

**ESTIMATED BLOOD LOSS, FACTORS ASSOCIATED WITH BLOOD
LOSS AND TRANSFUSION RATE IN PATIENT UNDER GOING
PRIMARY TOTAL HIP REPLACEMENT AT MUHIMBILI
ORTHOPAEDICS INSTITUTE**

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**MMed (Orthopaedics and Traumatology) Dissertation
Muhimbili University of Health and Allied Sciences
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Muhimbili University of Health and Allied Sciences

Department of Orthopaedics and Traumatology



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By

Omary J Doekulu

**A Dissertation Submitted in (Partial) Fulfillment of the Requirement for the Degree of
Master of Medicine (Orthopaedics and Traumatology) of**

Muhimbili University of Health and Allied Sciences

October, 2021

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for the acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: “Estimated Blood loss ,factors associated with blood loss and Transfusion rate among patients undergoing primary total hip replacement at Muhimbili Orthopaedic Institute”, in (partial) fulfillment of the requirement for the degree of Master of Medicine (Orthopaedics and Traumatology) of Muhimbili University of Health and Allied Sciences.

Dr. Violet Lupondo, (MD, MMED OT,FCS-ECSA)
(Supervisor)

Date:_____

DECLARATION AND COPYRIGHT

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

Signature.....

Date.....

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First and foremost, I thank Almighty God for his protection during my study period. I would like to express my appreciation to my supervisor, Dr Violet Lupondo Orthopaedic Surgeon, Senior Lecturer at Muhimbili University of Health and Allied Sciences first for accepting to be my supervisor and for her guidance in steps of developing of this dissertation. she has not only been my supervisor but my teacher in Orthopaedics and Traumatology as well as my mentor. Secondly, extend my appreciation to all the Faculty members of the Department of Orthopaedics, Traumatology and Neurosurgery for their constructive inputs which have been a cornerstone in helping this research work achieve its objectives. Thirdly to my dear wife Martha Kassanga who was been patience throughout my absence and to our lovely children Samweli, Stewart, Sharon and Shedrack, Lastly, I express my appreciation to MOI administration for permission to conduct my research at MOI.

DEDICATION

I dedicate this dissertation to my patients (research participants) for placing their deepest trust in me and make this work completed without difficult.

I dedicate the dissertation to my wife, Martha, and my children, Samweli, Stewart, Sharon and Shedrack,.

ABSTRACT

Background: Primary total hip arthroplasty is a highly effective surgical procedure that was performed in elderly and young patients. Total hip replacement (THR) relieves pain and functional disability experienced by patients with moderate to severe arthritis of the hip and improving their quality of life.

Prolong surgical time, medication(TXA) and longer incision were associated with substantial blood loss which leads to blood transfusion to most of the patients, most of the literature report more than 50% of the patients are transfused during primary THR, in a study done in Lagos among 41 patients, 37(90.2%) receive blood transfusion, there were two ways of estimating blood loss, direct methods was commonly used while the hidden blood loss which was detected by indirect method rarely considered.

Objectives: the purpose of this study was to determine estimated Blood loss, factors associated with blood loss and transfusion rate in patient undergoing primary THR at MOI.

Methodology: A prospective cross-section study was done at Muhimbili orthopedics institute from April 2020 to April 2021. Patients undergoing THR were recruited into the study using convenience sampling. A questionnaire was administered to capture their demographic data. Follow-up of the respondents was made to check preoperative and post-operative hemoglobin level and utilization of blood during the course of treatment. Duration of surgery, position of the patients, and size of incision were considered. The data were analyzed using SPSS version 23, the chi-square test was used in discrete variable and t-test in the case of continuous variables, in all cases, an alpha of 0.005 will be adopted for statistical significance.

Result: Total of 68 participants undergoing primary THR were included in this study, majority of the participants were male 38(55.88%), aged 60 years and above. The mean estimated blood loss was 1494 mls of blood). There was a 54.8% transfusion rate among the respondent and more than 2hours was associated with more blood loss.

Conclusion: There is significant blood loss in patients undergoing THR at MOI, which required most of the patients to receive blood transfusion. Longer operating time and lateral positioning were associated with increased blood loss.

Recommendations.

There is a need for long prospective study on blood loss, factors associated with blood loss and transfusion rate after primary THR, which preclude the decision when to consider for surgical interventions.

TABLE OF CONTENTS

CERTIFICATION	i
(Supervisor)	i
DECLARATION AND COPYRIGHT	ii
ACKNOWLEDGEMENT	iii
DEDICATION.....	iv
ABSTRACT	v
TABLE OF CONTENTS	vii
LIST OF TABLES.....	ix
LIST OF FIGURES	x
LIST OF ABBREVIATIONS	xi
DEFINITIONS OF KEY TERMS.....	xii
CHAPTER ONE.....	1
1.0 INTRODUCTION	1
1.1 Background	1
1.2 Problem Statement	2
1.3 Conceptual Frame Work.	3
1.4 Rationale.....	4
1.5 Research Questions	4
1.6 Research Objectives	4
1.7 Literature Review	5
CHAPTER TWO.....	8
2.0 METHODOLOGY	8
2.1 Study Design	8
2.2 Study Population	8
2.3 Study Area.....	8
2.4 Study duration:	8
2.5 Sample Size Estimation and sampling technique.....	9
2.8 Data Collection.....	10

2.9 Data Analysis and Presentation.....	10
2.10 Ethical Consideration and Consent.....	11
CHAPTER THREE.....	12
3.0 RESULTS.....	12
3.1 Social Demographic characteristics.....	12
3.2 The mean blood loss in patients undergoing primary THR.....	13
3.3 The factor associated with blood loss in patients undergoing primary THR at (MOI).....	14
3.4 The Transfusion rate among the patients undergoing primary THR at MOI....	15
CHAPTER FOUR.....	17
4.0 DISCUSSION.....	17
4.1 Study Limitations.....	19
CHAPTER FIVE.....	20
6.0 CONCLUSION AND RECOMMENDATION.....	20
6.1 Conclusion.....	20
6.2 Recommendation.....	20
REFERENCES.....	21
APPENDIX.....	23
Appendix I: Informed Consent Form – English Version.....	23
Appendix II: Informed Consent Form – Kiswahili Version.....	25
Appendix III: Research Questionnaire-English Version.....	27
Appendix IV: Research Questionnaire (Swahili Version).....	29
Appendix V: Ethical clearance letter.....	31
Appendix VI: Permission Letters.....	33

LIST OF TABLES

Table 1: Social and Demographic Characteristics of patients undergoing THR at MOI.....	12
Table 2: The factor associated with blood loss in patient undergoing primary THR.....	14
Table 3: The frequency table showing the proportions of blood transfusion status among patient in pre-Operative and post-operative	16

