THE INFLUENCE OF ARTERIAL TOURNIQUET APPLIED DURING LIMB SURGERY ON POSTOPERATIVE HEMOGLOBIN LEVEL: A SINGLE CENTRE PROSPECTIVE OBSERVATIONAL STUDY.

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STUDENT'S DECLARATION

I declare that this dissertation is my original work and has not been presented for a degree at any other university.

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DEDICATION

I dedicate this dissertation to the Almighty God for always being available for provision, nurturing, and protection. In addition, I dedicate it to my parents and siblings for their immense support and guidance throughout.

CONTENTS

LIST OF ABBREVIATIONS.

AOP	Arterial Occlusion Pressure
AORN	Association of periOperative Registered Nurses
ASA	American Society of Anaesthesiologists
CSEA	Combined Spinal and Epidural Anesthesia
CTR	Carpal Tunnel Release
ERC	Ethics and Research Committee
Hb	Hemoglobin
Hct	Hematocrit
KNH	Kenyatta National Hospital
LOP	Limb Occlusion Pressure
MAP	Mean Arterial Pressure
RCT	Randomized Control Trial
SBP	Systolic Blood Pressure
TKA	Total Knee Arthroplasty
UoN	University of Nairobi
WHO	World Health Organization

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ABSTRACT

Background: Limb surgeries are a major contributor of surgical burden, especially in low and middle-income countries. These surgeries are associated with considerable blood loss. Therefore anaesthetists and surgeons are encouraged to adopt mechanisms aimed at minimizing blood loss. The use of a tourniquet remains a popular method of reducing blood loss during limb surgery. **Main objective:** To determine the influence of arterial tourniquet applied during limb surgery on postoperative hemoglobin level at Kenyatta National Hospital.

Methodology: This was a prospective observational study carried out over 10 weeks (November 2020 to January 2021) at KNH. Participants were recruited in the operating theatre waiting area after meeting the inclusion criteria and using systematic sampling, a total of 81 participants were recruited into the study. They were followed up throughout the surgery and up-to day two post-surgery. Data were collected and uploaded into Research Electronic Data Capture (REDCap). These data were exported to SPSS Version 21 for cleaning and analysis.

Results: The mean age of the participants was 34.6 (SD 14.4), range of 8.0 years to 70.0 years. There were 65 (80.2%) male and 16 (19.8%) female participants. A majority (85.2%) of the patients had orthopedic conditions while 14.8% had other non-orthopedic conditions. The mean preoperative hemoglobin level was 12.5 (SD 1.5) g/dl in male participants and 12.6 (SD 1.7) g/dl in female participants, with a mean difference of 0.1 g/dl. This was not statistically significant ($p = 0.679$). The mean tourniquet cuff inflation pressures for the upper limb was 240.7 (SD 25.2) mmHg while for the lower limb it was 322.4 (SD 38.1) mmHg. The mean inflation time for the upper limb was 76.6 (SD 37.0) minutes while for the lower limb it was 89.2 (SD 32.3) minutes. The mean postoperative hemoglobin level was 10.5 (SD 1.7) g/dl. A paired-sample t-test of the differences in the mean Hb levels preoperatively and postoperatively revealed a mean difference of 2.0 (95% CI, 1.6 to 2.2). This was statistically significant ($p <0.001$).

Conclusion: The majority of participants had a pre-op Hb level of more than 10g/dl (96.3%), while postop a significant number (37%) had a Hb level of less than 10g/dl hence the need to do a Hb level post-op. Tourniquet cuff inflation pressures used were high compared to recommended values. Postoperatively there was a reduction in Hb level compared to preoperative levels with a mean difference of 2.0 g/dl which was statistically significant ($p<0.001$).

1.0 CHAPTER ONE: INTRODUCTION

Limb surgeries are a major contributor of surgical burden, especially in low and middle-income countries. Majority of these surgeries in Kenya are carried out following trauma which may result from road traffic accidents, falls, and sporting activities. Other non-trauma related procedures including TKA and carpal tunnel release contribute to this burden in many hospitals.

Limb surgeries in most cases involve substantial blood loss which makes surgeons overestimate the requirement for blood transfusion and ordering of blood which may not be required [1]. Blood loss in limb surgeries is caused by muscle dissection, periosteal elevation, callus, and bone cutting and is characterized by slow continuous oozing. Due to scarcity, high cost, and risks associated with blood transfusion, it is important for surgeons and anaesthetists to establish ways of minimizing blood losses. It is also necessary for institutions to have objective ways to estimate perioperative blood losses and requirements for the different surgeries done so that there is increased efficiency and minimal wastage.

Several mechanisms have been applied in an attempt to minimize blood loss during limb surgery. The methods include induced hypotension mediated by anaesthetic agents, use of drugs like tranexamic acid, use of diathermy, and application of a tourniquet. Regional and spinal anaesthesia are also associated with less blood loss [4]. The use of a tourniquet remains as one of the oldest and popular method applied to reduce blood loss during limb surgery because it is cheap, requires less expertise, and has undergone multiple modifications which guarantee safety and minimize complications.[5]

This study aimed at establishing whether using a tourniquet during limb surgery reduces the changes in hemoglobin level by comparing pre-op and post-op Hb levels. It also aimed to establish the cuff inflation pressures applied and duration of surgery during limb surgery with a tourniquet and whether these parameters had an influence on the hemoglobin level postoperatively.

2.0 CHAPTER TWO: LITERATURE REVIEW.

2.1 Definition and types of tourniquets.

A tourniquet is a pressure device that is applied on a limb and prevents blood circulation on the distal areas for a specific time period until it is released [6, 7]. The initial devices can be traced back to French societies and it was applied by rotating it which meant to "turn" hence the name tourniquet [8]. To date, many different types of tourniquets have been identified and broadly classified as either surgical or emergency, pneumatic, or non-pneumatic. Surgical tourniquets enable surgeries to be carried out in a bloodless site by occluding blood flow and this increases accuracy and speed.

Tourniquets can be either pneumatic or non-pneumatic. The most current type used is the pneumatic tourniquet which has a cuff inflated by pressurized gas to prevent blood flow. The tourniquet machine is fitted with a regulator which controls the number of cuff pressures applied on the extremity. The pneumatic tourniquet has undergone multiple modifications over time to increase safety and efficacy.

2.2 Evolution of tourniquet in surgery.

4 B.C-1700s Primitive	1700s-1900s Non-pneumatic	1900s-1980s Early pneumatic	1980s-2000s modern tourniquet	2000s and beyond personalized

Figure 1: A diagram showing the evolution of tourniquets.

Tourniquet use dates back to the 4th century (199 BC), whereby primitive devices were used by Romans to control hemorrhage during amputation. At around 1718 a French surgeon-Petit developed a device that had an encircling strapping with a screw on the upper part, the screw would be rotated leading to the application of pressure to compress the limb and subsequently obstruct blood flow. A century and a half later (1873) Friedric Von Esmarch developed a rubber material that was wrapped around an extremity to control bleeding and exsanguinate. Pneumatic tourniquets were introduced at the start of the 20th century (1904 by Harvey Cushing) and were found to have fewer complications as compared with former tourniquets [9].

Modern tourniquet systems were introduced in the 1980s and had micro-computer processors that were capable of monitoring pressures, leakages, inflation time, and other parameters. In 2000s new personalized tourniquets were introduced and they contain microchips synchronized with SBPs and their cuff pressures fluctuate with changes in blood pressure during surgery.

2.3 Use of tourniquet in extremity surgery.

Tourniquets are basically used to decrease hemorrhage perioperatively and allow bloodless field in limb surgeries. It is a device in which different studies have shown its benefits and it is in this regard that 58% of the members of the American Association of Hip and Knee Surgeons use it during total knee arthroplasty [10].

They are also used during biers blocks whereby a tourniquet is applied at a proximal area of a limb and then local administration of local or regional anaesthesia is done through a distal vein. This helps to maintain the concentration of the injected agents at the targeted area and prevent their systemic dissemination.

Despite their extensive use, tourniquets also have side effects and applicants should be on the lookout for nerve, muscle, skin, blood vessel, and other soft tissue injuries. They are also associated with limb swelling, deep venous thrombosis, and pulmonary embolism [11, 12]. Considering these complications a lot of changes have been done to optimize tourniquet use including use of low cuff pressures, cuff size alterations, and reducing their duration of application.

Zhang et al [13] in their study were able to show that the use of a tourniquet for a short period of time was associated with good clinical outcomes with decreased limb swelling, less pain and early rehabilitation after surgery.

Use of a tourniquet also reduces the operating time [14], which has been shown that it may decrease the incidence of infections [15].

2.4 Influence of tourniquet on hemoglobin level after limb surgery

In 2017 de Barros MF et al [16] did a retrospective cohort study involving 117 patients who had undergone knee replacement surgery involving two groups whereby one used and the other did not use a tourniquet. The study aimed to establish the difference in lost blood and blood transfusions between the two groups of patients. They did compare the variation in hemoglobin

and hematocrit values during the perioperative period on both groups. The change in Hb level in group 1 was 1.44g/dl and 2.04g/dl in group 2 (P=0.025) while the change in Hct level in group 1 was 4.49 and 6.82 in group 2 (P=0.01) respectively.

In this study, patients were transfused based on clinical signs and symptoms or if their Hb level was less than 8g/dl, and in this regard, few patients were transfused in group 1(tourniquet) compared to group 2(non-tourniquet) (9.3% vs 33.3%). In this study, they noted that patients undergoing total knee replacement with a tourniquet had less change in haematometric measurements and fewer blood transfusions were done.

Tourniquets are applied to decrease blood loss and requirement for transfusions during limb amputations. Christian Wied et al in 2017 [17] did a one center cohort study of patients who had undergone transtibial amputations retrospectively between 2013 and 2015. They aimed to establish the differences in hemoglobin level and blood transfusions between two groups of patients (one which used a tourniquet and the other which didn't use) after TTA. In their study, they had a total of 74 patients whereby 38 patients were operated with a tourniquet and 36 were operated without. In their findings, there was a reduction in Hb values postoperatively in both groups when compared to preoperative values.

Also, those subjected to a tourniquet during the surgery had less intraoperative blood loss and hence less change in Hb level and were transfused 3mls/kg less blood. They concluded that using a tourniquet during TTA decreases intraoperative blood loss and therefore the proportion of transfusions done. The total blood loss was not statistically significant when both groups were compared with a P-value of 0.754.

Tai TW et al [18] carried out a prospective RCT in which 72 participants planned for TKA were included. 36 patients underwent TKA with a tourniquet and in the other 36 patients, a tourniquet was not used.

They measured the Hb and Hct levels before surgery and on days 1, 2, and 4 post-surgery. In their findings, patients who underwent TKA while not using a tourniquet had a greater reduction in Hb and Hct levels compared to patients whom a tourniquet was used. The change in Hb level was 2.6±0.9g/dl compared to 3.7±1.3 g/dl, with a P-value of <0.001.

