COLLEGE OF HEALTH AND MEDICAL SCIENCE

SCHOOL OF GRADUATE STUDIES

Prevalence, Treatment Outcome and Associated Factors of Deep Vein Thrombosis Among Patients Visiting Hiwot Fana Specialized University Hospital, Harar, Eastern Ethiopia, 2024

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December, 2024

Haramaya University, Harar

ACKNOWLEDGMENTS

I would like to express my deep and sincere gratitude to my research advisors strongly thank full Dr. Natan Muluberhan and Dr. Melaku Getachew for giving me the opportunity to do research and providing invaluable guidance throughout this research proposal development. I am extremely grateful for Haramya University College of Medicine and Health for facilitating the accomplishment of this research proposal.

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ACKROYNM AND ABBERVATION

CI confidence interval

ED Emergency department

FDVT First deep venous thrombosis

HFCSUH Hiwot Fana comprehensive specialized university hospital

HIV Human immune virus

HRT Hormone replacement therapy

IDDVT isolated distal deep venous thrombosis

IV Intravenous

JUMC Jima university medical college

OCP Oral contraceptive

OR Odds ratio

P Proportion

PE Pulmonary Embolism

PHD Philosophy of doctorate

RDVT Recurrent deep venous thrombosis

SD Standard deviation

TASH Tikur Anbessa hospital

SPHMMC St Paul Hospital millennium medical college

VTE Venous Thromboembolism

SUMMARY

Background: Venous thromboembolism is the third common vascular disease after coronary artery disease and stroke. Which is experienced by 2-5% of people during their lifetime. The condition occurs in two forms deep-vein thrombosis and pulmonary embolism. The annual rate of Deep Vein thrombosis urban areas is reported to be 0.5-1.6 in every 1000 people which is probably much higher in reality due to asymptomatic forms of the disease. Despite the high prevalence of Deep vein thrombosis in Ethiopia, there is a scarcity of published data on prevalence, factors contributing for treatment outcome of deep vein thrombosis particularly at Hiwot Fana comprehensive specialized University Hospital. Therefore this study aimed to assess the prevalence, treatment outcome and associated factors of deep vein thrombosis among patients visiting Hiwot Fana Comprehensive Specialized University Hospital, Harar, Eastern, Ethiopia.

Objective: To determine the prevalence, treatment outcome and associated factors of deep vein thrombosis among patients visiting Hiwot Fana Comprehensive Specialized University Hospital Harar, Ethiopia from June 30, 2020 to June 30, 2024 .The data will be collected from December 20, 2024 to 01, January 20, 2025.

Methodology: Institutional based cross-sectional study will be undertaken among 261 Deep Vein Thrombosis patients visiting Hiwot Fana Comprehensive Specialized Hospital during the study period of June 30, 2020 to June, 2024. A total of 261 Deep vein thrombosis patients from this study period will be reviewed using a structured checklist. Simple random sampling technique will be used to select patients' chart. The collected data will be entered in to EpiData Version 3.8 and exported to statistical package for social science version 25 for analysis. Binary logistic regression model will be used. All covariate which have P-value less than 0.25 in bivariable analysis will be entered for multivariable analysis and said to be significantly associated if P-value is less than 0.05 and strength of association will be presented by an adjusted odd ratio with 95% confidence interval.

Expected Outcome: At the end of study high prevalence and good outcome will be expected among Deep Vein Thrombosis patients visiting Hiwot Fana Comprehensive specialized hospital. Additionally, the associated factors that significantly related with Deep vein thrombosis outcomes will be also identified.

Estimated Budget: The budget calculated is 25,000 (twenty-five thousand birr) and it will be funded by Haramaya University.

Keywords: Deep vein thrombosis, Prevalence, treatment Outcome, Eastern Ethiopia

1. INTRODUCTION

1.1 Background

Deep vein thrombosis (DVT) is the formation of a blood clot in a deep vein that can lead to pulmonary embolism (PE), or post-thrombotic syndrome (PTS). Deep Vein thrombosis is a serious condition with an incidence of 10–30% of death after diagnosis within 1 month and most of the patients with DVT have long-term complications. Deep venous thrombosis is the third common cardiovascular condition next to myocardial infarction and stroke, and due to the aging population, it is nowadays a growing public health problem (Mengesha et al., 2022).

Deep vein thrombosis (DVT) of the pelvic limbs and pulmonary embolism (PE) are two clinical manifestations of the same clinical entity: thromboembolic venous disease. Thromboembolic venous disease is a vascular emergency because of the immediate risk of life-threatening Pulmonary embolism . In addition to the acute episode, it can also lead to post-phlebitic disease resulting in venous insufficiency or varicose veins. DVT is common in Europe, where the annual incidence is estimated at 120 per 100,000 population(Ikama et al., 2023).

Acute venous thromboembolism including deep vein thrombosis and pulmonary embolism is a common disorder, with an annual incidence of approximately 1 or 2 cases per 1000 persons. Patients with VTE have increased morbidity and mortality related not only to VTE but also to cancer, surgical procedures, and other medical conditions. Moreover, the burden of VTE may well be underestimated (Monreal et al., 2019).

