

Complications related to the use of peripheral venous catheters: a randomized clinical trial

Complicações relacionadas ao uso do cateter venoso periférico: ensaio clínico randomizado

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Abstract

Objective: To analyze the complications deriving from the use and type of peripheral venous catheter in adults. **Methods:** Randomized clinical trial; undertaken at a teaching hospital between 2012 and 2015; 169 adults were included who were hospitalized at clinical and surgical services and needed peripheral venipuncture with an expected dwelling time of more than 96 hours. Through systemized randomization, 90 participants were allocated to the trial group (complete safety catheter) and 79 to the control group (short flexible catheter).

Results: The general complications rate was 55.62%, with 18.34% of phlebitis, 11.83% infiltration, 11.24% obstruction and 9.47% traction. No significant difference was found between the groups for the occurrence of complications, phlebitis, obstruction and traction.

Conclusion: The complication rate in peripheral venous catheterization was high but, when compared, without a statistically significant difference, the complete safety catheter showed lower complication rates after the fourth day of survival.

Resumo

Objetivo: Analisar as complicações decorrentes do uso e tipo de cateter venoso periférico em adultos.

Métodos: Ensaio clínico randomizado; realizado em um hospital de ensino, no período de 2012 a 2015; incluiu-se 169 adultos internados em unidades clínicas e cirúrgicas que necessitaram de punção venosa periférica e com permanência prevista de mais de 96 horas. A randomização aleatória sistematizada alocou 90 participantes no Grupo Experimental (cateter de segurança completo) e 79 no Grupo Controle (cateter curto flexível).

Resultados: A taxa geral de complicações foi 55,62%, houve 18,34% de flebite, infiltração 11,83%, obstrução 11,24% e tração 9,47%. Não houve diferença significativa entre os grupos para a ocorrência de complicações, flebite, obstrução e tração.

Conclusão: A taxa de complicações no cateterismo venoso periférico foi alta, mas quando comparados, sem diferença estatística significativa, o cateter de segurança completo teve taxas menores de complicações após o quarto dia de sobrevivência.

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Introduction

Intravenous therapy is widely used in hospital contexts, mainly through the placement of peripheral venous catheters. Most catheters are removed due to the occurrence of complications, the end of the treatment or lack of use.⁽¹⁾ The following local complications are associated with the use of peripheral intravenous catheter: hematoma, thrombosis, phlebitis, thrombophlebitis, infiltration, extravasation, local infection and venous spasm.⁽²⁾ More than 70% of inpatients need a peripheral venous catheter. In the United States (USA), about 200 million catheters are used each year.⁽³⁾ In Spain, about 50% of the inpatients receive an intravenous catheter, 95% of which are peripheral.⁽⁴⁾ Other studies appoint usage rates of peripheral venous catheters in 86.4%⁽⁵⁾ and 80.6%⁽⁶⁾ of the patients.

Thus, the nurses and nursing team's technical-scientific knowledge about intravenous therapy guarantee the treatment efficacy and the quality of care delivery, making it fundamental to know the best technologically and evidence-based care practices. That justifies the importance of this research for daily nursing care practice, as it produces knowledge and scientific evidence to support the nursing professionals' decision making on the most appropriate peripheral venous catheter for patients submitted to intravenous therapy. Hence, the objective in this research was to analyze the complications deriving from the use of peripheral venous catheters in adults.

Methods

A randomized, controlled clinical trial was undertaken at clinical and surgical services of a large teaching hospital. The randomization was achieved through systematic random sampling, in which two groups were set up: complete safety catheter (Trial Group) and short flexible catheter (Control Group). The complete safety catheter consists of a silicon needle with biangular and three-faceted bezel connected to the spindle through a metallic guide and knob; made out of polyurethane biomaterial; has a

complete needle protection device; activated after the puncture; wings with grooves; transparent vinyl extension tube; bioselective reflux chamber filter lid; rapid cut clamp; two access routes consisting of a female connector in "Y", being one Luer-Lok[®] connector and another with a removable male plug device. The short flexible catheter is of the over-the-needle type, with an internal safety device (passively activated) and flip, single use and disposable, needs to be coupled to an extensor for the infusion to take place; the extensors used at the research institution included cannulas, simple equipment and intermediary extensors with two or four access routes. The variable local complication of peripheral venous catheterization was the primary outcome and covered the occurrence of phlebitis, thrombophlebitis, extravasation, infiltration, obstruction, accidental catheter traction and local infection, assessed according to international guidelines.⁽²⁾

