Innovation in Central Venous Access Device Security: A Pilot Randomized Controlled Trial in Pediatric Critical Care

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Objectives: Central venous access devices enable many treatments during critical illness; however, 25% of pediatric central venous access devices fail before completion of treatment due to infection, thrombosis, dislodgement, and occlusion. This is frequently attributed to inadequate securement and dressing of the device; however, high-quality research evaluating pediatric central venous access device securement innovation to prevent central venous access device failure is scarce. This study aimed to establish the feasibility of a definitive randomized control trial examining the effectiveness of current and new technologies to secure central venous access devices in pediatrics.

Design: Single-center, parallel group, superiority, pilot randomized control trial.

Setting: Anesthetic and intensive care departments of a tertiary pediatric hospital

Subjects: One-hundred eighty pediatric patients with nontunneled central venous access device

Interventions: Participants were randomized to receive central venous access device securement via standard care (bordered polyurethane dressing, with prolene sutures, chlorhexidine gluconate disc), tissue adhesive (Histoacryl, B Braun, Melsungen, Germany) in addition to standard care; or integrated dressing securement (SorbaView SHIELD [Centurion Medical Products, Franklin, MA], with prolene sutures and chlorhexidine gluconate disc). Outcomes: Primary: Feasibility (including effect size estimates, acceptability); central venous access device failure; central venous access device complications; secondary: individual central venous access device complications, skin damage, dressing performance, and product cost.

Measurements and Main Results: Feasibility criteria were achieved as recruitment occurred with acceptable eligibility, recruitment, missing data, and attrition rates, as well as good protocol adherence. Family members and staff-reported comparable levels of acceptability between study arms; however, tissue adhesive was reported as the most difficult to apply. Overall, 6% of central venous access devices failed, including 6% (3/54; incident rate, 13.2 per 1,000 catheter days) standard care, 2% (1/56; incident rate, 3.65 per 1,000 catheter days) integrated, and 8% (5/59; 25.0 per 1,000 catheter days) tissue adhesive.

Conclusions: It is feasible to conduct an efficacy randomized control trial of the studied interventions. Further research is required to definitively identify clinical, cost-effective methods to prevent central venous access device failure by examining new dressing and securement technologies and techniques. (*Pediatr Crit Care Med* 2019; XX:00–00)

Key Words: central; critical care; dressing; evidence-based care; pediatrics; site care; vascular access

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Over 50% of children admitted to pediatric critical care units require a central venous access device (CVAD) for therapy administration, including inotropes,

nutrition, and complex sedation (1). Over the past 20 years, there has been increasing focus on the prevention of CVAD-associated bloodstream infection (BSI), due to its significant sequelae on morbidity, mortality, and healthcare resources (2, 3). Recent literature has highlighted other sources of harm associated with CVAD dysfunction, with 25% of pediatric CVADs failing prior to completion of therapy, due to mechanical, thrombotic, and infective origins, resulting in treatment disruption (4, 5).

Effective CVAD dressing and securement is central to the prevention of many causes of CVAD complication. Polyurethane dressings are used to protect the insertion site from external contaminants, with additional chlorhexidine-impregnated products (either via disc or impregnated gel) demonstrated to significantly reduce the rate of CVAD-associated BSI (risk ratio, 0.51; 95% CI, 0.33–0.78), by preventing extraluminal colonization of the CVAD insertion site (6). Additional securement devices, such as sutures, are used to minimize movement of the catheter from its optimal position. CVAD dislodgement is an increasingly prominent complication in pediatric critical care units, likely due to light sedation and early mobilization becoming the standard of care to facilitate long-term recovery (7).

Within the changing pediatric critical care environment, innovation is necessary to identify effective CVAD securement products. Tissue adhesive (TA), or medical grade superglue, provides a physical barrier against microbial entry, promotes hemostasis, and offers adhezion between the catheter and insertion site. TA has been successfully trialled with a reduction in failure and complication rates reported in adult intensive care (8) and for other types of CVADs (i.e., tunneled, cuffed CVADs, peripherally inserted central catheters) in pediatric patients (9, 10). TA has not been tested in pediatric critical care, where it may be of greatest value. Similarly, integrated securement and dressing (ISD) products have been developed as reinforced polyurethane products, with increased dressing border integrity and device security (9, 11). It is not known whether these new products are effective at reducing CVAD failure and complication, in pediatric critical care. The aim of this study was to evaluate the feasibility of an efficacy trial comparing innovations in nontunneled CVAD security, (using predefined criteria for recruitment, retention, protocol fidelity, satisfaction, and sample size estimates).

