



ORIGINALS

Interrater agreement of the classification of phlebitis, its signs, and symptoms in peripheral intravenous catheters

Concordancia Interevaluadores de la clasificación de flebitis, sus signos y síntomas en catéteres intravenosos periféricos

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ABSTRACT:

Aim: The objective of this study was to determine inter-rater agreement for the classification of phlebitis, its signs, and symptoms using the Visual Infusion Phlebitis Scale.

Methods: This was a prospective cohort study of patients aged 18 years and older hospitalized in an emergency department with their first peripheral venous catheter in place. Signs and symptoms of phlebitis were assessed daily using the scale. A descriptive analysis was performed, and agreement for the classification of phlebitis, its signs, and symptoms was calculated using Cohen's Kappa coefficient.

Results: 817 patients were included. The most common sign or symptom was erythema (13.59%), followed by pain (11.50%), edema (2.99%), and induration (2.02%). There was no palpable venous cord or pyrexia. The overall incidence of phlebitis was 11.44%; grade II (9.42%) and grade III (2.02%). Cohen's Kappa coefficient was 0.990 (95% CI 0.982-0.996) for the general classification of phlebitis. The highest reproducibility for signs and symptoms was pain ($k=0.946$), followed by induration ($k=0.894$), edema ($k=0.716$), and erythema ($k=0.649$).

Conclusions: This study showed high inter-rater agreement overall for the scale and good to very good agreement for each sign and symptom. Future research should evaluate whether purulence and pyrexia are useful signs for screening and early identification of phlebitis.

“Key words”: Observer Variation; Reproducibility of Results; Phlebitis; Signs and Symptoms; Catheters; Cohort Studies.

RESUMEN:

Objetivo: El objetivo de este estudio fue determinar la concordancia inter-evaluadores de la clasificación de flebitis, sus signos y síntomas utilizando la Visual Infusion Phlebitis Scale.

Métodos: Estudio de cohorte prospectiva en pacientes mayores de 18 años hospitalizados en un servicio de urgencias, con el primer catéter venoso periférico instalado. Los signos y síntomas de la flebitis fueron evaluados diariamente mediante la escala. Se realizó un análisis descriptivo y se calculó la concordancia de la clasificación de flebitis, sus signos y síntomas por medio del coeficiente Kappa de Cohen.

Resultados: 817 pacientes fueron incluidos. El signo o síntoma más frecuente fue el eritema (13.59%), seguido de dolor (11.50%), edema (2.99%) e induración (2.02%), no se presentó cordón venoso palpable ni pirexia. La incidencia general de flebitis fue de 11.44%; grado II (9.42%) y grado III (2.02%). El coeficiente de Kappa de Cohen fue de 0.990 (IC 95% 0.982 - 0.996) de la clasificación general de flebitis. La mayor reproducibilidad para los signos y síntomas fue la del dolor (k=0.946) seguido de induración (k=0.894), edema (k=0.716) y eritema (k=0.649).

Conclusiones: Este estudio evidenció una alta concordancia inter-evaluadores en general de la escala y una concordancia entre buena y muy buena para cada uno de signos y síntomas. Investigaciones futuras deberían evaluar si la purulencia y pirexia son signos útiles para el tamizaje e identificación temprana de la flebitis.

“Palabras clave”: Variaciones Dependientes del Observador; Reproducibilidad de los Resultados; Flebitis; Signos y Síntomas; Catéteres; Estudios de Cohortes.

RESUMO:

Objetivo: O objetivo deste estudo foi determinar a concordância interavaliadores para a classificação de flebite, seus sinais e sintomas utilizando a Escala Visual de Flebite por Infusão.

Métodos: Este foi um estudo de coorte prospectivo com pacientes maiores de 18 anos internados em um pronto-socorro com seu primeiro cateter venoso periférico implantado. Os sinais e sintomas de flebite foram avaliados diariamente utilizando a escala. Foi realizada uma análise descritiva e a concordância para a classificação de flebite, seus sinais e sintomas foi calculada utilizando o coeficiente Kappa de Cohen.

Resultados: Um total de 817 pacientes foram incluídos. O sinal ou sintoma mais comum foi eritema (13,59%), seguido por dor (11,50%), edema (2,99%) e endurecimento (2,02%). Não houve cordão venoso palpável ou pirexia. A incidência geral de flebite foi de 11,44%; grau II (9,42%) e grau III (2,02%). O coeficiente kappa de Cohen foi de 0,990 (IC 95% 0,982-0,996) de acordo com a classificação geral de flebite. A maior reprodutibilidade para sinais e sintomas foi dor (k=0,946), seguida por endurecimento (k=0,894), edema (k=0,716) e eritema (k=0,649).