The participants were adult patients over 18 years of age, hospitalized that inpatient services, who needed peripheral intravenous therapy. The study objects were the peripheral venous catheters installed. The inclusion criteria were: patients who needed peripheral venous access for intravenous therapy; expected length of stay more than 96 hours for clinical and/or surgical treatment; no previous inclusion in the research and use of already randomized catheter. The exclusion criteria were: impossibility of peripheral venipuncture due to capillary weakness, clinical conditions that contraindicated the venipuncture, specified by the responsible physician, as well as local changes that made the venipuncture impossible.

The data were collected between August and November 2014, when the number of participants proposed in the sampling calculation was reached (5% significance and 0.80 test power). Before the collection, the researchers were trained through meetings to standardize the collection and the concepts addressed (approximately 30 hours) and during the execution of the pilot test in pairs. The collection took place daily, in pairs, when material was replaced, the list of inpatients was updated and authorization was requested (free and informed consent form), analysis of inclusions and random-

ization, reading of registers, active search for participants, direct observation of catheter puncture in patients and control for complications.

The nursing teams at the investigated services also participated in training. Thirty-four meetings were held, taking 40 to 60 minutes, involving 109 collaborators, through dialogued lectures (concepts standardized according to an international guideline),⁽²⁾ watching a video and a puncture workshop.

The data were collected through a structured tool that contained sociodemographic, clinical, catheter and outcome variables. The patient was monitored daily from the inclusion in the research until the withdrawal of the catheter.

In the descriptive analysis of the data, absolute and percentage frequencies and central trend and dispersion measures were determined (means and standard deviations). In the univariate analysis, the characteristics of the catheter groups were compared, using chi-squared, Fisher, William's G, Mann-Whitney's U and the binomial test of proportions. In all tests, significance was set at 5%. A survival curve was established for each group, from the puncture date until the appearance of complications, using Kaplan-Meier's product limit estimate. To compare the obtained curves, Mantel-Haenzel's test (log-rank) was used with 5% significance.

The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 30398914.9.0000.0102.

Results

In total, 193 participants were eligible for inclusion in the research, 23 of whom were excluded from the data analysis, one dropped out and 169 participants were included (90 from the trial group and 79 from the control group); only one catheter was assessed per patient; all uninformed registers were excluded from the statistical analyses.

The sample was homogeneous and mostly characterized as Caucasian, approximately 50 years of age, unfinished primary education, retired, non-smokers and non-drinkers, with a family history of systemic arterial hypertension. Men were the

majority in the control group and women in the trial group. Hospitalization at the male medical clinic, clinical diagnosis of digestive diseases, no associated comorbidity, no surgical procedures during the hospitalization, absence of infection and discharge as the outcome were predominant. The length of the hospitalization was longer (in days) in the control group (Table 1).

The predominant catheter caliber in the two groups was number 20; location in upper left limb, forearm region and successful puncture during first attempt. Regarding the use of the devices, in the two groups, the prevalent drugs used were solutions and schedules with serum, sedatives and analgesics and other drugs (which were not part of the classifications considered) (Table 1), but a minority used antimicrobial agents, electrolytes, anticoagulants, vesicant drugs and corticosteroids.

Most catheters were inserted for two days. When referring to the dwelling time in hours, most catheters were inserted for 72 hours or longer (Table 1). The catheter in the experimental group was inserted without complications for an average 3.73 (± 2.25) and a maximum of 10 days, while the catheter in the control group remained for 3.28 (± 1.66) and a maximum of seven days. Among the motives for withdrawal, discharge was predominant, followed by phlebitis. A significant difference was found between the groups for the variables: puncture location ($p=0.0236$) and number of puncture attempts ($p=0.0047$), that is, the proportion of catheters in the trial group punctured in the upper left limb was significantly larger than in the control group when compared to the upper right limb and the proportion of successful puncture upon the first attempt was higher in the two groups.

Complication rates have been described in table 2, considering the two catheter groups, i.e. trial and control. No statistically significant difference was found between both groups regarding complications.

