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Risk factors and incidence of peripheral venous catheters-related phlebitis between 2017 and 2021: A multicentre study (Flebitis Zero Project)

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José Antonio Cernuda Martínez[1], María Belén Suárez Mier[2], María del Carmen Martínez Ortega[3], Raquel Casas Rodríguez[4], Carmelo Villafranca Renes[5] and Camino Del Río Pisabarro[6]

Abstract

Background: The peripheral venous catheter is one of the most frequently used devices in inpatient units worldwide. The risk of complications arising from use of peripheral venous catheters is low, but phlebitis frequently develops.

Methods: A multicentre, prospective cohort study was conducted in 65 Spanish hospitals on 10,247 inpatients who had had a total of 38,430 peripheral venous catheters inserted. Data were collected for 15 consecutive days in 2017, 2018, 2019, 2020 and 2021. Central tendency and dispersion were measured, cumulative incidence and incidence density were determined and odds ratios (OR) were also calculated using binary logistic regression.

Results: The incidence density of phlebitis, during the period from 2017 to 2021, was 1.82 cases of phlebitis per 100 venous catheter-days. The difference between average cumulative incidence of phlebitis per year was statistically significant as determined by ANOVA test results ($F = 10.51$; df = 4; $p < 0.000$). Unequivocal risk factors for phlebitis were revealed to be hospitals with more than 500 beds (OR = 1.507; $p < 0.001$), patients suffering from neoplastic disease (OR = 1.234; $p < 0.001$) and the first 3–4 days after insertion (OR = 1.159; $p < 0.001$).

Conclusions: A correct knowledge of insertion technique and venous catheter maintenance is likely to reduce the incidence of phlebitis and other complications, and hence continuing education of nurses is essential.

Keywords

Peripheral venous catheters, nursing, phlebitis, devices, epidemiology

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Introduction

The peripheral venous catheter (PVC) is one of the most frequently used devices in hospitalisation units around the world, especially in people requiring intravenous delivery of drugs, blood and blood derivatives or other fluids.[1] Overall, 30%–70% of hospitalised patients have had at least one PVC inserted during their hospital stay.[2] The risk of complications arising from the use of a PVC is low, but the occurrence of phlebitis, obstructions and infections related to these catheters is frequent.[3,4] Phlebitis, defined as inflammation of the tunica intima of the vein, can lead to discomfort, damage or involvement of neighboring veins, as well as missed drug doses resulting in increased length

[1]Faculty of Nursing of Gijón, University of Oviedo, Gijón, Asturias, Spain
[2]Health Observatory, Ministry of Health of the Principality of Asturias, Oviedo, Asturias, Spain
[3]Public Health Service, Central University Hospital of Asturias, Oviedo, Asturias, Spain
[4]Quality and Patient Safety Unit, Cabueñes Hospital, Gijón, Asturias, Spain
[5]University Hospital of Burgos, Burgos, Spain
[6]OSI Donostialdea, Donostia, Euskadi, Spain

Corresponding author:
José Antonio Cernuda Martínez, Faculty of Nursing of Gijón, University of Oviedo, Camino de los Prados, 395, Gijón, Asturias 33003, Spain.
Email: jacernudam@gmail.com

of hospital stays and additional treatment costs.[5] In addition, phlebitis is often associated with inflammation, pain, erythema and thrombosis of the affected vein(s), which will codetermine the severity of the clinical situation.[6]

A reduced incidence of phlebitis should be considered a basic indicator of quality of care. According to the standards set by the Infusion Nursing Society (INS),[7] the prevalence of phlebitis considered acceptable should not exceed 5%, although some centres in the UK consider a prevalence of phlebitis of less than 10% as tolerable.[8] Worldwide, however, the average prevalence of phlebitis, based on the different studies published, varies between 1.25% and 61.5%.[9]

The main risk factors for the development of phlebitis have not been fully clarified. Although studies have been conducted to attempt to determine the most frequent causes of phlebitis,[10] the results have been inconclusive due to limitations such as a small sample size, errors in the recording of procedures or lack of homogeneity in the definition or staging of phlebitis. Nevertheless, variables such as catheter caliber, insertion site or age of the individual have been associated with a higher incidence of phlebitis.

