A PROSPECTIVE STUDY TO DETERMINE THE PREVALENCE OF DEEP VEIN THROMBOSIS IN PATIENTS WITH PELVIC, FEMORAL AND TIBIA/FIBULAR FRACTURES AT THE UNIVERSITY TEACHING HOSPITAL IN LUSAKA.

BY

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DECLARATION

I Faith Tiza Chibeza declare that the work presented in this study for the Degree in Master of Medicine in Orthopaedic Surgery represents my own work and that all the sources that I have quoted have been indicated and acknowledged by means of complete references. I further declare that this dissertation has not been submitted previously for a Diploma, Degree or any qualification in this University or any other University.

Signature of Candidate……

Date……

Signature of Supervisor……..

Date……

CERTIFICATE OF APPROVAL

This dissertation by Faith Tiza Chibeza has been approved as partial fulfilment of the requirements for the award of Degree in Master of Medicine in Orthopaedic Surgery by the University of Zambia.

Examiner's Signature……Date……

Examiner's Signature……Date……

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ABSTRACT

1. Introduction

Deep vein thrombosis (DVT) is a known occurrence in patients who have suffered trauma, especially severe trauma. The complication of DVT that makes it a great concern in trauma and orthopaedics is the fact that it occurs in an occult manner only to manifest as a fatal complication in the form of pulmonary embolism (PE).

The PE may occur in a seemingly stable injured patient who suddenly changes condition with the prominent sign being difficulty in breathing. This can easily be misdiagnosed as pneumonia and the patient may die shortly after being symptomatic with the PE.

This study set out to find out the prevalence of DVT in patients admitted with pelvic and lower limb fractures at the University Teaching Hospital. The study furthur sought to find out if there was an association between the occurrence of DVT and the severity of the injury as well as an association between the risks identified and the occurrence of DVT.

2. Materials and Methods

Patients with pelvic and lower limb fractures had a doppler ultrasound on both their lower limbs was done in the between the 3rd and 13th day and then repeated about the 29th day on average. When a patient was found to have DVT, they were managed using Enoxaparin injection (Clexane).

Patient data was collected on a standardised data collecting sheet and the fracture was classified using the Association for the Study of Internal Fixation. The risk factors were identified and noted and the doppler results were recorded.

3. Results

DVT was found at a prevalence of 10.8% (8 subjects) were sample size was 74. Using Fisher's exact test, no association was made between the severity of injury and the occurrence of DVT (χ^2=2.133; df=4; p=0.701). The Fisher exact test also showed that no association was made between the risk factors identified and the occurrence of DVT (χ^2=1.877; df=2; p=0.559). The risk factors identified in this study were orthopaedic trauma, bed rest, old age, obesity and tumour.

4. Conclusion

The prevalence of DVT was found to be 10.8% where the sample size was 74. The study also ascertained that there was no relationship between the development of DVT and the severity of the trauma suffered. The identified risk factors for developing DVT did not show any relationship to the development of DVT in this group.

5. Recommendation

The study recommended that each ward where trauma patients are being managed should be fitted with a portable doppler ultrasound machine for easy patient monitoring of DVT development. The second recommendation was to make available the drugs needed for DVT treatment as they are not readily available in the hospital.

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Last but not least I would like to acknowledge the God of my Lord Jesus Christ who has seen me through this entire study period for my Master's Degree.

DEDICATION

I would like to dedicate this dissertation to my husband Stephen Mpundu Mwansa for all the understanding and encouragement. Thank you for taking my absence from our home very well. It shall be over soon.

I also dedicate it to my daughter Katongo Natasha Mwansa, grow up child.

This is also for my mother, Jane Malama Chibeza, my one and only sister Salome Beza Chikwanda and my baby brother Besa Kamopo.

TABLE OF CONTENTS **PAGE**

CHAPTER ONE

CHAPTER TWO

CHAPTER 3

3. RESEARCH METHODOLOGY

CHAPTER 4

4. PRESENTATION OF FINDINGS AND DATA ANALYSIS

CHAPTER 5

5. DISCUSSION

CHAPTER 6

CHAPTER 7

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

AO	Arbeitsgemeinschaft für Osteosynthesefragen
ASIF	Association for the Study of Internal Fixation
CVA	Cardiovascular Accident
DVT	Deep Vein Thrombosis
MI	Myocardial Infarction
PE	Pulmonary Embolism
SPSS	Statistical Package for Social Sciences
THR	Total Hip Replacement
TKR	Total knee replacement
UTH	University Teaching Hospital
VTE	Venous Thromboembolism

CHAPTER ONE

1.0 INTRODUCTION

1.1 BACKGROUND

Thrombosis is the formation of a solid mass called thrombus from the constituents of blood within the vascular system during life (Kumar & Clark 2002). When thrombosis occurs in the deep veins of the lower limb and pelvis, it is referred to as Deep Vein Thrombosis (DVT), (Kumar & Clark 2002). It is commonest in the veins of the calf in the lower limb (Mayo Clinic 2012). It has varied risk factors or predisposing factors which include prolonged bed rest in cases of hospitalization or illness, cancer, pregnancy, inherited clotting disorders, injury or trauma to the pelvis, hip and lower limbs, heart failure, obesity and smoking (Kumar & Clark 2002).

The pathophysiology of DVT was first described by Virchow in 1846 as coming from a triad of possible changes in the venous system. The triad includes changes in the vessel wall(vascular injury), changes in the pattern of blood flow(venous stasis) and changes in the constituency of blood. These physiological changes can occur as a result of pathology, therapies and treatments. Injury to the vessel wall may occur from orthopaedic trauma, surgery or invasive treatments. Patients on bed rest have venous stasis which changes blood flow through the venous system and patients on new medications may have changes in blood flow. (McCaffrey R., Blum C. 2009) The triad of changes that occurs makes it very favourable for the development of DVT.

A piece of thrombus called embolus can break off and move through the vascular system and this is known as embolism. The embolus can end up in the brain, heart, lungs or any part of the body and cause severe ischaemic injury tissue or organ damage and death. This phenomenon is a known complication of DVT (Isselbacher et al. 1994).

DVT can either have clinical manifestations or be occult. When it has clinical manifestations, there is painful swelling of the affected limb. This is usually quickly and easily detected (Kumar & Clark 2002). However, when it is occult and embolism occurs, it is not very easy to diagnose and can only be seen as a fatal lung complication which is known as Pulmonary Embolism (PE). PE is a common, frequently undiagnosed and potentially fatal result of DVT. 90% of deaths due to pulmonary embolism occur within an hour or two, before a diagnostic-therapeutic plan can be implemented (Isselbacher et al. 1994).

The diagnosis of DVT can be done in several ways one of which is by clinical evaluation of the patient. The major presentation is pain in the calf with swelling and engorgement of the superficial veins. However, thrombosis in the iliofemoral veins can be silent and it is commonest source of emboli in PE. Therefore, the only manifestation of DVT would be PE which is often fatal.

The other methods of diagnosis which are radiological include venograghy which is a gold standard, ultrasonography, computerized tomography and magnetic resonance imaging.

In the laboratory, fibrin degradation products which include soluble fibrin and D-dimers can also be analysed. The easiest, bedside method that can be used in the diagnosis of DVT is the measurement of fibrin degradation products. One of the fibrin degradation products that can be used are D-dimers. They are small protein fragments present in the blood after a blood clot is degraded by fibrinolysis. They can be measured using D-dimer ELISA test. D-dimers are sensitive markers for thrombotic diseases and are elevated in DVT/PE, disseminated intravascular coagulation and acute myocardial infarction (Wada & Sakuragawa 2008).

