EARLY DEEP VEIN THROMBOSIS IN

PATIENTS ADMITTED WITH FRACTURE FEMUR IN

KENYATTA NATIONAL HOSPITAL

A dissertation submitted in part fulfillment for the requirements of the degree of Master of Medicine (M.MED) in Orthopedic Surgery of the University of Nairobi

By

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DECLARATION

This dissertation has been prepared as part fulfillment of the requirements for the degree award of Masters of Medicine in Orthopedic Surgery by the University of Nairobi, School of Medicine. I hereby declare that this study is my original work and has not been presented for dissertation at any other university

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Date…….

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DEDICATION

This is dedicated to my parents Samuel and Anne Murage without whose support and encouragement I would not be where I am today.

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List of Abbreviations

KNH……..Kenyatta National Hospital

DVT……..Deep Vein Thrombosis

VTE……..Venous Thromboembolism

PE…….Pulmonary Embolism

ACCP……American College of chest physicians

UFH……..Unfractionated Heparin

HIT….....Heparin induced thrombocytopenia

LDUH……..Low dose unfractionated heparin

NOAC….....Novel oral anticoagulants

VCF…….Vena cava filter

ABSTRACT

Background:

Fractures of the femur constitute a significant disease burden at KNH with approximately 13 patients needing admission each week. In the year 2016 a total of 625 patients were admitted to KNH with fractures of the femur. Deep venous thrombosis and pulmonary embolism are serious complications that can occur in the early period following fractures of the femur[1,2], and pulmonary embolism has been shown to be third most common cause of death in patients surviving the first 24 hours following trauma[3]. Surgical intervention within 24 hours significantly reduces the mortality from pulmonary embolism[4]. However the majority patients with fracture femur seen at KNH are initially managed on traction while waiting to go to theatre for definitive management. This leads to prolonged immobilization. No study has been done to assess the incidence of early DVT in fracture femur. There are currently no protocols at Kenyatta National Hospital with regards to prevention of DVT in fracture femur. This study sought to establish the incidence of early DVT following admission in patients with fracture femur and the frequency and methods of prophylaxis commonly used in KNH in order to better inform policy and possible protocols for the management of DVT in KNH.

Objective: To determine the incidence of early DVT in patients with fracture femur at KNH.

Design: Prospective observational study.

Setting: Accident and Emergency department, orthopedic wards Kenyatta National Hospital.

Patient and methods: The study involved patients aged 18 years and above admitted in the orthopedic wards at KNH through A & E department with fracture femur. The patients were recruited using simple random sampling as they were seen at the Accident and Emergency

department. Patient demographics were recorded after consenting for the study. A total of 50 patients were recruited into the study. The patients were followed up for one week for symptoms of DVT and on day 7 following the fracture an ultrasound examination was done to look for the presence of DVT both in the injured and uninjured limb. The ultrasound was performed by two different radiographers in order to improve accuracy of the findings. Clear documentation of the presence or absence of clinical signs and symptoms was made and each patient was scored according to the modified well's score. The surgeons in the wards were informed of any patient found to have DVT for further treatment.

Results: A total of 50 patients were recruited into the study over a two month period. The mean age of the patients was 37 years (SD ± 14) with an age range between 18 and 88 years. There were 15 (30%) patients aged 18-29 years and 18 (36%) patients between 30 and 39 years. Males accounted for 68% of the patients with femoral fractures giving a Male-to-Female ratio of 2: 1. There were a total of four cases of DVT found corresponding to a prevalence of 8% and an incidence of 1.1 per 100 patient days of observation. There was a significant association between increasing patient age and DVT ($p = 0.016$). The prevalence of DVT in patients aged 60 years and above was 50% compared to 11.1% in 30-39 year olds while no DVT cases were reported outside these age groups. The prevalence of DVT in male (8.8%) and female (6.3%) patients was not significantly different ($p = 0.754$). There were no cases of pulmonary embolism observed during the study period.

Conclusion and recommendations

During the course of the study patients who were elderly patients and patients with proximal fracture femur were found to have DVT. Given the possible life threatening complications such as pulmonary embolism prophylaxis against DVT should be considered in patients with fractures of the femur.

2.0 INTRODUCTION

The association between trauma with fractures and DVT has been a topic of study for many years. As early as in 1934 McCartney found that there was an association between Trauma and sudden death from venous thromboembolism. This association was especially strong in patients who had sustained lower limb fractures[5]. Later in 1967 Freeark et al in a study on DVT found that 35 % of patients with trauma and fractures of the lower extremity had thrombus formation and that the thrombus formation began as early as within 24 hours of the injury[6].

In the year 2015, 625 cases of fracture femur were seen at Kenyatta National hospital. Currently there is no data on whether there were any cases of early DVT in these patients. There are also no studies that have been done on the incidence of DVT in fracture femur. Currently there are no protocols on DVT prevention in KNH.

3.0 LITERATURE REVIEW

Patients who sustain fractures of the femur are at a high risk for DVT[1,2,8]. The incidence of VTE has been reported to be variable. Greg et al found an incidence of 69% in patients with lower extremity fractures. Of these 40% of the patients with fracture femur had occult DVT[7]. The incidence of DVT following isolated lower limb fractures is poorly understood, and there are few studies on the same[8]. Decker et al studied DVT following different isolated lower extremity fractures and had similar findings to Greg et al with the incidence of DVT ranging from 5% to 86%[8]. In his study, fractures of the femur carried the highest risk for DVT[8]. These findings were similar to other studies fractures of the femur were shown to carry the highest risk of DVT with the risk being as high as 46 – 83 % for patients with proximal femur fractures[8]. The difference in incidence could be explained because of the differences in the

nature of the injuries, the method used to diagnose the VTE, the specific patient demographics[9].

Salzman[10] et al also found a preoperative incidence of 9% of DVT in orthopedic patients despite prophylaxis. Therefore preoperative DVT is a significant consideration in patients with fracture femur. This is especially so because during surgery or mechanical prophylaxis there has been shown to be a risk of detachment and proximal propagation of a thrombus which can further predispose to PE and sudden death[11].

The timing to development of DVT has also been a topic of study. Previous studies have shown that DVT can occur early following trauma within the first 7 days[1,2]. This can be explained from a hematological standpoint[12]. Venous thromboembolism has been studied and it has been demonstrated that hypercoagulopathy is present in the early period following trauma[13]. Schreiber et Al studied the hematological changes following trauma and found that hypercoagulability is most prevalent after the first 24 hours following injury[13]. These findings were similar to what Seyfer[14] et al found in his study. Seyfer et al found that coagulation changes following trauma tended towards a more hypercoagulable state. These changes occurred in the early post injury period from as early as 24 hours. Previous studies have addressed the incidence of DVT in the early post injury period[1,2]. It is therefore prudent to consider the possibility of DVT in the early post injury period amongst the population of patients with fracture femur at KNH.

