

**EFFICACY OF DILUTE POVIDONE-IODINE VERSUS 0.9%
NORMAL SALINE IRRIGATION IN PRIMARY ARTHROPLASTY
AT MUHIMBILI ORTHOPEDIC INSTITUTE.**

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**MMed (Orthopedics and Traumatology) Dissertation
Muhimbili University of Health and Allied Sciences
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MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES



DEPARTMENT OF ORTHOPEDICS AND TRAUMATOLOGY

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INSTITUTE.**

By

Mark Ogundo, (MBChB)

**Dissertation submitted in partial fulfillment of the Requirement for the Degree of
Master of Medicine in Orthopedics and Traumatology of the Muhimbili University of
Health and Allied Sciences**

October 2021

CERTIFICATION

The undersigned certify that he has read and hereby recommend for examination of dissertation entitled **“Efficacy of dilute povidone-iodine versus 0.9% normal saline irrigation in primary arthroplasty at Muhimbili Orthopedic Institute”** in partial fulfillment of the requirement for the degree of Master of Medicine of Orthopedics and Traumatology of Muhimbili University of Health and Allied Sciences.

Dr. Billy Haonga
(Supervisor)

Date: _____

DECLARATION AND COPYRIGHT

I, **Mark E Ogundo**, declare that this dissertation entitled “**Efficacy of dilute povidone-iodine versus 0.9% normal saline irrigation in primary arthroplasty at Muhimbili Orthopedic Institute**” is my own original work and that it has not been presented and will not be presented to any other university for similar or any other degree award.

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Lastly, I would like to take this opportunity to express my sincere gratitude and appreciation to the MUHAS management through the Director of Postgraduate studies and MOI administration who granted permission for this study to be conducted.

DEDICATION

This dissertation is dedicated to my late mum Elizabeth Ogundo.

ABSTRACT

Background

Arthroplasty is a surgical procedure that just like any other surgery, is associated with complications such as surgical site infection and blood loss. In Muhimbili Orthopedic Institute, during primary arthroplasty, intraoperative irrigation is among the techniques carried out, with the aim of preventing the above complications. Depending on the surgeon's preference, the wound is irrigated with either dilute povidone-iodine or 0.9% normal saline before closure.

Objective

This study was carried out to determine the efficacy of dilute povidone-iodine versus 0.9% normal saline irrigation in primary arthroplasty at Muhimbili Orthopedic Institute.

Methodology

It was a prospective cohort study that lasted six months. 88 participants who met inclusion criteria were enrolled. Data was collected using structured questionnaire. Important information collected were age, sex, surgery (TKR or THR), pre/post-operative hemoglobin, type of anaesthesia, positioning, limb operated, approach, duration of surgery, number of blood transfusions, Surgical Site Infection using suggestive criteria (pain, swelling, warmth, temperature, new onset of joint effusion, CRP, ESR and WBC) and Surgical Site Infection using confirmatory criteria (fistula, sinus, wound breakage, pus discharge and culture).

All participants were clinically examined post-operatively, at 2nd, 6th and 12th weeks.

Data was analyzed using SPSS version 21.

Results

Out of 88 participants (44 each in dilute povidone-iodine group and 0.9% normal saline group), those irrigated by dilute povidone-iodine were 17(38.6%) male and 27(61.4)% female, while those with 0.9% normal saline were 20(45.5%) and 24(54.5%) respectively. Median age was 26. The commonest diagnosis was Osteoarthritis 71(80.7%) while the lowest was Avascular necrosis 6(6.8%). Five participants had surgical site infection based on positive culture results (One in dilute povidone-iodine group versus four in 0.9% normal

saline group). This was not statistically significant with a p-value of 0.286. The mean difference in pre and post-operative hemoglobin in the dilute povidone-iodine group was -8.52 ± 24.18 and in the 0.9% normal saline group was -9.45 ± 20.35 . This was statistically significant with a p-value of 0.004.

Conclusion

There was no significant difference in surgical site infection rate between dilute povidone-iodine and 0.9% normal saline irrigation in primary arthroplasty. However, there was less blood loss among participants who were irrigated with dilute povidone-iodine than with 0.9% normal saline in primary arthroplasty at Muhimbili Orthopedic Institute.

Recommendation

A study with a higher sample size and longer duration of time should be conducted to determine efficacy of irrigation fluids in primary arthroplasty involving various arthroplasty centers in Tanzania to increase generalisation of results.

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LIST OF ABBREVIATIONS

BT:	Blood Transfusion
CRP:	C - reactive protein
ESR:	Erythrocyte Sedimentation Rate
FBP:	Full Blood Picture
Hb:	Hemoglobin
IRB:	Institutional Review Board
MNH:	Muhimbili National Hospital
MOI:	Muhimbili Orthopedic Institute
MUHAS:	Muhimbili University of Health and Allied Sciences
PJI:	Periprosthetic Joint Infection
THA:	Total Hip Arthroplasty
TJA:	Total Joint Arthroplasty
TKA:	Total Knee Arthroplasty
SSI:	Surgical Site Infection
Vs:	Versus
WBC:	White Blood Cells

DEFINITION OF TERMS

Surgical Site Infection: is defined as presence of pain at a surgically created wound, which is accompanied by erythema, induration and local tenderness or presence of purulent discharge at wound site or culture positive.

Arthroplasty: is referred to as joint replacement of the hip and knee joints.

CHAPTER ONE

1.1 INTRODUCTION

The number and demand for arthroplasty is on the increase. Just like other surgeries, they are associated with complications, such as surgical site infection and blood loss. (1)

Intraoperative irrigation is among the strategies in the prevention of SSI. (2). Intraoperative wound irrigation in arthroplasty is a routine practice among orthopedic surgeons in prevention of SSI. Despite this, there is little standardization as far as it's practice is concerned. (3) This has led to complications in arthroplasty which are serious and expensive. (4)

There are 3 components of irrigation: delivery method, volume, and type of solution (with and without additives). Irrigation with a low pressure delivery system of a 1 to 9-L volume of solution should be used on wounds. However, in contaminated or infected wounds, a greater volume is indicated.

Surfactants, antibiotics, or antiseptics are frequently added to operative irrigation solutions. (2) Solutions such as 0.9% normal saline, castile soap, antibiotic solutions, and antiseptics like dilute povidone-iodine or hydrogen peroxide have been proposed. However, lack of evidence has made it difficult to arrive at a consensus.

Theoretic studies have shown advantages of using povidone, which is a potent antiseptic with broad-spectrum efficacy while still being gentle on tissues. However, most surgeons still prefer 0.9% normal saline. (3) This study was to investigate the efficacy of povidone versus normal saline in primary arthroplasty at Muhimbili Orthopedic institute.

