TECHNIQUES OF SURGICAL TOURNIQUET APPLICATION IN ORTHOPAEDIC OPERATIONS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

BY

BULUMA PHILLIP

A THESIS SUBMITTED IN PARTIAL FULFILMENT FOR AWARD OF MASTER OF MEDICINE IN ORTHOPAEDIC SURGERY OF MOI UNIVERSITY

© 2022

DECLARATION

Declaration by Candidate

This thesis is personal original work and has not been presented in any other university/institution for consideration for any certification. It has been complemented by referenced sources duly acknowledged. Where text, data and tables have been borrowed from other sources, including the internet, these are specifically accredited and references cited using current APA system and in accordance with anti-plagiarism regulations.

Signature:……..…… Date:……

Name: Buluma Phillip
Registration number: SM/PGORT/03/18
Department: Orthopaedics

Declaration by Supervisors

This thesis has been submitted for appraisal with our approval as Moi University Supervisors.

Dr. B. R. Ayumba
Consultant Orthopedic surgeon and Senior lecturer
Dept. of Orthopaedics and Rehabilitation

Signature:……..…… Date:……

Dr. S. Nyabera
Consultant Orthopedic surgeon and Honorary lecturer
Dept. of Orthopaedics and Rehabilitation – MOI UNIVERSITY/ MTRH, Eldoret

Signature:……..…… Date:……

DEDICATION

This work is dedicated to my parents Mr. Buluma Caphus and Mrs Buluma Angella for their love, dedication and support.

ACKNOWLDEGMENT

The Candidate wishes to sincerely thank the Supervisors for their continuous guidance and support during the development of this thesis, also all the Lecturers and fellow Orthopaedic Residents for their continuous contributions.

LIST OF ABBREVIATIONS AND ACRONYMS

AOP	Arterial occlusion pressure
AORN	Association of perioperative registered nurses
APA	American Psychological Association
ARDS	Acute respiratory distress syndrome
ATP	Adenosine tri phosphate
DBP	Diastolic blood pressure
DVT	Deep venous thrombosis
EMLA	Eutectic mixture of local anaesthetic (lidocaine – prilocaine)
$ETCO_2$	Lactic acid
ICP	Intra cranial pressure
LOP	Limb occlusion pressure
Pa CO_2	Partial pressure of Carbon dioxide
ROS	Reactive oxygen species
SBP	Systolic blood pressure

OPERATIONAL DEFINITION OF KEY TERMS

Exsanguination- The process of draining blood from a limb in preparation for an orthopaedic procedure.

Intra-operative complication- Undesired effects of tourniquet use that occur during surgery.

Ischaemic reperfusion injury- A syndrome characterised by local limb oedema, systemic hypotension and pharmacological effects that occur after deflation of the tourniquet.

Post-operative complication- Undesired effects on the patient that occur after surgery and are due to the use of a tourniquet.

Principles of tourniquet use- Steps taken in application and use of the tourniquet and its associated complications.

Reperfusion (breathing) period- An interval during which a tourniquet is deflated to allow reflow of blood to a limb during an orthopaedic procedure.

Surgical tourniquet- A device used to occlude blood supply to a limb during an orthopaedic procedure.

Techniques of tourniquet use- modes of applying the principles of tourniquet use

Tourniquet time / duration- The period over which the tourniquet remains inflated during an orthopaedic procedure.

ABSTRACT

Background: A surgical tourniquet is an important instrument used in orthopaedic surgeries. It is applied on limbs to reduce blood supply to operation site thus provides the surgeon with a bloodless field, assisting in the clear visualisation of significant anatomical structures. Principles of tourniquet use exist but application is variable. Currently however, there are no guidelines in place governing the use of the tourniquet locally, predisposing patients to local and systemic complications, intra- and post-operatively.

Objective: To describe the techniques of tourniquet application used in orthopaedic operations at MTRH. To describe the complications arising from use of the surgical tourniquet at MTRH.

Methods: A descriptive prospective study conducted at Moi Teaching and Referral Hospital over a period of 6 months (March to August 2020). Eighty-six (86) patients who met inclusion criteria were recruited through convenience sampling technique. Cochran's formula was used to determine the sample size. Patients were observed in three stages, and data was recorded in data collection sheet guided by a checklist designed and pretested by the researcher. Preoperatively, sociodemographic and clinical findings were recorded. Intraoperatively, techniques of tourniquet application and intraoperative complications were recorded. Postoperatively, complications were recorded. Data was analysed for these study variables using STATA version 16. Continuous variables such as age, tourniquet time and inflation pressures were summarised in form of ranges and medians. Categorical variables such as exsanguinations, skin protection, pressure determination methods, and complications were summarised inform of frequency distribution. Statistical tests were used to analyse associations between tourniquet application techniques and complications.

Results: Males were 62 while females 24. Median age-34.0 (IQR: 27.0, 48.0) years. Clinical cases were mainly trauma (55.8%). Anaesthetics used (and number of procedures): general (29), regional (57). Limb procedures: upper (18), lower (68). Skin protective padding and exsanguinations by limb elevation were routinely done. Straight cuffs of different sizes were used. Inflation pressures (mmHg): upper limb (150-335), lower limb (300-350). Tourniquet pressure settings were mainly arbitrary (84.8%) and others (15.2%) were based on SBP. Tourniquet time (minutes): upper limbs (48-135), lower limbs (30-300). No breathing periods were used. Complications included tourniquet pain (45.4%), skin injury (24.5%), limb oedema (86.0%) and post tourniquet bleeding (39.5%).

Conclusion: Various techniques were used in application of the tourniquet during orthopaedic operations. Complications were associated with the techniques of tourniquet application.

Recommendations: Institutional guidelines should be established and be adhered to for the safe use of the tourniquet to prevent adverse effects. Further studies are recommended on comparisons between different tourniquet pressures and associated complications.

TABLE OF CONTENTS

Contents **Page**

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background to the study

A surgical tourniquet is an instrument applied onto a limb with the primary purpose of reducing blood supply to a part of the limb. The word tourniquet evolved from a French verb "***tourner''*** which means "***to turn'***"(Coudert, 2016; Rathore et al., 2018). It is an appliance used for occluding movement of blood in part of the limb for duration until it is released. It is beneficial when used properly but has risks associated with improper use. The tourniquet was first used as early as 199 BC by the Romans to reduce bleeding following traumatic limb amputations and was later applied during surgical procedures (Klenerman, 2003; Rathore et al., 2018; Sharma & Salhotra, 2012).

Surgical tourniquets are indispensable especially in orthopaedic operations as they are countlessly used in procedures mainly involving the forearm, hand, knee, leg, ankle, foot and distal parts of the arm and thigh (Yalcinkaya et al., 2014). Reports indicate their application in more than 1000 operations per year among surgeons across Canada and the United States (Kalla et al., 2003; Noordin et al, 2009).

Use of the surgical tourniquet has been known to provide surgeons with a bloodless field thus offering convenient visualisation of relevant anatomical structures during operations (Adhikari et al., 2017; Estebe et al., 2011; Sadri et al., 2010). This in turn has added benefits such as reducing operation time as well as frequency of blood transfusions after surgery.

It however should be noted that the use of a tourniquet requires a vast amount of knowledge of the various physiological changes that occur both locally and

systemically following its application and how they are influenced by different techniques(Van der Spuy, 2012). Furthermore, principles of tourniquet use such as; patient/limb preparation which involves knowing existing contraindications, limb exsanguination, type of tourniquet, inflation pressure, tourniquet inflation time and reperfusion intervals should be well understood by the operating staff as these have dynamic effects in the physiological changes occurring in the patient.

That being the case, use of the surgical tourniquet is accompanied by intra and post-operative adverse effects occurring both locally and systemically. These are a result of a combination of mechanical compression and ischaemic effects exerted by the tourniquet. Although these complications have been reported to be rare, they could have devastating results such as delayed recovery, partial or complete loss of limb function consequently leading to increased hospital stay and undesired medical legal implications (Sadri et al., 2010; Van der Spuy, 2012). Therefore, good knowledge of not only the mechanism of injuries but also of methods of prevention is of great importance (Noordin et al., 2009).

This study is aimed at analysing the different trends in tourniquet practises employed on patients undergoing orthopaedic procedures and complications arising from their use.

1.2 Statement of the problem

Although the surgical tourniquet has frequently been in use over decades of limb operations, standard protocols governing its use have not been clearly defined. Surveys have shown limited knowledge among theatre operating staff including surgeons, anaesthetists, residents and assistants on key aspects to consider in when using the tourniquet such as contraindications for use, correct site of application, correct cuff size, safe inflation pressure and duration(Bogdan & Helfet, 2018; Kalla et al., 2003; Yalcinkaya et al., 2014).

Thus, varying patterns in the practical use of the tourniquet exist among different surgical teams and facilities. Whereas these patterns may depend on resources limited to those specific centres, others are based on individual experiences and preferences of the surgeon. Studies have demonstrated a lack of consensus as well as suboptimal knowledge on the principles guiding the use of the surgical tourniquet (Kalla et al., 2003; Sadri et al., 2010).

The diverse patterns employed in using the surgical tourniquet are critical in determining the desired outcomes during surgery such as reduced bleeding but also account for the hazards arising from its use (Boya et al., 2016). Thus debates are arising on whether the tourniquet should continue to be used on patients following occurrences of these adverse effects (Adhikari et al., 2017; Oragui et al., 2011).

Therefore a thorough understanding of the safe practices and contraindications to use of the surgical tourniquet is of utmost significance in preventing the potential complications that accompany it (Rathore et al., 2018).

The most dominant method of training among orthopaedic surgeons currently revolves around learning of practical skills from senior colleagues as compared to

teaching in class depending on the schools syllabus, as a result, different surgeons adapt different techniques of using a tourniquet depending on what was availed or observed during their career training as opposed to having standard protocols that could be taught and examined on use of the tourniquet (Sadri et al., 2010).

In addition, the researcher's personal survey of the available studies is yet to identify any local protocols that govern the use of tourniquets in this local hospital setting. Locally, the tourniquet is used in approximately 5 surgeries in a week; however, there is no display or documentation of guidelines for its use in operation theatre. Some irregularities occurring in about three fifths (3/5) of the cases that have been observed in application include inadequate skin protection, inadequate exsanguination and use of high inflation pressures and time and overlooked maintenance. The type of tourniquet and specific use (indications and contraindications), the proper cuff size, exact location, proper timing of application in relation to medications, keen monitoring of vital parameters, and proper inflation and deflation procedures have not been strictly observed. These not only affect its efficiency but determine the complications that arise from its use which can be incapacitating to patients. The majority of such patients with complications due to physiological and mechanical derangements have had both local and multisystemic implications, which inconvenience in terms of further care hence financial burden and higher morbidity and disability rates in terms of prolonged hospital stay. The worst scenario is to encounter mortality. These problems can be solved by establishing proper guidelines on techniques of tourniquet use, and strictly adhering to them.

1.3 Justification

Data collected from this study will help provide details on the current patterns of tourniquet use as well as stipulate the need for guidelines or a standard protocol governing the use of the surgical tourniquet (Kalla et al., 2003; Sadri et al., 2010).Such guidelines can help reduce tourniquet associated injuries (Estebe et al., 2011). They can also be incorporated into the school syllabus to ensure that standards are observed by future graduate surgeons from this institution. This will ensure proper training, follow up to see how the guidelines are applied, close monitoring and evaluation and even further review of school syllabus or curriculum to keep up with the ever changing trends in technological developments.

Data analysed from this observational study can be used to form a basis for further studies to come as it will establish aspects of tourniquet use that need further inquiry (Kalla et al., 2003).

Information generated can also help in deducing probable correlations between variables such as tourniquet inflation time, cuff sizes and inflation pressures and their association with different intra and postoperative outcomes. This will in turn help in generating hypotheses for further studies on better use of the surgical tourniquet as well as devise approaches to reducing complications associated with its use.

1.4 Research question

What are the techniques used in application of the surgical tourniquet during orthopaedic operations at MTRH and their associated complications?

1.5 Research objectives

1.5.1 Broad objective

To analyse the techniques used in application of the surgical tourniquet during orthopaedic operations at MTRH and their associated complications.

1.5.2 Specific objectives

- To describe the techniques of tourniquet application used during orthopaedic operations at MTRH.
- To describe the intra-operative complications arising from use of the surgical tourniquet at MTRH.
- To describe the post-operative complications arising from use of the surgical tourniquet at MTRH.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Overview on the Tourniquet

A tourniquet is a device used to compress and occlude blood vessels in limbs.

