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INCIDENCE AND ASSOCIATED RISK FACTORS OF PHLEBITIS AMONG PATIENTS WITH PERIPHERAL INTRAVENOUS CANNULA.

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Abstract
It is estimated that more than 50-60% of hospitalized patients require intravenous therapy (IVT), implemented mainly with the use of peripheral intravenous catheters (PIC), since they provide quick access to the vascular system, being the most performed invasive intervention in the health care setting, and less invasive and more cost-effective than other types of intravenous catheters. Because catheterization is done for different purposes and for different lengths of time, it represents a potential risk for a number of safety incidents, including microbial growth . However, regardless of the generating factor, local complications take the form of bruises, infiltration, leakage, catheter obstruction and phlebitis.[1]Phlebitis not only causes patient discomfort and frequent catheter change, it may also cause further complications like cellulitis, septicemia, DVT, and make the patient stay in the hospital for a longer time and increase the cost of healthcare.[2]Due to its occurrence in patients with peripheral intravenous catheters (PIC) as found during clinical observation, it was decided to conduct this study to determine the incidence of phlebitis and risk factors associated with it.
Materials and Methods: This prospective observational study aimed to assess the incidence and associated risk factors of phlebitis among patients with peripheral intravenous cannula. 300 patients above 18 years of age with peripheral intravenous catheters (PIC) in place, were purposely selected from medical units, surgical units and intensive care units of SKIMS, Srinagar. The factors studied were age, gender, reason for cannulation, site of insertion, situation of insertion, cannula/ cathetersize, dwelling time of catheter, IV medications, and family history of thrombophlebitis. Phlebitis was graded using Visual Infusion Phlebitis Score.
Results: The incidence of phlebitis was expressed in percentage. Frequencies and Pearson's chi-square test [with 5% significance level] were implemented to find out the significance of associated risk factors of phlebitis. Incidence of phlebitis was found to be 25.33% in our study. The increased incidence rate of phlebitis was seen in the age group of 36->55 years, the female gender, IV drugs administration, large catheter size (18G), insertion in the dorsum of hand, catheters inserted in emergency situations, cannulation duration of 96 hours and family history of thrombophelebitis.
Conclusion: Phlebitis is an adverse complication when it gets advanced thus it needs to be arrested before it reaches blood stream. Avoiding of preventable risk factors, proper health professional practices, and, judicious administration of intravenous medication, daily inspection of catheters are needed for prevention of phlebitis.

Keywords*: Phlebitis, Incidence, Risk factors, Peripheral Intravenous Catheter (PIVC), Patients.*

Introduction

Peripheral IV catheterization (PIC) is the most frequently performed procedure in hospital settings. It is oneof commonly performed and at times lifesaving procedure performed in hospital. Approxiamately 33–67% of hospitalized patients require at least one peripheral vein insertion. One of commonly performed and at times lifesaving procedure, performed in hospital, is placement of peripheral intravenous catheter (PIC). Incidence rate of intravenous catheter placement in a patients admitted to hospital is about 50%. Peripheral vein catheters are required for administration of intravenous drugs, intravenous solutions, blood products, and parenteral feeding. It is as well necessary for access to vascular procedures.[3-13]

Despite PIVC benefits, its use is not without potential complications such as phlebitis, infiltration, extravasation, occlusion and dislodgment. Numerous factors can influence the development of phlebitis, such as inadequate technique when inserting the catheter, the patient's clinical situation, the characteristics and tonus of the vein, drug incompatibility, pH of the medicine or solution, ineffective filtration, catheter diameter, size, length and material of manufacture; prolonged use.It may also make the patient stay in the hospital for a longer time and increase the cost of healthcare. **[14]**

Factors contributing to occurrence of phlebitis include mechanical, chemical, biological, patient, and health practice-related factors.[6-3, 15-17]. Mechanical factors consist of cannula size, site of catheter placement, catheter dwell time and type of catheter (Teflon Vs Vialon). Teflon catheter type, large cannula size, near joint-catheter placement, and catheter dwell time > 96 h predispose to phlebitis. Type of intravenous drugs (irritant, vesicant) and solution characteristics (PH^+, osmolality) are components of chemical factors. Irritant intravenous drugs and hyperosmolar infusate solutions cause vascular endothelial injury, and results in phlebitis. Biological factors embrace bacterial colonization, biofilm formation and infection. Patient-related factors take account of age, gender, nutritional status, immunosuppression and co-existing comorbidities. Those with malnutrition, immunosuppression, co-morbidities, and elderly (age > 65 years) are vulnerable to phlebitis. Implementing aseptic precautions and health professional skill on catheter securement, are the frequently implicated health practice-related factors. Poor aseptic technique and improperly securing of cannula are among listed causes of phlebitis. Phlebitis is clinically manifested by pain, erythema, swelling, palpable venous cord, and pussy discharge at catheter site. Cannula-related blood stream infection (CRBSI) is recognized complication of phlebitis.[3, 5 ,8-1, 5-18]

