TITLE PAGE

Article title:

Securement methods for peripheral venous catheters to prevent failure: A randomised controlled pilot trial.

Short title:

Securement methods for PIVCs.

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ABSTRACT

Purpose:

To assess the effectiveness of four securement methods to prevent peripheral intravenous catheter (PIVC) failure.

Methods:

Single centre, four-arm, randomised, controlled, non-blinded, superiority pilot trial was conducted in a tertiary referral hospital in Queensland (Australia), between November 2012 and January 2013. Adult patients, with a PIVC expected to remain in-situ for ≥24 hours and admitted to general medical or surgical wards were randomly allocated to: standard polyurethane dressing (control, SPU), tissue adhesive (TA) with an SPU, bordered polyurethane dressing (BPU), or sutureless securement device (SSD) with an SPU, experimental groups. The primary endpoint was PIVC failure, defined as premature device removal before the end of therapy because of pain, blockage, leaking, accidental removal, and local or catheter related bloodstream infection.

Results:

PIVCs were used for an average of 2.6 days across all study groups (n=85). Catheter failure was lowest in the TA group (3/21, 14%) and highest in the control group (8/21, 38%), with BPU and SSD failure at 5/20 (25%) and 5/23 (22%) respectively. The adjusted Hazard Ratio of catheter failure was lowest in the TA group (0.50, 95% CI: 0.13-1.98), and then the BPU (0.52, 95% CI: 0.15-1.78) and SSD (0.61, 95% CI: 0.20-1.91) groups. No patient was suspected of a local or catheter-related bloodstream infection.

Conclusions:

Current SPU dressings alone do not prevent many cases of PIVC failure. TA appears promising as an innovative solution, but may not be suitable for all patients. A larger Australian National Health and Medical Research Council (NHMRC) funded trial has commenced.

Keywords:

Randomized Controlled Trial; Infusions, Intravenous; Vascular Access Devices; Occlusive Dressings; Tissue Adhesives; securement device

INTRODUCTION

Peripheral intravenous catheters (PIVCs) are the world's most frequently used invasive medical device, yet failure prior to completion of therapy occurs in up to 69% of PIVCs (1-3). This may be caused by inadequate securement of the device to the surrounding skin causing accidental removal, or partial dislodgement presenting as leakage of IV fluids from the site. Even micro-motion of the PIVC in the vein may contribute to vein inflammation and swelling causing PIVC failure from occlusion and phlebitis, or infection may result from skin organisms pistoned into the PIVC wound. Current clinical practice sees PIVCs secured with standard polyurethane dressings (SPUs), which, since transparent, have the advantage of enabling the insertion site to be clearly seen. However, there is concern, borne out of findings from two meta-analyses that SPUs, including the more recently developed films with greater vapour permeability, actually increase the risk of catheter-related bloodstream infections (4, 5).

Alternative products that offer additional catheter securement, such as bordered polyurethane dressings (BPUs) and sutureless securement devices (SSDs) have been developed. Maintaining a polyurethane window, BPUs have an additional adhesive border of foam or cloth fabric (e.g. Tegaderm™ Advanced (3M) or Veni-Gard® (ConMed)). In contrast, SSDs are used in conjunction with SPUs, and have anchor points or clips to hold the PIVC in place (e.g. StatLock®(Bard) or Grip-Lok® (Zefon)), aiming to reduce catheter movement and catheter failure from complications such as phlebitis, dislodgement, infiltration or vessel occlusion (6). Whilst several manufacturer-sponsored and/or non-randomised trials have compared

SSDs or BPUs to standard care, or SSDs to BPUs, the clinical benefit of these products over traditional SPU dressings remains unclear (6-8).

