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ORIGINAL ARTICLE

Flushing of peripheral intravenous catheters: A pilot, factorial, randomised controlled trial of high versus low frequency and volume in paediatrics

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Aim: To test the feasibility of an efficacy trial comparing different flushing frequencies and volumes to reduce peripheral intravenous cannula (PIVC) failure in paediatric inpatients.

Methods: Pilot, 2 × 2 factorial, randomised controlled trial comparing PIVC flushing techniques in intervention pairs: (i) low volume (3 mL) versus high volume (10 mL); and (ii) low frequency (24 hourly) versus high frequency (6 hourly). Patients were excluded if: fluids were restricted, weight < 5 kg, PIVC already *in situ* for >24 h or continuous infusion. The primary end-point was feasibility (eligibility, recruitment, retention, protocol adherence, missing data and sample size estimates) of a large trial. Secondary end-points were PIVC failure (composite and individual), bloodstream infection and mortality.

Results: A total of 919 children were screened from April to November 2015, with 55 enrolled. Screening feasibility criteria were not met, mainly due to continuous infusions and PIVCs *in situ* >24 h or planned for imminent removal. However, 80% of eligible participants consented, 2% withdrew, protocol adherence was 100%, and there was no missing primary end-point data. PIVC failure was significantly higher (hazard ratio = 2.90, 95% confidence interval: 1.11–7.54) in the 3 mL compared to the 10 mL group. There was no difference in failure between frequency groups (hazard ratio = 0.91, 95% confidence interval: 0.36–2.33). There was no interaction effect (P = 0.22).

Conclusion: Trial feasibility proved challenging due to eligibility criteria, which could be improved with additional recruiting staff. Firm conclusions cannot be made based on this small sample, but flush volume may impact PIVC failure.

Key words: adverse effects; catheterisation; paediatric; peripheral venous device; randomised controlled trial.

What is already known on this topic

1 Peripheral intravenous cannula (PIVC) is a commonly used medical device; however, failure is high.
2 PIVC requires regular flush to maintain patency.
3 There is a paucity of research and a high degree of practice variation in the flushing frequency and volume of PIVC to maintain patency.

What this paper adds

1 This is the first paediatric study to compare various flush volumes and frequencies.
2 Strategies to improve PIVC insertion and management must be inter-disciplinary and multi-dimensional.
3 Research is required to investigate additional interventions such as the benefit of continuous intravenous infusion to maintain PIVC patency in paediatric inpatients.

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Conflict of interest: T Kleidon's employer has, on her behalf, received unrestricted research or educational grants from makers of flush products (BD-Bard, Baxter, BBraun, Cardinal Health, Medline). T Kleidon's employer has, on her behalf, received consultancy payments for lectures or expert opinion (3M, Adhezion, Angiodynamics, BD-Bard, Centurion, Cook, Medical Specialties Australia, Smiths Medical, Vygon). S Keogh's employer has, on her behalf, received unrestricted research or educational grants from makers of flush products (Baxter, BD-Bard). S Keogh's employer has, on her behalf, received consultancy payments for lectures or expert opinion (3M, BD-Bard, BBraun). JM Flynn's employer has received, on her behalf, unrestricted research grants from BD-Bard manufacturer of study products. JM Flynn has no other conflict of interest related to this paper. J Schults and G Mihala have no conflict of interest to declare. CM Rickard's employer has, on her behalf, received unrestricted research or educational grants from makers of flush products (3M, Adhezion, Angiodynamics; Baxter; BD-Bard; Centurion Medical Products; Medtronic; Smiths Medical). CM Rickard's employer has, on her behalf, received consultancy payments for lectures or expert opinion (3M, BBraun, BD-Bard, ResQDevices, Smiths Medical).

