On a quest to prevent harm and safeguard paediatric venous catheters – A randomized control trial protocol

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En quête de façons de prévenir les échecs et de protéger les cathéters veineux chez les enfants – un essai comparatif à répartition aléatoire

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Abstract

Aim: *This study will evaluate the most effective peripheral intravenous catheter securement in paediatric emergency departments to reduce catheter failure, healthcare costs, patient distress, and improve satisfaction.*

Design: *A multisite, three-arm, parallel, superiority, randomized controlled trial of 506 children requiring peripheral intravenous catheter in the emergency department. The trial will be reported following CONSORT guidelines, is registered on the Australian New Zealand Clinical Trials Registry (ACTRN12619001026112) and ethics is approved via Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/19/QCHQ/45567).*

Methods: *Staff screen patients, six months to eight years old, requiring peripheral intravenous catheters and inpatient stay of more than 24 hours. Written informed consent is obtained from the legal guardian with 1:1:1 randomization ratio allocation:*

1. *Standard care: Bordered polyurethane dressing (Tegaderm Advanced®; 3M)*
2. *Integrated dressing and securement: SorbaView SHIELD® (Centurion Medical Products)*
3. *Integrated dressing and securement with tissue adhesive: SorbaView SHIELD® (Centurion Medical Products) and Tissue Adhesive Secureport IV™ (Adhezion Biomedical)*

Primary outcome is peripheral intravenous catheter failure; secondary outcomes are peripheral intravenous catheter complications, pain and distress, healthcare costs, and staff satisfaction or acceptability. Intention-to-treat analysis of time-to-event data will be completed using adjusted Cox regression. Direct costs calculated from the hospital perspective and cost-effectiveness analysis will estimate the incremental cost of each treatment option.

Discussion: *Most hospitalized children require a peripheral intravenous catheter, although persistent high rates of failure are recognized as a patient safety concern. The outcomes of this trial will directly inform clinical care for peripheral intravenous catheter securement in children in emergency departments.*

Résumé

Objectif : *Cette étude vise à déterminer le mode de fixation des cathéters intraveineux périphériques le plus efficace dans les services d'urgence pédiatrique afin de diminuer le risque d'échec de fixation du cathéter, les coûts des soins de santé et la détresse des patients, et d'améliorer le taux de satisfaction.*

Plan : *Essai comparatif de supériorité, multicentrique, à répartition aléatoire et avec trois groupes parallèles, portant sur 506 enfants nécessitant l'installation d'un cathéter intraveineux périphérique dans un service des urgences. Cet essai, dont les résultats seront rapportés conformément aux lignes directrices de CONSORT, est inscrit au registre des essais cliniques de l'Australie et de la Nouvelle-Zélande (ACTRN12619001026112) et a été approuvé par le comité d'éthique de la recherche sur des sujets humains du Children's Health Queensland Hospital and Health Service (HREC/19/QCHQ/45567).*

Méthode : *Les patients sélectionnés par les membres du personnel doivent être âgés de 6 mois à 8 ans, nécessiter l'installation d'un cathéter intraveineux périphérique et être hospitalisés pendant plus de 24 heures. Le tuteur légal du patient doit donner son consentement éclairé par écrit. Les patients seront répartis au hasard dans trois groupes de traitement selon un rapport de 1:1:1, comme suit :*

1. *Soins standards : pansement en polyuréthane avec bords (Tegaderm Advanced®; 3M)*
2. *Pansement avec fixation intégrée : SorbaView SHIELD® (Centurion Medical Products)*
3. *Pansement et fixation intégrée avec adhésif cutané : SorbaView SHIELD® (Centurion Medical Products) et adhésif Secureport IVTM (Adhezion Biomedical)*

Le paramètre d'évaluation principal est l'échec de fixation du cathéter intraveineux périphérique; les paramètres d'évaluation secondaires sont les complications, la douleur et la détresse associées à l'installation du cathéter intraveineux périphérique, les coûts des soins de santé et la satisfaction ou l'acceptabilité du personnel. L'analyse en intention de traiter des données sur le temps écoulé avant la survenue d'un événement sera effectuée à l'aide d'un modèle de régression de Cox ajusté. Les coûts directs calculés selon une perspective hospitalière et une analyse coût-efficacité permettront d'estimer le coût différentiel de chaque option thérapeutique.

