

RESEARCH PAPER

# Incidence and factors associated with the development of phlebitis: results of a pilot cohort study

Incidencia y factores asociados al desarrollo de flebitis: resultados del estudio piloto de una cohorte

Incidência e fatores associados com o desenvolvimento de flebite: resultados do estudo piloto de uma coorte

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## Abstract

**Theoretical framework:** Intravenous therapy is one of the most common procedures performed in hospitals; phlebitis became the most common complication of this type of treatment.

**Objetives:** Determine the incidence and factors associated with phlebitis secondary to peripheral venous catheterization.

**Methodology:** We performed a pilot prospective cohort study in August 2010 about the frequency of phlebitis in Bucaramanga, Colombia. It included 198 people over 18 years old who were admitted to the emergency room and had a hospital stay between 6-24 hours. Were evaluated variables related to sociodemographic, clinical and some potential risk factors for phlebitis. Were followed until discharge, to monitor the occurrence of phlebitis.

**Results:** The cumulative incidence of phlebitis was 10.1%. Six risk factors were associated with the development of phlebitis secondary to peripheral venous catheterization.

**Conclusions:** Evidence is provided for some of phlebitis risk factors that can be used for identification and early intervention by the nurse.

**Keywords:** phlebitis; incidence; risk factors; patient safety.

## Resumen

**Marco contextual:** La terapia intravenosa es uno de los procedimientos más realizados en los hospitales, mientras que la flebitis es la complicación más común en este tipo de tratamiento.

**Objetivos:** Determinar la incidencia y los factores asociados a la flebitis tras la realización de un cateterismo venoso periférico.

**Metodología:** En agosto de 2010, se realizó un estudio piloto para una cohorte prospectiva sobre la frecuencia de flebitis en Bucaramanga (Colombia). El estudio incluyó a 198 personas mayores de 18 años que ingresaron en el servicio de urgencias y que tenían un periodo de internamiento hospitalario de 6 a 24 horas. Se evaluaron variables sociodemográficas, clínicas y algunos posibles factores de riesgo para la flebitis. Se realizó un seguimiento de los participantes hasta que se les dio el alta hospitalaria, con el objetivo de monitorizar la aparición de flebitis.

**Resultados:** La incidencia acumulada de flebitis fue de 10,1 %. Seis factores de riesgo se asociaron al desarrollo de flebitis tras la realización del cateterismo venoso periférico.

**Conclusión:** Se aportan evidencias para algunos de los factores de riesgo de flebitis que se pueden utilizar para que el enfermero pueda realizar una identificación e intervención temprana.

**Palabras clave:** flebitis; incidencia; factores de riesgo; seguridad del paciente.

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## Resumo

**Enquadramento:** A terapia intravenosa é um dos procedimentos mais realizados na prática hospitalar; sendo a flebite a complicação mais comum neste tipo de tratamento.

**Objetivos:** Determinar a incidência e os fatores associados à flebite pós-cateterismo venoso periférico.

**Metodologia:** Foi realizado um estudo piloto para uma coorte prospectiva, em agosto de 2010, sobre a frequência de flebite em Bucaramanga, Colômbia. O estudo incluiu 198 pessoas com mais de 18 anos admitidas na sala de emergência hospitalar e com período de internação entre 6-24 horas. Foram avaliadas variáveis sociodemográficas, clínicas e alguns potenciais fatores de risco para flebite. Os participantes foram seguidos até a alta hospitalar para que fosse possível monitorar a ocorrência de flebite.

**Resultados:** A incidência cumulativa de flebite foi de 10,1%. Seis fatores de risco foram associados com o desenvolvimento de flebite secundária à cateterização venosa periférica.

**Conclusão:** Evidência é fornecida para alguns dos fatores de risco de flebite que podem ser utilizados na identificação e intervenção precoce pelo enfermeiro.

**Palavras-chave:** flebite; incidência; fatores de risco; segurança do paciente.

Received for publication: 03.07.14

Accepted for publication: 15.04.14

## Introduction

Intravenous therapy is one of the most common procedures performed in hospitals all over the world. Intravenous therapy aims to administer medications at intervals, administer only fluids or administer medications in the liquids that patients receive on a daily basis (Uslusoy & Mete, 2008). Phlebitis is the most common complication of intravenous therapy in inpatients. Studies reported incidents of phlebitis between 0.5% (Lee et al., 2009) and 59.1% (Singh et al., 2008) in patients who were receiving peripheral intravenous therapy. The incidence of phlebitis in people with peripheral venous catheter varies widely due to differences in the definition, the study design, the selection of patients and the duration of follow-up (Malach et al., 2006).

