BLOOD LOSS AND TRANSFUSION PATTERNS DURING OPEN INTRAMEDULLARY NAILING OF DIAPHYSEAL FEMORAL FRACTURES IN KENYATTA NATIONAL HOSPITAL

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT FOR THE AWARD OF DEGREE OF MASTER OF MEDICINE (ORTHOPEDIC SURGERY), THE UNIVERSITY OF NAIROBI

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DECLARATION

I declare that this dissertation is my original work and to the best of my knowledge has not been presented for award of degree at any other university.

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LIST OF ABBREVIATIONS

KNH	Kenyatta National Hospital
UoN	University of Nairobi
WHO	World Health Organization
HB	Hemoglobin
AO	Arbeitsgmeinschaft fur Osteosynthesefragen (German for Association for the Study of Internal Fixation)
SPSS	Statistical Package for the Social Sciences
EBL	Estimated blood loss
ORIF	Open Reduction and Internal fixation
SBOE	Surgical blood ordering equation
MSBOS	Maximum Surgical Blood Ordering Schedule
RBC	Red blood cells
C/T	Cross-matched to transfused ratio
Ti	Transfusion Index
HCT	Hematocrit
BMI	Body Mass Index
ILN	Interlocking Nail
BU	Blood Units

ABSTRACT

Background: Diaphyseal femoral fractures are some of the commonest injuries treated in Kenyatta National Hospital. The sharp increase in these patients is due to rise of motorizing mode of transport, making it a public health concern in our country. The intramedullary nailing system for fixation of these fractures commonly available in KNH is the one utilizing distal locking jig making it an open method. Lack of equipment like image intensifier, traction table and long duration of stay before surgery favors open intramedullary nailing. Determining the level of expected blood loss, predicts the need for blood transfusion during surgery. Factors that affect blood loss during open intramedullary nailing can greatly influence pattern of blood loss and transfusion needs. There is paucity of data on the quantity of blood loss and transfusion pattern in open intramedullary nailing of femoral fractures.

Objectives: To determine blood loss and transfusion pattern in patients undergoing open reduction and intramedullary nailing of diaphyseal femoral fractures.

Study design: Prospective observational cross-sectional study

Setting: KNH orthopaedic wards and theatres

Methodology: Consecutive sampling was used to enroll eligible patients with a closed diaphyseal femoral fractures undergoing open interlocking nailing procedure one day before operation. The patients were identified after decision to operate was made and one day before the day of surgery. Written consent was sought from the patient. Patients' biodata was acquired and recorded. The pattern of the fracture was observed and recorded. Time between admission and surgery was also noted. The blood sample was obtained and taken to the laboratory for hemoglobin level test before surgery, intraoperative parameters such as mode of anesthesia, diathermy use, average intra-operative blood pressure, duration of surgery, length of incision and units of blood transfused were noted. Repeat HB level test was done 72 hours after surgery. The collected data was analyzed using SPSS v.20 and Microsoft excels, and presented in the form of percentages, means and their 95% confidence intervals.

Timeline: The study was carried out between February 2017 and June 2018

Results: The study involved **s**eventy subjects comprising of males (84%) and females (16%). Average (mean) age of the subjects was 32 years. The mean blood loss estimated was 3.3g/dl which is equivalent to 1485ml. Of the total patients 94% had blood cross-match requested but only 35% received blood transfusion. For those who received transfusion, only one unit was given per patient. The main reason for transfusion was anesthetist assessment of intraoperative bleeding at 69.2%. The factors than mainly influenced blood loss was the complexity of fracture and duration between injury and surgery. All the patients were operated under spinal anaethesia and median length of operation was 120 minutes. Diathermy was used in 75% of the cases and most surgeries were done by registrars at 84%. The ratio of blood cross-matched to that which was transfused was 4.5:1.

Conclusion and recommendation: Fractures operated early have significant low blood loss. Lack of blood for transfusion should not be a limiting factor for operating patients with a HB above 13.5g/dl. There is unnecessary cross-matching for patient undergoing open ILN.

CHAPTER 1: INTRODUCTION

Femoral fractures are some of the most common orthopaedic trauma conditions in developing countries. The commonest causes of these injuries are major violent trauma like motor vehicle, motorcycle, auto-pedestrian, gunshots and falls from a height. There is an increase in the use of motor cycles as means of transport, especially in developing and low-income countries, contributing to the increase in the number of these injuries[1]. High energy is the most common cause in younger population and often it is due to high-speed motor vehicle accidents resulting in a direct blow or a twisting force to the thigh. Low energy injuries which may occur with relatively little force are commonest in the elderly[4]. Other associated injuries include ipsilateral femoral neck fracture with an incidence of 2-6% and it is often missed in 19-31% of time[5], especially when routine pelvic-hip x-rays are not done.

The gold standard of management of diaphyseal femoral fractures in adults is intramedullary nailing through a closed antegrade or retrograde insertion sites[6, 7]. Most intramedullary fixations in KNH are done without use of image intensifier and a traction table. Systems available in KNH are distal locking jig which require open reduction. Open reduction method as opposed to closed method maybe associated with considerable intraoperative and immediate post-operative hemorrhage[8].

Most studies done to assess blood loss in orthopaedic surgeries show considerable blood loss intraoperatively and post-operatively[9]. The volume of blood loss depends on many factors among them, patient factors and surgical factors. Blood losses can be reduced by employing right surgical techniques and anesthetic measures. Some of these techniques include meticulous diathermy use, early operative timing, regional anesthesia, lowering of blood pressure and reducing the operating time.

KNH is a resource constrained hospital with erratic supplies of blood. The lack of adequate blood is associated with surgical procedures postponement. Pre-operative transfusion often is not required and irrational perioperative blood transfusions should be avoided to optimize the already scarce resource. The cost of grouping and cross-matching can also be reduced by rational

use. It is also important to determine the rate at which cross-matched blood is transfused during open interlocking nails surgery. This is because this ratio of blood cross-matched to transfused can be is used to determine the efficiency of good blood requisition practice and should be kept at level of up to 2.5.

It is hard to measure blood loss during surgery due to lack of standardized surgical procedure[10]. Two methods can be used to measure blood loss; indirect or direct method[11, 12]. In the indirect method of estimating blood loss, hematocrit or hemoglobin change during perioperative time is determined. However, in direct method, estimation of blood loss involves weighing drainage bags, blood swabs collected, and suction bottles. In this study we used the latter method to determine the blood loss due to its reliability and accuracy.

From my study, peri-operative period was a day (24 hours) before surgery and 3 days (72 hours) after the surgery. The objective of my study was primarily determining the volume of blood loss during intramedullary nailing of isolated unilateral fractures of the femur. Secondarily determine the pattern of transfusion and factors contributing to significant blood loss. After establishing the above objectives, this study was able to deduce the cross-match to transfusion ration in KNH for the method of fracture fixation. Some of the variables recorded were; initial Hb, time from admission to surgery, length of surgery, fracture classification, age, gender, mode of anesthesia, and incision length in relation to blood loss.

CHAPTER 2: LITERATURE REVIEW

Femoral diaphyseal fractures and their classification

Femoral diaphyseal fracture by definition refers to a femur fracture between the adductor tubercle and a distance of 5 cm distal to the lesser trochanter. Fractures of femur are usually due to high energy trauma and young people are most involved[50]. In elderly, femoral shaft fractures are often after a low-energy secondary to a fall. By causes of injury, traffic accidents cause 78 per cent, industrial accidents 12 per cent and domestic accident 10 percent of these injuries[16]. Classification systems should guide the surgeon in treatment options and predict outcome. Closed femoral shaft fractures are generally classified to the alphanumeric coding system of the AO[35] into three main types (simple, wedge, and complex) with three main sub-groups which depend on the comminution pattern. Type A is a simple fracture with subgroups of spiral (32A1), oblique (32A2) or transverse fractures (32A3). Type B is wedge fracture with either an intact wedge fracture (32B2) or fragmentary wedge fractures (32B3). Type C is a comminuted fracture with either multifragmentary intact segmental fracture (32C2) or multifragmentary fragmentary segmental fracture (32C3). In the new AO classification revised in January 2018, subtypes 32B1 and 32C1 were removed. This classification correlates with stability, restoration of anatomy and function.