Phlebitis is the third most frequent cause of complications in hospitalised patients in Spain, and its prevalence in Spanish hospitals is between 23% and 54.5% in patients with a PVC.[11]

The need for regular training in catheter insertion and maintenance has been confirmed by trials such as PREBACP,[12] which reduced the levels of vascular access-related complications through a multimodal strategy, achieving a 9.39% decrease in failures in the intervention group after 12 months of monitoring.

Differences in risk factors associated with phlebitis have been reported in numerous publications,[11,13–15] revealing the lack of harmonised quality standards; recently, a European consensus[16] has been published that attempts to standardise the indications for and selection of peripherally inserted venous access devices, which can be taken as a benchmark when evaluating the management of these devices.

Considering the variability in the data and the publication between 2009 and 2012 of relevant information that resulted in a paradigm shift in healthcare practice,[17–20] in 2014, the Flebitis Zero Project was initiated.[21] This is a multicentre project throughout Spain that aims to promote a culture of safety and good clinical practice in inpatient units.

The goal of this study was to estimate the rate and incidence of PVC-related phlebitis in Spain in the period 2017–2021, as well as to determine the main clinical-epidemiological and insertion procedure-related risk factors for its development.

Methods

Study design, population and setting

A multicentre, prospective cohort study was conducted in 65 Spanish hospitals on 10,247 inpatients who had had a total of 38,430 PVCs inserted during their hospital stay. Data were collected for 15 consecutive days in February 2017, 2018, 2019 and 2020 and for 15 consecutive days in May 2021. Inclusion criteria were: (i) age 18 years or older, (ii) at some point during the hospital stay, intravenous drug therapy was administered through the PVC and (iii) consent to participate in the study. Exclusion criteria were: (i) patients who had PVCs inserted in the emergency, pediatric or resuscitation departments, (ii) patients who had the PVCs inserted in hospital units other than the unit where they were being treated at the time of the study and (iii) patients who had the PVCs inserted before the study start date.

The nurses responsible for the referral of each patient for the PVC study informed the patient or their legal representative about the study and obtained their oral consent to participate in the study.

Study variables and data collection

The primary study variable was the presence or absence of phlebitis in the vein in which the PVC was inserted. The Jackson visual infusion phlebitis (VIP) scale, based in turn on the Maddox scale,[22] was used to determine the presence of phlebitis. This scale consists of 6° of phlebitis assessment: 0 (no pain, erythema, swelling or palpable venous cord); 1 (pain without erythema, swelling or palpable venous cord at the puncture site); 2 (pain with erythema and/or swelling without palpable venous cord at the puncture site); 3 (pain, erythema, swelling, hardening or palpable venous cord of less than 6 cm above the insertion site); 4 (pain, erythema, swelling, hardening or palpable venous cord 6 cm or more above the insertion site); 5 (frank venous thrombosis with all the signs from the previous stages plus difficulty or arrest of perfusion). On this scale, a grade of 2 or higher is considered phlebitis, and in these cases the PVC should be removed immediately.

Clinical-epidemiological and socio-demographic variables of the patient and the hospital were collected: sex, age, age category (less than 50, 50–64, 65–79 and 80 years or more), presence or absence of diabetes mellitus, presence or absence of arterial hypertension, presence or absence of neoplastic disease, presence or absence of obesity, hospital beds (less than 200 beds; 200–500 beds and more than 500 beds) and dwell time (less than 3, 3–4, 5–6 and 7 days or more). This information is shown in Table 1.

Data analysis

The sample was analysed using measures of central tendency (mean) and dispersion (standard deviation) for quantitative variables, and absolute and relative frequencies (%) for categorical variables. The cumulative incidence was

Table 1. Cumulative incidence of phlebitis according to the clinical-epidemiological characteristics of the patients with the PVCs inserted and the characteristics of the hospital.

