

RESEARCH

EVENTOS ADVERSOS ASOCIADOS AL USO DEL CATÉTER VENOSO PERIFÉRICO: UN ESTUDIO PROSPECTIVO

ADVERSE EVENTS ASSOCIATED WITH THE USE OF THE PERIPHERAL VENOUS CATHETER: A PROSPECTIVE STUDY

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ABSTRACT

INTRODUCTION. The peripheral venous catheter is an invasive device widely used to enable infusional therapy in the hospital environment. Thus, patients with infusion therapy are more exposed to factors that trigger the occurrence of adverse events. **OBJECTIVE.** To estimate the incidence of local adverse events and identify risk factors associated with peripheral venous catheter management. **MATERIAL AND METHOD.** Prospective longitudinal study performed in the surgical hospitalization unit of a university hospital in the city of Rio de Janeiro, Brazil. It was observed the use of 114 catheters inserted in 58 patients. The research was conducted between March 2019 and February 2020. The data analysis was performed by descriptive and inferential statistics. **RESULTS.** The incidence of adverse events was 61,4%. Phlebitis and obstruction were the most frequent, both with 26,3%. The risk factors that presented a significant association were infiltration with administration of cefazolin (41,7%, p-value=0,029) and phlebitis with the act of touching the puncture site after antisepsis (47,8%, p-value=0,009). **CONCLUSION.** The nursing professionals' care practice in the management of peripheral venous catheter is associated with the occurrence of adverse events.

Keywords: Nursing, Peripheral venous catheter. patient safety. potential adverse event in health care.

RESUMEN

INTRODUCCIÓN. El catéter venoso periférico es un dispositivo invasivo ampliamente utilizado para permitir la terapia de infusión en el entorno hospitalario. Así, los pacientes con terapia de infusión están más expuestos a factores que desencadenan la ocurrencia de eventos adversos. **OBJETIVO.** Estimar la incidencia de eventos adversos locales e identificar los factores de riesgo asociados con el manejo del catéter venoso periférico. **MATERIAL Y MÉTODO.** Estudio longitudinal prospectivo realizado en la unidad de hospitalización quirúrgica de un hospital universitario en la ciudad de Río de Janeiro, Brasil. Se observó el uso de 114 catéteres insertados en 58 pacientes. La investigación se llevó a cabo entre marzo de 2019 y febrero de 2020. El análisis de los datos se realizó mediante estadística descriptiva e inferencial. **RESULTADOS.** La incidencia de eventos adversos fue del 61,4%. La flebitis y la obstrucción fueron las más frecuentes, ambas con un 26,3%. Los factores de riesgo que presentaron una asociación significativa fueron la infiltración con administración de cefazolina (41,7%, valor p = 0,029) y la flebitis con el acto de tocar el sitio de punción después de la antisepsia (47,8%, valor p = 0,009). **CONCLUSIÓN.** La práctica asistencial de los profesionales de enfermería en el manejo del catéter venoso periférico está asociada con la ocurrencia de eventos adversos.

Palabras clave: Enfermería, catéter venoso periférico. seguridad del paciente. evento adverso potencial en la atención médica

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INTRODUCTION

The peripheral venous catheter (PVC) is an invasive device widely used to enable infusional therapy in the hospital environment, which makes possible the administration of fluids, medications and collection of blood components⁽¹⁾. Studies show that approximately 70% of hospitalized patients require a PVC, characterizing high prevalence in the use of this device. Therefore, patients with infusion therapy are more exposed to factors that trigger the occurrence of local and systemic adverse events (AE)^(1,2).

Due to its widespread use, 30% to 50% of all inserted catheters are prone to incidents when the best practices in scientific evidence are not met, resulting in early removal or replacement of the device, often associated with local AEs. It is estimated that the incidence rates of these local events are on average 52,3%⁽²⁻⁵⁾.

Some forms of harm can be accompanied in this care context, such as the painful and unforgettable experience of the patient affected by an AE, which may cause a sense of frustration and guilt in the health team. Similarly, there is an increase in financial costs, either for the recovery of damage, compensation funds to the patient/family members, or for the need to perform a new procedure and/or correction interventions to maintain therapy⁽⁵⁾.

