Novel Technologies Can Provide Effective Dressing and Securement for Peripheral Arterial Catheters: A Pilot Randomised Controlled Trial in the Operating Theatre and the Intensive Care Unit (Australian Critical Care. 2015. January. On-line early. http://dx.doi.org/10.1016/j.aucc.2014.12.001.)

ABSTRACT

Background: Peripheral arterial catheters are widely used in the care of intensive care patients for continuous blood pressure monitoring and blood sampling. These catheters can fail from dislodgement, accidental removal, and other complications of phlebitis, pain, occlusion and infection. Appropriate methods of dressing and securement are required to reduce these complications which cause failure. Critical care nurses are the main staff group managing the care of patients with arterial catheters. There are few studies in the literature on dressings and devices used to prevent complications in arterial catheters.

Aims and Objectives: We aimed to determine initial effectiveness of one dressing and two securement methods with the potential to minimise failure in peripheral arterial catheters compared with usual care, in a pilot study. We specified feasibility objectives for this pilot trial to be considered successful if 90 out of 120 patients (75%) fulfilled the criteria of receiving the study intervention and protocol correctly, and had ease and satisfaction scores for the study dressing and securement devices of ≥ 7 on Numerical Rating Scale scores 1-10. This would show that the research methods were suitable for use in a larger trial.

Design: A single-site, 4-arm, parallel, pilot randomised controlled trial.

Setting: The operating theatre and the intensive care unit.

Participants: Patients were randomised to three interventional groups and a control group. The interventions were bordered polyurethane dressing (n = 30), a sutureless securement device (n = 31), and tissue adhesive (n = 32). The control group (n = 30) consisted of usual practice polyurethane dressing (not bordered).

Methods: Patients were recruited in the Pre-Admissions Clinic and were randomly assigned on the day of surgery to one of three treatment groups or the control group. Data were collected, and descriptive, survival and feasibility analyses were performed.

Results: There were 123 patients who completed the trial. The primary outcome of catheter failure was 2/32 (6.3%) for tissue adhesive, 4/30 (13.3%) for bordered polyurethane, 5/31 (16.1%) for the sutureless securement device, and 6/30 (20%) for the control usual care polyurethane. Feasibility criteria were fulfilled. Cost analysis suggested that tissue adhesive was the most cost effective.

Conclusions: The pilot trial showed that the novel technologies were at least as effective as the present method of a polyurethane dressing for dressing and securement of arterial catheters, and may be cost effective. The trial also provided evidence that a larger, multicentre trial to prove effectiveness would be feasible.

1. Introduction

Peripheral arterial catheters are widely used in the care of critically ill patients. They are a vital component of contemporary management of patients in the operating theatre (OT) and intensive care unit (ICU), and are usually inserted into a peripheral artery for continuous blood pressure monitoring and blood sampling for frequent blood gas analysis. Worldwide annual usage of arterial catheters is extensive, and is reported as up to eight million in the United States of America, and 2.5 million in Europe (Gowardman et al., 2010, Scheer et al., 2002). Arterial catheters can fail before the completion of treatment due to complications of accidental removal, partial/complete dislodgement, occlusion, pain, phlebitis and infection which may be either local or catheter-related. Catheter-related blood stream infections (CRBSI) incur hospital costs of $US 1.2 million annually in the USA (Centres for Disease Control (CDC), 2011), and increase patients' length of hospital stay (Dimick et al., 2001, Warren et al., 2006). The insertion site of an arterial catheter is usually dressed with a commercially produced transparent dressing which assists in maintaining the catheter's position and plays a role in the prevention of microbial entry to the wound. Catheter failure incidence in peripheral arterial catheters is not often reported in the literature. However, catheter failure in peripheral intravenous (IV) catheters due to dislodgement or other complications is a common problem which has been studied (Royer, 2003). Peripheral IV catheter failure incidence in the United States of America utilising similar dressings and securements to that used on arterial catheters has been reported as occurring in 50% to 80% of patients (Delp and Hadaway, 2011, Wood, 1997). A few studies report complications which cause arterial catheter failure. The Australian Incident Monitoring Study, AIMS-ICU found 69% (40/58) of arterial catheter insertion incidents related to inadequate securement, and 24%