A novel approach to PIVC securement is the use of tissue adhesive (TA), or medical grade 'super-glue', typically used as an alternative to sutures for closure of skin lacerations and internal tissue repair. To date, a case series and a small volunteer participant trial have reported TA as successful in securing "about" 100 central venous and epidural catheters, but there are no reports in PIVCs (9, 10). Further, there is evidence that TA may be helpful in preventing catheter-related infection via an inhibitory effect on gram positive organisms such as *Methicillin-Resistant Staphylococcus Aureus,* a serious problem when isolated on vascular catheters (11). In a previous laboratory study using a porcine skin model, we demonstrated that any of BPU, SSD or TA required higher pull-out force than SPU secured PIVCs, and in fact the force required to remove SPU-secured PIVCs was not significantly higher than that to remove PIVCs with no dressing at all (12). We also reported that neither TA nor TA removal agents (paraffin or Uni-Solve wipes) had a deleterious reaction with PIVC materials, and that TA was completely effective in preventing *S. epidermidis* or *S. aureus* of PIVC tracts for 72 hours *in vitro*.

The study

We compared SPU (controls) with BPU, SSD and TA for efficacy in securing PIVCs and prolonging their functional life by preventing catheter failure. The study represents initial pilot work undertaken in preparation for a larger Australian Commonwealth government funded randomised controlled trial (RCT). This study had three aims:

1. To identify clinically and cost-effective methods to prevent PIVC failure,

2. To compare usual care dressings (SPU) with a novel method (TA), and two new commercially available technologies (BPU and SSD), and
3. To assess the feasibility of a larger RCT.

MATERIALS AND METHODS

Study design, setting and participants

This four-arm, non-blinded, RCT of superiority design, was conducted within the Royal Brisbane and Women's Hospital in Queensland, Australia: a 929-bed referral teaching hospital. Patients in general medical and surgical wards who required a PIVC were screened by a research nurse from 26th November, 2012 to 14th January, 2013. Patients aged over 18 years, with a PIVC expected to remain for >24 hours, and who gave written informed consent were eligible to participate. Exclusion criteria included: non-English speaking patients without interpreter; patients requiring PIVCs through burned or diseased skin; extremely diaphoretic patients; and patients known to have an allergy to any study product.

For our pilot study (n=85), the recruitment target was a minimum of 20 participants per group. This number has been shown to adequately represent the target population of larger RCTs for the purposes of assessing piloting and feasibility assessment (13, 14).

The Hospital and University granted ethical approval, and the trial was registered with the Australian and New Zealand Clinical Trials Registry: ACTRN12611000769987.

Randomisation and masking

Following consent, the research nurse accessed a web-based centralised randomisation service to obtain group allocation. A computer-generated 1:1:1:1 ratio was used with no blocking. Allocation was concealed prior to each randomisation. Due to the nature of the intervention, it was not possible to mask clinical or research staff who were required to assess the catheters daily for complications.

Study intervention procedures

PIVCs in the first experimental group were secured with TA and SPU (Histoacryl™, B.Braun, Tuttlingen, Germany; and Tegaderm 1624W™, 3M Health Care, Neuss, Germany); the second group with BPU (Tegaderm™ Advanced, 3M Health Care, Neuss, Germany); the third group with SSD and SPU (Statlock™, C.R. Bard, Inc. Covington, USA and Tegaderm,1624W™), and the final (control) group with SPU (Tegaderm,1624W™).

A PIVC insertion-only team inserted catheters and applied study products. Skin preparation was chlorhexidine 2% with alcohol isopropyl 70% pre-moistened swabs (SOLU-IV$^{MC/}$™) . BD Insyte™ Autoguard™ BC catheters were used with BD Connecta™ extension tubing attached to catheters in the TA, BPU and SPU groups. The SSD group used extension tubing supplied with the StatLock™. Nursing (not research or IV team) and medical staff provided follow-up care, and PIVCs were removed based on clinical decision-making with no influence from the research staff. Catheter sites were tagged to identify study inclusion. Additional securement of intravenous tubing or the catheter with sterile or non-sterile tape, or the use of tubi-grip/bandaging, was permitted as clinically required, with all products recorded. PIVCs were replaced on clinical indication as per hospital policy, although occasionally medical staff still requested routine replacement.

