A pilot trial of bordered polyurethane dressings, tissue adhesive and sutureless devices compared with standard polyurethane dressings for securing short-term arterial catheters

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ABSTRACT

Objectives: To improve arterial catheter (AC) securement and reduce AC failure; to assess feasibility of a large randomised controlled trial.

Design, setting and participants: A four-arm, parallel, randomised, controlled, non-blinded pilot trial with 195 intensive care patients taking part, in a tertiary referral hospital in Brisbane, Australia from May to November 2012.

Interventions: Standard polyurethane (SPU) dressing (controls); bordered polyurethane (BPU) + SPU dressing; tissue adhesive (TA) + SPU dressing; and sutureless securement device (SSD) + SPU dressing (no sutures used).

Main outcome measures: AC failure, ie, complete dislodgement, occlusion (monitor failure, inability to infuse or fluid leaking), pain or infection (local or blood).

Results: Median AC dwell time was 26.2 hours and was comparable between groups. AC failure occurred in 26/195 patients (13%). AC failure was significantly worse with SPU dressings (10/47 [21%]) than with BPU + SPU dressings (2/43 [5%]; $P = 0.03$), but not significantly different to TA + SPU (6/56 [11%]; $P = 0.18$) or SSD + SPU (8/49 [16%]; $P = 0.61$). The dressing applied at AC insertion lasted until AC removal in 68% of controls; 56% of BPU + SPU dressings; 73% of TA + SPU dressings; and 80% of SSD + SPU dressings (all $P > 0.05$). There were no infections or serious adverse events. Patient and staff satisfaction with all products was high. Median costs (labour and materials) for securement per patient were significantly higher in all groups compared with the control group (SPU, \$3.48 [IQR, \$3.48–\$9.79]; BPU + SPU, \$5.07 [IQR, \$5.07–\$12.99]; SSD + SPU, \$10.90 [IQR, \$10.90–\$10.90]; TA + SPU, \$17.70 [IQR, \$17.70–\$38.36]; all $P < 0.01$).

Conclusion: AC failure occurred significantly less often with BPU + SPU dressings than with SPU dressings. TA + SPU and SSD + SPU dressings should be further investigated and compared with BPU + SPU dressings as controls. The novel approach of TA + SPU dressings appeared safe and feasible.

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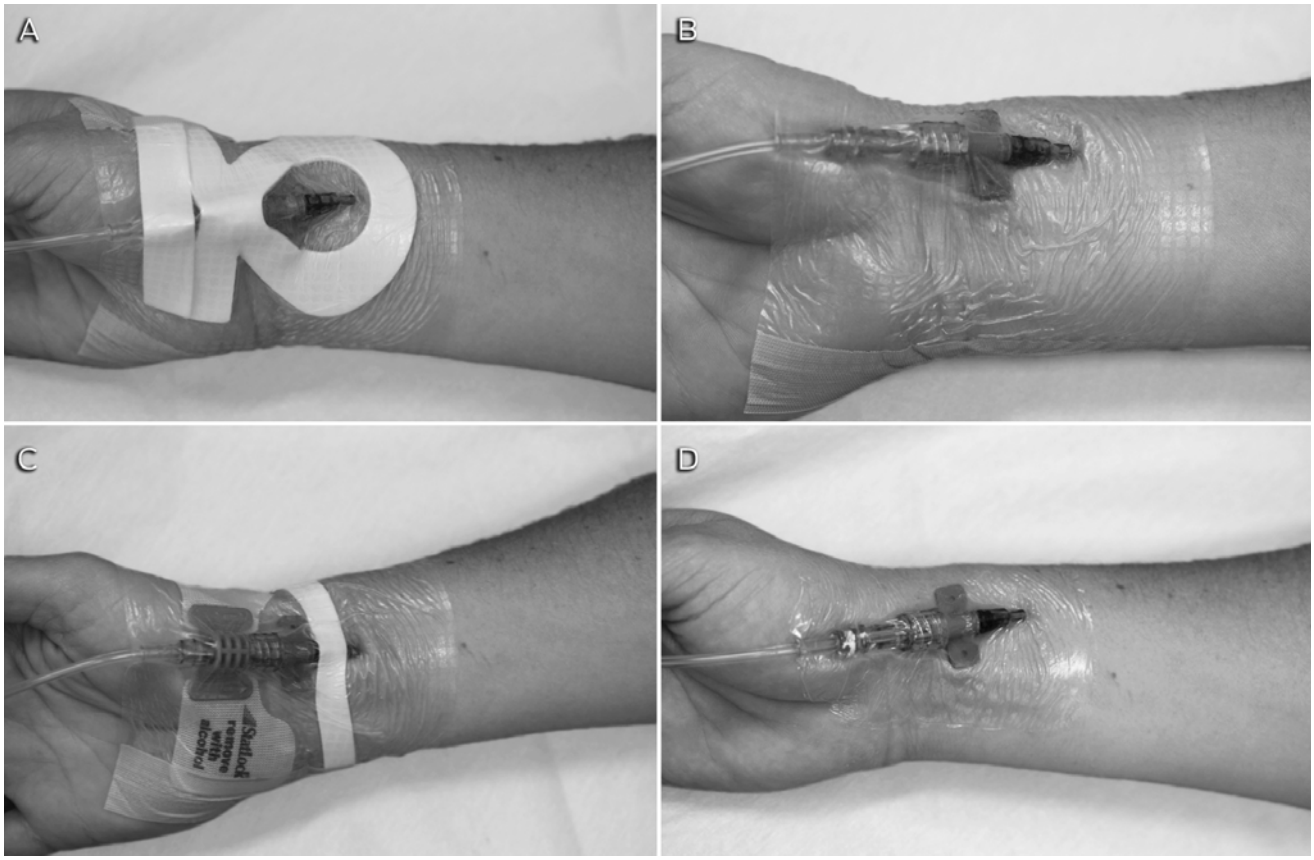
Millions of peripheral arterial catheters (ACs) are used around the world each year.[1] Intensive care unit patients typically require an AC for continuous blood pressure monitoring, repeated blood gas sampling, and, in particular, for arterial blood gas analyses. Despite the ubiquity of AC use, up to 25% of ACs fail prematurely by accidental dislodgement, occlusion or infection. This is often related to inadequate dressing and securement of catheters to the skin.[1-3] For many years, the most commonly used AC dressing has been standard polyurethane (SPU) transparent dressings, which are small, transparent, rectangular films with an adhesive layer. These are inexpensive and popular but there is no evidence that they provide adequate securement, apart from functioning merely as a wound dressing, and they rarely maintain adhesion in diaphoretic patients, or if the site is oozing or bleeding.[3,4] Guidelines recommend SPU dressings generically for all types of intravascular catheters,[5] but they may not be suitable for ACs due to the anatomical and usage characteristics of ACs. Guideline recommendations for SPU dressing use in ACs are expert-based rather than evidence-based.[6]

