ASSESSMENT OF VENOUS THROMBOEMBOLISM RISK AND PROHYLAXIS PRACTICES AMONG ELECTIVE SURGICAL PATIENTS AT KENYATTA NATIONAL HOSPITAL

A DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN GENERAL SURGERY OF THE UNIVERSITY OF NAIROBI

DR MWANGI PATRICK MUCHUNU MBChB (U.O.N)

Department of General Surgery

University of Nairobi

February 2018

DECLARATION

I declare that this dissertation is my own original work and has not been presented for a degree in any other University

Dr. Mwangi Patrick Muchunu

H58/68509/2011

MBChB (U.O.N).

Sign……..…… Date…….

SUPERVISORS' DECLARATION

This dissertation has been submitted with our approval as the University supervisors:

Dr.Dan Kipkemboi Kiptoon

MBChB (UON), MMed (UON)

Consultant General Surgeon and Lecturer,

Department of Surgery,

University of Nairobi

Sign……..…… Date…….

Dr Daniel Kinyuru Ojuka

MBCh.B (UON), MMED Gen. Surgery (UON), PHD (UON) FACS

Consultant Surgeon/ Senior Lecturer,

Department of Surgery,

University of Nairobi.

Sign……..…… Date…….

APPROVAL BY THE DEPARTMENT

This research proposal has been presented at the surgical departmental meeting and is hereby approved for presentation to the Kenyatta National Hospital/University of Nairobi Ethics and Research committee.

Sign……..…… Date…….

Prof Peter L. Ndaguatha

MBChB, MMed, F.C.S (ECSA) Fellow of Urology (U.K)

Associate Professor,

Chairman, Department of Surgery

School of Medicine, University of Nairobi

ACKNOWLEDGEMENT

First of all, I am grateful to my supervisors Dr. Daniel Kiptoon and Dr.Daniel Ojuka whose scholarly advice, help and constant encouragement have contributed significantly to the completion of this study.

I also wish to thank my colleagues, senior house officers in general surgery for their invaluable assistance, contribution and support to me during my study.

To my wife Jacqueline, my daughters, mum and siblings, thank you for supporting me along this journey.

I appreciate all the patients who voluntarily agreed to take part in this study.

DEDICATION

To my wife Jacqueline, my daughters Alice and Abby and my family for being my anchor, for your support, contribution, patience, your undying love and support along this journey;

Mum and Late Dad, for all your sacrifice to see me through school and grow into who I am;
My grandparent, uncles and aunts for always encouraging me to follow my dreams.

TABLE OF CONTENTS

LIST OF FIGURES AND TABLES

FIGURES

TABLES

ABBREVIATIONS

ACCP-	American College of Chest Physicians
DVT-	Deep venous thrombosis
KNH-	Kenyatta National Hospital
LMWH-	Low molecular-weight heparin
LDUH-	Low-dose unfractionated heparin
PE-	Pulmonary embolism
RAM-	Risk assessment models
UFH-	Unfractionated heparin
VTE-	Venous thromboembolism

ABSTRACT

Background

Venous thromboembolism (VTE) is a common and preventable complication of surgery. It's risk is determined by various factors with surgery being one of them. Thromboprophylaxis is effective and safe in surgical patients and should be used routinely used according to the available guidelines. There is scarcity of data on the distribution of risk factors and prophylaxis practices among non-orthopedic surgical patients at KNH.

Aim

The aim of the study was to assess the incidence of VTE risk in elective non orthopedic surgery patients using Caprini score and determine the proportion of the at-risk patients receiving VTE prophylaxis.

Design

Prospective descriptive study.

Materials and method

The study was carried out in surgical units in Kenyatta National Hospital (KNH) over a period of four months upon ethical approval. Elective non orthopedic surgical patients will be recruited into the study. Distribution of risk factors for VTE and coverage of prophylaxis in at-risk patients will be assessed using the Caprini VTE risk factor assessment tool.

Consecutive sampling in patients who met the inclusion criteria was used to enroll them into the study.

Data was collected in structured questionnaires and statistical analysis was performed using SPSS version 21. The statistical significant p-value of <0.05 was used.

Results

61.3% of all elective surgical patients were at risk of VTE. Among the at-risk only 26.3 % received VTE prophylaxis. Prophylaxis measures were implemented in only 52 of 323 elective patients studied. The only 2 patients with the highest VTE risk patients received prophylaxis but only 25.1% of high risk and 35.6% of moderate risk patients received prophylaxis.

Conclusion

Surgical patients undergoing elective surgeries are not well protected against VTE. Thromboprophylaxis are rarely prescribed and guidelines are not adhered to. There is need for improved VTE risk assessment and prophylaxis practices in surgery patients.

1.0 CHAPTER ONE: INTRODUCTION

Venous thromboembolism (VTE) is a collective term for both deep vein thrombosis (DVT) and pulmonary embolism (PE). Venous thrombi, composed of red blood cells, platelets and leukocytes bound together by fibrin, form when intimal injury of blood vessels occurs with release of certain chemical substances that promote clotting, i.e. antigens and venous stasis. Thrombi may remain in the peripheral veins, where they undergo endogenous fibrinolysis and recanalization or embolize to the pulmonary arteries and cause PE. For the development of thrombosis there has to be circulation stasis, endothelial damage and hyper-coagulation states. [1]

DVT is a major cause of morbidity and mortality worldwide, with an annual incidence of approximately 350,000 in the USA [2]. Occurrence of DVT during hospital stay is higher than in the general population; the incidence of this hospital-acquired DVT has been reported to account for about 50% of all cases of VTE. [3] This high incidence is due to the many risk factors that exist in patients admitted to hospitals. A third of patients undergoing an elective general surgical procedure develop VTE after surgical operation.[4] Approximately 10% of all in-hospital deaths are attributed to PE.[5]

Since surgery is an independent risk factor, postoperative patients are at a particularly high risk of developing DVT. Many of these patients have additional risk factors that may be the primary reason for the surgery like cancer or vascular disease as the reason for surgery.[6]

The clinically silent nature of the disease in the majority of patients, the morbidity and mortality as well as cost of care associated with VTE creates the need for thromboprophylaxis.[7, 8]

Since the first manifestation of the disease may be fatal PE, it is inappropriate to wait for symptoms and then rely on the diagnosis to treat established VTE. Those who have once suffered from DVT are at risk of getting it again thus it can be a chronic disease yet it is preventable. It is thought that at least 5-15% of hospitalized patients will develop VTE, making it the most common preventable cause of in-hospital death. [9, 10]

The study aimed at assessing the VTE risks and clinical practices among elective surgical patients in KNH with regards tothromboprophylaxis. This is as a result of unavailability of local data on VTE prevention in the region. Findings will help raise awareness on risk

assessment models that objectively categorize patients in risk categories preoperatively to help improve VTE prophylaxis practices in the country.

1.1 Literature Review

VTE is a global health concern with substantial morbidity and mortality[11]. It is often asymptomatic and under diagnosed, leading to long-term complications and reduced survival. Approximately 30 per cent of patients with symptomatic VTE manifest PE.[11] it is estimated that 75 per cent of all VTE-related deaths are from hospital-acquired VTE.[11] Evidence suggests that hospital-acquired VTEs can be prevented given the availability of effective prophylaxis. [12, 13]

An estimated 33% of patients undergoing an elective general surgical procedure will suffer some form of VTE as a postoperative complication.[5] Autopsies show that approximately 10% of all in-hospital deaths are attributed to PE.[6] A retrospective analysis in Nigeria found a prevalence of PE of 2.9%.[14]

In patients undergoing general surgery without prophylaxis, the rates of DVT and fatal PE range from 15% to 30% and from 0.2% to 0.9%, respectively.[15, 16] Early patient mobilization and improved perioperative care is thought to have contributed to lower incidences of VTE.[16]

PE frequently occurs in patients with symptomatic DVT. In the Indian subset data of the global Prospective Registry on Venous thromboembolic Events (PROVE) registry, proximal plus calf DVTs were found in 54 % of patients, proximal DVT in 17 %, and calf DVT in 13 %. This is comparable to the global PROVE population where both proximal and distal DVT was 52%, 18% for proximal, and 24 % for calf DVT.[12] VTE is common after general surgical operations. Morbidity and mortality from VTE is a significant post-operative problem.[17]

Data on the prevalence of VTE risk and prophylaxis in 32 countries according to ENDORSE[18] survey showed that 53% of hospitalized patients were at risk of VTE according to the 2004 ACCP guidelines [13] The variation in the prevalence of VTE risk between countries was huge (35.6—72.6%) and between types of wards (between 64% in surgical wards and 41% in medical wards).[18] The overall proportions of patients at risk of VTE who received adequate prophylaxis were low (58.5% in surgical patients and 39.5% in medical patients). [18]

Gikonyo demonstrated that the incidence of DVT stood at 0.16% between 1975 and 1979 in KNH with an overall mortality rate at 7%. The autopsy incidence of PE was 5.4%. This incidence rose from 3.8% in 1975 to 8% in 1978. Females (79.4%) were affected more than males. VTE occurred in all age groups with majority (63%) of DVT patients being younger than 40 years of age. 43% PE cases occurred in patients below 40 years. Long hospital stay was associated with higher incidence of PE at autopsy. Post treatment recurrence of DVT stood at 15%.[19]

Diagnosis of VTE is not easy due to low sensitivity and nonspecific signs and symptoms of both PE and DVT.[20] DVT is often silent and its worst consequence is often fatal.[6,21] Survival rates following PE are low, with less than 60% of patients surviving for more than a week after the acute event. Only less than 50% of these patients live for a year.[19] DVT causes long-term morbidity in the form of post-thrombosis syndrome (29%) and recurrent DVT (30%) within the next eight years after the initial event.[22]

VTE is a common complication after major surgeries.[15] Up to 5% of patients undergoing urologic surgical operation experience clinically apparent VTE. [23] Postoperative deaths are mainly due to PE and is estimated to occur in about 0.2% of surgical patients.[23, 24]

VTE prophylaxis is underutilized in orthopedic wards in KNH according to Lukuta. He observed a significant gap between evidence based thromboprophylaxis recommendations and actual clinical practice. VTE prophylaxis was only used in 17.7% of the patients during preoperative period and 37.7 % postoperatively. Only 41.8% of the participants received adequate prophylaxis [25].

