ETIOLOGY, COMMON PRACTICES AND EARLY COMPLICATIONS OF PRIMARY TOTAL HIP ARTHROPLASTY IN KENYA

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REG NUMBER: H58/75791/2014

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A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF MEDICINE IN ORTHOPEDIC SURGERY

APRIL, 2020

DECLARATION

I hereby declare that this thesis is my original work.

I also declare that it was developed with the guidance of my supervisors.

It has not been submitted to any other university for any purpose.

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This is to certify that this thesis is the original work of the author. This research was a multi-center study carried out in Kenyatta national hospital, Kikuyu mission Hospital, Kijabe mission Hospital, Coast general Hospital and Meru teaching and referral Hospital.

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ACKNOWLEDGEMENT

I convey my sincere and heartfelt gratitude to the Almighty God for the far I have come.

Special thanks to my supervisors Dr. J.K King'ori, Dr. T.S Mogire and Dr. E. Gakuya for all their support, guidance, and mentorship from the conception to development of this study.

I am also very thankful to the University of Nairobi and Kenyatta National Hospital for providing us with an enabling learning environment. I am especially thankful to all the consultants and lecturers in the Department of Orthopedic Surgery both at University of Nairobi and KNH for sharing their knowledge and experience with us during the Master of Medicine Program.

I want to extend my profound appreciation to all the facilities I collected data from.

Lastly but not least vote of thanks to all my colleagues and friends for their great support, co-operation and teamwork. Be blessed always.

DEDICATION

To my dearest wife Dr.Mariam Umar for her love, companionship, support and encouragement throughout the program and life.

To my beloved children-Zuhura Mwende and Marjan Mwendwa- my greatest inspiration and strength to carry on with life. May God bless you, you mean everything to me.

To my beloved parents, my late father, Mr. Abdullahi and my mother Mrs. Zuhura for their sacrifices to support me through my journey of life and their words of wisdom has always been a pillar of strength in my life.

LIST OF ABBREVIATIONS

AVN	–	Avascular Necrosis
DDH	–	Developmental Dysplasia of the Hip
PTHA	–	Primary Total Hip Arthroplasty
ORIF	–	Open Reduction and Internal Fixation
ROM	–	Range of Motion
RA	–	Rheumatoid Arthritis
THA	–	Total Hip Arthroplasty
JRF	–	Joint Reaction Force
MOM	–	Metal on Metal
MOP	–	Metal on Polyethylene
COM	–	Ceramic on Metal
COC	–	Ceramic on Ceramic
COP	–	Ceramic on Polyethylene
KNH	–	Kenyatta National Hospital
AIC	–	Africa inland Church
LCPD	–	Leg-Calve-Perthes Disease
OA	–	Osteoarthritis
TB	–	Tuberculosis
HIV	–	Human Immunodeficiency Virus
AIDS	–	Acquired Immunodeficiency Syndrome

OPERATIONAL DEFINITIONS

Etiology: the cause of a disease or medical condition

Early complications: complications arising either intraoperatively or just post- operative up to patient discharge

Lateral (Hardinge) approach: inter muscular plane between gluteus medius and vastus lateralis muscles.

Anterolateral (Watson-Jones) approach: inter muscular plane is between tensor fasciae latae and gluteus medius.

Leg length discrepancy: condition where the paired lower extremity limbs have a noticeably unequal length.

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ABSTRACT

Background: PTHA has transformed from its original invention to the current state. Etiologies leading to PTHA have shifted from the original primary osteoarthritis to include other etiologies due to improvement in implant designs and surgical techniques. In Kenya, the trends have shifted too, particularly, in keeping with the modern world despite various challenges. This study sought to find out the current state in respect to etiology, how the procedure is currently undertaken, and associated early complications. Similarly, the approaches, cementing techniques and type of antibiotic prophylaxis used by various surgeons in Kenya.

Study objective: To establish the etiology, current common practices and early complications of doing PTHA in Kenya.

Study design: Cross-sectional descriptive study.

Study setting: A Multi-center study was conducted in various orthopedic wards and hospitals in Kenya (Kenyatta National Hospital, AIC Kijabe mission Hospital, Kikuyu mission Hospital, Coast General Hospital and Meru County Teaching and Referral Hospital).

Study population: All age groups of patients consenting for the study and admitted for Primary total hip arthroplasty at the study centers during the study period (November 2019 - March 2020).

Methodology: Quantitative primary data was collected based on institution workload and recorded in data collection sheets.

Data analysis: Statistical analysis was performed with commercial software (SPSS 23).Descriptive analysis was done to determine the frequencies and proportions of the variables and presented accordingly. Univariate analysis was conducted to determine any associations.

Utility: The data and information acquired from this study have provided information on current state of PTHA and will act as a comparison in PTHA practices with the rest of the world.

Results: A total of 84 patients were recruited in the study from the five centers between November 2019 and March 2020,the mean age was 59 years(15-90 years).Majority were females(63.1%).The

commonest hip involved was the right(50%).Most of the patients (47.6%) etiology was primary OA. Cementless was the most common implant used (51.2%).Spinal block (78.6%) was the commonest anesthesia used. Ceftriaxone (70.2%) was the commonest antibiotics preferred at induction of anesthesia and as a continuation antibiotic. The commonest (66.7%) approach was lateral. Non-vacuum mixing was the preferred (82.9%) technique with most of the surgeons using bone block (70.7%) during plugging. Leg length discrepancy (15.5%) were the commonest early complication after PTHA procedure with 94.0% of the patients having no complications.

Discussion: The study established that, a relatively younger subject as compared to the western world undergo PTHA but comparable to Asiatic countries despite being higher than other African countries. The female gender was more prone to OA which is the commonest etiology found. This may be attributed to an increase in life expectancy in the last few decades in Kenya. Relatively, younger subjects undergoing PTHA may have been the reason why cementless implants preference was established in this study. The use of spinal block anesthesia found to be more common in this study is probably due to preference. The same finding globally of ceftriaxone as the preferred induction antibiotic was also noted in this study. The approach commonest used in our setup was lateral, probably due to surgeon's training. The study finding of non-vacuum cement mixing, cement delivery by finger packing and plugging by bone plug as the preferred technique shows that we are almost catching up with the developed world.

Conclusion: The etiologies leading to PTHA varies slightly in terms of frequency in comparison to the western world and Asiatic countries but similar to the rest of Africa. We somehow have managed to keep up with the developed world in terms of employing some of the latest techniques in various centers.

Recommendations: Formation of a national hip registry will come in handy in keeping our records and also for quick retrieval of the same. Formulation of national guidelines on PTHA may also provide a national guideline on PTHA practices.

CHAPTER 1: INTRODUCTION

The earliest recorded attempts on Primary total hip arthroplasty (PTHA) were in Germany by Professor Themistocles Gluck in 1891 using ivory to replace femoral head. Later, interposition of various tissues between the articulating hip surface of the arthritic hip like fascia lata, pig skin, sub mucosa etc. were experimented by various surgeons in the 19th and 20th century (1, 2). The first mould arthroplasty was created in 1925 by an American surgeon Marius Smith Peterson using glass. Although, failure of glass to withstand great forces submitted through the hip, inspired Marius to partner with Philip Wiles to start trials on stainless steel which led to the creation of the first total hip replacement that was fixed to the bone with bolts and screws (3).

Sir John Charnley is considered the father of modern hip arthroplasty after his low friction arthroplasty prosthesis design in 1960's, which is still the same in principle to the prosthesis used today (1–3). Charnley also introduced bone cement which has increased long term implant survivorship. He also managed to reduce the diameter of the head to 22mm improving frictional torque. Initially, the head used to be the exact size as the true anatomical femoral head. He adopted the use of high molecular polyethylene which showed good clinical performance (4).

The modern hip arthroplasty has been modified overtime on various areas;

- Biomaterials used for the bearing surface with Ceramic bearings gaining popularity (5, 6).
- Fixation techniques with non-cemented fixation tendency worldwide especially for the young patients (7).
- Femoral stem design especially, cementless stems modified to include surface, coating, and designs like single wedge, double wedge, tapered, cylindrical, modular, and anatomical stems (8).
- Acetabular cups improvements with the third generation cups being widely used nowadays (8).

PTHA was among the most commonly performed orthopedic procedures in 2014, an average of 370770 PTHA were performed in America and is expected to rise by 171% by 2030 (9).These has been attributed to advancement in implant designs and research on surgical techniques, pre-

operative and post- operative management. The average age of uptake has thus decreased hence appearance of a wider application of the procedure in pathologies affecting the hip. Total hip arthroplasty has been named as “The operation of the century” (10).

Worldwide, 1-3% of the population will undergo THA at some point. The mean age of the patients undergoing THA, is 65.4 years especially in the western population and more in women than men (11,12).

There has been a lot of improvement in surgical techniques, cementing techniques, prophylactic anti-biotherapy and anti-thrombolytic use. The operative technique has remained more or less the same with very minimum modifications. Collectively, this has improved outcomes and reduced complications. Reduction of complications has made it possible to widen the etiological indications for primary total hip arthroplasty as opposed to the original osteoarthritis. Younger subjects with a wide range of etiologies e.g. DDH are nowadays treated with PTHA (13, 14, 22, 23, 26,).

