

Phlebitis Signs and Symptoms With Peripheral Intravenous Catheters

Incidence and Correlation Study

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ABSTRACT

This study was undertaken to calculate the incidence of 8 signs and symptoms used for the diagnosis of phlebitis with peripheral intravenous catheters, or short peripheral catheters, and the level of correlation between them. A total of 22 789 daily observations of 6 signs (*swelling, erythema, leakage, palpable venous cord, purulent discharge, and warmth*) and 2 symptoms (*pain and tenderness*) were analyzed of 5907 catheter insertion sites. Most signs and symptoms of phlebitis occurred only occasionally or rarely; the incidence of *tenderness* was highest (5.7%). Correlations were mostly low; *warmth* correlated strongly with *tenderness, swelling, and erythema*.

Key words: correlation of data, phlebitis, Spearman's rank correlation coefficient, vascular catheters

A majority of hospitalized patients require a short peripheral catheter (SPC) at some stage during treatment for the administration of fluids and medications.¹ Monitoring these devices at regular intervals is a part of nursing practice worldwide and is becoming more important now that global guidelines recommend SPC removal only for clinical reasons, based on

assessment rather than at preset intervals.^{2,3} Phlebitis, or inflammation of the vein, is a complication often associated with SPCs.⁴ Phlebitis may cause significant pain and lead to catheter failure and treatment interruption, necessitating catheter replacement, which can result in future compromised venous access.^{5,6} The acceptable phlebitis rate has been suggested as <5%, but rates reported in the literature

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range from 0% to 91%, presumably because of variation in phlebitis assessment scoring measures and differences in the definition of phlebitis; for instance, 71 phlebitis scales currently exist, and none have been thoroughly validated.^{4,7,8}

Diagnosis of phlebitis is based on clinical judgment and observation of a range of signs and symptoms—for example, pain, tenderness, erythema, edema, local warmth, palpable venous cord, and purulence. Based on combinations of these signs/symptoms, numerous phlebitis assessment scales, such as the Infusion Nurses Society's Phlebitis Scale,^{2(S96)} and the PVC ASSESS, Maddox, Baxter, Lipman, and Dinley scales, have been created.⁸ Despite their widespread use, the diagnostic performance of the various signs, symptoms, and assessment scales has not yet been rigorously evaluated.⁸ Because phlebitis scores often prompt SPC removal, patients could be exposed to unnecessary catheter replacement as the result of false positives, or insertion sites with actual phlebitis could remain untreated as a result of false negatives.⁹ It is unclear whether clinicians' time is being used effectively to monitor SPCs for phlebitis.

Justification for the use of a certain sign/symptom to ascertain the presence of a condition relies on its diagnostic performance. In the case of phlebitis, little is known regarding which signs and symptoms are the most common, and how these findings relate to each other. In light of the current standard of routine phlebitis monitoring with numerous tools that are inadequately validated, this study aimed to provide initial information about the incidence of commonly used signs/symptoms and the levels of association between them. The results of this study are intended to provide information for future development and validation of phlebitis assessment scales.

METHODS

The authors conducted a post hoc analysis of data collected for a large, multicenter, nonblinded, randomized controlled equivalence trial (the DRIP Trial; registered at the Australian New Zealand Clinical Trials Registry, number 12608000445370), which compared different SPC replacement regimes in participating wards of 3 major metropolitan hospitals in Queensland, Australia.¹⁰ Ethical approval for the DRIP Trial and this substudy was obtained from all hospitals

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Mr Mihala and Dr Rickard were responsible for the conceptualization and design of the study. Mr Mihala performed the data

and Griffith University. All patients gave written informed consent. For this analysis, subjects in the intervention (clinically indicated catheter replacement) and control (routine replacement on the third day) arms were analyzed jointly.