Venography is regarded as the gold standard for diagnosis. However, recent studies demonstrate that Doppler ultrasound has very high sensitivity (up to 100%) and specificity (91.8%).[26] Doppler ultrasound is referred to as the current gold standard for diagnosis of DVT. [27, 28]. Screening protocols currently combine the Wells clinical scoring system with D-dimer assays to exclude DVT.[29]

VTE prophylaxis reduces the incidence of acute DVT by 66% and the mortality rate of PE by 50%.[27] These findings were confirmed by a consensus panel of the ACCP.[22] VTE prophylaxis is more effective in preventing death and more cost-effective than treating established disease.[27, 28] Despite the benefits, VTE prophylaxis is underutilized and

implementation of guidelines inconsistent and inadequate.[22, 28] Anderson et al.[21] demonstrated that VTE prophylaxis was prescribed to only a third of patients at high risk for VTE. Another study revealed that the implementation of VTE prophylaxis is as low as 35%.[21]

The ACCP guidelines are regarded as the standard of care in VTE prophylaxis.[18] VTE prophylaxis is generally poorly prescribed. The concept of VTE risk categories and the use of risk assessment models are not well implemented.[20] The Eighth American College of Chest Physicians Conference on Antithrombotic and Thrombolytic Therapy Guidelines help in the assessment of risk factors for VTE and recommend the appropriate use of prophylaxis to prevent VTE in patients at risk.[14] The guidelines recommend prophylaxis for patients at moderate to high risk of VTE, using either mechanical prophylaxis and or pharmacological prophylaxis. [14]

A number of evidence-based guidelines for assessment of VTE risk are recognized internationally. Assessment of VTE risk is done with Risk Assessment Model (RAM). ACCP guidelines are mainly used and aids in defining low, moderate, and high-risk patients based on the type of surgery, mobility status, and bleeding risk.[14] High-risk patients are those undergoing hip or knee surgeries, fracture surgeries, those with major trauma and patients at high risk of developing VTE and are at high risk of bleeding. These patients are estimated to have between 40-80% risks of developing VTE if no prophylaxis is provided.[14] Caprini's risk assessment model (RAM) [21] is founded on the ACCP guidelines. Caprini came up with a risk-scoring system in order to render the ACCP guidelines more user-friendly.

The practice guidelines provide recommendations for the continued management of patients with VTE, specifically addressing the risk stratification and appropriate use of low molecular weight heparins (LMWHs) in the prophylactic management of this condition.[30] Some studies have demonstrated that thromboprophylaxis reduces adverse outcomes along with reduction in overall costs.[13, 31]

Several risk assessment models that stratify patients according to their risk of VTE have been published, the most notable being those developed by Caprini, Cohen, Rogers and Kucher.[14, 32–35] These risk assessment models consist of a list of exposing risk factors (presenting illness or procedure) and predisposing risk factors, each with an assigned relative risk score.[14,34] The scores are summed up to produce a cumulative score, which is used to classify the patient risk levels and determine the onset, intensity, type, and duration of prophylaxis. These models have been criticized for being cumbersome but Caprini has been widely validated in surgery patients.[35]

Patients undergoing major surgical procedures or are older than 40 years are recommended for perioperative thromboprophylaxis.[15] Low-dose unfractionated heparin (LDUH) and low-molecular-weight heparin (LMWH) reduce the for VTE in these patients by 60%.[16, 36] The clinical value of LDUH and unfractionated heparin (UFH) in general surgery is equally potent as a prophylactic regimen as compared with no prophylaxis or placebo.[36] Use of LDUH has been shown to increase risk of bleeding events and formation of wound hematomas.[37] UFH has been shown to be effective and safe when administered three times a day in surgery for cancer.[36, 37]

LMWH and UFH have been shown to be safe and effective for the prevention of VTE after surgery.[15] Clinical advantages of LMWH is its once a day dosing and the reduced risk for heparin induced complications.[38] Higher prophylactic doses of LMWH provide greater protection than lower doses in patients undergoing surgery for cancer.[39] Mechanical thromboprophylaxis is effective in reducing the risk for VTE and is preferred in patients at a high risk of bleeding.[14]

Early postoperative mobilization is effective and recommended after surgery patients. Routine prophylaxis with pharmacologic agents is recommended for more extensive surgeries and studies shows markedly enhanced protection from VTE when combined with mechanical methods [41, 42]

Risk factors for VTE are well established. Risk of VTE is perceived as the overall combined result of constitutional risk factors and the risk attributable to the patient's current medical situation and/or surgical procedures.[43] The most common personal risk factors include advanced age, history of cancer, previous VTE, obesity, varicose veins, hormonal therapy, chronic heart failure and chronic or severe respiratory disease.[44] Immobility, endothelial

injury, coagulation disorders, stroke, and pregnancy worsens risk for VTE. [45]Trauma or major injury may also expose patients to a moderate-to-high risk of developing VTE.[14]

Additional risk factors for VTE in general surgical patients include cancer and long operation time, extensive procedures in patients with comorbidities and pelvic surgery with or without lymph node dissection.[46] The use of preoperative chemotherapy is also thought to increase the risk for VTE in patients undergoing surgery.[15]

Patients undergoing vascular surgeries are at high risk for VTE with additional risks including ischemia and venous injury.[47] The incidence of clinically overt VTE occurring in these patients during hospitalization period or requiring re-hospitalization within 3 months after surgery is significant.[15] Rates of DVT after major vascular surgery are comparable to those of abdominal and pelvic procedures. [48]

A possible effect of race and ethnicity on the incidence of VTE has been reported.[49]A study by White and Keenan observed that African-American patients have a significantly higher incidence of first-time VTE exposure and are more likely to manifest PE compared with other racial groups though the incidence of recurrent VTE is similar across racial groups.[49]
Studies show there is a knowledge gap on VTE prevention and implementation of appropriate prophylactic measures. Most of at-risk patients are not assessed for VTE and therefore end up not receiving prophylaxis. [50, 51, 52]

Despite the guidelines and the evidence of benefit after VTE prophylaxis, physicians often fail to use this important therapy in a variety of high-risk situations including the perioperative period.[11]Because of scarcity of data, the study sought to assess risk profile of elective surgical patients, and the clinical practice of VTE prophylaxis in KNH.

2.0 CHAPTER TWO: STUDY JUSTIFICATION

VTE is a major worldwide problem, is a preventable condition and without appropriate prophylaxis or prompt treatment carries a high morbidity and mortality rate.[2, 9, 10] There are no local studies that have explored the VTE risk profile of elective surgical patients, and the clinical practice of VTE prophylaxis in KNH.

Identification of the pattern of distribution of VTE risk factors in surgical patients in our resource constrained setting will enable early recognition of the patients at risk of VTE. As such, appropriate VTE prophylaxis to moderate, high and highest risk group prior to its development and progression to clinical VTE could potentially be prevented and have improved surgical outcomes with reduction on morbidity and mortality.

Knowledge of evidence-based VTE risk profile based on scoring system that has been validated is important in informing decisions on VTE prophylaxis and laying emphasis on the correct preventive measures.

The aim of this study was to establish the VTE risk profile and clinical practices in VTE prophylaxis in patients undergoing elective non-orthopedic surgery in KNH.

2.1 Main Objective

To determine the incidence of patients at risk of VTE, the proportion that gets thromboprophylaxis and the type of prophylaxis among surgical patients in KNH

2.2 Specific objectives

- To determine the incidence of surgical patients who are at risk of VTE.
- To determine the proportion of patients at risk of developing VTE receiving prophylaxis.
- To determine the DVT prophylaxis methods used

3.0 CHAPTER THREE: STUDY DESIGN AND METHODOLOGY

3.1 Study Design

Prospective descriptive study design.

3.2 Study Area

The study was carried out in the 3 general surgical ward, plastic surgery and cardiovascular wards in KNH.

3.3 Study Population

Adult patients who met inclusion criteria were recruited in to the study. Informed consent was sought from the recruited patients or their next of kin

3.4 Inclusion Criteria

Consenting adult (18 years and above) patients admitted for elective surgical operation in KNH: General surgical patients, vascular and thoracic patients and plastic and reconstructive patients.