CHAPTER 2: LITERATURE REVIEW

2.1 Literature Review

2.1.1 Etiology of PTHA

PTHA was originally designed and intended for use on the elderly (65years and above) with primary hip osteoarthritis for pain relief and improvement of joint function. Better understanding of the biomechanics of the hip and behavior of biomaterials led to improvement of prosthesis designs. This increased longevity of the prosthesis hence the average age of those receiving hip replacement reduced. Reduction in average age led to a change in etiologies treated with primary total hip arthroplasty (13,14).

The etiology in patients undergoing primary total hip replacement in the young includes a wider range of pathologies not necessarily primary osteoarthritis. There have been variations in different populations and geographies. These includes; avascular necrosis (AVN) to the head of femur, secondary to fracture of the femoral head or coagulopathies. Congenital deformities like congenital hip dislocations and developmental dysplasia of the hip (DDH). Others include hardware failure post-ORIF, post traumatic arthritis, post infection arthritis and rheumatoid arthritis (RA) (13, 14).

In different studies on etiologies of PTHA, primary osteoarthritis has been found to be the leading cause of up to 70-90% of cases especially in the western population. However, the predominant etiology of PTHA varies slightly in other populations and geographies (15–18).

Jimenez Garcia, et al, in Spain showed that between 2001-2008 in 161,791 patients where PTHA was done ; mean age was 65-74 years with a slight predominance in females above 65 year (55%), primary OA was the leading etiology at 75% (19).Havelin et al, demonstrated that primary OA to be the leading etiology of PTHA in Sweden at 78%, 74%in Norway and 77% in Denmark with female predominance at 60%, 70% and 58% respectively (20)

In a Brazilian cross-sectional retrospective study by Mario Lenza et al in 2013 on patients undergoing PTHA, they demonstrated that out of 344 patients in which 176 were female, mean

age was 71 years (31-99 years) ,47.5% had primary OA, 38.5% had fractures,8% had osteonecrosis, 6.5% had RA and 7% had other etiologies (21).

Liu Ye et al, in a retrospective study conducted in Singapore between 2003 and 2005 on 115 patients who underwent PTHA, he found out that the male to female ratio was 1:2, the mean age was 55 years(ranging between 23-80years),the predominant etiology was; inflammatory arthritis (32.2%), primary osteoarthritis (28.7%), avascular necrosis (22.6%), hip dysplasia (9.6%) and post traumatic osteoarthritis (6.9%) (22).

Woo-Yong et al, in another retrospective study done in a Korean population between 2000 and 2014 on 818 participants in which 477 were male and 341 female, showed that 44% had AVN, 10% had post-traumatic arthritis, 8.6% had LCPD, 6.3% had femoral-acetabular impingement (FAI) & DDH, 5.1% had RA, 4.7% had fractures & post-infectious arthritis, 3.9% had primary OA, 2.3% had other etiologies and 2.3% had ankylosing spondylitis (23).

Yoon et al, also in a retrospective study done in 2007-2011 in a Korean population reviewing among others the etiology of PTHA, he demonstrated that in 40760 hip arthroplasties done, majority were females (55.8%). The leading etiology was osteonecrosis of the femoral head at 59% followed by primary OA at 28% (24).

Xian gang et al, in a retrospective study in Hong Kong conducted in 1998-2010 showed that of the 512 PTHA done, mean age was 57.6 and the main etiology in males was osteonecrosis (50.9%), AS (19.5%) and post traumatic arthritis (18.5%) while in females osteonecrosis (33.0%) was also the leading etiology with primary OA (18.8%) and post traumatic arthritis (15.5%) being among the other important etiologies (25).

In the Middle East, a retrospective study conducted in Saudi Arabia in data review of 107 patients who underwent PTHA in 2001-2015 at tertiary hospital in Jeddah. Hamdi et al showed that percentage of females was 50.5% and the leading etiology was primary OA (49.9%) followed by osteonecrosis (25.2%).Post traumatic arthritis (22.4%), DDH (5.6%), AS (1.9%) and post infection arthritis (0.9%). The average age was 52 years (26).

In African studies, the commonest etiology seems to be primary OA even though in most countries the percentage figures are not as high as in the western populations; a study in a West African country (Burkina Faso) showed that AVN was the main etiology of PTHA. In Zambia, Mulla et al, a retrospective study conducted on records of evaluation of 44 patients who had PTHA done in 1998-2010 showed that majority of patients were females (59%) with primary OA as the main etiology at 70.6%. Avascular necrosis was at 13.7% and post traumatic arthritis trailing third at 11%. The average age was 58 years (23-82 years) (27).

Dossche et al, in Burkina Faso, in a study done in 2004-2011 on 155 patients, he demonstrated that the majority were males (55.5%) and a mean age was 49 years (21-78 years). Avascular necrosis was the leading etiology at 38.7%, primary osteoarthritis was at 36.7% and 24.5% had a diagnosis of fracture the neck of femur (28).

In another descriptive retrospective study conducted in Botswana between 2009-2010 on 41 PTHA done Lisenda et al showed that the leading etiology to be primary OA (76%) followed by AVN(22%) (29).

In a descriptive retrospective study by Bio Tamal Sambo et al in 2010-2015 in Benin on 245 subjects (53% males and 47%, with a mean age 41±13.7years), he noted that primary osteoarthritis (48.4%), osteonecrosis of femoral head due to sickle cell disease (31.3%) and post-traumatic arthritis (7.3%), neglected hip dislocation (6.5%), pseudo-arthrosis of the femoral neck (4.6%), fracture of the femoral neck (1.1%), sequel of first time treatment of femoral fracture (0.7%) as the leading etiologies leading to PTHA (30).

In a study in Kenya, Mulimba et al, illustrated that up to 25 patients between 1999-2000 , male to females ratio of 1:1 were done PTHA for osteonecrosis of the femoral head due to sickle cell disease, the age distribution ranged from as young as 16 years to 42 years with a peak at 16-20 years (31).

From the data available on the etiologies leading to PTHA, it appears that osteoarthritis is not necessarily the primary indication for PTHA in all geographical set up and populations. PTHA in younger subjects seems to be increasing with the predominant etiological pattern shifting from

primary OA. Seemingly, males seem to be predominating in other etiological patterns different from primary OA (22, 25, 30).

There also seems to be change in predominance of primary osteoarthritis as the leading cause of PTHA with geographical location and population setup of subject changes. The west and the European populations seems to have primary osteoarthritis as the main etiology leading to PTHA but as we shift to the Asian population avascular necrosis is gradually taking the lead (9, 16, 20).

Data from African set up is conflicting. The available documented studies in different geographies in the African continent show either primary osteoarthritis or avascular necrosis as the leading etiology in PTHA or either way, figures locking horns (28, 30, 32).

2.1.2 Prosthesis Materials

The current hip arthroplasty prosthesis used nowadays is made up of stainless steel, titanium, chromium nickel, cobalt or a combination of these metals. The bearing may be either Metal on Metal (MOM), Metal on Polyethylene (MOP), Ceramic on Metal (COM), Ceramic on Ceramic (COC) or Ceramic on Polyethylene (COP) (4,33).The designs varies widely and use of one design in respect to the other design depends mostly on the state of the femoral bone and the acetabulum and cost.

The hip prosthesis consists of an acetabular cup, femoral head of various sizes (ranging from 22 mm-36 mm as the most prevalent) and femoral stem (33).The use of any of the prosthesis type depends on availability, affordability and the type of pathology in the hip to be replaced. We currently lack documented data in Kenya on implant type used.

2.1.3 Surgical Procedure

1) Pre-operative planning-involves using AP and lateral plain x-ray views in comparison to the normal hip to approximate cup size and position, patient positioning (usually on lateral side) and anaesthetizing the patient with either spinal, epidural or general anesthesia (34).

2) Choosing the desired and appropriate surgical approach either posterior, direct lateral, anterolateral or anterior approach then superficial and deep dissections to expose the hip (34–36).
3) Preparation of acetabulum i.e. exposure after dislocation of the hip and reaming.
4) Acetabula cup trialing and positioning.
5) Implanting of definitive cup, assessing cup orientation and stability and removing the cup.
6) Preparing femur.
7) Trial reduction.
8) Repositioning the acetabular cup.
9) Implanting the definitive femoral stem.
10) Attaching the definitive femoral head.
11) Final hip reduction, assessing the ROM, stability and leg length.
12) Closure of incision.

2.1.4 Anesthesia

In a publication by Mathias in 2014, the type of anesthesia used was shown to have a very significant effect on intra-operative and immediate post-operative complications. Spinal or epidural was shown to have better outcome in terms of in-hospital mortality, thromboembolic events, blood loss and transfusion requirements (37).

In another study in Korea by Chan in 2010, general anesthesia was found to be 2.21 times more associated with intraoperative complications than spinal or epidural anesthesia (38).

Liang et al, in a study in china in 2014 managed to show that general anesthesia use for PTHA is associated with higher complication rates in terms of intraoperative blood loss, poor pain management control, and post-operative infection as compared to patients who receive either caudal epidural anesthesia or spinal anesthesia (39). In Britain a year later, Soffin et al showed the same observation using enhanced recovery after surgery(ERAS) protocols (40).

