A pilot randomized controlled trial of securement bundles to reduce peripheral intravenous catheter failure

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ABSTRACT

Background: Peripheral intravenous catheters (PIVCs) are ubiquitous in acute care settings however failure rates are unacceptably high, with around half failing before prescribed treatment is complete. The most effective dressing and securement option to prolong PIVC longevity is unclear.
Objectives: To determine feasibility of conducting a definitive randomized controlled trial (RCT) investigating evidence-based securement bundles (medical adhesive tapes and supplementary securement products) to reduce PIVC failure.
Methods: In this pilot non-masked 3-group RCT, adults requiring a PIVC for >24 hrs were randomized to Standard care (bordered polyurethane dressing plus non-sterile tape over extension tubing), Securement Bundle 1 (two sterile tape strips over PIVC hub plus Standard care) or Securement Bundle 2 (Bundle 1 plus tubular bandage) with allocation concealed until study entry. Exclusions: laboratory-confirmed positive blood culture, current/high-risk of skin tear, or study product allergy. Primary outcome: feasibility (eligibility, recruitment, retention, protocol fidelity, participant/staff satisfaction). Secondary outcomes: PIVC failure, PIVC dwell time, adverse skin events, PIVC colonization and cost.
Results: Of 109 randomized participants, 104 were included in final analyses. Feasibility outcomes were met, except eligibility criterion (79%). Absolute PIVC failure was 38.2% (13/34) for Bundle 2, 25% (9/36) for Bundle 1 and 23.5% (8/34) for Standard care. Incidence rate ratio for PIVC failure/1000 catheter days, compared to Standard care, was 1.1 (95% confidence interval [CI] 0.4−2.7) and 2.1 (95% CI 0.9−5.1) for Bundles 1 and 2, respectively.
Conclusions: A large RCT testing securement bundles is feasible, with adjustment to screening processes. Innovative dressing and securement solutions are needed to reduce unacceptable PIVC failure rates.
Trial registration ACTRN12619000026123.

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Introduction

Peripheral intravenous catheters (PIVCs) are one of the most commonly used medical devices, with nearly 2 billion purchased globally each year.[1] Despite up to 70% of hospitalized patients requiring one or more PIVCs during their stay,[2] PIVC failure rates are unacceptably high at between 30 and 69%.[3−8] Premature failure is caused by many factors, including phlebitis, occlusion, infiltration, extravasation, dislodgement and infection.[6,9,10] Subsequent PIVC replacement leads to

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pain, anxiety and distress for patients, negatively impacting their hospital stay[11,12]; and escalating healthcare costs.[9]

Effective PIVC dressing and securement may reduce failure through: anchoring the catheter to the skin, maintaining position within the vessel[13]; reducing catheter micromotion or pistoning (movement of the catheter in and out of the insertion site), thereby minimizing phlebitis, thrombosis, occlusion and infection[14-17]; and providing a physical barrier between the insertion wound and environment, reducing microbial colonization.[18] However, high-quality evidence-based guidance in dressing and securement methods to prevent PIVC failure is limited.[19]

Tapes and supplementary securement products provide additional PIVC stability and are used extensively in clinical practice, with 40−83% of primary dressings requiring reinforcement with medical adhesive tapes, bandages or other forms of securement.[5,6,20-23] Evidence from large cohort studies demonstrates any additional dressing/securement is associated with fewer complications.[5,10,20] Specifically, non-sterile tape was associated with less occlusion (Hazard ratio [HR] 0.46, 95% confidence interval [CI] 0.33−0.63), phlebitis (HR 0.63, 95%CI 0.48−0.82) and dislodgement (HR 0.06, 95%CI 0.01−0.46).[5,20] An elasticized tubular bandage over the PIVC was associated with less occlusion (HR 0.49, 95%CI 0.35−0.70),[5] and complications overall (HR 0.06, 95%CI 0.02−0.19).[10] Despite widespread use of tapes and supplementary securement products, little attention has been given to testing these as an intervention to reduce PIVC failure.

The concept of a securement bundle involves the use of a combination of dressing and securement products used together to improve PIVC stability and dwell time.[6] A large global dataset of PIVC management practices and outcomes was examined to identify dressing and securement approaches associated with fewer PIVC complications.[24] Four dressing and securement bundles, consisting of a primary dressing, with or without a primary securement such as medical adhesive tapes, and supplementary securement products such as a tubular bandage, were formulated *a priori* using the best available evidence and ensuring compliance with current clinical guidelines. In the examination of the global dataset, three of these securement bundles were associated with fewer insertion site complications[24] and two were subsequently chosen to be tested further.