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Peripheral intravenous catheters (PIVCs) are one of the most commonly used medical devices, used for drug, fluid and blood product administration.[1,2] Of hospitalised children, 47% require the insertion of a PIVC to facilitate medical treatment.[3] Despite their prevalence, PIVCs are inherently associated with mechanical, vascular and infectious complications precipitating failure.[4] PIVC failure remains unacceptably high and occurs, on average, in 40% of adults,[5] largely due to accidental dislodgement, infiltration, occlusion or phlebitis.[5–9] A recent study in acute care paediatrics reported PIVC failure of between 25 and 50%.[4,10] The negative consequences of PIVC failure include patient and health-care outcomes, such as delayed treatment and discharge and increase in pain, discomfort, potential vessel depletion and associated costs.[4,11]

The cost of PIVC replacement has health care, monetary and psychosocial impacts on our vulnerable paediatric patients. Replacement of PIVC in paediatric patients does not always occur on first insertion attempt, adding to the stress and anxiety of PIVC insertion. It is reported that some paediatric patients with difficult intravenous access may require as many as 9+ attempts and 3 h of insertion attempts.[4] It is conservatively estimated to cost 70 AUD (2012) when considering staff time and equipment[12]; however, this estimate is for the adult patient and is likely to be greater in the frightened, anxious paediatric patient where additional resources are required. Paediatric patients and their parents have previously communicated the experience of PIVC insertion to be painful and stressful.[4,13] Parents report that a confident, skilled and organised team can reduce the anxiety related to PIVC insertion.[4,14]

Maintaining PIVC function for the duration of treatment remains an elusive health-care goal. Strategies to reduce PIVC failure include different flushing regimens, but these are used inconsistently,[15] if at all.[12] To date, only one small trial of different flushing regimens[16] and a systematic review of studies evaluating intermittent flush versus slow continuous infusion have been published. This literature indicates that daily flushing is as safe and effective as twice a day. However, results comparing intermittent flushing with continuous infusion remain inconclusive.[17]

Keogh and colleagues[18] described the successful application of the flushing of peripheral intravenous catheters (FliP) protocol in an adult population. The feasibility of this protocol in the paediatric population has not been tested. Research in paediatric patients is challenging due to their distinctive physiology and psychology.[19] Children's vascular access needs and hydration requirements are unique, and research protocols have to reflect this. The aim of this study was to test feasibility aspects, including compliance and recruitment, prior to a full efficacy trial and to collect data for future sample size calculations.

Methods

Study design

A pilot, factorial randomised controlled trial (RCT) was used to compare the effectiveness of different flushing frequencies and volumes to maintain the patency of PIVCs. Pilot studies increase the efficacy of clinical trials by preventing problems with recruitment, retention, protocol adherence and acceptability.[20] The factorial design allowed for more than one clinical question to be tested and more than one intervention per comparison.[21,22] The four arms of the trial were:

1 Low frequency, low volume (Q24h, 3 mL)
2 Low frequency, high volume (Q24h, 10 mL)
3 High frequency, low volume (Q6h, 3 mL)
4 High frequency, high volume (Q6h, 10 mL)

Setting and sample

The Queensland Children's Hospital is a tertiary referral paediatric hospital in Queensland, Australia providing full-spectrum health services to children and young people from birth to 18 years of age.

Participants were consecutively recruited. Patients were eligible for trial enrolment if they required a PIVC for >24 h and were >5 kg. We excluded patients if they were fluid restricted, had continuous intravenous fluids prescribed, if their PIVC was already in place for >24 h or if they were non-English speaking. Ethical approval for the project was obtained through The Children's Health Service District, Queensland (HREC/14/QRCH/233) and Griffith University (NRS/10/14/HREC) Human Research Ethics Committees (HRECs). The trial was prospectively registered with Australian New Zealand Clinical Trials Registry: ACTRN12615000408583. Informed consent was obtained from parents or legal guardians, with children providing Youth Assent when developmentally appropriate.

Interventions

Current practice at the study site was PIVC flushing every 6 h with variable volume based on clinician prescription. Intervention definitions were based on the findings of a large survey of practice and literature.[23] The flushing solution used was isotonic 0.9% sodium chloride, manually prepared and administered by nursing staff. Individual patient study allocation was identified by a colour-coded sticker in the medication chart. Nurses' signature against the prescription on the medication chart confirmed protocol adherence. Clinical staff were provided with education regarding study aims and processes prior to commencement of the study to promote intervention fidelity.