Also, those operated with a tourniquet had less surgical time in comparison to those not subjected to a tourniquet. In their study, they found out that the rate of transfusion was the same in both groups despite changes in the other outcome parameters.

2.5 Duration of tourniquet application.

In order to prevent complications which include nerve, muscle, and skin injuries, many experts recommend that the least time applicable should be utilized during tourniquet inflation. There are no absolute figures in terms of safe tourniquet time as certain factors including patient's age, physical status, and blood supply to the extremity cause differences between subjects.

The AORN recommends that as a general rule, the duration of inflation should not be more than 1 hour for the upper extremity and 1 hour 30 minutes for the lower limb. When the tourniquet time is anticipated to be prolonged, the applicant is advised to release it after every 1 hour for 10-15 minutes to allow restoration of blood flow to the extremity.

Multiple clinical and animal studies have been done and recommendations put forward regarding the duration of tourniquet time. In view of these studies, Fitzgibbons et al in 2012 [19] did a systematic review of level 1 to level 5 studies both animal and clinical studies. The variables studied included tourniquet time, cuff inflation pressures, cuff width, injuries to muscle and nerves, metabolic abnormalities, post-operative pain, deep vein thrombosis, and other bleeding disorders. Prolonged tourniquet time was associated with increased incidence and severity of abnormalities. They recommended that inflation time should be kept at 2 hours, and if the surgery was anticipated to last more than 2.5 hours a 10 minutes deflation interval should be used at that point and each subsequent 1 hour.

The timing during which a tourniquet is applied influences perioperative blood loss and subsequently affects the hemoglobin and hematocrit levels postoperatively. Wang K et al [20] conducted an RCT to determine the effects of tourniquet use in TKA. The study included 50 participants who had undergone staged bilateral TKA and were categorized into two groups, either long duration tourniquet use (tourniquet inflated just before incision and deflated after hardening of cement with a mean duration of 54.8±6.7 minutes) or short-duration tourniquet use (inflated just before cement application and deflated after hardening with a mean time of 10.9±1.8 minutes). During the initial surgery, all patients underwent surgery using the long duration strategy then after

3 months the other method of using short duration tourniquet application was used for the opposite side TKA.

The primary outcome was changes in Hb, Hct levels, and total blood loss which was tested before surgery and on days1, 2, and 5 post-surgery. The total blood loss was determined by multiplying blood volume with the change in hematocrit [21]. In their findings, they noted that when using the long duration tourniquet strategy, the total blood loss was decreased compared to the short duration strategy with a P value=0.0411. Also the estimated blood loss intraop was decreased in the long duration tourniquet category.

Rames RD et al [22] in 2019 did a cohort study by looking at an orthopedic hospital data retrospectively of patients who had undergone TKA between November 2013 and November 2017. Participants were categorized into three groups depending on how the pneumatic tourniquet was utilized during surgery.

The first category was for participants who had the tourniquet applied throughout surgery and was only released before closure to identify and coagulate any bleeders. The second group had the tourniquet inflated just before placing cement on the implants and then deflated after the cement had cured and the third cohort was for patients whom a tourniquet was not used.

In their findings estimated blood loss during the cases were, 273mls for the no tourniquet cohort, 216mls for short tourniquet, and 99mls for long tourniquet cohort. They also evaluated the Hb index (the difference in Hb between pre and post-surgery levels) during the perioperative period. Patients in the long duration category had a lower Hb index compared to patients in the short duration tourniquet (-2.7 versus -2.9) respectively.

2.6 Tourniquet cuff inflation pressures in extremity surgery.

Since the beginning of 20th century when pneumatic tourniquets were introduced into surgery, multiple guidelines have been suggested concerning the cuff pressures required to maintain a bloodless field. These guidelines are based on studies that have looked at changes in metabolic parameters after surgery with a tourniquet use or on clinical experience. Therefore during limb surgery, studies recommend tourniquet pressures range of 250-350mmHg in adults which is adjusted to age, blood pressure, body mass index, and extremity size.

These fixed pressures have been associated with complications including pain, damage to nerves, and vessels. Therefore using the least cuff inflation pressures which are effective to provide a bloodless and clear surgical field is recommended.

Tuncali B et al in 2018 [23] did a prospective RCT comparing LOP determination and AOP estimation technique for tourniquet cuff pressure settings in patients undergoing TKA under combined spinal and epidural anesthesia (CSEA). Patients were placed into two groups, one in which cuff pressures were determined by AOP and the second group where cuff pressures were determined by LOP.

In their findings, initial tourniquet pressures were lower in group 1(182.44±14.59mmHg compared to 200.69±15.55 mmHg) in group 2 with a P value=0.000. These tourniquet pressures were lower than the routinely used fixed tourniquet pressures of 250-350mmHg or SAP+100-150 mmHg during lower limb surgery. In their conclusion, both methods of estimating cuff inflation pressures were comparable in regards to providing a bloodless and clear surgical field during TKA and no complications associated with the tourniquet use were observed intraop and post-surgery.

Levy O et al [24] did a study to evaluate the tourniquet cuff inflation pressures essential for appropriate hemostasis in the upper limb using a Doppler stethoscope. The study included 50 patients who were undergoing limb surgery with a tourniquet with the aim of determining the least tourniquet cuff inflation pressures that would achieve a bloodless and clear surgical site. They studied factors that influenced cuff pressures and the interactions between the factors. From their findings, they were able to derive an equation that was used to predict the minimum effective tourniquet pressures.

Tourniquet pressure=1.68×MAP+50. From the equation, the mean calculated pressure was 202.3±34.2mmHg which was less than the 250-300mmHg range previously used and this value provided a bloodless field.

The goal of tourniquet application is to use minimum and effective cuff pressures to provide bloodless surgery and prevent complications, especially during upper limb surgery. Different methods have been adopted to lower effective cuff pressures. In regards to this, in 2012 Sato J et al [25] did a prospective study on 120 patients who were undergoing upper limb surgery using a new tourniquet system. These tourniquets had their pressure integrated with systolic blood pressure

using an essential information microprocessor monitor and operated in real-time. They applied additional pressures of 100mmHg above SBP and a repeat time interval of 2.5 minutes.

The operating surgeon evaluated the quality of the surgical fields and rated them as either poor, fair, good, or excellent depending on whether there was blood which obscured the view or there was no blood at all present. In their findings, a total of 119 cases were deemed to be excellent and only 1 case was evaluated as poor and they had to increase the tourniquet pressure to 150mmHg due to oozing of the field. They concluded that probably this would be an ideal system since blood pressure varies during surgery and standard tourniquet systems remain on initial pressure setting throughout the surgery.

Sarfani S et al [26] did a study on patients who had undergone surgery for carpal tunnel syndrome retrospectively from June 2009- June 2012. They compared patients who had tourniquet cuff inflation pressures of 250mmHg with lower tourniquet pressures. A sample size of 432 patients was included in the study, and patients were assigned to either of the two groups depending on tourniquet inflation pressures. One group had 250mmHg and the other group had categories of cuff pressures of 125,150,175 and 200mmHg.The outcome variables of interest were breakthrough bleeding and whether tourniquet pressures were needed to be adjusted during surgery.

In their findings, both groups of cuff pressures provided excellent visualization of structures and there were no incidences of surgical site oozing. Also, there was no requirement of adjusting the cuff pressures upwards, and they recommended that surgeons may consider decreasing the cuff inflation pressures during surgeries for carpal tunnel syndrome.

2.7 Use of tourniquet in upper limb surgery.

Standard Pneumatic tourniquets are commonly used in upper extremity surgery especially for operations distal to the middle humerus. Sterling Bunnell said that “operating on a hand without a tourniquet is like trying to fix a watch in a bottle of ink” [27].

There have been some concerns as to whether tourniquets are safe to use in upper limb surgeries due to the potential risk of complications. Drolet BC et al [28] in 2014 did a retrospective study of 505 participants who had undergone upper extremity surgery under tourniquet over 1 year period. They looked at different variables including tourniquet pressures and application time. In their findings, there was no early or late tourniquet associated injuries which were isolated. They noted

that tourniquet pressures of 250mmHg or less and application time of 2 hours or less in an adult was safe in upper extremity surgeries.

Cox C et al [29] in 2010 did a brief review on the evidence underlying appropriate and safe tourniquet usage in upper limb surgery. They noted that the general rule on the use of the tourniquet regarding duration and occlusion pressures applies, and the recommendations is to use short application time (≤ 120 minutes) and low cuff pressures (≤ 250mmHg). Padding and limb exsanguination follows similar protocols as for the lower limb.

2.8 Use of tourniquets in non-orthopedic limb surgery.

Other than orthopedic surgery which accounts for the bulk of cases in which a tourniquet is applicable, this device is also used in plastic and reconstructive surgery as well as cardiovascular surgery. Some of the common surgeries which have been studied include decompression of median nerve in carpal tunnel syndrome, varicose vein surgery, and arterial bypass surgery of the extremities in peripheral vascular disease. Although they still continue to be used some relative contraindications are attached to some of these surgeries.

In view of this, Sykes TC et al in 2000 [30] carried out an RCT on 50 participants who were to undergo varicose veins surgery. Patients were randomized into two categories each with 25 participants, and in one group a tourniquet was used while the other group it was not used.

The outcome variables studied included perioperative bleeding, skin bruising, postoperative pain, patient activity, and cosmetic appearance post-surgery. In their findings, perioperative blood loss was markedly decreased in the tourniquet group with a range of 0-20 mls compared to the no tourniquet group range 20-300mls; $p < 0.01$. The duration of surgery was also reduced in the tourniquet group compared to the other group. In terms of patient pain scores and activity postop, there was no significant difference between the two groups.

Carpal tunnel release is a common procedure undertaken by plastic and reconstructive surgeons and involves releasing the median nerve which is usually trapped at the exit of the wrist as it enters the hand. Due to the complex, tiny structures, and the massive blood supply of the hand it is imperative to adopt mechanisms to provide a clear surgical field and reduce blood loss. Sasor SE et al in 2017 [31] did a retrospective study of patients who had undergone CTR between 2013 and 2016. The number of patients operated was 246 and the number of CTR done was 304.

Patients were placed into two groups, those who had a tourniquet applied and those who did not have with 90 cases having used a tourniquet. In their findings, blood loss was less in the tourniquet group compared to the non-tourniquet group. (3.16mls versus 4.25 mls) p=0.0004. Other outcome variables including surgical time, adverse effects, and demographics were not statistically significant.

2.9 Complications of tourniquet use-assessing their risk versus benefit

Despite their wide application in limb surgery, tourniquets have been linked with side effects including nerve and muscle injuries, deep venous thrombosis, thromboembolism, skin injuries, and tourniquet related pain.