Importantly, insertion and maintenance of PIVCs can negatively affect skin integrity, and using medical adhesive tapes for device securement contributes to this.[25] Current usage of tapes to secure PIVCs is largely *ad hoc*, does not focus on skin safety and is not evidenced-based. Medical adhesive-related skin injury is a preventable patient safety issue[26] therefore decision-making regarding extra securement with tapes involves balancing the importance of device security with potential skin damage.[27] Clinicians must consider these competing priorities to avoid patient harm, however scant evidence exists to guide clinical decision-making.[25]

The primary aim of this 3-arm pilot randomised controlled trial (RCT) was to assess the feasibility of conducting a definitive superiority RCT testing PIVC securement bundles against Standard care to reduce PIVC failure. Secondary aims were to compare the effect of securement bundles on PIVC failure (composite of phlebitis, infiltration, occlusion, dislodgement [partial or complete], primary laboratory-confirmed bloodstream infection, or local infection), individual complications, dwell time, adverse skin events, PIVC colonization and costs.

Methods

Study design, setting and sample

This single-centre, parallel group, pilot RCT was conducted in general medical/surgical wards of a large quaternary hospital in Queensland, Australia. Ethical approvals were obtained (HREC/18/QRBW/44571 and 2018/1000). The study protocol was previously published.[28] This trial was conducted and reported in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines,[29] and was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619000026123).

Hospitalized patients requiring PIVC placement were screened for eligibility. Patients ≥18yrs requiring a PIVC for >24 h were eligible. Patients were excluded for: laboratory-confirmed positive blood culture within 24 h of screening (excluding single common skin contaminants),[30] known study product allergy; current, or deemed high risk of, skin tear; non-English speaking without interpreter; previous recruitment to the study. Written informed consent was obtained prior to study commencement.

Sample size

For this pilot trial, a recruitment target of 105 (35 participants per study arm) was set based on primary feasibility outcomes.[31] Hence, this trial was not adequately powered to detect statistically significant differences between study groups for clinical outcomes.

Study interventions

Participants were randomized to receive standard care, Securement bundle 1 or Securement bundle 2 (Fig. 1)[24]:

1 Standard care

- bordered polyurethane dressing (Tegaderm™ IV Transparent Film Dressing with Border 1635, 10.5 × 8.5 cm, 3 M, St Paul, Minnesota, USA); *plus*
- two non-sterile tape strips (approximately 10 cm) over extension tubing (Medipore™ H Soft Cloth Surgical Tape, 3 M, St Paul, Minnesota, USA).

2 Securement bundle 1

- 1 sterile tape strip in chevron pattern around PIVC hub and 1 sterile tape strip over hub (Steri-Strip™ Adhesive Reinforced Skin Closures 6 × 75 mm, 3 M, St Paul, Minnesota, USA); *plus*

Fig. 1. A: Standard care − bordered transparent dressing plus two tape strips over dressing; Fig. 1B: Securement bundle 1 − Standard care plus two sterile tape strips over the PIVC hub (circled); and Fig. 1C: Securement bundle 2 − Bundle 1 plus tubular bandage.

- Standard care

3 Securement bundle 2

- Bundle 1; *plus*
- non-compression tubular bandage (Tubifast, Mölnlycke Heath Care, Belrose, Australia).

Outcome measures

Primary outcome

Feasibility of conducting a fully powered trial[32,33] based on a composite of eligibility; recruitment; retention; protocol fidelity; missing data; participant/staff satisfaction at insertion and removal; and the ability to provide effect estimates.

Secondary outcomes

1 PIVC failure, composite of any of the following at removal: phlebitis[6]; infiltration/extravasation,[34] occlusion,[6] accidental dislodgement/removal,[6] infection (primary laboratory-confirmed bloodstream infection or localized infection)[30]
2 PIVC dwell time[6]
3 Skin adverse events[6]
4 PIVC colonization (subset of six participants per study arm)
5 Cost estimate (subset of six participants per study arm), including costs of treating PIVC-related complications.

Randomization and blinding

A web-based central randomization service (https://randomisation.griffith.edu.au/) ensured allocation concealment until study entry, with computer-generated allocation sequence (1:1:1), using randomly-varied block sizes (3 or 6). It was not possible to blind research nurses (ReNs) or clinical staff to treatment allocation, however the Infectious Diseases specialist and data analyst were blinded.

PIVC care

All PIVCs were inserted, maintained and removed as per hospital policy[35] as previously outlined.[28] A ReN experienced in PIVC insertion performed all insertions. Staff maintaining PIVCs could redress/reinforce study interventions based on clinical need, and these additional products were recorded daily. If the ReN performing the daily check observed dressing integrity to be unsafe, the bedside nurse was notified immediately however the decision to act on that by reinforcing or changing the dressing was the responsibility of the bedside nurse. Protocol violations were participants not receiving the randomized intervention on PIVC insertion. Protocol deviations were participants receiving the correct intervention on PIVC insertion, but whose dressing and/or securement was modified during PIVC dwell.

Data collection

Data were entered directly into a REDCap database (Research Electronic Data Capture, Vanderbilt University).[36] A ReN visited participants daily until PIVC removal to assess protocol adherence and collect clinical data for secondary outcomes. Data were collected on recruitment, PIVC insertion, daily, PIVC removal, and at 48 h post-PIVC removal as previously published.[28] Inter-rater reliability testing between 2 outcome assessors was performed for 5% of daily PIVC site checks.

