

Time to Develop Phlebitis and Its Predictors Among Patients with Peripheral Intravenous Cannula at Public Hospitals of Bahir Dar City, Amhara, Ethiopia, 2022: A Prospective Observational Study

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Background: Phlebitis is an inflammation of vein and the common complication of peripheral intravenous cannula. Phlebitis leads patient to sepsis, pulmonary embolism and other serious complications that increase patient morbidity and mortality. Phlebitis-related literature is scarce in Ethiopia. Therefore, the incidence and predictors of phlebitis were the focus of this study.

Methods and Materials: An institution-based prospective observational study was carried out at public hospitals of Bahir Dar city. Four hundred sixty-two patients with peripheral intravenous cannulas who were admitted to the medical ward were selected using a systematic random sampling technique. Jackson's Visual Infusion Phlebitis Scoring system was used to determine the presence of phlebitis. We used Cox proportional hazards regression model, to identify significant predictors of phlebitis.

Results: In this study, 462 patients included, and 171 (37.01%) of them developed phlebitis. The median survival time of phlebitis was six days. Patients whose age group >60 years had low probability to develop phlebitis (AHR = 0.49, 95% CI 0.29–0.82), whereas chronic-diseases (AHR = 1.50, 95% CI 1.09–2.07), drugs and blood administer in one vein (AHR = 2.03, 95% CI 1.44–2.86), inappropriate cannula dressing (AHR = 1.81, 95% CI 1.31–2.51), large cannula size (AHR = 1.52, 95% CI 1.08–2.15) and longer cannula dwelling time (AHR = 7.39, 95% CI 4.12–13.32) had high probability to develop phlebitis.

Conclusion: The post-peripheral intravenous cannula phlebitis that frequently affects hospitalized cannulated patients requires particular attention and follow-up for cannulated patients with known risk factors.

Keywords: time, incidence, predictors, phlebitis, cannula, patients

Introduction

Post peripheral intravenous cannula (PIVC) is a device inserted into the peripheral veins for the purpose of administration of intravenous fluid, medication and blood.¹ Post peripheral intravenous cannula phlebitis is an inflammation of the vein, which is characterized by pain, erythema, edema, induration and palpable of the vein and pyrexia.¹ Most PIVC is done by a nurse practitioner, which accounts for 80% of all cannulation that is done at health facilities.² Up to 70% of hospitalized patients using PIVC acquire phlebitis, which is a common complication of the procedure. Phlebitis usually takes four days to develop.^{3,4}

Phlebitis can be caused on by a variety of mechanical, chemical, or bacterial factors and may appear alone or in combination with any of the other PIVC problems.⁵ The majority of medical facilities do not strictly follow the correct PIVC procedure.^{6,7} Hence, the majority of patients with PIVC are at risk of developing phlebitis.⁸ Phlebitis manifests in four grades, which are grade one (erythema around the puncture site, with or without local pain), grade two (pain at the puncture site with erythema and/or edema and hardening), grade three (pain at the puncture site with erythema, hardening and a palpable venous cord), and grade four (pain at the puncture site with erythema, hardening and a palpable venous cord that is >1 cm, with purulent discharge).^{9–12}

The acceptable phlebitis incidence rate, according to the Infusion Nurses Society, should be five percent or below.⁹ But still, 70% of hospitalized patients acquired phlebitis following the use of PIVC.^{6,9} There is evidence that showed the

incidence of phlebitis varies by country. According to studies, the incidence of phlebitis was 17% in Australia, 18% in Saudi Arabia, 10% in Brazil, 52% in Tunisia, and 70% in Ethiopia.^{6,13–16}

With the insertion of PIVC, phlebitis can develop for a number of causes. The main causes are comorbidities, high cannula gauge sizes, and protracted cannula dwell periods.⁶ The size of the cannula has an impact on the vein's physiology. The risk of phlebitis can be increased by choosing a cannula diameter that is too large.^{4,17} The risk of phlebitis is considerably reduced by properly stabilizing and securing the insertion site of PIVC.^{4,10,18} The administration of medications raises the risk that individuals will experience phlebitis after a cannulation.^{4,18} The problems of phlebitis are currently being addressed globally with various prevention and management strategies.¹⁹ The guideline states that PIVC should be removed if it has been in place for more than 96 hours because the risk of phlebitis increases with time.^{10,20}

Despite various phlebitis prevention and management strategies, phlebitis remains a serious challenge in clinical settings. In Ethiopia, many patients that received PIVC suffered by phlebitis. Little evidence has been done on the incidence of phlebitis in Ethiopia. Therefore, this study was aimed to determine the incidence and identify predictors of phlebitis among patients with PIVC.

