2022-08-19

Time to Develop Phlebitis and its Predictors Among Patients Admitted in Medical Ward with Peripheral Intravenous Cannula at Public Hospitals of Bahir Dar City, Amhara, Ethiopia, 2022 A Prospective Follow up Study

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BAHIR DAR UNIVERSITY

COLLEGE OF MEDICINE AND HEALTH SCIENCES

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DEPARTMENT OF ADULT HEALTH NURSING

TIME TO DEVELOP PHLEBITIS AND ITS PREDICTORS AMONG PATIENTS ADMITTED IN MEDICAL WARD WITH PERIPHERAL INTRAVENOUS CANNULA AT PUBLIC HOSPITALS OF BAHIR DAR CITY, AMHARA, ETHIOPIA, 2022

A PROSPECTIVE FOLLOW UP STUDY

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AUGUST, 2022

BAHIR DAR, ETHIOPIA

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Time to Develop Phlebitis and Predictors among Patients admitted in Medical Ward with Peripheral Intravenous Cannula at Public Hospitals of Bahir Dar City, Amhara, Ethiopia, 2022: Prospective Follow up Study

A Thesis Submitted to Department of Adult Health Nursing, College of Medicine and Health Sciences, Bahir Dar University for the Partial Fulfillment of Master of Science Degree in Adult Health Nursing

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Declaration Sheet

Through my signature below, I declared and affirmed that this thesis is my work. I have followed all ethical principles of scholarship in the preparation, data collection, data analysis, and completion of this thesis work. All scholarly matter that was included in the thesis has been given recognition through citation. I affirmed that I have cited and referenced all sources used in this document. Every effort has been made to avoid plagiarism in the preparation of this thesis work. This thesis is submitted for partial fulfillment of a master of health science degree in Adult health nursing from college of medicine and health sciences, Bahirdar University. The thesis would be deposited in the library of college of medicine and health sciences, Bahir Dar University and would be made accessible for readers under the rules of the library. I solemnly declared that this thesis has not been submitted to any other institution anywhere for the award of any academic degree, diploma or certificate.

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Date of Submission: _____12/12/2014_____

Bahirdar University, College of Medicine and Health Sciences, School of Health Sciences, Department of Adult health nursing

Advisors and Mock Examiner Approval Sheet

I hereby certify that I had advised, supervised, and evaluated the this thesis that was entitled "Time to Develop Phlebitis and Predictors among Patients admitted in Medical Ward with Peripheral Intravenous Cannula at Public Hospitals of Bahir Dar City, Amhara, Ethiopia, 2022". A Prospective Follow up Study was investigated by Tadios Lidetu with my advice, guidance, and support. Hence, I approved as this thesis can be submitted as the final thesis draft for different purposes.

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Bahirdar University, College of Medicine and Health Sciences, School of Health Sciences, Department of Adult health nursing

Final Approval of Thesis Report Sheet

I hereby certified that I have examined this thesis report entitled "Time to Develop Phlebitis and Predictors among Patients admitted in Medical Ward with Peripheral Intravenous Cannula at Public Hospitals of Bahir Dar City, Amhara, Ethiopia, 2022". A prospective follow-up study reported By Tadios Lidetu (BSc Nurse). We have recommended and approved this thesis report for a degree of "Master of Health Science degree in Adult health nursing".

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ACKNOWLEDGEMENT

I would like to express my sincere gratitude to my advisor Mr. Alemshet Yirga (BSc, MSc, Lecturer in Surgical nursing), for his unwavering support on this thesis work. I want to express my gratitude to the department of adult health nursing all staff members, for their supportive contributions to this thesis work and Bahir-Dar University for the chance of learning. My heartfelt thanks go to Getnet Dessie (BSc, MSc, Assistant professor in AHN and MPH in Epidemiology) and Sr. Dagmawit Zewudu (BSc, MSc, Lecturer in AHN) for their support on this thesis through different ways.

I would like to express my thanks to patients who participated on this study and staff members (hospital director, research coordinator, ward coordinator and others) of Bahir-Dar Public hospitals for their support and good collaboration for this thesis work. Finally, I would like to express my deepest gratitude to all of my families and friends who supported me in various ways to complete this thesis.

ABBREVIATIONS

AAPH ---------- Addis Alem Primary Hospital

AIDS ---------- Acquired Immune Deficiency Syndrome

BDU ---------- Bahir Dar University

CI ---------- Confidence Interval

CMHS ---------- College of Medicine and Health Sciences

CPHM ---------- Cox Proportional Hazards Model

CPHRM ---------- Cox Proportional Hazards Regression Model

DC ---------- Data Collector

DVT ---------- Deep Vein Thrombosis

FHCSH ---------- Felege Hiwot Compressive Specialized Hospital

HCW ---------- Health Care Worker

HR ---------- Hazard Ratio

HIV ---------- Human Immune Virus

IV ---------- Intravenous

MRN ---------- Medical Registration Number

MW ---------- Medical Ward

PHA ---------- Proportional Hazards Assumption

PIVC ---------- Peripheral Intravenous Cannula

TGSCTH ---------- Tibebe Gion Compressive Specialized Teaching Hospital

VIPS ----------Visual infusion phlebitis Score

TABLE OF CONTENT

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Background: Phlebitis is the inflammation of the vein and common complication of peripheral intravenous cannula. Phlebitis leads the patient to sepsis and pulmonary embolism that increase mortality. Incidence and median survival time of phlebitis varies across the world. The incidence, median survival time and predictors of phlebitis are not well addressed in Ethiopia. Therefore, this study focuses on the time to develop and predictors of phlebitis.

Objective: Time to develop phlebitis and predictors among patients admitted in medical ward with peripheral intravenous cannula at public hospitals of Bahir Dar, Amhara, Ethiopia, 2022

Methods and Materials: An institution based prospective follow up study was conducted at public Hospitals of Bahir Dar city and 462 patients who were selected through systematic random sampling technique. Phlebitis was identified by Jackson's Visual Infusion Phlebitis Scoring System. Cox proportional hazards regression model was used.

Results: In this study, 462 patients participated, of those, 171(37.01%) acquired phlebitis. The median survival time to develop phlebitis was six days. Patients in age group > 60 years were 51% times (AHR = 0.49, 95% CI 0.29-0.82) less hazardous to acquire phlebitis than age group 15-40 years. Patients with Chronic-diseases were 1.50 times (AHR =1.50, 95% CI 1.09-2.07) more risk to acquire phlebitis as compared to patients with no chronic disease. The statistical interaction effect of drugs and blood showed that if drugs and blood administer in one vein, the hazards/risk of phlebitis increase by 2.03 times (AHR=2.03, 95% CI 1.44-2.86). Patients with inappropriate cannula dressing were 1.81 times (AHR=1.81, 95% CI 1.31-2.51) more hazardous to develop phlebitis as compared to with appropriate cannula dressing. Patients with large cannula size and cannula short dwelling time were 1.52 times (AHR = 1.52, 95% CI 1.08-2.15) and 7.39 times (AHR =7.39, 95% CI 4.12-13.32) more risk to acquire phlebitis as compared to patient with small cannula size and longer cannula dwelling time respectively.

Conclusion and recommendation: the incidence density rate was 8/100 persons per day observation and the median survival time were six days. Younger age, chronic disease, using one intravenous line for more than one purpose, larger cannula size, inappropriate cannula dressing and longer cannula dwelling time were found as hazard/risk factors for phlebitis. Therefore, patients with those risk factors need to get special care and follow up.

Keywords: Time to Develop, Predictors, Phlebitis, Peripheral Intravenous Cannula, Patients

1. INTRODUCTION

1.1. Background

Post- peripheral intravenous cannula phlebitis is inflammation of the vein wall and characterized by symptom and signs of pain, erythema, edema, induration of cannulated vein, cannulated vein become palpable and pyrexia(1). Peripheral intravenous cannulation is the common procedures, which preformed through nurse professional that apply approximately on 80 percent of hospitalized patients(2). Among those patients, up to 70% develop phlebitis and the median time to develop phlebitis is four days. It is the common complication of PIVC(3, 4).

Phlebitis caused by mechanical, chemical or bacterial origin, and it can occur in isolation or in combination with any of the other known PIVC complications(5). Mechanical phlebitis is the most common cause that results from vein trauma during cannula insertion and movement of improperly secured cannula with in the vein(4). Chemical phlebitis is cause which caused by irritating chemicals that are too alkaline or hypertonic solutions(6). Bacteria phlebitis is caused by contamination of intravenous system during cannula insertion time (6-8). To diagnosis phlebitis, the patient showed at least two of the above listed clinical presentations and the occurrence of those clinical presentations take different time (9, 10).

Phlebitis classified into stages, based on the Jackson's Visual Infusion Phlebitis Scoring System, which is an internationally adopted tool that has been tested in literature and used in clinical settings worldwide. The stages are early stage that is all of the following evidenced, pain near IV site, erythema and swelling. Medium-stage, all of the following evidenced, pain along path of cannula, erythema and induration. Advanced-stage, all of the following evidenced in addition, extensive, which are pain along path of cannula, erythema, induration and palpable venous cord. More advanced-stage, all of the following evidenced and extensive, which are pain along path of cannula, erythema, induration, palpable venous cord and pyrexia (11, 12).

If cannula did not remove at the appropriate time, the risk of phlebitis is high and can lead to serious complications like septicemia and pulmonary embolism. Phlebitis damage the vein lining and make thrombus formation which resulting DVT and pulmonary embolism(13). Unless phlebitis can be diagnosis and manage as soon as early, the above listed complication of phlebitis increase the patent's morbidity and mortality (13, 14).

1.2. Statements of the problem

Majorities of health care facilities do not practice the appropriate peripheral intravenous cannula procedure strictly (15, 16). As a result, most patients exposed to phlebitis due to the poor practice of the procedure(17). The infusion nurses society indicates that the accepted phlebitis rate should be five percent or less than five percent(11). However, still the current incidence of phlebitis is up to 70 percent following peripheral intravascular cannula use(11, 15). According to evidence, different countries have different incidence of phlebitis. The distribution of phlebitis incidence showed that in Australia 17 percent, Saudi Arabia 18 percent, Brazil 10 percent, Tunisia 52 percent, and Ethiopia 70% as evidenced by literatures (15, 18-21).

Adverse outcomes of Phlebitis embrace patient discomforts(22, 23). Phlebitis causes patients to stay in the hospital for extended periods of time(most of the time beyond expected days), which increases their suffering and economic burden of the patient (1, 21). Phlebitis comprises systemic and local infections that can lead to pulmonary embolism, deep vein thrombosis, abscess formation, and other complications that increase the patient morbidity and mortality rates(13). Pulmonary embolism commonly results in patients with peripheral intravenous cannula, which has a 25% mortality rate(13, 24).

Post-peripheral intravenous cannula phlebitis is the most serious complication, which damages the patient's blood stream. Significantly, it increase the morbidity and mortality rates of patients in healthcare settings(15, 25). Early identification of different complications of phlebitis can facilitate the task of daily care of the nursing team. It help to produce scientific evidence to support the decision making of the nurses to minimizing the risk of phlebitis related morbidity and mortality of the patient (26, 27).

There are different factors that precipitate the occurrences of phlebitis after cannula insertion. Such as high cannula gauge size, prolonged cannula dwelling time and comorbidities are the major factors that lead the patient to risk of phlebitis (15). The physiology of the vein is affected by the cannula's size and other characteristics of the cannula, which exposes the patient to phlebitis. As a result, choosing a cannula diameter that is too large can increase the risk of phlebitis(4, 28). Proper stabilization and securing of the insertion site significantly reduce the risk of phlebitis (4, 8, 29). Medication/drugs administration increase the risk of the patients to develop phlebitis following cannula insertion(4, 29).

Different prevention and management strategies are currently being used globally to solve the challenges of phlebitis(30). According to the guideline, if the peripheral intravenous cannula (PIVC) has been in place for more than 96 hours, it should be removed because the risk of phlebitis increases over time(8, 31). The entire medical staff are responsible for check-out of phlebitis symptoms and signs and acting properly as necessary(10, 32). Understanding the best technically advanced and evidence-based care techniques that can lower the risk of phlebitis, which ensure that nurses and nursing teams have technical-scientific understanding about peripheral intravenous cannula therapy and quality of care(33). Nursing practitioners can use skills and clinical evidence from daily patient care to make decisions about the best peripheral intravenous cannula insertion and removal technique, to reduce the incidence of post-peripheral intravenous cannula phlebitis(17).

Medical professional can prevent phlebitis and lengthen the lifespan of the cannula, through doing basic things, like using gloves, fully cleaning their hands, and thoroughly cleaning the patient's skin before inserting the cannula(34). After insertion, the cannula should be wrapped to stop movement in the vein lumen that could result in mechanical phlebitis(34, 35). Good clinical practice must be followed when administering intravenous drugs, starting with the reconstitution and drawing up of the medication. When administering the medication, standard of care must be observed with frequent and special care of patients with peripheral intravenous cannula therapy, unless using a cannula increases the risk of phlebitis(35, 36).

Despite the different phlebitis prevention and management strategies that are practice currently, the complication of post peripheral intravenous cannula (phlebitis) is depends on several risk factors. Still phlebitis is a serious problem in clinical settings, which has a high incidence (up to 70 percent)(15, 37). There are no enough studies on the incidence of phlebitis and identification of the preventive and the risk factors of post-cannula phlebitis, which are paramount to design proper care practice of peripheral intravenous cannula at health care facilities level. In Ethiopia, the incidence and predictors of phlebitis are still not well addressed. Therefore, this study was aimed to determine the incidence and identify predictors of phlebitis among patients with peripheral intravenous cannula.

1.3. Significance of the study

This study brought very important findings from its particular area on incidence, time to occur and predictors of phlebitis. The finding was important for patients who participated in this study, through early detection of symptom and signs of phlebitis and recommendation for medical professionals to take the appropriate management.

The finding provided that crucial information for healthcare professionals on the incidence of phlebitis, the timing of its onset, and the risk and preventive factors of phlebitis. Based on the aforementioned information, healthcare professionals give care for patients with peripheral intravenous cannulas in an appropriate manner to prevent phlebitis.

Managers of the health facilities would use the finding during the resource allocation plan that would help to improve the quality of care, through using the available and appropriate resources. Moreover, the results would serve as a reference for other researchers working in the field.

