HARAMAYA UNIVERSITY
SCHOOL OF GRADUATE STUDIES

Clinical Presentation and Associated Risk Factors among Deep Vein Thrombosis Admitted to Medical Ward at Hiwot Fana Specialized University Hospital

A RESEARCH PROPOSAL TO BE SUBMITTED TO THE SCHOOL OF MEDICINE IN PARTIAL FULFILLMENT OF COMPLETION OF SPECIALITY IN INTERNAL MEDICINE

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Lists of Acronyms

BMI Body Mass Index

CHF Chronic Heart Failure

DC Data collector

DVT Deep Vein Thrombosis

HFSUH Hiwot Fana Specialised University Hospital

NS Nephrotic Syndrome

OCPs Oral Contraceptive Pills

PE Pulmonary Embolism

PI Principal Investigators

PTE Pulmonary Thromboembolism

TB Tuberculosis

US Ultrasound

USA United States of America

VTE Venous Thromboembolism

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Abstract

Background: Venous thromboembolism is one of the common cardiovascular diseases resulting in substantial morbidity and mortality worldwide. It comprises of deep vein thrombosis and pulmonary embolism. Symptomatic deep vein thrombosis is common cause of morbidity in both hospital setting and general population. The main risk factors for development of **DVT** are immobilization, various hypercoagulable states and tissue injury. Swelling and pain of the involved limb are the main manifestations of symptomatic deep vein thrombosis. The most series complication is pulmonary embolism which is documented as the major cause of preventable hospital death. Identification of primary risk factors using risk assessment with subsequent anti-thrombotic prophylaxis is crucial in reducing the morbidity and mortality associated with Venous thromboembolism.

Objective: To determine the clinical presentation and associated risk factors in patients admitted with diagnosis of deep vein thrombosis to medical ward at Hiwot Fana Specialized University Hospital, Harar, Ethiopia from 11/10/10 – 01/06/2019

Methodology: Retrospective cross-sectional study will be done by reviewing medical record charts of patients diagnosed with deep venous thrombosis admitted to medical ward at Hiwot Fana Specialized University Hospital from September 2009 to September 2018.The data will be collected using structured checklist from medical records of each patient. Data entry and analysis will be conducted using SPSS version software package. Both bivariate and multivariate logistic regression analysis will be done to determine the **effec**t of independent variables on deep vein thrombosis. The degree of association between independent and dependent variables will be assessed using adjusted odds ratio with 95% confidence interval and p-value <0.05.

Expected Outcome: Immobility and Pregnancy related factors are expected to be mostly associated factor with deep vein thrombosis because of tradition of inactivity of pregnant women after giving.

Budget: The total budget by will be 28,313EBR

Key Words: Deep vein thrombosis, pregnancy and postpartum, Hiwot fana Specialized University hospital

1. INTRODUCTION

1.1. BACKGROUND INFORMATION

Deep vein thrombosis (DVT) and pulmonary embolism (PE) are a continuum of the same disease. They are collectively termed as venous thromboembolism (VTE).[1] VTE is the major cause of morbidity and mortality in both hospitalized patients and in the general population. It is the third most common cardiovascular disease next to Ischemic heart disease and cerebrovascular accident. [2]

There are around 10 million cases of VTE each year worldwide.[3] Over 300,000 patients in United States of America(USA) and around 500,000 patients die in Europe as a result of complications of VTE each year.[4] There are scarcity of published studies on the prevalence of VTE in Africa.According to the study done in Nigeria by Sotunmbi et al the prevalence of VTE is 2.9%, with increased risk in male patients and in patients with cancer. [5]

DVT is mostly affects the deep veins of lower extremity(femoral vein, popliteal vein),other veins like deep veins of upper extremity, deep veins of the pelvis, mesenteric and cerebral veins can be affected.[6]DVT of lower extremity is classified as proximal and distal DVT. The proximal lower extremity DVT is thrombus that located in iliac, femoral and popliteal veins while distal DVT involves calf veins where most of thrombus originates.[7]

Thrombus formation is a natural process develops when there is an injury to the blood vessel resulting exposure of collagen and triggering platelet aggregation and formation of platelet plug to prevent bleeding. Our body has also natural occurring antithrombotic system to prevent excessive thrombus formation. When there is a mismatch between the two systems resulting in excessive thrombus formation which become pathological and results in formation of thrombus. [8]

The pathogenesis of venous thrombosis is delineated by major theory called Virchow's triad. It is proposed as VTE occurs as a result of immobility (stasis), hypercoagulable states either inherited or acquired and vascular endothelial injury. [9]

The most common inherited conditions associated with development of venous thrombosis are prothrombin gene and factor V leiden mutation, which are responsible for more than half of the cases. Protein C and S deficiency and antithrombin deficiency account for the remaining cases.[10] Due to limitation in investigation modalities these factors are not included in this study.

