulation, in which the femur is disarticulated from the acetabulum; and it is often due to trauma or malignancy. Hemipelvectomy (Hind quarter) consists of the ablation of the lower limb at the half of the pelvis usually due to malignancy(1,7,23,24).

#### II.1.3.Indications of LLA

Amputation is done in order to salvage the limb following a severe injury, occlusive vascular disease, an infection or malignancy(7,24). Generally the indication of any amputation have been classified as 3 D, i.e., the first D stands for dead (or dying) which comprise peripheral vascular disease, severe trauma, burns, frostbite. The second D stands for dangerous/ deadly which include malignant tumors, lethal sepsis, and crush injury. The third D stands for dead loss comprising gross malformation, congenital anomalies, recurrent sepsis, chronic osteomyelitis, severe loss of function, flail limb (polio) deformity and loss of sensation(1,23).

#### II.1.3.1.Peripheral vascular diseases

PVD results from arterial or venous occlusion. Arterial occlusive disease results from cardiac disease, mostly atrial fibrillation(1,22,25) which complicate into gangrene (dry or wet) and eventual amputation (1).

Arterial occlusive disease causes acute limb ischemia or chronic limb ischemia. Acute limb ischemia is caused by thrombosis, embolism or trauma; and presents with claudication. If left untreated in more than six hours, it results into gangrene and eventual amputation(26,27). Chronic limb ischemia is caused by progressive arterial occlusion due to mainly atherosclerosis, thromboangiitis obliterans (Buerger's disease), vasculitis, trauma, popliteal artery entrapment (26,28). Atherosclerosis is caused by progressive arterial deposition of atherosclerotic plaque made of a central core and lipid material(9,21,26). Thrombogenic activity of the central core lead to complete occlusion, if left untreated. Nine percent of people with atherosclerosis are prone to amputation (26,29,30).

#### II.1.3.2. Trauma

Trauma is the leading indication of LLA in young population (1,31). It results manly from road traffic crash, occupation, vocational hazards and it is among the commonest indications of LLA in developing countries at different rates(13,16,31,32). For instance, in Nigeria, in 1642 lower limb amputees in a nationwide research, 34% were amputated due to trauma(12). The amputation is done when Mangled extremity severity score is equal or greater than seven and it

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is calculated based on the energy that caused the injury, limb ischemia, shock, and the patient's age(1,33).

Туре	Characteristics	Injury	Points
1	Low energy	Stab wound,simpleclosed fracture, small caliber GSW	1
		Open/Multilevel fracture, dislocation, moderate	
2	Medium energy	crush	2
3	High energy	Shotgun, high velocity GSW	3
4	Massive crush	Logging, railroad, oil rig accidents	4
Shock group			
1	Normotensive	Blood pressure (BP)is stable	0
2	Transiently ypotensive	BP is unstable in field but responsive to fluid	1
3	Prolonged Hypotension	Systolic BP <90 mmHg in field and responsive to IV fluids in operating room	2
Ischemic			
group			
1	None	Pulsatile, no signs of ischemia	1
2	Mild	Diminished pulses, without signs of ischemia	2
3	Moderate	No dopplerable pulses, sluggish capillary refill, paresthesia	3
		Diminished motor activity	
4	Advanced	Pulseless, cool, paralyzed, numbness without capillary refill	4
Age group			
1	< 30 years		0
2	>30 years <50 years		1

Table 1. Mangled Extremity Severity Score

Mess score: Six or less consistent with salvageable limb. Seven or greater is an indication of the amputation

From Heifet DL, clin Orthop 1990 256:80

(33)

### II.1.3.3.Diabetic foot

The prevalence of Diabetes mellitus worldwide is 9%, and it is among the most common reasons of lower limbs amputation worldwide (34). Incidence of LLA is estimated to be 46.1 to

9600 per 100000 people in the population with diabetes in comparison to 5.8–31 per 100000 people of the general population, worldwide. Diabetic foot results from diabetic neuropathy and microvascular diseases (26,35).

Diabetic neuropathy results from progressive microangiopathy (occlusion of vasa nervorum) and hyperglycemia results from increased sorbitol and fructose in Schwann cell which impairs the sensation and eventual unrecognized limb injury and development of foot ulcers. Microvasculopathy and diabetic neuropathy predispose the limb to infection (1,36). Diabetic neuropathy leads to Charcot foot due to muscle wasting and bone destruction (26,35). Peripheral vascular disease associated to diabetes, predisposes the lower extremities to polymicrobial infection which potentiates the risk of limb loss (26).

In developing countries, foot ulcers in association with poverty, lack of sanitation and hygiene, and barefoot walking lead to complicated diabetic foot and eventual amputation(6).

#### II.1.3.4 Other indications

Other indications of LLA include burns (thermal or electrical), necrotized soft tissue infection (NSTI), prolonged shock (systolic blood pressure below 90 mmHg) in ICU settings, clostridial infection, frostbite. There are reported cases of gangrene following malaria in tropical regions and snake bite that lead to lower limb amputations(1, 29,30,31).

### II.1.4.Post lower limbs amputations complications

Stump related complications are multiple. These include early and late complications. Early complications include heart attack, deep vein thrombosis, surgical site infection, pneumonia, a second amputation and pressure sores(13). Late complications include neuroma ,prominence of bone, fracture of the stump ,contractures , infections, hematoma, back pain, contra-lateral limb pain , phantom pain, stump pain and psychological disturbances leading to probable suicide thought (1,25,39)

### II.2.Quality of life post lower limb amputations

### II.2.1.Definition of quality of life

Quality of life is defined as a subjective well being and the level of satisfaction with life(40). The QOL measures the outcomes related to physical health( physical functioning), emotion, cognitive functioning, role performance and work, sexual life, and life satisfaction(41). The QOL encompasses both subjective and objective dimensions of life. On subjective aspect, patient's perspectives ( perception of the illness, treatment, self expectations) are measured, although they change across the time and situations(42). Multidimensional measurements require investigations in different areas of patients life such as functional ability, physical, emotional, and social well-being(43).