2. LITERATURE REVIEW

2.1. Incidence of phlebitis

Globally, the incidences of phlebitis are different from region to region, due to different sociodemographic and other characteristics(8, 38). Study conducted at a global level, 70 percent of peripheral intravenous cannulas primarily use for intravenous medication administration. Among these, 70 percent of peripheral intravenous cannulas, two-thirds of cannulas placed in non-recommended sites such as the back of hand, hand of wrist and antecubital veins(18, 38). Even though, there is wide regional variation of cannula insertion procedure, most cannula-insertion procedures, which is up to 71 percent performed through Nurse Professionals(38). Studies conducted as a global level showed that the incidence of peripheral intravenous cannula related with phlebitis was 14 percent(18, 39). A randomized controlled trial study conducted in Australia showed that the incidence of post peripheral intravenous cannula phlebitis was 17 percent(19). Studies conducted in Brazil and Mexico found that the incidences of post peripheral intravenous cannula phlebitis were 18.34 and 33.02 percent respectively(9, 37).

Studies conducted in china showed that the incidence of post-peripheral intravenous cannula phlebitis was 17.8 percent. Among this Grade one post-peripheral intravenous cannula phlebitis accounts that 88.40 percent (40). Study in India showed that post peripheral intravenous complication was common event on the patients among that the incidence of post-peripheral intravenous cannula phlebitis was 17.57 percent(41). Another meta-analysis study conducted in India revealed that the pooled cumulative incidence of post-peripheral intravenous cannula phlebitis was five percent(42). Study conducted in Saudi Arabia showed that the cumulative incidence of post-peripheral intravenous cannula phlebitis was 17.60 percent and incidence density rate was 75.84/1,000 person- day observations (38). Comparative study (before professional training and after professional training regarding to peripheral intravenous cannula) conducted in Malaysia, the incidence of phlebitis prior to intervention was 15.4% and which reduced to 2.3 percent after professional training was carried out regarding to peripheral intravenous cannula (43). Prospective cohort study conducted in Japan showed that the incidence of post-peripheral intravenous cannula phlebitis is 12.90 percent(28).

Study conducted in Africa level showed that the cumulative incidence of post-peripheral intravenous cannula phlebitis was 13 percent(18). In Tunisia the cumulative incidence of

phlebitis secondary to peripheral intravenous cannula was 51.90 percent(20). Study conducted in Ethiopia (University of Gondar hospital) showed that the cumulative incidence of phlebitis secondary to peripheral intravenous cannula insertion was 70 percent(15).

2.2. Survival time of phlebitis

Millions of peripheral intravenous cannula preforms each year and for adult patients the recommended replacement time of peripheral intravenous cannula is from 72–96 hours(8, 17). Even though, the routine replacement of peripheral intravenous cannula increases health-care costs, staff workload and require patients to undergo repeated invasive procedures, it decrease the incidence of post-peripheral intravenous cannula phlebitis(44). The lifespan of a peripheral intravenous cannula is an important issue to avoid any complication after cannula insertion. The survival of peripheral intravenous cannula depends on many variables such as the size of the cannula, the frequency of cannula insertion trial, drugs and fluid administration, cannula procedure and securing/dressing status(17, 45).

As study showed that when certain drugs are administered, the peripheral intravenous cannula become infiltrated faster and complicated, which showed that there is survival difference between patients who have taken drug and not taken drug(35, 36). To prolong the life span/survival of peripheral intravenous cannula, health care professional use mechanisms that able to prolong the life spine of peripheral intravenous cannula. Among the mechanisms, heparin is able to prolong duration of the peripheral intravenous cannula(46). As study showed that post-peripheral intravenous cannula phlebitis can be develop starting from one day or after 24 hours duration of the insertion of peripheral intravenous cannula (9). As studies showed that post-peripheral intravenous cannula complications like phlebitis was the most indicator for the removal of peripheral intravenous cannula (39, 41).

2.3. Factors of phlebitis

2.3.1. Sociodemographic factors

There are different sociodemographic factors that contributing for the occurrences of post-peripheral intravenous cannula phlebitis (47). Studies conducted in Australia and Saudi Arabia showed that sex is one of the risk factor for phlebitis secondary to post-peripheral intravenous cannula. As studies revealed that females were more risk to develop post-peripheral intravenous cannula phlebitis as compare to male(47, 48). Different studies revealed that age is one of the

risk factor of post-peripheral intravenous cannula phlebitis. Among the age group, older age group (> 65 years) was more risk to develop PIVC related phlebitis (47, 49, 50).

The frequency and severity of phlebitis was different among patients due to their sociodemographic factors such as residence, religion, marital status, educational level and occupational status(15). According to research conducted in Qatar and Ethiopia showed that the risk of post-peripheral intravenous cannula phlebitis was decreased when patients were urban residents, married in their marital status and had a college or higher educational level in their educational status(15, 38).

2.3.2. Clinical related factors

There are different clinical predictors that are positively or negatively associated with peripheral intravenous cannula complication like phlebitis. Moreover, according to studies finding, admission of patients' diagnosis(more than one disease), performance level (not ambulatory) of the patient during hospitalization, and level of consciousness(< 8) of the patients were all positively associated with post-peripheral intravenous cannula phlebitis(41, 47). Study showed that physically inactive individuals were immunological weakened as a result peripheral intravenous cannula making them easily vulnerable to infections such as post-peripheral intravenous cannula phlebitis. (51).

As studies showed that patients with chronic diseases like diabetes mellitus, hypertension, heart diseases and chronic kidney disease were more risk to develop phlebitis as compared to patients who were free from such chronic diseases(15, 38). Patients with chronic diseases are immune-compromised who does not have the ability to resistance infection. This inability to fight infection can be caused by a number of chronic diseases that have contribution to the occurrences of post-peripheral intravenous cannula phlebitis(11, 30).

Study conducted in Ethiopia showed that use of intravenous fluids decrease the occurrences of post-peripheral intravenous cannula phlebitis as compared does not use intravenous fluids through cannula lumen (17). In other way, the use of dry cannula (using cannula for only drug administration) increases the risk of post-peripheral intravenous cannula phlebitis and the vein conditioning whether visible or not visible is the main predictor for the occurrence of phlebitis(9, 17). Randomized controlled trial Study conducted in Australia showed that administration of intravenous fluid at anti-cubital fossa site was less risk for post-peripheral intravenous cannula

phlebitis as compared with the administration of intravenous fluid at forearm (47). The use of cannula IV line for drug administrations was more vulnerable to post-peripheral intravenous cannula phlebitis as compare to using IV line for non-drug administration purpose like only fluid administration(52, 53).

2.3.3. Cannula related factors

Study conducted in Korea showed that post peripheral intravenous cannula phlebitis was found to be more common in patients with cannula-dwell time greater than 96 hours as compared to cannula-dwell time less than 96 hours (1). Study conducted in Ethiopia showed that patients who had prolonged cannula dwell time predisposes for continued trauma by the cannula itself and irritant drugs as compared to patients who had shorter cannula dwelling time (15).

The use of appropriate dressing has ability to make the insertion site clean and dry while also preventing external contamination and trauma that decrease the occurrence of phlebitis(48). Many risk factors alone can cause numerous health problems (38, 54). Study conducted in Thailand showed that behavioral risk factors cannot cause directly phlebitis, but can aggravate and used as cofactors of other factors that directly cause phlebitis (52). As study showed that the visibility/quality of the vein on fatty skin is not easy as non-fatty skin that leads to skin injury and repeated try that increase the risk of phlebitis(55).

Studies evidenced that inappropriate dressing type of IV site and methods of securing IV cannulas were contributed to the occurrence of post-peripheral intravenous cannula phlebitis(11, 48). Randomized controlled trial Study conducted in Brazil showed that the use of smaller cannula size decrease or reduce the occurrence of peripheral intravenous cannula complications like phlebitis. Because of it prevent mechanical irritation to the interior walls of small-diameter veins(26). As studies showed that patients with large-sized cannula were two times more likely risk of complications like phlebitis compare to those with small-sized catheters(26, 38, 47).

3. CONCEPTUAL FRAMEWORK

The conceptual framework described socio demographic factors, clinical factors, cannula related factors and the outcome variable. The conceptual framework used as only to explain the possible predictors that can affect the outcome variable. It was self-constructed through on review of different literature (1, 15, 26, 48, 54).

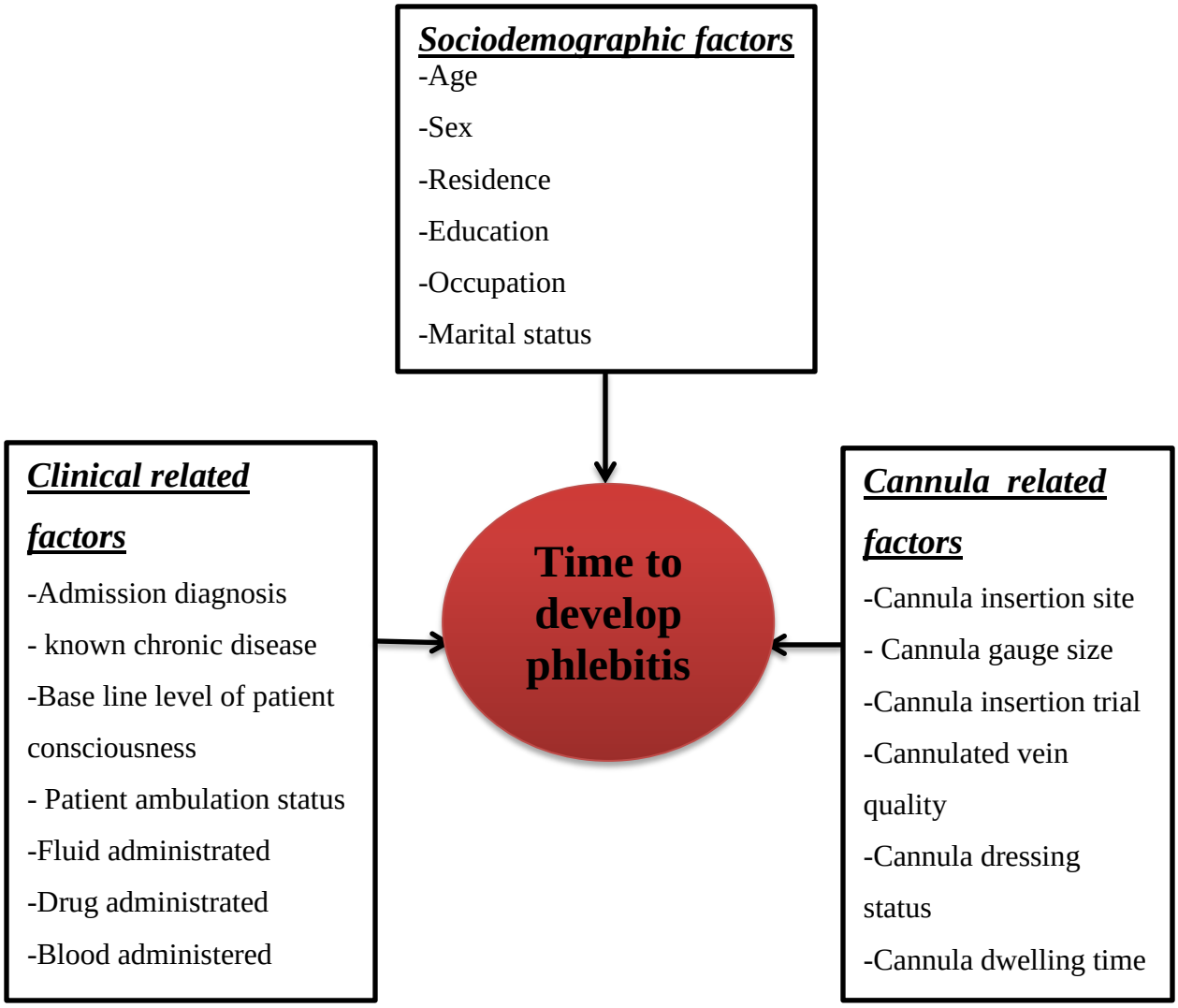


Figure-1 Conceptual framework for time to develop and its predictors of phlebitis among patients with cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022

4. OBJECTIVES

4.1. General objective

Assess time to develop phlebitis and predictors among patients admitted in medical ward with peripheral intravenous cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022

4.2. Specific objectives

1. Determine incidence rate of phlebitis among patients admitted in medical ward with peripheral intravenous cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022
2. Determine survival time of phlebitis among patients admitted in medical ward with peripheral intravenous cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022
3. Identify predictors of phlebitis among patients admitted in medical ward with peripheral intravenous cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022

5. METHODS AND MATERIALS

5.1. Study design

Institutional based prospective follow up study design was conducted

5.2. Study area and period

This study was conducted at public hospitals of Bahir Dar city. Bahir Dar city is the capital city of Amhara national regional state. In the city, there are three public hospitals. Among that, Felege-Hiwot compressive specialized Hospital is one of public hospital in Bahir Dar city, which gives service for patients in Amhara and neighboring regions. The hospital give service over 12 million people from the surrounding areas. It serves an average of 310 patients per a month through medical ward(56). The second hospital in Bahir Dar city is Tibebe Gion compressive specialized and teaching hospital, which is established by Bahirdar University for patients care and teaching purpose. Even if the hospital is recently established, it gives all services that given by the oldest hospital (Felege Hiwot comprehensive specialized hospital) in similar manner. It serves an average of 270 patients per month through medical ward(57). The third hospital in the city is Adisalem primary hospital that gives service for patients in the city and neighboring district woredas. It serves over one million people. Its services are limited compared to the other two hospitals. In average per month, it serves an average of 90 patients per a month through medical ward(58). This study was conducted from May/02 to June/17/2022.

5.3. Population

5.3.1. Source population

Patients admitted in medical ward with PIVC at public hospitals of Bahir Dar city

5.3.2. Study population

Patients admitted in medical ward with PIVC at public hospitals of Bahir Dar city from May/02 to June/13/2022

5.3.3. Study unit

Each patient admitted in medical ward with PIVC that be selected through systematic random sampling technique at public hospitals of Bahir Dar city during study period.

5.4. Eligibility criteria

5.4.1. Inclusion criteria

Patients admitted in medical ward with insertion of PIVC at public hospitals of Bahir Dar city during the study period (from May/02 to June/17/2022).

5.4.2. Exclusion criteria

There was no predetermined exclusion criterion

5.5. Sample size and sampling technique

5.5.1. Sample size determination

The sample size was calculated through stata version-15 software packages. Two population-proportion formulas with the following assumptions were applied. Confidence level = 95%, power =80%, ratio of unexposed to exposed group one to one and hazards ratio was used for calculation of sample size as observed in table one. Design effect was used for this study, due to the sampling method that start with stratified sampling techniques then systematic sampling method was applied for each hospital. Previous related studies were taken to calculate the appropriate sample size using three factors that have small hazard ratio (16, 47, 59) [Table-1].