In recent years, bordered polyurethane (BPU) dressings (similar to SPU dressings but with a toughened, adhesive fabric border) have come into use. They have not yet been rigorously and independently tested for use with ACs, compared with SPU dressings. An independent, non-randomised study in peripheral intravenous catheters ($n = 407$), reported less device failure with BPU dressings than SPU dressings but this was not statistically significant (BPU dressing failure, 19%; SPU dressing failure, 29%; $P = 0.18$).[7] Another option for ACs is to use a sutureless securement device (SSD), strong adhesive pads that offer additional anchor points into which the AC can be clipped for securement, with an SPU dressing still used as a wound covering. After implementation of SSDs in a United States ICU, AC failure rates were 60/468 (13%). A historical control group using adhesive strips saw AC failure of 253/995 (25%) ($P < 0.001$).[3] The Centers for Disease Control and Prevention recommend SSDs for central venous catheters to prevent vessel inflammation, catheter migration or

Figure 1. Intervention dressings for securing short-term arterial catheters.



A = BPU + SPU intervention. B = TA + SPU intervention. C = SSD + SPU intervention. D = SPU intervention (control). BPU = bordered polyurethane. SPU = standard polyurethane. TA = tissue adhesive. SSD = sutureless securement device.

dislodgement, and catheter-related blood infections, but there is no such recommendation for ACs.[5] The Infusion Nurses Society Standards of Practice recommend SSDs for all intravascular catheters to maintain patency, minimise catheter movement at the hub, prevent dislodgement and avoid suture-related complications such as infection, pain, tissue trauma if accidentally dislodged, and to avoid needle stick injuries.[4]

In a novel approach to intravascular catheter securement, we investigated the in vitro use of tissue adhesive (TA), finding it a potentially superior securement method to avoid catheter dislodgement and inhibit microbial growth.[8] TA had substantially stronger resistance to pull-out force than SPU or BPU dressings or SSDs, and had dramatically reduced bacterial growth 18 hours after inoculation.[8] TA has US Food and Drug Administration (FDA) and Australian Government Therapeutic Goods Administration (TGA) approval for internal and external wound use, and has been positively reported on in a case series of central and epidural catheter securements.[9,10] TA's bactericidal properties include inhibition of all gram-positive organisms, including methicillin-resistant *Staphylococcus aureus*.[10] We believe TA could be a major breakthrough in preventing AC failure.