MATERIALS AND METHODS

Design

A single-center, parallel group, pilot randomized controlled trial (RCT) in pediatric patients with nontunneled CVADs who were admitted to a PICU. The trial was prospectively registered with the Australian Clinical Trials Registry (ACTRN12615000977572), and the protocol was published (12).

Study Setting

The trial was conducted within the anaesthetic department and PICU at the Queensland Children's Hospital, Australia. The hospital is a tertiary-level, specialist pediatric teaching hospital, which provides full-spectrum services to children and young people from birth to 18 years old.

Participants and Sample Size

Eligibility criteria were: age less than 18 years old, requiring the insertion of a nontunnelled, percutaneously inserted CVAD (jugular, subclavian, or femoral) that would remain in situ for greater than 24 hours, PICU admission. Patients were ineligible if any other type of intravascular device was to be inserted (e.g., peripherally inserted central catheter), current blood stream infection (BSI) at recruitment, were receiving extracorporeal membrane oxygenation recruitment, CVAD insertion site was diseased, burned, scarred, torn, or extremely diaphoretic, patients had a known allergy to any of the study products or had previously participated in the study within the current hospital admission.

The enrollment plan included 60 subjects per intervention group (total $n = 180$), with patients eligible for participation multiple times (i.e., participation per CVAD). Sample sizes were based on requirements for feasibility testing and informing effect size estimates for the efficacy trial (13, 14).

Intervention

Participants were randomly assigned to receive one of three CVAD securement procedures (displayed in **Fig. 1**):

1) Standard care: Bordered polyurethane dressing (Tegaderm 1,655 [8.9 x 11.5cm] or 1,614 [6×7cm] [depending on patient size]; 3M, St Paul, MN).
2) TA: TA (Histoacryl; B Braun, Melsungen, Germany; two drops applied at the CVAD insertion wound, and under each CVAD wing), and bordered polyurethane dressing (Tegaderm 1,655 [8.9×11.5cm] or 1,614 [6×7cm] [depending on patient size]; 3M, St Paul, MN).
3) ISD: ISD (SorbaView SHIELD SV430UDT [9.53×11.75 cm] or SV254 [6.35×10.16 cm] [depending on patient size]; Centurion Medical Products, Williamston, MI).

To ensure safety as per existing hospital policy, all participants received primary device security via prolene suture (Ethicon, Somerville, MA) and infection prevention via CHG disc (Biopatch; Johnson & Johnson, Brunswick, NJ). A GripLok (3200S; Tidi Products, Neenah, WI) was used in all groups at attachment to the administration sets, to reduce drag.

Outcomes

The primary outcomes were feasibility of a definitive efficacy trial of CVAD securement in pediatric critical care, and CVAD failure. Feasibility was determined through composite analysis eligibility, recruitment, retention and attrition, protocol adherence, missing data, parent and healthcare staff ratings of product of satisfaction and acceptability, and sample size calculations based on effect size estimates (14, 15). Parent/caregiver and healthcare staff (nurses, physicians) satisfaction and acceptability of the securement products was determined using a 0–10 numeric rating scale of increasing satisfaction, at CVAD insertion and removal. CVAD failure

