OUTCOME OF FEMORAL NERVE BLOCK IN PATIENTS UNDERGOING TOTAL KNEE ARTHROPLASTY AT MUHIMBILI ORTHOPAEDIC INSTITUTE IN DAR ES SALAAM, TANZANIA

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Department of Anesthesiology

OUTCOME OF FEMORAL NERVE BLOCK IN PATIENTS UNDERGOING TOTAL KNEE ARTHROPLASTY AT MUHIMBILI ORTHOPAEDIC INSTITUTE IN DAR ES SALAAM, TANZANIA

By,

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Dissertation submitted in partial fulfilment of the Requirement for the Degree of Master of Medicine in Anesthesiology of the

Muhimbili University of Health and Allied Sciences

October, 2019

CERTIFICATION

The undersigned certifies that, they have read and hereby recommend for acceptance of the dissertation entitled***"Outcomeof femoral nerve block in patients undergoing total knee arthroplasty at Muhimbili orthopaedic institute in dar es salaam,Tanzania"*** in fulfillment of the requirements for the degree of Master of Medicine of in Anaesthesiology at Muhimbili University of Health and Allied Sciences.

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Date

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Dr, Albert Ulimali

(Co-Supervisor)

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Date

DECLARATION AND COPYRIGHT

I, **Dr Anastazia Emanuel Komba**, declare that this **dissertation** is my original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature _____ Date _____

ACKNOWLEDGEMENT

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DEDICATION.

To my loving husband John and our adorable children David and Daniella.

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LIST OF ABBREVIATIONS.

ACL	:	Anterior Cruciate Ligament
ASA	:	American Society of Anaesthesiologist.
BMI	:	Body Mass Index.
CFN	:	Continuous Femoral Nerve Block.
DM	:	Diabetic Mellitus.
ECG	:	ElectroCardioGram.
LA	:	Local Anaesthetic
LAST	:	Local Anaesthesia Systemic Toxicity.
MOI	:	Muhimbili Orthopaedic Institute.
NFNB	:	Non-femoral nerve block.
NRS	:	NumericRatingScale.
NSAID	:	Non Steroid AntInflammatory Drug
PCA	:	Patient Controlled Analgesia
PNB	:	Peripheral Nerve Block.
PNS	:	Peripheral Nerve Stimulator.
PUD	:	Peptic Ulcer Disease
SSFNB	:	Single Shot Femoral Nerve Block
THA	:	Total Hip Arthroplasty
TKA	:	Total Knee Arthroplasty
USS	:	Ultrasound.
VAS	:	Visual Analog Scale
VRS	:	Visual Rating Scale

DEFINITIONS OF KEY TERMS

Continuous Femoral Nerve Block: a technique of infiltrating a local anaesthetic drug around a femoral nerve through an extension catheter inserted through which on-demand top-up doses can be administered.

Single Shot Femoral Block: a technique of infiltrating local anaesthetic around the femoral nerve to provide analgesia /anaesthesia.

Pain: is a personal, subjective experience that involves sensory, emotional and behavioural factors associated with actual or potential tissue injury. It is also defined by International Associations for the Study of Pain(IASP) as" unpleasant sensory and emotional experience associated with actual or potential tissue damage".

Post-operative pain: is any unpleasant sensation experienced by the patient following surgical procedure with associated drains, tubing and procedure-related source.

Total Knee Arthroplasty: is the surgical procedural in which damaged parts of the knee joint are replaced with a metal shell on the femur,a metal and plastic trough on the tibia and sometimes a plastic button in knee cap.

Total Hip Arthroplasty: It is the procedure in which femoral head and cap are replaced with an artificial implant.

Neuritis: Is an inflammatory or degenerative lesion of a nerve marked especially by pain,sensory disturbances and impaired or lost of reflexes**.**

Local Anaesthesia Systemic Toxicity.

ABSTRACT

Background

Total knee arthroplasty is among the advanced orthopaedic surgical procedures and the trend of this intervention has been increasing over the last 2 to 3 decades worldwide. The major indication for total knee arthroplasty is osteoarthritis. Although the trend is growing up, the major challenge is on controlling postoperative pain. Total Knee Arthroplasty is regarded as among the painful procedure for up to 72hours postoperatively. In different parts of the world, femoral nerve block has been shown to improve pain management, especially when used in the multimodal approach in TKA patients. In our setting, no study has been done to evaluate the benefits of femoral nerve block versus conventional systemic opioids in the management of pain in patients post Total Knee Arthroplasty

Objective

To determine the outcome of femoral nerve block for postoperative analgesia in patients undergoing TKA at MOI

Materials and Methods

This was a hospital-based prospective randomized comparative study. The study population constituted 72 adult patients between 18 and 85yrs of age, who underwent TKA. Patients were randomized into two groups, each group having 36patients. During surgery, all patients received standard general anaesthesia.

In the post-anaesthesia care unit, one group received single-shot femoral nerve block with 30ml of 0.25% Bupivacaine under ultrasound guidance and the other group received conventional systemic opioids for pain management. One patient was drop out in femoral nerve block due to failure of the block.

Diclofenac 75mg was given to all patients as per schedule for preemptive analgesia. Pethidine 100mg 6hrly was given intramuscularly to the non-femoral block group. Also, pethidine given to patients receives femoral nerve block group once they started to complain pain NRS of> 4.

Data were collected from the written questionnaire transferred and analyzed with SPSS computer program version 20.0. The continuous variables were presented as mean, standard

deviation and categorical variables presented as a percentage. Associations were tested via Chi-square for categorical variables and t-test for continuous variables. A 95% confidence interval and P-value of 0.05 was used for statistical significance.

Results.

A mean pain score at rest for the first 6hrs was significantly less in patients received femoral nerve block compared to those who received conventional opioids 2.89 versus 6 ($p< 0.0001$). The benefit of pain control when femoral nerve block was used lasted for 24 hr ($p<0.04$. The total dose of pethidine administered in 48hrs was also significantly less in the femoral nerve block group ($p<0.041$). Two complications were noted that were, neuritis three patients and haematoma one patient. However, they spontaneously resolved before patients were discharged.

Conclusion. The femoral nerve block was found to improve the level of postoperative analgesia in the first 24hrs with less amount of opioid used.

Recommendations. Single-shot femoral nerve block should be added as part of the analgesia protocolpost-TKA, as an addition to other medication such as paracetamol, diclofenac and opioid.

1.0 INTRODUCTION

Joint arthroplasty constitutes a major advance in the treatment of refractory joint pain and it is mainly indicated when conservative medical therapy has failed (1-2). Total knee arthroplasty and total hip arthroplasty are two common cost-effective surgeries that reduce pain, improve mobility and quality of life (1-2). Not only is TKA performed for osteoarthritis, conditions like inflammatory arthritis, fracture, dysplasia and malignancy are also among the other indications for arthroplasty(1–3).

Currently, for the past 2-3 decades, the trend of performing arthroplasty is going up and this may be contributed by an increase in life expectancy and obesity (2). According to the England nation audit, it has been shown from the 1990s to 2000 the trends for arthroplasty have gone up for primary TKA doubled andtripled for revision TKA(2). The similar trend is now observed at Muhimbili Orthopaedic Institute (MOI) in which the average of 4 TKA are done per week.

Apart from the picture observed above, postoperative pain remains to be a majorchallenge(4,39,40). The prevalence of postoperative pain control is variable, worldwide it is estimated to be50% to 75% with orthopaedic surgery being among the surgery with high prevalence of postoperative pain(39). It has been known that TKA is among painful surgery, it is even more painful than total hip arthroplasty(4). The pain is attributed to the complex knee anatomy and acute pain can last up to 72hours(5).Inadequate acute postoperative pain management is among the factors which reduce patients' satisfaction, increases risk of nosocomial infections, deep vein thrombosis (DVT) and finally predisposes to the development of chronic pain and depression(40).

For total knee arthroplasty, several methods/medication are employed to control pain but they face the degree of setbacks(6). To start with anti-inflammatory drugs (NSAIDs), which have been shown to carry a risk of causing peptic ulcer disease (PUD), renal and hepatic failure as well as being insufficient to be used as sole agents to control severe pain postoperatively(7).

Opioids are the most commonly used drugs for pain management(8). They provide adequate analgesia in severe pain, however, patients' satisfaction is waned due to the common side effects such as nausea, vomiting, pruritus, constipation, dependence as well as tolerance.

However most of the time is effective in controlling severe pain but patients are less satisfied due to common opioid side effects including respiratory depression, nausea, vomiting, pruritus, constipation, dependence and tolerance. Another challenge is that patients tend to be undertreated due to opioid phobia from the health care provider (5,9).

