Title: Risk factors for peripheral intravenous catheter failure: a multivariate analysis of data from a randomized controlled trial

Short Title: Risk factors for PIVC failure

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Keywords

Catherization, Peripheral, Intravenous, Infusions, Risk factors, Phlebitis, Occlusion, Infiltration

Risk factors for peripheral intravenous catheter failure: a multivariate analysis of data from a randomized controlled trial

Abstract

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

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

Setting: Three acute care hospitals in Queensland, Australia.

Participants: The trial included 3283 adult medical/surgical patients (5907 catheters) with a PIVC of expected use > 4 days.

Results: Modifiable risk factors for occlusion included hand, antecubital fossa or upper arm insertion compared to forearm (HR=1.47, 95%CI=1.28 to 1.68; HR=1.27, 95%CI=1.08 to1.49; HR=1.25, 95%CI=1.04 to 1.50); and for phlebitis, larger diameter PIVC (HR=1.48, 95%CI=1.08 to 2.03). Operating/radiology suite inserted PIVCs had lower occlusion risk than ward insertions (HR=0.80, 95%CI=0.67 to 0.94). Modifiable risks for accidental removal included hand or antecubital fossa insertion compared to forearm (HR=2.45, 95%CI=1.93 to 3.10; HR=1.65, 95%CI = 1.23 to 2.22), clinical staff insertion compared to IV service, (HR=1.69, 95%CI=1.30 to 2.20); and smaller PIVC diameter (HR=1.29, 95%CI=1.02 to 1.61). Female gender was a non-modifiable 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=1.28-1.68).

Conclusion: PIVC survival is improved by: preferential forearm insertion, selection of appropriate PIVC diameter, and insertion by IV teams/other specialists.

Trial registration: The original randomised 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.

Introduction

Peripheral intravenous catheters (PIVCs) are the most frequently utilised invasive devices in acute care settings. Recent studies document that 33-67% of patients have a PIVC inserted during their admission [1-3] and approximately 330 million devices are used in the USA each year [4]. While 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 previous studies and reviews have focused on the risk factors for phlebitis alone [e.g.1, 9, 12], have used composite measures [e.g. 10, 13, 14] or have selected only two specific causes of failure [e.g. 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 (e.g. variable direction of phlebitis risk associated with gender) [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.

Methods

This study used data from a large multicentre trial comparing different regimens of PIVC replacement [18]. Data were collected in three 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 prior to participation. Adult patients, in medical and surgical units, with PIVCs expected to be required for 4 or more days were randomised 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 three 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 with also ~ 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 about 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, 3283 patients (5907 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™ Autoguard™, BD, Franklin Lakes). Separate data were collected by trained research nurses who assessed patients daily for outcomes and a range of potential risk factors. Of the 5907 catheters, 1512 (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 three 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 two or more of the following criteria, present simultaneously: (1) pain/ tenderness with a severity of two or more on a ten point scale (0 = no pain; 10 = worst imaginable pain); (2) erythema extending to at least 1cm from the insertion site; (3) swelling extending to at least 1cm from the insertion site; (4) purulent discharge from the insertion site (dichotomous); (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 where 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. As multiple catheters per patient were studied, the conditional risk set model developed by Prentice, Williams and Peterson (PWP)[25] 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 paper are based on the PWP model. All results are per PIVC since per patient analyses were not appropriate to considering PIVC-related covariates that vary within patients.

We pre-specified 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 three outcomes and all possible covariates using time-adjusted rates. The three outcomes were: (i) phlebitis; (ii) occlusion; and (iii) accidental removal. Following bivariate analyses, covariates were assessed in three separate multivariate models. The statistical software used for the analyses was StataSE 12 (StataCorp, TX, USA). A 2-sided significance level of 5% was used throughout.

Results

The baseline characteristics of patients and PIVCs, and their incidence against the three 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 ($p<0.01$). 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 IV antibiotics. Significantly less phlebitis was seen in those receiving "other" IV medications i.e. intravenous medications other than antibiotics, antipyretics or hydrocortisone.

Occlusion was significantly associated with being female; current infection; subsequent catheters compared to the first catheter; insertion in the antecubital fossa, hand or upper arm compared to the forearm; and receiving IV antibiotics. Significantly less occlusion was seen with 18 gauge (G) or larger catheters, insertion in the radiology/operating theatre suite, or being prescribed oral antibiotics, IV antipyretics, or "other" IV medications.