Discussion : *La plupart des enfants hospitalisés nécessitent l'installation d'un cathéter intraveineux périphérique. Toutefois, les taux d'échec élevés et persistants sont reconnus comme une source de préoccupations liées à l'innocuité des patients. Les résultats de cet essai auront une influence directe sur les soins cliniques relatifs à la fixation des cathéters intraveineux périphériques chez les enfants hospitalisés dans un service d'urgence pédiatrique.*

Introduction

Infants and children depend on peripheral intravenous catheters (PIVCs) for the provision of medical therapy within the emergency department (ED) and during hospitalization. However, PIVC insertion and management is challenging, and literature indicates that between 30–50% of devices fail (Indarwati et al., 2020; Kleidon et al., 2019; Kleidon et al., 2020). Peripheral intravenous catheter failure is costly for both the patient and healthcare organization (Goff et al., 2013). Failure may require the child to undergo traumatic reinsertion procedures, delay important medical treatment, and prolong length of hospital stay. One way to reduce PIVC failure is with effective PIVC dressing and securement, which ensures correct catheter position in the vein.

Background

A PIVC is a thin, pliable, plastic sheathed tube, inserted into a peripheral vein, to deliver drugs and fluids in the paediatric emergency department (Hollaway et al., 2017). Around 30 million intravascular devices, such as PIVCs, are used in Australia each year, with PIVC insertion considered the most performed invasive procedure in the hospital environment (Keogh, 2016). However, paediatric PIVC insertion and post-insertion management is complex, and complications are widespread.

National and international studies report that children require significantly more repeat PIVC insertion attempts compared to their adult counterparts (Goff et al., 2013; Kleidon et al., 2019). It is typical for two PIVC attempts to be required before a successful insertion and in children with difficult intravenous access several attempts have been reported (Goff et al., 2013; Kleidon et al., 2019). Goff reports the economic cost of PIVC insertion escalates as the number of attempts increase and this costs more than double when three or more attempts are required (Goff et al., 2013).

Paediatric PIVC insertion is also a resource-intensive procedure, requiring multiple personnel, consumables, and an average of 41 minutes per procedure (Goff et al., 2013; Hollaway et al., 2017). Developmental attributes of younger children result in low procedural compliance and complicates the insertion and management procedures. After successful PIVC insertion, children often remain unsettled, resulting in increased risk of accidental dislodgement thus ongoing need for replacement cannulation (Lim et al., 2018). This is further validated by observational and interventional studies demonstrating younger age and smaller catheter size are associated with an increased rate of accidental catheter dislodgement (Kleidon et al., 2020; Malyon et al., 2014; Rozsa et al., 2015). For this reason, effective external securement of the PIVC to the skin is imperative. Peripheral intravenous catheter dressings and securements also assist in protecting the insertion wound from microbial colonization (and thereby infection), and reducing micromotion at the insertion site (Found & Baines, 2000).

In 2015, a Cochrane review highlighted the lack of high-quality evidence regarding best practice for PIVC securement, consequently best practice for PIVC securement remains uncertain and practice unstandardized (Marsh, Webster, Mihala, et al., 2015). Previous paediatric (Kleidon et al., 2020) and adult (Bugden et al., 2016; Corley et al., 2017; Marsh, Webster, Flynn, et al., 2015; Rickard et al., 2018) trials have attempted to identify the most effective securement practice. Within this research, medical grade superglue or tissue adhesive and integrated securement dressings, have been studied individually in adults and paediatrics with some successful decrease in securement failures. Tissue adhesive was found to be effective in the adult ED population (Bugden et al., 2016), demonstrating a clinical and statistical improvement in PIVC failure at 48 hours from 27% to 17% ($p = 0.02$). In a recent pilot randomized control trial (RCT), Kleidon et al. (2020) demonstrated that integrated dressings and tissue adhesive both appeared to perform better in general paediatric settings compared with standard care; however, these products have not been studied yet in paediatric EDs and have never been studied in combination (Kleidon et al., 2020).

We hypothesize that by introducing an integrated dressing (SorbaView SHIELD®; Centurion Medical Products)[1], and/or tissue adhesive (Secureport IV™; Adhezion Biomedical)[2]to secure PIVCs, failure will be significantly reduced. SorbaView SHIELD® is a vascular access device dressing with incorporated enhanced securement ability, preventing both PIVC movement and dislodgement. Tissue adhesive has an increased tensile strength of 8.6 Mpa (pressure) directly at the insertion site, with additional

[1] The brand names were used for concise description in this protocol and in keeping with its ethical and control trial registry approvals.