Microbial substudy

PIVC insertion site swabs and catheter tips were aseptically collected to assess device colonization in a convenience sample of 6 participants per group, dependant on ReN availability. Specimens were sent to hospital pathology and analysed. Catheter tips were rolled across horse blood agar plate,[37] incubated in 5% CO_2 incubator at 35 °C for ≤72 h. Microbial growth was measured at 24, 48 and 72 h and deemed significant if >15 colony forming units. Site swabs were rolled across horse blood agar plate and a sterile loop used to perform 16 streak pattern from the original inoculum to produce isolated colonies. The plate was incubated in 5% CO_2 at 35 °C and examined for growth at 24, 48 h and 5 days, and reported semi-quantitatively.

Statistical analysis

Prior to analysis, completeness of primary outcomes measures was checked, data were cleaned, and missing fields found where able. Missing data were not imputed. Data were exported to STATA (StataCorp, College Station, TX, USA) for analysis. Trial feasibility outcomes were reported descriptively and compared against acceptability limits. The statistical plan for secondary outcomes was tested in preparation for a larger efficacy study. Analyses were performed on an intention-to-treat basis. Outcomes were summarized by frequency (percentage) for categorical variables and mean (Standard deviation) for continuous variables. PIVC failure incidence rates and incidence rate ratios with 95% CIs were calculated by study group using Poisson regression. Kaplan-Meier survival curves with log-rank for equality of survivor functions compared device failure over time between groups, both for overall failure, and stratified by failure type. Regression models tested for group differences in PIVC dwell time and adverse skin reactions. *P* values <0.05 were considered significant. Observed agreement between PIVC site outcome assessors was calculated manually. Costs of study products for PIVC insertion and maintenance (2019 hospital pricing, in Australian dollars; $1 AUD~$0.72152 USD) were tallied. Procedural timings were observed for 6 dressing and securement applications and removals, and costed at Registered Nurse Grade 5.4 (approximately AUD$40/hour~USD $29/hour). In PIVCs requiring replacement after device failure, reinsertion costs were included.[38] Costs were reported descriptively and compared between study groups.

Results

From 20 May to 2 September 2019, 109 participants were randomized with 104 included in the final analysis. Participant flow through the study is shown in Fig. 2. Baseline demographic and clinical characteristics were fairly similar between groups (Table 1). There were slightly more male participants than female (56% male); mean age was 61 years; a third were overweight or obese; nearly a third had three co-morbidities or more; and most were admitted for surgical procedures (64%). PIVCs were mainly 22 G (62%), inserted in the forearm (84%) on first attempt (80%), in participants who had fair to poor skin integrity (54%).

Feasibility outcomes

197 patients were screened for participation with 155 (79%) meeting eligibility criteria, therefore the eligibility criterion was not met. Of 155 eligible participants, only 5 (3%) declined, indicating the recruitment criterion was met. Retention was satisfactory with no participants withdrawing consent, but one participant was lost to follow-up when transferred to another hospital (0.9%). Protocol fidelity was high with 99% (103/104) of participants receiving the allocated intervention on PIVC insertion. However, protocol deviations, that is, additional securement products added to randomized interventions,

CONSORT Flow Diagram

Enrollment

Assessed for eligibility (n=197)

Excluded (n=88)
- Not meeting inclusion criteria (n= 30)
- Met exclusion criteria
  - Previous enrolment in study (n=8)
  - Allergy to study product (n= 3)
  - Current BSI (n=1)
- Recruited to concurrent study (n=41)
- Declined to participate (n=5)

Randomized (n=109)

Allocation

Allocated to Standard care (n=36)
- Received intervention (n=34)
- Did not receive intervention (PIVC cancelled, n=2)

Allocated to Securement bundle 1 (n=37)
- Received intervention (n=35)
- Protocol violation (n=1)
- Did not receive intervention (PIVC cancelled, n=1)

Allocated to Securement bundle 2 (n=36)
- Received intervention (n=35)
- Did not receive intervention (Unable to insert PIVC, n=1)

Follow-Up

Lost to follow-up (n=0)

Lost to follow-up (n=0)

Lost to follow-up (Transfer to another hospital n=1)

Analysis

Analysed (n=34)
- Excluded from analysis (n=0)

Analysed (n=36)
- Excluded from analysis (n=0)