At the University Teaching Hospital diagnosis can be made using clinical assessment that is confirmed with Doppler ultrasound. Computerized tomography and magnetic resonance imaging are available but are prohibitive in cost. Venography on the other hand is quite invasive.

In Orthopaedics and Trauma, DVT is a great concern as patients are predisposed to it by virtue of the injuries they sustain which result in immobilization. As our country develops and the middle class enlarges the burden of trauma will continue to increase. In 2000, the World Health Organisation (WHO) reported that injuries that result in fractures accounted for 12% of the world's burden of disease (Peden, Mcgee & Sharma 2002). At UTH in 2011, patients with spinal, pelvic and lower limb fractures accounted for 10% of all the admissions done in the department of surgery at casualty (UTH Register, 2011). A survey taken in G22 ward in the surgical department of UTH in November of 2012 revealed that 40% of the admitted patients awaiting surgery were orthopaedics and trauma patients

(UTH Register, 2012).

In this prospective study, orthopaedic trauma patients with pelvic and lower limb fractures were investigated for DVT using serial Doppler ultrasound.

1.2 STATEMENT OF THE PROBLEM

Orthopaedic trauma patients are seen at UTH on a daily basis. These patients are predisposed to DVT by the virtue of the trauma that they suffer. The risk for DVT is increased by the fact that they end up being immobilized, have a long hospital stay due to theatre logistical challenges and DVT prophylaxis is not routinely given as it is not readily available due to high cost leaving them at the fatal risk of PE. Mechanical prophylaxis,

mainly physiotherapy is available and cheaper but can only be started when the patient has a little less pain from the trauma suffered. This may take days to a week which still gives DVT a chance for the high risk patients.

PE is not a very common occurrence, it gives no warning, is not easily diagnosed and is fatal almost all the time.

1.3 JUSTIFICATION OF STUDY

DVT is a known occurrence in patients with spinal, pelvic and lower limb fractures as will be illustrated in the literature review. The DVT that occurs is occult in majority of the patients seen and might only manifest as a fatal complication of DVT in the form of PE, CVA

or MI. At UTH the incidence of DVT, let alone its complications such as PE has not been documented.

1.4 RESEARCH OBJECTIVES

1.4.1 General Objective

To study the occurrence of DVT in patients with spinal, pelvic and lower limb fractures.

1.4.2 Specific Objectives

1. To determine the prevalence of DVT in patients with spinal, pelvic, femur and tibia/fibular fractures at UTH.

2. To establish any association between the occurrence of DVT and severity of injury using the AO Classification of Fractures (Arbeitsgemeinschaft für Osteosynthesefragen) or the Association of the Study of Internal Fixation (ASIF).

3. To identify any other risk factors apart from trauma that are associated with the development of DVT in these patients.

RESEARCH QUESTION

What is the prevalence of DVT in orthopaedic trauma patients at UTH that do not get thromboprophylaxis?

1.5 HYPOTHESIS

The prevalence of DVT at UTH in orthopaedic trauma patient is less than 30%.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 INTRODUCTION

Literature is generally readily available from the western countries as they have done more research compared to our part of the world. The other regions are Asia and Japan, hence the bulk of the literature is from there.

2.2 GLOBAL PERSPECTIVE

A prospective study of DVT after major trauma was done in England in 1994 (Geerts et al. 1994). Serial impedance plethysmography and lower-extremity contrast venography to detect deep-vein thrombosis in a cohort of 716 patients admitted to a regional trauma unit was done. Prophylaxis against thromboembolism was not used.

Of all these patients DVT in the lower extremities was found in 201 of the 349 patients (58%) and proximal-vein thrombosis was found in 63 (18%). Three patients died of massive pulmonary embolism before venography could be performed. DVT is usually occult and in this group before any venography was done only three of the patients with deep-vein thrombosis had clinical features suggestive of the condition. This is what makes DVT a condition to be weary of in patients with trauma.

In the above study, breakdown of the type of injuries showed DVT in 41 of the 66 patients with spinal injuries (62%) and 126 of the 182 with lower-extremity orthopaedic injuries

(69%). Thrombi were detected in 61 of the 100 patients with pelvic fractures (61 %), in 59 of the 74 with femoral fractures (80%), and in 66 of the 86 with tibial fractures (77%). A multivariate analysis identified five independent risks which included spinal injuries and lower limb fractures. The authors concluded that DVT is a common complication in patient with major trauma and that effective and safe prophylaxis is needed.

This study showed that patients with spinal, pelvic and lower limb injuries are at risk of developing DVT (58%) especially if prophylaxis is not used and can be a basis for looking for DVT in similar patients in our environment.

Another study by Spain et al (1997) quoted an incidence of between 50%-80%.

At Metro Health Medical Centre, Case Western Reserve University, Cleveland, USA, a study was done in 1996 to warrant the usefulness of DVT surveillance in high risk trauma patients (Joseph & et al 1996). 343 patients identified as high risk based on established criteria (prolonged bed rest, Glasgow coma score (GCS) of 7, spinal injury, lower extremity or pelvic fracture). They were placed on a prospective surveillance protocol using colour-flow duplex scanning and received thromboembolic prophylaxis. This study reported that twenty-three thromboembolic complications occurred, including 20 DVTs (5.8%) and 3 pulmonary emboli (1 %). The data was further analyzed and showed that the risk of DVT was related to advanced age which was that of 52.6 years and above, a longer hospital stay of 31.4 days compared to an average of 17.8 days as well as the presence of spinal fracture which was 12.6% of all the DVTs that occurred. Of all the twenty DVTs that occurred 17 (85%) of them were unsuspected clinically. In the above study it was shown that the

occurrence of DVT was reduced in the presence of thromboembolic prophylaxis. However DVT still occurred, 85% of it unsuspected and still pointing to spinal fractures as a risk factor.

An Indian prospective study was performed in 2006 on 147 patients undergoing major orthopaedic surgery for total knee replacement (TKR), total hip replacement (THR) and proximal femur fracture fixation without any prophylaxis. These patients were profiled for presence of the known risk factors responsible for development of Venous Thromboembolism (VTE). A duplex ultrasound on both lower limbs was done 6 to 10 days after surgery. A total of 147 patients were enrolled. These patients were assessed clinically for any signs of DVT and PE. A helical CT scan was done in case of suspicion of PE and a duplex ultrasound was done in case of clinical suspicion of DVT irrespective of the stage of study.

The overall incidence of VTE was 6.12% and that of PE was 0.6%. This is much lower than the statistics in the West. The researchers in this study concluded that this result added evidence to this belief that DVT has a lower incidence in Indian patients as compared with other ethnic groups (Bagaria et al. 2006).

In 2005 there was an earthquake in Pakistan and people sustained varied injuries. Of all of them 187 patients with spinal cord injury were investigated for DVT and this assessment went on for 10 weeks post injury. Duplex ultrasound was done on the lower limbs and of all these patients only 17 had clinical signs of DVT. Ultrasound was positive only in nine (4.8%) of all the patients. This was the reason why this study was also said to add evidence

that the incidence of DVT is lower in trauma patients in Southeast Asia (Rathore 2008).The two studies mentioned above were specifically done to show that the Incidence of DVT in Southeast Asia is low compared to the western world and this is attributed mainly to ethnicity. In Zambia the one study that was done in 1978 showed an incidence of 33% and it is cited below.