Methods and Materials

Study Design

Institutional-based prospective observational study design was conducted.

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. Those are Felege-Hiwot Referral Hospital, Tibebe Gion Compressive Specialized Teaching Hospital, and Adisalem Primary Hospital. This study was conducted from May/02 to June/17/2022.

Population

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

Sample Size, Technique and Procedure

The sample size was calculated using two population-proportion formulas, confidence level = 95%, power = 80%. In considering of the adequate sample size and feasibility issues, the final sample size was 468. There are three hospitals in Bahir Dar city Administration from which the samples were taken. The total sample size was allocated to each hospital proportionally based on the number of patients they have. Then, patients were selected using systematic random sampling methods from each hospital.

Operational Definition

Event: Patients acquired phlebitis during the follow-up time.

Censored: Patients not acquired phlebitis during the follow-up time.

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

Phlebitis: Phlebitis was diagnosed based on the Jackson's Visual Infusion Phlebitis Scoring System, which means that patients have a score of two or higher.^{9–12}

Good vein (visibility): The vein could be simple to see, visible, and large enough to accommodate an adult cannula.^{11,21,22}

Appropriate cannula site dressing: Covering the site of the cannula insertion with an adhesive plaster in a V shape and applying an additional adhesive plaster over it at an angle of 180 degrees without tourniqueting the site a complete rotation.¹¹

Data Collection Tools and Procedure

Interviewer-based structured questionnaires were adapted from validated and standardized existing tools to measure peripheral intravenous catheter-induced phlebitis. The PIVC insertion technique at hospitals is standardized based on the hospital policy and infection control protocol for procedures. Observational checklists were used to collect patient-related and PIVC-related

characteristics. Three BSc nursing professionals and one general practitioner participated in the data collection process and the diagnosis of phlebitis. If disagreement happens on the diagnosis of phlebitis, the physician confirms whether it is phlebitis or not then the decision of the physician was taken as a final decision for this study. Patients with PIVC were followed two times per a day. Jackson's Visual Infusion Phlebitis Scoring System, an internationally accepted diagnosis approach and set of criteria that has been studied in the scientific literature and applied in clinical settings all over the world, was utilized to make the diagnosis of phlebitis. The Jackson's Visual Infusion Phlebitis Scoring System provides a score from zero to five in ascending order of severity of inflammation or phlebitis. Each grade identifies a more or less advanced state of phlebitis or thrombophlebitis and differs in the evidence of specific signs and actions to be taken.

Score zero - the insertion site appears healthy and there are no signs of phlebitis. Only continued observation of the cannula is indicated. Score one – one of the following signs is evident: slight pain or slight redness near intravenous insertion site. These are possible early signs of phlebitis. In addition, in this case it will simply be necessary to continue with monitoring. Score two – two of the following signs are evident: pain at intravenous insertion site, redness or swelling. This is the early stage of phlebitis, requiring repositioning of the peripheral venous catheter. Score three – all of the following signs are evident: pain along the path of the cannula, redness around the insertion site and swelling. This is the medium stage of phlebitis, so the catheter should be repositioned and treatment considered. Score four – all of the following signs are evident and extensive: pain along the path of the cannula, redness around the insertion site, swelling, palpable venous cord. This is the advanced stage of phlebitis or at the start of thrombophlebitis. It is recommended to reposition the catheter and consider treatment. Score five – all of the following signs are evident and extensive: pain along the path of the cannula, redness around the insertion site, swelling, palpable venous cord, pyrexia. This is the stage of advanced thrombophlebitis, which requires initiating treatment and repositioning the peripheral venous catheter. Clearly, it is important that detections and interventions are always documented for effective monitoring and prevention.^{6,12,23}

Data Quality Assurance and Control

Data quality was assured through designed proper data abstraction questionnaires. Pre-test was done on five percent of the sample size. Training was given for data collectors and supervisor. The investigator and supervisor closely monitored and supervised the data collection process to ensure the quality of data. Every day, the data was checked for consistency and completeness, and any problems that arose during data collecting were addressed appropriately.

