SECUREment bundles to prevent peripheral intravenous catheter failure—the SECURE-PIVC trial: study protocol for a pilot randomized controlled trial

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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/QRBW/44571) and Griffith University (2018/1000). Trial commencement was May 2019.

Trial registration: ACTRN12619000026123.

Peripheral intravenous catheters (PIVCs) are required by up to 70% of hospitalized patients to deliver medical treatment (Zingg & Pittet, 2009). However, despite their importance and widespread use, rates of PIVC failure and unscheduled reinsertions due to complications are reported to be between 30% and 69% (Bolton, 2010; Gunther et al., 2016; Marsh, Webster, Larsen Cooke, Mihala, & Rickard, 2018; Rickard, McCann, Munnings, & McGrail, 2010; Rickard et al., 2012; Smith, 2006; Rickard et al., 2018). Factors responsible for early failure include phlebitis, occlusion, infiltration, extravasation, dislodgement and infection (Bolton, 2010; Marsh et al., 2018; Rickard et al., 2010; Rickard et al., 2018). PIVC failure and subsequent resite

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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 (Alekseyev, 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 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 (March 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. (ACTRN12619000026123).

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

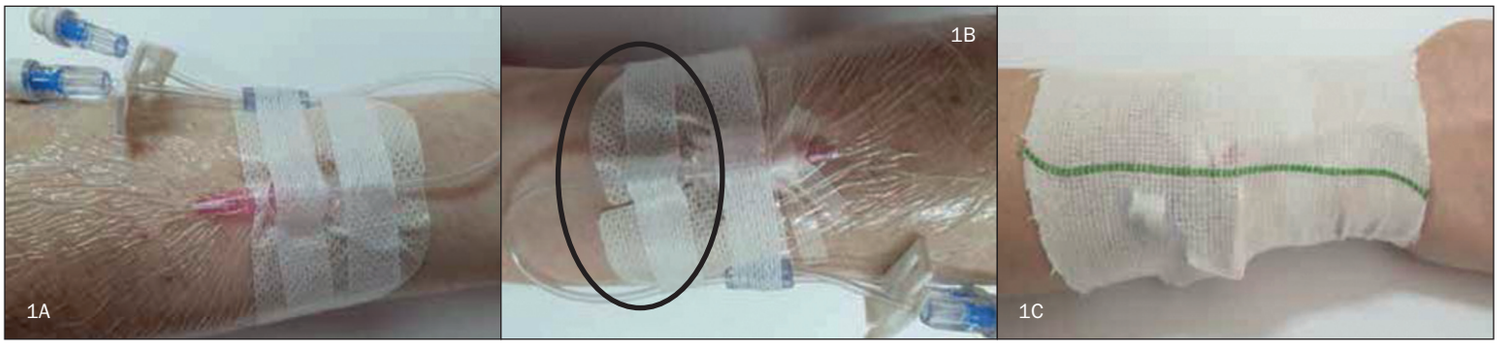

Figure 1. Control – bordered transparent dressing plus two tape strips over dressing (1A); Intervention 1 – two sterile tape strips in a chevron pattern around the PIVC hub (circled) plus Control (1B); Intervention 2 – Intervention 1 plus tubular bandage (1C)

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:

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);
ii. 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;

2. PIVC dwell time: from the time of PIVC insertion to removal (in hours) (Rickard et al., 2015);
3. Skin adverse events (rash, blister, itchiness, skin tears, adhesive residue) (Rickard et al., 2018);
4. 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. Cost analysis: in a subset of six patients per study arm, resources utilized (staff time, consumables) during their participation in the study. The cost of treating any complications associated with the PIVC dwell also are recorded.

Study procedures

Randomization and allocation concealment

After written informed consent is given, the patient is randomized to treatment allocation by the research nurse using a web-based central randomization service provided by Griffith University Clinical Trials Randomization Service (https://www151.griffith.edu.au/). The allocation sequence is computer generated in a ratio of 1:1:1, using randomly varied block sizes of three and six to avoid allocation prediction in addition to uneven group allocation in this small pilot trial.

Blinding

It is not possible, due to the nature of the interventions, to blind the research nurses or clinical staff to treatment allocation. For the infection outcomes, an Infectious Diseases specialist is blinded to treatment allocation. Similarly, the data analyst is blinded to treatment allocation.

PIVC care

All PIVCs are inserted as per hospital policy and by a research nurse (ReN) experienced in PIVC insertion. Insertion site and catheter gauge are chosen by the PIVC inserter based on their assessment of the patient and the patient's treatment needs. The study interventions and control are applied by the PIVC inserter as per treatment allocation. A sticker is placed on the dressing to indicate treatment allocation and is replaced on any subsequent dressing changes. After insertion and initial dressing and securement of the PIVC, all PIVCs are maintained by clinical staff, as per hospital policy. As a pragmatic trial, staff maintaining the PIVC are able to redress and/or reinforce the study interventions based on clinical need, and any such dressings and additional securement products are recorded daily by the research staff. The timing of removal of PIVCs is determined by the clinical team using usual hospital criteria, namely PIVC complication necessitating removal, 72-hourly resite, and/or completion of therapy. Protocol violations are defined as those randomized participants who never receive a PIVC or the randomized intervention. Protocol deviations are defined as randomized participants who receive the correct intervention on PIVC insertion, but whose dressing and/or securement is modified during the PIVC dwell.

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

Table 1. Data collected by study time point

On enrolment	On PIVC insertion	Daily data	On PIVC removal	At 48 hrs post removal
■ Age ■ Sex ■ Height/weight ■ Admission reason ■ Hospital diagnosis ■ Clinical ward ■ Skin type (Fitzpatrick scale) & skin integrity ■ Current infection ■ Comorbidities ■ Current wounds	■ Insertion time ■ Insertion site ■ Vein quality as per the Peripheral Vein Assessment Tool ■ PIVC gauge ■ Dressing and securement type ■ Extension tubing/ administration sets ■ Inserter and patients' satisfaction with study products on 11-point scale (with 0 = very dissatisfied and 10 = very satisfied) ■ If patient is diaphoretic ■ Hair at insertion site ■ Skin preparation used ■ Insertion risk factors (e.g., difficult insertion and cannulation attempts)	■ Dressing and securement type ■ Dressing and securement integrity ■ PIVC dressing change, when & why ■ Any additional dressing &/or securements, & reason for use ■ Extension tubing/administration sets ■ Maintenance risk factors (e.g., diaphoresis & agitation) ■ Site complications): ● Patient-reported pain/tenderness on palpation on 11-point scale (with 0=no pain and 10=maximal pain) ● Redness (none, redness in cm) ● Swelling (none, swelling in cm) ● Palpable cord (none, cord in cm) ● Leakage (yes or no) ● Purulence (none, from site, ulceration) ● Warmth (on palpation) ● Dislodgement (partial or complete) ● Infection suspected by clinical staff ■ Adverse skin event (rash, blister, itchiness, skin tears, adhesive residue)	■ PIVC removal time ■ Reason for removal (therapy complete, routine resite, PIVC failure) ■ Site complications (as for daily data) ■ Patient & staff satisfaction with study products on 11-point scale (with 0 = very dissatisfied and 10 = very satisfied) ■ Maintenance risk factors (e.g., mobility status, antibiotic administration and delirium)	■ Results of blood cultures, PIVC tips or insertion site swabs sent as part of usual care & any other positive microbiology results ■ Treatment of blood stream infection or any other complication associated with PIVC ■ Patient outcome – alive/deceased/ discharged before 48 hours

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

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.

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