Original Research Article

Post-injection thrombophlebitis in patients undergoing peripheral IV catheterization in a tertiary care hospital: incidence and risk factors

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ABSTRACT

Background: Intravenous catheters cause endothelial damage and trauma, which can predispose to venous thrombosis. Peripheral vein infusion thrombophlebitis occurs in 25-35% of hospitalized patients with intravenous catheters and has both patient-related implications (e.g., sepsis) and economic consequences (e.g., extra nursing time). This study is designed to address this issue, by assessing the potential risk factors in those who have developed phlebitis, and deriving conclusions based on the same.

Methods: A total of 830 patients were observed over a period of 2 months. All details of the patient were collected. Thrombophlebitis was graded using visual infusion phlebitis score. Each case was compared with a matching control.

Results: 53 of 830 patients observed, developed thrombophlebitis giving an incidence of 6.4%. 92.5% had IV cannulation flushed after insertion. IV cannula had to be changed at least 2 times during the hospital stay. All had an average IV cannulation for 5 days. All had insertion of same size cannula (20G). Level 1 Phlebitis was identified in 64.15% patients, level 2 Phlebitis in 33.96% patients and Level 3 Phlebitis was seen 1.88% patients.

Conclusions: Significant association was noted between the number of times the catheter was changed since admission and administration of Potassium chloride and Certain Medications such as Piperacillin through the cannula.

Keywords: Thrombophlebitis, Peripheral venous thrombosis, IV cannula, Infusion thrombophlebitis

INTRODUCTION

The word Phlebitis comes from the Latin word Phlebo meaning vein and -itis meaning inflammation. It basically stands for inflammation of the vessel wall and its origins can be dated back to when it was first described by John Hunter. The term thrombophlebitis is used when the venular inflammation is associated with formation of thrombus within the same region.

Peripheral IV administration has almost become a necessity (80%) in the indoor-patient department’s today. Peripheral Catheterization is an invasive procedure and requires an experienced clinician or nurse, local sterilization methods and knowledge of common precautions that need to be taken while giving the therapy.

Due to lack of knowledge, reasonable care and skill, thrombophlebitis has emerged as a very common complication (3.7-67.24%) in hospitalized patients. Phlebitis is the development of an inflammatory reaction in the vein, most commonly due to a thrombus. It classically presents with clinical signs of pain, induration, tenderness, swelling and/or erythema.

The reason why more light needs to be shed on this subject is that not only does it increase the nursing cost...
and time, along with putting the patient’s safety at risk, but also can be used as a crude indicator to assess the level of healthcare that is being provided at that institution, especially at a tertiary care setup in India where increasing patient burden is reciprocal to the intentness and observation that is given to them by the health-care providers.4

While there have been many studies demonstrating the incidence and risk factors, lesser ones have tried to use alternative interventional strategies to reduce the symptoms of thrombophlebitis. Since there is limited data to guide management of superficial thrombophlebitis, the initial step includes discontinuing IV therapy through the catheter, removing the catheter. Symptomatic treatment includes elevation of the limb, providing cold compresses and oral NSAIDs. Antithrombotic therapy remains a cornerstone of therapy, for relieving symptoms and reducing the risk of embolization. Heparin containing ointments are used in many institutions for cases of thrombophlebitis. The catheter site should be also monitored for further complication, and antibiotics must be initiated if there are any concerns for supplicative thrombophlebitis.

This study is designed to address this issue, by assessing the potential risk factors in those who have developed phlebitis, and deriving conclusions based on the same. The significance of this study is that using the derived data, we will be able to determine, or at least suggest ways so that the incidence of its development in future patients can be reduced. Most of the studies previously performed have been conducted in developed countries like Germany and Turkey, and the same results cannot be extrapolated to a developing nation like ours, where many new factors might be needed to be taken into consideration. This study, aims to address the problem in an Indian background, through a government owned tertiary care institute, where the same risk factors, along with added presumed ones have been used to quantify the problem, and to assess, indirectly, the quality of the healthcare setting.

METHODS

A prospective observational study was carried out in an HBT medical college, a tertiary care hospital from June 2017 to August 2017. Patients willing to participate in the study between the age group of 12 to 60 years receiving IV therapy in wards were included for the study. Patients not willing to participate, pregnant women, elderly (>60 years of age) and children (less than 12 years) were excluded from the study.