Participant characteristics and PIVC insertion and maintenance

All aspects of PIVC insertion and management were as per routine practice within the hospital. This included skin and hub decontamination with 2% chlorhexidine and 70% alcohol. The site and size of PIVC was based on clinical need and professional judgement. BD Insyte Autoguard (Franklin Lakes) PIVCs were used and secured with Tegaderm I.V. Adhesive Film Dressing Pediatric (3M, Minnesota). Post-insertion care and decisions about PIVC removal were carried out by usual clinical staff (not research staff or intravenous teams). The removal policy was on clinical indication (not time restricted). To ensure protocol fidelity, clinical nursing staff were provided with education regarding study aims and processes by the research nurse (ReN). Clinical nursing staff also provided care and maintenance, including a randomised flushing regimen, to maximise generalisability.

Outcomes

The first primary outcome for this study was feasibility measured as: patient eligibility, recruitment (consent), protocol adherence and retention. The second primary outcome was all-cause PIVC failure: a composite of infection (laboratory-confirmed local or bloodstream infection), occlusion/infiltration (includes leaking), dislodgement, phlebitis and thrombosis (suspected or confirmed). The secondary outcomes included individual elements of PIVC failure: infection (during dwell or up to 48 h after PIVC removal), occlusion (restricts or prevents the administration of fluids), infiltration (leaking of fluid/infusate into surrounding tissue, swelling), dislodgment (partial or total from insertion site) and phlebitis (inflammation of the vein as diagnosed by clinical staff), as well as mortality (collected at trial completion), cost (calculated based on dwell time and equipment used – to be reported in separate health economics evaluation) and dwell time (hours from insertion to removal of PIVC).[24,25]

Sample size

As this was a pilot trial, sample size calculations were not required. The target sample size was 80–100 participants, providing 20–25 patients in each arm, an appropriate sample size for feasibility assessment.[25]

Randomisation and blinding

A web-based randomisation service (https://www151.griffith.edu.au/random) was used to allocate patients to a treatment arm. Randomisation was generated on a 1:1:1:1 ratio with randomly varied block sizes. This ensured allocation concealment. It was not possible to blind patients or clinicians to treatment allocation due to the nature of the interventions. The study statistician was blinded to treatment allocation, as were laboratory staff processing microbiological specimens.

Study procedures

Patients were screened by an ReN for trial eligibility from Monday to Friday during the months of April and November 2015. The ReN obtained written informed consent and initiated the randomisation. Data collection was undertaken via REDCap (Research Electronic Data CAPture; http://project-redcap.org/). Demographic and clinical patient characteristics were collected by the ReN to assess success of randomisation, describe the participant group and capture characteristics that could impact PIVC failure. ReNs visited patients to visually inspect the PIVC daily and up to 48 h post-insertion to assess for infection. As part of