Studies have shown that these harmful effects are related to improper training of personnel using the devices, using high cuff pressures, and applying the tourniquet for prolonged durations. Several guidelines have been proposed to help mitigate the complications and include training of personnel, use of low cuff pressures, decreasing application time, and proper monitoring of patients both intraoperatively and postoperatively to identify any unfavorable effects and manage them accordingly.

Sharma JP et al in 2012 [32] did a systematic review of RCTs carried out between 2000 and 2010 which looked at preoperative precautions, application procedure, proper usage, physiological changes, and complications of tourniquet use during limb surgery. 46 RCTs were retrieved and 7 were disqualified (3 were animal studies and 4 plastic surgeries). In the 39 studies which were analyzed with a total of 63,484 cases, the incidence of complications was 26 with 15 being neurological and 2 of them being permanent. They concluded that the benefit of using a tourniquet outweighs the risk and personnel should adhere to laid down guidelines to avoid the few undesirable effects.

3.0 CHAPTER THREE: STUDY JUSTIFICATION AND OBJECTIVES.

Limb surgery is a common procedure done in KNH and is associated with significant blood loss and increased blood transfusion requirements. A substantial proportion of patients undergoing limb surgery usually have a tourniquet applied to reduce blood loss, especially those with borderline Hb levels. These patients are not routinely followed up to determine how their hemoglobin level changes after surgery, and whether their Hb level drops below the threshold for transfusion.

Patients going for limb surgery always have a preoperative hemoglobin level checked. But they do not have this haematometric test done postoperatively. Therefore, total blood loss during surgery cannot be determined objectively.

Besides, patients undergoing limb surgery whilst using a tourniquet may be transfused based on the estimation of intraoperative blood loss or clinical signs and symptoms: No objective markers of blood level changes are checked postoperatively to determine the patient status. This may lead to scenarios like patients getting only a single unit of blood, for which studies have revealed not to be necessary [33].

Blood products are critical in patient care. But they are limited in supply, they are costly, and they carry numerous risks [34]. Therefore, a combination of clinical signs and symptoms with a hemoglobin level would help minimize wastage and unnecessary transfusions.

No studies have been done in KNH to establish whether using a pneumatic tourniquet during limb surgery adequately reduces the changes in hemoglobin levels postoperatively. Many studies done locally and internationally focused on non-trauma related procedures, so it was imperative to have a study looking into trauma-related surgeries.

3.1Research Question

What is the influence of arterial tourniquet applied during limb surgery on postoperative hemoglobin level at KNH?

3.2 Study Objectives

3.2.1 Broad Objective

To determine the influence of arterial tourniquet applied during limb surgery on postoperative hemoglobin level at Kenyatta National Hospital.

3.2.2 Specific Objectives:

1) To determine the pre-operative Hb levels of patients undergoing limb surgery with a tourniquet at KNH.
2) To establish the cuff inflation pressures of tourniquets in patients undergoing limb surgery at KNH.
3) To determine the duration of tourniquet application during limb surgery at KNH.
4) To determine the post-operative changes in Hb levels of patients undergoing limb surgery with a tourniquet at KNH.

4.0 CHAPTER FOUR: RESEARCH METHODOLOGY

4.1 Study Design

The study design was a hospital-based prospective observational study.

4.2 Study Area and Setting

Kenyatta National Hospital; orthopedic wards, plastic ward, trauma and main theatres. Patients scheduled for limb surgery, whether elective or emergency, were prepared for theatre by having a full blood count and grouping and cross-matching done. Also, some units of blood were ordered and other strategies aimed at reducing blood loss including the use of a tourniquet were considered.

4.3 Study Population

All patients who underwent limb surgery in KNH main and trauma theatres where a tourniquet was applied and who met the inclusion criteria.

4.4 Inclusion Criteria

- Patients scheduled to undergo limb surgeries who gave consent to participate in the study.
- Patients who presented with unilateral limb condition in which a pneumatic tourniquet use was anticipated for surgical intervention.
- American Society of Anesthesiologists Classification (ASA Class) 1 and 2 patients scheduled to undergo limb surgery.

4.5 Exclusion Criteria:

- Patients scheduled to undergo limb surgeries who declined to give consent to participate in the study.
- Patients scheduled to undergo limb surgeries in whom a non-pneumatic tourniquet was used.
- Patients scheduled to undergo limb surgeries but were on anticoagulants preoperatively.
- Patients scheduled to undergo limb surgeries but had blood dyscrasias.
- Patients scheduled to undergo limb surgeries but had severe peripheral vascular disease.
- Patients scheduled to undergo limb surgeries but had uncontrolled or poorly controlled diabetes mellitus or hypertension.

4.6 Sample Size Calculation.

The sample size was determined using the formula for mean estimation as follows;

$$\boldsymbol{n = \frac{z^2\sigma^2}{d^2}}$$

Where,

- *z* is the critical value in standard normal distribution at α-level of significance (α=0.05 or 1.96 for 95% confidence level);
- *σ* is the standard deviation of the characteristic being measured. Two studies demonstrated calculated cuff inflation pressures of 202.3 ± 34.2 mmHg and 155 ± 38.7mmHg using LOP measurements for the upper limb (24), (35).
- *σ* = 36.45 (average of the two standard deviations)
- *d* is the desired margin of error (±8mmHg); one study showed that the mean difference of cuff pressures of a standard method of measuring LOP for the upper limb was ±8mmHg.(36)

Using our factors for the population, and solving for the sample size equation, we find;

$$n = \frac{1.96^2 * 36.45^2}{8^2} = 80 \text{ participants}$$

4.7 Participant Sampling

The sampling procedure was systematic sampling. This was by selecting every alternate participant from organized theatre lists starting from number 1 until the desired sample size was achieved. For example, if on a certain day the number of patients undergoing limb surgery with a tourniquet was six, following in order we selected numbers 1, 3, and 5 respectively.

4.8 Study procedure

Participants were recruited as they arrived in the main and trauma theatres waiting areas at KNH. All patients undergoing extremity surgery where a tourniquet was applicable and met the inclusion criteria were offered a chance to be involved in the research. The aim of the research was explained to the participant or their representatives in a language that they understood and they were given the consent form to read for themselves and any questions raised were answered.

Participants who agreed to be involved in the study were required to append their signatures at the end of the consent. Participants who were below the age of 18 years had their parents or guardians or a legally authorized representative give consent on their behalf. After signing the consent their biodata was entered into a questionnaire and their diagnosis and type of surgery was recorded from the file and theatre list.

A spot hemoglobin level was done during cannula fixation. Intraoperative the type of anaesthesia, use of a tourniquet, cuff pressures applied, tourniquet time and blood transfusion were all recorded from the anaesthetic chart. Patients were followed up in the wards whereby a repeat spot hemoglobin was done on day 2 post-op.

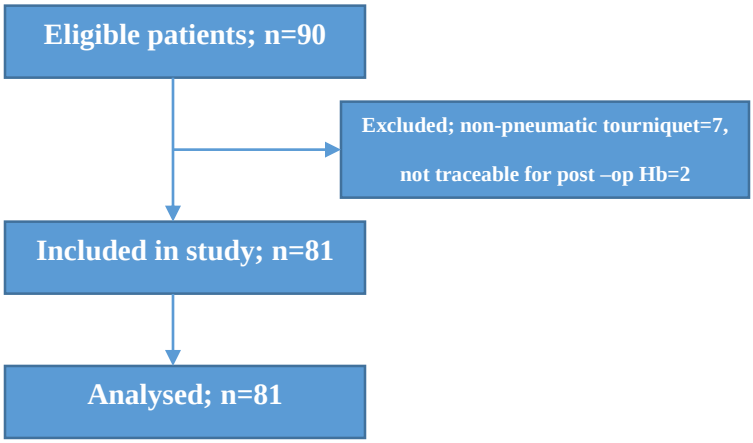

Figure 2: A flow chart of included and excluded participants

4.9 Hemoglobin level determination.

Following a written consent preoperative and postoperative Hb was determined by using a portable hemoglobin meter (Mission plus Hb; Hb Hemoglobin Testing System, Acon biotech San Diego USA). It has a range of Hb measurement of 4.5g/dl-25.6 g/dl, it is accurate and has been validated to be used at a point of care testing, (37, 38).

It is a portable device that uses a strip inserted on a slot and a drop of blood put on it with a reading time of less than 15 seconds. It also has a control solution that calibrates the machine and to ensure accuracy this was done in conjunction with the hematology lab. Preoperatively sample was taken from the cannula site while postoperatively it was taken from a finger prick.

4.10 Study duration

The study took a duration of 10 weeks from November 2020 to January 2021.

4.11 Data management and analysis

An electronic data capture, Research Electronic Data Capture (REDCap) was used whereby the questionnaire was coded and data uploaded into it. A username and password which were both specific and personal were used by the principal investigator and research assistant to input data by logging in.

The electronic questionnaire each with a label was moved into a Microsoft Access document created for the study. Data were exported into Statistical Package for Social Services (SPSS) Version 21 for further cleaning and analysis. The pre-operative Hb, cuff inflation pressures of tourniquets and duration of tourniquet application of patients undergoing limb surgery with a tourniquet at KNH were analyzed as means with standard deviation. Post-operative changes in Hb levels of patients undergoing limb surgery with a tourniquet at KNH were analyzed with the use of a Paired t-test. Statistical significance was defined as a p-value of less than 0.05.

During the study period, participants were identified by codes with no names recorded and the electronic data were kept in a safe cloud store and at the end of the project, it was given to the UoN/KNH ERC office. After completion of the study the unprocessed data in the REDCap application, soft copies in hard discs, computers, hard copy documents were destroyed by deletions, formatting of devices, and shredding as per UoN/KNH ERC instructions.

4.12 Data presentation

The distribution of data were presented as graphs. For categorical data, pie charts and bar charts were used while numerical data were presented using tables.

4.13 Ethical Considerations

Authority to conduct the research was obtained from Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee before beginning the study. Participants were enrolled after the nature of the study had been explained to them and a written informed consent obtained. Study subjects who declined to give consent or who decided to leave the study at any point were allowed to do so without victimization or compromise to their level of care. Confidentiality was maintained at all stages of the study and any complications were promptly and appropriately managed together with other caregivers. No additional costs were incurred by the participants.

5.0 CHAPTER FIVE: RESULTS

5.1 Introduction.

The results of the study are presented in this chapter. The broad objective of the study was to evaluate the influence of arterial tourniquet applied during limb surgery on postoperative hemoglobin levels at Kenyatta National Hospital.

5.2 Study Participants Characteristics.

The mean age of the participants was 34.6 (SD 14.4) years, and the youngest age was 8.0 years, while the oldest was 70.0 years. Majority of participants were aged between 36-45 years 24 (29.6%), with those aged less than 18 years being 9 (11.1%) and those above 55 years were 7 (8.6%). There were 65 (80.2%) male and 16 (19.8%) female participants.

