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Original Article

A Retrospective Study of Complications of Peripherally Inserted Central Venous Catheters in Oncology Patients

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Abstract

background and Aim: Central venous catheters can be considered as important pillars in the practice of modern-day intensive care including oncological and onco-hematological units. However, like all medical interventions, central venous catheters too are linked with a number of complications. The objective of the particular study had been aimed to assess the complications linked with peripherally inserted central catheters (PICCs) in a group of oncology patients.

Materials and Methods: In this retrospective study, we included all patients carrying PICCs (*n* = 201) inserted at SMH cancer Centre during June 2015–May 2018 (i.e., 36 months). The major variables that were collected and analyzed have been medical investigation, catheter care, placement, time span of catheterization, rationale of catheter removal, obstacles, and nursing care. Complications/obstacles were enumerated as infection, phlebitis, edema, thrombosis, ecchymosis, and/or migration.

Results: The same nursing care protocol was used to treat all the patients. The rate of incidence of complications was noted to be two cases per 1000 days of catheter time span. The most pertinent complications warranting the removal of PICCs were found to be infection and thrombosis, with an incidence of 0.17 cases per 1000 days of total catheterization duration. The average time period of catheterization was 170 days. In addition to common causes such as "treatment completion" (48.42%) and "death" (22.53%), the other most talked cause of catheter removal was its migration (displacement toward the exterior) of 5.90%.

Conclusions: The central venous catheter (PICC) is quite a safe device that allows the administration of long-term treatment in addition to preserving the integrity of the venous system of the patient. Adequate care of the catheter is quite crucial to prevent the occurrence of complications and improve the quality of life of the patients having oncological and hematological conditions. Thus, proper training with the latest recommendations for nursing staff as well as patients is particularly required.

Key words: PICC, Complications of PICC, PICC in oncology

INTRODUCTION

The utilization of central venous lines is required in patients undergoing chemotherapy continuously in fairly large doses. Central catheters are essential in the current medical profession, being specifically required when the treatment is vesicants or irritating, such as chemotherapy and certain IV antibiotics. Central venous catheters are also used when either the peripheral venous access is absent or is very damaged.

In today's time, the utilization of central venous catheter has grown predominant in medical specialties such as chemotherapy, critical care, dialysis, and nutritional support. Its use is frequently indicated in the dispensation of chemotherapy, parenteral nutrition, and ministrations which are considered vesicants or irritating. These devices are typically used on patients having difficult venous access, impaired lymphatic system, or complaint of pain while infusion or have fear of venipuncture.[1-7]

In addition, for the patients who are undergoing continuous perfusion of chemotherapy, the location of a

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central venous catheter becomes necessary in outpatient dispensation of drugs. Or else, hospital admission would be required for such patient to administer drugs through the peripheral venous line. With all credit to easy placement of central venous catheters in such cases, the need for hospital admission has been practically done away with, at our hospital.

To administer chemotherapy drugs in large volume, onco-hematological patients require catheters (that flow into a vein) with sufficient flow and caliber. Long-term peripherally inserted central catheters (PICCs) which run into the bottom third part of the vena cava fulfill the above-mentioned criteria and hence reduce injury to the peripheral vascular system.

The extravasation risk is significantly reduced with the use of PICC, which is particularly useful for administering drugs which are vesicant or irritating like certain cytostatics. Although this type of venous port provides a safe procedure for permanent access accompanied with significantly low complications rate, certain complications could still occur.

Thrombosis and infection are the major among all the complications due to their relevancy and clinical consequences in onco-hematological patients. Deep vein thrombosis has been a commonly occurring complication in patients undergoing chemotherapy, whose risk increases in patients suffering from diabetes, chronic obstructive pulmonary disease, or advent of metastases.

Onco-hematological patients are at greater risk of infection since the therapy and pathology both are linked with stretch of immunosuppression. The main purpose of this study had been to assess the occurrence of complications linked with PICCs in our center with a group comprising mostly of onco-hematological patients.[7-20]

MATERIALS AND METHODS

Study Design

It had been a retrospective longitudinal group study.

Setting

The study was conducted at SMH Cancer Center, New Delhi, a region in India, between June 2015 and May 2018 (i.e., 36 months) Figure 1. PICC line *in situ*. Participants included male/female patients aged above 18 years and bearers of PICCs during the project duration.