### II.2.2.Factors influencing quality of life after LLA

Quality of life is the sum of objectively and subjectively measurable individual's life conditions experienced. For LLA, these include mobility problems, stump problems, social relationships, presence of co-morbidities, psychological problems, advanced age, satisfaction with life and economical influences(34).

#### **II.2.2.1.Mobility problems**

The mobility has been shown to be an independent factor that affects the quality of life. The appropriate management of mobility problems alone results in better satisfaction with life, improved psychological and social discomfort (18).

#### **II.2.2.2.Social problems**

LLA is associated with poor social relationship. However available data have shown that having a partner and a timely social support in case of need results into improved QOL (18,22); while social isolation is associated with poor QOL(24).

#### **II.2.2.3.Presence of co-morbidities**

Diabetes mellitus is significantly associated with poor quality of life(2). It is the most known comorbidity in lower limb amputees. Poor QOL after LLA in diabetic is mainly due to poor blood sugar control, recurrent infection and second amputations (21). Other co-morbidities include cardiovascular diseases (hypertension, cardiomyopathies, arrhythmias, heart failure), underlying renal disease ; and they are associated with different levels of interferences to the QOL in addition to LLA(2).

#### II.2.2.4. Ageing

Advanced age post LLA impairs significantly the prosthetic use, crutches use and mobility, and this affect negatively the quality of life(44). The burden of LLA to the QOL in elderly is further aggravated by the presence of co-morbidities like DM, atherosclerosis, cardiovascular diseases including hypertension, stroke, renal disease, age related weakness commonly found in this specific age group (45).

#### **II.2.2.5.** Psychological problems

The common psychological problems encountered by patients post amputation are depression and anxiety(46) ,and these were mainly secondary to mobility problems, poor perception of body image and social discomfort (isolation and stigmatization) (46).

#### II.2.2.6. satisfaction with life

Generally LLA impairs the satisfaction of life with a negative impact on QOL. However management of mobility related problems improves significantly the general satisfaction and the QOL(47). In addition to mobility, sexual satisfaction is affected significantly after LLA in comparison to upper limb amputation, and it worsens in patients with advanced age(48–50).

#### II.2.2.7. Economical influence and level of education

Lower limb amputations causes disability, decreased level of productivity and delayed return to work mostly due to mobility difficulties(20). A study done in 2007 showed that the timing of return to work varies according to the type of occupation which may be linked to the level of education (20). In Rwanda, majority of lower limb amputees are economically affected and some of them became street beggars(5).

### II.3. QOL measurement tool in lower limb amputees

Post lower limbs amputation quality of life has been studied by using different tools which are validated. The tool that will be used to assess the QOL is the EQ-5D-5L (Health questionnaire). It is often used as health related quality of life measurement tool by EuroQol Research Foundation and can be adapted to adolescent (51). Its measurement comprise two parts : the first one is made by five dimensions such as mobility assessed by walking about, self-care

(grooming), usual activities , pain or discomfort , and anxiety or depression, and each dimension is assessed at five levels depending of the perception of the problem(51,52). Level one indicates that there is no problem, level two indicates that there is light problem, moderate problem for level three, severe problem for level four and extreme problem for level five. The second part is made by the patient, by rating his/her health out of one hundred. The higher figure being the best health, the lower number being the worse health (53). The advantage of EQ-5D-5L is that it is easy to use for lower limb amputees, because those dimensions are commonly impaired after amputations.

# **III METHODS AND MATERIALS** III.1.Study design

This study was a multicenter cross-sectional study, which included patients who underwent LLA

## III.2. Study settings

This study was a multicenter cross-sectional study, done in two tertiary hospitals in Rwanda. Those include CHUK (Centre Hospitalier Universitaire de Kigali) and CHUB (Centre Hospitalier Universitaire de Butare).

CHUK is a national tertiary hospital situated in Kigali (Capital city of Rwanda). It receives references from district hospitals located in Northern and Western provinces and part of the Southern and Eastern provinces. The hospital has the capacity 427 beds. It delivers specialized surgical services, with a staff made of general surgeons, orthopaedic surgeons, urologist surgeons, neurosurgeons, pediatric surgeons, plastic surgeon, ENT surgeons, nurses, physiotherapist, and a varying number of residents, medical students and other allied health sciences students as a teaching hospital.

CHUB, also as a national tertiary hospital, is situated in Huye district, in the Southern province. It receives references from district hospitals from Southern and part of Western provinces. It has the capacity of 403 beds. It delivers specialized surgical services, with a staff made of surgeons (general surgeons, urologist, orthopaedics, ENT) nurses, physiotherapists and a varying number of residents, medical students and other allied health sciences students as a teaching hospital.

## **III.3.Study population**

The target population of this study accounted for patients who underwent lower limb amputation, after a period between three months and five years from the time of the procedure

## III.4. Selection criteria

### III.4.1.Inclusion criteria

1. Patient who underwent lower limb amputations (Minor and major amputations)

3. Patients whose lower limb amputation was done in a period of 3 months or above.

#### III.4.2.Exclusion criteria

1. Patients with LLA and associated Upper limb amputation

2.Lower limbs amputees who are in ciritical care settings

3. Patients whose LL are amputated in a period of less than three months prior to data collection and above 5 years (<2016)

## III.5. Sample size calculation

*The Formula to be used is* :  $n = z^2 x p(1-p) / d^2$  in which N: sample size Z=1.96 for 95% level of confidence, P= Estimated prevalence ( estimated at 9% for this study D (from pivot): Level of precision 5% .) Calculated sample size: 126 participants.