2.3 REGIONAL PERSPECTIVE

In Nigeria, a Review of early diagnosis of posttraumatic DVT was done (Omeonu 2003) and it reported that the incidence of DVT was still as high as 80%. He concluded that despite the high interest shown in the study of this pathology, the great strides made in the past in our understanding of the natural history, prophylaxis and treatment of the disease, its early diagnoses remains a difficult clinical problem in our setting. He reported that there is need for early diagnosis of deep vein thrombosis to reduce morbidity and mortality from post phlebitic syndrome and pulmonary embolism.

2.4 LOCAL PERSPECTIVE

In Zambia a study was done in 1978 which was titled diagnosis of venous thrombosis using

125 I-fibrinogen**.** Fibrinogen labeled with 125 iodine was used as an epidemiological tool to study deep vein thrombosis (DVT) in Lusaka, Zambia. Twenty highly selected patients were studied and data was complete in 18. No prophylaxis was used for these patients. Six (33%) of the 18 had positive results for DVT and none had clinical evidence of DVT and pulmonary embolism (Wosomu, Dlamini & Mikolaijkov 1978).

CHAPTER 3

3.0 RESEARCH METHODOLOGY

3.1 STUDY DESIGN

This was a prospective cohort study involving patients with pelvic, femur and tibia/fibular fractures. On recruitment, the social demographic variables were collected using a questionnaire and their fractures were classified using the Association of the Study of Internal Fixation (ASIF)(16).

The patients who were recruited were then followed up with serial Doppler Ultrasound to check for any development of DVT. This was done in the first thirteen days and then repeated between the twenty first and thirty third day as patient logistics would allow. In total, patients were followed up for an average of 4 weeks. The patients that were found to have DVT were given started on Enoxaparin as all these patients had proximal DVT. This was given for the rest of their admission in hospital which was more than 3 weeks. Upon discharge they continued on enoxaparin to make a total of 2 months as out patients at their local clinic. Both pre and post operation patients in the initial 2 weeks of injury were included in the study. The in patients actually undergo routine physiotherapy whilst in admission.

Aside from following up for DVT, the participants also had a full blood count (FBC) done and it gave insight on the blood parameters especially the platelet level.

3.2 RESEARCH SETTING AND STUDY POPULATION

The participants recruited in the study were identified from the female and male surgical admission wards at University Teaching Hospital. This is the highest referral government health institution in Zambia where a diverse number of specialties are found. In the department of surgery there is a bed capacity of 371. There are 5 general surgical wards and 2 orthopaedic (Adults and Children) wards from where the participating patients were admitted.

3.3 SAMPLE SELECTION

The participants that fit the inclusion criteria were identified from the male and female admission wards as well as the general surgical admission wards and the orthopaedic wards. The study purpose and general information were presented to the would be participants and they were recruited when they fully understood the research and consent to participate in the study was obtained.

INCLUSION CRITERIA

Patients admitted to UTH that fit the following criteria

- Age of 16 and above
- Either sex
- Presence of fracture of the pelvis, hip, femur, tibia/fibular
- Patients with fractures that are less 2weeks old
- Assent and guardian permission

EXCLUSION CRITERIA

- Patients who are 15 years and below as they are considered minors
- Patients who also had head injury – needed a lot more staff to take to radiology and Ward staffing was not adequate
- Patients that declined to give participate
- Patients that did not give consent
- Tibial fractures patients that had their limbs immobilized in Plaster of Paris

3.4 SAMPLE SIZE

The sample size calculator on Open Epi gave 133 as the sample size. It was also calculated as shown below.

Sample size was calculated using the formula below

$$N = \frac{Z^2 \times P(1-P)}{E^2}$$

N = Sample required

Z = Z statistic for a given level of confidence = 1.282 when using a 80% CI

P = being 0.3 as 30% is the expected percentage

E = confidence interval, usually 0.05= this refers to the accuracy range (+/- 5%)

This gave 138 which was then standardised for a finite population of 3 707 which was the total number of patients admitted over a 6month period in the surgical admission ward.

New N = N / 1 + (N-1/3 707)

=133

3.5 DATA COLLECTION TOOL

The tool that was used to collect data in this research was a structured proforma that allowed us to collect the patient's particulars, cause of injury, severity of injury, risk factors and other information that was necessary for the research.

3.6 ETHICAL CONSIDERATIONS

The purpose of the study as well as all the procedures that were used in the study were fully explained to the participant. The benefits and complications that would have arisen were also made known to them. The researcher endeavoured to explain to the participant that their participation is purely voluntary and that there is no monetary gain.

They were free to decline and also to withdraw from the study at any given time without any repercussion on the type and quality of health care that they would receive during their hospital stay. Signed consent was then sort from the participants.

Approval was also sought from the University of Zambia Biomedical Research Ethics Committee and it was granted hence the research took place.

The patients that were found with DVT were treated with Enoxaparin for a total of 2 - 3 months as in patients as well as out-patient (local clinic).

CHAPTER 4

DATA PRESENTATION AND ANALYSIS

4.1 INTRODUCTION

Data was collected on to a structured form that started with personal data and then the data concerning the fracture that the client sustained. Lastly the form had the part that had information on the occurrence of DVT as the Doppler was done (Appendix 1). The data was then standardised and entered into Microsoft excel. From Excel it was transferred to the Statistical Package for Social Sciences (SPSS) version 20. The data was then analysed so as to interpret the results and make necessary conclusions. Aside from the general percentages, correlations were done between the occurrence of DVT and the variables for DVT risk and severity of injury. The values were too small for Chi square test hence the Fischer's Exact test was used.

Characteristics of the Participants

A total of seventy-four patients, admitted at UTH from 6th December 2013 to 6th July 2014, were recruited for this study. These were patients who had the injuries of interest to the study in the said period. Table 1 below presents the demographic characteristics of the patients. Twenty-six (35.1%) were females while 48 (64.9%) were males. The minimum age of the patients was 16 years while the maximum age was 85, with an average of 43.19 (SD=19.472). Fifteen (20.3%) were aged 16-25 years, 19 (25.7%) were aged 26-35 years,

12 (16.2%) were aged 36-45 years, 7 (9.5%) were aged 46-55 years, and 21 (28.4%) were aged 56 years and above.

Table 1: Characteristics of the participants (n = 74)

Variable	Values	Frequency (n=74)	Percent
Gender	Female	26	35.1
	Male	48	64.9
Age	16-25 years	15	20.3
	26-35 years	19	25.7
	36-45 years	12	16.2
	46-55 years	7	9.5
	56 years and above	21	28.4

Causes of Injury

The cause of injuries suffered by the patients are shown in Table 2 below. The table shows that 51.4% of the injuries suffered by the patients were caused by road traffic accidents, 45.9% were caused by a fall, and one percent each accounted for assault and intraoperative pathological injury, respectively. Road traffic accidents took the largest portion of the cause of injury.