Tourniquets are used during surgery to obtain bloodless fields for good visibility of anatomical structures. They are also used in emergency situations to prevent excessive bleeding for example in pre hospital management of trauma, to engorge veins for easy visibility when attempting venepuncture and during regional anaesthesia to localise intravenous anaesthetics and prevent their spread to the rest of the body such as the Bier's block (Bogdan & Helfet, 2018; Oragui et al., 2011).

2.1.1 Historical background

The concept of achieving a blood less field during surgical procedures dates back to periods of antiquity when bands were used to constrict vessels during amputation (Murphy, Winter, & Bouchier-Hayes, 2005). This proved the usefulness of technique when properly applied but risks were noted when improperly applied. This hence paved way towards development of tourniquet.

There is evidence of documentation on use of compression dressings to prevent excess bleeding that are thought to have been written by Hippocrates in ancient Greece during the 5th century BC(Coudert, 2016).

Between 5th century BC and 5th century AC, non-pneumatic bronze straps with leather for patient comfort were used in emergencies arising from battle and during amputations in the Roman Empire. The goal at that time was to save a life with limited consideration for the survival of the limb(Noordin et al., 2009). In the same

era, Heliodorus and Archigenes tied tight bands of cloth above and below the incision site during amputations(Coudert, 2016; Sharma & Salhotra, 2012).

In the 16th century, French surgeon, Ambroise Paré introduced the use of a knotted string that was to be placed above the amputation site. This was advantageous as it allowed for retention of reasonable lengths of skin and muscle for the stump while controlling bleeding and also reduced pain.

Also, Wilhem Fabry (from German), Morel (from France) and James Yonge (from England) introduced the use of constrictive bandage that was attached to a stick which was twisted to compress limb at different strengths. Using this concept of controlling the strength of compression, Jean Louis Petit (from France) in 1718 introduced the screw-controlled device made of two metallic compressors held together by straps to which a screw was attached. He called this the screw tourniquet. It was a superior device as it did not require an assistant to hold in place, its release and re application were easy and instant.

In 1864, Joseph Lister (from Britain) used tourniquet for other procedures besides amputation. He also performed limb exsanguination by elevating the limb for 4 minutes so blood could drain from the veins. These practices were later on called the Listerian methods. He did this while excising a wrist joint infected with tuberculosis(Bogdan & Helfet, 2018; Coudert, 2016; Klenerman, 2003).

In 1873, Johann T. Friederich Von Esmarch (German) used a flat rubber tube with the thickness of a finger alongside a roller to exsanguinate and compress limbs during surgery. He acknowledged use of this method by Grandesso Sylvestri (1871) and other methods by Sartorius (1806), Brunnighausen (1818) and Sir Charles Bell (1821).

Von Langenbeck later used similar equipment like Esmarch to design the Langenbeck bandage, known today as the Esmarch bandage. It was used by tightly winding it around the limb. Then rubber tube / elastic ligature is fastened at the end of the bandage to occlude the arteries. This replaced the screw tourniquet; however, the Listerian method of exsanguination remained popular(Klenerman, 2003)

In 1904, Harvey Cushing (American) introduced the pneumatic tourniquet. He decided to abandon the rubber tourniquet due to related nerve injury and difficulty in removal and re application. The pneumatic tourniquet was quick and easy to apply and remove. His model underwent a variety of modifications until he developed a tourniquet that had both an inflatable cuff and a manometer. He also advocated for the monitoring of blood pressure during surgical procedures (Klenerman, 2003; Noordin et al., 2009).

During the 1980s, James MacEwen, a biomedical engineer from Canada designed a modern pneumatic tourniquet containing microprocessor that controls the pressure exerted by the tourniquet. The modern pneumatic tourniquet is basically composed of a source of compressed gas and an inflatable cuff in addition to the microprocessor. Different designs have been modified to have safety pressure gauges or display monitors as well as warning systems like alarms and light emitting diodes (LEDs) mainly for monitoring inflation time, inflation pressures and gas leakages. This type of tourniquet is currently used routinely during orthopaedic operations(Bogdan & Helfet, 2018; Coudert, 2016; Klenerman, 2003; Murphy et al., 2005; Vaughan, et al, 2017). Due to the new modifications and safety measures employed in designing the new modern tourniquet system, the U.S. Food and Drug Administration placed the pneumatic tourniquet under Class-I medical devices, designating that it is not a

substantial source of injury to the patient when under normal use (Noordin et al, 2009).

It can be noted therefore that the tourniquet design has evolved with time, from primitive to even modern which include personalized systems: 4 BC- 1700s- primitive; 1700s- 1900s- nonpneumatic; 1900s- 1980s- early pneumatic; 1980s to date- modern pneumatic, with personalized tourniquet systems dominating from 2000s. The Esmarch bandage was previously used as a tourniquet but it's currently for exsanguination prior to inflation of pneumatic tourniquet. However despite its unpredictably high pressures, it is still used as tourniquet. Tourniquets can be categorized broadly based on function and design, with the former including emergency and surgical while the letter as inflatable and noninflatable. Emergency tourniquets are used to stop catastrophic exsanguination from injured limbs especially in prehospital triage and prehospital transfer during combat situations, as a last resort due to its adverse effects of improper and prolonged use. The surgical tourniquet on the other hand enables surgical intervention to be carried out quickly, precisely and without risk of excessive blood loss. A non-inflatable tourniquet is made of an elastic stretchable material, while an inflatable or pneumatic tourniquet uses compressed gas to inflate the bladder or cuff which then generates pressure to the applied area. Modern tourniquets have inbuilt capacity to allow for application of desired pressure (Kumar et al., 2016).

2.1.2 Physiological and mechanical effects of tourniquet application

There are effects resulting from exsanguination, inflation and deflation of the tourniquet.

2.1.2.1 Effects of exsanguination and Tourniquet inflation

This is associated with many effects some of which include the following:

Systematic hypervolemia occurs and is secondary to the initial exsanguination process(Coudert, 2016; Murphy et al., 2005). There is an approximate volume increase of 50ml during upper limb surgery and 500 – 800ml in the lower limb surgery. This does not persist, however, it may cause heart failure as a result of circulatory over load in patients who have low or poor cardiac reserves(Coudert, 2016; Van der Spuy, 2012).

There is also an increase in blood pressure that occurs later due to tourniquet induced pain. This is observed approximately 30 – 40 minutes following inflation of the tourniquet. Raised values of stress hormones like cortisol and noradrenaline have also been observed approximately 60 minutes after inflation and these are linked to the pain and hypertension phase following it(Coudert, 2016).

The triggers for pain are yet to be accurately established. However, this has been linked to activation of unmyelinated slow conducting C-neurones. The mechanism involves cutaneous as well as tissue compression and ischemia(Oragui et al., 2011; Van der Spuy, 2012).

There is generalised hyperthermia in the rest of the body due to reduced surface area for heat exchanges. Contrariwise, local hypothermia develops in the exsanguinated and occluded limb(Murphy et al., 2005; Sharma & Salhotra, 2012).

There is also accumulation of drugs initially meant for induction of anaesthesia in the occluded limb especially in the adipose and muscle tissues(Coudert, 2016; Estebe et al., 2011).

Thrombo-embolism may result from blood stasis which can cause micro emboli to accumulate in the operated limb. As a result, these particles can be released into the systemic circulation at the time of tourniquet deflation(Coudert, 2016).

Cutaneous lesions may also arise mainly from friction and abrasion forces from the tourniquet. Burns (chemical or mechanical) and pain have also been documented(Murphy et al., 2005).

Muscle lesions arise from prolonged ischemia as focal regions of necrosis developing within the tissue. These can be small lesions that progress to extensive ones between 3 to 5 hours of ischemia. They have been evidenced by increase in myoglobinaemia and hyperkalaemia that could result into rhabdomyolysis and acute kidney injury. Prolonged and unnecessarily high pressures have led to post tourniquet paralysis and even limb and digital necrosis and death(Coudert, 2016).

2.1.2.2 Effects of Tourniquet deflation

This allows for reperfusion thus fresh supply of nutrients and oxygen as well as elimination of products of metabolism(Murphy et al., 2005).

There is a decrease in central venous pressure and Mean Arterial Pressure accompanied by an increase in heart rate and occasionally distributive shock(Coudert, 2016; Rahman et al., 2015; Van der Spuy, 2012).

Systemic dissemination of accumulated metabolic molecules from ischaemic tissue also occurs upon release of the tourniquet. Metabolic changes mainly result from spread of products of anaerobic respiration to systemic circulation causing slight/ moderate acidosis, increased partial pressures of carbon dioxide ($PaCO_2$) by between 0.1 to 2.4 Kilopascals, and lactic acid ($ETCO_2$) and hyperkalaemia from muscle cell

necrosis(Wong & Irwin, 2018). This can result into increased right heart pressure, pulmonary vascular resistance and decreased oxygen saturation of haemoglobin. Such effects may be hazardous in poly traumatic cases with increased intra cranial pressure (ICP) and respiratory insufficiency. The disseminated metabolites may be accompanied by micro embolic particles, tumour cells as well as septic molecules, thus the subsequent effects may range from subclinical cerebral or pulmonary embolism to spread of infections and metastatic tumours. Thus, systemic dissemination can have fatal consequences(Coudert, 2016).

Reperfusion injury can also occur. This is characterised by swelling of cells associated with increased vascular permeability, these result into increased interstitial compartment pressures(Coudert, 2016). Thus there is associated hyperaemia and an immediate increase in girth by 10% which may extend to 50% within a day post operatively day and may significantly persist for over 6 weeks(Estebe et al., 2011).

2.2 The principles and practices of tourniquet application used by orthopaedic surgeons

2.2.1 Exsanguination technique

One of the methods that can be used is the simple and passive technique of limb exsanguination:

The commonly followed protocol in this method involves limb elevation for a five-minute period. Angles of elevation are 90 and 45 degrees for the upper and lower limb respectively. It is easy to perform and safe. No device is used thus there is a reduced risk of contamination. It makes the superficial vessels more visible and this offers and an added advantage in achieving haemostasis(Coudert, 2016; Estebe et al., 2011; Murphy et al., 2005; Sharma & Salhotra, 2012; Van der Spuy, 2012).

Another method to employ is the active or mechanical technique of exsanguination which requires the assistance of a device for example an Esmarch bandage or Rhys Davies exsanguinator. The former is made of rubber and is rolled over the limb while the latter is a cylindrical, elastic device which is inflated and wrapped around the limb to achieve exsanguination(Oragui et al., 2011).

Mechanical exsanguination is more aggressive and more effective. It has also been suggested that it offers better tolerance to intra and post-operative pain as well as quicker recovery time(Vaughan et al., 2017). However, it is also associated with increased risk of DVT, infection and tumour cell dislodgment/ dissemination(Coudert, 2016; Estebe et al., 2011). Its use is also contra indicated in cases of sickle cell disease and cases of existing pyogenic infections in distal parts of the limb(Noordin et al., 2009; Oragui et al., 2011; Vaughan et al., 2017; Wong & Irwin, 2018).

2.2.2 Skin padding and sterilisation preparations

It is important to use a padding between the tourniquet and the skin to minimise cutaneous injury(Murphy et al., 2005; Sharma & Salhotra, 2012; Vaughan et al., 2017).In a survey by Boya et al., (2016), it was found that 94.9% of surgeons practicing in Turkey used a skin protective padding.

Such padding should be free of creases in order to reduce shearing stresses(Coudert, 2016; Estebe et al., 2011; Van der Spuy, 2012). Note that more than two layers of skin padding usually reduce the efficiency of the tourniquet by decreasing the pressure transmitted to the underlying tissues(Vaughan et al., 2017; Wong & Irwin, 2018).An additional self-adhesive plastic drape offers added advantage as it shields the skin against chemical burns that could result if antiseptic agents seep underneath the tourniquet. A glove or any other impermeable drape material can also be used to serve this purpose(Adhikari et al., 2017; Bogdan & Helfet, 2018; Coudert, 2016; Estebe et

al., 2011; Sharma & Salhotra, 2012; Van der Spuy, 2012).During limb preparation, it is also recommended that the sterilising agent be allowed to dry before application of the tourniquet to reduce the risks of damage to the skin(Vaughan et al., 2017).