Management of diaphysis femur fractures in adults

Treatment of fractures of femur by intramedullary nailing is more effective than non-operative treatment (traction and cast bracing) in terms of cost, rational use of available beds and effectiveness, [13] and it is accepted widely as treatment option in adults. Kamau D.M et al did a study where he compared closed femur fracture management by skeletal traction to intramedullary nailing in terms of cost-effectiveness in KNH[74]. The study concluded that intramedullary nailing is more cost-effective and had better outcome than skeletal traction. The gold standard treatment for femur diaphysis fracture is reamed locked intramedullary nailing fixation through the greater trochanter or piriformis fossa entry[14, 15]. During intramedullary nailing of femoral fracture one may reduce the fracture by opening the fracture site or not.

Closed method is a technique of not exposing the fracture site and by using an image intensifier which enables reduction of fracture and passage of a guide wire which is critical whether a reamed or undreamed nail is used. It is better than open reduction in terms of functional results assessed upon the basis of return to pre-injury state.[16]. The main reason is least disturbances of fracture hematoma and periosteum thus influencing callous formation and union. Use of C-arm as already mentioned most of the time, facilitates closed nailing techniques and is the most widely used method of fixation. Even in open intramedullary nailing, fluoroscopy can make distal targeting quicker and reduce operating time. Reduction by open method and intramedullary nailing fixation of femur fractures is still performed in low resource centres due to lack of fluoroscopy that allow for closed method. In some cases, especially in centres where distal locking jig is used, open reduction is a good option[17]. Delay in early operative management necessitates open reduction technique due to tissue fibrosis which makes closed reduction method difficult. The system commonly used in KNH is that of distal locking jig which helps in locating and targeting the slots in both proximal and distal without the need of using fluoroscopy. Any problems encountered with targeting devices prolong intraoperative time and may contribute to increased blood loss.

Amount of blood loss during surgery

Procedures in both orthopedics and bone trauma may be associated with considerable loss of blood with need for blood transfusion[20]. This is according to a multicenter cohort study done by Vuille et al that showed transfusion rate of 29 % for all orthopedics surgeries. High transfusion rates are caused by extensive intraoperative bleeding. Prediction of transfusion requirement also depends on hemoglobin level before surgery, surgical technique, gender, among other surgery or patient related factors[21].

In a study done by Kajja etal at Mulago Hospital in Uganda, the mean volume of blood loss determined third day after surgery after the intramedullary nailing of femur fracture was 1,490 ml of whole blood[2]. Lieurance and Benjamin in a retrospective study of 53 patients with isolated femur fractures found an estimated averaged blood loss of 1,276ml[47]. In both studies, they used indirect method of estimating blood loss by calculating the difference between preoperative and

postoperative Haemoglobin. They also noted preoperative Haemoglobin as the main determinant of transfusion need in contrast to overt intraoperative blood loss. Kinyanjui C K from Mulago Hospital did a study to estimate the volume of blood loss calculation by direct method[53]. In his study he calculated blood loss by weighing soaked & dry gauzes gauze swabs, suction bottle before and after use at end of operation and blood onto the floor. His mean volume of blood loss intraoperatively was 930mls[53]. Lawrence and Benjamin on a similar study of 'Volume of blood loss in patients with isolated femur fractures,' the average blood loss was 1277mls[55]. A study on transfusion patterns in surgeries (orthopaedic) at a centre done by Mehran et al in Iran, the mean intraoperative bleeding volume for diaphyseal femoral fracture was 804ml[63]. The most limiting factor on this study was the author mixed both open and closed reduction technique in approximation.

Factors affecting blood loss

Timing of surgery is a major factor that determines perioperative blood loss. Abraham et al did a study of 21 patients and found that delayed open intramedullary femoral fracture fixations were associated with increased intraoperative blood loss. He found that patient operated three weeks after injury lost 400ml of blood more than the patient operated within 48 hours[32, 41]. Skeletal fracture is initially associated with disruption of blood supply of the bone. This decreased blood flow concurrent with metabolic demands increase for repair causes hypoxia at fracture site. This causes new blood vessels generation for tissue support through three distinct mechanisms i.e. vasculogenesis, angiogenesis and arteriogenesis. In one study using PET imaging, there was increased blood flow by three to six times more in the fracture of tibia than non-fractured contralateral tibia one day after injury[75]. Kinyanjui et al in a study done in Mulago noted that femur fractures fixed 3-4 weeks after injury bled more than fresh fractures by 450ml[53]. He found that blood loss volume increased with increasing duration of time from injury and attributed it to increased vascularity coupled with longer operation time caused by difficulty in achieving anatomical reduction. During bone repair process there is increased angiogenesis resulting in increased vascular channels and blood flow that contribute to significant bleeding during delayed surgery[5].

Pattern of fracture: The more the severe the injury the more the peri-operative blood loss[2]. This is because it is technically more demanding to reduce and fix a more severely comminuted fractures of femur due to longer length of operation and this has increased likely of disrupting the blood vessels in endosteal and periosteal system. According to Kaija, fracture classification significantly affects volume of blood loss. Patients with class types B and C lost more blood compared to class type A with a mean difference of 450ml[2]. According to a study done by Miano et al, patient with comminuted fractures were associated with more blood loss with a mean of 1325ml compared to patients who had simple fractures (570ml) managed by open reduction and internal fixation[41]. It was noted by Kinyanjui C K that intramedullary treatment of comminuted femoral fractures had higher (1972ml) blood loss compared to simple fractures with mean of 1250ml[53].

Surgical technique and surgeon level of training: There is a difference in volume of blood loss when comparing the size of incision and exposures. In surgeries where antegrade insertion sites were used blood loss was more than with retrograde techniques method[2]. Blood loss was less in patients operated by consultants assisted by residents (606) than cases done by registrars on their own (1038ml) according to a study done by Kinyanjui et al in Mulago Hospital[53]. This may be due to less surgical time, causing little soft tissue damage due to high experience.

Age and sex: There is a difference in volume of blood loss depending on age. Kajja et al demonstrated a difference in the mean volume blood loss between female and male with 1660ml and 1420 ml respectively. Comparing age, age group of 26-36 years lost least blood, while in age group of 33-46 years lost the most blood volume[2]. The losses are higher among the elderly patients due to their reduction in clotting formation abilities that occurs with age essential in stopping bleeding[38]. In another study done by Ciarallo and Fleisher, healthy pediatric patients with isolated femoral fractures who were managed by plating, rarely lost significant amount of blood to necessitate blood transfusion[52]. Mark et al in his study on open reduction and intramedullary nailing of femoral fracture, blood loss increased with age up to 45 years in a linear pattern, after which the decrease in blood loss was noted[53]. This can be explained by complexity of the fractures in younger age group. He also found that blood loss was higher in

women (1087ml) as one would find in men (870mls). In an earlier study done by Richard and Gardner, the average blood volume lost was high in females than males[57].

Anesthesia mode: Regional and especially spinal anesthesia has been associated with a significant low blood loss[42]. According to Yves, and Claude study on non-pharmacological methods to lower surgical blood loss, adequate anesthesia reduces hypertension and tachycardia that can be explained by sympathetic over activity by providing adequate anesthesia and analgesia[54]. Blood loss in patients where use of spinal anesthesia (650ml) was used was lower than in general anesthesia (944mls) [53]. This keeps with other studies that attributes it to the spinal regional hypotensive effects that causes sympathetic nerve blockage and hence less bleeding at the operation site[54]. Sympathetic nerve stimulation acting on beta-2 receptors causes arteriole vasodilatation in skeletal muscle. Hypotensive anesthesia was noted to reduce blood loss by ove 40% in orthopaedic procedures[56]. Andrews W.W studied the effect of anesthesia on blood loss during elective procedure and found that a greater number of patients under general anaethesia experienced a postoperative reduction in hematocrit of 5% volume or more as compared with those that received regional anesthesia[76].

Length of operation: The use of good surgical techniques that includes diathermy cauterization, fluoroscopy and traction operating tables reduces the length operation and intraoperative blood loss[51]. In his study Kearns et al showed a directly proportional of operation time and blood loss. In a study of ORIF for isolated femoral fracture done by Kinyanjui, volume of blood loss increased with an increase in length of operation time, and this relationship was significant statistically[53].

Diathermy: Significantly it reduced peri-operative blood loss[2]. Blood loss without diathermy was 360ml more than with use of diathermy according to Kajja. Kinyanjui C K in his study noted that use of diathermy was equally associated with lower blood loss[53]. In patient where diathermy was used, the blood loss was 672mls as opposed to 1188ml without. Another study demonstrated that that electrocautery reduced operation time, volume of blood loss, as well as early post-surgery pain and need for analgesia[51].