In order to prevent DVT Different strategies have been employed. This includes early surgical intervention within 24 hours which significantly reduces mortality from PE[4]. However not all patients will benefit from surgery within 24 hours. A second strategy that has been employed in is the use of prophylaxis is commonly instituted in the form of chemical,

mechanical, inferior vena cava filters and in certain cases a combination of these methods[15]. The ACCP recommends the use of prophylaxis in patients who have orthopedic trauma[15]. However studies done in African countries have shown that thromboprophylaxis may not routinely implemented[16]. This is possibly due to the fact that the incidence of deep vein thrombosis remains largely unknown[16]. The risk of early DVT in these patients who are diagnosed with fracture femur has not been assessed at KNH. At KNH there are no protocols for DVT prophylaxis in trauma patients. It is not also known if patients with fractures of the femur in KNH are put on prophylaxis for DVT.

In some cases DVT may be present despite the use of prophylaxis methods. Zahn[17] et al studied the preoperative incidence of DVT in 61 patients following fracture femur, 62 % of the patients who experienced a delay to surgery had radiological evidence of DVT. The most significant significant factor identified was delay to surgery greater than 48 hours. Majority of the cases of DVT occurred in the fractured limb, whereas in 23% of subjects the DVT was bilateral. In this study by Zahn et al the recommendation was that patients who experienced a delay in surgery should be investigated preoperatively and an inferior vena cava filter considered as a means of prophylaxis for those patients who had DVT.

Decker et al identified risk factors for developing DVT and found that delays from injury to surgery were a significant contributing factor to the development of DVT[8]. This was similar to the findings of Smith et al. who studied the incidence of pre-operative DVT in patients who experienced delays to surgery following fracture femur and found an incidence of 11.9%. The incidence increased with delays to surgery with delays greater that 7 days associated with an incidence of 33.3%[1]. Young-Ho et al also had similar findings when he studied the preoperative incidence of DVT in patients with fractures femur and found an

incidence of 2.6%[2]. In his study he found that delays amounting to greater than 72 hours increased the incidence of DVT and concluded that a workup for DVT may be considered in cases where admission or surgery were delayed for more than 72 hours[2].

In KNH it is not uncommon to find patients with fracture femur experiencing delays to surgery for various reasons. The patients are initially managed on traction in a recumbent position. This position has been shown to futher predispose to DVT by causing venous stasis of blood especially in the soleal veins[18].

Previous studies have sought to identify the reasons for delays to surgery. Adeleke[19] et al studied factors that delayed surgical procedures in 249 orthopedic patients and found that the cause for the delays may include lack of theatre facilities, patient comorbidities, and long waiting lists at the hospital amongst other factors. These delays are similar for patients with fracture femur and may therefore predispose to the development of DVT.

Coagulopathy associated with trauma has also been found to be present in 1 out of every 4 patients (25%) at admission following trauma[9], and PE has been shown to be third most common cause of death in patients surviving the first 24 hours following trauma[3]. Therefore this is a condition that warrants study in order to establish the incidence in our local setting as no other studies have addressed the same. Hence recently one of the biggest challenges for the orthopedic surgeon and other clinicians in the management of lower limb fractures is how to reduce the risk of these patients developing DVT.

3.1 DIAGNOSIS OF DVT

3.1.1 Clinical presentation

The classical clinical features of DVT are swelling, pain, warmth and redness of the affected limb. However patients with trauma to the lower limb may be asymptomatic[1,2].

Delayed Surgery for Patients with Femur and Hip Fractures—Risk

Of Deep Venous Thrombosis

Eric B. Smith, MD, Javad Parvizi, MD, and James J. Purtill, MD (Preoperative Incidence of Deep Vein Thrombosis after Hip Fractures in Korean

Smith et al found that none of the patients in his study had clinical symptoms of DVT despite a positive ultrasound.[1] Therefore alternate methods of investigation would be the choice for diagnosis, such as imaging via ultrasound as patients may be asymptomatic for DVT[1,2].

These findings are similar to the results of other studies. Clinical examination has been shown to have poor sensitivity and specificity in predicting DVT[20-22]. Goodcare et al studied the effectiveness of differences in calf diameter, swelling of the limb and tenderness and found that none of this had a good predictive value[23]. However despite this he found that a difference in calf diameter of greater than 2 cm had the best predictive value in diagnosing DVT[23]. In KNH there has been no study to identify if the signs and symptoms associated with DVT are present in patients who have DVT following fracture femur. Therefore in this study the patient will be examined for clinical signs and symptoms, and this will be correlated with the ultrasound findings.

3.1.2 Imaging in the diagnosis of DVT

In the past venography has been used as the gold standard for detection but is invasive, difficult to use and is expensive[24]. Venography is also associated with various risks. For example a risk of venography induced DVT exists after venography[25]. In up to 30% of venograms a segment of the venous system will not be visualized[26]. Because of this problem with viewing the entire venous system the accuracy of venography was found to be 90% in previous studies[27].

Venography is contraindicated in patients who have renal insufficiency, allergy, and cellulitis around the area of infusion[28]. Venography has also been associated with complications such as pain, hypersensitivity reactions, skin necrosis and chemical cellulitis from extravasation[29]. It can also cause acute renal failure[29].

Venous ultrasonography is more commonly used as it is less invasive, easy to use and is less expensive[29,30]. Venous ultrasonography has been shown to have a high sensitivity and specificity[30].

Previous studies done at KNH have proven ultrasound as a reliable means of diagnosis. Aywak[30] et al compared sonography with venography for the diagnosis of suspected DVT in patients at KNH and found the overall sensitivity of venous sonography at 88.9%. In her study the specificity of ultrasound was 91.8% and accuracy 90.9%[30]. When DVT above the calf was considered alone, the sensitivity improved to 100%[30]. An additional benefit was that an alternative diagnosis was found by ultrasound in 48.6% of the negative for DVT cases[30]. The findings from the study by Aywak[30] et al was similar to studies done before and therefore suggested ultrasound as the first choice for detection of DVT.

Other studies have demonstrated sensitivity and specificity of venous ultrasound in detecting DVT is 97% and 98% respectively[31]. Fletcher et al compared venous ultrasound imaging with ascending contrast venography for the diagnosis of DVT. He found that in comparison with venography ultrasound had an overall sensitivity of 95% and specificity of 92%[32]. He recommended the use of ultrasound given its less invasive nature[32]. The ACCP also recommends the use of ultrasound as part of the diagnosis of DVT[15].

The diagnosis of DVT via ultrasound involves compression ultrasonography as the diagnostic imaging test. Loss of compressibility of a venous segment is the most sensitive and specific diagnostic criterion for a first episode of DVT. In addition, Doppler with color flow is used to accurately identify vessels, especially if there is doubt in the compressibility of a vessel[30,33].