Outcome measures

The primary endpoint was PIVC failure, defined as premature device removal before the end of therapy because of pain, blockage, leaking, accidental removal, and local or catheter related bloodstream infection. Information collected at catheter insertion included demographics, clinical characteristics, catheter insertion details, and the inserter's satisfaction with product application (11 point scale, with 0=completely dissatisfied and 10= completely satisfied). The research nurse reviewed PIVCs daily, recording protocol adherence, patient reported pain (11-point scale, with 0=none and 10=maximum), tenderness (same scale as for pain), erythema (none, width <1cm, 1≤ width <2.5cm, 2.5≤ width <5cm, width ≥5cm), swelling (same as for erythema), palpable cord (none, <7.5cm, ≥7.5cm), leakage (yes/no), and purulence (none, from site, with ulceration). At catheter removal, the research nurse inspected the site for local skin complications, and recorded time in-situ, participant's and removing clinician's satisfaction with the product (10-point scale, with 0=completely dissatisfied and 10=completely satisfied). The number of dressings used, and product costs were also recorded.

Statistical analysis

Observations were entered by research nurses into an Access™ 2010 database. Data cleaning and analysis was performed with Stata, (12.1, Stata-Corp, Texas). An intention-to-treat analysis framework was used. Mean values and standard deviations (SD) were reported for normally distributed data; median values and 25th/75th percentiles were reported otherwise. As a pilot study, we tested our statistical comparison methods, but did not expect to find statistical differences. The potentially censored data of catheter life were analysed as single-record survival data. The null hypothesis that there is no overall difference between survival functions was tested

with the log-rank test of equality (sts). Incidence rates, rate ratios and catheter-hours were calculated (strate, stir). A graph of the Kaplan-Meier survival functions was generated, and the proportional hazards assumption checked with the log-log plot of survival (stphplot). A Cox proportional hazards model (stcox) was fitted, using manual stepwise removal of predictors at $p>0.05$, and with assumptions checked (estat phtest). Cost data were compared using the Mann-Whitney test. Costs were based on the Health Districts contract prices for 2012. *P*-values below 0.05 were considered statistically significant.

RESULTS

Ninety-eight patients were screened for eligibility, with *n*=89 recruited (Figure 1). Of these, four were randomised but did not receive a PIVC due to a clinical decision to cease intravenous therapy (SPU *n*=1, BPU *n*=2; TA *n*=1), resulting in the participation of *n*=85 patients. All participants received the allocated intervention, with many in all four groups receiving additional reinforcement products such as non-sterile tape and tubular elastic bandage (SPU *n*=23; BPU *n*=14; SSD *n*=9; TA *n*=13). In total, 5,305 catheter hours (h) were studied (SPU=1156h, BPU=1308, SSD=1591h, TA=1250h).

