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Original Research Article

An Evaluation of Adverse Events Due to Peripheral Intravenous Cannula in Paediatric Patients at a Tertiary Care Teaching Hospital

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Abstract

Background: Peripheral intravenous cannulation (PIVC) is one of the most frequently used invasive procedures in hospitalised patients. Despite its routine use, PIVC is associated with a range of medical device–associated adverse events (MDAEs) that can compromise patient comfort, interrupt therapy, and increase healthcare burden. Systematic documentation of PIVC-related adverse events within the framework of materiovigilance remains limited in tertiary care settings in India.

Objectives: To evaluate adverse events due to PIVC in terms of numbers, types, severity, seriousness, preventability and causality.

Methods: A cross-sectional, single-centre observational study was conducted over three months in the in-patient wards of a tertiary care teaching hospital. A total of 289 hospitalised patients with PIVC in situ were enrolled. Data were collected using a pre-tested case record form capturing demographic details, device characteristics, dwell time, number of drugs administered, fixation method, and adverse events. All MDAEs were assessed for severity, seriousness, preventability, and causality using standard materiovigilance tools. Associations between risk factors and MDAEs were analysed using Pearson's correlation coefficient and chi-square test ($p < 0.05$).

Results: Among 289 patients, 41 PIVC-related MDAEs were identified out of which swelling (70.7%) was the most common adverse event, followed by phlebitis (24.4%) and occlusion (4.9%). All adverse events were of moderate severity (Level 3), non-serious, non-preventable, and showed a possible causal association with PIVC use. A strong positive correlation was observed between PIVC dwell time and MDAEs ($r = 0.98$, $p = 0.019$), as well as between the number of drugs administered and MDAEs ($r = 0.97$, $p = 0.008$). A statistically significant association was found between fixation method using microporous tape and occurrence of MDAEs ($p = 0.015$).

Conclusion: PIVC-related adverse events are relatively less common, moderate in severity (level 3), nonserious, nonpreventable and with "possible" causality assessment. Prolonged PIVC dwell time, administration of multiple drugs and the use of microporous tape for fixation of PIVC are identified as associated risk factors for occurrence of MDAE.

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Introduction

Peripheral intravenous cannulation (PIVC) is one of the most frequent invasive procedures carried out in hospital settings for the delivery of fluids, medications, blood products, and parenteral nutrition. The high frequency of PIVC insertion, often considered routine, hides a high risk of local and systemic complications such as phlebitis, infiltration/extravasation, occlusion, dislodgement, and catheter-related bloodstream infection (CRBSI). These complications result in patient discomfort, treatment interruption, prolonged hospital stay, and increased healthcare expenditure, and are also a frequent cause of device failure and unplanned device replacement. More than one billion peripheral intravenous cannulas (PIVCs) are used annually worldwide, with an estimated 60% of hospitalized patients receiving PIVCs during the course of their hospital stay. [1,2] Among the complications of PIVC, phlebitis has been extensively documented: systematic reviews and observational studies have reported wide incidence ranges (commonly quoted between ≈13% and >50%, depending on population, definition, and method of monitoring) and have identified various risk factors, including catheter dwell time, site of insertion, catheter size, infuscate characteristics

(irritant and hyperosmolar drugs), and cannulation and care practices. The wide range of reported rate reflects the clinical significance of the problem and the variability of measurement and reporting practices. [2,3]

In addition to patient-level adverse events, there is also a concern regarding adverse events associated with PIVC use as a medical device safety issue. The increasing appreciation of the potential for medical devices (such as disposable cannula and IV sets) to cause adverse events has led to the development of materiovigilance systems and frameworks, which have shown that intravenous cannula is a contributing proportion of device-related reports and, importantly, that under-reporting and misclassification are issues for signal detection. In India, for example, the national materiovigilance programme reported adverse events associated with intravenous cannula and other devices following the introduction of structured reporting. [4]

Notwithstanding the efforts of guidelines and the accumulating evidence regarding PIVC complications, significant knowledge gaps remain in most tertiary care hospitals: (a) The incidence and distribution of cannula-related adverse events are not systematically documented; (b) The risk factors that are modifiable (e.g., site of cannula insertion, fixation and dwell time practices, staff education and adherence to asepsis) are not uniformly practiced; and (c) There is a poor connection between clinical practice, device-related events, and national materiovigilance reporting. This limits the ability to develop targeted interventions (education, standard operating procedures, device selection) to decrease harm and device failure. [5]

Thus, the current study was conducted to assess the adverse events related to the use of peripheral intravenous cannulas in hospitalized patients at a tertiary care teaching hospital. The adverse events were measured in terms of number, type, severity, seriousness, preventability, and causality.