### III.6.Data collection

The pre-established data collection form comprising demographic data, QOL measurement tool, post LLA problems, and the level of amputation was used. Data regarding the records of clinical aspects of the participants were retrieved from interview and patients file, while data regarding the QOL were exclusively obtained from direct interview.

### III.7.Data entry and Analysis

The data were analyzed by SPSS and continuous variables were compared by student's t –test. Categorical data were analyzed by using the chi-square test. Values were expressed as means and SD for continuous variable like age group and percentages for categorical variables( different aspects of QoL, indication of amputations, complications post LLA, ubudehe category, marital status, insurance, level of amputation, different factors interfering with the QoL, ) with Excel Microsoft software. P-value of 0.05 was considered significant.

## III.8.Ethical consideration

Prior to data collection, we obtained ethical clearance from University of Rwanda, College of Medicine and Health Sciences Institutional Review Board (IRB CMHS/ UR) and the approval

notice is: No301/CMHS IRB/2020 and from ethical committees of host hospitals CHUK (approval notice No : EC/CHUK/003/2021) and CHUB (approval notice No : CHUB/DG/SA/03/4335/2021).

We obtained the informed consent from participant and assent before data collection. Confidentiality was assured to the participant as well as the right to withdraw from the study at any time without any consequence.

Data were kept in hard copy and strictly kept in hard copy by the principal investigator .They are stored in cupboard, whose key are kept by the principal investigator and only used for research purpose. Encrypted data were kept on a laptop, on which only principal investigator and research supervisor had access. No financial award was warranted to participants.

## **III.9.Study limitations**

Those include incidental financial deteriorations for participants and movements restrictions resulting from lockdowns and curfew following Covid-19 pandemic prevention, which interfered in different steps of the study process, like participants enrolment and others.

# **IV.RESULTS** IV.1.Demographic

During six months, 126 participants fulfilling the inclusion criteria were enrolled. The age ranged from 15 years to 89 years with an average of 45 years and a median of 44 years and 6 months. Male were 73 percent whereas female were 27 percent with a male to female ratio of 2.7/1.



Figure 1 Participants age distribution

Figure 1. Illustrating the pattern of participants' age distribution. The average age was 45 years, and the median was 44 years, 6 months with the standard deviation of 18.9 years and it shows normal distribution.



Figure 2 Gender distribution

Male were 73 % (n=91) and female were 27 % (n=35); with a male to female ratio of 2.7/1

Demographic pattern of	Number			
participants	(N)	Percentage	Mean	
Age	[15-89]126	100%	45.12	
Gender				
Male	91	73%		
Female	35	27%		
Marital status				
Married	70	55.6%		
Single	43	34.1%		
Widow/ widower	10	7.1%		
Divorced	3	2.4%		
Level of education				
Primary school	83	65.9%		
Secondary school	20	15.9%		
Bachelor degree	4	3.2%		
Masters degree	2	1.6%		
None	17	13.5%		
Ubudehe category				
Category 1	56	44.4%		
Category2	43	34.1%		
Category 3	25	19.8%		
Unclassified	2	1.6%		
Health insurance				
CBHI	113	89.7%		
RSSB	4	3.2%		
MMI	1	0.8%		
MIS UR	1	0.8%		
NONE	6	4.8%		

#### Table 2. Demographic pattern of participants

Table 2 shows participants' demographic pattern where the majority of participants were married at 55.6% (n=70), whereas single people were 34.1% (n=43); divorced people and

widow/widower were 2.4%(n=3) and 7.1 %(n=9) respectively. The most frequent level of education found in participants was primary school (65.9 %; n=83) and those who didn't attend any school were 13.5%(n=17). To note that there was a decreasing of number in high level of education. The bulk of participants were in Ubudehe category one (44.4%; n=56), whereas 1.6%(n=2) didn't have Ubudehe category. The community based health insurance was the most common insurance used at 89.7 %( n=113) and 4.8% were found without health insurance.

## IV.2.Clinical pattern of lower limbs amputations

### IV.2. 1.Indications of amputation

The indications of LLA are multiple in this study as shown in the diagram below



#### Figure 3 Indications of LLA

Figure 3 illustrates indications of LLA, whilst trauma was the leading cause of LLA with 39.7% followed by peripheral vascular diseases resulting in limb ischemia and eventually gangrene at 27%, tumors at 11.9%, others including burn with, congenital limb deficiency, osteomyelitis and poliomyelitis with 11.9%, diabetic foot with 8.7% and gas gangrene with 0.8%. Amongst 50 amputees due to trauma, 82% resulted from road traffic crash, while 16% and 2% were due to assault and occupational/ environmental hazard respectively.

## IV.2.2.Level of amputation

In this study, LLA has been performed at different levels, but major amputations predominate to minor amputations, as shown in the figure below.



Figure 4. Level of lower limbs amputation

As shown in figure 4, major LLA predominate; representing 93.2 % of all LLA, with AKA being the most common lower limb amputation performed. Above knee amputation and below knee amputation represented the majority of major amputations in our patients representing 51.6% and 37.3% respectively.

## IV.2.3.Surgical complications post LLA

 Table 3. Surgical complications post LLA

Complications	Frequency	Percentage
Stump pain	40	31.70%
Phantom pain	31	24.60%
Back pain	25	19.80%
Surgical site Infection	11	8.70%
Ulceration	7	5.60%
Contractures	2	1.60%
None	10	7.90%

Table 3 illustrates different post LLA complications where pain syndromes predominate to stump infections or ulceration

# IV.3.Quality of life

Health related quality of life, often measured subjectively and objectively, as an outcome, after undergoing any medical or surgical procedure, has been assessed by using EQ-5D-5L tool in this study.