1.2 Literature review

Arthroplasty is on the rise especially due to the increasing life expectancy. It is the most common surgical intervention for end stage arthritis. (4,5)

In the western world, the number of men undergoing arthroplasty is equivalent to that of women. However, different literature shows that there is a higher number of women undergoing Total Knee Arthroplasty (TKA) in both the low income and high-income countries, with a rate of 57% and 77% respectively. (6) Similar studies done in Africa also show that the ratios of male to female requiring Total Hip Arthroplasty (THA) are equal in low income countries, (5) with chronological age of the patients at the time for arthroplasty being lower in countries of sub-Saharan Africa than in high income countries. (6)

Osteoarthritis is the most common indication for both THA and TKA. This applies to both high income and low-income countries. (6) Other indications for arthroplasty include inflammatory arthritis, fracture, dysplasia and malignancy. (5)

Surgical site infection (SSI) is one of the most devastating complications to both the surgeon and the patient following arthroplasty surgery. (7,8) In an attempt to mitigate this complication, surgical irrigation prior to wound closure has become a mainstay prevention technique. (9) This however, is hampered by the fact that there is no standardization pertaining to surgical irrigation fluids, (10) with different solutions such as povidone-iodine, chlorhexidine, normal saline, ringer lactate being used for this purpose (9, 10, 11) Worldwide, SSI in Total Joint Arthroplasty (TJA) has been stated at an incidence of 1 to 2.5%. (13) Meta-analysis done in Sub Saharan African has shown the incidence of SSI to be 1.6% for TKAs and 0.5% for THAs. (12) A research done by Anthony et al in MOI, showed the prevalence of SSI in elective orthopedic procedures to be 4.8%. (14) Another study done in Tanzania in 2017 showed that the prevalence of SSI in orthopedic procedures in MOI to be at 25% (15) but it did not narrow down to arthroplasty and has been contradictory. Many studies seem to be in favor of dilute povidone-iodine for irrigation in comparison to 0.9% normal saline as it has been associated with reduced surgical site infection rates. (15) In this prospective Random Controlled Trial, no difference in the effect of povidone- iodine or normal saline for irrigation on surgical site infection was reported. (16) The antibacterial effect of povidone has been reported to be increased with its dilution and one of the theories that supports this paradox is that dilution of povidone weakens the iodine linkage and therefore increases the amount of free iodine in the solution. (17,18) Brown et al reported that dilute iodine lavage reduced acute deep joint infection by 0.15% infection rate for patient who had iodine irrigation in comparison to 0.97% for patients who did not have the iodine irrigation. (19). Chang et al reported no infection in patients who had irrigation with povidone-iodine in comparison to the control (9) while Cheng et al recommended the use of iodine solution for irrigation. (10) In this study, there wasn't any significance of using dilute povidone-iodine solution for surgical irrigation which was assessed with rate of re-operation for infection (8) while in this study, use of povidone solution was shown to be superior to the use of normal saline. (20) No such studies have been conducted in Tanzania or East Africa.

Studies have shown that intraoperative fluid irrigation plays a role in bleeding in relation to arthroplasty surgeries. (3) However, these studies have not been conclusive. Both normal saline and povidone solution have been shown to have effect in reduction or cessation of bleeding. (16) Patient undergoing arthroplasty have been reported to lose an approximate of 1400 to 1800mls and have a 40% likelihood of needing a blood transfusion (10,21) hence the need for blood conservation strategies for example autologous blood transfusion, hypotensive anesthesia, use of tranexamic acid, pneumatic tourniquet application, cementing and plugging of the femoral canal. (22) In a 2006 study by Kumar et al, irrigation with povidone solution was shown to lead to cessation of bleeding during root canal surgery (20) and the proposed reason was that iodine may chemo-cauterize the tissues while povidone may aid in clotting which translates to reduced need for blood transfusion. Another 2011 study there was marked reduction in bleeding and clotting time for patients who were irrigated with povidone solution showing its potency as a hemostatic agent. (21) In respect to temperatures, cold saline has been thought to further promote hemostasis by inducing vasoconstriction while warm/hot saline has been thought to cause vasodilation and edema of the blood vessels thus reducing the risk of necrosis. This edema produces local pressure on the injured vessels, initiating and speeding the clotting mechanism. (23) Use of normal saline has been shown to be effective in reducing the intraoperative bleeding and further improve patient's quality of life post-operatively even though it was shown to be superior when augmented with chemicals like epinephrine, calcium or potassium. (24,25). There is not any data in Tanzania or East Africa that has shown the effect of dilute povidone iodine and plain normal saline on the hemostasis or postoperative bleeding.

1.3 Problem Statement

Prevention of SSI and blood loss should be a key strategy during arthroplasty. SSI and blood loss still remain major challenges in patients undergoing arthroplasty. This has led to extended hospital stays and increased hospital costs. They have also been associated with increased risk of deep joint infections which is the major cause of arthroplasty revision. Intraoperative irrigation in primary arthroplasty has been adopted in MOI by both firm A and B, by using 0.9% normal saline and dilute povidone-iodine respectively. Studies have

been conducted elsewhere on intraoperative irrigation in arthroplasty for prevention of SSI with few studies looking at blood loss.

However, there are contradicting information on the use of dilute povidone-iodine and 0.9% normal saline and their effect in reduction of SSI and blood loss with lack of enough evidence in regard to the optimal antiseptic or whether antiseptics confer any advantage at all. None of these studies have been conducted at MOI.