2.2.3 Site of application

The location of the tourniquet on the limb to be operated should be as proximal as possible even when the site of operation is distal(Coudert, 2016; Vaughan et al., 2017). However, some controversial studies state otherwise. For example there is literature supporting the efficiency and safety of tourniquets placed on the fore arm for minor operations performed on the under local anaesthesia and for periods not longer than 30 minutes(Oragui et al., 2011). The site of application should have good muscle or soft tissue bulk so as to shield the nerves from resultant cuff compressive forces(Kumar et al., 2016). Thus, placing the cuff over bony prominences should be avoided. In cases of hand and foot operations where wrist and ankle tourniquets are used, their position should be 2 cm proximal to the joint. This has been proven to be advantageous compared to more proximally applied tourniquets (proximal forearm and leg tourniquets) as it reduces pain and recovery is quicker(Sharma & Salhotra, 2012; Vaughan et al., 2017). For calf tourniquets, the position should be at the level of the mid-calf, 3cm to 4cm below the head of fibular to protect the common peroneal nerve from being damaged (Estebe et al., 2011; Sharma & Salhotra, 2012). The knee should not be in flexed position when inflating thigh tourniquets as later extension can result into stretching of the sciatic nerve(Sharma & Salhotra, 2012). It is also important to avoid moving the cuff after installation and inflation to reduce shearing forces acting against the skin, therefore its position should be monitored during the surgical procedure(Coudert, 2016; Estebe et al., 2011; Murphy et al., 2005; Vaughan et al., 2017).

2.2.4 Choice of Cuff, Shape and width

Re-usable cuffs are chosen in many centres. However, these can be contaminated with body fluids and pathogens and can potentially transmit infections between patients if not carefully used. Thus disposable cuffs can be used as an alternative though they could be expensive(Murphy et al., 2005; Vaughan et al., 2017).

The cuff of choice can also be conical or straight in shape. A conical or contoured cuff is superior to a cylindrical or straight cuff of the same width. It offers a better pressure distribution especially in cases where the patient is obese or muscular. This reduces the required arterial occlusion pressure and therefore minimises the chances of developing complications arising from high tourniquet inflation pressures(Coudert, 2016; Estebe et al., 2011; Murphy et al., 2005; Van der Spuy, 2012; Vaughan et al., 2017). If combined together with use of limb occlusion pressure, a blood less field can be achieved at significantly lower inflation pressures(Oragui et al., 2011).In a survey by Boya, et al., (2016), straight cuffs were used more commonly (73.5%) by orthopaedic surgeons in Turkey than conical cuffs.

In terms of length, it is ideal for the cuff to extend at least 7cm to 15 cm over the limb circumference(Estebe et al., 2011; Sharma & Salhotra, 2012; Vaughan et al., 2017).

In addition, a wide cuff is preferred compared to a narrow cuff. Like conical cuffs, a wider cuff also requires a lower arterial occlusion pressure. Studies demonstrate that wider cuffs gradually distribute pressure from the superficial to deep tissues and from the centre to the edges of the cuff. An optimal cuff width should be at least greater than half (0.5 times) the limb circumference, this reduces the required arterial occlusion pressure to a value closer or even lower to the systolic pressure(Coudert, 2016; Estebe et al., 2011; Oragui et al., 2011; Sharma & Salhotra, 2012; Vaughan et

al., 2017). However, in cases where such a cuff is not available, the widest available cuff can be used (Coudert, 2016; Murphy et al., 2005; Sharma & Salhotra, 2012; Van der Spuy, 2012).

2.2.5 Cuff inflation and inflation Pressure

When inflating the cuff, it is recommended that this should be done over a short time interval. Slowing the rate of inflation causes early venous occlusion before occluding the arterial flow which causes venous congestion and increases the possibility of more intra operative bleeding(Bogdan & Helfet, 2018).

Boya, et al., (2016) found no consensus on the proper methods used by surgeons in setting the tourniquet pressure.

Different strategies exist for estimating the appropriate inflation pressure. The objective is to use an inflation pressure value that is as low and effective as possible, since most complications are associated with high cuff pressures(Coudert, 2016; Rahman et al., 2015).

The optimal pressure is variable with different patients and is affected by different factors which include age. For example, younger patients require low inflation pressures to occlude their vessels. Other important factors to consider include the patient's blood pressure and the limb size(Murphy et al., 2005; Sharma & Salhotra, 2012).

Arbitrary inflation pressures can be used, for example surgeons commonly set fixed pressures at 250 mmHg and 300mmHg for the upper and lower limb respectively(Van der Spuy, 2012; Vaughan et al., 2017). However, these should be individualised and adjusted for each patient. Another common recommendation is use of pressures values that are between 50mmHg and 75mmHg above the systolic blood pressure

(SBP) for the upper limb while pressure values between 100mmHg and 150mmHg above SBP can be used for the lower limb(Coudert, 2016; Murphy et al., 2005; Sharma & Salhotra, 2012; Van der Spuy, 2012). Although some literature suggests pressure settings between 110mmHg and 150mmHg and 155 mmHg and 250 mmHg above the systolic blood pressure for the upper and lower limbs respectively(Rahman et al., 2015).

For lower limb operations, the cuff can be inflated to a pressure setting that is between 90mmHg and 100mmHg above the preoperative blood pressure recorded in the upper limb(Murphy et al., 2005).

A more optimal strategy involves the use of Graham's formula to determine the arterial occlusion pressure (AOP).

$$\text{AOP} = \frac{(\text{Systolic Blood Pressure} - \text{Diastolic Blood Pressure}) \times (\text{Limb Circumference})}{3 \times \text{Cuff Width}} + \text{Diastolic Blood Pressure}$$

Thereafter, the cuff pressure is set between 50mmHg and 75mmHg above the calculated AOP value. The cuff pressure is then monitored and adjusted accordingly during the course of the procedure(Coudert, 2016; Estebe et al., 2011). This formula also allows one to decrease the tourniquet pressure in adults by 20% to 40 % or in children by 50% or more(Estebe et al., 2011; Van der Spuy, 2012).

Alternatively, the cuff pressure can be set between 50mmHg and 75mmHg above the pressure at which the peripheral pulse is occluded when monitored with a Doppler probe in the operated limb(Murphy et al., 2005).

The Association of periOperative Registered Nurses (AORN) describes the use of Limb Occlusion Pressure (LOP), which should be calculated before the surgery. Here,

the patient's blood pressure is recorded and a pressure reading at which the pulse becomes absent from the limb is determined as the LOP using Doppler probe placed at a site distal to the tourniquet(Adhikari et al., 2017; Oragui et al., 2011; Sharma & Salhotra, 2012; Van der Spuy, 2012; Vaughan et al., 2017). Limb occlusion pressure is thus defined as the minimum pressure required, at a given time by a given cuff applied over a given limb at a given site. Earlier studies have demonstrated that pressures values determined using LOP measurements for individual cases prior to tourniquet inflation were grossly lower than fixed generic cuff inflation pressure of 300 to 350mmHg but were still adequate to maintain a suitable bloodless field during surgical procedures (Noordin et al., 2009).The tourniquet is inflated to the LOP value with a safety margin determined as shown in table2.2.5.1:

Table 2.2.5.1: Safety margins used for different LOP values

LOP (mmHg)	**Safety margin** (mmHg)
Below 130	40
130 to 190	60
Above 190	80

A safety margin of 50mmHg is used for children below 10 years of age(Adhikari et al., 2017; Oragui et al., 2011; Sharma & Salhotra, 2012; Van der Spuy, 2012; Vaughan et al., 2017; Wong & Irwin, 2018).

This method can be used in cases where the arterial walls are calcified to achieve a blood less field at low tourniquet inflation pressures. Although this method has been proven to be safe, it is exhausting and requires a lot of time and is therefore not often applied in practice. A study once revealed use of this method by only 7.0% among polled podiatrists(Bogdan & Helfet, 2018; Oragui et al., 2011).

2.2.6 Tourniquet time / duration

The tourniquet should be used for the shortest periods possible as complications arising from its use increase with time(Adhikari et al., 2017; Coudert, 2016; Oragui et al., 2011; Sharma & Salhotra, 2012; Van der Spuy, 2012; Vaughan et al., 2017). There is no proper consensus on the appropriate duration since complications have been reported even for inflation periods less than 2 hours(Bogdan & Helfet, 2018; Coudert, 2016; Wong & Irwin, 2018).

Different reviews suggest safe periods of continuous cuff inflation to be between 1 and 3 hours(Kumar et al., 2016; Murphy et al., 2005). For example, there are recommendations that tourniquet time should not exceed a period of 1 ½ hours in the upper limb or 2 hours in the lower limb(Sharma & Salhotra, 2012; Vaughan et al., 2017) and no more than 75 minutes in children(Kumar et al., 2016).

However, an ideal period of inflation should be less than 1 hour, after which a reperfusion period (breathing period)should be allowed(Coudert, 2016; Estebe et al., 2011; Van der Spuy, 2012). The recommended reperfusion period is between 3 and 20 minutes(Murphy et al., 2005; Sharma & Salhotra, 2012). These reperfusion periods allow for increase in tourniquet time while lowering the chances of nerve injury(Sharma & Salhotra, 2012; Vaughan et al., 2017). Randomised clinical trials have shown that use of reperfusion periods lowers the levels of lactic acid and carbon dioxide end tidal volumes at the end of surgeries compared to continuous tourniquet inflation (Bogdan & Helfet, 2018). However, reperfusion can predispose to more lesions on tissues underneath (especially the muscles) if initiated later than 2 hours of continuous ischemia. This is because the biological protective mechanisms in the tissues become over whelmed by pathophysiological and inflammatory processes when the duration of ischemia extends above 60-90 minutes(Estebe et al., 2011).

Some authors are however not in support of the reperfusion periods for surgical procedures that do not last longer than 3 hours(Murphy et al., 2005).

In addition, the use of dual tourniquets has been suggested as a modality to safely increase limb ischaemic time. This involves alternate inflation of the tourniquets after every hour. This however predisposes to paraesthesia if the ischaemic period exceeds 2 hours(Murphy et al., 2005).

2.2.7 Deflation

Concerning appropriate timing of cuff deflation, some studies have recommended that releasing the cuff early reduces the risk of tourniquet related complications(Wong & Irwin, 2018).

Deflation of the cuff before haemostasis and wound closure helps to shorten ischemic time(Coudert, 2016; McMillan & Johnstone, 2017). It also allows reperfusion and swelling within the limb to occur before application of dressings which prevents undesired effects of increased intra compartmental pressures(Estebe et al., 2011). However, it is also associated with increased loss of blood in quantities that are significantly greater than those where deflation is done after wound closure, thus suggesting that the cuff should be deflated after haemostasis and wound closure especially for patients who have pre-existing anaemia (Murphy et al., 2005; Wu & Wang, 2018). These observations relating blood loss to timing of tourniquet deflation have been made in studies mainly based on total knee arthroplasty (Wong & Irwin, 2018).In addition, another study also observed an increase in duration of surgery and need for blood transfusion following early deflation of the tourniquet(Rahman et al., 2015; Sharma & Salhotra, 2012). With the intension of reducing blood loss in mind, late deflation of the cuff can be done as after firmly applying the dressing in order to

produce a haemostatic effect during the initial reactive hyperaemia that occurs soon after releasing the cuff (Wong & Irwin, 2018). However, Generally, it's upon the surgeon to balance the potential hazards of early deflation such as increased haemorrhage with the risks of prolonging durations of cuff inflation(Noordin et al., 2009).

During the period after deflation, it is important to carefully monitor the patient for signs of pulmonary embolism which could manifest as dynamics in the patient's oxygen parameters(Murphy et al., 2005). The use of a tourniquet has not considered as a primary risk factor leading to embolism but it's deflation adds a risk of spontaneous dislodgement of emboli following procedures like cementation, prosthesis insertion and intramedullary instrumentation(Bogdan & Helfet, 2018; Noordin et al., 2009). The neurological and vascular status of the limb should also be monitored(Coudert, 2016; Estebe et al., 2011). A period of 24 hours in an ICU setting is recommended(Rahman et al., 2015).

2.2.8 Prophylactic antibiotic treatment

This is aimed at preventing post-operative infections. While using a tourniquet, this effect is best achieved by inflating the cuff when the drug is at its highest concentration in the tissues(Coudert, 2016). The period of at least 5 minutes should be allowed between administration of intravenous(IV) antibiotics and inflation of the tourniquet(Murphy et al., 2005; Oragui et al., 2011; Vaughan et al., 2017). However, there are randomised clinical trials that have also shown lower infection rates when prophylactic IV antibiotics are given 1 minute following inflation of the cuff which is contrary prior recommendations (Bogdan & Helfet, 2018). In events where the

tourniquet is inflated before antibiotic administration, they can be administered through regional IV injections or 10 minutes prior to deflation(Estebe et al., 2011).