LIST OF FIGURES

Figure 1: The line graph indicating the levels of HB at Pre and Post-Operative among patient 13

Figure 2: Rate of blood transfusion in patient undergoing THR at MOI 15

LIST OF ABBREVIATIONS

CM	Centimeters
DOT	Death on table
EBL	Estimated blood loss
FFP	Fresh frozen plasma
Hb	Hemoglobin
MOI	Muhimbili Orthopedic Institute
MUHAS	Muhimbili University of Health and Allied Sciences
PRBC	Packed red blood cells
RBC	Red blood cells
SPSS	Statistical Package for Social Science
SSA	Sub-Saharan Africa
THA	Total hip Arthroplasty
THR	Total hip replacement
TRALI	Transfusion related lung injury.
TXA	Tranexamic acid
USA	United states of America

DEFINITIONS OF KEY TERMS

- i. **Blood transfusion** - Refers to the process that involves taking blood from one person (the donor) and administers it to someone else (the recipient)
- ii. **Primary Total hip replacement** – The first surgery to be done in replacement of the hip joint due to varieties of causes
- iii. **Blood Transfusion reaction** - Is a reactions or complication that do occur after a blood transfusion
- iv. **Direct method of blood loss estimation** - Is a process of estimating blood loss intraoperative, from the nurse's implant form where blood loss is recorded.
- v. **Indirect method of blood loss estimation** - Is a process of estimating blood loss by subtracting post-operative hemoglobin from pre-operative hemoglobin.
- vi. **Inoperative blood loss** –is a blood loss during surgery.
- vii. **Postoperative blood loss**-is a blood loss after surgery.
- viii. **Total blood loss**-is a total blood loss during surgery and after surgery.
- ix. **Death on table** -The patient died during operation.
- x. **Orthopedic Surgeries**- Refers to the prevention, diagnosis, and treatment of disorders of the bones, joints, ligaments, tendons and muscles. Some orthopedists are generalists, while others specialize in certain areas of the body, such as: Hip and knee.
- xi. **Elective surgery or elective procedure**- (from the Latin: eligere, meaning to choose) is surgery that is scheduled in advance because it does not involve a medical emergency. Semi-elective surgery is a surgery that must be done to preserve the patient's life, but does not need to be performed immediately.
- xii. **Emergency Surgery**- can be defined as surgery that is required to deal with an acute threat to life, organ, limb or tissue caused by external trauma, acute disease process, acute exacerbation of a chronic disease process, or complication of a surgical or other interventional procedure. The skills needed for emergency surgery include the ability to undertake those abdominal (including urological), thoracic, vascular and soft tissue procedures that need to be performed within 24 hours.

xiii.**Exclusion and inclusion-** Inclusion criteria is everything that a study must have in order to be included in the researcher review. Exclusion criteria are the factors that would make a study ineligible to be included in your review. These criteria can include dates, how a study was designed, population, outcomes

xiv.**Hb Level-** Hemoglobin is a protein in red blood cells that carries oxygen to your body's organs and tissues and transports carbon dioxide from your organs and tissues back to your lungs. If a hemoglobin test reveals that your hemoglobin level is lower than normal, it means you have a low red blood cell count (anemia)

xv.**Unit of Transfused Blood -**To a standard dosing scheme of one unit of red blood cells (RBC), platelets or plasma in the non-bleeding patient, followed by an assessment of the patient –

xvi.**Patient Position** – Refers involves properly maintaining a patient's neutral body alignment by preventing hyperextension and extreme lateral rotation to prevent complications of immobility and injury.

xvii.**Duration of Surgery-**Refers to Length of surgery in minutes, from first incision to last suture

xviii.**Blood loss-** Refers is a total blood loss during surgery and after surgery.

xix.**A blood Transfusion-**Refers to a routine medical procedure in which donated blood is provided to you through a narrow tube placed within a vein in your arm. This potentially life-saving procedure can help replace blood lost due to surgery or injury.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Total hip arthroplasty is an effective surgical procedure in patients with end stage hip diseases and other degenerative hip diseases. Total hip arthroplasty was the mainstay treatment for osteoarthritis in adults with significant improvement of function and quality of life. (1)

Various causes and associated factor have been sited in literatures, among others osteoarthritis is one of the major causes as well as displaced femoral neck fractures in elderly (2).However avascular necrosis due to steroid treatment for various condition ,alcoholism and HIV patients on antiretroviral treatment is on the rise as a cause of joint replacement(3).

Total hip arthroplasty are associated with substantial blood loss the expected blood loss aids the surgeon to pre determine which patients are more likely to require transfusion, alternative methods for mitigating the need for allogeneic transfusion can also be sought.

Identify the risk factors associated with increased blood loss would high light the potential areas for intervention so as to prevent the blood loss during procedures (4).

The use of appropriate surgical approach, gentle and soft tissue handling during surgery and the benefit of surgical time of less than 90 minutes significantly reducing blood loss(4).Several methods has been employed in estimating blood loss after surgery, direct and indirect methods, indirect methods is described to be more accurate in detecting hidden blood loss postoperatively(4),As much as allogenic RBC transfusion is sometimes lifesaving but associated with a number of risk which include transfusion-related acute lung injury (TRALI), immunomodulation, and transmission of pathogens(5)

Studies have also indicated that blood transfusion in itself may increase the risk of early and late morbidity and mortality(3), However, other patient-related and surgery- associated factors, such as gender, preoperative hemoglobin levels, and operative technique are also