In the DRIP Trial, experienced research nurses (registered nurses with a minimum of a bachelor's degree) with training in SPC site assessment made daily assessments of 6 signs at the insertion site: *swelling, erythema, leakage, palpable venous cord, purulent discharge, and warmth*. Two patient-reported symptoms of *pain* and *tenderness* were also recorded. These signs and symptoms, with the exception of *leakage*, are commonly used in practice for phlebitis assessment, and definitions from previous literature and current tools were used in this study.⁸ *Swelling, erythema, leakage, and purulence* were assessed visually. *Swelling* and *erythema* were observed as the longest diameter of the affected area, categorized as 0 cm (none), <1 cm, 1 to <2.5 cm, 2.5 to <5 cm, or ≥5 cm. *Palpable cord* was assessed by palpation beyond the SPC tip, and *warmth* by palpation compared with other body parts. *Leakage, palpable cord, purulence, and warmth* were recorded as dichotomous (none or any). *Pain* was defined as any pain experienced at the insertion site, whether or not the SPC was in use. Following the ascertainment of a *pain* score from the patient, nurses palpated the SPC site for *tenderness*. *Pain* and *tenderness* were reported on a 0 to 10 scale of increasing severity (0 = none, 10 = maximum) and recorded categorized as 0, 1, 2 to 4, 5 to 8, or 9 to 10. Data for analysis included all daily observations reported during the DRIP Trial, including multiple catheters and multiple observations per patient, and excluding observations after the removal of the SPC. Missing data were not imputed.

Pairwise associations between signs/symptoms observed during the same daily check were assessed with the correlation coefficient, a simple method for variables with no causal relationships describing different outcomes.¹¹ The magnitude of correlation (*r*) between 2 signs/symptoms was described with the phi coefficient, which is a simplified Pearson's coefficient for 2 dichotomous variables, Spearman's rho coefficient for 2 ordinal variables, and Somers D coefficient for an ordinal and a dichotomous variable.¹² All 3 coefficients are comparable measures of *r*. They are absolute values, on the same 0% to 100% scale, and were interpreted similarly following the established rule of thumb: low at $r < 0.50$, moderate at $0.50 \leq r < 0.70$, and high at $r \geq 0.70$.¹³ For the purpose of this study, values of

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r were declared significant if $r \geq 0.70$ and the lower bound of the 95% confidence interval was ≥ 0.50 . Data management and analysis was completed with Stata 14.1 (StataCorp; College Station, Texas).

RESULTS

Data obtained from the DRIP Trial included 22 789 daily observations made of 5907 SPC sites (3283 patients; SPC duration: mean 3.86, maximum 23 days). The incidence of *tenderness* was highest (5.7%, any level) and lowest for *purulence* (0.02%) (Table 1).

Correlations ranged from 0.0 to 0.83 but were mostly at negligible ($r < 0.10$) or low levels (Table 2). Significant correlations were found between *tenderness* and *warmth* ($r = 0.81$), *swelling* and *warmth* ($r = 0.81$), and *erythema* and *warmth* ($r = 0.83$). *Purulence-tenderness* and *purulence-erythema* were also highly correlated, but these correlations were not statistically significant (Tables 1 and 2).

DISCUSSION

This is the first study to describe incidence and correlations between signs and symptoms of phlebitis related to SPCs. The study adds novel data through the use of a large patient cohort, with assessments performed daily by experienced nurses using standardized definitions. Furthermore, it provides a new contribution to knowledge on the incidence of these signs/symptoms in a general hospital population and sparks new opportunities to further refine and develop phlebitis assessment tools, which are used daily on tens of thousands of patients worldwide, despite minimal validation data.^{8,14}

The observed incidences ranged from $< 1\%$ (*palpable cord*, *purulence*, and *warmth*) to 5.7% (*tenderness*). The incidence of *tenderness* was more than double the next most frequent sign or symptom (*swelling*, 2.2%), which strongly suggests that nurses need to physically palpate and assess for tenderness, and not just ask the patient about pain.