Table-1 sample size for time to develop phlebitis and its predictors among patients admitted in medical ward with peripheral intravenous cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022

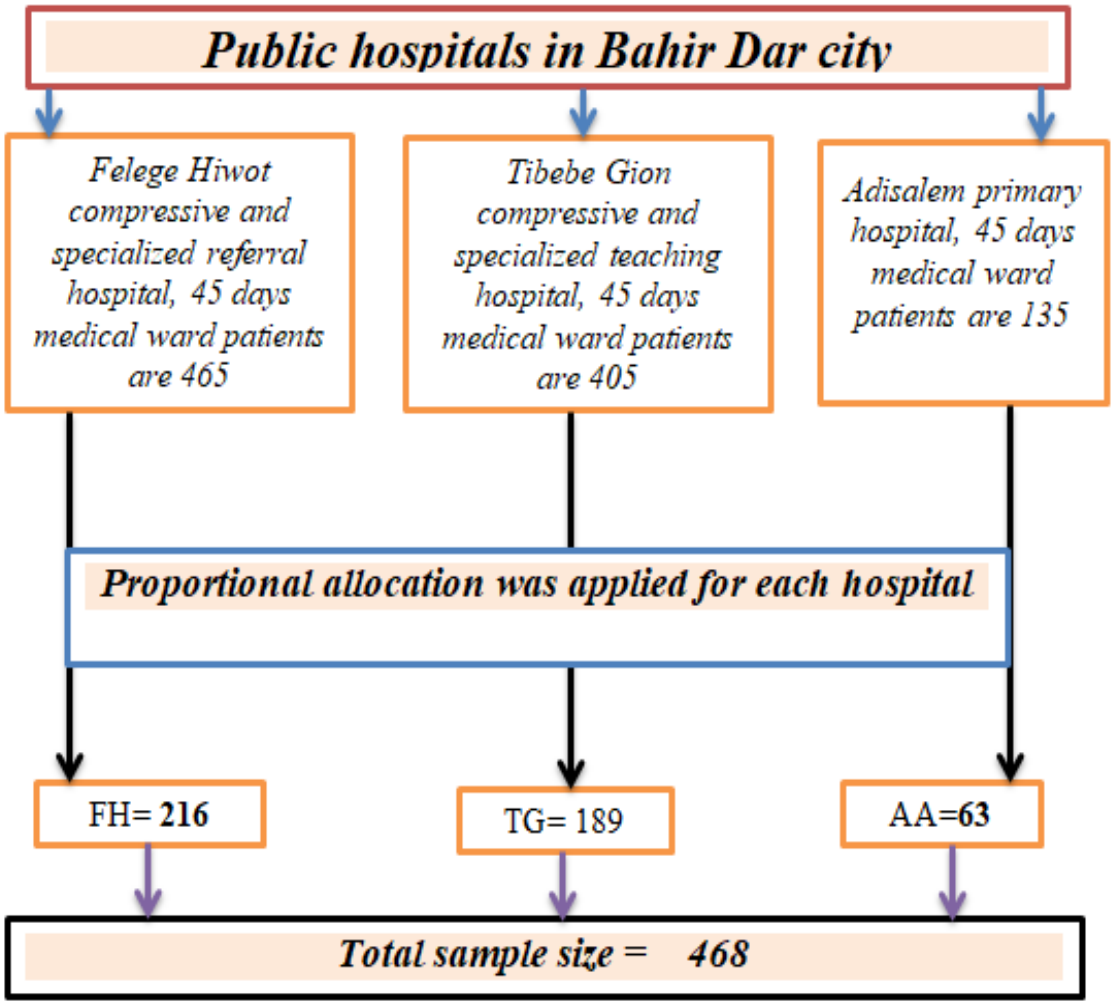
Variables	Hazard ratio	Sample size = through HR	Sample size = adding Design effect (1.5)	Sample size = adding Non-response rate (10%)	Final Calculated sample size
Cannula size	1.40	284	426	42	468(59)
Vein visibility status	1.42	262	393	39	432(16)
Fluid therapy	1.95	78	117	12	129(47)

In considering of the adequate sample size and feasibility issues, the final sample size was 468.

5.5.2. Sampling techniques and procedure

The source population was patients admitted in medical ward. One-year medical ward admissions were obtained from the data management offices of each hospital, and 45-day average numbers of admitted patients were determined across the three hospitals. Stratified

sampling technique was implemented. Due to the hospital difference, the three-hospital included for this study. A proportional allocation was carried out for the three hospitals based on their 45-day average number of admitted patients. After then, from May 02 to June 17/2022, a systematic random sampling technique was applied to select the appropriate sample size and study units at the three public hospitals.



Note: FH = Felege Hiwot, TG= Tibebe Gion, AA= Addis Alem

Figure-2 Sampling procedure of time to develop and its predictors of phlebitis among patients with cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022

5.6. Variables

5.6.1. Dependent variable

Time to develop phlebitis

5.6.2. Independent variables

Sociodemographic variables

Sex, age, residence, educational level, occupational status and marital status

Clinical related variables

Admission diagnosis of the patient, Known chronic diseases, base line consciousness level of the patient, ambulation status of patients, drug administration, fluid administration, blood administration

Cannula related variables

Cannula insertion site, cannula-gauge size, cannula insertion trial, cannula securing/dressing status, cannulated vein visibility status during cannula insertion time, and cannula dwelling time

5.7. Operational definition

Event: patients have developed phlebitis (peripheral intravenous cannula complication) during the study period (follow up time)

Censored: Patients have not developed phlebitis during the study period due to different reason such as died; discharge and transfer out to other health facilities or not developed up to the end of follow up time.

Follow up period: The time interval between insertions of peripheral intravenous cannula to the occurrence of phlebitis or removal time of the cannula.

Phlebitis: Phlebitis was defined as the presence of at least two of the following on patient's vein with peripheral intravenous cannula, pain near to intravenous site, erythema, swelling, induration, palpable venous cord and pyrexia with or without visible pussy discharge at intravenous site (8, 11, 12, 38).

Good vein quality/visibility: The vein could be easily accessible, observable and able to accommodate adult cannula size (12, 60, 61).

Appropriate cannula site securing/dressing: covering the cannula insertion site by V-shaped through adhesive plaster and add another adhesive plaster over it the half edges of the cannulated hand (180 degree) but not tourniquet the site 360 degree rotation(12).

Cannula size: the cannula size is the outer diameter of the needle that measured by its standard unit, which is gauge, 16-gauge in color gray and in metric 1.65mm, 18-gauge in color green and in metric 1.27mm, 20-gauge in color pink and in metric 0.91(62).

Cannulated Vein: is the vein of the patients that peripheral intravenous cannula inserted into it.

5.8. Data collection questionnaires

The data collection questionnaires were developed from different related studies. It was tested before the actual data collection-period on similar study area. The questionnaires were comprised different parts that including socio-demographic characteristics, clinical related characteristics, cannula related characteristics and the outcome (phlebitis) characteristics. The Visual Infusion Phlebitis score can range from zero, indicating no symptoms of phlebitis up to five that indicate with signs of pyrexia with or without visible pussy discharge.

5.9. Data collection procedure

After obtaining ethical clearance letter from college of medicine and health science, Bahir Dar University, permission letters from each hospitals research coordinators and written consent from each patient, data were collected through interviewer administered pre-designed structured questionnaire using systematic random sampling technique from each stratified hospitals. Patients were interviewed to obtain socio-demographic and other concerned data. Relevant medical history and related data were obtained from patients' records and the outcome variable information (phlebitis) was collected through direct observation of the patient cannulated vein by trained data collectors. In addition to this for clarity of doubtful data, the data collectors have asked health care professionals who were work in medical ward. Four BSc nursing Professionals (three data collectors) and (one supervisor) were participated in the data collection process. One day training was given for data collectors and supervisor. The training was theoretical and practical regarding to phlebitis, how to identify the symptom and signs of phlebitis (diagnosis of phlebitis) and other related issues of this study. Patients with peripheral intravenous cannula were followed two times per a day. This was based on pre-designed phlebitis scoring form at the morning and at the evening time by data collectors to check whether the patients developed the event (phlebitis) or not developed the event. Phlebitis was diagnosed based on Jackson's Visual Infusion Phlebitis Scoring System, which is international adopted diagnosis method/criteria that has been tested in literature and used in clinical settings worldwide(15, 38, 63). Data were

collected from patients that admitted in medical ward from May/02 to June/17/2022 at public hospitals of Bahir Dar city Amhara, Ethiopia, 2022.

5.10. Data quality assurance and control

Data quality was assured through designing proper data abstraction questionnaires. Pre-test was done on five percent (24 patients) of the sample size at public hospitals of Bahir Dar city on patients admitted in medical ward with peripheral intravenous cannula that admitted before the actual data collection period to check the appropriateness of the questionnaires. As a result, modification was takes place on some variables. Training was given for data collectors and supervisor, which concerning the data abstraction questionnaires and data collection process regarding to the purpose of the study, which data should be collected, how and from who/what collected and how to ensure the confidentiality issues of the patient information. During the data collection time, close supervision and monitoring were carried out through investigator and supervisor to ensure the quality of the data. Daily evaluation of the data for completeness and consistency and encountered difficulties on the time of data collection was attended accordingly. Finally, all the collected data was checked by investigator for its completeness and consistency during the data management process using descriptive statistics.

5.11. Data management and analysis

After the data were collected, the completeness and consistency of the questionnaires was checked manually. Epi data version 3.1 was used to enter the data then it was exported to Stata version-15 for analysis. Before analysis, missing values were checked through descriptive statistics. Multicollinearity was checked through spearman's rank test for categorical independent predictors. Descriptive analyses were carried out to determine frequency, proportion, mean, interquartile range, standard deviation, cumulative incidence and person-time incidence-rate (incidence density). Survival life table carried out to estimate cumulative survivor probability of patients to developed phlebitis. Kaplan-Meier curve was used to estimate the median survival time and the overall cumulative survival probability. Kaplan-Meier curve and log rank test were implemented to estimate the survivor differences between categories of independent variables. Graphical method (log minus log plot of survival estimation) and statistical method (global test) were used to check the proportional hazards assumption. Cox Snell residual test and log likelihood ratio test were implemented to check the overall model fitness. Bi-variable Cox

proportional hazards regression analysis was applied for each predictor of phlebitis to select those candidate predictors for the multivariable Cox proportional hazards regression analysis. Predictors their p-value on bi-variable Cox proportional hazards regression analysis ≤ 0.25 and they fulfilled the Cox proportional hazards ratio assumption were chosen for multiple Cox proportional hazards regression analysis. To identify predictors of phlebitis, Cox proportional hazards regression analysis was carried out at 95 percent confidence level. Statistical significance of the measure of association (hazards ratio) between outcome variable and independent variables was declared at P-value less than five percent. Findings of this study were presented through texts, tables and figures.

5.12. Ethical consideration

Ethical clearance was obtained from the Ethical review board of CMHS, BDU. Permission letter was obtained from each public hospital and written informed consent was taken from each participants. Patients MRN was replaced by new identification number during data entry. The daily collected data was kept in locked cabinets. Information retrieved was used for the study purpose only.

6. RESULTS

6.1. Socio-demographic characteristics

In this study, 462 patients participated with the response rate of 98.72%. Of those, 243(52.60%) were females, from these, 115(47.33%) acquired phlebitis. The median age of the patients was 42 years old, with an interquartile range 27 to 60 years old and a range of 15 to 88 years. Majority of the patients, 286 (61.90%) were rural residents, from these 125(43.71%) patients showed the event (acquired phlebitis). Regarding to educational level, 213(46.10%) patients could not read and write, of those, 73(34.27%) patients experienced phlebitis [Table-2].

Table-2 Socio-demographic characteristics of patients with PIVC at Bahir Dar city public hospitals, Amhara, Ethiopia, 2022 (N=462)

Variables	Categories	Event		Censored		Total	
		FR.	Percent	FR.	Percent	FR.	Percent
Sex	Male	56	25.57	163	74.43	219	47.40
	Female	115	47.33	128	52.67	243	52.60
Age	15 – 40	83	36.89	142	63.11	225	48.70
	41 – 60	57	42.54	77	57.46	134	29.00
	> 60	31	30.10	72	69.90	103	22.29
Residence	Urban	46	26.14	130	73.86	176	38.10
	Rural	125	43.71	161	56.29	286	61.90
Educational status	Unable read and write	73	34.27	140	65.73	213	46.10
	Able to read and write	25	40.32	37	59.68	62	13.42
	Up to elementary	23	38.33	37	61.67	60	12.99
	Up to secondary	23	40.35	34	59.65	57	12.34
	College and above	27	38.57	43	61.43	70	15.15
Occupational status	Unemployed	15	37.50	25	62.50	40	8.66
	Employed	17	29.31	41	70.69	58	12.55
	Merchant	27	35.06	50	64.94	77	16.67
	Farmer	90	37.66	149	62.34	239	51.73
	Student	22	45.83	26	54.17	48	10.39
Marital status	Single	26	29.89	61	70.11	87	18.83
	Married	114	37.75	188	62.25	302	65.37
	Divorced	14	42.42	19	57.58	33	7.14
	Widowed	17	42.50	23	57.50	40	8.66

Note: Event is patient acquired Phlebitis, Censored is patient not acquired phlebitis, FR. = Frequency

6.2. Clinical related characteristics

From all (462) participated patients, 185(40.04%) were admitted with two or more diseases, of them, 69 (37.30%) patients developed phlebitis. During the study period, 165(35.71%) patients had at least one chronic disease, of these, 97(58.79%) patients showed the event (phlebitis). Most patients, 414 (89.61 %) were treated through drugs (medications). Among those, 165(39.86%) patients acquired phlebitis. From all participated patients, 85(18.40%) were received blood transfusion, of those, 48 (56.47%) patients experienced phlebitis [Table-3].

Table-3 Clinical related characteristics of patients with PIVC at Bahir Dar city public hospitals, Amhara, Ethiopia, 2022 (N=462)

Variables	Categories	Event		Censored		Total	
		FR.	Percent	FR.	Percent	FR.	Percent
Patient admitted with	One disease	102	36.82	175	63.18	277	59.96
	≥ two diseases	69	37.30	116	62.70	185	40.04
Known chronic disease	No	74	24.92	223	75.08	297	64.29
	Yes	97	58.79	68	41.21	165	35.71
Base line patient consciousness level	(≤ 8)	21	37.50	35	62.50	56	12.12
	(9– 12)	55	44.72	68	55.28	123	26.62
	(>12)	95	33.57	188	66.43	283	61.26
Patient ambulation status	Ambulatory	87	27.27	232	72.73	319	69.05
	Not ambulatory	84	58.74	59	41.26	143	30.95
Drugs/medications administered through cannula	No	6	1.25	42	98.75	48	10.39
	Yes	165	39.86	249	60.14	414	89.61
Fluid administered through cannula	No	107	37.94	175	62.06	282	61.04
	Yes	64	35.56	116	64.44	180	38.96
Blood administered through cannula	No	123	32.63	254	67.37	377	81.60
	Yes	48	56.47	37	43.53	85	18.40

Note: Event is patient acquired Phlebitis, Censored is patient not acquired phlebitis, FR. = Frequency

6.3. Cannula related characteristics

Most of the peripheral intravenous cannulas were inserted on the patient's dorsum of hand that accounted, 210 (45.45%). Among those, 85(40.48%) patients acquired phlebitis. Above half of the patients, 241 (52.16%) used 18-gauge cannula size, from those, 115(47.72%) acquired

phlebitis. During the study period, 240(51.95%) patients had improper cannula dressing, of those, 106 (44.17%) patients developed phlebitis. Near to the half of peripheral intravenous cannula, 229(49.57 %) dwelling times were longer than four days. Among them, 56(24.45) patients acquired phlebitis during the study period [Table-4].