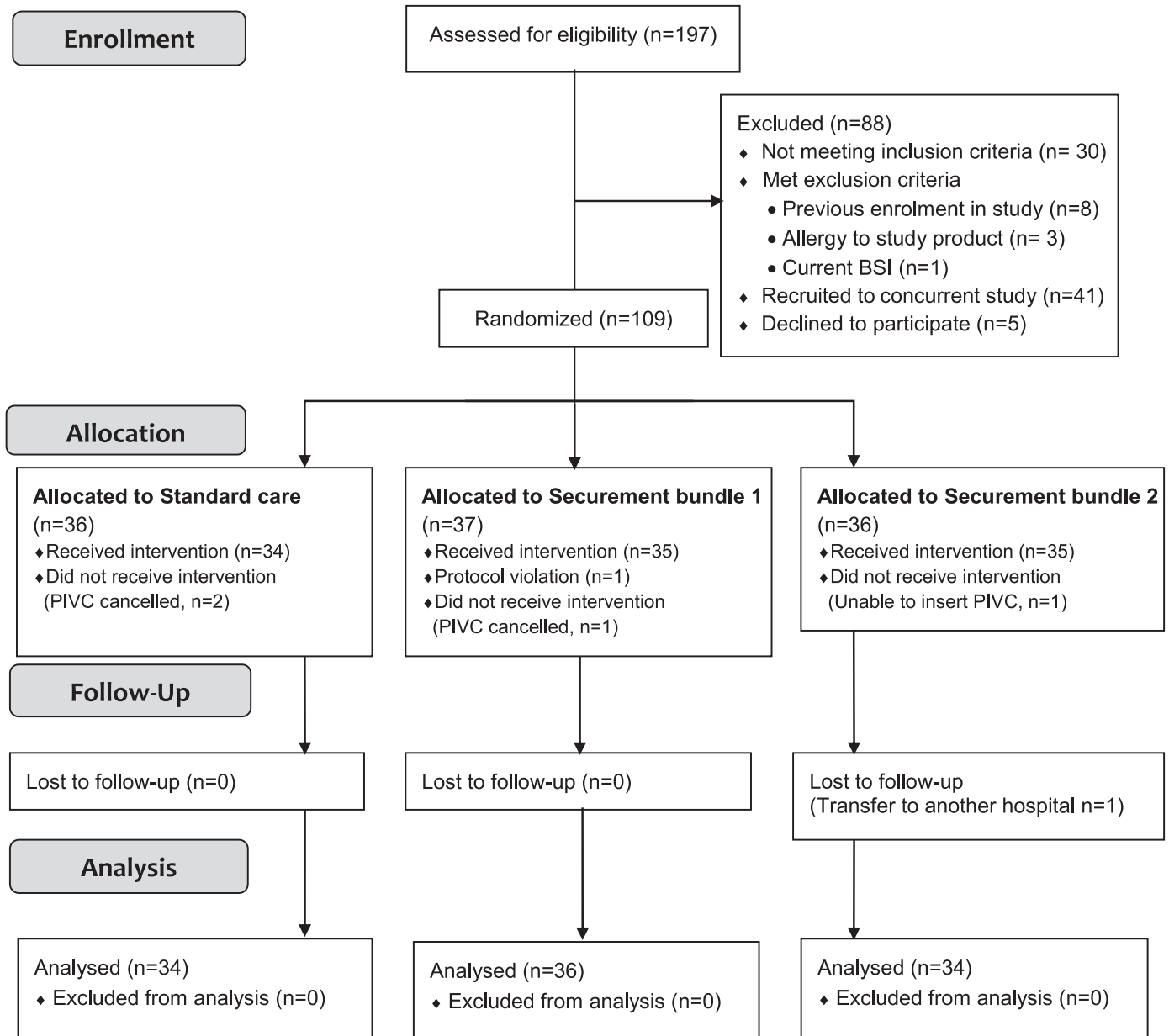Analysed (n=34)
- Excluded from analysis (n=0)

Fig. 2. CONSORT flowchart of study participants.

were very common. Data collection processes were robust with <1% primary clinical outcome data missing. Participants and staff reported high satisfaction with application and removal of securement interventions (Table 2). Effects estimates to inform a larger trial are described below.

Secondary clinical outcomes

Overall PIVC failure was 29% (30/104). The highest rate of failure was in Bundle 2 with 38% (13/34) followed by Bundle 1 (25%, 9/36) then Standard care (24%, 8/34). The incidence rate ratio for PIVC failure per 1000 catheter days, relative to Standard care, was 1.1 (95% CI 0.4−2.7) and 2.1 (0.9−5.1) for Bundles 1 and 2, respectively (Table 2). Kaplan Meier survival curves showed no statistically significant differences between groups for PIVC failure over dwell (Log-rank test;

Standard care vs Bundle 1: p = 0.95; Standard care vs Bundle 2: p = 0.07) (Fig. 3).

The most common complications leading to PIVC removal were phlebitis and infiltration/extravasation (each 16%) (Table 2). Kaplan Meier survival analysis (with log-rank test) identified failure due to phlebitis to be significantly higher in Bundle 1 when compared to Standard care (p = 0.04). No other significant differences were found in PIVC complications between study groups. Inter-rater reliability between PIVC assessors was high, with 100% agreement except for site redness which scored 93.3%. No suspected or confirmed PIVC-related bloodstream or local infections were identified in any group (Table 2).

PIVC dwell time was shorter in Bundle 2 group (mean [SD] 55.5 hrs [37.9]) compared with Standard care (71.5 [46.2]) and Bundle 1 (71.6 [49.5]), however this didn't meet statistical significance in this small sample (Table 2). Adverse skin events were observed in all

Table 1
Patient and PIVC characteristics.