Three pairs of signs/symptoms were found to be significantly correlated: *tenderness-warmth*, *swelling-warmth*, and *erythema-warmth*. *Purulence-tenderness* and *purulence-erythema* also demonstrated high correlations, but their confidence intervals were too wide to achieve the significance criteria established for this study. The remaining pairwise correlations were negligible or low.

Significant correlation indicates a high level of association between 2 signs/symptoms—ie, the 2 seem to have appeared together. It does not mean, however, that 1 of them was unnecessary to observe, because they measured different things and their diagnostic performance should also be considered before drawing such a conclusion. The authors are planning to investigate the diagnostic results further in a separate study.

As many as 24 daily observations were made per patient at an average of 1.8 SPC insertion sites per patient.

TABLE 1

Descriptive Statistics of Phlebitis Signs/Symptoms Observed

Sign/Symptom	n (%)
Pain (n = 22 783) ^a	
None	22 385 (98.2)
1	132 (0.6)
2 to 4	197 (0.9)
5 to 8	51 (0.2)
9 to 10	18 (0.1)
Any pain	398 (1.7)
Tenderness (n = 22 770) ^a	
None	21 479 (94.3)
1	757 (3.3)
2 to 4	428 (1.9)
5 to 8	89 (0.4)
9 to 10	17 (0.1)
Any tenderness	1291 (5.7)
Swelling (n = 22 783)	
None	22 282 (97.8)
<1 cm	183 (0.8)
1 to <2.5 cm	170 (0.8)
2.5 to <5 cm	111 (0.5)
≥ 5 cm	37 (0.2)
Any swelling	501 (2.2)
Erythema (n = 22 784)	
None	22 308 (97.9)
<1 cm	244 (1.1)
1 to <2.5 cm	132 (0.6)
2.5 to <5 cm	85 (0.4)
≥ 5 cm	15 (0.1)
Any erythema	476 (2.1)
Palpable cord (n = 22 783)	96 (0.4)
Purulence (n = 22 786)	5 (0.0)
Warmth (n = 22 789)	66 (0.3)
Leakage (n = 22 789)	229 (1.0)

Abbreviation: cm, centimeters.

^aOut of 10 (maximum) on a severity scale.

Because most patients contributed more than 1 set of observations to the dataset, this had the potential to introduce systematic error, which likely was overcome by the large sample size.

Phlebitis assessment is acknowledged to be problematic because of both the diversity of available scores and scales and the general lack of agreement between scales.^{8,15} More rigorous and validated means of identifying the signs of phlebitis are needed. If nurses are to spend time completing such

TABLE 2

Correlations Between Phlebitis Signs/Symptoms^a

	Pain	Tenderness	Swelling	Erythema	Palpable Cord	Purulence	Warmth
Tenderness	0.19 (0.18-0.20)	NA	NA	NA	NA	NA	NA
Swelling	0.28 (0.26-0.29)	0.33 (0.32-0.34)	NA	NA	NA	NA	NA
Erythema	0.19 (0.17-0.20)	0.27 (0.26-0.29)	0.35 (0.34-0.36)	NA	NA	NA	NA
Palpable cord	0.30 (0.18-0.42)	0.55 (0.42-0.68)	0.34 (0.21-0.46)	0.61 (0.49-0.74)	NA	NA	NA
Purulence	0.03 (0.02-0.03)	0.76 (0.32-1.00)	0.55 (0.00-1.00)	0.78 (0.37-1.00)	0.00 (0.00-0.01)	NA	NA
Warmth	0.50 (0.34-0.66)	0.81 (0.70-0.92)^b	0.81 (0.71-0.92)^b	0.83 (0.72-0.93)^b	0.16 (0.15-0.17)	0.00 (0.00-0.01)	NA
Leakage	0.05 (0.00-0.09)	0.08 (0.02-0.15)	0.05 (0.00-0.09)	0.01 (0.00-0.04)	0.01 (0.00-0.02)	0.03 (0.02-0.04)	0.01 (0.00-0.02)

Abbreviation: NA, not applicable.