Data Management and Analysis

The questionnaires' consistency and data completeness were carefully reviewed. The data was entered using Epi Data version 3.1 and exported to Stata version 15 for analysis. For categorical independent predictors, the Spearman's rank test was used to examine multicollinearity. To determine frequency, proportion, interquartile range, cumulative incidence, and person-time incidence-rate, descriptive analyses were performed. The proportional hazards assumption was checked using a graphic way (log minus log plot of survival estimation) and a statistical method (global test). The overall model fitness was examined using the Cox Snell residual test and the log-likelihood ratio test. The candidate predictors for the multivariable Cox proportional hazards regression analysis were selected using the bi-variable Cox proportional hazards regression method. In multiple Cox proportional hazards regression analysis, predictors were included if their p-value for bi-variable Cox proportional hazards regression analysis was ≤ 0.25 and they satisfied the Cox proportional hazards ratio assumption. Cox proportional hazards regression analysis with a 95% confidence level was used to find the predictors of phlebitis. The measure of association between the outcome variable and the independent variables was declared statistical significance at a P-value of less than five percent.

Results

Socio-Demographic Characteristics

Four hundred sixty-two patients participated in this study. Among those, 243 (52.60%) were females. The median age of the patients was 42 years old, with an interquartile range 27 to 60 years old. Majority of the patients, 286 (61.90%), were rural residents (Table 1).

Table 1 Socio-Demographic Characteristics of Patients with PIVC at Bahir Dar City Public Hospitals, Amhara, Ethiopia, 2022 (N = 462)

Variables	Categories	Frequency	Percent
Sex	Male	219	47.40
	Female	243	52.60
Age	15–40	225	48.70
	41–60	134	29.00
	> 60	103	22.29
Residence	Urban	176	38.10
	Rural	286	61.90
Educational status	Unable read and write	213	46.10
	Able to read and write	62	13.42
	Up to elementary school	60	12.99
	Up to secondary school	57	12.34
	College and above	70	15.15
Occupational status	Unemployed	40	8.66
	Employed	58	12.55
	Merchant	77	16.67
	Farmer	239	51.73
	Student	48	10.39
Marital status	Single	87	18.83
	Married	302	65.37
	Divorced	33	7.14
	Widowed	40	8.66

Clinical-Related Characteristics

From all (462) participated patients, 185 (40.04%) were admitted with two or more diseases. During the study period, 165 (35.71%) patients had at least one chronic disease (hypertension, heart diseases, chronic kidney diseases, asthma or diabetes mellitus). Most patients, 414 (89.61%) were treated through drugs (medications) (Table 2).

Cannula-Related Characteristics

In this study, to insert cannula, three different site superficial veins were used, which were dorsum of hand vein, radial vein and antecubital fossa vein. Most of the PIVC were inserted on the patient's dorsum of hand that accounted, 210 (45.45%). Above half of the patients, 241 (52.16%) used 18-gauge cannula size. In this study, near to half of the PIVC dwelling time was more than four days (Table 3).

Incidence and Median Survival Time of Phlebitis

The incidence rate of post-peripheral intravenous cannula phlebitis was 8/100 persons per day observation (95% CI 7/100 – 9/100). The overall median survival time of phlebitis was six days with a survival interquartile range of five up to

Table 2 Clinical Related Characteristics of Patients with PIVC at Bahir Dar City Public Hospitals, Amhara, Ethiopia, 2022 (N = 462)

Variables	Categories	Frequency	Percent
Patient admitted with	One disease	277	59.96
	≥ two diseases	185	40.04
Known chronic disease	No	297	64.29
	Yes	165	35.71
Base line patient consciousness level	(≤ 8)	56	12.12
	(9–12)	123	26.62
	(>12)	283	61.26
Patient ambulation status	Ambulatory	319	69.05
	Not ambulatory	143	30.95
Drugs/medications administered through cannula	No	48	10.39
	Yes	414	89.61
Fluid administered through cannula	No	282	61.04
	Yes	180	38.96
Blood administered through cannula	No	377	81.60
	Yes	85	18.40
Drug and blood administered in one vein	No	372	80.52
	Yes	90	19.48

Table 3 Cannula-Related Characteristics of Patients with PIVC at Bahir Dar City Public Hospitals, Amhara, Ethiopia, 2022 (N = 462)

Variables	Categories	Frequency	Percent
Cannula insertion site	Antecubital fossa	73	15.80
	Forearm	179	38.74
	Dorsum of hand	210	45.45
Cannula gauge size	20 gauge	221	47.84
	18 gauge	241	52.16
Cannulated Vein quality status	Good visible	353	76.41
	Poorly visible	109	23.59
Cannula insertion trial	One time	345	74.68
	More than one time	117	25.32
Cannula dressing status	Appropriate	222	48.05
	Not appropriate	240	51.95
Cannula dwelling time	≤ four days	233	50.43
	> four day	229	49.57

seven days. During the study period, 171 (37.01%) patients developed phlebitis, while the rest 291 (62.99%) patients did not develop phlebitis.