Aim: To evaluate medical device adverse events due to peripheral intravenous cannula in hospitalized patients at a tertiary care teaching hospital.

Objectives

- To evaluate adverse events due to PIVC in terms of numbers, types, severity, seriousness, preventability and causality.
- To identify the risk factors causing these MDAEs.

Materials and Methods

Study Design and Setting: This was a cross-sectional, single-centre observational study conducted at a tertiary care teaching hospital, situated in a western region of India. The study was carried out in the in-patient wards of the hospital over a period of three months.

Study Population: The study population comprised paediatric patients with peripheral intravenous cannula (PIVC) in situ admitted to various in-patient wards of a tertiary care teaching hospital.

Inclusion Criteria

- Patients of any age and gender admitted to paediatric in-patient wards
- Patients whose guardian were willing to provide informed consent along with patients assent (if patient's age is more than 6)

Exclusion Criteria

- Patients admitted to Neonatal Intensive Care Units (NICU), Peadiatric Intensive Care Units (PICU)
- Patients admitted to emergency wards

Sample Size and Sampling Method: The investigator visited single in-patient ward per day during the study period. All eligible patients present in the ward at the time of visit and fulfilling the selection criteria were enrolled in the study. (Total sample size for the study was 289)

Data Collection Tool: Data were collected using a pre-tested Case Record Form (CRF). The CRF was designed to record information related to patient demographics, clinical details, device characteristics, and adverse events associated with PIVC use.

Data Collection Procedure

After enrolment, the following information was recorded in the CRF:

- Demographic details: age, gender, address, contact details
- Clinical details: diagnosis at the time of admission, indication for PIVC insertion
- Device-related details:

1. Cannula size
2. Total dwell time (dwell of cannula insertion in days)

All identified adverse events related to PIVC were documented and reported using the Medical Device Adverse Event Reporting Form under the Materiovigilance Programme of India (MvPI).