Many factors have been involved in the origin of phlebitis (Mestre Roca et al., 2012). These can be divided into chemical factors, such as irritating drugs and fluids, physical factors such as the catheter's material and the site and duration of cannulation (Monreal et al. 1999). It is also known that advanced age, the female gender, the Caucasian group and the presence of certain underlying processes, such as the hypoalbuminemia or neutropenia have a greater predisposition to develop phlebitis (Ferrete-Morales et al. 2010). A review of the literature on the causes of phlebitis highlighted other key factors: the catheter's material, the size of the catheter's lumen (larger catheters have a greater risk than smaller catheters), low pH, potassium chloride, hypertonic solutions, amino acids and some antibiotics (Curran, Coia, Gilmour, McNamee & Hood, 2000).

In our environment, the insertion and care of the peripheral venous catheter is a responsibility of the nursing staff. It is also important to emphasize that one way to assess the quality of the nursing care is through the presence or absence of adverse events and, in this case, phlebitis is considered an adverse event resulting from nursing care. For these reasons, this study aimed to determine the incidence and the factors associated with the development of phlebitis in people with peripheral venous catheterization in a health care institution of third-level of care, analysing the data from a pilot test based on a prospective longitudinal cohort study on adverse events related to nursing care.

## Theoretical background

Phlebitis is an inflammation of a superficial vein caused by the irritation of its walls (Zarate, Mandelco, Wilshaw & Ravert, 2008). Its clinical manifestations are: pain, sensitivity, inflammation, induration, erythema, heat and palpable venous beading. Phlebitis is considered a major problem in clinical practice that can result in more serious complications that lead to the use of antibiotics or a possible surgical intervention, extending hospital stay and increasing health care costs (Nassaji-Zavareh & Ghorbani, 2007). Since the publication in 1999 of the Institute of Medicine report "To err is human" (Kohn, Corrigan & Donaldson, 2000), health care safety has raised great interest in health care systems worldwide. This way, the culture of patient safety is an important indicator of the quality of care, although sometimes the perception of nursing professionals towards patient safety is negative, since it only focuses on punishment and on hiding the error (Fernandes & Queirós 2011). In Colombia, phlebitis is considered an adverse event resulting from nursing care, since the insertion, management, monitoring and withdrawal of peripheral venous catheters are an activity that is assigned to nursing staff.

Faced with the possibility of introducing interventions with effective impact on the decrease of the incidence of phlebitis (Oliveira & Parreira, 2010), it is necessary to understand the factors associated with the development of phlebitis. There are some studied in the literature related to this issue since 1991, such as the case of a randomized clinical trial in which 21 risk factors of the development of phlebitis were assessed, thus obtaining four potential predictors of development of phlebitis: catheter's dwell time, female gender, use of antibiotics and catheter's material (Maki & Ringer, 1991). Among the most recent publications, a study assessed the influence of the risk factors on the incidence and kinetics of phlebitis (Mestre Roca et al., 2012), identifying five independent predictors of development of phlebitis: gender (female), the insertion of the catheter in the emergency room or in the medical-surgical units, the location in the forearm and the administration of amoxicillin/clavulanic acid and aminoglycosides.

## Methodology

The pilot test of a prospective cohort study was carried out in a health care institution of third level of care in the city of Bucaramanga, Colombia. During 15 days of August 2010, the study included all patients with 18 years or more who were admitted through the emergency room and had a hospital stay of between 6 and 24 hours.

Two teams were established for data collection: the first group applied an instrument to the patients who met the criteria and carried out the first assessment. This instrument assessed mainly the variables related to the possible risk factors for the development of phlebitis. After that, data such as co-morbidities, background, laboratories and medications were taken from the patient's medical history. Later, the person was examined and some information that had not been described in the medical history was added.

The second group performed a daily monitoring of those patients who had been included in the study in order to check the incidence of phlebitis. The nurse in charge of the report of phlebitis informed about the discharges in order to know the daily number of users who were being monitored and the exact date of discharge. Each group was led by a nurse with experience in adverse events, quality audit, surveillance and reporting of this type of events in health care institutions. The groups functioned independently, *i.e.* none of the groups knew the information collected by the other. The field team was qualified and previously trained in the procedures, instruments and instructions designed for the collection of information, as well as for the quality control of the data.