When considering only catheters that developed complications ($n=94$; $n=50$ Trial Group; $n=44$ Control Group), the upper right limb revealed more prone to the development of complications in the trial group and the upper left limb in the

Table 1. Sociodemographic, clinical and catheter group characteristics

| Variable/Catheter | Trial Group n=90 n(%) | Control Group n=79 n(%) | p-value |
|--|-----------------------------|-------------------------------|---------------------|
| Sociodemographic data | | | |
| Gender | | | |
| Female | 48(53.33) | 34(43.04) | 0.2372** |
| Male | 42(46.67) | 45(56.96) | |
| Age | 90(54.5±18.05) | 79(54.53±16.55) | 0.9159 [†] |
| Caucasian ethnic origin | 79(87.78) | 61(77.22) | 0.2138* |
| Unfinished primary education | 43(47.78) | 29(36.71) | 0.0681* |
| Occupation retired | 29(32.22) | 32(40.51) | 0.9375* |
| Clinical data | | | |
| Family history of systemic arterial hypertension | 47(52.22) | 47(59.49) | 0.4271** |
| Smoking not mentioned | 68(75.56) | 49(62.03) | 0.0732** |
| Alcohol consumption not mentioned | 78(86.67) | 64(81.01) | 0.3656* |
| Male Medical Clinic | 24(26.67) | 25(31.65) | 0.5221* |
| Length of Hospitalization | 86(11.53±8.40) | 76(13.14±8.82) | 0.1861 [†] |
| Diagnosis of digestive diseases | 29(32.22) | 24(30.38) | 0.6538* |
| No associated comorbidity | 62(68.89) | 54(68.35) | 0.8618* |
| No surgical procedure | 73(81.11) | 55(69.62) | 0.1163** |
| Absence of preexisting infection | 65(72.22) | 48(60.76) | 0.2320** |
| Discharge / Transfer from Service | 85(94.44) | 74(93.67) | 0.7899* |
| Catheter data | | | |
| 20 Gauge Caliber | 66(73.33) | 47(59.49) | 0.2397** |
| Location upper left limb | 62(68.89) | 40(50.63) | 0.0236** |
| Forearm region | 59(65.56) | 48(60.76) | 0.7233* |
| Successful puncture upon first attempt | 76(84.44) | 51(64.56) | 0.0427* |
| Solutions and serum schedules | 51(56.67) | 42(53.16) | 0.7629** |
| Sedatives and analgesics | 60(66.67) | 51(64.56) | 0.8998** |
| Other drugs | 75(83.33) | 65(82.28) | 0.9817** |
| Dwelling time ≥ 72 hours | 54(60.00) | 47(59.49) | 0.9281** |

*Williams' G test; **Chi-Squared Test; [†] Mann-Whitney's U test

control group (p=0.0234). Successful first puncture attempts were statistically significant (p=0.0289) in both groups.

Regarding the catheters that developed phlebitis, the caliber 20 gauge (G) was predominant, puncture in the upper left limb, in the forearm region, use of other drugs and dwelling time 72 hours or longer, as well as non-infusion of electrolytes, anticoagulants, vesicant drugs and corticosteroids. In the trial group, the use of analgesics and sedatives, solutions and serum schedules stood out, as well as the non-administration of antimicrobial agents.

In the control group, the infusion of solutions and schedules and the non-administration of analgesics and sedatives stood out. No statistically significant differences were found between the research variables and the occurrence of phlebitis.

Phlebitis was present in different grades, predominantly grade I, followed by grade II. Only the trial group presented grade III. Grade IV phlebitis was not developed in any of the groups analyzed.

In the comparison between the catheter groups that developed infiltration, in the two groups, the most used caliber was 22G, punc-

Table 2. Distribution of complications in the groups

| Variable/Catheter | Total n=169 n(%) | Trial Group n=90 n(%) | Control Group n=79 n(%) | p-value |
|-------------------|------------------------|-----------------------------|-------------------------------|----------|
| Complication | 94(55.62) | 50(55.56) | 44(55.70) | 0.4927* |
| Phlebitis | 31(18.34) | 19(21.11) | 12(15.19) | 0.6147** |
| Infiltration | 20(11.83) | 11(12.22) | 9(11.39) | |
| Obstruction | 19(11.24) | 8(8.89) | 11(13.92) | |
| Traction | 16(9.47) | 8(8.89) | 8(10.13) | |

*Binomial test between two proportions; **Williams' G test

tured in the forearm region, with infusion of electrolytes, anticoagulants and vesicant drugs in a minority of cases, and administration of other drugs. In the trial group, the most punctured site was the upper left limb, with a predominance of no use of antimicrobial drugs, infusion of analgesics and sedatives and solutions and serum schedules, dwelling time 72 hours or more. Infiltration was significant ($p=0.0379$) for punctures in the upper left limb in the trial group and in the upper right limb in the control group.

