MAXILLECTOMY: INDICATIONS, TYPES, AND FACTORS ASSOCIATED WITH ITS EARLY COMPLICATIONS AMONG PATIENTS WHO UNDERWENT SURGERY AT MUHIMBILI NATIONAL HOSPITAL.

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By

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A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Medicine in Otorhinolaryngology at

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CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance **of dissertation** entitled; **''Maxillectomy; Indication, types and factors associated with its early complications among patients who underwent surgery at Muhimbili National Hospital'',** in (partial) fulfillment of the requirement for the degree of Master of Medicine in Otorhinolaryngology of Muhimbili University of Health and Allied Sciences.

_____

Dr Kassim Mapondela

(Supervisor)

Date: _____

_____

Dr Henry Swai

(Co-supervisor)

Date: _____

DECLARATION

I, **Baraka Marco**, declare that this dissertation is my original work and that has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature _____ Date _____

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Furthermore, I appreciate the wonderful support from my research assistant, Dr Jesca Bisigoro and my classmates.

DEDICATION

To my lovely wife, **Grace**

My wonderful children, **Barrett and Shofar**

And my beloved parents, **Mr & Mrs Marco Nkondo**

‘‘I love you and always will I’’

ABSTRACT

Background: A global rise in surgical complications has been reported in recent years, ranging from 3-22%. It continues to be a public health problem in terms of patient mortality, morbidity and hospital costs. A higher burden of complications is documented in maxillectomy procedures ranging from 10.6 to 43.9%. However, In Tanzania and Africa, little is known about complications of maxillectomy and their associated factors.

Aim: We conducted this study to determine indications, types, and factors associated with early maxillectomy complications among patients at Muhimbili National Hospital.

Materials and Methods: We conducted a hospital-based cross-sectional study and recruited 62 patients who underwent surgery at MNH between September 2023 and February 2024. A convenient sampling technique was employed and a semi-structured questionnaire was used for data collection. Descriptive and Logistic regression analyses were performed to determine indications, types, and factors associated with early complications of maxillectomy. A p-value of <0.05 was considered statistically significant.

Results; The median age was 38.5 years,51.6% were males,16.1% were underweight,33.9% had known comorbidities,9.7% and 29.0% had positive history of tobacco use and alcohol consumption respectively. Malignant tumors (50%) and partial maxillectomy (79%) respectively, were the most common indications and type of maxillectomy performed. Overall, 56.5% of study participants had some form of early complications, with wound infections being predominant (32.3%). Total maxillectomy, malignant tumors and, > 3 hours duration of surgery showed significantly higher rates of complications in their respective subgroups. However, > 3 hours duration of surgery was ultimately the factor associated with early complications of maxillectomy after multivariate logistic regression analyses.

Conclusion; Malignant tumors constitute about half of maxillectomy indications.Early complications of maxillectomy affect more than half of patients undergoing surgery at MNH. Duration of surgery of >3 hours has the potential to increase the odds of complications up to 12.9 times.

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ABBREVIATIONS

BMI	BODY MASS INDEX
ENT	EAR NOSE AND THROAT
MNH	MUHIMBILI NATIONAL HOSPITAL
MUHAS	MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
ORL	OTORHINOLARYNGOLOGY
OMFS	ORAL MAXILLOFACIAL SURGERY
OR	ODDS RATIO
AOR	ADJUSTED ODDS RATIO
USA	UNITED STATES OF AMERICA

DEFINITION OF TERMS

Maxillectomy is a surgical procedure for the partial or total removal of the maxilla.

Early complications of maxillectomy are undesirable effects or events experienced by patients or noticed by a clinician that occur within 7 days exclusively as the result of surgery.

Indications are valid reasons (mainly disease process) for a specific treatment modality.

CHAPTER ONE

1.0 INTRODUCTIONS

1.1 Background

Maxillectomy is one of the old surgical procedures performed by oral and maxillofacial/head and neck surgeons. Historically, maxillectomy was first conducted in 1829 by Syme. In the beginning, most maxillectomy attempts resulted in high mortality and morbidity. However, improvements were reported around the 1950s due to remarkable progress in anesthesia and surgical fields(1,2).

For better surgical descriptions, numerous classifications of maxillectomy defects have been proposed with a lack of uniformity. However, among many, Cordeiro's classification meets several criteria of satisfaction hence is the most widely used and accepted (3).

According to Cordeiro, maxillectomy types are classified as:

Limited or partial maxillectomy: Resection of One or two Maxilla walls, palate is preserved.
Subtotal maxillectomy: Resection of 5 out of the 6 Maxilla walls with orbital floor preservation.
Total maxillectomy: all six Maxilla walls are resected.
Radical maxillectomy: Removal of the orbit, upper 5 walls of Maxilla walls with palate preservation (1–3)
Also, as far as surgical anatomy is concerned, diverse maxillectomy approaches have been developed over the years ranging from trans oral midfacial degloving, lateral rhinotomy, Weber Ferguson, and the recent transnasal endoscopic approach(4–6)

For decades now, maxillectomy whether through open or endoscopic approach, with or without adjuvant chemoradiotherapy, has been a mainstay in the management of benign and malignant maxillary tumors, chronic invasive fungal infections, and tumors of the base of the skull(6–10)

Nevertheless, despite its benefits, maxillectomy often results in devastating psych-sociological challenges and functional complications. This is due to most of the maxillary sinus pathologies extending to tissue beyond the maxilla and may invade vital structures. Challenges include aesthetic facial disfigurement, phonation, and chewing difficulties that may progress into nutritional impairments, poor quality of life, and death. For this reason, maxillectomy becomes one of difficult procedures to undertake.(4,7,11–15)

1.2 Statement of the problem

Globally, surgical complications continue to be a significant public health problem in terms of patient morbidity, mortality, and hospital costs. In developed countries, major complications burden is estimated to occur in 3-22% of all surgical patients with a mortality rate of 0.4–0.8% (16,17). Additionally, studies from developing countries where resources are limited the burden is remarkably higher, with surgical site infections reported to be the most common preventable serious complication (18,19)

Recent studies demonstrate a global increase in maxillectomy indications (8,20). However, despite this fact, maxillectomy complications are rarely trivial and potentially affect quality of life, resulting in permanent disability and death. This is due to the complex anatomy of the head and neck region that consists of numerous vital anatomical structures contained within a small area(10,12,16,21).

Numerous studies from different settings have reported a high burden of maxillectomy complications ranging from 10.6- 43.9%.(12,21) Nevertheless, despite these several studies conducted on maxillectomy, little is known about the predictors of maxillectomy complications. Again, most of these studies were conducted retrospectively hence their findings provide less statistical evidence. Specifically, in Tanzania, literature about complications of maxillectomy in general is scanty.

1.3 Conceptual framework

This conceptual framework shows the organization, order, and direction of the proposed study. It depicts the cause-effect relationship whereby independent variables in this context the sociodemographic, preoperative, and intraoperative factors affect the early complications of maxillectomy which is the key outcome of the study.