Trauma patients have the highest risk of developing DVT. Trauma leads to significant physiologic changes that result in patients at elevated risk for thromboembolism. Serum levels of inflammatory cytokines, procoagulant micro particles, and thrombin are increased following traumatic injury. The increment of systemic inflammatory response results in a hypercoagulable state that increases the risk of developing DVT. Virchow’s Triad (Hypercoagulability, endothelial injury, and venous stasis) is the set of conditions that contributes to venous thrombosis., Virchow’s Triad is often present due to post-operative immobilization and protected weight-bearing following orthopedic surgery in trauma patients (Mengesha et al., 2022).

Venous thromboembolism is the most common preventable cause of hospital mortality and it has a great impact on life quality. It is the third most common cardiovascular disease after ischemic

heart disease and stroke. The incidence of VTE is estimated to be 122 per 100,000-years (DVT, 56 per 100,000; PE, 66 per 100,000) in a 35-year population-based study from United States. It is reported that the prevalence of VTE varies among different ethnic/racial groups, and Asian population have a lower incidence of VTE compared with Americans and Caucasians (Li et al., 2022).

The most common risk factors of DVT were immobilization (38%), malignancy (27%), and trauma or surgery (21%). Majority of the patients' thrombosis was located at the left leg (66%) and 8 patients had bilateral lower limb DVT. Femoral vein was involved in 52 patients (52%), while iliofemoral thrombosis was identified in 48 patients (48%). PE was identified in 58 patients (58%), including 3 massive and 55 non massive PE (Li et al., 2022).There was no statistical difference between the PE group and the non-PE group in terms of age, sex, and risk factors. The D-dimer level was associated with the existence of PE ($P = 0.038$). Patients with iliofemoral thrombosis had a similar incidence of PE compared with those with femoral thrombosis alone ($P = 1.000$) (Li et al., 2022).

Critically ill patients, especially complicated by bedridden, presence of hypo albuminemia, high SOFA score, elevated D-dimer, obesity and other infection, is considered a risk factor for venous thromboembolism. Hypoalbuminemia is associated with highly increased DVT risk (almost twofold higher risk) (Chen et al., 2021).

1.2 Statement of the problem

Venous thromboembolism (DVT) is among the three leading causes of cardiovascular disease worldwide. In developed countries, venous thromboembolism is already a serious public health problem and ranks among the main causes of mortality. Mortality from this disease is also increasing in none developed countries. The risk of DVT is increased after a patient has different risk factors. DVT affects 0.1% of people per year (Fall et.al., 2018).

The incidence rate of venous thrombosis was 35.2% (50 patients out of 142) in hospitalized patients at Jin Jan Hospital, Wuhan china. Moreover, the location of thrombus at the proximal extremity veins was 5.6% (n 1⁄4 8), while at distal extremity veins was 35.2% (n 1⁄4 50) of the patients(Yu et al., 2020).

Autopsy reports showed a prevalence of 2.9% to 3.8%, with an in-hospital incidence of 0.1% in Nigeria. Data on the epidemiology of VTE are scarce in sub-Saharan Africa (SSA), with an in-

hospital prevalence of 7%. The yield for acute pulmonary embolism (PE) was 37.5% for suspected cases(Kamdem et al., 2018).

The prevalence of confirmed DVT was 37.0% (658/1779) in men vs. 24.3% (730/2,998) in women ($p<0.001$). Among patients with confirmed DVT, proximal DVT was more common in men (59.6% vs. 44.5% in women, $p<0.001$).

The prevalence of DVT was determined to be 19.0% [95% confidence interval (CI) 18.2–19.9%], which significantly increased with Caprini score among Chinese >34,000 orthopedic patients(Zhang et al., 2023).

Venous thromboembolism is a serious condition with an incidence of 10% to 30% of people dying within 1 month of diagnosis and half of those diagnosed with a DVT have long-term complications(Mulatu et al., 2020).

Including Ethiopia, VTE is common in developing countries. Mortality rate is high, hospitalizations are frequent and associated with worse outcomes with high use healthcare cost. Moreover, in developing countries priority, is given to acute disorders, child and maternal health care, and control of communicable diseases; with little emphasis on non-communicable diseases. Advanced age, malignancy, trauma, post-surgery, obesity, chronic disease, pregnancy, oral contraceptive, long-term immobilization, and HIV infection are the most common risk factors for VTE reported from different studies (Kebede & Ketsela, 2022).

Particularly in this study area, the prevalence, outcome, and associated factors of DVT are not known. Therefore, this study aimed to assess the prevalence, outcome, and associated factors and of Deep Vein Thrombosis patients visiting Hiwot Fana Specialized University Hospital in Harar, Eastern Ethiopia.

1.3. Significance of the study

DVT prevalence, outcome and associated factors in adult emergency department in Ethiopia has not been researched and published till now. So, this research will serve as a bridge for further researches to be done in the future. It also plans to recognize the prevalence of DVT in ED and will help the department as well as the hospital in understanding the magnitude of DVT.

1.4 Objective

1.4.1 General Objective

To assess the prevalence, Treatment outcome of DVT and its associated factor among patients from June 30, 2020 to June 30, 2024 visiting at Hiwot Fana comprehensive specialized hospital Harar, Eastern Ethiopia from December 20, 2024 to, January 20, 2025.

1.4.2. Specific objectives

- ✓ To assess the prevalence of DVT among patients visiting Hiwot Fana comprehensive specialized hospital Harar, Eastern Ethiopia.
- ✓ To determine treatment outcome of DVT among patients visiting Hiwot Fana comprehensive specialized hospital Harar, Eastern Ethiopia.
- ✓ To identify associated factors of DVT among patients visiting Hiwot Fana comprehensive specialized hospital Harar, Eastern Ethiopia.