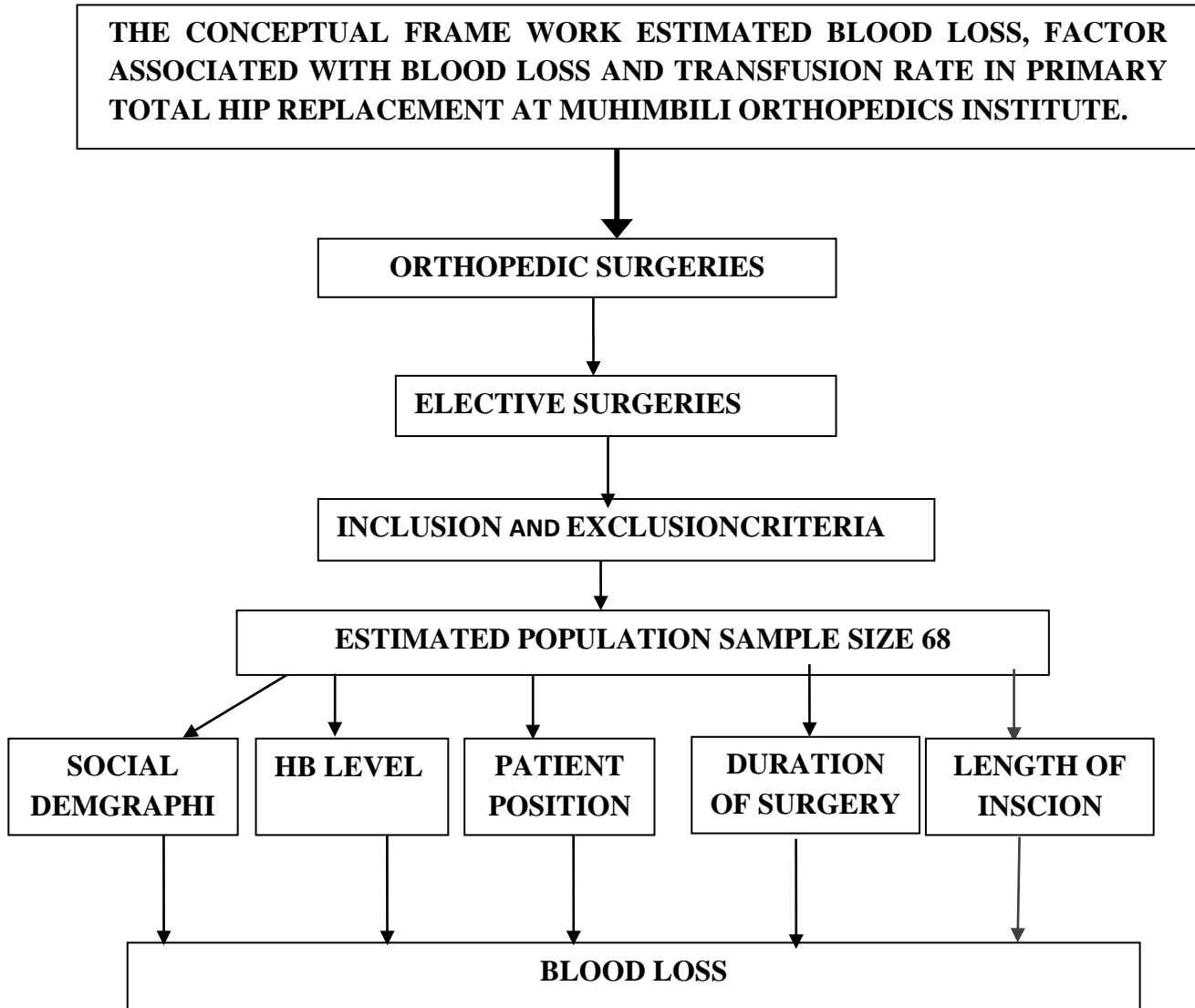
predictive of transfusion requirement in different surgical setting(5).

1.2 Problem Statement

Most of the patient undergoing primary total hip replacement (THR) was transfused regardless of what preoperative hemoglobin and the amount of blood loss. This brought an apparent shortage of blood in the institute hence some patients may denied operations due to lack of pre-operative prepared blood resulting in disruption of operation list which was associated with increases in resource utilization and cost to both institute and patient's relative but often time associated with transfusion complication reaction.

Direct and indirect method, were ways of estimating blood loss but in our setting, mainly direct method, in this study indirect blood loss method which was more accurate and detect the hidden blood loss postoperatively was used. Which was able to evaluate the blood loss and rate of transfusion in patient undergoing primary THR at MOI.

1.3 Conceptual Frame Work.



From the above conceptual framework where among patients who underwent elective orthopedic surgeries (Primary THR) were screened for inclusion and exclusion criteria to study population. In the study population, the social demographic characteristics (Age, sex), position of the patient during surgery, duration of surgery, length of incision and transfused blood, at which all of these factors determine the Blood loss during primary THR

1.4 Rationale.

Understanding the estimated blood loss for THR, factors associated with blood loss in patient underwent total hip arthroplasty and its transfusion rate assist in the planning for surgical care and preparedness for patients who on need of transfusion. The study will provide knowledge on the estimated blood loss, factors associated with blood loss and transfusion rate in patient underwent THR. Also, the study will provide baseline information for further researches.

1.5 Research Questions

What are the estimated blood loss in primary total hip replacement, factor associated with blood loss and transfusion rate in patient who underwent total hip arthroplasty at Muhimbili orthopedic institute?

1.6 Research Objectives

1.6.1 Broad Objective

To determine estimated Blood loss, factors, associated with blood loss and transfusion rate in patient undergoing primary THR at Muhimbili Orthopedics Institute (MOI) from July 2019 to April 2020.

1.6.2 Specific Objectives

- i. To determine the demographic characteristics among primary THR at Muhimbili Orthopedics Institute (MOI) from July 2019 to April 2020.
- ii. To determine the mean blood loss in patients undergoing primary THR at Muhimbili orthopedics institute (MOI) from July 2019 to April 2020.
- iii. To determine the factor associated with blood loss in patient undergoing primary THR at Muhimbili orthopedics institute (MOI) from July 2019 to April 2020.
- iv. To determine the Transfusion rate among the patients undergoing primary THR at Muhimbili orthopedics institute (MOI) from July 2019 to April

1.7 Literature Review

Total hip arthroplasty has widely been indicated in young adult

In the study by Wamisho et al in Addis Ababa Ethiopia the mean age at primary THA was 48years with men predominance 52% in a mean follow up study duration of 4 years (19). In the study by Bierbaum et al St Mary's hospital in USA the mean age of arthroplasty is higher compared to Wamisho et al study with 67years with predominance of women as well 59% (20). In a study done by Carling et al in Sahlgrenska university hospital in Sweden for 2years showed the mean age at total hip arthroplasty similar to Wamisho et al study of 48 years with females' predominance of 51% (5). There is no local study in Tanzania and east Africa on THA in young adults.

Sahlgrenka University Hospital in Sweden did a prospective observation study of 193 patients for THR which conclude the median EBL was 984mls during intra and postoperative period (5), similarly study done by Hogan et al shows that the hidden blood loss during THR accounts for volume losses equivalent to an additional of 500mls (7), while Dreinhoffer et al out of 212 patients for THR performed in one year found the mean total blood loss was 1090mls (2)

Carling et al in prospective observation study with a total of 114 patients undergoing unilateral THR had median intraoperative bleeding was 450 mL (range 150–3,000),(5). While in a study done in Korean Hip Society it shows pre and post THR blood loss was approximately 1500mls (14). Keating EM et al conducted a study of 200 patients who undergoing total hip replacement which an average blood loses are 4g/dl of hemoglobin (15).

Ugbeye et al in lagos did Prospective observation study of 41 patient aged 18-81years undergoing primary THR which reveals intraoperative blood loss was 1222.7 ± 334.7 ml, ranging from 450–1900mls, the mean postoperative blood loss and total blood loss were 574.3 ml and 1786.2 ml, respectively (16) However at PCEA Kikuyu Hospital in Kenya did retrospective cohort study in THR of 266 patients the result shows mean blood loss is 4.3g/dl. (4)

In study done in Sweden involved THR patients shows that there is greater intra-operative

and postoperative blood loss in male patients than in female patients, the hemoglobin drop and average number of units of transfusion received per patient were higher in male patients, these results from this series support that gender does play a role in blood loss and male patients experience greater loss (6).