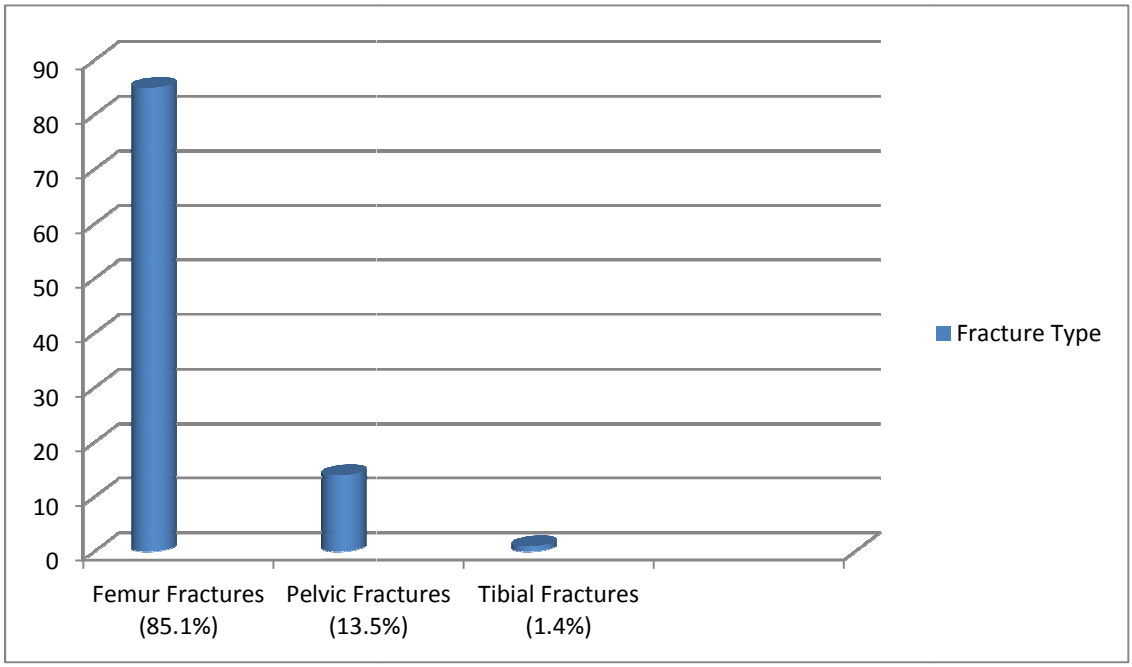
Table 2: Causes of injury (n = 74)

Cause of Injury	Frequency	Percent
Road Traffic Accident	38	51.4
Fall	34	45.9
Assaulted	1	1.4
Intraoperative Pathological Fracture	1	1.4
Total	74	100.0

Types of Fractures

Table 3 shows that 85.1% of the fractures were femoral, 13.5% were pelvic, and 1.9% were tibia fractures.

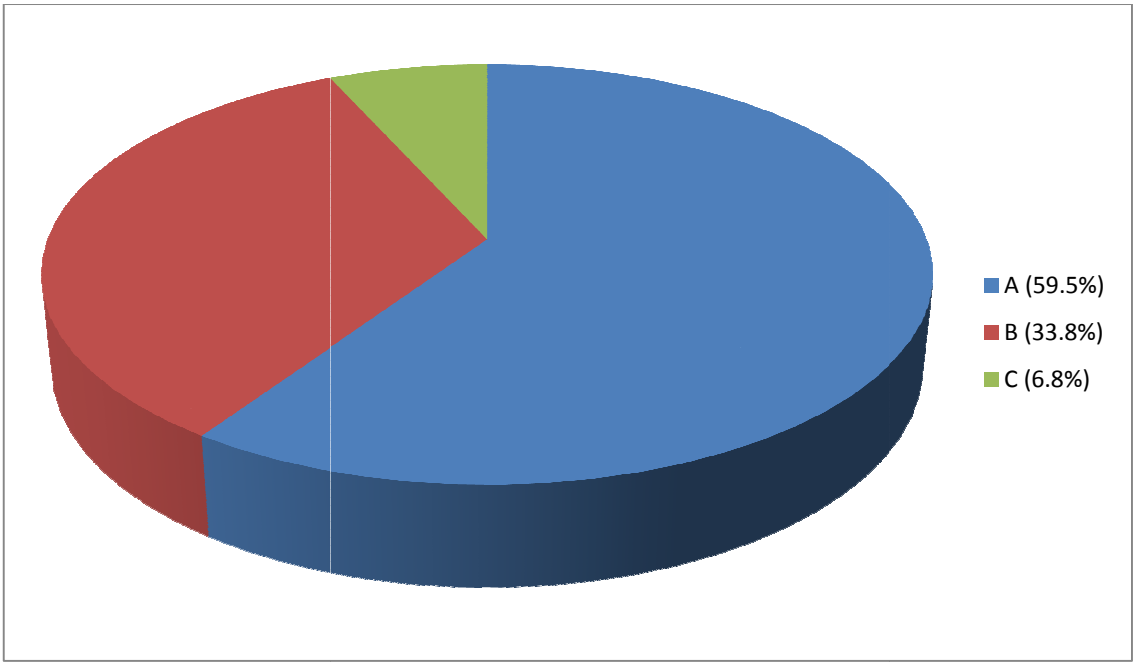
Figure 1: Different types of fractures that the patient sustained (n=74)



AO Classification, Severity of injury

Table 4 shows fracture severity where A is simple, B is moderate and C is severe in injury. Most (59.5%) were simple fractures and some (33.8%) were of moderate severity whilst the very small percentage (6.8%) were severe injuries.

Fig 2: Severity of the injuries (n=74)



Risk Factors or Predisposing factors to developing DVT

The table below shows the different types of risk factors that were identified among the patients.

Table 3: Risk factors in the development of DVT (n=74)

	Frequency	Percent
Immobilization, Trauma	50	67.6
Immobilization, Trauma, Old age	19	25.7
Immobilization, Trauma, Obesity	1	1.4
Immobilization, Trauma, Old age, Obesity	1	1.4
Immobilization, Trauma, Old age, Tumour	1	1.4
Immobilization, Trauma, Tumour	1	1.4
Immobilization, Trauma, Tumour, Old age	1	1.4
Total	74	100.0

Full blood count results

Each patient had a full blood count done to check for any abnormalities in the blood picture that might contribute to the occurrence of DVT. The University Teaching Laboratory reference ranges that were used are attached in Appendix 5. Any value outside of the ranges was considered either low or high.

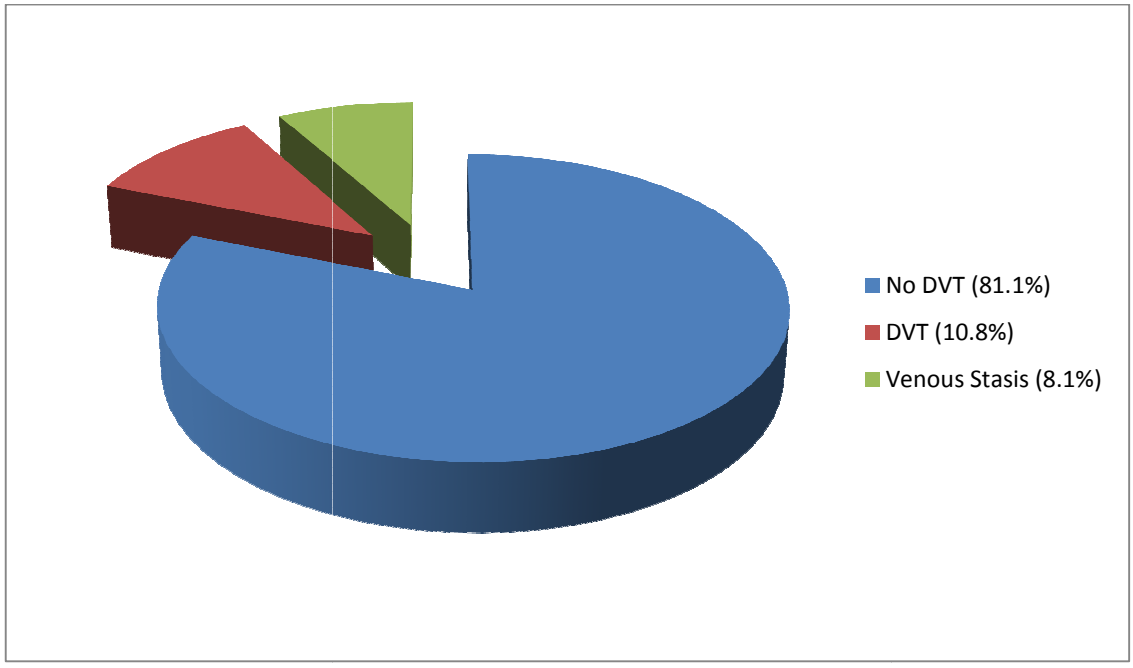
Table 4: Full blood count results (n=74)

Blood Result	Frequency	Percent
Normal Parameters	68	91.1
Low Hb	3	4.1
Raised Platelets	2	2.7
Low Hb, Raised Platelets	1	1.4
Total	74	100.0

DVT Results in the first 13 days of the study (Doppler1)

Figure shows the number of people that developed DVT and venous stasis in the first 13 days after the injury. Sixty(81.1%) of the patients did not develop DVT, 8(10.8%) had DVT whilst 6(8.1%) had venous stasis.