1.4 Conceptual framework

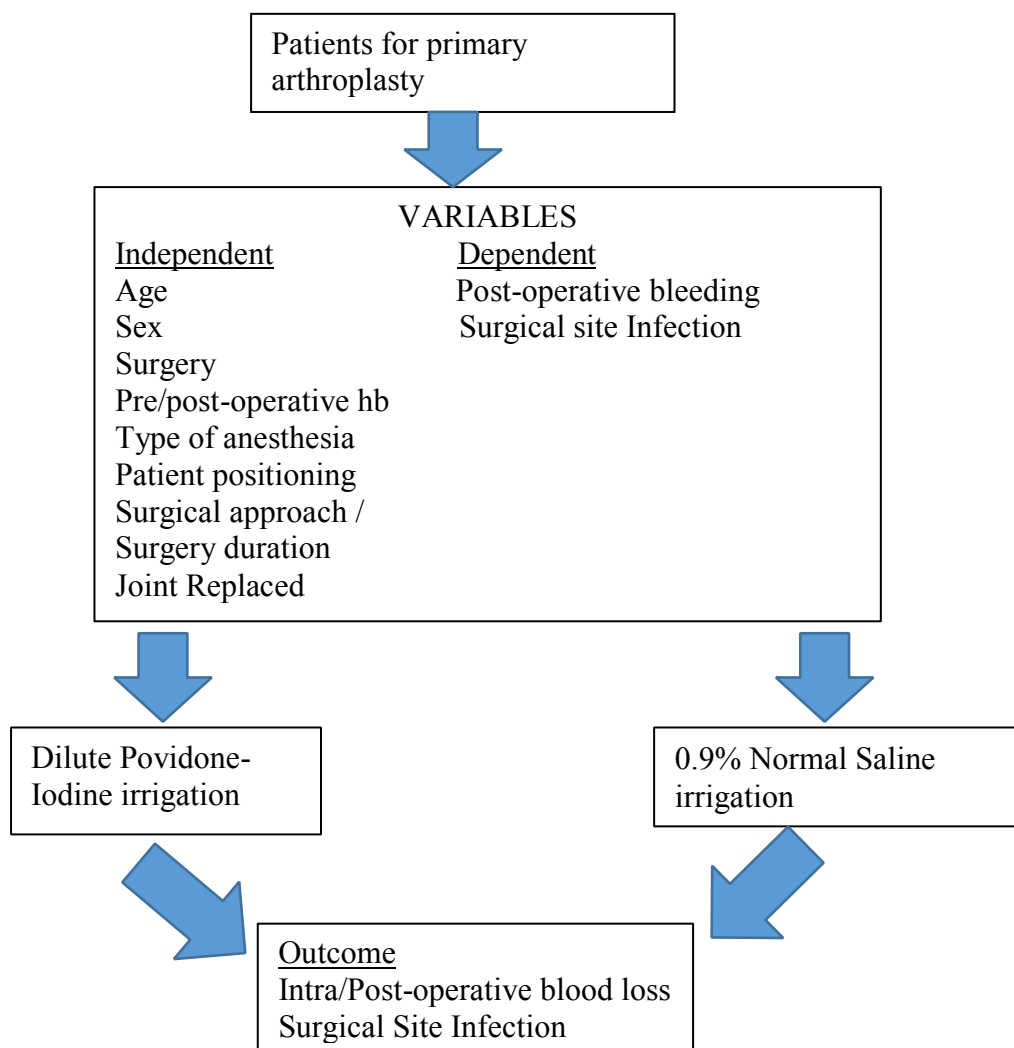


Figure 1: Conceptual framework

The independent variables of this study included the demographics of the subjects, surgery, and patient's positioning, surgical approach, duration of surgery and pre and post-operative hemoglobin which all contributed to the dependent variable of having surgical site infection and/or intra/post-operative bleeding.

1.5 Rationale

This was the first study to directly examine and compare the efficacy of intra-operative wound irrigation with dilute-povidone and 0.9% normal saline in primary arthroplasty at MOI. There is no literature published so far in our setting or surroundings.

Due to lack of enough evidence on the effect of irrigation fluids, there is a lack of consensus on the best irrigation solution to use at MOI. Therefore, scientific evidence is needed to provide an effective choice of irrigation fluid at MOI. This study will also add knowledge to literature, guide future decisions and act as a basis for further research.

1.6 Hypothesis

Null hypothesis which stated that there is no difference in SSI or blood loss following intraoperative irrigation with dilute povidone-iodine or 0.9% normal saline among patients undergoing primary arthroplasty at MOI.

1.7 OBJECTIVES

1.7.1 Broad objective

To determine the efficacy of dilute-povidone versus 0.9% normal saline irrigation in primary arthroplasty at Muhimbili Orthopedic Institute.

1.7.2 Specific objectives

1. To compare the rate of surgical site infection in primary arthroplasty irrigated with dilute povidone-iodine and 0.9% normal saline at Muhimbili Orthopedic Institute.
2. To determine blood loss in relation to intraoperative irrigation solution used in primary arthroplasty at Muhimbili Orthopedic Institute.

CHAPTER TWO

2 METHODOLOGY

2.1 Study design

Prospective cohort study design

2.2 Study Duration

The study was conducted for a period of 6 months.

2.3 Study Population

Primary arthroplasty patients at MOI between July to December, 2020 were included.

The study was conducted at MOI which is based in Dar-es-salaam, Tanzania and serves as the largest and national orthopedic and trauma referral center.

Services offered at MOI include Orthopedics, Traumatology and Neurosurgery. It has a 360-bed capacity and six arthroplasty surgeons.

For efficiency in service provision, the department of Orthopedic and Traumatology is divided into three firms (A, B and Pediatrics) while the department of Neurosurgery has two firms. Arthroplasty surgeries are performed by firms A and B. Firm A majorly uses 0.9 % normal saline for irrigation while Firm B uses dilute povidone-iodine.

2.4 Sample size

To compare the rate of SSI in arthroplasty irrigated with dilute povidone-iodine vs 0.9% normal Saline in MOI, the sample size formula for comparing the proportions in two groups was used (26).

$$n = \frac{(Z_1 + Z_2)^2 2P(1 - P)}{(p_1 - p_2)^2}$$

Where;

Z_1 = standard normal value at 95% confidence interval

Z_2 = standard normal value at 80% power

p_1 = proportion who were irrigated with dilute povidone-iodine that had SSI

p_2 = proportion of the individuals who were irrigated with 0.9% normal saline that had SSI

n= number in each group

$$p = \frac{p_1 + p_2}{2}$$

From previous studies done at MOI, the overall prevalence of SSIs was 4.8% (14).

Therefore, we assumed that the average prevalence in the two groups is 4.8%.

Substituting $P = 0.048$

$$n = \frac{\{(1.96 + 0.84)^2 \times 0.048(0.952)\}}{0.04^2}$$

n=447 persons

Thus participants for both groups totaled 894.

Given the fewer numbers seen at MOI, we used the sample size of finite population to calculate the appropriate sample size.

For small populations n was adjusted so that,

$$n(adj) = \frac{N \times n}{N + n}$$

Adjustment for finite population size is described by Thrusfield M. (27)

Given that the study was carried out for six months, a pilot study showed that 400 arthroplasties were done in MOI in 2019.

Therefore, for 6 months, an estimated 200 surgeries were projected to be carried out at MOI. Thus, $n=200$

Substituting,

$$n(adj) = \frac{447 \times 200}{200 + 894} = 82$$

Thus, the entire study considered a sample size of 82 participants.

2.5 Sampling Technique

Consecutive technique.

2.6 Inclusion criteria

All consenting primary arthroplasty patients to whom dilute povidone-iodine irrigation and those to whom 0.9% normal saline irrigation were used intra-operatively at MOI during the study period

2.7 Exclusion criteria

Patients who underwent revision arthroplasty, hemi-arthroplasty and consecutive arthroplasty. Patients to whom both methods were used. Patients to whom antibiotics or any other additives were added to the irrigation fluid. Patients to whom drainage were applied.

2.8 Variables

Data on independent variables of this study were collected on demographics such as Age, Sex, Pre and post-operative hemoglobin, Diagnosis, Surgery (Type i.e. THR or TKR), Limb operated, Type of anesthesia i.e. Spinal anesthesia or General anesthesia, Positioning of patient i.e. Supine or Lateral, Surgical Approach and Duration of surgery (minutes). The dependent variables included intraoperative blood loss amount, and SSI was assessed by Pain, Swelling, Warmth, Temperature, New onset joint effusion, Fistula, Sinus, Wound breakage, Pus discharge, WBC, ESR, CRP and Culture.