- Assessment of Medical Device Adverse Events

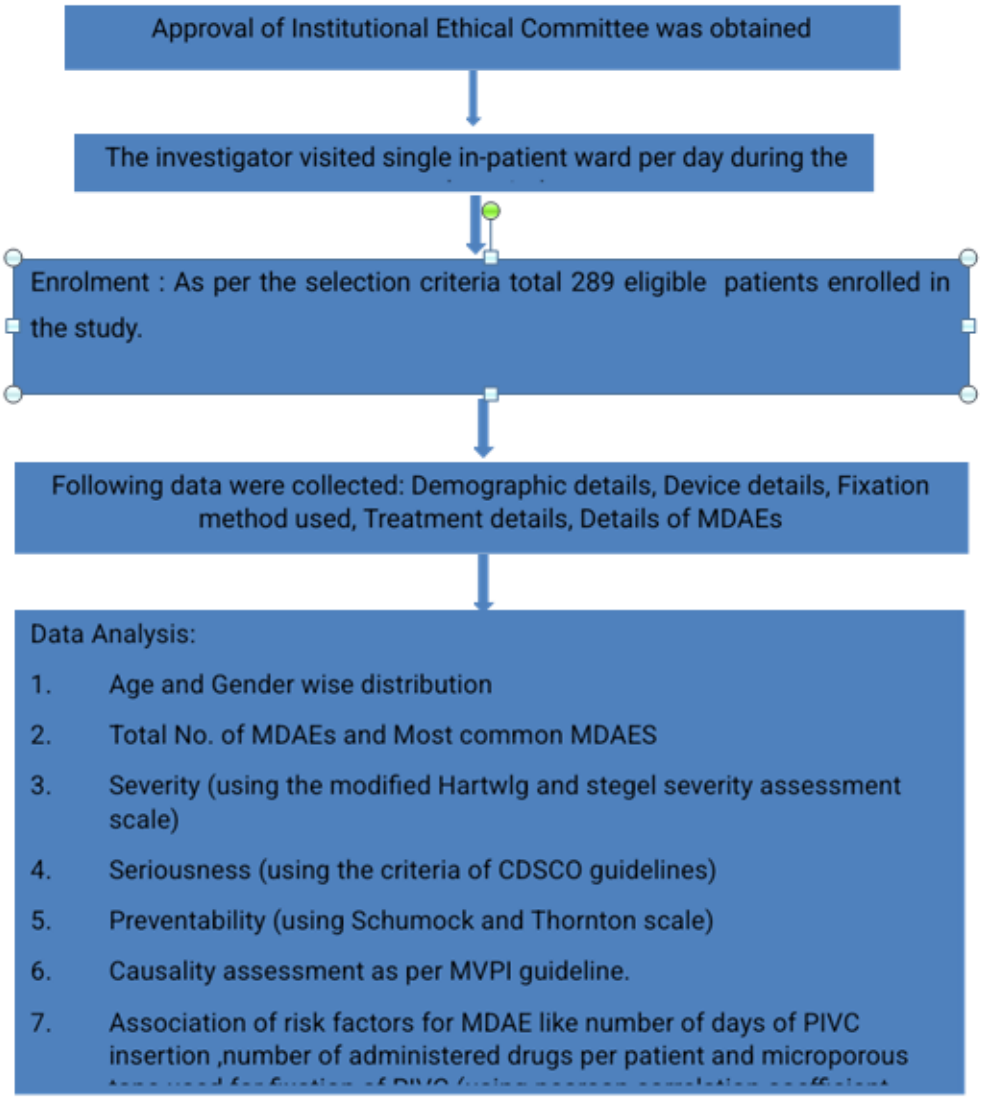
Each reported adverse event was evaluated for:

1. Name (Type) of adverse event
2. Severity and seriousness
3. Preventability
4. Causality, based on standard causality assessment principles used in pharmacovigilance and materiovigilance practices

- Treatment details

1. Number of drugs used

Ethical Considerations: Prior to initiation of the study, Ethical approval was granted by the Institutional Ethics Committee (Approval letter no. II-117A/2024). Written informed consent was obtained from all eligible participants or from parents/guardians before enrollment. Confidentiality of patient information was strictly maintained throughout the study.



Results

The incidence of PIVC-related MDAEs was 14.2% among the study population.

- **Distribution of participants according to age group (n=289):** The majority of participants (142,49.1%) belonged to 6–10 years of age , followed by 74 (25.6%) participants of 1-5 years of age and 73 (25.3%) participants of 11–15 years of age.
- **Distribution of participants according to gender (n=289):** Almost equal distribution between females 148 (51.2%) and males 141 (48.8%) among the 289 participants.
- **The most common types of reported MDAEs in the study population (n = 41);** Among the 41 reported medical device–associated adverse events (MDAEs), swelling was the most common, observed in 29 cases (70.7%). Phlebitis was reported in 10 cases (24.4%), while occlusion was the least frequent adverse event, occurring in 2 cases (4.9%) as shown in Figure 1.

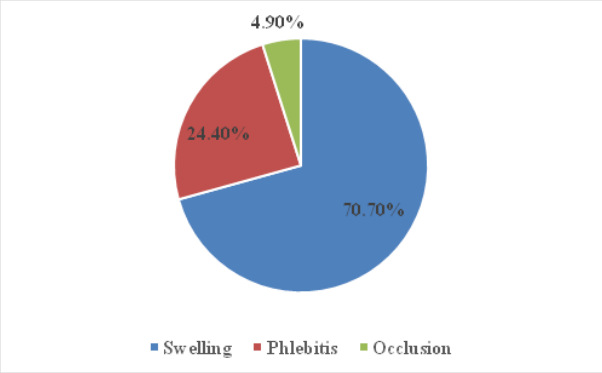


Figure 1: The most common types of reported MDAEs in the study population (n = 41)

- **Severity of MDAEs:** All reported MDAEs were moderate (Level 3) in severity as per modified Hartwig and Siegel scale.
- **Seriousness of MDAEs:** All reported MDAEs were non-serious as per CDSCO criteria.
- **Preventibility of MDAEs:** All reported MDAEs were non-preventable as per Schumock and Thornton scale.
- **Causality assessment of MDAEs:** All reported MDAEs were having 'possible' causality as per MvPI guidelines.