It is not well documented on the common anesthesia type used in Kenya and the complications arising from their use.

2.1.5 Complications

The rates of common intra operative and immediate post- operative complications have significantly reduced due to the advancement of knowledge and amelioration of operative know how by research. Sung et al in 2014, reviewed over 30 years cases of intraoperative and immediate post-operative complications of PTHA noting that in-hospital mortality rate after PTHA was at 0.16-0.52%. He also noted a higher mortality rate in the US for patients with cardiovascular diseases aged 70 years and above (up to 1%). Pulmonary embolism was the second leading complication. Use of intermittent pneumatic compression devices, ankle exercises pre- and post-operative anti-thromboembolism agents has been very effective in reducing this risk. Hematoma formation due to blood vessel injuries was found to be the third leading complication. Fracture, leg length discrepancies and nerve injury were the other intra operative complications (37, 41–43).

In a 2017, study in the US, Healy et al showed that bleeding, wound complication, thromboembolic disease, neural deficit, vascular injury and dislocation/instability as possible intraoperative complications of PTHA (44).Abbas et al in Karachi on 199 patients who underwent PTHA in Aga Khan university hospital between 2000-2010, showed that complications occurred in 39 patients (19.6%). Dislocation was the most common at 6.5%, followed by wound infection at 2.5%, urinary tract infection at 2.5%, pleural effusion and pneumonia at 2%, deep venous thrombosis at 0.5% and myocardial infarction at 0.5%.This clearly shows that the complications spectrum is wide (45).The situation in Kenya is currently unknown.

2.1.6 Surgical Approaches to the Hip

Approaches to the hip for PTHA include direct anterior, lateral, posterior or anterolateral (46). Excellent results are achievable despite the approach chosen. In context of the debate on which approach is superior to the other, no enough evidence has shown superiority in one approach over the other. In a 2017 study in the US, Moretti et al analyzed different approaches in terms of preference by various surgeons, complications including stability, infection, Harris hip score, intra-operative fractures, neurovascular injury etc. and concluded that no approach is superior to the other (47).

The best guide in terms of approach choice should be guided by surgeons comfort and familiarity with the approach (46). In a recent study in the US in 2018, Marc et al showed that the choice of approach for PTHA should be determined by the surgeon's familiarity with the approach. Nevertheless, some approaches may be more prone to certain complications as compared to others, for example; nerve injury is more associated with posterior approach as compared to other approaches while abductor insufficiency is more associated with direct lateral approach. The learning curve in direct anterior approach is about 50-100 procedures. Rate of infection and hip instability have not being found to be more in any of the chosen approach compared with the others (48).

Posterior approach has been shown to be the commonest preferred choice worldwide (35,48).In 2019 in US, Abdel et al showed that the most common approach to be posterior approach at 47% followed by direct anterior approach at 40% while two incision approach was at 1% (49).

Surgical procedures have not changed in terms of approaches but various modifications have been incorporated in the existing old techniques namely posterior, lateral and anterolateral. Anterior approach and minimum two incision lateral approaches is being practiced in some western countries even though not widely used worldwide (36).In our country the preferred approach by various surgeons is not documented.

2.1.7 Implants

Implants used can be either cemented, cementless or hybrid. Of late, cementless prosthesis use has been on the increase (50). Kigera et al, in a retrospective study on subjects done PTHA done in Kikuyu mission hospital in 1998-2012 that 96.4 % of implant used was cemented impregnated with antibiotic (51).In Britain in 2017, Kumar et al, showed that increase in younger subject (54 years and below) has made cementless implants more preferred (52).In 2018, in the US, Abdel showed use of up to 56% of cementless stems (47).The general common implant use in Kenya is not documented.

2.1.8 Cementing

Cementing techniques have nowadays shifted from first generation to third generation. Currently, techniques for centralization of the femoral stem have been developed and are being

termed as the '*fourth generation cementing techniques'* (53). Nedungayil et al, conducted a study in 2006 in Britain on cementing techniques noting that, majority of the surgeons have adopted third generation cementing techniques in hip arthroplasty. Nevertheless, he noted that still a significant number of surgeons still used first generation techniques. They demonstrated that 82% of cement used contained antibiotics. The method of mixing was in vacuum at 94%, in cement gun 56% or in bowl 38% or mixing by hand at 5%) (54).

Femoral canal was plugged before cement delivery by proprietary restrictors at 80%, bone block 17%, cement plug 2% or other methods at 1%. Before delivery of cement to the femoral canal, the canal was prepared by pulsed lavage or brushes. Delivery of the cement was done through cement gun at 95% and finger packing at 5%. Before stem insertion, cement was pressurized with a finger at 33%, proprietary pressurizers 30% or both at 36% (55).The practice in Kenya is currently unknown.

2.1.9 Prophylactic Anti-biotherapy

Antibiotic use has been shown to reduce infection rate in PTHA in up to 1-2%. In Netherlands Veltman et al, in a 2018 study showed that despite the timing, duration and type of antibiotic used still being debatable, cefazolin or cefuroxime stat dose and continuation for 24 hours to be adequate for infection prevention. Use of prophylactic antibiotics and antibiotic impregnated cement has been shown to be more effective than use of antibiotics prophylaxis alone (56).

2.1.10 The Future of PTHA

The advancement of technology has led to development of minimally invasive PTHA using computer navigation in implant positioning that has a very good clinical outcome. Robotic assisted PTHA trials are still going on and positive outcomes are expected (4).

2.1.11 Conclusion of Literature Review

There seems to be discrepancies in data on primary total hip arthroplasty depending on the geographical region of the world. In our setting, there lacks a comprehensive study showing the etiology, surgical practice, early complication of PTHA. The findings of this study may be helpful in giving some useful insights on the current practices of PTHA in Kenya.

2.2 Study Justification

PTHA is currently being practiced in many medical centers in Kenya. The numbers are expected to increase with time. There's lack of local current documented data on etiology, the common practice, early complications of PHTA, therefore there is need to conduct this study to provide current information on the same in an attempt to harmonize the practice.

2.3 Study Question

What is the etiology, common practices and early complications of PTHA in Kenya?

2.4 Objectives

2.4.1 Broad Objective

To determine the etiology, common practices and early complications of primary total hip arthroplasty in Kenya.

2.4.2 Specific Objectives

a) To describe the etiologies of PTHA in Kenya.

b) To describe intra-operative events during PTHA procedure (i.e. anaesthesia used, approaches preferred, type of cement used, types of implant used, cementing techniques, antibiotic prophylaxis used, intraoperative complications).

c) To describe immediate post-operative complications after PTHA procedure.

CHAPTER 3: METHODOLOGY

3.1 Study Design

This was a descriptive cross-sectional study.

3.2 Study Setting

This was a multi-center study conducted in KNH, Coast General Hospital, Meru County Referral Hospital, Kikuyu and Kijabe Mission hospital's orthopedic wards.

Kenyatta National Hospital, Kikuyu Mission Hospital ,Kijabe mission Hospital, Coast general Hospital and Meru county referral hospital receive the bulk of patients presenting for PTHA thus it was ideal as the study setting. The centers distribution can be used to represent the whole of Kenya as a country.

a) Kikuyu Mission Hospital's Orthopaedic and Rehabilitation Centre has a bed capacity of 37 beds. It's located in Kikuyu town, 20km from Nairobi City Centre. It acts as a referral hospital for most orthopedic procedures including hip arthroplasties with a wide catchment area of central Kenya.

b) Kenyatta National Hospital's orthopedic wards. It's a tertiary teaching and referral hospital located at Upper hill 5km from CBD with a bed capacity of 2500 beds. It's one of the two referral hospital in Kenya that serves the greater East and Central Africa regions.

c) Kijabe Mission Hospital is a mission hospital in Kenya with a bed capacity of 350. The hospital is located 60km north of Nairobi and 6km away from Nairobi-Nakuru highway.

d) Coast general Hospital is a public main referral Hospital in the coastal region located in Mombasa, Kenya's second largest city

e) Meru County referral Hospital located in Meru county covers mainly the upper eastern and north eastern regions of Kenya.

3.3 Study Duration

From 15th November 2019 to March 2020

3.4 Study Population

Patients admitted for PTHA in orthopedic wards at Kikuyu Mission Hospital, Kijabe mission hospital, KNH, Meru, and Coast general hospital

Inclusion criteria	**Exclusion criteria**
1. Patients admitted for PTHA 2. Consenting patients	1. Non-consenting patients

3.5 Sampling

All eligible patients meeting the inclusion criteria and consenting were enrolled until the desired sample size was achieved.

3.6 Sample Size

The following formula was used to calculate the required sample size for the study:

$$\mathrm{N} = \frac{Za/2^2\{P(1-P)\}}{d^2}$$

Where:

Zα/2 was critical value for 95% confidence interval that is 1.96

P was estimated prevalence of the disease. (The prevalence of discernible hip pathology in patients who underwent spinal surgery was 32.5%.Lee et al., 2012). (57)

d was margin of error = 10%

$$\mathrm{N} = \frac{1.96^2\{0.325(1-0.325)\}}{0.1^2}$$

Substituting the above in the formula we got N = 84 patients

3.7 Patient Recruitment

Approval to conduct the study was sought from UON-KNH ERC. Once study approval and an official letter was granted by the UON-KNH ERC, permission to conduct the study in Kikuyu , Kijabe Hospital, Coast general and Meru referral hospital management was sought. Upon approval, patients meeting the inclusion criteria and consenting to an informed consent were enrolled till desired sample size was achieved.