Table-4 Cannula related characteristics of patients with PIVC at Bahir Dar city public hospitals, Amhara, Ethiopia, 2022 (N=462)

Variables	Categories	Event		Censored		Total	
		FR.	Percent	FR.	Percent	FR.	Percent
Cannula insertion site	Antecubital fossa	24	32.88	49	67.12	73	15.80
	Forearm	62	34.64	117	65.36	179	38.74
	Dorsum of hand	85	40.48	125	59.52	210	45.45
Cannula gauge size	20gauge (0.91mm)	56	25.34	165	74.66	221	47.84
	18gauge (1.27mm)	115	47.72	126	52.28	241	52.16
Cannulated Vein quality	Good visible	122	34.56	231	65.44	353	76.41
	Poorly visible	49	44.95	60	55.05	109	23.59
cannula insertion trial	One time	121	35.07	224	64.93	345	74.68
	More than one	50	42.74	67	57.26	117	25.32
Cannula dressing status	Appropriate	65	29.28	157	70.72	222	48.05
	Not appropriate	106	44.17	134	55.83	240	51.95
Cannula dwelling time	≤ four days	115	49.36	118	50.64	233	50.43
	> four day	56	24.45	173	75.55	229	49.57

Note: Event is patient acquired Phlebitis, Censored is patient not acquired phlebitis, FR. = Frequency

6.4. Incidence of Phlebitis

The cumulative incidence and incidence rate of post-peripheral intravenous cannula phlebitis were 37.01% (95% CI 32.59% - 41.59%) and 8/100 persons per day observation (95% CI 7/100 – 9/100) respectively. All patients who participated in this study had a total follow-up time of 2107 days, with a median follow-up time of four days and a range of two to eight days. The following figure-3 showed that score zero and score one indicated that patients not acquired phlebitis but score two/early stage of phlebitis up to score five/extensive stage of phlebitis and uncategorized symptom and signs indicated that patients acquired phlebitis. In this study 291(62.99%) patients found that in the categories of zero and one (score zero = 260 and score one = 31). The rest 171(37.01%) patients found that in the categories of score two up to score five and uncategorized group, which showed that patients developed phlebitis during the follow

up period. Among all patients 153 (33.12%) found that in categories of score two/early stage of phlebitis up to score five/extensive stage of phlebitis and 18(10.53%) patients showed symptom and sign of phlebitis from different categories, as a result those patients did not categorized in any scores/stages, such as patients showed swelling and pyrexia. Those patients did not included in any categories, even if they satisfied the phlebitis diagnosis criteria. Because of swelling found in score two but pyrexia found in another category that is score five.

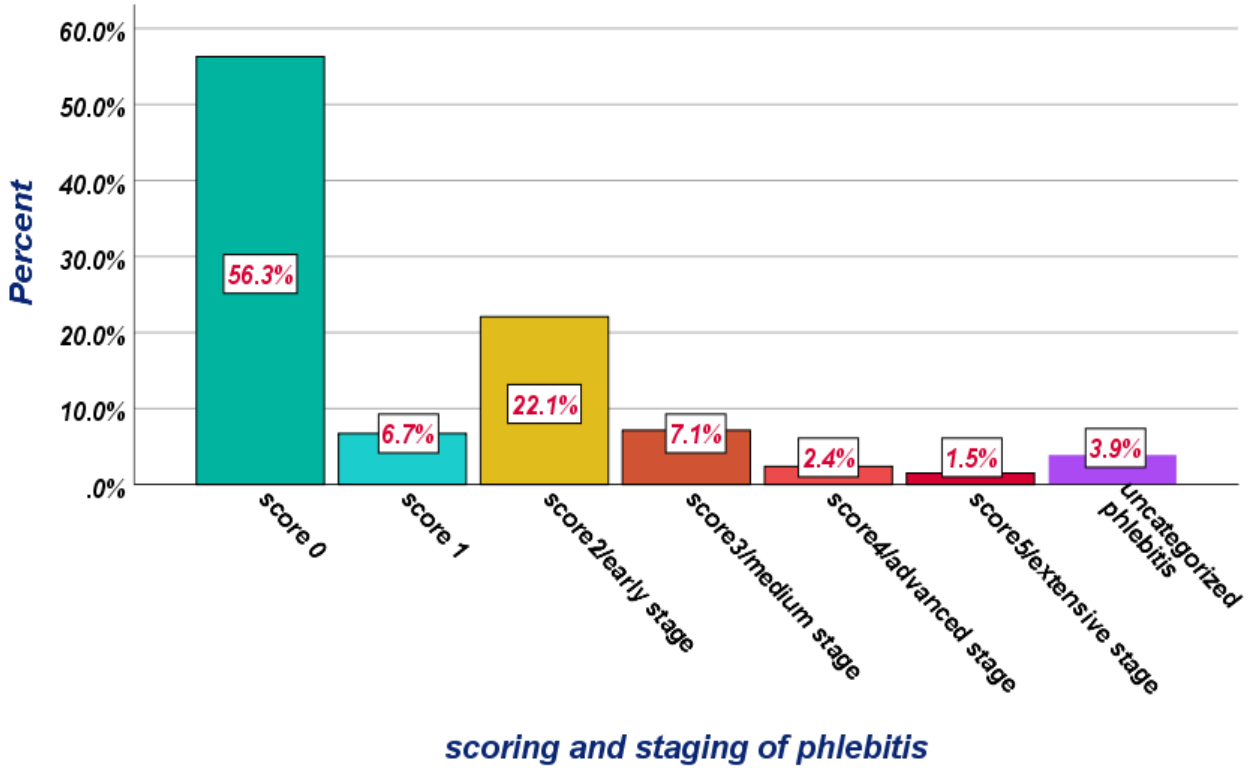


Figure-3 Staging and scoring of Phlebitis among patients with peripheral intravenous cannula at Bahir Dar city public hospitals, Amhara, Ethiopia, 2022 (N=462)

6.5. Survival time of Phlebitis

The overall median survival time to develop phlebitis was six days with the survival interquartile ranges of five up to seven days. During the study period, 171(37.01%) patients have showed the event while the rest, 291(62.99%) patients were not showed the event, which were censored that was due to lost to follow up 13 (2.81%) and not developed the event throughout the follow up time (cannula removal time) 237 (51.30%). In addition to the Kaplan Meier graphical presentation the cumulative survival probability to develop phlebitis was presented using

statistical method (life table), [Annex-1]. The overall Kaplan Meier survival curve indicated that 50% of patients could survive to developed phlebitis up to six days [Fig-4].

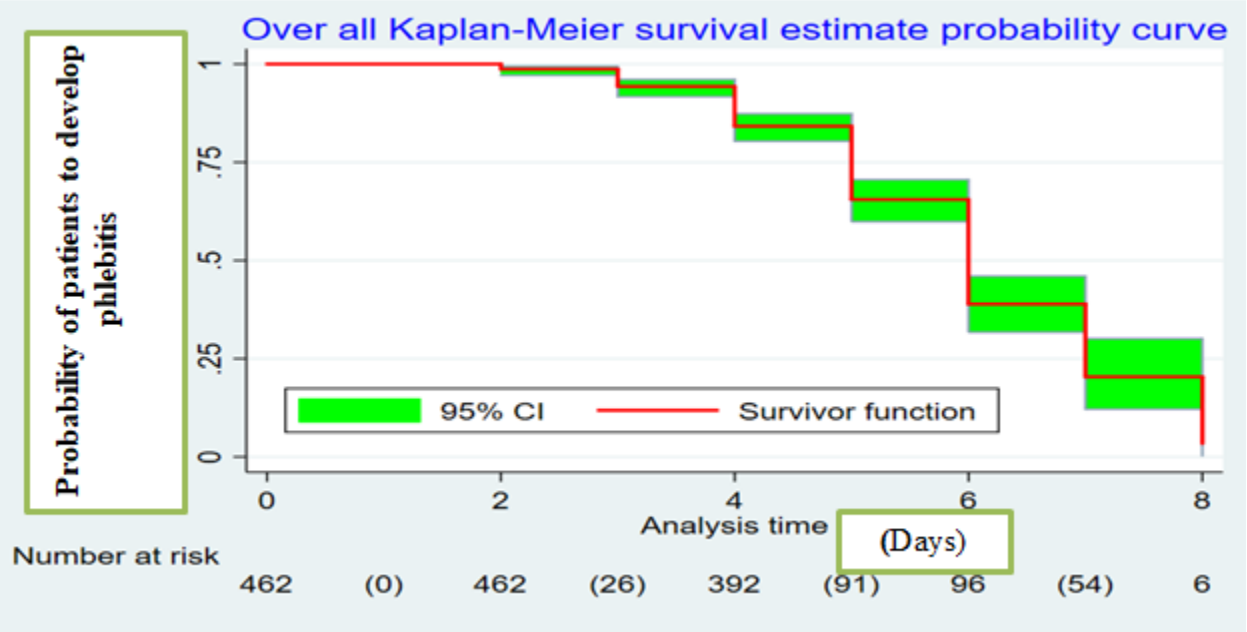


Figure-4 Over all Kaplan Meier survival probability curve of Phlebitis among patients with PIVC at Bahir Dar city public hospitals, Amhara, Ethiopia, 2022 (N=462)

6.6. Comparision of survival difference between categories of predictors

For categorical predictors survival differences were assessed using both KM graphical curve and log-rank test. From the result of Kaplan Meier survival curve or log rank test, survival differences to develop phlebitis was observed between categories of predictors. Such as sex, age group, occupational status, marital status, chronic disease, patient ambulatory status, drug administration, cannula insertion site, cannula gauge size, cannula-dressing status, cannula dwelling time and the statistical interaction effect of drugs and blood administration. Figure-five showed that an example of the Kaplan Meier graph and log rank test for predictor that had survival difference between its categories to develop post cannula phlebitis [Fig. 5].

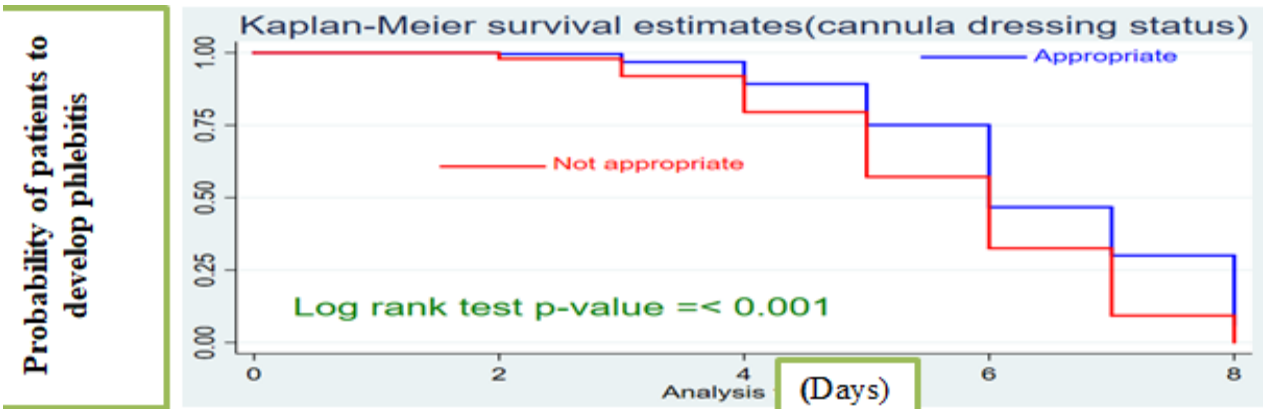


Figure-5 KM survival difference curve for cannula dressing status among patients with PIVC at Bahir Dar city public hospitals, Amhara, Ethiopia, 2022 (N=462)

On some variables, the Kaplan Meier survival curve or log rank test showed that there was no clear survival difference to develop post-peripheral intravenous cannula phlebitis between their categories. Such as residence, educational status, patient admission diagnosis, patient consciousness level, fluid administration, blood administration, cannulated vein visibility or quality status and cannula insertion trial. Figure six showed that an example of the Kaplan Meier graph and log rank test for predictor that had not survival difference between its categories to develop post cannula phlebitis [Fig. 6].

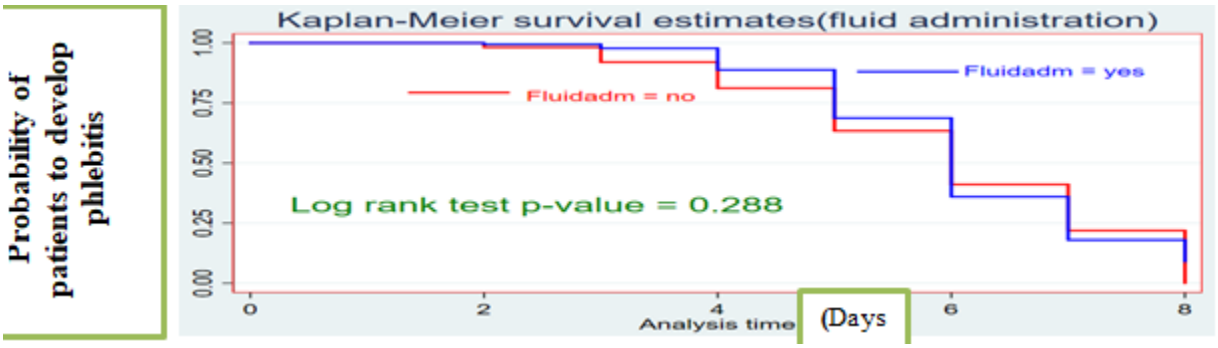


Figure-6 KM survival difference curve for fluid administration among patients with PIVC at Bahir Dar city public hospitals, Amhara, Ethiopia, 2022 (N=462)

Log-rank test is also the most commonly used statistical test for comparision of the median survival differences between categories of predictors. In this study, the median survival time difference was observed for variables like cannula insertion site and cannula dwelling time. However, Predictors like sex, age group, drug administration, cannula size, cannula dressing status, etc. did not showed that median survival time difference between their categories to develop post

cannula phlebitis. The detail of median survival difference for each predictors presented in table, on the annex part of this document [Annex-II].