After taking permission from the institutional ethics committee, and the head of institution, 830 participants were clinically observed over a period of 2 months for the development of thrombophlebitis during the course of hospital stay in the surgical wards. Among these 53 participants developed thrombophlebitis along with their 53 age and sex matched controls without thrombophlebitis were selected in the ratio of 1:1 during the same period. Hence, a total 106 patients were selected for the study.

Patients were screened during their stay and at the time of their discharge, based on the inclusion and exclusion criteria as mentioned above. A case record form was prepared and used for collecting all preliminary details of the patient, reason for admission, local symptoms of thrombophlebitis (redness, induration, pain) at the catheter site (if present) and systemic signs such as fever. Thrombophlebitis was graded using visual infusion phlebitis score suggested by infusion nurse’s society (Table 1).

The case record form was also used for noting down the site of peripheral catheter placement, the drugs administered via the intravenous route, type of drug, its concentration, frequency of administration, duration of administration, duration of keeping the Intravenous line empty after the drug is administered and whether the IV line was administered in first attempt or not, whether flushed after removing the line, how many times the catheters were changed during admission, treatment being given (if any) to them for remedying them of thrombophlebitis.

The model of this study is a quantitative one, that is, it is a systematic investigation concerning thrombophlebitis, and the final objective is to apply the analysis of collected data for making a definitive statement regarding the risk factors, both patient and health administration related. The data was statistically analyzed using IBM SPSS version 21.0 and microsoft office excel 2007. Continuous data has been expressed as mean (standard deviation) and median (interquartile range). The categorical data is summarized as frequencies and percentages. The normally distributed continuous variables were analyzed by unpaired t-test and data failing to meet the normality assumption was analyzed by Mann-Whitney U test. Categorical data was analyzed using chi-square test and fisher’s exact. P<0.05 were accepted as indicative of statistical significance.

RESULTS

Duplex ultrasound examination has been considered a screening tool of choice for evaluating superficial thrombophlebitis as it is non-invasive and easy to perform. However due to time constraints and the absence of appropriate funding, we had to adhere to using clinical manifestations and the VIPS as the mainstay to diagnose and classify the patients.

The study included 830 participants who were clinically observed over a period of 2 months for the development of thrombophlebitis. Among these, only 53 participants developed thrombophlebitis which gives an incidence of 6.4%.
Average age of the cases and controls was 41.3 years and 40.5 years respectively. Among the cases, 23 (43.4%) were females and 30 (56.6%) were males and among the controls, 24 (45.3%) were females and 29 (54.7%) were males. The various sites of IV cannulation in our study as shown (Table 2).

Table 1: Visual infusion phlebitis score suggested by infusion nurse’s society.

| Intravenous site appears healthy | 0 | No sign of phlebitis | Observe the cannula |
|--------------------------------|---|----------------------|---------------------|
| One of the following is evident: | 1 | Possible first signs of phlebitis | Observe the cannula |
| • Slight pain near IV site | | | |
| • Slight redness near IV site | | | |

| Two of the following are evident: | 2 | Early signs of phlebitis | Re-site the cannula |
|--------------------------------|---|------------------------|---------------------|
| • Pain near IV site | | | |
| • Erythema | | | |
| • Swelling | | | |

| All of the following are evident: | 3 | Medium stage of phlebitis | Re-site the cannula |
|--------------------------------|---|-------------------------|---------------------|
| • Pain along the path of the cannula | | | |
| • Erythema | | | |
| • Induration | | | |

| All of the following are evident and extensive: | 4 | Advanced stage of phlebitis and start of thrombophlebitis | Re-site the cannula |
|--------------------------------|---|--------------------------|---------------------|
| • Pain along the path of the cannula | | | |
| • Erythema | | | |
| • Induration | | | |
| • Palpable venous cord | | | |

| All of the following are evident and extensive: | 5 | Advanced stage of thrombophlebitis | Initiate treatment |
|--------------------------------|---|--------------------------|---------------------|
| • Pain along the path of the cannula | | | |
| • Erythema | | | |
| • Induration | | | |
| • Palpable venous cord | | | |
| • Pyrexia | | | |