2.3 The complications arising from use of the surgical tourniquet in hospitals

Animal and clinical studies have shown that the rate of complications arising from tourniquet use are directly related to high inflation pressures and increase in time of use thus resulting into a common practice of limiting this time to a period shorter than 2 hours(Bruce, 1978; Oragui et al., 2011; Vaughan et al., 2017).

Patients at high risk of developing complications from tourniquet use include the elderly, women and those classified as ASA 2 and ASA 3(Rahman et al., 2015).

2.3.1 Systemic complications

These are usually attributed to inflation and deflation of the tourniquet(Murphy et al., 2005; Oragui et al., 2011).

2.3.1.1 Pain and cardiovascular reactivity

This is a complex mechanism involving activation of nociceptive C-fibres. Under normal conditions, pain is mediated along the myelinated fast transmitting Aδ fibres and these have an inhibitory effect on the pain transmitted along the unmyelinated slow conducting C-fibres. During tourniquet use, the Aδ fibres are inactivated by ischemia and compressional forces from the tourniquet which leads to activation of the slow conducting C-fibres(Coudert, 2016; Oragui et al., 2011; Van der Spuy, 2012).

Cardiovascular reactivity has been observed during this process and is characterised by an increase in heart rate and arterial pressure. This reactivity is also known as tourniquet pain(Murphy et al., 2005). It is observed in approximately two thirds of cases that undergo general anaesthesia and in only 2.7% of cases under spinal

anaesthesia(Murphy et al., 2005). In a study by Kumar et al., (2016), it was found to occur commonly under general anaesthesia with an incidence of between 53 -67%. Without anaesthesia, the pain is intolerable after 20 to 30 minutes, whereas with general anaesthesia, cardiovascular changes are noted after 20 to 30 minutes. It has been suggested that deeper regional blocks aid in decreasing the extent of the pain. This follows higher incidences of tourniquet pain being reported with use of hyperbaric bupivacaine which has an incomplete subarachnoid distribution compared to use of isobaric bupivacaine during spinal anaesthesia (Wong & Irwin, 2018). Use of local anaesthetic infiltrations, regional nerve blockage and analgesics (such as morphine, EMLA cream), clonidine as well as preoperative gabapentin have been demonstrated to help delay and reduce the associated cardiovascular reactivity by a few minutes, while deepening of general anaesthesia has no effect on the reactivity(Coudert, 2016; Estebe et al., 2011; Sharma & Salhotra, 2012; Van der Spuy, 2012; Vaughan et al., 2017). However, while administration of intravenous anti hypertensives like labetalol can aid in relieving the hypertension, tourniquet deflation seems to be the most satisfactory way of decreasing the occurrence of such pain. Studies have demonstrated that temporary deflation of the tourniquet for 10 to 15 minutes allows for clearance of cellular acidosis thus relieving the pain (Van der Spuy, 2012; Wong & Irwin, 2018).

In some cases, cardiac arrest has resulted from hypervolemia that usually occurs following limb exsanguination(Murphy et al., 2005). Houng et al, (2012) reported a related case of cardiac arrest in an initially healthy male following deflation of the tourniquet after a tibial plateau surgery.

In addition, short episodes of hypotension have been observed following the tourniquet deflation. The hypotension can partly be explained by hyperkalaemia and

acidosis which can also cause cardiac arrest in incapacitated and elderly patients(Estebe et al., 2011). It is also partly attributed to the restoration of circulation in the previously exsanguinated limb. During this post-surgical phase, there is increased vascular permeability in the tissues, this together with the vasodilation contribute to the hypovolaemia and resulting hypotension. This can be worsened in cases of prior haemorrhage either preoperatively as seen in poly trauma cases or intraoperatively(Coudert, 2016; Estebe et al., 2011).

Furthermore, limb reperfusion pain also occurs following deflation of the cuff during which restoration of blood circulation to the limb and clearing of toxic products of metabolism from the tissues takes place(Oragui et al., 2011). Post-operative pain occurring at the site of tourniquet application has been shown to reduce with use of limb occlusion pressure(Adhikari et al., 2017).

2.3.1.2 Temperature changes

Hyperthermia occurs after tourniquet inflation. It is attributed to the decrease in peripheral heat loss from the limb due to lack of perfusion to the limb. Use of bilateral tourniquets during limb surgeries can produce a progressive increase in body temperature of greater than one degree(Klenerman, 2003). It is more notable in children and thus they should not be actively warmed during the surgical procedure. Hot lights should also be avoided during these surgical procedures(Sharma & Salhotra, 2012).

Similarly, the core body temperature drops after tourniquet deflation. During this reperfusion cycle, the body temperature is capable of decreasing by up to 0.6 degrees Celsius for every hour that the cuff was inflated(Wong & Irwin, 2018). It is also attributed to thermal redistribution to the previously hypo perfused limb. Hypothermic

blood also returns to the general circulation from the previously hypo perfused limb(Murphy et al., 2005; Sharma & Salhotra, 2012).

2.3.1.3 Thromboembolic events

These occur due to damage to the blood vessels resulting from compression forces. Venous stasis occurs during tourniquet application causes accumulation of micro embolic particles that are later released into the systemic circulation on deflation of the tourniquet. The size of the emboli formed varies and this can also have variable effects, for example subclinical embolization has been observed using Doppler investigation/ imaging for micro emboli where as potentially fatal respiratory and neurological events such as pulmonary and cerebral embolism can arise. Pulmonary embolism causes pulmonary hypertension which later results into increased right ventricular pressure causing left to right shunting through the oval foremen and resultant predisposition to cerebral embolism. Although these events are noted to be quite rare, pulmonary embolism remains a major cause of mortality following orthopaedic procedures especially total knee arthroplasties(Coudert, 2016; Wong &Irwin, 2018). Embolus formation has a correlation with the tourniquet time(Estebe et al., 2011).

Thromboembolism can be indicated by the presence of tachycardia, hypotension and hyperthermia(Rahman et al., 2015). In circumstances of pre-existing DVT, there is an increased chance of developing pulmonary embolism from dislodgement of emboli especially during active exsanguination with the Esmarch bandage(Coudert, 2016; Van der Spuy, 2012).

Increased duration of tourniquet application is also perceived to increase the risk of thromboembolism(Rahman et al., 2015).

2.3.1.4 Metabolic and respiratory consequences

Following release of the tourniquet, products of anaerobic respiration from muscular tissue are released systemically causing a surge in partial pressures of carbon dioxide ($PaCO_2$) thus increased carbonic acid and lactic acid ($ETCO_2$). As a result, the body compensates through hyperventilation. The adaptation process is quicker under local anaesthesia compared to general anaesthesia. In incidences of raised intracranial pressure (ICP) such as poly trauma victims, hypercapnia resulting from tourniquet release can cause cerebella herniation which can be deadly.

Furthermore, pulmonary oxidative damage can result from reactive oxygen species (ROS) released by locally activated polynuclear leucocytes at the time of tourniquet release thus leading to acute respiratory distress syndrome (ARDS). Severe complications can also result from cardiac and renal damage. This is called the reperfusion injury phenomenon(Coudert, 2016; Murphy et al., 2005; Sharma & Salhotra, 2012; Van der Spuy, 2012; Vaughan et al., 2017). It has been observed in hand and lower limb surgeries and procedures involving tissue transplant(Murphy et al., 2005; Sharma & Salhotra, 2012). L-alanine and hydrogen sulphide have been shown to reduce reperfusion injury. Pre-treating using monoclonal anti bodies also helps in this process(Sharma & Salhotra, 2012).

Studies have also demonstrated the occurrence of myonephropathic syndrome following release of toxic products of metabolism into the circulation. This is manifests with metabolic acidosis, raised serum potassium levels and myoglobinaemia. myoglobinuria and renal failure may result(Noordin et al., 2009; Oragui et al., 2011).

2.3.1.5 Pharmacologic consequences

When the tourniquet if inflated, there is accumulation of induction anaesthetic molecules in the tissues of the operated limb thus they are not metabolised or cleared from such tissues. These molecules are released into the systemic circulation after tourniquet deflation and at this point can cause deepening of anaesthesia. Occasionally, respiratory depression has been noted approximately 20 minutes after deflating the tourniquet(Coudert, 2016; Estebe et al., 2011).

Similarly, drugs such as antibiotics administered after tourniquet inflation cannot reach the operated limb and have minimal effect on the targeted micro-organisms due to their low tissue concentrations. It is therefore recommended to allow a 5 minute interval for the drugs to penetrate the tissues before the tourniquet is inflated(Murphy et al., 2005).

2.3.2 Local complications

They are attributed to compression forces from the tourniquet as well as tissue ischemia(Murphy et al., 2005; Oragui et al., 2011). The extent tissue damage due to ischemia is determined by different factors. As experiments have shown these to include the inflation time and type of tissue(Murphy et al., 2005).

2.3.2.1 Mechanical injury

Mechanical injury can be to the skin, muscles, nerves and blood vessels of the operated limb.

The skin is in closed proximity or contact with the tourniquet. Blistering is the commonest injury occurring to the skin. This can result from a number of factors for example frictional forces arising from improper installation of the cuff on the limb leaving folds within the skin under the tourniquet(Coudert, 2016; Murphy et al., 2005;

Van der Spuy, 2012). Blistering can also be due to chemical burns arising from leaching of alcoholic antiseptic liquid between the tourniquet and the skin(Adhikari et al., 2017; Oragui et al., 2011; Van der Spuy, 2012). The inflation pressure and prolonged inflation time also play a role in the extent of skin damage(Murphy et al., 2005). In addition, patient related factors can also predispose to skin injury, these include the fragility and integrity of the skin which may be compromised in children and the elderly(Coudert, 2016; Vaughan et al., 2017).

Muscle injury can also occur although its mechanism is not yet well stated. However, has been attributed to mitochondrial dysfunction and rapid release of calcium into the muscular tissue that results from a cascade involving depletion of adenosine tri phosphate (ATP), accumulation of carbon dioxide and lactic acid leading to electrolyte imbalance (hyperkalaemia) and release of cytokines and reactive oxygen radicles. This results into apoptosis / necrosis of muscle cells(Coudert, 2016; Estebe et al., 2011; Van der Spuy, 2012). Necrotic changes can be histologically evidenced in muscle tissue under the cuff following two hours of compression(Murphy et al., 2005; Van der Spuy, 2012). Such lesions can be exacerbated by high cuff inflation pressures as have been reported individual cases where inflation pressures were 540mmHg and others where tourniquet time went beyond 4 hours(Wong & Irwin, 2018). The local microscopic changes in the muscle tissues lead to clinical manifestations such as disturbances in posture. Muscle oedema, ischemia, local micro vascular congestion and injury to mixed peripheral nerve fires result into post tourniquet syndrome. This is associated with limb stiffness, paresis, numbness and pallor (Murphy et al., 2005; Oragui et al., 2011; Sharma & Salhotra, 2012; Van der Spuy, 2012; Wong & Irwin, 2018). It tends to recover within a postsurgical period of 3 months, however, this is also dependant on the duration of ischemia and is worsened in periods exceeding 3

hours(Noordin et al., 2009; Oragui et al., 2011; Sharma & Salhotra, 2012). These manifestations are often mistaken to be due to trauma from the surgery and reduced patient motivation(Estebe et al., 2011; Van der Spuy, 2012). Such injury to muscles is also more likely to occur in cases of peripheral vascular disease and in the elderly in prolonged periods of tourniquet application (Rahman et al., 2015). Although there is limited evidence supporting it, use of reperfusion / breathing periods has been suggested as a technique of reducing prolonged muscle ischaemia (Noordin et al., 2009). In addition, compartment syndrome and rhabdomyolysis leading to acute kidney injury can result in cases where the tourniquet has been highly inflated for periods exceeding four hours, however, similar cases have been observed even for shorter lengths of tourniquet application time(Coudert, 2016; Estebe et al., 2011; Murphy et al., 2005; Oragui et al., 2011; Van der Spuy, 2012).