2. LITERATURE REVIEW

2.1. Prevalence of DVT

DVT is one of the common problem seen in the Emergency department. There are very few reports regarding the prevalence of DVT among Asian patients without routine prophylaxis, however one study done shows approximately 13-31% of medical critical care patients develop deep vein thrombosis (Padayachee et al.,2021).

A retrospective cohort study in China enrolling orthopedic trauma inpatients from seven tertiary and secondary hospitals during a 3-year period (from April 1, 2018 through April 30, 2021) , the prevalence of DVT was 19.0% [95% confidence interval (CI) 18.2–19.9%], which significantly increased with Caprini score(Zhang et al., 2023).

A systematic review done in south Africa, Cape town, the prevalence of deep vein thrombosis varied between 2.4% and 9.6% in postoperative patients, and between 380 and 448 per 100 000 births per year in pregnant and postpartum women (Wendelboe ,Raskob, et.al 2016).

A cross sectional study done in Rwandan university teaching hospitals states that proximal DVT was found in 5.5% of the study population, with similar rates in medical, pregnant and postpartum patients(Mugeni et al., 2019).A prospective study done in Cameroon among 1445 patients admitted for medical illnesses, a total of 79 venous thrombo-embolic diseases were detected (55 deep vein thrombosis, 14 pulmonary embolism, 9 post-phlebitic syndrome and 1 cerulae alba dolens) (Abah et al., 2016).

An institutional based cross-sectional study done in Bahirdar Felege Ghion Hospital ,among 196 trauma patients admitted at orthopedic ward ,showed that the prevalence of deep vein thrombosis was 4.1% (Mengesha et al., 2022). Another cross sectional study done at Hawassa university comprehensive specialized hospital among adult medical patients the overall prevalence of DVT was 10.6% [95% CI: 8.5%, 13.1%] (Alemu et al., 2023).

2.2 Treatment Outcome of DVT

A multicenter study done in Canada and United states McMaster University Medical Center, Hamilton, Ontario and University of Massachusetts Medical School, Worcester, MA states that Patients presenting with PE or isolated DVT experienced similar rates of subsequent PE, overall venous thromboembolism (VTE), and major bleeding during 3-year follow-up (5.9% vs. 5.1%,

15% vs. 17.9%, 15.6% vs. 12.4%, respectively). Mortality was significantly increased at 1month follow-up in patients initially presenting with PE (13.0% vs. 5.4%) - this difference persisted at 3 years (35.3% vs. 29.6%).(Spencer, 2008).

A Prospective study done at University School of Medicine, Cleveland, Ohio and University of Texas Medical School Health Science Center at Houston showed that Fifty-two (42%) of the 124 patients died. The cumulative incidence of death was 17% at 1 year and 39% at 5 year ,especially common among patients older than 75 years and those with cancer or stroke (5-year cumulative incidence, 66%, compared with 12% among other patients; *P*<.0001).

A prospective multicenter study done in Europe among 10 679 patients with acute VTE that were recruited in the VTE registry between May 2014 and January 2017,post thrombotic syndrome was detected in 27.8% of patients(Prandoni et al., 2023).

A cross-sectional descriptive study conducted at the Douala General Hospital, Cameroon in 2018 stated that VTE was seen in 4.4 cases per 1000 admissions in the internal medicine unit and ICU and about twelve cases of VTE are seen yearly at the DGH, with an in-hospital mortality of 10%(Kamdem et al., 2018b).

A prospective open cohort study conducted among adult patients diagnosed with DVT, who was admitted to inpatients wards of JUMC and SPHMMC states that the mortality rate of DVT in the first 6 months after the disease onset was 6%. A relapse after a 5-year disease-free interval is observed in 20% to 30% of the patients. While some studies reported the annual incidence rate of the first recurrent attack to be 3% to 5%, which is generally most probable to happen during the first 2 years after the discontinuation of anticoagulation treatment(Mulatu et al., 2020b).

2.3 Factors associated with DVT

2.3.1 Socio-demographic factors

A prospective, multicenter, observational study done among patients admitted in ICU of 54 hospitals in Zhejiang Province in China from September 2019 to January 2020 shows that age (≥75 vs 60-74 years old, odds ratio (OR) = 2.091, 95% confidence interval (CI): 1.308-2.846, $P = 0.001$ is independently associated with DVT (Li et al., 2022).

A prospective cohort trial at the Third Hospital of Hebei Medical University from October 2018 to June 2020, a total of 160 patients with closed Displaced femoral fracture revealed that age of ≥

65 years of age (odds ratio [OR], 4.390; 95% confidence interval [CI] 1.727–11.155; $p = 0.002$), is the independent risk factors of DVT(Barco et al., 2019).

A met-analysis study among 24,911 patients in Forsberg, Germany with sonographically documented acute deep vein thrombosis shows that men are more likely to present with proximal deep vein thrombosis in the lower limbs or isolated distal DVT than women (Barco et al., 2019).

A prospective study done among 79 medical patients of the Military Hospital of Bamenda , north west region ,Cameroon states that the risk factors were age > 40 years (78.9%), obesity (43%)(Abah et al., 2016).