	Phlebitis											
	Year 2017		Year 2018		Year 2019		Year 2020		Year 2021		Global (2017–2021)	
	n (PVC)	% phlebitis	*n* (PVC)	% phlebitis	*n* (PVC)	% phlebitis	*n* (PVC)	% phlebitis	*n* (PVC)	% phlebitis	*n* (PVC)	% phlebitis
Age category (years)												
Less than 50	648	10.49	670	11.64	973	6.89	1195	9.04	1002	7.19	4488	8.76
From 50 to 64	1023	13.59	1133	10.33	1470	10.27	1659	12.24	1515	12.08	6800	11.66
From 65 to 79	1761	13.91	1971	11.16	2549	9.10	2959	11.73	2740	11.53	11,980	11.35
80 or more	215	10.47	2963	10.36	3352	8.80	3497	11.01	3200	10.78	15,162	10.27
Gender												
Woman	2566	11.26	3376	10.72	4232	8.96	4787	11.26	4273	11.89	19,234	10.80
Man	3016	12.86	3361	10.71	4112	8.90	4523	11.14	4184	9.75	19,196	10.55
Diabetes mellitus												
Yes	4208	12.17	5057	10.92	6303	8.88	6952	11.05	6336	11.14	28,856	10.74
No	1374	12.01	1680	10.12	2041	9.06	2358	11.66	2121	9.90	9574	10.50
Arterial hypertension												
No	3152	12.09	3691	10.59	4497	8.87	5168	11.30	4259	10.57	20,767	10.62
Yes	2430	12.18	3046	10.87	3847	8.99	4142	11.08	4198	11.10	17,663	10.75
Neoplastic disease												
No	4915	11.98	5937	10.59	7317	8.39	7957	10.97	7348	10.57	33.474	10.40
Yes	667	13.19	800	11.63	1027	12.76	1353	12.56	1109	12.53	4956	12.53
Obesity												
No	4968	12.18	5942	10.70	7342	8.91	8173	10.91	7345	11.01	33,770	10.65
Yes	614	11.73	795	10.82	1002	9.08	1137	13.28	1112	9.62	4660	10.88
Hospital beds												
Less than 200 beds			1093	7.41	1660	6.39	1672	8.79	2228	10.37	6653	8.49
From 200 to 500 beds			2668	10.08	3378	7.61	3682	8.94	3160	8.86	12,888	8.81
More than 500 beds			2934	12.61	3306	11.55	3956	14.33	3069	13.20	13,265	13.00
Dwell time (days)												
Less than 3	2972	12.31	3532	10.79	4564	8.92	5049	11.03	4639	10.13	20,756	10.51
3–4	871	12.74	1066	11.91	1267	9.63	1468	12.33	1331	13.30	6003	11.96
5–6	1228	13.11	1525	11.08	1877	9.06	2027	11.69	1819	11.21	8476	11.10
7 or more	510	7.65	613	7.34	635	7.24	762	8.92	658	9.88	3178	8.28

calculated by determining the ratio between the number of phlebitis cases and the number of PVCs inserted (both per year and over the entire period), and the incidence density for the period 2017–2021 was obtained by finding the ratio between the number of phlebitis cases and the sum of days of dwell time of all PVCs surveyed, multiplied by 100. The difference in the average cumulative incidence ratio of phlebitis per year was calculated using ANOVA, and Bonferroni post hoc contrasts were applied.

Univariate analysis was performed by binary logistic regression, taking as dependent variable the existence or absence of phlebitis and, as independent variables, the clinical-epidemiological characteristics of the patients with a PVC inserted and of the hospital, factors related to the PVC and factors related to the insertion technique. Odds ratios (OR) and their 95% confidence intervals (95% CI) were calculated.

For all tests, results with a *p*-value of less than 0.05 were considered statistically significant.

Statistical analyses were performed with Stata v.15. This study was authorised by the Research Ethics Committee of Asturias, Spain (Authorisation Code 121/14).

Results

The study included a total of 10,247 patients, with a mean age of 70.60 years (SD = 17.33). Of the total, 5103 (49.80%) were women. The mean number of PVCs inserted per patient was 3.75 (SD = 0.84). The mean dwell time of each PVC was 5.84 days (SD = 1.65).

Of the 38,430 PVCs inserted in patients between 2017 and 2021, 31,635 (82.32%) resulted inthe patient scoring a Maddox grade of 0; 2692 PVCs (7.00 %),in a Maddox grade of 1; 3244 PVCs (8.44%),in a Maddox grade of 2; 736 PVCs (1.92%), in a Maddox grade of 3; 98 PVCs (0.26%) resulted in the patient scoring a Maddox grade of 4 and 25 PVCs (0.07%), in a Maddox grade of 5.