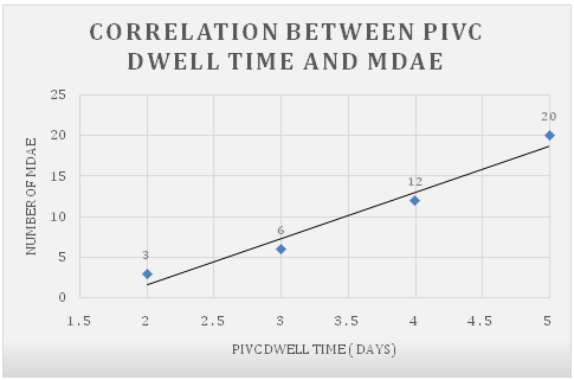


Figure 2: Correlation between PIVC dwell time (days) and occurance of MDAEs

A strong positive correlation was observed between PIVC dwell time (days) and cumulative MDAEs ($r = 0.98$, $p = 0.019$), indicating that longer cannula time is associated with increased adverse events.

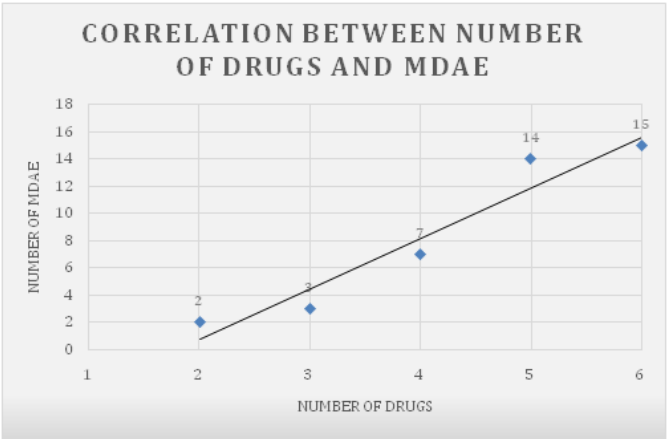


Figure 3: Correlation between number of drugs administered and MDAEs

A strong positive correlation was found between the number of drugs administered and the number of MDAEs observed ($r = 0.97$, $p = 0.008$), suggesting that multiple drug administrations are associated with a higher occurrence of adverse events.

Table 1: Association between fixation method and occurrence of MDAEs

Fixation method	MDAEs present	MDAEs absent	Total	χ^2 (p- value)
Adhesive tape	12	123	135	5.84 (0.015) *
Microporous tape	29	125	154	
Total	41	248	289	

*A statistically significant association was observed between fixation method and occurrence of MDAEs ($\chi^2 = 5.84$, $p = 0.015$), with a higher proportion of adverse events reported among cannulas fixed with microporous tape compared to adhesive tape.

Discussion

Peripheral intravenous (IV) cannulation is a fundamental component of inpatient care and plays a particularly critical role in the management of paediatric patients. However, the use of peripheral intravenous cannulas (PIVCs) is frequently associated with medical device–associated adverse events (MDAEs), which can negatively impact patient comfort and the overall quality of care. The present study evaluated the occurrence and characteristics of MDAEs related to PIVC use among hospitalized paediatric patients in a tertiary care teaching hospital.

The age distribution observed in this study demonstrated that the majority of participants belonged to the 6–10-year age group, followed by children aged 1–5 years, and subsequently those aged 11–15 years. All paediatric age groups contribute substantially to hospital admissions, commonly due to conditions such as infections, dehydration, and other clinical indications necessitating IV therapy [6].

In terms of gender distribution, the study included an approximately equal proportion of male and female participants, with a slight predominance of females. Comparable findings have been reported in studies conducted in other settings, including Ethiopia, where gender distribution was nearly equal, although a marginal male predominance was noted [7,8]. Importantly, these findings suggest that gender does not significantly influence the risk of complications associated with PIVC use, and thus, it is unlikely to be an independent risk factor for adverse medical device–associated events (MDAEs) in paediatric populations.