Presence and severity of phlebitis is evaluated by Jackson's Visual Infusion Phlebitis Scoring System. The scoring and grading is as per the manifested signs and symptoms. Grade 1 - erythema around the puncture site, with or without local pain; Grade 2 - pain at the puncture site with erythema and/or edema and hardening; Grade 3: pain at the puncture site with erythema, hardening and a palpable venous cord; Grade 4: pain at the puncture site with erythema, hardening and a palpable venous cord that is > 1 cm, with purulent discharge.[19.]

Table 1 Jackson's Visual Infusion Phlebitis Scoring System

Grade/ Score	Manifestations	Phlebitis possibility	Recommended treatment
Grade 0	I/V site appears healthy	No signs of phlebitis	Nil
Grade 1	ONE of the following is evident: Slight pain near I.V. site slight redness	Possible first signs of phlebitis	Observe cannula
Grade 2	TWO of the following is evident: pain near I.V. site erythema; induration	Early stages of phlebitis	Resite cannula
Grade 3	ALL of the following is evident: pain along path of cannula erythema; induration, palpable venous cord	Medium stages of phlebitis	Resite/remove cannula consider treatment
Grade 4	ALL of the following is evident and extensive: pain along path of cannula erythema; induration; palpable venous cord.1cm with purulent discharge	Advanced stage of phlebitis or start of thrombophlebitis	Initiate treatment resite/remove cannula

Jackson's Visual Infusion Phlebitis Scoring Systemas shown in table 1 indicates grading/scoring, manifestations, phlebitis possibility and recommended intervention/treatment.

The lack of a strict protocol and education on PIVC management usually might lead to the increased occurrence of phlebitis. Due to the wide variation in the results among the available literature, it was decided to conduct this study to evaluate the incidence of phlebitis and risk factors associated with it.

Materials and Methods

This was a prospective, observational study conducted at Tertiary Care Hospital, SKIM, Srinagar, J&K (India) after taking approval from Institutional ethical committee during the period from June 2023 to April 2024. The study involved 300 patients who were admitted to the medical, surgical and intensive care units of the hospital. Inclusion criteria for study participants was patients who were 18 years or above, who had no preexisting skin diseases,no history of allergy to any medications, patients with PIC in place for atleast 48-96 hours and patients or their guardians who gave acceptance of the proposals expressed in the Free Informed Consent Form.The patients with venous thrombosis or

other vascular disorders, who were on antiplatlet therapy, who were on oral or subcutaneous anti coagulants,medical diagnosis of Catheter-related Blood Stream Infection and/or sepsis; neutrophil count of less than or equal to 1000/mm^3 and simultaneous use of more than one PIC were excluded from the study. The intravenous catheter site was observed daily from 48 hours of insertion to 96 hours for any signs and symptoms ofphlebitis, using "visual infusion phlebitis score (VIPS)".

RESULTS: Total 300 subjects were included in the study. The findings related to demographic and clinical variables like age, gender, reason for cannulation, details of intravenous fluid, medications administered, size of the cannula, place of insertion, cannula insertion situation, cannulation dwelling time and family history of thrombophlebitis if any ,were noted and presented in table 2.

Table 2 Frequency and percentage distribution of subjects according to demographic and clinical variables
N=300

Demographic/ clinical variables	**F (Percentage)**
1.Age in years: 1.1) 18-35	78 (26%)
1.2) 36-55	108 (36%)
1.3) >55	114 (38%)
2. Gender: 2.1) Male	116 (38.67%)
2.2) Female	184 (61.33%)
3. Reason for cannulation: administration of	
3.1) I/V fluids	62 (20.67%)
3.2) I/V drugs	103 (24.33%)
3.3) Both I/V fluids and drugs	135 (45%)
4.Type of drugs: 4.1) Antibiotics	150(50%)
4.2) Antiepileptics	72 (24%)
4.3) Steroids	38 (12.67%)
4.4) Others	40 (13.33%)
5.Cannula size (Gauze): 5.1) 16G	51 (17%)
5.2) 18G	135 (45%)
5.3) 20G	114 (38%)
6.Cannulation site: 6.1) Dorsum of hand	115 (38.34%)
6.2) Antecubital fossa	94 (31.33%)
6.3) forearm	51(17%)
6.4) Wrist	40 (13.33%)
7.Cannula insertion situation: 7.1) Emergency	268 (89.33%)
7.2) Non emergency	32 (10.67%)
8. Cannulation dwelling time: 8.1) 48 hours	36 (12%)
8.2) 72 hours	73 (24.33%)
8.3) 96hours	191 (63.67%)
9.Family history of thrombosis: 9.1) Yes	13 (4.33%)
9.2) No	287 (95.67%)