2.9 Data collection technique

Participants who fit the inclusion criteria were recruited from the ward. They were then educated about the study and consent was sought.

Pre-operatively, participants' demographic features, preoperative hemoglobin level, diagnosis and type of planned surgery were recorded in the questionnaire.

Post-operatively, type of anesthesia, patient positioning, the approach used, surgery duration and post-operative hemoglobin level were recorded.

Irrigation procedure was done as follows;

The dilute povidone-iodine irrigation solution was prepared in a sterile technique by the nurse recruited in the study as 10mls of 0.25% povidone-iodine mixed with 500mls of saline solution. This was then poured by the surgeon with the use of a 60ml syringe both before and after implant placement and left in place for at least two minutes before draining.

For irrigation with normal saline, the nurse recruited in the study ensured that the fluid was at room temperature with a concentration of 0.9%. Irrigation was done by the surgeon by pouring the saline into the surgical site by use of a 60ml syringe before and after implant placement and left in place for at least two minutes before draining.

A total of 1.5litres of irrigation fluids were used in both groups.

Surgery duration was recorded.

Skin closures were done as per standard procedure. The wounds were dressed with sterile gauze and held by adhesive tape or compression bandage. Placement of a drain in TKR was left at the discretion of the surgeon.

The intra-operative blood loss was recorded as indicated by the nurses and anesthetists' forms found in theatre and copies inserted in the patient's file.

The principal investigator continued to follow up on the patients and recorded the postoperative hemoglobin level.

Surgical site was examined for infection post-operatively for a period of three months as follows: at two weeks, six weeks and three months post-operative visits and recorded as per the following criteria by Metsemaker et al, 2018. (28)

We started with suggestive criteria and then confirmatory criteria to confirm the diagnosis.

SSI

Suggestive criteria for

- i. Clinical signs (pain, redness, swelling, warmth, fever)
- ii. Radiological signs (bone lysis, Implant loosening, Sequestration, non-union, involucrum)
- iii. New onset joint effusion
- iv. Elevated inflammatory markers (ESR, WBC, and CRP).

Confirmatory criteria for SSI

- i. Fistula, sinus or wound breakdown
- ii. Purulent/ pus discharge from the wound
- iii. Positive culture
- iv. Histopathological confirmation

However, for the purpose of this study, confirmatory criteria for SSI included; fistula, sinus or wound breakdown, purulent/ pus discharge from the wound and positive culture with exclusion of histopathological confirmation.

Culture was done on three different samples of pus swab taken from the same patient under aseptic technique and sample was taken to MNH laboratory for analysis.

Suggestive criteria for SSI for this study included; clinical signs (Pain, redness, swelling, warmth, fever), new onset joint effusion and elevated inflammatory markers (ESR, WBC, CRP).

In an event of SSI, an appropriate antibiotic was initiated.

Participants were discharged from the study after the elapse of three months follow up period.

2.10 Investigation tools

Questionnaire was used to record data collected from; Patient's file, arthroplasty theatre records, nurses' records, anesthetists' records and physical examination of the participant.

2.11 Data management and analysis

All collected data were coded, cleaned and analyzed using SPSS software version 21. The principal investigator performed data cleaning for consistency, logic, and accuracy. Univariate analysis was done. Continuous variables were summarized with means and standard deviations for normally distributed data, and medians and interquartile ranges for skewed data. Categorical variables were presented as proportions or percentages where appropriate. Tables were used to present the data while pie charts, bar graphs and box plots were plotted to visualize the data. Categorical variables were compared using Fisher's exact or Chi-square tests while continuous variables were compared using either Student's t test or Mann Whitney-U test after checking for assumptions.

The proportion of SSIs and mean blood loss were calculated for the 0.9% normal saline and dilute povidone-iodine. The proportions were compared using Fisher's exact test. A p-value of less than or equal to 0.05 was considered significant to reject the null hypothesis that there is no difference in proportions of SSIs between the two study groups.

Linear regression modeling was also performed to determine if the difference between these groups remain even in the presence of con-founders like age and sex. Confounding was assessed as a more than 10% change in the odds ratio when a model with the variable was compared to a model without the variable. The beta coefficients and their 95% confidence intervals were presented.

2.12 Ethical issues

The proposal was ethically cleared by IRB of MUHAS and permission to conduct the study was sought from the executive director of MOI.

Informed consent was sought from the patient or next of kin for those who were not in a position to give consent by themselves. This was after detailed explanation on the study objectives. Confidentiality assurance was provided. Patient management was not altered by refusal to participate in the study.

The study participants underwent all the available standard post-operative management.