Injury to the nerves is also possible mainly secondary to compression forces from the tourniquet. Compression is greatest in portions of the nerve that are under and near the edge of the cuff. Nerve fibres with a small neuron diameter are less affected compared to the large thicker fibres(Noordin et al., 2009). In addition, nerve damage can also occur due to ischemia which brings about metabolic stress to the nerves. As a result, there is depolarisation and spontaneous firing of impulses throughout the neuro and later conduction blockade occurs, first affecting the slow conducting fibres and then the entire nerve (Wong & Irwin, 2018). A combination of mechanical forces and ischemia can displace the nodes of Ranvier and cause focal / segmental damage to the myelin sheath (distending of the para- nodal myelin on one end of the node with invagination of the para- nodal myelin on the other end) and axonal shrinkage which can further lead to Wallerian degeneration(Coudert, 2016; Estebe et al., 2011; Noordin et al., 2009; Oragui et al., 2011; Wong & Irwin, 2018). Various reports of

nerve injury are attributed to faulty pressure gauges. Prolonged ischaemic periods are also associated with neuropathy. Injury to the nerves brings about muscle weakness, sensory reduction or loss and neuropathic pain(Murphy et al., 2005). In the upper limb, the radial nerve is most susceptible to injury followed by the ulnar nerve with the median nerve being less susceptible while in the lower limb, the common peroneal nerve is commonly injured followed by the tibial nerve with the femoral nerve being rarely injured(Oragui et al., 2011; Van der Spuy, 2012). Although such occurrences have been found to be rare, they can continue for up to a 6 months postsurgical period or remain permanent in some cases(Bruce, 1978; Coudert, 2016; Oragui et al., 2011; Sharma & Salhotra, 2012; Vaughan et al., 2017). Nerve injury is presumably under diagnosed since the nerve recover quickly and since presence of post-operative muscle weakness can be due to muscle injury(Van der Spuy, 2012).

Injury to the blood vessels has also been noted especially in patients with atherosclerosis(Coudert, 2016; Murphy et al., 2005). Atherosclerotic vessels are less elastic and therefore require a high arterial occlusion pressure. In these cases, application of high tourniquet pressures causes vascular endothelial injury and can result into splitting / dislodgment of the atherosclerotic plaques. This can result in to vascular compromise to the limb and adversely lead to amputation or need for vascular reconstruction surgery(Coudert, 2016; Estebe et al., 2011; Van der Spuy, 2012). These have been reported in approximately 25% of cases with atherosclerosis who have undergone orthopaedic operations with tourniquets(Coudert, 2016). Tourniquet time extending over 60 minutes can significantly raise the chances of developing deep venous thrombosis (DVT) whose formation begins at the point of inflation and is highest upon deflation(Estebe et al., 2011). Such injury is hard to detect in approximately 50 % of the cases(Murphy et al., 2005).Similarly, Neil &

Sheppard, (1989) reported a case of transient compartment syndrome of the fore arm that resulted from venous congestion that was induced by a tourniquet. It is therefore important to always assess the vascular status of the limb after tourniquet deflation(Coudert, 2016; Estebe et al., 2011; Murphy et al., 2005). It is however important to note that such events are rare in patients with healthy vessels as they can accommodate high compression pressures.

2.2.3.2 Reperfusion injury

This occurs during post ischemia reperfusion of the limb following release of the tourniquet. The process is mediated by release and activation of polynuclear lymphocytes which produce reactive oxygen species. Locally, these bring about endothelial damage to the capillaries which leads to increased capillary permeability. This leads to reperfusion oedema that can lead to an up to 150% increase in limb girth (Coudert, 2016). In a clinical study by Kosucu, et al., (2014), features of ischaemic reperfusion injury were found to occur more in cases where spinal anaesthesia was used than when intravenous and inhalational types were used.

2.2.3.3 Bleeding / Haemorrhage

This may happen intra operatively (tourniquet failure) and is usually due to faulty equipment which may display incorrect pressure readings. It may also be due to inadequate limb exsanguination or non-compressible (calcified) vessels like in the elderly. Occasionally, displacement of the tourniquet from its desired position could also occur resulting into intra operative bleeding. Slow inflation has also been documented to cause this bleeding. It is important to note that blood may flow through the intramedullary vessels and cause bleeding in which case it becomes un necessary to increase the cuff pressure(Sharma & Salhotra, 2012; Van der Spuy, 2012; Vaughan et al., 2017).

Post tourniquet bleeding also occurs following deflation and is attributed release of plasminogen activator in the tissues which activates anti thrombin III and Protein C thrombolytic pathways (Oragui et al., 2011; Van der Spuy, 2012). Quick deflation is important in preventing capillary bleeding(Estebe et al., 2011; Sharma & Salhotra, 2012).

2.2.3.4 Wound infection

During operations on the lower limb, wound hypoxia occurs and is due to activation of neutrophils and injury to the endothelium which lead to a systemic inflammatory response. This may predispose to wound infection and delay healing. Tourniquets may also harbour infectious agents(Ekwunife et al., 2019; Estebe et al., 2011).

In summary of the literature reviewed, it is crucial to comprehend that despite the benefits of tourniquet use, it is not without risks. Additionally, it is important to follow the correct and recommended usage of surgical tourniquet with emphasis on the precautions for each indication, as well as understanding the deleterious outcomes and contraindications of its use. Healthcare workers involved in surgical tourniquet use should be familiar with the recommended practices with overall aim of promoting patient safety.

CHAPTERTHREE

3.0 METHODOLOGY

3.1 Study design

A descriptive prospective study.

3.2 Study site

Moi teaching and Referral Hospital (MTRH), a public health institution located in Eldoret, about 310 kilometres northwest of Nairobi the capital city of Kenya. MTRH is the second largest health institution after Kenyatta National Hospital in Nairobi. It has a wide catchment area extending and not limited several counties in Kenya, Southern Sudan, Uganda, Rwanda, Burundi and Tanzania, serving at least 20 million people. It is hosting several educational institutions including the College of Health Sciences of Moi University, Kenya Medical Training College, Academic Model Providing Access To Health Care (AMPATH), and Chandaria Chronic Diseases Centre. It has also been used as students' attachment centre. MTRH offers several services through several departments, including surgery, medicine, obstetrics and gynaecology, mental health and paediatrics. The actual study site was the main theatre and orthopaedics wards all under Orthopaedic Surgery Department.

3.3 Study population

Patients undergoing orthopaedic surgical procedures involving the upper and lower limbs.

3.3.1 Inclusion criteria

I. Scheduled operation that included the use of a tourniquet.

3.3.2 Exclusion criteria

i. Cases involving use of finger tourniquets.
ii. Patients with head injury.
iii. Patients with diagnosed mental illnesses.
iv. Patients who did not consent to being involved in the study.

3.4 Sampling technique and sample size

Sample size was determined using the prevalence of complications based on available studies. Reviews conducted have shown tourniquet pain to be the most common complication occurring in 66% of cases intra operatively (Sharma & Salhotra, 2012). So far, the Researcher has not yet come across locally available statistics reporting on tourniquet complications. In order to have a 95% confidence interval and a 10% margin of error, a minimum sample size of 86 cases was included in the study.

This has been calculated using the formula by Cochran, (1977) as stated below:

$$n = \frac{Z^2 pq}{d^2}$$

Where: Z - is the critical value for a 95% confidence interval, Z=1.96

d- is the margin of error, d=10% for this study

p- is the prevalence of tourniquet pain as the most commonly reported complication, p=66%.

q=1-p

n- is the estimated sample size required for this study.

Sampling was by convenience, a nonprobability technique which included patients who fitted the inclusion/exclusion criteria.

3.5 Data collection tool and technique

Data was collected using a data collection sheet designed by the researcher. This sheet included information on patient's social demographics, diagnosis and pre-operative assessment, technique of tourniquet application employed and any associated intra and post-operative complications. Thus, data was collected by following each patient in three stages namely pre- operatively, intra-operatively and post-operatively through the following steps:

Patients' personal information and any underlying medical conditions were collected pre operatively through history taking and examination.

Data regarding the patients' preparation while in theatre including administration of anaesthesia, limb exsanguination and skin preparation was recorded.

Techniques of tourniquet application (e.g., site of application, tourniquet pressures and duration of application) including the properties of the tourniquet used (such as type of tourniquet, cuff size and shape), for each patient were recorded. Methods of pressure determination were recorded after consulting the applicant.

The outcomes or events resulting from tourniquet use were recorded when noticed or observed both intra operatively (over the period of inflation) and post operatively (after deflation) based on signs and symptoms of such complications.

Tourniquet pain was considered to occur if the patient complained under regional anaesthesia or if the blood pressure rose by 30 % from the base line.

Paediatric participants were monitored for intra operative hyperthermia by taking their temperature half hourly using an infrared thermometer.

Intraoperative bleeding was recorded if the surgeons expressed dissatisfaction with the bloodless field during surgery after inflation of the tourniquet.

Skin injury was determined by inspecting the site of tourniquet application for blisters, abrasions and bruises after removal of the tourniquet.

Limb oedema was determined by taking limb circumference 5 cm above the elbow and 10 cm above the superior pole of the patella for the upper and lower limbs respectively before inflation and after deflation of the tourniquet.

Patients were monitored for hypotension after deflation of the tourniquet while under observation in the post anaesthesia care unit.

While in the wards, post tourniquet bleeding was recorded if the patients experienced significant soiling of the dressings that necessitated change of dressing in the first 24 hrs following surgery. Patients were also assessed for features of DVT, compartment syndrome and nerve damage. Wound sepsis was assessed by following up patients up to the third (3^{rd}) postoperative day for presence of pus at the surgical site. For patients who were discharged before the third post-operative day, follow up was done through phone calls.

3.6 Data analysis

Descriptive analysis was used to summarise findings from the study sample and to compare relationships between variables.

Data was analysed for study variables using STATA version 16.

Continuous variables such as age, tourniquet time and inflation pressures were summarised in form of ranges, means and medians.

Categorical variables such as exsanguination, skin protection, pressure determination methods, and complications were summarised inform of frequency distribution.

Statistical tests such as Pearson's Chi Square test, Fishers exact test, and Wilcoxon rank-sum test were used to analyse associations between tourniquet application practices and complications.

3.7 Ethical consideration

Permission to carry out the study was granted by the Institutional Research and Ethics Committee (IREC), (FAN: 003425) of MTRH/ Moi University. Permission was also granted by MTRH administration.

A research license was obtained from the National Commission for Science, Technology and Innovation (Ref. No. 673465) prior to commencement of the study.

Patients' enrolment into the study was on voluntary basis and they retained the freedom to exit the study at their own will.

Patients enrolled into the study had written or signed consent sought, and benefits and risks they might encounter during the study were explained to them in a language best understood by them.

Identity of the patients in the study was withheld to maintain anonymity.

Absolute confidentiality about the patients' data was ensured.

Findings from the study will be disseminated for the benefit of the public by providing copies of the bound theses to the university public library and through publication in scientific journals.

3.8 Study assumptions

Patients under the age of 15 years were considered as the paediatric population while those aged 15 years and above were considered as the adult population.

The patient's baseline blood pressure was considered as the blood pressure reading after administration of anaesthesia at the time of tourniquet inflation.

Surgical site infection as a late complication from tourniquet use was assumed to occur 3 days after surgery.

3.9 Limitations to the study

The data collection method involved the use of a data collection tool that had been designed by the researcher. Thus, the tool was pre tested by the Researcher.

Since the study involved reviewing patients at different stages, there was potential for loss of follow up. Therefore, the study had been limited to observing patients up to the third post-operative day during their hospital stay to minimise loss of follow up. Patients who were discharged prior to the third post-operative day were followed up through phone calls.

Patients were observed up to time of discharge, this limited observation of some late complications such as post tourniquet syndrome which occurs a week after surgery and required physical examination.

CHAPTER FOUR

4.0 RESULTS

4.1 Sociodemographic features and clinical diagnoses

Eighty-six patients were recruited into the study. There were 62 male patients and 24 female patients. The age of participants ranged between 3 and 71 years with a mean age of 36.5 (SD 51.7) and median age of 34.0 (IQR: 27.0, 48.0) years. Patients under the age of 15 years were 6 in number and these were considered as the paediatric population while those aged 15 years and above were 80 in number and were considered as the adult population.

In 29 cases, the surgeries were done under general anaesthesia while regional anaesthesia was applied for 57 cases. Out of those under regional anaesthesia, spinal anaesthesia was used in 55cases while axillary blocks were used in 2 cases.

Only 18 patients underwent procedures involving the upper limbs while 68 patients underwent procedures involving the lower limbs.

Table 4.1.1: Summary of clinical diagnoses

Diagnosis	Number (percentage)
Fracture tibia	36 (41.9%)
Tendon cut	7 (8.1%)
Malunion	7 (8.1%)
Arthritis	5 (5.8%)
Fracture radius	5 (5.8%)
Others	36 (41.9%)

4.2 Techniques of tourniquet application used during orthopaedic operations

Pneumatic tourniquets were used in all the cases. In 11 cases, the tourniquet was applied by the consultant surgeon while in 75 cases, the residents applied the tourniquet.

In all the cases, a time period of at least 5 minutes was allowed between administration of prophylactic antibiotics and inflation of the tourniquet.