Predictors of Phlebitis

Ten of the twenty potential demographic, clinical, and cannula-related predictors were significantly associated in bi-variable regressions with phlebitis at a significance level of 0.25 and were therefore entered into the multivariable regression. Six of these predictors were significant at p-value of <0.05 in the final Cox proportional hazards model. When compared to individuals between the ages of 15 and 40, people older than 60 had a 51% lower risk of developing phlebitis (AHR = 0.49, 95% CI 0.29–0.82). Patients with chronic diseases had a 1.50 times greater risk of getting phlebitis than individuals without chronic disease (AHR = 1.50, 95% CI 1.09–2.07). When blood and medications were administered through a single vein as compared to independently, the risk of phlebitis increased by 2.03 times (AHR = 2.03, 95% CI 1.44–2.86). The risk of developing phlebitis was 1.52 times higher in patients who used an 18-gauge cannula size compared to those who used a 20-gauge cannula size (AHR = 1.52, 95% CI 1.08–2.15). Individuals who had improper cannula dressing had a 1.81 higher risk of developing phlebitis than those who had proper cannula dressing (AHR = 1.81, 95% CI 1.31–2.51). Phlebitis was 7.39 times more likely to develop in patients with a cannula dwelling time of more than four days as compared to individuals with a cannula dwelling time of less than or equal to four days (AHR = 7.39, 95% CI 4.12–13.32) (Table 4).

Table 4 Bi-Variable and Multi-Variable Cox Proportional Hazards Regression for the Predictors of Phlebitis Among Patients with PIVC at Bahir Dar City Public Hospitals, Amhara, Ethiopia

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*
Known chronic disease	No	74	223	1	1	
	Yes	97	68	1.64	1.50 (1.09–2.07)	0.014*
Patient ambulation	Able to ambulate	87	232	1	1	
	Unable to ambulate	84	59	1.88	1.38 (0.98–1.93)	0.062
Drug administration	No	6	42	1	1	
	Yes	165	249	2.85	1.88 (0.81–4.37)	0.145
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	20 gauge	56	165	1	1	
	18 gauge	115	126	1.64	1.52 (1.08–2.15)	0.017*

(Continued)

Table 4 (Continued).

Variables	Categories	Phlebitis		CHR	AHR (95% CI)	P-value
		Event	Censored			
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	≤ four days	115	118	1	1	
	> four days	56	173	5.38	7.39 (4.12–13.32)	< 0.001*
Drug and blood administered in one vein	No	95	277	1	1	
	Yes	76	14	2.58	2.03 (1.44–2.86)	< 0.001*

Note: *Indicated significant predictors their p-value less than five percent.

Abbreviation: GCS, Glasgow Coma Scale.

Discussion

This study found that the incidence density rate of phlebitis was 8/100 persons per day of observation and the cumulative incidence of 37.01%. The incidence was far higher than the acceptable phlebitis rate of five percent or below, as recommended by the Infusion Nurses Society (INS).⁹ This might be a reference to poor PIVC procedures and unsuccessful prevention efforts. This result was in line with research conducted in Saudi Arabia.²⁴ The similarities were because both studies used a comparable study design and phlebitis diagnosing approach.

The current finding was higher than studies done in Africa (13%) and other nations like Malaysia (15.41%) and Brazil (18.34%).^{13,19,25} The discrepancy might be due to diagnosis approach and sampling differences. A study carried out in Malaysia used a laboratory-based approach to diagnosing microorganisms, which is a reliable way of diagnostics that lowers the incidence of phlebitis. The study in Brazil was a retrospective follow-up study, but the current study was prospective follow-up; therefore, this difference might bring discrepancy between two studies on the incidence of post-cannula phlebitis.

However, the finding was lower than studies conducted in Ethiopia (Gondar) (70%) and Tunisia (51.90%).^{6,15} The discrepancy of the study might be due to sampling technique and sample size difference. The current study used probability-sampling technique and relatively used large sample size. However, study conducted in Tunisia used small sample size and study conducted at the University of Gondar Compressive Specialized Hospital used nonprobability-sampling technique. Using small sample size and non-probability sampling techniques might increase the incidence of post-cannula phlebitis.

According to this study, the median cannula dwelling time was four days, ranging from two to eight days. This finding was similar to study conducted in Saudi Arabia and 25 European countries.^{26,27} The median survival time to develop phlebitis was six days with a survival inter-quartile range of five up to seven days. This showed that 50% of the patients acquired phlebitis before six days of after PIVC 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 Saudi Arabia and Australia.^{10,27} The discrepancy might be due to difference in sampling and diagnosis criteria of phlebitis.