Among the catheters that developed obstruction, the following stood out in the two groups: caliber 22G; inserted in the forearm region; absence of infusion of: antimicrobials, sedatives and analgesics, electrolytes, anticoagulants, vesicant drugs and corticosteroids; use of solutions and serum schedules and other drugs. In the trial group, puncture in the upper right limb and dwelling time shorter than 72 hours were predominant. In the control group, the upper left limb and dwelling time 72 hours or longer stood out. No significant difference was found between the variables analyzed for obstruction.

The comparison between the catheter variables and the complication traction for both groups was similar. The caliber 20G was predominant, as well as insertion in the upper left limb, in the forearm region, use of catheter for infusion of sedatives and analgesics, solutions and serum schedules and other drugs, minimal use for infusion of electrolytes, vesicant drugs, anticoagulants and corticosteroids, dwelling time less than 72 hours. No statistically significant differences were found between the variables.

The survival was estimated for all complications, as well as for the four most frequent complications in this research: phlebitis, infiltration, obstruction and traction. No significant difference was found between the curves. Nevertheless, for the development of complications ($p=0.0650$), survival was longer in the trial group after the fourth day of the catheter dwelling time. When comparing the groups concerning the occurrence of phlebitis, the survival function in the trial group was only shorter on the third dwelling day of the catheter ($p=0.2900$). Sur-

vival was similar for infiltration up to the second day. After the third, it was longer in the trial group when compared to the control group ($p=0.1650$). For the occurrence of obstruction, survival in the experimental group was shorter between the second and fifth day of the dwelling time ($p=0.9510$). Traction obtained longer survival for the trial group as from the second day ($p=0.3950$) (Figure 1).

Discussion

Regarding the results, the population was homogeneous, predominantly Caucasian, age range 50 years, similarity between the sexes, absence of reported smoking and drinking, history of systemic arterial hypertension and absence of comorbidities, in line with different studies that assessed the peripheral venous catheters.^(4,7-13)

Concerning the catheter characteristics, studies appoint that caliber 20G is the most used,⁽¹⁰⁻¹⁴⁾ location in upper left limb^(3,10) and forearm region,^(1,8,9,13) successful puncture upon the first attempt,^(1,4) and dwelling time superior to 72 hours,^(8-10,13,15) similar to the present findings. The use of antimicrobials in this research differed from studies that appoint frequent use.^(1,3,4,14,15)

Similar complication rates in peripheral venous catheterization are found in 52%⁽⁷⁾ and 51.1%⁽⁴⁾ of the catheters. Data appoint a larger proportion of complications in peripheral venous catheters in women ($p=0.0300$), patients aged 85 years or older, when compared to participants younger than 65 years of age ($p=0.0500$), puncture in the forearm region when compared to other puncture regions ($p\leq 0.0001$) and other regions punctured. when compared to the hands or wrist ($p=0.0300$)⁽⁹⁾ In that region, however, no significant relations were found for any of the variables analyzed. As regards the dwelling time, the literature does not recommend programmed catheter change, but when clinically indicated, as this is safe, makes the patient more comfortable and reduces costs for the institution.⁽¹⁶⁻¹⁸⁾

When considering the phlebitis rate, similarity was found when compared to other studies,