3.8 Data Collection

In patients who have enrolled and consented, a pre-tested data collection sheet was used to record the bio-data of the patients with special consideration to age, gender and etiology History of the presenting illness was interrogated, targeting previous history of trauma, hip joint infection, previous ORIF to the hip and congenital hip diseases. Intra-operative practices and early complications.

Data was collected by the principal investigator, qualified orthopedic surgeons conducting the procedure and orthopedics registrars in the various centers of studies via patient interviews on their bio-data, past and present history to aid in getting the diagnosis. Plain hip x-rays were reviewed and diagnosis was confirmed by an independent qualified orthopedic surgeon and a radiologist.

Procedure was attended by either the chief investigator or the research assistants as mentioned above in order to obtain information on anesthetic agent used, prophylactic antibiotic given, surgical approach preferred, type of implant and cementing techniques used or any intra-operative complications (intra operative mortality, pulmonary embolism, fractures, leg length discrepancy) noted.

Post-operative follow- up for three days was conducted to record any immediate post-operative complication (hematoma formation, nerve injury, LLD, dislocation etc.). The data was recorded in data collection sheet and verified by the investigator for completion and accuracy.

3.9 Data Variables

a) Bio-data; age, gender, identification number, contacts.

b) Hip involved either right, left or both

c) Past and present medical history;

- Previous trauma to the hip.
- Aseptic arthritis to the hip.
- Congenital hip disease.
- Coagulopathy.
- ORIF to the hip.
- Hip dislocation.

1. Etiology;

    - Primary osteoarthritis.
    - Post –traumatic osteoarthritis.
    - Avascular necrosis.
    - Post-infectious arthritis.
    - Post-failed ORIF.
    - Congenital hip abnormalities (DDH).
    - Fractures including intertrochanteric femur, neck, head and the acetabulum.
    - CLPD (calves leg perthes disease).
    - Rheumatoid arthritis.
    - Others.

2. Implant used;
    - Cemented.
    - Cementless.
    - Hybrid.

3. Anaesthesia used;
    - General.
    - Epidural block.
    - Spinal block.
4. Antibiotic used;
    - At induction of anaesthesia.
    - Continuation antibiotic.
5. Approach used;
    - Lateral.
    - Posterior.
    - Anterior.
    - Anterolateral.
6. Cementing technique;
    a. Mixing;
    i. Vacuum.
    ii. Non vacuum.
    b. Cement delivery;
    Cementing
    Gun, Finger packing.
    c. Plugging (propriety restrictors, bone block, cement plug)

7. Intra-operative complications (intra-operative mortality, fracture, pulmonary embolism, leg length discrepancy).

8. Immediate post-operative complications (wound infection, dislocation, hematoma formation, nerve injury, thromboembolism, in-hospital mortality).

3.10 Data Analysis

All data sheets were inspected by the principal investigator for completion. The results were entered and analyzed via SPSS version 23 with the aid of a qualified statistician.

Data on all variables was summarized as percentages and frequencies and presented in frequency tables, charts and bar graphs.

The data was protected using passwords and backed up using external hard drive like flash discs. At the end of the study, raw data was destroyed via shredding.

3.11 Ethical Considerations

Confidentiality

The principal investigator maintained maximum confidentiality for all information and data presented by participants. All information collected from participants was confidential and treated as such and used only for the purpose of the study. The data collection sheet was void of participant's names to ensure confidentiality. Documents containing participant's information was not photocopied.

Participation in the study was voluntary without compensation of any sort. A participant could withdraw from participation at any time with no consequences. Participation in the study did not jeopardized participant's treatment.

The information on the data collection sheets was stored in locked cabinets and was only accessible to the principal investigator and the statistician.

Ethical approval

The proposal was submitted to UON-KNH Ethics and Research Committee for approval.

Permission to conduct the study in KNH, Kikuyu, Kijabe Mission, Coast general and Meru referral Hospital was sought from the various center's administrators.

Data collection commenced after approval was granted.

3.12 Dissemination of Results

Study findings will be compiled and availed to:

- **a)** Department of Orthopedic Surgery-UON.
- **b)** University of Nairobi, faculty of medicine, College of health sciences.
- **c)** Board of Postgraduate studies UON.
- **d)** KNH.

e) University of Nairobi library.

f) Peer reviewed scientific journals for purposes of publishing.

3.13 Study Limitations

a) Participants not recollecting some past details e.g. past medical history

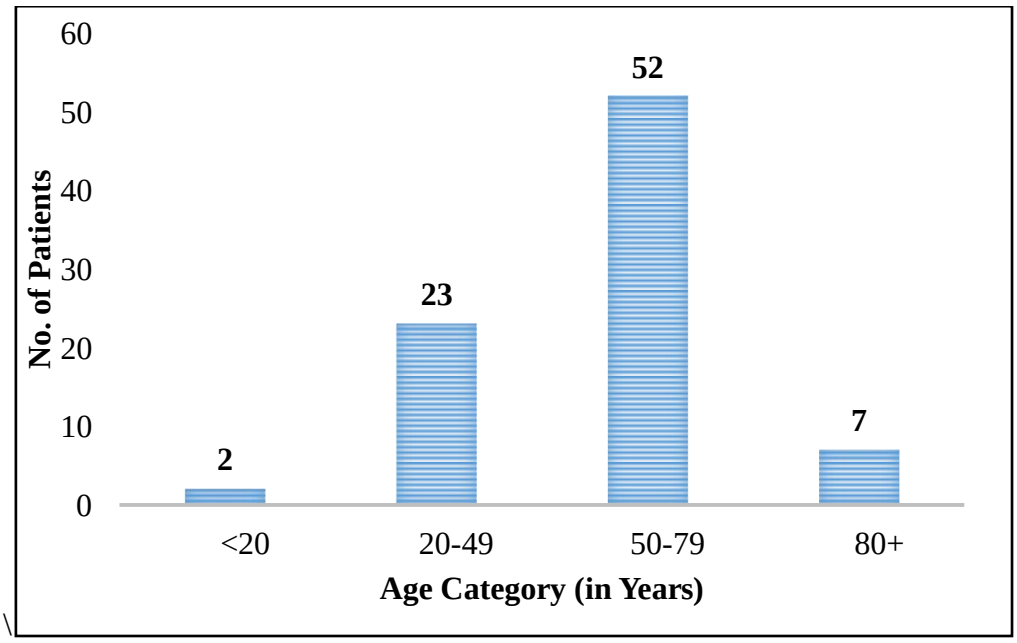
3.14 Delimitation

Correlation of the diagnosis with the clinical presentation, history and imaging.

CHAPTER FOUR: RESULTS

A total of 84 patients that were admitted for PTHA in orthopedic wards at selected health facilities were enrolled in the study. The distribution was as follow, Kikuyu Mission Hospital (23 patients), Kijabe mission hospital (35 patients), KNH (8 patients), Meru (6 patients) and Coast general hospital (12 patients).

Figure 4. 1: *Age classification of patients (n=84 patients)*



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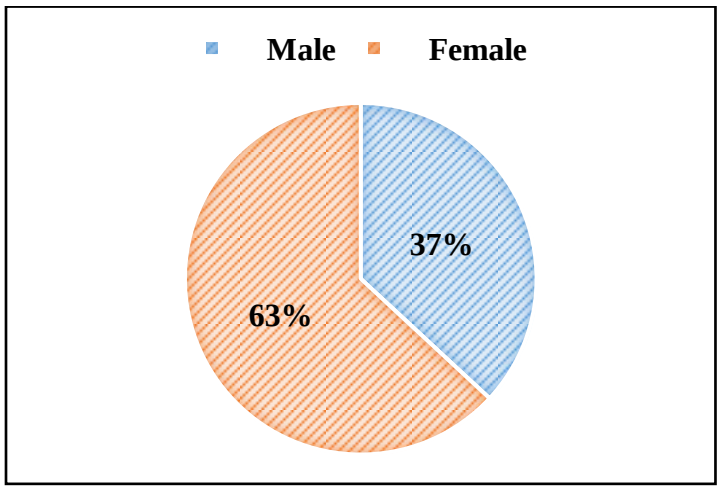
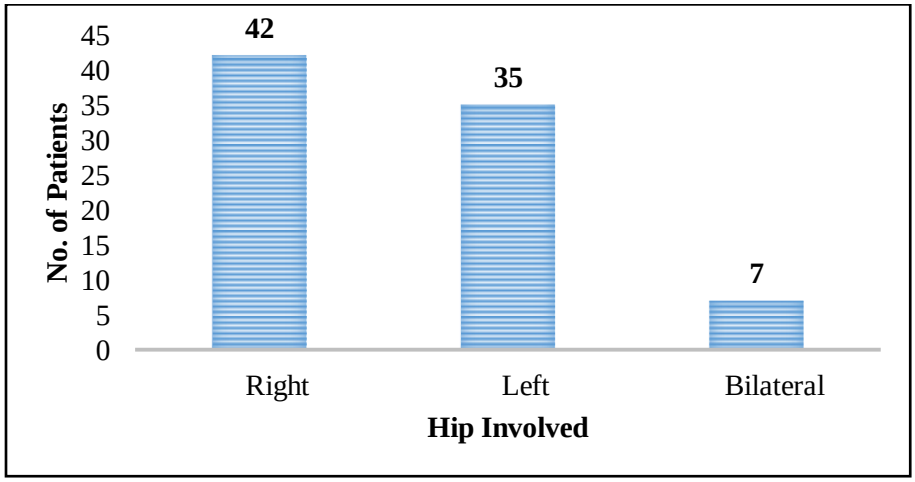
Eighty four patients were identified with majority of them aged between 50-79 years (61.9%), the mean age was 59 years (SD 18.2, range 15–90 years).