Lumbar epidural analgesia/anaesthesia can also be done for anaesthesia/analgesia, as a single shot or continuous through catheterization(3,10). Lumbar epidural analgesia it has been proven to be effective in providing postoperative analgesia in total knee arthroplasty(10). Despite its pros, there are cons when used for a procedure involving unilateral limb, it causes motor blockade even to the contralateral limb, hypotension, urine retention spinal haematoma and even abscess (3,10,11). Another feared complication is spinal haematoma since patients usually delay taking anticoagulant prophylaxis, this increased risk of deep venous thrombosis and pulmonary embolism (3,12,13).

In current practice, due to the above challenge, the worldwide emphasis is put on pre-emptive analgesia and multimodal approach in pain control (6,14).

In a multimodal approach additional peripheral nerve block is preferred and most of the time it has proved to be effective (3,6,14,15). A peripheral nerve block can be done for upper and lower limb surgeries, but the trend of using peripheral nerve block increases for upper limb surgery where an interscalene, a supraclavicular block is commonly done. But for lower limb surgery the preferred peripheral nerve block is femoral nerve block either alone or in combination with these, either of the sciatic nerve, obturator and lateral cutaneous femoral nerve. Femoral nerve block alone can be used for analgesia or anaesthesia depending on the complexity of surgery and region involved in the lower limb. The single-shot femoral nerve block has a variable duration of action from 12hoursto 48hours (20,22). But if prolongation of action is needed perineural catheter is inserted so as topping up of medication can be done.

Although it has been shown that femoral nerve block is advantageous but there is feared complications like increase incidence of postoperative fall this is attributed to temporary quadriceps muscle weakness(16). Although the incidence is significantly low when the single-shot femoral nerve is used rather than continuous femoral nerve block(16,17).

Pharmacology of anaesthetic drug used in the femoral block.

Drugs that were commonly used during femoral nerve block it ranges from lidocaine, Bupivacaine, Mepivacaine, Levobupivacaine and Ropivacaine. Sometimes a combination of fast onset lidocaine with long-acting is used to synergize the benefit that is for fast onset and longer duration of action(41).

Bupivacaine is an amide local anaesthetic long-acting but slow in onset. Its commonly used in our setting although is cardiotoxic and neurotoxic (29). Ropivacaine and Levobupicaine are long-acting with less cardiotoxic effect and almost the same potency with bupivacaine (3). The concentration of bupivacaine used varies from 0.25% to 0.5 %.

To minimize the risk of a motor block a less concentrated preparation of bupivacaine should be used. And during femoral nerve apart from local anaesthetics drug like dexamethasone, clonidine, epinephrinecan be added. This has shown to improve patient satisfaction and reducing the systemic effect of local anaesthetic.

Anatomy of the femoral nerve.

The femoral nerve is the largest branch of lumbar plexus, it arises from lumbar nerve L2 to L4(30). It runs through the psoas muscle and it emerges at the lower part of its terminal border and then runs through iliopsoas muscle under fascia iliac then passes behind inguinal ligament to enter the femoral triangle where it divides into the superficial and deep branch. At this level fascia of iliopsoas thicken to form iliopectineal bend which separates a nerve from the vessel(30). It is situated most superficially and wider at the inguinal creases as compared at the inguinal ligament(31). It is 1-1.5cm lateral to the femoral artery (30). The femoral nerve it has both sensory and motor innervations on the lower limb mainly it supplies the anterior medial of the thigh, patella and most of the knee joint. A femoral nerve block can be used for analgesia and anaesthesia purpose. Analgesia in fixation of fractured of the femur, TKA, THRandAC(30,32).Anaesthesia, when used alone, is for skin graft or muscle biopsy involving the anterior aspect of the thigh but when combined with sciatic nerve block it can be used for anaesthesia for a procedure involving knee joint(5)

The technique of performing a femoral nerve block:

Localization of femoral nerve can be done with the assistance of PNS, USS and sometimes both, but the previous study had shown by using USS significant less volume of LA is used and also decrease the chance of nerve injury(20,33). After preparation of equipment and, obtaining informed consent the patient is put on supine position. The patient`s femoral region will be cleaned by a 70% iodine or chlorhexidine solution(16) and then patient draped with sterile draper.

High frequency6-13MHZ linear probe is used since the femoral nerve is superficial(20,30).Approximately1-1.5cm lateral to femoral artery is where the femoral nerve is found it appears as a hyperechoic triangle or flattened shaped speckled hyperechoic appearance and become less obvious as it quickly fans out distally(34). The femoral nerve is found within from external is fascia lata to fascia iliaca which gives its hyperechoic view, which is continuous rather than discrete of lymph node(5,30). The 50mm to 100mm22G B-Braun, non-insulated needle in plane is advanced 1cm distal to the linear probe with 30 to 45-degree angulation cephalad to the patient's skin and advance close to femoral nerve during that time direct visualization of the needle tip should be maintained through the ultrasound guidance. The calculated volume of local anaesthesia is given usually it is around 10to 40mls, either alone or premixed with epinephrine, dexamethasone(30,32). The designated volume is injected in a small aliquot of 5mls while assessing for a sign of local anaesthetics toxicity(29,32). Usually, it takes around 30 minutes the desired effect to be reached. Loss of sensation on the region supplied by the nerve is confirmation.

1.1. LITERATURE REVIEW.

- Prevalence of post operative pain.

Incidence of postoperative pain is variable world wide ranging between 50-75%.In the UK it is estimated to be11-30% , 63% in South Africa , 90 %in Uganda and 85.6% in Tanzania(reference)

The pain severity in postoperative Total Knee Arthroplasty Patients.

It has been known that replacement surgeries are painful surgery and knee replacement is the most painful. In most of the studies done worldwide on knee joint arthroplasties, it shows a significant benefit of femoral nerve block when used alone or with the addition of extra blocks like sciatic, obturator and lateral cutaneous nerve

In the retrospective study done by Lee et al, it showed that continuous femoral nerve block was beneficial in reducing the incidence of severe pain from 62.3% to 32.1% as well as lowering mean pain score for three consecutive days during rest and motion(18). Similarly, it has been shown that the femoral nerve block reduces the severity of pain as compared to those who did not receive, but the duration lasted for 8hours(16). The benefit of femoral nerve block was seen by Sahin et al reported less pain score with a high degree of satisfaction if femoral nerve block was given(20).

In one study done at Taiwan, patients who did not receive femoral nerve block they experience significant moderate pain on 24hrs postoperative (21).In another study done by Chelly et al, shows that femoral nerve block is superior to epidural analgesia in controlling severe to mild pain post total knee arthroplasty(22). But in the study which compares the effectiveness of CFNB against SFNB shows that on the first day there is no significant difference in pain control over the first 12 hrs but the difference is significant from the first day evening in which patients received CFNB had significantly less pain score (23). The study was done in South Africa regarding acute postoperative pain control in resource-limited area it shows that single-shot peripheral nerve block results in immediately no complain of pain in about 97% but later moderate to severe pain occur in 58% rather than 62% in those who did not receive single-shot peripheral nerve block(24). Another study was done in Nigeria it was observational study

regarding the initial experience of regional analgesia for postoperative analgesia in this study it was found patients delay to complain about pain when they received peripheral nerv**e** block (25). Another study which was done by Good et al report different from most of the studies above as it shows that there is no statistically significant benefit when single-shot femoral nerve block is given preoperatively for postoperative analgesia(19).

The opioid usage in postoperatively Total Knee Arthroplasty patients

In most of the studies, it shows significantly less opioid used in the postoperative period after total knee arthroplasty when femoral nerve block is used**.**

According to the study done by Good et al, it has found significant less amount of morphine used in three consecutive postoperative days when the femoral nerve was given on preoperative period as an adjuvant for pain control(19). In his study report, 37.5mg of morphine used in those patients PCA versus 25.5mgof morphine in the femoral nerve block group(19). Similarly in the study done by Chelly shows 74% reduction in morphine use during the postoperative period when femoral nerve block is used after total knee arthroplasty. Moreover, the study was done by Szczukowsk et al it reported patients who receive single-shot femoral nerve block they used less morphine throughout four postoperative days,94.9mg in femoral nerve block group versus 141.7mg in the non-femoral group(26).The study which was done in Southern Africa regarding "acute postoperative period incidence and risk factor in developing countries ". Because of limited resource morphine is among the common drug used and its difficult to get the real amount patients received for postoperative analgesia since patients received less than prescribed dose, in this study patients received 46% of the prescribed amount(24).