The current study's findings showed that patients between the ages of 15 and 40 years had a higher risk of developing phlebitis than patients older than 60 years. This finding contradicted with studies conducted in Spain and Australia.^{28,29} Patients in the adult age group had more sensitive immune systems than old age group, which caused them to experience an inflammatory process because of an antigen–antibody response that led to an infection-like phlebitis.^{9,19} Patients with chronic disease were more risk for phlebitis as compared to patients free from chronic disease. This finding was similar to studies conducted at other parts of Ethiopia and Qatar.^{6,12} Because patients with chronic disease are physiologically unstable compared to healthy individuals, patients with chronic conditions like diabetes mellitus, hypertension, and others are more immune-compromised and unable to combat infection/inflammation such as phlebitis.^{4,18}

Evidence showed that when drugs and blood were administered through one vein, the vein become infiltrated more quickly as a result of the drugs' and blood's irritating effects of the blood vessel.^{30,31} The irritation effects of intravenous medication and reaction of blood make the blood vessels become inflamed. As a result, drugs and blood lead the blood vessel more susceptible to post-cannula phlebitis.³²

Patients who used 18-gauge cannula size were more risk to develop phlebitis as compared to patients that used 20-gauge cannula size. This result was similar to studies conducted in Qatar.¹² Eighteen-gauge cannula size is comparably large in its diameter and length as compared to 20 gauge cannula sizes. A smaller diameter cannula accommodates the patient's vein that minimizes the risk of phlebitis. However, choosing larger cannula diameter size can increase the rate of phlebitis, and the risk rises with increasing the diameter of the cannula. This is because of the physical properties and the size of the cannula that affect the physiology of the vein tissues by irritating and physically damaging the cannulated vein.^{4,17}

Patients with improper PIVC dressing experienced more phlebitis than those with appropriate PIVC securing or dressing. This finding was similar to studies conducted in Spain and Saudi Arabia.^{9,24} To minimize the risk of blood clotting from over-tightening the vein and phlebitis from direct contamination, the cannula insertion site should be secured and dressed appropriately.^{4,10,18} Patients who had longer cannula dwelling time (greater than four days) were more risk to develop phlebitis as compared to patients who had shorter cannula dwelling time (less than or equal to four days). The finding was consistent with studies done in other counties.^{1,24} Different factors like shortage of medical supply (cannula), low human resources (healthcare providers) and poor coordination of resources at health-care settings increase dwelling time of the cannula. As a result, prolonged cannula dwell times cause continued trauma of the vein due to longer contact to irritant drugs and colloids that contribute to high chance of inflammation or phlebitis.^{6,33}

Limitation of the Study

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

Conclusion

The incidence of post-PIVC phlebitis was much higher than the acceptable rate. The median time to develop phlebitis was six days with the survival inter-quartile range of five up to seven days. Hence, all patients with PIVC better to be screened for phlebitis at least once daily. It is also important to have appropriate nursing care and patient education to reduce the associated risk factors that were identified in this study. An observation chart to document the development of signs of phlebitis may be developed in hospitals, which may help detect PIVC complications (phlebitis) much earlier. The use of an adequate cannula size and a shorter cannula dwell time significantly lowers the risk of phlebitis. Therefore, in order to prevent PIVC phlebitis healthcare providers should consequently emphasize using proper medical equipment, such as choosing the appropriate cannula size and lowering cannula dwell duration. Future researchers should incorporate patients who were admitted to other than medical wards for better generalizability of the problem of PIVC phlebitis.

Abbreviations

AIDS, Acquired Immune Deficiency Syndrome; BDU, Bahir Dar University; DVT, Deep Vein Thrombosis; HR, Hazard Ratio; HIV, Human Immune Virus; PIVC, Peripheral Intravenous Cannula; VIPS, Visual Infusion Phlebitis Score.

Availability of the Data

The data used to support the findings of this study are available from one of the authors for reasonable request.

Ethical Approval and Consent

Ethical clearance was obtained from Institutional Review Board (IRB) of Bahir Dar University College of Medicine and Health Sciences. A letter of cooperation was written for all public hospitals of Bahir Dar city with a letter written on April/22, 2022, with a protocol number of 418/2022. During the study period, written informed consent was taken from

each patient that participated in this study. However, for patients whose age was under 18 years, informed consent was taken from the parent. Confidentiality of the information was secured throughout the study by excluding names and patient medical record numbers on the data extraction form and the data were used only for the proposed study. This study followed the ethical standard of the declaration of Helsinki.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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