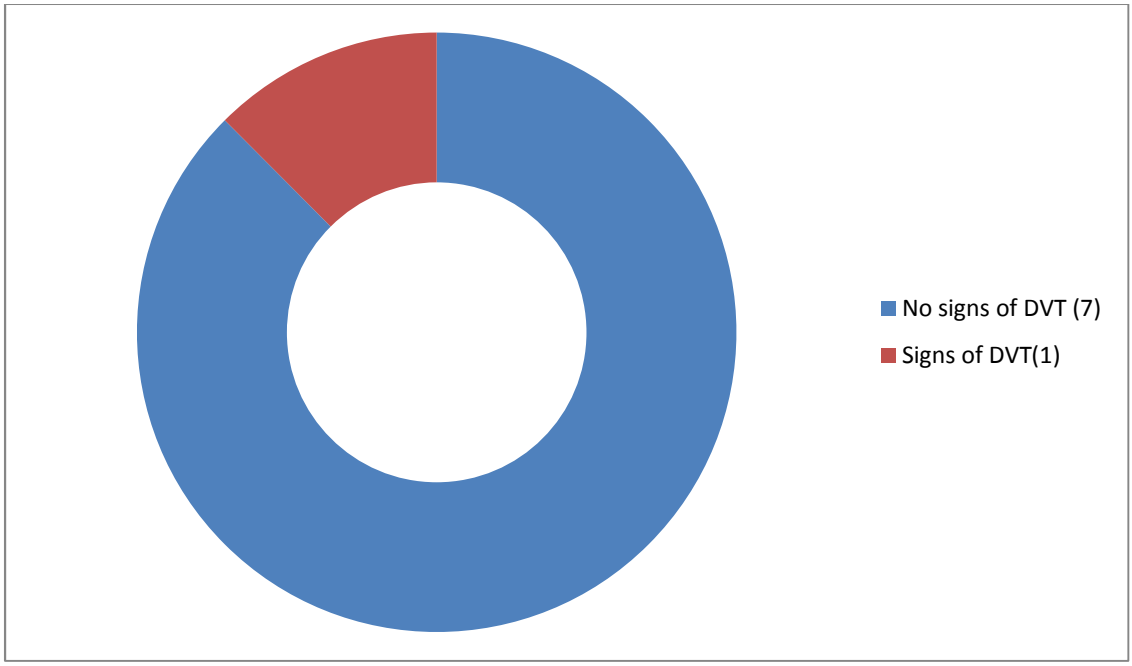
Figure 3: Results of the presence of DVT for the first Doppler (n=74)



Signs of DVT

Figure 4 below shows the number of people who showed any signs of DVT. Of the 74 patients recruited, DVT developed in 8(10.1%) people and DVT signs showed only in one of them.

Figure 4: The number of patients that developed signs of DVT (n=8)



Veins involved in DVT

Table 5 shows the veins involved in those that had DVT. The external iliac, common femoral, femoral and popliteal veins were involved in DVT.

Table 5: The veins involved in DVT and Venous Stasis (n=8)

Vein Involved	Frequency
External Iliac, Common femoral, Femoral, Popliteal,	2
Common Femoral, Femoral, Popliteal	1
Common Femoral, Femoral	1
Popliteal	4
Total	**8**

Correlation tests

These were carried out to verify if there was a correlation between occurrence of DVT and the severity of the fracture as well as between DVT occurrence and the risk factors that were identified. Both tests used Fisher's Exact test as the values were too small to use Chi Square

Further analysis was conducted to establish whether there was an association between severity of injury and the occurrence of DVT. Fishers' Exact Test was conducted at alpha=0.5 (Tables 6 and 7 below). The results indicated that there was no association between severity of injury and the occurrence of DVT (χ^2=2.133; df=4; p=0.701).

Table 6: Association between the occurrence of DVT and the severity of the injury (n = 74)

			Doppler Result			Total
			No DVT	DVT	Venous Stasis	
AO classification (Severity)	A	Count	35	4	5	44
		Expected Count	35.7	4.8	3.6	44.0
	B	Count	21	3	1	25
		Expected Count	20.3	2.7	2.0	25.0
	C	Count	4	1	0	5
		Expected Count	4.1	0.5	0.4	5.0
Total		Count	60	8	6	74
		Expected Count	60.0	8.0	6.0	74.0

Table 7: Fishers' Exact Test Results, DVT and Severity (n = 74)

	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	2.084[a]	4	.720	.728		
Likelihood Ratio	2.472	4	.650	.805		
Fisher's Exact Test	2.133			.701		
Linear-by-Linear Association	.584[b]	1	.445	.541	.283	.100
N of Valid Cases	74					

a. 7 cells (77.8%) have expected count less than 5. The minimum expected count is .41.
b. The standardized statistic is -.764.

Analysis was conducted to establish whether there was an association between risk factors and the occurrence of DVT. Fishers' Exact Test was conducted at alpha=0.5 (Tables 8 and 9 below). The results indicated that there was no association between risk factors and the occurrence of DVT (χ^2=1.877; df=2; p=0.559).

Table 8: Association between the occurrence of DVT and the risk factors (n = 74) .

			Doppler 1			Total
			No DVT	DVT	Venous Stasis	
Predisposing factors	Immobilization and trauma	Count	42	3	5	50
		Expected Count	41.3	4.3	4.3	50.0
	Immobilization, trauma and old age	Count	15	3	1	19
		Expected Count	15.7	1.7	1.7	19.0
Total		Count	57	6	6	69
		Expected Count	57.0	6.0	6.0	69.0

Table 9: Fishers' Exact Test, DVT and Risk Factors (n = 74)

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	1.915[a]	2	.384	.459		
Likelihood Ratio	1.789	2	.409	.459		
Fisher's Exact Test	1.877			.559		
Linear-by-Linear Association	.000[b]	1	.985	1.000	.562	.171
N of Valid Cases	69					

a. 4 cells (66.7%) have expected count less than 5. The minimum expected count is 1.65.
b. The standardized statistic is .019.

The table below shows the results for the second doppler. Only one patient in this group showed DVT among those that didn't have in the first doppler test. It is worth noting that 15 of the patients did not have a chance to repeat the doppler as they were not available

Table 10: Results of the presence of DVT about 30 days after injury (n = 74)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	no DVT	58	78.4	98.3	98.3
	DVT	1	1.4	1.7	100.0
	Total	59	79.7	100.0	
Missing	Not repeated	15	20.3		
Total		74	100.0		

The minimum number of days for Doppler 1 was 3 days, the maximum number of days was 13, and the average number of days 9.12. The minimum number of days for Doppler 2 was 21 days; the maximum number of days was 33, and the average number of days 27.47.

