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# **ORIGINAL ARTICLE**

# PERIPHERAL CATHETER WITH CLOSED INFUSION SYSTEM: TECHNOLOGY IMPLEMENTATION

CATETER PERIFÉRICO COM SISTEMA FECHADO DE INFUSÃO: IMPLEMENTAÇÃO DE TECNOLOGIA

CATÉTER PERIFÉRICO CON SISTEMA CERRADO DE INFUSIÓN: IMPLEMENTACIÓN DE TECNOLOGÍA Jolline Lind¹, Mitzy Tannia Reichembach Danski², Luana Lenzi³, Edivane Pedrolo⁴, Alessandra Amaral Schwanke⁵, Derdried Athanasio Johann⁴

### **ABSTRACT**

**Objective:** to estimate the incidence of local complications related to the use of a peripheral intravenous catheter with a closed infusion system and to identify the associated risk factors. **Method:** this is a quantitative, prospective cohort study with 90 adults. The collection was performed by daily observation of the catheter. The Chi-Square, Fisher's exact, Williams's Correction, Mann-Whitney and Relative Risk tests were used in the statistical analyzes. Results were presented in the form of tables. **Results:** the incidence of local complications was 55.6%, with 15 (16.7%) phlebitis, 12 (13.3%) traction, ten (11.1%) infiltrations, seven (7, 8%) extravasations, five (5.6%) obstructions and one (1.1%) local infection. The risk factors were female gender (p = 0.005), hospitalization time (p = 0.001) and pump infusion (p = 0.014). **Conclusion:** it is believed that the rate of local complications was high and three risk factors related to the use of the peripheral intravenous catheter with closed infusion system were identified. **Descriptors:** Peripheral Catheterization; Biomedical Technology; Risk factors; Evidence-Based Nursing; Adult; Intravenous Infusions.

#### RESUMO

Objetivo: estimar a incidência de complicações locais relacionadas ao uso do cateter intravenoso periférico com sistema fechado de infusão e identificar os fatores de risco associados. *Método*: trata-se de um estudo quantitativo, de coorte prospectivo, realizado com 90 adultos. Realizou-se a coleta mediante a observação diária do cateter. Utilizaram-se, nas análises estatísticas, os testes Qui-Quadrado, Exato de Fisher, Correção de Williams, Mann-Whitney e Risco Relativo. Apresentaram-se os resultados em forma de tabelas. *Resultados*: informa-se que a incidência de complicações locais foi de 55,6%, sendo 15 (16,7%) flebites, 12 (13,3%) trações, dez (11,1%) infiltrações, sete (7,8%) extravasamentos, cinco (5,6%) obstruções e uma (1,1%) infecção local. Têm-se como fatores de risco o sexo feminino (p=0,005), o tempo de internação (p=<0,001) e a infusão em bomba (p=0,014). *Conclusão*: acredita-se que a taxa de complicações locais foi alta e identificaram-se três fatores de risco relacionados ao uso do cateter intravenoso periférico com sistema fechado de infusão. *Descritores*: Cateterismo Periférico; Tecnologia Biomédica; Fatores de Risco; Enfermagem Baseada em Evidências; Adulto; Infusões Intravenosas.

#### **RESUMEN**

**Objetivo:** estimar la incidencia de complicaciones locales relacionadas al uso del catéter intravenoso periférico con sistema cerrado de infusión e identificar los factores de riesgo asociados. **Método:** se trata de un estudio cuantitativo, de cohorte prospectivo, realizado con 90 adultos. Se realizó la recolección mediante la observación diaria del catéter. Se utilizaron, en los análisis estadísticos, las pruebas Chi-Cuadrado, Exacto de Fisher, Corrección de Williams, Mann-Whitney y Riesgo Relativo. Se presentaron los resultados en forma de tablas. **Resultados:** se informa que la incidencia de complicaciones locales fue 55,6%, de los cuales 15 (16.7%) flebitis, 12 (13,3%) tracciones, diez (11,1%) la infiltración, siete (7 8%) extravasaciones, cinco (5,6%) obstrucciones y una (1,1%) infección local. Se toman como factores de riesgo el sexo femenino (p = 0,005), el tiempo de internación (p = <0,001) y la infusión en bomba (p = 0,014). **Conclusión:** se cree que la tasa de complicaciones locales fue alta y se identificaron tres factores de riesgo relacionados al uso del catéter intravenoso periférico con sistema cerrado de infusión. **Descritores:** Cateterismo Periférico; Tecnología Biomédica; Factores de Riesgo; Enfermería Basada em la Evidencia; Adulto; Infusiones Intravenosas.