Similar findings were reported by Jai Hyung Park et al in 1171 patients who had THR, however found that being a male was a protective factor against allogeneic blood transfusion. (14) In his multivariate analysis, the amount of blood loss rises by increasing age (3.44mls) per one-year increase (14), Carling et al observed age above 75 years of age had more blood loss compared to those below (5).

A prospective randomized study by Widman et al of 74 patients undergoing THR, he compared blood loss in lateral and supine position, lateral position had a significant lower total blood loss, on average 201mls. (9), Gvozdenovic L had similar findings and this is postulated to be a result of reduced venous engorgement due to the effect of gravity (10). Prolonged surgical time has been shown to increase blood loss as in a study done by Hogan et al reveals Surgical time of more than 2hrs showed a higher blood loss, compared to surgical time of less than 2hrs, ($P = 0.003$ and $P = 0.014$) (7). Also, this was a significant factor in a study done in Kenya where surgery which took 90 minutes or less was blood loss was 4.1g/dl while for those surgery lasting more than 90 minutes the blood loss was 4.6g/dl ($p=0.004$) (18).

A study by Hogan et al reveals Patients undergoing primary THR, preoperative administration of Tranexamic acid was associated with diminished blood loss and lesser resource utilization and reduce transfusion requirements (7). Similarly study by Song et al shows TXA is known to be an effective agent for reducing postoperative bleeding and the need for transfusions for patient undergoing primary arthroplasty (8)

In a prospective study done by Miao et al on the length of incision done in China, a total of 322 participants were enrolled the result showed the longer the incision increases the blood loss significant (12), Similar study by Wood et al done in Bristol, sixty-two patients were enrolled showed the significant correlation between longer incision and more duration of dryness to the wound resulting into more blood loss (13).

Dreinhofer in a retrospectively Study of 45%(163) patients undergoing THR, receive blood transfusion (2), However park et al out of 1171 patients 17.7% in the total hip arthroplasty group received blood transfusion (14), while Dreinhofer et al out of 212 THR performed with a mean total blood loss of 1090mls and 74% of the patients had BT (7), similarly carling et al in his prospective observation study transfusion rate in THR was 114(18%) (5). However in a prospective observation study by keating et al high dose 300u/kg/d of epoetin alfa in 200 patients show low transfusion risk compared to those with reduced dose(100u/kg/d) and placebo group(15). Ugbeye et al of 41patients undergoing THR, 37(90.2%) had intra operative transfusion 80.5% received at least two pints ((16).

In 50 patients who had THR an average EBL was 750mls (350- 1000mls) and only 5 patients required blood transfusion (17)

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study Design

A hospital based prospective cross section study.

2.2 Study Population

All patients scheduled for primary THR at Muhimbili orthopedic institute (MOI).

2.3 Study Area

This study was conducted at Muhimbili Orthopedic Institute (MOI), located in Ilala district (Dar es Salaam region). The area of the study was chosen basing on the fact that MOI is the one of tertiary institute providing specialized Orthopedic, Trauma and Neurosurgical Care in the country receiving patients from all over the country and from neighboring countries. It is the one of the hospital within the Muhimbili complex, receiving and attending the patients within Dar es Salaam and other regions of Tanzania, but not only that receiving the patients from other countries also it's a center for training student from MUHAS as orthopedic and neurosurgery resident. With this, the researcher is hoping to develop much from this study.

2.4 Study duration:

This study was conducted from May 2020 to April 2021

2.4.1 Inclusions Criteria

All patients scheduled for primary THR at Muhimbili orthopedic institute.

2.4.2 Exclusions Criteria

All patients who refused to participate in the study.

All patients who died during surgery (DOT)

2.5 Sample Size Estimation and sampling technique

Calculation for sample size of a large population which is not known whose degree of variability is not known. Assuming the maximum variability, which is equal to 50% ($p = 0.5$) and taking 90% confidence level with $\pm 10\%$ precision, Cochran (1977) developed a formula to calculate a representative sample for proportions, the calculation for required sample size will be as follows;

$$n = \frac{z^2 pq}{e^2}$$

$$n = \frac{(1.645)^2 \times 0.5 \times 0.5}{(0.01)^2}$$

$$n = 68 \text{ patients}$$

P=Therefore, the sample size in this study will be 68 patients

Where, N= is the sample size,

z =is the selected critical value of desired confidence level

p= is the estimated proportion of an attribute that is present in the population.

$$q = 1 - p$$

e= is the desired level of precision

2.6 Variables.

Age, sex, patient position during surgery, surgical approach, Hb level, size of incision, medications, Duration of surgery, unit of transfused blood, Blood loss.

2.7.1 Dependent variables

Blood loss.

Blood transfusion.

2.7.2 Independent variables.

Age, sex, patient position during surgery, Hb level, size of incision, medication (TXA), Unit of transfused blood, Duration of surgery

2.8 Data Collection.

Data will be collected using a standard structured questionnaire which will constitute the following items

2.8.1 Preoperative Information

For eligible patient, hospital registration number, social demographic data (age, sex) and Hb level were obtained.

2.8.2 Intraoperative Information

Intraoperative details such as position of the patient, supine or lateral, Blood transfusion unit received (whole blood, PRBC, FFP), Medication–TXA, duration of surgery less than 2hours, more than 2hours.

2.8.3 Post-operative Information up to 48hrs

Postoperative Hb and unit of blood transfused, size (length) of incision. Then estimated blood loss from indirect method will be obtained by formula as follows

Pre-operative – Post-operative=Estimated blood loss. if no blood transfusion, but if transfusion done the formula is Pre- operative Hb–Post-operative Hb +unit transfused Estimated blood loss(18)

Note: 1 unit of transfused blood is 450mls=1gm/dl

2.9 Data Analysis and Presentation

Data obtained was analyzed by using the SPSS Version 23 software. Continuous variables are presented as means with standard deviation. Associations of continuous variables with

the final outcome are demonstrated using Students t-test. Categorical variables were summarized using proportions. Associations of categorical variables with the final outcome are demonstrated using the Chi-square test. All statistical tests are performed at 5% level of significance (95% confidence interval). The results of the study are presented in forms of tables, pie charts, bar graphs.

2.10 Ethical Consideration and Consent

Ethical clearance was sought from MUHAS institution review board (IRB) and the Permission to conduct the study was sought from MOI management. All patients were informed about the study and requested for signed consent before they are enrolled. These procedures were followed while observing the principles of good clinical practice. These include telling the patients the right and freedom to participate or not and, the protection of the patient's data and privacy, they will be allowed to have a confident help in case any assistance is needed.