	Standard care (N = 34)	Securement bundle 1 (N = 36)	Securement bundle 2 (N = 34)	Overall (N = 104)
Age mean (SD)	62.4 (16.9)	62.4 (14.6)	57.3 (18.2)	60.7 (16.6)
Gender – male	21 (61.8)	20 (55.6)	17 (50.0)	58 (55.8)
Body mass index				
Overweight/Obese	23 (69.7)[a]	21 (60.0)[a]	22 (64.7)	66 (64.7)
Skin integrity				
Good	15 (44.1)	15 (41.7)	18 (52.9)	48 (46.1)
Fair	17 (50.0)	21 (58.3)	14 (41.2)	52 (50.0)
Poor	2 (5.9)	0 (0)	2 (5.9)	4 (3.9)
Skin type (Fitzpatrick scale)				
Pale White	6 (17.7)	7 (19.4)	4 (11.8)	17 (16.4)
White	23 (67.7)	28 (77.8)	28 (82.4)	79 (76.0)
Light Brown	5 (14.7)	1 (2.8)	2 (5.9)	8 (7.7)
Primary Reason for Admission				
Medical	10 (29.4)	11 (30.6)	9 (26.5)	30 (28.9)
Surgical emergent	8 (23.5)	4 (11.1)	5 (14.7)	17 (16.4)
Surgical elective	15 (44.1)	17 (47.2)	17 (50.0)	49 (47.1)
Trauma	1 (2.9)	4 (11.1)	3 (8.8)	8 (7.7)
Infection at recruitment[b]	10 (29.4)	7 (19.4)	5 (14.7)	22 (21.2)
Wound at recruitment[b]	13 (38.2)	13 (36.1)	16 (47.1)	42 (40.4)
Comorbidities				
None	3 (8.8)	2 (5.6)	7 (20.6)	12 (11.5)
1	3 (8.8)	9 (25.0)	1 (2.9)	13 (12.5)
2	3 (8.8)	6 (16.7)	6 (17.7)	15 (14.4)
3 or more	25 (73.5)	19 (52.8)	20 (58.8)	64 (61.5)
PIVC insertion site				
Hand	1 (2.9)	1 (2.8)	2 (5.9)	4 (3.9)
Wrist	5 (14.7)	4 (11.1)	3 (8.8)	12 (11.5)
Forearm	28 (82.4)	31 (86.1)	28 (82.4)	87 (83.7)
Antecubital Fossa	0 (0)	0 (0)	1 (2.9)	1 (1.0)
Inserted in dominant side	20 (58.8)	19 (52.8)	16 (47.1)	55 (52.9)
PIVC gauge				
20	16 (47.1)	13 (36.1)	9 (26.5)	38 (36.5)
22	17 (50.0)	23 (63.9)	24 (70.6)	64 (61.5)
24	1 (2.9)	0 (0)	1 (2.9)	2 (1.9)
Difficult insertion	13 (38.2)	15 (41.7)	19 (55.9)	47 (45.2)
Multiple insertion attempts	7 (20.6)	6 (16.7)	8 (23.5)	21 (20.2)
Vein quality (Peripheral Vein Assessment Tool)				
Excellent	6 (17.7)	4 (11.1)	4 (11.8)	14 (13.5)
Good	12 (35.3)	11 (30.6)	6 (17.7)	29 (27.9)
Fair	15 (44.1)	21 (58.3)	23 (67.7)	59 (56.7)
Poor	1 (2.9)	0 (0)	1 (2.9)	2 (1.9)
Hair clipped at insertion site	16 (47.1)	18 (50.0)	14 (41.2)	48 (46.2)
Diaphoretic, ever	4 (11.8)	3 (8.3)	1 (2.9)	8 (7.7)
Additional intravascular device present	7 (24.1)	6 (20.0)	9 (33.3)	22 (25.6)
Medications infused				
Antibiotics	15 (47.1)	18 (58.3)	15 (41.2)	48 (49.0)
Crystalloid fluids	28 (82.4)	26 (72.2)	29 (85.3)	83 (79.8)
Blood Products	3 (8.8)	3 (8.3)	2 (5.9)	8 (7.7)
Drowsy, ever	4 (11.8)	3 (8.3)	1 (2.9)	8 (7.7)
Restless/agitated, ever	3 (8.8)	6 (20.0)	4 (11.8)	13 (12.5)

Data shown as frequencies (column proportions) unless stated otherwise; Standard care = bordered polyurethane dressing plus non-sterile tape over the extension tubing; Securement bundle 1 = standard care plus two sterile tape strips over PIVC hub; Securement bundle 2: Bundle 1 plus a tubular bandage; PIVC, peripheral intravenous catheter
[a] 1 missing observation
[b] multiple answers possible.

study groups, with an overall incidence of 13%. Bruising was the most common adverse skin event which was found to be highest in Standard care (9%, Bundle 1 3%; Bundle 2 6%) (Table 2). Logistic regression, using Standard care as the reference group, showed no statistically significant differences in adverse skin events between groups (Bundle 1 p = 0.65; Bundle 2 p = 0.72). No evidence of microbial colonization of device tip or insertion site was found in a subset of participants (Table 2). Cost estimates per patient showed Bundle 1 was most expensive (AUD$19.61), followed by Bundle 2 (AUD$19.40) then Standard care at AUD$16.68 (Table 3).