Opioids related side effects in postoperative Total Knee Arthroplasty patients

Regarding opioids side effect among study participants, different studies have reported variable.

In the prospective study done by Good et al reported the incidence of opioids adverse outcome to be similar between patients who receive femoral nerve block and those who did not receive femoral nerve block (19)**.** The study reported by Chelly et al reported significantly fewer

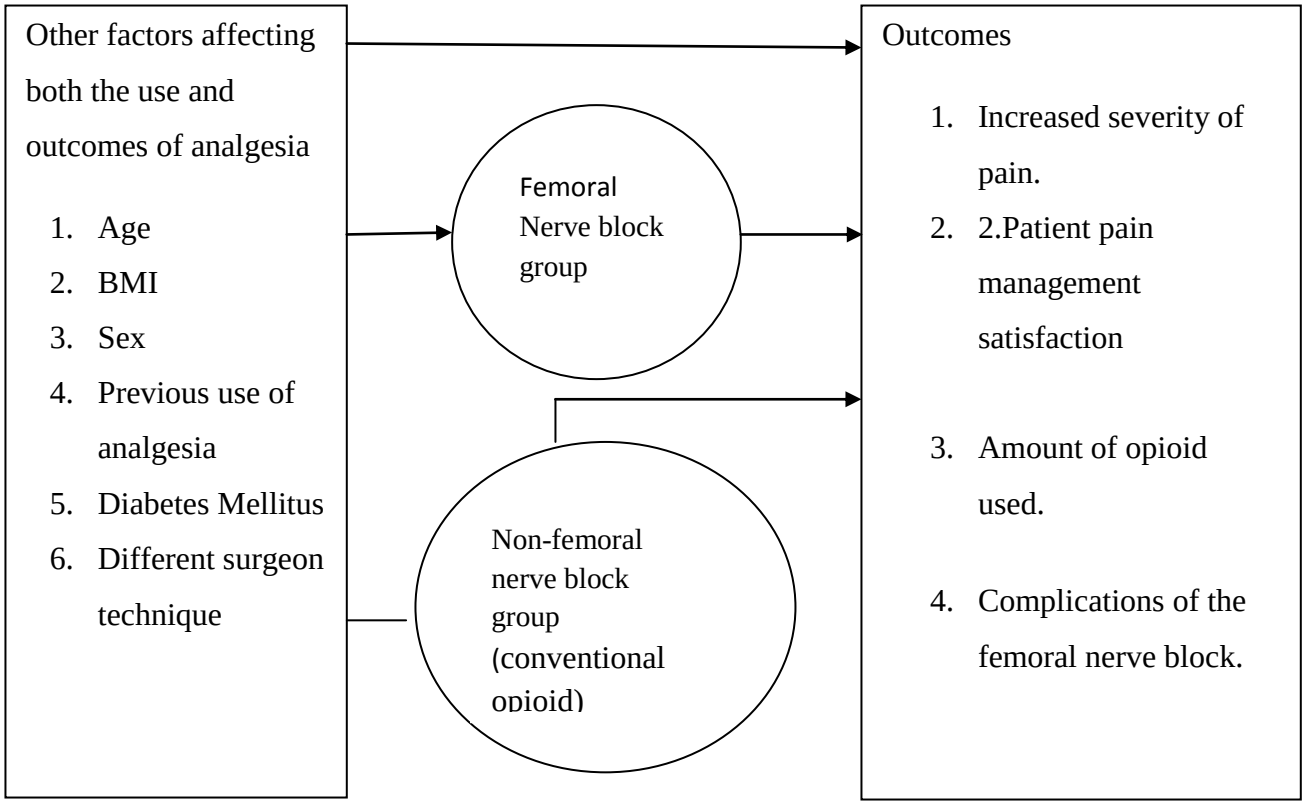
opioid-related side effects from nausea and vomiting to pruritus as compared when PCA with morphine and even epidural analgesia itself (9).In the study done by Allen et al, it was reported no incidence of opioids related sedation of score>2 when femoral nerve block is used as an adjuvant in postoperative pain management (15). Also, the study done by Szczukowski et al, report patients who receive femoral nerve block has significant less sedation score on the first day but no significant difference in other opioid-related side effects(26).

Femoral nerve block complications.

There are different well known and documented complications of the peripheral nerve block. Most of them are not specific for femoral nerve block. They range from those caused by a local anaesthetic drug such as LAST, allergyto technical mishaps, such as peripheral nerve injury, haematoma. The incidence of peripheral nerve injury varies between 0.7to 10% and this was for the minor injury which ranges from paresthesia on the affected region, tingling sensation and for major injury is about 1.5/10000**(**(16,27,28) In a situation when the procedure is not done aseptically there is a chance of introducing infection. One of the common feared complications of the femoral nerve block is the quadriceps muscle weakness, which increases the possibility of fall. In a study done by Sharma et al reported an incidence rate of 1.6% and in this study some of the patients after sustain fall, they had haemarthrosis which needs reopen(16). While in the study done by Feibel et al reported a rate of 1.3% of patients sustaining fall (27). The incidence of patients to fall may delay ambulation and jeopardise patient satisfaction. Also, Sharma reported incidence atrial fibrillation in about 0.7% it is a sign of LAST(15).

1.2 CONCEPTUAL FRAMEWORK

POST TKA ANALGESIA



Prepared by KombaAnastazia 2018.

Figure 1: Conceptual Framework

Explanation of conceptual framework: Femoral nerve block compared to conventional opioid used may be effective in post total knee arthroplasty pain management. But if factors like age, BMI, sex, DM and difference in surgeon technique not equally distributed the outcome may be affected.

.

1.3. PROBLEM STATEMENT

Pain is the complex and subjective interaction between multiple physical and psychological factors. A study which was done in South Africa shows that pain is undertreated (24). The previous study done at MOI, about 10 yrs ago is consistent with the findings that pain is under-managed among orthopaedic surgical patients whereby62.4%ofpatients had a severe pain score(36). Although total knee arthroplasty is a painful surgery, in our settings the analgesia protocol is not different from other surgeries which do not include femoral nerve block. Furthermore, no study in our setting has been done to evaluate the contribution of the femoral block, as a coadjuvant to manage postoperative pain among patients undergoing total knee arthroplasty. Moreover, most studies worldwide have compared the effectiveness of femoral nerve block versus PCA and not against the convention care giver-dependent mode that is classic of our protocol.

1.4. RATIONALE

From previous studies, it has been shown that adequate postoperative pain management fastens time to start ambulation (23). Adequate postoperative pain control decreases the number of days patient stays in the hospital, which finally reduces the risk of nosocomial infection, thromboembolic events and even postoperative delirium (19,37). Therefore the study will help to determine if the patients received single shot will have a better outcome compared to conventional caregiver dependent opioid group. Therefore this study may help to address the existing problem of pain under management and it may improve postoperative pain management quality inpatient undergoing total knee arthroplasty. Since no other study regarding the benefit of femoral nerve block has been done, so it will act as a benchmark of further studies but also impose knowledge of femoral nerve block to junior staff in the anaesthesia department at MOI. It is also part of fulfilment my Mmed in Anaesthesiology.

1.5. RESEARCH QUESTION

Will post-TKA patients receiving single-shot FNB have less severe pain and require less opioid than those without SSFNB?

1.6. OBJECTIVE

1.6.1 BROAD OBJECTIVE:

To determine the outcome of the femoral nerve block among patients undergoing total knee arthroplasty at MOI from June to December 2019.

1.6.2. SPECIFIC OBJECTIVES

1. To determine the difference in pain severity between patients who received femoral nerve block versus non-femoral nerve block group after total knee arthroplasty at MOI from August 2018 to February 2019
2. To determine the difference in the amount of opioid used between patients who received femoral nerve block versus non-femoral nerve block group after total knee arthroplasty at MOI from August 2018 to February 2019.
3. To asses complications associated with femoral nerve block among patients who underwent TKA at MOI from August 2018 to February 2019.

2.0 MATERIALS AND METHODS

2.1 Study Design

Hospital-based prospective randomized comparative study

2.2 Study Area.

The study was conducted at Muhimbili Orthopedics Institute. It is a tertiary level consultant Hospital as well as a teaching hospital located at Ilala district Dar es Salaam. It is the institute that deals with orthopaedic and neurosurgical patients. Currently, the hospital has five working theatres for elective cases and one for an emergency case with average of four TKA per week.The hospital has eleven wards nine for adult patients and two pediatric wards.

