ABSTRACT

Introduction: Peripheral intravenous catheters (PIVCs) are widely used, but failure is unacceptably common with up to 69% failing before treatment is complete. PIVC securement reduces failure, but the optimal way to achieve this is unclear. Tapes and supplementary securement products are widely used, however rigorous testing of these to reduce PIVC failure remains unexplored.

Methods and analysis: In adult medical-surgical wards at a tertiary hospital, this pilot randomized controlled trial tests standard care (bordered polyurethane dressing plus nonsterile tape over the extension tubing) against two securement interventions (intervention one: standard care plus two sterile tape strips over the PIVC hub; intervention two: intervention one plus a tubular bandage). Patients >18 years of age requiring a PIVC for >24 hours are eligible. Patients with laboratory-confirmed positive blood cultures within 24 hours of screening, known allergy to study products, current or high-risk of skin tear, or non-English speaking without interpreter are excluded. Sample size is 35 per trial arm, and central randomization is computer-generated with allocation concealed until entry. Patients and clinical staff cannot be blinded to treatment allocation. However, infection outcomes are assessed by a blinded investigator. Primary outcome is study feasibility. Secondary outcomes (PIVC failure, dwell time, skin adverse events, PIVC colonization, and cost) are compared between groups. Feasibility outcomes are reported descriptively.

Ethics and trial commencement: Ethical approvals were received from Royal Brisbane and Women’s Hospital (HREC/18/QRWB/44571) and Griffith University (2018/1000). Trial commencement was May 2019.

Trial registration: ACTRN12619000026123.
may lead to pain, anxiety and distress for patients with repeated
and frequent cannulation attempts, negatively impacting their
hospital stay (Helm, Klausner, Klemperer, Flint, & Huang,
2015). Furthermore, PIVC failure is costly to the healthcare
institution due to the human and material resources required to
replace failed PIVCs, in addition to the cost of treating PIVC
complications and any sequelae (Helm et al., 2015).

PIVC dressing and securement has an important role to play
in reducing PIVC complications and failure. Optimal dressing
and securement: 1) anchors the catheter to the skin, maintaining
the position within the vessel; 2) reduces catheter micromotion
or pistoning, thereby minimizing phlebitis, thrombosis, occlusion
and infection (Aleksyev, Byrne, Carpenter, Franker, Kidd,
& Hutton, 2012; Frey & Schears, 2006; Gorski, Hadaway,
Hagle, McGoldrick, Orr, & Doellman, 2016; Moreau et al.,
2012; Rickard et al., 2015); and 3) provides a physical barrier
between the insertion site and environment, reducing a microbial
colonization (Ullman, Cooke, & Rickard, 2015). However,
evidence regarding the most effective dressing and securement
methods to prevent PIVC failure is lacking, with a recent
Cochrane review concluding that there was insufficient high-
quality evidence informing clinical practice (Marsh, Webster,
Mihala, & Rickard, 2015).

A recent large multicentre randomized controlled trial (RCT)
found no significant difference in PIVC failure between four
different dressing and securement methods and, therefore,
recommended investigating multiproduct dressing and securement
combinations and their effect on PIVC failure rates (Rickard et
al., 2018). The use of a PIVC securement bundle, which combines
the use of a primary dressing with medical adhesive tapes and
supplementary securement products, may be effective at reducing
PIVC failure rates, but has yet to be rigorously tested.

The use of tapes and supplementary securement products
to provide additional stability to PIVCs is widespread, with
between 40–83% of dressings requiring reinforcement with
medical adhesive tapes, bandages or other forms of securement
(Marsh et al., 2018; Rickard et al., 2018; Marsh et al., 2015;
New, Webster, Marsh, & Hewer, 2014; Russell, Chan, Marsh,
& New, 2014). Recent evidence from large cohort studies
demonstrates that any additional PIVC securement with tapes,
secondary dressings or bandages/splints is associated with
fewer complications (Marsh et al., 2018; Miliani et al., 2017).
Specifically, the use of non-sterile tape was associated with
lower rates of occlusion, phlebitis and dislodgement (Marsh
et al., 2018); the addition of an elasticised tubular bandage over
the PIVC was associated with fewer episodes of occlusion (Marsh
et al., 2018), and complications overall (Miliani et al., 2017);
and the presence of any other form of additional securement
with less occlusion/infiltration, phlebitis and dislodgement
(Marsh et al., 2018).