Data collection was retrospective. The population under the study comprises all the patients in which PICC was inserted during treatment at our institution in the stipulated duration. A total of 201 patients were there in the final study.

Figure 1: PICC line *in situ*

Variables and Measures

For each patient, the following data were collected: Date of birth, sex, medical investigations, nursing care of the catheter, the placement of the catheter, time span of catheterization (days), causes for catheter removal, and complications.

Catheters were positioned by adequately trained nursing staff, through sterile and ultrasound-guided procedure (two-dimensional ultrasound imaging). The PICCs were installed in the middle third part of the upper arm, above the antecubital fossa, primarily in the cephalic or basilic vein. A vein of caliber similar to the caliber of the catheter was chosen.

The distal tip of the catheter was positioned in the lower third part of the superior vena cava that was affirmed by chest radiograph.[8] We used BARD, a polyurethane, 4-Fr diameter, single-lumen catheter. Fixing and stabilizing of the catheter were attained with a sterile latex-free device specifically designed for this purpose. The "protocol of care" was applied to each and every patient who is bearer of PICCs and comprised of sterile dressing using transparent bandages, and cleaning was done with betadine solution in line with the recommendations of the United States Centers for Disease Control and Prevention (CDC) weekly.

When the fixing device got deteriorated, a new one was replaced. The catheters were then sealed with heparin after use. The time span of catheterization was calculated as the difference between the date of its insertion and the date of removal. This date was handled in the analyses such as a continuous quantitative variable.

Complications were categorized as thrombosis, phlebitis, infection, migration, ecchymosis, and/or edema. The criteria for defining the occurrence of "infection" were the central line-associated bloodstream infection.[9] Symptoms of thrombosis were pain, swelling, erythema, and vein blockage by a blood clot (thrombus) with a subsequent lack of permeability.[12]

The criteria for the diagnosis of "thrombosis" were the presence of symptoms and final confirmation by Doppler. Phlebitis was defined as irritation of the venous endothelium by the catheter. Its symptoms were similar to those of thrombosis, but the catheter remained permeable because there was no venous blockage: Pain, tenderness, swelling, erythema, palpable venous cord, purulent discharge, and warmth of the area.[13]

The criteria for a diagnosis of "phlebitis" were the presence of symptoms and final confirmation by ultrasound. The criterion for catheter migration was outward displacement of the catheter by >2 cm (displacement toward the exterior). The diagnostic criterion for edema was swelling caused by fluid accumulation in the arm near the catheter insertion point.

The criterion for the diagnosis of ecchymosis was the presence of a bruise near the catheter insertion point. The catheter was considered to have a "lumen occlusion", if there was a total occlusion, occlusion to flushing only, occlusion on aspiration only or subjective difficulty with flushing or aspiration only, under the following circumstances: If the vein was not damaged, inflamed or obstructed and if fibrinolytic treatment was required.[8,10]

Study Limitations

In retrospective studies based on secondary information (medical records), one of the main limitations is that the data obtained from computer records may be subjected to bias by the researcher who collected the information. In this study, the personnel of the unit responsible for the care of the PICCs was trained for data collection by standardized training sessions with the objective of reducing the interobserver differences as much as possible. In addition, another study limitation is that the nursing protocol has been currently updated.

This study was conducted between June 2015 and May 2018, and our protocol at that time consisted of the prophylactic use of heparin.[11,14] Statistical analyses for the descriptions of the variables, frequency distributions, averages with 95% confidence intervals (95% CI), standard deviations (SD), and ranges were calculated. The normal distribution of data was assessed using Kolmogorov–Smirnov test.

The cumulative incidence and incidence density rates per 1000 days of catheter use of the various complications were calculated. For comparison of proportions, Chi-square test was performed, using Fisher's exact test when necessary. Non-parametric tests were used, such as Mann–Whitney *U*-test, for the comparison of averages, and Kendall test was used in the correlation studies when the variables did not have a normal distribution.

For the study of associated independent factors, an automated stepwise forward multiple logistic regression model was used. The alpha error was set at 0.05, and all *P* values were bilateral. All statistical analyses were conducted using IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY).

Ethics Statement

Approval of the research protocol was obtained on August 2018 from the Administrative Committee of SMH Hospital.