Figure 4. 2: *Gender of patients (n=84 patients)*



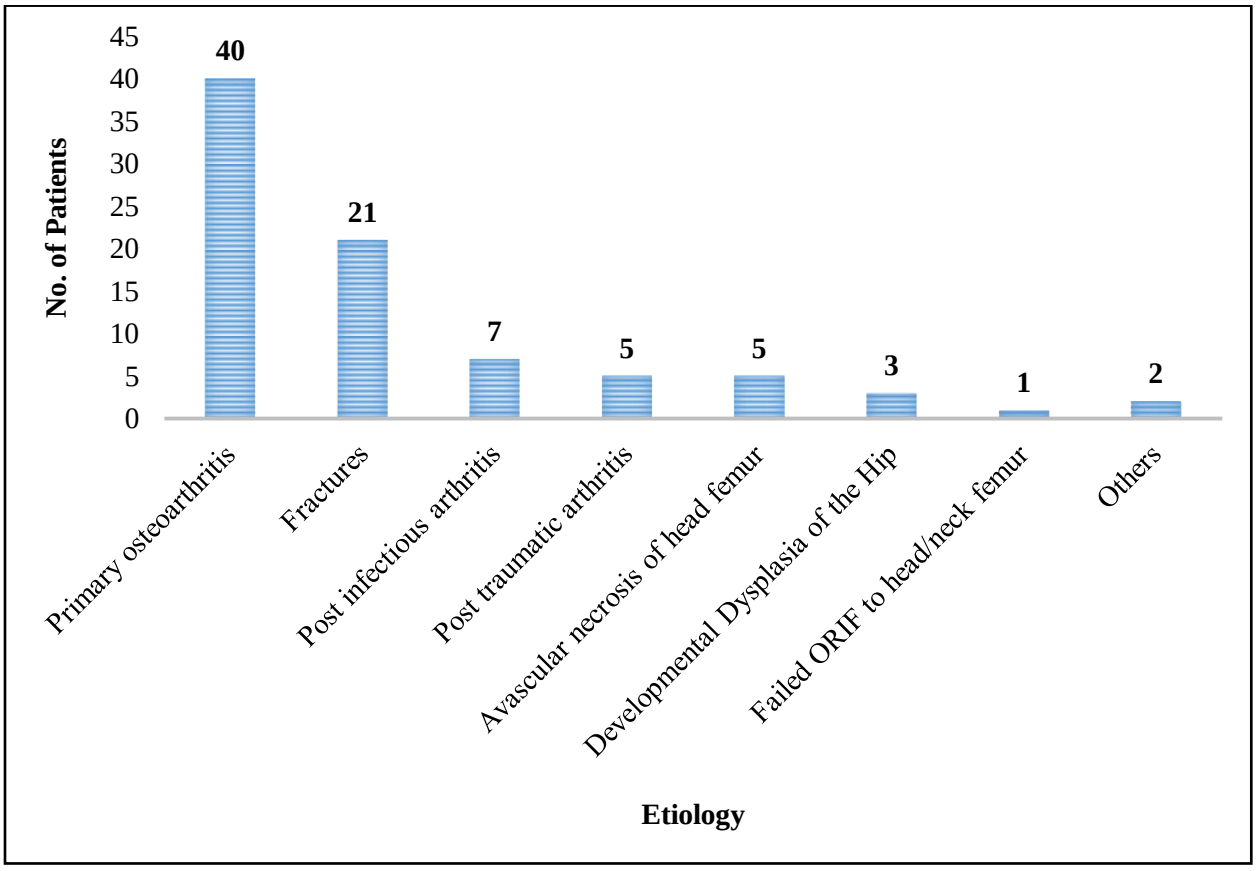
Majority of patients who were recruited in the study were females, 53 (63.1%).

Figure 4. 3: *Hip Involved (n=84 patients)*



The most common hip involved was the right hip, 42 (50.0).

Figure 4. 4: *Etiology (n=84 patients)*



Most of the patients, 40 (47.6%) etiology was primary osteoarthritis with those with fracture being 21 (25.0%). Those patients with fracture, 16 (76.2%) had neck of femur fracture and 5 (23.8%) had intertrochanteric fracture of the femur.

***Table 4. 1**: Association of age and etiology (n=84 patients)*

Etiology	*Age (in Years)*		*P Value*
	<50	*50+*	
	(n = 25 patients)	*(n = 59 patients)*	
Primary osteoarthritis	3 (12.0)	37 (62.7)	0.000
Fractures	7 (28.0)	14 (23.7)	0.438
Post infectious arthritis	2 (8.0)	5 (8.5)	0.656
Post traumatic arthritis	3 (12,0)	2 (3.4)	0.153
Avascular necrosis of head femur	4 (16.0)	1 (1.7)	0.026
Others	6 (24.0)	0 (0.0)	NA

Table 4.1 shows that there was a significant association between patients with primary osteoarthritis and avascular necrosis of the head of the femur with age. Majority of the patients who were 50+ years had primary osteoarthritis compared to patients <50 years. AVN was more on those who were 50 years and below.

***Table 4. 2:** Association of gender and etiology (n=84 patients)*

Etiology	*Gender*		*P Value*
	Male	*Female*	
	(n = 31 patients)	*(n = 53 patients)*	
Primary osteoarthritis	12 (38.7)	28 (52.8)	0.153
Fractures	10 (32.3)	11 (20.8)	0.180
Post infectious arthritis	1 (3.2)	6 (11.3)	0.191
Post traumatic arthritis	1 (3.2)	4 (7.5)	0.387
Avascular necrosis of head femur	4 (12.9)	1 (1.9)	0.060
Others	3 (9.7)	3 (5.7)	0.390

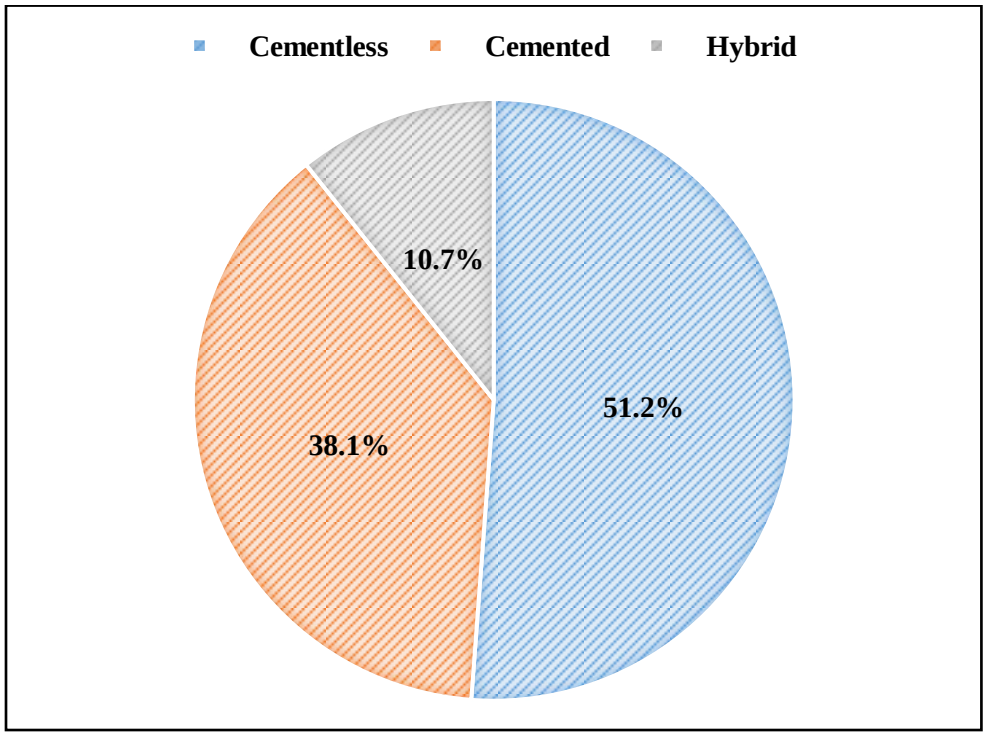
Table 4.2 shows association between etiology and gender of the patients and the P value for each showing no association for all etiology based on the calculated P value i.e.>0.05