It is observation study so no risk encountered to the patient, rather than benefit of being aware of estimated blood loss which will predict whether there is possibilities of transfusion or not as psychological preparedness, also postoperative Hb was be taken which guides whether to transfuse or not, lastly knowing estimated blood loss reduce the chances of cross matching of the blood unnecessarily which reduce cost to the institute.

CHAPTER THREE

3.0 RESULTS

3.1 Social Demographic characteristics

A total of 68 participants who were scheduled to undergo total hip replacement were enrolled in our study. Most of the participants were males (55.88%). The mean age was 64 (18 – 85) years. Most of the respondents (58.82%) were aged 60 years and above.

Table 1: Social and Demographic Characteristics of patients undergoing THR at MOI

Variable	Frequency	Percent
Sex		
Male	38	55.88
Female	30	44.12
Age Group		
< 40	14	20.59
40 to 59	14	20.59
≥ 60	40	58.82

3.2. The mean blood loss in patients undergoing primary THR.

The mean hemoglobin level in Pre-operative was 12.42g/dl(SD=1.55) and post-operative was 9.10gdl (SD=1.79) . The difference in the means was 3.32 g/dl (95% CI 2.12 – 3.92) and $P < 0.0001$. Therefore, the post-operative hemoglobin level was significantly lower than the pre-operative levels. Figure 1 below shows the differences in hemoglobin levels.

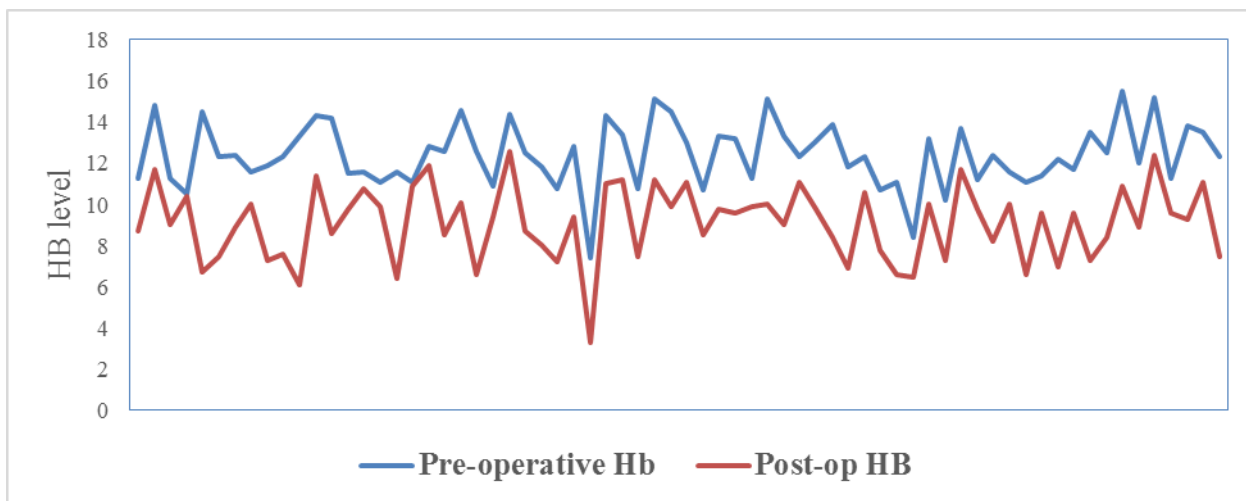


Figure 1: The line graph indicating the levels of HB at Pre and Post-Operative among patient

3.3 The factor associated with blood loss in patients undergoing primary THR at (MOI)

From **Table2** showed that patient aged 60years and above had more chances of losing more blood but P-value 0.736. There is no statistically significance association between male and female on blood loss. Patients in lateral position were more likely to lose more blood with P=0.024, duration of surgery was statistically significant associated with blood loss (P=0.028) The patients who did not receive Tranexamic acid (TXA) had more chances to loss more blood but was not statistically significant. The higher the length of the incision was not statistically significant with amount of blood loss.

Table 2: The factor associated with blood loss in patient undergoing primary THR

Variable	< 3g/dl	≥ 3g/dl	Total	P. Value
Age group	Frequency (%)	Frequency (%)	N	
< 40	8(57.14)	6(42.86)	14	0.736
40 to 59	8(57.14)	6(42.86)	14	
≥ 60	19(47.50)	21(52.50)	40	
Sex				
Male	20(52.63)	18(47.37)	38	0.829
Female	15(50.00)	15(50.00)	30	
Position				
Lateral	16(40.00)	24(60.00)	40	0.024
Supine	19(67.86)	9(32.14)	28	
Duration of surgery				
> 2 hrs	14(38.89)	22(61.11)	36	0.028
≤ 2 hrs	21(65.63)	11(34.38)	32	
Medication (TXA)				
No	2(22.220)	7(77.78)	9	0.079
Yes	33(55.93)	26(44.53)	59	
Size of incision(length)				
< 15 cm	7(77.78)	2(22.220)	9	0.197
15 to 20	24(50.00)	24(50.00)	48	
≥ 21	4(36.36)	7(63.64)	11	

3.4 The Transfusion rate among the patients undergoing primary THR at MOI

There were 37 patients (54.4%) who received a blood transfusion in the course of their treatment. Among those patients 27(39.7%) who had blood transfusions during surgery, and 16(23.53%) received blood after surgery. Most of the respondents who were transfused received one unit of blood in the course of treatment.

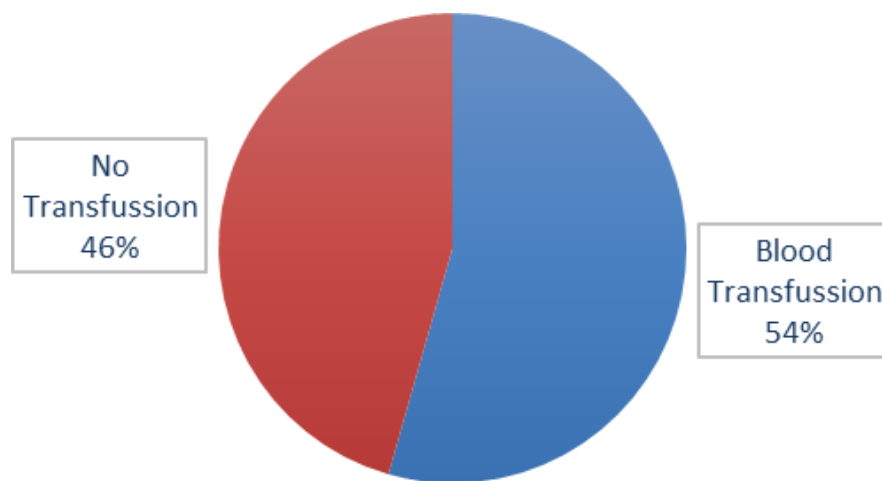


Figure 2: Rate of blood transfusion in patient undergoing THR at MOI

Table 3: The frequency table showing the proportions of blood transfusion status among patient in Intra-Operative and post-operative

	Intraoperative	Post operative
Transfusion Status	Frequency (%)	Frequency (%)
One Unit	22(32.35)	10(14.71)
Two Units	5(7.35)	6(8.82)
Not Transfused	41(60.29)	52(76.47)

CHAPTER FOUR

4.0 DISCUSSION

Blood loss in total hip replacement remains a challenge, as efforts are constantly being made to minimize the loss and the associated morbidity and mortality due to blood loss which leads to blood transfusion.