This study utilised duplex ultrasound as a means of diagnosis for deep vein thrombosis.

3.1.3 Use of D Dimers

D-dimer forms when cross-linked fibrin is cleaved, and is often increased in patients with DVT. D-dimer blood testing is a sensitive, but not specific, assay for DVT and cannot be used alone to diagnose DVT[33]. Normal laboratory values can, however, be used to exclude DVT[33]. D – Dimers therefore form a useful tool in an outpatient setting in patients who do not have other conditions such as trauma that can elevate its levels.

D dimers are non specific and can be elevated in many conditions and in patients with comorbidities. D dimer levels can also be elevated physiologically[33]. Physiologic states where the D dimers can be elevated are age >65 years, cigarette smoking, trauma, and the postoperative period[33]. Pathological causes of elevated D dimer levels are thrombosis,

infections and chronic inflammatory conditions amongst others. Therefore it is not uncommon to find the levels elevated in patients who are hospitalised[33,34].

The specificity of D-dimers in regard to testing for DVT is low with prior studies demonstrating a specificity of 40%[35,36].

Therefore the use of D dimers is limited in patients with comorbidities such as trauma. The 2012 ACCP guidelines recommend the use of ultrasound in patients with comorbidities and trauma as opposed to D dimer testing[15].

3.7CLASSIFICATION OF DVT

Deep vein thrombosis can be classified into proximal DVT and distal DVT depending on the location of the thrombus[37]. Proximal DVT involves the popliteal vein and deep veins of the thigh. Proximal DVT has been shown to carry a higher risk of embolisation and is therefore more significant[37].

Distal or below knee DVT involves the anterior and posterior tibial veins, and the peroneal veins. The muscular calf veins in the soleus and the gastrocnemius may also be involved. Distal DVT has a lower risk for embolisation[37]. Complications associated with both proximal and distal DVT include post thrombotic syndrome[38,39].

3.8 Prophylaxis for DVT

There are different options available for prophylaxis against DVT namely chemical prophylaxis, mechanical prophylaxis and inferior vena cava filters[40]. There are different guidelines that have been published such as the American College of Chest Physicians (ACCP) guidelines[15] and the Eastern Association for the Surgery of Trauma (EAST) guidelines[41]. The ACCP guidelines recommend the use of prophylaxis preoperatively and

post operatively in trauma patients[15]. The guidelines also recommend the use of chemical prophylaxis and mechanical prophylaxis where possible. The EAST guidelines recommend the use of low molecular weight heparin in patients with complex fractures of the lower limb[41]. The EAST guidelines also recommend the use of prophylaxis in patients with fractures of the lower limbs with prolonged bed rest[41].

3.8.1 Low molecular weight heparin

The effects of the use of low molecular weight heparin have been studied extensively[42]. LMWH is derived from the chemical depolymerization of unfractionated heparin. Due to the smaller size, LMWH has greater activity towards factor Xa than UHs [40]. Therefore LMWH has a more selective binding effect to factor Xa[43]. This preferential binding to factor Xa makes LMWH more effective than UFH[40]. Geerts et al compared the effectiveness of LMWH compared to LDH heparin[44]. In this study the rate of proximal DVT was reduced from 15 % to 6 % with the use of LMWH[44]. Therefore LMWH is more efficacious and more widely used than UH.

3.8.2 Low dose unfractionated heparin

Low dose unfractionated heparin (LDUH) was one of the earliest anticoagulants adopted for use. Typically it is given in doses of 5000 IU sc for the prevention of DVT [41].

The anticoagulant effect of heparin is complex involving the activation of antithrombin III [45]. Heparin has also been shown to possess a binding effect to thrombin, factor IX and Xa, subsequently reducing their effect.

Ruiz[46] et al studied the efficacy of low dose heparin and found that it was not as efficacious for the prevention of DVT in trauma patients. In this study 28% of the patients receiving heparin developed DVT[46].

UFH heparin has also been associated with higher incidences of heparin induced thrombocytopenia type II (HIT II) [47]. There are two types of heparin induced thrombocytopenia; type 1 HIT is a non immune disorder that presents within the first 2 days and is as a result of platelet activation. HIT II is an autoimmune disorder that typically presents 5- 10 days after initiation of heparin therapy[48,49].

IgG is generated against heparin - platelet factor 4 complex[49]. This in turn causes platelet activation and consumption leading to thrombocytopenia. The activation leads to endothelial lesions and therefore HIT II is a prothrombotic disorder and it may therefore it may present with further thrombosis[49].

HIT II takes 5 to 15 days to resolve but in some cases may persist for several months[50]. In some studies HIT II has been shown to develop in 6% of patients with a 30% incidence of thrombotic complications and a 30% mortality rate [51].

Clinical signs and symptoms of HIT are skin lesions at the injection sites, or, fever, chills, chest pain and dyspnoea after an i.v. bolus injection of heparin[52].

The frequency of HIT II with complications is 0.3 % for LMWH compared to 3% for UFH[44].

3.8.3 FONDAPARINUX

Fondaparinux is a synthetic pentasaccharide that targets factor Xa[50,51] . In a study by Eriksson[52] et al comparing fondaparinux and enoxaparin for thromboprophylaxis following

hip surgery, a risk reduction of 56.4% was found in the fondaparinux group versus enoxaparine group.

However these results have not been reproduced and Donath et al found similar rates of VTE in LMWH and fondaparinux[53].

Fondaparinux has been proven to have a similar safety profile to LMWH in terms of risk of bleeding[53,54]. However futher studies are needed in order to assess the efficacy of fondaparinux in orthopedic patients[53].

3.8.4 Novel Oral anticoagulants

These include drugs that target thrombin and factor Xa[55]. Dagibatran inhibits thrombin which catalyses the formation of fibrin from fibrinogen[56]. It has a half life of 12 – 14 hours. Because of the long half life NOAC may not be ideal for the prophylaxis of pre-op patients[55].

3.8.5 Mechanical prophylaxis

Mechanical devices have also been used such as pressure compression stockings and pneumatic compression devices[57]. These devices work by reducing the laminar diameter of the vessels and increasing blood flow[54]. The advantage of these devices is the low risk for bleeding in trauma patients[54]. Ginzburg et al compared the use of pneumatic compression devices with that of heparin. The rate of DVT was 2.7% in the IPC group compared to 0.5% in the LMWH group. The rate of pulmonary embolism and bleeding were comparable[58,59]. In a systematic review, Guyatt[61] et al found that the efficacy of mechanical prophylaxis is not the same as chemical prophylaxis. Therefore mechanical prophylaxis may not be sufficient if used alone for trauma patients.