The extensive use of supplementary securement products,
which is often ad hoc and not evidence-based, to stabilize PIVCs
indicates that current dressings and securement options alone do
not meet the needs of clinicians and patients and that there is a lack
of standardization in practice. However, despite their widespread
use, little attention has been given to testing the effectiveness
of medical adhesive tapes and supplementary products as an
intervention to prevent PIVC failure and complications, with
no randomized controlled trials identified. Effective PIVC
securement prevents failure and complications. However, an
optimal dressing and securement combination has not yet
been identified, and more innovative solutions are required. An
evidence gap exists in the current literature regarding the use of
medical adhesive tapes and supplementary securement products
in PIVC care. We propose a pilot RCT to assess the feasibility
of conducting a large-scale RCT testing PIVC securement bundles
against standard care to prevent PIVC failure.

Methods and analysis

Design
In this single-centre, parallel group, pilot RCT, two dressing and
securement combinations (securement bundles) are compared
to standard care (control). The trial is conducted and reported
in accordance with The Consolidated Standards of Reporting
Trials (CONSORT) statement (Schulz, Altman, & Moher, 2010)
and has been prospectively registered with the Australian New
Zealand Clinical Trials Registry. (ACTRN1261900026123).

Hypotheses

Primary hypothesis
Using evidenced-based criteria (Thabane et al., 2010), it will
be feasible to conduct a full scale RCT based on the following
objectives:

- Eligibility (≥90% of screened participants are eligible);
- Recruitment (≥90% of eligible participants provide informed
  consent);
- Retention (<5% of participants are lost to follow up);
- Protocol fidelity (≥80% of participants in the intervention
  arms receive the allocated intervention);
- Missing data (<5% of outcome data not collected);
- Patients and clinical staff find the intervention arms acceptable
  (>80% satisfaction and acceptability);
- Sample size estimates, based on the incidence of PIVC failure
  in each trial arm, can be calculated for an adequately powered
  study.

Secondary hypotheses
1. PIVCs secured with a securement bundle intervention
have fewer episodes of failure (composite of phlebitis,
infiltration, occlusion, dislodgement (partial or complete),
primary laboratory-confirmed bloodstream infection, or
local infection) compared with those secured by standard
care dressings and securements.
2. PIVCs secured with a securement bundle intervention
have longer dwell times than those secured by standard
care dressings and securements.
3. PIVC securement bundles are associated with equivalent
costs when compared with standard care dressings and
securements.

Setting and sample
This pilot RCT is conducted in the general medical and surgical
wards of a large quaternary referral hospital in Queensland,
Australia. Adult patients within these wards requiring placement
of a PIVC as part of their treatment are screened for eligibility. Patients 18 years of age or older requiring a PIVC for longer than 24 hours are eligible for inclusion. These patients are excluded: those with a laboratory-confirmed positive blood culture within 24 hours of screening, with the exclusion of a single common skin contaminant (Centers of Disease Control and Prevention, 2019); a known allergy to any study product; a current skin tear, or deemed at high risk of skin tear by PIVC inserter; non-English speaking without an interpreter; or previously recruited to the current study. Written informed consent is obtained by the research nurse prior to study commencement.

Sample size
The recruitment target of 105 (35 participants per study arm) is adequate to assess the primary feasibility outcome (Hertzog, 2008; Viechtbauer et al., 2015). Hence, this study is not powered adequately to detect statistically significant differences in clinical outcomes between study groups.

Study interventions
Participants randomized to the control arm have their PIVCs dressed and secured as per standard practice (Figure 1A), which consists of:

- A bordered polyurethane dressing (Tegaderm™ IV Transparent Film Dressing with Border 1635, 10.5 x 8.5 cm, 3M, St. Paul, Minnesota, USA); plus
- Two tape strips (approximately 10cm in length) over the extension tubing (Medipore™ H Soft Cloth Surgical Tape, 3M, St. Paul, Minnesota, USA; contained within the package of the bordered polyurethane dressing above).