6.7. Proportional Hazards Assumption

The proportional hazards assumption is vital to a fitted the cox proportional hazards model and the interpretation of its result. The CPHM assumes that the proportional hazards ratio is constant over time(64). The most common methods to assess this assumption are visualization of log minus log curve (graphical method) and use of global goodness of fit test (statistical method)(65, 66). In this study, a graphical method was used to check proportional hazards assumptions by plotting log minus log survivor curves versus survival time for categorical predictors and evaluating whether the curves are reasonably parallel or crossed each other.

The graph was drawn for each predictor and those fulfilling the requirement were considered for the final model, if they also fulfilled the statistical method. They were sex, age group, occupational status, marital status, known chronic disease, patient ambulation status, drug administration, cannula insertion site, cannula gauge size, cannula-dressing status, cannula dwelling time and the interaction term of drug and blood. To show as example, one variable log minus log curve presented in this document on the annex part [Annex-III].

Predictors that were not fulfilled log minus log proportional hazards assumption were residence, educational status, patient admission diagnosis, base line patient level of consciousness, fluid administration, blood administration/transfusion, vein visibility/quality status and cannula insertion trial. To show as example, one variable log minus log curve presented in this document on the annex part [Annex-III].

The graphical assumption test is somewhat subjective test to the interpretation in different persons and not enough to be certain test of the proportional hazards assumption of the cox proportional hazards model. Therefore, there is a need to support it with other method employed statistical test. The global goodness-of fit test, proposed by Schoenfeld is an objective test, and it is recommended as the best among the methods compared. The overall global test with P-value of greater than 0.05 indicated that the proportional hazards assumption was fulfilled(64, 66). In this study, the overall global test and tests for each predictors had a P-value greater than 0.05 (overall, Chi=22.48 and P-value = 0.261), indicating that the proportional hazards assumption was fulfilled. The detail presented on the annex part of this document [Annex-IV].

6.8. The Cox proportional hazards regression model adequacy test

After fitting multivariable Cox proportional hazards regression model, the adequacy of a fitted model was assessed graphically through Cox Snell residuals. Finally, the graph of Nelson Aelon hazard function (cumulative hazard function of residual for Cox model) and the Cox Snell residuals were compared. The graph of Nelson Aelon hazard function (cumulative hazard function of residual for Cox proportional hazards model) follows the 45-degree line, which approximately, indicated that the model fitted the data well(67). The following graph indicated that the Nelson Aelon hazard function (cumulative hazard function of residual for Cox proportional hazards model) follow the Cox Snell residual. Despite the wriggling of the line, it showed the model fitted the data well.

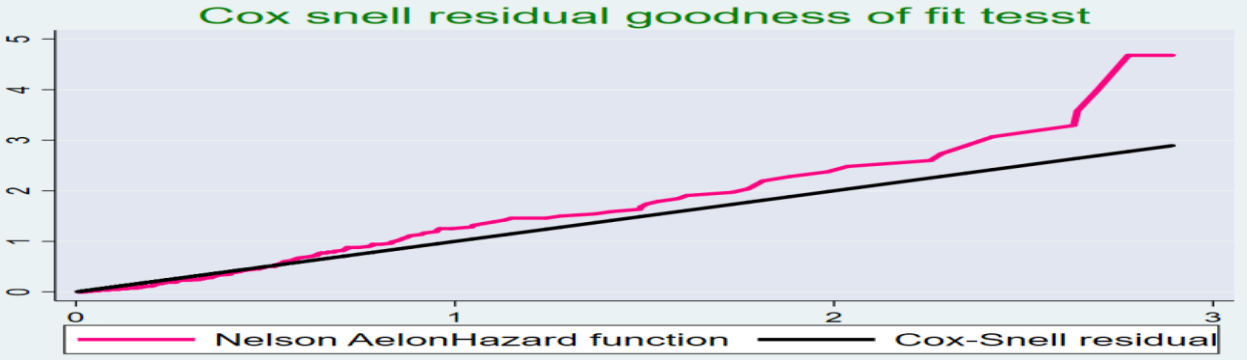


Figure-7 Cox Snell residual goodness of model test among patients with PIVC at Bahir Dar city public hospitals, Amhara, Ethiopia, 2022 (N=462)

Graphical (Cox Snell residual) of model check method is subjective; therefore, there is need of support it through objective model fitting method/technique that is the likelihood ratio test. Statistical method (likelihood ratio test) implemented to check the CPHRM goodness of fitness test (adequacy test). The result showed the likelihood ratio test = 131.22 with chi-square probability < 0.001, which indicated the Cox proportional hazards model was well fitted.

6.9. Predictors of time to develop Phlebitis

Nineteen possible predictors believed to be predictors of time to develop phlebitis that entered into bi-variable CPHRM. Those were sex, age group, residence, educational status, occupational status, marital status, patient admission diagnosis, known chronic disease, patient consciousness level, patient ambulation status, drug administration, fluid administration, blood administration, cannula insertion site, cannula gauge size, cannulated vein quality, cannula insertion trial,

cannula dressing status and cannula dwelling time. On bi-variable CPHRM, 14 predictors were significant at level of significance 0.25. Those were sex, age-categorized, residence, occupational status, marital status, known chronic disease, patient ambulation status, drug administration, blood administration, cannula insertion site, cannula gauge size, cannulated vein quality, cannula dressing status and cannula dwelling time.

Among 14 predictors, eleven predictors could passed graphical and statistical assumptions of proportional hazards ratio that were sex, age-categorized, occupational status, marital status, known chronic disease, patient ambulation status, drug administration, cannula insertion site, cannula gauge size, cannula dressing status and cannula dwelling time. All these eleven predictors and the statistical interaction effect of drug and blood were entered into multi-variable Cox proportional hazards regression model. On the final Cox proportional hazards model, five predictors and the statistical interaction effect of drugs and blood became significant (p-values less than 0.05) which were age group, chronic disease, cannula size, cannula dressing status, cannula dwelling time and the statistical interaction effect of drugs and blood.

For patients whose age group > 60 years old, the hazard of developing phlebitis decreased by 51% times as compared to patients of age group 15-40 years old (AHR = 0.49, 95% CI 0.29-0.82). The hazard of developing phlebitis for patients with chronic disease was 1.50 times higher as compared to patients without chronic disease (AHR = 1.50, 95% CI 1.09-2.07). The statistical interaction effect of drugs and blood showed that if drugs and blood administer in one vein, the hazard of developing phlebitis increased by 2.03 times (AHR= 2.03, 95% CI 1.44-2.86).

Patients who used 18-gauge cannula size were 1.52 times more risk to develop phlebitis as compared to patients who used 20-gauge cannula size (AHR=1.52, 95%CI 1.08-2.15). Patients with inappropriate cannula dressing were 1.81 times more risk to develop phlebitis as compared to patients with appropriated cannula securing/dressing (AHR = 1.81, 95% CI 1.31-2.51). Patients with a cannula dwelling time of more than four days, the hazard of develop phlebitis were 7.39 times as compared to patients with a cannula dwelling time of less than or equal to four days (AHR = 7.39, 95% CI 4.12-13.32) [Table-7, Annex-6 and Annex-7]. These significant predictors contributed a favorable impact on patients with peripheral intravenous cannula to acquired phlebitis in hospital setting.

Table-5 Bi-variable and Multi-variable Cox proportional hazards regression analysis for the predictors of phlebitis among patients with PIVC at Bahir Dar city public hospitals, Amhara, Ethiopia, 2022 (N=462)

Variables	Categories	Phlebitis		CHR	AHR(95% CI)	P-value
		Event	Censored			
Sex	Male	56	163	1	1	
	Female	115	128	1.54	1.28 (0.91-1.80)	0.154
Age	15 – 40	83	142	1	1	
	41 – 60	57	77	1.25	0.89 (0.59-1.31)	0.551
	> 60	31	72	0.84	0.49 (0.29-0.82)	0.008*
Residence	Urban	46	130	1	-	-
	Rural	125	161	1.63	-	-
Educational status	Unable to read and write	73	140	1	-	-
	Able to read and write	25	37	1.27	-	-
	Up to elementary school	23	37	1.01	-	-
	Up to secondary school	23	34	1.27	-	-
	College and above	27	43	1.05	-	-
Occupational status	Unemployed	15	25	1	1	
	Employed	17	41	1.29	1.16 (0.55-2.45)	0.695
	Merchant	27	50	1.55	1.40 (0.69-2.72)	0.372
	Farmer	90	149	1.54	1.18 (0.65-2.13)	0.585
	Student	22	26	1.59	1.33 (0.65-2.72)	0.437
Marital status	Single	26	61	1	1	
	Married	114	188	1.57	1.46 (0.82-2.50)	0.201
	Divorced	14	19	1.10	1.05 (0.50-2.19)	0.896
	Widowed	17	23	1.59	2.21 (0.98-5.02)	0.057
Patient admission diagnosis	One disease	102	175	1	-	-
	More than one	69	116	1.01	-	-
Known chronic disease	No	74	223	1	1	
	Yes	97	68	1.64	1.50 (1.09-2.07)	0.014*
Patient base line GCS level	(≤8)	21	35	1	-	-
	(9-12)	55	68	1.21	-	-
	(>12)	95	188	1.00	-	-
Patient ambulation status	Able to ambulate	87	232	1	1	
	unable to ambulate	84	59	1.88	1.38 (0.98-1.93)	0.062

This table is continuing from the above table (table-5)

Variables	Categories	Phlebitis		CHR	AHR(95% CI)	P-value
		Event	Censored			
Drug administration	No	6	42	1	1	
	Yes	165	249	2.85	1.88 (0.81-4.37)	0.145
Fluid administration	No	107	175	1	-	-
	Yes	64	116	0.86	-	-
Blood administration	No	123	254	1	-	-
	Yes	48	37	1.65	-	-
Cannula insertion site	Antecubital fossa	24	49	1	1	
	Forearm	62	117	1.29	1.04 (0.63-1.72)	0.881
	Dorsum of hand	85	125	1.69	1.01 (0.62-1.66)	0.968
Cannula gauge size	20gauge	56	165	1	1	
	18gauge	115	126	1.64	1.52 (1.08-2.15)	0.017*
Cannulated vein quality	Good visible	122	231	1	-	-
	Poorly visible	49	60	1.34	-	-
Cannula insertion trial	one times	121	224	1	-	-
	> one time	50	67	1.13	-	-
Cannula dressing status	Appropriate	65	157	1	1	
	Not appropriate	106	134	1.67	1.81 (1.31-2.51)	< 0.001*
Cannula dwelling time	Less/equal four days	115	118	1	1	
	More than four days	56	173	5.38	7.39 (4.12-13.32)	< 0.001*
Statistical interaction effect of drug and blood	No	95	277	1	1	
	Yes	76	14	2.58	2.03 (1.44-2.86)	< 0.001*

Note: *1-Reference category, AHR – adjusted hazards ratio, CHR – crude hazards ratio, CI- confidence interval, GCS = Glasgow comma scale, * = indicated significant predictors their p-value less than five percent*

7. DISCUSSION

This study finding showed that the cumulative incidence and incidence rate of phlebitis were 37.01% and 8/100 persons per day observation respectively. The incidence was much higher than acceptable phlebitis rate recommended by Infusion Nurses Society (INS), which should be five percent or less (11). This might be referring to ineffective preventive measures and poor peripheral intravenous cannula care practice. This finding was similar with study conducted in Saudi Arabia (48). The similarity was due to both studies used similar study design and diagnosis approach of phlebitis.

This current finding was higher than studies conducted in Africa level (13%) and other countries such as Malaysia (15.41%) and Brazil (18.34%)(18, 30, 37). The discrepancy might be due to diagnosis approach and sampling differences. Study conducted in Malaysia used laboratory based microorganism-identification diagnosis approach, which was conservative diagnosis that decreases the incidence of phlebitis and in Brazil, the design was retrospective follow up study and the study used small sample size compared to this study, those difference might be decreases the incidence of post cannula phlebitis.

However, the current finding was lower than studies conducted in Ethiopia (Gondar) (70%) and Tunisia (51.90) (15, 68). The discrepancy of the study might be due to sampling technique and sample size difference. This study used probability-sampling technique and used relatively large sample size. However, study conducted in Tunisia used small sample size and study conducted at University of Gondar hospital used non-probability sampling technique that might be increases the incidence of post cannula phlebitis.

This study showed that the median cannula dwelling time (length time) was four days with the range of two up to eight days. This finding was similar with study conducted in other countries and guideline(standard duration of the intravenous cannula) (39, 41). The median survival time to develop phlebitis was six days with the survival inter-quartile range of five up to seven days. This showed that 50% of the patients acquired phlebitis before six days of after peripheral intravenous cannula inserted. In the other ways, 50% of the patients could survive to develop phlebitis beyond six days. This finding was inconsistent with studies conducted in other countries (8, 39, 41). The discrepancy might be due to difference in sample size, sampling techniques, and diagnosis criteria of phlebitis.

The current study found that patients in the age group of 15-40 years old were linked to a high risk for post cannula phlebitis. The hazard of acquired phlebitis was higher for patients whose age group of 15-40 as compared to patients whose age group > 60 years old. This finding contradicted with studies conducted in other countries (47, 49, 50). The reason of the difference was due to adult age group participants have strong immune system to fight any infection and foreign material and more sensitive as compared to older age group. As a result, adult age group (15-40 years) were more exposed for the risk of phlebitis (11, 30).

Patients with chronic disease were more hazardous as compared to patients free from chronic disease. This finding was similar with studies conducted in other countries (15, 38). Patients with chronic diseases such as diabetes mellitus, hypertension and others are more immune-compromised that unable to resist infection/inflammation like phlebitis because they are physiological unstable as compared to healthy individual(4, 29).

The statistical interaction effect of drugs and blood showed that if drugs and blood administer in one vein, the risk of developing phlebitis increase. As my searching level, I could not found that study that support or contradict this finding. However, studies showed that in separately drug and blood were risk factors for phlebitis. The evidence revealed that when drugs or blood is administer, the vein become infiltrated faster due to the irritation effect of drug and clotting and reaction of blood on the blood vessels(69, 70). The irritation effects and reaction of blood make the blood vessels be inflamed. As a result, drugs and blood lead the blood vessel susceptible to develop post cannula phlebitis(46, 70).