Nursing is the main responsible for managing PVC in the hospital environment, especially in actions aimed at intervening in the modifiable factors of this practice, contributing to the prevention and mitigation of AEs and approaching this practice to the recommendations validated by evidence⁽¹⁾. The technological advance and the development of new researches in the area of infusional therapy (IT) make that the care practice needs to be continuously reviewed and discussed. This requires readjustment to the new needs and evidence found, in addition to promoting the development of studies and discoveries of new technologies that facilitate the care exercised by the nursing team when meeting the patient's clinical needs and contributing to the safety and quality of therapy⁽⁶⁾.

It is expected that this study will contribute to the adequacy of work processes in health and specifically in nursing for mitigation of AE care. Thus, it is intended to direct the actions of health managers and professionals in decision-making and implementation of best practices in accordance with national and international guidelines⁽⁷⁾.

The research question for this study was: What is the incidence and what are the risk factors associated with local adverse events in peripheral venous catheters? The proposed objectives were: to estimate the incidence of local adverse events and identify risk factors associated with peripheral venous catheter management.

METHODOLOGY

This is a quantitative, observational, longitudinal, prospective, analytical study. It is presented in line with the guidelines recommended by the initiative Strengthening the Reporting of Observational Studies in Epidemiology (STROBE). The scenario was a surgical hospitalization unit of a federal university hospital located in the city of Rio de Janeiro, Brazil, between March 2019 and February 2020.

The population was defined by all patients with indication for infusional therapy through PVC. For the calculation of the sample, a retrospective profile of the use of PVC in the last three months of the hospital sector was considered, totaling approximately 150 catheters.

The estimated sample was 108 catheters, selected randomly (sampling error: 5%, confidence level: 95%). The inclusion criteria addressed: adult patients over 18 years, indication of PVC insertion for IT and minimum hospitalization forecast of 72 hours. Patients with central venous catheters for peripheral insertion (PICC), patients with PVC inserted in the lower limbs and patients who did not remain hospitalized 48 hours after removal of the PVC were not included. It was observed 114 PVC prospectively, from their insertion until 48 hours after the removal of them. Data were collected from March to October 2019. Among the nursing staff responsible for managing the PVC, 31 participated in this study, distributed among technicians and nursing assistants and nurses.

The data collection included three phases applied concomitantly, which are: non-participant observation, characterization and profile of professionals and documentary search. The observation included four structured forms for monitoring variables related to the technique of insertion, maintenance and removal of PVC, as well as compliance with good practices recommended in the Guideline of the Infusion Nurses Society (INS)⁷ together with the identification and traceability of potential local AEs.

The independent (predictive) variables analyzed were: care required in the insertion, maintenance

and removal of PVC, as well as variables related to the characterization of professionals and clinical and sociodemographic characterization of patients. The outcome (dependent) variables analyzed were restricted to the presence of local AEs (obstruction, phlebitis, infiltration, hematoma, extravasation, accidental traction, and local infection). The concepts, instruments, and scale of the INS 2021⁽⁷⁾ were used to support, evaluate, and describe these AEs.

Systematic observation occurred from the moment of insertion of the PVC to 48 hours after its withdrawal, being divided into three stages: insertion, maintenance and removal of the PVC. During the maintenance phase, the observation was made at two different times: at 6am and at 6pm. The periods that concentrate a greater amount of drugs administered were chosen as observation times, due to the greater propensity for the occurrence of AE⁽⁸⁾.

For characterization and profile of professionals was applied questionnaire with the following variables: function, shift work, training time, training in maintenance of PVC. The collection was carried out in a closed environment and individually, according to the participants' prior scheduling during their work shifts. For the extraction of documentary data, the search of clinical and sociodemographic records was carried out from the patient's medical records and prescriptions. Patients who did not have legible records in the medical records or incomplete information or unfilled data were excluded from the sample.

The data were organized in Excel spreadsheet (Microsoft Excel 2007[®]) in database format. They were subsequently submitted to the program Statistical Package for Social Science (SPSS)[®] version 22.0.

For the characterization of patients and nursing professionals, descriptive analysis of data was applied through measures of absolute and relative frequency, central tendency (mean, median) and dispersion (standard deviation, coefficient of variation – CV).

For inferential analysis of quantitative variables, the normality hypothesis of the distribution was verified by the Kolmogorov-Smirnov (KS) and Shapiro-Wilk tests. The association between the occurrence of AE with qualitative variables was measured by univariate analysis through the chi-square test (χ^2) and the Fisher's Exact Test.