EQ-5D-5L made of 2 parts (the first one is made of 5 dimensions, each assessed at 5 levels depending on the severity of the problem and the second one measured individual self rated health (the level of satisfaction with the current health status), in which the higher the number, the better is the QoL).

#### IV.3.1.1.Mobility aspect

Table 4. Mobility aspect and age

		Quality of life, mobility aspect						
Variable		Level 1 N (%)	Level 2 N (%)	Level 3 N (%)	Level 4 N (%)	Level 5 N (%)	Pearso n chi - square	P-value
Participan t age	10-20 years	0	0	7(5.5%)	5(4%)	1(0.8%)		
	21-30 years	1(0.8%)	3(2.4%)	6(4.7%)	9(7.1%)	2(1.6%)		
	31-40 years	2(1.6%)	1(0.8%)	3(2.4%)	14(11.% )	2(1.6%)		
	41-50 years	3(2.4%)	1(0.8%)	0	13(10.% )	1(0.8%)	30.188	
	51-60 years	2(1.6%)	3(2.4%)	2(1.6%)	15(12%)	2(1.6%)		0.354
	61-70 years	1(0.8%)	1(0.8%)	4(0.8%)	7(5.5%)	3(2.4%)		
	71- 80year	0	1(0.8%)	3(2.4%)	3(2.4%)	0		
	81-90 years	0	0	1(0.8%)	3(2.4%)	1(0.8%)		
Total		9(7.1%)	10(8%)	26(20.6 %)	69(54.7 %)	12(9.5% )		

The above table illustrates the problem of mobility according to the age where the majority of lower limbs amputees are found to remain with level four have mobility problems (54.7 %, n=69). 9.5% (n=12) remained with level five mobility problems and only 7.1% (n=9) remained without mobility problems post LLA.



Figure 5 USUAL SELFCARE

Figure 5 represent the aspect of usual self-care (washing and dressing) whilst 50% of participants reported to have problem self-care.

 Table 5.Performance of any activity

Variable			leisu	ire, going to	school			
Variable					5 5011001			
Variable								
Variable							Pearson	
Variable		Level 1	Level 2	Level 3	Level 4	Level 5	Chi-	
variable		n (%)	n (%)	n (%)	n (%)	n (%)	square	P-value
Participa	10-20	6(4.7%	2(1.6%	A(3.1%)	0	1(0.8%)	24 234	
nt age	years	)	)	4(3.1%)	0	1(0.0%)	24.234	0.669
	21-30	5(4%)	8(6.3%	4(3,1%)	2(1.6%)	2(1.6%)		
	years	5(170)	)	1(3.170)	2(1.070)	2(1.070)		
	31-40	6(4.7%	7(5.5%	3(2,4%)	2(1.6%)	4(3.1%)		
	years	)	)	- ()	_()			
	41-50	5(4%)	6(4.7%	1(0.8%)	4(3.1%)	2(1.6%)		
	years		)	· · ·	. ,	· · ·		
	51-60	7(5.5%	6(4.7%	5(4%)	4(3.1%)	2(1.6%)		
	years	)	)	. ,	. ,	· · · ·		
	61-70	3(2.4%	5(4%)	4(3.1%)	1(0.8%)	3(2.4%)		
	years	)		. ,	. ,	· · · ·		
	/1-	1(0.8%	1(0.8%	0	2(2, 40/)	2(1, 60())		
	80yea	)	)	0	3(2.4%)	2(1.0%)		
	18 81 00	1(0.90/	1(0.90/					
	01-70 Vears	1(0.0%)	1(0.0%)	2(1.6%)	0	1(0.8%)		
Total	years	) 34(27%	) 36(28.5	23(18.2	16(12.7%	17(13/1%		
1 1 1 1 2 1		3+(21/0)	50(20.5	23(10.2	10(12.770	1/(13.+70		
Total	21-30 years 31-40 years 41-50 years 51-60 years 61-70 years 71- 80yea rs 81-90 years	5(4%) 6(4.7% ) 5(4%) 7(5.5% ) 3(2.4% ) 1(0.8% ) 1(0.8% ) 34(27%	8(6.3% ) 7(5.5% ) 6(4.7% ) 6(4.7% ) 5(4%) 1(0.8% ) 1(0.8% ) 36(28.5	4(3.1%) $3(2.4%)$ $1(0.8%)$ $5(4%)$ $4(3.1%)$ $0$ $2(1.6%)$ $23(18.2$	2(1.6%) $2(1.6%)$ $4(3.1%)$ $4(3.1%)$ $1(0.8%)$ $3(2.4%)$ $0$ $16(12.7%)$	2(1.6%) $4(3.1%)$ $2(1.6%)$ $2(1.6%)$ $3(2.4%)$ $2(1.6%)$ $1(0.8%)$ $17(13.4%)$		

The above table shows the performance of usual activities by the age whilst 71.4% remained with problems of usual activities performance by different degree of severity whereas only 28.6% exhibited normal usual activities performance post amputation.

IV. 3.1. 4. Presence of pain or discomfort





The majority, complained of pain or discomfort at 70.6% in different levels of severity whereas 29.4 % remained pain free after LLA

#### IV.3.1.5. Psychological disturbance after LLA.

. 53.2% were neither anxious nor depressed. 19% reported to be slightly depressed, while 11.1% were moderately depressed, 15.1% were severely depressed and 1.6% were extremely depressed, as shown in the figure below.