The demographic characteristics of patients scheduled for hip arthroplasty in the estimation of blood loss and transfusion rate, in this study shows the majority of the participants were male, with a ratio of 1.3:1. These findings were similarly to Wamisho et al and carling et al which revealed male were majority of the participants (5,19) contrary to kigera et al and ugbeye et al which shows female were majority of the participants,(16,18),The mean age of the participants in this study was 64years which in line with study done by Bierbaum et al (20) but differ to Wamisho et al in which the mean age was 48years (19).

Blood loss findings shows, the mean blood loss was 1494mls(3.32g/dl) which nearly correlates with study done by Miao et al with mean blood loss of 1155mls (2.6g/dl)(12),but this findings differ with study done by Keating et al and Ugbye et al whose blood loss was 1800mls(4g/dl) and 1786mls(4.0g/dl) respectively(15,16),this could be explained probably due to longer operating time and difference in sample size .The mean difference in pre to post- operative hemoglobin level was 3.32g/dl with the $P < 0.001$, this findings were similar to Gvozdenovic et al and others showing difference in pre to post-operative haemoglobin level (10,19,17)

Regarding the factor associated with blood loss, the study shows extreme age (>60years) had highest blood loss than other age groups, though it was not statistically significant ($P=0.736$), this findings correlates with study done by carling et al, however the age margin was 75years and above.(5) . There was a difference in blood loss with regarding gender ($P=0.829$) ,this correlates with Miao et al study done in China which showed female had high blood loss than male (12) but differ with a studies done by Surgenor et al and Park et al which showed blood loss is higher in male,(6,14).

Supine position during surgery had a significant low total blood loss with a P-value of 0.024, these findings differ with studies by Widman et al and Gvozdenovic et al which shows lateral position had low blood loss. (9, 10), this difference could be explained by the fact that a small proportional of patient were placed in supine position compared to those who were place lateral position. Prolonged surgical time more than 2hours was noted to increase blood loss significantly with a P-value of 0.028, this finding in line with the study done by Hogan et al and others (7, 5, 4). The use of tranexamic acid (TXA) was also assessed and revealed that patients who did not received the drugs (TXA) experience more blood loss with a P value of 0.079, Carling et al and others had similar findings (5,7,21),There was no significant difference in this study between larger incision with blood loss ($P=0.197$),Wood et al and Miao et al had similar finding (12,13).

The arthroplasty surgery often associates with Bood transfusion , In this study among 68patients, 37(54%) received blood transfusion, this finding differ with Carling et al and park et which shows lower overall transfusion rates(5,14), these difference could be explained in this study the findings were 36(53%) had longer operating time, 59(87%) had more than 15cm length of incision and 9(13%) did not receive Tranexamic acid, these factors were the one which associates with excessive blood loss which leads to higher transfusion rate.

In this index study went further and analyzed intra-operative and post-operative Blood transfusion rate which were 27(39.7%) and 16(23.53%) respectively, which contrary to Ugbeye et al from Nigeria had 37(90.2%) which had intra-operative blood transfusion,

despite have the same cohort patients undergoing primary THR (16).These difference could be due to larger sample size intra- operative patients who transfused and only one Surgeon operated all cases in Nigeria. .

4.1 Study Limitations

- This study was done at MOI, progress of the study depends on Implants from **(J&J Europe)** which was interfered with COVID 19 pandemic disease, delay the early completion of the data collection, finalize the study and leads to small sample size.
- Patients were operated by different surgeon, with different experiences.

CHAPTER FIVE

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

This study has revealed the following;

1. Male gender is the highest number who underwent hip replacement, female and sixth decade of life are associates with slightly higher blood loss.
2. Supine position, prolong surgical time and surgical incision are factors which associates with blood loss. During surgery (THR) associates with minimal blood loss.
3. The mean blood loss was 1494mls
4. The overall blood transfusion rate was 54%

6.2 Recommendation.

There is a need for long prospective study on blood loss, factors associated with blood loss and transfusion rate after primary THR, which preclude the decision when to consider for surgical interventions.

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APPENDIX

Appendix I: Informed Consent Form – English Version

Consent to participate in the study titled “ESTIMATED BLOOD LOSS, FACTORS ASSOCIATED WITH BLOOD LOSS AND TRANSFUSION RATE IN PATIENT UNDERGOING TOTAL HIP REPLACEMENT AT MUHIMBILI ORTHOPAEDIC INSTITUTE.

Greetings: I am Dr. OMARY J DOEKULU, a postgraduate student doing a research on ESTIMATED BLOOD LOSS, FACTORS ASSOCIATED WITH BLOOD LOSS AND TRANSFUSION RATE IN PATIENT UNDERGOING PRIMARY TOTAL HIP REPLACEMENT AT MUHIMBILI ORTHOPAEDIC INSTITUTE.

Purpose of the Study: ESTIMATED BLOOD LOSS, FACTOR ASSOCIATED WITH BLOOD LOSS AND TRANSFUSION RATE IN PATIENT UNDERGOING PRIMARY TOTAL HIP REPLACEMENT AT MUHIMBILI ORTHOPAEDIC INSTITUTE.

What participation involves: If you agree to participate in this study, you will be asked questions and examined before and be followed up after the operation.

Confidentiality: All information collected will be entered into computer with only an identification number; no name included.

Risk: We expect no harm to happen to you during the course of this study.

Rights to withdraw: Taking part in this study is completely voluntary and refusal to participate or withdrawal will not involve penalty or loss of any benefits to which you are entitled. You will be treated and followed up as per the usual treatment protocol of the Institute for all patients who require primary Total hip replacement.

Benefits: If you agree to participate in this study, you will be followed-up closely and be assessed on the progress of your condition by the investigating doctor. We hope that the obtained information from this study will benefit others.

Who to contact: If you have any other questions regarding this study, feel free to contact me, the investigator, Dr. OMARY J DOEKULU, MUHAS, P.O. Box 65001, MUHAS, Tel no;+255716-651261 ,Dar es Salaam.