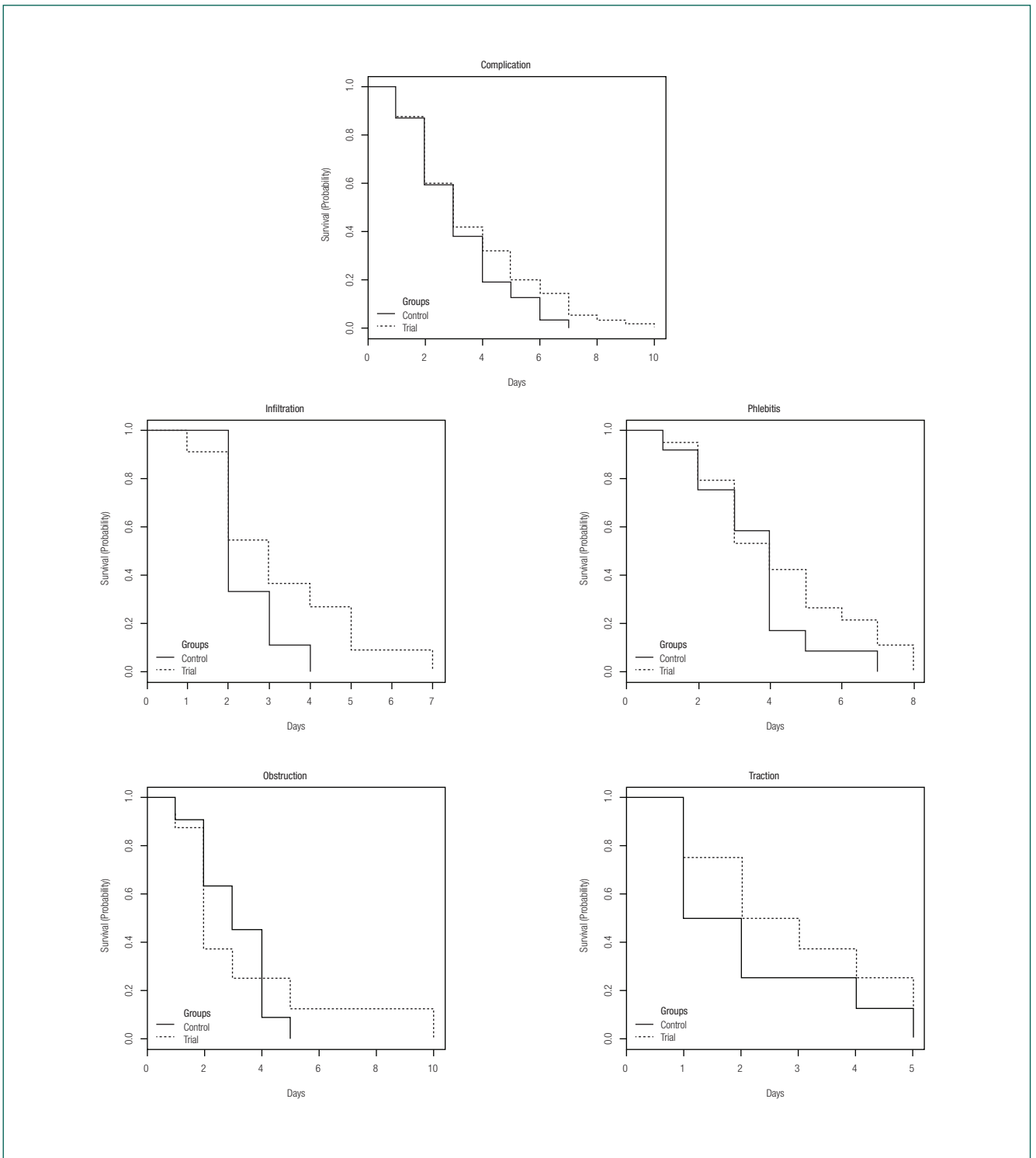


Figure 1. Survival functions per catheter group in complications

with 17.58%⁽¹⁹⁾ (n=148); 15.4%⁽¹³⁾ and 16.9%⁽⁴⁾ (n=101). In this research, no significant associations were found between phlebitis and catheter-related variables. Independent analyses appoint significant relations for the development

of phlebitis, including: lower limb puncture (p=0.015) and use of antimicrobials (p=0.009);⁽¹²⁾ puncture site in cubital fossa was vulnerable to more severe phlebitis when compared to the forearm (p<0.05);⁽²⁰⁾ regions of flexion or great mo-