Other factors: Another factor associated with significant intraoperative blood loss and need for blood transfusion is pre-operative systolic blood pressure above 140 mmHg[39,41]. In a study on hip arthroplasty, perioperative blood loss was not significantly associated with gender, age, hypertension or weight when considered alone but they had synergistic effect that increased the risk of transfusion in these patients[40].

Estimation of blood loss

Methods of approximating intraoperative volume of blood loss can be the gauze visual analogue, the gravimetric method and the haemodilution mathematical model. Estimation of perioperative volume of blood loss (EBL) has been difficult for decades, and most studies shows that the practice of visual inspection to be very inaccurate[36]. This discrepancy is usually between blood loss estimated by the anesthesiologist and the surgeon with the former overestimating and surgeons who tend to underestimate. This fuels an increase in over transfusion during surgery, with about 20-60% of transfusion being unnecessary[29]. Some of clinical parameters that trigger transfusions intraoperatively are acute bleeding, drop in blood pressure, chest pain, restlessness and tachycardia unresponsive to fluid resuscitation. Pre-operative Haemoglobin is one of the main laboratory marker of intra-operative transfusion trigger[2]

A new mathematical method of estimating blood loss for surgical patients was developed and is based on principles of hemodilution and blood loss. In a study by Brecher in 1997, the calculated volume loss was compared with estimations of intraoperative blood which was done by anesthesiologist in 250 patients[24]. The volume of blood loss higher by 2 times the intraoperative loss that which was calculated by the anesthesiologist. He concluded that this model of mathematical could rapidly calculate patient's volume of blood loss to allow ready, clear objective comparisons of sites and even among surgeons. EBL can be calculated on basis of drop in HB with the preoperative measurement and the measurement 72 hour postoperatively after full haemodynamic equilibrium according to a formula developed by Brecher[24].

According to the equation 1 below, Pre-opHB is defined as preoperative hemoglobin (g/dl) which is measured one day before surgery; Post-opHb is defined as hemoglobin in g/dl level

measured three days (72hours) after surgery; BU is defined as hemoglobin in g/dl that is provided by transfused whole blood in units in the intraoperative time.

(Pre-opHB – Post-opHb)+BU = Hb-lost ……equation 1

In those patients who were not transfused the amount of volume lost iss calculated using secod equation

Pre-opHb – Post-opHb = Hb-lost……equation 2

Haemoglobin estimations and hematocrit measurement are made in duplicate both in pre- and postoperatively. Blood transfused during either operatively and early postoperative is carefully measured. The volume loss is calculated by finding the difference between the corrected postoperative red cells volume (the post-op red cell volume less the transfused) from the pre-op red cell volume[30]. The optimal timing for Hemoglobin concentration determination after surgery is 48 hours according to a study done by Mahdi and Charles[46]. The reason was to counter the effect of haemodilution from fluid infusion intra-and post-surgery which may make estimation innacurate.
This study also demonstrated no significant differing information provided through Hematocrit or Hemoglobin determination.

With above knowledge a surgical blood ordering equation (SBOE) is used to calculate the RBC units to order for surgery[58].

HBlost – (PreHB-MinHB) = Units to order……. the SBOE equation

MinHb is minimal (lowest) acceptable Hb (g/dl) considered as the trigger for transfusion or minimal (least) allowable Hb, and units to requests (order) is the number of RBC units to be cross matched for surgery. In theory, minimal acceptable pre-operative Haemoglobin in fracture femur is 10g/dl.

From the study, in practice, the uses equations similar to above were a better in predicting of the units to be crossed and matched. It has been observed that the preoperative requisition of blood frequently overshoots the need resulting in unwanted crossmatching[59]. The consequences of unnecessary cross matching results in overburdening blood bank, depleting blood bank resources, time wastage and financial loss to the patients[60]. The concept of grouping and saving serum can help to reduce unnecessary blood wastage[73]. In this concept storing separated and saved plasma at -30^0C, and retaining the red cells at 4^0C. On basis of this information Red cell unit that are RhD and ABO compatible if necessary can be quickly issued for a patient.

Evaluation of Haemoglobin level can be done by a Complete Blood Count test. Studies done in American blood donors have reproduced good and accurate results of this method in estimation of haemoglobin[31]. Venous samples give more constant values than capillary samples. If the procedure is performed properly, the degree of accuracy is +2 to 3 percent[37].

Pattern of blood transfusions

Most studies have shown that the least acceptable pre-operative blood level adequate for oxygen delivery and healing of tissue in a physiologically fit man is the Hb of 10g/dl and hematocrit level of about 30%.

Historically, the decision to transfuse was influenced by many of factors that are widely differing between countries[48]. Low Hb and actively bleeding patient are basis of transfusion trigger. Other intraoperative signs of blood loss are; chest pain, restlessness, hypotension with tachycardia that does not respond to fluid resuscitation[16].

Appropriate transfusion is defined as blood transfusion at Hb<8g/dl or 10g/dL in elderly and those with medical comorbidities. Transfusion of a whole unit of 450mls leads to a 1gm/dl increase in the Hb level measured when full hemodynamic equilibrium at 3rd day after surgery assuming no occult bleeding after closure of wound or arrested RBC in thrombosed vessels[25]. One unit of packed RBCs should increase hemoglobin by 1 g per dL and hematocrit by 3 percent[28].

In a study done by Kajja et al, at Mulago Hospital in Uganda, patient with unilateral diaphyseal femoral fractures who underwent open reduction and nailing had transfusion rate of 27%[2]. This was despite having a mean pre-operative hemoglobin level of 12.6g/dl. In a local study by Paul Miano et al in KNH the rate of intraoperative blood transfusion was 11.4% in all orthopedic operations[41]. He also found that most transfusion category was in trauma. In a different study done to review peri-operative blood transfusion practice in a tertiary hospital in Nigeria, patients were transfused based on end organ function change, volume lost, anesthetist clinical acumen, hemoglobin as measured prior to transfusion and 24 hours postoperatively[43]. A separate study by Sonam et al on facture femur operations, the rate of blood transfused to patients was 24.3%[62].

Over-transfusion is an issue not just in regard to inefficient use of limited resource, but it can pose additional risks to the patients. The 2010 annual Serious Hazards of Transfusion (SHOT) report (Knowles 2011) noted an increase in cases where patients were transfused with many units, given their underlying comorbidities, body mass or blood loss or where there had been a failure to monitor adequately the vital signs of patients or Hb response during transfusion[44]. In a study published in the Royal College of Surgeons of England annals, it was noted high blood issuing and transfusion rates[45]. The study found transfusion rate of 75% in hip and knee replacement surgeries. This was against demonstration in same study that on average patient lost 1g/dl during surgery. In a study done by Keller on causes of elective surgery cancellation, lack of blood products accounted for 3%[66]. In a similar study done in KNH by Okonu et al, the cancellation rate of orthopaedic operations due to lack of blood was 14.9%[67]. Two similar studies in West Indies showed that lack of blood accounted for 4.9% and 2.5 % of the cancellations respectively which is less than that found in KNH[68]. This could be due to frequent shortages of blood in KNH or due to the blood transfusion practices in KNH.

Several studies have been done to propose for Maximum Surgical Blood Ordering Schedule (MSBOS). In one of the study by Chawla T et al in Aga Khan University Hospital, in majority procedures of elective surgery routine cross match is not necessary[61]. Cross-matched to transfused ration (C/T) and Transfusion Index (Ti) for each elective surgery was studied.

C/T ratio= Number of units cross-matched

Number of units transfused

C/T ration is a measure of how effectively blood ordering practice is done and should ideally be less than 2.5. Implementation of MSBOS by Chawla et al resulted in 60% reduction of cost to the patients. Similarly, Hardy et al. found 33% reduction in the number of blood units cross matched for an elective surgical procedure after introducing MSBOS at their hospital[62]. In a similar study by Rehmatullah et al crossed and matched to transfusion ratio was 20.27, meaning only less 4.9% of blood was fully utilized while 95.1% of blood ordered was not utilized[71]. A study by Maha on blood conservation in elective surgery, C/T ratio was 4.8 as compared to 2.8 after implementation of MSBOS[72].

A protocol on the guidelines for perioperative blood management exists in most developed countries. In KNH there is no protocol on perioperative blood management in orthopedics trauma surgery.