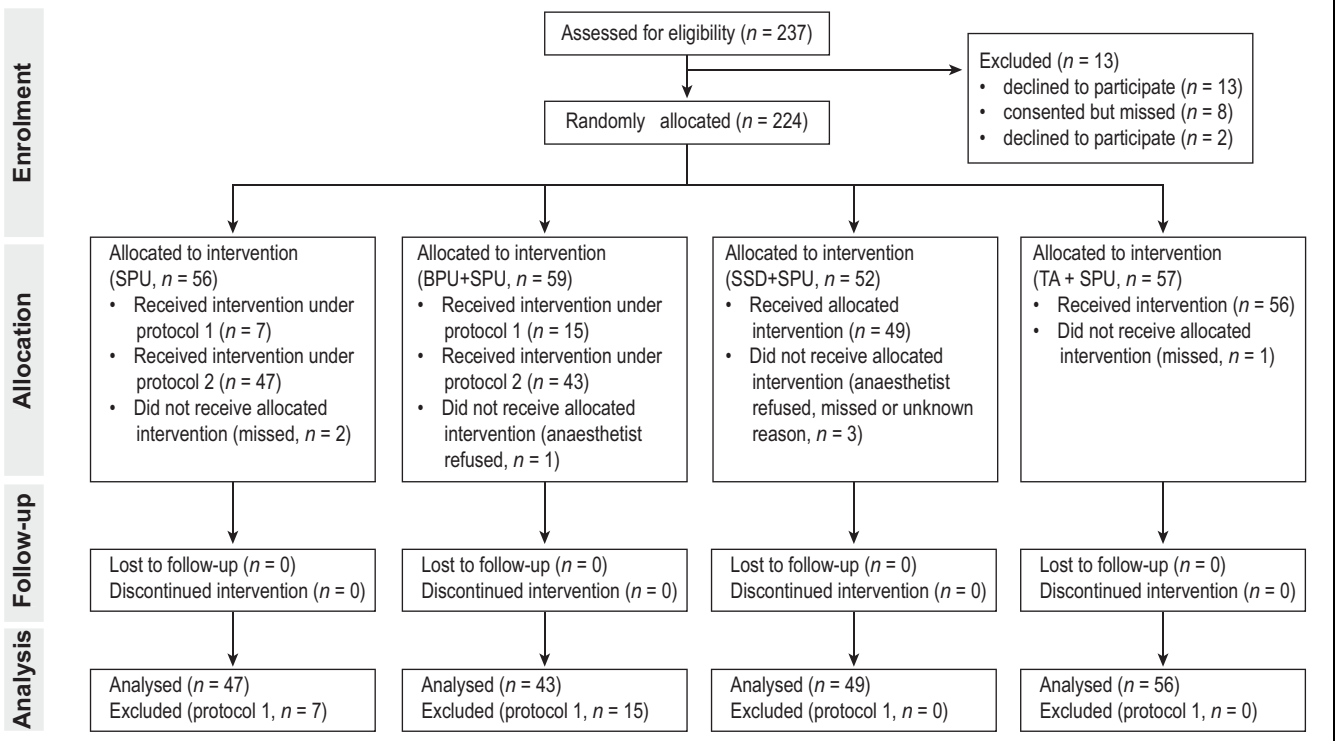
To our knowledge, there have been no randomised controlled trials (RCTs) in ACs comparing the popular SPU transparent dressings to BPU dressings, SSDs or TA. We undertook a pilot RCT to consider study feasibility, safety and acceptability, to refine clinical and cost protocols, and to prioritise products for future trials.[11] Our pilot study had a primary hypothesis that AC securement with TA, a BPU dressing, or SSDs would significantly reduce catheter failure compared with usual care (an SPU dressing).

Methods

Design, setting and participants

We conducted our four-arm, parallel, randomised, controlled, non-blinded, pilot trial in the operating theatres and the 21-bed ICU of The Prince Charles Hospital (TPCH) in Brisbane, Australia. Clinical research nurses (CRNs) screened elective cardiac surgical patients preoperatively, and general ICU patients throughout admission, from 8 May to 3

Figure 2. Patient flow through study (Consolidated Standards of Reporting Trials diagram)



SPU = standard polyurethane. BPU = bordered polyurethane. SSD = sutureless securement device. TA = tissue adhesive.

November 2012. Only one AC per patient was studied. Inclusion criteria were that the participant was ⩾18 years, had given written informed consent, and had an AC inserted that was expected to be in use for a minimum of 24 hours. Exclusion criteria were that the participant had a blood infection, was non-English speaking without an interpreter, had burned or diseased skin at the AC site, had existing skin tears or papery skin, was extremely diaphoretic, or had a known allergy to any study product.

The target sample was 220 participants (50 per group plus 10% to allow for potential attrition), which is consistent with recommendations for sample sizes in pilot trials.[11] Ethics approval was granted by the hospital and university human research ethics committees (HREC/11/QRCH/152) and the study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12611000769987).

End points

The primary end point was catheter failure (defined as any reason for premature AC removal, ie, before completion of therapy). A composite measure was used because AC failure is the outcome of importance to patients; loss of the AC means the patient needs a new AC inserted, which is an invasive procedure. Catheter failure included complete dislodgement, occlusion (monitor failure, inability to infuse or fluid leaking when infused), pain or infection (laboratory-confirmed local or AC-related blood infection).[5,12] AC-related blood infection was defined as a peripherally drawn positive blood culture, clinical signs of infection (fever, chills or hypotension), no other apparent source for the blood infection except the AC, and a colonised AC tip culture with the same organism as that identified in the blood.[5]

Secondary end points included: AC dwell time (hours); dressing failure (any replacement required); patient satisfaction; ease of use by staff for application and removal; and costs (calculated from dressings, consumables and labour cost components).

Randomisation, concealment and masking

The CRN performed randomisation using an independent web-based service to ensure allocation concealment until study entry. Patients were randomly assigned in a 1:1:1:1 ratio with computer-generated and randomly varied block sizes of four and eight. Staff blinding was not possible since CRNs and clinical staff needed to apply randomly assigned products and to monitor ACs for complications.