The most frequently observed complication in the present study was swelling, followed by phlebitis, while occlusion was the least common. Swelling is most often attributable to infiltration or extravasation of fluids, which may occur due to catheter dislodgement or mechanical injury to the venous wall. Such events are particularly common in children owing to increased limb movement and the relative fragility of peripheral veins [8].

However, variations in the pattern of complications have been reported in the literature. For instance, Kumar et al. identified phlebitis as the most common complication, followed by occlusion, with similar findings reported by Foster et al. [9,10]. These discrepancies may be explained by differences in patient demographics, clinical practices related to cannulation, PIVC dwell time, and monitoring protocols across different study settings.

All adverse events reported in the present study were classified as moderate in severity (Level 3), non-serious, non-preventable, and demonstrated a possible causal relationship with PIVC use. These findings are consistent with existing evidence in the field of materiovigilance, which indicates that most PIVC-related adverse events are mild to moderate in severity and rarely result in serious clinical outcomes [11].

Furthermore, regulatory risk classifications reported in prior studies indicate that the majority of PIVC-related adverse events fall within Class B (low to moderate risk), with a substantial proportion categorized as Class C (moderate to high risk) [12]. Although these events are generally not immediately life-threatening, delayed recognition and management may lead to significant clinical consequences. The findings of the present study align with these observations, as most adverse events were of moderate severity, non-serious in nature, and non-preventable. The results of this study are also in concordance with findings from a surveillance programme conducted at a medical device monitoring centre in Central India, where the majority of reported MDAEs were classified as non-serious, with causality assessments predominantly falling under the “possible” or “probable” categories [13]. These findings underscore the importance of strengthening materiovigilance systems and promoting routine reporting and monitoring of device-related adverse events to enhance patient safety. A strong positive correlation was observed between prolonged cannula dwell time and the occurrence of adverse events in this study. Extended indwelling duration is known to increase the risk of mechanical irritation, endothelial injury, and microbial colonization, thereby predisposing patients to complications such as swelling and phlebitis. These findings are supported by existing literature in paediatric settings, which have consistently identified prolonged dwell time as a significant risk factor for PIVC failure and related complications [14].

Overall, the findings of the present study indicate that PIVC-related adverse events are less common

among hospitalized paediatric patients and are largely influenced by modifiable factors such as cannula dwell time and fixation method used. Strengthening compliance with evidence-based PIVC management guidelines and integrating routine materiovigilance reporting into clinical practice may significantly reduce the incidence of these adverse events and improve patient safety outcomes.

The present study contributes valuable evidence to the relatively under-reported area of materiovigilance by systematically evaluating medical device–associated adverse events related to peripheral intravenous cannula use among paediatric in-patients in a tertiary care teaching hospital. By identifying modifiable risk factors such as cannula dwell time, number of drugs administered, and fixation method, the study provides clinically relevant insights that may help improve routine cannula management practices and reduce the occurrence of PIVC-related adverse events. In addition, the documentation and reporting of adverse events within the framework of the Materiovigilance Programme of India (MvPI) enhance the applicability of the findings for strengthening national medical device safety surveillance systems. However, certain limitations should be considered while interpreting the results. The study was conducted only in paediatric in-patient wards, while patients admitted to emergency wards and intensive care units were excluded; therefore, the overall burden of PIVC-related adverse events may have been underestimated. Furthermore, the possibility of observer bias cannot be completely ruled out, as identification of some adverse events depended on clinical examination and documentation at the time of ward visits.

Conclusion

The current research indicates that adverse events due to peripheral intravenous cannula devices are relatively less common within an inpatient population. Two of the most common complications associated with peripheral intravenous cannula use are swelling and phlebitis. The majority of the adverse events reported in this study were classified as moderate in severity, non-serious, non-preventable. In addition, prolonged dwell time of the cannula, increased number of drug administrations, and the manner in which the peripheral intravenous cannula device was secured were found to be significant modifiable risk factors associated with adverse events in the study. The results of this study emphasise the need for regular assessment of peripheral intravenous cannula and using appropriate fixation method. Strengthening routine reporting under the Materiovigilance Programme of India, may assist in reducing peripheral intravenous cannula-related adverse events and improving patient safety in a tertiary care settings.

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