Conclusões: Este estudo mostrou alta concordância interavaliadores geral para a escala e concordância de boa a muito boa para cada um dos sinais e sintomas. Pesquisas futuras devem avaliar se purulência e pirexia são sinais úteis para triagem e identificação precoce de flebite.

Palavras-chave: Variações dependentes do observador; Reprodutibilidade dos Testes; Flebite; Sinais e Sintomas; Catéteres; Estudos de Coortes.

INTRODUCTION

Peripheral intravenous catheters (PIVCs) are often removed before the recommended dwell time, with incidences ranging from 22.6% to 69.1%⁽¹⁻⁵⁾. The main causes of premature removal include leakage (26.6 %) ⁽³⁾, occlusion (17.5 % to 23%) ^(3,6), suboptimal placement (59.5 %) ⁽³⁾, and phlebitis (40.4 %) ⁽¹⁾. Phlebitis is an inflammatory process of the vascular endothelial wall called the tunica intima. It is characterized by local redness and heat, edema, and the formation of fibrous cords that are palpable

along the venous duct ^(7,8). Phlebitis incidences in peripheral intravenous catheters (PIVCs) vary, ranging from 6,1% to 70% ^(6,9-14). This wide variability may be attributed to several factors, including the characteristics of the study participants, such as age ⁽¹³⁻¹⁶⁾, sex ^(13,16,17), and the presence of comorbidities ⁽¹³⁻¹⁵⁾. Likewise, the type of clinical setting in which the patient is hospitalized, for example, emergency departments or surgical units ^(13,18), may increase the risk of this event. Other possible explanations are related to the variables considered in the analyses, such as the catheter material and diameter ^(14,15,19,20), the anatomical insertion site ^(5,21-23), the administration of specific medications ^(9,10,17,24), and the use of antibiotics ^(5,10,13,25), among others. Finally, methodological design may also account for these differences, as retrospective studies tend to underestimate the occurrence of phlebitis ⁽¹⁵⁾. Also, the definition used to determine phlebitis means the increase or decrease in incidence ⁽²⁾. For example, in some studies, it has been established with a single sign or symptom of phlebitis ⁽²⁶⁻²⁸⁾, in others with 2 or 4 of them ^(24,26,27), while other authors have chosen to use more objective scales for its definition ^(24,26,29).

Although several tools have been described in the literature to evaluate the presence and severity of PIVCs, standardized guidelines are still lacking, and further research is needed to develop valid and reliable assessment tools. Still, they have yet to be thoroughly validated in clinical practice ^(15,28,30). Among the best-known are the Visual Infusion Phlebitis Score (VIP Score), the Infusion Nursing Society Phlebitis Scale (INS Phlebitis Scale), and Peripheral Venous Catheter Assessments (PVC ASSESS) ^(28,31,32). The authors also indicate an unanswered question concerning the VIP Score: What is the inter-rater reproducibility of previously trained observers? ⁽³⁰⁾. Given this situation and the need to continue evaluating phlebitis as a possible complication of PIVCs use in clinical practice, the need arose to carry out a study to determine the inter-rater agreement of phlebitis classification, its signs, and symptoms using the VIP Score in PIVCs.

METHODS

A prospective cohort study was conducted in a tertiary care health institution in Bucaramanga, Santander, Colombia, from August to October 2014. All patients over 18 years of age who were hospitalized in the service emergency room, with the first PIVCs installed, were included. Those patients with catheters inserted in other institutions or with more than one catheter were excluded. This corresponds to secondary data analysis; therefore, a size calculation was not performed; the entire sample from the initial study was included, which aimed to evaluate independent phlebitis predictors. The sample was selected in a non-probabilistic way. All patients who met the criteria above were taken consecutively during the recruitment period. The information was collected in the following way: a nurse applied an assessment format with prior informed consent from the patient, which inquired about general aspects of the participant, such as age, sex, and medical diagnosis, among others, and specific elements, such as the catheter insertion site, catheter caliber, fixation status, intravenous medications administered, and infusion devices. To carry this out, it was necessary to conduct an interview, a physical examination, and a review of the medical history. Two other nurses, different from the one who carried out the general assessment, visited the patient daily in his unit and observed where the catheter was inserted, looking for signs and symptoms of phlebitis such as pain, erythema, edema, induration, venous cord palpable and pyrexia, for which they used the VIP Score ⁽²⁸⁾ (Figure 1). The catheter insertion site assessment and the VIP Score results were conducted independently.