Interventions

Anaesthetic technicians (not CRNs or investigators) applied the randomised study products immediately after AC insertion,

Table 1. Baseline patient characteristics, by study group ($n = 195$)

Characteristic	SPU ($n = 47$)*	BPU + SPU ($n = 43$)*	SSD + SPU ($n = 49$)*	TA + SPU ($n = 56$)*
Sex (male), *n* (%)	38 (81%)	28 (65%)	36 (73%)	41 (73%)
Age (years), median (IQR)	68 (53–75)	68 (60–75)	65 (57–74)	69 (55–79)
Comorbidities per participant, median (IQR)	1 (0–1)	1 (1–3)	1 (1–2)	1 (1–2)
Comorbidities, *n* (%)				
Myocardial infarction	18 (38%)	26 (60%)	25 (51%)	32 (57%)
Congestive heart failure	12 (25%)	7 (16%)	10 (20%)	7 (12%)
Diabetes without chronic complications	5 (11%)	9 (21%)	5 (10%)	10 (18%)
Renal disease	2 (4%)	7 (16%)	6 (12%)	9 (16%)
Cerebrovascular disease	4 (8%)	6 (14%)	3 (6%)	6 (11%)
Peripheral vascular disease	0 (0%)	5 (12%)	3 (6%)	5 (9%)
Chronic pulmonary disease	1 (2%)	4 (9%)	3 (6%)	7 (12%)
Any malignancy	3 (6%)	1 (2%)	2 (4%)	4 (7%)
Diabetes with chronic complications	1 (2%)	0 (0%)	2 (4%)	1 (2%)
Liver disease (mild)	1 (2%)	0 (0%)	2 (4%)	1 (2%)
Rheumatic disease	1 (2%)	1 (2%)	0 (0%)	0 (0%)
Liver disease (moderate or severe)	1 (2%)	0 (0%)	0 (0%)	1 (2%)
Metastatic cancer (solid)	0 (0%)	0 (0%)	1 (2%)	0 (0%)
Peptic ulcer disease	0 (0%)	1 (2%)	0 (0%)	0 (0%)
Current smoker, *n* (%)	2 (4%)	0 (0%)	3 (6%)	0 (0%)
Diagnosis, *n* (%)				
Surgical (elective)	45 (96%)	42 (98%)	46 (94%)	52 (93%)
Surgical (emergency)	2 (4%)	1 (2%)	3 (6%)	3 (5%)
Medical	0 (0%)	0 (0%)	0 (0%)	1 (2%)
Surgery type, *n* (%)				
Cardiac	46 (98%)	43 (100%)	48 (98%)	53 (95%)
Thoracic	1 (2%)	0 (0%)	0 (0%)	2 (4%)
Plastic/reconstructive	0 (0%)	0 (0%)	1 (2%)	0 (0%)
Infection, *n* (%)	0 (0%)	0 (0%)	2 (4%)	0 (0%)
Patient confused, *n* (%)	2 (4.3%)	0 (0%)	2 (4%)	1 (2%)
Patient agitated, *n* (%)	0 (0%)	0 (0%)	2 (4%)	1 (2%)
Patient drowsy, *n* (%)	42 (89%)	38 (88%)	47 (96%)	48 (86%)
Glasgow coma scale score,† median (IQR)	15 (15–15)	15 (15–15)	15 (15–15)	15 (15–15)
Patient mobility, *n* (%)				
Required assistance	46 (98%)	43 (100%)	46 (94%)	53 (95%)
Unable to mobilise	1 (2%)	0 (0%)	3 (6%)	1 (2%)
Could turn themselves	0 (0%)	0 (0%)	0 (0%)	2 (4%)

SPU = standard polyurethane. BPU = bordered polyurethane. SSD = sutureless securement device. TA = tissue adhesive. IQR = interquartile range. * Some % values do not total 100% due to missing data or multiple comorbidities. † 3 = coma, 15 = awake.

with replacement by ICU nurses if the dressing was loose, soiled or moist. ACs were not sutured in any group. Extensive prestudy staff education was undertaken by CRNs, with all dressing changes and data on date, time and reason for the dressing change recorded by bedside nurses. CRNs visited daily to check protocol adherence.

Because it was a feasibility trial, modification of study procedures occurred as the trial progressed. Under Protocol 1, the BPU group had one Veni-Gard (ConMed) dressing applied, but after 15 patients, clinical staff had safety concerns about frequent loosening and inadequate securement. These patients did not experience catheter failure according to the study definitions, but we amended the protocol and the subsequent 43 patients had an SPU dressing (IV3000 [Smith and Nephew] 10 cm × 14 cm) applied directly over the BPU dressing (Figure 1A). We referred to this group under Protocol 2 as BPU + SPU.

For the TA group, blue Histoacryl (B Braun) tissue adhesive was applied at the AC insertion site and under the AC anchor points. One SPU dressing (IV3000 10 cm × 14 cm) was used over the catheter entry site. The interventions in the TA + SPU group (Figure 1B) were identical for Protocol 1 and Protocol 2.

In the SSD group, StatLock (Bard Access Systems) arterial select stabilisation devices were adhered to the skin with the supplied 20 cm Luer lock extension set connected to the AC hub and then fastened into the Luer retainer. An SPU dressing (IV3000 10 cm × 14 cm) was used over the catheter entry site (Figure 1C). The interventions in the SSD + SPU groups were identical for Protocol 1 and Protocol 2.

Under Protocol 1, the control group (SPU dressings) had IV3000 10 cm × 14 cm dressings applied but, after seven patients, clinical staff had safety concerns about frequent loosening and inadequate securement. These patients did not experience catheter failure according to the study definitions, but we amended the protocol and for the rest of the trial, Tegaderm 1626W (3M) 10 cm × 12 cm dressings (Figure 1D) (recommended by cardiac anaesthetists from TPCH) were used (Protocol 2).