CHAPTER 3: STUDY RATIONALE

3.1 Study justification

Diaphyseal femur fractures are among the commonest injuries encountered in our hospital and they have serious morbidity consequences. Operative management is the gold standard of management of these fractures hence the need for hemoglobin optimization. This may require transfusion of blood products and due its scarcity, there is need for judicious use to prevent delayed surgery and cancellation of operations. There was no local study to determine the perioperative blood loss and pattern of transfusion in open intramedullary nailing of femoral fractures. This study was able to correlate blood loss and transfusion pattern. The study also established the cross-match to transfusion ratio so as to help limit the routine unnecessary transfusion procedures and hence reduce cost of operative treatment

3.2 Primary objective

To determine blood loss and transfusion pattern in patients with diaphyseal femoral fracture peri-operatively managed by open nailing.

3.3 Specific objectives:

1. To determine the volume of blood loss during open nailing of femur diaphyseal fractures
2. To determine the transfusion rate in open interlocking nailing system
3. To determine the factors that contribute to blood loss
4. To determine the cross-matched: transfused ratio for these surgeries

CHAPTER 4: METHODOLOGY

4.1 Study design

Observational cross sectional study design

4.2 Study Setting

The conduction of the study was at the KNH theatres and orthopaedic wards.

4.3 Study population

It was a prospective study of 70 consecutive patients admitted in KNH of age 18 years and above with an isolated closed diaphyseal femoral fracture that was treated with open intramedullary nailing after giving consent.

4.4 Patient recruitment

The principle investigator with help of assistants recruited patients for the study using convenient sampling technique followed them pre-operatively, in theatre and post-operatively. The collected data was recorded in spreadsheets for analysis.

4.5 Data collection

The potential patients were identified immediately after admission in Orthopaedics Wards in KNH and they were recruited 24 hours before surgery. Patient's biodata that includes age, sex, and date of injury was taken and duly filled in the data spread sheet. The data analyzed include fracture pattern according to AO/OTA classification. Hemoglobin level before and after surgery. Estimation of perioperative blood loss was represented by change in hemoglobin (Hb-lost) calculated using Brecher method. Volume of blood transfused and criteria used in deciding on transfusion intraoperatively and post-surgery was recorded. The mode of anaethesia used, use of

diathermy, and duration of surgery were recorded. The surgeons' level of training or practice, incision length and duration from injury to operation were also noted.

4.6 Quality control

Pretesting of questionnaire was done and data collected was counterchecked before leaving study site. A statistian helped in data analysis. One day before operation and 72 hours after operation from each participant, 2.0mls of blood was obtained under sterile conditions from cubital vein, by use of a Becton Dickinson vacutainer system that contains EDTA-K_3. The tube was legibly labeled and shaken to allow proper mixing of blood. A laboratory request was filled by staff drawing the blood, and sample taken to the University of Nairobi Hematology and Transfusion Department for HB level testing. A technician determined the hemoglobin level using the Coulter STKS photometric system. This system is calibrated on daily basis according to manufacturer's recommendations.

4.7 Duration

The data collection for the study was done between February 2018 and June 2018.

4.8 Inclusion criteria

1. Patients with isolated diaphyseal fracture femur admitted in KNH
2. Patients who underwent intramedullary nailing of diaphyseal femoral fractures
3. Age above 18 years who provided written consent

4.9 Exclusion criteria

1. Pathological fractures
2. Compound fractures
3. Patients on long term treatment for anaemia
4. Patients on warfarin.

5. Sickle cell patient
6. Patients undergoing more than one operation
7. Liver pathology and/or coagulation disorder
8. Refusal to give consent

4.10 Ethical approval and consenting

Ethical approval was sought from KNH-UoN Ethics and Research Committee before the start of the study. Authorization to conduct this study in KNH was also sought from the hospital administration. An explanation to all participants on the nature of the study was done. Those willing to participate were required to give a written consent or consented for, on their behalf, by their guardians prior to enrollment into the study. This process was undertaken by the principal investigator and his assistants only after explaining to the participants their roles, risk and benefits of the study in details.

4.11 Sample Size

KNH medical statistics estimates that 508 femur fractures are admitted every year with 364 fractures being managed by interlocking nail translating to 71%. This study was conducted in 3 months period hence the estimated number of accessible population in the period is 91. Sample size calculation was done by use of a formula that has a finite population correction as suggested by Daniels (1999)[64,65].

$$n = \frac{NZ^2P(1-P)}{d^2(N-1) + Z^2P(1-P)}$$

N is the population of subjects accessible in KNH during the study period (N = 91 patients)

P is Prevalence of blood transfusion – 27% (Kajja et al, 2010)

1-P is 1 minus the prevalence of blood transfusion

Z is statistic that represents 95% as the level of confidence (1.96)

d is desired level of precision set to 5% (0.05)

$$n = \frac{91 \times 1.96^2 \times 0.27\ (1 - 0.27)}{0.05^2(91 - 1) + 1.96^2 \times 0.27\ (1 - 0.27)}$$

n = 70

A minimum of 70 patients were required to estimate the rate of blood loss and transfusion within 5% level of precision.

4.12 Study limitations

Lack of guidelines on transfusion during surgery

Lack standardized level of surgeon expertise

4.13 Implementation timetable

Proposal writing	March - December 2017
Presentation of proposal	January 2018
Submission for ethical approval	January 2018
Data collection and analysis	February 2018- June 2018
Dissertation writing	July-August 2018
Presentation for examination	September 2018

4.14 Budget

ITEM	COST (SHS)
Research fees (KNH/ERC)	2,000
Stationery, printing and binding	17,000
Statistician fee and Assistants	35,000
Hemoglobin estimation process	20,000
Printing and binding	25,000
Contingencies	15,000
Total	**114,000**

CHAPTER 5: RESULTS

5.0 Demographic profile

Age categories: The mean age of patients in years was 32 (SD 9.9). Majority of the participants, were between 30 and 39 years.

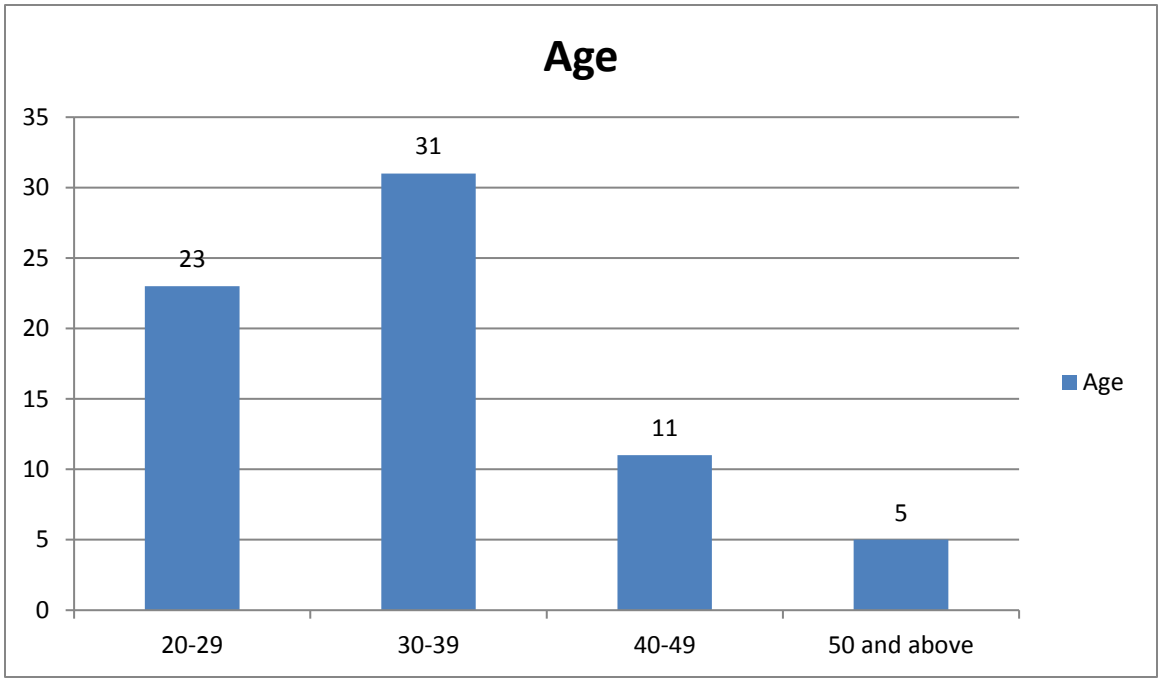

Figure 1: Age of patients

Sex categories: Majority of patient were males 59 (84.3%) while females were 15 (7%)