3.5 Exclusion Criteria

- Patients who refused to consent to the study
- Patient already on VTE management
- Cardiac surgery patients
- Prior DVT
- Patients with jaundice/hepatic impairment
- Known bleeding disorder
- Orthopedic patients
- Neurosurgery patients (The recommended prophylaxis is mechanical methods because of high risk of intracranial bleeding)
- Pediatric patients
- Gastroduodenal ulcer

Neurosurgery patients (The recommended prophylaxis is mechanical methods because of high risk of intracranial bleeding).

This was achieved through history taking, enquiry of past medical history and working diagnosis of the surgical candidates from their medical records.

3.6 Sample size determination

The sample size was calculated using the Cochran formula given by:

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

Where

n is the sample size in surgical wards

p is the expected prevalence 15-30%.[15]

q is (1-p)

e is the level of precision (5% for this study)

Z statistic for a level of confidence of 95%, conventional value is 1.96

Therefore the sample size is:

$$n=\frac{Z^2pq}{e^2}=\frac{1.96^2 \times 0.3 \times (1-0.7)}{0.05^2}=322.69$$ rounded off to 323

3.7 Sampling Method

Consecutive sampling method was used to recruit elective surgical patients in the surgical units of KNH into the study. They were assessed for VTE risks and graded using Caprini score (appendix 2). The proportion of at-risk patients who received effective prophylaxis in accordance with 2004 ACCP guidelines was assessed. Recruitment of study subjects was on a rolling basis throughout the study period.

3.8 Recruitment and Consenting

After ethical approval, elective surgical patients who met the study criteria were included into the study. Informed consent was obtained from patient or their next of kin in all the patients recruited into the study. Data was collected using pre-designed questionnaires by the principle investigator or either of the two research assistants with a minimum qualification of MBChB. The research assistants were trained on methodology and briefed on study objectives by the principal investigator before the start of the research. They assisted with administering of questionnaires and data entry.

3.9 Data Collection Procedures

Patients were recruited in to the study on admission. Data was collected from the eligible candidates by use of a pretested questionnaire before surgery and filled in after the intervention on 1st day post operatively and on discharge. Some data was extracted from the patients' medical records and some collaborative information gotten from patients or their next of kin and recorded in MS Excel data sheets.

A major surgical procedure was considered as one requiring general or epidural anesthesia and lasted at least 45 minutes and all minor elective surgeries as those lasting less than 45 minutes. VTE risk assessment in surgical patients was classified as high, moderate or low risk for VTE depending on Caprini scoring system.

Collected data included: patient age, gender, diagnosis on admission, date of admission, medical history, surgical intervention, VTE risk factors, and factors associated with risk of bleeding. The risk factors included family history of VTE, obesity, stroke, pregnancy or postpartum period, immobilization, oral contraceptives use, use of central venous access, sepsis, acute medical illness like pneumonia, acute myocardial infarction, congestive heart failure, inflammatory bowel disease, major surgery, presence of cancer, cancer therapy and presence of varicose veins

Enrolled patients were assessed for VTE risk and graded using the Caprini Risk Assessment tool (appendix 2). Patients considered at risk of VTE were classified as moderate, high or highest risk in line with Caprini risk assessment model. Evaluation of prophylaxis was done according to the type and dose of VTE prophylaxis patients received. Patients were considered at a significant bleeding risk if they present with hepatic impairment, bleeding at admission, active gastric or duodenal ulcer, or known bleeding disorder.

From the data collection sheets, all data was saved in MS Excel data sheets that were protected from access by unauthorized person. Hard copy back-up copies securely locked in a cabinet under lock and key, only accessed by personnel involved in the project.

3.10 Data Analysis

Questionnaires were coded and data entered into a password protected database. Analysis was done using descriptive statistics. Analysis was done at 95% confidence interval and a level of significance of 0.05%. Bar graphs, tables and pie charts were used for presentation of results. Confidentiality was maintained throughout the study.

3.11 Ethical Consideration

The study commenced upon approval by the department of surgery (UON) and KNH Ethics and Research committee.

An informed consent was obtained from each of the participant prior to enrolment into the study. A next of kin was required to sign consent on behalf of the participants who could not do so due to their condition. Those who declined participation were not coerced to participate and were not denied quality treatment. There was no extra cost incurred for participating in the study.

Electronic data was saved under password and any hard copy research data was kept in a safe locked cabinet only accessed by the research team.

4.0 CHAPTER FOUR: RESULTS

We aimed to assess the incidence of patients at risk of VTE, the proportion that got thromboprophylaxis and the type of prophylaxis used among surgical patients in KNH. Consecutive sampling method was used to select and recruit the 323 eligible participants who underwent elective surgery into the study.

This section presents the demographic information of the patients in terms of their gender.

Table 1: Demographic characteristics

Variable	**Frequency (%)**
Gender	
Male	164 (50.8)
Female	159 (49.2)

There were 323 participants in total and the distribution by gender 164 (50.8%) were male and the rest 159 (49.2%) were female patients. The ratio of male to female was 1:1.

Table 2 : At risk population demographic characteristics

Variable	**Frequency (%)**
Gender	
Male	24 (28.9)
Female	59 (71.1)
Male: Female	1:3
Median age (IQR)	54.0 (42.5-66.7)
Age group	
<40	15 (18.8)
40-60	38 (47.5)
61-74	16 (20.0)
≥75	11 (13.8)
Mean BMI (SD)	21.1 (3.3)
BMI categories	
Underweight	24 (30.4)
Normal	43 (54.4)
Overweight	11 (13.9)
Obese	1 (1.3)

83 patients were considered at-risk for VTE. There were 24 (28.9%) males and 59(71.1%) females with a male to female ratio of 1:3. The majority of the at-risk patients were aged between 40 and 60 years of age at 38% with only 11(13.8%) patients being older than 75 years and 11 (18.8%) younger than 40 years. The rest, 16 (20.0%) were between the age of 61 and 74 years. The median age was 54.0 years with an interquartile range between 42.5 and 66.7 years. The study revealed that majority of the at-risk, 38 (47.5%), patients had normal BMI. 24 (30.4%) were underweight, 11 (13.9%) were overweight and only one patient was obese. The mean BMI was 21.1 with a standard deviation of 3.3.

4.1 Clinical Characteristics

The study found that 310 (96.0%) of the patients were confined to bed for less than 72 hours while 13 (4.0%) were confined to bed for more than 72 hours. The study found that 117 (36.2%) of the patients had surgeries lasting less than 45 minutes and 206 (63.8%) had surgeries lasting more than 45 minutes from the cutting time as shown in the table below.

The commonly used surgical approach was open surgery with 243 (75.9%) patients followed by laparoscopic at 76 (23.8%) while combined method contributed to only 0.3%. which was mainly due to conversion. Of all the participants, only 15 (4.6%) were on cancer treatment at the time of this study. 11(73.3%) of them were receiving chemotherapy while 4 (26.7%) were receiving radiotherapy as a form of cancer treatment.

Table 3 : Clinical characteristics

Variable	**Frequency (%)**
Confined to bed	
<72 Hours	310 (96.0)
>72 Hours	13 (4.0)
Duration of Surgery	
<45 Min	117 (36.2)
>45 Min	206 (63.8)
Type of surgery	
Open	243 (75.9)
Laparoscopic	76 (23.8)
Combined	1 (0.3)
Cancer treatment	15 (4.6)
Treatment type (n=15)	
Chemotherapy	11 (73.3)
Radiotherapy	4 (26.7)

4.2 VTE Prophylaxis

Only 52 (16.1%) of the 323 patients who underwent elective surgery were put on VTE prophylaxis. 13 (25%) patients were on VTE prophylaxis even before surgery. 44 (84.6%) patients were put on VTE prophylaxis on the first day after surgery and only 3 (5.8%) were on prophylaxis at discharge.

Majority of these patients, 48 (92.3%), were on pharmacologic prophylaxis. Only 4 (7.7%) were on mechanical methods and 2 (3.8%) patients were on both the pharmacologic and mechanical methods.