*Table 4.3**: Association of age and fracture (n=21 patients)***

Age (in Years)	*Fracture n (%)*	*P Value*
<20	2 (9.5)	0.052
20-49	5 (23.8)	0.013
50-79	11 (52.4)	0.672
80_{+}	3 (14.3)	0.299

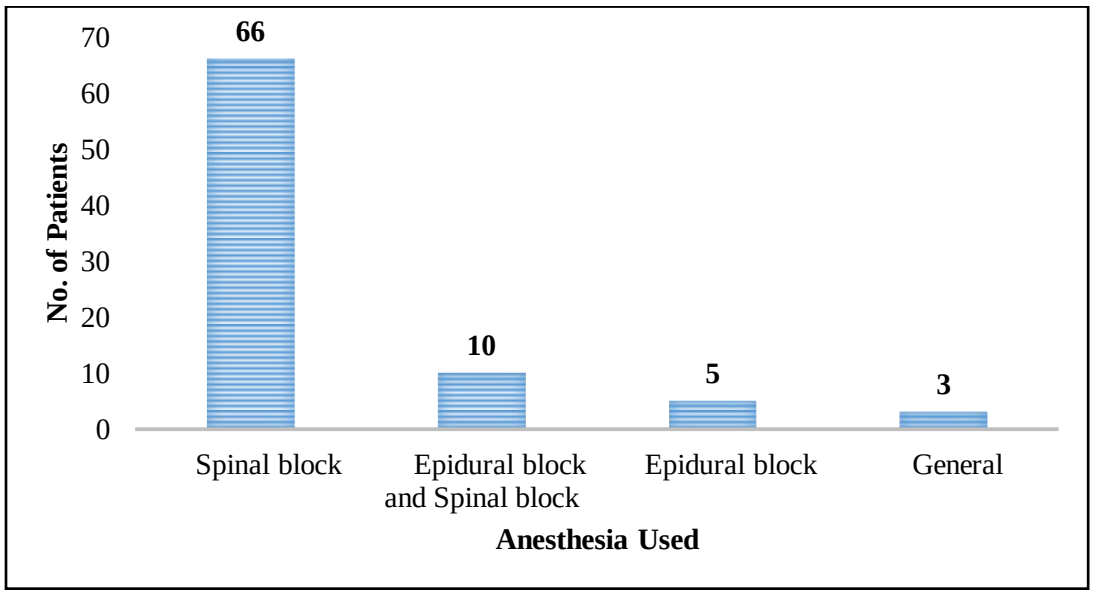
Table 4.4 shows that there was significant association of age and fracture for those at age group 20-49 with a P value of 0.013 but not to other age groups.

***Figure 4. 5:** Implant Used (n=84 patients)*



Cementless was the most common implant used in forty three patient (51.2%).

Figure 4. 6: *Anaesthesia Used (n=84 patients)*



Spinal block at 66 (78.6%) was the commonest anesthesia used followed by a combination of epidural block and spinal block at 10 (11.9%).

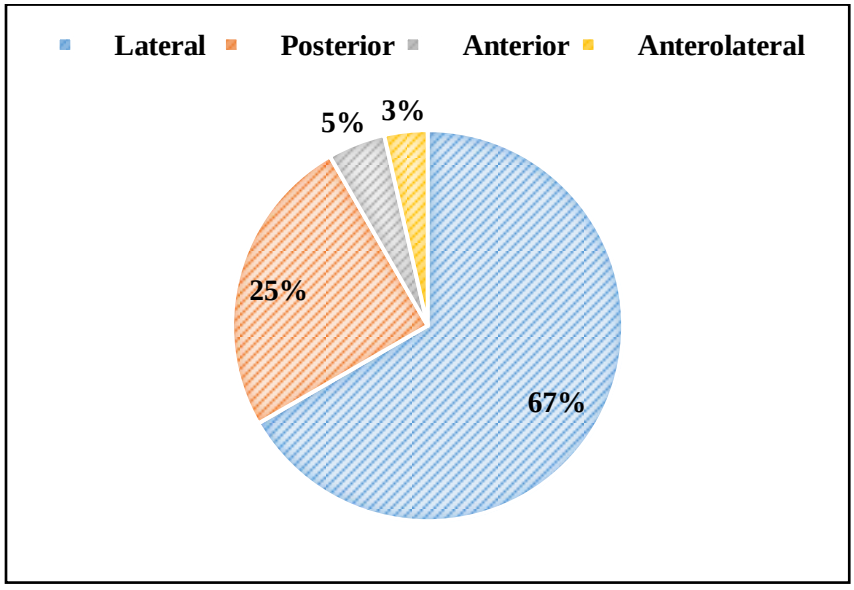
Table 4. 3: *Antibiotic use during PTHA procedure (n=84 patients)*

Antibiotic Use	*Number of patients (%)*
Antibiotic use at Induction of Anesthesia	
Ceftriaxone	59 (70.2)
Cefazolin	18 (21.4)
Cefuroxime	7 (8.3)
Continuation of Antibiotic	
Ceftriaxone	42 (50.0)
Ceftriaxone and Flagyl	28 (33.3)
Cefazolin	5 (6.0)
Cefuroxime	4 (4.8)

Ceftriaxone and Gentamycin	3 (3.6)
Ceftriaxone and Floxapen	1 (1.2)
Cefuroxime and Flagyl	1 (1.2)

Ceftriaxone at 59 (70.2%) and Cefazolin at 18 (21.4%) were the commonest antibiotics used at induction of anesthesia, with Ceftriaxone at 42 (50.0%) being the commonest continuation antibiotic.

Figure 4. 7: *Approach Used (n=84 patients)*



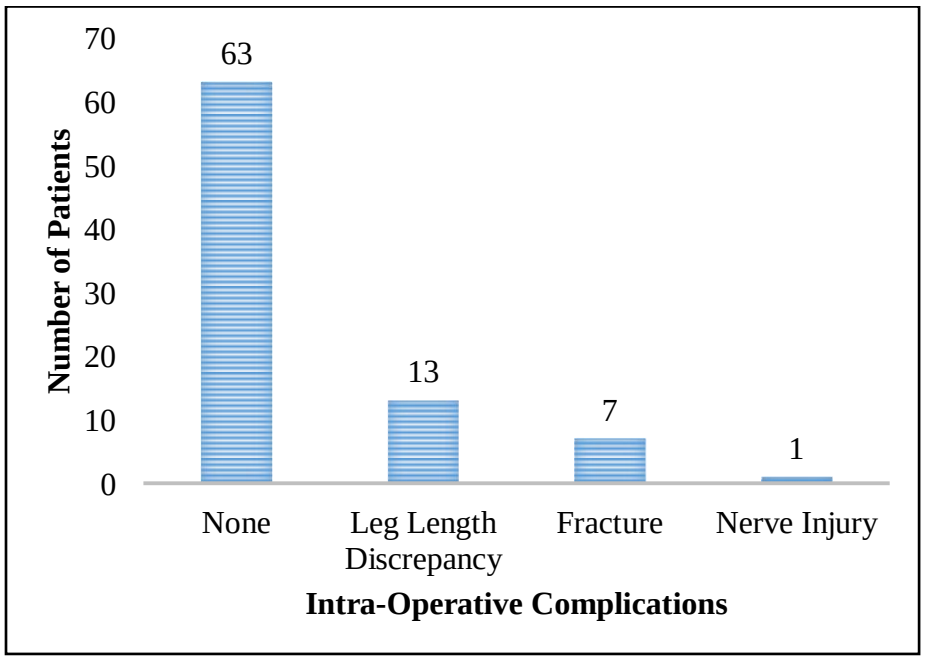
Most of PTHA was done via lateral (Hardinge) approach 56 (66.7%) followed by posterior approach 21 (25.0%)

Table 4. 4: *Cement Techniques (n=41 patients)*

Cement techniques	*Number of patients (%)*
Mixing	
Non-vacuum	34 (82.9)
Vacuum-gun	7 (17.1)
Cement delivery	
Finger packing	32 (78.0)
Gun	9 (22.0)
Plugging	
Bone block	29 (70.7)
Cement plug	11 (26.8)
Propriety restrictions	1 (2.4)

Non-vacuum at 34 (82.9%) was the most common cement technique used with most of the surgeons using bone block in 29 (70.7%) cases during plugging.

Figure 4. 8: *Intra-operative Complications (n=84 patients)*



Patients with leg length discrepancy i.e. shortening were 13 (15.5%) becoming the most common intra-operative complication after PTHA procedure.

Table 4.5: *Post-operative Complications (n=84 patients)*

Complications	*Number of patients (%)*
None	79 (94.0)
Infection(superficial)	2 (2.4)
Hip dislocation(posterior approach)	1 (1.2)
Thromboembolism(PTE)	1 (1.2)
Hematoma	1 (1.2)

Majority of the patients (94.0%) did not have any post-operative complications up to discharge at day five post-surgery.

CHAPTER FIVE: DISCUSSION AND RECOMMENDATIONS

5.1 Discussion

Despite PTHA being with us for a number of decades, the etiology and practice varies from population to population. The surgical practice has not been standardized and mostly left to the surgeon's preference and expertise. Availability of the most current implants and PTHA tools like vacuum cement mixers and guns is still a challenge in Kenya. This study aimed at determining the etiology, common practices and early complications of PTHA in our set up.