A prospective open cohort study was conducted among adult patients diagnosed with DVT, who was admitted to inpatients wards of JUMC and SPHMMC in 2018 for three months shows that from a total of 129 study participants included in the final analysis, about 84 (65.1%) were females, with male to female ratio of 1:1.86. The mean ± SD age of participants was 38.63 ± 17.67 years. The majority of the patients 76 (58.9%) were within the age-group between 18 and 35 years. About 57.4% of participants were residing in a rural area. A large number (111 [86.0%]) of study participants were living with their immediate family (Mulatu et al 2020).

2.3.2 Clinical factors of DVT

A cross-sectional survey done at Rwandan university teaching hospitals among 901 adult patients admitted to the Departments of Internal Medicine and Obstetrics Gynecology between August 2015 and August 2016, showed active malignancy, immobilization, prolonged recent travel and history of DVT to be significant risk factors for proximal DVT (all p values <0.05) (Mugeni et al. 2019).

A cross sectional study done at three teaching hospitals in Yaoundé: Yaoundé Central Hospital, Jamot Hospital, and Yaoundé University Teaching Hospital in Cameroon from 2013 to 2017 states that risk factors for VTE prolong rest/immobilization, high adiposity (BMI > 25 Kg/m^2), pregnancy/early post-partum (<6 weeks), recent surgery, use of OCP in women, cancer, nephrotic syndrome, genetic thrombophilia, vascular trauma, antiphospholipid syndrome, and chronic inflammatory diseases and also recorded the associated co-morbidities: Chronic obstructive Pulmonary Disease (COPD), Asthma, and confirmed HIV(Simeni Njonnou et al., 2019).

A prospective cross sectional study done in Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia, among 81 ultrasound proven cases of DVT involving the extremities during the study period showed that the majority (58%) were under the age of 40 years. Malignancy was the most common identified risk factor (30.9% of the cases) followed by prolonged immobilization 19.8%, pregnancy related problems6.2% and severe trauma 6.2% of the patients. No apparent risk factor was found in 12.3%. (Haile et al., 2013).

A retrospective study done at Hawassa Specialized university Hospital among 660 randomly selected patients from July1-August 30, 2022 shows that orthopedic trauma; AOR = 2.6 (95% CI (1.2–5.4), corona virus; AOR = 2.5 (95%CI (1.07–5.1), and hospital stay > 15 days; AOR = 2.2 (95% CI (1.25–3.94) were significantly associated with deep vein thrombosis(P value < 0.05) (Alemu et al., 2023).

A cross-sectional study done at Tibebe Ghion Specialized Hospital Bahir Dar, North West Ethiopia from April 1, 2021, to July 30, 2021 ,among 196 lower extremity trauma patients ,age greater than 60 years(AOR= 16.32; 95% CI: 1.02, 260.06) ; injury severity scores greater than or equal to 15 (AOR= 33.08; 95% CI:3.60, 303.65) ; any comorbidity (AOR= 8.62; 95% CI: 1.10, 67.50) , and length of hospital stay greater than20 days (AOR= 8.77; 95% CI: 1.20, 64.44) were associated factors of deep vein thrombosis occurrence (Mengesha et al., 2022).

2.4 Conceptual Framework

This conceptual framework was developed after systematic and careful review of different literatures which are related to Deep vein thrombosis(Alemu et al., 2023) (Mengesha et al., 2022). It shows the possible relation of Deep vein thrombosis with different independent variables and it was developed based on evidences found from findings of literatures.

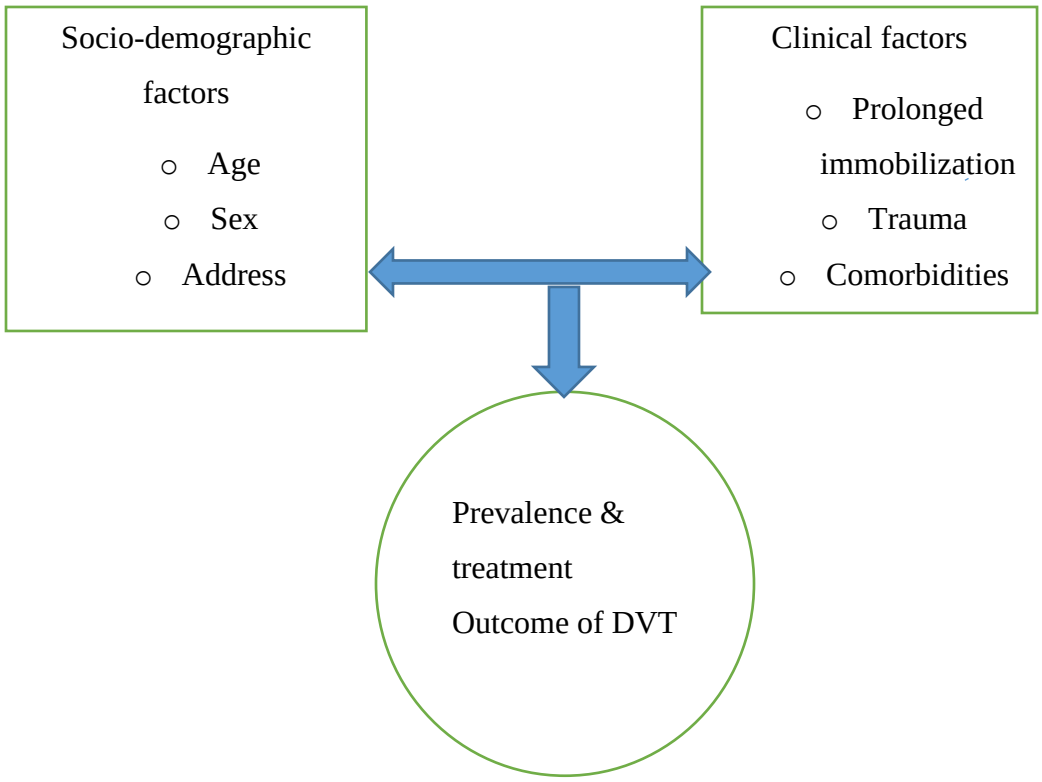

Figure 1 Conceptual framework showing the relationship between potential factors and prevalence, treatment outcome of DVT (adapted by principal investigator from different literature)