There are multiple acquired risk factors resulting in DVT this include previous VTE event, malignancy, surgical procedures, major trauma, pregnancy, drugs like OCPs, prolonged immobilization, renal diseases like nephrotic syndrome, cardiovascular risk factors like age, smoking, obesity and infections like HIV are the major causes of acquired factors in development of deep vein thrombosis. [5]

DVT diagnosis is based on the risk factors, sign and symptoms complimented with investigative procedures. However up to 50% of patients with VTE are asymptomatic. Symptomatic DVT patients present with pain, tenderness along the involved deep led veins, swelling, erythema or cyanosis.[11] There is pretest probability scoring system in patients suspected to have DVT called Wells score developed in 1995. [8]

This pretest probability score is based on clinical signs, symptoms and risk factors. Using the Wells score patients with a score of ≥ 3 are classified as high risk, those with a score of 1 or 2 as moderate risk and those with a score of ≤ 0 as low risk. Well's score is further used to stratified patients into categories of DVT likely if the clinical score is more than 1 and DVT unlikely if the score is 1 or less. [12]

Table 1: pretest probability of deep vein thrombosis

Clinical Features	Score
Active cancer (treatment ongoing or within the previous six months or palliative)	1
Paralysis, paresis, or recent plaster immobilization of the lower extremities	1
Recently bedridden for more than three days or major surgery, within four weeks	1
Localized tenderness along the distribution of the deep venous system	1
Entire leg swollen	1
Calf swelling by more than 3 cm when compared to the asymptomatic leg (measured below tibial tuberosity)	1
Pitting edema (greater in the symptomatic leg)	1
Collateral superficial veins (nonvaricose)	1
Alternative diagnosis as likely or more likely than that of deep venous thrombosis	-2
Score	
DVT likely	2 or greater
DVT unlikely	1 or less

Due to the serious complications associated with DVT early detection and diagnosis are important in assessing thromboembolic risk and initiating therapy. Clinical diagnosis of suspected DVT patients are often difficult and mostly not accurate in detection of DVT in which up to 50% of cases are missed Imaging modalities are necessary to make the clear diagnosis.[13] Contrast enhanced venography provided that the patient has normal renal function, it is the standard of reference when compared to other imaging modalities. The sensitivity and specificity for diagnosis of DVT is 88–100% and 92–100%,respectively. [7]

Doppler compression ultrasound with real-time, B-mode imaging is now the preferred choice of imaging DVT in patients with high or moderate pretest probabilities. Amongst its advantages includes its noninvasive nature, reliability, availability and safety.[21] The major diagnostic criterion for venous thrombosis by compression ultrasound scan is demonstration of venous non compressibility[14].

1.2. STATEMENT OF THE PROBLEM

VTE is one of the leading cardiovascular diseases challenging the health care system as world is shifting from communicable disease to non-communicable disease. Worldwide in 2010 one in four deaths are due to thrombosis, which encompass stroke and heart attack in addition to VTE. VTE is one of the most common causes of preventable in hospital deaths worldwide.[15] Mortality rate due VTE in US ranges from 19.4 to 32.3 per 100,000 in 2000. [16]

DVT results from abnormal thrombus formations in deep veins mostly in the extremities. These thrombi propagate to pulmonary vasculatures and result in pulmonary embolism, which is associated with significant morbidity and mortality.[17] Primary prevention of DVT based on risk assessment and subsequent thrombo-prophylaxis is essential to counter the high morbidity and mortality associated with DVT.[18] Identifying at risk patients and early diagnosis and treatment are important to prevent the serious complications associated with DVT.

The main identified risk factors for DVT are immobilization(63%), recent hospitalization(25%), recent surgery(36%), trauma, cancer(16%), inherited and acquired hypercoagulable states and cardiovascular risk factor, inherited factors account for 7% to 22% of the population attributable risk in the elderly.[19] Approximately 60-80% of DVT cases are associated with recent hospitalization and cancer associated. The remaining are burden is due to unprovoked DVT with no known risk factors or only minor factors.[20]

The main clinical presentations of symptomatic DVT are swelling and pain of involved limb followed by erythema and tenderness. But there is variation in risk factors and presentation among different communities worldwide.[21] Public awareness to VTE (44%) is also lower when compared with heart attack (88%) and stroke (85%).[19]

There are limited documentation on patient characteristics in patients with DVT in developing countries particularly Ethiopia. Knowing patient characteristics and presentation is important in preventing the documented mortality associated with the complications of DVT. In addition, despite the morbidity and mortality associated with DVT there is no guideline for anti-thrombotic prophylaxis for high risk hospitalized patients in HFSUH medical ward. Ma thesis……is des

1.3. SIGNIFICANCE OF THE STUDY

As disease characteristics are not the same among populations in different countries due to different in lifestyles, ethnic background, health seeking behavior, advances in diagnosis and treatment. There are also limited studies done on presentation and risk factors of DVT in Ethiopia and none of them in HFSUH in the city of Harar.