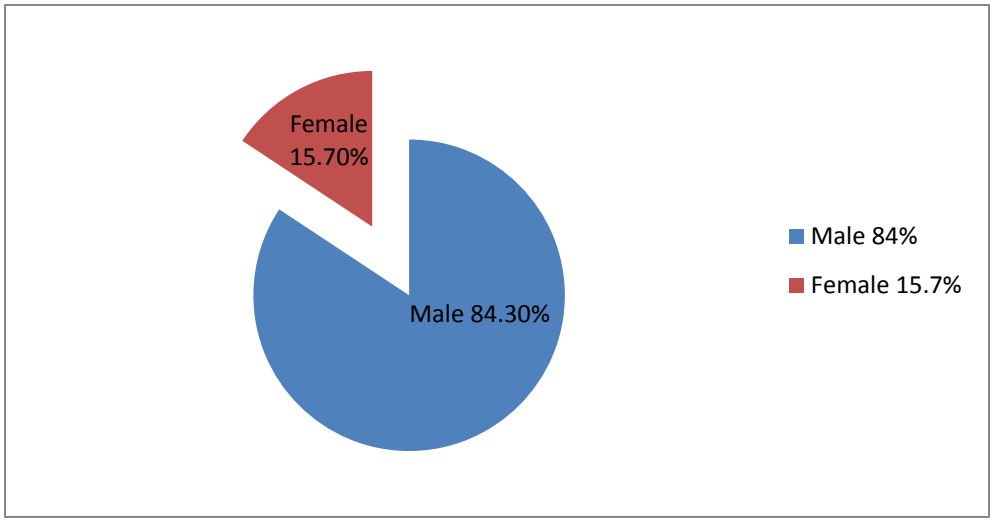

Figure 2: Sex of the patient

Fracture morphology: Transverse and wedge were the most common fracture patterns with prevalence of 35% and 37% respectively.

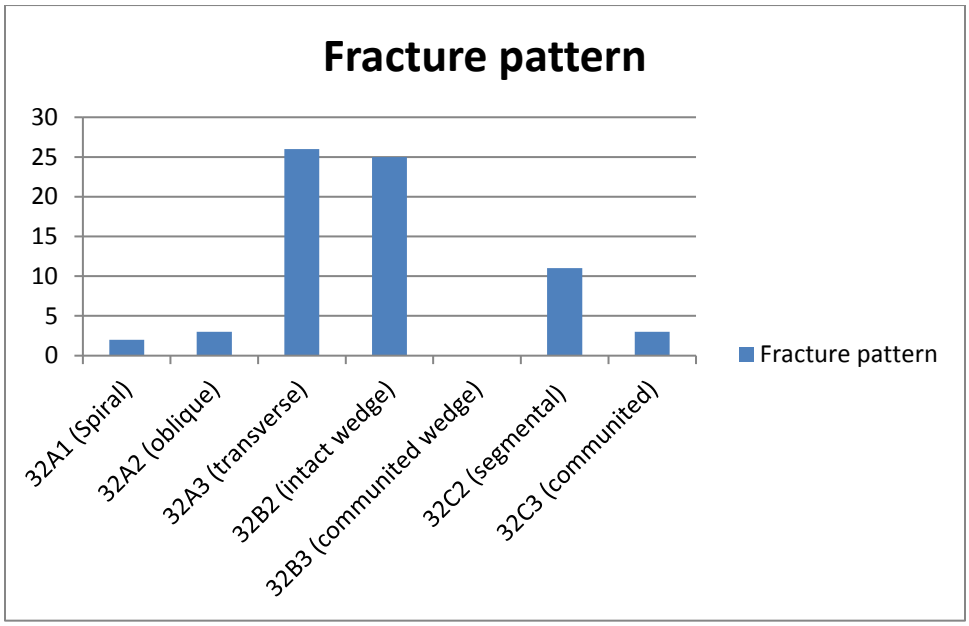

Figure 3: Pattern of fracture

Duration between operation and injury: Most patients were operated after two to four weeks (35%) after the date of injury.

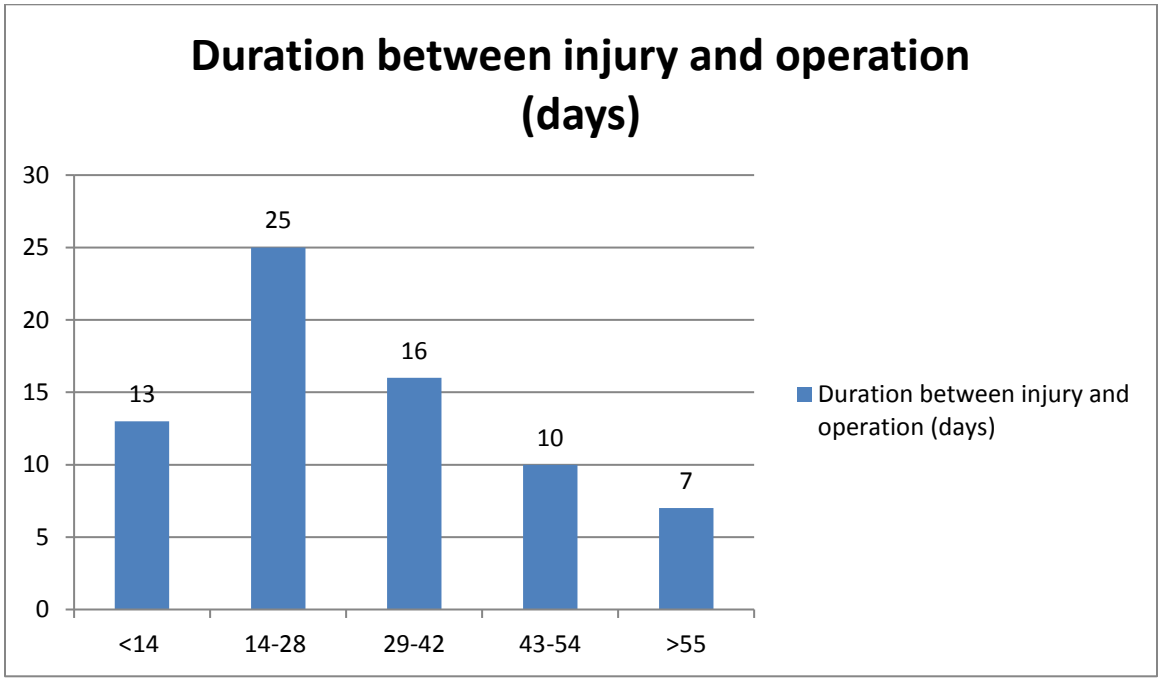

Figure 4: Duration between injury and operation

5.1: Operative details

Diathermy: In most of the operations, the surgeon used diathermy for cauterization and arresting bleeding (74%)

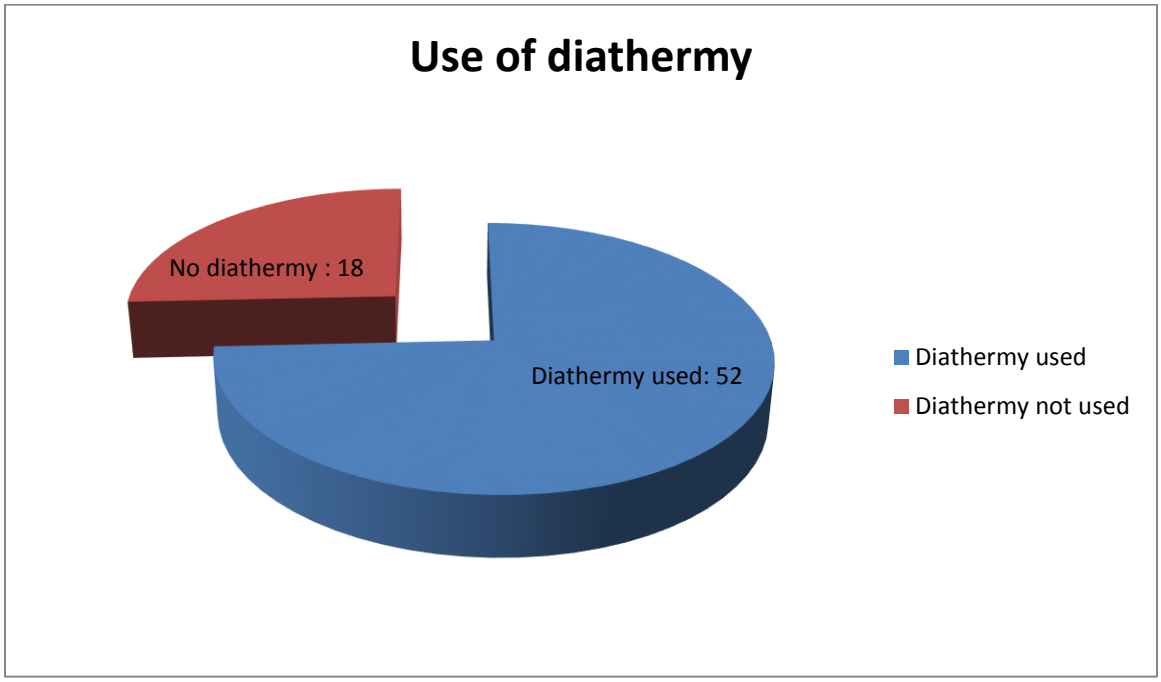

Figure 5: Use of diathermy

Surgeon level of training: Registrars accounted for greatest percentage of surgeons at 83.1%