[2] Same as above.

potential benefits surrounding the prevention of microbial colonization of the insertion site, and hemostasis (Kleidon et al., 2020; Kleidon et al., 2017). Using integrated dressing, or the combination of the dressing and tissue adhesive, will allow for an increased pull-out force of the PIVC, without obscuring the insertion site from frequent viewing (Simonova et al., 2012). These interventions have shown promise to improve PIVC function in other populations, and other paediatric IV devices (Kleidon et al., 2017; Ullman et al., 2017; Ullman et al., 2019).

High-quality and pragmatic evidence to support paediatric PIVC securement is vital to ensure the best practice is easily implemented and translated throughout all areas of health for patients with a PIVC. Complications, including dislodgement, are likely with inadequate PIVC dressing and securement, as is phlebitis and extravasation, as result of increased micro-motion. It is predicted that the introduction of an improved approach to dressing and securement will improve ease of routine inspection resulting in increased nurses' compliance with routine PIVC inspection and early detection of complications. The suggested approach could also see a significant decrease in changing PIVC securement dressings, which will aid in reducing healthcare costs.

The study

Research aims

1. To undertake a randomized controlled trial of children requiring a PIVC during an ED admission, to determine the efficacy of novel PIVC securement methods to reduce PIVC failure.
2. To investigate whether PIVC securement with novel PIVC securement methods reduce associated healthcare costs and patient distress, and improve PIVC dwell and staff satisfaction/acceptability.

Primary hypothesis

Integrated dressing and securement product, or a combination of integrated dressing and securement and tissue adhesive, in comparison to standard care (bordered polyurethane), will reduce PIVC failure in paediatric patients in the ED.

Secondary objectives

1. Integrated dressing, or advanced dressings and tissue adhesive, in comparison to standard care, will reduce PIVC complications in paediatric patients in ED.
2. Integrated dressings, or advanced dressings and tissue adhesive, in comparison to standard care, will increase PIVC longevity, in paediatric patients in ED.
3. Integrated dressings, or advanced dressings and tissue adhesive, in comparison to standard care, will be acceptable to clinicians involved in their application, management and removal.
4. Integrated dressings, or advanced dressings and tissue adhesive, in comparison to standard care, will reduce healthcare utilization, products, and associated costs.

Design

A three-arm, parallel group, multi-site superiority RCT is being undertaken to compare the effectiveness of two integrated PIVC dressing and securement methods, in comparison to standard care, to reduce PIVC failure in paediatric patients who had the PIVC inserted in the emergency department. The trial recruitment commenced on the 10/02/2020 and recruitment is scheduled to be complete in late 2022. The trial is prospectively registered on the Australian New Zealand Clinical Trials Registry (ACTRN12619001026112).

Setting

This multi-site study is being conducted in Australia at two regional hospitals: Logan Hospital (Metro South Health, Queensland, Australia) and Ipswich Hospital (West Moreton Health, Queensland, Australia). Metro South is the most populated Hospital and Health Service in Queensland, caring for 23% of Queensland's population. Logan Hospital is a 435-bed secondary teaching hospital with a high proportion of people aged 0-14 years. In 2017, Logan Hospital ED cared for 88,255 patients, including 24,289 children (28%). Annually, Logan ED admits 2,309 paediatric patients, with clinical audits indicating 50% of these admissions require a PIVC for therapy. West Moreton has a rapidly increasing population. Ipswich Hospital is a 341-bed secondary teaching hospital, with the 0–14-year-old population accounting for the largest portion of admissions. In 2017, 61,898 patients were managed in the Ipswich Hospital ED, with 20% of patients being less than18 years old. The study includes both paediatric and mixed trained staff.

Participants

Children presenting to the ED requiring a PIVC for medical treatment are eligible for trial participation if they meet inclusion criteria and no exclusion criteria.