This study will have substantial input to the health care system in identifying the major clinical manifestation and associated risk factors in patients to DVT. Since early detection and treatment can change the course of the disease.

Since this study is the first of its kind in HFSUH located in the city of Harar it will also lay a foundation for future studies on this field.

Benefits of the study

1.4. OBJECTIVE OF THE STUDY

1.4.1. GENERAL OBJECTIVE

The objective of this study is to determine clinical characteristics and associated factors in adult among deep venous thrombosis patients admitted to medical ward at Hiwot Fana Specialized University, Harar from September 2009 to September 2018.

1.4.2. SPECIFIC OBJECTIVES

- ✓ To assess clinical characteristics of patients with DVT admitted to medical ward at HFSUH

- ✓ To identify associated factors with DVT in medical patients admitted to HFSUH

2. LITERATURE REVIEW

2.1 Clinical Manifestation of DVT

Worldwide doubling of life expectancy in 20th century is marked by a transition from infectious to non-communicable diseases as the major causes of mortality and morbidity. Venousthromboembolism (VTE) is one of the three major cardiovascular diseases contributing to the burden caused by non-communicable diseases. [22]

Major clinical manifestation of DVT are divert from asymptomatic to swelling of involved limb, pain, erythema and warmth. The most commonly involved leg is left leg in pregnancy. [23] This may be due to compression of right iliac artery on left iliac vein. According to study done in Iran, 2003 on demographic characteristics and risk factors of DVT showed that 18.6% of patients have also PTE, only 4 of 139 patients involved in this study have family history of DVT, the most commonly involved veins are femoral vein(69.2%), popliteal vein(53.3%) followed by Iliac vein and veins of upper extremity.[24]

In study done in Brazil Clinica Aurea in 2013 to assess correlation of clinical features with the risk of lower limb DVT 192 patients with confirmed DVT are identified. External iliac vein is most commonly involved vein followed by femoral vein. In this study the most common clinical features were swelling and pain 68% and 57% respectively. In addition, 79(15%) patients undergone recent surgery in the past one month, 93(17) are patients with diagnosis of cancer.[25]

In study done in Cameroon 2018 on epidemiology, clinical presentation and in hospital mortality of VTE from total 113 patients 47 patients are diagnosed with DVT. According to the results of this study the most common clinical presentation was swelling of lower leg (89%), pain (78%) followed by Homans sign positivity and calf stiffness.[26]

In prospective cross sectional study done at TikurAnbessa specialized university hospital in Addis Ababa, Ethiopia 81 cases of ultrasound confirmed DVT patients from 2011 to 2012 identified and assessed for the associated risk factor. From the total patients females were greater in number (65.4%) and most patients were under the age of 40 (58%). The most common clinical presentation were swelling (93.8%) followed by pain (70.4%). The most common risk factor associated with DVT were found to be cancer (30.9%), prolonged immobility (19.8%), pregnancy and postpartum(6.2%) and trauma cases (6.2%) were noted in this study.[27]

2.2. Associated factors with Deep Vein Thrombosis

The incidence of VTE is 1 per 1000 yearly in adult population worldwide.[28] It is higher in males than females slightly. In United states the national prevalence of VTE is studied over 5 year period of time from 2002 t0 2006 showed that from 12.7 million enrollees the prevalence of VTE is 3.2 and 4.2 per 1000 enrollees in 2002 and 2006 respectively, the national prevalence is 0.95 million cases according to data in 2006. According to this study older patients have higher prevalence. The prevalence in patients greater than 65 years old is 13.8 per 1000 enrollees but in patients less than 65 years the prevalence is 3.2 per 1000 enrollees. [29]

In another study done in US by the same author, shows ethnic difference in the prevalence of DVT the highest being among African Americans and the least is in Hispanic individuals. [30]