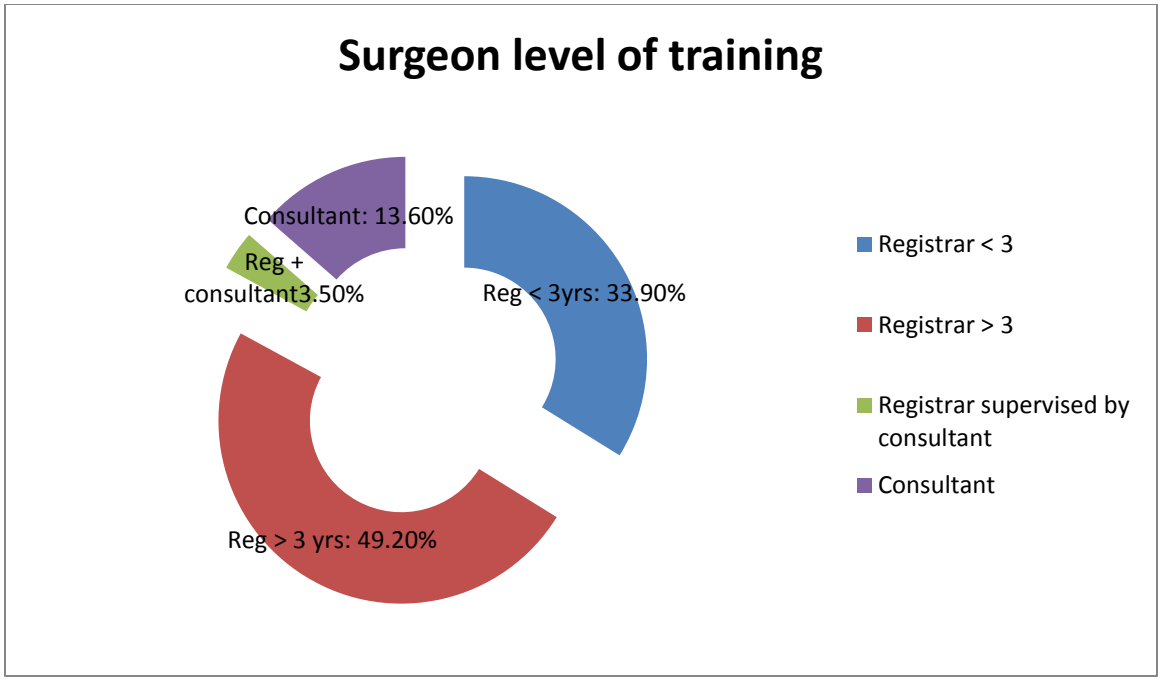

Figure 6: Surgeon level of training

Blood loss: Blood loss was calculated by finding the difference between pre-operative hemoglobin and post-operative hemoglobin. Units of blood transfused were also factored in to find the difference. Estimated volume of blood loss after 72 hours was change in Hb multiplied by 450ml. The average blood loss was 3.3g/dl or 1485ml.

Variable	Mean	SD
Hemoglobin taken 24hrs before operation	13.6 g/dl	1.82
Haemoglobin taken 72hrs postoperative day	10.4 g/dl	
Blood loss (Haemoglobin difference)	3.3 g/dl	

Table 1: Volume of blood loss

Correlation of various factors with volume of blood loss: The most positive linear correlation of volume of blood loss was found in pattern of fracture, duration between injury and surgery and length of operation.

Table 2: Factors associated with blood loss

Variable	Mean HB loss (SD)	P value
Classification & Pattern of fracture		0.011
32C3 (Comminuted)	5.6 (1.9)	
32A2 (Oblique)	3.2 (1.7)	
32C2 (Segmental)	3.7 (2.0)	
32A3 (Transverse)	2.9 (1.6)	
32B2 (Wedge)	2.9 (1.4)	
Time from injury to operation		
<14 days	2.7 (1.1)	0.054
14-28 days	3.6 (1.9)	
>28 days	4.4 (2.7)	
Use of diathermy		
Yes	3.2 (1.8)	0.035
No	3.4 (1.8)	
Length of operation		
<2 hours	3.2 (1.6)	0.344
2 hours	3.3 (2.0)	
>2 hours	3.3 (1.9)	
Incision		
<25 cm	2.2 (0.8)	0.125
>=25 cm	3.0 (1.5)	
Surgeon		
Registrar =<3 years	2.4 (1.1)	0.115
Registrar >3 years	3.6 (2.0)	
Registrar supervised by consultant	2.7 (0.8)	
Consultant	3.8 (2.0)	

5.3 Transfusion details

Correlation of ratio of cross-match and transfusion: The numbers of units requested were 122 while the numbers of units transfused were 27. The cross match to transfusion ratio therefore was 4.5:1

	Total units	Mean units per patient	Ratio
Blood requested (cross-matched)	122	2.0	4.5:1
Blood transfused	27	1.3	

Table 3: Cross-matched: transfused ratio

Reason of blood transfusion: The most established reason for transfusion was intraoperative bleeding during surgery (85.7%)

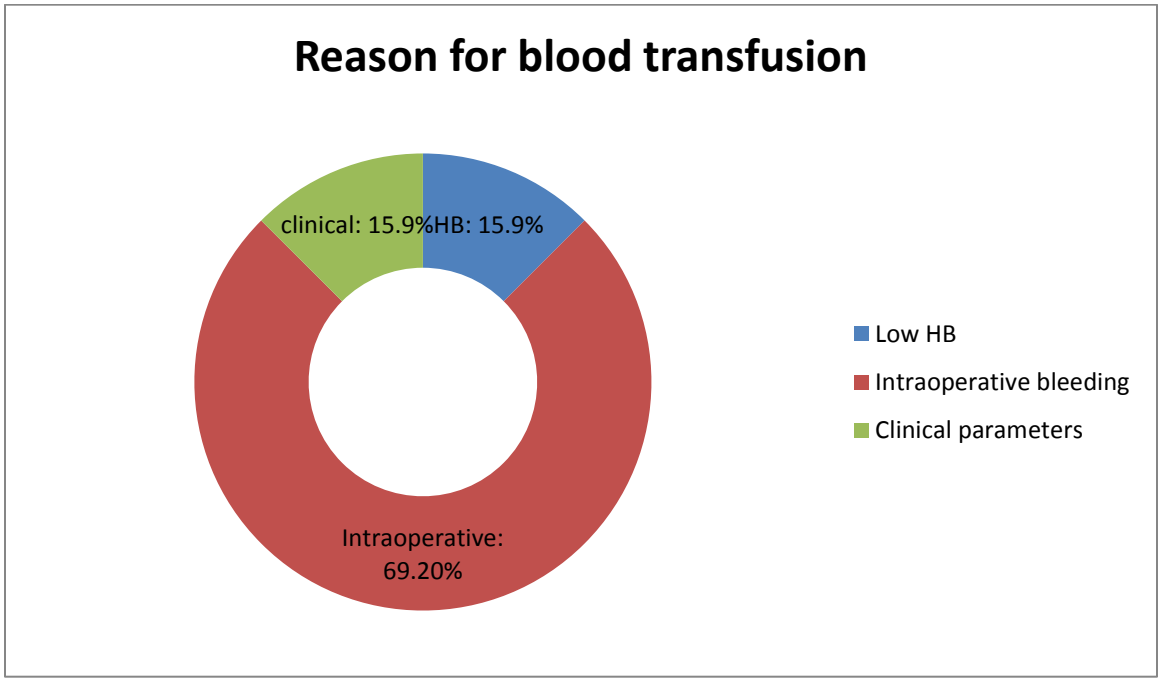

Figure 7: Reason for blood transfusion

CHAPTER 6: DISCUSSION

Seventy patients were recruited, 84.3 percent males and 15.7 females. The average age of the patients in my study was thirty two years. The biggest fraction of patients who sustained this injury was in age bracket between twenty and forty years. This pattern of age distribution was noted in studies done by Kajja[2] and Kinyanjui[55] in Mulago in Uganda. It was also documented in several other studies done in developing countries[16, 50]. There was no study that showed a different age distribution of diaphyseal fracture femur. This age group distribution comprises people in early adulthood who are active and involved in various occupational risks such as motor cycling, construction works and sporting activities[16].