If you have any questions concerning your rights as a participant, you may contact Dr. Bruno Sunguya, Chairman of the university senate research and publication committee, P.O. Box 65001, Dar es Salaam. Telephone: (+255) 222-152-489.

Signature

Do you agree to participate

Participant does not agree to participate.....

I,have read the consent form and my questions have been answered and I agree to participate in this study.

Signature of Participant.....

Signature of Investigator.....

Date of signed consent.....

Appendix II: Informed Consent Form – Kiswahili Version

Ruhusa ya Kushiriki Utafiti Kuhusu kuangalia matokeo matibabu ya awamu ya wagonjwa wenye maumivu ya chini/mwisho wa mgongo katika taasisi ya mifupa (MOI).

Salaam!

Mimi naitwa **Dr. OMARY J DOEKULU**, ni mwanafunzi wa udhamili chuo kikuu cha tiba Muhimbili. Nachunguza matokeo ya awali ya kuhusu **MAKADIRIO YA UPIMAJI WA UTOKAJI DAMU NA VISABABISHI VYA UMWAGAJI MKUBWA WA DAMU NA KUONGEZWA DAMU KWA WAGONJWA WANAObADILISHWA NYONGA (MOI)**.

Dhumuni la utafiti huu: Kupata taarifa muhimu kuhusu **MAKADIRIO YA UPIMAJI WA UTOKAJI DAMU NA VISABABISHI VYA UMWAGAJI MKUBWA WA DAMU NA KUONGEZWA DAMU KWA WAGONJWA WANAObADILISHWA NYONGA(MOI)** katika taasisi ya mifupa ili kutoa mapendekezo ya uboreshaji.

Ushiriki: Kama unakubali kushiriki kwenye utafiti huu, utaulizwa maswali, utachunguzwa kwa kina na utafuatiliwa hata baada ya upasuaji katika kliniki yetu

Usiri: Taarifa zote za uchunguzi zitaingizwa kwenye kompyuta na nambari ya utambulisho; jina halitanukuliwa.

Madhara: Tunategemea kwamba hakuna madhara yoyote yatokanayo na utafiti huu

Haki ya kujitoea kwenye utafiti: Kushiriki katika utafiti huu ni hiari, na kutokubali kushiriki au kujitoea hautaadhibiwa au kupoteza haki yako ya matibabu. Utatibiwa na kuendelea kufuatiliwa kama taratibu za hospitali zinavyoelekeza kwa mtu katika taasisi ya mifupa ili kutoa mapendekezo ya uboreshaji. Upimaji wa **MAKADIRIO YA UPIMAJI**

WA UTOKAJI DAMU NA VISABABISHI VYA UMWAGAJI MKUBWA WA DAMU NA KUONGEZWA DAMU KWA WAGONJWA WANA OBADILISHWA NYONGA(MOI) utokaji dama na kuongeza damu.

Kutokea kwa madhara: Tunategemea kwamba hakuna madhara yoyote yatokanayo na utafiti huu. Hata hivyo kama madhara ya mwili yatatokea kutokana na utafiti huu, utatibiwa kulingana na kanuni na taratibu za matibabu ya Tanzania.

Faida ya kushiriki kwenye utafiti: Kama utakubali kushiriki kwenye utafiti huu, Faida utakazopata ni pamoja na kuonwa na kufuatiliwa kwa ukaribu na daktari anayefanya utafiti. Tunatumaini kwamba taarifa zitakazopatikana zitawanufaisha wengine pia

Kwa mawasiliano zaidi: Kama una maswali or maelezo kuhusu utafiti huu, uwe tayari kuwasiliana na mtafiti, **Dr. OMARY J DOEKULU**, P.O. Box 65001, MUHAS, Simu:+255716651261.

Kama una maswali kuhusu haki yako kama mshiriki wasiliana na Dr. Bruno Sunguya, Mwenyekiti wa kamati ya utafiti, P.O. Box 65001, DSM. Simu (+255) 222-152-489.

Je,umekubali, kushiriki?.....

Mimi.....Nimesoma maelezo

n

a kuyaelewa vizuri, na nimekubali kushiriki kwenye utafiti huu.

Sahihi ya Mshiriki.....

Sahihi ya Mtafiti.....

Tarehe

Appendix III: Research Questionnaire-English Version

TITLE: ESTIMATED BLOOD LOSS, FACTOR ASSOCIATED WITH BLOOD LOSS AND TRANSFUSION RATE IN PATIENT UNDER GOING PRIMARY TOTAL HIP REPLACEMENT AT MUHIMBILI ORTHOPAEDICS INSTITUTE (MOI). (MAY 2020 TO APRIL 2021)

PART A: Evaluation

- 1) Form number:
- 2) Registration No
- 3) Phone no:
- 4) Place of residency:
- 5) Age:
- 6) Sex..... a) Male..... b) Female.....
- 7) Diagnosis
- 8) Date of treatment.....
- 9) Pre-Operative Hb

PART B: Intraoperative [Data from the Nurse and Anaesthology]

10. Positioning of the patient.
 - i. Lateral.....
 - ii. Supine.....

- 11. Duration of surgery.
 - More than 2hours.....
 - Less than 2hours.....

- 12. Unit of blood transfusion. Whole blood, PRBC, platelets, FFP
 - i. One unit.....
 - ii. Two units.....
 - iii. More than two units.....

Note: 1 unit of transfused blood is 450mls=1gm/dl(standard)

- 13. Medication Tranexamic acid
 - i. Yes.....
 - ii. No.....

PART C:Post-Operative

- 14. Unit of blood transfused.....
 - a) Whole blood.....
 - b) PRBC.....
 - c) FFP.....

- 15. post op Hb.....
- 16. Size of the wound (length)

Appendix IV: Research Questionnaire (Swahili Version)

**DODOSO LA UTAFITI WA MATOKEO YA MAKADIRIO YA UPOTEZAJI
DAMU UONGEZWAJI DAMU KWA MATIBABU YA UBADILISHAJI
VIKOMBE NA SHINGO KATIKA NYONGA KWA MARA YA KWANZA.**

KIPENGELE A: Taarifa za Kabla ya Upasuaji

1. Namba ya Dodoso
2. Namba ya usajili ya mgonjwa.....
3. Namba ya simu ya mgonjwa.....
4. Mahali anapotoka(mkoa).....
5. Umri.....
6. Jinsia a) Mme.....b)Mke.....
7. Utambuzi.....
8. Tarehe ya matibabu.....
9. Wengi wa damu kabla ya upasuaji.....

KIPENGELE B:Kipindi cha Upasuaji (Matokeo kutoka kwa Nurses na IdarayaUsingizi)

9. Mlalo wa mgonjwa
 - a) Ubavu.....
 - b) Chali.....
10. Muda uliotumika kwa upasuaji.....
 - i. Zaidi ya dakika 120.....
 - ii. Chini ya dakika 120.....