Table 2: Risk factors based on site of catheterization and vein accessibility across cases and controls for the development of thrombophlebitis: patient factors.

| Factors | Cases | Controls |
|---------|-------|----------|
| Site    | N (%) | N (%)    |
| Upper/left/basilic vein | 3 (5.7) | 5 (9.4) |
| Upper/left/cephalic     | 5 (9.4) | 4 (7.5) |
| Upper/left/dorsal arch  | 17 (32.1) | 18 (34) |
| Upper/left/median cubital vein | 3 (5.7) | 1 (1.9) |
| Upper/right/basilic vein | 3 (5.7) | 4 (7.5) |
| Upper/right/cephalic    | 5 (9.4) | 4 (7.5) |
| Upper/right/dorsal arch | 10 (18.9) | 16 (30.2) |
| Upper/right/median cubital vein | 5 (9.4) | 1 (1.9) |
| Upper/right/multiple    | 1 (1.9) | 0 (0) |
| Lower/right/dorsal arch | 1 (1.9) | 0 (0) |
| Vein visibility during IV catheterisation | | |
| Visible even without tourniquet | 15 (28.3) | 21 (39.6) |
| Seen after using tourniquet | 17 (32.1) | 11 (20.8) |
| Not visible even with tourniquet | 21 (39.6) | 21 (39.6) |

# Chi-square test used, significance level <0.05.

All the patients had IV cannula in their upper limbs. Of the 53 cases, 15 patients (28.3%) had veins visible even without tourniquet application, 17 patients (32.1%) had veins visible after tourniquet application and 21 patients (39.6%) had no veins visible even after tourniquet application, whereas, Of the 53 Controls, 21 patients (39.6%) had visible veins without tourniquet application, 11 patients (20.8%) had visible veins after tourniquet application, and 21 patients (39.6%) had no veins visible even after tourniquet application.
application and 21 patients (39.6%) had no visible veins even after tourniquet application, p value was 0.319. Of the 53 cases, in 34 patients (64.2%) IV cannulation was done in First attempt and 19 patients (35.8%) required more than one attempt for IV cannulation, whereas, 35 patients (66%) out of 53 controls had IV cannulation done in First attempt and 18 patients (34%) required more than 1 attempts, p value was 0.839 (>0.05, not significant) (Table 3). Of the 53 cases, in 49 patients (92.5%) IV cannulation was followed by flushing of cannula and in 4 patients (7.5%) IV cannulation was not followed by flushing of cannula, whereas, all 53 patients (100%) of controls had IV cannula flushed post insertion, p value was 0.118 (Table 3).

### Table 3: Risk factors based on technique of catheterization across cases and controls for the development of thrombophlebitis: procedural factors.

| Factors                                      | Cases        | Controls     | P value  |
|----------------------------------------------|--------------|--------------|----------|
| IV catheterization at first attempt          | N (%)        | N (%)        | 0.839    |
| Yes                                          | 34 (64.2)    | 35 (66)      |          |
| No                                           | 19 (35.8)    | 18 (34)      |          |
| IV flushed after insertion                   |              |              | 0.118    |
| Yes                                          | 49 (92.5)    | 53 (100)     |          |
| No                                           | 4 (7.5)      | 0 (0)        |          |
| Number of times catheter changed during indoor stay | 2 (2)        | 0 (0)        | <0.0005* |
| Duration during which IV line kept empty     | 5 (5)        | 5 (5)        | 0.580    |
| Local treatment given                        |              |              |          |
| Ice pack application                         | 20 (37.7)    | 0 (0)        |          |
| Local heparin                                | 1 (1.9)      | 0 (0)        |          |
| Both local heparin and ice pack              | 1 (1.9)      | 0 (0)        |          |
| None                                         | 31 (58.5)    | 53 (100)     |          |
| Duration of IV catheterization (in days)     | 4            | 5            | 0.969    |
| Total                                        | 53 (100)     | 53 (100)     |          |

#Chi-square test used, ^Fisher exact test used, *significant at 0.05 level. \( \text{median (Interquartile Range). Mann Whitney U test used.} \)

### Table 4: Risk factors based on IV canula properties and drugs administered across cases and controls for the development of thrombophlebitis: equipment/drug related factors.