Age

Majority of patients in this study were between 52 and 79yrs old (61.9%, N=84). Mean age was 59 years ranging from 15-90 years. In our literature review, the mean age of patients undergoing PTHA in European studies was slightly higher (around 70yrs), Asian countries had comparable mean age with the findings of our study while in Africa, the mean age was found to be much lower (41years) (19,21,22,25,26-28,30).This finding may be due to the fact that in European countries, the predominant etiology is primary osteoarthritis which is a condition found mostly in older age groups while in Asiatic studies, the predominant etiology is AVN which mostly occur in younger subjects (15-18,22-25). In African studies as is our case, the majority of the patients are in their fifties as opposed to European studies. The patients tend to have an arthroplasty due to a fracture sustained after being involved in a motorcycle accident as passengers. Those in there seventies tend to have primary OA as their European counterparts. Nevertheless osteoporosis related fractures in those above seventy years was also common in our study (20-25, 28, 30).

Gender

This study revealed that most participants who underwent PTHA were females (61.3%, N=84), a predominant finding in all studies apart from few Asian studies where AVN due to chronic alcoholism abused by males has been reported as the predominant etiology (20- 22, 26). These finding may be due to higher prevalence of primary osteoarthritis in female gender and a known good health seeking habit in females as compared to males.

Affected Hip

This study showed that the right hip was more commonly affected than the left hip. There exists no previous studies that have showed the same likelihood. Thus, the significance of this finding still need to be established in future studies.

Etiology

Most of the participants (47.6%) had primary osteoarthritis as the etiology, (25%) had fractures of whom (76.2%) had fracture neck of femur and (23.8%) had intertrochanteric fracture.

Previous European studies showed primary osteoarthritis as the predominant etiology leading to PTHA up to 75%. (19, 20). This study also found out that primary osteoarthritis as the leading etiology leading to PTHA although at a lesser percentage of 47.6%. A Brazilian study by Mario Lenza et al had comparable results of primary OA at 47.5% just similar to our findings (21).This may be attributed to aging population in Europe as compared to Africa and Latin America.

The second etiology leading to PTHA in this study was fractures at 25% (Kigera et al in 2017 found the prevalence in Kikuyu-Kenya to be 9.8%) while in Brazil it was found to be as high as 38%. Increase in fractures may be attributed to increased use of motor cycles in Kenya as a means of transport (21). The third commonest etiology leading to PTHA in this study was post-infectious arthritis due tuberculosis. We attribute this to low socio-economic status associated with poor sanitation, hygiene and infection control measures in our country e.g. TB preventive measure and the burden of HIV/ AIDS which has made TB to be prevalent in the last few decades. Asian studies found out that AVN secondary to chronic alcoholism or post-infectious arthritis to be the third commonest etiology which is different from our study (22- 25).

An African study by Dossche et al in Burkina-Faso showed AVN and primary osteoarthritis to be the leading etiology for PTHA followed at a distant third by fractures at 24% which is almost similar to our second etiology at 25%. This shows the importance of fractures as an etiology for PTHA not only in Kenya but in Africa as a whole (28).

Tamal Sambo et al from Benin demonstrated primary osteoarthritis as the leading etiology leading to PTHA (48.4%) similar to this study's finding followed by AVN (31.3%). Fractures accounted for only 1.1% different from our study's 25%.The AVN in Benin was attributed to high incidences of sickle cell disease (30).

Other African studies from Botswana (Lisenda et al) and Zambia (Mula et al) found primary osteoarthritis to be the leading etiology (75%) for PTHA comparable to European studies, a finding higher than our study and the Nordic hip arthroplasty registry (27, 29).

Table 4.1 shows association of primary osteoarthritis and AVN with age which was statistically significant with p-values of 0.000(age>50 years) and 0.026 (<50years).This is in keeping with various studies showing OA to be more prevalent in age above 50 years and AVN more prevalent in younger subjects below 50% years (15-18).

Table 4.2 shows a positive association of AVN with the male gender with a significant p-value of 0.060.This was found to be due to chronic alcoholism in those males in some Asiatic studies (23-25).

Table 4.3 results found a significant association of fracture to age for those between 20-49 years old with a P value of 0.013.This finding may be attributed to increase of motor cycles use in Kenya which is prone to road traffic accidents. No other studies found the same association. Further study on the same needs to be undertaken

Implant use

This study found out that cementless implant was the commonest used implant at 51.2%; with antibiotic being used in all patients with cemented or hybrid implants contrary to study done in Kenya by Kigera et al (2012) that showed that 96.4% was cemented (51). This may be attributed to availability and enhanced training which has been ongoing for the last few years in tandem with what is going on with rest of the world. The increase in application of PTHA to younger subjects mostly below 54 years and in our setting up to below 70 years, where uncemented

implants ware preferred may also be the reason why this study has shown a dramatic increase in uncemented implant use (50,52).

Abdel et al (2018, USA) showed that 56% of implant used in the United States were cementless in comparison to our study (51%) (37).Scandinavian countries and the better part of Europe prefers cemented implants (58).

Anesthesia used

Spinal block was shown to be the predominant anesthetic agent used at 78.6%, followed by combination of epidural and spinal at 11.9%, epidural alone accounted for 5.9% while general anesthesia was used in only 3.5% of procedures. In comparison to American studies, most procedures were done under general anesthesia (74.8%), followed by combination of spinal and general anesthesia at 14% followed by spinal alone at 11%. This finding is completely different from other studies worldwide (37-40).

A South Korean study by Chan et al showed that general anesthesia was at 38.6% while 61.4% was epidural combined with spinal, different from this study's finding (38).

The choice of anesthesia has been shown to have a significant effect on the complications associated with PTHA both intra-operative and post-operative. General anesthesia has been associated with more complications compared with spinal anesthesia (37-40).

Antibiotic use during PTHA procedure

It was noted in this study that ceftriaxone (70.2%) and cefazolin (21.4%) were the antibiotics mostly used during induction while ceftriaxone remained the antibiotic of choice post-operatively. This finding is in keeping with other studies globally in systemic review met analysis studies (58,59).

Veltman et al (Netherlands, 2018) study showed that 24 hours of cefazolin and cefuroxime continuation antibiotics was adequate but in our setup anti-biotherapy continues for 5-7 days post operatively after the pre/intra operative prophylaxis dose (56).

Approach used

The study found out that in most patients (66.7%), lateral approach was the commonest approach used, followed by posterior approach at 25.0%, both anterior and antero-lateral approaches were less commonly used.

Various studies worldwide have however demonstrated that posterior approach to be commonest approach used especially in North America (42, 46, 47). Abdel et al (USA, 2019) showed that posterior approach is the preferred approach (47%) in the United States (49). Other European countries preferred a lateral approach (34-36). Moretti et al (2017, USA) showed that there wasn't an approach superior to the other and that the best approach should be guided by the surgeon's comfort and familiarity (46).

Cementing techniques

The study showed that non-vacuum cement mixing (82.9%), cement delivery by finger packing (78.0%) and plugging by bone block (70.7%) being the commonest technique used in our set-up (table 4.6). A slightly different finding from European and American studies that showed that fourth generation cementing technique to be predominantly used (52-55), while in our setting both second, mostly third and some few fourth generation cementing techniques were used. The difference may be attributed to availability and the surgeon's preference in our set up.

Early complications.

The study established that patients with leg length discrepancy (15.5%) were the most common intra-operative complication after PTHA procedure. Previous studies have also recorded similar results, where incidence of leg length discrepancy has been reported between 1- 27% , minor leg length discrepancy of less than 1 cm may be tolerated well by the patients but more than 2 cm may cause gait abnormalities as well as increase in physiological demand. (37, 41-43).

The study also found that 8.3% of the patients recorded fractures (especially the greater trochanter) as an intra-operative complication. This result was significantly high compared to

previous studies where they reported intraoperative and postoperative fracture at 1 and 1.1% respectively (43-45).

An overwhelming majority of the patients (94.0%) did not record any post-operative complication after PTHA procedure, with only (2.4%) cases of infection, 1 case of hip dislocation and thromboembolism (table 4.7). Overall, incidence of complications have improved over time as surgical and anesthetic techniques have improved along with the diagnosis and management of such complications (41, 43-45).

5.2 Conclusion:

This study established that in our set up despite the challenges of being a third world, we still conduct our primary total hip arthroplasty with relatively less complications. We have adopted the latest technologies and advancement in terms of implants, cementing techniques and Antibiotherapy use. We still do our primary hip arthroplasty majorly due to primary osteoarthritis but fractures as an etiology is not uncommon. Nevertheless some improvements can still be done to be as competitive as the developed world.

5.3 Recommendations

1. A hip arthroplasty registry is needed in our set up, for quick retrieval of data and comparison of the challenges and successes experienced by surgeons in Kenya.
2. A standard guideline is needed for doing hip arthroplasty in relation to type of anesthesia, approaches and antibiotic use to be adopted by all centers in our country.
3. Policy makers to put up measures to reduce fractures from accidents especially from motorcycles.
4. Meticulous treatment of hip infections by orthopedic surgeons to prevent post-infectious arthritis.
5. A bigger study in all centers across Kenya doing PTHA is needed to shed more light on this important Orthopaedic in our set up.