CHAPTER THREE

3 RESULTS

3.1 Study description flow chart

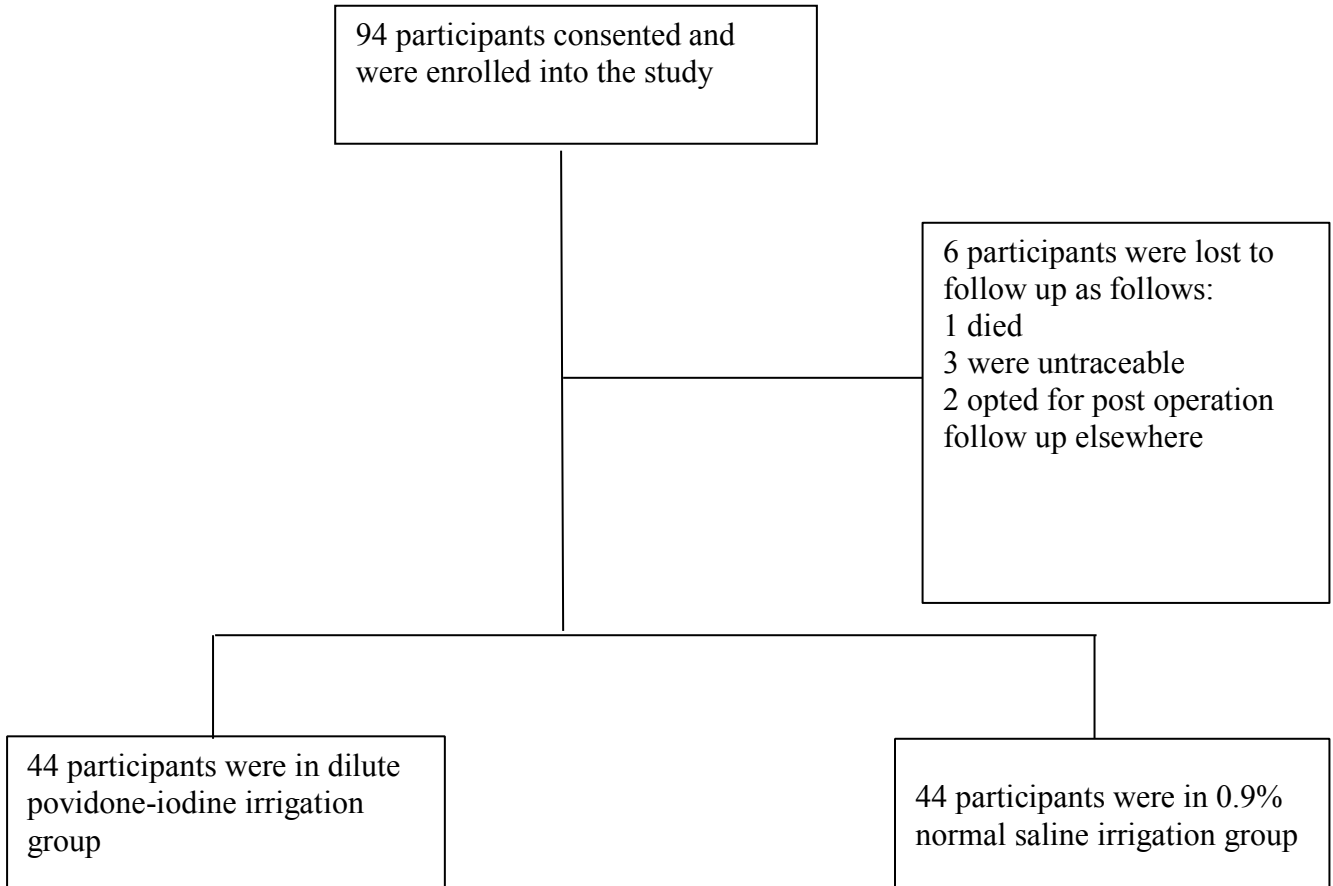


Figure 2: Study description flow chart

3.2 Demographic Characteristics of participants

The demographics are presented per irrigation exposure status.

The study had 37(42.1%) male participants and 51(57.9%) female participants. The youngest was 18 yrs old while the oldest was 84 yrs old with a median of 26. Based on Mann Whitney U test for age, the p-value was 0.761. This did not give statistical evidence to reject the null hypothesis, thus age showed no statistical significance in SSI or blood loss between those irrigated with dilute povidone-iodine versus those irrigated with 0.9% normal saline.

The rest of the characteristics are shown in table 1.

Table 1: Demographic Characteristics of Study Participants

Characteristic	Total, N	Dilute Povidone Iodine, N (%)	0.9% Saline, N (%)	Pvalue
Sex				
Male	37 (42.1)	17 (38.6)	20 (45.5)	
Female	51 (57.9)	27 (61.4)	24 (54.5)	0.666*
Age				
Median (IQR)	26 (17.5 -32)	26 (19.5-32)	26.5 (15-31.5)	0.761***
Diagnosis				
AVN	6 (6.8)	4 (9.1)	2 (4.5)	
NOF	11 (12.5)	2 (4.5)	9 (20.5)	
OA	71 (80.7)	38 (86.4)	33 (75.0)	0.070**
Preoperative hb (g/dl)				
Median (IQR)	20 (11.5-30.5)	19.5 (10-30)	21 (12.5-31)	0.661***
Limb operated n=88				
Left side	50 (57.5)	24 (55.8)	26 (59.1)	
Right side	37 (42.5)	19 (44.2)	18 (40.9)	0.830*
Surgery Joint placed				
Total hip replacement	48 (55.7)	22 (50.0)	27 (61.4)	
Total knee replacement	39 (44.3)	22 (50.0)	17 (38.6)	0.391*
Patient positioning				
Supine	66 (75.0)	22 (50.0)	44 (100.0)	

Lateral	22 (25.0)	22 (50.0)	0 (0.0)	<0.001**
Surgical approach				
Lateral (Hardinge)	50 (56.8)	22 (50.0)	28 (63.6)	
Medial parapatellar	38 (43.2)	22 (50.0)	16 (36.4)	0.282*
Duration of surgery				
Below 1 hour	4 (4.5)	4 (9.1)	0 (0.0)	
1-2 hours	46 (52.3)	33 (75.0)	13 (30.0)	
2-3 hours	32 (36.4)	7 (15.9)	25 (56.8)	
Over 3 hours	6 (6.8)	0 (0.0)	6 (13.6)	<0.001***
Post-operative hb (g/dl)				
Below 10	59 (67.1)	28 (63.6)	31 (70.5)	
10-12	23 (26.1)	12 (27.3)	11 (25.0)	
12-15	5 (5.7)	3 (6.8)	2 (4.5)	
Above 15	1 (1.1)	1 (2.3)	0 (0.0)	0.817**
Number of transfusions (number of units) n=70				
0	36 (51.4)	20 (64.5)	16 (41.0)	
1	22 (31.4)	9 (29.0)	13 (33.3)	
2	4 (5.7)	0 (0.0)	4 (10.3)	
3	8 (11.4)	2 (6.5)	6 (15.4)	0.106**

*based on chi square test **based on fisher's exact test ***based on the Mann Whitney U test

3.2.1 Sex of the participants

Those irrigated by dilute povidone-iodine were 17(38.6%) male and 27(61.4) % female while those with 0.9% Normal Saline were 20(45.5%) and 24(54.5%) respectively. Based on the chi square test, the p-value was 0.666. This did not give statistical evidence to reject the null, thus sex showed no statistical significance in SSI or blood loss in those irrigated with dilute povidone-iodine versus 0.9% normal saline.

3.2.2 Diagnosis of participants at enrollment

The commonest diagnosis was Osteoarthritis 71(80.7%) followed by Neck of femur fracture 11(12.5%) and then Avascular Necrosis 6(6.8%). Based on Fisher's exact test, p-value was 0.070. This did not give statistical evidence to reject the null hypothesis, thus diagnosis showed no statistical significance in SSI or blood loss of sex in those irrigated with dilute povidone-iodine versus 0.9% normal saline.