2.3Study period

This study was conducted between August 2018 and February 2019

2.4Study Population

The study included all patients between 18 age to 85 age who underwent total knee Arthroplasty surgery under general anaesthesia and were eligible for a femoral nerve block.

2.5. Sample size estimation

The formula for sample size calculation for two side test obtained from (37). From the study done at Tan Tock Seng Hospital in Singapore, it has shown severe postoperative pain had been reduced from 69.1% to 32.3% when femoral nerve block was used(17)**.**

M (size per group) $= \mathbf{c} \times \frac{\boldsymbol{\pi 1(1-\pi 1)+\pi 2(1-\pi 2)}}{\boldsymbol{(\pi 1-\pi 2)^2}}$

Where c=10.5 for 90% power of the study.

$\pi 1$=69.1%

$\pi 2$=32.3%

m (size per group) $=10.5\times \frac{0.691(1-0.691)+0.323(1-0.323)}{(0.691-0.323)^2}$

Size per group= $10.5\times\frac{0.4313}{0.1369}$

sample size per group=33.0.

it is two group study so =33×2 The sample size was 66.

10% of the loss to follow up $=\frac{10}{100}\times 66=6$

Addition of 6 members 72 patients

Adjusted total sample size in the study was72 patients

2.6Sampling procedure

Patients listed for TKA were enrolled and assessed for eligibility. Those who did not meet the inclusion criteria were excluded. A sealed envelope with pieces of papers written either F, which stands for a femoral nerve block or N for the non-femoral group,Principal investigator/assistant opened the envelop and patient picked up the piece of paper . Patients were then randomly allocated into two groups of either femoral or non-femoral after randomly picking a paper written N or F.

2.7Selection of Participants

2.7.1 Inclusion criteria.

All patients between age 18 to 85 who underwent and eligible for femora nerve block

ASA 1 to ASAIII.

2.7.2. Exclusion criteriae

A patient who underwent additional surgery

Use of opioids for more than 2weeks prior.

The operation was done under spinal anaesthesia.

A patient of opioid drug abuse.

2.7.3.Drop out criteria.

Patient refusal.

Total Failure of femoral nerve block

Cardiac arrest.

Death within study period

2.8 Recruitment and training of research assistant

One research assistant was recruited. A research assistant was a registrar in the anaesthesia department. She was trained for two days regarding the study and to familiarize herself with the research questionnaire and other data collection tools. She also received training on research ethics, work schedule and logistics. The main role of a research assistant was to recruit patients and occasional obtaining pre operative information . The principal investigator met with the research assistant on the same day after data collection.

2.9.Variable of Interest

Considering our exclusion criteria the following were collected for patients who met our inclusion criteria**.**

2.9.1. Independent Variable

Demographic: age, sex, weight, level of education.

Anaesthetic Variable: Received a single-shot femoral block and did not receive a single-shot femoral nerve block.

2.9.2. Dependent Variable

Patient satisfaction measured by the Likert scale, Severity of pain assessed by NRS, amount of opioid used, opioid side effects and femoral nerve block complication

2.10. Patient Recruitment and Data Collection

The principal investigator and trained research assistant enrolled adult patient aged between 18 to 85 years who underwent TKA under general anaesthesia and were eligible for femoral nerve block

2.11. Pilot study

A 2 weeks pilot study was conducted. The ease of obtaining data was assessed and necessary changes were made**.**Data obtained in pilot study were not included in the final result.

2.12. Data collecting tools

NRS and Likert scale.

Weighing scale

Questionnaire, Nursing and anaesthetic charts.

Numerical pain score (NRS)

Patient were asked to rate the intensity of pain out of ten. The NRS is an11-point numerical rating scale with end points representing the extremes of the pain experience: 0 = "no pain at all" and 10 = "worst possible pain". NRS score were classified as mild when the score is 0 to 3, moderate when the score is 4 to 7 and severe when the score is 8 to 10(42).

Questionnaire

Back to back questionnaire was used for data collection. Demographic data ,drug given and amount recorded, pains assessment.

Likert scale.

Nursing Charts:were used to obtained information regarding amount of opioid used

2.13. Validity

The tools used were valid since standardized scale-like NRS and Likert scale was used and the assistant for collecting data was a trained medical officer with experience of three years on a relevant field and lastly study the population was adults who can express themselves clearly.

2.14. Reliability

Since the tools used in this study were standard and validated, it can be used on a similar study to assess the severity of pain. However since this was a single-centre study, the difference in the hospital setting on pain management modalities and availability of analgesia, also the sample size is small so the result cannot be generalized. However, this study may be useful as a reference and startup in improving postoperative pain management at MOI.

2.15. Data collection

Principal investigator and research assistant corrected the data. A research assistant was a registrar who is working at MOI. The structured questionnaire was used to obtain the required demographic data. Intraoperative information and analgesic and time it was given were obtained from anaesthetic charts. Post-operative information was obtained from the patient and nurse treatment chart from admission up to 72 hours post-operatively.

2.15.1. Anaesthetic procedure

All 72 patients were seen one day before the day of operation and evaluated for eligibility to be included in the study.

Basic information was obtained and patients randomly chose an envelope inside which were written either F or N ie, F for patients who will receive femoral nerve block and N for non-femoral nerve group.

All 72 patients were given general anaesthesia in which midazolam 2mg, morphine between 5mg to 10mg, propofol were used dose titrated according to loss of verbal response all medication given through intravenous route. Muscle relaxation was achieved by atracurium, and Isoflurane was used for maintenance of anaesthesia. If there was additional opioid given it was recorded corresponding with type, time and dose. During the intraoperative period and recovery, patients were monitored by using noninvasive blood pressure, pulse oximeter, and ECG.

Post-operative. On the recovery area, a group which chose F written envelop were subjected to an ultrasound Guided Femoral Nerve Block. While the subject was lying supine, the inguinal and femoral area was swabed by povidone-iodine andpatient draped with sterile linen. By using linear probe at high frequency Femoral region was scanned.Visualization of hyperechoic triangular shape close lateral to single pulsating artery and vein medial it which collapse on application of pressure is mark the region.

Then under direct view, 30ml of 0.25% bupivacaine was injected under the fasciailliaca. Patient was tested by inability to raise the limb ,and if is positive block is successful.Sensory

block was confirmed by loss of pinprick sensation over the anterior lower limb. One patient in femoral nerve block was excluded due to failure of the block.Patients were continued to receive diclofenac 75mg 6hrly intramuscular up to 72hrs and once they started to complain of pain above NRS of 4, pethidine was given in a dose of 100mg 6hrly up to 72hrs and if it was less or equal to NRS 4 additional diclofenac was given irrespective of the pethidine given if they feel pain of NRS greater than›4 extra pethidine was given and charted.

For the non-femoral group they continued with diclofenac 75mg intramuscular 6hrly and pethidine 100mg 6hrly given and despite scheduled analgesia given if still complain pain was above NRSof 4 extra pethidine was given and if it was less diclofenac was given,

Follow up

In the first day, postoperative patients have assessed three times interval, after the first 6hours, 12hours and 24hours. Once per day on2nd day that is on 48hours and 72hours. During those time information like pain score, amount of opioid, opioid side effects and complications of femoral nerve block were obtained.

2.16. Data analysis

Data were collected and entered into a computer and analyzed using Statistical Package for Social Scientists (SPSS) from IBM SPSS Statistics Version 20.0 computer program**.**
Dependendent variable and independent variable were identified.

The dependent variables were patient severity of pain score, amount of opioid, length time for analgesia, opioid complications and femoral nerve block complications while independent variables were, age, sex, level of education, different surgeon and weight**.** The means and standard deviations used to summarize continuous variables since data were parametric.While categorical data were expressed as frequencies with their corresponding percentages. The Chi-square testing used to test for association between independent variables and dependent variables for categorical data. If the p-value was found to be less than 0.05 then the association will be deemed significant. In the case of continuous variables, a Student t-test for an independent sample was used.

2.17. Data presentation and dissemination

The obtained data will be presented. The data will be useful for clinical seminars presentation to improve care for patients.