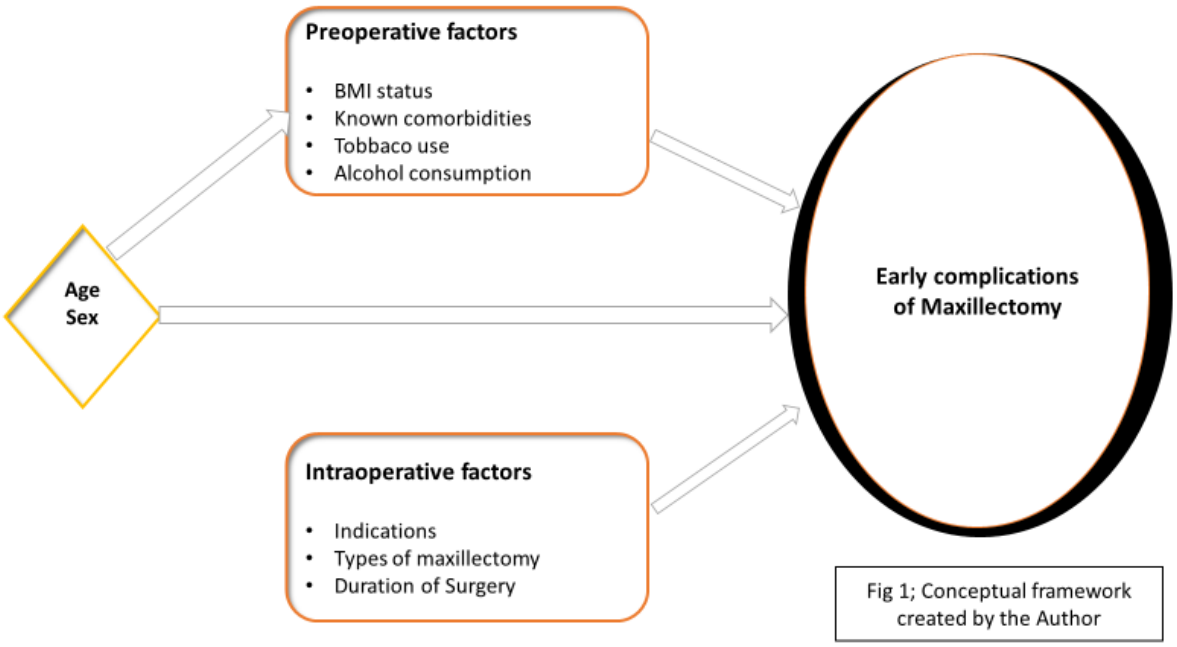


Figure 1: Conceptual framework

1.4 Rationale of the study

Findings from this study will provide baseline information acting as a stepping stone for further research. Importantly, knowledge from this research will shed light, facilitating evidence-based practice leading to the improvement of post maxillectomy treatment guidelines at MNH and the Tanzanian community at large.

Furthermore, this study is a requirement for partial fulfillment of a master's degree of medicine in otorhinolaryngology of MUHAS.

1.5 Research questions

1.5.1 Main research question

What are the indications, types, and factors associated with early complications of maxillectomy among operated patients in dental and Otorhinolaryngology departments at Muhimbili National Hospital (MNH)?

1.5.2 Specific questions

1. What are the indications of maxillectomy among operated patients at MNH?
2. What are the types of maxillectomy among operated patients at MNH?
3. What are the early complications of maxillectomy among operated patients at MNH?
4. What are the factors associated with early complications of maxillectomy among operated patients at MNH?

1.6 Objectives

1.6.1 Main objective

The main objective of the study was to determine indications, types, and factors associated with early complications of maxillectomy among patients operated in oral maxillofacial surgery and otorhinolaryngology departments at Muhimbili National Hospital (MNH).

1.6.2 Specific objectives

1. To determine the indications of maxillectomy among patients operated at MNH.
2. To determine types of maxillectomy among patients operated at MNH.
3. To determine early complications of maxillectomy in patients operated at MNH.
4. To determine factors associated with early complications of maxillectomy among patients operated at MNH.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Sociodemographic characteristics

The sociodemographic characteristics of patients undergoing maxillectomy have variations from one study to another. A study done in India by Baliarsing et al shows the mean age of maxillectomy patients is 21 years which differs remarkably from the mean age of 50.6 years documented in a study done in China by Liu et al(5,11).On the other hand, about six studies in Nigeria document almost similar mean age(35.88 to 44.3 years) for maxillectomy patients at the time of surgery(7,12,14,21–23). However, In East Africa or Tanzania, there are no studies that show the mean ages of patients undergoing maxillectomy.

Again, there are variations in sex distribution from studies. Baliarsing et al(India) show female predominance among patients who underwent maxillectomy(11), in contrast to findings from other five studies done in China, India, and Papua New Guinea which document male predilection(5,8,15,24,25). Moreover, In Nigeria, three studies show female predominance(12,22,23) in contrast to the other three studies which document male predilection(7,14,21). However, there are no studies in East Africa or Tanzania that show the sex distribution of patients undergoing maxillectomy.

Therefore, from the reviewed research, there is variation in age and sex distribution among maxillectomy patients. Through this study, we aimed to determine the age and sex distribution among patients undergoing maxillectomy specifically in our local settings.

2.2 Indications of maxillectomy

Indications of maxillectomy among patients vary greatly from one study to another and place to place. Baliarsing et al in a study done in India document benign tumors of the maxillary sinus as the common indication in patients who underwent maxillectomy(11) which is contrary to other four reviewed studies from China, Papua New Guinea, and India which show malignant

neoplasms of the maxillary sinus is the common indication (5,15,24,25). Again, Kumari et al(India) and Schneider et al(USA) found fungal rhinosinusitis as the common indication of maxillectomy(4,8).

In Nigeria, two studies by Olojede et al and Akinmoladun et al show benign tumors of the maxillary sinus as the common indication(12,14) oppositely to the other four studies which document malignant neoplasms as the common one.(7,21–23) . No study has been conducted so far in Tanzania or East Africa in general. That is to say, the researcher objectively determined indications of maxillectomy among patients at Muhimbili National Hospital.

2.3 Types of Maxillectomy

Distributions of maxillectomy types differ among patients from one study to another.

Two studies done by Schneider et al(USA) and Kumari et al(India) show limited and partial maxillectomy respectively are the most type performed(4,8). However, these findings are at odds with other four studies in China, Papua New Guinea, and India which document that total maxillectomy is frequently performed followed by extended maxillectomy(5,15,24,25).

Moreover, In Nigeria, studies by Akinomladum et al and Fomete et al both show hemi-maxillectomy was commonly performed while the other three studies found total maxillectomy to be the most prevalent type(12,21). It is unfortunate that in East Africa there is no study has been conducted on types of maxillectomy performed among patients. Within this context, we determined the type of maxillectomy among patients who attended at Muhimbili National Hospital.

2.4 Early complications of maxillectomy

2.4.1 Ocular complications

There is a great variation of ocular complications from one research to another and from place to place. In a retrospective study by Sweeney et al in the USA, the most common ocular complications reported were lid retraction (50%), epiphora, and dry eye(26) contrary to another retrospective study by Pitak et al(Germany) that shows epiphora(17.2%) the most frequent followed by conjunctivitis and lid retraction(27). Additionally, Goyal et (India) found conjunctiva and lid edema the most common ocular complication among all post-maxillectomy patients(24).