The measure expressed for risk was the odds ratio (OR), and also the prevalence ratio (PR) was calculated. For comparison of the distributions of the

quantitative or ordinal variables, the normality tests presented p-value less than 5%, rejecting the normality hypothesis, allowing the comparison of two independent groups by the nonparametric test of Mann-Whitney. The results were considered statistically significant by accepting p-value < 0,05 and 95% confidence interval.

The study met Resolution 466/2012 and was approved by the Ethics Committee, under opinion n. 3.106.677.

RESULTS

During the management of PVC, 31 nursing professionals were observed, 26 (83,9%) being female and 05 (16,1%) male. Of these professionals, 17 (54,8%) work as nursing technicians. Considering the age group, 13 (41,2%) are between 49 and 63 years old, and the average age was 47 years. Of the professionals, 21 (67,7%) have six to 24 years of training, with an average of 21 years. Regarding the time spent in the sector, 24 (77,5%) have up to 12 years of experience, with an average of 8.1 years. Regarding the training in PVC management, 10 (32,3%) were trained, and 21 (67,7%) had no on-duty training. The time elapsed since the completion of the training is, on average, 3.8 years.

Catheters were inserted in predominantly female patients totaling 81 (71,1%); 100 (87,7%) patients were in the age group between 37 and 82 years, 54 (47,4%) were elderly (over 60 years). In summary, the patients' average age was 55.4 years and median 57.5 years, standard deviation of 16.3 years. At least 49 (43,0%) patients present comorbidity, the most incidents being: infection in 52 (45,6%) patients; systemic arterial hypertension (SAH) in 40 (35,1%); and diabetes mellitus (DM) in 23 (20,2%).

The results showed that 114 catheters were inserted in 58 patients, due to some patients having more than one catheter inserted. The most frequent drug classes were analgesics in 73 (64,0%) patients, crystalloids in 61 (53,5%), and antimicrobials in 38 (33,3%). It was found that the average of drugs administered was 3,2 drugs per patient, with a minimum of four prescription drugs in 25,4% of cases. Table 1 shows the frequency of the characteristics observed in the PVC and the management of nursing professionals at the stage of insertion of the PVC.

Regarding the puncture attempt, the data show great assertiveness in the practice of inserting PVC, since 101 (88,6%) catheters were inserted in the first at-

Table 1. Frequencies of characteristics related to PVC insertion and management of nursing professionals in the PVC insertion stage. Rio de Janeiro, RJ, Brazil, 2020.

Characteristic	N	%
Catheter insertion site		
Back of the hand	51	44,7%
Outer surface of the forearm	12	10,5%
Inner surface of the forearm	50	43,9%
Cervical	1	0,9%
Catheter caliber		
18 G*	6	5,3%
20 G	49	43,0%
22 G	53	46,5%
24 G	6	5,3%
Therapy Type		
Continuous	69	60,5%
Intermittent	45	39,5%
Number of puncture attempts		
1	101	88,6%
2	12	10,5%
3	1	0,9%
Used procedure glove	114	100,0%
Used mask	33	28,9%
Used a cap	43	37,7%
Used protective glasses	0	0,0%
Performed adequate hand hygiene before insertion	107	93,8%
Performed adequate hand hygiene after insertion	108	94,7%
Performed antiseptics of the insertion site	114	100,0%
Wait for the antiseptic solution to dry naturally before puncturing	57	50,0%
Used a catheter for each puncture attempt	114	100,0%
Did not touch the puncture site after performing antiseptics	91	79,8%
Identified the PVC puncture site	114	100,0%
Solution used for antiseptics of the insertion site		
Alcohol 70%	56	49,1%
Chlorhexidine gluconate 0.5% to 2%	58	50,9%

G*: gauge. Source: The authors, 2020.

tempt, which demonstrates a mastery of the technique by the professionals responsible for insertion.

The cumulative incidence of AE was 61,4%⁽⁷⁰⁾. The new cases were higher in the mean period of 15,4 to 70.6 hours after catheter insertion, and 56 out of 70 AEs occurred during this period. Table 2 shows the cumulative incidences, global and by type of local AE.

