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ORIGINAL ARTICLE

Risk Factors for Peripheral Intravenous Catheter Failure: A Multivariate Analysis of Data from a Randomized Controlled Trial

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OBJECTIVE. To assess the relative importance of independent risk factors for peripheral intravenous catheter (PIVC) failure.

METHODS. Secondary data analysis from a randomized controlled trial of PIVC dwell time. The Prentice, Williams, and Peterson statistical model was used to identify and compare risk factors for phlebitis, occlusion, and accidental removal.

SETTING. Three acute care hospitals in Queensland, Australia.

PARTICIPANTS. The trial included 3,283 adult medical and surgical patients (5,907 catheters) with a PIVC with greater than 4 days of expected use.

RESULTS. Modifiable risk factors for occlusion included hand, antecubital fossa, or upper arm insertion compared with forearm (hazard ratio [HR], 1.47 [95% confidence interval (CI), 1.28–1.68], 1.27 [95% CI, 1.08–1.49], and 1.25 [95% CI, 1.04–1.50], respectively); and for phlebitis, larger diameter PIVC (HR, 1.48 [95% CI, 1.08–2.03]). PIVCs inserted by the operating and radiology suite staff had lower occlusion risk than ward insertions (HR, 0.80 [95% CI, 0.67–0.94]). Modifiable risks for accidental removal included hand or antecubital fossa insertion compared with forearm (HR, 2.45 [95% CI, 1.93–3.10] and 1.65 [95% CI, 1.23–2.22], respectively), clinical staff insertion compared with intravenous service (HR, 1.69 [95% CI, 1.30–2.20]); and smaller PIVC diameter (HR, 1.29 [95% CI, 1.02–1.61]). Female sex was a nonmodifiable factor associated with an increased risk of both phlebitis (HR, 1.64 [95% CI, 1.28–2.09]) and occlusion (HR, 1.44 [95% CI, 1.30–1.61]).

CONCLUSIONS. PIVC survival is improved by preferential forearm insertion, selection of appropriate PIVC diameter, and insertion by intravenous teams and other specialists.

TRIAL REGISTRATION. The original randomized controlled trial on which this secondary analysis is based is registered with the Australian New Zealand Clinical Trials Registry (http://www.anzctr.org.au; ACTRN12608000445370).

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Peripheral intravenous catheters (PIVCs) are the most frequently used invasive devices in acute care settings. Recent studies document that 33%–67% of patients have a PIVC inserted during their hospitalization,[1-3] and approximately 330 million devices are used in the United States each year.[4] Although some PIVCs are never used,[5,6] and others are removed when treatment ceases, many PIVCs are removed because of complications. These complications include phlebitis, local infection, bloodstream infection, infiltration, occlusion, extravasation, and inadvertent removal.[1,7-11] These lead to personal discomfort, increased medical treatment and length of hospital stay, increased costs, and death.[11]

Many earlier studies and reviews have focused on the risk factors for phlebitis alone,[1,9,12] have used composite measures,[10,13,14] or have selected only 2 specific causes of failure,[7] and thus have not considered all major complications causing PIVC failure. In addition, the results of previous studies related to risk factors for catheter failure have produced contradictory results (eg, variable direction of phlebitis risk associated with sex).[15-17] In this study, we sought to determine the potentially modifiable factors associated with catheter failure, and so provide guidance for prevention of catheter failure, improvement in patient outcomes, and reduction in healthcare costs.

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METHODS

This study used data from a large multicenter trial that compared different regimens of PIVC replacement.[18] Data were collected in 3 hospitals in Queensland, Australia, from May 2008 to September 2009. Ethics committee approval was obtained from Griffith University (NRS/07/08/HREC). All participants gave written, informed consent before participation. Adult patients in medical and surgical units with PIVCs expected to be required for 4 or more days were randomized to third-daily routine replacement or replacement on clinical indication. Exclusion criteria were a current bloodstream infection, planned PIVC removal within 24 hours, or PIVC already in situ for more than 72 hours.