11. Idadi ya pakiti za damu aliyopewa mgonjwa
 - i. Whole blood.....
 - ii. Cell hai nyekundu.....
 - iii. Chembesahani.....
 - iv. FFP.....
12. Dawa aliyopewa mgonjwa(TXA).....
 - i. Ndiyo.....
 - ii. Hapana.....


KIPENGELE C:Baada ya Upasuaji

13. Idadi ya pakiti za damu aliyopewa mgonjwa:
 - a. Whole blood.....
 - b. Cell hai nyekundu.....
 - c. Chembesahani.....
 - d. FFP.....
14. Wengi wa damu baada ya upasuaji.....
15. Ukubwa wa mchanoCM

Appendix V: Ethical clearance letter

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

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Ref. No.DA.282/298/01.C/ Date: 07/10/2020

MUHAS-REC-10-2020-382
DR OMARY JOHN DOEKULU
MMed in Orthopedic and Traumatology, School of Medicine
MUHAS

**RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED:
ESTIMATED BLOOD LOSS AND TRANSFUSION RATE IN PATIENTS
UNDERGOING PRIMARY TOTAL HIP REPLACEMENT AT MUHIMBILI
ORTHOPAEDICS INSTITUTE**

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.

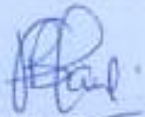
APPROVAL DATE: 07/10/2020
EXPIRATION DATE OF APPROVAL: 09/10/2021

STUDY DESCRIPTION:
Purpose:
To determine estimated Blood loss and transfusion rate in a patient undergoing primary THR at Muhimbili Orthopedic Institute (MOI) from July 2019 to April 2020

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-%20185.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 data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
8. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country.
9. 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)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. 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/>.

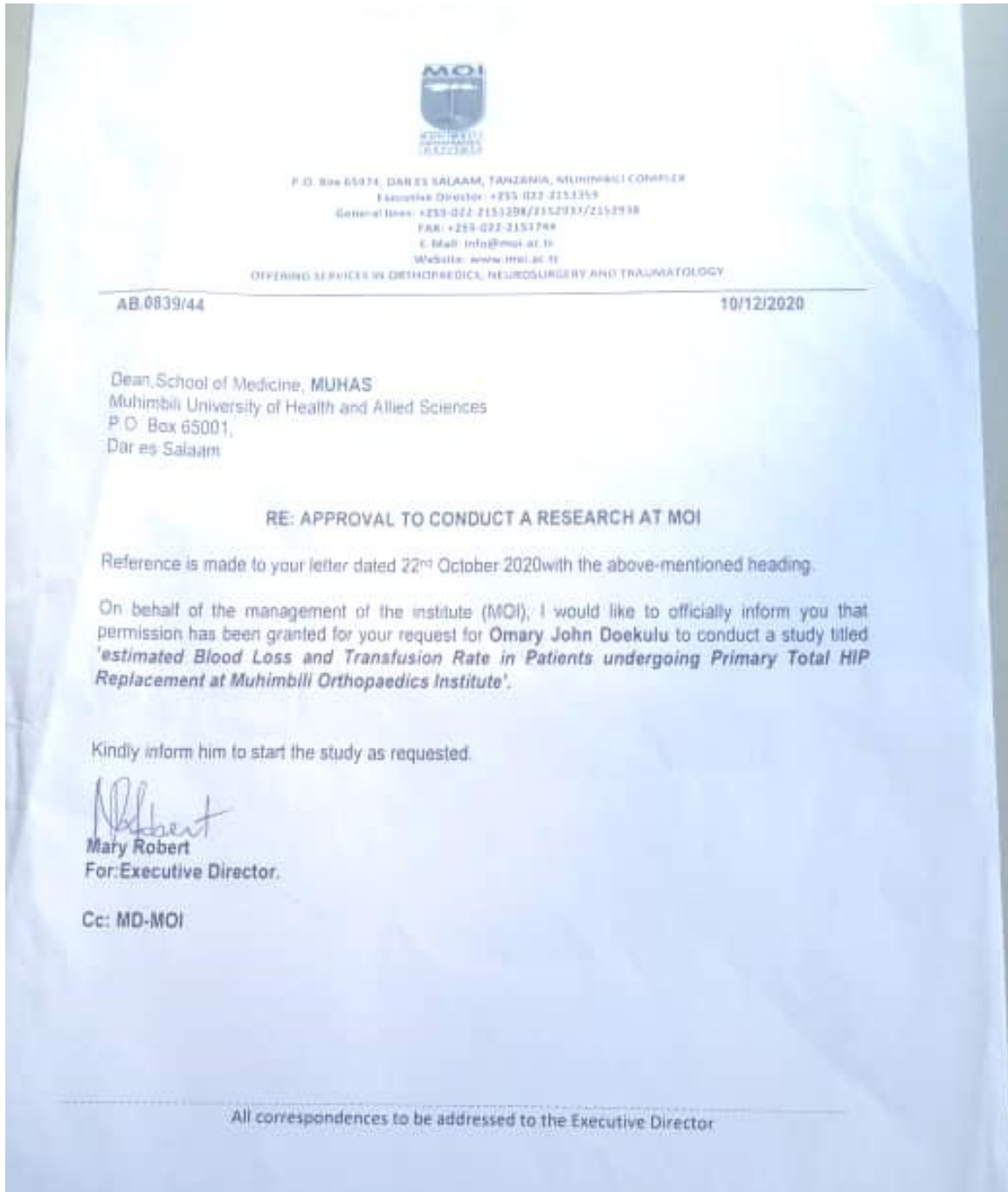


Dr. Bruno Sunguya

Chairman, MUHAS Research and Ethics Committee



Appendix VI: Permission Letters





P.O. Box 65474, DAR ES SALAAM, TANZANIA, MUHIMBILI COMPLEX
Executive Director: +255-022-2158359
General lines: +255-022-2151298/2152937/2152938
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OFFERING SERVICES IN ORTHOPAEDICS, NEUROSURGERY AND TRAUMATOLOGY

AB.0839/44

10/12/2020

Dean, School of Medicine, MUHAS
Muhimbili University of Health and Allied Sciences
P.O. Box 65001,
Dar es Salaam

RE: APPROVAL TO CONDUCT A RESEARCH AT MOI

Reference is made to your letter dated 22nd October 2020 with the above-mentioned heading.

On behalf of the management of the institute (MOI), I would like to officially inform you that permission has been granted for your request for Omary John Doekulu to conduct a study titled '*estimated Blood Loss and Transfusion Rate in Patients undergoing Primary Total HIP Replacement at Muhimbili Orthopaedics Institute*'.

Kindly inform him to start the study as requested.


Mary Robert
For: Executive Director.

Cc: MD-MOI

All correspondences to be addressed to the Executive Director.