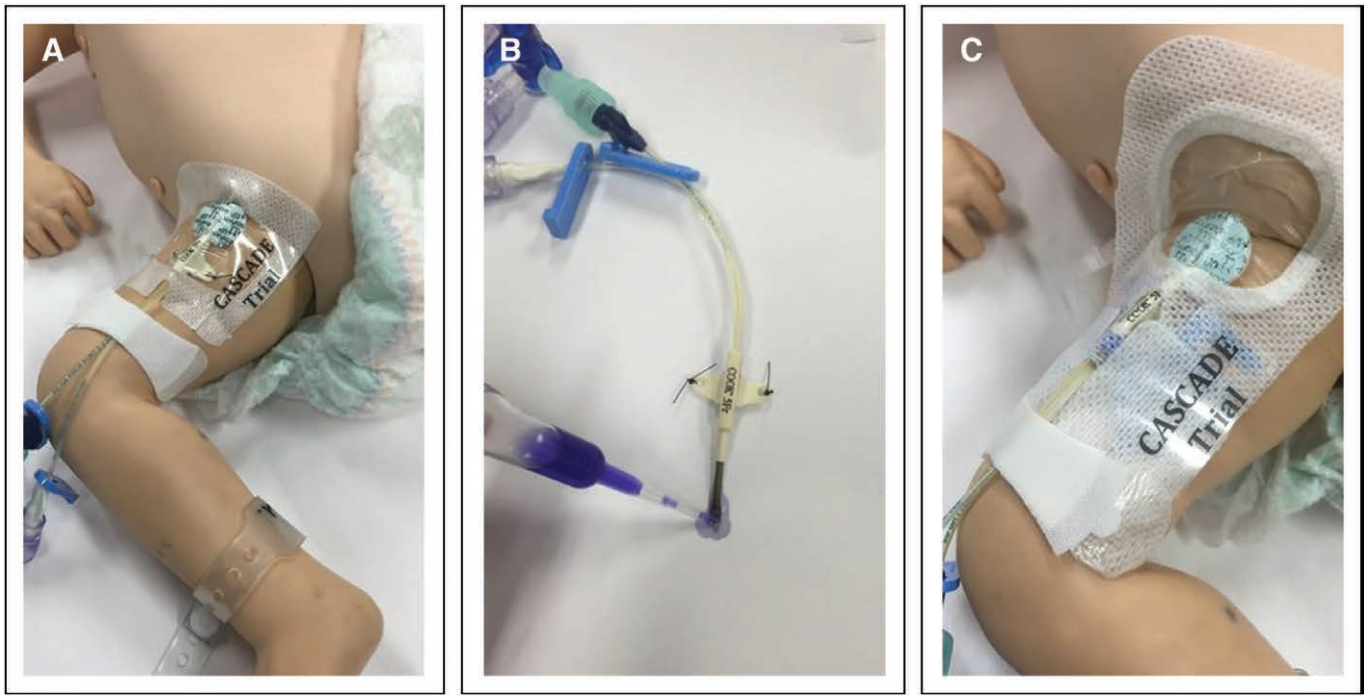

Figure 1. Central venous access device securement groups: **A**, Standard care; **B**, tissue adhesive; and **C**, integrated securement and dressing.

was defined as cessation of device function prior to completion of therapy (4).

Secondary outcomes were CVAD complications, dressing performance (durability), skin complications, and serious adverse events. CVAD complications were as follows: (1) CVAD-associated BSI (16), (2) local skin infection (16), (3) venous thrombosis (radiologically confirmed), (4) partial or complete CVAD dislodgement (17), (5) partial or complete occlusion (18), and (6) CVAD breakage (19). Diagnoses of CVAD-associated BSI and venous thrombosis were made by an independent, blinded infectious disease or radiologist specialist, respectively. Dressing performance was measured through the dwell time of the first dressing application and requirement for nonroutine (i.e. every 7 d [20]) dressing change. Skin complications included pressure injuries, dermatitis, and mechanical injuries (e.g., skin tear and blisters) (21). We initially planned to compare cost-effectiveness; however, this was not completed due to resource availability, so cost estimates were of direct product costs, only.

Study Procedures

Research nurses (ReNs) completed daily screening of patients who were either in the PICU or booked for PICU admission after a cardiac procedure, obtained informed consent, and accessed the allocated randomization. Randomization was web-based via Griffith University (https://www151.griffith.edu.au/random) and generated in a 1:1:1 ratio for the study groups, stratified by CVAD site (jugular vs other), including randomly varied block sizes, with concealment until after consent.

The ReN provided the CVAD inserting clinician with a prepared study pack, including all necessary products. Extensive education and user guides were provided via multimedia to clinicians to ensure consistency and protocol adherence for initial and subsequent applications. TA was applied only on insertion by the CVAD inserting clinician, with no further application at later dressing changes, since otherwise build up occurs on the catheter body (9–11). PICU nursing staff changed all CVAD dressing and securements weekly or as clinically indicated (i.e., if no longer clean, dry and intact), with additional dressing changes and reinforcements permitted and (e.g. tape) recorded.