| Factors                                      | Cases        | Controls     | P value  |
|----------------------------------------------|--------------|--------------|----------|
| Cannula size \( ^a \)                        | 20 G         | 20 G         | 0.223    |
| KCl administered through IV catheter         |              |              |          |
| Yes                                          | 6 (11.3)     | 0 (0)        | 0.027*   |
| No                                           | 47 (88.7)    | 53 (100)     |          |
| Total                                        | 53 (100)     | 53 (100)     |          |
| Piperacillin and tazobactam                  |              |              |          |
| Given                                        | 12 (22.6)    | 2 (3.7)      | 0.004121 |
| Not given                                    | 41 (77.4)    | 51 (96.3)    |          |
| Total                                        | 53 (100)     | 53 (100)     |          |

#Chi-square test used, *significant at level <0.05, \( \text{median (Interquartile Range).} \)

Among the 53 cases, on an average IV cannula had to be changed at least 2 times during the hospital stay, whereas, in 53 controls, none of them needed to change the cannula during the hospital stay. P value was <0.0005 (Table 3).

On an average all the cases and controls had an average IV cannulation for 5 days, p value was 0.580. It was also noted that 37.7% of the cases were given ice pack, ointment was given to only 1 case (1.9%), and both ointment and ice pack was given to 1 case (1.9%). Remaining cases (58.5%) were not given any local treatment. Both the cases and controls had insertion of same size cannula (20G). P value was 0.223 (>0.05, not significant) (Table 4). Of the 53 cases, 6 patients (11.3%) were administered IV KCL injection through the canula and 47 (88.7%) were not administered, whereas, of the 53 controls, all 53 patients (100%) were not given IV KCL injection through the canula, p value was 0.027 (Table 4). Of the 53 cases, 12 patients (22.6%) were administered piperacillin and tazobactam injection through the canula and 41 patients (77.4%) were not administered, whereas, of the 53 controls, 2 patients (3.7%) were administered piperacillin and tazobactam injection through the canula and 51 patients (96.3%) were not administered the injection, p value was 0.004 (Table 4). Of the 53 cases, level 1 phlebitis was identified in 34 patients (64.15%), level 2 phlebitis was identified in
18 patients (33.96%) and level 3 phlebitis was seen 1 patient (1.88%) (Figure 1).

There was no direct relationship identified between the gender of the cases and development of phlebitis. This is contradictory to the results obtained by Nyika et al, where the male gender has been demonstrated as a risk factor for development of phlebitis. A point prevalence study by Washington, Georgita et al however showed the female gender to be a risk factor. Similar to the results obtained by Abolfotouh et al.

In a study done previously to calculate the incidence of 8 signs (swelling, erythema, leakage, palpable venous cord, purulent discharge, and warmth) and symptoms (pain and tenderness) used for the diagnosis of phlebitis with peripheral intravenous catheters, or short peripheral catheters, and the level of correlation between them, it was found that most signs and symptoms of phlebitis occurred only occasionally or rarely; the incidence of tenderness was highest (5.7%). Correlations were mostly low; warmth correlated strongly with tenderness, swelling, and erythema.

If the patient has a history of deep vein thrombosis, then the risk of upper extremity thrombosis due to catheterization increases. It has also been noted that many congenital or acquired pro-thrombotic states have been associated with increased risk for catheter induced venous thrombosis. Malignancies have also been proposed as a potential cause of thrombophlebitis in catheterized patients.

Previous studies done on the subject of incidence and risk factors for phlebitis has shown that the clinical assessment of phlebitis in patients poses a lot of difficulty due to the low agreement with phlebitis diagnosis. A study published in 2001 described the incidence of phlebitis in patients who were undergoing peripheral intravenous therapy. The result of the study demonstrated that 10 cases developed phlebitis within 72 hours. And in 3 cases, even though infusion site was clear at the time of catheter removal, post infusion phlebitis still developed within 24 hours.