Inclusion criteria

- Aged more than 6 months to 8 years
- Anticipated requirement for a PIVC within 24hours
- Hospital admission to the inpatient unit requiring an expected stay of 24 hours or more; an admission to an ED short-stay unit is classified as a hospital admission

Exclusion criteria

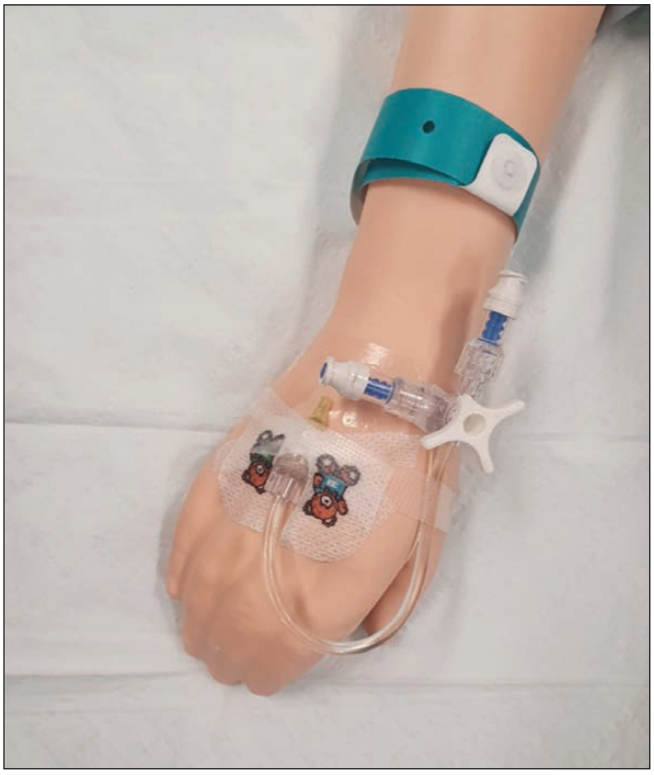
- Known allergy to study products
- Non-English-speaking family without interpreters
- Current skin tear at PIVC insertion site, or at high risk of tear due to overall skin integrity
- Previous participation in the study

Interventions

1. **Standard care**: Bordered polyurethane dressing (BPU; Tegaderm Advanced®; 3M)[3] utilizing Paediatric I.V. Transparent Dressing (1610K): Securement of the PIVC with 2 pieces of steri-strip tape is chevroned, at PIVC site. Tegaderm Advanced® will then be applied (see image Figure 1).

Figure 1

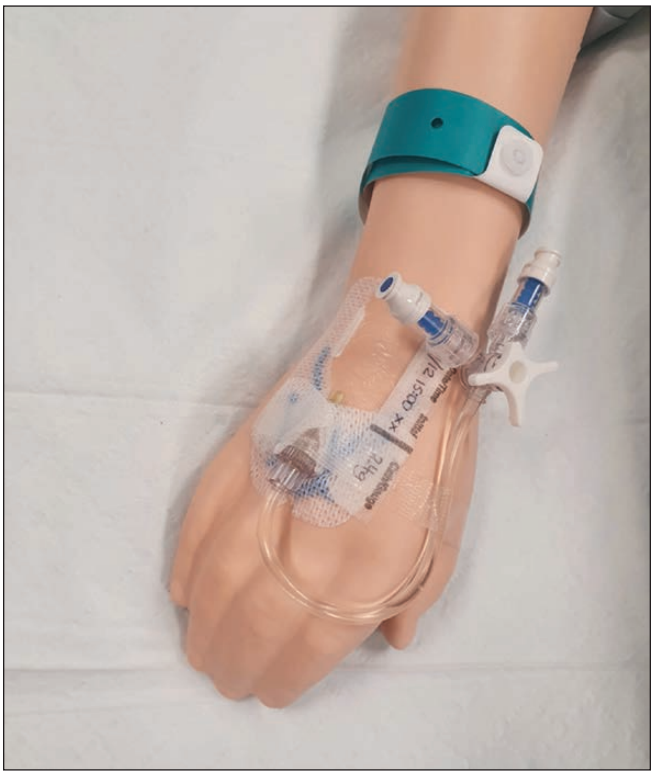
Standard Care



2. **Integrated dressing:** SorbaView SHIELD® (Centurion Medical Products) utilizing Nano (SV118UDT-6), Micro (SV226UDT-6) and Peripheral (SV233UDT-6) sizes depending on child age: Securement of the PIVC with the SorbaView SHIELD® at the PIVC site (see image Figure 2).