Incidence of DVT in patients with HIV is two to ten times increased in comparison withgeneral population. The increased risk is due to hypercoagulable state associated with HIV infection.[31] Studies from United States supports there is increased risk of clinically detected VTE in patients with HIV infection. Study done by Malek*et al* HIV infected patients are significantly higher odds ratio of 50% than HIV negative patients. Other study done in South Africa in retrospective review of confirmed DVT patients in Urban Cape Town Public Hospital 64% of patients are HIV infected and 43% of patients were infected with both HIV and TB.[25]

Pregnancy is one of main risk factors for development of increased thrombotic incident. The incidence of VTE in pregnancy is 13 per 10,000 deliveries. The risk is of VTE is 5 to 6 fold during pregnancy. The increased risk is due to hypercoagulable state in pregnancy to decrease bleeding risk.[31]

According to retrospective study done in Nara Medical University School in Japan in the year 2016 there were 25 cases of VTE cases out of 9,041 deliveries during pregnancy and postpartum period 16 and 9 respectively. The risk of VTE is highest during early periods of pregnancy in this study two thirds of cases of DVT are occurred in the first trimester. This is due to increased early pregnancy problems like immobility and hyperemesis. There is also increased susceptibility in patients with cesarean delivery when compared with vaginal delivery in postpartum period.[32]

The risk of VTE in estrogen containing oral contraceptive users is high when compared with non-users although the absolute risk is low. An absolute risk of VTE of less than 1/10,000 patients/y increased to only 3 to 4/10,000 patients/year during the time oral contraceptives were used. According some studies there were no difference in risk of the VTE among different doses of estrogen level.[33]

Reports of relation of duration of OCP use and VTE risk are inconsistent with some studies shows increased risk in long duration of use and other studies showed the opposite effect. [34]

In Africa the epidemiologic data's are limited and the most authors estimate the prevalence of VTE to be around 1.2% to 3.1%.[19]In study done in Burkina Faso cardiology department in 2014 VTE admissions are second after to heart failure.[35]

In study done in Iran Rasoul-e-Akram Hospital 2013 a descriptive cross sectional study on demographic and risk factors of DVT confirmed by Doppler ultrasound over 5 year period 371 patients enrolled with male to female ratio of 232/139. In this study the main risk factor identified was prior history of hospitalization the main causes of admissions are lower respiratory tract infections, cardiac illnesses and cancer and chemotherapy. 35.8% of patients have history of recent surgery because of trauma or general operative procedures.

In addition this study also shows 21.8% of the patients with diagnosis of DVT are pregnant at time of admission.[24]

A total of 81 patients confirmed DVT are identified I study done in Kwazulu-Natal public hospital in Zambia over a period of 7 months in 2014. The median age was 40 years and there were higher number of femalescomprising of 59(72%) of the total 81 patients. The most common presentations were swelling and pain of the involved limb. The most common identified risk factors in this study are HIV and TB infection 42 and 29 respectively. Other risk factors identified in this study in descending order are recent hospital admission, prior history of DVT and heart failure.[36]

In prospective study done in Burkina Faso university hospital in 2014 total of 194 patients with confirmed VTE were admitted to cardiology department over 17 months. From the total number of patients PE is higher in number compared with DVT, 50.5 of PE casesversus 38% of DVT cases the rest were present with both DVT and PE. In this study the mean age of patients were 49 years and females were accounts for 56.7% of cases. The most common risk factor identified in this study were immobility in 38.5% of cases, obesity in 3% of cases and pregnancy and postpartum in 20.6% of cases. No risk factors were identified in 11.8% of patients. In addition, the most common comorbid conditions in descending order were anemia, hypertension, renal failure and diabetes mellitus.[37]

In retrospective study done in hospitals in Kimberley, South Africa from 2010 to 2014 852 patients were diagnosed with DVT in radiology department. Among those patients majority of them were female patients (62.9%), the median age was 45 the highest percent of patients were age greater than 60 (22.9%). From the total patients more than half of the patients were HIV positive (52%). The most common risk factors were Tuberculosis 106(12.4%) mostly in HIV positive patients, other associated factor were cancer, smoking, immobility, previous history of DVT, pregnancy and postpartum and heart failure.[38]

In retrospective cross-sectional study done in University Teaching Hospital in Lusaka, Zambia in 2016, 296 hospitalized medical patients are studied for prevalence and risk factors of DVT. According to this study the mean age was 42.2 years and the most common associated factor is HIV infection (69.7%), followed by heart failure, renal failure, active malignancy and stroke. This study also showed that patients with DVT have lower BMI when compared with non DVT patients.[39]