Nevertheless, It is unfortunate that no study documents ocular complications of maxillectomy in Africa. Herein, this study determined early ocular complications of maxillectomy. This objective will provide baseline information in Tanzania and Africa at large.

2.4.2 Wound complications

Chaukar et al (India) reported that overall wound complications are 29% in head and neck surgeries (28). Specifically, maxillectomy wound complications differ among studies. Two studies done by Schneider et al (USA) and Meena Kumar et al(India) show bleeding, delayed wound healing, and cheek numbness are the most common wound complications(4,8).

These findings are similar to a study by Eziyi Josephine et al (Nigeria) which shows postoperative nasal bleeding (27%), delayed wound healing (18%), and cheek numbness (18%) as the most common. However, a retrospective study by Fomete et al shows that delayed wound healing is the only wound complication reported(21).

In East Africa or Tanzania, there is no study concerning about wound complications in post-maxillectomy patients. Determining wound complications in our local settings through this scientific study will bridge the knowledge gap in the surgical arena.

2.4.3 Feeding difficulties

Challenges in feeding affect the quality of life and nutrition status of post-maxillectomy patients. Meena Kumar et al (India) in a prospective study shows 35% of all post-maxillectomy patients had palatal defects that impair chewing(8). Again, these findings are supported by retrospective studies done in Nigeria by Akinmoladum et al and Fomete et al which show 43.9% of patients have chewing difficulties with nasal regurgitations(12,21).

There is no research has been conducted in East Africa or Tanzania that focuses on the feeding complications among post-maxillectomy patients.

2.5 Factors associated with maxillectomy complications

There are limited studies on factors associated with complications of maxillectomy in general. Yeo et al(South Korea) in a prospective study found tumor type (malignant vs benign) and adjuvant radiotherapy were the only contributing factors to post-maxillectomy epiphora(29). These findings are supported by Pitak et al (Germany) in a retrospective cohort study who found post maxillectomy epiphora was associated with squamous cell carcinoma tumor type, big tumor size, adjuvant radio chemotherapy, male gender, poor general health (ASA III-IV), large maxillectomy defect, cervical lymph node metastasis (N1-2), long operating time > 3 h(27).

In Tanzania and Africa in general, there is no research done so far focusing on factors associated with maxillectomy complications. Through this proposed scientific study we determined these contributing factors in our local settings.

CHAPTER THREE

3.0 MATERIAL AND METHODS

3.1 Study design and setting

An analytical cross-sectional study was conducted at Muhimbili National Hospital (MNH) in the dental and otorhinolaryngology departments.

MNH is a tertiary and national referral hospital with the highest volume of surgeries performed in Tanzania. It performs an average of 170 procedures per week. Specifically, the Unit of OMFS-Dental department has a 20-bed capacity with 15 oral and maxillofacial surgeons and 2 doctors of dental surgery, performing about 70 major surgeries per month. Again, the ENT department has 16 otorhinolaryngologists,7 medical officers with a 30-bed capacity, and about 120 major surgeries are conducted monthly. In both departments (ENT and OMFS) average of 7 patients require maxillectomy per month.

3.3 Study population

Patients who underwent maxillectomy at MNH in dental and otorhinolaryngology departments during the study period.

3.4 Study duration

The study was conducted from September 2023 to February 2024

3.3 Sample size

A sample size of the study (n) has been calculated using the Yamane formula(22).

From a retrospective pilot study done at ORL and OMFS-dental departments (MNH) from October 2022 to March 2023, the number of patients who underwent maxillectomy, N was 65. In considering the random likely error, e is estimated to be 5%.

$$n = \frac{N}{1+N(e^2)}$$

$$n = \frac{65}{1+65(0.05)^2}$$

n= 65/1.16

n=56.

Considering a 10% Nonresponse rate: 56×0.1=5.6

The actual sample size was 62 patients who underwent maxillectomy**.**

3.4 Sample selection

3.4.1 Inclusion criteria

- Patients who underwent maxillectomy at MNH in dental and otorhinolaryngology departments.

3.4.2 Exclusion criteria

- Patients who underwent revision maxillectomy at MNH.

3.5 Sampling procedure and technique

The study employed a non-probability convenience sampling technique where patients were recruited consecutively until the sample size was reached.

3.6 Variables

3.6.1 Dependent variable

Early complications of maxillectomy were the dependent variable for this study.

3.6.2 Independent variables

Socio-demographic factors: Age and Sex

Preoperative factors: BMI status, known comorbid condition, tobacco use, and alcohol consumption

Intraoperative factors: indications and type of maxillectomy, duration of surgery

3.7 Data collection procedures

Before the data collection, the research assistant was trained on how to use the data collection tool. Then, we started collecting data by interviewing patients, caregivers, and or next of kin using questionnaires.

Both predictor and outcome variables were gathered using a standardized data collection form through interviews, theatre notes, and daily clinical notes. BMI was obtained after measuring the weight and height of the patients using digital weighing scale and portable height rods respectively

Follow-up was conducted from admission day to 7 days postoperatively. In cases where participants were discharged before 7 days, scheduled daily phone calls were used to trace them. Data were entered after the completion of the follow-up.

Furthermore, Data collection tools were reviewed daily before being entered into the Microsoft Excel database.

3.10 Data Analysis Plan

Data were compiled, cleaned, coded, and analysed using SPSS software version 25, according to the objectives of the study.

3.10.1 Socio-demographic factors

Age which was the only continuous variable, median was calculated while categorical data such as sex, proportions, and ratios were determined. Findings are presented in terms of frequency tables.

3.10.2 Indications of Maxillectomy

Proportions of indications of maxillectomy were determined. Then, the findings are presented in the pie chart figure.

3.10.3 Types of Maxillectomy

Proportions of types of maxillectomy were determined. Findings are presented in a pie chart figure.

3.10.4 Early complications of maxillectomy

Proportions and distributions of early complications of maxillectomy among patients were determined. Then, the findings are presented in a bar chart figure.

3.10.5 Factors associated with early complications of maxillectomy

Chi-square test, and bivariate and multivariate logistic regression analysis were conducted to determine the association of socio-demographic, preoperative, and intraoperative factors with early complications of maxillectomy.

All independent variables with P value < 0.2 were set in multiple logistic regression models to minimize the effects of the confounders.

A p-value below 0.05 will be denoted as statistically significant.

3.11 Ethical consideration

Ethical clearance to conduct the study was obtained from the Muhimbili University of Health and Allied Science Institution Review Board. Again, permission for data collection was obtained from the Muhimbili National Hospital research administrative office. Written informed consent were obtained from patients and caregivers. The identities of the respondents were concealed to ensure confidentiality.

3.12 Dissemination

This dissertation was presented at the 12th MUHAS Scientific conferences. Then findings will be published in a peer reviewed journal.