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### **INTRODUCTION**

It is known that intravenous therapy (IVT) is an intervention experienced daily in health settings<sup>1</sup> and Nursing inserts and cares for more than two billion catheters / year globally.<sup>2</sup> It is possible to associate this practice, although the IVT brings benefits to the patient, 3 to the development of local complications. such as hematoma, phlebitis, obstruction, infiltration. extravasation, traction and local infection.4 It is reported in Brazil, through studies, incidences of complications above 55%.5-6

It is understood that the occurrence of these complications is a frequent reality of professionals, however, attention should be paid to the identification of risk factors that may potentiate them, and patient-related risk factors include gender, age, skin color; the factors inherent in drug therapy and peripheral venous access include: nature of drugs; catheter type and gauge; place of insertion; type of fixation; length of stay, among others.<sup>2,5-7</sup>

In order to implement IVT, intravascular catheters are used, including a peripheral intravenous catheter, with a closed infusion system, a technology that is not very widespread in Brazil. This device is indicated medium-duration treatments, characterized by being of the type needle", as it has two access routes, a siliconized needle, a septum to remove blood from the needle after the activation of the safety device; confection in radiopaque biomaterial vialon®; stabilization platform; high pressure transparent extension set and two connectors for closed infusion system.8 It should be noted that the complications and risk factors described in the literature currently refer to the traditional peripheral catheter and not to the device with closed infusion system object of this research. It is believed, therefore, that such knowledge facilitates the professional practice, as well as ensure the quality of care through the use of technologies little applied in the Brazilian reality.

# **OBJECTIVE**

• To estimate the incidence of local complications related to the use of the peripheral intravenous catheter with closed infusion system and to identify the associated risk factors.

# **METHOD**

It is a prospective cohort study conducted in medical clinic units of a large university hospital in the southern region of the country. An estimated sample of 90 patients was obtained, guaranteeing a power of 0.80 (1 -  $\beta$  = 0.80) to detect a minimum difference of 20% between the occurrence or not of complications at the significance level of 0.05 ( $\alpha$  = 0.05). Thus, the amount of patients required, according to the sample calculation, was obtained with the collection of data from September 22, 2015 to April 9, 2016.

The study participants were patients older than 18 years of age, male and female, who underwent venipuncture with the intravenous infusion catheter with closed infusion system (calibers 20, 22 and 18 Gauges, commonly used in the units surveyed and in adults). The was selected for convenience. sample consecutively, composed of patients who met the eligibility criteria. They were listed as inclusion criteria: being 18 years of age or older; prediction of hospitalization and need for IVT greater than 96 hours (for daily monitoring of the catheter). Exclusion criteria were: insertion of catheter into external jugular vein or caliber different from those specified. The evaluation of a single catheter with a closed infusion system per patient not with other catheters concomitant highlighted.

Meetings held between were the researchers, prior to data collection, in order to standardize concepts and collection instruments, with a duration of approximately 20 hours, by the researchers responsible. Nursing teams were trained in the units in which the research was carried out to use the device in order to meet the specifications of use and achieve the recommended benefits, such as minimization of adverse effects. increase the residence time of peripheral venous accesses and the reduction accidents with biological and sharp material between the professionals who handle these devices.

The training was conducted in September 2015, in three shifts, conducted by the researchers through meetings of about one hour each. It is added that the training totaled ten meetings, with 33 employees, and took place through an expository-dialogic class, directed to the peripheral catheters in general and specifically to the closed infusion system, in which standardized concepts were approached according to international guidelines, <sup>4</sup> visualization of illustrative video and puncture workshop.