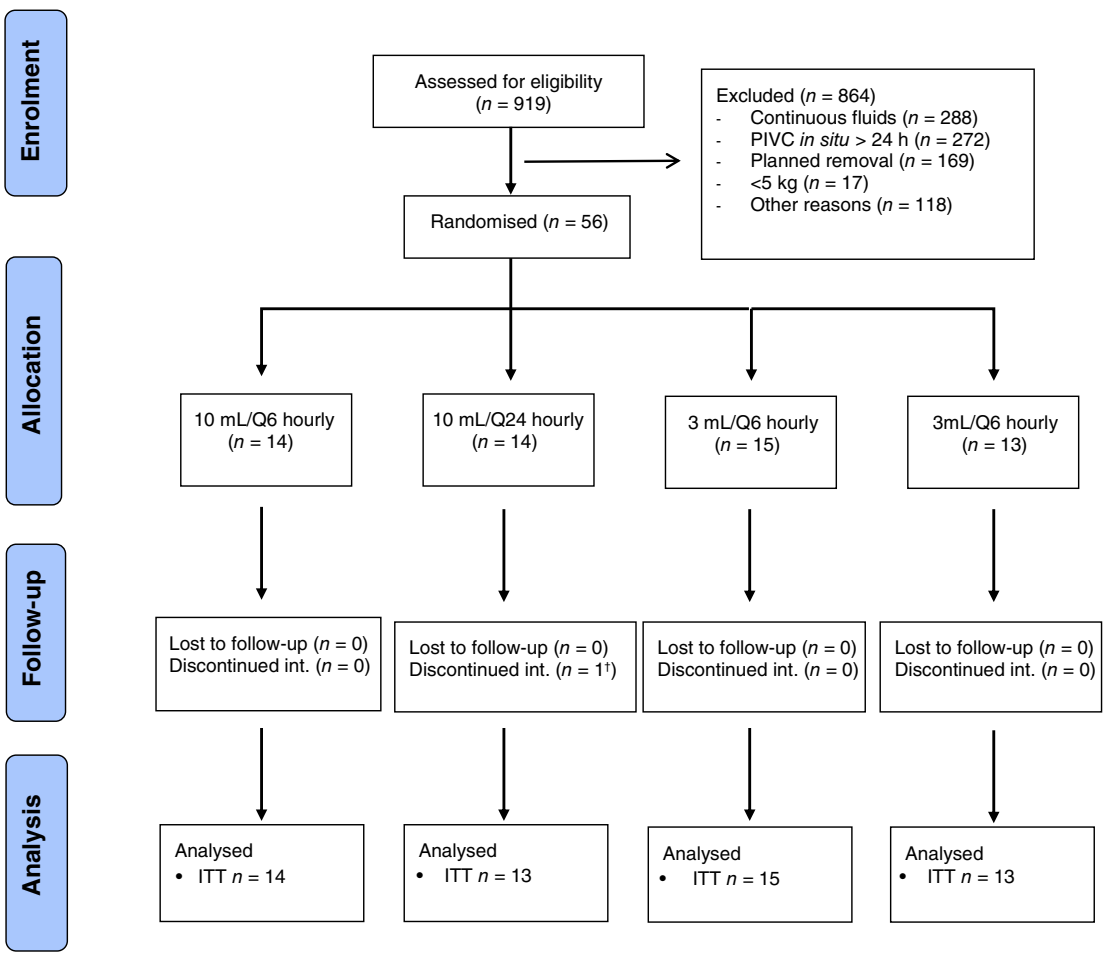

Fig. 1 Participant flow chart. †Parent withdrew patient from study. Int, intervention; ITT, intention to treat.

normal clinical practice, ward registered nurses documented the condition and status of the PIVC, and the ReN collected data on primary and secondary outcomes using the predefined criteria. At device removal (or within 24 h), the ReN asked the patient or parent to rate his or her confidence in the flushing regimen. If bloodstream infection was suspected by clinical staff (not researchers), they ordered blood cultures, and a blinded infectious disease consultant determined outcome of infection. The costs of interventions in each arm were calculated using direct product costs only and did not consider staff resources.

Data analysis

Data were exported to Stata 14 (StataCorp, LLC, TX, USA) for cleaning and analysis. Data cleaning of outlying figures and missing and implausible data was undertaken. Missing values were not imputed. All randomised patients were analysed on an intention-to-treat basis,[26] with patients used as the unit of measurement. Trial feasibility was evaluated using descriptive measures (percentages). Comparability of groups at baseline was assessed using clinical parameters. Mean and standard deviation were used to report continuous data. Kaplan–Meier survival curves and log-rank test were used to compare PIVC survival between interventions. Incidence rates were calculated per 1000 device hours with 95% confidence intervals (CIs). A Cox proportional hazard model (unadjusted for covariates due to low sample size; included only the two interventions and their interaction) was fitted to confirm the findings. An alpha of <0.05 was considered statistically significant.

Ethical considerations

The Children's Health Service District, Queensland (HREC/14/QRCH/233) and Griffith University (NRS/10/14/HREC) HRECs provided ethics and governance approval. Informed, written consent was obtained from parents or legal guardians, with children providing Youth Assent when developmentally appropriate.

Results

Between April and November 2015, 919 children were screened for recruitment, with 68 eligible, and 56 children were recruited to the study. The participant flow chart is displayed in Figure 1, demonstrating enrolment, allocation, follow-up and analysis of participants. One parent withdrew consent following enrolment but provided consent to use data collected to the point of consent withdrawal.