Data were prospectively collected into Research Electronic Data CAPture (http://project-redcap.org/), during daily patient visits by the ReN. Follow-up was until 4 weeks after insertion, study withdrawal, removal of the CVAD, or hospital discharge. This included data on outcomes, with additional demographic and clinical data collected to describe the participant group, enable comparisons to inform generalisability, and characteristics that are known to increase the risk of CVAD failure (19, 22–27).

CVAD Procedures

Other than the CVAD securement interventions, CVADs were inserted and managed as per local clinical policy (28) and international clinical practice guidelines (20). Standardized CVAD practices included maximum sterile procedures throughout insertion, uncoated polyurethane catheters (Cook [Cook Medical, Bloomington, Indiana] and Arrow [Teleflex, Morrisville, NC]), skin and connector decontamination with 2% CHG in alcohol, ultrasound (as per clinician choice), and neutral needleless connectors (N-Pulse; TUTA Healthcare, Victoria, BC, Canada) during therapy. The CVAD inserter selected site (e.g., jugular, subclavian), size and number of lumens, based on predicted patient needs, vessel availability,

and insertion-associated risks. Decisions regarding blood and CVAD tip cultures and ultrasound for identification of symptomatic venous thrombosis were requested by the clinical team.

Data Analysis

Deidentified data were transferred to Stata 15 (StataCorp, College Station, TX) for analysis. The unit of analysis was the CVAD. Prior to analysis, data cleaning of outlying figures, missing, and implausible data were undertaken, and a random 5% sample of primary and secondary outcome data reentered and checked. Descriptive statistics were used to ascertain the primary outcome of feasibility, with predetermined acceptability criteria as being (1) greater than 80% of patients screened will be eligible, (2) greater than 80% will agree to enrol, (3) greater than 90% will receive the allocated intervention, and (4) less than 5% of enrolled patients will be lost to follow-up. Acceptability was compared between treatment groups using appropriate statistics, relevant to data distribution. All randomized patients were analyzed on an intention-to-treat basis, and baseline variables were compared using clinical criteria. Incidence rates (IRs) and incident rate ratios (IRRs) of CVAD failure were used to summarize the impact of each securement program, with group differences evaluated by 95% CIs and p values. Kaplan-Meier survival curves (with log-rank test) were used to compare failure over time between groups. Secondary endpoints including individual CVAD complications, dressing performance, and skin complications were compared between groups using parametric or nonparametric test as appropriate. Univariable regression (Cox) was performed to test the effect of patient and device variables associated with CVAD failure. Variables were recategorized to suit regression analysis, as necessary (e.g. to eliminate categories with < 20 cases). p values of less than 0.05 were considered statistically significant. Costs were calculated using Queensland Health purchase prices for dressing and securements in Australian dollars (2016).

Ethics

Approval to undertake the trial was received from both the Children's Health Services Queensland (HREC/13/QLD/181) and the Griffith University (NRS/10/14/HREC) Human Research Ethics Committees. Written informed consent was gained from parents or legal guardians, with the use of either an immediate [prospective] or a deferred [retrospective] consent process.

RESULTS

Participation, Feasibility and Demographics

Between February and August 2016, 282 subjects (impending CVAD insertions) were screened, with 103 not meeting the inclusion and exclusion criteria; however, this was mainly due to 70 potential participants who were missed due to CVAD insertion after ReN work hours. No families refused to participate. After randomization one CVAD was not successfully inserted, and three subjects were accidentally double randomized (these were managed as per the initial randomization). One patient withdrew from the study due to extreme diaphoresis, no CVAD was lost to follow-up. The subject flow is displayed within the Consolidated Standards of Reporting Trials flow chart (**Fig. 2**). As displayed in **Supplementary Table 1** (Supplemental Digital Content 1, http://links.lww.com/PCC/B30), the composite of feasibility outcomes was met. Protocol adherence was high, with 93% of CVADs receiving the allocated intervention throughout the study, and no missing data for primary or secondary outcomes.