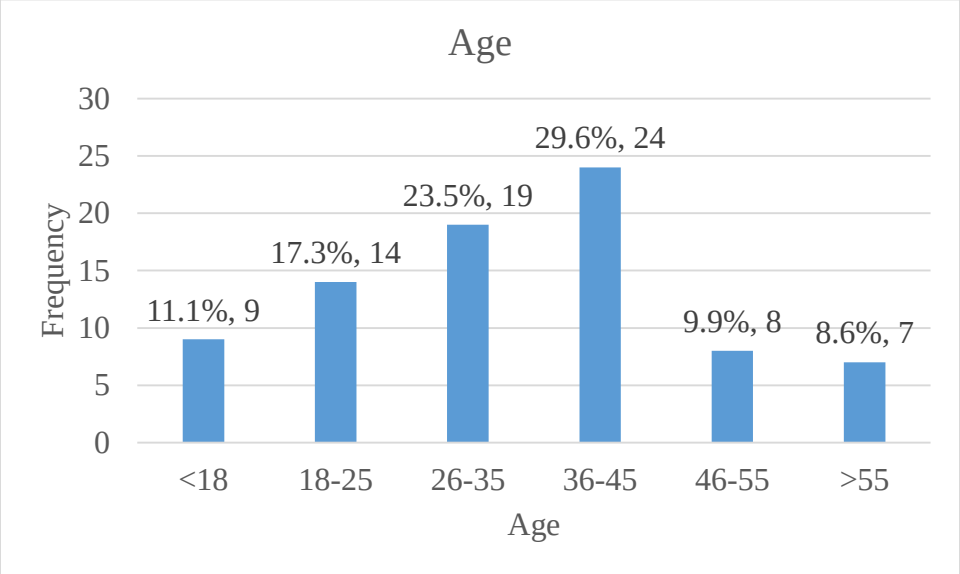

Figure 3: bar graph showing the age of the participants.

Majority of the patients had orthopedic conditions accounting for 85.2% while 14.8% had other non-orthopedic conditions.

Non-orthopedic cases included amputations, contracture release for burns patients, and tendon repairs. Majority of the patients were ASA 1 (figure 3).

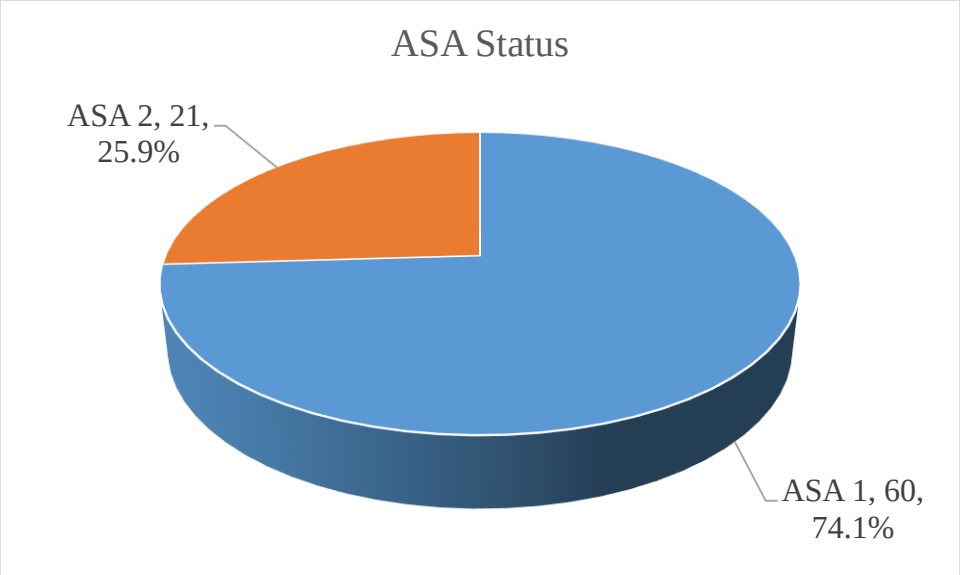

Figure 4: Pie chart on ASA status of the participants

81.5% of the surgeries were performed as electives while 18.5% were done as emergencies.

Majority of the participants (96.3%) had a hemoglobin level of more than 10g/dl with only 3.7% of patients having a hemoglobin level less than 10g/dl (Table 1 below).

Table 1: A table of preoperative Hb Levels of Participants

Preoperative	Frequency (n)	Percent (%)
<10.0	3	3.7
10.0-12.0	27	33.3
>12.0	51	63.0

The mean preoperative hemoglobin level was 12.5 (SD 1.5) g/dl in male participants while in the female patients it was 12.6(SD 1.7) g/dl (Table 2) and its distribution is as shown in the scatter diagram below (Figure 4).

Table 2: A table showing the comparison of male and female preoperative Hb level

	Frequency	Mean	SD
Male	65	12.5	1.5
Female	16	12.6	1.7

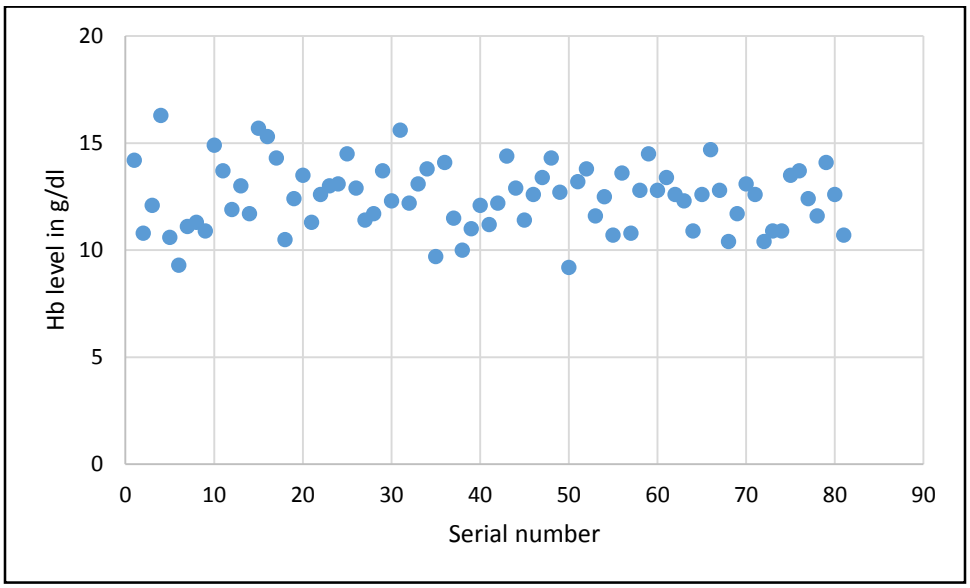

Figure 5: Scatter diagram of preoperative Hb levels.

An independent-sample t-test was run to determine if there were differences in the preoperative Hb levels between the males and female patients. The mean difference of 0.1 (95% CI, -0.7 to 1.0) was not statistically significant (p = 0.679).

5.3 Intraoperative tourniquet use parameters.

Intraoperatively the site of tourniquet application, duration of surgery, inflation pressures utilized and their basis were established and recorded as shown in table 3 below.

Table 3: A table of intraoperative tourniquet use.

Placement (n=81)	Frequency (n)	Percentage (%)
Arm	24	29.6
Forearm	4	4.9
Wrist	1	1.2
Thigh	52	64.2
Time (Upper limb, n=29)		
≤ 60	12	41.4
61-90	9	31.0
≥91	8	27.6
Time (Lower limb, n=52)		
≤ 90	30	57.7
91-120	17	32.7
≥121	5	9.6
Deflation (n=81)		
Before skin closure	74	91.4
After skin closure and dressing	7	8.6
Cuff pressure (Upper limb, n=29)		
<200	6	20.7
201-250	21	72.4
≥251	2	6.9
Cuff pressure (Lower limb, n=52)		
<300	21	40.4
301-350	30	57.7
≥351	1	1.9
Basis (n=81)		
Fixed	14	17.3
Systolic blood pressure	67	82.7

All lower limb surgeries were performed with the tourniquet application done on the thigh while for the upper limb it was applied on different locations with the most preferred site being the arm, forearm, and wrist in that order.

The mean cuff inflation pressures for the upper limb was 240.7 (SD 25.2) mmHg, with the lowest cuff pressures being 180mmHg and the highest inflation pressures were 280mmHg. Majority of participants (72.4%) had cuff inflation pressures of between 201-250mmHg.

For the lower limb, the mean cuff inflation pressure was 322.4 (SD 38.1) mmHg, with a range of (213-380mmHg). 57.7% of participants had cuff inflation pressures of (301-350mmHg) with only 1.9% having cuff pressures of more than 351mmHg.

In majority of the patients 67 (82.7%) the cuff inflation pressures were based on systolic blood pressure while in 14 (17.3%) of the cases, fixed pressures of between 250-350mmHg were used.

Tourniquet deflation was done before skin closure in 91.4% of the participants while in the remaining 8.6% it was deflated after skin closure and application of dressing.

For the upper limb, the mean inflation time was 76.6 (SD 37.0) minutes with a range of (20-150 minutes). 41.4% of participants had a tourniquet application time of less or equal to 60minutes, while in 31% of participants it was applied for between 61-90 minutes. In 27.6% the application time was more than 91 minutes with 4 patients with an application time of more than 120 minutes.

During lower limb surgery 90.4% of participants had the tourniquet applied for less than 120 minutes while in 9.6% had it applied for more than 120 minutes. The shortest application time for the lower limb was 21 minutes while the longest inflation time was 149 minutes and the mean time was 89.2 (SD 32.3) minutes.

Anaesthesia Technique

Spinal anaesthesia was the commonly used method for anaesthesia accounting for 59.3% of all cases while general anaesthesia was used in 27.2%. Regional and combined general anaesthesia and regional block accounted for 11.1% and 2.5% respectively.

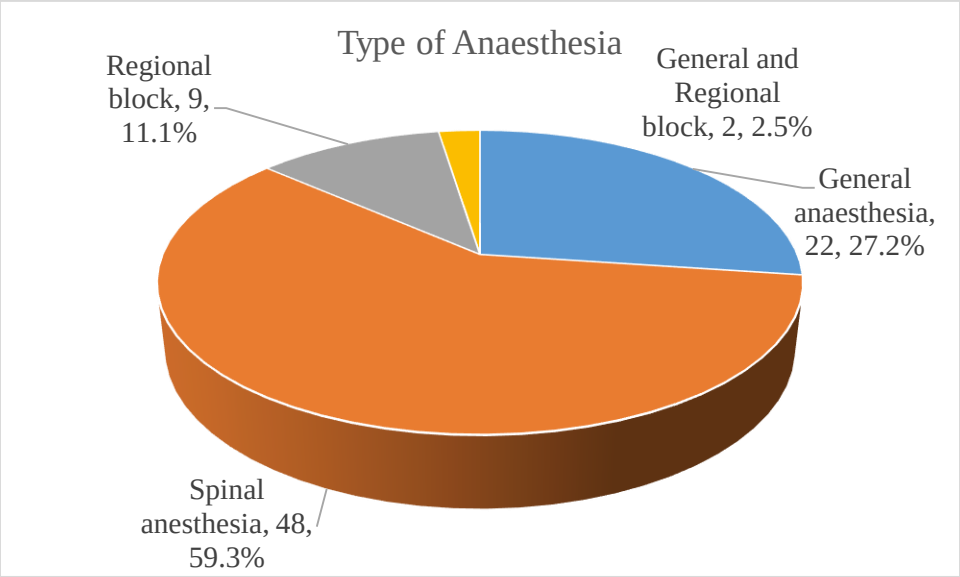

Figure 6: Pie chart on the technique of anaesthesia used.