Table 2 shows that phlebitis and catheter obstruction are the most prevalent AEs. The results show that the occurrence of new cases of phlebitis was higher in the average period from 15.4 to 70,6 hours after insertion of the catheter. Among these cases, 22 (73,3%) occurred immediately after the insertion of the catheter. The incidence of obstruction was higher in the average period from 27,4 to 55,9 hours, corresponding to 17 (56,7%) of the devices. Infiltrations were outstanding in the average period of 3,9 to 27,4 hours, equivalent to 12 (63,2%) devices. The catheters that were removed by accidental traction were between 3.9 and 27.4 hours, these three (60,0%). The hematomas occurred in the mean period of 15,4 to 42,6 hours after insertion of the catheter, which was the case for two (1,8%).

Table 2. Cumulative global incidences and by type of local adverse event. Rio de Janeiro, RJ, Brazil, 2020.

Adverse Event	N	Cumulative Incidence
Global (presented at least one of the adverse events)	70	61,4%
Obstruction	30	26,3%
Phlebitis	30	26,3%
Infiltration	19	16,7%
Accidental Catheter Pull	5	4,4%
Hematoma	2	1,8%
Local Infection	0	0,0%
Extravasation	0	0,0%

Source: The authors, 2020.

The incidence of global occurrence of AE in catheters is associated with the patient's sex. In 69,1% of the women (p-value=0,008 of the chi-square test), at least one AE occurred. OR was 3,0 (CI = 1,0-7,0), which suggests that the chance of AE occurring in females is 3,0 times higher than in males. In terms of prevalence ratio, it can be said that the prevalence of AE in catheters of patients from the female group is

1,7 times, or 70% higher when compared to the male group.

During the insertion of the catheter, it was evidenced that the act of touching the site of the puncture after antisepsis is associated with the occurrence of phlebitis. Among the 23 insertions touched at the PVC insertion site after antisepsis, 11 (47,8%) (p-value = 0,009 of chi-square test) presented phlebitis. It is estimated that the chance (OR=3,5 / CI = 1,3-9,1) of a catheter inserted by a professional who touched the site of the puncture to present phlebitis was 3,5 times higher than those that were not touched. The act of touching the site of the puncture after antisepsis is a significant risk factor for the occurrence of phlebitis.

No significant association was found between the other failures occurred by professionals in the practice of PVC insertion and the other adverse events. The cumulative global incidence of AE and the isolated incidences of obstruction, phlebitis and infiltra-

tion were not significantly associated with the catheter size (p-values greater than 5% of the test χ^2).

The overall incidence of AE, phlebitis, infiltration, accidental traction and hematomas was higher in catheters inserted on the outer face of the forearm. The obstruction was more frequent in catheters inserted on the back of the hand. The significance of the difference between incidences cannot be investigated by statistical analysis tests due to the small sample size of subgroups. Table 3 shows the global and isolated incidence of adverse events according to the location of catheter insertion.

Table 4 presents the results of the association analysis of variables observed in the maintenance of PVC and the occurrence of local Ea. The overall mean survival time of PVC until the occurrence of AE, estimated by the Kaplan Meier method, was 64,1 hours. Figure 1 shows the survival curve behavior by the Kaplan Meier method until occurrence of adverse events.

Table 3. Incidence of adverse events according to catheter insertion site. Rio de Janeiro, RJ/Brazil, 2020.

Catheter insertion site	Incidence of adverse event			
	Global	Phlebitis	Obstruction	Infiltration
Back of the hand	58,8%	17,6%	35,3%	13,7%
Outer surface of the forearm	75,0%	41,7%	8,3%	25,0%
Inner surface of the forearm	62,0%	32,0%	22,0%	18,0%
Right external jugular	0,0%	0,0%	0,0%	0,0%

Source: The authors, 2020.

DISCUSSION

Kaplan Meier method until occurrence of adverse events. The professionals who predominantly manage the PVC perform the nursing technician function, corresponding to most of the professionals participating in this study. A preliminary study states that this result is expected since the middle-level professionals represent greater quantity in the composition of the nursing team⁽⁹⁾.

Regarding the patients' gender, the literature evidences that there is a relationship between the occurrence of AE and female sex, corroborating with the data from this study, which demonstrated greater chance for the development of phlebitis in women. However, there is still no causality explained, requiring further studies^(2,10,11).