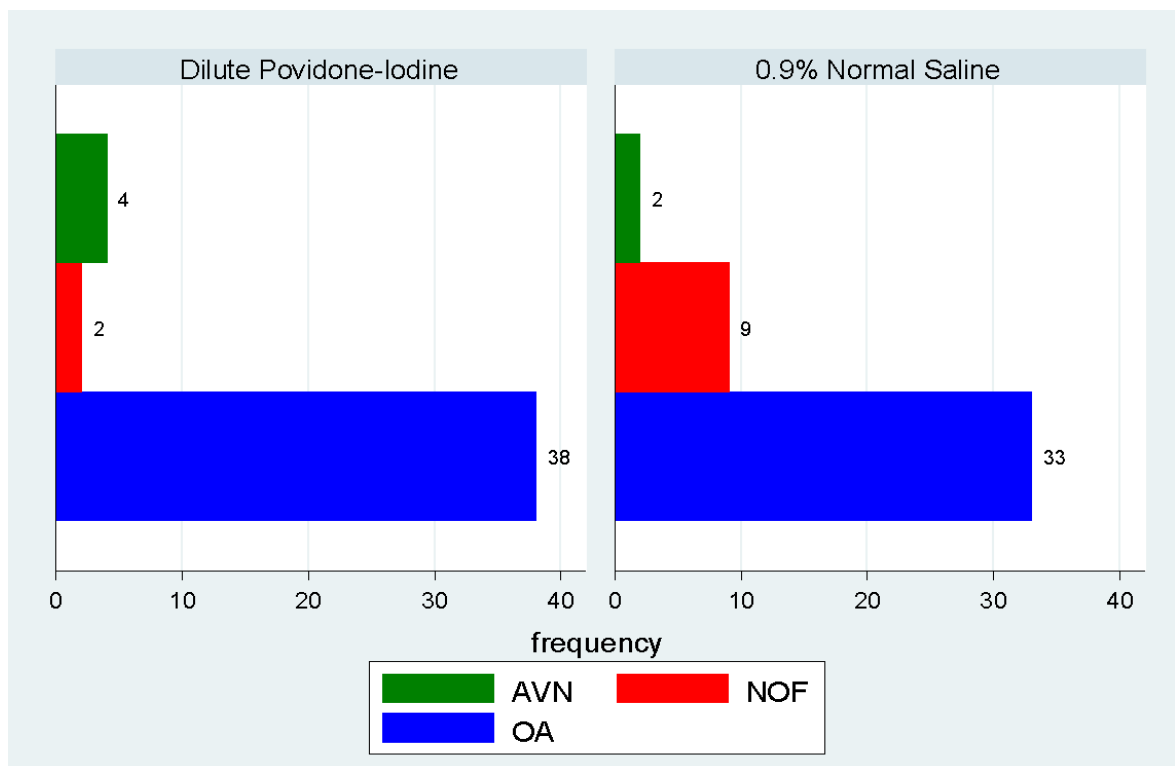


Figure 3: Bar graph showing the distribution of the different diagnoses by the irrigation fluid.

3.3 To compare the rate of Surgical Site Infection in primary arthroplasty irrigated with dilute povidone-iodine and 0.9% normal Saline.

3.3.1 Surgical Site Infection Characteristics of participants

Under suggestive criteria for SSI, 3 participants under dilute povidone-iodine irrigation group had pain, swelling and elevated ESR while 7 participants under 0.9% normal saline irrigation group had pain and swelling but only 5 had elevated ESR. Based on Fisher's exact test, a p-value of 0.157 and 0.357 respectively was not found to give statistical evidence to reject the null hypothesis, thus suggestive criteria showed no statistical significance in SSI in those irrigated with dilute povidone-iodine versus 0.9% Normal Saline.

Using confirmatory criteria, under the dilute povidone-iodine group, 2 participants had wound breakage and pus discharge and culture done for the 2, while under 0.9% normal saline irrigation group, wound breakage was 5 and pus discharge were 6, while culture was done for the 6. P-value of 0.217, 0.157 and 0.286 respectively was found not to be statistically significant to reject the null hypothesis. This did not give statistical evidence to reject the null, thus confirmatory criteria showed no statistical significance in SSI in those irrigated with dilute povidone-iodine versus 0.9% normal saline.

Table 2: Surgical Site Infection Characteristics of participants

Characteristic	Total, N (%)	Povidone Iodine, N (%)	0.9% Saline, N (%)	P Value
SSI using suggestive criteria				
a) Pain (n=88)				
No	78 (88.6)	41 (93.2)	37 (84.1)	
Yes	10 (11.4)	3 (6.8)	7 (15.9)	0.157 *
b) Swelling				
No	78 (88.6)	41 (93.2)	37 (84.1)	
Yes	10 (11.4)	3 (6.8)	7 (15.9)	0.157 *

c) Warmth				
No	79 (89.8)	42 (95.5)	37 (84.1)	
Yes	9 (10.2)	2 (4.5)	7 (15.9)	0.157*
d) Temperature in Celsius				
Below 36.5	2 (2.3)	0 (0.0)	2 (4.5)	
36.5 to 37.5	80 (90.9)	43 (97.7)	37 (84.1)	
Above 37.5	6 (6.8)	1 (2.3)	5 (11.4)	0.065*
e) New onset joint effusion				
No	81 (92.0)	42 (95.5)	39 (88.6)	
Yes	7 (8.0)	2 (4.5)	5 (11.4)	0.217*
f) Inflammatory Markers				
i) C-RP n=88				
No	80 (90.9)	42 (95.5)	38 (86.4)	
Yes	8 (9.1)	2 (4.5)	6 (13.6)	0.133*
Mean,sd	3.63,1.03	1.5,0.71	4.33, 1.03	0.012
ii) ESR n=88				
No	80 (90.9)	41 (93.2)	39 (88.6)	
Yes	8 (9.1)	3 (6.8)	5 (11.4)	0.357*
Mean,sd	3.43,1.5	1.5, 0.71	4.2, 0.84	0.010
ii) WBC, n=88				
No	79 (89.8)	42 (95.5)	37 (84.1)	
Yes	9 (10.2)	2 (4.5)	7 (15.9)	0.157*
Mean, sd for n=9	3.55,0.71	3.5 , 3.5	3.57, 1.98	0.970
SSI using confirmatory criteria				
a) Fistula n=88				
No	88 (100.0)	44 (100.0)	44 (100.0)	

Yes	0 (0.0)	0 (0.0)	0 (0.0)	Not calculated
b) Sinus, n=88				
No	87 (98.9)	44 (100.0)	43 (97.7)	
Yes	1 (1.1)	0 (0.0)	1 (2.3)	0.500*
c) Wound breakage, n=88				
No	81 (92.1)	42 (95.5)	39 (88.6)	
Yes	7 (7.9)	2 (4.5)	5 (11.4)	0.217*
d) Pus discharge from wound, n=88				
No	80 (90.9)	42 (95.5)	38 (86.4)	
Yes	8 (9.1)	2 (4.5)	6 (13.6)	0.133*
e) Culture n=88				
No	80 (90.9)	42 (95.5)	38 (86.4)	
Yes	8 (9.1)	2 (4.5)	6 (13.6)	0.133*
Culture status , n=88				
Negative	3 (37.5)	2 (66.7)	1 (20.0)	
Positive	5 (62.5)	1 (33.3)	4 (80.0)	0.286*

**based on fisher's exact test*

3.3.2 Culture Status of participants

Assuming that those participants to whom culture was not indicated plus those to whom culture was done but turned negative were all grouped as negative, we had a total of 83 (94.3%). 5 (5.7%) turned positive. Based on Fisher's exact test, p-value was 0.180. This was found to not give statistical evidence to reject the null hypothesis, thus culture showed no statistical significance in SSI in those irrigated with dilute povidone-iodine versus 0.9% normal saline.

3.4 To determine blood loss in relation to intraoperative irrigation solution used in primary arthroplasty at MOI

Using the t test, to determine intraoperative blood loss, there was a p-value of 0.466. Based on the box plot, the intraoperative blood loss was normally distributed in both groups of irrigation.