A retrospective cross sectional descriptive study conducted in Douala General Hospital, in Cameroon over 6 years between 2008 up to 2014 patients confirmed with VTE (78) are included, out of 78 cases 37(47.4%) are diagnosed with DVT and 10 (12.8%) of them DVT with PE, and the rest were PE cases. The most common associated risk factor were obesity (44.9%) followed by hypertension (37.2%) and immobility (37.2%). The most common clinical presentations were lower limb swelling and pain in patients with diagnosis of DVT. Homan sign was positive in 24 (51.1%) in DVT patients.[26]

2.3 Conceptual Framework

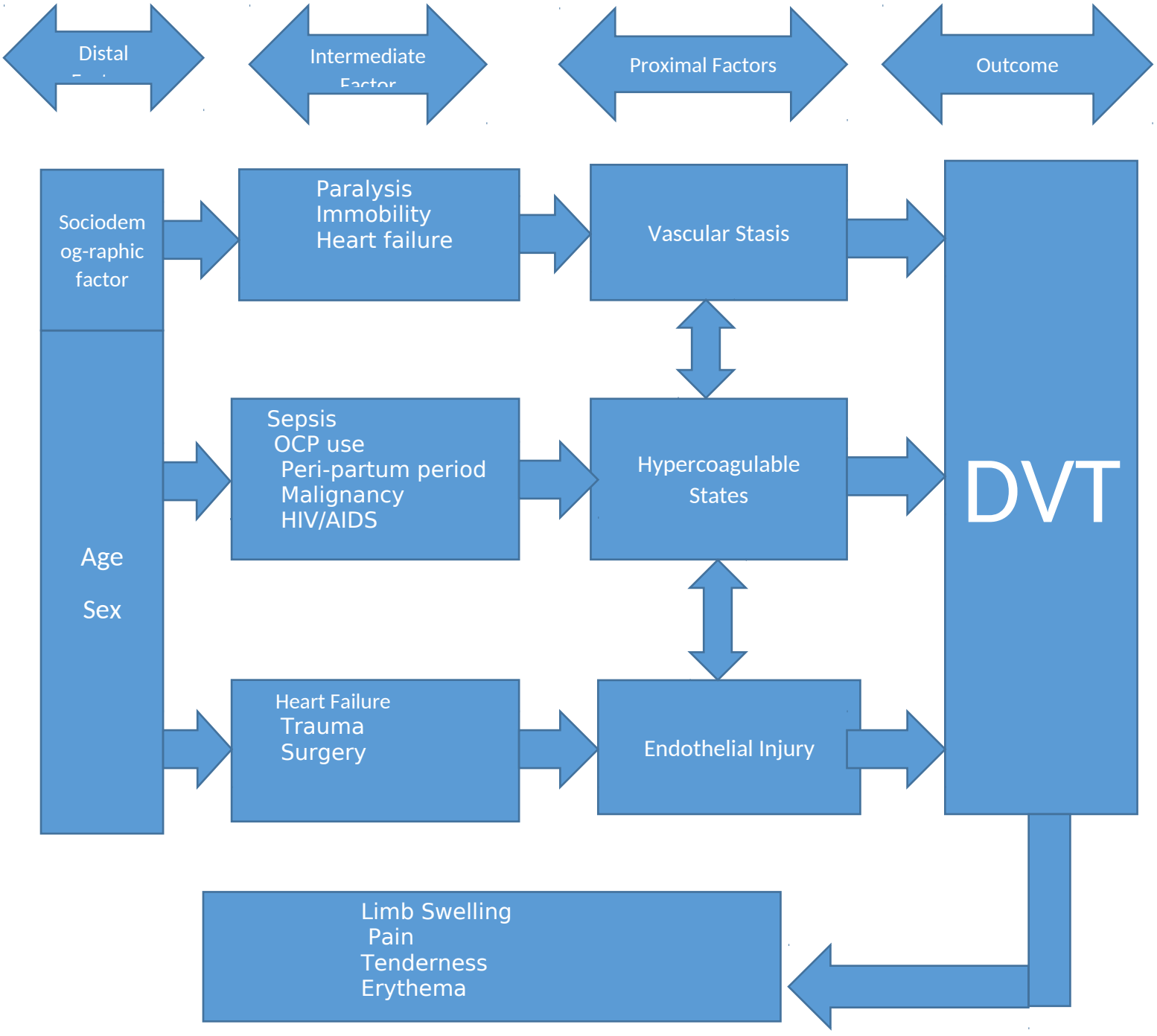

Figure 1: Conceptual framework showing factors affecting development of DVT

Developed by investigator after reviewing literatures.