Table 2. Baseline arterial catheter (AC) characteristics, by study group ($n = 195$)

Characteristic	SPU ($n = 47$)*	BPU + SPU ($n = 43$)*	SSD + SPU ($n = 49$)*	TA + SPU ($n = 56$)*
AC location, *n* (%)				
Radial artery	46 (98%)	42 (98%)	49 (100%)	53 (95%)
Brachial artery	1 (2%)	2 (2%)	0 (0%)	2 (4%)
Femoral artery	0 (0%)	0 (0%)	0 (0%)	1 (2%)
Inserted by, *n* (%)				
Senior registrar	37 (79%)	28 (65%)	42 (86%)	38 (68%)
Consultant	8 (17%)	15 (34.9%)	6 (12%)	17 (30%)
Registrar	2 (4%)	0 (0%)	1 (2%)	1 (2%)
Insertion attempts, *n* (%)				
1	41 (87%)	35 (81%)	45 (92%)	43 (77%)
2	5 (11%)	4 (9%)	2 (4%)	6 (11%)
⩾ 3	1 (2%)	3 (7%)	2 (4%)	5 (9%)
Catheter type, *n* (%)				
Vygon	33 (70%)	21 (49%)	25 (51%)	32 (57%)
Arrow	1 (2%)	1 (2%)	2 (4%)	3 (5%)
BD Medical	13 (28%)	21 (49%)	22 (45%)	21 (37%)
AC order, *n* (%)				
Initial	46 (98%)	43 (100%)	49 (100%)	53 (95%)
Subsequent	1 (2%)	0 (0%)	0 (0%)	3 (5%)
Infusate flush, *n* (%)				
Heparin	42 (89%)	38 (88%)	47 (96%)	51 (91%)
Non-heparin	8 (17%)	11 (26%)	2 (4%)	9 (16%)
Times blood taken, median (IQR)	12 (10–15)	13 (11–19)	12 (10–14)	13 (12–19)

SPU = standard polyurethane. BPU = bordered polyurethane. SSD = sutureless securement device. TA = tissue adhesive. IQR = interquartile range. * Percentages may not total 100% due to missing data, rounding or due to some patients having both types of infusate.

Catheter insertion and care

All other aspects of AC insertion and maintenance were performed according to routine practice in order to assess the acceptability of the study products in the clinical setting. ACs were inserted in the operating room by anaesthetists, or in the ICU by intensive care specialists or senior registrars. ACs were all 20 gauge and were Leadercath Arterial catheters (Vygon), Insyte cannulae (BD Medical Systems) or from Radial Artery Catheterization sets (Arrow International), with the AC choice determined by the inserter. Chlorhexidine 2% in 70% alcohol (Persist, BD Medical Systems) was used for skin preparation. ICU nurses undertook postinsertion care, including blood sampling from ACs. Prepacks of study products were left at the bedside and were used by ICU nurses to replace dressings that were loose, or had blood ooze under the dressing.[5] The decision to remove ACs was made by the clinical staff (not the investigators or CRNs) based on the clinical condition.

Data collection

At AC insertion, CRNs collected information on demographic and clinical conditions, AC type, insertion site, number of insertion attempts, time taken to insert and number of staff required to apply the allocated dressing regimen. The staff member applying the dressing was asked to rate the level of difficulty in applying the products, using a 10-point numerical rating scale (NRS) from 0 (very difficult) to 10 (very easy). Each day, CRNs assessed AC sites for:

- erythema and swelling (none [< 1 cm], 1–2.5 cm, 2.6–5 cm or > 5 cm)
- leakage or purulent discharge (yes or no)
- patient-reported pain or tenderness (10-point NRS from 0 [none] to 10 [worst]).

Additional dressings or tape reinforcements added by clinical staff were recorded. At AC removal, the dwell time, the number of times it was accessed for blood sampling, and the reason for catheter removal (the primary end point) were recorded. Clinical data were recorded on the patient's mobility and cognitive state. The nurse who removed the study product was asked to rate the level of removal difficulty on a 10-point NRS from 0 (very difficult) to 10 (very easy). Patients were also asked to rate their satisfaction with the product on a 10-point NRS from 0 (very unsatisfied) to 10 (very satisfied). At 48 hours after AC removal, patients were assessed for clinical and microbiological evidence of AC-related blood infection. Data were entered directly by CRNs into a password-protected, custom-built Access database (Microsoft). A study manager undertook quality control and checked a random subset of source data.

Material and procedure costs were priced at Queensland Health 2012 purchase and employment rates. Labour costs were $28.90/hour (anaesthetic technician, grade 004) for initial dressings, and $37.86/hour (nursing officer grade 5, year 7) for subsequent dressings. Time included gathering equipment, removal of the old dressing, hand hygiene, skin preparation and dressing application. Dressing unit costs were: Veni-Gard dressing, $0.92; IV3000 dressing, $1.28; Histoacryl adhesive, $13.17; StatLock device, $6.29; and Tegaderm 1626W dressing, $0.62. Consumables prices were: dressing pack, $0.43; Persist skin disinfectant, $1.58; sterile gloves, $0.48; and plastic gown, $0.07.