The effects of using combined chemical and mechanical prophylaxis have also been studied. Kakkos[62] et al studied the use of combined chemical and mechanical prophylaxis and found that the risk of DVT reduced from 3% to 1% when chemical prophylaxis was added to mechanical prophylaxis. The rate of PE was also reduced in patients with combined prophylaxis from 4% to 1%.

3.8.6 Vena cava filters

Vena cava filters (VCF) have been used in patients with contraindications to chemical prophylaxis, patients who have bled on chemical prophylaxis and those who have had episodes of PE despite being on anticoagulants[62].

However VCF are not without risks[63]. Given the short transient risk of thrombosis in trauma patients and the associated risks of complications with VCF, this option has become less attractive[63]. Complications that are associated with VCF are filter migration, filter fracture, VCF thrombosis or stenosis, and inferior vena cava perforation. The VCF are also associated with poor rates of device retrieval which may be as high as 34%.

The 2012 American College of Chest Physicians (ACCP) guidelines do not recommend the use of VCF filters as prophylactic measure for trauma patients[61]. This is because the risk of DVT in trauma is of a transient nature.

4.0 STUDY QUESTION

What is the incidence of early DVT in patients admitted to Kenyatta National Hospital with fracture femur?

5.0 STUDY JUSTIFICATION

Fractures involving the femur are common in our setting. With the growing body of evidence that fractures of the lower limb are associated with deep vein thrombosis, it is important to establish an incidence. This is because of the complications such as pulmonary embolism that are serious and life threatening.

Knowledge of the incidence of deep vein thrombosis in femoral fractures at KNH will enable formulation of local policies on thromboprophylaxis. This will enable the orthopedic surgeon to further manage his patients and possibly reduce adverse outcomes.

6.0 STUDY OBJECTIVES

Main objective

To determine the incidence of early DVT in patients with fracture femur who are admitted to Kenyatta National Hospital.

Specific objectives

- To determine the incidence of DVT in patients admitted to Kenyatta National Hospital with fracture femur.

- To establish the type and frequency of use of DVT prophylaxis use amongst orthopedic patients with fractures to the shaft of femur

- To establish whether clinical signs and symptoms of DVT are always present in patients with DVT following fracture femur

- To establish if risk factors such as age influence development of DVT in these patients.

7.0 METHODOLOGY

7.1 Study design

Prospective observational study

7.2 Study setting

The study was a two month study conducted at the Accident and emergency Department and the orthopedic wards of Kenyatta National Hospital.

Kenyatta National Hospital is an 1800 bed national teaching and referral centre. The accident and emergency department serves the population of Nairobi and its environs and also receives referrals from level 5 hospitals all over the country. It is also the entry point for all acute trauma patients. There are 3 adult orthopedic wards admit and manage patients with fractures of the femur.

7.3 STUDY POPULATION

All adult patients aged 18 years who presented with fracture femur and were able to give legal consent were considered for this study. The patients also had to meet the inclusion criteria. Any patients with pre-existing DVT or patients presenting more than seven days after fractures of the femur were excluded from the study.

7.4 SAMPLE SIZE

Sample Size Calculation

The Woolson formula for calculating the sample size for a simple random sample without replacement was used:

$$n = \left(\frac{z}{m}\right)^2 p(1-p)$$

Where,

z is the z value (1.96 for 95% confidence level);

m is the margin of error (0.10 = + or – 10%); and

p is the estimated value for the proportion of the sample that has DVT (0.33 for 33%).

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

$$n = \left(\frac{1.96}{0.10}\right)^2 0.33(1-0.33) = 85$$

However, for a study period of about 2 months there would be approximately 13 patients admitted every week. This is about 52 patients per month yielding a population size of N= 104 patients seen in a 2 months period. The sample size equation solving for n' (new sample size) when taking the Finite Population Correction (FPC) into account since our sample is greater (10% plus) relative to the population of patients available within the study period is:

$$n' = \frac{n}{1 + \frac{n}{N}}$$

Where,

n is the sample size based as above, and

N is population size.

Working out the new sample size for using the formula above, we find:

$$n' = \frac{85}{1 + \frac{85}{104}} = \frac{85}{1.81} = 46$$

In order to address patient fall out or withdrawal from the study an additional 8% was added to the sample size. The total sample size therefore was

n = 46 + (8/100 *46) = 50

7.5 Inclusion criteria

1. Male and female patients aged above 18 years who were able to give consent.
2. Patients with fractures femur who were admitted to KNH.
3. Fractures presenting within 7 days of injury.

7.6 Exclusion criteria

1. Patients who declined consent
2. Patients with pre-existing documented DVT.

7.7 Data collection

Ethical consideration

Approval to perform the study was sought and obtained from the ethics, research and standards committee of the Kenyatta National Hospital/University of Nairobi.

The principal investigator and his assistants were informed of patients admitted with fracture femur. The principle investigator and his assistants confirmed the diagnosis by examining the radiographs. Thereafter informed consent was obtained after a thorough explanation of the study and its aims and reassurance that all the data will be handled with utmost confidentiality. After giving consent patients were recruited into the study. Data collection commenced once informed consent was obtained from the patient.

The patients' biodata was taken and dully filled in the questionnaire. The data collection was procured by the researchers obtaining information via directly interviewing the patients and examination of the radiographs. Seven days after the injury a clinical examination was done

and patients scored according to the Modified Wells Score for DVT. An ultrasound was thereafter done on the same day by two different ultrasonographers and the results compared for accuracy. The ultrasound machine used was a Sonoace 3 which is cable of diagnosing DVT via Duplex ultrasound. Both the fractured limb and the other limb were examined with ultrasound. In the cases where patients were found with DVT the primary surgeons in the ward were informed for further action and for the decision on treatment.

7.8 Data Management

Data was collected via written paper forms. This data was verified and cross checked to ensure quality and accuracy. It was then entered in a Microsoft Excel worksheet, from where it was imported into the statistical analysis software for processing.

Continuous data such as Age of patient and times since fracture (person time of follow-up) were presented using means and respective standard deviations (SD) or medians and inter-quartile range (IQR) as deemed appropriate. Counts and corresponding percentages (%) were used for categorical variables such as sex of patient, diagnosis/ fracture classification, and modified wells score categories, occurrence of events. The Incidence Rate (IR) of DVT was also be calculated and reported. Regression analysis of factors such as age, smoking, obesity was done to see the association of these factors to the development of DVT in the study subjects.

Pictorial presentation of the same was done using pie and bar charts as deemed appropriate. Stata version 12 (Stata Corp, College Station Texas) was used for all statistical analyses.