Staff reported reduced mean acceptability of applying the TA (5.4/10; SD (SD) 2.3), in comparison to standard care (6.2/10; SD 2.3) and ISD (6.2/10; SD 1.9; $p = 0.023$). There were no differences in all other assessments of acceptability by staff, including dressing change and dressing removal. Parents and caregivers reported higher mean satisfaction with the ISD (9.4/10; SD, 1.7), in comparison with standard care (8.2/10; SD 2.7) and TA (8.2/10; SD 2.5).

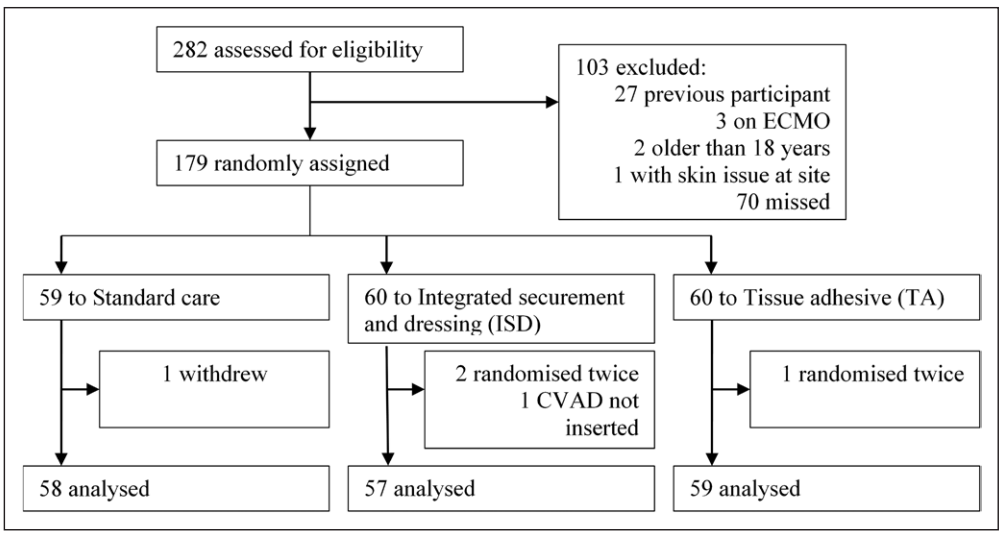

Figure 2. Consolidated Standards of Reporting Trials flow chart of study participation (unit of analysis: central venous access device [CVAD]). ISD = integrated securement and dressing, ECMO = extracorporeal membrane oxygenation, TA = tissue adhesive.

In total, 702 catheter days were studied. Participants were on average 38 months old (interquartile range [IQR], 33–61), undergoing a cardiac surgical procedure (126/174; 72%), with a median Pediatric Index of Mortality 3 of 0.5 (IQR, 0.3–1.4) (Supplementary Table 1, Supplemental Digital Content 1, http://links.lww.com/PCC/B30). The majority of CVADs were placed in the operating theatre (116/169; 69%), in the internal jugular (99/169; 59%) or femoral veins (68/169; 40%), and with ultrasound guidance (99/112; 88%) (**Supplementary Table 2** Supplemental Digital Content 2, http://links.lww.com/PCC/B31). Overall, the

TABLE 1. Central Venous Access Device Failure and Complications (*n* = 169)