CHAPTER FOUR

4.0 RESULTS

4.1 Descriptive characteristics of patients who underwent maxillectomy surgery at MNH

Participants had a median age of 38.5 years with an interquartile range (IQR) of 26 (25, 51). The majority (51.6%) were males and were in age category 25-39 (30.6%)

Participants with normal nutrition status were 71.0%, known comorbidities (33.9%.), history of tobacco use (9.7%), history of alcohol consumption (29.0%), and the majority had 3 hours or less duration of surgery (66.1%), **shown in table 1.**

Table 1; descriptive characteristics of patients who underwent maxillectomy (N=62) at MNH from September 2023 to February 2024

Variable	Frequency(N=62)	Percent
Median age; IQR (values)	**38.5; 26 (25,51)**	
Age group (Years)		
10-24	13	21.0
25-39	19	30.6
40-54	17	27.4
55-69	10	16.1
70-84	3	4.8
Sex		
Male	32	51.6
Female	30	48.4
BMI Status		
Normal	44	71.0
Underweight	10	16.1
Overweight	8	12.9
Known comorbidities		
Yes	21	33.9
No	41	66.1
Tobacco use		
Yes	6	9.7
No	56	90.3
Alcohol consumption		
Yes	18	29.0
No	44	71.0
Duration of Surgery		
More than 3 Hours	21	33.9
3 hours or less	41	66.1

4.2 Indications of maxillectomy among patients who underwent maxillectomy at MNH

Among 62 patients, malignant tumors were the most common indication for maxillectomy (50%), benign tumors were 43.5%, and invasive fungal sinusitis was the least indicated (6.5%), **shown in Figure 2**

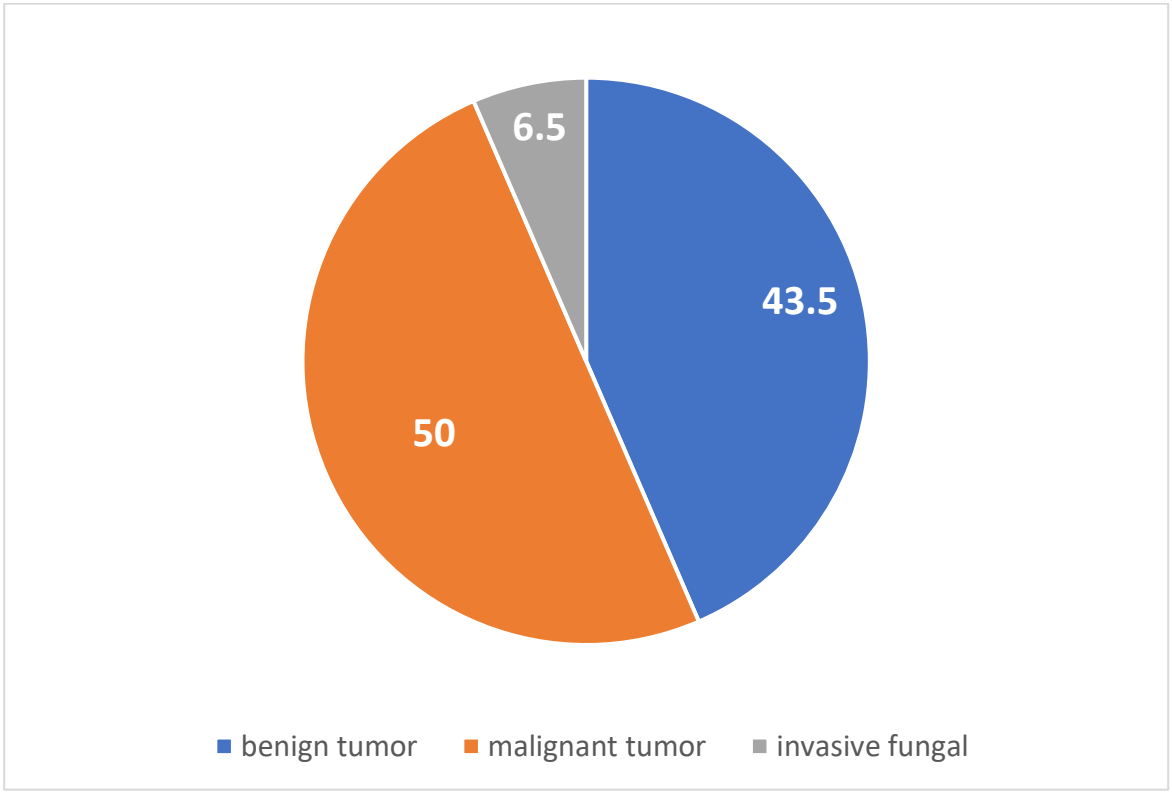


Figure 2: Indications of maxillectomy (%) among patients operated at MNH

4.3 Type of maxillectomy among patients who underwent surgery at MNH

Among 62 patients, partial maxillectomy was the most common type (79.0%), total maxillectomy (11.3%) and radical(extended) maxillectomy was the least type (9.7%), **shown in Figure 2**