Table 11: Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Number of days for Doppler 1	74	3	13	9.12	2.881
Number of days for Doppler 2	57	21	33	27.47	2.619

CHAPTER 5

5.0 DISSCUSSION

5.1 CHARACTERISTICS OF THE PATIENTS

In the results the characteristics are shown in table 1 and the sample size was 74. Of all the patients 48(64.9%) of them were male whilst 26(35.1%) were female. This result is expected as males are more likely to be injured than females as their lifestyle and jobs predispose them to trauma. A study done at different hospitals in Brazil showed that the largest number of orthopaedic trauma patients were males (Souza C. et al, 2014). Interestingly the largest age group was the elderly group of above 56 years which had 21(28.4%) subjects. This was followed by 26-36years which had 19(25.7%) patients and the 16-25age group which had 15(20.3%) patients. There were 12(16.2%) for the 36-45 age group and 7(9.5%) for the 46-55 age group. The elderly are more prone to injuries like fractures as they tend to fall easily. At this age, strength is reduced and balancing is not as accurate as the young. 19 of the 21 patients above 55 sustained their injuries from falls. The more active younger age group followed as is expected. However the economically active age groups put together are than the elderly.

5.2 CAUSES OF INJURIES/FRACTURES

Road traffic accidents were the main cause of fractures at 38(51.4%) followed by falls at

34(45.9%) with assault and intraoperative pathological fracture taking 1(1.4%) each. The large number of vehicles on our roads that were not built to carry so much traffic is a danger on the roads. Human proportion of human error has increased as the number of vehicles has increased. All these factors may explain why Road Traffic Accidents (RTA) were the largest cause of injury. The number of RTAs is actually on an increase as reported by Zambia Police in the Road Traffic Section. The records show that there were 29 118 RTAs in 2013 which was an increase of 6.2% from the 2012 figure of 28 247(Independent Observer Reporter, 2014).

Falls were also a cause of injury in this study. What this study did not document was whether the falls were associated with intake of alcohol in the young and fit individuals (12 out of 34) not struggling with strength and balance as compared to the elderly.

RTAs and falls were the main causes (97%) of fractures. One person (1.5%) was assaulted and then another (1.5%) had a pathological fracture secondary to a tumour.

5.3 TYPES OF INJURIES

In this study group there were 63(85.1%) femur fractures, which was the majority, 10(13.5%) with pelvic fractures and 1(1.4%) person with bilateral tibial fractures. This is not to say that tibial fractures are rare at UTH, they are almost as many as femur fractures. The tibial fractures are immobilized in Plaster of Paris (POP) which covers the limb where the Doppler needs to be done. Including tibial fractures would have meant removing the

POP immobilizing the fractures with the possibility of losing the fracture alignment and re-application of the POP in theatre which was not feasible. Therefore in this study pelvic fractures are even more than tibial fractures because of the reason mentioned above. Lower limb fractures may be common as they have long bones, hence big surface area and are appendage in nature. The multicentre study done in Brazil (Souza C. et al, 2014) showed that lower limb orthopaedic trauma was the most (52.3%) common reason for surgery.

5.4 SEVERITY OF INJURIES USING THE AO CLASSIFICATION

The severity of the injuries was assessed using the AO classification of fractures. Type A fractures are of mild severity, type B are moderate whilst type C are severe injuries. This classification is based on the fracture pattern on radiology. In this research the majority 44(59.5%) of the people recruited had type A injuries, 25(33.8%) had type B injuries and 5(6.8%) had type C injuries. Findings in literature review that spinal, pelvic and lower limb fractures are independent risk factors for the development of DVT especially if the injuries are said to be severe (Geerts et al.1994). The more the severe these injuries are, the more likely one is to develop DVT. This study has however not shown significant association between the severity of the injury and the development of DVT.

5.5 RISK FACTORS

There were some risk factors that were identified in this cohort. These include the trauma

suffered, bed rest, old age, obesity and the presence of cancer. Bed rest and trauma was common to all. Therefore bed rest and trauma put together were the highest in risk at 50(67.6%) and when old age was added to bed rest and trauma, this combination became the next highest risk factor at 19(25.7%). This shows that the older patients, that is those that are above 55years old who have suffered trauma and are bedridden have a high risk of developing DVT. Though the elderly show high risk of developing DVT in this study, they were not the most affected in the cohort. Of those affected with DVT, half were the elderly whilst the other half were the younger patients. It could be that trauma and being bedridden has the same effect in the young and in the old in this cohort.

Tumour and obesity when added to bedridden and trauma each had a frequency of 1 and did not contribute much to risk factors. All the above factors are well known risk factors for the development of DVT.

Other risk factors like a pre-existing clotting disorder and medication were all ruled out from history using the data collection tool. In addition a clotting profile would have been very useful but it was not done as the cost was prohibitive.

A Full blood count was done and 3(4.1%) had abnormal blood results that included low haemoglobin(HB) level and raised platelets and one of them significantly (648 to the power 6). In this cohort studied the participants that developed DVT did not any abnormal blood results which entails that the DVT was not of a haematological origin. In trauma a low HB is as a result of blood loss. The patients with severe injuries are more likely to have low HB level and more interventions in post trauma care. A condition of high platelets is known as

thrombocytosis and post traumatic thrombocytosis is a known phenomenon. It increases the risk of complications in recovery period but it is also associated to the reduced risk of death (Hadjizachzria S.A. et al). None of these risks were seen in the patients that participated in this research.

5.6 PREVALENCE OF DVT AND THE CORRELATIONS TO SEVERITY OF INJURY AND RISK FACTORS

Of all the 74 patients enrolled for this study 8(10.8%) patients developed DVT in the first 13 days post trauma. 4 were female and the other 4 were male, only 3 were above the age of 55, one was 55 and the rest were all below 30 years of age. Of the 8 that developed DVT only one patient had signs of DVT. The rest of the patients had occult DVT which may only manifest as fatal PE which results in death in less than 2 hours if diagnosis is not made and resuscitative measures are not put in place (Isselbacher et al. 1994).

The 10.8% prevalence found in this study is much lower than the 30% that was found in a similar study at UTH (Wosomu, Dlamini & Mikolaijkov 1978). Both were done with no thromboprophylaxis. This difference in prevalence in the two studies is that the later was a blood based with no radiological evidence in which a lot of inference may have been done reducing specificity and increasing positive results whilst the later was radiological increasing specificity. Other than that the earlier research had a much smaller sample size of 30 (current study had 74) such that a figure in the results represents a large percentage.

The prevalence of DVT was found and to establish if there was a relationship between the

severity of injuries and the risk factors identified with the DVT occurrence, correlation tests were carried out. For both parameters, Fisher's Exact test was used as the values were too small to use Chi Square.

Fishers' Exact Test was conducted at alpha=0.5 (Tables 6 and 7 above). The results indicated that there was no association between severity of injury and the occurrence of DVT (χ^2=2.133; df=4; p=0.701).

The other Fishers' Exact Test was conducted at alpha=0.5 (Tables 8 and 9 above). The results indicated that there was no association between risk factors and the occurrence of DVT (χ^2=1.877; df=2; p=0.559).

These correlation results are similar to the results in southeastern Asia (Rathmore et al 2009) where DVT has low prevalence as well as absence of any association to risk factors of severity of injury.