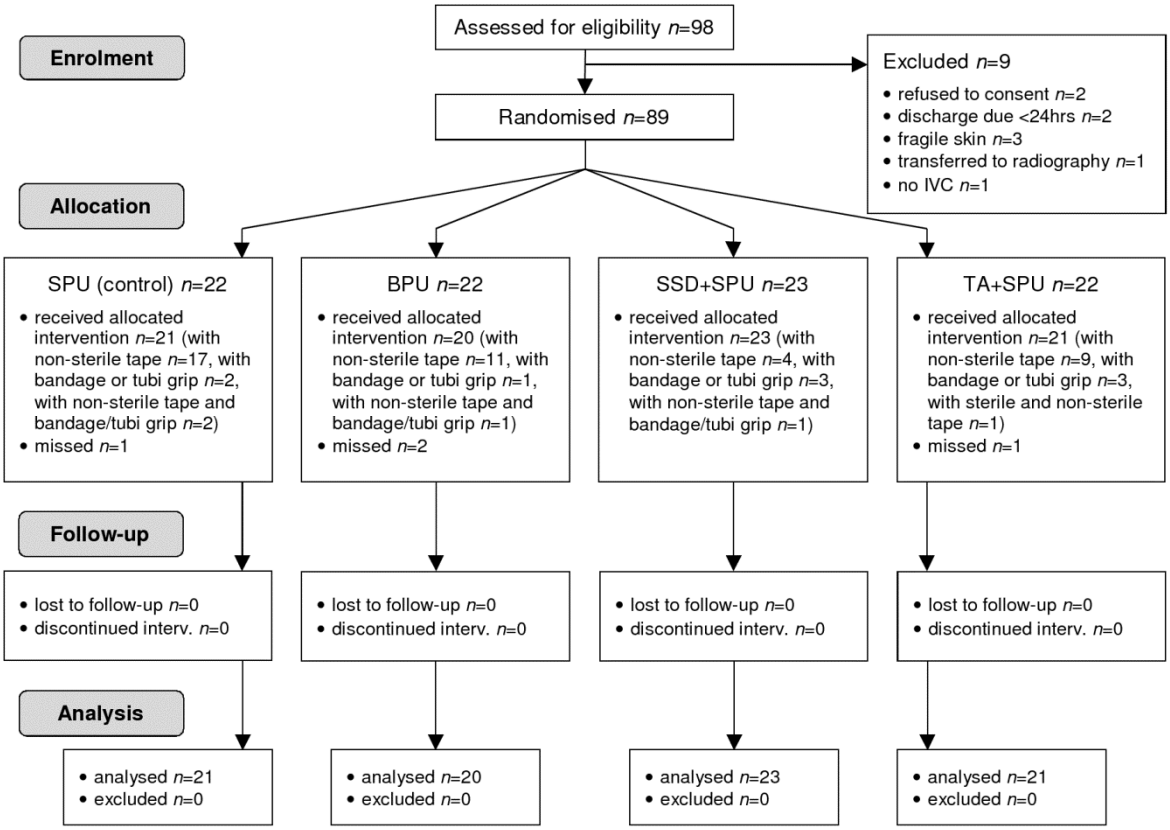

Fig. 1. Patient flow through the study. hrs: hours. SPU: standard polyurethane dressing group. BPU: bordered polyurethane dressing group. SSD+SPU: sutureless securement device group. TA+SPU: tissue adhesive group; interv.: intervention.

Table 1. Baseline demographic and risk factor data of patients (n=85)	SPU *n*=21	BPU *n*=20	SSD *n*=23	TA *n*=21
Gender (male)	15 (71.4)	13 (65.0)	17 (73.9)	13 (61.9)
Age (years)[a]	65 (53-76)	56 (42-70)	61 (44-74)	60 (47-72)
Comorbidities[a]	1 (0-2)	0 (0-1)	1 (0-3)	1 (0-1)
Insertion site				
cubital fossa	1 (4.8)	1 (5.0)	1 (4.4)	0 (0.0)
hand	2 (9.5)	1 (5.0)	0 (0.0)	4 (19.1)
wrist	2 (9.5)	6 (30.0)	7 (30.4)	1 (4.8)
lower forearm	7 (33.3)	5 (25.0)	5 (21.7)	10 (47.6)
upper forearm	9 (42.9)	7 (35.0)	10 (43.5)	6 (28.6)
Insertion attempts				
one	20 (95.2)	18 (90.0)	20 (87.0)	15 (71.4)
two	1 (4.8)	0 (0.0)	2 (8.7)	0 (0.0)
three or more	0 (0.0)	2 (10.0)	1 (4.4)	6 (28.6)
Catheter order				
initial	2 (9.5)	3 (15.0)	1 (4.4)	2 (9.5)
subsequent	19 (90.5)	17 (85.0)	22 (95.7)	19 (90.5)
Smoker	3 (14.3)	4 (20.0)	2 (8.7)	3 (14.3)
Diagnosis				
medical	13 (61.9)	7 (35.0)	11 (47.8)	9 (42.9)
oncology	0 (0.0)	0 (0.0)	1 (4.4)	1 (4.8)
surgical elective	3 (14.3)	7 (35.0)	9 (39.1)	7 (33.3)
surgical emergency	5 (23.8)	6 (30.0)	2 (8.7)	4 (19.1)