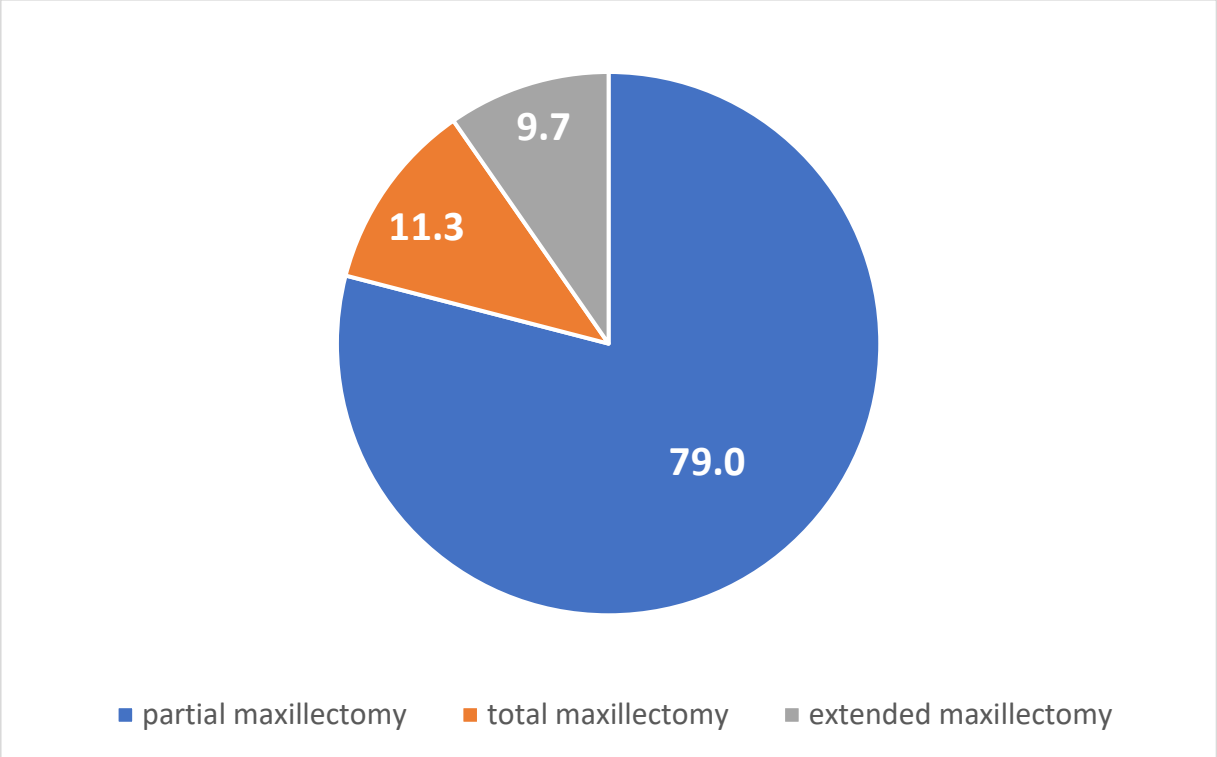


Figure 3: Types of maxillectomy (%) among patients who operated at MNH

4.4 Early complications of maxillectomy among patients operated at MNH

The overall prevalence of complications of maxillectomy among study participants was 56.5%. Wound infections were the most common complications (32.3%), followed by hemorrhage (30.8%) and the least was trismus (16.1%), as **shown by Figure 3**

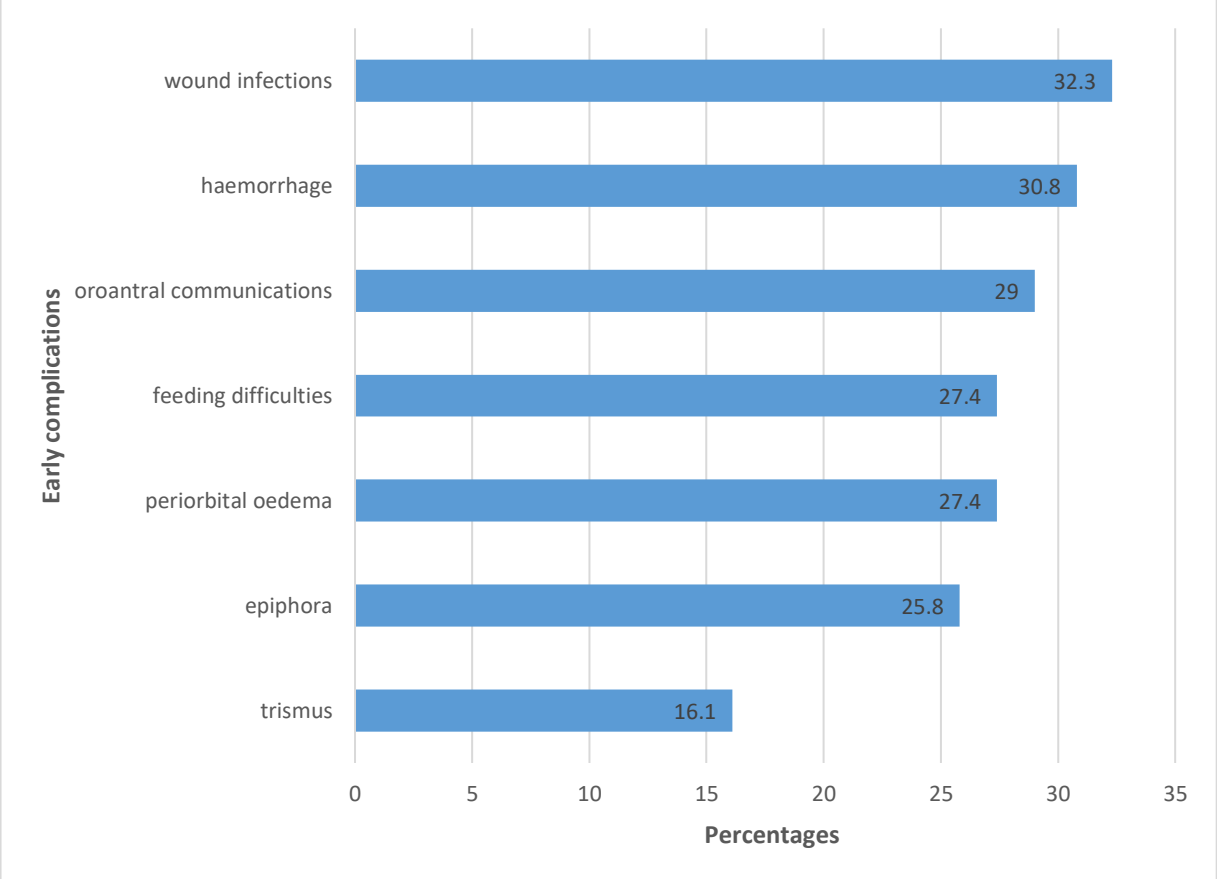


Figure 4: Early complications of maxillectomy among patients operated on at MNH

4.5 Factors associated with early complications of maxillectomy among patients operated at MNH

Early complications of maxillectomy and characteristics of study participants(N=62)

Malignant tumors had higher proportion of complications (74.2%) than other indications of maxillectomy, p=0.01.

Total maxillectomy showed a higher proportion of complications (85.7%) compared with other types of maxillectomy, p=0.05

Duration of surgery of more than 3 hours had higher proportion of complications (90.5%) compared to ≤ 3 hours, p=0.00

Older age ≥70 years, male sex, underweight, tobacco use, alcohol consumption showed higher rates of complications in their respective subgroups however these were not statistically significant, as shown in table 2

Table 2: Early complications of maxillectomy and characteristics of patients operated on at MNH

Variable	Complications No (%)	Yes (%)	Total	X2	p-value
Age					
10-24	7(53.8)	6(46.2)	13	1.24	0.87
25-39	7(36.8)	12(63.2)	19		
40-54	7(41.2)	10(58.8)	17		
55-69	5(50)	50(50)	10		
≥70	1(33.3)	2(66.7)	3		
Sex					
Male	13(40.6)	19(59.4)	32	0.23	0.63
Female	14(46.7)	16(53.3)	30		
BMI status					
Normal	19(43.2)	25(56.8)	44	1.91	0.38
Underweight	3(30)	7(70)	10		
Overweight	5(62.5)	3(37.5)	8		
Known comorbidities					
Yes	10(47.6)	11(52.4)	21	0.21	0.64
No	17(41.5)	24(58.5)	41		
Tobacco use					
Yes	2(33.3)	4(66.7)	6	0.28	0.59
No	25(44.6)	31(55.4)	56		
Alcohol consumption					
Yes	7(38.9)	11(61.1)	18	0.22	0.63
No	20(45.5)	24(54.5)	44		
Indications of maxillectomy					
Benign tumors	16(59.3)	11(40.7)	27	**8.29**	**0.01**
Malignant tumors	8(25.8)	23(74.2)	31		
Invasive fungal sinusitis	3(75.0)	1(25.0)	4		
Types of maxillectomy					
Partial	25(51.0)	24(49.0)	49	**5.85**	**0.05**
Total	1(14.3)	6(85.7)	7		
Extended	1(16.7)	5(83.3)	6		
Duration of surgery					
More than 3 Hours	2(9.5)	19(90.5)	21	**14.95**	**0.00**
3 hours or less	25(61.0)	16(39.0)	41		

Bivariate logistic regression for factors associated with early complications of maxillectomy

Duration of surgery of > 3 hours had 14.8 times the odds of complications compared to ≤ 3 hours, p=0.001.