The mean pharmacologic dosage of the drug (Clexane) used was 39.2 mg with a standard deviation of 5.7

Table 4 : DVT prophylaxis and methods used

Variable	**Frequency (%)**
Thromboprophylaxis given	52 (16.1)
Prophylaxis administration (n=52)	
Preoperatively	13 (25.0)
Day 1 post operatively	44 (84.6)
At discharge	3 (5.8)
Type of prophylaxis (n=52)	
Pharmacologic	48 (92.3)
Mechanical	4 (7.7)
Both	2 (3.8)
Mean pharmacologic dosage (SD)	39.2 (5.7)

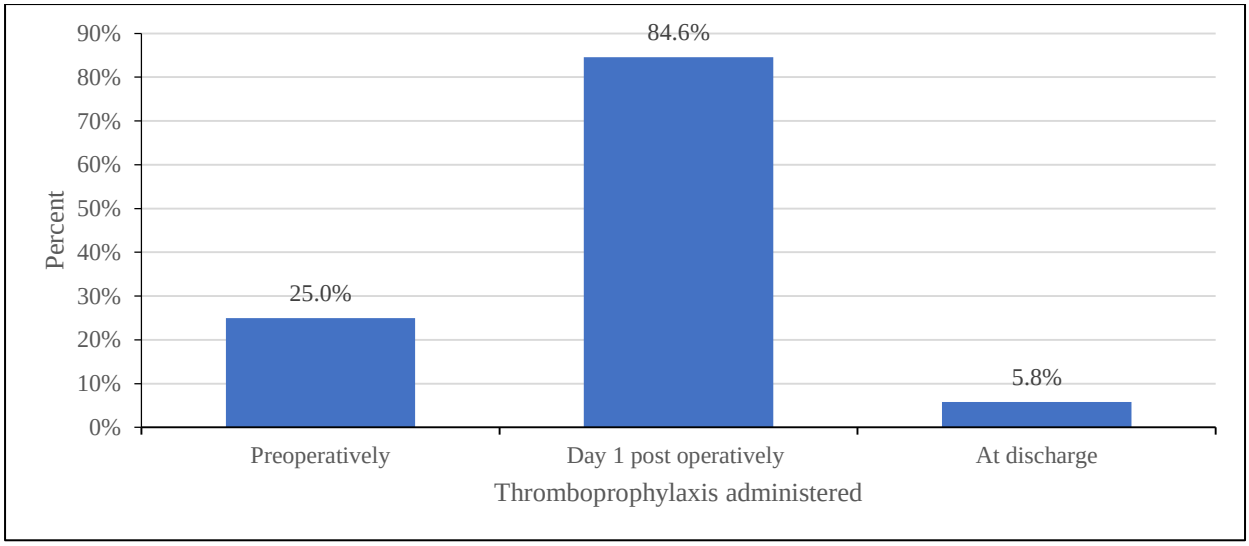


Figure 1: Patients on VTE prophylaxis

125 (38.7%) of the elective surgery patients had low risk of developing VTE followed closely by the moderate risk group 115 (35.6%). The high risk group had 81 (25.1%) patients and the highest risk group had only 2 (0.6%) patients.

Table 5: VTE risk

Risk level	**Frequency (%)**
Low	125 (38.7)
Moderate	115 (35.6)
High	81 (25.1)
Highest	2 (0.6)

The distribution of patients according to venous thromboembolism risk is presented inform of pie chart as shown below

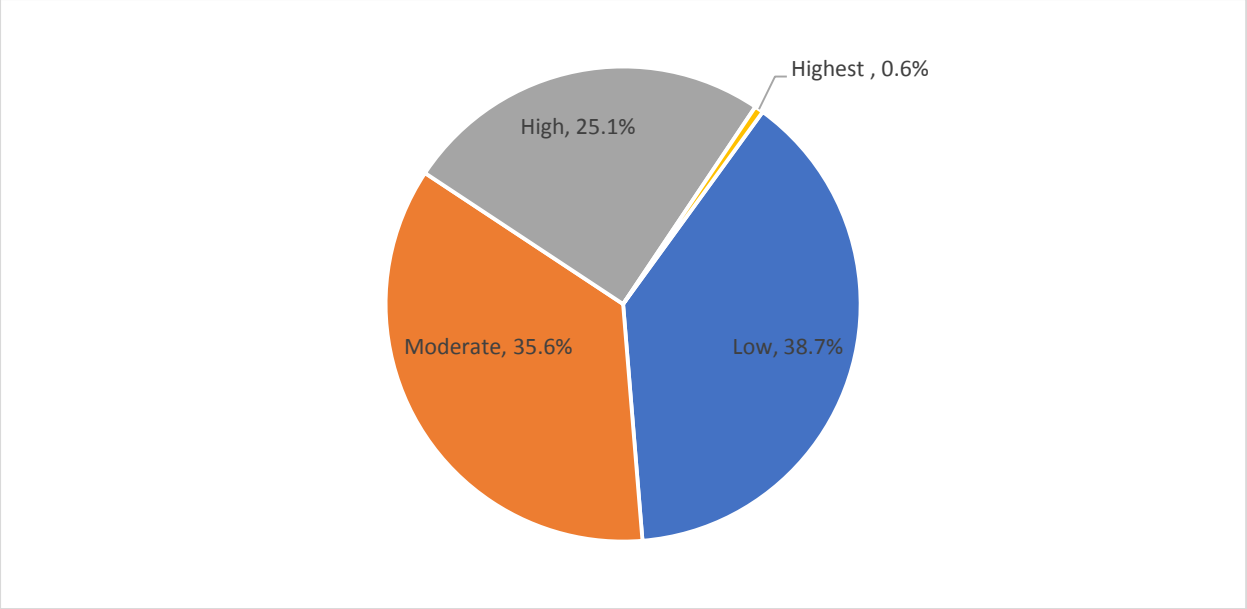


Figure 2: VTE risk

Table 6: Patients at risk of developing VTE receiving prophylaxis

Variable	VTE risk grade				P value
	Low	Moderate	High	Highest	
Prophylaxis given	5 (9.6)	13 (25.0)	32 (61.5)	2 (3.8)	<0.001
Method					
Preoperatively	2 (15.4)	4 (30.8)	7 (53.8)	0	0.101
Day 1 post operatively	5 (11.4)	11 (25.0)	26 (59.1)	2 (4.5)	<0.001
At discharge	1 (33.3)	2 (66.7)	0	0	0.631

52 (16.1%) patients were put on VTE prophylaxis. 13(25.0%) of these were on prophylaxis even before surgery. On postoperative day 1, 44(84.6%) patients were on VTE prophylaxis and only 3(5.8%) patients were on VTE prophylaxis at discharge.

Majority of those who received prophylaxis were high risk 32(61.5%) patients followed by the moderate risk 13(25.0%) patients, low risk 5 (9.6%) and highest risk 2 (3.8%) patients as shown in the table above. The high risk group had the highest numbers of the candidates who received VTE prophylaxis before and after surgery with 53.8% and 59.1% respectively followed by moderate risk with 30.8% and 25.0% before and after surgery respectively. The probability of finding patients at risk of VTE on prophylaxis was statistically significant, p value <0.001, on day one after surgery.

4.3 Patients at risk of VTE receiving prophylaxis

Table 7 : Proportion of patients at risk of developing VTE

Risk level	Population at risk	Population at risk who received prophylaxis	Proportion of at risk of VTE receiving prophylaxis (%)
Low	125	5	4
Moderate	115	13	11.3
High	81	32	39.5
Highest	2	2	100

The VTE prophylaxis was 100% for the highest risk group followed by the high risk with 39.5% of all the candidates in this cohort. Only 11.3% of the moderate risk patients and 4% of the low risk group received VTE prophylaxis.

5.0 CHAPTER FIVE: DISCUSSION

VTE remains a significant cause of morbidity and mortality in the world of today, Kenya included. Given that it is one of preventable causes of morbidity and mortality, researchers and health practitioners have tried to come up with simple tools to identify risks of patients likely to develop VTE. Some of these tools are complicated and difficult to use while others are simple and easy to use. Reliability of a tool is a determinant of the repeatability of its measurements, and is usually measured in various ways, while its validity is the estimate of its effectiveness. Caprini model assessment tool has proved to be of good validity and reliability demonstrating that the score can be used for the evaluation and determination of patients at various levels of VTE risk.

This study revealed that majority of our patients 63.8% had major surgeries lasting more than 45 minutes, 4% were confined to bed for than 3 days and 4.6% were suffering from cancer and were on treatment with either chemotherapy or radiotherapy. All these contribute to higher risk of VTE. The average patient undergoing elective surgery at KNH is at risk for developing perioperative VTE. This is mainly attributable to the various risk factors. Surgery is considered high risk if the length of surgery is longer than 45 minutes, if malignancy is present, if major surgery is performed to pelvic organs, and if there is prolonged postoperative immobilization or bed rest.

Our study demonstrated that the most common type of VTE prophylaxis administered was clexane, a LMWH (enoxaparin) anticoagulant. It was prescribed to 48 (92.3%) patients of the total that got prophylaxis. Mechanical (7.7 %) or combined methods (3.8%) was less commonly used as compared to a study done in USA[56] where the mechanical (elastic stocking) prophylaxis was used in 29% of the studied subjects. This spells out possibility of a strict adherence to VTE prophylaxis guidelines.

VTE prophylaxis practices were generally inadequate. Prophylaxis was mainly given until discharge and not as recommended for a minimum period of 7 days.[21] The study did not follow those patients who never received adequate VTE prophylaxis to determine whether they developed any clinical VTE or its complication.

61.3% of patients in this study had moderate to very high risk and were eligible for VTE prophylaxis according to ACCP guidelines. Only 16.1% of the recruited subjects received VTE prophylaxis. This constitutes only 24.7% of the proportion of at-risk eligible for VTE prophylaxis. This shows that majority of elective surgical patients at KNH do not get the appropriate VTE prophylaxis. This compares with the West Africa endorse study that was conducted in Senegal.[53] The at-risk population stood at 60.3% of the 242 studied subjects. In their study, only 35.6% were put on the appropriate and effective prophylaxis. This could be higher than that of KNH since they enrolled all surgical patients including orthopedics, neural surgery and all surgical emergency cases that met inclusion criteria as opposed to our study. Our study revealed that a quarter of the patient received preoperative prophylaxis. Majority of patients (84.6%) were given prophylaxis on the first day after surgery and only 5.8% were discharged on extended VTE prophylaxis. This contrasts sharply with a study that were done in USA where preoperative prophylaxis stood at 45% of the 160 studied subjects. Prophylaxis stood at 76% and 66% for the high and the highest risk patients respectively.[56] Prophylaxis practice is much better in their study as compared with the results of our study.