Patients who used 18-gauge cannula size were more hazardous to develop phlebitis as compared to patients that used 20-gauge cannula size. This result was similar with studies conducted in other countries (26, 38, 47). The 18-gauge cannula size is comparably large in its diameter and length as compared to 20-gauge cannula. A smaller diameter peripheral intravenous cannula that accommodates the patient's veins and prescribed therapy minimizes the risk of phlebitis. However, choosing an inappropriate or larger cannula diameter size can increase the rate of phlebitis, and the risk rises with increasing diameter. Because of the physical properties and the size of the cannula, affect the physiology of the vein tissues by irritating and physically damaging the cannulated vein. The repeated irritation and physical damaging of the vein tissues resulted inflammation and infection of the vein (4, 28).

Patients who had inappropriate peripheral intravenous cannula dressing were more risk to develop phlebitis as compared to patients that had appropriated peripheral intravenous cannula securing/dressing. This finding was similar with studies conducted in other countries(11, 48). Improper stabilization and dressing of the cannula insertion-site that significantly increase the risk of phlebitis through direct contamination and blood clotting due to over tourniquet of the vein(4, 8, 29). Patients who had longer cannula dwelling time (greater than four days) were more hazardous/risk to develop phlebitis as compared to patients who had shorter cannula dwelling time (less than or equal to four days). This result was similar with studies conducted in other countries (1, 48). Prolonged cannula dwell times predisposes for continued trauma by the cannula itself and longer contact to irritant drugs and colloids that contribute to higher chance of inflammation or phlebitis (9, 15).

8. LIMITATION OF THE STUDY

This study included patients who admitted at medical wards but did not incorporate/included patients that admitted in other wards.

9. CONCLUSION

In conclusion, the incidence of post-peripheral intravenous cannula phlebitis was much higher than the recommended of Infusion Nurses Society. The median cannula dwelling time (duration of intravenous cannula) was four days that consistent with the standard/recommended one and the median time to develop phlebitis was 6 days with the survival inter quartile range of five up to seven days. The current study found that adult age group (15-40 years old), chronic disease, the statistical interaction effect of drugs and blood, 18-gauge cannula size, inappropriate cannula dressing and cannula dwelling time more than four days were found as significant risk factors of phlebitis. The finding of this study would help the health-care professionals through providing information regarding to incidence, time to develop and predictors of post-peripheral intravenous cannula phlebitis, which were very important for the prevention and the treatment of phlebitis.

10. RECOMMENDATION

For health care providers/professionals

To decrease/prevent the risk of phlebitis better to give special attention and clinical care for patient the risk factors of phlebitis like patients with chronic disease. Shall remove the intravenous cannula at the appropriate time (at four days, if no any reasons to remove the cannula, it can stay up to four days)

Health care providers shall avoid administering drugs and blood in one peripheral intravenous cannula, use the appropriate cannula size, avoid rolling adhesive plaster 360 degrees on cannulated hand and remove the cannula at the appropriate time (based on peripheral intravenous cannula condition).

For health organizations

Better to give a greater emphasis on the prevention of post-peripheral intravenous cannula phlebitis through providing necessary resources (medical equipment and supplies like cannula) for all health-care facilities, based on their needs.

For researchers

Future researchers, better to incorporate patients who admitted in other than medical wards for better generalizability of the problem of post cannula phlebitis.

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12. ANNEX

Annex- I Life table for time to develop Phlebitis

Time (days)	Beg. Total	phlebitis	Censored	Survival	Std.Error	95% CI
2 – 3	462	6	9	0.9869	0.0053	0.9710 - 0.9941
3 – 4	447	20	35	0.9409	0.0112	0.9144 - 0.9594
4 – 5	392	42	129	0.8203	0.0200	0.7772 - 0.8558
5 – 6	221	49	76	0.6006	0.0306	0.5380 - 0.6576
6 – 7	96	39	36	0.3003	0.0373	0.2293 - 70.3743
7 – 8	21	10	5	0.1380	0.0388	0.0731 - 0.2232
8 – 9	6	5	1	0.0125	0.0173	0.0003 - 0.0941

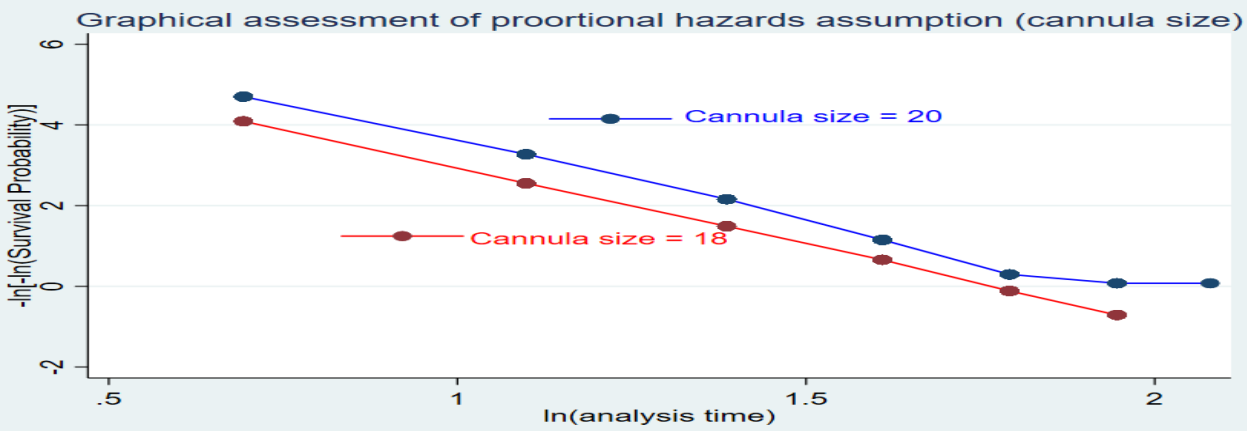
Annex-II Median survival time and Log-rank test for categories of predictors

Variables	Category	Phlebitis			Median time to develop phlebitis	Log rank test P-value	KM curve survival difference b/n categories
		Event	Censored	Total			
Sex	Male	56	163	219	6	0.003	yes
	Female	115	128	243	6		
Age	15 – 40	83	142	225	6	0.111	Yes, b/n age group 15-40 and 60-88
	41 – 60	57	77	134	6		
	60 – 88	31	72	103	6		
Residence	Urban	46	130	176	7	0.001	No, grossly crossed each other
	Rural	125	161	286	6		
Educational status	Unable to read and write	73	140	213	6	0.687	No
	Able to read and write	25	37	62	6		
	Up to elementary school	23	37	60	6		
	Up to secondary school	23	34	57	6		
	College and above	27	43	70	6		
Occupational status	Unemployed	15	25	40	7	0.419	Yes, b/n unemployed and merchant
	Employed	17	41	58	6		
	Merchant	27	50	77	6		
	Farmer	90	149	239	6		
	Student	22	26	48	6		
Marital status	Single	26	61	87	6	0.065	Yes, b/n single and married
	Married	114	188	302	6		
	Divorced	14	19	33	6		
	Widowed	17	23	40	6		
Patient admission	More than one	102	175	277	6	0.964	No
	One disease	69	116	185	6		
Known chronic disease	No	74	223	297	6	<0.001	Yes
	Yes	97	68	165	6		
Patient level of	(≤8)	21	35	56	6	0.642	No

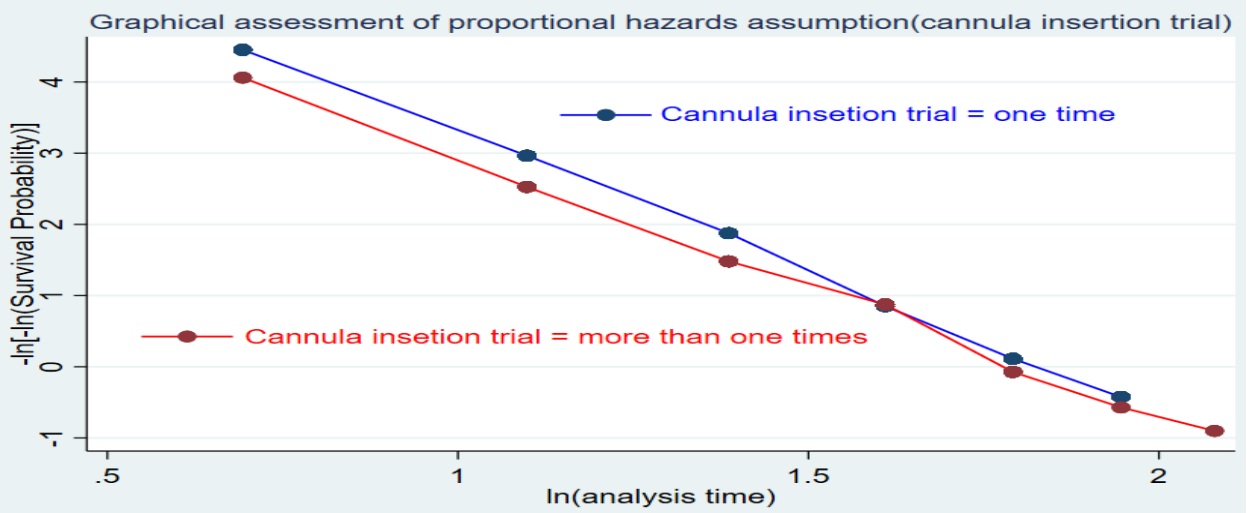
consciousness	(9-12)	55	68	123	6		
	(>12)	95	188	283	6		
Patient ambulation status	Able to ambulate	87	232	319	6	< 0.001	Yes
	unable to ambulate	84	59	143	6		
Drug administration	No	6	42	48	-	0.003	Yes
	Yes	165	249	414	6		
Fluid administration	No	107	175	282	6	0.288	No
	Yes	64	116	180	6		
Blood administration	No	123	254	377	6	0.001	Yes
	Yes	48	37	85	6		
Cannula insertion site	Antecubital fossa	24	49	73	7	0.019	Yes, b/n dorsum of hand and forehand
	Forearm	62	117	179	6		
	Dorsum of hand	85	125	210	6		
Cannula gauge size	20gauge	56	165	221	6	0.001	Yes
	18gauge	115	126	241	6		
Cannulated vein quality	Good visible	122	231	353	6	0.046	No
	Poorly visible	49	60	109	6		
Cannula insertion trial	One time	121	224	345	6	0.406	No
	> one time	50	67	117	6		
Cannula dressing status	Appropriate	65	157	222	6	< 0.001	Yes
	Not appropriate	106	134	240	6		
Cannula dwelling time	≤four days	115	118	233	6	< 0.001	Yes
	>Four days	56	173	229	5		
Statistical interactional effect of drug and blood	No	95	277	372	7	< 0.001	yes
	Yes	76	14	90	5		

Annex-III Graphical testing of proportional hazards assumption (log-log)

Example of predictor that passed graphical proportional hazards assumption (log-log)



Example of predictor that did not pass graphical proportional hazards assumption (log-log)



Annex-IV Statistical test of proportional hazards assumption (global test)

List of variables	Chi-square	Degree of freedom	P-value
Sex (female)	1.69	1	0.193
Age cat (41-60)	0.21	1	0.648
Age cat (61-88)	0.30	1	0.581
Occupation (employed)	0.12	1	0.732
Occupation (merchant)	1.35	1	0.244
Occupation (farmer)	0.02	1	0.894
Occupation (student)	0.41	1	0.523
Marital (married)	1.62	1	0.202
Marital (divorced)	0.38	1	0.537
Marital (widowed)	2.92	1	0.087
Chronic disease(yes)	0.96	1	0.328
Ambulation status(unable to ambulate)	1.95	1	0.162
Drug (yes)	1.31	1	0.251
Cannula insertion(forearm)	1.42	1	0.233
Cannula insertion(dorsum of hand)	0.13	1	0.719
Cannula size(18gauge)	0.20	1	0.653
Cannula dressing status(not appropriate)	1.03	1	0.310
Cannula dwelling time(>4days)	1.33	1	0.248
Interaction term of drug and blood(yes)	0.49	1	0.485
Global test (over all)	22.48	19	**0.261**

Annex-V Bi-variable Cox Proportional Hazards Regression Model

Sno	*Variable name*	*Categories*	*HR*	*Robust std. error*	*Z value*	*P value*	*CI lower limit*	*CI upper limit*
1	Sex >25%	Male	1					
		Female	1.544579	.2534907	2.65	0.008	1.119731	2.130621
2	Age categorized	15-40	1					
		41-60	1.24589	.2152663	1.27	0.203	.8879901	1.74804
		61-88	.8438748	.1790959	-0.80	0.424	.5567076	1.279172
3	Residence <5%	Urban	1					
		Rural	1.634613	.2828123	2.84	0.005	1.164513	2.294486
4	Educational status 5 – 25%	Unable to read & write	1					
		Able to read & write	1.266525	.2963323	1.01	0.313	.8006744	2.003419
		Elementary school	1.011655	.2424925	0.05	0.961	.6324121	1.61832
		secondary school	1.273343	.3065706	1.00	0.316	.7943461	2.041179
		College and above	1.053771	.2393378	0.23	0.818	.6751761	1.644657
5	Occupational status	Unemployed	1					
		employed	1.298205	.4612924	0.73	0.463	.6469711	2.604963
		Merchant	1.546118	.5001551	1.35	0.178	.8201373	2.914732
		Farmer	1.538315	.4299126	1.54	0.123	.8895291	2.660299
		Student	1.58756	.5318037	1.38	0.168	.8233663	3.061027
6	Marital status	Single	1					
		Married	1.570759	.3438869	2.06	0.039	1.022717	2.412478
		Divorced	1.103061	.370188	0.29	0.770	.571394	2.12943
		Widowed	1.588596	.495745	1.48	0.138	.8617543	2.928489
7	Admission DX diseases	> one Disease	1					
		One disease	1.00619	.1577393	0.04	0.969	.7400108	1.368113
8	Chronic diseases	No	1					
		Yes	1.641826	.2584141	3.15	0.002	1.206015	2.235123
9	Base line GCS level	Less than & 8	1					
		b/n 9 – 12	1.21477	.3130168	0.76	0.450	.7330943	2.012927
		Above 12	1.100219	.2676479	0.39	0.695	.6829816	1.772348
10	Ambulation status	Ambulatory	1					
		Not ambulatory	1.882913	.2890016	4.12	0.000	1.393742	2.543772
11	Drug administration	No	1					
		Yes	2.850431	1.18558	2.52	0.012	1.26145	6.440965
12	Fluid administration	No	1					
		Yes	.8629187	.1367124	-0.93	0.352	.6325776	1.177134
13	Blood administration	No	1					
		Yes	1.645707	.2808813	2.92	0.004	1.177805	2.299489
14	Cannula insertion site	Antecubital	1					
		Forearm	1.294504	.3125881	1.07	0.285	.8064197	2.078002
		Dorsum of hand	1.69476	.3956995	2.26	0.024	1.072424	2.678245
15	Cannula gauge	20	1					

	size	18	1.63781	.2685848	3.01	0.003	1.187612	2.258667
16	Vein quality status	Good visible	1					
		Poorly visible	1.344656	.2276064	1.75	0.080	.9650068	1.873664
17	Cannula insertion trial	One time only	1					
		> one time	1.129969	.1903753	0.73	0.468	.8121896	1.572083
18	Cannula dressing	Appropriate	1					
		Inappropriate	1.671776	.2668351	3.22	0.001	1.22269	2.285808
19	Cannula dwelling time	≤ 4 days	1					
		>4 days	5.377031	1.570124	5.76	0.000	3.033799	9.53012
20	Drug & blood interaction	No	1					
		Yes	2.580731	.4003332	6.11	0.000	1.90415	3.497716