Older age ≥70 years, male sex, underweight, tobacco use, alcohol consumption, malignant tumor, and total maxillectomy showed higher odds of complications in their respective subgroups however these were not statistically significant, **as shown in table 3**

Table 3: **Bivariate logistic regression for factors associated with early complications of maxillectomy among patients operated on at MNH**

Variable	OR (95%CI)	P-Value
Age		
10-24	Ref	
25-39	2.00(0.47-8.8.39)	0.34
40-54	1.67(0.39-7.15)	0.49
55-69	1.17(0.22-6.08)	0.85
≥70	2.33(0.16-32.58)	0.52
Sex		
Male	1.28(0.49-3.49)	0.63
Female	Ref	
Nutrition status		
Normal	Ref	
Underweight	1.77(0.40-7.71)	0.44
Overweight	0.46(0.97-2.15)	0.32
Known comorbidities		
Yes	0.78(0.27-2.24)	0.64
No	Ref	
Tobacco use		
Yes	1.6(0.27-9.50)	0.59
No	Ref	
Alcohol consumption		
Yes	1.3(0.43-4.00)	0.63
No	Ref	
Indications of maxillectomy		
Benign	2.06(0.19-22.50)	0.55
Malignant	**8.63(0.78-95.25)**	**0.07**
Invasive fungal	Ref	
Types of maxillectomy		
Partial	Ref	
Total	6.25(0.7-55.8)	0.10
Extended	5.20(0.57-47.90)	0.14
Duration of surgery		
More than 3 Hours	**14.8(3.03-72.5)**	**0.001**
3 hours or less	Ref	

4.2.1 Multivariate logistic regression for factors associated with early complications of maxillectomy

Duration of surgery of > 3 hours had 12.94 times odds of complications compared to ≤ 3 hours, p=0.003, **shown in table 4**

Table 4: Multivariate logistic regression for factors associated with early complications of maxillectomy among patients operated at MNH

Variable	AOR (95%CI%)	P-Value
Types of Maxillectomy		
Partial	Ref	
Total	3.04 (0.1-93.09)	0.52
Radical	1.7 (0.51-10.07)	0.80
Duration of Surgery		
> 3 hours	12.94 (2.39-69.72)	0.003
≤ 3 hours	Ref	

CHAPTER FIVE

5.0 DISCUSSION

This chapter objectively discusses key findings obtained in this study compared to other research conducted in developed and developing countries.

5.1 Demographic characteristics

This study demonstrated a median age of 38.5 years among patients who underwent maxillectomy at Muhimbili National Hospital. This is congruent with the other 3 studies conducted in Nigeria (7,21,23). However, our findings differ from studies in India and China which demonstrated a mean age of 21 and 50.6 years respectively. This may be explained by differences in indications of study populations.

Also, our study findings revealed a marginal male predominance which is similar to other studies in Nigeria, China, and India (5,14,15,21,24)

5.2 Indications of Maxillectomy

In this current study, malignant tumors were found the most common indication of maxillectomy. This is supported by multiple studies from Nigeria,China, India (5,15,24,25).

However, in one study in India, it was found that benign tumors were a predominant indication(11).However only 8 patients were included in this previous study, and six of them were below 18 years. This has implications for indications of maxillectomy as malignant tumors of the maxilla are less common in the young population.

5.3 Types of Maxillectomy

Our research revealed that partial maxillectomy was the most common type performed among patients who underwent surgery at MNH. This is concordant with a study conducted by Kumar et al in India(8).

However, these findings are contrary to other several studies done in Nigeria, China, and India (5,12,15,21,22,24,25). To our knowledge, these previous studies were retrospectively conducted almost 10 years ago. Advances in diagnostic techniques in recent years may have resulted in

early diagnosis of maxillary tumors, hence partial maxillectomy preferences. Also, our clinical setting has insufficient obturators and fewer experts for the reconstruction of large maxillectomy defects. This may have influenced surgeons to lose favor for total maxillectomy.

5.4 Early complications of maxillectomy

This study demonstrated wound infections were the most common early complications among patients who underwent surgery at MNH. In the current study, the rate of wound infections(32.3%) was remarkably higher compared to previous studies conducted in Nigeria and India (12,28). This may be attributable to lower compliance to infection prevention and control standard precautions reported in Sub-Saharan countries(30). Also, these previous were retrospectively designed, hence lower rates of wound infections may be due to reporting bias.

Again, findings from this current study revealed one-third of patients who underwent maxillectomy had hemorrhage complications. Our findings are concordant with a study done by Eziyi et al, Nigeria (23)

In this study, we found almost a quarter of patients who underwent maxillectomy at MNH, had epiphora. This aligns with findings from a study by Sweeney et al, German (26). However, a study by Pitak et al (India) demonstrated a lower rate of epiphora among study participants. This previous study was retrospectively designed and only patients who underwent orbital sparing maxillectomy were recruited. Hence, reporting bias and differences in the study populations might have caused this discrepancy.

Moreover, in this study, trismus was found the least common complication. This may be due to the conservative nature of partial maxillectomy that was commonly performed. These findings were similarly reported in studies done in Nigeria(12,21).

5.5 Factors associated with early complications of maxillectomy

Our current study demonstrated that participants with malignant tumor indications and total maxillectomy had significantly higher rates of early complications. Also, this study showed, that a duration of surgery of >3 hours was strongly associated with early complications of maxillectomy. These findings correlate with the other two studies which revealed that malignant

tumors, large maxillary defects, and long operating time of>3 hours were factors associated with post-maxillectomy epiphora (27,29). This current study is the first to focus on factors associated with maxillectomy complications in general.

5.6 Study limitations and mitigations

Information about the history of alcohol consumption and tobacco use was self-reported by participants, which is subject to report bias. To mitigate this, validity of information was ensured only after interviewing participants on more than two occasions.

Our study had a small sample size, and we employed a non-probability sampling technique. This is due to the rarity of patients who underwent maxillectomy. We acknowledge this may have affected the generalizability and precision of our findings. However, we managed to attain the expected sample size with a 100% response rate.

5.7 Strength of study

To the best of our knowledge, this current prospective study is the first in Tanzania and East Africa to focus on indications, types, and factors associated with complications of maxillectomy. Hence, novel findings from this study will assist in the optimization of patients for maxillectomy.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study revealed that more than half of the patients who underwent maxillectomy had some form of complications, > 3 hours duration of surgery being the only associated factor. This burden of maxillectomy surgical complications is unacceptably higher compared to global statistics.

Practically, most of these maxillectomy complications are preventable. Wound infections are the most common preventable complications reported in this study. To minimize the high burden of complications, prompt perioperative measures are essential in patients undergoing maxillectomy.

Malignant tumors were found to be the most common indication, with partial maxillectomy being the prevalent type of maxillectomy performed.