Figure 7. Rate of Psychological disturbances

Figure 7 shows that 46.8 %( n=59) reported to remain with psychological sequellae involving anxiety and depression at different levels

### V.3.2.EQ-Visual analogue scale

Table 6EQ-Visual analogue scale

Variable		Frequency	Percent	
Self	Not	65	51.6	
rated	satisfied	05	51.0	
health	Partially satisfied	36	28.6	
	Satisfied	25	19.8	

Table 6 shows different levels of self rating health, in which 51.6 % (n=65) have shown not to be satisfied with health and only 19.8 % (n=25) exhibited better satisfaction with life on EQ-visual analogue.

# IV.3.Modifiable factors affecting the QOL after LLA

Variables		Frequency	Percent
Economical level	Increased income	1	0.8
	Decreased income	106	84.1
	Student	15	11.9
	The economy remained the same	4	3.2
Occupation	Same job (pre and post amputation	7	5.6
	changed job	21	16.7
	Sacked	8	6.3
	Resigned	6	4.8
	Jobless	75	59.5
	Retired	8	6.3
	Begging	1	0.8
Drug abuse	Alcohol	73	57.9
	Tobacco	5	4.0
	Recreational drugs	1	0.8
	None	47	37.3
Perception of body	Satisfied	27	21.4
image	Moderately satisfied	13	10.3
	Not satisfied	86	68.3
Social isolation	Yes	66	52.4
	No	60	47.6
Access to prosthesis	Yes	43	34.1
	No, due to financial issues	83	65.9
Access to crutches	Yes	120	95.2
	No	6	4.8
Abandoned by the	Yes	8	6.3
family	No	118	93.7
Decreased	Yes	38	30.2
self*esteem	No	88	69.8

Table 7. Modifiable factors affecting the QoL

Table 7 summarises the factors affecting QoL and it demonstrates the predominance of: the decrease of income (84.1%),joblessness (59.5%), alcohol abuse (57.9%), poor satisfaction with the body image (68.3%), social isolation (52.4%), poor access to prosthesis (65.9%), Stump pain (31.7%), good relationship with the family members (93.7%), the decrease of self-esteem (69.8%) and lack of prosthesis and disability (61.1%) to be the reason of poor satisfaction.

## IV.4.Statistical analysis of factors affecting different aspects of QoL

		Presence of problem in mobility			
Variable		No problem	presence problem in mobility	Pearson chi square	P-value
Level of amputation	Toe amputation/disarticulation	0	5(4%)		
	Midfoot amputation	1(0.8)	0		0.03
	Below knee amputation	2(1.6%)	47(37.3%)		
	Knee disarculation	0	3(2.4%)	19.9	
	Above knee amputation	5(4%)	60(47.6%)		
	Hemipelvectomy	0	1(0.8)		
	Hip disarticulation	1(0.8)	1(0.8)		

 Table 8 Impact of level of amputation to the QoL

Table 8 shows that major amputations performed were associated with mobility problems significantly(p=0.03)

Table 9 Impact of Occupation to the QoL

		Occupation								
		Same job								
Dimensio	n of QoL	post amputati on N(%)	Change d the job N(%)	Sacke d N(%)	Resigne d N(%)	Jobles s N(%)	retire d N(%)	Beggi ng N(%)	Pearso n Chi- square	P- valu e
Presence of anxiety or depressi	Absence of anxiety/ depressi on	7(5.5%)	7(5.5%	3(2.4 %)	5(4%)	39(31 %)	6(4.7 %)	0	15	0.01
on	Presence of anxiety / depressi on	0	14(11.1 %)	5(4%)	1(0.8%)	36(28. 5%)	2(1.6 %)	1(0.8 %)		9
Total		7(5.5%)	21(16.6 %)	8(6.3 %)	6(4.7%)	75(59. 5%)	8(6.3 %)	1(0.8 %)		

Table 9 shows that occupational issues were associated with psychological compromise significantly (p=0.019) effect of the lack occupation to the psychological compromise post LLA, whilst 46.8% (n=59) remained with psychological sequelae due to occupational disturbances post LLA.

Table 10. Impacts of perception of body image on QoL

	Perce	Perception of body image				
			Moderately	Not	Chi	
Dimensions of QoL		Satisfied	satisfied	satisfied	square	P-value
Presence of anxiety or depression	Abcence of anxiety / depression	24(19%)	6(4.7%)	37(29.3%)	18	0.000
	Presence of anxiety / depression	3(2.4%)	7(5.5%)	49(38.8%)		
Presence of pain/	no pain	13(10.3%)	4(3.1%)	20(15.8%)	6	0.046
discomfort	Presence of pain ordiscomfort	14(11.1%)	9(7.1%)	66(52.3%)		
Presence of problem in	No problem	8(8%)	0	1(0.8%)	26	0.000
mobility	presence problem in mobility	19(15%)	13(10.3%)	85(67.4%)		
Presence of problem in	No problem	12(9.5%)	2(1.6%)	22(17.4%)	4.8	0.000
performing usual activities	presence of problem	15(12%)	11(8.7%)	64(50.7%)		

Table 10 illustrates that the distorted body image post LLA was found to significantly affect QOL in its dimensions: anxiety and depression, problems of mobility, discomfort and performance of usual activities with a p value of 0.000, 0.000, 0.046 and 0.000 respectively.