Of the 3 hospitals involved in the trial, the Royal Brisbane and Women's Hospital (RBWH) and the Princess Alexandra Hospital (PAH) are large metropolitan hospitals managing 80,000 admissions per year (average length of stay, 6.5 days). The Gold Coast Hospital (GCH) is a large regional hospital which also has approximately 80,000 admissions a year but a shorter average length of stay (4.7 days). GCH did not have a PIVC insertion or monitoring service. The RBWH and PAH had PIVC insertion-only services that inserted approximately half of the catheters in the study. The remainder were inserted by general clinical staff. All study PIVCs were inserted into the upper limb.

In total, 3,283 patients (accounting for 5,907 catheters) were enrolled. Baseline data were collected at the time of study entry and with every new catheter. Clinical staff cared for the catheters (Insyte and Autoguard; Becton Dickinson). Separate data were collected by trained research nurses who assessed patients daily for outcomes and a range of potential risk factors. Of the 5,907 catheters, 1,512 (25.6%) failed as a result of occlusion, 375 (6.4%) were accidentally removed, and 273 (4.6%) were inserted in patients who developed phlebitis.

DEFINITIONS

In this multivariate analysis, 3 separate catheter failure outcomes were considered: (1) phlebitis; (2) occlusion (including infiltration, unintended iatrogenic leakage of fluids from vein into surrounding tissues, and obstruction of flow); and (3) accidental removal. Phlebitis was defined as the simultaneous presence of 2 or more of the following criteria: (1) pain and/or tenderness with a severity of 2 or more on a 10-point scale (with 0 defined as no pain and 10 defined as the worst imaginable pain); (2) erythema extending to at least 1 cm from the insertion site; (3) swelling extending to at least 1 cm from the insertion site; (4) purulent discharge from the insertion site (dichotomous); and (5) a palpable venous cord beyond the tip of the catheter (dichotomous).

Occlusion and accidental removal were the terms used by the clinical staff to describe failure when they removed a catheter. Occlusion was defined as any circumstance in which the PIVC was still in place but it was not possible to flush the catheter or infuse fluids (relatively synonymous terms include blockage, infiltration, extravasation, and "tissuing"). Accidental removal was defined as catheter dislodgement that was not planned.

STATISTICAL ANALYSIS

The outcomes of interest were time-dependent (survival data/hazard rates); thus, Cox proportional hazards regression models were used for time-to-event analysis. Because multiple catheters per patient were studied, the conditional risk set model developed by Prentice, Williams, and Peterson (PWP)[19] was used, which extends the Cox model conditional on patients only being at risk of the jth event after the $(j-1)$th event occurs. All results reported in this article are based on the PWP model. All results are per PIVC, because per patient analyses were not appropriate to considering PIVC-related covariates that vary within patients.

We prespecified potential patient-related, catheter-related, and healthcare-related risk factors for the risk models (included in Table 1). Initially, bivariate associations were examined for the 3 outcomes and all possible covariates using time-adjusted rates. The 3 outcomes were (i) phlebitis, (ii) occlusion, and (iii) accidental removal. After bivariate analyses, covariates were assessed in 3 separate multivariate models. The statistical software used for the analyses was StataSE 12 (StataCorp). A 2-sided significance level of 5% was used throughout.

Admission type, presence of a drain or stoma, receipt of oral antibiotics, and receipt of intravenous potassium were also tested but were not significantly associated with the 3 outcomes and were not risk factors in the multivariate analyses.

RESULTS

The baseline characteristics of patients and PIVCs as well as their incidence against the 3 types of failure outcomes are presented in Table 1. The mean age of all subjects was 54.8 years, with the mean age of patients with phlebitis being 51.6 years ($P < .01$). There was no statistically significant difference in age associated with occlusion or accidental removal.

Bivariate Analyses

The bivariate analyses are shown in Table 1. Phlebitis was significantly associated with being female, being younger, having a current infection, or currently receiving intravenous antibiotics. Significantly fewer cases of phlebitis were seen among those receiving "other" intravenous medications (ie, intravenous medications other than antibiotics, antipyretics, or hydrocortisone).