Figure 1: VIP^a Score

Grade 0	IV site appears healthy.
Grade 1	One of the following signs is evident: -Slight pain near IV site or -Slight redness near IV site
Grade 2	Two of the following are evident: -Pain at IV site -Redness -Swelling
Grade 3	All of the following signs are evident: -Pain along path of cannula -Erythema -Induration (abnormal hardening)
Grade 4	All of the following signs are evident and extensive: -Pain along path of cannula -Erythema -Induration -Palpable venous cord
Grade 5	All of the following signs are evident and extensive: - Pain along path of cannula -Erythema -Induration - Palpable venous cord -Pyrexia

^a**VIP**: Visual Infusion Phlebitis. IV: Intravenous

The signs and symptoms of the scale were evaluated in the following way and arbitrarily dichotomized by the researchers: pain near the insertion site and referred by the patient during the interview, the analogous pain scale was used (No = 0 points; Yes = 1 -10 points); erythema and edema, visual observation of redness or swelling, regardless of its extent (No/Yes); induration, palpation of hardening around the catheter insertion, irrespective of its area (No/Yes); palpable venous cord, palpation of hardening in the vein trajectory, regardless of its extension (No/Yes) and pyrexia, axillary body temperature greater than 38 °C (No/Yes). Phlebitis was defined as having a score ≥ 2 on the VIP Scale. The follow-up was carried out for three days because the institution had established as a protocol the removal of the catheter after 72 hours. If phlebitis occurred, a form was filled out where the degree, signs, and symptoms were recorded. At this time, the patient was censored for presenting the event, and the nursing staff on duty was informed so that they could provide the respective care. The work groups, initial assessment, and follow-up of the event of interest (phlebitis) remained masked. Neither knew the information the other group was collecting. All personnel who participated in the research were previously trained on the procedures to follow, the instruments and instructions for data collection, and data quality control. The two evaluators were registered nurses working in the clinical and research areas with clinical experience of approximately three years. A descriptive analysis of the cohort's general characteristics were carried out through absolute and relative frequencies or measures of central tendency and dispersion as appropriate. Interrater reproducibility was evaluated to determine phlebitis and its signs and symptoms using Cohen's Kappa coefficient for dichotomous and ordinal variables and their 95% confidence intervals. The analysis was carried out using Stata statistical software version 14. The authors report that they did not use Artificial Intelligence, language modeling, machine learning,

or similar technologies to create or assist with the preparation or editing of any of the contents of this document.

RESULTS

A total of 817 patients were studied. There were no losses to follow-up, and all observations had complete data. The median participant age was 49 years, ranging from 18 to 99 years. 60.95% (n=498) were male, 93.88% (n=767) had an acute illness, and 99.02% (n=809) had a stable general condition. Regarding comorbidities, those that have been associated with phlebitis were studied, with diabetes mellitus being found most frequently in 10.77% (n=88), anemia at 10.16% (n=83), and cancer at 10.04% (n=82). 50.18% (n=410) of the catheters were inserted in the forearm, and the most used caliber was 20, with 85.66% (n=699) (Table 1).

Table 1: Characteristics of the cohort of hospitalized patients with peripheral venous catheters, Bucaramanga, Santander, Colombia, 2014 (n=817).

Characteristics	n (%)
Sex	
Men	498 (60.95)
Women	319 (39.05)
Type of Disease	
Acute	767 (93.88)
Chronic	50 (6.12)
Overall status	
Stable	809 (99.02)
Chronic	8 (0.98)
Comorbidities	
Mellitus diabetes	88 (10.77)
Anemia (<9g/dl)	83 (10.16)
Cancer	82 (10.04)
Peripheral venous disease	62 (7.59)
HIV/AIDS	23 (2.82)
Polytrauma	44 (5.39)
Autoimmune diseases	15 (1.84)
Sepsis	13 (1.59)
Peripheral arterial disease	12 (1.47)
Place of insertion	
Hand	236 (28.89)
Doll	100 (12.24)
Forearm	410 (50.18)
Arm	37 (4.53)
Arm joint	32 (3.92)
Jugular	1 (0.12)
Lower limbs	1 (0.12)
Catheter size	
16 gauge	7 (0.86)
18 gauge	92 (11.27)
20 gauge	699 (85.66)
22 gauge	18 (2.21)

The overall incidence of phlebitis was 11.44%, grade II (9.42%), and grade III (2.02%). Regarding the sign or symptom with the highest incidence, erythema was the most frequent (13.59%), followed by pain (11.50%), edema (2.99%), and induration (2.02%). There was no palpable venous cord or pyrexia, therefore, neither grade 4 nor 5 phlebitis (Table 2).