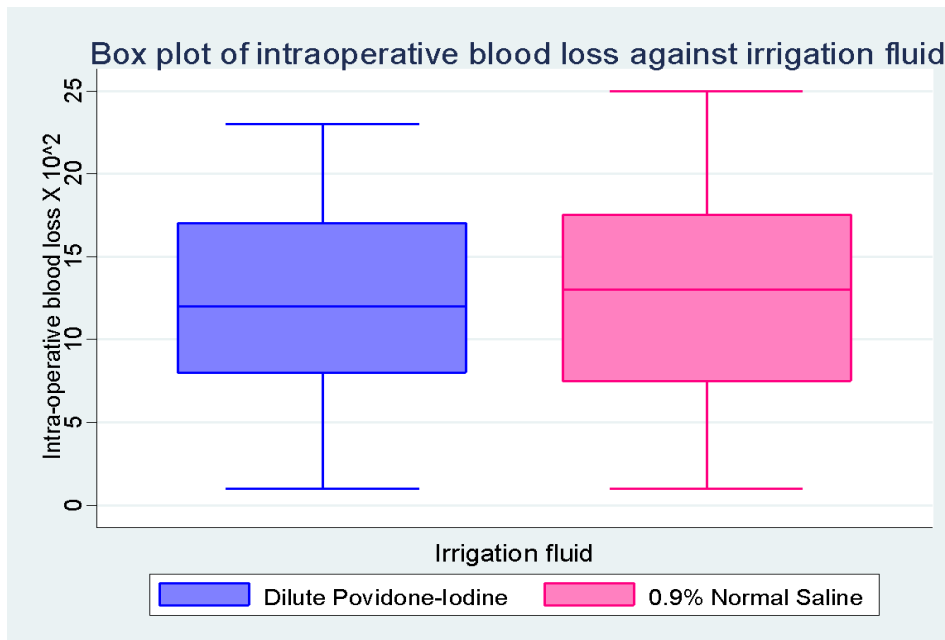


Figure 4: Intraoperative blood loss of participants

3.4.1 Difference in pre and post-operative hemoglobin

Based on paired t tests to determine the difference between pre and post hemoglobin, the p-value was 0.004. It was determined that there is statistical evidence between the two groups to reject the null hypothesis. Therefore, there was statistical significance between irrigation fluid and intraoperative blood loss.

Table 3: Difference in pre and post-operative hemoglobin

Characteristic	Dilute povidone-iodine	0.9% normal saline	P value
Mean differences between pre and postoperative hb(g/dl)	-8.52 ± 24.18	-9.45 ± 20.35	0.004**

3.5 Linear Regression

We ran a linear regression model. This was to assess whether the relationship between intra-operative blood loss remains the same, even with consideration of other confounding variables.

There were no statistically significant relationships between the irrigation fluid and blood loss. Other variables are shown in the table below.

Table 4: Linear Regression

Characteristic	Beta estimate (95 % Confidence Interval)	P value
Sex		
Male	Reference	
female	1.41 (-1.44-4.26)	0.327
Irrigation fluid		
Dilute Povidone -iodine	Reference	
0.9% normal saline	0.61 (-3.92- 5.14)	0.789
Age in years	0.12 (-0. -.82-1.05)	0.801
Joint placed		
THR	Reference	
TKR	-0.17 (-4.23-3.88)	0.932
Limb operated		
Left side	Reference	
Right side	-1.16 (-4.05 -1.72)	0.424
Duration of surgery		
Below 1 hour	Reference	
1-2 hours	-2.83 (-9.66-3.99)	0.412
2-3 hours	-0.22 (-7.65-7.22)	0.954
Over 3 hours	-6.08 (-15.09-2.93)	0.183
Position of the patient		
Supine	Reference	
Lateral	-0.54 (-6.23-5.151)	0.851

CHAPTER FOUR

4 DISCUSSION

In this prospective cohort study, we sought to determine surgical site infection and amount of blood loss between individuals who were intra-operatively irrigated with either dilute povidone-iodine or 0.9% normal saline during arthroplasty.

88 participants took part in the study and underwent arthroplasty with 44 undergoing irrigation with dilute povidone iodine and the other 44 with 0.9% normal saline.

In this study, the ages ranged from 18 years to 84 years, with a median age of 26. This finding was similar to a previous study (7) that showed that a fairly young population group are undergoing arthroplasty in our setting. This could be due to increased Sickle Cell disease in our area which causes great insult to young people's joints and therefore predisposes them to the articular damage hence the need for arthroplasty. It could also be due to increased availability of arthroplasty in our setting.

A large percentage of our participants were female which is in keeping with previous studies (5, 6) that showed women being more likely to undergo arthroplasty procedures than men. We believe that this could be due to arthritis affecting more women in postmenopausal age or perhaps better health seeking behaviour in females as compared to male.

In addition, the commonest indication for arthroplasty in our study was osteoarthritis which is also in line with other studies (4, 5, 6). This could be due to most patients choosing arthroplasty as the treatment of choice for osteoarthritis over other treatment modalities.

A higher number of participants who developed surgical site infection had irrigation with normal saline. However, this was found not to be statistically significant, it is in keeping with other studies (8, 16) that found no difference in infection rates between dilute povidone-iodine and 0.9% normal saline. The short duration of follow up, the study design and the small sample size in our study could have contributed to a p value of 0.286.

Finally, we found less blood loss and higher haemoglobin levels both intra-operatively and post-operatively respectively in the group of participants who were irrigated with dilute povidone-iodine, with less blood transfusion as compared to 0.9% normal saline group. This was found to be statistically significant with a p-value of 0.04.

This observation was noted in another study (20) that showed cessation of bleeding following povidone irrigation. We believe this could be due to the fact that iodine may chemo cauterize the tissues while povidone may aid in blood clotting. This could translate to reduced need for blood transfusion. It could also be due to the lateral positioning of THA patients in dilute-povidone group.

4.1 STUDY LIMITATION

It is important to note that this study had limitations.

The findings might not be representative of the population due to lower sample size and short follow up period.

Considering no published data on the local situation, the sample size was calculated using research done on overall orthopedic surgeries at MOI, and not just arthroplasties alone, with some assumptions. This might not be entirely representative.

The study may only offer clues about the effects of dilute povidone-iodine vs 0.9% normal saline irrigation, but not definitive proof of links between SSI and intra/post-operative bleeding.

There was loss to follow up whereby, participants opted out of the study or died in the course of the study. These could have led to bias. This was mitigated by recruiting additional participants, that is extra 10% of the sample size, and also by assessing confounding during analysis.

The participants were called to remind them of their clinic visits to minimize loss to follow up.

CHAPTER FIVE

5 CONCLUSION

1. There was no significant difference in surgical site infection rate between dilute povidone-iodine and 0.9% normal saline irrigation in primary arthroplasty at Muhimbili Orthopedic Institute.
2. There was less blood loss among participants who were irrigated with dilute povidone-iodine than with 0.9% normal saline in primary arthroplasty at Muhimbili Orthopedic Institute.