Figure 2

Integrated Dressing



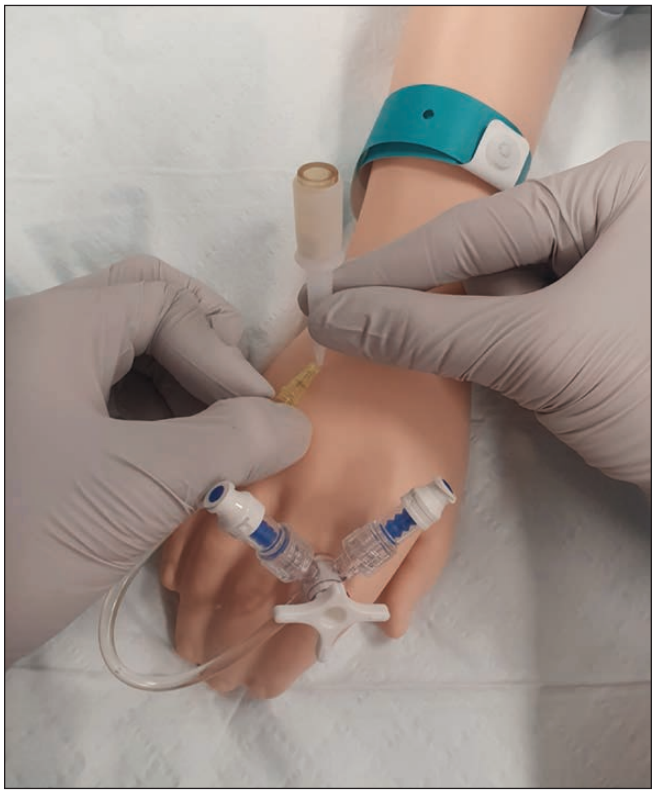
3. **Integrated dressing with tissue adhesive:** SorbaView SHIELD® (Centurion Medical Products) utilizing Nano (SV118UDT-6), Micro (SV226UDT-6) and Peripheral (SV233UDT-6) (sizes depending on child age) and Tissue Adhesive: Secureport IVTM (Adhezion Biomedical). Securement of the PIVC with one drop of tissue adhesive at the PIVC skin site and one drop of tissue adhesive under the PIVC hub. After waiting 30 seconds the advanced dressing (SorbaView SHIELD®) will be applied (see image Figure 3).

All participants will also have their PIVC stabilized with an arm board and tubular bandage as part of standard practice for the participating sites.

[3] The brand names were used for concise description in this protocol and in keeping with its ethical and control trial registry approvals.

Figure 3

Integrated Dressing with Tissue Adhesive



Outcomes

The outcomes are presented in Table 1.

Table 1

Study Outcomes

Outcome	Definition
Primary outcome	
PIVC failure	Any unplanned PIVC removal, where reinsertion is required. This includes complete dislodgement, infection, occlusion (PIVC cannot be flushed, or leakage occurs when fluid infused), infiltration (fluid perfusion into the surrounding tissue), or phlebitis (2 or more of pain, redness, swelling).
Secondary outcomes	
PIVC complications	Individual PIVC complications will be explored (dislodgement, occlusion, infiltration, infection, phlebitis).
Pain and distress	Associated with PIVC insertion, dressing, measured using validated scales appropriate to patient age and development (Malviya et al., 2006; Voepel-Lewis et al., 2005)
Healthcare costs	Including direct product costs, healthcare resource utilization (including additional equipment, staff time) and failure-associated resource usage using previously established cost estimates) Staff satisfaction and acceptability
PIVC Longevity	Reported at PIVC securement application and removal, on a numeric rating scale of 0 (min.) to 10 (max.) Individual PIVC time of insertion until time of removal will be captured

Sample size

Previous studies in paediatric and adult hospitals have estimated PIVC failure between 25% and 69% (Bugden et al., 2016; Corley et al., 2017; Marsh, Webster, Flynn, et al., 2015; Rickard et al., 2018; Simonova et al., 2012). This study is conservatively estimating PIVC failure of 40% in the standard care arm. Assuming 80% power to demonstrate statistical superiority of the study interventions over standard care (equal group sizes) with a reduction of primary outcome (PIVC failure) from 40% (control) to 25% (intervention), and a type 1 error rate of 0.05 (two-sided), a total of 460 participants would be required (using the 'power' command in Stata 16). Allowing for 10% attrition, the total number increases to 506 (169 per group).