3 .METHODS AND MATERIALS

3.1. Study Setting and study period

The study will be conducted in Harari regional state, found 526 KM away from Addis Ababa. Harari is the smallest of the 13 states of Ethiopia, located in the eastern part of the country and surrounded by the east Hararghe zone of the Oromia regional state. It has 2 public hospitals and 5 health centers. This study will be conducted from medical charts of deep vein thrombosis patients visiting HFCSH from June30,2020 to June 30.2024. Currently more than 1000 patients are visiting per month. It is the teaching hospital for Haramaya University and comprehensive hospital for East Ethiopia (including Harari region, some parts of Somali region, and eastern Hararghe zone of Oromia) that is expected to serve about 5.8 million people in the Eastern part of Ethiopia. The data will be collected from December 20, 2024 to January 20, 2025.

3.2 Study Design

Hospital based cross-sectional study will be conducted using a secondary data.

3.3 Population

3.3.1 Source population

All patients visiting Hiwot Fana comprehensive specialized hospital from June 30, 2020 to June 30, 2024.

3.3.2 Study Population

All patients visiting Hiwot Fana compressive specialized hospital from June 30, 2020 to June 30.2024, and those who fulfill the inclusion criteria.

3.4. Inclusion and exclusion criteria

3.4.1. Inclusion Criteria

All patients visiting Hiwot Fana Comprehensive specialized hospital in the time period of June30, 2020 to June30, 2024.

3.4.2. Exclusion Criteria

- ✓ In this study, patients who left against medical advice, patients who were referred to other services, those patients without complete patient data (absence of patient information, diagnosis, management plan, and discharge or death summary) will be excluded from our study.

3.5 Sample Size Determination

3.5.1 **Sample size for first objective**

The Sample size was calculated using a single proportion formula. By considering 95% CI, 5% margin of error, and 5 percent level of significance (= 0.05), 95 percent confidence level (Z /2 = 1.96), and the prevalence of DVT is 19 % from previous study (Zhang et al., 2023). To determine sample sizes, use the formulas below.

$$ni = \frac{\left(z\alpha/_2\right)^2 * p(1-p)}{d^2}$$

Where, ni = initial sample size

p= 0.19

d= 0.05

ni = 237

3.5.2 Sample size for the second objective

Sample size was determined for second objective using a single population proportion formula,

$$ni = \frac{\left(z\alpha/_2\right)^2 * p(1-p)}{d^2}$$ With following assumptions:

ni=the required sample size, Z=the value of standard normal distribution corresponding to α/2, 1.96,

d=precision assumed as 0.05

p=proportion of DVT patients who died or develop complication

q= proportion of DVT patients without complication or discharge improved.

So by this formula, sample size was calculated from a cross-sectional descriptive study conducted at the Douala General Hospital, Cameroon in 2018 states that the mortality was 10% which revealed the prevalence of of DVT with poor outcomes was 10% (Kamdem et al., 2018b). It makes the calculated the sample size of n = 1.96 ∗2 (0.10)(1−0.10) 0.05 =139

3.5.3 Sample size for the third objective

For the third objective, considering the several associated risk factors of deep vein thrombosis associated factors from previous studies, by using double proportion ratio, sample size was calculated using Open Epi as it is depicted in the table below.

Associated factors	Assumptions	Sample size	Reference
Age	AOR =16.32 Power = 80% Ratio 1:1	44	(Mengesha et al., 2022)
Prolonged immobilization	AOR =8.67 Power = 80% Ratio 1:1	80	(Mengesha et al., 2022)
Malignancy	AOR =7.41 Power = 80% Ratio 1:1	136	(Alemu et al., 2023b)
comorbidity	AOR =8.62 Power = 80% Ratio 1:1	94	(Mengesha et al., 2022)
Orthopaedic trauma	AOR =6.40 Power = 80% Ratio 1:1	150	(Alemu et al., 2023)
Injury severity score	AOR =33.08 Power = 80% Ratio 1:1	26	(Mengesha et al., 2022)

So the maximum sample was from the first objective which is 237 adding 10% nonresponse rate (24) making the final sample size is 261.

3.6. Sampling Procedure and Technique

The data will be collected from Hiwot Fana Comprehensive Specialized University Hospital. There are about 54,000 patients visiting Hiwot Fana Comprehensive specialized University Hospital from June30, 2020 to June 30, 2024. For data collection first, a list of medical record numbers of DVT patient's registered on logbook that fulfil the inclusion criteria will be considered as final sample size.