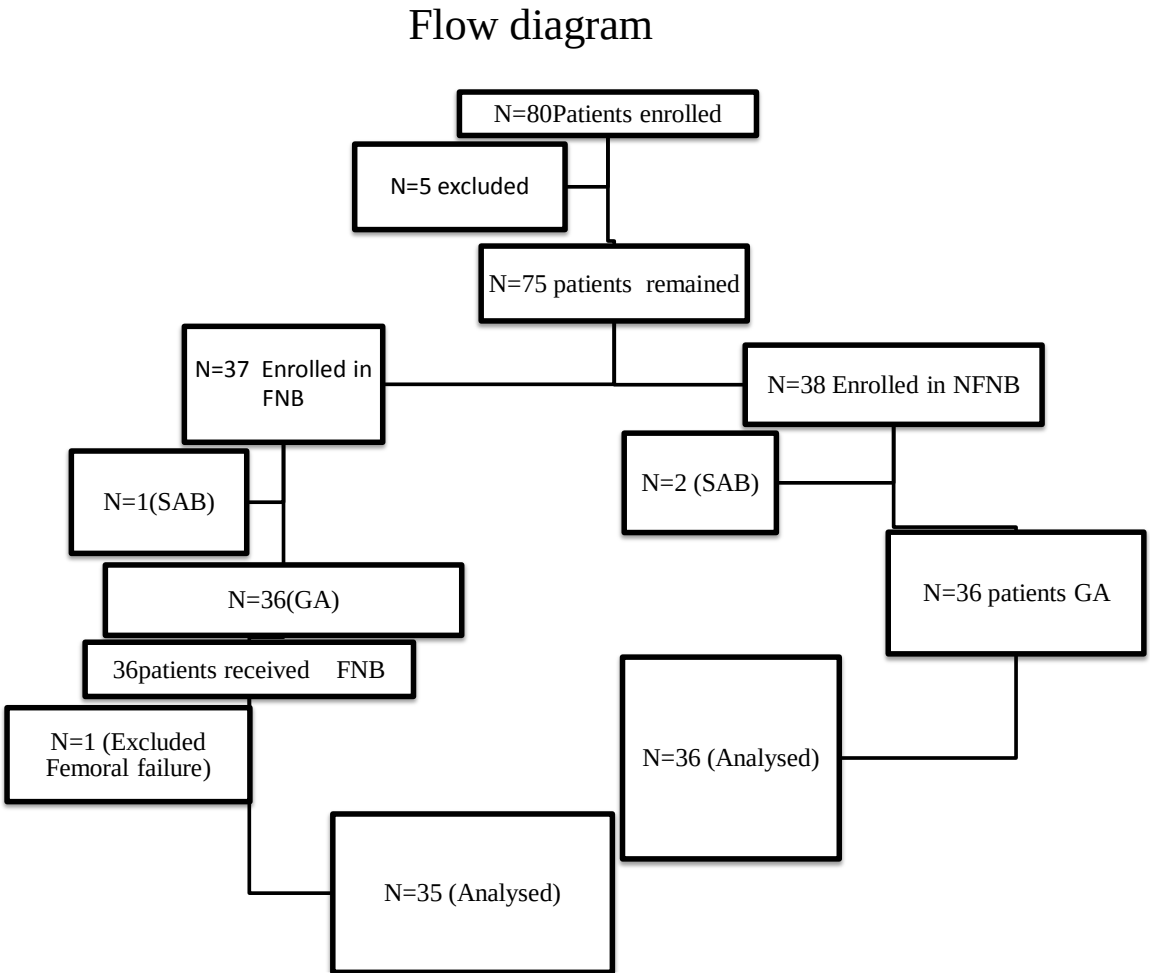
The findings of the study will be presented to the executive director and the head of the department of anaesthesiology at MOI, for them to understand the situation and for them to introduce USS Guided femoral block forTKA postoperative analgesia in case findings show it is significantly beneficial.

2.18. Ethical Considerations and ethical clearance

Official ethical clearance was obtained from the Senate Research and Publication Committee of MUHAS. Permission to conduct the study was obtained from respective authorities at MOI. In the ward, patients were informed about the purpose of the study and written consent was obtained before each patient was enrolled in the study. All collected data were treated and stored confidentially and safely in a coded computer. Refusal to participate or withdraw from the study did not involve any penalty or loss of the patient right to the planned procedure. Patients were not paid for being involved in this study.

3.0RESULTS.

FIGURE 2



This study was done at MOI between August 2018 to February 2019. Initially, they were 72 patients 36 patients for the femoral nerve block group and 36 for non-femoral block group, but one patient in the femoral nerve block group was excluded due to failure of the femoral nerve block.

Table 1: Background characteristics of study participants

	SSFNB(n=35)	NFNB(n=36)	p-value
Mean age (years)	62.9±5.89	61.78±5	0.396
Sex			
Male	11(31.4%)	12(33.3%)	0.533
Female	24(68.6%)	24(66.7%)	
Weight(kg)	85.7±10	89+11	0.141
Level of Education			
No formal education.	4(11.4%)	3(8.3%)	0.944
Primary education	6(17.1%)	7(19.4%)	
Secondary education	17(48.6%)	19(52.8%)	
Higher education	8(22.9%)	7(19.4%)	
ASA			
I	11(31.4)	11(30.6%)	0.996
II	23(65.7)	24(66.7%)	
III	1(2.8)	1(2.8%)	
Type of Surgery			
New	31(88.6%)	33(91.7%)	0.489
Revision	4(11.4%)	3(8.3%)	

This study comprises male and female, two-thirds were female. Mean age of 62yrs for the femoral nerve block group and 61yrs for non-femoral nerve block group. The mean weight for the femoral nerve block group was 85.7kg and mean weight for non-femoral nerve block group it was 89kg. The study participants in both groups comprised of the mixed level of education but half of the study participants were secondary education level and the lowest contribution was from no education Level. Regarding ASA classification patients in both groups were from ASA 1 to ASA111 but a major contribution was from ASA 11. Almost 90% of the patients in each group it was a first attempt total knee replacement. The two groups were comparable in background patient characteristics as there were no statistically significant differences between the 2 groups (Table 1).

Table 2: The difference in the severity of pain among study participants.

Duration	Mean pain score±SD for SSFNB	Mean pain score ±SD for NFNB	p-value
Baseline	7.4+2.1	7.19+1.6	0.649
6hrs	2.89±1.1	6.03±1.7	<0.0001
12	4.14±1.1	6.06±9.5	<0.0001
24	4.86±1.2	6.3±1.1	0.04
48	5.74±0.9	6.14±0.9	0.71
72	5.26±0.7	5.47±0.9	0.289

SSFNB-Single-shot femoral nerve block.

NFNB-Non femoral nerve block.

The baseline; Immediately after surgery full awake

Values mean pain score and standard deviation.

The mean severity of pain for the two groups was comparable at baseline, that is immediately after surgery and it was 7.4 and 7.19 for the femoral and non-femoral group respectively which correspond to severe pain. But for the first 6hours patients who received a femoral nerve block, had a mean pain score of 2.89 which corresponds to a mild pain while for non-femoral nerve block participants had a mean pain score of 6.03 which corresponds to moderate pain and The difference was statistically significant as the p-value was less than 0.0001. From the next 7 to 12 hrs still the mean pain score in the femoral group was less compared to a non-femoral nerve block group, although still statistically significantly different, the mean pain score for the femoral group had gone up to 4.14 while for non-femoral nerve block group were almost unchanged. From13hrs up to 24hrs still mean pain score was low and the difference was statistically significant as the p-value was 0.04. Beyond the first 24hrs, there were no statistically significant differences in mean pain score as the level of significance was above 0.05 (Table 2).

Table 3: Mean of satisfaction score among study participants.

Duration(hrs)	SSFNB	NFNB	p-Value
6	4.3±0.7	2.89±0.8	<0.001
7-12	4.03±0.4	2.94±0.7	<0.0001
13-24	3.89±0.6	2.97±0.7	<0.001
25-48	3.58±0.6	3.06±0.7	0.041
49-72	3.36±68	3.06±0.86	0.280

SSFNB-Single-shot femoral nerve block.

NFNB-Non femoral nerve block.

Values mean ± standard deviation.

In this study, the highest mean satisfaction score was seen in the femoral nerve block group on the first 6hrs and it was satisfaction agree to level score, while at that time in non-femoral nerve group it shows the least mean satisfaction score which corresponding to not agree. For non-femoral nerve block group, the trend of satisfaction was almost unchanged. After 48hrs there was no statistically significant difference in the mean rate of satisfaction score between two groups (Table3).

Table 4: The mean amount of pethidine in mg at different time intervals among study participants.

Duration(hrs)	SSFNB	NFNB	p-Value
6	8.5±16.6	95.6±25	<0.0001
7-12	52.8±49.9	111±39.8	<0.001
13-24	131.4±58	172±65	0.002
Cum24hrs	192.7±60	378±70	0.003
25-48	248±50	283±65	0.041
49-72	34±68	55.56±93	0.280

SSFNB-Single-shot femoral nerve block.
NFNB-Non femoral nerve block.