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The data was collected daily, in the evening, in pairs, by the researchers, from the reading of the medical records and direct observation of the device, using an own instrument elaborated and based literature, with international closed questions which addressed sociodemographic, clinical and catheter-related data (insertion, manipulation, maintenance and withdrawal). The participants were followed from the time of insertion of the catheter until the catheter withdrawn. Puncture, manipulation, maintenance and withdrawal of the devices were carried out by the Nursing teams of the units previously trained to do so.

The primary outcome was the occurrence of local complications (extravasation, infiltration, phlebitis, obstruction, accidental catheter traction and local infection), assessed according to international guidelines.<sup>4</sup>

Infiltration and extravasation were classified according to the type of drug / solution administered, infiltration of infusion of non-vesicant drugs into surrounding tissue and extravasation to infiltration of vesicant and/or irritant solution into extravascular space.<sup>4</sup>

Phlebitis was assessed using the Phlebitis Classification scale every six hours. The obstruction was related to the slowness of the infusion, as well as to the infusion, the presence of a blood clot or other obstructing factor.<sup>4</sup>

Unintentional removal of the catheter was considered accidental removal of the catheter

in the intima of the vein, making it impossible to administer drugs and/or solutions. Finally, the evaluation of local infection was evaluated in the presence of different degrees of phlebitis plus the presence of purulent exudate at the insertion ostium of the catheter.<sup>4</sup>

The data was entered in spreadsheets of the program Microsoft Excel®, analyzing them with the aid of the program Bioestat, ® version 5.3. In the analysis of factors that may interfere in the response variable, Chi-Square, Fisher's Exact and Williams Correction tests used for categorical explanatory variables and the Mann-Whitney test for the quantitative explanatory variables. relative risk (RR) calculation was applied to measure the degree of association, and the category considered as a reference is indicated in the results tables with the value 1.0 in the column for RR values.

Ethical precepts were complied with according to the opinion of the Research Ethics Committee number 1,204,990 and Coparticipant Institution number 1,239,228. The precepts of Resolution 466/2012, which regulate research with human beings in Brazil, were respected.

## **RESULTS**

A total of 91 participants were excluded, one per outlier in the analysis (caliber of the 24 Gauges catheter). The final sample was composed by 90 participants and the predominance was female and mean age close to 50 years of age (Table 1).

Table 1. Characterization of the sample according to sociodemographic and clinical profiles. Curitiba (PR), Brazil, 2015-2016.

and clinical profiles. Curitiba (PR), Brazil, 2015-2016.				
Variable	n=90	%		
Sex				
Female	55	61.1		
Male	35	38.9		
Ethnicity				
Caucasoid	71	78.9		
Negroid	18	20		
Asian	1	1.1		
Main diagnosis				
Circulatory system	10	11.1		
Digestive system	21	23.3		
Genitourinary system	15	16.7		
Respiratory system	13	14.4		
Skin and Subcutaneous	3	3.3		
Tissue Diseases				
Diseases of blood and	6	6.7		
haematopoietic organs				
Diseases of the	3	3.3		
nervous system				
System diseases	1	1.1		
Osteomuscular and	1	1.1		
connective tissue				
diseases				
Endocrine, nutritional	4	4.5		
and metabolic				
diseases				
Pregnancy, childbirth	1	1.1		

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and the puerperium		
Congenital	1	1.1
malformations and		
chromosomal		
abnormalities		
Neoplasias	12	13.4
Amount of		
comorbidities		
None	22	24.4
One to three	53	58.9
More than three	15	16.7
Degree of nutrition		
Low weight	9	10
Eutrophic	39	43.3
Obesity	14	15.6
Overweight	24	26.7
Not evaluated	4	4.4
Smoking		
Yes	7	7.8
Ex-smoker	26	28.9
No	57	63.3
Drinking		
Yes	3	3.3
Ex-drinker	12	13.3
No	75	83.3
Surgical procedure		
Yes	10	11.1
No	80	88.9
Concomitant infection		
Yes	40	44.4
No	50	55.6
Outcome of		
Hospitalization		
Discharge/Transfer	79	87.8
from the unit		
Remained hospitalized	1	1.1
at the end of		
collection		
Death	10	11.1

It is revealed that there was a predominance of punctures with 20-gauge catheters in the left upper limb; assertiveness

in the first puncture attempt; mean residence time of 82.6 ( $\pm$  82.02) hours (minimum of three and maximum of 528 hours) (Table 2).