Results from table 1indicate that of 300 subjects, 116 were male (38.67%) and 184 were female (61.33%). Almost equal number of subjects belonged to age group of 36-55 years (36%) and more than 55 years (38%). Catheters were inserted for the reasons such as administration of fluids (20.67%), intravenous drugs (34.33%), or both IV fluids and drugs (45%). The drugs administered intravenously included antibioticse.g; ceftrioxone, tazobectum(50%), antiepileptics e.g; phenytoin, diazepam (24%), steroids e.g; dexamethasone (12.67%) and others e.g; KCL, Omprazole, tramadol (13.33%). Catheter size used was 18 G (45 %), 20 G (38%) and 16 G (17%). Most common cannula insertion site was dorsum of hand (38.33%) and antecubital fossa (31.33%). Two hundred and sixty eight (89.33%) cannulas/catheters were inserted in emergency situations and 32 (10.67%) in non-emergency situations. Regarding dwelling time, highest duration was 96 hours (63.67%), whereas 24.33% had 72 hours and 12% had 48 hours of cannulation duration. Majority of the subjects reported no family history of thrombophlebitis (95.67%).

Table 3 Association of risk factors with incidence of phlebitis. N=300

Risk factors (Variables)	Number of study subjects	Number of subjects developed phlebitis		Incidence of phlebitis	Chi squre Df	P value
		Yes	No			
Subjects studied with inserted PIC	**300**	**76**	**224**	**25.33**		
1.Age in years: -18-35	78	2	76	56	29.747	
-36-55	108	39	69	36.11	df-2	3.5e-7
- >55	114	35	79	30.70		
2. Gender: - Male	116	24	92	20.68	2.156	0.142
-Female	184	52	132	28.26	df-1	
3. Reason for cannulation: administration of						
- I/V fluids	62	2	60	3.23	35.426	2e-8
- I/V medication	103	45	58	43.68	df-3	
-Both I/V fluids & drugs	135	29	106	21.48		
4.Type of drugs:						
-Antibiotics	150	47	103	31.33	39.657	1e-8
-Antiepileptics	72	2	70	2.78	df-3	
-Steroids	38	6	32	15.79		
-Others	40	21	19	52.5		
5.Cannula size (Gauze):						
-16G	51	9	42	17.65	9.925	0.006**
-18G	135	46	89	34.07	df-2	
-20G	114	21	93	18.42		
6.Cannulation site:						
-Dorsum of hand	115	41	74	35.65	13.796	0.003**
-Antecubital fossa	94	20	74	21.28	df-3	
-Forearm	51	5	46	9.80		
-Wrist	40	10	30	25		
7.Cannula insertion situation: - Emergency	268	70	198	26.12	0.821	0.364
-Non emergency	32	6	26	18.75	df-1	
8. Cannulation dwelling time: - 48 hours	36	6	30	16.67	18.499	0.00**
-72 hours	73	25	48	34.25	df-2	
-96 hours	191	99	92	51.83		
9.Family history of thrombosis:						
- Present	13	10	3	76.92	23.888	0.00**
- Absent	287	56	231	19.51	df-1	