Phlebitis - the outcome variable - was defined as the presence of at least two of the following signs or symptoms in the site of insertion of the peripheral catheter: redness, swelling, palpable venous bending, sensitivity or pain. Those phlebitides that occurred in the early hours of hospitalization and before the initial examination were not considered as events. This type of phlebitis was considered as a history of phlebitis. If a patient developed the same type of event more than once, each one was considered an independent phenomenon.

Other variables of interest collected and included in this analysis were: socio-demographic variables (age, gender, completed and approved years of education, origin, if the patient was referred); patient-related

variables (some co-morbidities, such as diabetes, cancer, Human Immunodeficiency Virus-HIV); others, such as the type of disease, general condition, administered medications, some laboratory values, the autonomy in the activities of daily living (Barthel Index), assessment of the activities of daily living (Katz Index) and the Glasgow Scale; variables related to the event and the quality of care (patients receiving care from the nurse and the severity of the event).

An independent double digitization of the information and validation were performed. A descriptive analysis was carried out in which the median, the interquartile range and the range of the continuous variables without a normal distribution were used. In relation to the categorical variables, the absolute and relative frequencies were used. The incidence to the first event and the cumulative incidence with its respective confidence intervals at 95% (95% CI) were calculated. In the bivariate analysis, the cumulative incidence and its 95% CI for each category of the independent variables were calculated using hypothesis testing for comparison: Chi-squared tests or Fisher tests for binary variables, according to the case, and the Chi-squared test for trend for ordinal categorical variables. This study was considered to be a risk-free investigation within the scope of Resolution 8430 of 1993 (Ministerio de Salud, 1996) for research with human subjects because an observational design was used and no intervention was performed. The informed consent was requested to all the participants. The study and the information obtained were managed under the ethical principles for health research (Consejo de Organizaciones Internacionales de Ciencias Médicas, 2002), with the approval of the Ethics Committee of the Faculty of Health Sciences of the Universidad Industrial de Santander.

## Results

Incidence of peripheral intravenous catheter-related phlebitis: The median age (Q1-Q3) of patients with phlebitis was 45 (39-51) years, with a minimum age of 20 and a maximum age of 74 years. A total of 58.8% (n= 10) were male participants. The main characteristics of the people who developed phlebitis are shown in Table 1.

The incidence of peripheral intravenous catheter-related phlebitis in the first event was 8.5% (n=17;

95% CI 5.08 - 13.3) and the cumulative incidence was 10.1 (n=20; 95% CI 6.2 -15.1). Phlebitis represented 53.1% (n=17) of the total adverse events identified in this study. A total of 82.3% (n=14) of the patients presented one phlebitis and 17.6% (n=3) two phlebitis.

The median (Q1-Q3) of patients who developed phlebitis and were receiving care from the nurse was 26 (21-30) patients, with a minimum of 15 and a maximum of 53 patients. A total of 88.3% of the events were considered to be of moderate severity (extended the hospital stay in at least 1 day) and 11.7% of mild severity (injury or complication that did not extend the hospital stay). This classification was based on the

concept of the severity of the adverse event in the study IBEAS (Aranaz-Andrés et al. 2011).

Factors associated with the development of peripheral intravenous catheter-related phlebitis: in the bivariate analysis, a statistically significant correlation with age ( $p=0.007$ ), the length of hospital stay ( $p=0.003$ ), the platelet count ( $p=0.043$ ), the number of administered drugs ( $p<0.001$ ), the administration of mucosa protectors or gastric antisecretory drugs ( $p=0.041$ ) and the use of antibacterial drugs ( $p=0.002$ ) was found. No statistically significant correlation was found between phlebitis and the type of disease, general condition, presence of cancer, diabetes, HIV and others (see Table 1).

Table 1

*Characteristics of the sample, cumulative incidence and factors related to peripheral intravenous catheter-related phlebitis.*