Two intervention arms will be tested. The first intervention arm consists of the following:

- The control arm; plus
- Sterile tape strip in a chevron pattern around hub (Steri-Strip™ Adhesive Reinforced Skin Closures 6mm x 75mm, 3M, St Paul, Minnesota, USA); plus
- Sterile tape strip over hub (Steri-Strip™ Adhesive Reinforced Skin Closures 6mm x 75mm, 3M, St Paul, Minnesota, USA).

The second intervention arm is made up of two factors:

- The first intervention arm; plus
- A non-compression tubular bandage (Tubifast, Mölnlycke Health Care AB, Belrose, NSW, Australia).

As a pragmatic pilot RCT, staff responsible for PIVC maintenance can add additional dressing or securement products as appropriate.

**Outcome measures**

**Primary outcome**
Feasibility outcomes are determined based on the following criteria:

- Eligibility (percentage of eligible screened patients);
- Recruitment (percentage of eligible patients providing informed consent);
- Retention (percentage of patients lost to follow up or withdrawing consent);
- Protocol fidelity (percentage of randomized patients receiving their allocated intervention on PIVC insertion);
- Missing data (percentage of total data not collected for primary clinical outcome);
- Patient and staff satisfaction with study intervention(s) at insertion and removal (percentage of patients and staff scoring ≥ 7 on an 11-point scale with 0=very dissatisfied to 10=very satisfied); and
- Ability to provide effect estimates for sample size calculation for a larger RCT.

**Secondary outcomes**
There are five secondary outcomes.

1. **PIVC failure**, as a composite measure of any of the following complications at removal:
   - Phlebitis (one or more of pain, tenderness, warmth, erythema, swelling, palpable cord) (Rickard et al., 2018);
   - Infiltration or extravasation (permeation of intravenous fluid into the interstitial compartment, causing swelling or damage of the tissue around the site of the catheter) (Webster et al., 2008);
   - Occlusion (PIVC does not infuse or flush or leakage occurs when fluids are infused or flushed) (Rickard et al., 2015);
   - Accidental dislodgement or removal (partial or complete dislodgement from vein) (Rickard et al., 2018);
   - Infection (primary laboratory-confirmed bloodstream infection [LCBI] or localised venous infection [CDCP, 2019])

   a) LCBI (from blood collected as part of routine care), in accordance with one of the following criteria:
A recognized pathogen, identified from one or more blood specimens obtained by a culture or non-culture based microbiologic testing method AND organisms identified in blood are not related to an infection at another site

Patient has at least one of the following signs or symptoms: fever (>38.0°C), chills, or hypotension AND organisms identified in blood are not related to an infection at another site AND the same National Health and Safety Network (NHSN) common commensal is identified by a culture- or non-culture-based microbiologic testing method, from two or more blood specimens collected on separate occasions.

Localized venous infection (from swab collected as part of routine care), according to the NHSN VASC-Arterial or venous infection criteria, with no laboratory-confirmed blood stream infection, but at least one of the following criteria:

i. Organisms from extracted vein identified by culture- or non-culture-based testing, performed for clinical diagnosis (not surveillance);

Evidence of venous infection on gross anatomic or histopathologic exam;

iii. At least one of: fever (>38.0°C), pain*, erythema*, or heat* at involved vascular site; and >15 colony forming units cultured from PIVC tip using semiquantitative method (*with no other recognized cause);

iv. Purulent drainage from the PIVC site;

PIVC dwell time: from the time of PIVC insertion to removal (in hours) (Rickard et al., 2015);

Cost analysis: in a subset of six patients per study arm, PIVC colonisation: on PIVC removal, a subset of six patients per study arm will have their PIVC tip and an insertion site swab collected to assess device colonization; and

5. Skincare events (rash, blister, itchiness, skin tears, adhesive residue) (Rickard et al., 2018);

PIVC insertion: a subset of six patients per study arm will have their PIVC tip and an insertion site swab collected to assess device colonization; and

Data collection

Data are collected by the research nurse and entered in a de-identified format directly into a purpose-designed database built in REDCap (Research Electronic Data Capture, Vanderbilt University). For the primary outcome of feasibility, data regarding eligibility and recruitment are sourced from the screening log (held at the study site), which will contain 1) all patients screened for study inclusion, regardless of whether they met the eligibility criteria, 2) recruitment status, and 3) treatment allocation. Data for the remaining feasibility outcomes (retention, protocol fidelity, missing data, and patient and staff satisfaction) are held in the REDCap database. The research nurse visits the patient daily to collect clinical data until the PIVC is removed. Clinical data are collected from the inserter, the patient, the staff maintaining the PIVC, the medical notes and the electronic pathology record. Table 1 details data collected at each time point.