^aAbsolute values shown, including 95% confidence intervals.

^bBold values indicate a significant result at ≥ 0.70 and lower bound ≥ 0.50 .

tools, they need to reliably identify SPCs in need of removal and to prompt appropriate action. Until such a tool exists, the authors advocate regular reassessment of the insertion site and early removal for signs of any complications and as soon as the SPC is no longer clinically needed.^{10,16}

This study found that the incidences of phlebitis signs/symptoms were generally low, and the signs/symptoms did not correlate with each other, apart from *warmth* with *tenderness*, *warmth* with *swelling*, and *warmth* with *erythema*. The study will inform future development and validation of phlebitis diagnostic and prediction procedures that can potentially improve nurses' ability to assess, make decisions, and improve outcomes for patients with SPCs.

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REFERENCES

- Hadaway L. Short peripheral intravenous catheters and infections. *J Infus Nurs.* 2012;35(4):230-340.
- Gorski L, Hadaway L, Hagle ME, McGoldrick M, Orr M, Doelman D. Infusion therapy standards of practice. *J Infus Nurs.* 2016; 39(suppl 1):S1-S159.
- Loveday HP, Wilson JA, Pratt RJ, et al. epic3: national evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. *J Hosp Infect.* 2014;86(suppl 1): S1-S70.
- Tagalakis V, Kahn SR, Libman M, Blostein M. The epidemiology of peripheral vein infusion thrombophlebitis: a critical review. *Am J Med.* 2002;113(2):146-151.
- Dychter SS, Gold DA, Carson D, Haller M. Intravenous therapy: a review of complications and economic considerations of peripheral access. *J Infus Nurs.* 2012;35(2):84-91.
- Hawes ML. A proactive approach to combating venous depletion in the hospital setting. *J Infus Nurs.* 2007;30(1):33-44.
- Helm RE, Klausner JD, Klemperer JD, Flint LM, Huang E. Accepted but unacceptable: peripheral IV catheter failure. *J Infus Nurs.* 2015;38(3):189-203.
- Ray-Barruel G, Polit DF, Murfield JE, Rickard CM. Infusion phlebitis assessment measures: a systematic review. *J Eval Clin Pract.* 2014;20(2):191-202.
- Doust J. Using probabilistic reasoning. *BMJ.* 2009;339:b3823. doi: 10.1136/bmj.b3823.
- Rickard CM, Webster J, Wallis MC, et al. Routine versus clinically indicated replacement of peripheral intravenous catheters: a randomised controlled equivalence trial. *Lancet.* 2012;380(9847):1066-1074.
- Altman DG, Bland JM. Measurement in medicine: the analysis of method comparison studies. *Statistician.* 1983;32(3):307-317.
- Newson R. Confidence intervals for rank statistics: Somers' D and extensions. *Stata J.* 2006;6(3):309-334.
- Hinkle DE, Wiersma W, Jurs SG. *Applied Statistics for the Behavioral Sciences.* 5th ed. Boston, MA: Houghton Mifflin; 2003.
- Alexandrou E, Ray-Barruel G, Carr PJ, et al. International prevalence of the use of peripheral intravenous catheters. *J Hosp Med.* 2015;10(8):530-533.
- Marsh N, Mihala G, Ray-Barruel G, Webster J, Wallis MC, Rickard CM. Inter-rater agreement on PIVC-associated phlebitis signs, symptoms and scales. *J Eval Clin Pract.* 2015;21(5):893-899.
- Webster J, Lloyd S, Hopkins T, Osborne S, Yaxley M. Developing a Research base for Intravenous Peripheral cannula re-sites (DRIP trial). A randomised controlled trial of hospital in-patients. *Int J Nurs Stud.* 2007;44(5):664-671.