Patient records/date were randomized and deidentified before analysis. Since the data were analyzed anonymously, patient consent was not necessary. We obtained the consent of the Administrative Committee and authorization from the hospital to perform this study.

RESULTS

A total of 201 patients aged between 18 and 95 years [Table 1] were analyzed. Regarding sex, 54.73% were female and 45.27% were male.

With regard to diagnosis, 100% (n = 201) of the patients had been diagnosed with an oncologic or onco-hematologic disease [Table 2]. The average duration of catheterization was 171.20 days (SD 6.06) with a minimum of 2 days and a maximum of 540. All the catheters were located in the middle third of the upper arm, above the antecubital fossa: 34% (n = 70) were placed in the right basilic vein, 56.21% (n = 113) were placed in the left basilic vein, 2.98% (n =

Table 1: Age distribution of patients with peripherally inserted central catheters

Age range	*n*=201 (%)
10–19	0
20–29	5 (2.48)
30–39	15 (7.46)
40–49	31 (15.42)
50–59	54 (26.8)
60–69	62 (30.8)
70–79	25 (12.4)
80–89	8 (3.98)
90–99	1 (0.5)

6) were placed in the right cephalic vein, and 5.97% (*n* = 12) were placed in the left cephalic vein.

At least one complication occurred in 40% of the patients (*n* = 80), whereby the incidence of complications was two complications per 1000 days of the total duration of catheterization. The individual analysis of complications is presented in Table 3. In addition, 3.15% (95% CI 1.67–4.63%) (*n* = 19) of patients presented an infection profile. Complication onset after catheterization occurred at an average of 114.26 (SD 22.21) days.

The incidence rate of complications was 0.17 cases per 500 days for the total duration of catheterization. Thrombosis occurred in 3.48% (95% CI 1.81–4.83%) (*n* = 7) of the patients, at an average onset of 28.90 (SD 9.12) days of the total duration of catheterization. The incidence rate of thrombosis was 0.17 cases per 1000 days of the total duration of catheterization. In 13 of the patients, a fibrinolytic agent was used at least once.

In all cases, the thrombosis event was local. In 6.96% (95% CI 4.99–9.27%) (*n* = 14) of patients, phlebitis was registered at an average onset of 2.23 (SD 0.21) days after catheter insertion. The incidence rate was 0.38 cases per 1000 days of the total catheter days. In 12.93% (95% CI 10.32–15.88%) (*n* = 26) of the catheters, at least one episode of migration was registered at an average onset of 163.75 (SD 14.15) days after insertion.

The latest case occurred on day 406. The incidence rate was 0.69 cases per 500 days of the total duration of catheterization.

In 8.99% (*n* = 18) (95% CI 10.32–15.88%) of patients, edema onset occurred at an average onset of 28.16 (SD 9.36) days of the total duration of catheterization.

In 20 patients, this complication occurred on the day following catheter insertion. In contrast, four cases were registered between days 237 and 282 of catheterization. The incidence rate was 0.50 cases per 500 days of the total duration of catheterization. In 18.40% (*n* = 37) (95% CI 15.23–21.58%) of patients, an ecchymosis was produced at an average onset of 3.96 (SD 0.42) days of the total duration of catheterization, although a high frequency of cases (*n* = 07) was noted on the day following catheter insertion.

This complication showed the highest incidence rate, with 1.93 cases per 1000 days of the total duration of catheterization. In 44.27% (95% CI 40.23–48.32) (*n* = 89) of the patients, a fibrinolytic therapy was used at least once due to catheter lumen occlusion. The incidence rate was 2.32 cases per 1000 days of the total duration of catheterization. The average onset was at 76.48 (SD 73.66) days after insertion.

No major differences were established considering age, sex, medical investigations, and location of the catheter with respect to infection, thrombosis, phlebitis, migration, edema, ecchymosis, and/or lumen occlusion. None of the variables was found to be significant in the multivariable model [Table 4].