Participant and device characteristics

Table 1 outlines participant and device characteristics. The majority of participants required PIVC insertion for a medical diagnosis (n = 30; 55%), with a mean age of 5.0 years (standard deviation 5.1). In general, PIVCs were inserted by medical officers (n = 45; 82%) in the emergency department (n = 27; 49%), with a 22G PIVC being the most frequently inserted catheter (n = 36; 65%). During the study period, the majority of PIVCs were inserted for intravenous antibiotics (n = 30; 55%) or other intravenous medication (n = 24; 44%). Some imbalance (>10% absolute difference between intervention pairs) was evident in the number of pre-existing comorbidities, presence of wound or infection on admission, location of device insertion, device size and multiple insertion attempts required for successful insertion.

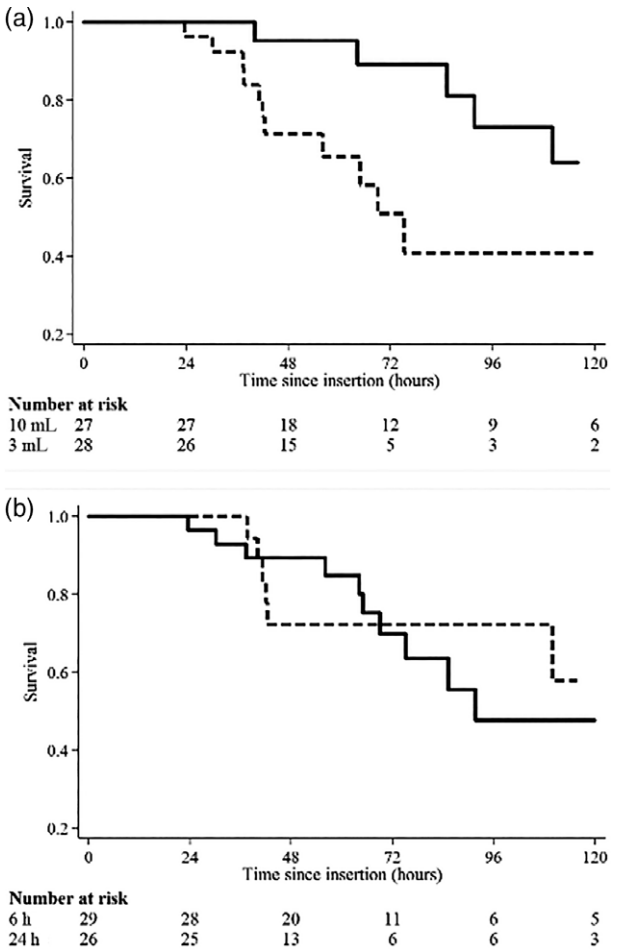

Fig. 2 Kaplan–Meier survival from PIVC failure by (a) flushing volume and (b) flushing frequency. (a) Volume: (——), 10 mL; (-----), 3 mL. (b) Frequency: (——), 6 h; (-----), 24 h.

Feasibility outcomes

Recruitment feasibility was met, with 80% of patients who were approached to participate agreeing to enrol. However, the eligibility feasibility criteria was difficult to achieve using the current protocol. We had anticipated that 80 patients would be recruited over 6 months; however, 94% of patients screened were ineligible due to the exclusion criteria. The main reason for exclusion was administration of continuous intravenous therapy or a PIVC more than 24 h *in situ* when seen by the ReN. No participants were lost to follow-up, and only one participant discontinued the intervention upon parental withdrawal from the study; thus, the retention feasibility criteria were met. All participants received their allocated interventions (feasibility criteria met for protocol adherence). Missing data were less than 5%, and so, these feasibility criteria were also achieved.