8.0 RESULTS

8.1 Patient characteristics

A total of 50 adults admitted to KNH with fractures of the femur were recruited in the study. The demographic characteristics of the sample are summarised in table 1. The mean age of the patients was 37 years (SD ± 14) with an age range between 18 and 88 years. There were 15 (30%) patients aged 18-29 years and 18 (36%) patients between 30 and 39 years. Males accounted for 68% of the patients with femoral fractures giving a Male-to-Female ratio of 2: 1. There was no significant difference in the mean age of male (35.5 years ± SD 10) and females (40.2 years ± SD 20.7) admitted at KNH with femoral fractures (p = 0.398).

Table 1: Demographic characteristics of patients with femoral fractures in KNH

	Frequency (n)	**Percent (%)**
Age		
18-29 years	15	30
30-39 years	18	36
40-49 years	10	20
50-59 years	3	6
60 years and above	4	8
Sex		
Male	34	68
Female	16	32
Total	**50**	**100**

8.2 Femoral fracture classification

Fractures of the shaft of the femur occurred in 28 (56%) of the patients admitted in KNH (Figure 1). The remaining patients had fractures involving the proximal 14 (28%) or distal 8 (16%) femur.

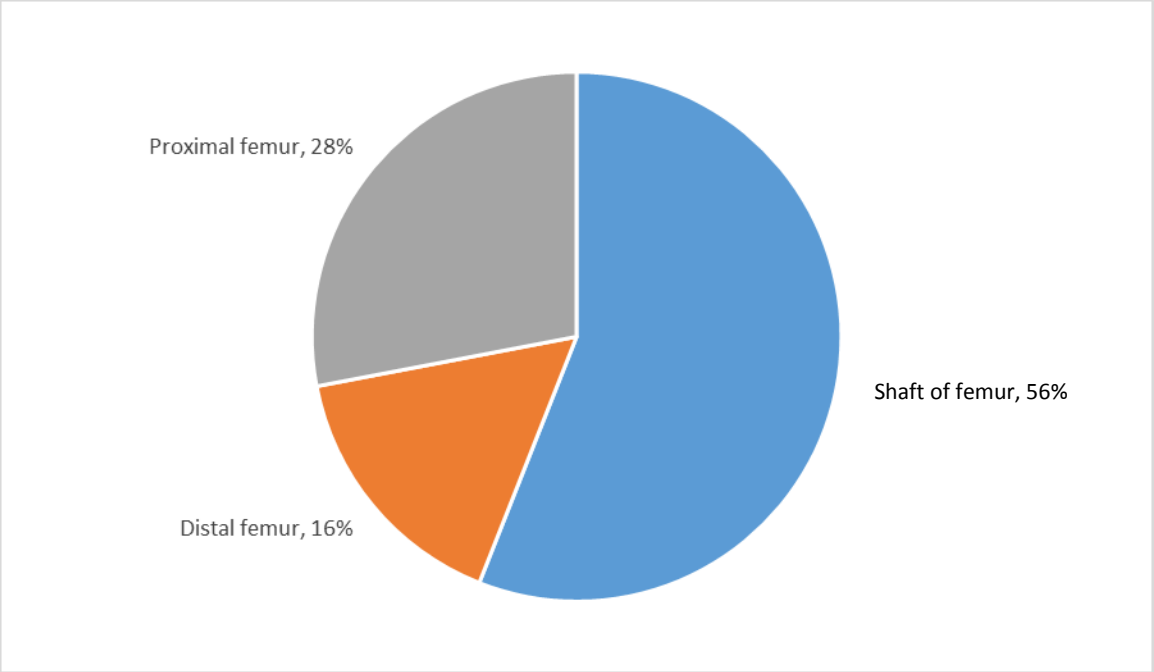

Figure 1: Classification of femur fracture in adult patients in KNH

There was no significant association between patient age and femoral fracture classification ($p = 0.078$), Table 2. Between 50 and 66.7% of the patients in each age group had fractures of the shaft of the femur. Twenty-six percent of patients aged 18-29 years had distal fractures while 22.2 to 33.3 percent of those in older age groups (30 years and above) had proximal fractures. Patient gender did not show a significant association with femoral fracture classification ($p = 0.163$) with 58.8% of males and 50% of females presenting with mid shaft fractures (Table 2).

Table 2: Femoral fracture classification and patient characteristics

	Femur fracture classification					
	Shaft	**Distal**	**Proximal**	**Chi**	**DF**	**P**
Age						
18-29 years	9(60.0)	4(26.7)	2(13.3)	14.1	8	0.078
30-39 years	12(66.7)	2(11.1)	4(22.2)			
40-49 years	5(50.0)	2(20.0)	3(30.0)			
50-59 years	2(66.7)	0(0.0)	1(33.3)			
Sex						
Male	20(58.8)	7(20.6)	7(20.6)	3.6	2	0.163
Female	8(50.0)	1(6.3)	7(43.8)			

8.3 Incidence of early DVT

The fifty patients recruited after admission to KNH with fractures of the femur underwent ultrasound examination for DVT at day 7 resulting in 350 person days of follow-up. Of these patients 4 had thrombus indicative of DVT on ultrasound yielding a prevalence of 8% (95% CI, 2 to 19%) and an incidence of 1.1 cases per 100 person days.

8.4 Use of DVT prophylaxis

The use of DVT prophylaxis was assessed and it was found that it was administered in 6 (12%) of the 50 patients. In all the cases who received prophylaxis chemical prophylaxis was used as a sole method.