6.2 Recommendations

6.2.1 To the surgical team

Regarding infection prevention, antibiotic redosing must be initiated among post maxillectomy patients to minimize the high burden of wound infections shown in this study.

Moreover, Surgeons must plan preoperatively for the reconstruction of maxillary defects in all patients undergoing maxillectomy. This will minimize the feeding difficulties and oroantral communication complications reported in this research. Hence, improving the health-related quality of life among patients.

6.2.2 To the field of clinical research

Given the time and fund limitations of our study, we recommend further studies involving larger sample sizes and multiple settings. This will ensure the generalizability of findings to the Tanzanian community and Africa.

Owing to the high burden of complications among patients who underwent open maxillectomy from our study, it is high time for surgeons to consider an endoscopic maxillectomy. The endoscopic approach offers better visualization of the tumor bed, allowing more precise resection of the tumor hence fewer complications(6)

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APENDECES

Appendix I: Data Collection Tool

A SOCIODEMOGRAPHIC CHARACTERISTICS

I. **IDENTITY NUMBER…….**

II. **AGE** (years)…….

III. **SEX (Tick)**; 1.M…2.F…

B PREOPERATIVE FACTORS

IV. **BMI STATUS: WEIGHT(Kg)……HEIGHT(cm)…….**

(Tick the appropriate response)

1.Normal…..

2.Underweight…...

3. Overweight ……..

V.KNOWN CORMOBID CONDITION (Tick the appropriate response)

1.Yes….2. No…….

VI.TOBACCO USE (Tick the appropriate response)

1.Never…...2.Yes……

VII.ALCOHOL CONSUMPTION (Tick the appropriate response)

1.Never…...2.Yes

B. INTRAOPERATIVE FACTORS

I.INDICATIONS OF MAXILLECTOMY (Tick the appropriate response)

1.Benign tumor…. 2.Malignant tumor…. 3.Invasive fungal rhinosinusitis…….

II.TYPE OF MAXILLECTOMY (Tick the appropriate response)

1. Partial maxillectomy…2. Total maxillectomy…. 3.Radical maxillectomy…….

III.DURATION OF SURGERY (Tick the appropriate response)

1. More than 3 hours….

2. ≤ 3 hours…….

C EARLY COMPLICATIONS OF MAXILLECTOMY (Tick the appropriate response)

I. Any surgical complication 1YES 2No

II. IF YES, complications by type;

Ocular complications; Epiphora 1Yes 2No

Periorbital edema 1Yes 2No

Wound complications; Haemorrhage 1Yes 2No

Wound infections 1Yes 2No

Oral complication; Feeding difficulties 1Yes 2No

Oroantral communication 1Yes 2No

Trismus 1Yes 2No

Appendix 2: Informed consent (English version)

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATION

Research title on Maxillectomy: Indications, types and factors associated with its early complications among patients undergoing surgery at Muhimbili National hospital.

PART I: INFORMATION

Introduction: Greetings, my name is Dr Baraka Marco, a post graduate student from Muhimbili University of Health and Allied Sciences. I am conducting this research as part of my master's degree program in otorhinolaryngology. I kindly invite you to participate in this study. Be assured that your choice whether to participate or not will have no effect on the care and management. Please, welcome and feel free to ask any question concerning this research.

Aim of the study: This research aims at determining indications, type and factors associated with early complications of maxillectomy among patients undergoing surgery at Muhimbili national hospital.

Benefit: There are no direct benefits to participants. However, findings from this research will facilitate evidence-based practices among surgeons at Muhimbili national hospital and Tanzanian community at large.

Risk; There will be no risk to research participants**.**

What does this research involve? In this research, you will be asked about your age and gender, alcohol drinking and smoking habits, known comorbid conditions and later report any undesirable event related to maxillary surgery.

Again, some of your clinical information will be obtained from your hospital file . We guarantee you that any information about you will be kept confidential and exclusively be used for research purposes with no disclosure of your identity.

Right to withdraw: Taking part in this study is voluntary. Therefore, you are assured from any negative effect associated with refusal to consent. Again, you are free to withdraw from the study any time as per your wish.

Confidentiality: Your information will be highly valued. Hence, they will be stored confidentially in protected computer files and paper record. This information will be exclusively accessed and utilized by research staff.

Whom to contact: In case of questions, you are free to contact I, Dr Baraka Marco (Principal investigator) on phone number +255629057011 or through my email: barakamd016@gmail.com

Also, If you feel unfairly treatments in this research process, please submit your queries to Muhimbili University of Health and Allied Sciences through the Director of Research and Publication, Dr Nahya Salim 0713250074 P.O Box 65001 Dar es Salaam.

PART II: Certificate of Consent

I confirm that I have read and understood the purpose and procedure of this research. Also, I know my participation is voluntary and understand there are no risks involved in this study. I, therefore, voluntarily agree to participate in this study.

Name (participant)……. Signature……. Dates……

Name (investigator)……Signature……. Dates……

Appendix 3: Fomu ya ridhaa (Kiswahili)

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI

KURUGENZI YA TAFITI NA MACHAPISHO

Utafiti kuhusu **sababu na aina za upasuaji wa kutoa mfupa wa taya yaani kwa kitaalamu "maxillectomy" baina ya wagonjwa waliofanyiwa upasuaji huo katika hospitali ya taifa Muhimbili.**

SEHEMU YA I:TAARIFA

Utangulizi

Wasalaam,Naitwa Baraka Marco, daktari na mwanafunzi wa shahada ya Uzamili kutoka chuo kikuu cha afya na Sayansi Muhimbili. Ninafanya utafiti huu kama sehemu ya takwa la kitaaluma katika masomo yangu ya udaktari bingwa wa sikio,pua na koo.Hivyo, nakukaribisha sana kusoma maelezo haya na kisha kutoa ridhaa ya kushiriki kwako katika utafiti huu.

Kusudi la utafiti: Kutambua sababu anuai na aina za upasuaji wa kutoa taya zinazofanywa kwa wagonjwa katika hospitali ya taifa Muhimbili.

Faida: Japokuwa hakutakuwa na malipo ya kifedha moja kwa moja kwa mshiriki wa utafiti huu, lakini matokeo yatakayopatikana yatasaidia katika kupanua wigo, rejea na weredi kwa madaktari wa upasuaji ,katika hospitali ya Muhimbili na Tanzania kiujumla.

Madhara ambatano: Utafiti huu hautaambatani na madhara yoyote kwa mshiriki

Utahusikaje katika utafiti huu?: Katika dodoso, utaulizwa kuhusu umri,jinsi, matumizi ya pombe au sigara,magonjwa mengine na baada ya upasuaji wako tutafatilia matokeo mbalimbali ya upasuaji na hivyo utatakiwa kutoa taarifa wa adha mbalimbali utakazozihisi au kuziona.

Aidha, baadhi ya taarifa zinazokuhusu hasa za kitabibu kwa idhini yako zitachukuliwa kutoka kwenye faili la matibabu yako hospitalini.