Statistical analysis

Data were exported to Stata, version 12.1 (StataCorp) for cleaning and analysis. The failure of seven SPU dressings

Table 3. Arterial catheter (AC) clinical outcomes, by study group ($n = 195$)

Outcome	SPU ($n = 47$)	BPU + SPU ($n = 43$)	SSD + SPU ($n = 49$)	TA + SPU ($n = 56$)
AC failure, *P**	na	0.029	0.606	0.176
Yes, *n* (%)	10 (21%)	2 (5%)	8 (16%)	6 (11%)
No, *n* (%)	37 (79%)	41 (95%)	41 (84%)	50 (89%)
AC hours, *n*	1528	1763	1692	2165
AC life (hours), median (IQR)	25.2 (22–30.5)	26.8 (21.9–51.3)	25.9 (23.8–34.3)	26.5 (23.5–49.6)
Incidence rate,† median (IQR)	6.55 (3.52–12.2)	1.13 (0.28–4.54)	4.73 (2.36–9.45)	2.77 (1.25–6.17)
Incidence rate ratio, median (IQR)	na	0.17 (0.02–0.81)	0.72 (0.25–2.03)	0.42 (0.13–1.29)
Survival functions,‡ *P*	na	0.014	0.514	0.082
Dressings				
1,§ *n* (%)	32 (68%)	24 (56%)	39 (80%)	41 (73%)
2, *n* (%)	11 (23%)	17 (39%)	7 (14%)	11 (20%)
⩾ 3, *n* (%)	4 (8%)	2 (5%)	3 (6%)	4 (7%)
Per patient, median (IQR)	1 (1–2)	1 (1–2)	1 (1–1)	1 (1–2)
Reason for removal, *n* (%)				
Completed therapy	38 (81%)	42 (98%)	43 (88%)	50 (89%)
Safety concerns	8 (15%)	0 (0%)	0 (0%)	0 (0%)
Blocked	1 (2%)	1 (2%)	5 (10%)	2 (4%)
Monitor failure	1 (2%)	0 (0%)	2 (4%)	2 (4%)
Leaking	0 (0%)	1 (2%)	1 (2%)	1 (2%)
Cannot aspirate	0 (0%)	1 (2%)	0 (0%)	0 (0%)
Dislodgement	0 (0%)	0 (0%)	0 (0%)	1 (2%)
Routine replacement	0 (0%)	0 (0%)	1 (2%)	0 (0%)
Skin observations on removal, *n* (%)				
Residue	0 (0%)	1 (2%)	2 (4%)	3 (5%)
Skin tear	0 (0%)	0 (0%)	1 (2%)	1 (2%)
Erythema	0 (0%)	0 (0%)	0 (0%)	1 (2%)
Swelling < 1 cm	0 (0%)	2 (5%)	1 (2%)	3 (5%)
Swelling 1–2.5 cm	0 (0%)	0 (0%)	0 (0%)	1 (2%)
Swelling 2.5–5 cm	0 (0%)	1 (2%)	0 (0%)	0 (0%)
Leakage	1 (3%)	0 (0%)	0 (0%)	0 (0%)

SPU = standard polyurethane. BPU = bordered polyurethane. SSD = sutureless securement device. TA = tissue adhesive. IQR = interquartile range. * Fisher exact test. † Per 1000 AC hours. ‡ *P* of log-rank test for equality of survival functions. § No group differed to control (all $P > 0.05$).

and 15 BPU dressings in patients under Protocol 1 were reported descriptively but not included in other analyses due to the small numbers. Patients were the unit of measurement (one AC per patient studied). Each intervention group (BPU + SPU, SSD + SPU and TA + SPU) was compared against the control group (SPU) for AC failure, using the Fisher exact test. Failure incidence rates (per 1000 catheter-hours) and incident rate ratios were calculated using the "strate" and "stir" survival-time data commands. Time-to-event data were analysed with a Kaplan–Meier survival curve and the log-rank test ("sts" survival-time data command). The proportional hazards assumption was investigated using the "stcoxkm" survival-time data command. Costs were compared using the non-parametric Mann–Whitney test. The number of dressings used, patient and staff satisfaction, and the difficulty of product application were reported descriptively. Statistical significance was considered as $P < 0.05$.

Results

Of 237 screened patients, 224 were randomly allocated to one of the four interventions and 195 were analysed (Figure 2). Seven of the 224 randomly allocated patients [3%]) received no study treatment, mostly due to cancellation of planned surgery or surgery being scheduled at times when

CRNs were not available. The numbers of patients affected by this were comparable between groups (two in the SPU group, one in the BPU + SPU group, three in the SSD + SPU group and one in the TA + SPU group). Under Protocol 1, AC failure occurred in none of the seven SPU dressing-only patients, and in one of 15 (6%) of the BPU + SPU dressing patients. These patients were similar to other patients at baseline, but were excluded from further analysis due to the amended treatment protocol and the small numbers of patients treated.

The 195 patients, as a group, had ACs in for a total of 7147 hours, all received the allocated intervention, and no patient was lost to follow-up. Eight patients with SPU dressings (under Protocol 2) were withdrawn from the study by clinical staff who were seriously concerned about inadequate AC securement and the possibility that the AC would imminently dislodge; these were recorded as AC failures. In all groups, clinical staff reinforced dressings with tape, gauze or foam. This involved 13 of 72 dressings (18%) in the SPU group, six of 64 dressings (9%) in the BPU + SPU group, one of 71 dressings (1%) in the SSD + SPU group and seven of 77 dressings (9%) in the TA + SPU group.

The demographic and clinical characteristics of the four study groups were comparable (Table 1). Most patients were men (143/195 [73%]), had a median age of 68 years (interquartile reange [IQR], 56–75 years), and underwent elective cardiac surgery (185/195 [95%]). AC characteristics were also similar between study groups (Table 2). Most ACs (190/195 [97%]) were inserted in the radial artery, using a 20-gauge Leadercath arterial catheter (111/195 [57%]). Blood was drawn on average 13 times (IQR, 11–17) from each catheter.