5.4 Perioperative conditions including blood loss and transfusion, fluids used, and duration of surgery.

The quantity and type of perioperative fluids utilized, blood loss and transfusions done, and duration of surgery were determined and recorded as shown in table 4 below.

Table 4: A table showing intraoperative fluid use, blood loss, duration of surgery, and blood transfusion.

Crystalloids	**Frequency (n=81)**	**Percentage (%)**
<500	2	2.5
500-1000	22	27.2
1001-1500	32	39.5
≥1501	25	30.9
Colloids		
<500	2	
500-1000	3	
1001-1500	1	
Estimated blood loss		
<100	14	17.3
100-300	52	64.2
301-500	10	12.3
≥501	5	6.2
Duration of surgery (mins)		
<60	16	19.8
60-120	55	67.9
121-180	9	11.1
≥181	1	1.2
Transfused		
Yes	4	4.9
No	77	95.1
Blood product		
1 whole blood	2	50.0
2 packed cells	2	50.0
Transfusion reason		
1 low preoperative Hb	2	50.0
2 increased intra-op bleeding	2	50.0

Intraoperatively, crystalloids were used in all patients with the majority receiving a volume of between 1000-1500 mls of fluid 32 (39.5%). Colloids were only used in 6 (7.4%) patients. 14(17.3%) patients had an intraoperative blood loss of less than 100mls, while 5(6.2%) had blood loss of 500mls or more with a majority of participants, 52(64.2%) having an estimated blood loss of 100-300mls.

4 patients were transfused with two receiving whole blood while the other two received packed cells. Among those transfused, two had borderline preoperative Hb level (10.2 and 10.7 g/dl), while the other two had increased intraoperative bleeding (estimated blood loss of 500 and 600mls).

Other methods of reducing blood loss

Tranexamic acid was used in 34.6% of participants with the majority getting a dosage of 1000mg (Table 5 below).

Table 5: A table showing other methods used to reduce blood loss.

Tranexamic acid	**Frequency (n=81)**	**Percentage (%)**
Yes	28	34.6
No	53	65.4
Dosage	**Frequency (n=28)**	**Percentage (%)**
500	3	10.7
1000	25	89.3

5.5 Postoperative Hb levels and their correlation with pre-op Hb and surgical duration.

3.7% of the participants had a postoperative Hb level of less than 7 g/dl while a 33.3% had an Hb level of between 7-10 g/dl and the majority 63% had an Hb more than 10g/dl (Table 6 below).

Table 6: A table showing postoperative Hb levels.

Postoperative	Frequency	Percent
<7.0	3	3.7
7.0-10.0	27	33.3
>10.0	51	63.0

A paired-samples t-test was run to determine if there were differences in the mean Hb levels preoperatively and postoperatively (Table 7 and Figure 6). The mean difference of 2.0 (95% CI, 1.6 to 2.2) was statistically significant (p <0.001).

Table 7: A table showing pre-op and post-op Hb level paired analysis.

	Frequency	Mean	SD	MD	P value
Preoperative Hb level	81	12.5	1.5	2.0	p <0.001
Postoperative Hb level	81	10.5	1.7		

A line graph showing the change between preoperative and postoperative hemoglobin levels was drawn as shown in figure 6 below.

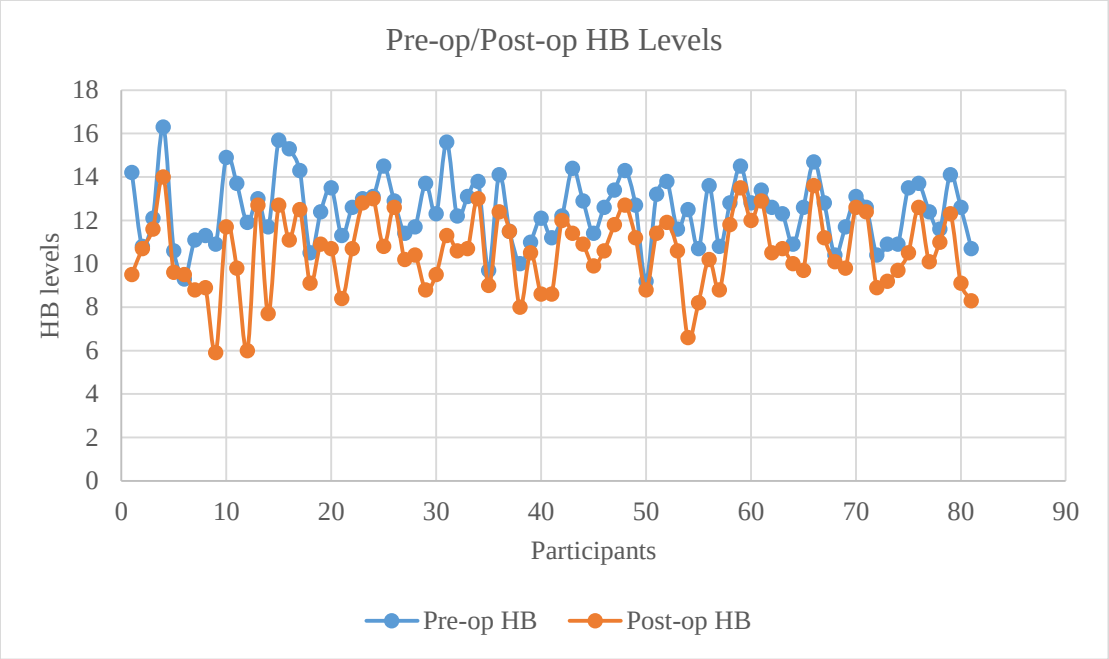

Figure 7: A line graph showing the relationship between pre-op and post-op Hb levels.

The Pearson correlation for the difference in the pre and post-Hb levels and the duration of surgery indicates a negative and weak relationship (r = -0.033, p=0.769), as shown in Figure 7 below.

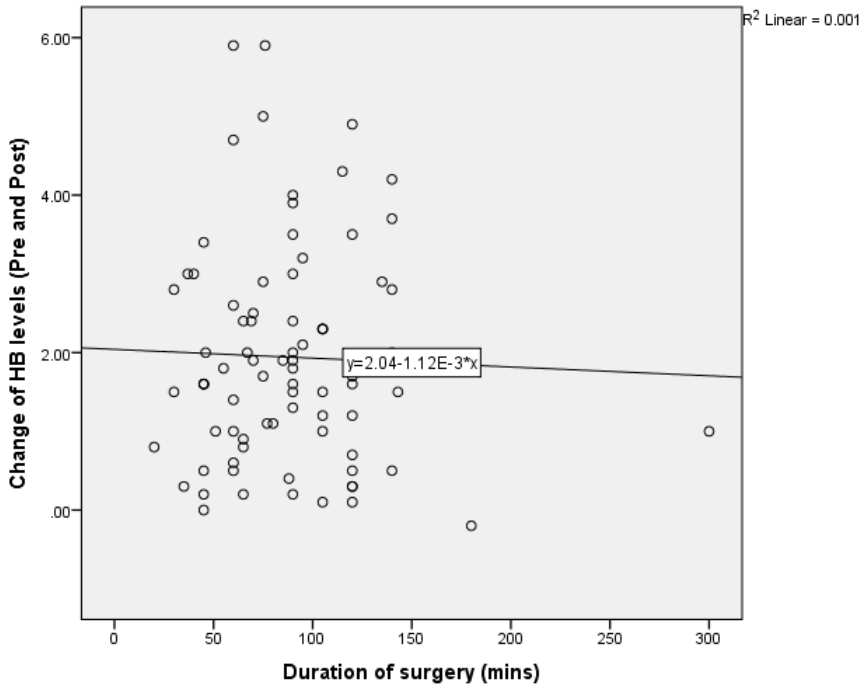

Figure 8: Relationship between duration of surgery and change in Hb level (pre/post).

6.0. CHAPTER SIX: DISCUSSION.

Limb surgeries account for a significant surgical burden, especially in low and middle-income countries. The majority of these surgeries are trauma-related and occur mainly in young and middle-aged adults due to road traffic accidents. They are also actively involved in sporting activities.

These surgeries are associated with significant blood loss and hence the tourniquet has been in use more so actively since the 20th century in an attempt to decrease blood loss perioperatively. Increased clinical evidence surrounding the usefulness of a tourniquet to reduce blood loss, its modifications to increase safety and reduce complications have been topics of discussion in the literature. [5, 10, 13]

In this study, there was a higher number of male patients than female patients, (80.2% male vs.19.8% females). This was probably due to the fact that most participants were orthopedic patients with trauma-related conditions. This was similar to the results obtained in other studies [39, 40] which showed male dominance. We attribute this to the fact that more males than females are engaged in high-risk physical activities which predispose them to high energy trauma.

The ages of the study participants were normally distributed and ranged from 8 years to 70 years. Majority of participants were aged between 36-45 years (29.6%). This comprises people in young adulthood who are extremely active and involved in multiple high-risk activities including sports, construction, and motorcycling which predisposes them to increased risk of injuries.

The mean preoperative hemoglobin level was 12.5 (SD 1.5) g/dl in male participants while in the female patients it was 12.6(SD 1.7) g/dl. The majority of the participants (96.3%) had a hemoglobin level of more than 10g/dl with only 3.7% of patients having a hemoglobin level less than 10g/dl. This can be attributed to the fact that majority of the surgeries were done as elective (81.5%) and most patients are usually worked up pre-operatively. It may also be possible that many patients with hemoglobin levels less than 10g/dl were not included in the elective lists due to the previous practices where only patients with hemoglobin levels of 10g/dl or higher are considered fit for elective surgery. Also, this hemoglobin level is considered normal for a large proportion of the Kenyan population. [41] A similar study done in Mulago hospital in Uganda by Kajja et al [42] showed a similar preoperative Hb level.