Table 2. Variables related to the peripheral intravenous device. Curitiba (PR), Brazil, 2015-2016.

Variable	n=90	%
Caliber		
18	22	24.4
20	51	56.7
22	17	18.9
Location		
Upper Left Limb	51	56.7
Upper Right Limb	39	43.3
Region		
Forearm	60	66.7
Back of the hand	22	24.4
Arm	6	6.7
Antecubital mole	2	2.2
Number of attempts		
1	67	74.4
2	17	18.9
3	2	2.2
5	1	1.1
Not informed	3	3.3

It is detailed, in relation to the primary endpoint, the complication rate was 55.6% (n = 50); as to the incidence of complications, the most frequent was phlebitis (16.7%; n=15) followed by traction (13.3%; n=12), infiltration (11.1%; n=10), extravasation (7.8%; n=7),

obstruction (5.6%; n=5) and local infection (1.1%; n=1).

As for the analysis of the risk factors associated with complications, for the sociodemographic variables, it was shown that female patients significantly increased the risk for the development of complications

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and, among the clinical variables, the risk of complications was significantly length of hospital stay; with regard to catheter variables, the infusion method of infusion

drugs and solutions significantly increased the risk of developing complications, as evidenced in Table 3.

Table 3. Risk factors associated with the development of complications. Curitiba (PR), Brazil, 2016.

Variable	Complication		p-value	RR*	CI(95%)**
	Yes	No			
	n=50	n=40			
	(%)	(%)			
Sex					
Male	13 (26)	22 (55)	$0.005^{\dagger}$	1	
Female	37 (74)	18 (45)		1.81	[1.13; 2.89]
Length of					
hospitalization (days)					
1 to 10	15 (30)	30 (75)	<0.001 <sup>‡</sup>	1	
11 to 21	16 (32)	6 (15)		2.18	[1.34; 3.55]
22 to 32	16 (32)	3 (7.5)		2.53	[1.60; 3.99]
33 to 39	0	0			
40 to 50	3 (6)	0 (0)		3.00	[1.98; 4.53]
More than 50	0 (0)	1 (2.5)			
Use of pump infuser	9 (18)	1 (2.5)	0.014 <sup>‡</sup>	1.76	[1.30; 2.36]

\*RR relative risk; \*\* CI 95% confidence interval; † Chi-square; ‡ Williams' correction

## **DISCUSSION**

It should be emphasized that the discussion was based on the profile, complications and risk factors related to traditional peripheral catheters due to the scarcity of studies regarding the catheter with closed infusion system. is corroborated by the sociodemographic and clinical results presented in this study, a national cohort that also aimed to estimate the incidence of local complications associated with peripheral catheterization.<sup>5</sup> It was added that the majority of the patients presented associated comorbidities, non-alcoholic and non-smoking, data pointed out worldwide in studies with the same object of study: peripheral catheters. 10-1

It is pointed out, in relation to the characteristics of the catheters, by studies carried out with a population also hospitalized medical clinical units, predominance of punctures with catheters of 20 gauge catheters, 5-6,12 in the upper left limbo, 6,12-3 in the forearm region, 3,6,10 as well as the findings of this research; however, the mean length of stay of the peripheral catheter was lower than that reported in an international multicenter study (99 hours).<sup>13</sup> The recommendation for non-replacement of the intravascular device based on length of stay is considered, since an ideal replacement time has not yet been established, 4 but, as a result of some complication or absence of use for more than 24 hours.