Table 11 Impact of social isolation on QoL

		Social i	solation	Pearson	
				chi	P-
Dimensions of	QoL	Yes	No	square	value
Presence of problem in	No problem	1(0.8%)	8(6.3%)	6.61	0.01
mobility	presence problem in mobility	65(51.5%)	52(41.2%)		
Presence of anxiety or depression	The absence of anxiety / depression	19 (15%)	48(38%)	33	
	Presence of anxiety / depression	47(37.3%)	12(9.5%)		0.000

Table 11 exhibits that social isolation post LLA was found to be significantly associated with mobility (p=0.01) and psychological sequelae (p=0.000)

Table 12 Impact of Access to prosthesis to the perception of body image

		Access to	prosthesis		
			No, due to	Pearson	
			financial	chi	
Variable		Yes	issues	square	P-Value
Perception	Satisfied	23(18.2%)	4(3.1%)	40	
of body image	Moderately satisfied	4(3.1%)	9(7.1%)		0.000
	Not satisfied	16(12.7%)	70(55.5%)		

Table 12 shows that the lack of prosthesis post LLA was found to affect significantly the patient's satisfaction of the body image (p=0.000).

Table 13. Impact of access to prosthesis to QoL

		Access to	prosthesis		
			No, due to		
			financial	Pearson Chi	P-
Dimensions of QoL		yes	issues	square	value
Presence of problem in mobility	No problem	8(6.3%)	1(0.8%)	12.9	0.00
	presence problem in mobility	35(27.7%)	82(65%)		
Psychological status	The absence of anxiety / depression	34(27%)	33(26.2%)	18	0.00
	Presence of anxiety / depression	9(7.1%)	50(39.6%)		

Table 13 exhibiting the impact of poor access to walking device post LLA was significantly associated with the presence of mobility problems and presence of anxiety (p=0.000 and 0.000 respectively)

Table 14. Factors affecting EQ-5D VAS

			EQ-5D VAS			
		Not	Partially		Pearson	
		satisfied	satisfied	Satisfied	Chi	
Variables		(<50	<80 >50	>80	square	P-value
Reason of	Financial	10(8%)	4(3.1%)	0	135	0.00
poor satisfaction with health	Lack of prosthesis and disability	49(38.8%)	25(19.8%)	0		
	Co- morbidities	3(2.4%)	0	0		
	Isolation	1(0.8%)	2(1.6%)	0		
	Stump related problems	2(1.6%)	5(4%)	0		
	No problem	0	0	25(19.8%)		

Table 14 exhibiting different reasons of poor self-rating of health whilst lack of prosthesis and disability constitute the majority (p=0.000) whereas only 19.8% (n=25) rated well their health.

Factors		Frequency	Percentage
Level of amputation	Minor amputation	6	4.7%
	Major amputation	120	95.3%
Occupation	Same job (pre and post amputation	7	5.6
	changed job	21	16.7
	Sacked	8	6.3
	Resigned	6	4.8
Social isolation	Yes	66	52.4
	No	60	47.6
Access to prosthesis	Yes	43	34.1
-	No, due to financial issues	83	65.9
Demonstion of image	Satisfied	27	21.4
body	Moderately satisfied	13	10.3
	Not satisfied	86	68.3

Table 15. Summary of factors affecting significantly the QoL

Table summarizing important factors with great impact on QoL. To note the predominance of poor access to prosthesis and poor perception of distorted body image.

# **Chapter V.DISCUSSION**

In our study, the average age for LLA in this study is 45 years whose families depend on them and the majority of them, LLA was due to acute trauma and our results resembles the ones found elsewhere in LIC like in a study done in Ethiopia where average age of lower limb amputees was 40.5 years(32). However in comparison to MIC and HIC, LLA are performed commonly in advanced age above 65 years (1). This might be due to increasing rate of comorbidities resulting in potential limb loss in adulthood above 60 years(54). In Sweden one study about outcome from LLA due to peripheral vascular diseases, the average age was 69 years(15,55). Globally, male are prone to undergo LLA in comparison to female, what is similar to findings in our study. The finding of lower level of education (primary school) and lower socioeconomic status found in our study correlates with the findings elsewhere in LIC (e.g Ethiopia)(32). The level of education is one of the pillar of success return to the job(22).

Clinically, trauma resulting from road crush is the leading cause of lower limb amputation followed by peripheral vascular diseases in our study, which is similar in many Southern countries like Kenya, Tanzania ,Ethiopia and others (14,32,56). The causes of limb loss depend on infrastructure, age of the population, civil wars, terrorisms and natural catastrophes common in LIC(55). In contrary to high income countries, in which the leading cause of LLA are peripheral vascular diseases and diabetic foot complications(9) although some rare papers have shown trauma to be one of the leading causes of LLA in USA(57). Major amputations are the most performed , with the predominance of above knee and below knee amputations in this study, which look like same results in Ethiopia, USA, (32).Post operative surgical complications include in LLA include surgical site infections, phantom pain , stump pain, back pain, ulceration, and contractures. In our study, pain syndromes predominate infections , which don't differ from results of studies done in other countries (1,39,58).

In this study, the most affected aspect of QoL found in majority of LLA is mobility and the similar findings were found in studies done in other countries, (24,59) like US, South Africa, whilst different studies have shown the mobility to be the most factor influencing the QoL at higher rates(19,24,60). Other aspects of QoL like self caring (washing, dressing), performance of usual activities, comfortability and psychological sequelae were affected at different rates. However, different factors resulting from limb loss play roles in hindering the QoL.

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Mobility issue is affected by the level of amputation, poor access to walking device (mainly prosthesis), and this absence influence the social isolation, perception of body image, psychological sequelae and self-rating of the health. This doesn't differ from available data, there is a scientific evidence that management of mobility problems relieve grievances (28).

Half of participants are having problems of usual self care, although no factor was affecting it significantly statistically. Other studies suggest that the presence of upper limbs and timely social support improve the usual self-care(28).

About two third of our participants reported to have their level of performing the usual activities declined at different levels of severity. The factors which affected it include advanced age, high level of amputations, the type of occupation, and psychological discomfort posed perceived body image. This finding correlates with the one found in a longitudinal study done in South Africa, comparing pre and post lower limbs amputations, which found a decline in performing usual activities of more than a half (59) and this becomes worse for lower limb amputees(19).