(60/249) of catheter use problems involved dislodgement or inadvertent removal (Durie et al., 2002). High rates of accidental removal of arterial catheters have been described compared with accidental removal of central venous catheters in intensive care studies, with twice as many (Lorente et al., 2004), and four times as many reported (Carrión et al., 2000). Other literature acknowledges the importance of infection in peripheral arterial catheters, which also causes catheter failure. The incidence of arterial catheter-related infection in intensive care has been reported as 0.59 per 1,000 catheter days, with 0.34% developing CRBSI (Lorente et al., 2006), and point prevalence rates stating 0.8% and 1.7 per 1,000 catheter days (Maki et al., 2006). Systematic review and meta-analysis have confirmed and consolidated impressions that arterial catheters may have a substantial burden of CRBSI, with pooled incidence of CRBSI in arterial catheters reporting a rate of 0.96 per 1,000 catheter days (O'Horo et al., 2014). In general, all catheter-related complications, either mechanical or infectious, may progress to catheter failure. This can cause associated patient suffering, additional insertions, prolonged hospitalisation, and more expensive healthcare costs, with the potential for increased mortality and morbidity.

Inadequate peripheral intravascular catheter securement remains a poorly researched area of patient care, and has been identified as a priority for improvement (Schears, 2006). There is a paucity of quality studies reporting efficacy of dressing and securement methods for peripheral arterial catheters, with only one previous study (not randomised) (Stephenson, 2005) and a recent pilot randomised controlled study in cardiac surgical intensive care patients (Edwards et al., 2014, Stephenson, 2005). Specialty anaesthetic and ICU nurses are largely responsible for post-insertion care of arterial catheters, in particular dressings and securement,

and play a pivotal role in preventing the catheter-related complication of failure, including premature catheter removal.

1.1 Dressing/securement methods

The current Guidelines by the Centres for Disease Control (CDC) recommend covering the peripheral arterial catheter site with sterile gauze or a sterile, transparent, semipermeable dressing (O'Grady et al., 2011). A sutureless securement device (SSD) is the specified recommended method for securement of the catheter instead of sutures, in order to reduce the risk of infection and needlestick injury (O'Grady et al., 2011). Different dressings are available for use over the arterial catheter site. They are small and large transparent, semipermeable dressings, termed in this trial as usual care polyurethane, and include Tegaderm™ (3M™, St Paul, 2013b) and Opsite® (Smith & Nephew, North Ryde, 2013). A more recent version of transparent dressing involving novel technology to enhance adhesion and including a reinforced opaque adhesive border is Tegaderm™ I.V. Advanced (3M™, St Paul, 2013a), referred to in this study as Bordered Polyurethane (BPU). Traditionally, these dressings have been used in conjunction with adhesive tape to secure the arterial catheter tubing. An alternative to tape is a precision made SSD specifically used with arterial catheters, such as the novel approaches of the StatLock® arterial stabilisation device (Bard®, Salt Lake City, 2013) or the Grip-Lok® device (Zefon, Ocala, 2013). Transparent dressings, tapes, and SSDs which are used for arterial catheters are also used for IV catheters. Skin glue, also termed tissue adhesive (TA), has had novel use in a limited capacity for the securement of intravascular catheters, providing another alternative to sutures or a SSD. There have been a few small reports of the use of Histoacryl® TA to secure central venous catheters and epidural catheters in the United Kingdom (Wilkinson and Chikhani, 2007, Wilkinson and Fitz-Henry,

2008, Wilkinson et al., 2007). The effectiveness of the use of an SSD in arterial catheters has been reported (Stephenson, 2005), and recent pilot work on the novel dressing and securement technologies of BPU, an SSD, and TA for arterial catheters has been performed to inform of effectiveness and the feasibility of further study (Edwards et al., 2014).

1.2 Aims and objectives

We aimed to determine initial effectiveness of the selected dressing and securements to prevent failure in peripheral arterial catheters which were inserted in the operating theatre and cared for in the intensive care unit, as well as their suitability for study in a large multi-centre randomised trial. The pilot trial would be considered feasible if 90 out of 120 patients (75%) fulfilled the criteria of receiving the study intervention and protocol correctly, and had ease and satisfaction scores for the study products of ≥ 7 on increasing Numerical Rating Scale scores 1-10. This was to show that the research methods were suitable for use in the larger trial. Evaluations of effectiveness, resources and costs were also performed to further investigate feasibility. We modelled our approach on a previous pilot study which set feasibility criteria to determine success, systematically determining the feasibility of progression to a larger-scale trial (Cook et al., 2005).