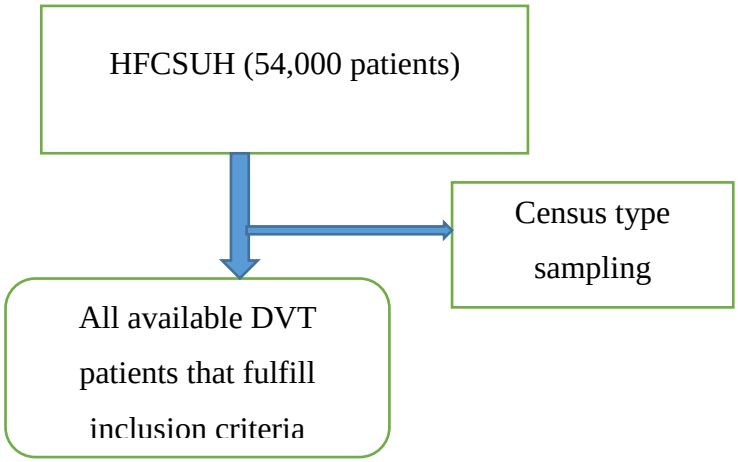

Figure 2: schematic presentation of the study on the prevalence, Treatment outcome of DVT and its associated factor among patients from June 30, 2020 to June 30, 2024 visiting at Hiwot Fana comprehensive specialized hospital Harar, Eastern Ethiopia

3.7. Data collection methods

3.7.1. Data Collection Tool

The data will be collected using a structured and pretested checklist adapted from different literatures (Mengesha et al., 2022b) (Mulatu et al., 2020) (Simeni Njonnou et al., 2019) and data will be collected from HFCUH using checklist from triage registration logbook , patient's charts and the data will be prepared in English language The tools are comprised of four parts; section one is about patients general information which contains three variables ; section three is about clinical characteristics of patients and contains three variables ; and section four is about treatment outcome (smoking ,cancer)and contains four variables.

3.7.2 Data collectors & supervisors

The data will be collected by two bachelor nurses and one general practioner who have 2 years of experience in data collection will be assigned to collect the data. The data collectors will be trained by principal investigator on the purpose of the study, the study procedures, data collection steps, and supervision activities, mainly focused on the responsibilities of data collectors and supervisors, for two days. After, preparation of the necessary equipment and tools data collectors will be deployed for work. Principal investigator will supervise the data collection process.

3.7.3 Data collection procedure

Pretesting will be done on around 5% of the sample size at Haramaya General Hospital ahead of the actual data collection and appropriate modification will be made. Data will be collected by assigned nurses by first collecting the medical record number (MRN) from the Medical Registration book. Then assigned liaison officers will collect the charts. Followed by the nurses using a paper-based checklist to capture the necessary data. During data collection, each checklist will be reviewed and cross checked for completeness and consistency as well as making appropriate follow up on the procedures. The researcher will follow the data collector daily for data cleaning and data entry will be performed and all the necessary feedback will be given to the data collectors immediately.

3.8 Study variables

3.8.1 Dependent variables

- ✓ Prevalence of DVT
- ✓ Treatment outcomes

3.8.2 Independent variable

- ➢ Socio demographic factors: age , sex , address
- ➢ Clinical factors: prolonged immobilization , malignancy , trauma

3.9 Operational definitions

Treatment outcome: Indicates whether the patient has good or poor outcome (Yang, S., Wang, Z., Liu, Z. et al, 2016).

Good outcome: Number of Patients, who survived during hospital stay, including patients who were improved. (Seifu, A. et al. 2022).

Poor outcome: Number of Patients who are dead during hospital stay or develop complications like venous insufficiency, pulmonary thromboembolism. (Garland A, et al, 2013).

Prevalence of DVT: The number of DVT patients divided by the total patients visiting HFCUH during the study period of time.

3.10 Data quality control

To assure the quality of the data collected 2 hours basic training will be given for all data collectors on the contents of the data collection tool, data collection procedures and ethical considerations during data collection by the principal investigator (PI). A pre-test will be conducted at Haramaya General Hospital on randomly selected 5% of the calculated sample size, a week before the actual data collection. Then, adjustments will be made on the tool for final data collection. Close supervision will be carried out on daily basis by the supervisor and the PI during the data collection time. Data from each questionnaire will be checked for completeness, clarity, consistency, and accuracy by the PI. Any missed or incorrectly filled questionnaire will be sent back to the respective data collector for correction. Data cross check and data clean-up will be done before analysis.

3.11 Data processing and analysis

The collected data will be checked for its completeness and consistency before entering data on the computer. The collected data will be checked, coded and entered into Epi-data software, and then exported into SPSS software (version 25) for further statistical analysis. Based on the nature of variables descriptive statistical analysis will be carried to compute frequency, percentage, and mean for independent and dependent variables and data will be presented using frequency tables, figures and graphs. Bivariate regression analysis will be done, and variables with $p \leq 0.25$ in the bivariate analysis will be included in the final model of multivariable logistic regression analysis to control all confounding variables. The direction and strength of statistical association will be measured by odds ratio with 95% CI. Finally, in multivariable regression, variables with a P value less than 0.05 will be considered as statistically significant.

3.12 Ethical consideration

Ethical clearance will be obtained from the Institutional Health Research Ethics Review Committee (IHREC) of Haramaya University, College of Health and Medical Science. After explaining the aim and the benefit of the study, Informed, Voluntary, Written and Signed Consent

will be obtained from head of the hospital. All the collected data, paper and computer records of the study will be treated with confidentiality and will not be accessible to unauthorized personnel. A formal letter will be given to the hospital and HMIS for the access of the patient charts and data will be collected after informed, voluntary, written and signed consent is obtained from hospital medical director.