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ESTIMATED BUDGET

ITEM	QUANTITY	UNIT COST	TOTAL
KNH/ERC fees	1	@2500	2500
Printing	1 page printing 1page photocopying	@KSh 10x40pages @KSh 5x40	600
Statistician	1	@30000	30000
Stationaries	Rims		3000
Research assistant	2	@2x10000	20000
Printing thesis	10 books	@500x10	5000
	Binding, ant plagiarism check, flash disk		20000
TOTAL			81100

STUDY TIMELINES

Year	**2019**											**2020**							
Activities	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**
Proposal Development																			
ERC Approval																			
Data Collection																			
Data Analysis																			
Report Writing																			
Dissemination of Findings																			

CHAPTER 7 APPENDICES

7.1 DATA COLLECTION SHEET

DEPARTMENT OF ORTHOPEDIC SURGERY
COLLEGE OF HEALTH SCIENCES
UNIVERSITY OF NAIROBI

ETIOLOGY, COMMON PRACTICES AND COMPLICATIONS OF PRIMARY TOTAL HIP ARTHROPLASTY IN KENYA.

A. PATIENT'S DEMOGRAPHIC CHARACTERISTICS

ID…….

Age……

Gender……

Contacts…….

B. Hip involved;

Right

Left

Bilateral

C. ETIOLOGY DATA

1. ETIOLOGY:

- Primary osteoarthritis.
- Post traumatic arthritis.
- Post infection arthritis.
- Avascular necrosis of head of femur.

- Congenital hip diseases.
- Fractures (intertrochanteric of the femur, neck, head and acetabulum).
- Failed ORIF to head/neck femur.
- DDH.
- LCPD.
- Rheumatoid arthritis.
- Others.

2. PAST AND PRESENT MEDICAL HISTORY

- History of previous trauma to the hip.
- History of aseptic arthritis to the hip.
- History of congenital hip disease.
- History of coagulopathy.
- History of ORIF to the hip.
- History of hip dislocation.

3. IMPLANT USED

- Cemented.
- Cement less.
- Hybrid.

4. ANTIBIOTIC IN CEMENT

- Yes
- No

5. ANAESTHESIA USED

- General.
- Epidural block.
- Spinal block.

6. ANTIBIOTIC USE

- At induction of anesthesia……
- Continuation antibiotic……

7. APPROACH USED;

- Lateral.
- Posterior.

- Anterior.
- Anterolateral.

8. CEMENTING TECHNIQUE:

- Mixing:
  - -Vacuum -gun, bowl or hand
  - - Non-vacuum
- Cement delivery:
  - -gun,
  - -finger packing
- Plugging:
  - -propriety restrictions
  - -bone block
  - -cement plug

9. INTRA-OPERATIVE COMPLICATIONS

- Intraoperative mortality.
- Fracture.
- Pulmonary embolism.
- Leg length discrepancy.

10. **IMMEDIATE POST-OPERATIVE COMPLICATIONS NOTED**

- Infection
- Hip dislocation.
- Thromboembolism.
- In hospital mortality.
- Hematoma formation
- Nerve injury
- Others.
-

7.2 CONSENT FORM

UNIVERSITY OF NAIROBI		
COLLEGE OF HEALTH SCIENCES	**KNH-UoN ERC**	**KENYATTA NATIONAL HOSPITAL (KNH)**
P O BOX 19676 Code 00202	**Email:**	**P O BOX 20723 Code 00202**
Telegrams: varsity	**uonknh_erc@uonbi.ac.ke**	**Tel: 726300-9**
(254-020) 2726300 Ext 44355	**Website:**	**Fax: 725272**
	http://www.erc.uonbi.ac.ke	**Telegrams: MEDSUP,**
	Facebook:	**Nairobi**
	ttps://www.facebook	

Participant Information and Consent Form

Title of Study: Etiology, common practice and complications of primary total hip arthroplasty

Principal Investigator and institutional affiliation: Dr.Hassan Abdullahi Abdulrahman Kenyatta National Hospital

Supervisors: Dr. Tom Siekei Mogire and Dr. J.K King'ori

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) your decision to participate is entirely

voluntary. ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal. iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No.**P757/08/2019**

What Is This Study About?

The researcher listed above is interviewing individuals **who are about to undergo primary total hip arthroplasty**. The purpose of the interview **is to know about your past medical history in relation to your condition**. Participants in this research study will be **asked questions about the prior symptoms before your current condition**.

There will be approximately **84** participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

What will happen if you decide to be in this Research Study?

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 10 minutes. The interview will cover topics such as **history of previous trauma to trauma, history of aseptic arthritis to the hip, history of congenital hip disease, history of coagulopathy, history of hip dislocation**.

After the interview is finished**.** We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: **further communication in relation to the study**

Are There Any Risks, Harms Discomforts Associated With This Study?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your

confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

Are There Any Benefits Being In This Study?

You may benefit by receiving free counseling and health information .We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand hip diseases their operations and complications. This information is a contribution to science and **preventive medicine and research.**

Being in this will not cost you any expense.

What If You Have Questions In Future?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

What Are Your Other Choices?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

Consent Form (Statement of Consent)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to have (define specimen) preserved for later study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____ **Date**: _____

Signature _____

Role in the study: _____

For more information contact _Dr. Hassan Abdullahi Abdulrahman at Kenyatta National Hospital from 800AM to 530PM.

1. Dr. Hassan A.Abdulrahman Contact;0716489021 Email: Hassan.wambua@yahoo.com

2. Dr. T.S Mogire
Consultant and lecturer, Orthopedic surgery
University of Nairobi
Contact;0722854139

3. Dr. J.K King'ori
Consultant and lecturer, Orthopedic surgery,
University of Nairobi
Contact: 0725979524

4. Kenyatta National Hospital/Uon ERC
P.O BOX 19676-00200 Nairobi
Tel NO;[+254-020]2726300
Email;Uonknh-erc@Uonbi.ac.ke

7.3 FOMU YA IDHINI

IDARA YA UPASUAJI WA MIFUPA
CHUO CHA SAYANSI ZA AFYA
CHUO KIKUU CHA NAIROBI

JINA LA UTAFITI: Sababu zinazo leteaupasuajiwanyonganamaafayaupasuajihuu.

MCHUNGUZI: Daktari Hassan Abdfullahi Abdulrahman

WASIMAMIZI WA UCHUNGUZI: Dakatari T. Mogirena J. Kingori

UTANGULIZI:
Upasuajiwanyongaumekuwanasisikwatakribanikarnemojahividunianinatakribanimiakahamsinihu munchini Kenya lakinihakunautafitimzuriuliochapishwakuhusiananaupasuajihuumuhimunchinimwetu.Mathumini yautafitihuunikuwezeshakutatuashidahiiinayotukumba.

MADHUMUNIYAUTAFITIHUU:Kubainishasababuzinzoleteaupasuajiwanyonga,namnaupasua jiwenyeweunavyoendelezwanamadharayanayowezapatikanakatikaupasuajihuu.
UTARATIBU:Habariifuatayoitaombewakutokakwako;umriwako,jinsia,utambuzikulingananahist oriailiyochukuliwanapichazakiboko.Habarizaidiitakusanywakatikaukumbiwamichezoikiwanipa mojanaainaya anesthesia inayotumiwa,dawainayotumiwawakatiwamatibabu,njiainayopendekezwayaupasuaji,ainayakuingi za, shidazozotezakushirikiananazabaadayaupasuajizinazohusiananaupasuaji. Hizizitaandikwa katika karatasi ya ukusanyaji wa data.

FAIDA: Habari inayotokana na utafiti huu itakuwa muhimu katika kuboresha na pengine kusawazisha jinsi TPHA bora itafanywa katika siku zijazo. Kwa kuongezea habari inayopatikana inaweza kusaidia watunga sera kuunda sheria za kuzuia sababu zinazochagia operasheni hiikwa mfano kuvunjika kwa mfupa wa nyonga.

HATARI: Hakutakuwa na hatari yoyote uliyopewa wakati wa utafiti huu.
KUJITOLEA: Tafadhali kumbuka kuwa ushiriki wako ni wa hiari na unaruhusiwa kukataa au kujiondoa wakati wowote. Kupungua kwako au kujiondoa kwenye masomo hakuathiri matibabu yako kwa njia yoyote.

USIRI:kumbuka kuwa jina lako halitaonekana mahali popote na karatasi yaukusanyaji wa data itapatikana kwangu tu na / au mtaalamu wa takwimu.

CHETI CHA IDHINI;
Ninathibitishakwambautafitiumeelezewakwanguvyakutoshananikotayarikushiriki.
SainiyaMshiriki …… Tarehe ……
Ninathibitishakwambanimeelezeawaziainayautafitinayaliyomokatikafomuhiiyaidhinikwamaelezokwamshirikinaamekubalikushirikibilakulazimishwa au kwa shinikizo.
Saini ya mpelelezi …… Tarehe …….
Saini ya Shahidi …… Tarehe …….
Kwamaswaliyoyotewasilianana:

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