The commonest patterns of fractures were transverse at thirty seven (37%) percent followed by wedge type at thirty five (35%) percent. These patterns of injury are due to direct trauma and results from high energy mechanisms. The least common pattern was spiral at three percent (3%). The most common cause of spiral fracture is torsion and it is of low energy. It is commonly seen in elderly patients and at times as a fragility fractures. In a study done by Salminem found that femoral fractures that were caused by low-energy were spiral pattern and was common in elderly female[4]. In this study there were few elderly patients and the fractures morphology were spiral which is consistent with studies done elsewhere[4, 16]. Since most of our patients are young and the most mechanism of injury in young is high energy as a result of direct trauma, spiral fractures pattern were very few.

There was a higher rate of diathermy use as one of modality of achieving hemostasis at seventy four percent than thirty six percent for those who did not use it. The rate of diathermy use was comparable to studies done in East African countries[2, 16]; however, it was less than what was documented in developed countries as shown by these studies[23, 32]. The main reason for low use was faulty and unavailability of diathermy machines. From the study most operations were done by registrars with three or more years level of training at forty nine percent. Consultant did the fewest number of surgeries at 3.5 percent. Fracture of femur surgeries are usually regarded as of moderate complexity hence does not necessity the need of consultants to operate[2]. Consultants are usually required to perform high skill demanding surgeries and complex femur surgeries being assisted by registrars.

Mode of Anaethesia in operations of diaphyseal femoral fractures in Kenyatta National Hospital is spinal. The entire group of patients who underwent this surgery was done under spinal anaethesia. This however is in contrast to studies done in Uganda where a good percentage of patients were operated by general anaethesia[22, 55]. There are many documented safety profiles for this modality of anaethesia making it a preferred one[23]. This may explain why the mode was most preferred in KNH and highly recommended by department of anesthesiology.

The mean time from injury to operations was thirty two days. The long delay between injury and operations was attributable to low resource set up of the study occasioned by lack of money for patients to buy ILN implants and limited theatre space. This is in contrast to studies done in Mulago where ILN implants are provided free of charge with mean delay of one week[4]. In developed countries mean operation delay was between 24-48 hours due to availability of resources. Length of operations took a mean of two hours with very few taking more than this. The more the complex the fracture was, the longer it took to attain anatomical reduction and fixation with average of 3 hours. Operations done by registrars with less than three years of surgical training took longer time by 30 minutes than one done by registrars with more years of training due to good expertise and experience.

Using Brecher Technique to estimate blood loss, the mean was 3.3g/dl which is equivalent to 1485 ml. In a study done in Mulago Hospital using this formula, the mean blood loss assessed three days after the intramedullary nailing of femur fracture was 1,490 ml of whole blood[2]. Another similar study done in Pakistan also demonstrated loss of 1276ml[47]. A study done using volumetric weighing method by Kinyanjui et al, in Uganda, mean loss blood was 930mls. Direct visual estimation of blood loss is associated by underestimation of blood loss as compared to the formula of determining the change in HB[36].

With above knowledge a surgical blood ordering equation (SBOE) was used to determine the number of units of RBCs to order for surgery[58].

HBlost – (PreHB-MinHB) = Units to order……. the SBOE equation

In the equation MinHb is minimal (least) acceptable Hb (g/dl) considered to be the transfusion trigger or least allowable Hb, and units to request (order) is the number of RBC units to be cross matched before surgery. Therefore with a known HB level and a known EBL, one can calculate on whether to order for cross-match and transfuse. Patients with Haemoglobin of above 13.3g/dl should probably not have cross-match as anticipated blood loss is less than 3.3g/dl. It also implies that cancellation of elective orthopaedic surgery in patient with that HB due to lack of blood should not happen.

From the study, in practice, the use of similar equation is a good predictor of the units to crossmatch. It has been observed that the preoperative request of blood frequently is higher than the actual need, this results in unnecessary crossmatching[59].

The more complex the fracture was the more bleeding occurred during surgery in this study and it compared with other similar studies. Comminuted fractures blood loss went up to 2550ml against simple ones where blood loss was 900ml. This is because it is technically more demanding to reduce and fix a more severely comminuted fractures of femur due to longer length of operation and this has increased likely of disrupting the blood vessels in endosteal and periosteal system. This also was also seen in segmental fractures where blood loss was 1700ml. Fixation of these fractures took longer time of operation and involved longer incision than simple fractures. The difference between simple and complex fracture was 1200ml which is statistically significance. There was no difference between fractures with transverse and wedge patterns in terms of blood loss. The mean blood loss was 1300ml which is slightly below those with oblique and spiral fracture patterns at 1450ml. Transverse and wedge fractures are of higher energy injury than oblique and spiral fractures, but blood loss was more significant in the latter because of difficulty in achieving anatomical reduction and fixation during surgery. Similar findings were also noted in other studies[47].

Timing of surgery was very significant in terms of blood loss with operations done more than one month having 2000ml of blood loss while one done in less than a two weeks having 1200ml

of blood loss. Similar findings were noted by studies done by Kajja, Miano and Kinyanjui[2,41,47]. Blood loss increases with increase in duration from the date of injury and is attributed to increased vascularity coupled with longer operation time caused by difficulty in achieving anatomical reduction caused by extensive soft tissue fibrosis. During bone repair process there is increased angiogenesis resulting in increased vascular channels and blood flow that contribute to significant bleeding during delayed surgery.

Patients whose surgeries were done by consultants and senior registrars lost more blood than the one done by junior registrars. This is different from studies done in Uganda which showed the reverse[2]. The possible explanation for this is, complex fractures were reserved for surgeons with higher level of training while simple fractures operations were reserved for junior surgeons.

The rate of blood transfusion after open intramedullary nailing of diaphyseal femoral fractures in KNH was 35%. A study done at Mulago in Uganda, transfusion rate was 27%[2]. A separate study by Sonam et al on facture femur operations, the rate of blood transfused to patients was 24.3%[62]. The rate for KNH is higher than similar local and international studies. Over-transfusion is an issue in KNH just like other studies and not just in regard to inefficient use of limited resource, but it can pose additional risks to the patients[44, 45].

The median unit of blood transfused was one while the median units of blood requested were two units. The main reason for blood transfusion was intraoperative observation by anesthetists accounting for 69.2%. Low pre-operatively HB and clinical parameters had least influence on transfusion at 15.9% each.

Total units of blood requested i.e cross-matched were 122 while the total units transfused were 27 units. The crossed and matched to transfused ratio(C/T) was 4.5:1. The ratio is high as compared to other studies[61] and higher than recommended one. C/T ration is a measure of how efficiency we do blood ordering practice and ideally should be less than 2.5. A ratio of more

than 2.5 is considered as significantly high for blood wastage. A value of less than 0.5 is considered indicative of significant blood utilization. In this study C/T ratio of 4.5:1 means there was over ordering of blood for transfusion.

CONCLUSION

- The average blood loss after interlocking nail is 1500ml and it compares with other studies.
- Delay before surgery is the most significant factor that increases blood loss
- Transfusion rates in KNH (35%) are higher than in other local African and non-African studies.
- There is over cross-matching of blood in KNH for patient undergoing open reduction and intramedullary nailing of femoral fractures.