Occlusion was significantly associated with being female; current infection; subsequent catheters compared with the first catheter; insertion in the antecubital fossa, hand, or upper arm compared with the forearm; and receiving intravenous antibiotics. Significantly fewer cases of occlusion were seen with 18-gauge or larger catheters; insertion in the ra-

TABLE 1. Baseline Clinical Characteristics and Crude Outcome Counts by Type of Catheter Failure

Category	All catheters, % (n = 5,907)	Cases per 1,000 days (IRR, 95% CI)		
		Occlusion (n = 1,512)	Accidental removal (n = 375)	Phlebitis (n = 273)
Sex				
Male (reference)	64.3	77.9 (1.00)	21.8 (1.00)	13.4 (1.00)
Female	35.7	104.5 (1.34, 1.21–1.49)[a]	21.0 (0.97, 0.77–1.20)	20.5 (1.51, 1.17–1.93)[a]
No. of comorbidities				
0 (reference)	23.9	82.8 (1.00)	26.2 (1.00)	16.1 (1.00)
1	21.4	89.9 (1.09, 0.93–1.27)	19.5 (0.74, 0.54–1.02)	15.1 (0.94, 0.64–1.37)
2 or more	54.7	87.0 (1.05, 0.92–1.20)	20.4 (0.78, 0.61–0.99)[b]	15.6 (0.97, 0.72–1.32)
PIVC size				
20 gauge (reference)	55.4	88.0 (1.00)	18.9 (1.00)	15.2 (1.00)
18 gauge or larger	15.4	74.3 (0.84, 0.72–0.98)[b]	27.0 (1.43, 1.08–1.88)[a]	18.6 (1.22, 0.88–1.68)
22 gauge or smaller	29.2	91.2 (1.04, 0.92–1.16)	23.8 (1.26, 0.99–1.60)	14.9 (0.98, 0.73–1.31)
Inserted by				
IV service (reference)	39.8	88.4 (1.00)	12.8 (1.00)	15.1 (1.00)
Clinical staff	60.2	85.5 (0.97, 0.87–1.07)	27.4 (2.15, 1.69–2.76)[a]	16.1 (1.06, 0.83–1.37)
Hospital				
A (reference)	39.4	90.5 (1.00)	12.7 (1.00)	15.3 (1.00)
B	35.7	80.7 (0.89, 0.79–1.00)	21.9 (1.73, 1.31–2.27)[a]	13.7 (0.89, 0.67–1.20)
C	24.9	89.0 (0.98, 0.86–1.12)	36.8 (2.90, 2.22–3.80)[a]	19.0 (1.24, 0.92–1.68)
Inserted in				
Ward (reference)	77.1	89.4 (1.00)	20.5 (1.00)	15.3 (1.00)
DEM	10.0	89.0 (1.00, 0.84–1.18)	23.7 (1.15, 0.81–1.61)	21.4 (1.40, 0.96–2.00)
OT/radiology	12.9	72.8 (0.81, 0.69–0.96)[b]	25.3 (1.23, 0.91–1.64)	14.8 (0.97, 0.65–1.40)
Current infection				
No (reference)	82.3	80.9 (1.00)	21.9 (1.00)	14.4 (1.00)
Yes	17.7	113.7 (1.41, 1.24–1.59)[a]	19.6 (0.90, 0.67–1.18)	21.3 (1.48, 1.10–1.96)[a]
Which PIVC				
First (reference)	55.6	77.0 (1.00)	22.0 (1.00)	14.0 (1.00)
Second	25.0	99.9 (1.30, 1.15–1.47)[a]	20.1 (0.91, 0.70–1.19)	17.0 (1.21, 0.89–1.63)
Third	11.4	104.0 (1.35, 1.15–1.59)[a]	19.4 (0.88, 0.60–1.26)	18.3 (1.30, 0.86–1.91)
Fourth	5.3	101.9 (1.32, 1.05–1.65)[b]	28.9 (1.31, 0.83–1.99)	22.0 (1.57, 0.92–2.53)
Fifth	2.7	96.9 (1.26, 0.92–1.68)	15.8 (0.72, 0.31–1.44)	17.8 (1.27, 0.57–2.47)
Insert in vein				
Forearm (reference)	54.5	78.6 (1.00)	14.7 (1.00)	15.0 (1.00)
Antecubital fossa	12.8	92.6 (1.18, 1.00–1.38)[b]	29.2 (1.99, 1.44–2.71)[a]	15.8 (1.05, 0.70–1.55)
Hand	22.4	102.1 (1.30, 1.14–1.48)[a]	40.0 (2.72, 2.13–3.47)[a]	15.0 (1.00, 0.71–1.39)
Wrist	2.6	86.4 (1.10, 0.85–1.39)	21.9 (1.49, 0.87–2.41)	17.3 (1.15, 0.63–1.96)
Upper arm	7.7	99.6 (1.27, 1.05–1.52)[b]	15.8 (1.07, 0.65–1.68)	20.1 (1.34, 0.86–2.01)
IV antibiotics				
No (reference)	31.1	65.8 (1.00)	18.8 (1.00)	11.8 (1.00)
Yes	68.9	96.3 (1.46, 1.30–1.65)[a]	22.7 (1.21, 0.96–1.53)	17.5 (1.48, 1.12–1.99)[a]
IV antipyretic				
No (reference)	94.6	87.9 (1.00)	20.9 (1.00)	15.8 (1.00)
Yes	5.4	67.5 (0.77, 0.60–0.97)[b]	31.4 (1.50, 1.02–2.15)[b]	13.3 (0.84, 0.45–1.44)
IV hydrocortisone				
No (reference)	97.2	86.1 (1.00)	21.4 (1.00)	15.5 (1.00)
Yes	2.8	106.6 (1.24, 0.92–1.64)	25.1 (1.17, 0.60–2.07)	20.9 (1.35, 0.64–2.52)
IV "other"				
No (reference)	57.9	96.3 (1.00)	19.2 (1.00)	18.0 (1.00)
Yes	42.1	74.8 (0.78, 0.70–0.86)[a]	24.3 (1.26, 1.03–1.56)[b]	12.8 (0.71, 0.55–0.91)[a]