Device outcomes

The incidence rate of PIVC failure in the 3 mL group was 2.28 times higher (95% confidence interval (CI): 0.83–6.82)

Table 1 Participant and insertion characteristics at baseline (n = 55)

		Volume		Frequency	
Characteristic	Total, n (%)	10 mL (n = 27), n (%)	3 mL (n = 28), n (%)	6 h (n = 29), n (%)	24 h (n = 26), n (%)
Group size	55 (100)	27 (49)	28 (51)	29 (53)	26 (47)
Age (years in 2015)†	8.5 (5.1)	8.3 (5.0)	8.6 (5.4)	9.1 (5.4)	7.8 (4.9)
Boys	38 (69)	19 (70)	19 (68)	18 (62)	20 (77)
Dominant side: Right	36 (75)	17 (77)	19 (73)	18 (75)	18 (75)
Weight category: Healthy‡	40 (73)	19 (70)	21 (75)	19 (66)	21 (81)
Diagnosis§					
Medical	30 (55)	15 (56)	15 (54)	17 (59)	13 (50)
Emergency surgery	16 (29)	8 (30)	8 (29)	8 (28)	8 (31)
Comorbidities§					
None	30 (55)	14 (52)	16 (57)	16 (55)	14 (54)
One	16 (29)	10 (37)	6 (21)	9 (31)	7 (27)
WBC count low¶	1 (2)	1 (4)	0 (0)	0 (0)	1 (4)
Skin integrity: Good	38 (69)	18 (67)	20 (71)	20 (69)	18 (69)
Wound	16 (29)	10 (37)	6 (21)	7 (24)	9 (35)
Infection	25 (45)	10 (37)	15 (54)	15 (52)	10 (38)
Antibiotic treatment	30 (55)	13 (48)	17 (61)	18 (62)	12 (46)
IV medication therapy	24 (44)	10 (37)	14 (50)	16 (55)	8 (31)
IV therapy					
Intermittent 1–2 time	4 (7)	2 (7)	2 (7)	3 (10)	1 (4)
Intermittent 3–4 time	27 (49)	12 (44)	15 (54)	15 (52)	12 (46)
Intermittent 5+ time	2 (4)	2 (7)	0 (0)	2 (7)	0 (0)
Non-saline flush only	12 (22)	6 (22)	6 (21)	6 (21)	6 (23)
Continuous IV fluids	1 (2)	0 (0)	1 (4)	1 (3)	0 (0)
Nothing	9 (16)	5 (19)	4 (14)	2 (7)	7 (27)
Device location§					
Cubital fossa	21 (38)	11 (41)	10 (36)	14 (48)	7 (27)
Hand	25 (45)	13 (48)	12 (43)	10 (34)	15 (58)
Device in left arm	36 (65)	19 (70)	17 (61)	20 (69)	16 (62)
First device in patient	29 (53)	15 (56)	14 (50)	17 (59)	12 (46)
Inserted by§					
Doctor	45 (82)	23 (85)	22 (79)	24 (83)	21 (81)
Nurse	6 (11)	2 (7)	4 (14)	3 (10)	3 (12)
Inserted at§					
Emergency department	27 (49)	14 (52)	13 (46)	15 (52)	12 (46)
Ward	16 (29)	7 (26)	9 (32)	10 (34)	6 (23)
Operating theatre	9 (16)	5 (19)	4 (14)	2 (7)	7 (27)
Device size§					
Gauge 20	10 (18)	6 (22)	4 (14)	6 (21)	4 (15)
Gauge 22	36 (65)	20 (74)	16 (57)	16 (55)	20 (77)
Gauge 24	8 (15)	1 (4)	7 (25)	7 (24)	1 (4)
Vein quality: Good	16 (84)	6 (75)	10 (91)	8 (80)	8 (89)
Multiple insertion attempts	10 (25)	6 (33)	4 (18)	7 (29)	3 (19)
Preparation with chlorhexidine 2%	26 (81)	11 (73)	15 (88)	15 (83)	11 (79)

†Mean and standard deviation shown. ‡Estimated. §Minor categories not shown. ¶Absolute leukocyte count < 1000/μL within 72 h of trial entry. Proportions (%) calculated with the number of non-missing observations in the denominator. IV, intravenous; WBC, white blood cell.

compared to the 10 mL group (Table 2), with a significantly higher incidence rate ratio (log-rank P = 0.02, Table 2). This was also statistically significant when the *time to event* was considered (hazard ratio (HR): 2.90, 95% CI: 1.11–7.54, P = 0.03, Table 3). These results are consistent with the Kaplan-Meier PIVC survival curve (illustrated in Figure 2). PIVC failure in the 24-hourly flushing group was lower, 0.80 (95% CI: 0.27–2.19, log-rank P = 0.85, Table 2), than that of the 6-hourly group but was not statistically different even when considering the time to event (HR 0.91, 95% CI: 0.36–2.33, P = 0.85, Table 3). There was no significant interaction between the study interventions (P = 0.22, Table 3). No study-related adverse events (bloodstream infection or mortality) occurred.