The application of additional securements to reinforce study interventions was widespread, occurring more commonly in Standard care and Bundle 1 (Standard care: 22/34 (65%); Bundle 1: 19/36 (53%); Bundle 2: 6/34 (18%)) (Supplementary Table 1). Forty percent of PIVC dressings were soiled, wet or lifting on daily assessment

(Supplementary Table 1). No serious adverse events related to study interventions occurred during the trial.

Discussion

Clinicians currently use additional PIVC dressings and securements based largely on tradition and personal belief. This pilot trial is the first to test evidence-based bundled securement interventions to reduce PIVC failure. The primary outcome of study feasibility was met, except for the eligibility criterion, indicating screening processes should be streamlined before a larger trial. Only five participants declined participation indicating acceptability of trial interventions to patients. Study interventions were initially easy to administer with only one protocol violation and high staff/patient satisfaction. Data collection processes were thorough with little missing data and

Table 2
Clinical outcomes and patient/staff satisfaction.

	Standard care (N = 34)	Securement bundle 1 (N = 36)	Securement bundle 2 (N = 34)	Overall (N = 104)
PIVC Failure	8 (23.5)	9 (25.0)	13 (38.2)	30 (28.0)
Log rank test	ref	p = 0.946	p = 0.069	
Incidence rate (per 1000 catheter days)	79.0	83.8	165.4	104.4
(95% CI)	(39.5 to 158.0)	(43.6 to 161.0)	(96.0 to 284.8)	(73.0 to 149.3)
Incidence rate ratio (per 1000 catheter days) (95% CI)	ref	1.1 (0.4 to 2.7)	2.1 (0.9 to 5.1)	1.5 (0.7 to 3.4)
Reasons for PIVC failure[a], n,%				
Phlebitis	7 (20.6)	5 (13.9)	5 (14.7)	17 (16.3)
Infiltration/Extravasation	5 (14.7)	6 (16.7)	6 (17.6)	17 (16.3)
Accidental removal/dislodgement	5 (14.7)	2 (5.6)	4 (11.8)	11 (10.6)
Occlusion	0 (0.0)	0 (0.0)	2 (5.9)	2 (1.9)
Suspected infection (BSI or local infection)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PIVC dwell time (hours), Mean (SD)	71.5 (46.2)	71.6 (49.5)	55.5 (37.9)	66.3 (45.1)
95% CI, p-value	ref	0.2 (−21.1 to 21.5), p = 0.988[b]	−16.0 (−37.6 to 5.6), p = 0.145[b]	
PIVC days	112	115	90	317
Site complications during PIVC dwell, n,%				
Redness	3 (8.8)	3 (8.3)	1 (2.9)	7 (6.7)
Swelling	3 (8.8)	1 (2.8)	0 (0.0)	4 (3.8)
Palpable cord	1 (2.9)	1 (2.9)	2 (5.9)	4 (3.8)
Pain or tenderness	4 (11.8)	6 (16.7)	4 (11.8)	14 (13.5)
Leakage	4 (11.8)	0 (0.0)	1 (2.9)	5 (4.8)
Warmth	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.0)
Partial dislodgement	2 (5.9)	0 (0.0)	1 (2.9)	3 (2.9)
Adverse skin events[c], n,%				
No skin adverse events	29 (85.3)	32 (88.9)	29[d] (87.9)	90 (87.4)
OR (95% CI), p value	reference	1.4 (0.3 to 5.6), p = 0.654[e]	1.3 (0.3 to 5.3), p = 0.721[e]	
Bruising	3 (8.8)	1 (2.8)	3 (8.8)	7 (6.7)
Itchiness	2 (5.9)	1 (2.8)	0 (0.0)	3 (2.9)
Adhesive residue remaining on skin	1 (2.9)	2 (5.6)	1 (2.9)	4 (3.9)
Pressure Injury	0	1 (2.8)	0	1 (1.0)
PIVC tip/insertion site colonization (n = 6 per arm)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Patient satisfaction (0=least, 10=most), median (IQR)				
On application	10 (10, 10)[f]	10 (9, 10)[g]	10 (9, 10)[h]	10 (10, 10)
On removal	10 (10, 10)[h]	10 (10, 10)[i]	10 (9, 10)[j]	10 (10, 10)
Staff satisfaction (0=least, 10=most), median (IQR)				
On application	10 (10, 10)	9.5 (8, 10)	9 (8, 10)[k]	10 (9, 10)
On removal	10 (10, 10)[l]	10 (10, 10)[m]	10 (9.5, 10)[n]	10 (10, 10)