About three quarter reported to have pain/or discomfort after LLA, and it is due stump related problems such as stump pain, phantom pain, and back pain mostly, and the discomfort is worsened by poor perception of body image which don't differ from worldwide data , which stipulates that pain or discomfort may be present with or without walking device (19,61). One study have shown the pain or discomfort following LLA to be worse for traumatic LLA(62). Pain or discomfort may be from the back , stump, contralateral limb , phantom pain, ulceration or infection (54,63).

More than 90% remained with psychological sequelae (anxiety/depression) after undergoing LLA and it was due to many factors like access to walking device (prosthesis), social isolation, poor perception of body image, and lack of occupation. This don't differ from other studies that have shown the persistence of psychological sequelae after LLA , although decreasing in severity by time (15,64). Psychological compromise becomes worse when LLA is performed at lower age, because of loss of future dreams(64). Studies have shown that Amputees whose indications are trauma are prone to depression and anxiety comparing to others(62).

Nevertheless, depression and anxiety are encountered at every individual prone to undergo surgery for any reason, and it become worse when it is about limb loss(28,65). LLA, as a major

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life changing event, is followed by many physical psyco-social problems and this impair the QoL in terms of body image perception, perception of future life, and social life(28,39,66).

# **VI. CONCLUSION**

LLA is a common and serious event that our patients sustain and causes impairment of QoL due to limitation dictated by the body capacity. Among different indications of LLA, trauma due to road crash, peripheral vascular diseases and diabetic foot are the most common causes of LLA by decreasing level of importance. LLA bears a significant socioeconomic impact on amputees with a resultant social isolation and hence a more decline of their overall QOL. Their QoL is affected in different aspects, like mobility, self care, and performance of usual activities, presence of pain or discomfort and anxiety or depression with poor rating of overall self-rated health. Ambulation is a primary determinant of rehabilitation and when this is compromised by LLA by the lack of walking devices and prosthesis it affects the overall QoL. Appropriate management of post amputations surgical complications (stump pain, phantom pain, back pain, ulceration) different co-morbidities, education, and availability of walking devices (prosthesis), would release the psychological burden posed by limb loss.

# **VII. Recommendation**

In the light of our results we recommend the following:

We recommend to the government preventive measures of road traffic crash by strict follow up of traffic regulations and impose speed governor to motorcyclist, rehabilitation of infrastructures (roads) and to creates many jobs for people with disabilities. To the ministry of health ,in particular, we recommend to keep increasing the workforce in prevention and controlling of non communicable diseases (Diabetes, hypertension, and others), and to expand in every province a rehabilitation centre to manage post LLA co-morbidities.

We recommend to CHUK and CHUB to manage timely traumatic patients and to incorporate rehabilitation experts in regular outreach to manage those factors impairing the QoL. We recommend also to decrease the prolonged appointment time as. We emphasize on having perioperative counselling for improving post operative psychological status.

To scientist, we recommend to conduct a study in our population about the prevention of development of ischemic limb and to conduct longitudinal study about the quality of life in LLA for a known period to assess their progressive capacity and to assess the effect of mirror therapy in management of distorted body image.

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# **IX.APPENDICES**

IX. Data collection form

I.	DEMOGRAPHICS	
1.	Study number :	
2.	Age :	(years)
3.	Date of birth :	DDMMYYYY
4.	Sex :	1.Male
		2. Female
5.	Marital status	1. Married Widow/widower2 Divorced 4.Single3.
6.	Ubudehe	1 2 3 4 Unclassified (
7.	Insurance	1.Mutuelle de Sante2.RSSB3. MMI4.Radiant5.MIS UR6. Others7.None
8.	Level of education	1.Primary2.Secondary3.Dechalor4. Masters5 PhD
		6. None
II		Indication of amputation
1	-	1.Trauma A – RTA
	Reasons of LLA	B.Assault
		2.Gangrene Peripheral vascular disease A.Dry B. Wet
		3.Gas gangrene
		4 Diabetic foot

		5 Tumor					
		6 Others(burn, frostbite, elephantiasis, congenital limb disease					
		which?					
	Quality	of life nost amputation					
	Quanty						
•	Mobility	EQ-5D index 1.No problem in walking about					
		<ol> <li>Slight problem in walking</li> </ol>					
		3. Moderate problem in walking					
		4.Severe problem in walking					
		5.Unable to walk					
2	Usual self-care	1.No problem in washing and dressing myself					
		2. Slight problem in washing and dressing					
		3.Moderate problem in washing and dressing myself					
		4.Severe problem in washing and dressing myself					
		5.Unable to dress and wash myself					
3.	Usual activities (Job,	1. No problem in doing my usual activities					
	house work, shopping, Familial leisure, going	2.Slight problem in doing my usual activities					
	to school	3.Moderate problem in doing my usual activities					
		4.Severe problem in doing my usual activities					
		.5. Unable to perform any activity.					
4	Any pain	1.No pain or discomfort					
		2. Slight pain or discomfort					

			3.Moderate	pain or discomfort		
			4. Severe pa	in or discomfort		
			5.Extreme pain or discomfort			
5	Anxiety		1.I am not a	nxious or depressed		
	Depression		2.I am sligh	tly anxious or depressed		
			3.I am mode	erately anxious or depressed		
			4.I am sever	rely anxious or depressed		
			5.I am extre	mely anxious or depressed		
			post amputa	tions problems (Factors which affect		
the QOL)				_		
1	Economical	1.Increased income2.Decreased income3.Student4.The same		Occupation. 1.Same job (Pre and post amputation )         2.Changed job         3.Sacked         4.Resigned         5.Jobless       6.Retired         7.Decreased income         8.Begging		
2	Psychological problems	1.Drug abuse		1.Alcohol     2.       Tobacco     3. Recreational       drug     2		
		body in	nage	Moderately satisfied 3.Not satisfied		