Recruitment

Using pre-determined inclusion and exclusion criteria, screening will be conducted by research nurses (ReNs) and trained clinicians for all eligible paediatric patients. Prior to approaching the family for informed consent, the recruiting clinician will discuss the suitability for enrolment with the managing clinician and PIVC inserter. Written informed consent by appropriate legal guardians will be obtained at time of enrolment, prior to intervention.

Randomization and masking

A computer-generated randomization is being used to allocate patients in a 1:1:1 ratio with randomly varied block sizes of 169 per group stratified to both hospitals (Logan vs Ipswich).

Due to workflow pressures, allocation concealment is maintained through sequentially numbered, sealed, opaque envelopes provided to sites that indicate the allocated treatment arm upon opening. A research nurse or clinician selects the lowest numbered study pack (next pack system) from study baskets in each ED. This procedure is regularly

audited by the ReNs and chief investigator (CI). It is not possible to mask the intervention, as the clinicians who are completing skin checks are not blinded due to inclusion of the study treatment arm on the paperwork. In addition, the dressings are visibly different. However, the study investigators note that the tissue adhesive is transparent and cannot be appreciated on skin inspection. This differs to previous trials where the tissue adhesive was coloured and could not be blinded, giving an opportunity to run a blinded study of efficacy of tissue adhesives. The statistician undertaking the data analysis will be masked to the study group. Intervention fidelity will be monitored through daily PIVC site checks and weekly site audits by the coordinating CIs.

Interventionist training

Before trial recruitment commenced, we provided study education to more than 70% of clinicians seeing paediatric patients in the EDs and paediatric inpatient wards of both sites. Staff were provided with a brief training session, by the ReNs and/or research champions, on how securement dressings are applied (integrated into usual securement procedures) and photographic guides with instruction sheet were prominently displayed in both areas to enhance consistency. Group education sessions and instruction sheets were developed to guide inpatient ward staff.

Clinical processes

The clinician who inserts the PIVC will use local hospital, standard procedures to prepare skin by cleaning with 2% chlorhexidine gluconate in 70% alcohol, or 70% alcohol if emergent PIVC insertion is required. The PIVC inserter will select the most appropriate PIVC insertion site and size, based on clinical judgement of patient needs. Ongoing care of the PIVC will be in accordance with standards of best practice (Gorski et al., 2021).

Data collection

Streamlined data collection instruments and procedures are used. All data are collected by the Research Nurse or clinical champion and entered onto the paper case report form (CRF) directly from source data within the clinical area (ED or inpatient ward). Data are then retrospectively transcribed onto electronic data platform REDCap™ (Research Electronic Data Capture, Vanderbuilt), Version 6.10.6, by the research nurse. A screening log records patient information (name, unique reference number [URN], eligibility, enrolment, and treatment allocation). Patient characteristics collected at baseline include primary diagnosis, demographics, insertion site, size, skin quality, dominant limb, location, inserter group, insertion difficulty, reason for insertion.

After PIVC removal, we collect reason for PIVC removal, dwell time, and length of stay at hospital. The ReNs and clinical champions will visually inspect PIVCs, as per local guidelines, and assess for phlebitis (two or more of redness, pain, swelling, palpable cord or vein streak) and any residue, rash, blister, itchiness or tearing of skin on dressing removal (adverse event). At device removal, a satisfaction score from caregivers, of between 1–10, will be recorded along with hospital length of stay, and completed forms will be sent to the ReN to be stored in a secure location.

Ethical considerations

Human research ethics committee (HREC) approval has been obtained through Children's Health Queensland (HREC/19/QCHQ/45567). Written informed consent by appropriate legal guardians is obtained prior to intervention, at time of enrolment. There are no additional foreseeable risks to patients involved in this study beyond those that exist as part of routine clinical care. Adverse events (e.g., skin irritation) are recorded in the patient record and serious adverse events (e.g., death) are being reported in the health service clinical incident management system, as well as being reported to the Human Research Ethics Committee. Participant confidentiality will be ensured and anonymity guaranteed. Only aggregate data will be published, and data will be stored according to National Health & Medical Research Council guidelines (National Health and Medical Research Council et al., 2019).