Since the introduction of pneumatic tourniquets at the beginning of the 20th century, multiple guidelines have been suggested regarding the cuff pressures needed to achieve a clear surgical field. These guidelines are based on human and animal surveys that have looked at changes in metabolic parameters after surgery with a tourniquet use or on clinical experience. Existing literature has recommended a tourniquet pressures range of 250-350mmHg during limb surgery in adults which is adjusted to systolic blood pressure, limb size, body mass index, and age. These fixed pressures have been associated with complications including damage to nerves, vessels, and tourniquet pain. Thus, the recommendation is to use the least cuff inflation pressures which are effective to provide a bloodless and clear surgical field.

In this study, the mean cuff inflation pressures for the upper limb was 240.7 (SD 25.2) mmHg with a majority of participants (72.4%) having cuff inflation pressures of between 201-250mmHg. This is similar to other studies conducted in United States Universities of Stamford and Rhode island hospital by Drolet BC and Cox C et al respectively [28, 29] which have shown that during upper limb surgery with a tourniquet, using cuff pressures of 250mmHg or less is effective to provide a bloodless surgical field and it is also safe with no early or late tourniquet associated complications identified.

For the lower limb surgeries, the mean cuff inflation pressures was 322.4 (SD 38.1) mmHg, with a range of (213-380mmHg). These cuff pressures are extremely high as compared to other studies [23, 24] which have used the LOP, AOP, and Doppler stethoscope methods of determining cuff inflation pressures. In the above studies, Tuncali B et al and Levy et al demonstrated that the cuff inflation pressures needed to produce a bloodless surgical field for the lower limb were less than 250mmHg.This implies that in our setup we may still be using high cuff pressures which are associated with complications rather than using recommended lower pressures which studies have shown to be effective.

In majority of the patients (82.7%) the cuff inflation pressures were based on systolic blood pressure whereby a margin of 100-150mmHg was added to the initial preoperative systolic blood pressure of the patient, while in 17.3% of the cases, fixed pressures of between 250-350mmHg were used as routinely done by some surgeons and orthopedic technicians based on experience. This means that we may be exposing participants to complications associated with high tourniquet

pressures and there is a need to familiarize and train tourniquet users on new and recommended guidelines on tourniquet use.

Tourniquet deflation was done before skin closure in 91.4% of the participants while in the remaining 8.6% it was deflated after skin closure and application of dressing. This is similar to what is recommended by AORN whereby the tourniquet is released before skin closure and dressing to help identify any bleeders for cauterization or suture ligation to minimize postoperative hemorrhage.

Many authors and experts recommend that the least time applicable should be utilized during tourniquet inflation in order to prevent complications which include nerve, muscle, and skin injuries. There are no absolute figures in terms of safe tourniquet time as certain factors including patient's age, physical status, and blood supply to the extremity cause differences between subjects. The AORN recommends that as a general rule, the duration of inflation should not be more than 1 hour for the upper extremity and 1 hour 30 minutes for the lower limb based on what is believed to be an optimal level of practice from clinical studies. When the tourniquet time is anticipated to be prolonged, the applicant is advised to release it after every 1 hour for 10-15 minutes to allow restoration of blood flow to the extremity.

In this study, for the upper limb, the mean inflation time was 76.6 (SD 37.0) minutes with a range of (20-150 minutes). 41.4% of participants had a tourniquet application time of less or equal to 60minutes, while in 31% of participants it was applied for between 61-90 minutes. 4 patients had a tourniquet time of more than 120 minutes during upper limb surgery and there was no deflation interval for some few minutes at the 2-hour mark as recommended. Although our study did not look at complications related to prolonged tourniquet time, a similar study by Drolet BC et al [28] noted that keeping tourniquet application time at 2 hours or less in an adult was safe in upper extremity surgeries.

During lower limb surgery 90.4% of participants had the tourniquet applied for less than 120 minutes while 9.6% had it applied for more than 120 minutes. The shortest application time for the lower limb was 21 minutes while the longest inflation time was 149 minutes and the mean time was 89.2 (SD 32.3) minutes.

A systemic review by Fitzgibbons et al [19] where they analyzed multiple variables during lower limb surgery with a tourniquet: tourniquet time, cuff inflation pressures, cuff width, injuries to muscle and nerves, metabolic abnormalities, post-operative pain, deep vein thrombosis, and other bleeding disorders. They recommended that inflation time should be kept at 2hours, and if the surgery was anticipated to last more than 2.5 hours a 10 minutes deflation interval should be used at that point and each subsequent 1 hour.

In this study, spinal and regional anesthesia were the most preferred method for anesthesia accounting for 70.3% of all cases. Some patients received general anesthesia and also had a nerve block especially during upper limb surgery and this accounted for 2.5%. Other studies have shown that regional and spinal anaesthesia are associated with less blood loss and hence less change in hemoglobin levels [4]. This evidence may explain why most patients received spinal and regional anaesthesia.

We found liberal intraoperative fluid administration, with crystalloids being given to all patients. The majority of the participants received a volume of between 1000-1500 mls of fluid (39.5%). Currently, there is a lot of debate on the volume and type of fluid to use intraoperatively during major surgeries or those surgeries anticipated to have increased blood loss with a tendency toward liberal perioperative fluid administration [42]. On the other arm, restrictive fluid therapy is advocated for especially in abdominal surgeries and patients with poor cardiac reserve. In addition to using liberal and restrictive fluid administration protocols, the amount of perioperative fluid to be administered should be guided by anticipated implications of anaesthetic pharmacology, positioning, thermoregulation, ventilatory support, surgical manipulation, operative site, duration, tissue trauma, and blood loss. Providing sufficient intravenous volume and pre-load is essential for adequate vital organ perfusion.

In this study, 63% of the participants had a postoperative Hb level of more than 10g/dl while in 37% of the patients, the Hb level was less than 10 g/dl. A total of four patients received a blood transfusion with the transfusion trigger being low preoperative Hb level for two patients and increased intraoperative bleeding for the other two patients. All patients received single-unit transfusions which studies have shown not to be useful in adult patients [43]. This may have been caused by an acute shortage of blood experienced during the study period as a result of the Covid 19 pandemic, such that patients got transfused based on blood availability.

In regards to blood transfusions, multiple guidelines exist: For stable patients, almost all guidelines prefer conservative transfusion triggers. The European Surgical Society's guideline states that the target for RBC transfusion is to maintain a hemoglobin of 7 to 9 g/dl and the Eastern Association for the Surgery of Trauma (EAST) guideline states that a transfusion trigger of 7g/dl is as effective as a transfusion trigger of 10g/dl. Locally, the Kenya National Guideline for Appropriate Use of Blood and Transfusion Services (KNG-AUBTS) [44] recommends that the decision to transfuse should be based on an estimate of the patient risk of developing complications of inadequate tissue oxygenation and delivery. This is based on Hb measurement, intraoperative blood loss, and clinical signs and symptoms. Following this criteria, none of the patients in this study qualified for the blood transfusion and the decision was left to the discretion of the anaesthetist. Postoperatively, three patients had Hb level of less than 7g/dl but they did not have any clinical signs and symptoms of anaemia and had hematinics prescribed as "boosters" for their Hb level.

7.0 CHAPTER SEVEN: CONCLUSIONS, RECOMMENDATIONS, AND LIMITATIONS.

CONCLUSIONS

The study revealed that although a majority of patients had a preoperative Hb level of more than 10g/dl, one-third of these patients had a low postoperative Hb level and hence the need to do a post-op Hb check so that necessary interventions can be instituted.

Also, the study revealed that during limb surgery with a tourniquet the cuff pressures were based on old methods which are either based on systolic blood pressure or fixed methods while there are modern methods that are individualized and have been shown to be more effective.

Also when it comes to the duration of tourniquet application during upper limb surgery for surgeries lasting more than 2 hours, there was no deflation interval at the 2-hour mark for 10-15 minutes as it is recommended.

Post-operatively participants had a reduction in Hb level as compared to preoperative levels, with a mean difference of 2.0g/dl and this was statistically significant with a p-value of less than 0.001.

RECOMMENDATIONS

There is a need for tourniquet users to familiarize themselves with the current guidelines on tourniquet pressures and application duration as advised by various medical association bodies and published studies.

A similar study targeting tourniquet complications will aid in setting up guidelines on maximum pressures and cut-off duration of tourniquet application in our setup.

For limb surgery there is a need for doing routine post-operative hemoglobin level as patients with low Hb level may have necessary interventions instituted before discharge.

A randomized controlled trial is required to determine the effectiveness of using a tourniquet in reducing Hb level change.

LIMITATIONS

Lack of pediatric pneumatic tourniquet cuffs in KNH may have skewed the data towards the adult population.

The absence of a control group meant that we could not establish the causal-effect relationships as biases and confounders were not taken care of. That means that the postoperative Hb level change could not be attributed to the tourniquet application alone.

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APPENDICES

Appendix I (a): Consent Form (English)

Topic: Influence of arterial tourniquet on hemoglobin level after limb surgery at KNH

Informed Consent form for _____ _____

The principal investigator is Dr. John Mwanzia under supervision from Dr. Susane Nabulindo and Dr. Timothy Mwiti intends to carry out a study looking at the influence of arterial tourniquet on hemoglobin level after limb surgery at Kenyatta National Hospital. The study will be carried under the department of Anaesthesia at the University of Nairobi.

The Form has two parts:

- Information section -to discuss about the research with you.
- Certificate of Consent -for signatures if you agree to take part in the study

Introduction

I am a student currently doing my Masters in Anaesthesia at the University of Nairobi. I am doing a study looking at the influence of arterial tourniquet on hemoglobin level after limb surgery. I will share all the information with you and feel free to ask questions before participating in the research. If there are words or terms which you do not understand, please ask me to explain as we go through the information. If you have questions later, you can ask them my contacts are available on this consent form.

Purpose of the research

Limb surgery using a tourniquet is a common procedure done in Kenyatta National Hospital. The tourniquet is applied to allow a bloodless field during surgery and to reduce blood loss. The purpose of the study is to establish the changes in Hb observed after these surgeries which is an objective marker of blood loss and also aims to establish the cuff pressures and duration of tourniquet application for the various limb surgeries done at KNH.

Risks

The study poses no risk to the participant and all information given will be treated with the utmost confidentiality.

Only some mild pain will be felt from the site of pinprick as we get the hemoglobin level.

Benefits -The study will improve patient management and follow up.

Participant selection

We invite all patients undergoing limb surgery whereby a tourniquet is applicable at Kenyatta National Hospital to participate in the research.

Voluntary Participation

Your involvement in this research is entirely voluntary as such no payment will be offered. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change. If you choose to participate in this research project, no extra cost will be incurred.

Procedure.

Description of the Process

Once consented, a set of questions will be presented to you mainly asking about your condition, explain nature of surgery, and the purpose of the study.

Duration

We will require about 10 minutes of your time, in the beginning, to gather information from you and get the initial hemoglobin level from your cannula site, then you will be followed throughout intraop and day 2 postoperatively whereby we will get a prick Hb level.