A protective padding underneath the tourniquet was used in all cases to prevent damage to the skin. However different padding materials were uses which included the draping towels, cotton cast padding, gauze and crepe bandage.

Table 4.2.1: Use of skin protective padding

Type of padding	**Number (percentage)**
Towel	58 (67.4%)
Cotton cast padding	14 (16.3%)
Gauze	8 (9.3%)
Crepe bandage	6 (7.0%)

There was no observed use of an adhesive skin drape to prevent liquids from seeping underneath the cuff.

Tourniquet cuffs used were all straight in shape but of different sizes in terms of width and length. The extra-large cuff of 42 inches was the most commonly used. Table 4.2.2 summarises the frequencies at which different cuff sizes were used.

Table 4.2.2: Choice of cuffs used

Cuff size	Number (percentage)
Extra-large (42'')	32 (37.2%)
Large (30'')	30 (34.9%)
Medium (24'')	11 (12.8%)
Small (15'')	13 (15.1%)

The tourniquet cuffs were applied over the arms and thighs for upper and lower limb procedure respectively. There was no use of fore arm, wrist, calf or ankle cuffs.

Exsanguination was done passively through limb elevation in all the cases. There was no use of active exsanguination methods.

Table 4.2.3: Exsanguination mode

Exsanguination mode	Number (percentage)
Elevation	100%
Esmarch bandage	0%
Rhys exsanguinator	0%

Tourniquet inflation pressures ranged between 150 -335 mmHg for the upper limbs and 250 – 350 mmHg for the lower limbs.

The most applied method of pressure determination was the arbitrary setting which was used in 73 cases. While other methods based on SBP were used in 13 cases. There was no use of AOP or LOP settings.

Table 4.2.4: Inflation pressure

Limb	Pressure (mmHg)
Upper	150 – 335
Lower	250 -350

Table 4.2.5: Methods of pressure determination

Method	Number (percentage)
Arbitrary	73 (84.9%)
AOP	0(0%)
LOP	0(0%)
Others	13(15.1%)

Table 4.2.6: Other methods of pressure determination

Method	Number (percentage)
SBP +200	**8 (9.3%)**
SBP x1.5	**2 (2.3%)**
SBP +100	**1 (1.2%)**
SBP x2	**1 (1.2%)**
SBP +75	**1 (1.2%)**

Tourniquet time ranged between 48 minutes to 135 minutes in upper limbs, and 30 minutes to 200 minutes in lower limbs. In children, it ranged between 30 to 95 minutes.

Table 4.2.7: Tourniquet time

Variables	time (minutes)
Upper limb	48 – 135
Lower limb	30 – 200
Children	30 – 95

Tourniquet deflation was commonly done after wound closure and dressing in 68 cases while in 18 cases, it was done prior to wound closure and dressing.

Table 4.2.8: Timing of tourniquet deflation

Timing of deflation	Number (percentage)
After closure	68 (79.1%)
Before closure	18 (20.9%)

All the patients were observed in the post anaesthesia care unit for at least an hour after deflation of the tourniquet.

4.3 Intra operative complications arising from use of the surgical tourniquet

Tourniquet pain was observed in 39 cases. It was the most common intra operative complication.

Intraoperative bleeding was observed in 10 cases and there were no incidences of intraoperative hyperthermia.

Table 4.3.1: Intra operative complications

Complication	**Frequency (percentage)**
Tourniquet pain	39 (45.3%)
Hyperthermia	0 (0%)
Intraoperative bleeding	10 (11.7%)

Table 4.3.2: Tourniquet pain by clinical and demographic characteristics

Variables		**Tourniquet pain**		
		Absent	**Present**	**p-value**
Limb	Lower	41 (60.3%)	27 (39.7%)	0.041[c]
	Upper	6 (33.3%)	12 (66.7%)	
Anaesthesia	General	9 (31%)	20 (69%)	0.002[c]
	Spinal	37 (67.3%)	18 (32.7%)	
Cuff pressure	Median (IQR)	350 (300, 350)	300 (250, 350)	0.004[w]
[c] Persons Chi Square test, [f] Fishers exact test, [w] Wilcoxon rank-sum test				

Statistically, Tourniquet pain was found to be significantly associated with general anaesthesia with a p value of 0.002. It was also significantly associated with lower limb procedures with a p value of 0.041. There was also a statistically significant association between tourniquet pain and a median inflation pressure of 300mmHg with a p value of 0.004.

4.4 Post-operative complications arising from use of the surgical tourniquet

The frequency of occurrence of post-operative complications is shown in table 4.4.1

Table 4.4.1: Postoperative complications

Complication		**Frequency (percentage)**
Skin injury		21 (24.5%)
Post tourniquet bleeding		34 (39.5%)
Ischaemic-reperfusion injury	Oedema	74 (86.0%)
	Hypotension post deflation	8 (9.3%)
	Pharmacological complications	4 (4.7%)
Nerve injury		4 (4.7%)
Wound sepsis		3 (3.5%)

Skin injury occurred in 21 cases. Of these, blistering occurred in 20 cases while bruising occurred in 1 case. Ischaemic reperfusion injury was the most observed post-operative complication with limb oedema occurring in 74 cases, hypotension following tourniquet deflation occurred in 8 cases and pharmacological effects following tourniquet deflation were observed in 4 cases.

Nerve injury was characterised by paraesthesia was reported in 4 cases and no sensory or motor loss was reported.

Wound sepsis was observed in 3 cases and all these involved the lower limbs.

There were no cases of DVT or compartment syndrome.

Table 4.4.2: Skin injury by clinical and demographic characteristics

Variables	**Skin injury**		
	Absent	**Present**	**p-value**
Limb			
Lower	**48 (70.6%)**	**20 (29.4%)**	**0.060[f]**
Upper	**17 (94.4%)**	**1 (5.6%)**	
Anaesthesia			
General	**26 (89.7%)**	**3 (10.3%)**	**0.024[c]**
Spinal	**37 (67.3%)**	**18 (32.7%)**	
Age			
Median (IQR)	**34 (26, 49)**	**35 (28.5, 47)**	**0.527[w]**
TQT time (minutes)			
Median (IQR)	**84 (60, 100)**	**116 (106, 120)**	**<0.001[w]**
Cuff pressure			
Median (IQR)	**350 (250, 350)**	**320 (300, 350)**	**0.474[w]**
[c] Persons Chi Square test, [f] Fishers exact test, [w] Wilcoxon rank-sum test			

Skin injury was found statistically to be significantly associated with median tourniquet time of 116 minutes with a p-value of <0.001. There was also a statistically significant association between skin injury and spinal anaesthesia with a p-value of 0.024.

Table 4.4.3: Oedema by clinical and demographic characteristics

Variables	**Oedema**		
	Absent	**Present**	**p-value**
Limb			
Lower	**5 (7.3%)**	**63 (92.7%)**	**0.002[f]**
Upper	**7 (38.9%)**	**11 (61.1%)**	
Anaesthesia			
General	**10 (34.5%)**	**19 (65.5%)**	**<0.000[f]**
Spinal	**2 (3.6%)**	**53 (96.4%)**	
Age			
Median (IQR)	**27 (13, 36.5)**	**34 (28, 50)**	**0.022[w]**
TQT time (minutes)			
Median (IQR)	**60 (43, 84.5)**	**100 (73, 117)**	**0.003[w]**
Cuff pressure			
Median (IQR)	**250 (250, 275)**	**350 (300, 350)**	**<0.001[w]**
[c] Persons Chi Square test, [f] Fishers exact test, [w] Wilcoxon rank-sum test			

Oedema statistically was significantly associated with procedures on the lower limb with a p-value of 0.002, use of spinal anaesthesia with a p-value of < 0.000, a median age of 34 years with a p value of 0.022, median tourniquet time of 100 minutes (p value-0.003) and median cuff pressure of 350mmHg (p-value <0.001).

Table 4.4.4: Post tourniquet bleeding by clinical and demographic characteristics

Variables	**Post tourniquet bleed**		
	Absent	**Present**	**p-value**
Limb			
Lower	**36 (52.9%)**	**32 (47.1%)**	**0.006[c]**
Upper	**16 (88.9%)**	**2 (11.1%)**	
Deflation time			
After closure	**40 (58.8%)**	**28 (41.2%)**	**0.545[c]**
Before closure	**12 (66.7%)**	**6 (33.3%)**	
TQT time (minutes)			
Median (IQR)	**75.5 (60, 105.5)**	**104.5 (95, 125)**	**<0.001[w]**
Cuff pressure			
Median (IQR)	**300 (250, 350)**	**350 (300, 350)**	**0.003[w]**
[c] Persons Chi Square test, [f] Fishers exact test, [w] Wilcoxon rank-sum test			

Post tourniquet bleeding statistically was significantly associated with lower limb procedures (p-0.006), median tourniquet time of 104.5 minutes (p value <0.001) and median cuff pressure of 350mmHg (p-value 0.003). There was no statistically significant association between post tourniquet bleeding and time of tourniquet deflation in relation to wound closure.

CHAPTER FIVE

5.0 DISCUSSION

5.1 Sociodemographic features and clinical diagnoses

Majority of the patients were males (62), who were relatively young. Trauma cases formed the majority of the clinical diagnoses, with lower limb injuries forming the majority. Other authors (Adhikar et al., 2017; Sharma & Salhotra, 2012) had more males than females in their studies. Yalcinkaya et al., (2014) on the contrary had more females than males in their study. Males and in particular the relatively young ones are more likely to be involved in risky undertaking associated with trauma in any population in the world.

5.2Techniques of tourniquet application used during orthopaedic operations

In all cases, there was a time period of at least 5 minutes between administration of antibiotics, anaesthetics and inflation of the cuff. This is in agreement with Murphy, et al., (2005) who recommended a similar time period. This time period of at least 5 minutes prior to inflation is crucial as it allows for venous drainage as well as for the adequate concentration of antibiotics reaching the operation site and hence exerts its efficacy against microorganisms associated with surgical site infections. Some authorities have documented a period of 30 minutes of prophylaxis antibiotic administration prior to tourniquet application.

In all cases, pneumatic tourniquets were used. This is in agreement with Vaughan, et al., (2017) who reported pneumatic tourniquets as the currently used tourniquet systems in modern operating theatres. Pneumatic tourniquet is safe when used at just the occlusion pressure, and for recommended time to avoid associated complications noted in patients who are operated with tourniquet at higher pressures and prolonged time. Complications such as deep venous thrombosis and infections have been

documented (Coudert, 2016; Estebe et al., 2011). Use of mechanical exsanguination has been contraindicated in some situations such as sickle cell disease and infectionsin distal parts of limbs to avoid complications (Noordin et al., 2009; Oragui et al., 2011; Vaughan et al., 2017; Wong & Irwin, 2018).

A protective padding was used in all cases to minimise cutaneous injury. This finding is closely in agreement with that of Boya, et al., (2016) who found a 94.9% rate of use of a skin protective padding among surgeons practicing in Turkey. Padding should be used between the tourniquet and skin to minimize cutaneous injury (Murphy et al., 2005; Sharma & Salhotra, 2012; Vaughan et al., 2017). A protective padding particularly the soft crease- free type is quite important so as to avoid skin- related post tourniquet complications such as shearing stress (Coudert, 2016; Estebe et al., 2011; Van der Spuy, 2012). The padding should not be more than a layer to retain its effectiveness in pressure transmission (Vaughan et al., 2017; Wong & Irwin, 2018).

There was no use of an adhesive skin protective drape. This contrasts recommendations by Van der Spuy, (2012) who reccomended that a water proof adhesive plastic drape should be used during skin prepation to guard alcoholic solvents from seeping underneath the tourniquet. The inavailability of these adhesive materials can be attributed to their cost. Use of adhesive material is recommended for skin protection as it prevents chemicals (e.g., antiseptic agents) from reaching skin proximal to operation site and causing chemical burns underneath turniquet.

Exsanguination was done by limb elevation technique. This concurs with findings by Estebe, et al., (2011) who reported limb elevation to be a better and safer method of exsanguination which also provides better visualisation of superficial vessels compared to active exsanguination. Usually the lower limb is elevated up to 45° while

upper limb at twice that for a short interval (5-15 minutes) to facilitate venous drainage by gravity, followed by exsanguination and eventually tourniquet application.

The sites of tourniquet application were the arm and the thigh for upper and lower limbs respectively. This concurs with Kumar, et al., (2016) who recommended that tourniquets should be applied at the parts of the limb with the greatest circumference (related to muscle and soft tissue bulk). The practice of identifying correct location for tourniquet application is quite important as it prevents associated post tourniquet complications of nerve palsy. Other considerations include placing tourniquet as much proximal as possible (Coudert, 2016; Vaughan et al., 2017), and avoiding bony prominences (Kumar, et al., 2016).