An independent Data, Safety, and Monitoring Committee (DSMC), comprising experts in clinical trials and vascular access was established. The DSMC is being forwarded a copy of all serious adverse events reports as soon as they become available. The DSMC will review all reports and report back to the chief investigators of the study, if any further action is required. There is no interim analysis planned for the trial.

Data analysis

Cleaned and de-identified study observations will be transferred to Stata v16 for data management and analyses. Data cleaning will be completed including checks of missing and improbable data values. Missing values will not be imputed. Participant and clinical characteristics, including outcomes, will be presented in tables using descriptive

statistics, appropriate to data characteristics. Hypothesis tests will be completed using the chi-squared, Fisher's exact, Kruskal-Wallis, and log-rank tests, as appropriate. Incidence rates will be calculated using the total dwell times by groups. Kaplan-Meier curve will display survival (of PIVCs) over time by study groups.

The relative risk (hazard ratio, HR) of failure will be computed with Cox regression. The following variables at baseline will be investigated using univariable Cox regression analyses (one model for each) and rejected at $p \geq 0.20$ (likelihood ratio test): treatment arm, hospital, age category, sex, skin integrity, reason for admission, infection, comorbidities, difficult insertion, successful insertion by, device gauge, device location, additional device immobilizations, and connections; correlations between the remaining variables will be checked; and variables with a statistically significant pairwise correlation (rho) of greater than 0.40 will not be entered into multivariable models together. The Bayesian Information Criteria may be used to select the variable(s) for the best fit. The shortlisted covariables will be entered into a multivariable model; final model will be achieved using the manual backward/forwards method by removing/adding covariables at $p \leq 0.05$. Options for different setups of the covariables may be necessary, if the proportional hazards assumptions are not met. The 'goodness of fit' of the final model will be checked using Cox-Snell residuals. Age will be entered into models as continuous or categorical (age groups, i.e., 12 months old or less) variable, depending on univariable results. Results will be evaluated using clinical and statistical significance ($p < 0.05$ two-sided). No interim analysis will be performed.

Estimating cost parameters

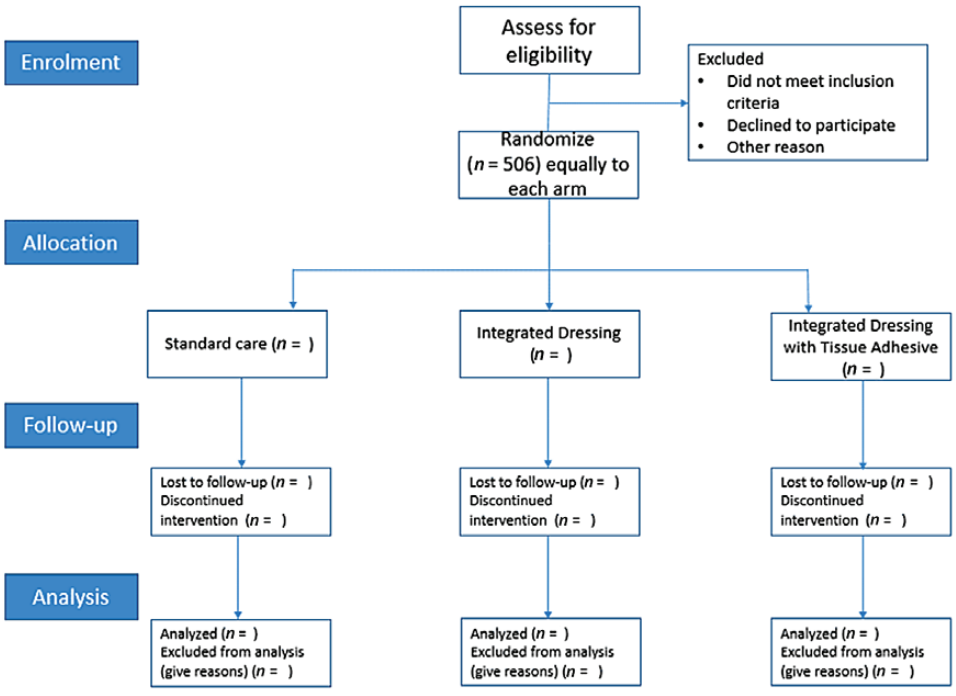
Cost-effectiveness for all groups across the whole sample will be calculated from the hospital perspective. Direct costs to the hospital will be captured including purchase costs of products, and costs incurred by PIVC failure (e.g., PIVC replacement or antibiotics to treat PIVC infections). The data will be used to estimate total resource use and costs for each of the groups during the study period. Costs will be analyzed with bootstrapped t-tests and generalized linear models with adjustment for covariates to estimate the mean difference in costs per securement strategy. Extensive one-way sensitivity scenario analyses will also be conducted, and analyses will explore explanatory clinical and demographic variables (in addition to group). A subsequent cost-effectiveness analysis will be undertaken to estimate the incremental costs of each securement strategy, per additional PIVC failure avoided.