		3.Social isolation	Yes		No
3	Access to walking devices	1.Access to prosthesis	Yes	No	If No ,why?
		2.Access to wheel chair	Yes	No	
		3.Access to crutches	Yes	No	

4	Stump problems		1.Infection	
			2.Ulceration	
			3.Hematoma	
			4. Contractures	
			5.Phantom pain	
			6.Back pain	
			7. Stump pain	
			8. Others	
5	co-morbidities/Ill	ness	1.Diabetes mellitus	
			2.Cardiovascular di	sease
			3.Renal diseases	
			4.others	
			5.None	
6	Social problems	A.Abandonned by the family	Yes	No
		B.Decreased self-		
		esteem		
			Yes	No
				<u>.</u>
7			Yes	%
	Satisfaction	with life	No Why	? Lools of
			prosthesis.3. Co mo	rbidities
			4. Social isolation,	5. Stump
			related problems	
	Level of am	putation	1	

Toe amputation/ disarticulation	1
Mid foot amputation	2
Ankle disarticulation	3
Below knee amputation	4
Knee disarticulation	5
Above knee amputation	6
Hemipelvectomy	7
Hip disarticulation	8
Bilateral lower limb involvement	9 (Left :Right : (put the number)

IX.1. Ethical clearances IX.1. 1.UR/CMHS IRB approval notice



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# COLLEGE OF MEDICINE AND HEALTH SCIENCES

#### DIRECTORATE OF RESEARCH & INNOVATION

#### CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 29<sup>th</sup>/September/2020

Dr HERI Eric School of Medicine and Pharmacy, CMHS, UR

#### Approval Notice: No 301/CMHS IRB/2020

Your Project Title "Factors Affecting Quality of Life After Lower Limbs Amputation – A Multicenter Cross-Sectional Study, Five Year Experience in Rwanda." has been evaluated by CMHS Institutional Review Board.

	Institute	Involved in the decision		
		Yes	No (Reason)	
Name of Members			Absent	Withdrawn from the proceeding
Prof Kato J. Njunwa	UR-CMHS	X		
Dr Stefan Jansen	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		C LOUI DELEVISION
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS		Х	
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district	X		
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		Х	
Prof Condo Umutesi Jeannine	UR-CMHS		Х	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		Х	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 29<sup>th</sup> September 2020, **Approval has been granted to your study.** 

Please note that approval of the protocol and consent form is valid for 12 months.

You are responsible for fulfilling the following requirements:

- 1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
- 2. Only approved consent forms are to be used in the enrolment of participants.
- 3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
- 4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
- 5. Failure to submit a continuing review application will result in termination of the study
- 6. Notify the IRB committee once the study is finished

Sincerely,



Dr Stefan Jansen Ag. Chairperson Institutional Review Board, College of Medicine and Health Sciences, UR

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

## IX.1. 2. CHUK ethical clearance approval notice



CENTRE HOSPITALIER UNIVERSITAIRE UNIVERSITY TEACHING HOSPITAL

Ethics Committee / Comité d'éthique

13<sup>th</sup> Jan,2021

Ref.:EC/CHUK/003/2021

#### Review Approval Notice

Dear Eric Heri,

Your research project: "Factors affecting quality of life after lower limbs amputation – A multicenter cross-sectional study, five years experience in Rwanda "

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 13<sup>th</sup> Jan,2021 to evaluate your request for ethical approval of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your research project.

You are required to present the results of your study to CHUK Ethics Committee before publication by using this link:<u>www.chuk.rw/research/fullreport/?appid=221&&chuk</u>.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

Dr Emmanuel Rusingiza Kamanzi The Chairperson, Ethics Committee, University Teaching Hospital of Kigali





Scan code to verify.

"University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations "

Web Site : www.chuk.rw; B.P. 655 Kigail- RWANDA Tél.: 00 (250) 252575462. E-Mail: chuk.hospital@chuk.rw

## IX.1.3. CHUB ethical approval notice



#### CENTRE HOSPITALIER UNIVERSITAIRE UNIVERSITY TEACHING HOSPITAL

CENTRE HOSPITALIER UNIVERSITAIRE DE BUTARE (CHUB) OFFICE OF DIRECTOR GENERAL

Nº Ref: CHUB/DG/SA/03/...../2021

Dr. HERI Eric University of Rwanda College of Medicine and Health Sciences Resident in Department of Surgery Phone: +250 785729273 Email: herihenrieric1@gmail.com

Dear Dr. Heri,

#### Re: Your request for data collection

Reference made to your letter requesting for permission to collect the data within University Teaching Hospital of Butare for your research project entitled "Factors affecting quality of life after lower limb amputation, a multicenter cross-sectional study, five years experienced in Rwanda", based to the approvals No 301/CMHS IRB/2020 from Institution Review Board of University of Rwanda and No: REC/UTHB/015/2021 from our Research-Ethics Committee, we are pleased to inform you that you are accepted to collect data within University Teaching Hospital of Butare. Please note that your stand document will be submitted in our research office.

Sincerely,

Dr. SENDEGEYA Augustin

Director General of CHUB

- > Head of Clinical Education and Research Division
- > Director of Research
- > Chairperson of Research-Ethics Committee
- > Head of Department of Surgery
- > Ag. Research officer

#### **CHUB**

E-mail : info@chub.rw Website: www.chub.rw B.P : 254 BUTARE Hotline: 2030