The cuffs used were straight / cylindrical in shape. These findings are closely in agreement with those by Boya, et al., (2016) who found that straight cuffs were used more commonly (73.5%) by orthopaedic surgeons in Turkey than conical cuffs. However the findings of such practice in this research is not in agreement with that by Estebe, et al., (2011) who recommended use of conical cuffs as they offer better pressure distribution when the tourniquet is inflated. Use of conical or contoured cuffs distributes pressure more evenly than the straight and cylindrical types and hence least associated with post tourniquet complications related to high pressure inflation (Coudert, 2016; Estebe et al., 2011; Murphy et al., 2005; Van der Spuy, 2012; Vaughan et al., 2017).

Wide cuffs were used more frequently. This is partly because the majority of the surgeries were on the lower limb. It is also in agreement with recommendations by Sharma and Salhotra, (2012) who recommended that wider cuffs reduce pressure related complications by achieving tissue compression gradually and at lower

pressures compared to narrow cuffs. The use of wide cuff at MTRH is also in agreement with what was recommended by other authors (Coudert, 2016; Estebe et al., 2011; Oragui et al., 2011; Sharma & Salhotra, 2012; Vaughan et al., 2017).

Tourniquet inflation pressures ranged between 150 -335 mmHg for the upper limbs and 250 – 350 mmHg for the lower limbs. These findings are closely in agreement with those by Yalcinkaya, et al., (2014) who found ranges of 150-350mmHg in upper limbs and 250-500mmHg in lower limbs used by orthoapaedic residents and surgeons in Insatabul, Turkey. Great precaution is required as higher than required tourniquet pressure and prolonged time are detrimental since they are associated with post tourniquet complications.

The method of pressure determination most commonly used was the arbitrary setting. While other methods based on systolic blood pressure accounted for 15.2%.This concurs with findings by Boya, et al., (2016) who found no consensus on the proper methods used by surgeons in setting the tourniquet pressure. It is quite essential that a method of tourniquet pressure determination be established for patient safety purposes. Limb occlusion pressure method has been advocated as it is least associated with post tourniquet complications. Method of pressure determination may be influenced by age (younger age require lower inflation pressure), blood pressure level and limb size (Murphy et al., 2005; Sharma & Salhotra, 2012).

Tourniquet time ranged between 30 minutes to 03:20 hours and 01:53hours in adults and children respectively. This is not in agreement with recommendations by Kumar, et al., (2016) and Murphy, et al., (2005) who described a maximum safe limit of 3 hours in adults and no more than 75 minutes in children. Prolonged tourniquet time

has been known to be associated with post tourniquet complications including nerve palsy, skin ischaemia and myoglobinuria which can cause kidney damage.

Reperfusion/breathing periods were not used in any of the cases. This contrasts recommendations by Kumar, et al., (2016) who suggested use of a 10 minute breathing period in case tourniquet time exceeded 2.5 hours. The practice contravened what has been established and recommended in the literature. Reperfusion time is crucial as it helps in increasing tourniquet time while lowering nerve injury as noted by Sharma and Salhotra, 2012 and Vaughan, et al., 2017. Reperfusion should be done not later than every 2 hours in order to preserve biological protective mechanisms since the tissues are not overwhelmed by pathophysiological and inflammatory processes (Estebe et al., 2011).

Tourniquet deflation was frequently done after wound closure and dressing. This is not in agreement with recommendations by McMillan and Johnstone, (2017) who recommended early deflation before wound closure to minimise tourniquet time and allow for haemostasis. Early tourniquet deflation allows reperfusion and swelling within the limb to occur prior to dressing application thus preventing undesired effects of compartment syndrome as noted by Estebe, et al., 2011. This however may cause significant blood loss (Murphy et al., 2005; Rahman et al., 2015; Sharma & Salhotra, 2012; Wong & Irwin, 2018; Wu & Wong, 2018). In this later scenario, firm application of dressings in order to achieve haemostasis during the initial reactive hyperaemia is recommended (Wong & Irwin, 2018). However it is up to the discretion of the operating surgeon (Noordin et al., 2009) who should balance the potential hazards between early and late deflation.

In all cases, patients were monitored in the post anaesthesia care unit for at least an hour prior to discharge to the ward. This is in agreement with recommendations by Rahman, et al., (2015) who recommended that patients should be kept under observation by the anaesthetist for at least one hour following deflation of the tourniquet. This practice helps in early diagnosis of postoperative post tourniquet complications and taking prompt corrective measures.

5.3 Intra operative complications arising from use of the surgical tourniquet

Tourniquet pain was observed in 45.3% of the cases.

A higher percentage was observed with general anaesthesia (***p***-0.002) than with spinal anaesthesia. This concurs with findings by Kumar, et al., (2016) who found it to be commonest under general anaesthesia with an incidence of between 53 -67%.

There were more incidences in the upper limb (***p-value*** 0.041) than in the lower limb which contrasts findings by Kumar, et al., (2016) who reported a higher occurrence during lower limb surgeries.

Intra operative bleeding was observed in 11.6% of the cases. This contrasts findings by Ekwunife, et al., (2019) who reported no cases. This can be attributed to the fact that Ekwunife used a specific prescribed method of setting the inflation pressure in all the cases he studied.

There were no cases of intraoperative hyperthermia observed in the paediatric population. This is partly because no duo tourniquets were used as these have been implicated as the main causes by Klenerman, 2003.

5.4 Post-operative complications arising from use of the surgical tourniquet

Skin injury was recorded in 24.5% of the cases.

Blistering was the commonest skin injury occurring in 20 of the 21 cases of skin injury. This concurs with reports by Coudert, 2016.

There was an association between skin injury and tourniquet time (***p***-value <0.001) with a median noted at 116 minutes of tourniquet time. This is in agreement with findings by Murphy, et al., (2005) who attributed skin injury to excessive tourniquet time.

There was no association between skin injury and age. This contradicts reports by Coudert, (2016) who reported skin injury to be affected by extremity of age.

Post tourniquet bleeding was noted in 39.5 % of the cases.

There was no significant association between post tourniquet bleeding and timing of tourniquet release in relation to wound closure. This is in disagreement with Wu and Wang, (2018) who reported increased post-operative blood loss to be associated with tourniquet deflation before wound closure.

Ischaemic reperfusion injury consisting of limb oedema, pharmacological effects and hypotension following tourniquet release was noted in 88.4 % of the cases. Oedema occurred in 86.0 % of all cases however. It was associated with spinal anaesthesia (***p***-value <0.000). These findings concur with those by Kosucu, et al., (2014)who found features of ischaemic reperfusion injury more commonly in spinal anaesthesia than in intravenous and inhalational types. Pharmacological effects occurred in 4.7% and hypotension in 9.3%.

However, no morbidities resulted in any of the cases of ischaemic – reperfusion injury. This in agreement with Klenerman, (2003) who reported ischaemic reperfusion injury to be the most common but also the most well tolerated complication from tourniquet release.

Nerve injury characterised by paraesthesia were noted in 4.7% of the cases however no motor or total sensory loss was observed. This is in agreement with Estebe, et al., (2011) who reports an incidence of between 0.1-7.7percent.

Wound sepsis was observed in 3.5% of the cases. This in contrast to Ekwunife, et al., (2019) who found surgical site infection at 1.9 % prevalence.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Various techniques were used in application of the tourniquet during orthopaedic operations at MTRH.

Complications from tourniquet use occurred frequently but rarely resulted into disability or fatality

Complications arising from tourniquet were affiliated to the different techniques used in application of the tourniquet.

6.2 Recommendations

Institutional guidelines should be established for the safe use of the tourniquet to prevent adverse effects. Recommended guidelines include

Application of a skin protective padding that is crease free and consisting of at least two layers of a given material of choice.

Avoid seepage of surgical site prep solutions underneath the tourniquet

Use of the widest available cuff of a length ranging between 7cm to 15 cm greater than the limb circumference.

Application of cuffs at the places of greatest muscle bulk

Exsanguination for at least 5 minutes through elevation at an angle of 90 degrees (upper limb) and 45 degrees (lower limb).

Inflation of the cuff at least 10 minutes after administration of pre-operative medications

Use of AOP or LOP methods for setting inflation pressures

Limit inflation time to 3 hours in adults and no more than 75 minutes in children.

Deflation of cuff prior to wound closure and dressing.

Monitor patients for at least an hour after deflation of the tourniquet

It is important to anticipate adverse effects of tourniquet use and work towards their attenuation.

Further studies are recommended on comparisons between different tourniquet pressures and associated complication.

REFERENCES

Adhikari, G. H., Nekkanti, S., Ravikiran, H. G., & Ravishankar, R. (2017). A clinical study of the safe use of pneumatic tourniquet in orthopaedic surgery. *International Journal of Orthopaedics Sciences*, *3*(4), 74–78.

Bogdan, Y., & Helfet, D. L. (2018). Use of Tourniquets in Limb Trauma Surgery. *Orthopedic Clinics of North America*, *49*(2), 157–165.

Boya, H., Tuncali, B., Ozcan, O., Arac, S., & Tuncay, C. (2016). Practice of tourniquet use in Turkey : a pilot study. *Acta Orthopaedica et Traumatologica Turcica*, *50*(2), 162–170.

Bruce, L. (1978). The Tourniquet. *Australian and New Zealand Journal of Surgery*, Vol. 48, pp. 66–70.

Cochran, W. (1977). *Sampling Techniques* (3rd ed., Vol. 3). New York: John Wiley and Sons. In.

Coudert, M. M. (2016). *The use of tourniquet in limb surgery*. Retrieved from https://urn.nsk.hr/urn:nbn:hr:105:581445

Ekwunife, R. T., Iyidobi, E. C., Enweani, U. M., Nwadinigwe, C. U., Okwesili, C. I., Ekwedigwe, H. C., & Agbo, E. O. (2019). *Assessment of complications following use of pneumatic tourniquet for elective orthopedic procedures at National Orthopedic Hospital , Enugu*. *5*(5), 764–771.

Estebe, J. P., Davies, J. M., & Richebe, P. (2011). The pneumatic tourniquet: Mechanical, ischaemia-reperfusion and systemic effects. *European Journal of Anaesthesiology*, *28*(6), 404–411.

Houng, W., Lee, C., Chiou, H., & Wei, Y. (2012). Cardiac arrest after tourniquet deflation in tibial plateau fracture surgery in a healthy man. *Formosan Journal of Musculoskeletal Disorders*, *3*(1), 34–38.

Kalla, T. P., Younger, A., McEwen, J. A., & Inkpen, K. (2003). Survey of tourniquet use in podiatric surgery. *Journal of Foot and Ankle Surgery*, *42*(2), 68–76.

Klenerman, L. (2003). *The Tourniquet Manual : Principles and Practice*.

Koşucu, M., Coşkun, I., Eroglu, A., Kutanis, D., Menteşe, A., Karahan, S. C., … Topbas, M. (2014). The effects of spinal, inhalation, and total intravenous anesthetic techniques on ischemia-reperfusion injury in arthroscopic knee surgery. *BioMed Research International*, *2014*.

Kumar, K., Railton, C., & Tawfic, Q. (2016). Tourniquet application during anesthesia: "What we need to know?" *Journal of Anaesthesiology Clinical Pharmacology*, *32*(4).

McMillan, T. E., & Johnstone, A. J. (2017). Tourniquet uses and precautions. *Surgery (United Kingdom)*, Vol. 35. https://doi.org/10.1016/j.mpsur.2017.01.011

Murphy, C. G., Winter, D. C., & Bouchier-Hayes, D. J. (2005). Tourniquet injuries : pathogenesis and modalities for attenuation. *Acta Orthopædica Belgica*, *71*(6), 635–645.

Neil, D. O., & Sheppard, J. E. (1989). Transient compartment syndrome of the forearm resulting from venous congestion from a tourniquet. *Journal of Hand Surgery*, *14*(5), 894–896.

Noordin, S., McEwen, J. A., Kragh, J. F., Eisen, A., & Masri, B. A. (2009). Surgical tourniquets in orthopaedics. *Journal of Bone and Joint Surgery*, *91*(12), 2958–2967.

Oragui, E., Parsons, A., White, T., Longo, U. G., & Khan, W. S. (2011). Tourniquet use in upper limb surgery. *Hand*, *6*(2), 165–173. https://doi.org/10.1007/s11552-010-9312-6

Rahman, O., Hafeez, S., Amin, M. S., Ameen, J., & Adnan, R. (2015). Early release of tourniquet in total knee arthroplasty : Is it worthwhile? *Journal of Pakistan Medical Association*, *65*(11), 77–81.