Variables	Control	Integrated Securement Product	Tissue Adhesive	*p*
Group size[a], *n* (%)	54 (32)	56 (33)	59 (35)	
CVAD removal due to, *n* (%)				
CVAD failure	3 (6)	1 (2)	5 (8)	0.300[b]
Treatment completed: no complications	44 (81)	49 (88)	51 (86)	
Treatment completed: with complications	3 (6)	6 (11)	1 (2)	
Treatment incomplete: with complications	3 (6)	1 (2)	5 (8)	
Patient deceased	3 (6)	0 (0)	1 (2)	
Discharged with device: no complications	1 (2)	0 (0)	1 (2)	
CVAD failure incidence rate (1,000 catheter days, 95% CI)	13.2 (4.25–40.8)	3.65 (0.51–25.9)	25.0 (10.4–60.0)	
CVAD failure incident rate ratio (1,000 catheter days, 95% CI)	Referent	0.28 (0.01–3.46)	1.89 (0.37–12.2)	0.174[c]
CVAD complications[d], *n* (%)				
Dislodgement (complete)	2 (4)	0 (0)	0 (0)	
Dislodgment (partial)	1 (2)	0 (0)	3 (5)	
Suspected CVAD-associated bloodstream infection	1 (2)	1 (2)	1 (2)	
Confirmed central line-associated bloodstream infection	1 (2)	0 (0)	0 (0)	
Thrombosis	1 (2)	1 (2)	1 (2)	
Local infection	0 (0)	1 (2)	0 (0)	
Occlusion (complete)	0 (0)	1 (2)	0 (0)	
Other	1 (2)	2 (4)	1 (2)	
Unknown	1 (2)	1 (2)	0 (0)	
Skin complications, *n* (%)				
Any	2 (4)	3 (5)	2 (3)	
Tear	1 (2)	2 (4)	1 (2)	
Rash	1 (2)	1 (2)	1 (2)	
Blister	0 (0)	2 (4)	0 (0)	
Bruising	0 (0)	0 (0)	1 (2)	
Serious adverse events, *n* (%)				
Death	3	0	1	
Dwell time (d), median (interquartile range)	2.69 (1.15–6.24)	2.23 (1.21–6.06)	2.18 (1.12–5.01)	
Catheter days (total)	228	274	200	

CVAD = central venous access device.
[a]Row percentages shown.
[b]Fisher exact test.
[c]Log-rank test.
[d]Participants could have multiple CVAD complications during study.
Percentages calculated using the number of nonmissing observations as denominator.

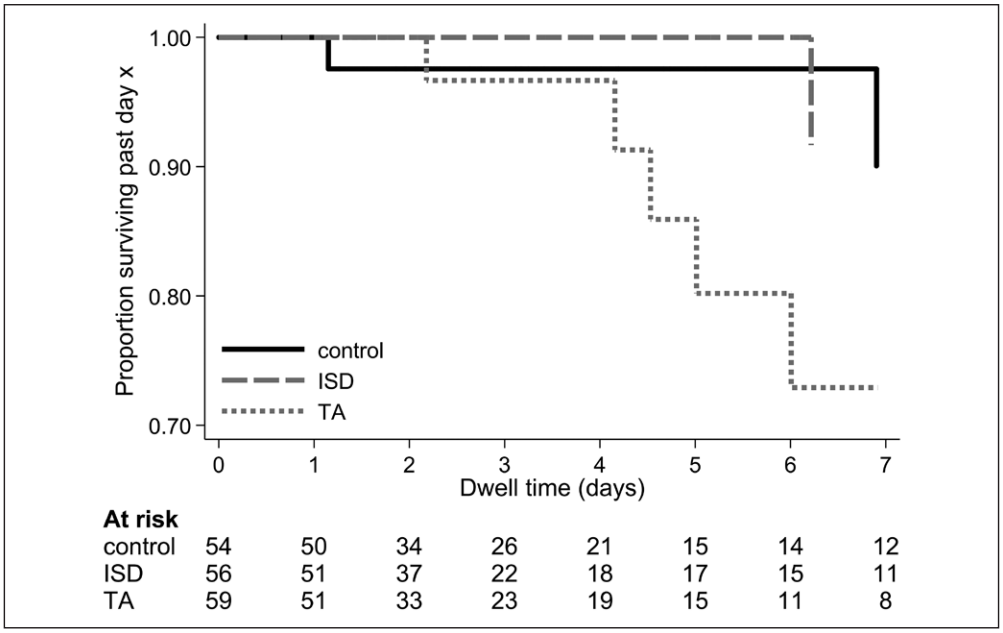

Figure 3. Kaplan-Meier survival curve of central venous access device failure by study groups. ISD = integrated securement and dressing, TA = tissue adhesive.

majority of clinical characteristics were distributed evenly between the study groups; however, others had greater than 10% imbalance (e.g., gender, CVAD placement, location inserted).