They are however different from literature and studies done (literature review) on DVT in trauma patients in the western world. They report that there is an association between the severity of injury and DVT in that it will most likely occur. Risk factors like old age are also known and established in the occurrence of DVT.

5.7 FOLLOWUP DOPPLER ULTRASOUND

The patients also had to have a second Doppler at around the 30the day. 53 of the patients managed to have the Doppler done whilst the rest did not manage to have it done as they were either discharged or lost to follow up.

The first Doppler was done between the 3rd and 13th day whilst the second was done between the 21st and the 33rd day with an average of 9 and 27days respectively.

CHAPTER 6

6.0 CONCLUSION

1. The study set out to find the prevalence of DVT among patients with pelvic and lower limb fractures admitted to the surgical wards at UTH. This prevalence was found to be 10.8% where the sample size was 74.

2. The study also wanted to ascertain if there was a relationship between the development of DVT and the severity of the trauma suffered. The correlation studies done did not show that those who suffered severe trauma developed DVT.

3. The study wanted to identify risk factors for developing DVT the risk factors identified and the development of DVT. The correlation tests did not show any particular risk factor related to development of DVT in this group.

The documented facts and literature that say that the development of DVT is associated with the severity of trauma and presence of known risk factors remains unchallenged by this study. It is our view that a follow up study is needed to find out why the results in this study differ with the findings in literature reviews.

6.1 LIMITATIONS OF THE STUDY

The study was limited in terms of sample size. The calculated sample size was 133 but the total sample size used after 8 months of data collection was 74. A bigger sample size always adds validity to the study.

The other limitation was the fact that the spinal fracture patients could not be easily added to the study due to the logistics of movement from the ward to the radiology department.

Patients that had tibia fractures immobilized in POP were also not added as they may have required another session in theatre so that the fracture is immobilized again. This would have been time consuming and needed extra hands at a cost.

Lack of finances for clotting profile investigations was also a limiting factor.

CHAPTER 7

7.0 RECOMMENDATIONS

This study will make the following recommendation

1. Surgical wards with trauma patients should have a portable Doppler ultrasound to detect DVT in all the trauma patients.
2. All trauma patients should be subjected to doppler scanning because there is no relationship between known risk factors and the development of DVT.
3. Enoxaparin (low molecular weight synthetic heparin) should be made available in government hospitals for the treatment of DVT in patients who cannot afford to buy it from the private pharmacies.

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APPENDIX 1

DATA COLLECTION SHEET
(To be filled in by the Interviewer)

Patient Serial Number _____ Date of Admission _____/_____/_____

1. Age _____
2. Sex M F
3. Date of Injury_____/_____/_____
4. Cause of Injury

   RTA

   Fall

   Human Inflicted Violence

   Workplace Accident/Industrial Accident

   Object Falling on Individual

   Pathological

   Other (specify)_____
5. Type Of Injury/Fracture

   Spinal fracture/dislocation

   Pelvic fracture

   Hip Fracture

   Femoral fracture

   Tibial fractures
6. AO Classification of the fracture

7. Predisposing Disposing Factors

   Age

   Obesity

   Drugs

   Family History

   Pregnancy

   Malignancy

8. Full blood Count Results

   Abnormal Parameter _____

   _____

   _____

9. Serial Doppler Ultrasound (Circle One)

Week 1 Positive Negative

Name of Vein Involved_____

Week 4 Positive Negative

Name of Vein Involved_____

11. Date of Operation

12. Signs

   Leg Pain_____Swelling_____

   Warm Skin _____Visible Surface Veins_____

APPENDIX 2

BUDGET

(a)	Tests	
	Full blood count…….. ……. ……. ……. …….	K 1, 330.00
	Doppler Ultrasound payment….. ……. …….	K 6, 000.00
(b)	Stationary	
	Paper….. ……. ……. ……. ……. ……. …….	K 60.00
	Pens……. ……. ……. ……. ……. ……. …….	K 70.00
	Folders... ……. ……. ……. ……. ……. …….	K 50.00
	Printing and Binding….. ……. ……. ……. …….	K 300.00
(c)	Personnel	
	Research Assistants.. ……. ……. ……. …….	K 2, 000.00
(d)	Fees	
	Research and Ethics Committee Fee…... …….	K 500.00
(e)	Contingency…. ……. ……. ……. ……. …….	K 1, 000.00
	GRAND TOTAL …….. ……. ……. ……. …….	**K11, 310.00**

APPENDIX 3

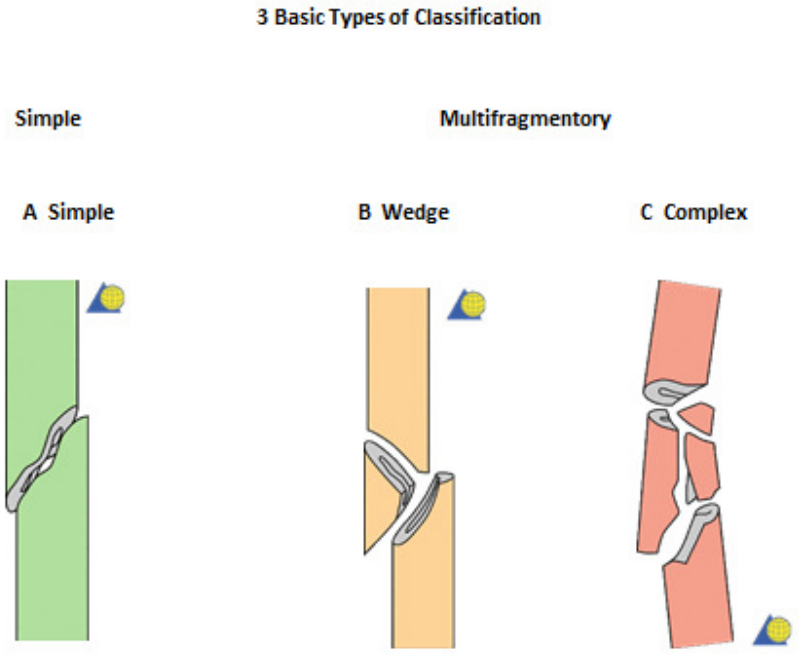
Time in Months

	0	1	2	3	4	5	6	7	8	9	10	11
Activity	May 2013	June 2013	July 2013	Aug 2013	Sept 2013	Oct 2013	Nov 2013	Dec 2013	Jan 2013	Feb 2013	Mar 2013	Apr 2013
Graduate Forum Presention												
UNZABREC												
UNZABREC Corrections												
Data Collection												
Data Analysis												
Report Writing												

APPENDIX 4

AO CLASSIFICATION OF FRACTURES

This classification is for the severity of the fracture.



APPENDIX 5

UNIVERSITY TEACHING HOSPITAL LABORATORY REFERENCE VALUES

Parameter Investigated	Reference Range
White Cell Count	4.00 – 10.00 *10^9/L
Red Cell Count	4.89 – 6.11 *10^12/L
Haemoglobin	14.3 – 18.3g/dl
Platelet Count	137 – 373 * 10^9/L

APPENDIX 6

PATIENT INFORMATION SHEET

INTRODUCTION

My name is Dr. Faith Chibeza, a postgraduate student for a Master's Degree in Orthopaedic Surgery at the University of Zambia.

PURPOSE OF STUDY

Am conducting this study to find out how significant formation of blood clot in the blood vessels is following the breaking of bones of the back, pelvis, hip, thigh and legs.

STUDY PROCEDURES

You are being invited to join the study because you have had a fracture of one of the bones listed above. If you agree to participate in the study, you will be examined and 6mls of blood will be drawn from you for a full blood count and an HIV test. You will then be asked some questions using a standardised questionnaire. Thereafter you will be followed up for serial doppler ultra sound.