Characteristic	n (%)	CI of phlebitis (95% CI)	p-value
Age			0.007*
1 <sup>st</sup> tertile (18 to 47 years)	67 (33.8)	14.9 (7.4 - 25.7)	
2 <sup>nd</sup> tertile (48 to 68 years)	68 (34.4)	8.8 (3.3 - 18.2)	
3 <sup>rd</sup> tertile (69 to 92 years)	63 (31.8)	1.6 (0.04 - 8.5)	
Gender			0.068
Male	121 (61.7)	5.8 (2.3 - 11.5)	
Female	75 (38.3)	13.3 (6.6 -23.1)	
Completed and approved years of education			0.126 *
None	69 (38.5)	4.3 (0.9 - 12.2)	
1-5 years	69 (38.5)	11.6 (5.1 - 21.6)	
≥ 6 years	41 (23.0)	12.2 (4.1 - 26.2)	
Procedence			1.000
Rural	45 (23.2)	8.9 (2.5 - 21.2)	
Urban	149 (76.8)	8.7 (4.7 - 14.5)	
Referred			0.771
Yes	147 (74.6)	8.2 (4.3 - 13.8)	
No	50 (25.4)	10 (3.3 - 21.8)	
Hospital stay			0.003*
1 <sup>st</sup> tertile (≤3 days)	87 (43.9)	2.3 (0.3 - 8.1)	
2 <sup>nd</sup> tertile (4 - 5 days)	48 (24.2)	10.4 (3.5 - 22.6)	
3 <sup>rd</sup> tertile (≥6 days)	63 (31.8)	15.9 (7.9 - 27.2)	
Type of disease			0.524
Chronic	34 (18.5)	11.8 (3.3 - 27.4)	
Acute	150 (81.5)	8.7 (4.7 - 14.4)	
General condition			1.000
Critical	22 (12.2)	9.1 (1.1 - 29.2)	
Stable	158 (87.8)	9.5 (5.4 - 15.2)	
Diabetes			1.000

Characteristic	n (%)	CI of phlebitis (95% CI)	p-value
Yes	22 (11.1)	9.1 (1.1 - 29.2)	
No	176 (88.9)	8.5 (4.8 - 13.7)	
Cancer			0.207
Yes	10 (5.1)	20 (2.5 - 55.6)	
No	188 (94.9)	8.0 (4.5 - 12.8)	
HIV			0.175
Yes	9 (4.6)	22.2 (2.8 - 60.0)	
No	189 (95.4)	7.9 (4.5 - 12.7)	
Haemoglobin (g/dL)			0.751*
1 <sup>st</sup> tertile (< 11)	43 (33.3)	9.3 (2.6 - 22.1)	
2 <sup>nd</sup> tertile (≥11 to 13.2)	43 (33.3)	18.6 (8.4 - 33.4)	
3 <sup>rd</sup> tertile (≥13.3)	43 (33.3)	11.6 (3.9 - 25.1)	
Leukocytes			0.294*
1 <sup>st</sup> tertile (≤7,600)	42 (33.6)	9.5 (2.6 - 22.6)	
2 <sup>nd</sup> tertile (7,700 - 12,000)	43 (34.4)	13.9 (5.3 - 27.9)	
3 <sup>rd</sup> tertile (≥12,100)	40 (32.0)	17.5 (7.3 - 32.8)	
Platelets			0.043*
1 <sup>st</sup> tertile (≤210,000)	38 (33.3)	7.9 (1.6 - 21.4)	
2 <sup>nd</sup> tertile (211,000 - 302,000)	38 (33.3)	7.9 (1.6 - 21.4)	
3 <sup>rd</sup> tertile (≥303,000)	38 (33.3)	23.7 (11.4 - 40.2)	
Number of medicines			<0.001
0-2	75 (38.1)	0 (0 - 4.8)	
3 or more	122 (61.9)	13.9 (8.3 - 21.4)	
Antibacterial			0.002
Yes	62 (31.5)	17.7 (9.2 - 29.5)	
No	135 (68.5)	4.4 (1.6 - 9.4)	
Antiepileptic			0.209
Yes	10 (5.1)	20 (2.5 - 55.6)	
No	187 (94.9)	8.0 (4.5 - 12.9)	
Potassium chloride			0.114
Yes	7 (3.5)	28.6 (3.7 - 70.9)	
No	190 (96.5)	7.9 (4.5 - 12.7)	
Gastric antisecretory			0.041
Yes	115 (58.4)	12.2 (6.8 - 19.6)	
No	82 (41.6)	3.6 (0.8 - 10.3)	
Corticoids			0.458
Yes	25 (12.7)	12 (2.5 - 31.2)	
No	172 (87.3)	8.1 (4.5 - 13.3)	
Autonomy in ADLs**			0.924
Some degree of dependence	107 (54.0)	8.4 (3.9 - 15.4)	
Independence	91 (46.0)	8.8 (3.9 - 16.6)	
Glasgow Scale			0.521
< 15	36 (18.3)	11.1 (3.1 - 26.1)	
15 points	161 (81.7)	8.1 (4.4 - 13.4)	

\* = Chi-squared test for trend.

\*\* = Measured using the Barthel Index.