CVAD Failure and Complications

Nine CVADs (9/169; 5.3%) failed during treatment. The highest frequency and IR of failure occurred in the TA group (8%; IR 25 per 1,000 catheter days [IRR compared with controls 1.89, 95% CI, CI 0.37–12.2]) (Table 1). In the ISD group, failure was IR 3.65, IRR 0.28 (95% CI, 0.01–3.46) compared with controls. These findings were consistent over time (**Fig. 3**). CVAD dislodgement was the most common overall complication (6/169; 4%) but did not occur in the ISD group. Although three CVADs were removed on suspicion of CVAD-associated BSI, this diagnosis was only confirmed in one participant (*Pseudomonas aeruginosa*; standard care). No CVAD breakage occurred, and the average CVAD dwell time was similar between groups. Skin complications, including rash, blistering, and bruising, occurred in seven participants (4%). No allergic dermatitis reactions or itchiness occurred within the study

Univariate Cox regression demonstrated no clinical variables to be significantly associated with risk of CVAD failure (as defined as $p < 0.05$).

Dressing and Securement Performance

The overall dressing and securement performances are displayed in **Table 2**. Each of the intervention securement products was associated with increased direct purchasing costs, in comparison with standard care. For subjects requiring a dressing change during CVAD dwell, mean first dressing dwell time was lower for standard care (2.5 d [IQR 1.6–4.8]), in comparison with ISD (4.8 d [1.4–8.0]) and TA (5.4 d [2.1–6.7]). There was also reduction in the need for dressing changes in each of the intervention groups, in comparison with standard care. Within the TA group, dressing changes due to bleeding were reduced (8%) in comparison with standard care 20% and ISD 11%. There was use of additional securement products across the study arms, including nonsterile tapes.

DISCUSSION

We report the results of the first RCT conducted in PICU to inform effective CVAD securement. Employing robust methods, including a published and registered protocol, we have demonstrated that a large-scale efficacy trial of CVAD securement is feasible, meeting the a priori composite feasibility criteria surrounding recruitment, attrition, and protocol adherence. Although 70 potential participants were missed for recruitment, this is likely to be improved with increased resourcing. The CVAD failure rate reduction between the standard care and ISD group, estimates a 35% relative reduction in failure may be confirmed in future trials, especially in decreasing CVAD dislodgement, further strengthening efficacy trial feasibility. As recommended by the U.K.'s Medical Research Council's Developing and evaluating complex interventions framework (29), this project has provided much needed feasibility data for these future efficacy trials. Additional innovations also require testing, since the rapidly changing PICU environment continues to see emerging technologies (e.g., subcutaneous CVAD anchors [30]).

Despite our study cohort being short-term CVADs (mean duration 2.2 d), 5.3% failed prior to the completion of therapy. This level of failure is similar to rates recently reported in adult critical care settings (31) and demonstrates a serious health and economic burden for PICUs worldwide. CVAD failures cause disruptions to treatment during PICU admission and may have serious effects on patient morbidity and mortality (32). Although the PICU has previously targeted clinical improvements to prevent central line-associated bloodstream infection (3, 33), other significant causes of CVAD-associated harm, such as catheter dislodgement, have yet to receive similar innovation and attention.

The two interventions tested have biological and mechanical plausibility to prevent many causes of CVAD failure and complication, in comparison with bordered polyurethane dressing. Medical-grade cyanoacrylate glues, or TA, has been demonstrated in in vitro and clinical studies to improve attachment of vascular access devices, and to inhibit microbial growth, in comparison with current polyurethane dressings (34, 35). Modern ISDs are the considered the "next generation"

TABLE 2. Dressing and Securement Performance

Variables	Control	Integrated Securement Product	TA
Group size, *n* (%)	54 (32)	56 (33)	59 (35)
Initial application product purchase costs[a]	$0.06–0.24	+$3.53	+$11.80
Patients with a dressing/securement change, *n* (%)	16 (28)	12 (21)	8 (14)
Number of additional dressing/securements used (excluding first)	38	27	8
Life of first dressing, d (*n* = 36), median (interquartile range)[b]	2.5 (1.6–4.8)	4.8 (1.4–8.0)	5.4 (2.1–6.7)
Life of first dressing ≥ 7 d (*n* = 36), *n* (%)	1 (6)	5 (42)	2 (25)
Reasons for dressing changes, *n* (%)[b]			
Lifting (*n* = 93)	17 (41)	17 (44)	5 (38)
Bleeding (*n* = 92)	8 (20)	4 (11)	1 (8)
Leakage (*n* = 92)	3 (7)	3 (8)	0 (0)
Routine (*n* = 92)	2 (5)	2 (5)	1 (8)
Sweating (*n* = 92)	2 (5)	2 (5)	0 (0)
Allergy (*n* = 92)	0 (0)	1 (3)	0 (0)
Other (*n* = 92)	3 (7)	5 (13)	1 (8)
Additional securing devices (at any time during study; *n* = 165), *n* (%)			
Strips of nonsterile tape	2 (4)	2 (4)	3 (5)
Bordered dressing	1 (2)	2 (4)	0 (0)
TA	1 (2)	2 (4)	0 (0)
Additional randomized study product	0 (0)	0 (0)	1 (2)
Foam	1 (2)	0 (0)	0 (0)
Sterile gauze	1 (2)	0 (0)	0 (0)
Other	4 (8)	1 (2)	1 (2)