Validity and reliability

Strategies used to ensure the internal validity of the trial include: web-based randomization with randomly varying block size and allocation concealment until randomization reduces selection bias, blinding of the infectious outcomes assessor and the data analyst reduce detection bias, and intention-to-treat analysis is used to reduce attrition bias, and all randomized patients are reported. External validity is enhanced by sampling from a general medical and surgical population of a large metropolitan tertiary hospital so that, despite this being a single-centre trial, the results are generalizable to the majority of general ward patients requiring a PIVC as part of their care. Additionally, the outcome measures of the trial are clinically relevant and important to patients.

As PIVCs are inspected daily to provide data for the study endpoints, inter-rater reliability testing between the researcher

i. A recognized pathogen, identified from one or more blood specimens obtained by a culture or non-culture based microbiologic testing method AND organisms identified in blood are not related to an infection at another site

ii. Patient has at least one of the following signs or symptoms: fever (>38.0°C), chills, or hypotension AND organisms identified in blood are not related to an infection at another site AND the same National Health and Safety Network (NHSN) common commensal is identified by a culture- or non-culture-based microbiologic testing method, from two or more blood specimens collected on separate occasions.

b) Localized venous infection (from swab collected as part of routine care), according to the NHSN VASC-Arterial or venous infection criteria, with no laboratory-confirmed blood stream infection, but at least one of the following criteria:

i. Organisms from extracted vein identified by culture- or non-culture-based testing, performed for clinical diagnosis (not surveillance);

Evidence of venous infection on gross anatomic or histopathologic exam;

iii. At least one of: fever (>38.0°C), pain*, erythema*, or heat* at involved vascular site; and >15 colony forming units cultured from PIVC tip using semiquantitative method (*with no other recognized cause);

iv. Purulent drainage from the PIVC site;

PIVC dwell time: from the time of PIVC insertion to removal (in hours) (Rickard et al., 2015);

Data collection

Data are collected by the research nurse and entered in a de-identified format directly into a purpose-designed database built in REDCap (Research Electronic Data Capture, Vanderbilt University). For the primary outcome of feasibility, data regarding eligibility and recruitment are sourced from the screening log (held at the study site), which will contain 1) all patients screened for study inclusion, regardless of whether they met the eligibility criteria, 2) recruitment status, and 3) treatment allocation. Data for the remaining feasibility outcomes (retention, protocol fidelity, missing data, and patient and staff satisfaction) are held in the REDCap database. The research nurse visits the patient daily to collect clinical data until the PIVC is removed. Clinical data are collected from the inserter, the patient, the staff maintaining the PIVC, the medical notes and the electronic pathology record. Table 1 details data collected at each time point.

Validity and reliability

Strategies used to ensure the internal validity of the trial include: web-based randomization with randomly varying block size and allocation concealment until randomization reduces selection bias, blinding of the infectious outcomes assessor and the data analyst reduce detection bias, and intention-to-treat analysis is used to reduce attrition bias, and all randomized patients are reported. External validity is enhanced by sampling from a general medical and surgical population of a large metropolitan tertiary hospital so that, despite this being a single-centre trial, the results are generalizable to the majority of general ward patients requiring a PIVC as part of their care. Additionally, the outcome measures of the trial are clinically relevant and important to patients.

As PIVCs are inspected daily to provide data for the study endpoints, inter-rater reliability testing between the researcher...
and a vascular access specialist is performed for 5% of the daily site inspections to assess the reliability of outcome assessment.