Table 1. Baseline demographic and risk factor data of patients (n=85)

	SPU	BPU	SSD	TA
	n=21	*n*=20	*n*=23	*n*=21
Skin colour				
white	12 (57.1)	15 (75.0)	17 (74.0)	11 (52.4)
light brown	5 (23.8)	5 (25.0)	6 (26.1)	6 (28.6)
moderate/dark brown	4 (19.0)	0 (0.0)	0 (0.0)	4 19.1)
Any infection	12 (57.1)	8 (40.0)	10 (43.5)	7 (33.3)
Infusate/Medicine				
IV antibiotics	13 (61.9)	11 (55.0)	12 (52.2)	11 (52.4)
blood products	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
IV hydration	7 (33.3)	7 (35.0)	10 (43.4)	7 (33.3)
IV bolus meds	4 (19.1)	4 (20.0)	10 (43.4)	7 (33.3)
IV heparin	1 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)
nil (flush only)	0 (0.0)	7 (35.0)	1 (4.4)	2 (9.5)
Patient confused/agitated	1 (4.8)	0 (0.0)	0 (0.0)	3 (10.3)
Patient drowsy	0 (0.0)	1 (5.0)	0 (0.0)	1 (4.8)
Patient mobility				
independent	14 (70.0)	13 (61.9)	15 (65.2)	15 (71.4)
requires assistance	4 (20.0)	5 (23.8)	5 (21.7)	5 (23.8)
can turn only/immobile	2 (10.0)	1 (4.8)	3 (13.1)	1 (4.8)

n(%) presented unless specified otherwise. [a] median (25%-75%); SPU: standard polyurethane dressings group. BPU: bordered polyurethane dressings group. SSD: sutureless securement devices group. TA: tissue adhesive group.

Table 2. Patient outcomes by study group (n=85)	SPU *n*=21	BPU *n*=20	SSD *n*=23	TA *n*=21
Catheter failed	8 (38.1)	5 (25.0)	5 (21.7)	3 (14.3)
Catheter fail rate (95% CI)[a]	6.92	3.82	3.14	2.40
	(3.46,13.84)	(1.59,9.18)	(1.31,7.55)	(0.77,7.44)
Catheter fail rate ratio (95% CI)[a]	n/a	0.55	0.45	0.35
		(0.14,1.91)	(0.12,1.57)	(0.06,1.45)
Catheter survival[b]	-	p=0.201	p=0.093	p=0.142
Catheter removal reason[c]				
completed therapy	11 (52.4)	15 (75.0)	14 (60.9)	17 (81.0)
routine replacement	4 (19.1)	2 (10.0)	4 (17.4)	1 (4.8)
blockage	5 (23.8)	2 (10.0)	1 (4.4)	2 (9.5)
leaking	1 (4.8)	1 (5.0)	1 (4.4)	0 (0.0)
accidental removal	0 (0.0)	1 (5.0)	1 (4.4)	1 (4.8)
painful	4 (19.1)	1 (5.0)	2 (8.7)	1 (4.8)
unknown	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)
Catheter hours in-situ[d]	55.0 (30.4)	65.4 (32.3)	69.2 (35.2)	59.5 (27.7)
Dressing time to apply (sec)[e]	20.0 (10-30)	25.0 (20-30)	45.0 (40-50)	48.0 (40-55)
Dressing ease of application[e]	10.0 (9-10)	9.0 (9-10)	7.0 (5-8)	8.0 (7-9)
Dressing ease of removal[e]	7.5 (4-10)	10.0 (9-10)	8.0 (7-9.5)	8.5 (3-9)
Dressing patient satisfaction[e]	8.0 (5-9)	9.0 (8-10)	8.5 (7-10)	10.0 (9-10)