Table 2: Incidence of phlebitis, its signs, and symptoms according to the evaluator, Bucaramanga, Santander, Colombia, 2014 (n=817).

Characteristics	Evaluator 1 n (%)	Evaluator 2 n (%)
Grade of phlebitis		
0	700 (85.68)	700 (85.68)
1	23 (2.82)	24 (2.94)
2	77 (9.42)	77 (9.42)
3	17 (2.08)	16 (1.96)
Pain		
No	24 (2.94)	22 (2.69)
Yes	93 (11.38)	95 (11.63)
Erythema		
No	6 (0.73)	6 (0.73)
Yes	111 (13.59)	111 (13.59)
Edema		
No	94 (11.50)	91 (11.14)
Yes	23 (2.81)	26 (3.18)
Induration		
No	100 (12.24)	101 (12.36)
Yes	17 (2.08)	16 (1.96)
Palpable venous cord		
No	817 (100.0)	817 (100.0)
Pyrexia		
No	817 (100.0)	817 (100.0)

The inter-rater agreement of general phlebitis classification was $k=0.990$ (95% CI 0.982 - 0.996), which indicates almost perfect agreement. The highest reproducibility for signs and symptoms was pain ($k=0.946$), followed by induration ($k=0.894$), edema ($k=0.716$), and erythema ($k=0.649$) (Table 3).

Table 3: Interrater agreement of the classification of signs and symptoms of phlebitis, Bucaramanga, Santander, Colombia, 2014 (n=817).

Characteristics	Observed agreement (%)	Expected agreement (%)	Kappa*	CI 95%
Grade of phlebitis	99.89	88.66	0.990	0.982 - 0.996
Pain	98.29	68.40	0.946	0.849 - 1.000
Erythema	96.58	90.27	0.649	0.192 - 0.928
Edema	90.60	66.86	0.716	0.550 - 0.873
Induration	97.44	75.77	0.894	0.730 - 0.972

*Weighted Kappa; CI=Confidence interval.

DISCUSSION

Our main finding of this study was the high reproducibility of the scale (reproducibility >0.8), even for the majority of the items that compose it (2/3 >0.8), and an almost perfect inter-rater agreement of $k=0.99$ (95% CI:0.982-0.996). This result is highly relevant for clinical practice, considering that the existing scales to evaluate phlebitis lack psychometric rigor ^(28,30). Therefore, it is necessary to have several observers and consider their agreement until a valid and reproducible scale is available.

In line with the above, a recent study ⁽³³⁾ reported Cohen's kappa values of 0.918, indicating an almost perfect level of reliability for nominal data. Likewise, Betül Kuş et al ⁽³⁴⁾ reported an intraclass correlation coefficient (ICC) of 0.91 (ICC = 0.906; $p < 0.001$) and a content validity index of +1 ⁽³⁴⁾. These findings support using the VIP scale as a valid and reliable tool for the early detection of phlebitis signs and symptoms in different clinical settings ⁽³⁴⁻³⁶⁾.

On the other hand, when comparing our findings related to the signs and symptoms of phlebitis, it was observed that there is limited information available. In this regard, a study that aimed to examine the agreement among registered nurses on the signs, symptoms, and scales commonly used in the evaluation of phlebitis found that the most common sign was tenderness (19.0%), followed by erythema (6.9%), edema (6.1%), pain (4.9%), palpable venous cord (2.0%), heat (0.4%) and purulent discharge (0.0%) ⁽³⁷⁾. Similarly, Mihala et al ⁽²⁷⁾ analyzed 22,789 observations across 5,907 catheter insertion sites. They identified that phlebitis signs and symptoms occurred only occasionally or rarely, with tenderness being the most frequent (5.7%), followed by swelling (2.2%), erythema (2.1%), palpable cord (0.4%), local warmth (0.3%), and purulence (0.0%). Significant correlations were also documented between tenderness and warmth ($r = 0.81$), swelling and warmth ($r = 0.81$), and erythema and warmth ($r = 0.83$). In contrast, in our study the most frequent signs and symptoms were erythema, pain, edema, and induration, with no evidence of palpable venous cord or pyrexia.