No correlation was reported (correlation coefficient 0.0023; *P* = 0.379) between age and timespan, placement, and migration (displacement to the exterior) of the catheter. Although the occurrence of complications was significantly higher, when the total timespan of catheterization exceeded

Table 2: Distribution diagnosis of patients with peripherally inserted central catheters

Medical diagnosis	*n*=201 (%)
Breast carcinoma	149 (24.70)
Carcinoma ovary	106 (17.58)
Colorectal cancer	18 (8.9)
Carcinoma biliary pancreas	16 (7.9)
Sarcoma	12 (5.9)
Leukemia	8 (3.9)
Hodgkin's	7 (3.5)
Carcinoma lung	18 (8.9)
Carcinoma bladder	6 (2.98)
Carcinoma stomach	18 (8.9)
Head and neck	10 (4.9)
Multiple myeloma	7 (3.49)
Carcinoma esophagus	6 (2.9)
Carcinoma cervix	14 (6.2)
Carcinoma prostate	9 (4.48)
Others	2 (1)

Table 3: Analysis of complications of PICC

Complication	*n* (%)	95% CI	Incidence rate	Day of onset
Infection	7 (3.48)	1.67–4.63	0.17	114.26 (22.21)
Thrombosis	7 (3.48)	1.81–4.83	0.17	28.90 (9.12)
Phlebitis	14 (6.96)	4.99–9.27	0.38	2.23 (0.21)
Migration	26 (12.93)	10.32–15.88	0.69	163.75 (14.15)
Edema	2 (0.99)	10.32–15.88	0.50	28.16 (9.36)
Ecchymosis	37 (18.4)	15.23–21.58	1.93	3.96 (0.42)
Lumen occlusion	89 (44.27)	40.23–48.32	2.32	76.48 (73.66)

PICC: Peripherally inserted central catheter, 95% CI: 95% confidence intervals

Table 4: Presence of complications with respect to sex, age, location and duration of PICC

Variables	Total	Complications *n* (%)
Sex		
Men	91	33 (16.41)
Women	110	44 (21.89)
P=0.0388[b]		
Age		
>65 years	60	22 (10.94)
<65 years	141	55 (27.36)
P=0.238[b]		
Locations		
Basilic right	270	24 (11.94)
Basilic left	113	45 (22.38)
Cephalic right	6	2 (0.99)
Cephalic left	12	6 (2.98)
P=0.252[b]		
Duration		
>150 days	100	44 (21.89)
<150 days	101	34 (16.91)
P=0.006[b]		

PICC: Peripherally inserted central catheter

Table 5: Reasons for catheter removal of the PICC

Cause of withdrawal	*n*=201 (%)	95% CI
End of treatment	97 (48.25)	44.35–52.50
Exitus	45 (22.38)	19.13–25.97
Migration	12 (5.9)	3.85–7.75
Infection	8 (3.99)	2.47–5.82
Lumen occlusion	8 (3.99)	2.47–5.82
Replacement	4 (1.99)	0.79–3.18
Phlebitis or thrombosis	4 (1.99)	0.67–2.97
Not collected	23 (11.45)	8.52–13.70

PICC: Peripherally inserted central catheter, 95% CI: 95% confidence intervals

150 days(P = 0.006), found in 43.62% (n = 130) of cases, out of total 201 cases.

Regarding the reason for removal of the catheter, in 48.25% (n = 97) of the patients, the main cause was "end of treatment;" other reasons included "exitus" in 22.55% (n = 136), "migration" in 5.80% (n = 35), "infection" in 4.14% (n = 25), "lumen occlusion" in 4.14% (n = 25), "replacement" in 1.99% (n = 12), and "thrombosis/thrombophlebitis/phlebitis" in 1.82% (n = 11) of the patients. In 11.10% (n = 67) of the patients, the reason could not be found out [Table 5].

DISCUSSION

The PICC care is commonly practiced by health-care professionals. Although,the PICC care is commonly practiced by health care professionals, on certain occasions, our practices do not corraborate with evidence based practice. Some studies have reported that the differences obtained in the rate of complications are directly related to the knowledge of health-care personnel regarding catheter placement and port insertion care. Significant reduction in the rate of complications has been achieved with good training.

In fact, the CDC, in its memorandum for the care of central venous catheters, states that adequate training of personnel is a basic way of preventing infections having a level of evidence of 1A. Therefore, insertion procedure and care of the catheters make a major area for research among health-care providers, to achieve not only the reduction in bad effects but also to improve the patient experience. When juxtaposed with other published studies, the infection rate and thrombosis in our study were found to be lower (0.17 cases per 1000 days of the total catheter duration) and reported cumulative incidences of 3.99% and 1.99%, respectively.