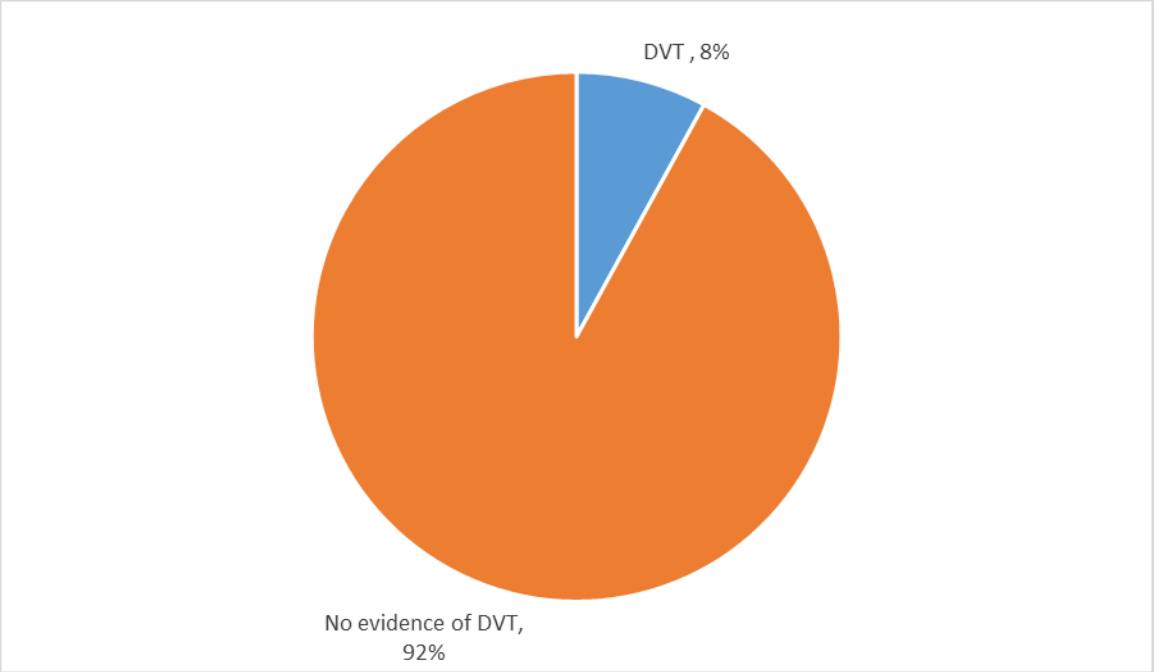

Figure 2: Prevalence of DVT in patients with fractured femur admitted in KNH

Of the four cases of DVT two occurred in fractures of the proximal femur, none occurred in patients with distal fracture femur. Twenty-one percent of the proximal fractures and 3.6% of the shaft fractures were associated with DVT (Table 3).

Table 3: Association between fracture location and DVT prevalence

	DVT		
	Yes	**No**	**P value**
Shaft of femur	1(3.6)	27(96.4)	0.088
Distal femur	0(0.0)	8(100.0)	
Proximal femur	3(21.4)	11(78.6)	

8.4 Clinical signs and symptoms of DVT

All the 50 (100%) patients with femur fracture had at least one of the factors or signs and symptoms of DVT presented in Figure 3. Most patients had either three signs (30%), or two

signs (24%) occurring together while 28% had a single DVT sign. Recent immobilization was present in all patients due to immobilization through traction. Sixty percent of patients had entire leg swelling, and 36% presented with local tenderness along the distribution of the deep venous system.

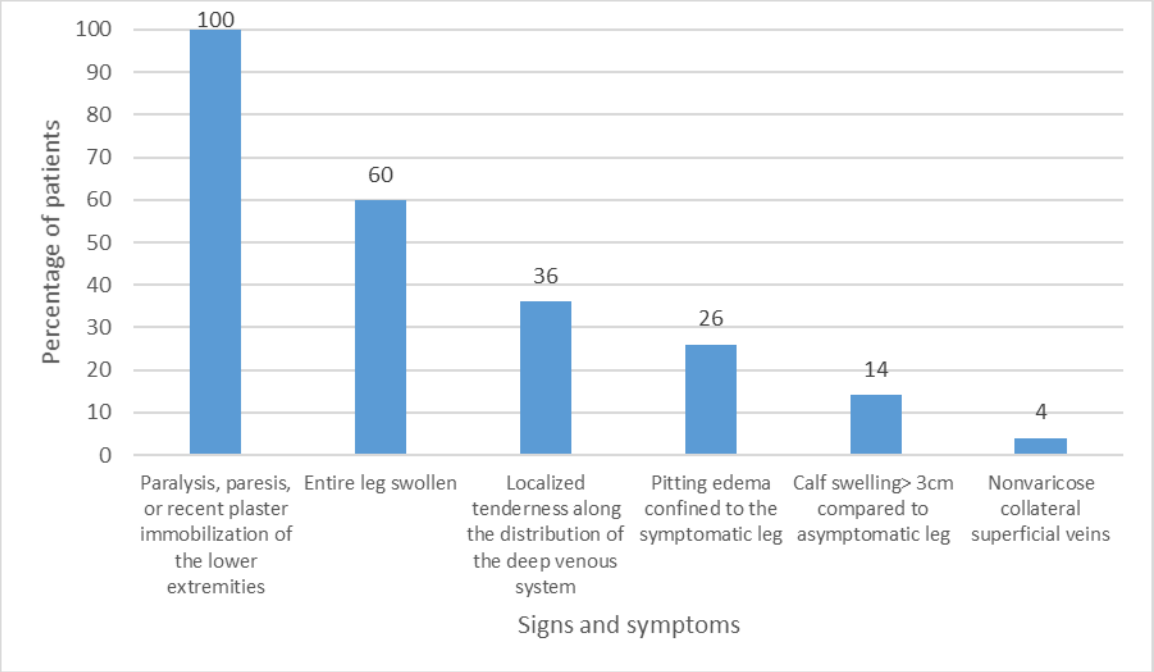

FIGURE 3: SIGNS AND SYMPTOMS OF DVT IN PATIENTS WITH FEMUR FRACTURE

There were 2 (4%) patients in whom an alternative diagnosis of was at least as likely as DVT. These patients were identified as having artherosclerosis. Of the risk factors for DVT contained in the modified Well's score 50 (100%) patients had recently been bedridden for 3 days or more.

Figure 4 shows that 37 (74%) of the adult patients with femur fracture had a high pre-test probability of DVT.

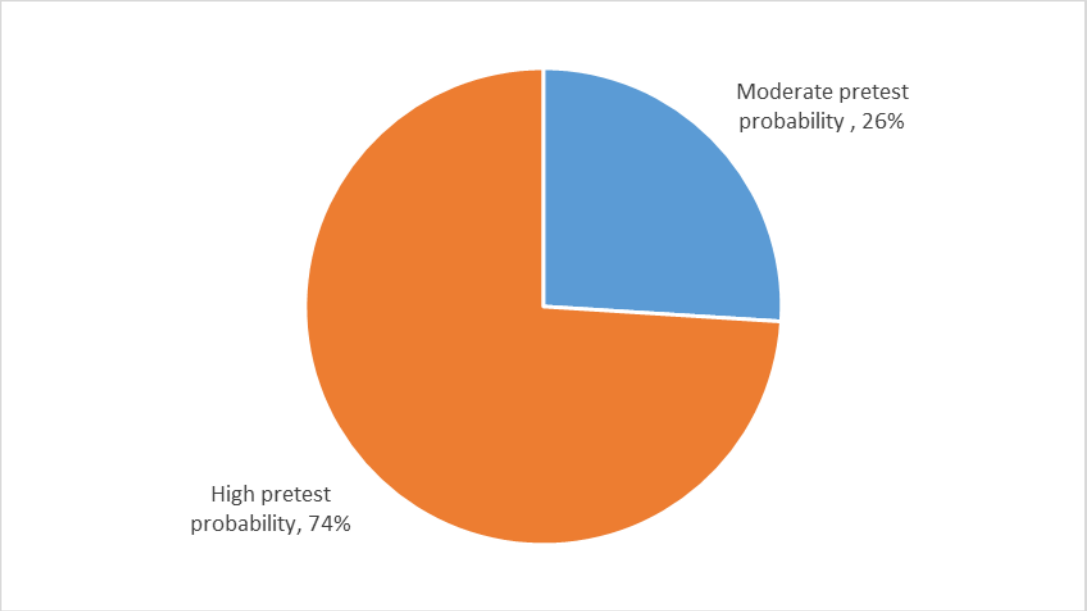

FIGURE 4: MODIFIED WELL SCORE IN FEMUR FRACTURE PATIENTS IN KNH

All the four patients with DVT had a high pretest probability based on the modified Well's score while none of the 13 patients with a moderate Well's score developed DVT (Figure 5).