** Significant at 0.05 and 0.01 level

Incidence of phlebitis in the present study was 25.33 %. It was highest in age group of 36-55years (36.11%) and above 55 years (30.70%). Females (28.26%) had shown higher incidence than males where it was 20.68% during their stay in hospital. Phlebitis was more when cannula/catheter was used for administration of I/V medication (43.68%) or when used for both administration of I/V fluids and I/V medication (21.48%). Phlebitis was more when medicine used was antibiotics (31.33%), steroids (15.79%) ; and phlebitis was among 52.5% subjects where other medicines like KCL, omeprazole, tramadol were administered through I/V catheter.Incidence of phlebitis was significantly found higher in subjects who had 18 G catheter (34.07%) when compared to subjects with 20 G (18.42%), and 16G (17.65%). Phlebitis was significantly highest when insertion site of the catheter was dorsum of hand (35.65%) as compared towrist (25%) and antecubital fossa (21.28%) and it was least (9.80%) in subjects with catheter inserted in forearm Incidence of phlebitis was higher in the subjects where catheters were inserted in emergency situations (26.12%) as compared to non-emergency situations (18.75%).Incidence of phlebitis was higher when catheter dwelling time was 96hours (51.83%) as compared to catheter dwelling time of 72 hours (34.25%) and 48 hours (16.67%). Subjects who had reported family history of thrombophelebitis had shown significantly higher incidences (76.92%) of phlebitis.(Table 3)

Discussion

The present study was to find out the incidence of peripheral intravenous catheter associated phlebitis and its contributory factors among 300 subjects above 18 years of age.In our study, we found higher number of females subjects who were almost equally distributed among 36-55 years and above 55 years of age. Mostly catheter was inserted to administer drugs and fluids, by using 18 G or 20 G catheter on dorsum of hand or antecubital fossa. In majority of the cases, PIC was done in emergency; majority was used among subjects with family history of thrombophelebitis. The drugs administered intravenously included antibiotics e.g; ceftrioxone, tazobectum and catheter duration was for 96 hours in majority, followed by 72 hours. These study findings are consistent with the results of a prospective observational study to assess effectiveness of heparin flush on occurrence of phlebitis among the patients

with PIC at SKIMS, Srinagar, India.[20]She found that highest number of study subjects were females with age above 55 years, received antibiotics via PIC 20 G, inserted on dorsum of hand in maximum number of subjects.
Similar results are indicated by*Mandal and Raghu*[12]in their prospective observational study to find out incidence of phlebitis following the use of pherpheral intravenous catheter at 4 Airforce hospitals, Kalaikunda, Kathmandu. The males gender was found higher (59.33%) as compared to female gender(40.7%), patients aged less than 60 years were 54%.
In a prospective cohort study conducted by *Yasuda etal* at Japan[21]to find out occurrence and incidence rate of peripheral intravascular catheter-related phlebitis and complications in critically ill patients, the mean ± SD age of the study population was 67.3 ± 15.5 years. The most frequently used site of insertion was the forearm (56.2%), followed by the back of the hand (21.3%). The most commonly inserted catheter gauge was 22G (49.0%), followed by 20G (35.2%). The rate of infections during catheterization was 17.8%, with a median PIVC insertion duration of 36 h. PIC related phlebitis are also related to its appropriate insertion. When PIVCs inserted in critically ill patients are used inappropriately, the complications may increase. A study reported in 2013, which compared CVCs and PIVCs as the initially used catheter among patients in ICU, showed that the risk of complications increased when PIVCs were used inappropriately.[22]The study results are further supported by similar studies.[26-29]