n(%) presented unless specified otherwise. [a] per 1000 catheter hours. [b] *p*-value of the log-rank test for equality of survival functions. [c] more than one reason could be recorded. [d] mean (SD). [e] median (25%-75%). SPU: standard polyurethane dressings group. BPU: bordered polyurethane dressings group. SSD: sutureless securement devices group. TA: tissue adhesive group.

At baseline, groups were similar in demographic and clinical risk profiles (Table 1). Catheter failure was highest in the SPU group (38%) and lowest in the TA group (14%), with the BPU and SSD groups having failure rates of 25% and 22% respectively. As predicted with this pilot, comparison of proportions, incidence and survival rates for PIVC failure between groups found only non-significant statistical differences, but absolute differences were clinically important (Table 2). Expressed as failure per 1,000 PIVC days, rates remained lower for all experimental groups (TA 2.4, SSD 3.1, BPU 3.8) compared to SPU (6.9). The Kaplan-Meier curve shows PIVC survival with SPU consistently the worst performer (Figure 2). The curves on the log-log graph (not provided) were reasonably parallel, indicating non-violation of the proportional hazards assumption. Overall, blockage and/or pain were the most common forms of failure that caused PIVC removal. Blockage occurred most frequently in the SPU group. No suspected or confirmed PIVC-related infections occurred in any group. Cox regression (Table 3) found patients with a surgical wound or any baseline infection had more than three times the risk of PIVC failure ($p<0.05$). Study group remained not significant as a predictor of in this analysis although the estimates of effect remained large, with failure halved or almost halved in all experimental groups (HR 0.50-0.61).

Four adverse effects (in three patients) were observed, all in the TA group (one skin tear, two rashes and one blister) – these were all minor and resolved with no treatment. Only one nurse was required to apply each dressing, and the original dressing remained intact for the duration of device dwell in all PIVCs. The time needed to apply the products was higher in the SSD and TA groups compared with the SPU and BPU groups, but the actual difference was small (approx. 20 seconds). No differences were observed in the ease of application or removal between groups.