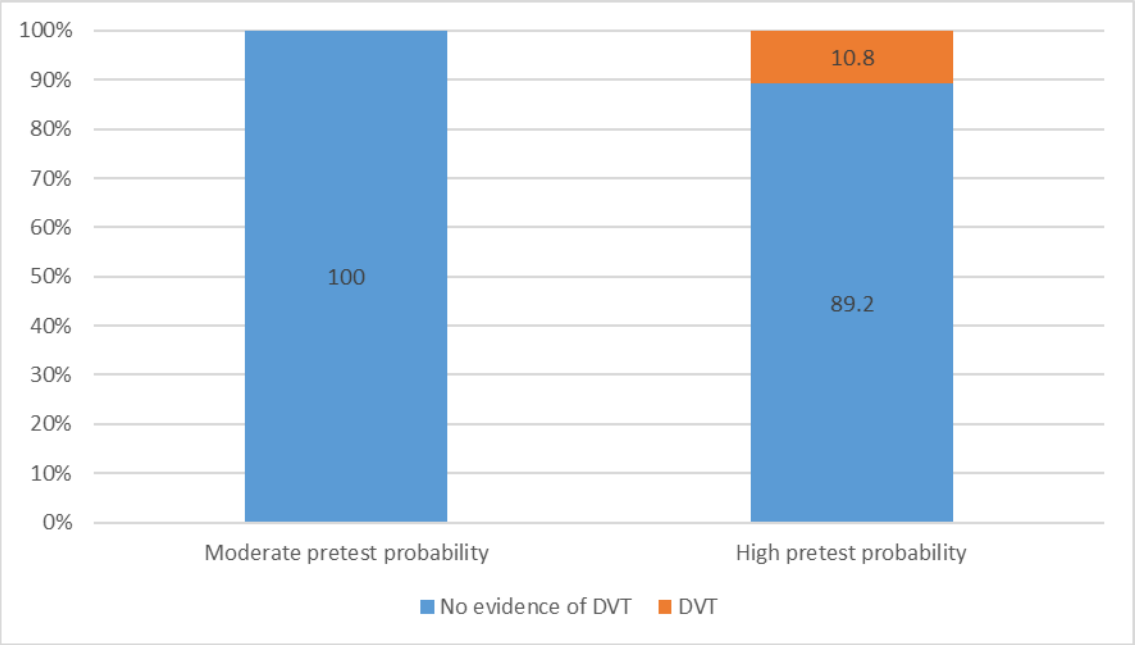

FIGURE 5: MODIFIED WELL'S SCORE AND DVT OCCURRENCE IN PATIENTS WITH FEMUR FRACTURE

8.5 INDIVIDUAL PATIENT RISK FACTORS FOR DVT

There was a significant association between patient age and DVT (p = 0.016). Although the number of patients aged above 60 was low, the prevalence of DVT in patients aged 60 years and above was 50% compared to 11.1% in 30-39 year olds (Table 4). The prevalence of DVT in male (8.8%) and female (6.3%) patients was not significantly different (p = 0.754).

TABLE 4: RISK FACTORS FOR DVT IN PATIENTS WITH FEMUR FRACTURE IN KNH

		DVT		
		Yes	**No**	**P value**
Age	18-29 years	0(0.0)	15(100.0)	0.016
	30-39 years	2(11.1)	16(88.9)	
	40-49 years	0(0.0)	10(100.0)	
	50-59 years	0(0.0)	3(100.0)	
	60 years and above	2(50.0)	2(50.0)	
Sex	Male	3(8.8)	31(91.2)	0.754
	Female	1(6.3)	15(93.8)	

9.0 DISCUSSION

In the two month recruitment period, 50 patients were recruited into the study. From the study the mean age of the patients was 37 years (SD $\pm$ 14). Majority of the patients (66%) were aged between 18 to 39 years. Most of the patients sustained fractures to the shaft of the femur whereas 28% had proximal femur fractures and 16 % had distal femur fractures. The male to female ratio was 2:1.

The prevalence of DVT was 8% (95% CI, 2 to 19%) and the incidence of DVT was 1.1 per 100 person days. This was similar to previous study done by Smith et al who found an incidence of 11.9% in fractures of the femur[1]. Whereas the prevalence in the study was not high it was significant given the possible complications of DVT such as pulmonary embolism.

The use of prophylaxis against DVT amongst the patients recruited into the study was low with only 6 (12 %) of the patients receiving prophylaxis. This was similar to the findings of Ballu et al[9] who found that the use of prophylaxis was low with none of the patients in his study receiving prophylaxis for DVT. The use of prophylaxis might also be low because there have been few studies on the incidence of DVT in Kenyatta National Hospital. In this study it was found that age was a significant factor with patients who were above the age of 60 years predisposed to DVT. This is similar to previous studies that have shown that the relative risk for DVT increases with every increase in a decade of life[83]. Patients with proximal fractures were also found to have a higher incidence of DVT. Therefore the use of prophylaxis should be considered.

During the course of the study only one method of prophylaxis was observed. The method used was chemical prophylaxis. The other methods such as mechanical prophylaxis, the use

of inferior vena cava filters and so forth were not used during the study. This is possibly because the other means of prophylaxis that can be used such as intermittent pneumatic compression are not readily available at KNH.

During the study there were no cases of occult DVT discovered. The patients who were found to be suffering from DVT were found to have symptoms of DVT. The patients with DVT had a high pretest probability. However amongst the patients who had a high pretest probability only 10.8 % had DVT. The majority of patients who had a high pretest probability (89.2%) did not have DVT on ultrasound. Therefore in this study the modified Well's score had a poor positive predictive value for patients with DVT.

Individual risk factors were assessed and age was found to be a significant risk factor to developing DVT ($p=0.016$). The prevalence of DVT in patients aged 60 and above was 50%. This is similar to findings in previous studies done on DVT. There was no significant difference found in the prevalence of DVT in male (8.8%) and female (6.3%) patients ($p = 0.754$).

Fractures of the proximal femur were associated with a higher rate of DVT. Twenty-one percent of the proximal fractures were associated with DVT as compared to 3.6% of the fractures to the shaft of the femur.

10. CONCLUSIONS

Patients with fractures to the femur are at a risk of DVT. Though the prevalence may be low at 8%, the possibility of serious life threatening complications may warrant the use of DVT prophylaxis.