NOTE. CI, confidence interval; DEM, Department of Emergency Medicine; IRR, incidence rate ratio; IV, intravenous; OT, operating theater; PIVC, peripheral intravenous catheter.

[a] $P \leq .01$ for bivariate association.

[b] $P \leq .05$ for bivariate association.

TABLE 2. Independent Risk Factors for Phlebitis

Risk factor	HR	95% CI	*P*
Female sex	1.64	1.28–2.09	<.001
Size 18 gauge or larger compared with size 20 gauge	1.48	1.08–2.03	.014
Current infection	1.41	1.05–1.89	.022
Age	0.99[a]	0.98–0.99	<.001
Other drugs infused through IV	0.72	0.56–0.92	.009

NOTE. Findings are from a multivariate Cox proportional hazards regression model with conditional risk sets that included phlebitis events as time-dependent covariates. CI, confidence interval; HR, hazard ratio; IV, intravenous catheter.

[a] Increase in age by 1 year decreased the HR by 1.1%.

diology or operating theater suite; or being prescribed oral antibiotics, intravenous antipyretics, or "other" intravenous medications.

Accidental removal was significantly associated with 18-gauge or larger catheter size, insertion by clinical (non–intravenous service) staff, hospital B or C, insertion in the hand or antecubital fossa, and injection of intravenous antipyretics or other intravenous medications. Significantly lower rates of accidental removal were associated with multiple comorbidities and receiving oral antibiotics.

Independent Risk Factors for Phlebitis

Multivariate analysis demonstrated that phlebitis risk increased with younger age (each increased year of age decreased the hazard ratio [HR] by 1.1%), being female, having a larger catheter (18 gauge or larger), or current infection, whereas decreased risk was associated with infusion of "other" intravenous drugs (Table 2).

Independent Risk Factors for Occlusion

Table 3 outlines that significantly higher occlusion was associated with insertion in the hand, antecubital fossa, or upper arm compared with forearm; being female; infusion of antibiotics and/or hydrocortisone; current infection; and use of subsequent rather than first catheters. Significantly reduced risk was associated with insertion in the operating theater or radiology department and with intravenous antipyretic infusion.

Independent Risk Factors for Accidental Removal

Significant predictors of accidental removal included hand or antecubital fossa insertion, compared with the forearm; insertion by non–intravenous service staff, and 22-gauge or smaller PIVC (Table 4). Practice comparison indicated that intravenous service staff, compared with ward staff, inserted smaller catheters (20 gauge or smaller) more frequently (intravenous service, 98.2%; ward staff, 75.7%) and showed a greater preference for using the forearm rather than the hand (intravenous service, 70.6% and 9.6%, respectively; ward staff, 41.9% and 28.6%, respectively).