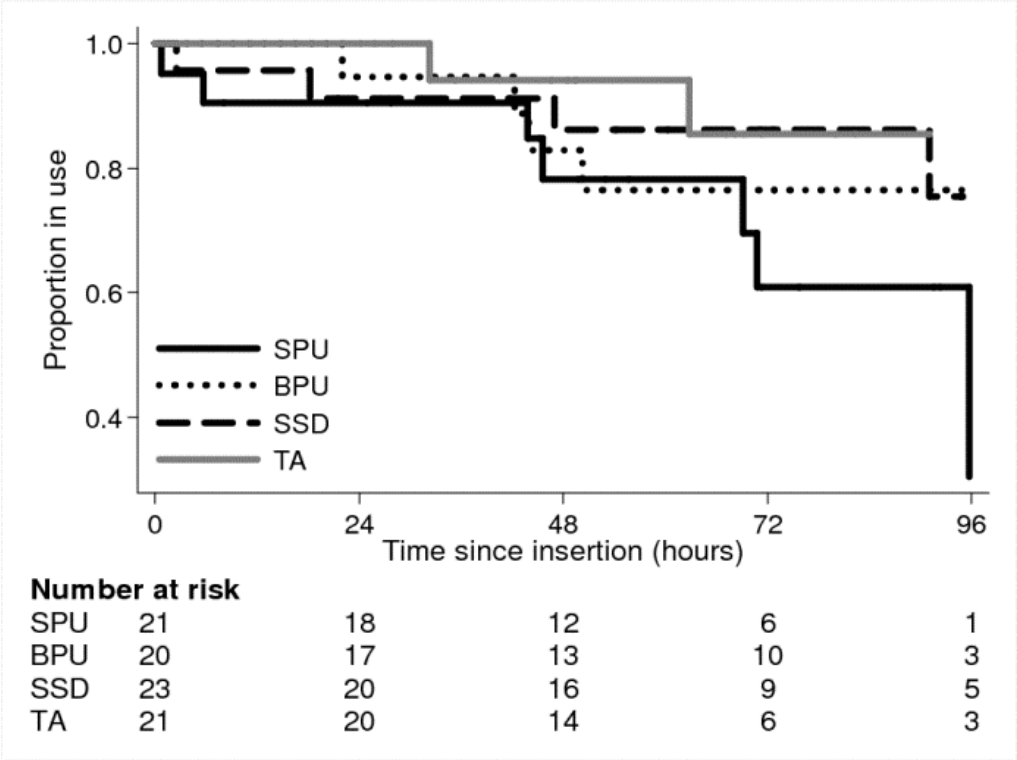

Fig. 2. Kaplan-Meier survivor functions by treatment group. SPU: standard polyurethane dressings group. BPU: bordered polyurethane dressings group. SSD: sutureless securement devices group. TA: tissue adhesive group.

Table 3. Cox proportional hazards regression (n=85)

	Univariable		Multivariable	
	HR	95% CI	HR adjusted[a]	95% CI
Treatment arm (ref=SPU)				
BPU	0.46	0.14,1.54	0.52	0.15,1.78
SSD	0.39	0.13,1.21	0.61	0.20,1.91
TA	0.36	0.10,1.38	0.50	0.13,1.98
Age[b]	1.01	0.98,1.03	-	-
Gender (ref=male)				
female	0.81	0.29,2.24	-	-
Comorbidities (ref=none)				
one	1.63	0.57,4.68	-	-
two or more	1.13	0.38,3.36	-	-
Smoker (ref=never)				
current/past	1.51	0.61,3.73	-	-
Skin type (ref=white)				
other	1.91	0.79,4.65	-	-
Diagnosis (ref=medical)				
surgical elective	1.42	0.53,3.82	-	-
other	0.94	0.28,3.18	-	-
Wound (ref=none)				
yes	2.70*	1.10,6.63	3.29*	1.29,8.41
Infection (ref=none)				
yes	3.19*	1.26,8.06	3.22*	1.22,8.51
Antimicrobial therapy (ref=yes)				

Table 3. Cox proportional hazards regression (n=85)

	Univariable		Multivariable	
	HR	95% CI	HR adjusted[a]	95% CI
no	4.29*	1.25,14.71	-	-
Catheter insertion side (ref= non-dominant arm)				
dominant arm	1.64	0.67,4.04	-	-
Catheter insertion location (ref=forearm)				
wrist	0.56	0.13,2.52	-	-
cubital fossa/hand	1.56	0.54,4.58	-	-
upper arm	0.36	0.05,2.76	-	-
Catheter insertion multiple attempts (ref=none)				
yes	0.63	0.15,2.73	-	-
Catheter size (ref=gauge 20)				
gauge 22	0.60	0.23,1.57	-	-
Injection ports (ref=zero)				
three	1.03	0.37,2.83	-	-
Dressing ease of application[c]	1.11	0.87,1.41	-	-

[a] adjusted for other risk factors in the multivariable model. [b] centered, years. [c] centered, 'very difficult' to 'very easy'. * $p<0.05$. SPU: standard polyurethane dressings group. BPU: bordered polyurethane dressings group. SSD: sutureless securement devices group. TA: tissue adhesive group. ref: referent level for dummy coding. dressing: dressing or securing device. HR: Hazard Ratio, where HR<1 indicates lower hazard (risk) of catheter failure than at the referent level, and HR>1 indicates higher hazard. Hyphen indicates predictor was removed from multivariable model.