With respect to infection, in 2013, the National Healthcare Safety Network reported that the incidence rate of infection in onco-hematological patients by laboratory-confirmed temporary catheter use has increased to 0.25 per 1000 days of total PICC duration.[21,22] Chopra *et al*.[23] examined this area through a systematic review with meta-analysis. They reviewed 57,250 patients from 23 studies and concluded that the incidence rate of bacteremia (collected in 13 of the studies) in PICC patients was 0.91% (95% CI 0.46–1.79) cases per 1000 days of total PICC duration.

Another study carried out in a French University Medical College on 222 patients yielded an overall infection rate of 2.35 per 1000 days of catheter use with an occurrence of 0.86 cases per 1000 days of total PICC time span.[24] Baxi *et al*.[25] found 57 cases of bacteremia while evaluating 609 patients with an occurrence rate of 2.69/1000 PICCs/day.

However, none of the mentioned studies specifically included onco-hematological patients. The study conducted by Mollee *et al*.[26] resembled our own. In that study, they analyzed 727 onco-hematological patients retrospectively and got the occurrence rate of infection as 2.5 an average rate of infection at 5.6% compared with our rate of 3.15%.

Taking the case of thrombosis, our results provided a lower than usual incidence rate with 0.170 cases per 1000 days PICC use and a cumulative incidence of 3.32%. Baxi *et al*.[25] also evaluated the same variable and got an incidence rate of 1.23/1000 PICC days. The aggregate incidence was approximately 8.4% during a study conducted on neurological patients in the intensive care, where 431 patients with PICCs[26] were analyzed. Though, Aw *et al*.[7] studied a population of 340 cancer patients of which 19 presented with infection, comprising 5.6% (95% CI 3.06–8.06) of the total patients. Their patient database was

similar to our sample study in terms of the characteristics; but, the occurrence of complication in our study was much lower. Malpositioning of the catheter tip could make blood withdrawal difficult and lead to catheter occlusion.

Therefore, to reduce this complication, it is imperative to check its placement through radiology.[8] It is important to preclude occlusions since they can lead to infection and thrombosis.[10] Moreover, the probability of thrombophlebitis can be reduced by placing the catheters above the antecubital fossa.[8]

It is important to note that the time span of catheterization in our project study was quite longer as compared to those in listed studies.[20,22,23] This was even true in some cases of catheterization longer than 2 years, with an average of 8 months. It can be attributed to the low rate of complications, which helped in maintaining the catheter for a longer period of time.

This is specifically useful in case of onco-hematological patients because they can complete their treatment without change of devices. However, it is to be noted that the incidence of complications in our study started increasing after 5 months of catheterization, reaching to a rate of 43.62% (n = 13). Such data cannot be compared due to the absence of a similar study that achieved a duration of catheterization similar to ours.

The differences in the study results are attributed to the heterogeneity among patients and the care applied to the catheters. The recommendations for their care show significant variability.[27,28] However, in our case, latest recommendations were followed during project duration,[9] and the insertion was done in a USG-guided manner that reduces complications.[29]

In addition, the patient was handled in a systematic manner specifically by the same operating group which had personnel trained specifically for this purpose. "Protocol of care," given to each and every patient by professionals with hands-on training in PICC care, in a structured manner, is considered to be somehow attributable for the low occurrence of complications. In today's time, it is recommended to wash the catheter with saline, therefore our "PICC line care protocol" needs to be revised.[8]

Perhaps, with these new suggestions, the occurrence of lumen occlusion can be significantly reduced. Finally, it is considered that the occurrence of complications is influenced by the catheter material. In our case, the material used was polyurethane, which causes less infection, dislodgment, thrombus, and rupture complications.[30,31]

The main drawback of retrospective studies using secondary information such as medical records is inconsistent information, due to incomplete records or a lack of agreement among the different records. In our study, information about the main variables was collected in >95% of patients. But we were unable to find the catheter removal cause in 23 cases. Another aspect to consider is the lack of other potential confounders (e.g., the presence of metastases), which were unavailable from the secondary registers used in our study.

CONCLUSIONS

In our study, the occurrence rate of complications was quite low, taking into account complications such as infection, lumen occlusion, edema, and ecchymosis. The latter were temporary and innocuous complications that required catheter removal.

We will extend the present line if research and study the correlation between the training of our healthcare personnel and the Advent of complications.

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