**Statistical analysis**

Trial data are exported from the REDCap database to STATA (StataCorp, College Station, TX) for analysis. Trial feasibility outcomes are reported descriptively and compared against the acceptability limits. As this is a pilot RCT, there is no expectation that statistically significant differences between groups will be found for the clinical outcomes. However, the statistical plan will be tested in preparation for a larger efficacy study. All randomized patients are analyzed by intention to treat, regardless of treatment received. Incidence rates of PIVC failure with 95% confidence intervals summarize the effectiveness of each intervention. Kaplan-Meier survival curves (with log-rank test) compare device failure between groups over time. Other secondary clinical outcomes are compared between groups with appropriate parametric or non-parametric techniques. P values <0.05 (two-tailed) are considered significant. Missing values are not imputed. Inter-rater reliability is tested using proportions of specific agreement and Cohen's kappa.

**Trial status**

Patient recruitment commenced in May 2019 and data collection took place over a 12-week period.

**Discussion**

The global problem of PIVC failure remains unresolved and requires innovative solutions to reduce the currently high failure rates. This pilot RCT is first in investigating the use of bundled, evidence-based securement interventions, and tests the feasibility and safety of the study protocol prior to embarking on a larger definitive trial. Additionally, it is expected that the findings will provide preliminary evidence for clinical practice guideline development, which currently offer little guidance on the use of tapes and supplementary securement products in PIVC care.

**Strengths and limitations of this study**

- This three-arm, parallel pilot randomized controlled trial (RCT) assesses the feasibility and safety of the study protocol before progressing to a larger, adequately powered RCT.
- Thirty-five adult medical-surgical participants are recruited per trial arm to test the primary outcome of feasibility. However, the trial is under-powered to detect differences in the secondary clinical outcomes.
- Specific items to be tested include recruitment methods and timeframe, data collection tools and techniques, safety of the intervention arms, protocol adherence, outcome assessment, and statistical methods.
- Inter-rater reliability is assessed for a proportion of the clinical outcome data to ensure reliability in outcome assessment.

**Ethics and dissemination**

Ethical approval for the study was granted by the Royal Brisbane and Women’s Hospital (HREC/2018/ QRBW/44571) and Griffith University (2018/1000) Human Research Ethics Committees (HREC). Participation in this research poses no more than minimal risk to the patient as all study products are approved for use and used in accordance with their approval, and all study procedures are performed by staff with appropriate training. Written informed consent is obtained from all participants prior to randomization. Study patients are visited daily while on the trial and adverse events, such as skin reactions to study products, are actively monitored. Protocol violations and deviations are

<table>
<thead>
<tr>
<th>Table 1. Data collected by study time point</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>On enrolment</strong></td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Insertion time</td>
</tr>
<tr>
<td>Dressing and securement type</td>
</tr>
<tr>
<td>PIVC removal time</td>
</tr>
<tr>
<td>Results of blood cultures, PIVC tips or insertion site swabs sent as part of usual care &amp; any other positive microbiology results</td>
</tr>
</tbody>
</table>
recorded by the research nurse and are reported in the study results. All serious adverse events, defined as death, intensive care unit admission, or positive blood culture, are reported to both HRECs. Data (paper and electronic) are stored securely, as per the Australian National Health and Medical Research Council guidelines (National Health and Medical Research Council, 2018), and are available to other parties on request to the primary author. No individual patient data are presented in any publications or presentations arising from the research.

Study findings are presented at relevant local, national and international meetings. Results are published in peer-reviewed nursing and/or vascular access journals. Presentation and publication of results is intended to encourage and facilitate translation into clinical practice.


Rickard, C. M., McCain, D., Munnings, J., & McGrail, M. R. (2019). Routine reuse of peripheral intravenous devices every 3 days did not reduce complications compared with clinically indicated reinsertion: A randomised controlled trial. BMJ Medicine, 8, 53.


Funding statement: This work was supported by the Cardinal Health 2018 Infection Control Scholarship, the Centaur Memorial Fund for Nurses, and The Prince Charles Hospital Foundation. No funder had any part in study design, conduct or analysis, or in the preparation of this manuscript.

Disclosure statement: Griffith University has received educational grants, investigator-initiated research grants, unrestricted investigator initiated research or educational grants, and consultancy payments from various product manufacturers (3M, Adhezion, Angiodynamics, Baxter, BBraun, Becton Dickinson [BD]- Bard, Centurion Medical Products – Medline, Elaquest, Medtronic, ResQDevices, and Smith’s Medical), on behalf of all authors except for Gabor Mihala and Patrick N. A. Harris, who have nil to declare.