Atay et al in an independent prospective observational study have demonstrated that phlebitis was observed in 31.8% individuals receiving peripheral IV therapy, and a large number of them (79.2%) were identified to be level I phlebitis. In addition, in our study, while no relationship was found between the development of phlebitis and the age, site of IV catheter, catheter number, and use of antibiotics, there was a significant relationship between the presence of chronic disease, duration of catheterization and type of fluid used and the development of phlebitis. This study in many ways is similar to the one conducted in Zimbabwe as mentioned previously.
Majority of the cases in our study were diagnosed with level 1 phlebitis (64.15%) which is similar to the results obtained by Cicolini et al. (94.4%) and by Atay et al, (79.2%) in their respective studies. Although, as per the study done by Nyika et al, the most common stage diagnosed was level 4, and as per the study by Urbanetto et al the most common stage was grade 3 in patients of post-infusion phlebitis and grade 2 in patients having phlebitis with catheter in place.10,16

In our study, there was no statistically significant difference between the groups in relation to whether the vein was visible at the time of catheter insertion, or whether the IV catheterization was successful in first attempt or not. Thus, we can establish that neither of these variables are risk factors for the development of phlebitis. Also, no significant risk was identified in those patients in whom the intravenous catheter was not flushed after insertion. The study results however, obtained by Nyika et al, show that 72.7% patients in whom catheters were never flushed had developed thrombophlebitis.16

The no. of days of catheter dwell time was not a significant risk factor for the development of phlebitis in our study. Catney et al, in their study concluded that the dwell time of catheters can be extended beyond 72 hours under certain conditions. Ansel, Brenda and Boyce et al, recommend keeping the IV Catheters in situ until a clinical reason warrants their removal. Homer et al, in their study also deduced that restarting the catheters after 72 hours instead of simply continuing the original catheter does reduce the risk of development of phlebitis within the next 24 hours. The CDC recommends changing the peripheral IV catheters every 72-96 hours to reduce the risk of catheter related infection and phlebitis.27

A related study to this tried to assess whether the indwelling time has any correlation to the development of phlebitis and described that drug irritation was the most significant predictor of phlebitis and infiltration rates in this study. The total difference in the estimated failure rates for the catheter lasting 6 days versus a new catheter inserted for another 3 days is 1.3%. Because the conditional failure probability estimates for days 4, 5, and 6 are slightly higher than for days 1, 2, and 3, consideration may be given to extending the dwell time of a peripheral IV catheter beyond 72 hours under certain circumstances.24

It was found that the number of times the peripheral IV catheter was changed since admission was itself a risk factor for development of superficial thrombophlebitis. This finding is also in accordance with similar results obtained by Nyika et al, in their study. Maki et al have described phlebitis with a previous catheter as having a relative risk of 1.54 for the development of phlebitis in the future.27

There was no significant association between the development of phlebitis and the time for which the catheter was empty after the infusion of the drug or fluid had stopped had stopped. Nyika et al, in their study, have reported that continuous infusion was a positive risk factor for the development of phlebitis.16

The size of the catheter is a risk factor since for a similar sized vein, a large diameter centrally placed catheter will pose a greater risk than a smaller diameter catheter. In our study, cannula size was not been identified as a positive risk factor for the development of phlebitis. This is similar to the findings of Zavareh et al and the result of the metanalysis by Chang et al. In the study by Webster and Marsh et al, it was found that 22-gauge catheters are a positive risk factor for the development of phlebitis (HR, 1.43; 95% CI, 1.02-2.00). Similarly, Nyika et al, have identified 18-gauge catheters as risk factors for development of phlebitis (75%). Singh et al, have identified 20 gauge catheter as a relative risk and Tripathi et al have estimated increased complications being associated with 24-gauge catheters.30,31

Another factor is catheter infection, which may occur directly from the patient’s flora or a remote site. Using sterile techniques while inserting and timely removal of indwelling catheters can reduce the incidence of catheter related infections.33

A meta-analysis and systematic review by Chang et al has tried to show the influence of catheterization site, gauge and duration of infusion on the development of phlebitis. This showed no statistical difference between the use of catheters of gauges less than or more than 20. There was no statistical difference between the occurrence of phlebitis at catheters inserted in the antecubital fossa and catheters inserted at other sites on the upper limb. There was also no statistical difference in the development of phlebitis in the catheters inserted for more than 96 hours and those inserted for 96 hours or less. The last statement contradicts the study mentioned previously where catheter failure rates were higher in those with indwelling time over 72 hours.25