Values are a mean± standard deviation in mg.

On the first 6hours patients in femoral nerve block used about ten times less pethidine as comparable to femoral group and from 7hoursup to 12hours mean amount of pethidine used in femoral nerve block was almost twice less compared to Non- femoral nerve block and from 13hrs up to 24hrs patients who received femoral nerve block used about 30% less pethidine as compared to non-femoral nerve block . From 25hours to the 48hours patients in femoral nerve block still use less amount of opioid and the difference was statistical significance. The difference in the amount of pethidine used did not persist beyond 48hours since the p-value was above 0.05 (Table 4).

Table 5: Opioids side effects among study participants.

Duration(hrs)		Nausea	Vomiting	Sedation	Pruritus	Respiratory depression
6	Femoral	0	0	0	0	0
	Non femoral	15	5	1	6	0
7-12	Femoral	10	0	1	0	0
	Non femoral	8	2	3	2	0
13-24	Femoral	7	2	2	0	0
	Non femoral	6	0	4	1	0
25-48	Femoral	2	4	2	2	0
	Non femoral	3	5	2	1	2
49-72	Femoral	3	1	0	0	0
	Non-femoral	1	1	0	0	0

From this study, it has been shown that on the first 6hours no participant in femoral nerve block reported opioid-related side effects contrarily to the non-femoral nerve block group in which there were about 13 participants complaining nausea, 5vomiting and 6sedation. The high rate of side effects for the femoral nerve block group was seen from 24hrs to 48hrs and no difference was seen between 48hrs to 72hrs.

Femoral nerve block complications among study participants who received the femoral nerve.

From this study, about five known femoral nerve block complications were assessed. Those complications were neuritis, fall, hematoma, infections at femoral site and LAST. Two complications were mentioned. Only 3 patients out of 35 patients reported neuritis but it resolved before they were discharged from the ward and 1 patient developed a haematoma on the femoral site.

4.0 DISCUSSION AND LIMITATIONS

4.1 DISCUSSION

This study was conducted on a total of 72 patients, aimed at determining the outcome of USS Guided femoral nerve block analgesia post-TKA. The outcome which was assessed was the difference in pain severity between study participants who received femoral nerve block versus Non-femoral nerve block patients, the difference in the amount of opioid used between femoral nerve block versus Non- femoral nerve block and complications associated with Femoral nerve block. The femoral nerve block group remained with 35 patients after exclusion of one patient due to failure of block taking and 36 patients for Non-femoral nerve block. The two groups were comparable in patient's background characteristics (Table1).

The severity of Pain and patients satisfaction

In this study, it had been shown that the baseline pain score was comparable between the two groups as the difference was statistically not significant (Table2). But the study found the femoral nerve block to reduce the severity of pain up to 24hrs(Table2). Also, the degree of satisfaction was higher among patients who had received femoral nerve block up to 48hours(Table 3). A similar result was also seen in the study done by Sahin et al which aimed at evaluating the effect of single-shot femoral nerve block on pain control,morphine consumption and satisfaction, in that study it was shown that patients who had received femoral nerve block had less VRSand also a better degree of satisfaction up to 48hours(20). The difference of this result from Sahin may be attributed firstly, plain bupivacaine was used and no addition of adrenaline1;200,000, secondly the volume used was 30mls not 40mls thirdly this was not a sham study element of observer bias not eliminated. A similar result was also seen in the study done by Lee et al but for this study, the analgesic benefit extended up to 48hrs(18). Prolongation of analgesic effect may be contributed by the ability to top up medication since the catheter was inserted which was not the case in my study. Also, another study in Nigeria which was observational showed that fewer patients complain about postoperative pain after receiving femoral nerve block(25). In another study done by Salinas et al shows that patients who received femoral nerve had less pain score, mean pain score was 2.6 at 12hrs versus mean score of 4 in my study, the difference may be due to in that study

patients were under PCA of 1mg and lockout time 5minutes(23). In another study done by Chan et al, also shows the similar result with significantly less mean pain score in patients who had received femoral nerve block compared to those who did not receive but contrary to my study, the effect persisted for up to 48 hours in their study(21). The difference may be attributed to the basal morphine delivered by PCA and the volume of bupivacaine which were administered according to weight while in my study it was fixed at 30mls and plain bupivacaine used in this study. Another study done by Good et al showed there is less pain in patients who received femoral nerve block but the difference was not statistically significant, but in this study contrary to our study, the femoral nerve block was given preoperatively. This variance in results could be explained by the fact that analgesia was started preoperatively, and as such the drug's life span was already shortened postoperatively(19). Another randomized study was done by Szczukowski et al show almost similar result regarding the mean degree of pain it was 4.07 for those received femoral nerve block versus 6 for patient control analgesia on first-day post total knee arthroplasty. While in my study it was mean pain score of 4.86 for femoral nerve block versus 6.3 in non-femoral nerve block group(Table 2).For the first 24hours in my study caregiver were more concerned about the patients and most of the prescribed medication were given this may be the reason for the similarity.

Amount of Opioids used

In our setting pethidine is the most opioid used opioid, so the amount of opioid used was equivalented to pethidine, for uniformity while in other studies it was equivalented to morphine. This study has shown that less amount of Pethidine was used in patients received femoral nerve block up to 48hrs (Table 4). This result is similar to the studies done bySahin et al and Chan et al in which one of the aims was to determine the amount of morphine used if would be different compared to those who had not received the femoral nerve block, those study showed significantly less morphine were used(20-21,26).But contrarily to this study amount of opioid used were less in femoral nerve block group up to 48hrs rather than 24 hours in their studies (20-21). The difference in duration may be attributed by three reasons, bias from an observer(non-blinded), missing of prescribed opioids and not charting medication.

Nevertheless, another study done by Szczukowski reported less amount of pethidine when femoral nerve block was given. But the amount of opioid was less in my study compared to his study(26).The possible reason was,pethidine was underestimated because it is caregiver dependent so there is room for bias, due to busy schedule not receiving medicationand uncharted medication.

Opioid-related side effect

In this study regarding opioid-related side effects, results are similar to most of the study in which femoral nerve block was given. As patients received femoral nerve block show fewer opioids related side effect especially on first 12hrs (Table5). A complication which was much seen was nausea especially on the first 12hours on non-femoral nerve block. A similar finding was seen in the Chan study in which nausea was higher in patients not received the femoral nerve block, although it was not timely specified(21). However, a study done by Allen et al and Szczukowskidid not report if the incidence of nausea were different between study participants, only report no sedation above a score of 2 for patients who received a femoral block. But in our study sedation score was not categorized and it was not statistically different between participants(15,26). Also, the study which was done by Chelly et al it showed less opioid-related side effects when femoral nerve block is used but the side effects were not assessed daily(9)**.** The study was done by Good et al it showed no difference in nausea and vomiting between patients received femoral nerve block versus systemic patient control opioid group(19), the difference may be due to the period when femoral nerve block was done it was postoperative rather preoperative..

Complications of the femoral nerve block

In this study, five complications were assessed and the complications which were reported include neuritis 3 out of 35 and haematoma 1/35. The result of my study was similar to most of the studies with a minor difference. Like in one of the studies done by Sharma et al, it was a randomized controlled studycomparing if there were a statical difference in complications between femoral nerve block and Sham block. It reported an incidence of1.6% sustained fall in femoral nerve block versus0.4% in a sham block(16).In my study no patient-reported to fall,

maybe was due to the less concentration of bupivacaine 0.25% versus 0.5%. In another study done by Feibel et al reported an incidence of fall about 1.3%, although it was low incidence, all patients developed haemarthrosis and arthrotomy was done(27). And another study was done by Widmer et al, also report a neurological complication of about 2.7%. Although the incidence rate of neurological complications was different 3 patients out of 35, thismay be due to a huge difference in sample size 709versus 35 and lesslevel of experience of the femoral nerve block (28). Moreover, the study done by Szczukowski reports no neurological complication, infection or bupivacine toxicity when femoral nerve block is done(26).In contrarily to the study done by Chan no patients develop neuritis for three consecutive days while three patients developed transient neuritis the reason may be the difference in the level of experience (21). Also similar to mine no patient sustain fall this is due to in our setting similar ambulation should be started after 24hours(21).

4.2 LIMITATIONS

- Randomization was done but double-blinding was not done this could mean that an element of observational bias was not completely removed.
- There was an element of missing the prescribed medication so the calculated amount of opioid used was underestimated.
- This study just asses the degree of pain at rest and a specific point interval. This could mean important information regarding the severity of pain during physiotherapy is not known.