Annex-VI Multi-Variable Cox Proportional Hazards Regression Model

List of variables	Haz. Ratio	Std. Err.	Z	P>z	CI lower limit	CI upper limit
Sex (male)	1					
Female	1.280252	.2218357	1.43	0.154	.911598	1.79799
Age cat (15-40)	1					
41 – 60	.8871944	.1780711	-0.60	0.551	.5986485	1.314818
61 – 88	.4925301	.1306445	-2.67	0.008	.2928532	.8283533
Occupation(unemployed)	1					
Employed	1.161697	.4445407	0.39	0.695	.5487414	2.459336
Merchant	1.368254	.4802991	0.89	0.372	.6876522	2.722479
Farmer	1.180046	.357734	0.55	0.585	.6514108	2.137681
Student	1.329508	.4875291	0.78	0.437	.6479722	2.727882
Marital (single)	1					
Married	1.457699	.4294041	1.28	0.201	.818321	2.596641
Divorced	1.05022	.393948	0.13	0.896	.5034846	2.190658
Widowed	2.214714	.9253708	1.90	0.057	.9764751	5.023125
Chronic disease (no)	1					
Yes	1.501056	.2477766	2.46	0.014	1.086152	2.074451
Ambulation(able to ambulate)	1					
unable to ambulatory	1.378061	.2369701	1.86	0.062	.9837767	1.930368
Drug administer(no)	1					
Yes	1.874998	.8084607	1.46	0.145	.8053415	4.365374
Cannula insertion site(no)	1					
Forearm	1.039507	.2683478	0.15	0.881	.6267442	1.724107
Dorsum of hand	1.010099	.2554229	0.04	0.968	.615349	1.658085
Cannula size(20)	1					
18	1.522031	.2680467	2.39	0.017	1.077748	2.149461
Cannula dressing(appropriate)	1					
not appropriate	1.809339	.3007122	3.57	0.000	1.306322	2.50605
Cannula dwelling time(≤4 days)	1					
>4 days	7.395322	1.219693	6.67	0.000	4.106486	13.31815
Interaction effect of drug and blood (no)	1					
Yes	2.030988	.3535457	4.07	0.000	1.443889	2.856807

Annex-VII Participants information and consent sheet English version

Dear Participant

My name is..... I am here on behalf of Tadios Lidetu who is a master's degree student at Bahir Dar University in department of Adult health nursing. Your participation is very important for this study therefore, I ask you politely to responding the questions accordingly.

Introduction: Information sheet provided for patients who admitted at Felege Hiwot compressive and specialized hospital, Tibebe Gion specialized and teaching hospital and Adisalem primary hospital and concerned bodies so that a clear view about the purpose of research, confidentiality and data collection procedures will be created for participants and concerned bodies.

Title of the Research: Time to develop and its predictors of phlebitis among patients admitted in medical and surgical wards with peripheral intravenous cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022

Name of Investigator: Tadios Lidetu (BSC Nurse)

Name of the Organization: Bahir Dar University, College of Medicine and Health Sciences, Department of Adult health Nursing

Purpose of the Research: To assess the time to develop and its predictors of phlebitis among patients admitted in medical ward with peripheral intravenous cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022

Procedure: After checking for the inclusion criteria of the participants, data will be obtained based on the written questionnaires. The total number of questions for one participant will be takes around 30 minutes.

Risk and /or Discomfort: Since data for this research is obtaining from the participants by asking, therefore it will not inflict any harm to the patients. Any other identifying information will not be recorded on the questionnaire and all information taken from the participant will be kept strictly confidential and in a safe place. The information retrieved from the participants will be only used for the study purpose.

Benefits: The research has direct benefit for the participant by identify the problem of phlebitis then recommendation will give the concerned bodies to manage it accordingly. It has also the indirect benefit of the research for the participant and other clients in the area of the research.

Generally, the research work has a paramount direct benefit for health care planners and managers to design appropriate policies.

Confidentiality: to assure confidentiality the data on the participant will be collected by those individuals who have working experience in the health facility and information will be collected without the name. The information collected from this research project will be kept confidential and will be stored in a locked cabinet. Besides, it will not be revealed to anyone except the investigator and will be kept with a password only on the investigator's computer.

Person to contact: If there are any questions or inquiries at any time about the study or the procedures, you can contact any of the following individuals (Investigator and Advisors) at any point in time.

Name of Investigator: Tadios Lidetu (BSc Nurse), Email address: tadioslidetu@gmail.com, Cell phone: 0955185671

Name of Advisors: Mr. Gebrie Yitayih (BSC, MSC, PhD fellow, Assistant professor in adult health nursing), Email address gebyit45@yahoo.com , Cell phone +251963039143 and Mr. Alemishet Yirga (BSC, MSC, lecturer in medical surgical adult health nursing), Email address alemyirga25@gmail.com, Cell phone +251918065664

Based on the understanding of the above information, Are you willing to participate in the Study? Yes_____ (continue) No _____ Thank you

Respondent: Signature _____Date_____

Questionnaires number_____

Date of interview_____ Starting time_____ Completed time _____

Result of interview A) Completed B) not completed C) Partially completed D) Refused

Data collector: Name _____Signature_____ date _____

Supervisor: Name _____Signature_____ date _____

Annex-VIII Questionnaire sheet English Version

Instruction: Dear participant please respond the appropriate alternative/answer from interview/provided accordingly.

Identification related information

Data collector's Name: _____ Signature: _____Date_____

Supervisor's Name: _____ Signature: _____

Code of participant patient: _____/_____/_____

Questionnaires Code No: _____ Hospital Name: _____

Part-I: sociodemographic variables

Table-4 Sociodemographic variables for time to develop and its predictors of phlebitis among patients admitted in medical ward with peripheral intravenous cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022

Sno	Variable(questions)	Answers	Codes	Skipping	Remarks
01	What is sex of the patient?	Male	0		
		Female	1		
02	How old are you (Age)?	_____			Put in years
03	Where is your residence?	Urban	0		
		Rural	1		
04	What is your educational level?	Unable to read and write	0		
		Able to read and write	1		
		Elementary school	2		
		Secondary school	3		
		College and above	4		
05	What is your occupation?	Unemployed	0		
		Employed	1		
		Merchant	2		
		Farmer	3		
		Student	4		
		Others			
06	What is your Marital status?	Single	0		
		Married	1		
		Divorced	2		
		Widowed	3		

Part II: Clinical related Variables

Table-6 Clinical variables for time to develop and its predictors of phlebitis among patients admitted in medical ward with peripheral intravenous cannula at public hospitals of Bahir Dar city, Amhara, Ethiopia, 2022

Sno	Variable	Answers	Codes	Skipping		Remarks
07	What is the patient admission diagnosis?	_____				Write the diagnosis
08	Is/are any known chronic disease/s	No	0			
		Yes	1			
09	What is the patient base line level of consciousness/GCS?	≤ 8	0			
		9 – 12	1			
		> 12	2			
10	What is the patient base line ambulation's status?	able to ambulate	0			
		unable to ambulate	1			
11	Is Drug administered through cannula	No	0			
		Yes	1			
12	Is fluid administered through cannula	No	0			
		Yes	1			
13	Is blood administered through cannula	No	0			
		Yes	1			

Part-III: cannula related variables

Sno	Variable	Answers	Code	Skip	Remarks
14	Where is the cannula insertion site?	Antecubital fossa	0		
		Forearm	1		
		Dorsum of hand	2		
		Others	3		
15	What is the cannula gauge size?	20 gauge(0.91mm)	0		
		18 gauge(1.27mm)	1		
		16 gauge(1.65mm)	2		
		Others	3		
16	How many time the cannula insertion trial on one vein (at insertion time)	One time	0		
		> one time	1		
17	The quality/visibility of cannulated	Good visible	0		

	vein during insertion time	Poorly visible	1		
18	The cannulated vein securing/dressing condition	Appropriate	0		
		Not appropriate	1		
19	How many days the cannula stay, (the cannula dwelling times)	_____			Write in day

Table-8 Outcome variable characteristics for time to develop and its predictors of phlebitis among patients admitted in medical ward with peripheral intravenous cannula at public hospitals

Part-IV: Outcome Variable

Sno	Variable	Answers	Codes	Skipping	Remarks
20	Date of cannula insertion	_____			Write in
21	What is the patient phlebitis scoring system?	Score zero (intravenous site healthy)	0		
		Score one (slight pain near IV site or slight redness near IV site)	1		
		Score two (pain, erythema, swelling)	2		
		Score three (pain along path of cannula, erythema, induration)	3		
		Score four (pain along path of cannula, erythema, induration, palpable venous cord)	4		
		Score five (pain along path of cannula, erythema, induration, palpable venous and pyrexia	5		
		Unspecified score(stage (two or more symptom and signs but not included in one of the scoring of phlebitis)			
22	Did patient acquired phlebitis	No	0		
		Yes	1		
23	If phlebitis developed, what is the stage of phlebitis?	Early stage (pain, erythema, swelling)	0		
		Medium stage (pain along path of cannula, erythema, induration)	1		

		Advanced stage (pain along path of cannula, erythema, induration, palpable venous cord)	2		
		More advanced stage = grade five (pain along path of cannula, erythema, induration, palpable venous and pyrexia)	3		
		Unspecified stage (two or more symptom and signs but not included in one of the stage of phlebitis)	4		
24	When is the date of phlebitis developed and after how many day developed	_____ and _____			Write both date and length day
25	When Cannula removed and after how many day it removed	_____/_____			Write date and day

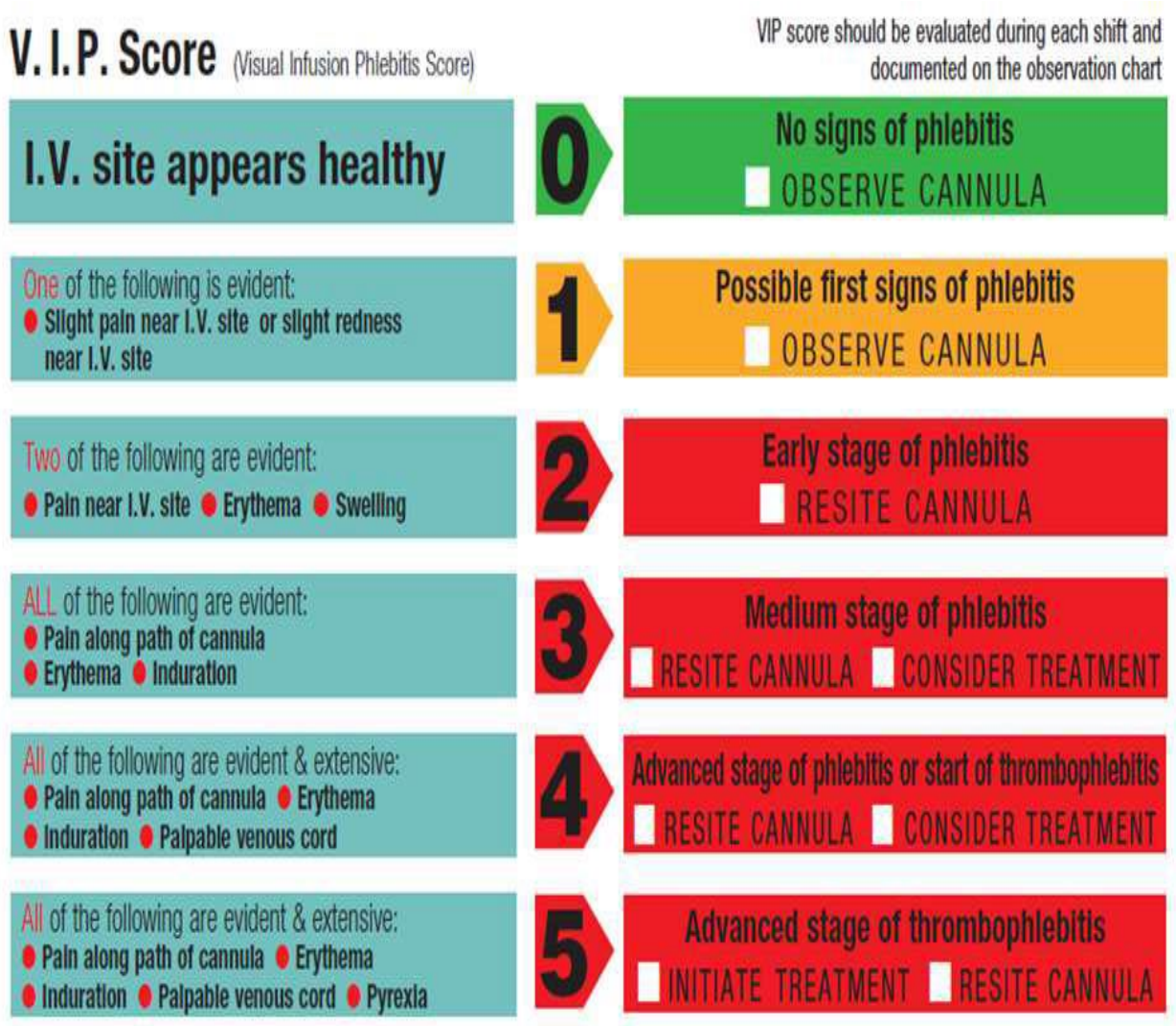
Part-V Phlebitis Scoring form (observation chart) during each follows up time

Day	Time	Please put phlebitis score (from 0-5) at each follow up time. If phlebitis occurred (two of its s/s), put all necessary information on the main questionnaire							
		Bed no=	Bed no=	P Bed no=	Bed no=	Bed no=	Bed no=	Bed no=	Bed no=
		Score	score	score	score	score	score	score	score
Day1	M								
	E								
Day2	M								
	E								
Day3	M								
	E								
Day4	M								
	E								
Day5	M								
	E								
Day6	M								
	E								
Day7	M								
	E								
Day8	M								