Table 2 Device outcomes at removal

Outcome	Total, *n* (%)	Volume		Frequency	
		10 mL (*n* = 27), *n* (%)	3 mL (*n* = 28), *n* (%)	6 h (*n* = 29), *n* (%)	24 h (*n* = 26), *n* (%)
Group size	55 (100)	27 (49)	28 (51)	29 (53)	26 (47)
Device failure	19 (35)	7 (26)	12 (43)	12 (41)	7 (27)
Complications					
Occlusion	7 (13)	1 (4)	6 (21)	5 (17)	2 (8)
Infiltration	6 (11)	5 (19)	1 (4)	4 (14)	2 (8)
Phlebitis	4 (7)	0 (0)	4 (14)	3 (10)	1 (4)
Dislodgement	3 (5)	0 (0)	3 (11)	1 (4)	2 (8)
Other	5 (9)	1 (4)	4 (14)	4 (14)	1 (4)
Dwell time (h)†	60 (39–85)	68 (40–116)	49 (37–69)	68 (46–85)	45 (33–71)
Device-hours	3779	2155	1624	2180	1599
Incidence rate‡·§	3.8 (3.2–7.9)	3.25 (1.55–6.81)	7.39 (4.20–13.0)	5.5 (3.1–9.7)	4.4 (2.1–9.2)
Incidence rate ratio‡		Referent	2.28 (0.83–6.82)	Referent	0.80 (0.27–2.19)
Log-rank test		$P = 0.024$		$P = 0.848$	

†Median and 25th–75th percentiles. ‡Including 95% confidence interval. §Per 1000 device-hours. Proportions (%) calculated with the number of non-missing observations in the denominator.

Table 3 Results of unadjusted Cox regression (*n* = 55)

	Crude HR (95% CI)	*P* value
Volume (0 = 10 mL, 1 = 3 mL)	2.90 (1.11–7.54)	0.030
Frequency (0 = 6 h, 1 = 24 h)	0.91 (0.36–2.33)	0.848
Interaction term	3.58 (0.47–27.4)	0.221

CI, confidence interval; HR, hazard ratio.

Cost

Less frequent PIVC flushing might reduce nursing activity and health-care costs and improve the patient experience. However, the combined cost of one 0.9% sodium chloride flush in this trial was AUD1.37. This suggests there is very little cost savings to be derived directly from consumables. However, we did not factor labour into cost calculations, which would be a significant expense to consider when changing the frequency of recommended PIVC flushes.

Discussion

This study was a pilot factorial RCT of intermittent normal saline flushing practices to inform the research protocol and sample size calculations of a definitive trial. This pilot trial in the paediatric setting indicates that a definitive RCT would only be feasible with significant process modifications to improve eligibility. Based on recruiting of between 5 and 10 patients per month, a factorial RCT that would detect an absolute reduction of 10% in PIVC failure would require approximately 950 participants, which is not feasible in one paediatric hospital. However, a group of paediatric centres could achieve this as a multicentre trial if more extensive ReN hours for recruitment were available (including weekends) so as not to miss PIVCs already in place for >24 h at the time of screening.[27] Once eligible patients were approached for consent, or entered the trial, all feasibility criteria, such as retention and protocol adherence, were satisfactorily met.

PIVC failure was significantly associated with decreased flushing volume, suggesting flush volume is associated with PIVC failure in paediatric patients, perhaps due to better clearance of the PIVC with a larger volume or haemodilution of irritant medications. It may also be that nurses incorrectly used syringes that were smaller than the recommended size (e.g. 3 mL or 5 mL instead 10 mL) in the low volume group, which would have increased flush injection pressure on the vein wall. However, our unadjusted analysis did not control for baseline imbalances or other contributing factors such as medication administration (drug type) or flushing injection pressure due to syringe size selection and cannot be seen as definitive.[16]

Initial group comparisons of flushing frequency suggested there was no significant difference in PIVC failure between groups, indicating that once-daily flushing was as good as 6-hourly flushing; however, this may represent a type II error due to the small sample size. Considering the HR of 0.91, once-daily flushing may reduce PIVC failure by a relative 9%, compared to 6-hourly flushing; this would be a clinically important benefit to detect in future studies.