5.0 CONCLUSION AND RECOMENDATIONS

5.1 CONCLUSION

Significant less degree of pain was observed in patients who received femoral nerve block for postoperative analgesia in TKA surgeries but the effect did not persist beyond the first 24hours. Most patients who had received femoral nerve block for the first 6hours managed to stay without the need of even a single dose of pethidine and for the 48hours the mean amount of pethidine used was less than in the non-femoral nerve block group. Our study concludes that there is a significant benefit to the use of Ultrasound-Guided Femoral Nerve Block for postoperative analgesia after Total Knee Arthroplasty.

5.2 RECOMMENDATIONS.

- Ultrasound-guided Single-shot femoral nerve block should be used as an adjuvant mode of analgesia for total knee arthroplasty since it has been shown it is effective within the first 24hrswhen used in combination with opioid, diclofenac etc.
- Another study should be done to evaluate why patients are missing their medication and ways to minimize it.

Opioid should prescribed according to patient weight to reduce feared complications.

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QUESTIONNAIRE .ENGLISH VERSION

SERIAL NO.

Date of previsit……

Date of operation

PATIENT INFORMATION.

1. Age….

2. Sex.
   a) Male
   b) Female.

3. Weight

4. Level education.
   a) No formal education.
   b) Primary education.
   c) Secondary education.
   d) Higher Education

PREOPERATIVE INFORMATION

5.Asa class.

6. Do you have any chronic illness?
   a) Yes.
   b) No

7. If yes mention it

8. Are you experiencing any degree of pain now
   a) Yes.
   b) No

9. Using any number from 0 to 10, where 0 is the total pain-free state and 10 worst pain experienced, what number would you use to rate your degree of pain. Tick the appropriate answer. Where 10 is the worst pain and 0 is no pain.

10	9	8	7	6	5	4	3	2	1	0

10. Were you on an analgesic before?
    a) Yes.
    b) No.
11. If the answer is **yes**, what kind of medications and routes used to administer the drug.

	Drug	IV	IM	ORAL	OTHERS
a	Tramadol				
b	Paracetamol				
c	Diclofenac				
d	Gabapentin				
e	Others				

12. For how long have you been on these medications
    a) Less than a week.
    b) One to four weeks.
    c) Between one to two months.
    d) More than two months.
13. Is it a new operation or revision tick appropriate.

TKA	New	Revision

INTRAOPERATIVE INFORMATION.

14. Time to start general anaesthesia
15. Time to start the surgery.
16. Time and dose of opioid received intraoperative.
17. Is there any surgical complication occurring intraoperatively?
    a) Yes.
    b) No
18. The end time for surgery.
19. Time to end general anaesthesia.

20.The baseline pain score by using NRS

21. Did she/he receive femoral block

a) Yes

b) No.

22.1I f yes researcher/assistant should document the time**.**

6 HRS POSTOPERATIVE PERIOD.

23. Are you experience any degree of pain

a) Yes

b) No

24. If yes Using any number from 0 to 10, where 0 is the total pain-free state and 10 worst pain experienced, what number would you use to rate your degree of pain. Tick the appropriate

answer. Where 10 is the worst pain and 0 is no pain.

10	9	8	7	6	5	4	3	2	1	0

25. Has she received any form of analgesia during this duration interval **YES**/NO?

26. If yes the dose and type of medication and specific time given

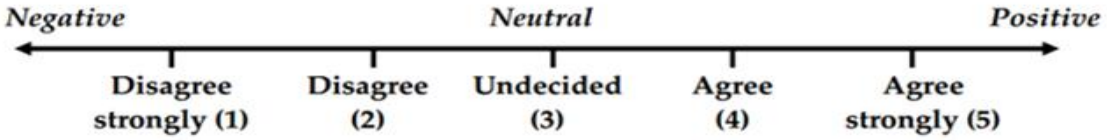
Drug	route	Dose
Morphine		
Pethidine		
Fentanyl		
Diclofenac		
Paracetamol		

27. Are you feeling any of the symptoms below?

Symptom	Yes	No
Nausea		
Vomiting.		
pruritus		
sedation		
respiratory depression		

28. Which level of satisfaction can you give to the mode of analgesia, tick to the appropriate

Five point Likert scale



29. If your relative get operated can you advise to receive the same mode

a) Yes

b) No

7 TO 12 HRS POSTOPERATIVE PERIOD

30. Did you experience any degree of pain

a) Yes

b) No

31. If yes Using any number from 0 to 10, where 0 is the total pain-free state and 10 worst pain experienced, what number would you use to rate your degree of pain. Tick the appropriate answer. Where 10 is the worst pain and 0 is no pain**.**

10	9	8	7	6	5	4	3	2	1	0

32. Did she/he received analgesic

a) Yes

b) No

33.If she/he received analgesic which type dose and route and time given

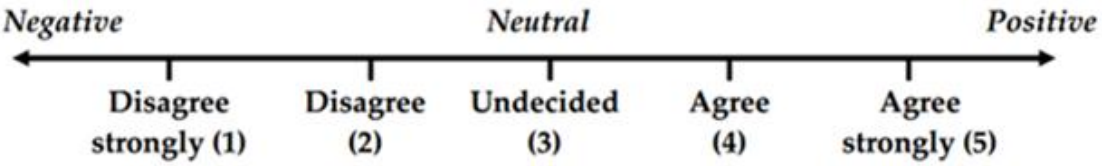
Drug	route	Dose
Morphine		
Pethidine		
Fentanyl		
Diclofenac		
Paracetamol		

34. Did you feel any of the below symptoms tick for appropriate

Side effects	
Nausea	
Vomiting	
Pruritus	
Sedation	
Respiratory depression	

35. Which level of satisfaction can you give to the mode of analgesia tick to the appropriate

Five point Likert scale



36. If your relative gets operated can you advise to receive the same mode a. Yes.

b.No

13 to 24 hr

37. Did you experience any degree of pain

a) Yes
b) No

38. If yes Using any number from 0 to 10, where 0 is the total pain-free state and 10 worst pain experienced, what number would you use to rate your degree of pain. Tick the appropriate answer. Where 10 is the worst pain and 0 is no pain.

10	9	8	7	6	5	4	3	2	1	0

39. Has she received any form of analgesia during this time interval
    a) YES
    b) NO.

40. If yes the dose and type of medication and a specific time is given.

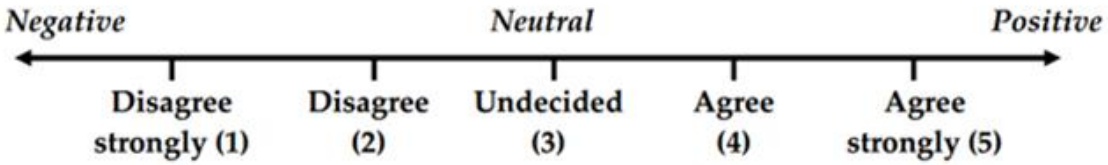
Drug	route	Dose
Morphine		
Pethidine		
Fentanyl		
Diclofenac		
Paracetamol		

41. Did you experiencing any of the below symptoms during this time interval

Side effects	
Nausea	
Vomiting	
Pruritus	
Sedation	
Respiratory depression	

42. Which level of satisfaction can you give to the mode of analgesia tick the appropriate?

Five point Likert scale



43. If your relative gets operated can you advise to receive the same mode

a) Yes.

b) No

25hr to 48hr

44. Did you experience any degree of pain

a) Yes

b) No

45. If yes Using any number from 0 to 10, where 0 is the total pain-free state and 10 worst pain experienced, what number would you use to rate your degree of pain. Tick the appropriate answer. Where 10 is the worst pain and 0 is no pain.

10	9	8	7	6	5	4	3	2	1	0

46. Has she received rescue form of analgesia during this time interval analgesia **YES**/NO

47. If yes the dose and type of medication

.

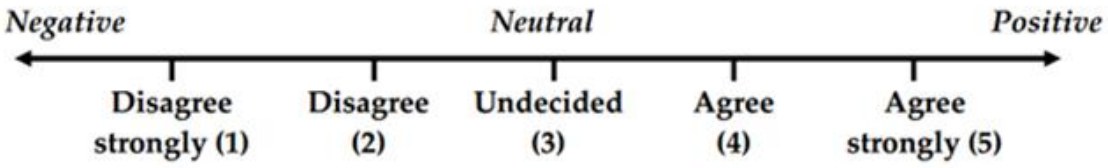
Drug	route	Dose
Morphine		
Pethidine		
Fentanyl		
Diclofenac		
Paracetamol		

48. Did she experience any of the below symptoms during that time interval?

Side effects	
Nausea	
Vomiting	
Pruritus	
Sedation	
Hypotension	

49. Which level of satisfaction can you give to the mode of analgesia tick to the appropriate?

Five point Likert scale



50.. If your relative get operated can you advise to receive the same mode

a) Yes.

b) No. For either answer explain……..