3.13 Expected Outcome

At the end of the study high prevalence and good outcome will be expected among DVT patients those admitted at HFSCH. Additionally, the associated factors that significantly related with DVT outcomes will be also identified.

3.14 Information dissemination

The result of the study will be submitted and presented to Haramaya University, College of Health Science, the School of Post Graduate and Department of Emergency and Critical care as partial fulfilment for the requirement of Specialty Certificate in Emergency and Critical care. The final result of this study will be accessed from Haramaya University, Health Science College library as the source for future learning. It will be submitted as hard copy for HFSH which will be used as an input for health care professional training and development. It will also be submitted to national or international peer reviewed scientific journals for possible publication.

4.0 WORK PLAN

TABLE 1: A WORK PLAN FOR RESEARCH PROPOSAL, PREVALENCE, OUTCOME AND ASSOCIATED FACTORS OF DEEP VEIN THROMBOSIS PATIENTS VISITING HIWOT FANA SPECIALIZED UNIVERSITY HOSPITAL, HARAR, EASTERN ETHIOPIA, 2024

S. N	Activities	Responsible Body	Time Frame (August 1, 2024 – January 30, 2025)					
			August	Septem ber	October	November	Decem ber	January
1	Proposal development and submission to advisors	PI	■					
2	Feedback from advisors and finalization of the document	Advisors and PI		■				
3	Proposal defense	PI			■			
4	Ethical Approval	IHRERC				■	■	
5	Pilot testing and Data collection	PI and Data collector					■	
6	Data entry and analysis	Principal Investigator					■	
7	Feedback from Advisors, finalization of the document	Advisors and PI						■
8	Final paper submission	PI						■
9	Monitoring and Evaluation	PI and Advisors	■	■	■	■	■	■

Key: PI principal investigator

IHRERC: Institutional Health Research Ethics Review Committee

5. BUDGET BREAKDOWN

Table 2. Shows budget breakdown of the study on Prevalence, Outcome and Associated Factors of Deep Vein Thrombosis Patients Visiting Hiwot Fana **S**pecialized University Hospital, Harar, Eastern Ethiopia, 2024

Sr.no	**Activity**	**Duration in days**	**Cost description**	**Unit**	**Quantity**	**Unit cost in ETB**	**Subtotal cost in ETB**
1	Duplication	-	Stationary	#paper	1660	2.00	3,320.00
2	Writing materials	-	Notebook	Each	8	150	600.00
			Pencil	Each	8	5	40.00
			Pen	Each	10	10	100.00
			RW-CD	Each	1	100	100.00
			Flash	Each	1	500	500.00
			CDMA	Each	1	2500	2500.00
3	Refreshment	1 day	Training	#participant	8	30	240.00
		~10 days	Data Collection	#participant	10	500	5,000.00
4	Per diem	~10 days	Data collectors	#participant	110	50	5,500.00
			Supervisors	#participant	2	200	4,000.00
5	Mobile card	-	D. Collectors	No. card	5	500	2500.00
			Supervisors	NO. card	2	300	600.00
Total Budget expenditure							**25,000.00**

Funding for research project will be covered by Haramaya University

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7. ANNEXES

7.1 Information sheet and informed voluntary consent form for the head of hospital

Introduction: My name is Amanuel Assefa (MD,EMCC Resident) and I am the principal investigator of the study being conducted in Hiwot Fana specialized university examining the prevalence ,treatment outcomes and associated factors of DVT among admitted patients.

I kindly request you to lend me your attention to explain you about the study. Thank you for your time.

The Study/Project Title: Prevalence, Treatment outcome and Associated Factors of Deep Vein Thrombosis among Patients Visiting Hiwot Fana Specialized University Hospital, Harar, Eastern Ethiopia, 2024

Purpose of the study: The findings of this study will have a paramount importance for the hospital to develop health education program for the community about the magnitude and outcome of DVT and used as an input to health care providers to provide information to their patients and to improve service by providing evidence based care. More ever, the aim of this study to write a thesis as a partial requirement for the fulfillment of a post graduate program in Emergency and critical care Medicine for the principal investigator.

Procedure and Duration: : Data collectors will collect the data from the HMIS registration book will used to get the card numbers of deep vein thrombosis patients who were admitted from June 30, 2021 to June 30, 2024. After getting the card numbers, patient charts will be retrieved from the record and documentation office. The checklist contains 4 parts, has 23 checklists and it will take a maximum of 40 minutes. The interview will take about 15-20 minutes.

Risks and Benefits: The risks of participating in this study are very minimal, there would not be any direct payment for participating in this study. But the findings from this research may reveal important information for health planners, improve care and outcome for patients with DVT.

Confidentiality: The information that will be provided will be kept confidential. There will be no information that will identify the patient history in particular. The questioner will be coded to exclude showing names. The findings of the study will be general for the study community and

will not reflect anything particular of individual persons. No reference will be made in oral or written reports that could link participants to the research.

Contact Address: If there are any questions or enquires any time about the study or the procedures, please contact and speak to Dr. Amanuel Assefa (principal investigator).