bility contribute to traumatic phlebitis;⁽¹²⁾ closed infusion systems reduce phlebitis rates by 29% ($p=0.004$);⁽⁴⁾ age (between 60-100 years), smoking ($p=0,030$), hospitalization at clinical, geriatrics and cardiology wards, emergency admission, use of intravenous antimicrobial drugs, catheter inserted in the back of the hand, calibers 22 and 24 gauge and other catheter materials different from polyurethane;⁽¹³⁾ diabetes ($p=0.003$), 18 gauge caliber ($p=0.031$), punctured in antecubital fossa region ($p=0.001$), dwelling time longer than 49 hours ($p=0.0000$), continuous infusion ($p=0.039$), use of antimicrobials ($p=0.002$);⁽²¹⁾ hospitalization time longer than 18 days ($p=0.002$) and dwelling time longer than 72 hours ($p<0.001$).⁽¹⁰⁾ A study that related the catheter dwelling time with phlebitis identified its development in 28% of the catheters between fourth and fifth day of the dwelling time ($p=0.03$).⁽²²⁾ In line with the research findings, a study appointed grade I phlebitis as the most frequent in 94.4% of the catheters and grade III was the most severe.⁽¹³⁾ Other studies appoint that grade I predominates in 77.66%,⁽²²⁾ 46.2%⁽¹⁰⁾ and 41.6%,⁽⁸⁾ followed by 22% grade II,⁽²²⁾ 40%,⁽¹⁰⁾ and 37.5%.⁽⁸⁾ Grade III, only found in the trial group, was appointed with 12%,⁽²²⁾ 16.7%,⁽⁸⁾ 19.3%,⁽²³⁾ 18.3%,⁽¹⁰⁾ 9.9%⁽¹⁵⁾ and 7.2%.⁽¹²⁾ As opposed to the present data, in which no grade IV phlebitis was developed, these cases did occur in studies, with rates of 4.2%,⁽⁸⁾ 2.2%⁽¹²⁾ and 22.8%.⁽²³⁾ When relating the dwelling time with the grades of phlebitis, the results appoint grade I and II phlebitis for catheters inserted for up to 72 hours and grade III and IV after 72 hours of dwelling time, with a statistically significant difference ($p=0.006$), as well as a significant relation ($p=0.0130$) for grade I in the back of the hands and grades II, III and IV in the forearm region.⁽²³⁾

The rates of infiltration were similar to the literature, measured at 12.5%⁽²⁴⁾ and 13%.⁽¹²⁾ In this research, no significant difference was found between the variables analyzed for obstruction, but a study involving surgical patients appointed that the 22 gauge caliber, used in 8.1% of the participants, presented more cases of obstruction, with a prov-

en statistical difference ($p=0.0004$).⁽²⁵⁾ Equivalent rates resulted in 10%⁽⁹⁾ ($n=11$ out of 110 catheters) and in 11.7%⁽¹²⁾ for obstruction or function loss. For traction, similar to the present findings, studies measure rates of 10.2%,⁽⁴⁾ 7.8%,⁽²⁴⁾ and between 6 and 9%.⁽¹⁴⁾

The absence of information records on venipuncture from the patient histories was a limiting factor in this research. Thus, at the end of the pilot test, besides reading the nursing notes, an active search for this information was undertaken through daily assessment at the nursing stations of the investigated services, as well as direct questions to the professionals, with a view to solving cases of bias in the completion of the data collection form, reaching the necessary precision to conduct the research. In a study undertaken in Australia, involving 327 patients, 190 (86.4%) of whom received peripheral venous catheterization, lack of daily care records on the venipunctures and their use was found, highlighting the importance of training the professionals and promoting the best clinical practices.⁽⁵⁾

These research results are applicable as they can help the professionals to choose the best or most appropriate peripheral venous catheter technology for the therapeutics prescribed to the patient in the care process. The findings can permeate public policies, clinical guidelines, protocols and standard procedures in patient care with a view to reduce the occurrence of complications.

Conclusion

The complication rate in peripheral venous catheterization was high but, when compared, the complete safety catheter obtained lower complication, obstruction and traction rates, without a statistically significant difference after the fourth day of survival.

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Collaborations

Danski MTR contributed to the conception of the project, execution of the research, relevant critical review of the intellectual content and final approval of the version for publication. Johann DA cooperated with the conception of the project, execution of the research, analysis and interpretation of the data, writing of the article and final approval of the version for publication. Vayego SA cooperated with the analysis and interpretation of the data and relevant critical review of the intellectual content. Oliveira GLR contributed to the conception of the project, execution of the research and final approval of the version for publication. Lind J participated in the execution of the research, writing of the article and final approval of the version for publication.

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