48 to 72hr

51. Did you experience any degree of pain

a) Yes

b) No

52.. If yes Using any number from 0 to 10, where 0 is the total pain-free state and 10 worst pain experienced, what number would you use to rate your degree of pain. Tick the appropriate answer. Where 10 is worst pain and 0 is no pain

10	9	8	7	6	5	4	3	2	1	0

53. Has she received a rescue form of analgesia apart **YES**/NO?

54. If yes the dose and type of medication and specific time given

Drug	route	Dose
Morphine		
Pethidine		
Fentanyl		
Diclofenac		
Paracetamol		

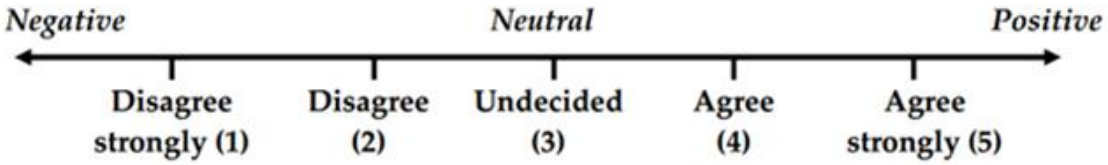
55. Did he/she experienced any of the below symptoms

a) Yes.
b) No

Side effects	
nausea	
vomiting	
pruritus	
sedation	
Respiratory depression	

56. Which level of satisfaction can you give to the mode of analgesia tick to the appropriate and explain……..

Five point Likert scale



57. If your relative get operated can you advise to receive the same mode

a) Yes.
b) No. For either answer explain……..

58. Did the patient develop any of below complication for the past three days(only applicable for the femoral nerve block group?

	YES	**NO**
Fall		
Hematoma		
LAST		
Infection on femoral sites		
neuritis		

APPENDICES

Appendix I: Consent Form English Version

Introduction

I am Dr Anastazia Emanuel Komba, a researcher from the Muhimbili University of Health and Allied Sciences (MUHAS). I am conducting a study titled the Outcome of the femoral block for postoperative analgesia in patients who are undergoing total knee Arthroplasty at Moi. This research aims to 'To determine the outcomes related to the use of Femoral block in patients undergoing total knee arthroplasty.

Participation in the study

You are kindly requested to participate in this study. If you accept to participate in this study your particulars/information will be taken and used for this research and this will certainly not bother you or cause any discomfort to you. Your participation in this study will involve the following: Taking your records from clinical notes, being directly observed in during the intraoperative and postoperative period for a maximum of three days. You will be as well called through your phone number during the follow-up period.

Confidentiality

You are strongly assured of the confidentiality of the information obtained that will only be used for this research and anonymity will highly be observed when collecting data and compiling the report. To assure you, even your name will not be required to appear in the questionnaire.

Risk to participant

No anticipated risk or harm that may result from participating in this study.

Right of participation in the study. Your participation is voluntary and there is no penalty for refusing to participate. You are free to ask any question and you may stop to participate in this study any time.

Contact Person

The principal investigator DR ANASTAZIA EMANUEL KOMBA (0768057474, is a key contact person about any queries about this study. If you have any questions/concerns about your rights as a participant you may contact, Dr Bruno Sunguya, The Director of research and

publications, MUHAS P.O.BOX 65001 Telephone: 2150302-6,Dar es salaam. And Dr Fredrick Mbanga who is the supervisor of this study, Phone:0658288171

The signing of the consent

If you agree to participate in this study please sign in this consent form.

I (initials)…… have read and understood the contents of this form and I have been given a satisfactory explanation with all my questions answered. I, therefore, consent to participate in this study.

Signature of interviewee .....……Date.....

Signature of interviewer .....Date ……

Appendix II: Fomu ya ridhaa ya Kiswahili

FOMU YA RIDHAA KUSHIRIKI KATIKA UTAFITI YA KISWAHILI

Utangulizi

Mimi naitwa Dr. Anastazia Emanuel Komba, mtafiti kutoka Chuo Kikuu cha Sayansi ya Tiba Muhimbili. Ninafanya utafiti kuhusiana na wagonjwa wanaofanyiwa upasuaji wa goti Matokeo yatokanayo na matumizi ya njia za kuondoa maumivu kwa kutumia njia ya sindano femoral '. Lengo la utafiti huu kutaka kujua kama njia ya kuzuia maumivu kwa sindano ya Femoral itakuwa ni bora zaidi na isiyokuwa na madhara ukilinganisha na njia zetu za kawaaida,

Kushiriki katika utafiti huu

Tafadhali unaombwa kushiriki katika utafiti huu, na mara tu utakapo ridhia ,unahakikishiwa kuwa habari zako na maelezo utakayotoa yatatumika kwa makusudio na malengo ya utafiti huu tu na kuwa hii haitakuletea usumbufu wowote.

Usiri wa taarifa za mshiriki

Unahakikishiwa tena kuwa taarifa zozote zitakazopatikana kutoka kwako wakati wa utafiti huu zitapewa usiri mkubwa sana na hazitatumika kwa malengo mengine yeyote tofauti na utafiti husika. Kuhakikisha hilo dodoso litakalo husika halitakuwa na jina lako wakati wote wa utafiti na hata baada ya utafiti.

Athari za utafiti huu kwa mshiriki

Hakuna athari au madhara yeyote yatakayokupata kutokana na kushiriki katika utafiti huu.

Haki ya kushiriki au kutoshiriki katika utafiti huu

Ushiriki wako katika utafiti huu ni wa hiari kabisa.unayohaki ya kushiriki au kutoshiriki bila kulazimika. Pia unayo haki ya kukataa kuendelea kushiriki/kuacha kujibu maswali wakati wowote utakapojisikia kufanya hivyo na hakutakuwa na hatua yeyote itakayochukuliwa dhidi yako au kulaumiwa kwa kufanya hivyo.

Mawasiliano

Wasiliana na mtafiti mkuu, Dr. Anastazia Emanuel Komba (0768057474) wakati wowote utakapokuwa na maswali au jambo lolote lenye kuhitaji ufafanuzi kuhusu utafiti huu. Hata hivyo endapo utakuwa na maswali kuhusu haki yako kama mshiriki unaweza pia kuwasiliana na Mwenyekiti wa Baraza la Utafiti na Uchapishaji wa Chuo Kikuu cha Sayansi ya Tiba Muhimbili. Dr Bruno Sunguya, S.L.P. 65001 Dar es salaam, Simu namba 2150302-6 . Na Dr. F.Mbanga msimamizi wa utafiti huu simu namba 0658288171

Kukubali kushiriki

Ukikubali kushiriki tafadhali thibitisha kwa kujaza na kusaini sehemu ya fomu hii hapa chini.

Mimi …….nimesomewa na kuelewa yaliyomo kwenye form hii na maswali yangu yote yamejibiwa vizuri. Hivyo ninakubali mwenyewe kwa hiari yangu bila kushurutishwa au kushawishiwa kushiriki katika utafiti huu.

Sahihi ya mhojiwa……..... Tarehe…….....……..

Sahihi ya mhoji. ……Tarehe …….

Appendix III: Ethical Clearance

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF POSTGRADUATE STUDIES

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Ref. No. DA.287/298/01A/ 31st July, 2018

Dr. Anastazia Komba
MMed. Anaesthesiology
MUHAS

RE: APPROVAL OF ETHICAL CLEARANCE FOR A STUDY TITLED: "OUTCOME OF FEMORAL NERVE BLOCK FOR POSTOPERATIVE ANALGESIA IN PATIENTS UNDERGOING KNEE ARTHROPLASTY AT MOI"

Reference is made to the above heading.

I am pleased to inform you that, the Chairman has, on behalf of the Senate, approved ethical clearance for the above-mentioned study. Hence you may proceed with the planned study.

The ethical clearance is valid for one year only, from 24th July, 2018 to 23rd July, 2019. In case you do not complete data analysis and dissertation report writing by 23rd July, 2019, you will have to apply for renewal of ethical clearance prior to the expiry date.

Dr. Emmanuel Balandya
ACTING: DIRECTOR OF POSTGRADUATE STUDIES

cc: Director of Research and Publications
cc: Dean, School of Medicine