Confidentiality

We will not be sharing the identity of those participating in the research and the information that we collect from this research project will be kept confidential. The questionnaire containing your data will be put away and no one but the researchers will be able to see it and the information will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up. It will not be shared with or given to anyone except the department of Anaesthesia at the University of Nairobi and KNH.

Right to Refuse

You do not have to take part in this research if you do not wish to do so and declining to participate will not affect the services you receive in the hospital in any way.

You can ask me any more questions about any part of the research study if you wish to.

PART II: a) Certificate of Consent **Serial Number: _____**

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it which have been answered to my satisfaction. I (name) _____consent voluntarily to be involved as a participant in this research.

Name of participant_____signature_____date_____

Researcher: Dr. John Mwanzia Signature _____ date_____

Who to Contact

You may contact any of the following in case you have questions:

Name: Dr. John Mwanzia (Primary Researcher)

Mobile Number: 0723-581 672

Email: emwanzis@gmail.com

Name: Dr. Susane Nabulindo

Mobile Number: 0721-418 587

Email: nabulindosusane@gmail.com

Name: Dr. Timothy Mwiti

Mobile Number: 0721-366 294

Email: tmwiti@uonbi.ac.ke

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Kenyatta National Hospital/University of Nairobi Ethics and Research Committee

College of Health Sciences

P. O. Box 19676 00202 Nairobi

Telephone: (254-020) 2726300-9 Ext 44355

Email: uonknh erc@uonbi.ac.ke

Appendix I (b): Consent Form (Swahili)

IDHINI.

Mada; Athari ya torniketi kwenye kiwango cha hemoglobini baada ya upasuaji wa miguu na mikono katika hospitali kuu ya kitaifa ya Kenyatta.

Fomu ya idhini ya _____

Mpelelezi mkuu ni Dkt. John Mwanzia chini ya usimamizi wa Dkt. Susane Nabulindo na Dkt. Timothy Mwiti katika utafiti wa kuangalia athari ya torniketi kwa kiwango cha hemoglobini baada ya upasuaji wa miguu na mikono kwenye Hospitali ya Kitaifa ya Kenyatta. Utafiti huu unafanywa chini ya idara ya Anaesthesia katika Chuo Kikuu cha Nairobi.

Fomu ya idhini ina sehemu mbili:

- Sehemu ya maelezo -kukueleza zaidi kuhusu utafiti
- Sehemu ya idhini ama assent (Swahili) -kuweka saini ikiwa unakubali kushiriki utafiti.

Utangulizi

Mimi ni Mwanafunzi katika Chuo Kikuu cha Nairobi, ninasomea shahada kuu kwenye idara ya Anaesthesia. Ningependa pamoja na wasimamizi wangu kufanya utafiti wa athari ya torniketi kwa kiwango cha hemoglobini baada ya upasuaji wa miguu na mikono .Maelezo zaidi utapewa kuhusu mada hii na pia una uhuru kuuliza maswali yoyote kabla ya kushiriki katika utafiti.

Ikiwa una maswali baadaye, unaweza kuyauliza kupitia nambari ya simu yangu ambayo inapatikana kwenye hii fomu.

Kusudi la utafiti

Upasuaji wa mguu na mikono kwa kutumia kifaa cha torniketi ni utaratibu wa kawaida unaofanywa katika Hospitali ya Kitaifa ya Kenyatta .Torniketi ni kifaa ambacho hutumika wakati wa upasuaji ili kupunguza upotezaji wa damu. Madhumuni ya utafiti ni kuchuguza mabadiliko katika kiwango cha hemoglobini baada ya upasuaji, ambayo ni njia mwafaka ya kujua idadi kamili ya damu inayopotea baada ya upasuaji. Pia inakusudia kuchuguza kiwango cha presha na muda ambao kifaa hicho hutumika wakati wa upasuaji wa miguu na mikono katika hospitali Kuu ya Kenyatta.

Hatari

Hakuna hatari yoyote itakayotarajiwa utakaposhiriki utafiti huu.

Faida-Utafiti utaboresha huduma kwa wagonjwa baada ya upasuaji.

Wanaoalikwa kujihusisha na utafiti

Mtafiti anawaalika wagonjwa wote wa upasuaji wa miguu na mikono ambapo kifaa cha torniketi kitatumika katika Hospitali ya Kitaifa ya Kenyatta.

Kushiriki.

Kushiriki katika utafiti huu ni kwa hiari na kwa hivyo hakuna malipo yatakayotolewa. Ikiwa hungependa kushiriki, uamuzi huu hautakuathiri kwa njia yoyote vile utakavyohudumiwa. Ukichagua kushiriki hamna gharama zozote utakazotozwa juu ya utafiti

Maelezo ya Mchakato

Iwapo utakubali kushiriki, maswali kadhaa yatawasilishwa kwako kuhusu hali yako, kufafanua zaidi juu ya upasuaji na madhumuni ya utafiti ambayo yatajazwa kwenye fomu.

Muda

Tutahitaji dakika kumi kupata ujumbe kutoka kwako na tupime kiwango cha damu alafu tutakuja kwa wodi yako baada ya siku mbili kukupima damu tena.

Usiri

Matokeo ya utafiti huu yatawekwa siri. Habari yoyote kuhusu wewe itakuwa na nambari juu yake badala ya jina lako. Watafiti tu ndio watajua nambari yako na matokeo yatazungumziwa na idara ya Anaesthesia pekee.

Haki ya Kukataa

Kushiriki utafiti huu ni kwa hiari na iwapo haungependa kushiriki uamuzi wako hautaathiri matibabu yako kwa njia yoyote.

Pendekezo hili limeangaliwa na kuidhinishwa na idara ya Anaesthesia katika Chuo Kikuu Cha Nairobi na kamati ya maadili ya utafiti ya Kenyatta inayohakikisha kuwa haki.

SEHEMU YA PILI: a) Shahada ya idhini

Nambari maalum_____

Nimesoma maelezo yote yaliyotangulia ya utafiti, au nimesomewa maelezo haya na nimepata nafasi ya kuuliza maswali ambayo yamejibiwa kwa njia mwafaka. Mimi (jina) _ _____ niko na hiari ya kushiriki katika utafiti huu.

Jina la Mshiriki_____sahihi_____tarehe_____

Mtafiti Mkuu Dkt John Mwanzia Sahihi _____ tarehe_____

Ukiwa unataka maelezo zaidi unaweza kuwasiliana na watu wafuatao kupitia anwani na nambari za simu zilizoandikwa hapa chini.

Jina: Dkt. John Mwanzia (Mtafiti wa Mkuu)
Nambari ya simu: 0723-581 672
Barua pepe: emwanzis @ gmail.com

Jina: Dkt. Susane Nabulindo
Nambari ya simu: 0721-418 587
Barua pepe: nabulindosusane@gmail.com

Jina: Dkt. Timothy Mwiti
Nambari ya simu: 0721-366 294
Barua pepe: tmwiti @ uonbi .ac.ke
.

Hospitali ya Kitaifa ya Kenyatta / Chuo Kikuu cha Nairobi Kamati ya Maadili na Utafiti
Chuo cha Sayansi ya Afya
PO Box 19676 00202 Nairobi
Simu: (254-020) 2726300-9 Ext 44355
Barua pepe: uonknh erc@uonbi.ac.ke

Appendix II (a): Assent Form (English

TOPIC; The influence of arterial tourniquet on hemoglobin level after limb surgery at KNH

Informed Assent Form for _____

This informed assent form is for participants above 7 years and below 18 years of age who will undergo limb surgery under a tourniquet at Kenyatta National hospital main and trauma theatres. The principal investigator is Dr. John Mwanzia under supervision from Dr. Susane Nabulindo and Dr. Timothy Mwiti on a study looking at the influence of arterial tourniquet on hemoglobin level after limb surgery at Kenyatta National Hospital. The study is being done under the department of Anaesthesia at the University of Nairobi.

This Informed Assent Form has two parts:

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

I am a student currently doing my Masters in Anaesthesia at the University of Nairobi. I am doing a study looking at the influence of arterial tourniquet on hemoglobin level after limb surgery. Information will be given to you and you may feel free to ask questions before participating in the research.

There may be some words that you do not understand, please ask me to explain as we go through the information. If you have questions later, you can ask them my contacts are available on this assent form.

Purpose: Why are you doing this research?

Tourniquet use during limb surgery is a common practice done in KNH. The tourniquet is applied to reduce blood loss, therefore determining hemoglobin level post-operatively would help determine the device's influence on hemoglobin changes.

Choice of participants: Why are you asking me?

We want to get some information from children undergoing limb surgery with a tourniquet.

Participation is voluntary: Do I have to do this?

You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, it is okay and nothing changes.

I have checked with the child and they understand that participation is voluntary _____ (signature)

Procedures: What is going to happen to me?

If you allow us we are going to ask you some questions and also get a hemoglobin level from you now and 48hours after the surgery.

I have checked with the child and they understand the procedures _____ (signature)

Risks: Is this bad or dangerous for me?

You will not be in any harm when you take part in this research only some mild pain from the pinprick site.

I have checked with the child and they understand the risks and discomforts ____ (signature)

Benefits: Is there anything good that happens to me?

Nothing might happen to you, but the information you give us might help us learn more about the use of a tourniquet to reduce blood loss in limb surgery.

I have checked with the child and they understand the benefits_____ (Signature)

Reimbursements: Do I get anything for being in the research?

Unfortunately, there will be no gifts if you choose to participate in the study.

Confidentiality: Is everybody going to know about this?

We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study.

Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone.

Sharing the Findings: Will you tell me the results?

When we are finished with the research we will not contact you personally to give you the results but you can come to find out about the research at the Department of Anaesthesia, University of Nairobi. We will be telling more people, scientists, and others, about the research and what we found. We will do this by writing and sharing reports.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You do not have to be in this research. No one will be mad or disappointed with you if you say no. It's your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.

Who to Contact: Who can I talk to or ask questions to?

You can ask me questions now or later. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone else that you know like your teacher or doctor or auntie, that's okay too.

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the research study if you wish to. Do you have any questions?

PART II: Certificate of Assent **Serial Number: _____**

I understand that this research is about finding out the influence of a tourniquet on hemoglobin level after limb surgery and I will be asked a set of questions if I choose to participate in the research.