3. METHODS AND MATERIALS OF THE STUDY

3.1. Study Area and Period

The study will be conducted in Hiwot Fana Specialized University Hospital in the city of Harar, Ethiopia from data collection per.

Harar is a walled city in the eastern Ethiopia. It is a capital of Harari region. The city is located on a hilltop in the eastern extension of the Ethiopian Highlands, about five hundred kilometers from the national capital Addis Ababa at an elevation of 1,885 meters.[40] There are nine woredas in Harari region, under the woreda there are 19 city kebeles and 17 rural kebeles. The State's size is estimated at 340 km2.The Harari National Regional State (HNRS) is populated by 183,344 people (CSA 2007). The percentage share of males and females is about 50% each. The urban residents of the State were 99,321 while its rural inhabitants were 84,023.[41]

According to the current regional health bureau, there are University hospital, Government Hospital, Army Hospital, Federal Police Hospital, two private Hospitals, one non-government (Fistula) hospital, eight Health Centers,twenty nine private clinics, twenty six health posts and one regional laboratory serving the people of the state.[41]

Hiwot Fana Specialized University Hospital is one of the hospitals in the city administered under Haramaya University. It serves as the Referral Hospital for the State and East Harage. It has four main departments; Internal Medicine, Gynecology and Obstetrics, Surgery, and Pediatric with 33, 42, 50 and 60 beds respectively. The medical ward has female and male wing and intensive care unit. In my experience the trends on DVT is not as rare as in literatures, in our ward specially those who are in post partal period.

3.2. Study Design

Hospital-based retrospective cross sectional study will be conducted on patients admitted to medical ward with diagnosis of DVT.

3.3. Source Population

All patients admitted to HFSUH medical ward from September 2009 to September 2018.

3.4 Study Population

All patients with diagnosis of DVT admitted to HFSUH medical ward from September 2009 to September 2018.

3.5. Inclusion and Exclusion Criteria

3.5.1. Inclusion Criteria

- All patients with diagnosis of Deep vein thrombosis

3.5.2 Exclusion Criteria

- Lost medical record chart
- Incompletes data

3.6. Sample Size

The sample size will be determined by using the following formulae

$$n = \frac{Z^2 p\,(1 - p)}{w^2}$$ and

Where n= the minimum sample size required

p= proportion of population, which was found to be 40% (0.4) taken from study done in University teaching Hospital in Lusaka, Zambia 2016.

W=margin of error expressed in proportion (0.05)

N_f =final sample

$n = \frac{(1.96)^2 \times 0.4 \times (1-0.4)}{(0.05)^2}$ n= 220

Adding 10% lost medical record to the above figure

$N_f = \frac{220 \times 10}{100} = 22$ 220 + 22 =**244**

The final sample size will be 240.

The final sample size will be 240, but in this study we included all the patients admitted with DVT diagnosis in the past 10 year from the time medical recording started.

3.7. Sampling Procedure

After reviewing medical record chart at at HFSUH patients admitted with diagnosis of DVT are under the calculated sample size, which was 244. So we included all patient admitted with the diagnosis of DVT since 2009 the time the hospital is taken under administration of University and formal recording is started under University administration.

3.8. Data Collection Method

3.8.1. Data Collection Tools

Data will be collected from individual record charts using structured checklist prepared by principal investigator that will be developed by English.

3.8.2. Data Collectors

Data will be collected from medical record chart of each patient by six trained Medical interns and me. From the six medical interns one medical intern also act as supervisor to coordinate data collecting process. One day training will be given to data collectors and supervisor by principal investigator.

3.8.3 Data Collection Procedures

Data will be collected using pre-tested structured checklist prepared in English-language. Charts of patients with the diagnosis of DVT will be retrieved from log book at medical ward HFSUH who are admitted over the study period. The medical record chart with diagnosis of DVT will be collected from the hospital card room and will be used by data collection team to fill a questionnaire. Data will be collected from March 1st to 30th 2019. Data will be pre tested on medical record charts DVT diagnosed patients by taking 5% of sample size, and the result of pre-test will be analyzed and necessary modification will be made prior to the start of the actual study.

3.9. Variables

3.9.1 Dependent Variable

The dependent variable to be tested in this study is DVT.

3.9.2 Independent Variables

Age, sex, occupation, pregnancy, immobility, chronic heart failure, Nephrotic syndrome, recent surgery, recent history of trauma, HIV AIDS, malignancy, paralysis are the main independent variables believed to affect the dependent variables.