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

Table 1: Baseline Clinical Characteristics and Crude Outcome Counts by Type of Catheter Failure

Characteristic	**Category**	**All catheters (n=5907)**	**Occlusion (n=1512)**	**Accidental Removal (n=375)**	**Phlebitis (n=273)**
	***Reference* / Comparator group**	**%**	**Rate /1000 days (IRR, 95% CI)**	**Rate /1000 days (IRR, 95% CI)**	**Rate /1000 days (IRR, 95% CI)**
Gender	Male	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)†	21.0 (0.97, 0.77-1.20)	20.5 (1.51, 1.17-1.93)†
Number of Comorbidities	0	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+	54.7%	87.0 (1.05, 0.92-1.20)	20.4 (0.78, 0.61-0.99)*	15.6 (0.97, 0.72-1.32)
PIVC Size	=20	55.4%	*88.0 (1.00)*	*18.9 (1.00)*	*15.2 (1.00)*
	<=18	15.4%	74.3 (0.84, 0.72-0.98)*	27.0 (1.43, 1.08-1.88)†	18.6 (1.22, 0.88-1.68)
	>=22	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	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)†	16.1 (1.06, 0.83-1.37)
Hospital	A	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)†	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)†	19.0 (1.24, 0.92-1.68)

Table 1 continued

Characteristic	Category	All catheters (n=5907)	Occlusion (n=1512)	Accidental Removal (n=375)	Phlebitis (n=273)
	***Reference* / Comparator group**	**%**	**Rate /1000 days (IRR, 95% CI)**	**Rate /1000 days (IRR, 95% CI)**	**Rate /1000 days (IRR, 95% CI)**
Inserted In	Ward	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)*	25.3 (1.23, 0.91-1.64)	14.8 (0.97, 0.65-1.40)
Current infection	No	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)†	19.6 (0.90, 0.67-1.18)	21.3 (1.48, 1.10-1.96)†
Which PIVC	1st	55.6%	*77.0 (1.00)*	*22.0 (1.00)*	*14.0 (1.00)*
	2nd	25.0%	99.9 (1.30, 1.15-1.47)†	20.1 (0.91, 0.70-1.19)	17.0 (1.21, 0.89-1.63)
	3rd	11.4%	104.0 (1.35, 1.15-1.59)†	19.4 (0.88, 0.60-1.26)	18.3 (1.30, 0.86-1.91)
	4th	5.3%	101.9 (1.32, 1.05-1.65)*	28.9 (1.31, 0.83-1.99)	22.0 (1.57, 0.92-2.53)
	5th	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	*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)*	29.2 (1.99, 1.44-2.71)†	15.8 (1.05, 0.70-1.55)
	Hand	22.4%	102.1 (1.30, 1.14-1.48)†	40.0 (2.72, 2.13-3.47)†	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)*	15.8 (1.07, 0.65-1.68)	20.1 (1.34, 0.86-2.01)

Table 1 continued

Characteristic	Category	All catheters (n=5907)	Occlusion (n=1512)	Accidental Removal (n=375)	Phlebitis (n=273)
	Reference / Comparator group	**%**	**Rate /1000 days (IRR, 95% CI)**	**Rate /1000 days (IRR, 95% CI)**	**Rate /1000 days (IRR, 95% CI)**
Insert in vein	Forearm	*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)*	29.2 (1.99, 1.44-2.71)†	15.8 (1.05, 0.70-1.55)
	Hand	22.4%	102.1 (1.30, 1.14-1.48)†	40.0 (2.72, 2.13-3.47)†	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)*	15.8 (1.07, 0.65-1.68)	20.1 (1.34, 0.86-2.01)
IV antibiotics	No	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)†	22.7 (1.21, 0.96-1.53)	17.5 (1.48, 1.12-1.99)†
IV antipyretic	No	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)*	31.4 (1.50, 1.02-2.15)*	13.3 (0.84, 0.45-1.44)
IV hydrocortisone	No	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	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)†	24.3 (1.26, 1.03-1.56)*	12.8 (0.71, 0.55-0.91)†

*P≤0.05 for bivariate association †P≤0.01 for bivariate association

IRR = incidence rate ratio; CI = Confidence Interval; DEM = Department of Emergency Medicine; OT = Operating Theatre.

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

Independent risk factors for phlebitis

Multivariate analysis demonstrated that phlebitis risk was increased by being younger (each increased year of age decreased the hazard ratio (HR) by 1.1%), being female, having a larger catheter (≤ 18G) or current infection, while decreased risk was seen with having "other" IV drugs infused (See Table 2).

Table 2: Independent Risk Factors for Phlebitis*

Risk factor	Hazard ratio	95% CI	P-value
Female	1.64	1.28 - 2.09	<0.001
Size ≤18 compared to size 20 G	1.48	1.08 – 2.03	0.014
Current infection	1.41	1.05 - 1.89	0.022
Age	0.99**	0.98 - 0.99	<0.001
Other drugs infused through IV	0.72	0.56 - 0.92	0.009

IV = Intravenous

*Findings are from a multivariate Cox proportional hazards regression model with conditional risk sets that included phlebitis events as time-dependent covariates.
** Increase in age by one year decreased the hazard ratio by 1.1%

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 to forearm, being female, infusion of antibiotics and/or hydrocortisone, current infection and use of subsequent rather than first catheters. Significantly reduced risk was seen with insertion in the operating theatre or radiology department, and with IV antipyretic infusion.