Regarding incidence of phlebitis and its associated risk factors in our study. Incidence of phlebitis was found to be 25.33% from our study. The increased incidence rate of phlebitis was seen in the age group of 36->55 years, the female gender, IV drugs administration, large catheter size (18G), insertion in the dorsum of hand, catheters inserted in emergency situations, cannulation duration of 96 hours and family history of thrombophelebitis. *Mandal and Raghu[12]*reported the incidence of phlebitis as 31.4%. Thirty percent (30%) of male patients and 32% of female patients had phlebitis during the stay in hospital. Thirty-five percent (35%) phlebitis occurred in the age group less than 60 years and 26% in more than 60 years. Phlebitis was more in the catheter inserted in lower limb (56.66%) when compared to upper limb (16.6%). Incidence of phlebitis was found to be higher in patients who had an18 G catheter (37.97%) when compared to patients with 20 G (23.94%). Incidence of phlebitis was higher in the catheters inserted in emergency situations (34%) when compared to non-emergency situations. Patients who were given Intravenous drugs (37.93%) and blood products (53.33%) had higher incidences of phlebitis.The incidence of phlebitis was almost similar to phlebitis rate reported in other studies, which ranged from 13–56%. [5-6, 9-13, 15, 16]
A study[23]indicates association with the occurrence of phlebitis: family history of deep vein thrombosis (p = 0.05), catheterization of veins on the back of the hand (p = 0.012), administration of Antibiotic (Amoxicillin-Potassium Clavulanate; p = 0.015), and Omeprazole Sodium (p = 0.029) and these results are consistent with our study results.
Similar results are indicated in another study[24] where Incidence of phlebitis was 11.09%. A multivariate analysis of risk factors for phlebitis showed patients with KCI (OR: 2.112; CI: 1.124-3.969), who were on antibiotics (OR: 1.877; CI: 1.141-3.088) and who had a catheter in an upper limb (OR: 0.31; CI: 0.111-0.938) were at higher risk for phlebitis.
*Yasuda eta*l[21]who conducted a prospective multicenter cohort study in 23 ICUs in Japan who included 2741 patients aged ≥ 18 years admitted to the ICU with PIVCs inserted prior to ICU admission and those newly inserted after ICU admission totalling 7118 PIVCs, of which 48.2% were inserted in the ICU. PIVC-related phlebitis occurred as primary outcome in 7.5% (95% confidence interval [CI] 6.9–8.2%) of catheters (3.3 cases / 100 catheter-days) and 12.9% (95% CI 11.7–14.2%) of patients (6.3 cases / 100 catheter-days). Most PIVCs were removed immediately after diagnosis of phlebitis (71.9%). Grade 1 was the most common phlebitis (72.6%), while grade 4 was the least common (1.5%). The incidence rate of Catheter related blood stream infection (CRBSI) was 0.8% (95% CI 0.4–1.2%).
The findings of a study[25] conducted at Northwest Ethiopia in2021 correlate demographically and clinically with present study findings. In their study, the mean age of study subjects was 46 years, with a range of 19 to 96 years. More than half (52%) of them were males**.** Indications for PIVC insertion were administration of intravenous drugs (73%), infusates (65%), and blood products (14%). Half (53%) of the catheters were inserted in emergency situations. Forearm was used as catheter placement in half (52%) of patients. 20 G sized cannula was used in most (81%) patients. Two-third (66%) of patients had PIVC in-situ for 96 h or less. The incidence of phlebitis was 70% among study subjects. Among those who developed phlebitis, mid-stage (grade 3) and advanced-stage (grade 4) phlebitis were noticed in (51%) and (33%) respectively. Advanced stage thrombophlebitis (grade 5) occurred in (1.5%) of phlebitis cases.only gender, catheter dwell time and infusates use were independently associated with occurrence of phlebitis. Odds of developing phlebitis were twofold higher in patients with catheter-in situ > 96 h (AOR = 2.261, 95% CI 1.087–4.702, P-value = 0.029) as compared to those with catheter dwell time < 72 h. Patients who used infusates were 53% (AOR = 0.472, 95% CI 0.280–0.796, P-value = 0.005) less likely to develop phlebitis as compared to those who didn't use infusates. Phlebitis significantly occurred among those with catheter dwell time > 96 h as compared to catheter-in situ < 72 h (AOR = 2.261, 95% CI 1.087–4.702, P-value = 0.029). This finding was consistent with other studies. [5,10,11,14,17]. Prolonged catheter dwell time predisposes for continued trauma by the catheter itself, longer contact to irritant drugs and infusates, and higher chance of exposure to bacterial colonization and infections. Consistent results are revealed in other studies. [26-32]

Conclusion:
We found that phlebitis risk factors varied so clinicians should not focus on a single risk factor but should consider that various factors may become risk factors thus the results suggest the importance of preventing PIVC-related complications by adoptingphlebitis protective measures and catheter management strategies. The results show the accurate selection of the catheterisation site, cannula size, type of medication, cautious infusion of risk drugs, promoting

patient mobility if possible, not catheterizing veins near the joint. avoiding prolonged placement of catheter at one site, intermittent change of site and valuing pain complaints are important phlebitis preventive measures. The cannula must be reviewed on daily basis, and it should be removed if it stayed later than 96 h. CDC guideline (2011) recommended routine replacement of PIVC no later than 96 h.

The patients who have a high risk of phlebitis, such as difficulty of insertion and high-risk drugs, tend to have CVCs inserted instead of PIVCs.The low incidence of phlebitis in our study might be due to the intervention, such as discontinuation or change of drug, performed at the stage of redness alone as daily observation of such patients becomes the priority for clinicians.

Limitations

This study has several limitations. First, the data collected were limited to information on PIVC insertion and drugs administered during medical unit, surgical unit and ICU admission. Information regarding drugs administered via catheters before study period was not included. Therefore, phlebitis incidence may be underestimated. The subjects selected were limited to study areas thus generalization was not possible. The secondary outcomes, including CRBSI, was not studied.

Implications

The present results could lay an important foundation for future studies on PIVC-related complications in PIVC inserted patients.

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