Haki ya kushiriki au kutoshiriki: Napenda kukuhakikishia kuwa ushiriki wako katika utafiti huu si wa shurti na hakuna tatizo litakalokupata kama sababu ya kutokushiriki au kutokuwa tayari kuendelea na utafiti.

Usiri wa taarifa: Taarifa zako zote zinapewa uthamani mkubwa na hivyo zitatunzwa kwa usiri mkubwa.Pia ni dhahiri kuwa taarifa hizi zitatumiwa pekee na timu ya utafiti kwa ajili ya utafiti na si vinginevyo.

Nani wa kuwasiliana naye?: Kwa maulizo a yoyote tafadhali usisite kunipigia au kunitumia ujumbe Mimi Dr Baraka Marco kupitia simu namba 0629057011 Au Kupitia anuani ya email; **barakamd016@gmail.com**

Aidha, endapo una dukuduku kuhusu mwenendo mzima wa utafiti huu unayo haki ya kuwasiliana na uongozi wa Chuo kikuu cha Afya na Sayansi Shirikishi Muhimbili kupitia kwa mkurugenzi wa utafiti na machapisho, Dr Nahya Salim 0713250074

SEHEMU YA II: Uthibitisho wa mshiriki

Ninathibitisha kuwa nimesoma na kuelewa kwa upana kuhusu utafiti huu. Natambua pia ushirikiwi wangu ni wa muhimu lakini sio shurti na hakuna madhara yoyote katika kushiriki au kutoshiriki utafiti huu.

Hivyo, ninatoa ridhaa yangu kushiriki katika utafiti huu.

Jina mshiriki……Sahihi…….Tarehe……..

Jina mtafiti……..Sahihi…….Tarehe……..

Appendix 4: Ethical clearance

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/1871 Date: 20/08/2023

MUHAS-REC-08-2023-1871
BARAKA MARCO
SCHOOL OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: MAXILLECTOMY: INDICATIONS, TYPES AND FACTORS ASSOCIATED WITH ITS EARLY COMPLICATIONS AMONG PATIENTS UNDERGOING SURGERY AT MUHIMBILI NATIONAL HOSPITAL

Reference is made to the above heading,

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 20/08/2023
EXPIRATION DATE OF APPROVAL: 20/08/2024

STUDY DESCRIPTION:
Purpose:
The purpose of this analytical cross-sectional study is to determine indications,types and factors associated with early complications of maxillectomy among patients at Muhimbili national hospital.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014844.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,
Chairperson, MUHAS Research and Ethics Committee



Appendix 5: Permission Letter

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/527 Date: 16th October, 2023

Head Department,

- Dental

- ENT

Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH.

Name of Student	**Baraka Marco**
Title	**"Maxillectomy; Indications, Types and Factors Associated with Its Early Complications Among Patients Undergoing Surgery at"**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Kassim Mapondela (MUHAS)
Co - Supervisor	Dr. Henry Swai (MNH)
Period	16th October, 2023 to 30th April, 2024

Approval has been granted to the above mentioned student to collect data at MNH. **A final study report should be lodged with Clinical Research, Training and Consultancy Unit.** Dissemination of study findings to MNH stakeholders shall be overseen by Dr. Henry Swai (MNH) Co – supervisor.

Kindly ensure that the student abide to the ethical principles and other conditions of the research approval.

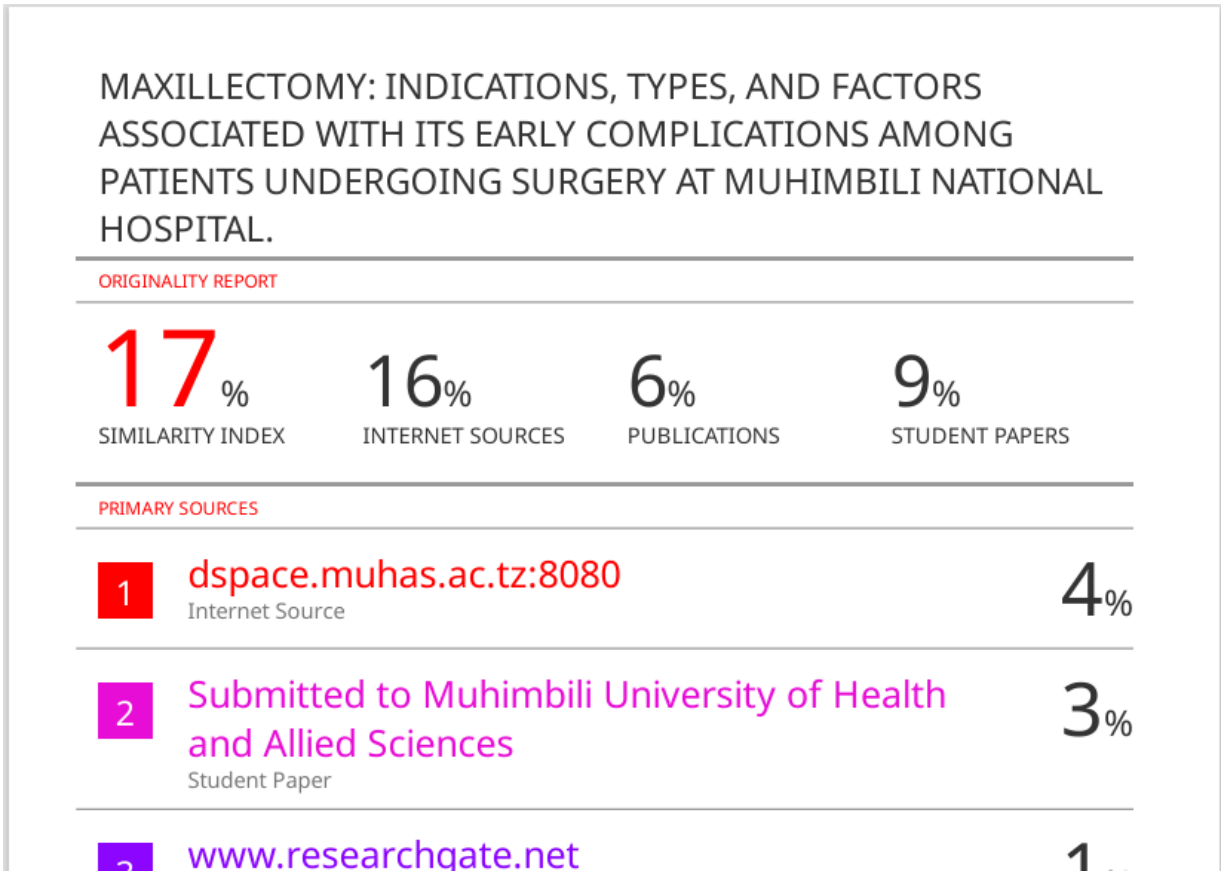
Yours Sincerely,

Dr. Jessie Mbwambo
Head of Clinical Research, Training and Consultancy Unit

HEAD, TEACHING, RESEARCH & CONSULTANCY UNIT
P. O. Box 65000
DAR-ES-SALAAM
MUHIMBILI NATIONAL HOSPITAL

c.c DSS
c.c Dr. Henry Swai
c.c **Baraka Marco**

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