Table 3: Independent Risk Factors for Occlusion*

Risk factor	Hazard ratio	95% CI	P-value
Hand compared to forearm	1.47	1.28 - 1.68	<0.001
Female	1.44	1.30 - 1.61	<0.001
Antibiotics infused through IV	1.41	1.25 - 1.59	<0.001
Hydrocortisone infused through IV	1.36	1.03 - 1.80	0.028
Current infection	1.27	1.12 - 1.44	<0.001
Antecubital fossa compared to forearm	1.27	1.08 - 1.49	0.004
Upper arm compared to forearm	1.25	1.04 - 1.50	0.016
2^{nd} – 5^{th} cannula compared to 1^{st} cannula	1.17	1.01 - 1.35	0.037
Inserted in OT/Rad compared to ward	0.80	0.67 - 0.94	0.009
Antipyretic infused through IV	0.76	0.59 - 0.97	0.030

OT/Rad = Operating Theatre or Radiology; IV = Intravenous

*Findings are from a multivariate Cox proportional hazards regression model with conditional risk sets that included occlusion events as time-dependent covariates.

Independent risk factors for accidental removal

Significant predictors of accidental removal included hand or antecubital fossa insertion, compared to the forearm, insertion by non-IV service staff, and size 22G or smaller PIVC (see Table 4). Practice comparison indicated that IV service staff, compared to ward staff, inserted smaller catheters (≥20G) more frequently (clinical staff, 75.7%; IV service, 98.2%), and used the forearm more frequently (70.6% v 41.9%) than the hand (9.6% v 28.6%).

Table 4: Independent Risk Factors for Accidental Removal*

Risk factor	Hazard ratio	95% CI	P-value
Hand compared to forearm	2.45	1.93 – 3.10	<0.001
Insertion by clinical staff compared to IV service	1.69	1.30 - 2.20	<0.001
Antecubital fossa compared to forearm	1.65	1.23 - 2.22	0.001
Size ≥22G compared to size 20G	1.29	1.02 - 1.61	0.030

IV = Intravenous

*Findings are from a multivariate Cox proportional hazards regression model with conditional risk sets that included accidental removal events as time-dependent covariates.

Discussion

This study confirms that larger catheter size (≤18G) predicts phlebitis-associated catheter failure [9] but provides new data to show that smaller catheter size (≥ 22G) predicts accidental removal. Current guidelines do not recommend catheter size [19, 20] but could recommend preferential use of 20G PIVCs which are suitable for almost all infusion requirements. This study also confirmed 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 [19], avoidance of the wrist and preferring distal areas [20]. Updated guidelines should advise preferential forearm insertion, and emphasise the importance of not routinely replacing catheters since the first is the least likely to fail.

The use of an IV service reduced the risk of accidental removal, and insertion by other specialist staff reduced the risk of occlusion. Previous studies support less catheter failure with the use of IV services [21, 22], but only one was a randomised controlled trial (RCT)[22]. Further RCTs are needed to understand optimal IV service models e.g. insertion only, or including post-insertion management and/or training and surveillance. Extrapolating from our observed associations between IV infusion experts and their selection of catheter size and insertion site suggest other potentially effective interventions that need to be tested. These include approaches to up-skilling general staff, the use of care bundles [23, 24] and the use of new dressings and sutureless securement devices [25, 26].

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; further research in this area is warranted. Thus, clinical guidelines need to promote standardised 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, and data collection by clinical trials nurses – thereby ensuring reliable data [18]. Limitations include the lack of potentially important data on specific dressings, securement and flushing regimens, all medications infused, and patient variables such as BMI, mobility or cognitive status.

In conclusion, these results indicate that having skilled staff insert size 20G catheters into the forearm, and careful monitoring and care of women and those receiving highly irritant infusates will maximise PIVC survival, 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 models for dedicated IV teams needs to be undertaken as a matter of urgency.

Competing Interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) MW, CR, JW, JG & NM have support from an Australian National Health and Medical Research Council (NHMRC) Project Grant for the submitted work; (2) MM has relationship with NHMRC that might have an interest in the submitted work in the previous 3 years; (3) CR and NM have received a grant in aid from Becton Dickinson (BD) that is unrelated to this project; (4) their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (5) all authors have no non-financial interests that may be relevant to the submitted work.

Authorship

All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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