Among the professionals who handled catheters, there was a predominance of those who did not undergo training, a distance from updates and scientific evidence in the area. This is a condition that potentially contributes to the occurrence of failures and AE, being considered as an important risk factor^(2,5,6,10).

One of the important pillars to ensure safety and quality care is tangenciated by professional updates and training. Training is considered a differential factor and essential in patient care, its absence directly affects the professional's lack of knowledge and adequate technical performance^(4,6).

The planning of nursing care should consider the changes resulting from the senescence and senility process. Studies indicate that this population has factors that increase the chances of AE, due to

Table 4. Association of the incidence of AE with the variables observed in the maintenance of PVCs by nursing professionals. Rio de Janeiro, RJ, Brazil, 2020.

Observed variable	AE	Incidence of AE when the event did not occur	Incidence of AE when the event occurred	p-value of chi-square test	OR*	OR CI (95%)
Aspirated before each infusion	Phlebitis	33,3%	6,7%	0,004	7,00	(1,6 - 31,5)
	Global	52,2%	100,0%	<0,001	nc	Nc
Forced flushing in case of resistance	Infiltration	10,0%	45,0%	<0,001	7,4	(2,4 - 22,5)
	Obstruction	17,8%	65,0%	<0,001	8,6	(3,0 - 24,9)
Protects the insertion site and connections during bathing	Global	69,3%	34,6%	0,001	4,3	(1,7 - 10,8)
	Obstruction	31,8%	7,7%	0,014	5,6	(1,2 - 25,4)
Used mask for maintenance	Phlebitis	31,9%	0,0%	0,003	nc	Nc
Used positive pressure technique to minimize blood return to the catheter lumen	Phlebitis	41,7%	14,5%	0,002	4,2	(1,6 - 10,8)
	Global	97,2%	44,9%	<0,001	43,0	(5,6 - 333,0)
Valued the patient's complaints regarding any sign of discomfort	Phlebitis	52,8%	14,1%	0,000	6,8	(2,7 - 17,0)
	Infiltration	33,3%	9,0%	0,001	5,1	(1,8 - 14,4)
	Obstruction	38,9%	20,5%	0,038	2,4	(1,1 - 5,9)

* Calculated ratio of highest chance to lowest chance. nc – not calculable.

physiological characteristics inherent to age, such as: greater capillary fragility and a higher number of comorbidities that alter the vascular network. These characteristics directly influence and impact the likelihood of causing damage, being considered a risk factor for AE^(7,12,13).

There was a predominance of chronic diseases such as SAH and DM, very frequent in the elderly, which age group is predominant in this research, being in line with the current population epidemiological profile, with an expressive increase in non-communicable chronic diseases. Diseases such as diabetes were identified in a meta-analysis as an important risk factor for phlebitis by generating potential endothelial lesions and contribute to peripheral neuropathy, a chronic complication of diabetes that compromises pain perception, impairing the early detection of local alterations^(2,11).

Developing PVC insertion skills is considered an important factor for reducing the occurrence of catheter failure and for mitigating the occurrence of AE. Professionals with more years of experience in this type of procedure have their chances of assertiveness increased in a first attempt, confirming the importance of competence and technical skill for such a procedure^(2, 4,10).

The main Guidelines recommend that initial catheterization should be done in the veins located in the distal areas of the upper limbs, in the distal – proximal direction, endorsed by the data found in this study, since the accesses were mostly inserted into veins on the back of the hand^(7,12). As for the location of insertion of the catheter, the dorsal region of the hand and the inner face of the forearm were the predominant locations. The metacarpal and cephalic veins were more used because they had better visibility

and caliber, increasing the chances of success in the first attempt when technological resources for visualization were not used^(13,14).

Evidence demonstrates the association of the insertion site, for example the most frequently chosen metacarpal veins, with the occurrence of AE, suggesting a failure in the planning of the infusion therapy process. It is assumed that the predominant factors in the choice of vessel are ease of access and greater chances of assertiveness, rather than pharmacological characteristics compatible with the location of insertion of the catheter^(13,14).

Regarding the device size, there was a predominance of medial sizes commonly prevalent in other studies. The choice of appropriate catheter size directly interferes with the success of the puncture, survival of the device and prevention of AE^(2,3,13,14).