Rathore, O. M., Amin, S. M., & Rathore, U. M. (2018). Tourniquet practices in orthopaedic surgery: a questionnaire based study. *Pakistan Armed Forces Medical Journal*, *68*(3), 506–509.

Sadri, A., Braithwaite, I. J., Abdlu-Jabar, H. B., & Sarraf, K. M. (2010). Understanding of intra-operative tourniquets amongst orthopaedic surgeons and theatre staff - A questionnaire study. *Annals of the Royal College of Surgeons of England*, *92*(3), 243–245.

Sharma, J. P., & Salhotra, R. (2012). Tourniquets in orthopedic surgery. *Indian Journal of Orthopaedics*, *46*(4), 377.

Van der Spuy, L.-A. (2012). Complications of the arterial tourniquet. *South African Journal of Anaesthesiology*, *18*(1), 14–18.

Vaughan, A., Hardwick, T., Gaskin, J., & Bendall, S. (2017). Tourniquet use in orthopaedic surgery. *Orthopaedics and Trauma*, *31*(5), 312–315.

Wong, S., & Irwin, M. G. (2018). Procedures under tourniquet. *Anaesthesia and Intensive Care Medicine*.

Wu, Q.-F., & Wang, D.-X. (2018). Tourniquet-Induced Ischemia-Reperfusion Injury during Total Knee Arthroplasty. *Journal of Anesthesia and Perioperative Medicine*, *5*(1), 41–47.

Yalcinkaya, M., Sokucu, S., Erdogan, S., & Kabukcuoglu, Y. S. (2014). Tourniquet use in orthopedic surgery : a descriptive survey study among Turkish orthopedic surgeons and residents in Istanbul. *Acta Orthopaedica et Traumatologica Turcica*, *48*(5), 483–490.

APPENDICES

Appendix 1: Introductory letter and consent

STUDY TITLE: TECHNIQUES OF SURGICAL TOURNIQUET APPLICATION IN ORTHOPAEDIC OPERATIONS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

INVESTIGATOR: BULUMA PHILLIP OF P.O BOX 4606, ELDORET, KENYA

You are being asked to take part in the above mentioned study. The study aims at finding out the different methods used in applying the tourniquet during orthopaedic operations at Moi teaching and referral Hospital in Eldoret as well as any complications that are associated with the use of the tourniquet. The findings from this study will help in establishing proper protocols that govern the use of the tourniquet in our hospital as well as lay a foundation for further investigations on how to avoid the associated complications. Your participation in this study will therefore be of great help in archiving the objectives of this study. Your involvement is voluntary and you can pull out at any point of the study even after consenting. We shall value every piece of information we are going to get from you and keep it confidential. Thank you for your time and consideration.

Consent

I……of P.O Box…….

Tel……..hereby willingly give informed consent to participate in above mentioned study that is being conducted at Moi Teaching and Referral Hospital.

The study has been explained to me clearly by the investigator (or his appointed assistants) in a language and terms I can understand.

I have understood that to participate in this study, I shall volunteer information regarding my health and undergo medical examination and observation during and after the required orthopaedic surgery. I am aware that I have the right to withdraw from this study at any time without prejudice to my right of treatment at this hospital now or in the future. I have been assured that no injury shall be inflicted on me from my participation in this study. I have also been assured that all information shall be treated and managed in confidence.

Initials of participant…… Signature……

Date…….

Name of Witness……..Signature……

Date…….

Appendix 2: Data collection sheet
Name

Age **Sex**

Institution **IP No.**

Diagnosis

Operation **Site**

Other underlying conditions

Diabetes mellitus ☐ Localised tumour ☐

Hypertension ☐ Sickle cell disease ☐

Obesity ☐ Rheumatoid arthritis ☐

Chronic Heart Disease ☐ Peripheral neuropathy ☐

Peripheral Vascular disease ☐ Head trauma ☐

Deep venous Thrombosis ☐ Severe crush injury ☐

Severe infection in limb ☐ Poor limb skin condition ☐

In theatre

Pre operative temperature: ……^{0}C

Initial blood pressure: Systolic ….. mmHg Diastolic….. mmHg

Type of anaesthesia: Local ☐ Regional ☐ General ☐

Time of IV drug administration.

Anaesthetics ……..

Antibiotics ……..

Pre operative Limb Circumference:

Exsanguination: Yes ☐ No ☐

Technique: Elevation ☐

Crepe bandage ☐

Esmarch bandage ☐

Rys exsanguinator ☐

Protective skin padding: Yes ☐ No ☐

Anti septic / sterilising agent:

Protective adhesive skin drape: Yes ☐ No ☐

Type of tourniquet: Pneumatic ☐ Non pneumatic ☐

Posses a warning system ☐

Date of last calibration ……..

Type of cuff:

Shape: Straight ☐ Conical ☐

Size: Length ….cm Width ....cm

Site of application: Upper limb Lower limb

Arm ☐ Thigh ☐

Proximal fore arm ☐ Calf ☐

Distal fore arm ☐ Distal leg ☐

Inflation pressure: .....mmHg

Determined by: Arbitrary setting ☐

AOP ☐

LOP ☐

Other ☐

Inflation time: Time of inflation …….

Time of Deflation …….

Reperfusion period(s)

Deflation : Before wound closure ☐ After wound closure ☐

Monitoring done: 1 hour post deflation ☐

24 hours In ICU setting ☐

Observed Complications

Intraoperative observations

Tourniquet pain:

Intra operative hypertension ☐

Intra operative tachycardia ☐

Hyperthermia (paediatric cases)

Highest Intra operative temperature ……^{0}C

Intra operative bleeding ☐

Postoperative observations

Post deflation Hypotension ☐

Toxic / pharmacologic consequences:

- Respiratory depression ☐
- Dizziness ☐
- Tinnitus ☐
- Bradycardia ☐
- Seizures ☐

Clinical Thromboembolism:

- Hypotension ☐
- Tachycardia ☐
- Hypothermia ☐
- DVT ☐

Post operative Hypotension after tourniquet deflation. ☐

Post tourniquet bleeding ☐

Skin injury:

- Abrasion ☐ Blister ☐ Bruise ☐

Post operative limb circumference …….

Post tourniquet syndrome

- Stiffness ☐
- Pallor ☐
- Paresis ☐
- Paraesthesia ☐

Compartment syndrome

- Muscle weakness ☐
- Paresthesia ☐
- Decreased / Absent Pulses ☐
- Tense skin over Limb ☐

Neuropathy

- Muscle weakness ☐
- Sensory loss ☐
- Neuropathic pain ☐

Wound infection ☐

Appendix 3: Budget

ITEM	**COST (Ksh)**
Stationery	5,000
Printer	20,000
Personal computer	40,000
Measuring tapes	500
Research assistants	20,000
Transport	25,000
Data analysis	50,000
Contingency	50,000
Total	**210,500**

Appendix 4: Work plan

ACTIVITY	DURATION	PARTICIPANT
Selection of research topic	December 2018	Researcher
Proposal writing	January to May 2019	Researcher and supervisors
Proposal submission to IREC	July 2019	Researcher
Proposal approval by IREC	September 2019	IREC members
Training research assistants on patient recruitment and data collection	October 2019	Researcher
Data collection	November 2019 to June 2020	Researcher and trained research assistants
Data analysis	July 2020	Researcher and Biostatistician
Report writing	October 2020	Researcher
Discussion with supervisors	January 2021	Researcher and supervisors
Submission of thesis	July 2021	Researcher
Defence of thesis	August 2021	Researcher

Appendix 5: Pictures of the pneumatic tourniquet system and associated components

Figure 1: Modern tourniquet systemat MTRH

Figure 2: Cuffs of different sizes at MTRH

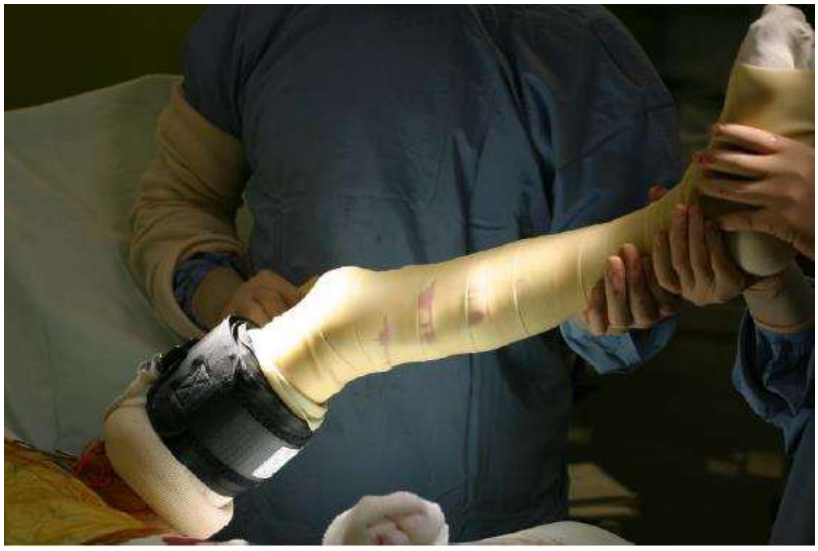

Figure 3: Limb preparation during tourniquet application.
(Source: The Japanese Society for Cardiovascular Surgery website)

Appendix 6: Nacosti Approval

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **673465**

Date of Issue: **08/November/2019**

RESEARCH LICENSE

This is to Certify that Dr.. Buluma Phillip of Moi University, has been licensed to conduct research in Uasin-Gishu on the topic: THE PRINCIPLES AND PRACTICE OF TOURNIQUET USE DURING ORTHOPAEDIC OPERATIONS AT HOSPITALS IN ELDORET TOWN, KENYA for the period ending : 08/November/2020.

License No: **NACOSTI/P/19/2662**

673465

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

Appendix 7: IREC Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference IREC/2019/179
Approval Number: 0003425

21st October, 2020

Dr. Buluma Philip,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Buluma,

RE: APPROVAL OF AMENDMENT

The Institutional Research and Ethics Committee has reviewed the amendment made to your proposal titled:-

"The Principles and Practices of Tourniquet Use during Orthopaedic Operations at, Moi Teaching and Referral Hospital, Eldoret Kenya".

We note that you are seeking to make amendments as follows:-

1. To reduce the number of study site from five to one by excluding the private health facilities.
2. Rhabdomyolysis has been excluded from the data collection tools as one of the investigated postoperative complications of tourniquet use.

The amendments have been approved on 21st October, 2020 according to SOP's of IREC. You are therefore permitted to continue with your research.

You are required to submit progress(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change(s) or amendment(s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
21 OCT 2020
APPROVED
P. O. Box 4606 - 30100 ELDORET

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc: CEO - MTRH Dean - SPH Dean - SOM
Principal - CHS Dean - SOD Dean - SON

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2019/179
Approval Number: 0003425

29th August, 2019

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
29 AUG 2019
APPROVED
P. O. Box 4606-30100 ELDORET

Dr. Buluma Philip,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Buluma,

THE PRINCIPLES AND PRACTICES OF TOURNIQUET USE DURING ORTHOPAEDIC OPERATIONS AT HOSPITALS IN ELDORET TOWN, KENYA

This is to inform you that ***MU/MTRH-IREC*** has reviewed and approved your above research proposal. Your application approval number is ***FAN:0003425.*** The approval period is ***29th August, 2019 – 28th August, 2020.***

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***MU/MTRH-IREC***.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***MU/MTRH-IREC*** within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***MU/MTRH-IREC*** within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. 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.
vii. Submission of an executive summary report within 90 days upon completion of the study to ***MU/MTRH-IREC.***

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc	CEO	-	MTRH	Dean	-	SOP	Dean	-	SOM
	Principal	-	CHS	Dean	-	SON	Dean	-	SOD

Appendix 8: Hospital Approval

An ISO 9001:2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Telephone :(+254)053-2033471/2/3/4
Mobile: 722-201277/0722-209795/0734-600461/0734-683361
Fax: 053-2061749
Email: ceo@mtrh.go.ke/directorsofficemtrh@gmail.com

Nandi Road
P.O. Box 3 – 30100
ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

18th September, 2019

Dr. Buluma Philip,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"The Principles and Practices of Tourniquet Use During Orthopaedic Operations at Hospitals in Eldoret Town, Kenya".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

DR. WILSON K. ARUASA, *MBS*
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

cc - Senior Director, (CS)
- Director of Nursing Services (DNS)
- HOD, HRISM