The high incidence of local complications found in this study was described in other national prospective observational studies ranging from 55% to 78%. 5-6,14 The incidence of phlebitis higher than the 5% considered as standard by the international recommendations 4 and, when considering the phlebitis rate of this study, international studies present a similar percentage, with 15.4% 15 and 17.6% 16 of the catheters removed; for traction, the second most frequent complication, international studies describe lower values, ranging from 7.8% 17 to 10.2%, 18 in which the same closed infusion system technology was evaluated.

In terms of infiltration, there was similarity when compared to studies with 12.5% <sup>17</sup> and 13%, <sup>14</sup> but when compared to national studies, the values were lower (23.08% <sup>5</sup> to 35.5 % <sup>10</sup>). It is inferred that the extravasation rate was lower than the findings of two international studies, which were around 10% 14,19 and higher, when compared to a prospective national observational study with clinical and surgical patients (1.9%).5 In a multicenter study conducted in three Australian hospitals with adults, the rate of obstruction was higher than that described in this study, with 20.9% of the cases, but with no occurrence of local infection (0.0%).<sup>13</sup>

National studies on TIV complications indicated higher rates of obstruction, varying from 11 to 15%, <sup>5-6</sup> of which local infection of 3.8% in a national prospective cohort was superior to the findings of this study.<sup>5</sup> The development of complications related to the catheter with closed infusion system is highlighted, as well as in recurrent use catheters in the units surveyed. It is important to analyze the risk factors associated with this specific catheter in order to avoid or minimize

the complications arising from the use, as well as to standardize protocols and guidelines to be applied in professional practice.

It is, therefore, the analysis of the risk factors for the occurrence of a primordial complication to avoid its development. In the female, the risk for the development of complications was 1.94 times higher, 20 and observational studies report a higher risk of 1.4,<sup>21</sup> 1.7<sup>16</sup> in the development of phlebitis and obstruction (RR = 1.44, p <0.001) <sup>3</sup> when compared to male patients, as well as in the findings of this study. It is believed that among the female aspects that explain the greatest occurrence of phlebitis are the anatomies of peripheral vessels whose veins have smaller calibers and more difficult visibility, as well as increased hormonal circulation, which predisposes the tunica intima to inflammatory events.<sup>22</sup>

is noted that the longer hospitalization time, the greater the chances of complication of the inserted catheter, which demonstrates similarity to a national randomized clinical trial that identified higher risks to hospitalized patients between 10-19 days (RR = 1.36) and 20-29 days (RR = 1.61).<sup>23</sup> In another study, we report a significant relationship with hospitalization longer than 18 days and the occurrence of phlebitis (p = 0.002).<sup>12</sup> It is also reported by other authors that this variable was significantly associated with the development of phlebitis (p = 0.003).<sup>24</sup> It is reiterated that this period is related to the clinical picture and its comorbidities, contributing to the severity of the patient and, consequently, to the possible increase of complications in the therapy.

Differently from the results presented in this study, an exploratory study performed in a medical clinic showed that the method of infusion of drugs and solutions (gravitational, infusion pump, or bolus) it is not a significant risk factor for the occurrence of phlebitis (p= 0.269). In studies with the objective of identifying risk factors related to IVT, the use of the infusion pump as a risk factor for complications (OR = 4.6, p = 0.023), and phlebitis was more frequent in patients who used the infusion pump (p = 0.021), corroborating the findings of this research.

It was verified the occurrence of complications related to the use of the infusion pump statistically, but the inability to determine the risk factor inherent to its use was a limitation of the research. The applicability of the research is facilitated in order to facilitate the choice of the professional by the most appropriate device for intravenous therapy, as well as the

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disclosure of the risk factors inherent in the practice of catheterization, which will underpin the quality of the care provided, as well as encouraging the elaboration of institutional protocols and guidelines. Despite the fact that it is not the object of the research, the high rate of assertiveness of catheter puncture, the good progress of the professionals' training, and the safety and easy handling of the catheter as indicated by the manufacturer.

## CONCLUSION

It was evidenced a high incidence of complications related to the use of the peripheral intravenous catheter with closed infusion system, among which phlebitis was the most frequent. It was observed that the risk factors for the development of local complications were female, the longer time of hospitalization and the infusion pump infusion method.

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