Generally, the proportion of elective surgical patients who were in highest risk category was small. The 2 patients in the highest risk category received VTE prophylaxis as recommended by ACCP guidelines. However, the rate of prophylaxis use in KNH is comparable to other countries, ranging from 3% to the 70% globally.[18] There is a big room for improvement with potential for huge benefits if a goal of 100% was to be achieved.

This study reveals that the mechanical prophylaxis in KNH is rarely practiced as recommended by the ACCP guidelines. Only 7.7% and 3.8% of the prophylactic measures were mechanical and combined methods respectively. There was a low rate of mechanical prophylaxis use comparable to other international studies.[56]

The study of VTE prophylaxis revealed that the moderate and high risk group for VTE was mostly inadequately treated at 11.3% and 39.5% respectively while 4% of the low risk received unnecessary prophylaxis. The highest risk group 2(100%) patients received the appropriate prophylaxis. Only 42(24.7%) of 198 of the population at risk of VTE received the appropriate prophylaxis. There was no tool used to individualize prophylaxis for patients but rather the patients factors and perioperative management. Prophylaxis prescription was by

use of a ‘one size-fits-all’ approach. 88.7% and 60.5% of patients in moderate and high risk group respectively probably demonstrates a perceived lack of risk factors for VTE. This observation triggers one to conclude that the knowledge, attitude and practices of VTE prophylaxis is wanting in clinical setting. Current guidelines and recommendations are never observed. Among all patients at risk, less than a third of surgical patients were receiving prophylaxis. Prophylaxis in elective surgical patients was very low in their study. Less than a third of patients at risk received VTE prophylaxis. Prophylaxis use in surgical patients was also low in West Africa Endorse study with less than 40% of all at-risk VTE patients received prophylaxis. [53]

VTE is a common complication of major surgery.[54] Major surgeries, malignancies, use chemotherapy and patients comorbidities are known to increases the risk for VTE.[55] Use of VTE prophylaxis is recommended in surgical patients undergoing major general procedures and are at increased risk of VTE.[15] Various prophylactic modalities are efficacious and are safe for the prevention of VTE. Mechanical VTE prophylactic measures are effective in reducing the risk for VTE in patients at high risk of bleeding.

To reduce risk of developing a preventable VTE, seminars, continuous medical education, proper risk assessment and adherence to prophylaxis guidelines must be encouraged to health care providers.

There is a room for improvement to achieve close to a 100% identification of the patients at risk of VTE and commencement of the appropriate VTE prophylaxis by using the recommended methods and dosing of prophylaxis. Use of simple scoring assessment screening tools and recommended guidelines on use of thromboprophylaxis can help in assessing VTE risk and guide in appropriate use of prophylaxis. These tools should be availed in all surgical patient admission files for easy identification of the at-risk patients and appropriate planning of VTE prophylaxis.

5.1 Limitations

This was a single centre observational study and thus the results should be validated in other settings. Given that KNH is one of the few training institutions of health, the VTE

prophylaxis may greatly differ with the rest of health facilities spread throughout the country. This may mean consideration of VTE risk factors is better here hence better prophylaxis practices.

There is lack of similar studies to compare the elective surgical patients VTE risks patterns and prophylaxis practices to aid in interpretation of our results.

5.2 Conclusion

VTE can be a major complication with a substantial risk of morbidity and mortality in all hospitalized patients. Surgical patients have added risk resulting from surgical intervention, length of surgery, type of anesthesia used and length of hospitalization besides the reasons for admission. Clinicians should make an effort to raise the level of awareness for VTE risks in surgical patients and practice appropriate VTE prophylaxis. Both pharmacological and mechanical VTE prophylaxis must be made readily available and affordable. Universal health insurance should also be compelled to assist by taking care of the financial burden of VTE prophylaxis and management.

The study concludes that use of a simple screening tool can help in VTE risk stratification in surgical patients. This can help to determine the set of patient who requires to be put on thromboprophylaxis. Thromboprophylaxis is recommended to help in reduction of morbidity, mortality and the attendant cost associated with VTE and its complications. Reduction in the incidences of VTE after surgery is possible through the appropriate patient selection and institution of various prophylactic measures. Simple VTE prevention guidelines should be developed and adapted by the Ministry of health to improve on the thromboprophylaxis practices. A simple to use tailor-made VTE risk assessment tool for surgical patients can help in the assessment of the-at-risk patients for appropriate therapeutic intervention.

5.3 Recommendations

From the findings in this study, it is recommended that

- Simple VTE risk assessment tools with the aim of identifying the at-risk patients with the aim of appropriate prophylaxis treatment should be adopted into the patient files to improve prophylaxis practices in our clinical setting.
- More local studies should be conducted to establish whether there are patients who develop VTE after surgery as a result of inadequate or failure of prescription of the appropriate prophylactic measures
- Consideration of extended VTE prophylaxis in line with the ACCP guidelines
- Formulation of local guidelines on VTE prophylaxis especially for the surgical patients.

REFERENCES

1. Virchow, R. Never fall von todlichen, Emboli der lungenarterie. *Arch Pathol Anat.* 1856; 10: 225-228.
2. Silverstein M, Heit J, Mohr D, Petterson T, O'fallon M, Melton J: Trends inthe incidence of deep vein thrombosis and pulmonary embolism. A 25-year population-based study. Arch Intern Med 1998, 158:585–593
3. Bergqvist D: Venous thromboembolism: a review of risk and prevention in colorectal surgery patients. Dis Colon Rectum 2006, 49:1620–1628.
4. Bratzler DW, Raskob GE, Murray CK, Bumpus LJ, Piatt DS. Underuse of venous thromboembolism prophylaxis for general surgery patients: Physician practices in the community hospital setting. Arch Intern Med 1998;158(17):1909-1912.
5. Caprini JA. Thrombotic risk assessment: A hybrid approach. In: Bergan JJ, ed. The Vein Book. Burlington, MA: Elsevier Academic Press 2007:359-365.
6. Kelly J, Rudd A, Lewis RR: Screening for subclinical deep-vein thrombosis. QJ Med 2001, 94:511–519.
7. Bergqvist D, Lindgren B, Matzsch T. Cost-effectiveness of preventing postoperative deep vein thrombosis. In: Hull RD, Pineo GF, editors. *Disorders of thrombosis*. Philadelphia, PA: WB Saunders; 1996. p. 228-33
8. Bick RL. Proficient and cost-effective approaches for 12. the prevention and treatment of venous thrombosis and thromboembolism. *Drugs* 2000; *60* : 575-95.
9. Samama MM, Cohen AT, Darmon JY, Desjardins L, Eldor A, Janbon C, LeizoroviczA, Nguyen H, Olsson CG, Turpie AG, Weisslinger N: A comparison of enoxaparin with placebo for the prevention of venous thromboembolism in acutely ill medical patients. Prophylaxis in Medical Patients with Enoxaparin Study Group. N Engl JMed 1999, 341(11):793–800.
10. Leizorovicz A, Cohen AT, Turpie AGG, Olsson CG, Vaitkus PT, Goldhaber SZ: Randomized, Placebo-Controlled Trial of Dalteparin for the Prevention of Venous Thromboembolism in Acutely Ill Medical Patients. Circulation 2004, 110(7):874–9.
11. Cohen AT, Agnelli G, Anderson FA, Arcelus JI, Bergqvist D, Brecht JG, *et al*; for the VTE Impact Assessment Group in Europe (VITAE). Venous thromboembolism (VTE) in Europe: The number of VTE events and associated morbidity and mortality. *Thromb Haemost* 2007; *98* : 756-64.