5.1 RECOMMENDATION

A study with a higher sample size and longer duration of time should be conducted to determine efficacy of irrigation fluids in primary arthroplasty involving various arthroplasty centers in Tanzania to increase generalisation of results.

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APPENDICES

APPENDIX I: Consent form (English)

Part A:

Introduction

My name is **Dr. Mark Emmanuel Ogundo**, MMed. Student at MUHAS, department of Orthopaedic and Traumatology. I am conducting a study on **efficacy of povidone versus normal saline irrigation in primary arthroplasty surgery at MOI**. You are kindly invited to take part in this study, read this form and understand it well before agreeing to the study

Purpose of the study

The purpose is to obtain data on blood loss and infection development after arthroplasty surgery which can then lead to management and protocol change in the hospital in particular and nation at large. It is also for a partial fulfillment of my MMed degree in Orthopaedic and Traumatology.

Study procedures

The main information required from you is your social demographics and brief medical history which will be recorded in data collection sheets. Hemoglobin level will be recorded during admission and another for comparison within 3 days after surgery. Other laboratory tests like Full Hemogram, C - reactive protein, Erythrocyte Sedimentation Rate and Pus or blood culture will be done only if you develop signs and symptoms of infection after surgery

Risks and benefits to the participant

No risks are directly expected from the study because there can be many benefits including early recognition and diagnosis of surgical site infection which can then be managed according to the protocol.

Confidentiality

The data collection sheet is strictly confidential. Your name will not appear in it.

Participant information

Your participation in this study is voluntary and failure to participate or withdrawal from the study will not affect your management in any way at any stage.

Contacts and Questions

Dr. Mark Emmanuel Ogundo
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markog411@gmail.com

Chairperson,
Institutional Review Board (Muhas)
+255222152489

Part B

Participant consent form

I have understood the above information which has been fully explained to me by the investigator and I voluntarily consent to participate.

Signature.....

Or participants thumb print.

Date.....

Witness signature.....

APPENDIX II: Consent form (Kiswahili version)**Ridhaa ya kushiriki kwenye utafiti:****Sehemu A:****Utambulisho**

Mimi ni **Dr. Mark Emmanuel Ogundo**, mwanafunzi wa Chuo kikuu cha Afya cha Muhimbili (MUHAS), Idara ya Mifupa na Ajali. Nachukua shahada ya uzamili ya Tiba (MMed). Ninafanya utafiti juu wa kulinganisha chanzo cha kupata madhara baada ya matumizi ya povidone kulinganishwa na normal saline katika operesheni kubwa ya kubadilisha viungo.

Hivyo unakaribishwa ushiriki kwenye utafiti huu. Tafadhali soma dodoso hili vizuri na kuelewa kabla hujashiriki.

Shabaha ya Utafiti

Shabaha ya utafiti huu ni kukusanya taarifa muhimu ili kujua chanzo cha kupata madhara baaada ya operesheni kubwa ya kubadili viungo. Matokeo ya utafiti huu yanaweza kusaidia mabadiliko ya sera kwa hospitali na nchi nzima katika utoaji wa matibabu. Aidha, taarifa hizi zitamsadia mtafiti kuhitimu shahada yake ya uzamivu ya tiba katika upasuaji wa mifupa.

Taratibu za Utafiti

Taarifa muhimu zinazohitajika zitaingizwa kwenye dodoso maalum ya kukusanyia taarifa. Aidha, taarifa kuhusu mgonjwa, madhara ambaye aliopata, pamoja na vipimo kama kuwa utapata madhara.

Athari na Faida za Kushiriki kwenye Utafiti

Hakuna athari zozote zinazotarajiwa kujitokeza kutokana na utafiti huu, bali kuna faida nyingi kwa mgonjwa kama, kutambua madhara mapema ili matibabu kamili kwa mgonjwa yapatikane.

Siri

Taarifa zote zitakazo kusanywa zinatajazwa kwenye fomu maalum na zitakuwa siri. Jina lako au namba yako ya simu zitatumika kwa madhumuni ya matibabu na kufuatilia maendeleo yako.

Taarifa za Mshiriki

Ushiriki wako kwenye utafiti huu ni wa hiari, unaweza kushiriki au kutoshiriki. Aidha, unaweza kujiondoa kushiriki na hautaathiri matibabu yako.

Kwa maswali

Jina la mtafiti: Dr. Mark Emmanuel Ogundo

Namba ya simu: +255766159074

Barua pepe: markog411@gmail.com

Mwenyekiti

Bodi ya Utafiti

+25522152489

Sehemu B

Kiapo cha ridhaa ya Kushiriki

Nimesoma na kuelewa taarifa zilizotolewa hapo juu kama zilivyo fafanuliwa na mtafiti, na kwa ridhaa yangu mwenyewe nimeamua kushiriki.

Sahihi.....

Au alama ya dole gumba

Tarehe.....

Sahihi ya Shahidi.....

APPENDIX III: Questionnaire of Efficacy of dilute povidone-iodine vs 0.9% normal saline irrigation in primary arthroplasty at MOI

Patient identification.....

Instruction (Tick where appropriate)

1. Age

- a. 20
- b. 21-30
- c. 31-40
- d. 41-50
- e. 51-60
- f. 61-70
- g. 71-80
- h. Above 80

2. Sex

- a. Male
- b. Female

3. Preoperative Hemoglobin

- Below 10
- 10 -12
- 12 – 15
- Above 15

4. Surgery

- a. Joint replaced
 - Total Hip Replacement
 - Total Knee Replacement
- b. Type of anesthesia
 - General anesthesia
 - Spinal anesthesia
 - Nerve block

c. Positioning of patient

Supine Lateral Prone

d. Surgical Approach

Anterior (Smith and Peterson) Antero-lateral (Watson Jones) Lateral (Hardinge) Posterior (Moore and Southern) Medial Parapatellar

e. Duration of surgery

Below 1 hour 1-2 hours 2-3 hours Over 3 hours

5. Irrigation Fluid

Dilute Povidone-Iodine 0.9% Normal Saline

6. Intra operative blood loss amount (mls) as reported by anesthetists and nurses

0-500mls 501-1000 mls 1001-2000 mls Over 2000 mls

7. Post-operative Hemoglobin

Below 10 10 -12 12 -15 Above 15

8. Surgical site Infection using suggestive criteria

Pain

Yes No

Swelling

Yes No

Warmth

Yes No

Redness

Yes No

Temperature (Celsius)

Below 36.5 36.5 - 37.5 Above 37.5

New onset joint effusion

Yes No

Elevated Inflammatory markers

i) C Reactive Protein.....

Yes No

ii) Erythrocyte Sedimentation Rate.....

Yes No

iii) FBP: WBC.....

Yes No

9. SSI using confirmatory criteria

i) Fistula

Yes No

ii) Sinus

Yes No

iii) Wound breakage

Yes No

iv) Pus discharge from wound

Yes No

v) Culture

Positive Negative