However, a study with a population more comparable to that of the present study ⁽³⁸⁾ which aimed to describe the processes and practices related to peripheral intravenous catheter (PIVCs) use in hospitalized patients across five Latin American countries (Argentina, Brazil, Chile, Colombia, and Mexico), determined that the most common PIVCs complication was blood in the tubing/connection (12%), followed by pain on palpation (5%), dried blood around the PIVCs (4%), and both hyperemia and edema >1 cm from the insertion site (1%). Likewise, a recent study conducted in Brazil by Silva-dos Santos et al ⁽¹⁷⁾ on the incidence of phlebitis, using the Infusion Nurses Society

Scale, reported the following signs and symptoms: hyperemia in 6.12%, redness in 22.44%, erythema in 8.16%, edema in 12.24%, pain in 12.24%, palpable venous cord formation in 4.08%, while 71.42% of patients presented no signs or symptoms.

This low prevalence of the signs and symptoms, compared with our findings could be explained by variations in how phlebitis is defined, the follow-up period after catheter insertion, and the assessment scales employed ^(13,26,28). In our study, follow-up ended at the moment of catheter removal, which may have limited the detection of late manifestations (censoring). Furthermore, the low prevalence of signs such as purulence and pyrexia, both in our results and those reported in the literature ^(27,37), raises questions about their usefulness as screening criteria for early phlebitis detection. These findings suggest that such signs may represent late indicators of the complication or its more severe consequences, limiting their value in clinical practice. Another possible explanation for these findings is the relatively short follow-up period (3 days).

In contrast, in another investigation, the agreement was poor ⁽³⁷⁾, with a value of $k=0.19$. Likewise, they evaluated the accord for each of the signs and symptoms, pain ($k=0.38$), erythema ($k=0.62$), and edema ($k=0.40$) ⁽³⁷⁾, data in which we only have similarity with erythema. Regarding a possible limitation of this study, the definition and operationalization of some signs stand out. These signs could be measured more objectively and precisely, such as using cm or mm to evaluate their extension. However, it is essential to consider research scenarios very close to daily clinical practice, as reflected in the present study's methodology. Among the strengths, the prospective design stands out, which allowed daily monitoring of the person with a catheter and the independence of the evaluators' observations, the sample size, the training, standardization, and supervision of the procedures carried out throughout the research.

Consequently, our results highlight the need to standardize diagnostic criteria and evaluation scales to strengthen clinical surveillance and improve early detection of phlebitis across different hospital settings.

Practical implications for clinical nursing

The VIP scale's high reproducibility and strong inter-rater agreement directly affect clinical nursing practice, as they provide a valid and standardized tool that facilitates continuous monitoring, early detection of phlebitis signs and symptoms, and timely implementation of interventions. Its application supports the unification of criteria in clinical practice, optimizes decision-making related to catheter management, strengthens nursing staff training, and contributes to enhancing patient safety, preventing complications, and generating comparable data to support evidence-based practice.

Limitation of this study

As mentioned in previous paragraphs, a limitation of this study was that patient follow-up ended at the time of catheter removal, which may have restricted the identification of late-onset manifestations of phlebitis reported in the literature. This aspect could have led to an underestimation of the true incidence of the event. In addition, some clinical signs and symptoms were operationalized in a subjective manner; for example, erythema and edema were not quantified using objective measures (e.g., millimeters or

centimeters), and pain assessment was similarly subjective, which may have introduced variability in their evaluation. These factors underscore the need for future studies to include longer follow-up periods and more precise measurement criteria in order to strengthen the validity and generalizability of the findings.

CONCLUSIONS

This study allowed us to determine a high inter-rater agreement of the VIP Scale in general and an agreement between good and very good for each of the signs and symptoms. Additionally, it established the non-frequency of signs such as purulence and pyrexia during the first three days of catheter insertion. Compared with previous studies, our findings provide additional evidence on the variability of phlebitis signs and symptoms and highlight the inconsistencies in their operationalization, definition, and frequency across different populations and clinical contexts. Future research should evaluate whether these last two signs mentioned are helpful as screening signs to identify phlebitis early.

Ethical considerations

A Research Ethics Committee approved this study. All people previously gave their informed consent. In cases where the patient could not do so, this consent was obtained from a family member.

Conflict of interests

The authors declare no conflict of interest.

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