Effects of interventions

Catheter failure and AC dwell times

The incidence of AC failure was significantly worse in the SPU (control) group, in which 10 of 47 ACs (21%) failed, compared with the BPU + SPU group, in which two of 43 ACs failed (5%, $P = 0.03$) (Table 3). The failure incidence was not significantly different between the control group and the other two experimental groups (TA + SPU failure, six of 56 [11%], $P = 0.18$; SSD + SPU failure, eight of 49 [16%], $P = 0.61$). Overall, 173/195 (89%) of ACs were removed due to completion of therapy, with the remainder removed because of complications, most commonly blockage (nine of 195, [5%]). There were no cases of catheter-related blood infection, local (site) infections or patient deaths in any group. The median AC dwell time across the study was 26.2 hours (IQR, 23–45 hours) and comparable between groups. The log-rank test confirmed that only the survival of ACs secured with BPU + SPU was significantly different to that of the control group over time ($P = 0.02$). The proportional hazards assumption was not violated until after 96 hours, by which time 187 of 195 of ACs (96%) had been removed.

Dressing failure and costs

The initial dressings of 136 patients (70%) lasted for the duration of the AC dwelling time (Table 3). This was not different between groups. The other patients required dressings to be replaced for looseness or blood ooze under the dressing. The median time to the first dressing replacement was similar in all groups (SPU, 25.2 hours [IQR, 22–30.5 hours]; BPU + SPU, 26.8 hours [IQR, 21.9–51.3 hours]; SSD + SPU, 25.9 hours [IQR, 23.8–34.3 hours]; TA + SPU, 26.5 hours [IQR, 23.5–49.6 hours]). Median total labour and material costs per patient were: SPU dressing group, $3.48 (IQR, $3.48–$9.79); BPU + SPU group, $5.07 (IQR, $5.07–$12.99, $P = 0.01$); SSD + SPU group, $10.90 (IQR, $10.90–$10.90, $P = 0.01$) and TA + SPU group, $17.70 (IQR, $17.70–$38.36, $P = 0.01$).

Ease of use, patient satisfaction and adverse events

Staff satisfaction with the ease of application and removal of study products was high in all groups (median application NRS score, 9 [IQR, 8–9]; median removal NRS score, 9 [IQR, 8–10]). Patient satisfaction was also high with study products in all groups. None of the study products resulted in any associated rash, blistering or itchiness. All patients rated the dressings as 0 out of 10 for pain. There was one mild skin tear in each of the SSD + SPU and TA + SPU groups, which required dry dressings, and in six patients (one in the BPU + SPU group, two in the SSD + SPU group and three in the TA + SPU group) the dressing left residue on the skin after removal (Table 3). Erythema and swelling were rare and generally mild (erythema, one patient in the TA + SPU group and three in the BPU + SPU group; swelling, one in the SSD + SPU group and four in the TA + SPU group) (Table 3).

Discussion

ACs are crucial for critically ill patients, yet failure rates are high and likely relate to inadequate securement.[1-3] We could find no published RCTs on AC securement, so conducted this pilot trial to provide point estimates of failure and to consider the feasibility of a future larger trial. Because it was a pilot study, we did not expect significant differences between groups, but we observed significantly less AC failure in the BPU + SPU group compared with controls. This difference was clinically important, with an absolute AC failure reduction of 17%, even in the light of the short AC dwell time in this population. Clinical staff had serious concerns about the

SPU-only dressings, and eight patients with SPU dressings were withdrawn from the study due to safety concerns about dislodgement. It is possible that nurses paid additional attention to the control ACs, including frequent dressing replacements to prevent dislodgement; without this, the control group AC failure rate may have been even higher. We had anecdotal evidence that a change in the SPU dressing brand partly allayed the safety concerns, but it may also have been that familiarity and confidence with SPU dressings increased during the study. Our results suggest that SPU dressings are inadequate for AC securement, at least for patients after cardiac surgery, who tend to be diaphoretic and ooze fluid from puncture sites. We plan in future research to use BPU + SPU dressings as the control treatment, since this had the lowest failure rate. Future trials are needed in longer dwell ACs to assess the effect of product selection on failure over longer time periods.

The use of tissue adhesive was an innovative approach and proved to be a potentially useful and safe way to secure ACs. Failure incidence associated with TA + SPU dressings was an absolute 11% lower than for controls, but this was not statistically significant. It is likely that it represented a Type II error, given the small sample. Application and removal of TA + SPU dressings took slightly longer than for SPU or BPU + SPU dressings, but was similar to the time required for SSD + SPU dressings. We found the TA glue could easily be removed with paraffin or adhesive remover, and there was anecdotal evidence that it degraded over about 3 days. Initially, we used only a small amount of glue, but after several studied patients had no remaining glue at AC removal, we began applying a more generous amount to secure the catheter. The only adverse event noted was one minor skin tear, and some adhesive residue occasionally left on skin. TA + SPU securement of ACs is worthy of examination in larger trials.

Absolute AC failure incidence with SSD + SPU dressings was 5% lower than with controls, but this was not statistically significant, again possibly a Type II error. Our observed incidence of 16% SSD + SPU failure was comparable to the 12.8% failure of 468 SSD + SPU secured ACs studied by Stephenson.[3] SSD + SPU dressing-associated failure in our study was most commonly due to blockage. Our ACs were positioned relatively distally in the radial artery, and we observed ACs kinking against the hard surface of the SSD when patients bent their wrists, potentially contributing to catheter failure. In Stephenson's study, a 22.5 cm arm board was used to minimise movement; this may be a beneficial adjunct to SSD products.[3] On SSD removal, one skin tear was observed when (despite instructions to the contrary) the product was removed without the use of commercial adhesive remover to dissolve the sticky residue on the skin.