3.10. Operational Definition

Deep Vein Thrombosis (DVT): When blood clots formed in one of deep veins of extremity. In this study DVT is diagnosed based on doppler compression ultrasound scan. Its sensitivity for proximal DVT is 95-100%.[42]

Adult: Patients age greater than or equal to 18 years old.

Immobilty: Patients bedridden for greater than three days.[43]

Recent Surgery: A patient who undergone major surgical procedure in the past 12 weeks. [44]

Leg swelling: Discrepancy of greater than 3cm between the two limbs.[45]

Puerperal period: The period after delivery up to 6 weeks.[46]

Body Mass Index (BMI): Calculated as: weight in kg/ (Height in meters)^2

<18 under weight
18-24 Normal
25-29 overweight
30-34 Obese
>35 Morbid obese [47]

Recent Hospital admission: Any admission to hospital in the past 3 month

Leg Swelling: Swelling of limb with discrepancy greater than 3cm

3.11. Data quality control

The data collection team will be trained on data collection process and one medical intern is also trained on supervising the overall process.Completeness, accuracy and consistency of data collection will be checked on each day of the data collection period before using the filled questionnaires. Data will be cleaned and filled to SPSS statistical software version 20 by the principal investigator.

3.12. Methods of Data Processing, Analysis and Management

After data collection is complete, the data will be edited and coded for processing and analysis. Data processing and analysis will be done using Epi info and using SPSS statistical software version 20 with the assistant of experienced data analyst. Bivariate analysis will be performed to asses the significance of the relationship between deep venous thrombosis and variables using Pearson's Chi-square test, while controlling the effects of other characteristics, multiple logistic regression will be used to assess a possible relationship between DVT and risk factors. The results will be presented in the form of tables, figures, and text using summary statistics like mean, median, standard deviation to describe the study population. The degree of association between dependent and independent variables will be assessed using odds ratio with 95% confidence interval and P-value <0.05.

3.13. Ethical Consideration

Ethical clearance will be secured from the Ethical committee of Haramaya University College of health and medical sciences prior to data collection. Official permissions will be asked from HFSUH administration and inpatient director. Information gained from medical record charts will be held anonymous and confidential.

3.14. Expected Outcome

Since in this study only symptomatic deep vein thrombosis is included swelling and pain of involved limb will be the common presentation. From associated factors excluding inherited factors, immobility and pregnancy related will be more commonly associated with development of deep vein thrombosis.

3.15. Information Dissemination

The finding of the study will be submitted to the department of Internal Medicine, School of Medicine and College of Health and Medical Sciences Haramaya University in partial fulfillment of the requirements for the degree of doctor of medicine. The copy of the research will be given to the hospital as well. The finding will also be presented for different work-shops and seminars and will be published in a peer reviewed journal.

3.16. Limitation of the study

For development of deep vein thrombosis inherited factors are also responsible for significant account but due to the limitation of investigational agents they are not included in this study. And also asymptomatic cases are also not included since there is no regular screening for admitted patients.

4. Work plan

Table 2; Work plan for the study on clinical presentation and associated factors in patients admitted to medical ward HFSUH.

Activities	**Responsible body**	Jan 2019	Feb 2019	Mar 2019	Apr 2019	Nov 2019	Dec 2019	Jan 2020
Topic selection	PI							
Proposal development	PI							
Ethical Review	IHRERC							
Training of Data collectors	PI							
Pre testing	PI							
Data collection	PI and DC							
Data management	PI							
Analysis and result writing	PI and RA							
Final thesis submission to school	PI							
Final thesis submisiion to SGS	PI							
Final thesis defence	PI							
Result dissemination	PI and RA							
Monitoring and evaluatioon	PI and RA							

5. Budget Breakdown and Source of the Budget

5.1. Budget Breakdown

Table 3: Budget needed to study the clinical presentation and associated factors of DVT

S. No	Cost item	Unit	Amount required	Unit price (ETB)	Total price(ETB)	Remark

I. Personal Cost						
1	Data collector fee	Per person	4 person x 30 days	171.00	20,520	
2	Secretary fee	,,	80 pages	10.00	800	
II. Stationary cost						
1	Duplicate papers	Pack	2	100.00	200	
2	Pencil	Each	4	5.00	20	
3	Pen	,,	8	10.00	80	
4	Eraser	,,	4	5.00	20	
5	Binder	,,	4	50.00	200	
6	CD	,,	2	25.00	50	
7	Ruler	,,	4	15.00	60	
III. Miscellaneous cost						
1	Telephone	,,	100min/person	40.00	160	
2	Internet	,,	1GB/person	100.00	400	
3	Transport	"	50 hours	5.00	250	
				Total	**22,760**	
				Contingency	**2,276**	10% contingency is used
				Grand Total	**25,036ETB**	

5.2. Budget Summary

Table 4: Budget summary for the study to be conducted on to assess clinical a manifestations and associated factors in patients admitted to Hiwot Fana Specialized University Hospital medical ward.