12. Cohen AT, Davidson BL, Gallus AS, Lassen MR, Prins 3. MH, Tomkowski W, *et al*; ARTEMIS investigators. Efficacy and safety of fondaparinux for the prevention of venous thromboembolism in older acute medical patients: randomized placebo controlled trial. *BMJ* 2006; *332* : 325-9.
13. Leizorovicz A, Cohen AT, Turpie AGG, Olsson C-G, 2. Vaitkus PT, Goldhaber SZ; for the PREVENT Medical Thromboprophylaxis Study Group. Randomized, placebo-controlled trial of dalteparin for the prevention of venous thromboembolism in acutely ill medical patients. *Circulation* 2004; *110* : 874-9.
14. Sotunmbi PT, Idowu AT, Akang EE, et al. Prevalence of venous thromboembolism at post-mortem in an African population: a cause for concern. Afr J Med Med Sci 2006;35:345
15. Geerts WH, Heit JA, Clagett GP, et al. Prevention of venous thromboembolism. *Chest.* 2001;119(suppl 1):132S–175S.
16. Mismetti P, Laporte S, Darmon JY, et al. Meta-analysis of low molecular weight heparin in the prevention of venous thromboembolism in general surgery. *Br J Surg*. 2001;88:913–930.
17. Lee AD, Stephen E, Agarwal S, Premkumar P. Venous 8. Thrombo-embolism in India. *Eur J Vasc Endovasc Surg* 2009; *37* : 482-5.
18. Cohen AT, Tapson VF, Bergmann JF, et al. Venous thromboembolism risk and prophylaxis in the acute hospital care setting (ENDORSE study): a multinational cross-sectional study. Lancet 2008;371:387—94.
19. Gikonyo D. Deep vein thros and pulmonary embolism in Kenyatta National Hospital: a five year study 1975-1979
20. Motykie GD, Zebala LP, Caprini JA, et al. A guide to venous thromboembolism risk factor assessment. J Thromb Thrombolysis 2000;9(3):253-262.
21. Caprini JA, Arcelus JI. State-of-the-art venous thromboembolism prophylaxis. Scope on Phlebology and Lymphology 2001;1:228-240.
22. Anderson FA, Audetand A, St. John R. Practices in the prevention of venous thromboembolism. J Thromb Thrombolysis 1998;5 (1):7-11. [http://dx.doi.org/10.1023/a:1013224617860]

23. Heinzer H, Hammerer P, Graefen M, et al. Thromboembolic complication rate after radical retropubic prostatectomy. Impact of routine ultrasonography for the detection of pelvic lymphoceles and hematomas. *Eur Urol*. 1998;33:86 –90.
24. Donat R, Mancey-Jones B. Incidence of thromboembolism after transurethral resection of the prostate (TURP)—a study on TED stocking prophylaxis and literature review. *Scand J Urol Nephrol*. 2002;36: 119–123.
25. Lukuta RH. Patterns of thromboprophylaxis among orthopaedic surgery patients at Kenyatta National Hospital, Kenya.
26. Aywak AA, Masesa JV: Comparison of sonography with venography in diagnosis of deep venous thrombosis. East Afr Med J 2007, 84(7):304–311.
27. Wells PS, Anderson DR, Bormanis J, Guy F, Mitchell M, Gray L, Clement C, Robinson KS, Lewandowski B: Value of assessment of pretest probability of deep-vein thrombosis in clinical management. Lancet 1997, 350:1795–1798.
28. Forbes K, Stevenson AJM: The use of power Doppler ultrasound in the diagnosis of isolated deep venous thrombosis of the calf. Clin Radiol 1998, 53:752–754.
29. Martino MA, Williamson E, Rajaram L, et al. Defining practice patterns in gynecologic oncology to prevent pulmonary embolism and deep venous thrombosis. Gynecol Oncol 2007;106(3):439-445.
30. Parakh R, Somaya A, Todi SK, Iyengar SS, for Consensus Development Guidelines Panel. Consensus development recommendations for the role of LMWHs in prophylaxis of venous thromboembolism: An Indian perspective. *J Assoc Physician India* 2007; *55* : 5-30.
31. Bergqvist D, Lindgren B, Matzsch T. Cost-effectiveness of preventing postoperative deep vein thrombosis. In: Hull RD, Pineo GF, editors. *Disorders of thrombosis*. Philadelphia, PA: WB Saunders; 1996. p. 228-33.
32. Cohen AT, Alikhan R, Arcelus, et al. Assessment of venous thromboembolism risk and the benefit of thromboprophylaxis in medical patients. *Thromb Haemost*. 2005;94:750 –759.
33. Kucher N, Koo S, Quiroz R, et al. Electronic alerts to prevent venous thromboembolism among hospitalized patients. *N Engl J Med*. 2005;352:969–977.

34. Caprini JA, Arcelus JI, Reyna JJ. Effective risk stratification of surgical and non-surgical patients for venous thromboembolic disease. *Semin Hematol*. 2001;38(suppl 5):12–19.

35. Zakai NA, Wright J, Cushman M. Risk factors for venous thrombosis in medical inpatients: validation of a thrombosis risk score. *J Thromb Haemost*. 2004;2:2156 – 2161.

36. Mismetti P, Laporte S, Darmon JY, et al. Meta-analysis of low molecular weight heparin in the prevention of venous thromboembolism in general surgery. *Br J Surg*. 2001;88:913–930.

37. Collins R, Scrimgeour A, Yusuf S, et al. Reduction in fatal pulmonary embolism and venous thrombosis by perioperative administration of subcutaneous heparin. Overview of results of randomized trials in general, orthopedic, and urologic surgery. *N Engl J Med*. 1988;318:1162–1173.

38. Warkentin TE, Levine MN, Hirsh J, et al. Heparin-induced thrombocytopenia in patients treated with low-molecular-weight heparin or unfractionated heparin. *N Engl J Med*. 1995;332:1330 –1335.

39. Koch A, Ziegler S, Breitschwerdt H, et al. Low molecular weight heparin and unfractionated heparin in thrombosis prophylaxis: meta-analysis based on original patient data. *Thromb Res*. 2001;102:295–309.

40. Haas S, Flosbach CW. Antithromboembolic efficacy and safety of enoxaparin in general surgery. German multicentre trial. *Eur J Surg.* 1994; (suppl 571):37– 43.

41. Koch MO, Smith JA. Low molecular weight heparin and radical prostatectomy: a prospective analysis of safety and side effects. *Prostate Cancer Prostatic Dis*. 1997;1:101–104.

42. Amarigiri SV, Lees TA. Elastic compression stockings for prevention of deep vein thrombosis. Cochrane Database Syst Rev. 2000;3:CD001484.Koch

43. Flordal PA, Bergqvist D, Ljungstrom KG, et al, for the Fragmin Multicentre Study Group. Clinical relevance of the fibrinogen uptake test in patients undergoing elective general abdominal surgery–relation to major thromboembolism and mortality. *Thromb Res*. 1995;80:491– 497.

44. Killewich LA, Aswad MA, Sandager GP, et al. A randomized, prospective trial of deep venous thrombosis prophylaxis in aortic surgery. *Arch Surg.* 1997;132:499 –504.
45. Beckman MG, Hooper WC, Critchley SE, Ortel TL: Venous thromboembolism: a public health concern. Am J Prev Med 2010 Apr, 38(4 Suppl):S495–501.
46. Turpie AG. Thrombosis prophylaxis in the acutely ill medical patient: insights from the prophylaxis in MEDical patients with ENOXaparin (MEDENOX) trial. Am J Cardiol 2000;86:48M—52M.
47. Anderson FA Jr., Spencer FA. Risk factors for venous thromboembolism. *Circulation.* 2003;107:I9 –I16.
48. Hollyoak M, Woodruff P, Muller M, et al. Deep venous thrombosis in postoperative vascular surgical patients: a frequent finding without prophylaxis. *J Vasc Surg*. 2001;34:656–660.
49. White RH, Keenan CR. Effects of race and ethnicity on the incidence of venous thromboembolism. Thromb Res 2009;123(Suppl. 4):S11—7.
50. Sadler C: Minimising the risks. Nurs Stand 2007, 22(4):24–25.
51. Bonner L, Coker E, Wood L: Preventing venous thromboembolism through risk assessment approaches. Br J Nurs 2008, 17:12,778–782.
52. Lees L, McAuliffe M: Venous thromboembolism risk assessment in acute care. Nurs Stand 2010, 24(22):35–41.
53. A cross-sectional evaluation of venous thromboembolism risk and use of venous thromboembolism prophylaxis in hospitalized patients in Senegal; Serigne AbdouBâaSeydou B.BadianebSaid N.DiopcFatou S.DioufdDiadiéFalleMamadou M.KafAbdoulKanegMouhamadouNdiayehon behalf of Comité TROMBUS Senegal
54. Shekarriz B, Upadhyay J, Wood DP. Intraoperative, perioperative and long-term complications of radical prostatectomy. Urol Clin North Am. 2001;28:639–653.
55. Flordal PA, Bergqvist D, Ljungstrom KG, et al, for the Fragmin Multicentre Study Group. Clinical relevance of the fibrinogen uptake test in patients undergoing elective general abdominal surgery–relation to major thromboembolism and mortality. Thromb Res. 1995;80:491–497.
56. Tapson VF, Decousus H, Pini M, et al: Venous thromboembolism prophylaxis in acutely ill hospitalized medical patients: findings from the international medical prevention registry on venous thromboembolism. Chest 2007, 132:936–45.

APPENDICES

Appendix I: Consent (English version)

ASSESSMENT OF VENOUS THROMBOEMBOLISM RISK AND PROHYLAXIS PRACTICES AMONG ELECTIVE SURGICAL PATIENTS AT KENYATTA NATIONAL HOSPITAL

English version

This Informed Consent form is for surgical patients aged eighteen years and older admitted in Kenyatta National Hospital surgical ward (general surgery, plastic surgery, and cardiothoracic wards). This consent will be administered to the eligible patients or patient's next of kin. We are requesting these patients to participate in this research project whose title is "Assessment of venous thromboembolism risk and prohylaxis practices among elective surgical patients at Kenyatta National Hospital''.

Principal investigator: Dr. Mwangi Patrick Muchunu.

Institution: School of Medicine, Department of surgery- University of Nairobi

Supervisors: Dr Dan Kiptoon and Dr Daniel Ojuka.