The closest study compared to ours in recent years was one conducted in Zimbabwe, which was a descriptive one, conducted on 46 adult inpatients to check for the incidence of phlebitis using a systematic random sample. The visual infusion phlebitis score was used for assessment. It was found that most participants came under the classification of stage 4 phlebitis. Other risk factors identified included the male gender, immunosuppression, number of catheters inserted, site of catherization, and catheter dwell time, catheter gauge, and securement, regularity of flushing and continuous infusion.16

Other factors that are culprits for thrombophlebitis, include chemical irritation from infused drugs as well as the catheter material. Some common causes include...
potassium chloride, antibiotics such as oxacillin and vancomycin, some chemotherapeutic drugs, and hypotonic (<250 mosmol/kg) or hypertonic solutions (>350mosmol/kg).34

The administration of KCL has long been associated with the potential risk of causing thrombophlebitis.35-36 In our study, there is a statistically significant association between the infusion of KCL through the peripheral intravenous catheter and the development of phlebitis. Ervin Susan in her study demonstrated a positive association between the administration of KCL and the development of phlebitis.35 The reason for this could be the fact that potassium chloride is an irritant to the endothelium, which may cause damage to the cells of the endothelial lining and make them prone to inflammation and subsequent thrombophlebitis. Dragana et al in their survey also obtained similar results.36

In our study, there was a statistically significant difference with the administration of piperacillin and tazobactam through the peripheral IV catheter. Infusion of medication has been documented as a potential cause of development of thrombophlebitis in multiple studies.9,18,24,30,36 Among these, beta lactams, especially benzyl-penicillin and flu-cloxacillin have been noted in previous studies as risk factors.36,39 Thus, it is not surprising to find piperacillin as another irritant medication in our study as a significant risk factor. The reason behind this could be the fact that the drug itself behaving as an irritant, has a mechanism of irritating the endothelial lining, similar to potassium chloride.

There was no statistically significant difference to the development of phlebitis between the comparison groups in relation to the presence of chronic disease. The results obtained by Atay et al show that the presence of chronic disease has a statistically significant correlation to phlebitis.11 Zavareh et al in their study have shown diabetes mellitus as a relative risk factor.36

It was also observed that after the development of phlebitis, while 22 patients were either given ice pack, heparinoid ointment or both, more than half (31) patients were not given any remedial measure. This might be a crude indicator of the quality of healthcare that is being administered at the institution.

Newer modalities for management of thrombophlebitis such as use of notoginseny have been studied, but the results are not conclusive enough to recommend it as a standard for management without further evidence.37 Experimental studies have been carried out in animal models testing the effectiveness of newer methods such as Mirabiliite and Chinese medicine treatment, but without conclusive human trials, the prospect remains unexplored and enigmatic.38,39

CONCLUSION

Based on our study results, we can say that post-injection thrombophlebitis affects patients regardless of the age, sex and diagnosis. Most cases are level 1 or level 2 according to VIPS grading system. While no relationship was found between the visibility of vein at the time of insertion of the catheter, whether inserted in first attempt or not, whether flushed or not, time for which catheter was left empty after infusion, dwell time, cannula size and the presence of a chronic disease, in relation to the development of phlebitis, significant association was noted between the number of times the catheter was changed since admission and administration of potassium chloride and certain medications such as piperacillin through the cannula.

Through this study, we were also able to estimate the standard of healthcare that is being offered at our institution. The fact that more than half the patients were not offered any remedy for alleviating their symptoms suggests a big lapse in the quality of nursing that is being provided at our hospital.

Since the incidence rate is above the recommended rate by CDC, we can try using certain preventive measures such as removing peripheral catheters after 72 hours electively as suggested by the CDC, to avoid post-injection thrombophlebitis. KCI and Antibiotics should be diluted appropriately and infused at a slower rate, or whenever possible, given through a centrally placed IV catheter. There needs to be an institutional management algorithm to tackle this problem, so that appropriate treatment is provided to each case of phlebitis and thereby future complications can be avoided. Nurses need to be further sensitized to this problem, since in a south Asian country like India, complexion may lead to a misdiagnosis on the visual infusion phlebitis scale, and thrombophlebitis may be missed, and at the same time heavy patient load in the in-patient department may further numb the nursing staff to their distress.

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