Cell Phone: +251923544478, E-mail: amanuelassefa938@gmail.com
Contact address of Institutional Health Research Ethics Review Committee (IHRERC)
Office phone 0254662011
P.O.Box 235, Harar

Declaration of Informed Voluntary Consent:

I have read the participant information sheet. I have clearly understood the purpose of research, the procedures, the risks and benefits, issues of confidentiality, the rights of participating and the contact address for any queries. I have been given the opportunity to ask questions for things that may have been unclear. I am also informed that the Hospital administration has the right to stop this study from being conducted if any misdeeds and unethical procedures are observed during the data collection process in the institution. Therefore, I declare my voluntary consent to allow this study to be conducted in this institution on behalf of _____hospital administration with my signature as indicated below.

Name and signature of Head of institution _____ Date_____

Name and signature of principal investigator _____Date_____

Thank you for your cooperation!!

7.**2 Data extraction check lists**

Topic: prevalence, treatment outcome and its associated factors of Deep vein thrombosis patients admitted at Hiwot Fana Specialized university hospital, Harar, Ethiopia.

Instruction: Dear data collector, this is a data abstraction form designed to collect data of patients among Deep vein thrombosis patients at HFSUH, Harar, Ethiopia. Please try to fill all the requested fields that are prepared in the section of the data abstraction form.

The form has four sections:-

The First section: General information

The Second section: the Socio-demographic characteristics of the patient

The Third section: clinical data

The Fourth section: DVT outcomes

Part I General information

1. Date: _____

2. Name of the data collector_____

3. Name of the supervisor_____

II. Socio- demographic data of the patients

no	characteristics	response
1	sex	1. Male 2. female
2	Age	1------years
3	Address	1. urban 2. rural
4	Occupation	1.farmer 2. civil servant 3. driver 4. other
5	Religion	1.christian 2.muslim 3.others

PART II Clinical data

6	Types of DVT	1. proximal 2. distal 3. both
7	Duration of DVT	1. acute 2. chronic
8	Sites of DVT	1. upper extremity 2. lower extremity 3. both
9.	Sign and symptom of DVT	1. swelling 2. pain 3. skin discoloration 4. pitting oedema 5.local tenderness 6. others justify

PART III: Risk factors associated with DVT

10	Age >75	1. yes 2. no
11	Active cancer	1. yes 2. 2. no
12	Pregnancy	1.Yes 2. If yes what is her trimester? I. 1st TM II. 2nd TM III. 3rd TM
13.	OCP	1. Yes 2. 2. no
14	Recent immobilization	1.bed ridden 2.Paralysis

		3.ICU admission
15	Recent surgery	1.orthopedic 2.general surgery 3.neurologic 4.others specify?
16	Previous VTE	1. Yes 2. no
17	Family History of VTE	1.yes 2. no
18	Unprovoked	1.yes
19	Other comorbidities	1.yes 2. if yes specify ?

PART IV: DVT outcome Measurement

20	Did the patient develop complications**?**	1.Pulmonary thromboembolism 2.Phlegmasia alba or cerulea dollens 3. venous insufficiency 4. death 5. others specify
21	Disposition	1. home 2. ICU admission 3. wards
22	Does the patient develop recurrent VTE	1. yes 2. no
23	Length of hospital stay	_____ days

7.3. Curriculum vitae of principal investigator

1. **Personal details**

Name Amanuel Assefa Mengste

Age 30

Sex male

Date of birth April 19/1994 GC

Place of birth Dimama

Marital status Married

Nationality Ethiopian

Mobile- +251 923544478

E- mail- amanuelassefa938@ gmail.com

No.	**Name of the School(s) /organization/**	**Grades Attended**	**Location**
1.	Ashifa primary school	From Grades 1 – 8	Ashifa , Ethiopia
2	Tilili 2nd and preparatory school	From Grades 9-12	Tilili , Ethiopia
3	Bahirdar university CMHS	1st-6th year medical student	Bahirdar ,Ethiopia

2. **Work experience**
   - Working at Alem ketema Enat hospital for 3 years as General practitioner.
   - Currently Emergency and critical care medicine resident year 3

Title of qualification: - Doctor of Medicine

3. **Language skill**

Language	**Speaking**	**Writing**	**Listening**	**Reading**
English	Excellent	Excellent	Excellent	Excellent
Amharic	Excellent	Excellent	Excellent	Excellent

4. **Personality: -**

Free from any addiction, sociable, respectful, hard worker, optimistic, creative,

OTHER COMPETENCIES

- Basic skill in use of Microsoft (Word, Excel, PowerPoint) and internet
- Ability to solve problems in the work environment

Ability to organize and lead in tasks. Good communication skills in the work place

REFERENCES

1 Dr Nathan Mulubirhan

Assistant professor of Emergency and critical care medicine

Haramaya university college of Health and medical science school of medicine head

Email. natanxy@gmail.com

2 Dr Melaku Getachew

Associate professor of Emergency and critical care medicine

Haramaya university college of Health and medical science school of medicine head

Email. Melakug02@gmail.com

I Undersigned the above information is true and explains about me. I can submit all my credentials I was be entitled to do so.

7.4 APPROVAL SHEET

SCHOOL OF GRADUATE STUDIES

HARAMAYA UNIVERSITY

Submitted by:

_____ _____ _____

Name of student Signature Date

Approved by:

1. _____ _____ _____

Name of Major Advisor Signature Date

2. _____ _____ _____

Name of Co-Advisor Signature Date

3. _____ _____ _____

Name of Chairman, DGC Signature Date

4. _____ _____ _____

Name of Dean, SGS Signature Date

5. _____ _____ _____

Name of Chairman, CGS Signature Date