This informed consent has three parts:

1. Information sheet (to share information about the research with you)
2. Certificate of Consent (for signatures if you agree to take part)
3. Statement by the researcher

You will be given a copy of the full Informed Consent Form.

Part I: Information sheet

Introduction

My name is Dr Patrick Muchunu Mwangi, a post graduate student at the University of Nairobi's School of Medicine. I am carrying out a study to determine the incidence of high-risk surgical patients and determine the proportion of the at-high risk patients receiving appropriate VTE prophylaxis in non orthopedic surgical wards in Kenyatta National Hospital. This will be determined by data collection through filling of questionnaires.

Purpose of the Research

The information obtained will help health care providers to know the magnitude of the problem in elective surgical patients and determine the proportion of non-orthopedic surgical patient at-risk of VTE who require thromboprophylaxis, in a bid to reduce the risk of VTE and its complications.

Voluntary participation/right to refuse or withdraw

I am inviting you to participate in my study and you are free to either agree immediately after receiving this information or later after thinking about it. You will be given the opportunity to ask questions before you decide and you may talk to anyone you are comfortable with about the research before making a decision. After receiving this information concerning the study, please seek for clarification from either myself or my assistant if there are words or details which you do not understand.

Confidentiality

All the information which you provide regarding your kin will be kept confidential and no one but the researchers will see it and their name will not appear in any document. The information about them will be identified by a number and only the researchers can relate the number to patient.

Sharing of the results

The information will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UoN-ERC).

This proposal has been reviewed and approved by the KNH/UoN-ERC which is a committee whose work is to make sure research participants are protected from harm.

Risks to participants

Your kin's involvement in this research will be through an interview and clinical evaluation and they will not expose themselves to any risks if you consent on their behalf, to participate. There will be no extra cost incurred for participating in the study. Participation in this study is out of your own free will; your kin will not be denied medical care in case you refuse him/her to participate in the study. You may stop participating at any time with no consequences whatsoever. All the information that you give us will be used for this research only.

This proposal has been reviewed and approved by the KNH/UoN-ERC which is a committee whose work is to make sure research participants are protected from harm.

Who to contact

The contact information is given below if you wish to contact any of them for whatever reason;

- **Secretary, KNH/UoN-ERC**
  P.O. Box 20723 KNH, Nairobi 00202
  Tel 726300-9
  Email: uonknh_erc@uonbi.ac.ke

- **University of Nairobi research supervisors**
  1. **Dr. Dan Kipkemboi Kiptoon**
     MBChB, M.Med. General surgery, UoN
     Department of Surgery, School of Medicine, University of Nairobi
     P.O. Box 19676 KNH, Nairobi 00202
     Tel 0202726300
  2. **Dr Daniel Kinyuru Ojuka**
     MBChB (U.O.N), M.Med Surgery (U.O.N), F.C.S (ECSA)
     Department of Surgery, School of Medicine, University of Nairobi
     P.O. Box 19676 KNH, Nairobi 00202
     Tel 0202726300

- **Principle researcher:**

  Dr. Patrick Muchunu Mwangi

  Department of Surgery, School of Medicine, University of Nairobi

  P.O. Box 19676 KNH, Nairobi 00202

  Mobile phone 0720281283

Part ii: Consent certificate by patient

I……..freely give consent to take part in the study conducted by Dr. Patrick Muchunu Mwangi, the nature of which has been explained to me by him/his research assistant. I have been informed and have understood that my participation is entirely voluntary and I understand that I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care being given to my proxy. The results of the study may directly be of benefit to my proxy and other patients and more significantly to the medical professionals to better understand the risk of developing VTE in elective surgical patients using RAM score and the proportion of at-risk who are not on prophylaxis, an information that will impart positively in increasing thromboprophylaxis awareness, hence reduction in morbidity and mortality associated with the complication.

……

Signature/dominant hand thumb print (Guardian/Next of kin)

Date……

Thumb print of participant if

Unable to sign due to illiteracy

Statement by the witness if guardian or proxy is illiterate

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

Name of witness……

Signature of witness……..

Date……

Part iii: Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands the following:

- Refusal to participate or withdrawal from the study will not in any way compromises the quality of care and treatment given to the patient.
- All information given will be treated with confidentiality.
- The results of this study might be published to enhance knowledge and to help improve in thromboprophylaxis practices in non-orthopedic patients undergoing elective surgical operations.

  .

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

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher taking consent……

Signature of researcher taking the consent……

Date……

Appendix II: Consent (Swahili version)

Fomu ya idhini

(i) Sehemu ya kwanza – Maelezo ya Daktari mtafiti.

kitambulizi

Mimi ni Dkt. Patrick Muchunu Mwangi, kutoka shule ya Elimu ya Afya idara ya upasuaji Chuo Kikuu cha Nairobi (University of Nairobi). Ninafanya utafiti wa kuangalia wagojwa wa upasuaji walio katika hatari ya kuganda damu kwa mishipa ya damu kwa mapafu ama pengineko na kama wanapata dawa zinazofaa kuzuia tukio kama hilo katika idara ya upasuaji katika hospital kuu ya Kenyatta (Kenyatta National Hospital).

Nia ya utafiti huu

Ningependa kumjumulisha jamaa wako katika utafiti huu wangu. Ninafanya hivyo kwa kuuliza maswali fulani ya afya. Katika utafiti huu utatakiwa kutoa taarifa inayomhusu jamaa wako.

Hatari unayoweza kupata

Hakuna hatari yoyote ambayo yaweza kutokea kwa sababu ya kuhusishwa kwa utafiti huu.

Taadhima ya siri

Habari zote zitakazokusanywa zitashughulikiwa kwa siri na hazitasambazwa ila tu kwa ruhusa kutoka kwa mkurugenzi mkuu wa utafiti wa chuo kikuu cha Nairobi na Hospitali Kuu ya Kenyatta.

Utafifi huu utawasaidia madaktari kuulewa tatizo hili kwa kina hivyo basi kuweza kuwahudumia wagonjwa wao kwa ubora zaidi na kuwapa mbinu ya kutambua walio kwa hatari ya kuganda damu kwa mishipa ya damu, katika juhudi za kupunguza maafa yanayotokana na shida hii. Kuhusika kwa jamaa wako kwenye utafiti huu hakuna malipo yoyote ila ni kwa hiari yako mwenyewe na pia unaweza kujiondoa kushiriki katika utafiti wakati wowote bila kuhatarisha matibabu ya jamaa wako katika Hospitali Kuu ya Kenyatta. Naomba mimi ama wasaidizi wangu katika utafiti wakuulize maswali ambayo yatajibiwa kwa fomu maalum.

Hifadhi ya matokeo

.Habari yote ambayo utatuarifu ni ya siri kati yako nasi watafiti na haitaenezwa kwa watu wengine. Jina la jamaa wako halitaandikwa kwenye fomu yoyote wala kwenye vipimo vyovyote.

Gharama au fidia

Utafiti huu hautakugharimu zaidi ya matibabu yako ya kawaida. Vilevile, hakuna malipo yoyote au fidia utakayopokea kutokana na kujiunga kwako katika utafiti huu. Muda wako ndio utakaotumiwa wakati wa kukubali kushiriki katika utafitiUnaweza kuuliza maswali yeyote kuhusu utafiti huu na ukiridhika tafadhali ijaze fomu ya idhini iliyopo hapa chini. Unaweza pia kuuliza swali lolote baadaye kwa kupiga simu kwa mtafiti mkuu ama mkuu wa idara ya upasuaji katika chuo kikuu cha Nairobi ama walimu wasimamizi wa utafiti ukitumia nambari za simu zifuatazo;

- Katibu wa utafiti, Hospitali Kuu ya Kenyatta na Chuo kikuu cha Nairobi.

  Sanduku la Posta 20723 KNH, Nairobi 00202.

  Nambari ya simu 726300-9.

Walimu wakuu wa Chuo kikuu cha Nairobi:

1. **Dkt Dan Kipkemboi Kiptoon,**

   MBChB, M.Med, surgery(UoN)

   Sanduku la Posta 19676 KNH, Nairobi 00202.

   Nambari ya simu: 0202726300

2. **Dkt Daniel Kinyuru Ojuka**

   MBChB (U.O.N), M.Med Surgery (U.O.N), F.C.S (ECSA)

   Sanduku la Posta 19676 KNH, Nairobi 00202.

   Nambari ya simu: 0202726300

- **Mtafiti: Patrick Muchunu Mwangi,**

  Idara ya Upasuaji ya Shule ya Afya – Chuo kikuu cha Nairobi,

  Sanduku la Posta 19676 KNH Nairobi 00202.

  Nambari ya simu ya rununu 0720281283

(ii) Sehemu ya pili – Idhini ya mgonjwa.

Mimi (Jina)……..kwa niamba ya mgonjwa wangu (Jina la Mgonjwa.....
…….) nimekubali kushiriki katika utafiti huu unaofanywa na Daktari Patrick Muchunu Mwangi kutokana na hali ambayo nimeelezwa na sio kwa malipo ama shurutisho lolote. Nimeelewa kwamba ninaweza kujiondoa wakati wowote nitakapo na hatua hii haita hatarisha matibabu anayoyapata mgonjwa wangu. Matokeo ya utafiti yaweza kuwa ya manufaa kwangu ama kwa wagonjwa wengine kwa jumla na hata madaktari wenyewe, kwa kuendeleza elimu, na hata kupunguza vifo vinavyo epukika.