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have <u>NOT</u> signed the assent below._____ (initialed by child/minor)

<u>Only if child assents:</u>

Print name of child _____

Signature of child: _____ Date: _____

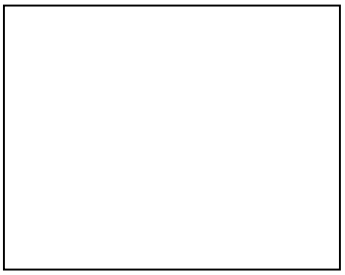
If illiterate:

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent) _____ AND Thumb print of participant

Signature of witness _____

Date _____



I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Name of researcher: Dr. John Mwanzia

Signature of researcher_____ Date_____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the purpose and procedure of the study

I confirm that the participant was allowed to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Name of Researcher: Dr. John Mwanzia

Signature of Researcher _____ Date _____

Copy provided to the participant _____ (initialed by researcher)

Parent/Guardian has signed an informed consent: Yes_____ No_____

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Name: Dr. John Mwanzia (Primary Researcher)
Mobile Number: 0723-581 672
Email: emwanzis@gmail.com

Name: Dr. Susane Nabulindo
Mobile Number: 0721-418 587
Email: nabulindosusane@gmail.com

Name: Dr. Timothy Mwiti
Mobile Number: 0721-366 294
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College of Health Sciences
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E-mail: uonknh_erc@uonbi.ac.ke

Appendix II (b): Assent Form (Swahili)

MADA; Athari ya torniketi kwenye kiwango cha hemoglobini baada ya upasuaji wa miguu na mikono katika hospitali kuu ya kitaifa ya Kenyatta.

Fomu ya kutiwa saini na washiriki walio na umri wa juu ya miaka 7 na chini ya miaka 18

_____

Fomu hii ni ya kutiwa saini na washiriki wenye umri wa juu ya miaka saba na chini ya miaka kumi na nane wanao hudumiwa kwa upasuaji wa miguu na mikono kwa kutumia torniketi. Mpelelezi mkuu ni Daktari John Mwanzia chini ya usimamizi wa Daktari Susane Nabulindo na Daktari Timothy Mwiti katika utafiti wa kuangalia athari ya torniketi kwa kiwango cha hemoglobini baada ya upasuaji. Utafiti utafanyika chini ya Idara ya Anaesthesia katika Chuo Kikuu cha Nairobi.

Hii fomu ya kutiwa saini na watoto ina sehemu mbili:

- **Sehemu ya Maelezo (kukuelezea zaidi kuhusu utafiti)**
- **Shahada ya Kutiwa saini na watoto (sahihi ikiwa umekubali kujihusisha na utafiti huu)**

Utapewa nakala ya maalezo ya utafiti huu.

SEHEMU YA I: Maelezo

Mimi ni mwanafunzi katika chuo kikuu cha Nairobi, ninasomea shahada kuu kwenye Idara ya Anaesthesia. Ningependa pamoja na wasimamizi wangu kutafiti athari ya torniketi kwa kiwango cha damu baada ya upasuaji wa miguu na mikono katika hospitali ya kitaifa ya Kenyatta. Kando na haya utapewa maalezo zaidi kuhusu mada na pia una uhuru wa kuuliza maswali yoyote ili kuelewa uafiti huu zaidi.

Kusudi la utafiti

Upasuaji wa mguu na mikono kwa kutumia kifaa cha torniketi ni utaratibu wa kawaida unaofanywa katika Hospitali ya Kitaifa ya Kenyatta .Torniketi ni kifaa ambacho hutumika wakati wa upasuaji ili kupunguza upotezaji wa damu. Madhumuni ya utafiti ni kuchuguza mabadiliko katika kiwango cha hemoglobini baada ya upasuaji, ambayo ni njia mwafaka ya kujua idadi kamili ya damu inayopotea baada ya upasuaji. Pia inakusudia kuchuguza kiwango cha presha na muda ambao kifaa hicho hutumika wakati wa upasuaji wa miguu na mikono katika hospitali Kuu ya Kenyatta.

Hatari

Hakuna hatari yoyote itakayotarajiwa utakaposhiriki utafiti huu.

Faida-Utafiti utaboresha huduma kwa wagonjwa baada ya upasuaji.

Nimethibitisha kuwa mtoto ameelewa faida ya utafiti _____ (saini)

Wanaoalikwa kujihusisha na utafiti

Mtafiti anawakaribisha wagonjwa wote watakaofanyiwa upasuaji wa miguu na mikono kwa kutumia torniketi katika hospitali ya kitaifa ya Kenyatta.

Kushiriki

Kushiriki utafiti huu kutakuwa kwa njia ya kujitolea na kwa hivyo hakuna malipo yoyote atakayolipwa mshiriki wa utafiti huu. Iwapo hungependa kushiriki, uamuzi huu hautaathiri kwa njia yoyote matibabu yako au utakavyohudumiwa.

Nimethibitisha kuwa mtoto ameelewa ya kwamba kujihusisha na huu utafiti ni kwa njia ya kujitolea _____ (saini)

Maelezo kuhusu mchakato

Iwapo utakubali kushiriki, maswali kadhaa yatawasilishwa kwako kuhusu hali yako, kufafanua zaidi juu ya upasuaji na madhumuni ya utafiti ambayo yatajazwa kwenye fomu.

Nimethibitisha kuwa mtoto ameelewa maelezo kuhusu mchakato_____ (saini)

Muda

Tutahitaji dakika kumi kupata ujumbe kutoka kwako na tupime kiwango cha damu alafu tutakuja kwa wodi yako baada ya siku mbili kukupima damu tena.

Usiri

Matokeo ya utafiti huu yatawekwa siri. Habari yoyote kuhusu wewe itakuwa na nambari juu yake badala ya jina lako. Watafiti tu ndio watajua nambari yako na matokeo yatazungumziwa na idara ya anaesthesia pekee.

Haki ya Kukataa

Kushiriki utafiti huu ni kwa hiari na iwapo haungependa kushiriki uamuzi wako hautaathiri matibabu yako kwa njia yoyote.

Pendekezo hili limeangaliwa na kuidhinishwa na Idara ya Anaesthesia ya Chuo kikuu cha Nairobi na kamiti ya maadili ya utafiti katika hospitali ya Kenyatta inayohakikisha kuwa haki za wanaoshiriki utafiti wowote nchini zinazingatiwa.

Iwapo utakuwa na swali lolote kumbuka una uhuru kuuliza.

SEHEMU YA II: Shahada ya Kutiwa Saini na Watoto Nambari Maalum: _____

Nimesoma maelezo yote ya utafiti huu au nimesomewa maelezo haya na nimekuwa na fursa ya kuuliza maswali ambayo yamejibiwa kadri na matarajio yangu kwa njia ya kuridhisha. Kwa hivyo ningependa kupeana saini yangu na pia kujitolea kushiriki kwa utafiti huu. Nakubali kujihusisha na utafiti huu.

AMA

Sikubali kujuhusisha na utafiti huu na sijatia saini lolote._____ (alama ya mshiriki)

<u>Mtoto akikubali:</u>
Jina la mtoto: _____
Saini la mtoto: _____
Tarehe:_____

Iwapo mtoto hawezi kusoma:
Nimeona na ninaweza kuthibitisha ya kwamba mtoto amesomewa yaliyo kwenye hii fomu ya kutiwa saini na mwenyewe ameweza kuuliza maswali atakayo. Nathibitisha ya kwamba mtoto amekubali kwa hiari yake kushiriki kwa huu utafiti.

Jina la shahidi (isiwe mzazi): _____ Alama ya Kidole ya Mshiriki
Saini la shahidi: _____
Tarehe: _____

Nimemsomea ama nimeona na ninaweza kuthibitisha ya kwamba m wa yaliyo kwenye hii fomu ya kutiwa saini na washiriki walio umri wa chini ya miaka 18 na mwenyewe

ameweza kuuliza maswali atakayo. Nathibitisha ya kwamba mtoto amekubali kwa hiari yake kushiriki kwenye utafiti huu.

Jina la mpelelezi: Dkt. John Mwanzia

Saini ya mpelelezi: _____

Tarahe: _____

Nakala imepewa kwake mshiriki _____ (alama ya mpelelezi)

Mzazi/Mgarini ameitia saini Shahada ya Idhini : Ndiyo_____ Hapana_____

Kwa maelezo zaidi hata baada ya utafiti huu una uhuru wa kuwasiliana na watu wafuatao kupitia anwani na numbari za simu zilizoandikwa hapa chini.

Jina: Dkt John Mwanzia (Mtafiti mkuu)
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Barua pepe: emwanzis@gmail.com

Jina: Dkt Susane Nabulindo
Namba ya simu: 0721-418 587
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Appendix III: Data Collection Tool

(Tick as appropriate)

1. Biodata.

a. Date …….

b. Serial number …….

c. Age …….....years ……..months

d. Sex (a) male ……. (b) Female……

e. Diagnosis; 1) orthopaedic……

a) Trauma…….. Specify……

b) Non-trauma…… specify……

2) Non-orthopaedic……specify……

f. In case of trauma; Age of the injury in days……

h. Type of Surgery…….

i. ASA status……..

j. Nature of surgery

elective	
emergency	

2. Pre-operative parameters.

Hemoglobin levels…….g/dl

3. Pre-operative vital signs

Bp: ……. mmHg Spo2: …..... HR……

Post-operative vital signs

Bp: ……. mmHg Spo2: …..HR……..

4. Tourniquet use

Method of exsanguination

a) Rising limb…..
b) Esmarch bandage……

Area of placement;

a) Arm……
b) Forearm….
c) Wrist…..
d) Thigh…..
e) Calf region…..

Tourniquet time……

Timing of tourniquet deflation

a) Before skin closure……
b) After skin closure and dressing……

Tourniquet cuff pressures……..

Basis of cuff pressures

a) Fixed……..
b) Systolic blood pressure…….
c) LOP…….

5. Type of anaesthesia (tick as appropriate).

General anaesthesia	
Spinal anaesthesia.	
Regional block.	

Induction (indicate the drugs used)

a. inhalational agents
b. intravenous agents
c. Subarachnoid block agents.

d. Regional agents

6. Other methods used to decrease blood loss.

a. use of tranexamic acid

(a) Yes……..dosage……...

(b) No……..

b. use of diathermy…….

7. Intraoperative fluids.

Fluid type	Volume. (mls).
Crystalloids	
Colloids	

7. Intraoperative estimated blood loss……..mls

8. Duration of surgery? Minutes…….

9. Was the participant transfused? (If yes indicate the type of blood product and number of units)

a) yes……type of blood product……..number of units……

b) no…….

10 Reason for transfusion……

11. Post-operative haematometric parameters.

(a) 2nd POD Hemoglobin……g/dl

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Ref: KNH-ERC/A/339

6th October 2020

Dr. John Evans Mwanzia
Reg. No.H58/7596/ 2017
Dept. of Anaesthesia
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Mwanzia

RESEARCH PROPOSAL – THE INFLUENCE OF A TOURNIQUET ON HEMOGLOBIN LEVEL AFTER LIMB SURGERY AT KENYATTA NATIONAL HOSPITAL (P396/07/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 6th October 2020 – 5th October 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website**http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept.of Anaesthesia, UoN
Supervisors: Dr. Susanne Nabulindo,Dept.of Anaesthesia, UoN
Dr.Timothy Mwiti, Dept.of Anaesthesia, UoN

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