Standard care = bordered polyurethane dressing plus non-sterile tape over the extension tubing; Securement bundle 1 = standard care plus two sterile tape strips over PIVC hub; Securement bundle 2: Bundle 1 plus a tubular bandage; PIVC, peripheral intravenous catheter; CI, confidence interval; [a] more than one complication could be present at time of removal; [b] Linear regression; [c] more than one type of adverse skin event per patient could be present; [d] n = 33, one patient missing itch assessment; [e] Logistic regression; [f] n = 31; [g] n = 29; [h] n = 21; [i] n = 26; [j] n = 17; [k] n = 33; [l] n = 18; [m] n = 15; n = 8.
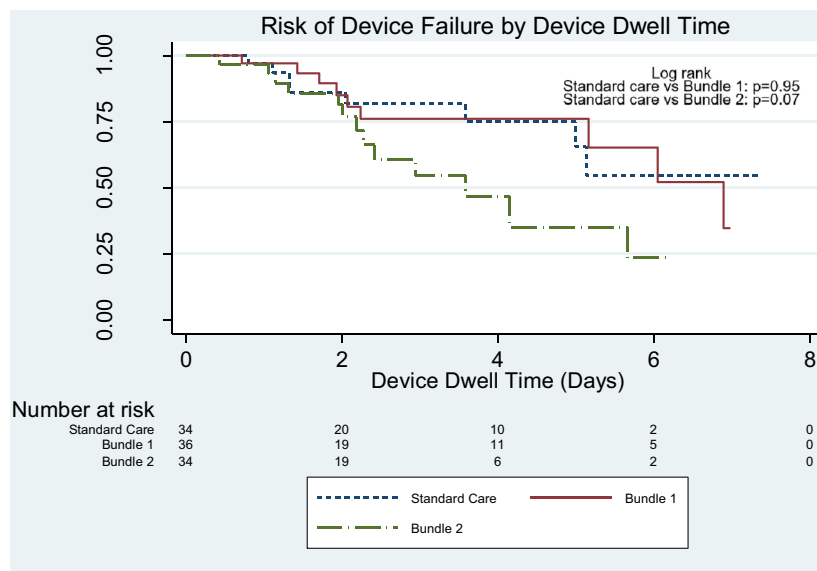

Fig. 3. Kaplan Meier survival curve of PIVC failure. Standard care = bordered polyurethane dressing plus non-sterile tape over the extension tubing; Bundle 1 = two sterile tape strips over PIVC hub plus Standard care; Bundle 2: Bundle 1 plus a tubular bandage.

Table 3

Cost estimate per patient by study group (in a subset of 6 patients per group) in Australian dollars. The estimate includes average cost of dressing & securement products used on insertion and for maintenance during dwell; human costs on initial dressing application and on PIVC removal; in PIVC's requiring replacement after device failure, PIVC replacement; and treatment of any complications.

	Standard Care	Securement bundle 1	Securement bundle 2
Dressing & securement products applied at insertion	$1.12	$3.17	$3.41
Additional dressing & securement products added*	$0.09	$0.08	Nil used
Labour costs for application of dressing & securement products*	$2.13	$2.90	$2.91
Labour costs for removal of dressing & securement products*	$1.21	$1.33	$0.95
PIVC replacement*	$12.13	$12.13	$12.13
Treatment of complications~	0	0	0
Total costs^	**$16.68**	**$19.61**	**$19.40**

PIVC, peripheral intravenous catheter; Standard care = bordered polyurethane dressing plus non-sterile tape over the extension tubing; Securement bundle 1 = standard care plus two sterile tape strips over PIVC hub; Securement bundle 2: Bundle 1 plus a tubular bandage;.
 * averaged over 6 PIVCs; ~no PIVC related complications within subgroup; ^in Australian dollars based on 2019 figures ($1 AUD~ $0.72152 USD).

effect estimates for a larger trial were obtained. Therefore, we confirm that further testing of securement bundles in a definitive superiority trial should proceed as a strategy to address currently high rates of PIVC failure.

Concerningly, one in three PIVCs failed, in keeping with published estimates.[5,6,10,20,39] Failure rates were higher in the securement bundle groups but this should be interpreted with caution due to small sample size. Furthermore, failure rates may be impacted by some baseline imbalances (eg. difficult insertion, vein quality) between groups, factors known to be associated with PIVC failure. These imbalances would be overcome in an adequately powered study. Device failure was most commonly due to phlebitis and infiltration, similar to recent studies,[5,6,9,40] and these were spread fairly evenly across study groups. Some of the dressing and securement products used in the securement bundles have been tested individually in previous RCTs[4,21,41,42] however no large scale trial has found an individual product more effect than another in preventing PIVC failure.[4,6] Rickard et al.[6] suggests that multi-product dressing and securement options should be explored further and this small pilot trial confirms the feasibility of testing securement bundles in a larger RCT.