DISCUSSION

This study confirms that larger catheter size (18 gauge or larger) predicts phlebitis-associated catheter failure[9] but provides new data to show that smaller catheter size (22 gauge or smaller) predicts accidental removal. Current guidelines do not recommend catheter size[20,21] but could recommend preferential use of 20-gauge PIVCs, which are suitable for almost all infusion requirements. This study also confirmed

TABLE 3. Independent Risk Factors for Occlusion

Risk factor	HR	95% CI	*P*
Hand compared with forearm	1.47	1.28–1.68	<.001
Female sex	1.44	1.30–1.61	<.001
Antibiotics infused through IV	1.41	1.25–1.59	<.001
Hydrocortisone infused through IV	1.36	1.03–1.80	.028
Current infection	1.27	1.12–1.44	<.001
Antecubital fossa compared with forearm	1.27	1.08–1.49	.004
Upper arm compared with forearm	1.25	1.04–1.50	.016
Second through fifth cannula compared with first cannula	1.17	1.01–1.35	.037
Inserted in OT/rad compared with ward	0.80	0.67–0.94	.009
Antipyretic infused through IV	0.76	0.59–0.97	.030

NOTE. Findings are from a multivariate Cox proportional hazards regression model with conditional risk sets that included occlusion events as time-dependent covariates. CI, confidence interval; HR, hazard ratio; IV, intravenous catheter; OT/rad, operating theater or radiology.

TABLE 4. Independent Risk Factors for Accidental Removal

Risk factor	HR	95% CI	*P*
Hand compared with forearm	2.45	1.93–3.10	<.001
Insertion by clinical staff compared with IV service	1.69	1.30–2.20	<.001
Antecubital fossa compared with forearm	1.65	1.23–2.22	.001
Size 22 gauge or smaller compared with 20 gauge	1.29	1.02–1.61	.030

NOTE. Findings are from a multivariate Cox proportional hazards regression model with conditional risk sets that included accidental removal events as time-dependent covariates. CI, confidence interval; HR, hazard ratio; IV, intravenous.

insertion site as a predictor of phlebitis-associated catheter failure[9,12,16] but provides new data to show that site also predicts occlusion (the most common failure type).

Current guideline site recommendations are limited to using the upper extremities,[20] avoiding the wrist, and preferring distal areas.[21] Updated guidelines should advise preferential forearm insertion and emphasize the importance of not routinely replacing catheters, because the first catheter is the least likely to fail.

The use of an intravenous service reduced the risk of accidental removal, and insertion by other specialist staff reduced the risk of occlusion. Earlier studies support fewer instances of catheter failure with the use of intravenous services,[22,23] but only one of these studies was a randomized controlled trial (RCT).[23] Additional RCTs are needed to understand optimal intravenous service models (eg, insertion only or including postinsertion management and/or training and surveillance). Extrapolating from our observed associations between intravenous infusion experts and their selection of catheter size and insertion site suggests other potentially effective interventions that need to be tested. These include approaches to training ward staff, the use of care bundles,[24,25] and the use of new dressings and sutureless securement devices.[26,27]

Being female and having an infection were strong predictors of both phlebitis and occlusion. Thus, staff should particularly target these high-risk groups for best-practice insertion, monitoring and maintenance regimens. The increased risk of occlusion with antibiotic and hydrocortisone infusion suggests that improved dilution and flushing regimens are needed; additional research in this area is warranted. Thus, clinical guidelines need to promote standardized inspection and flushing procedures, plus evidence-based dilution of infusates known to predispose to inflammation.

The main strength of this study is that the data were collected during a rigorous RCT with usual insertion and maintenance practices, thus ensuring generalizability; data collection by clinical trials nurses ensured that data were reliable.[18] Limitations include the lack of potentially important data on specific dressings; securement and flushing regimens; all medications infused; and patient variables, such as body mass index, mobility, or cognitive status.

In conclusion, these results indicate that having skilled staff insert 20-gauge catheters into the forearm and careful monitoring and care of women and those receiving highly irritant infusates will maximize survival of PIVCs and decrease adverse patient consequences. These factors will assist in developing education, policies, and guidelines related to PIVC insertion and management. Future research on optimal dressing, securement, dilution, and flushing regimens as well as on models for dedicated intravenous teams needs to be undertaken as a matter of urgency.

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