During the period from 2017 to 2021, the incidence density of phlebitis was 1.82 cases per 100 days of PVC dwell time. Of the 38,430 PVCs inserted in that period, a total of 4103 caused phlebitis in the patients, which yields a cumulative incidence of 10.68%. In 2017, 677 PVCs out of 5582 caused phlebitis (cumulative incidence of 12.13%); in 2018, 722 PVCs out of 6015 caused phlebitis in the respective patients (cumulative incidence of 10.72%); in 2019, 745 PVCs out of 7599 resulted in phlebitis (cumulative incidence of 8.93%); in 2020, out of a total of 8267 PVCs inserted, 1043 resulted in phlebitis in the patient (cumulative incidence of 11.20%) and, in 2021, 916 out of a total of 7541 PVCs inserted caused phlebitis in the patients (cumulative incidence of 10.83%). The cumulative incidence of phlebitis per year was statistically significant according to the ANOVA test results ($F = 10.51$; df = 4; $p < 0.000$). After applying Bonferroni post hoc contrasts, the following statistically significant relationships were found: year 2019 versus 2017 ($t = -5.99$; $p < 0.000$); year 2019 versus 2018 ($t = -3.54$; $p = 0.004$); year 2019 versus 2020 ($t = 4.89$; $p < 0.000$) and year 2019 versus 2021 ($t = 3.99$; $p < 0.000$).

Table 2. Univariate binary logistic regression for the risk factors for developing phlebitis.

	OR	CI 95%		*p*-Value
		Lower	Upper	
Age category (years)				
Less than 50	Reference			
From 50 to 64	1.376	1.211	1.562	<0.001*
From 65 to 79	1.334	1.186	1.501	<0.001*
80 or more years	1.192	1.062	1.339	0.003*
Gender				
Woman	1.023	0.962	1.095	0.438
Diabetes mellitus				
Yes	0.975	0.905	1.051	0.512
Arterial hypertension				
Yes	1.013	0.950	1.081	0.686
Neoplastic disease				
Yes	1.234	1.126	1.352	<0.001*
Obesity				
Yes	1.024	0.928	1.130	0.632
Hospital beds				
Less than 200 beds	Reference			
From 200 to 500 beds	0.996	0.900	1.103	0.940
More than 500 beds	1.507	1.369	1.660	<0.001*
Dwell time (days)				
Less than 3	Reference			
3–4	1.159	1.075	1.249	<0.000*
5–6	0.973	0.874	1.083	0.619
7 or more	0.768	0.672	0.878	<0.000*

*Statistically significant value ($p < 0.05$).

Table 1 shows the cumulative incidence of phlebitis by year and as a total for the entire period 2017–2021, according to the clinical-epidemiological characteristics of the patients and the characteristics of the hospital. Table 2 shows the results of the univariate binary logistic regression for the risk factors for developing phlebitis.

Discussion

In the present study, the cumulative incidence of phlebitis found, both per year and over the 5 years (10.68%), was lower than the cumulative incidence detected in the multicentre study in seven Spanish hospitals PREBACP[12] (13.43%–16.66%) and exceeded the cumulative incidence reported in the multicentre CATHEVAL study[23] in France, which was 4.1%. However, Simin[9] and Helm[24] found higher cumulative incidence rates of phlebitis (44% and 22.7%, respectively). In Simin's study, the Maddox grade observed in most cases of the phlebitis diagnosed was 3, which corresponds to the findings of the Flebitis Zero Project.