Schreiber *et al*.[16] studied 400 children and found no significant difference in PIVC failure between different flushing frequencies (12 vs. 24 h). Differences between that study and our study were that flushes in Schreiber *et al*.' study were delivered using prefilled syringes (ours were manual), and apart from flushes, their patients did not receive intravenous therapy following enrolment.[16] The results of our study contextualise the use of intermittent flushing in the paediatric clinical setting where medications other than normotonic sodium chloride are infused with the potential to provide various degrees of venous irritation, depending on the chemical make up of the medication that could contribute to PIVC failure.

Zimmerman *et al*.[28] insist that excellent paediatric care is coupled with the inclusion of research. However, undertaking

research in specialised populations is challenging.[19] Parents and health-care professionals are sometimes protective of children and reluctant to involve them in research, although this was not seen in our study. The widespread use of therapies in the neonatal population that are not based on evidence as part of standard clinical care has been described as a lottery, and as 'random' care rather than 'randomised' care,[29] and is not subject to rigorous and unbiased evaluation. Thus, in these specific populations, continuation of standard therapy carries potential risks; treatments may not be effective and may even cause harm. An exclusion criterion in this trial was the prescription of continuous infusion (for fluid replacement or 'to keep vein open' – TKVO). Anecdotally, clinicians prescribe this on the assumed basis that it carries a lower risk than intermittent flushing. The limited evidence available suggests that equipoise exists between these two techniques. Both methods are used variably and inconsistently in clinical practice.[16,17,30]

Our eligibility rates were impacted by PIVCs inserted for greater than 24 h before screening. This could be remedied by sufficient funding to support timely screening, recruitment, data collection and follow-up for a larger trial. We recommend adopting the following strategies in future studies:

1 Tailoring research question to clinical setting and population.
2 Modifying intervention arms to suit the clinical setting and population.
3 Increased funding for study to optimise screening and recruitment.
4 Engaging local staff from study inception to proactively notify potential study recruits.[23]
5 Providing more education to parents and children to optimise participation.

Limitations

Although the pilot data provided valuable information, it also identified the difficulty in identifying eligible paediatric patients for a study of flushing techniques. The small sample size and lack of multivariate adjustment is the most notable limitation and should be considered when interpreting clinical outcomes. Firm conclusions and recommendations for clinical practice cannot be made. It was not possible to mask the respective interventions, so there was potential for outcome assessment bias. This was ameliorated to some extent by blinding of the data analyst. Sodium chloride 0.9% flushes pre- and post-medication administrations (in addition to the randomised flushes) were not controlled, potentially confounding the effect of the randomised flush; however, this reflects the pragmatic nature of the trial and supports generalisability. We do not know if the recommended syringe size (10 mL) was always used, and excessive pressure generated from smaller syringe sizes may have been a confounder, especially in children randomised to low volume flush. Therefore, we recommend standardising equipment in future trials.

Conclusion

High PIVC failure rates indicate the inadequacy of current PIVC care and maintenance including flush technique in paediatric patients. This pilot trial demonstrated that the protocol in its current format is not feasible in the paediatric population due to eligibility issues. A study evaluating the effectiveness of slow continuous infusion versus intermittent flushing might be more feasible and would fill a longstanding knowledge–practice gap. Analysis of the clinical outcomes suggests clinicians could use 10 mL flushing volumes every 24 h with no increase in PIVC failure or cost; however, the small sample size associated with the pilot nature of this study precludes our ability to draw firm conclusions. Maintenance of PIVCs extends beyond intermittent flushing. A comprehensive programme of rigorous research to improve PIVC outcomes in paediatric patients is urgently needed to extend the functional dwell of PIVCs and generate high-level evidence to inform policy and practice.

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