Validity and reliability

High-quality study processes have been adhered to in accordance with CONSORT Statement (CONSORT, 2010). This has included prospective registration of all study decisions, including primary and secondary outcomes. Allocation concealment will be maintained through sequentially numbered, sealed, opaque envelopes. Regular auditing for allocation and protocol adherence is maintained by dedicated staff, project managers, and locally based chief investigators. While masking the intervention or outcome assessors is not feasible, the statistician is masked to the study group (see CONSORT Diagram Figure 4).

Figure 4

CONSORT Diagram



Discussion

The process of intravenous cannulation for children is no menial task. The difficulty in obtaining peripheral intravenous access is remarkably high in children, with up to 23% of this patient population requiring more than four attempts to gain access (Goff et al., 2013; Helm et al., 2015) and successful placement takes, on average, 41 minutes to complete per child (Goff et al., 2013; Hollaway et al., 2017). Consider, then, the challenge of revisiting the entire process when cannulas are accidentally removed due to inadequate fixation. Peripheral intravenous catheter failure is heavily documented as an economic burden on the healthcare system and patient groups, as each re-site requires significant human and material resources to continue treatment (Ben Abdelaziz et al., 2017).

This research trial will test a change in practice from the traditional securement methods of PIVCs in paediatric patients, to a potentially longer-lasting, improved, but cost-effective method. These changes will aim to create a sustainable best practice model that will encompass the strategic goal of best patient outcomes. This kind of innovation not only has the potential to positively impact the healthcare system, but it will create real value at scale through fiscal and productivity improvements. It is an expectation that this new fixation process will limit the likelihood for unnecessary re-cannulations due to inadequate securement, thus laying the foundation for a more positive patient experience with a longer lasting baseline for intravenous treatment in an acute care facility. A PIVC insertion is often a traumatic experience for both the paediatric patient and their supporting family members and should be performed as infrequently as possible (Kleidon et al., 2019; Schmitz et al., 2015). We hope that the knowledge gained through this trial will ascertain the optimal method for securement and increase the best practice surrounding the ideal method for preserving and maintaining PIVCs in children.

Limitations

Study recruitment has been occurring throughout the COVID-19 pandemic and, as such, several implications surrounding recruitment have been experienced. In 2020, there was a local 14.3% decrease in paediatric patient presentations, thus recruitment time had to be extended in order to recruit to the required number of patients to prove significance. This has resulted in other flow-on effects for the study, namely, several large re-education drives, as there have been many medical and nursing rotation changes over the course of the prolonged study time. Fortunately, the study has been able to continue to recruit and a funding extension was granted by the funding administrator. The decision to record the data on paper CRFs was made at inception of the study, and the CRFs are then entered into an electronic platform by trained research staff. This process does leave the potential for missed data by way of missing paper documentation. However, we have allowed 10 % attrition to capture the minimal expected missed, and processes to ensure data quality checking (see Data analysis). Whilst this study is not masked at the intervention or outcome assessment stage, we have ensured the outcomes are masked from the collating and analysis team. This study is looking at the paediatric population across two sites, and while this represents limited locations, it is expected the large volume of patients seen and enrolled can be applied to larger patient populations.

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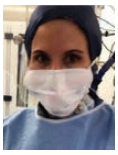

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Conflict of interest statement

TK reports her employer Griffith University has received unrestricted investigator-initiated research or educational grants on her behalf from product manufacturers (Becton Dickinson [BD]). Griffith University has received consultancy payments on her behalf from manufacturers (3M, BD, Medical Specialties Australia, Smiths Medical, and Vygon). These are unrelated to the current project.

AU's former employer has received investigator-initiated research grants from product manufacturers (3M, BD, and Cardinal Health), unrelated to the current project.

JB's current employer has received investigator-initiated research grants and consultancy payments on his behalf from product manufacturers (3M and BD).

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