Incidence rates from this trial can help determine the sample size requirements of future trials. To confirm an absolute difference in the proportion of failed ACs from 16% (SSD + SPU) to 5% (BPU + SPU) with 90% power at $P = 0.05$, a study would need 162 patients per group. To confirm an absolute difference from 11% (TA + SPU) to 5% (BPU + SPU), a study would need 428 patients per group (see http://www.stat.ubc.ca/~rollin/stats/ssize/b2.html). We conclude that a study of BPU + SPU (controls) v TA + SPU and SSD + SPU would be feasible and acceptable, in light of the high satisfaction scores from clinical staff and patients for all products.

The study was, unavoidably, non-blinded, and this may have influenced nurses' decisions to change AC dressings more frequently, which could have influenced catheter failures. Although the figure was not statistically significant, a higher number of patients in the SSD + SPU and TA + SPU groups had only their initial dressing used from AC insertion to removal. This may reflect the fact that both methods were less familiar to staff, and were more complex to remove and replace, in comparison with the more simple SPU and BPU dressings. Dressing reinforcements such as tape were often added in all groups, suggesting either that all securement approaches tested are inadequate on their own, or that staff lack confidence in these products to prevent failure. Future research could explore these areas.

Our cost comparison favoured SPU dressings as the cheapest approach, and found TA + SPU dressings to be the most expensive. Our calculations were largely influenced by the purchase prices for products. In this patient cohort with short-term therapy, AC failure rarely resulted in a new AC insertion but future studies would need to factor in the costs of inserting replacement ACs; this would likely change outcomes in favour of products with the lowest failure, not just the cheapest purchase price. Although there were no AC-related blood infections found in our trial, such infections are known to cause longer hospitalisations and higher hospital costs.[13] As we have previously identified,[8] glue prohibits bacterial growth, therefore its higher purchase price may be offset by avoiding treatment costs for AC-related local or blood infections. If any of BPU + SPU, SSD + SPU or TA + SPU dressings became used routinely for AC securement and purchased in bulk, this would likely lead to price reductions.

Conclusion

Popular SPU dressings are not an effective securement for ACs, particularly for patients after cardiac surgery. Our trial suggests that BPU + SPU dressings are the most effective securement option for ACs, and that TA + SPU and SSD + SPU dressings are potentially beneficial. Further stud-

ies need to be performed to determine which dressing is most effective in securing ACs and preventing AC failure over the longer term.

Competing interests

None declared.

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References

1 Scheer B, Perel A, Pfeiffer UJ. Clinical review: complications and risk factors of peripheral arterial catheters used for haemodynamic monitoring in anaesthesia and intensive care medicine. *Crit Care* 2002; 6: 199-204.
2 Durie M, Beckmann U, Gillies DM. Incidents relating to arterial cannulation as identified in 7,525 reports submitted to the Australian incident monitoring study (AIMS-ICU). *Anaesth Intensive Care* 2002; 30: 60-5.
3 Stephenson C. The advantages of a precision-engineered securement device for fixation of arterial pressure-monitoring catheters. *J Assoc Vascular Access* 2005; 10: 130-2. doi: 10.2309/java.10-3-8.
4 Infusion Nurses Society. Infusion Nursing Standards of Practice. *J Infus Nurs* 2011; 34 (1 Suppl): S1-110.
5 O'Grady NP, Alexander M, Burns LA, et al. Guidelines for the prevention of intravascular catheter-related infections. *Clin Infect Dis* 2011; 52: e162-93.
6 Jones T, Rolls K; Intensive Care Coordination and Monitoring Unit. Nursing managment of arterial catheters for critically ill patients. Sydney: NSW Health, 2007.
7 Callaghan S, Copnell B, Johnston L. Comparison of two methods of peripheral intravenous catheter securement in the pediatric setting. *J Infus Nurs* 2002; 25: 256-64.
8 Simonova G, Rickard CM, Dunster KR, et al. Cyanoacrylate tissue adhesives - effective securement technique for intravascular catheters: in vitro testing of safety and feasibility. *Anaesth Intensive Care* 2012; 40: 460-6.
9 Wilkinson JN, Sheikh N, Jayamaha J. Tissue adhesive as an alternative to sutures for securing central venous catheters. *Anaesthesia* 2007; 62: 969-70.
10 Wilkinson JN, Chikhani M, Mortimer K, Gill SJ. The antimicrobial effect of Histoacryl skin adhesive. *Anaesthesia* 2008; 63: 1382-4.
11 Arnold DM, Burns KE, Adhikari NK, et al. The design and interpretation of pilot trials in clinical research in critical care. *Crit Care Med* 2009; 37 (1 Suppl): S69-74.
12 Webster J, Clarke S, Paterson D, et al. Routine care of peripheral intravenous catheters versus clinically indicated replacement: randomised controlled trial. *BMJ* 2008; 337: a339.
13 Koh DB, Gowardman JR, Rickard CM, et al. Prospective study of peripheral arterial catheter infection and comparison with concurrently sited central venous catheters. *Crit Care Med* 2008; 36: 397-402. ❑