No	Budget Category	Total Cost in ETB
01	Personnel	21,320
02	Stationary Supply	630
03	Miscellaneous	810
	Sub Total	22,760
Grand Total		25,036

NB: All the payments are covered by Haramaya University, College of Health and Medical Sciences.

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7. Annexes

Annexe 1: Information sheet and informed voluntary consent form for hospital

Annexe 2: Data Collection check list

Instructions: write the required information or put"√ "mark in the space provided

Date: _____/_____/_____ Code no:_____

I. Socio-demographic variables

1. Age in years: _____
2. Sex: _____
3. Occupation: _____
4. Address: _____
5. Residence

A. Urban: _____ B. Rural: _____

II. Baseline laboratory results

1. WBC with differential count_____ ____Hgb/Hct _____Platelet _____
2. Organ function tests

A. Liver Function test: SGOT_____SGPT_____

Other_____

B. Creatinine_____

II. Clinical presentations

1. BMI_____

2. Cigarette Smoking_____ Amount in pack/year_____

3. Presenting symptoms

A. Leg swelling: Right _____ Left _____
B. Warmth _____
C. Leg pain_____
D. Erythema_____
E. Other _____

4. Wells Score

A. Zero_____ B. One or two_____ C. Greater or equal to three _____

5. Anatomic location of DVT by Ultrasound

A. Right Iliac vein_____
B. Left iliac vein_____
C. Right femoral vein_____
D. Left femoral vein_____
E. Right popliteal vein_____
F. Left popliteal vein_____
G. Others _____

6. Other diagnosis _____

7. Outcome: discharged improved _____ Pulmonary Embolism_____ Death_____ Other _____

IV. Associated Risk factors

1. Pregnancy _____ if yes 1st trimester_____2nd trimester _____ 3rd trimester _____
2. Postpartum _____if yes <6 weeks_____6 weeks to 6 month_____
3. Use of Oral contraceptive in the past (specify type) _____duration_____
4. Immobilization for greater than 3 days _____
5. Previous VTE_____
6. HIV AIDS _____
7. Tuberculosis (current)_____
8. Stroke in the past6 month _____
9. Malignancy_____ if yes specify_____
10. Heart failure _____ Specify cause _____
11. Renal failure_____ Cause _____
12. Surgery in the past 12 weeks _____if yes specify type _____

13. Trauma in the past 12 weeks_____ Specify _____
14. Diabetes mellitus _____
15. Hospital admission in the past 3 months _____
16. Family History f DVT_____-

Thanks

Annexe 3: CURRICULUM VITAE (CV)

1. Personal data

Name: Dr.Chala Mohammed

Date of birth: 1991 G.C

Place of birth: Fellana, Kombolcha woreda, East Hararghe

Sex: Male

Marital status……Unmarried

Nationality……..Ethiopian

Address……..Harar,

TEL—0972203354

E-mail chalagyne2014@gmail.com

2. Educational background
   - 2.1 . Graduated from Aboker preparatory School
   - 2.2 Graduated from Haramaya University with Doctoral degree in in 2014G.C with GPA of 3.19
   - 2.3 Year III resident in internal medicine speciality training
3. Work Experience
   - 3.1 Work as general physician at Haramaya Hospital for one year
   - 3.2 Work as Lecturer at Haramaya university school of medicine
4. Language proficiency

Language	Listening	Reading	Writing	Speaking
English	Excellent	Excellent	Excellent	Excellent
Amharic	Excellent	Excellent	Excellent	Excellent
Afaan oromo	Excellent	Excellent	Excellent	Excellent

5. Short term Training
   - 5.1 Basic training HAART, MDR TB, Malaria

6.References

Dr. Tekabe Abdosh (MD)…0911404990

Dr.Hussein Mohammed(MD)….0911006036

Annexe 4: Approval Sheet

ASSURANCE OF PRINCIPAL INVESTIGATORS

We the undersigned agree to accept all responsibilities for the scientific and ethical conduct of the research project. I will provide timely progress report to my advisor and seek the necessary advice and approval from my primary advisors in the course of the research. I will communicate timely to my advisors all stakeholders involved in the study including any source of funding for this research.

Name of the students: _____

Signature: _____

Date: _____

Approval of the Advisor

Name of the advisor:_____

Signature: _____

Date: _____