There was a strong association between touching the puncture site after antisepsis and absence of training in PVC. The lack of updating in care related to PVC management was a risk factor for the occurrence of AE. Adherence to good practices by nursing professionals is higher in professionals who are up-to-date, being considered a protective and mitigating factor of care failures⁽¹⁵⁾.

The factors that contribute to catheter failures are strongly associated with the frequency at which the device is used to administer drugs. There is also a relationship with infusional therapies with polydrugs and the insertion site of the catheter catheter^(1,2).

Recent evidence has shown that the size of the catheter can have an impact on device survival rates. In adults, larger diameter catheters showed an increased rate of thrombosis, and smaller diameter catheters showed higher rates of displacement and occlusion/infiltration. The recommended catheter size for adults based on the latest evidence for most clinical applications was 20G^(1,13).

In the present study, a global incidence of 61,4% of AE was found. It is observed that catheter obstruction and phlebitis are the most incident AEs in this study. The Infusion Nurses Society⁽⁷⁾ recommends a phlebitis rate of less than 5%. However, the data showed a rate of incidence of phlebitis converging with the results of other studies with rates ranging from 20,1% to 43,2%^(3,5,11,13,14).

Research shows the importance of performing flushing to maintain catheter permeability, thus preven-

ting the occurrence of obstruction of the device and increasing its survival time. Obstruction was identified in this study as the second major cause of AE^(16,17).

Regarding infiltration, compared to the rates found in other studies, it is considered that such variability may be due to the multiplicity of patterns and scales used in the identification of the event^(5,14).

The lack of consensus on the measures used to evaluate the scales of phlebitis and infiltration makes it difficult to make a meaningful and accurate comparison between the rates found in national and international studies^(2,3,13,14). The diversity of scales used as an instrument to evaluate phlebitis in the most diverse health services and research conducted in the area hinders the production of scientific evidence and the advancement in this thematic area, directly impacting on the quality of care, contributing, even, to an underestimated rate of incidence of phlebitis^(5,13).

With regard to the occurrence of AE with catheter residence time, no significant association was identified in this variable. However, the importance of regular evaluation of the permanence of the device and the adoption of catheter replacement only when clinically indicated are highlighted^(3,13).

Recent evidence indicates that residence time has no significant impact on the degrees of phlebitis. Thus, the routine exchange of the catheter does not guarantee the reduction of the occurrence of this event, as well as extending the residence time is not defining for the increase in risk. Inadequate insertion and maintenance practices are decisive, reinforcing the relevance of providing nursing care based on individual clinical needs^(3,18).

Intervening in modifiable risk factors, such as lifelong education and the development of insertion skills, is important to reduce the high failure rate in PVC management. Nevertheless, the implementation of tools such as algorithms, protocols and standardized operating procedures can serve as important allies to enable IT management^(2,4).

The literature points to effective strategies for preventing adverse events related to peripheral catheter handling, such as hand hygiene before and after catheter handling, adequate selection of the puncture site, rigorous antisepsis and use of appropriate solutions, adequate fixation and coverage to maintain the catheter as a safe device, systematic monitoring with assessment for signs of phlebitis, infiltration, extravasation or signs of infection, and early removal or dis-

continuation of use when no longer necessary in order to avoid complications and unpredictable events. These strategies aid in decision making, assessment of management and timely removal of PVC and early identification of catheter-related AE. Furthermore, it contributes to the improvement of care provided, patient safety and reduction of hospital costs^(2,4).

The study's limitation is due to the fact that it was local, constituted by a heterogeneous sample, restricting the generalization of the findings. Nevertheless, the robustness of the method is a strength for this study and allows the continuity of investigations from broader research and longitudinal studies.

CONCLUSIÓN

The AE incidents were phlebitis and obstruction. The risk factors associated with phlebitis were: touch at the site of the puncture after antisepsis at the time of insertion, not aspirating the catheter before administration of the drugs and not performing the positive pressure technique in the catheter washing. The obstruction was associated with catheters inserted in metacarpal veins.

Being a care that demands extensive technical-scientific knowledge supported in the advancement of scientific evidence and proven multifactorial, requires nursing professional not only manual dexterity, but also continuing education. Training and technical capacity were identified in this study as important factors for safe and quality care.

The results of this study are intended to contribute to the nursing team's practice in attending to the patient's clinical needs, as well as contributing to the prevention of AE associated with infusional therapy.

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