DISCUSSION

This pilot study of PIVC securement methods was initiated in response to an unacceptably high PIVC failure rate in our organisation and others causing much morbidity and costs (1-3). A novel product, TA, was tested for the first time internationally in PIVCs, and has shown promise, with catheter failure in this group being reduced by two-thirds (IRR 0.35) compared to the current SPU dressing used routinely in many hospitals. In addition, both BPU and SSD had failure rates half that of the control dressing (IRR 0.55 and 0.45 respectively). Although this was a pilot study, these clinically meaningful effect sizes are encouraging. In the past there have been few RCTs performed on PIVC dressing and securement. More recently, clinically indicated replacement has allowed catheters to be used for longer periods, trials such as this are needed to investigate how improved maintenance can keep PIVCs functional over time. (15, 16)

It took approximately twice as long to apply the SSD or TA compared with SPU or BPU alone. However, the difference was only around 20 seconds - inconsequential compared to the time required for catheter replacement and the problems associated with catheter failure. For example, the cost of catheter replacement after failure is as high as AUD $69.30.(19). Adverse events, although minor, occurred only in patients whose catheter was secured with TA. In the only previous comparative study of TA and other products for securing PIVCs, no adverse skin reactions occurred when TA was removed from fresh newborn porcine skin (12). There were also no adverse events in case studies of TA use for securing epidural and central venous catheters (9, 10). There is a possibility that certain skin types, or skin conditions, may be limiting factors for the use of TA for securing PIVCs. In this study, the only skin

classification used was colour, and this had no relationship to observed complications.

In the multivariable model, PIVC failure was significantly more than three times higher ($p<0.05$) in patients with a surgical wound and in those who had any baseline infection. The reasons for this are unclear, but perhaps reflect different IV medications used or a generalised inflammatory process affected the local vein causing irritation and failure. Although receiving anti-microbial therapy was not a significant predictor of failure in the multivariable model, it was significant in the univariate comparison. The specific method of anti-microbial delivery (e.g. push versus slower infusion) was not collected, but device failure may be related to the pH/osmolarity of the therapy and its effect on peripheral veins (18). Improved securement is unlikely to overcome the effect of inadequate dilution/flushing or inappropriate peripheral instillation of irritants, but with current PIVC failure rates affecting 4 in ten of the millions of PIVCs used each year, there is great scope for improvement from a range of sources (2, 19).

Limitations

Limitations were: 1. As a pilot, this study was not powered to find statistical differences in outcomes; 2. Only one hospital was involved, and an IV team performed insertions and applied the securements therefore limiting generalisation to other settings; and 3. It was not possible to mask the intervention and so there remains potential for outcome assessment bias.

Implications for practice and research

This study shows that TA and other new PIVC securement products may considerably reduce catheter failure; when converted into improvements in the

patient experience and cost savings, this amount would be extremely substantial. Up to 80% of hospital patients receive a PIVC (18), and preventing failure of this device will save many people painful complications and reinsertions as well as reduce organisational costs for labour and materials (19).

For research, questions remain regarding the most effective securement to prevent PIVC failure. Future trials should include an economic analysis, data on skin condition, and important end-points such as catheter related bloodstream infection, phlebitis, and patient perspectives. Another possible area of research relates to TA. Manufacturers recommend a solvent is used to remove the adhesive, but we observed that some catheters came out easily without requiring a removal agent. As we were using TA for the first time, entry sites were covered with SPU dressing, and there is a possibility that the occlusive dressing may have interfered with the potency of the adhesive. Costs would reduce further if TA was used without a dressing, but this would require further testing..

Conclusions

Current SPU dressings performed poorly at preventing PIVC failure. Alternative products are likely to reduce failure rates, and further testing in larger multi-centre studies is feasible. TA appears promising as an innovative use for the product, but may not be suitable for all patients.

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