CONFIDENTIALITY

Any information concerning you will be kept well out of reach of other people except the research assistants. Your identity will also be coded.

RISKS

There are no obvious risks from the enrollment into the study. The enrollment and any investigation that will be carried out on you will not harm your health in any way or put you at risk of any condition. If anything they will be of great help to your health. Some questions may remind you of the events leading to the trauma you sustained. Should such a thing happen your interview will be delayed until such a time when you are in a state to answer the questions. The drawing of blood may cause some discomfort from the needle prick.

BENEFITS

We will be able to determine the possible presence of blood clots in the veins of your legs and measures to prevent them from migrating will be taken promptly and prevent any complication.

VOLUNTARY PARTICIPATION

Enrollment into the study is entirely voluntary and your refusal to do so will not jeopardize the quality of care you will receive as a patient in this hospital.

RIGHT TO WITHDRAW

Know from the outset that you are free to withdraw from the study at any time that you feel uncomfortable. It is your right and it will not affect the health care that you will receive from us.

PROVISION FOR STANDARD OF CARE

The standard of care will in no way be influenced by the kind of treatment that one will receive whether they are enrolled or not enrolled in this research.

COMPENSATION

You will not receive any payment for participating in this study.

CONTACT DETAILS

Should you have any questions concerning this study you can contact:

Dr. Faith Chibeza
University Teaching Hospital
Department of Surgery
P. Bag RW 1X
Lusaka,
Zambia
Cell No. +260 977 518952

And if you want to find out more about your rights as a study participant, you may contact

The Chairperson
University of Zamia Biomedical Research Ethics Committee
Ridgeway Campus
P.O. Box 50110
Lusaka
Zambia
Tel 0211 256067

APPENDIX 7

CONSENT TO PARTICIPATE IN RESEARCH

STUDY TITLE: A Study to Determine the Incidence of Deep Vein Thrombosis in Patients with Spinal, Pelvic, Femoral and Tibia/Fibular Fractures at the University Teaching Hospital In Lusaka: A Prospective Cohort 2013

I have been asked to participate in the above research and give my consent willingly and freely after reading the patient information sheet.
I understand that:

1. If I do not volunteer or if I withdraw after volunteering, my decision will be accepted and not negatively affect the service I will receive from this institution.
2. I have read and understood the information given to me or read to me and I fully understand all and am satisfied.
3. Any information that I will divulge will be treated confidentially and my identity will be hidden.

_____ _____

Patient Signature or Thumb Print Signature of Researcher

_____ _____

Date Date

In case of any questions, please contact me Dr. Faith Chibeza at the University Teaching Hospital in the Department of Surgery.

APPENDIX 7

MBIRI YA WODWALA

CHIYAMBI

Dzina langa ndine Dr. Faith Chibeza, ndichita maphunziro yapamwamba ya Orthopaedic surgery pa sikulu lalikulu la University of Zambia

CHIFUKWA CHAKE CHA KAFUKUFUKU

Ndichita kafuku-fuku kufuna kupeza mwazi ungati womwe ugwirana mumizipe pambuyo mafupa ya mumsana, chiuno ndi mendo atyoka.

NJIRA YA KAFUKU-FUKU

Mufunsidwa kutengako mbali ku kafuku-fuku aka chifukwa limodzi ya mafupayanu monga yachulidwa poyamba ndi yotyoka. Ngati mwabvomera kutengako mbali, muzapimidwa ndipo mwazi wanu wokwanira 6mls uzatengedwa ndikupimidwa ngati muli ndi HIV. Muzafunsidwanso mafunso pambuyo pake.

ZOCHITISA MANTHA

Kulibe chinthu chochitisa mantha pakutengako mbali ngakhale mafunso ena yakhoza kukukumbusani zinthu zakale zomwe zikhoza kukupasani chisoni. Ngati zotelezi zachitika, wofunsa mafunso azalekeza kufukira pomwe mwakhazikika kuti muyambeso kuyankha mafunso. Ndiponso, nsingano potenga mwazi ikhozanso kuwawa.

ZOPHINDULA

Tizakhoza kuziwa ngati muli ndi mwazi wogwirana mu mafupa yatyoka ndipo tizakhoza kuchinjiliza bvuto ili yonse.
KUZIPEREKA

Kutengako mbali kwanu sikwachikakamizo, ndipo ngati simufuna kutengako mbali, muzalandirabe thandizo monga wodwala ali yense muchipatala chino.

MALIPIRO

Simuzalandira malipiro pakutengako mbali.

CONTACT DETAILS

Ngati muli ndi mafunso yokhuza kafuku-fuku aka, funsani:

Dr. Faith Chibeza
University Teaching Hospital
Department of Surgery
P.Bag RW 1X
Lusaka,
Zambia
Cell: +260 977 518952

Ndiponso ngati mufuna kudziwa zambiri zokhuza ufulu wanu pakutengako mbali ku kafuku-fuku aka, funsani:

The Chairperson
University of Zambia Biomedical Research Ethics Committee
Ridgeway Campus
P.O. Box 50110
Lusaka
Zambia
Tel 0211 256067

CHILOLEZO CHOTENGAKO MBALI

MUTU WAKE: Maphunziro yofuna kudziwa zochitika mu mizipe ya wodwala msana, chiuno, mafupa yosiyana-siyana ya mendo pa chipatala cha University Teaching Hospital, mumzinda wa Lusaka: A Prospective Cohort 2013

Ndafunsidwa kutengako mbali ku kafuku-fuku ka maphuziro ya kugwirana kwa mwazi mu mafupa yotyoka ndipo ndabvomera mopanga kukakamizidwa pambuyo powerenga uthenga okhuza wadwala mafupa.

Ndazindikira kuti:

1. Ngati sindifuna kutengako mbali kapena ngati ndasintha maganizo yanga ndikuleka kutengako mbali, sindizapeza bvuto ili yonse polandira thandizo kuno ku chipatala.
2. Ndawerenga ndikumvetsesa wonse ndapasidwa kapena kuwerengeredwa ndipo ndakhutira nazo zoikika.
3. Uthenga uli wonse ndizapereka uzasungidwa machisinsi ndipo dzina langa siiza chulidwa konse.

_____	_____
Wodwala	Wofunsa mafunso
_____	_____
Tsiku	Tsiku

Ngati muli ndi mafunso ena, chonde funsani Dr. Faith Chibeza opezeka pa chipatala cha University Teaching Hospital ku Department of Surgery

APPENDIX 8

VERBAL ASSENT SCRIPT

Study Title: A Study to Determine the Incidence of Deep Vein Thrombosis in Patients with Spinal, Pelvic, Femoral and Tibia/Fibular Fractures at the University Teaching Hospital In Lusaka: A Prospective Cohort 2013

Principle Investigator: Dr. F. Chibeza
Principle Supervisor: Dr. J. Munthali
Co-Supervisor: Prof Y. Mulla

I am a doctor working at the University Teaching Hospital and I would like to learn more about Deep Vein Thrombosis in patient that have had trauma.

When you consent agree to participate in this study, we will document your particulars, describe your surgical condition as well as note the kind of treatment received. We will do serial Doppler ultrasound to check for the presence of Deep Vein Thrombosis as well as do the blood tests. We will endeavour to keep your identity confidential. Every participant will be number coded, names will not be used.

If for any reason, personal or not you decide to withdraw from this study, please be rest assured that it will not in any way affect the kind of service that you will receive from this institution.