11. RECOMMENDATIONS

From this study the incidence of DVT was noted to be 1.1 per 100 person days of observation. The prevalence was 8% amongst the study population. Given the possibility of life threatening complications of DVT such as pulmonary embolism the use of thromboprophylaxis should be considered.

During the study it was noted that prophylaxis use was low at 12%. This might be due to the fact that there have been no previous studies on the incidence of DVT in femur fractures. It was also noted that only one method of prophylaxis (chemical prophylaxis) was employed. This may be due to the fact that other methods have not been readily availed at KNH. The hospital could look into the provision of varied methods of prophylaxis such as mechanical prophylaxis. A study on the efficacy of prophylaxis in our population should also be done in order to assess the efficacy of each different method.

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APPENDIX 1

CONSENT INFORMATION FORM

Study number …….

My name is Dr. Antony Kamau Murage, a master's of orthopedic surgery student at the University of Nairobi, Department of orthopedic surgery. I am carrying out a study on the incidence of early deep vein thrombosis in fractures of the femur. Deep vein thrombosis is a medical condition in which blood clots form in the veins of the body in an inappropriate manner. This study will involve selected patients seen at A & E department and admitted in the orthopedic surgical wards at Kenyatta National Hospital. This study has been approved by the Kenyatta National Hospital /University of Nairobi Ethics and research committee. The aim of this study is to determine the occurrence of deep vein thrombosis following fractures of the femur. The findings of this study will help to create a better understanding of the risk of suffering from DVT in fracture femur and thus how best to prevent them.

Your participation in this study is on a voluntary basis. It is not a must that you participate in this study and your decision will not affect the treatment you receive in the hospital.

R**isks and benefits**

There are no risks foreseen in this study as it will only look at the clinical features of the illness. The study will benefit you as a patient by checking for DVT as a complication of your fracture.

This study will also benefit by helping doctors in future to make early decisions on prevention of deep vein thrombosis

All the information that is collected will be treated with confidentiality. Your identity will not be published whatsoever. The results obtained from the study will always be in my possession and no other parties will be allowed to see the individual information.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

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

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

I agree to participate in this research study: Yes No

Name of patient----------

Signature ----------

Thumb stamp _____Date----------

Researcher's statement

I have fully explained the relevant details of this research study to the participant named above and believe the participant has understood and has willingly given his consent

Name of researcher----------

Signature of researcher ----------

Date----------

Contacts for clarification:

If during the course of this you have any questions concerning this research you should contact **DR. ANTONY KAMAU MURAGE** at **UNIVERSITY OF NAIROBI, DEPARTMENT OF ORTHOPEDICS. Mobile 0720325254,** PO Box 57522 – 00200 NAIROBI

KIBALI CHA RUHUSA

Kichwa cha utafiti Kuganda kwa damu katika miguu kufuatia kuvunjika kwa miguu

Mtafiti mkuu\ na uhusiano wa kitaasisi Dr Antony Kamau Murage, musajili katika masomo ya upasuaji ya mifupa, Chuo kikuu cha Nairobi.

Sababu ya utafiti Huu utafiti una lengo la kusaidia kuelewa kama wagonjwa huugua ugonjwa wa kuganda damu katika mishipa ya miguu baada ya kuvunjika mifupa ya mguu. Utafiti huu utasaidia madaktari kuelewa kutibu huu ugonjwa vizuri.

Hatari na manufaa

Hakuna hatari ameazimia kwa sababu huu utafiti ni kuangalia makala ya kliniki ya ugonjwa na matibabu hakuna itakuwamo jakwa moja aliweka. Hakutakuwa na gharama za ziada zilizotumika wakati kushiriki katika utafiti.

Uhusika Kwa hiari

Kuhusika kwa utafiti huu ni kwa hiari yako mwenyewe na hauwezi kushurutishwa. Utahudumiwa hata kama ukikataa kuhusika kwa huu utafiti. Una uhuru kutamatisha kuhusika wakati wowote bila madhara yoyote ile.

Usiri

Taarifa zote yatashughulikiwa kwa siri. Utambulisho wako hautachapishwa popote. Matokeo yakupatikana kutoka utafiti itakuwa daima katika milki yangu na hakuna mtumwingine ataruhusiwa kuona matokeo ya mtu binafsi.

KIBALI CHA RUHUSA

Kauli mshiriki

Ninathibitisha yakuwa nimesoma fomu hii ya idhini au nimesomewa taarifa hii. Nimekuwa na nafasi ya kujadili utafiti huu na mtafiti. Nimefahamu yale nimeelezwa na mtafiti na maswali yangu yamejibiwa kwa lugha ninayoelewa. Ninaelewa kwamba ushiriki wangu katika utafiti huu ni wa hiari yangu na ninaweza kuchagua kujiondoa wakati wowote. Mimi nimeelewa na nimekubali kwa hiari yangu mwenyewe kuhusika katika utafiti huu. Ninaelewa juhudi zote zitafanywa kuweka habari kuhusu utambulisho wangu binafsi za siri.

Mimi nakubali kushiriki katika utafiti huu : **Ndiyo** **La**

Sahihi/KidolechaGumba (Mhusika/piliyajamaa) **Tarehe**

Sahihi/ Kidole cha daktari

Mshiriki kuchapishwa jina :

Mshiriki saini :

Alama ya kidole

Mawasiliano kwa ajili ya ufafanuzi:

Dkt ANTONY KAMAU MURAGE. **Chuo Kikuu cha Nairobi** Nambari ya simu 072032524

Appendix 2: Data collection sheet

Patient details and biodata

Patient Research no		
AGE		
SEX		
DATE OF ADMISSION		
DIAGNOSIS/FRACTURE CLASSIFICATION		
Time since fracture of the femur		

Use of prophylaxis

Is there any prophylaxis given (Yes/No)	
Kindly indicate the type of prophylaxis	
Date prophylaxis was started	

Date of ultrasound	
Is there any thrombus on US (Y/N)	
IF YES GIVE THE LOCATION	

Modified Well's score

Active cancer (treatment ongoing or within previous six months, or palliative treatment)	1
Paralysis, paresis, or recent plaster immobilization of the lower extremities	1
Recently bedridden for 3 days or more, or major surgery within the previous 12 weeks requiring general or regional anesthesia	1
Localized tenderness along the distribution of the deep venous system	1
Entire leg swollen	1
Calf swelling> 3cm compared to asymptomatic leg (measuring 10 cm below the tibial tuberosity)	1
Pitting edema confined to the symptomatic leg	1
Non-varicose collateral superficial veins	1
Previously documented DVT	1
Alternative diagnosis at least likely as DVT	-2
</=0 LOW pretest probability; 1 or 2, Moderate pretest probability; >3 HIGH pretest probability	