Kidole cha gumba kwa yule asiyeelewa kuandika

…….

Sahihi/ama alama ya kidole cha gumba katika sanduku →

Tarehe…….....

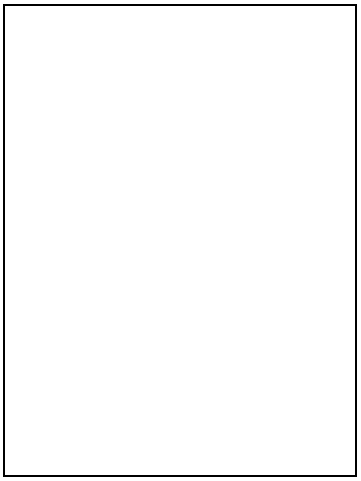
Siku/Mwezi/Mwaka

Jina la shahidi……

Sahihi…….

Tarehe…….

(Siku/Mwezi/Mwaka)



(iii) Sehemu ya tatu – Dhibitisho la mtafiti

Hii nikuidhinisha ya kwamba nimemueleza msimamizi wa mshiriki(mgonjwa) kwenye utafiti kuhusu utafiti huu na pia nimempa nafasi yakuuliza maswali. Nimemueleza yafuatayo;

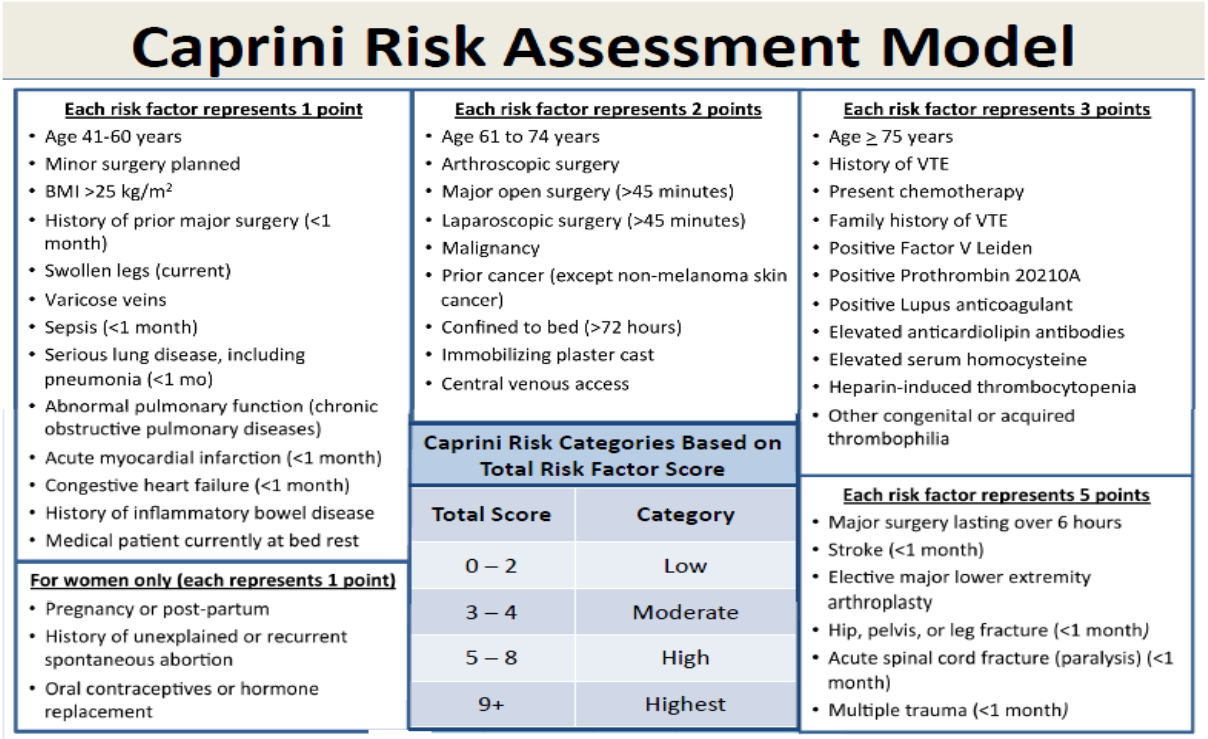
- Kwamba kushiriki ni kwa hiari yake mwenyewe bila malipo.
- Kushiriki hakutasababisha madhara ama kuhatarisha maisha kamwe.
- Anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuhatarisha matibabu anayoyapata katika hospitali kuu ya Kenyatta(KNH).
- Habari ambazo atapeana hazitatangazwa hadharani bila ruhusa kutoka kwa mshiriki na pia kutoka kwa mdhamini mkuu wa utafiti wa hospitali kuu ya Kenyatta na chuo kikuu cha matibabu (UoN).

Jina la anayesimamia mshiriki ……

Sahihi……..

Tarehe…….

Appendix III: Caprini Risk Factor Assessment Tool



Caprini Risk Assessment Model

Each risk factor represents 1 point

- Age 41-60 years
- Minor surgery planned
- BMI >25 kg/m^2
- History of prior major surgery (<1 month)
- Swollen legs (current)
- Varicose veins
- Sepsis (<1 month)
- Serious lung disease, including pneumonia (<1 mo)
- Abnormal pulmonary function (chronic obstructive pulmonary diseases)
- Acute myocardial infarction (<1 month)
- Congestive heart failure (<1 month)
- History of inflammatory bowel disease
- Medical patient currently at bed rest

For women only (each represents 1 point)

- Pregnancy or post-partum
- History of unexplained or recurrent spontaneous abortion
- Oral contraceptives or hormone replacement

Each risk factor represents 2 points

- Age 61 to 74 years
- Arthroscopic surgery
- Major open surgery (>45 minutes)
- Laparoscopic surgery (>45 minutes)
- Malignancy
- Prior cancer (except non-melanoma skin cancer)
- Confined to bed (>72 hours)
- Immobilizing plaster cast
- Central venous access

Caprini Risk Categories Based on Total Risk Factor Score

Total Score	Category
0 – 2	Low
3 – 4	Moderate
5 – 8	High
9+	Highest

Each risk factor represents 3 points

- Age ≥ 75 years
- History of VTE
- Present chemotherapy
- Family history of VTE
- Positive Factor V Leiden
- Positive Prothrombin 20210A
- Positive Lupus anticoagulant
- Elevated anticardiolipin antibodies
- Elevated serum homocysteine
- Heparin-induced thrombocytopenia
- Other congenital or acquired thrombophilia

Each risk factor represents 5 points

- Major surgery lasting over 6 hours
- Stroke (<1 month)
- Elective major lower extremity arthroplasty
- Hip, pelvis, or leg fracture (<1 month)
- Acute spinal cord fracture (paralysis) (<1 month)
- Multiple trauma (<1 month)

Appendix IV: Questionnaire

Data Collection Sheet

Date of admission	
Patient identification code	
sex	
Confined to bed for (a) <72 hours (b) >72 hours	
Diagnosis	
Type of surgery - minor (<45 Min) _____ - Major (>45 min) _____ - open_____ - Laparascopic_____ - combined_____	
Any thromboprophylaxis given (a) Preoperatively _____ (b) Day 1 post operatively _____ (c) At discharge _____ If yes i. Which one (a) pharmacologic_____ (b) mechanical_____ If pharmacologic ii. dosage_____	
Any cancer treatment_____ If yes a. chemotherapy_____ b. radiotherapy_____	
1 point for each risk factor	**points**

Age 40-60 years	
Acute mi (<1month)	
BMI >25	
CHF exacerbation (1 month)	
History of inflammatory bowel disease (IBD)	
Procedure with local anesthesia	
Swollen legs/varicose veins (current)	
Sepsis(1 month)	
Severe lung disease e.g. pneumonia (<1 month)	
1 point for women only (for each risk factor)	
Oral contraceptives or HRT	
Pregnancy or postpartum (< 1 month)	
History of unexplained stillborn infant, spontaneous abortion (≥3), premature birth with toxemia or growth restricted in ant	
2 points for each risk factor	
Age 61-74 years	
Central venous access insitu	
Immobile >72 hours	
Leg plaster cast or brace	
Malignancy	
Surgery >45 minutes	
3points for each risk factor	

Age >75	
Established thrombophylia	
Heparin Induced Thrombocytopenia (HIT)	
History of Superficial Venous Thrombosis/ Venous Thromboembolism	
Family history of VTE (first degree relative)	
5 points for each risk factor	
Acute spinal cord injury (< 1 month)	
Stroke (< 1 month)	
Total points	

Turnitin Originality Report

ASSESSMENT OF VENOUS THROMBOEMBOLISM RISK AND PROHYLAXIS PRACTICES AMONG ELECTIVE SURGICAL PATIENTS AT KENYATTA NATIONAL HOSPITAL by Patrick Mwangi Muchunu

From General Surgery (Medicine)

- Processed on 07-Feb-2018 18:39 EAT
- ID: 912491510
- Word Count: 6055

Similarity Index
13%
Similarity by Source
Internet Sources:
7%
Publications:
8%
Student Papers:
4%