TA = tissue adhesive.

[a]In Australian dollars according to local hospital prices 2016.

[b]Multiple answer question.

of dressing products, reducing procedural complexity associated with applying multiple separate securement devices, and involve an adhesive component holding below and above the CVAD (36). These characteristics suggest ISDs would perform well to minimize CVAD accidental dislodgement during movement.

As expected in a pilot trial, the CVAD securement innovations tested did not clinically or statistically impact CVAD failure rates, but some procedural results were demonstrated. Despite education resources, and one-on-one support from ReNs, CVAD inserting clinicians found TA difficult to apply, especially during the early phases of the trial, and this added complexity to an already difficult CVAD insertion procedure. TA may have a role in the promotion of hemostasis at the CVAD insertion wound, as evident in the prolonged first dressing dwell, reduced need for nonroutine dressing changes due to bleeding, and previous studies on other CVAD types (9, 10). If some of the practical issues around the application of TA were rectified, the hemostatic properties may be of benefit for some specific patient groups, such as patients recently therapeutically anticoagulated for cardiac procedures (9).

Despite improvements in hemostasis within the TA group, there was still a high dressing failure rate within the overall cohort, with only 5% of CVAD dressing change procedures initiated due to routine requirements; 95% of dressing changes were initiated due to dressing disruption, primarily due to dressing edges lifting. Timsit et al (37) in their secondary analysis of a CVAD dressing RCT in adult critical care previously highlighted the three-fold increased risk for BSI associated with dressing disruption within critical care, highlighting that innovation in this area is warranted. Additionally, there is significant risk associated with accidentally dislodging CVADs during dressing change procedure on a non-compliant, recently anesthetised child (9, 10). Acceptability of the ISD was

high, and parents reported high levels of satisfaction associated with the product. However, further study of TA and other innovations to economically promote CVAD security, and wound hemostasis, is necessary.

Although both interventions tested had a higher direct purchasing price in comparison with standard care, the potential overall savings associated with a reduction in CVAD failure, complications and repetitious dressing changed procedures are considerable (38, 39). An additional immediate cost would be warranted, if these products were to reduce these complications, and could be safely incorporated into PICU management. Cost-effectiveness has yet to be demonstrated, and further research is necessary.

Although using high-quality methods, our trial has some limitations. The study was undertaken in a single, tertiary referral pediatric hospital, limiting generalizability. However, a variety of insertion sites and clinical areas were included, increasing generalizability. Decisions regarding CVAD insertion sites, lumens and size were made by the inserting clinician, not by study staff, decreasing standardization within underlying practice. The impact of imbalance in risk factors between study groups is relatively greater in pilot trials (due to lower sample size), and some imbalances between the groups were seen. Clinicians, participants, family members, and ReN were not blinded to the intervention, due to obvious visual differences. However, it is unlikely this would have influenced clinical decision-making. The data analyst was blinded for analysis, and a blinded infectious disease and radiological physicians determined outcomes for the infectious and thrombotic complication reported, thus avoiding potential biases.

CONCLUSIONS

CVAD complications and failure remain problematic within PICUs. Innovation in CVAD security is warranted, to ensure the safety of children relying on CVAD function during critical illness. An efficacy trial of CVAD securements in PICU is feasible, provided there are adequate resources to recruit and follow-up patients, and education of clinicians regarding practice changes. Further research is necessary to definitively identify clinical, cost-effective methods to prevent CVAD failure within pediatric critical care.

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