RECOMMENDATIONS

- Patients should be operated on early to minimize intraoperative blood loss.
- Patients with complex injury should be operated with anticipation of blood loss while the one with simple injuries the surgeon should anticipate minimal blood loss.
- Blood transfusion criteria should be adapted to minimize over transfusion and conserve the already scarce resource.
- Knowledge of a surgical blood ordering equation (SBOE) should be used to determine the number of units of RBC to order before surgery to minimize over requisition.
- Cross-matching and saving serum should be adapted in situations where anticipated blood loss is significant.
- Autotransfusion can be explored as way of reducing the need for allogenic transfusion

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APPENDICES

Appendix 1: Data collection sheet

Patient details and biodata

Study number	
Sex	
Age	
Date of injury	
Date of operation	
Pattern of fracture (AO classification)	

Operative details

Mode of Anaethesia		
Length of operation		
Use of diathermy		
Units of blood requested		
Units of blood transfused		
Reason for transfusion	Low HB	
	Intaoperative bleeding	
	Clinical parameters	
	Others (state)	
Length of incision in cms		
Surgeon (registrars, consultant, Both)	Registrar $\leq$ 3 years	
	Registrar > 3 years	
	Registrar supervised by consultant	
	Consultant	

Laboratory data

Haemoglobin taken 24hrs before operation	
Haemoglobin taken 72hrs postoperative day	

Appendix 2: Consent form

PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY (ENGLISH)

Title of study: Blood loss and pattern of transfusion in open interlocking nail surgery

Principal Investigator and institutional affiliation: Dr James Mwaniki Kirii from The University of Nairobi

Introduction: I would like to tell you about a study being conducted by the above researcher. The purpose of this consent form is to give you the information you will need to help decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits and your rights as a volunteer. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. Once you understand and agree to be in the study, I will request you to sign your name in this form. You should understand that decision to participate is voluntary, you may withdraw from study at any time and refusal to participate will not affect the services you are entitled to. We will give you a copy of this form for your records.

May I continue? YES/NO

This study has approval by KNH-UoN Ethics and Research Committee protocol No. P33/01/2018

What is this study about? The researcher is interviewing individuals admitted in KNH suffering from fractured thigh bone. Participants will also have the choice to undergo a Complete Blood Count test. This will help find out the amount of blood you will lose while undergoing surgery of your femur fracture. It also seeks to establish whether you will have had a blood transfusion and amount transfused. There will be approximately 70 participants and we are asking for your consent to consider participating in this study.

What will happen if you decide to be in this research study? You will be interviewed in a private area for approximately 10 minutes and after interview has finished we shall draw blood for testing your blood level before and after surgery.

Are there any risks, harms, discomforts associated with this study? Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort will always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. You may feel some discomfort when drawing blood or may have a small swelling. In case of any injury, please contact the staff right away and we shall treat you as necessary.

Are there any benefit being in this study? You may benefit by receiving free complete blood testing. The information will help us understand the amount of blood loss during surgery. This information is a contribution to science in future to anticipate the amount of blood loss during surgery, factors that contribute and whether to transfuse.

Will being in this study cost you anything? Your participation will not cost any monetary value.

What if you have questions? If during or in future you have any questions concerning this study, please call or send a text message to Dr James Mwaniki Kirii Mobile: 0722231632 or Chairman, KNH/UON ethics and research committee. Telephone: (+254020) 2726300 Ext 44102

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

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

Participant's printed name……

Participant's Signature/Thumb stamp: ……Date…….

Researcher's statement

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

Researcher's Name……Date……Signature……..

For more information contact Dr James Mwaniki Kirii Mobile: 0722231632 or Chairman,

KNH/UON Ethics and Research Committee. Telephone: (+254020) 2726300 Ext 44102

FOMU YA MAELEZO NA RIDHAA YA MSHIRIKI KWA UANDIKISHAJI (KISWAHILI)

Kichwa cha utafiti: Kiwango cha damu kinachopotea wakati wa upasuaji na mfano wa kuongezwa damu

Mtafiti mkuu na taasisi: Dr James Mwaniki Kirii kutoka chuo kikuu cha Nairobi

Kuanzishwa: Mimi ningetaka kukuelezea juu ya utafiti unaofanywa na mtafiti aliodhoreshwa hapo juu. Maana ya hii ridhaa ni kukupatia maelezo unayohitaji kabla ya kujuimuishwa kwa utafiti huu. Unastahili ujisikie bure kunjua maelezo juu ya hatari, faida and haki yako katika utafiti huu. Nitakuomba utie sahihi kwa fomu hii ukikubaliana na maelezo hii. Tutakupatia nakala ya fomu hii kwa rekodi yako.

Tunaeza endelea? Ndio/Hapana

Utafiti huu umeidhinishwa na kamati ya maadili ya KNH-UoN itifati Nambari P33/01/2018

Utafiti huu ni wa nini? Utafiti huu unatafuta kiasi cha damu utapoteza ukifanyiwa upasuaji. Pia unatafuta kiasi cha damu utakayoongezwa. Washirika katika utafiti huu watakuwa sabini na tunakuuliza utupatie idhini ya kuufanya.

Nini itafanyika ukijumuishwa kwa huu utafiti: Nitakuuliza maswahili kwa ziri na utahitaji kuniruhusu nipime damu yako kabla na baada ya upasuaji

Kunayo hatari katika utafiti huu? Utafiti wowote unaweza kudhuru kwa jia mingi. Ujumbe wowote nitakoupata kwako utawekwa kwa njia ya siri. Huu utafiti hautakudhuru kwa njia yoyote ya kiafya

Kunayo Faida kutoka kwa utafiti huu: Utapata kipimo cha damu bila malipo. Pia utapata kunjua matoke ya hiyo kipimo bila malipo. Utafuti huu utasaidia madaktari kwa wakati ujao kujua kiwango cha damu kinachopotea wakati wa upasuaji, sababu zinaosababisha na kama itaongezwa

Kuna gharama yeyote: Hakuna gharama yeyote ya kifedha katika utafiti huu.

Ikiwa utakuwa na swali? Kama wakati huu bila shaka utakuwa na swali kuhusu utafiti huu, unaweza wasiliana na: Daktari James Mwaniki Kirii, Simu ya mkono: 0722 231 632, SLP 213-10301 Kianyaga or Chairman, KNH/UON Kamati ya Maadili na utafiti. Simu: (+254020) 2726300 Ext 44102

Uchaguzi wa kushiriki: Kuwa kwa huu utafiti ni kwa hiari yako. Unaweza kutoshiriki kwa wakati wowote bila kupoteza faida kwa matibabu yako.

FOMU YA RIDHAA

Kauli ya Mshiriki

Nimesoma kauli ya fomu hii na nimeelewa hatari na faida ya utafiti huu.

Nathibitisha ya kwamba nimeelezewa juu ya huu utafiti na kwa hiari yangu nitashiriki

Sahihi ya mshiriki…….tarehe……

Jina la mshiriki…….

Kauli ya mtafiti

Nathibitisha ya kwamba nimemweelezea mshiriki juu ya utafiti, na naamini mshiriki amenipatia ridhaa kwa hiari yake

Jina ya mtafiti ……tarehe…….Sahihi……

Mawasiliano kwa ajili ya ufafanuzi:

Kama wakati huu bila shaka utakuwa na swali kuhusu utafiti huu, unaweza wasiliana na:

Daktari James Mwaniki Kirii, Simu ya mkono: 0722 231 632, SLP 213-10301 Kianyaga or

Chairman, KNH/UON Kamati ya Maadili na utafiti. Simu: (+254020) 2726300 Ext 44102

Appendix 3: Ethical approval

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KENYATTA NATIONAL HOSPITAL APPROVED 02 MAY 2018 KNH/UoN-ERC P.O Box 20723-00202 NRB

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/150

May 2, 2018

Dr. James Mwaniki Kirii
Reg. No.H58/ 69091/2013
Dept. of Orthopaedic Surgery
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Kirii

RESEARCH PROPOSAL – BLOOD LOSS AND TRANSFUSION PATTERNS DURING OPEN INTERLOCKING NAILING OFDIAPHYSEAL FEMORAL FRACTURES IN KENYATTA NATIONAL HOSPITAL (P33/01/2018)

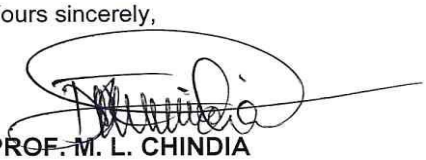
This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is from 2nd May 2018 – 1st May 2019.

This approval is subject to compliance with the following requirements:

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

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

Yours sincerely,



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

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
The Chairperson, KNH-UON ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine,UoN
The Chair, Dept. of Orthopaedic Surgery,UoN
Supervisor: Dr.Richard Ombachi Bwana, Dr.Joseph Chege Mwangi