	E								
Day9	M								
	E								
Day10	M								
	E								

P Bed no = patient bed number, M = morning, E = evening

Part-VI The Jackson's Visual Infusion Phlebitis (VIP) Scoring System



Annex-IX Participants information and consent sheet Amharic version

ጤና ይስጥልኝ ስሜ .....ይባላል። በባህር ዳር የኒቨርሲቲ የአዋቂዎች ነርሲነግ የሁተኛ ዴግሪ ተማሪ ለሆነው የተማሪ ታዴዎስ ልደቱ ተወካይ ነኝ። ለዚህ ጥናት የእርስዎ ተሳትፎ በጣም አስፈላጊ ነው። ስለዚህ ለጥያቄው መልስ እንዲሰጡ በትህትና እጠይቃለሁ።

መግቢያ፡- ስለጥናቱ አጠቃላይ መረጀ ለፈለገ ሕይወት ሁለገብ እና ስፔሻላይዝድ ሆስፒታል፣ ለጥበበ ግዮን ስፔሻላይዝድና ማስተማሪያ ሆስፒታል ፤ ለአዲስዓለም የመጀመሪያ ደረጃ ሆስፒታል ፤ ለሚመለከታቸው አካላት እና ለተሳታፍዎች ይሰጣቸዋል።

የጥናቱ ርዕስ፡- በ2014ዓም ፤ በኢትዮጵያ፣ በአማራ ክልል፣ በባህርዳር ከተማ የሕዝብ ሆስፒታሎች ውስጥ ተኝተዉ ከሚታከሙ አዋቂዎች ህሙማን እና በደም ስራቸዉ የመድሃኒት መስጫ ፕላስቲክ ቱቦ ካላቸዉ መካክል መቸ የደም መላሽ የደም ስር እንደሚበከል እና አጋላጭ መንሴዎች ምርምር ማድረግ ነዉ።

የተመራማሪው ስም፡- ታዴዎስ ልደቱ (ቢኤስሲ ነርስ)

የድርጅቱ ስም፡- ባህር ዳር ዩኒቨርሲቲ የህክምና እና ጤና ሳይንስ ኮሌጅ የአዋቂዎች ጤና ነርሲነግ ትምህርት ክፍል

የጥናቱ ዓላማ፡- በ2014ዓም ፤ በኢትዮጵያ፣ አማራ፣ በባህርዳር ከተማ የሕዝብ ሆስፒታሎች ውስጥ ተኝተዉ ከሚታከሙ አዋቂዎች ህሙማን እና በደም ስራቸዉ የመድሃኒት መስጫ ፕላስቲክ ቱቦ ካላቸዉ መካክል መቸ የደም መላሽ የደም ስር እንደሚበከል እና አጋላጭ መንሴዎች ምርምር እና ጥናት ማካሄድ ነዉ።

የጥናቱ ሂደት፡ ተሣታፊዎችን የማካተት መመዘኛዎች ከተጣራ በኋላ እና ተሳታፊዎች ከተለዩ በኋላ፣ በጥያቄዎች ላይ በመመስረት መረጃው ይሰበሰባል። አንድ ተሳታፊ ጠይቆ ለመጨረስ 30 ደቂቃ አካባቢ ይወስዳል።

የጥናቱ ስጋት እና/ወይም አለመመቸት፡- የዚህ ጥናት መረጃ ተሳታፊዎችን በመጠየቅ የሚገኝ ስለሆነ በበሽተኞች ላይ ምንም አይነት ጉዳት አያስከትልም። ማንኛውም ሌላ ተሳታፊዉን ሊለይ የሚችል መረጃ በጥያቄዉ ላይ አይመዘገብም እንዲሁም ሁሉም ከተሳታፊው የተወሰዱ መረጃዎች በጥብቅ ሚስጥር እና በአስተማማኝ ቦታ ይቀመጣሉ። ከተሳታፊዎች የተገኘው መረጃ ለጥናት ዓላማ ብቻ ጥቅም ላይ ይውላል።

የጥናቱ ጥቅም፡ ጥናቱ ለተሳታፊው ቀጥተኛ ጥቅም አለው የህም የደም መላሽ የደም ስር የመበከል ችግርን በመለየት ከዚያም የሚመለከታቸው የህክምና አካላት በህክምናዉ መሰረት እንዲቆጣጠሩት ምክረ ሃሳብ ይሰጣል። በተጨማሪም በጥናቱ ዘርፍ ለተሣታፊው እና ለሌሎች ደንበኞች የሚሰጠው ቀጥተኛ ያልሆነ ጥቅም አለዉ። በአጠቃላይ፣ የምርምር ስራው የደም ስር የመበከል ችግርን በተመለከተ ተገቢ ፖሊሲዎችን ለመንደፍ ፤ ለጤና አጠባበቅ እቅድ አውጪዎች እና አስተዳዳሪዎች በጀት ለመበጀት ከፍተኛ የሆነ ቀጥተኛ ጥቅም አለው።

የጥናቱ ምስጢራዊነት፡ የጥናቱን ምስጢራዊነት ለማረጋገጥ በተሳታፊው ላይ ያለው መረጃ በጤና ተቋሙ ውስጥ የስራ ልምድ ባላቸው ግለሰቦች ይሰበሰባል እና የተሳታፊዎችን ስም ሳይጨምር መረጃ ይሰበስባል። ከዚህ

የምርምር ፕሮጀክት የሚሰበሰበው መረጃ በሚስጥር ይጠበቃል እንዲሁም በተዘጋ ካቢኔ ውስጥ ይቀመጣል። በተጨማሪም፣ ከተመራማሪዉ በስተቀር ለማንም አይገለጽም ። በተመራማሪዉኮምፒውተር ላይ በሚስጥር ይቀመጣል።

የጥናቱ ተጠሪ ሰው፡- ስለ ጥናቱ ወይም አካሄዶቹ በማንኛውም ጊዜ ጥያቄዎች ካሉ፣ ከሚከተሉት ግለሰቦች መካከል በማንኛውም ጊዜ ማግኘት ይቻላል።

የተመራማሪው	ታዴዎስ ልደቱ (ቢኤስሲ ነርስ), ኢሜል፡ tadioslidetu@gmail.com, የሞባይል
የአማካሪዎች ስም	ገብሬ ይታይህ (ቢኤስሲ፣ ኤም.ኤስ.ሲ፣ በአዋቂዎች የጤና ነርሲንግ ረዳት ፕሮፌሰር), ኢሜል አድራሻ gebyit45@yahoo.com, የሞባይል ስልክ +25196303914 አለምሸት ይርጋ (ቢኤስሲ፣ ኤም.ኤስ.ሲ፣ በነርስ የቀዶ ጥገና ህክምና መምህር), ኢሜል አድራሻ, alemyirga25@gmail.com, የሞባይል ስልክ +251918065664

ከላይ ባለው ወይም በተሰጠዎት መረጃ መሰረት በጥናቱ ለመሳተፍ ፈቃደኛ ኖት? አዎ _____ (ቀጥል) አይደለሁም _____ አመሰግናለሁ።

የተሳታፊ፡ ፊርማ _____ ቀን_____

የጠያቂ፡ ስም _____ ፊርማ

የጠያቂ መለያ ቁጥር _____

የቃለ መጠይቁ ቀን _____ የመነሻ ሰዓት _____ የተጠናቀቀበት ጊዜ _____

የቃለ መጠይቁ ውጤት ሀ) የተጠናቀቀ ለ) ያልተጠናቀቀ ሐ) በከፊል የተጠናቀቀ መ) የተቃወመ።

የመረጃ ሰብሳቢ፡ ስም _____ ፊርማ_____ ቀን _____

የተቆጣጣሪ፡ ስም _____ ፊርማ _____ ቀን _____

Annex-X Questionnaire sheet Amharic Version

መግቢያ፡ (ከመጋቢት/1/2014ዓም እስከ መጋቢት/30/2014ዓም መረጃ ከእያንዳንዱ ተሳታፊ ይሰበሰባል ። ጥያቄዎቹ ከተለያዩ ጽሑፎች የተወሰዱ እና የተሻሻሉ ናቸዉ። ከትክክለኛው የመረጃ መሰብሰቢያ ጊዜ በፊት የጥያቄዎቹ ትክክለኛነት በተግባር የታያል።ውድ ተሳታፊ እባኮትን ተገቢውን መልስ ይስጡ።

የመረጃ ሰብሳቢው ስም፡ _____ ፊርማ፡ _____ ቀን_____

የተቆጣጣሪው ስም፡ _____ ፊርማ፡ _____

የተሳታፊዉ ኮድ፡- _____/_____/_____

የጥያቄዉ ኮድ ቁጥር፡ _____ የሆስፒታል ስም፡ _____

ክፍል አንድ፡ዲሞግራፊ እና ማህበራዊ ሁኔታዎችን በተመለከተ የተዘጋጁ ጥያቄዎች

ተቁ	መጠይቅ	መልስ	ኮድ	ማለፍ	ምርመራ
01	የህመምተኛዉ ጾታ?	ወንድ	0		
		ሴት	1		
02	እድሜዎ ስንት ነዉ?	_____ በአመት ፃፍ			
03	የት ነዉ የሚኖሩ?	ከተማ	0		
		ገጠር	1		
04	የትምህርት ደረጃዎ ምንድ ነዉ?	ማንበብና መጻፍ እችላለሁ	0		
		ማንበብና መጻፍ አልችልም	1		
		እስከ መጀመርያ ደረጃ ትምህርት ተምሬአለሁ	2		
		እስከ ሁለተኛ ደረጃ ትምህርት ተምሬአለሁ	3		
		ኮሌጅ እና በላይ ተምሬአለሁ	4		
05	ስራዎ ምንድን ነዉ?	ስራ አጥ	0		
		ተቀጣሪ	1		
		ነጋዴ	2		
		አርሶ አደር	3		
		ተማሪ	4		
		ሌላ (ግለጽ)----------	5		
06	የጋብቻዎ ሁኔታ ምንድን ነዉ?	አላገባሁም	0		
		አግብቻለሁ	1		
		ፈትቻለሁ	2		
		ሙቶብኛል/ሙታብኛለሽ	3		

ክፍል ሁለት ከክምና እና ተዛማጅ ሁኔታዎችን በተመለከተ የተዘጋጁ ጥያቄዎች

ተቁ	መጠይቅ	መልስ	ኮድ	ማለፍ	ምርመራ
07	በሽተኛዉ/ዋ ሆስፒታል የተኛበት/ችበት በሽታ ምንድን ነዉ?				ይፃፍ
08	የታዎቀ የቆየ የማይድን በሽታ አለቦዎት?	የለም	0		

		አዎ	1		
09	የህመምተኛዉ/ዋ የንቁነት ሁኔታ ምንድን ነዉ?በመጀመርያዉ ቀን	እራሱን የሳተ (≤ 8)	0		
		በንቁነት እና እራሱን በመሳት መካከል ያለ (9 – 12)	1		
		ንቁ (>12)	2		
10	የአካላዊ እንቅስቃሴዎ ሁኔታ ምንድን ነዉ?	እንቅስቃሴ አደርጋለሁ	0		
		እንቅስቃሴ አላደርግም	1		
11	የመርፌ ምግብ (ፈሳሽተሰጪል)	የለም	0		
		አዎ	1		
12	መድሃኒት ወስዷል በደም ስር ፕላስቲኩ	የለም	0		
		አዎ	1		
13	ደም በደም ስር ፕላስቲኩ ተሰጪል	የለም	0		
		አዎ	1		

ክፍል ሶስት፡ የደም ስር ፕላስቲክ እና ተጓዳኝ ሁኔታዎች

ተቁ	መጠይቅ	መልስ	ኮድ	ማለፍ	ምርመራ
14	የደም ስር ፕላስቲክ የተደረገበት የሰዉነት ክፍል የትኛዉ ላይ ነዉ?	የክርን መታጠፍያ ለይ	0		
		የፊት እጅ ላይ	1		
		ለእጅ መዳፍ የቀረበ ላይ	2		
		ሌላ ካለ ይገለፅ	3		
15	የደም ስር ፕላስቲኩ መጠን በጌጅ መለኪያ ስንት ነዉ?	20 gauge(0.91ሚሜ)	0		
		18 gauge(1.27ሚሜ)	1		
		16 gauge(1.65ሚሜ)	2		
		ሌላ ካለ (ሚሜ)	3		
16	የደም ስር ፕላስቲክ በደም ስር ሲገባ የደም ስር የእይታ ሁኔታዉ እንዴት ነበር?	በደንብ የሚታይ	0		
		በደንብ የማይታይ	1		
17	አንድ ቬን ላይ የደም ስር ፕላስቲክ ለማስገባት ስንት ጊዜ ተሞከረ?	አንዴ ብቻ	0		
		ሁለቴ እና በላይ	1		
18	የደም ስር ፕላስቲክ የተደረገበት የደም ስር እሸጋ ሁኔታ እንዴት ነዉ?	ትክክል	0		
		ትክክል አይደልም	1		
19	የደም ስር ፕላስቲክ በህሙማኑ የሰዉነት ክፍል የቆይታ ጊዜ ምን ያህል ነዉ?	_____			በቀን ፃፍ

ክፍል አራት የደም ስር መርፌ ህክምን እና ተጓዳኝ ጠንቆች ሁኔታ

ተቁ	መጠይቅ	መልስ	ኮድ	ማለፍ	ምርመራ
20	መቸ ነዉ የደም ስር ፕላስቲክ የተደረገዉ?	_____			ቀኑን ፃፍ
21	የደም ስር ፕላስቲክ ከተደረገ በኋላ የደም መልስ የደም ስር መበከል ዉጤት በነጥብ(ስኮር)	ነጥብ(ስኮር) 0	0		
		ነጥብ(ስኮር) 1	1		
		ነጥብ(ስኮር) 2	2		
		ነጥብ(ስኮር) 3	3		
		ነጥብ(ስኮር) 4	4		
		ነጥብ(ስኮር) 5	5		
		ያለተገለፀ ነጥብ(ስኮር)	6		
22	የደም ስር ፕላስቲክ ከተደረገ በኋላ የደም መልስ የደም ስር መበከል ተከስተዋል?	አዎ	0		
		የለም	1		
23	መልሱ አዎ ከሆነ የደም መልስ ቧንቧ መበከል ደረጃ ምንድን ነዉ?	የመጀመርያ ደረጃ	0		
		መካከለኛ ደረጃ	1		
		ከፍተኛ ደረጃ	2		
		በጣም ከፍተኛ ደረጃ	3		
		ያለተገለፀ ደረጃ	4		
24	መልሱ አዎ ከሆነ/ምልክቶች ከታዩ መቸ ነዉ የደም መልስ የደም ስር መበከል የተፈጠረዉ እና በስተኛዉ ቀን ተከሰተ?	---------- ----------			በቀን እና የፈጀዉን ቀን ፃፍ
25	መቸ ነዉ የደም ስር ፕላስቲክ ትቦዉ የወጣዉ እናም በስተኛዉ ቀን ወጣ?	_____			ሁለቱንም ፃፍ