## Discussion

This pilot test shows that the incidence of peripheral intravenous catheter-related phlebitis in the first event was 8.5% and the cumulative incidence was 10.1%, which are above the recommendations by The Intravenous Nurses Society, which accepts incidences of phlebitis of less than 5% in a given population (White, 2001). These results are slightly higher than those reported by the project IBEAS: prevalence of adverse effects in Latin American hospitals, with an incidence of 5.7% (Ministerio de Sanidad y Política Social, 2007), a study in which Colombia took part. The differences in the incidences could be explained due to the study design. The IBEAS was a retrospective cohort study based on the review of medical histories. Thus, in this type of design the incidence can be affected by an under-reporting of these events.

This study considered the presence of two or more signs or symptoms of phlebitis at the site of catheter insertion at the time of diagnosis of phlebitis. Other studies which also used this definition were those by Maki and Ringer (1991), who found higher rates than ours, 41.8%; Monreal et al. (1999), who found an incidence of phlebitis of 39%; and Karadag and Gorgulu (2000), who reported an incidence of 36.5%. On the other hand, Nassaji and Ghorbani (2007), who used four criteria for the diagnosis of phlebitis, found an incidence of phlebitis of 26%. This is one of the reasons for the many incidences found in the literature, specifically because of the various definitions used to specify phlebitis.

In this study, an inverse relationship was found between age and incidence of phlebitis, which differs from the results of Nassaji and Ghorbani (2007) and Uslusoy and Mete (2008), who found no association. However, Singh et al. (2008) found that the age range between 21-30 years has an *odds ratio* (OR) of 4.12 (95% CI 1.43 - 11.87) and the age range of 31-40 years an OR of 3.06 (95 % CI 1.04 - 9.0). No associations were found between phlebitis and gender which is in line with the results of Ferrete-Morales et al. (2010) and Singh et al. (2008).

No statistically significant correlation was found between phlebitis and diabetes, nor cancer or HIV infection, a fact that is consistent with the results of Ferrete-Morales et al. (2010) and Monreal et al. (1999), who found no association with HIV infection, while Nassaji and Ghorbani (2007) found a

statistically significant association with diabetes with OR 7.78 (95% CI 4.59 - 13.21).

A statistically significant correlation was found with the administration of platelets ( $p=0.043$ ). No association was found with the levels of hemoglobin and leukocytes. However, Monreal et al. (1999) found an association with the levels of hemoglobin, 12.5-13.9 g/dL of hemoglobin with a *bazard ratio* (HR) of 1.81 (95% CI 1.27 - 2.58) and hemoglobin higher than 13.9 g/dL with HR of 2.29 (95% CI 1.58 - 3.32), but found no association with the levels of leukocytes and platelets.

With regard to the administration of medications, an association was found with two groups: gastric antisecretory agents ( $p=0.041$ ) and antibacterials ( $p=0.002$ ). Ferrete-Morales et al. (2010) found a statistically significant association with cefotaxime ( $p=0.026$ ), but found no association with cloxacillin, amoxicillin-clavulanate, cefepime, piperacillin/tazobactam, imipenem, gentamicin, ciprofloxacin, levofloxacin. Ferrete-Morales et al. (2010) also found an association with amoxicillin-clavulanate with HR of 2.1 (95% CI 1.4 - 3.2) and the aminoglycosides with HR of 2.1 (95% CI 1.01 - 4.6). This could be explained by the pH value of these drugs, some of them with an acid pH and others with a too basic pH, which could damage the vein's inner lining.

Among the factors explored in the literature and investigated in this study, an association was found with the patient's length of hospital stay ( $p=0.003$ ) and the number of administered drugs ( $p=0.001$ ). No associations with the autonomy in activities of daily living and with the Glasgow scale were found.

The fact that the associations found in this study derived from a bivariate analysis can be considered as a limitation. A multivariate analysis should be performed with a higher number of events and large sample size to confirm the associations found here.

## Conclusion

These are the preliminary results of the pilot test of a prospective cohort study on four adverse events resulting from nursing care (pressure ulcers, phlebitis, falls and removal of biomedical devices), but in this paper only phlebitis is analysed. Six risk factors were found to be associated with the development of peripheral intravenous catheter-



related phlebitis such as age, length of hospital stay, administration of platelets, number of administered drugs and administration of antibacterial and gastric antisecretory drugs. However, in the future, we would also like to explore other important risk factors, such as the catheter's gauge, the anatomical region of catheter insertion, the use of buretrol and IV pump, among others.

## Acknowledgments

The Research Vice-chancellorship of the Universidad Industrial de Santander for financing the project No. 5659.

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