This study found that the highest risk of developing PVC-related phlebitis occurred within 3–4 days after device insertion. This result is consistent with that obtained by

Simin,[9] who concluded that the highest rates of phlebitis occurred between 72- and 96-h post-insertion. Ozger[25] found that most PVC-related complications, including phlebitis, occurred within 4 days of venous catheter insertion. Buetti[26] asserted that replacement of a PVC at 4 days decreased the incidence of complications, including phlebitis, compared to replacement when clinically indicated, with no increase in rates after 96 h. CDC clinical practice guidelines[27] stipulate that routine PVC replacement at 96 h does not decrease phlebitis rates, as PVC failures tend to occur mostly within the first 96 h. This suggests that the first 3 days after catheter insertion are critical, as complications are more likely and require more intensive care. After the first 3 days, the likelihood of complications (phlebitis) decreases, which is consistent with Webster's findings[28] that routine replacement does not outperform clinically indicated replacement in reducing complications, including thrombophlebitis. Probably, the only observable benefit of routine replacement would be in the case of potential extravasation of irritating intravenous fluids (as in the case of patients with malignancy). In these situations, the results appear to indicate that phlebitis is prevented by removing the catheter at grade 1 assessment (pain without erythema, swelling or palpable cord at the puncture site), which would imply that it is beneficial to adopt preventive measures beforehand (the catheter should be removed when there is pain, which almost inevitably leads to redness and palpable cord).

In this study, females were at higher risk than males, although these differences were not statistically significant. Ozger,[25] Alexandrou[29] and Marsh[30] obtained the same results. It has been suggested that hormonal differences may play a prominent role in the development of PVC-related phlebitis.[31]

This study found a statistically significant increase in the rates of phlebitis after the age of 50 years, as did other authors.[9,32,33] This can be explained by two facts: firstly, as people age, changes occur in the skin and subcutaneous tissue, so that PVC insertion tends to induce adverse effects more often.[34] On the other hand, the ageing process leads to a decrease in the immune response (immunosenescence), which increases the risk of developing phlebitis.

Among the underlying diseases that may be predictors of the development of phlebitis, only neoplasia was found to increase the risk of developing PVC-related phlebitis in a statistically significant manner in the present study. Enes[35] and Campbell[36] obtained the same results. The present study found no statistically significant association between diabetes, hypertension or obesity and PVC-related phlebitis. In contrast, Simin[9] and Ozger[25] found a statistically significant relationship between diabetes mellitus and the occurrence of phlebitis.

The increase in the cumulative incidence of phlebitis in the years 2020 and 2021, compared to previous years, as well as the increase in PVC-associated infections, are likely to be related to the changes in healthcare procedures due to the COVID-19 pandemic.[37,38]

This study has some limitations: firstly, the daily recordings of the status of the vein in which the PVC was inserted were not made by the same nurse. Therefore, there may be a slight potential for inter-rater variability in the interpretation of the Maddox grade in the data collection, which would be minimised by the optional training received by some of study's raters to reduce variability. Secondly, variables such as the type and number of intravenous solutions administered through the PVCs, the technique for cannulating a peripheral vein or the material from which the devices were manufactured were not considered, meaning that they were not controlled for in the analysis and may be implicated in the rates of PVC-related phlebitis. Thirdly, the cause of the phlebitis (chemical, mechanical or biological) was not determined once the phlebitis was diagnosed, nor did the patients undergo follow-up checkups once the phlebitis was diagnosed. Lastly, the study did not take into account whether the phlebitis occurred in the first catheter inserted in the patient or in successive catheters.

In view of the results of the present study, the main risk factors for developing PVC-related phlebitis are advanced age, concomitant neoplastic disease and the first 3 days of PVC dwell time. In addition, a review of cases in which the decision was made to remove a catheter without waiting to reach Maddox Grade 2 due to pain in the first 72 h after insertion will surely reduce the rates of phlebitis and other associated complications. Ongoing training of nurses in hospitalisation units, the expected PVC dwell time and early removal of the PVC are key elements in reducing adverse events related to vascular access, thus preserving the patients' vascular patrimony, and ensuring safe care.

Author contributions

José Antonio Cernuda Martínez: Formal analysis and methodology; María Belén Suárez Mier: Conceptualisation, data curation and supervision; María del Carmen Martínez Ortega: Investigation, project administration and methodology; Raquel Casas Rodríguez: Supervision and validation; Carmelo Villafranca Renes: Writing – original draft; Camino del Río Pisabarro: Writing – original draft and supervision; All authors: Writing – review and editing.

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ORCID iD

José Antonio Cernuda Martínez https://orcid.org/0000-0003-2907-4081

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