In this general medical/surgical population, many had risk factors for skin damage associated with the use of medical adhesive tapes, namely older age (over a third were ≥70 years), fair or poor skin integrity, and multiple comorbidities.[26] Adverse skin events were more prevalent in the Standard care group with one in five PIVCs experiencing either bruising (9%), itchiness (9%) or adhesive residue left on skin (3%) compared with only one in ten in the intervention groups, suggesting that adding sterile tape under the primary dressing does not increase adverse skin events. Maintaining a balance between adequate securement with adhesive securement products and skin preservation is difficult for clinicians due to lack of high-quality evidence guiding decision-making. Therefore, maintaining skin integrity for patients with vascular access devices is a patient safety priority which requires vigilant assessment of both device patency and skin health.

Furthermore, placing additional tape under the primary dressing, albeit sterile, could lead to increased device and site colonization, however no growth was identified from any insertion site swabs or PIVC tip. This is at odds with previous studies[6,43] in which 2−4% of device tips and 12−15% of insertion sites were colonised. This difference may be due to specimen analysis being performed in a busy hospital laboratory using semi-quantitative clinically relevant values and incubated up to 5 days, rather than in a research laboratory in which specimens may be incubated for longer and any level of growth reported. Additionally, all PIVC insertions were performed by an experienced inserter who strictly adhered to infection prevention regimes which may contribute to the disparity. In a larger trial, a similar microbial sub-study will add more evidence regarding the placement of additional tapes in device and site colonization.

Dressing integrity continues to be of concern in PIVC maintenance,[10,44] with 40% of dressings found to be soiled, damp and/or loose in this study. Importantly, Bundle 2 had half as many suboptimal dressings as Standard care (22% vs 48%), specifically less lifting at the edges and less soiling, perhaps due to the tubular bandage reducing catheter movement. Significantly more PIVC complications occur in patients with unclean dressings and poorly secured catheters[10] and, furthermore, higher rates of catheter-related bloodstream infection occur if dressings have poor durability and/or soiling.[45] Maintaining dressing integrity may be better achieved with a securement bundle consisting of an external covering, such as the tubular bandage in Bundle 2, but this requires further testing in a larger RCT.

Additional PIVC securement was prevalent in this study, likely reflecting the suboptimal state of primary dressings, in keeping with previous studies.[5,6,10,20] Two thirds of PIVCs in the Standard care group required reinforcement with additional non-sterile tape, a tubular bandage or both, potentially indicating a lack of confidence in this dressing and securement combination to reliably secure the PIVC. In contrast, one in six PIVCs in Bundle 2 group had extra securements added suggesting clinical staff felt the intervention was providing satisfactory securement. Interestingly, two-thirds of additional securement products were applied on the same day as PIVC insertion. This could suggest poor dressing durability but could also indicate nurses habitually reinforce PIVC dressings as they lack confidence in dressing security or, alternatively, patients may request extra dressing reinforcement for their own comfort. In a larger RCT investigating PIVC securement bundles, a qualitative component should be included to better understand the widely-reported practice of additional PIVC securement.

This pilot RCT has some limitations. Firstly, clinical outcomes need to be interpreted with caution due to small sample size. Secondly, all PIVC insertions were performed by one highly skilled inserter which is not reflective of clinical practice in every hospital. Despite this, subsequent maintenance of PIVCs was performed by clinical staff, reflecting clinical practice more closely. Lastly, this is a single centre study in a medical-surgical population therefore, to maximize generalizability, a larger trial should be multisite and include a wider population.

Conclusion

This pilot trial established that future research directions should include a larger definitive trial to test securement bundles and their effects on PIVC failure and complications. Such a trial must include a qualitative component to further understand nurses decision-making practices around additional securement for PIVCs; a microbiologically substudy to ensure that the addition of tapes underneath the primary dressing does not increase microbial colonisation; and close

observation that adverse skin events are not increased with this bundled intervention of tapes and adhesives. PIVC failure remains unresolved and urgently requires innovative solutions to reduce high failure rates.

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Declaration of Competing Interest

AC's employer on her behalf has received investigator-initiated research grant from Cardinal Health (unrelated to the current project). AJU's employer on her behalf has received investigator−initiated research grants and speaker fees from 3 M, Becton Dickinson-Bard, Cardinal Health (unrelated to the current project). NM's employer has received on her behalf investigator−initiated research grants unrestricted educational grants and from Becton Dickinson-Bard, and Cardinal Health; and a consultancy payment from Becton Dickinson-Bard for expert advice (unrelated to the current project). ENL's employer has received on her behalf, an investigator-initiated research grant from Cardinal Health and a conference scholarship attendance supported by Angiodynamics (unrelated to the current project). CR's employer has received on her behalf investigator−initiated research or educational grants from Becton Dickinson−Bard; and consultancy payments for educational lectures/expert advice from 3 M, Becton Dickinson−Bard, BBraun (unrelated to the current project). JG, EM, CB, PNAH − no conflicts of interest to declare

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.hrtlng.2022.07.015.

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