2. Methods

2.1 Study design and participants

We performed a pilot, single-site, 4-arm, parallel, randomised controlled trial. This trial was intended to function as a test for the novel interventions as feasible inclusions, and to ensure that the proposed bigger trial was designed optimally, and could be implemented in practice (Arnold et al., 2009). The primary outcome was peripheral arterial catheter failure which was a composite of one or more of complete arterial catheter dislodgement, occlusion,

phlebitis, and infection, either local or CRBSI. Each of these failure types was considered on an individual basis for a secondary outcome. In addition to peripheral arterial catheter dwell time, the costs, workload, ease of dressing/device application, and patient/staff satisfaction were included as secondary outcomes.

Group sizes of 30 were used to achieve at least a 68 per cent confidence of an accurate estimate of arterial catheter failure within a seven per cent margin of risk for inaccuracy. (Hertzog, 2008). The trial design consisted of three experimental groups each of 30 patients with peripheral arterial catheters secured with the novel technologies. Group One was Bordered Polyurethane (not sutured) (Tegaderm™ I.V. Advanced Securement Dressing 1683, 3M™, St Paul), Group Two was the SSD and a small polyurethane dressing over the catheter insertion site (StatLock® Arterial Select Stabilisation Device, Bard®, Salt Lake City), and Group Three was TA (Histoacryl®, B Braun, Bella Vista) and a small polyurethane dressing over the catheter insertion site. The control group of 30 patients had arterial catheters which were not sutured, and were secured with usual care polyurethane (Tegaderm™ 1624W, 3M™, St Paul).

2.2 Study setting

The research setting was the OT complex and the Department of Intensive Care Medicine at the university affiliated government hospital, Royal Brisbane and Women's Hospital, Herston, Australia. A single nurse researcher, the Principal Investigator, screened and recruited the patients, and collected the data.

2.3 Recruitment

Recruitment was from September 1, 2012 to March 28, 2013. The Principal Investigator screened patients in the anaesthetic Pre-Admissions Clinic and inpatients,

Monday to Friday. Inclusion criteria were patients of at least 18 years of age, for elective major surgery requiring an arterial catheter, and booked ICU post-operative care. Exclusions were patients with known allergy to the study products, unavailability of an interpreter if non-English speaking, the need for the arterial catheter to be inserted through burned, diseased, or damaged skin, and diaphoretic patients. The trial was conducted under the jurisdiction of the Royal Brisbane and Women's Hospital and Griffith University. The human research and ethics committees at both institutions approved the protocol. Written, informed consent from all participants was obtained, prior to enrolment.

2.2 Sampling framework

The study population consisted of patients with arterial catheters inserted in the OT and admitted to the ICU postoperatively. The study sample was drawn from all surgical patients for postoperative admission to the Department of Intensive Care who met the inclusion criteria. Since the primary aim of this pilot trial encompassed feasibility rather than hypothesis testing, formal power calculations were not the appropriate consideration in choosing sample size. A sample size of 120 with three intervention groups and one control group, each of 30, was selected. This was to provide a useful comparison between groups for feasibility and intervention efficacy. Such a group size was realistic regarding time and cost, and would yield confidence intervals with lower limits to assist in the definition of a range of values for later power analysis (Hertzog, 2008).

2.3 Randomisation and concealment

Random allocation was undertaken by the Principal Investigator. A computer-generated system of centralised web-based randomisation was provided by Griffith University (http://www151.griffith.edu.au/), and was used at the point of each patient's study entry.

Patients were randomly assigned on the day of surgery to one of the three treatment groups or the control group. Block randomisation and stratified blocks were used, with a randomly varied block size. There was concealment of allocation to patients, clinical staff, and the Principal Investigator until the point of entry into the study. Patients and clinical staff were not blinded following allocation due to the nature of the intervention. Laboratory staff were blinded for assessment of microbiological endpoints.

2.3 Data Collection

A standardised data collection tool was developed and then adapted by Griffith University Information Technology Services, to be used on a personal laptop computer by the Principal Investigator. A paper data collection form mirrored some of the computer-based data points and was kept at the bedside for convenient documentation by ICU nurses. Data were collected on insertion of the arterial catheter in the OT, at each ICU patient's bedside daily, and on ICU discharge. Other points of data collection were at the time of dressing adjustment or changes, at catheter removal, and final assessment at 48 hours post catheter removal. The reasons for catheter removal were documented as completed therapy (not failed), blocked, could not aspirate, monitor failure, accidental dislodgement, and/or signs of infection.

2.4 Statistical analyses

Data were exported from the Microsoft Access 2010 database into Stata 12.1 (StataCorp LP, College Station, Texas, USA, 2014) for cleaning and analysis. The statistical analyses of the pilot work were mainly descriptive, and these data were used to discuss the sample, with analyses piloted in the manner that they would be performed for a larger trial. All randomised patients were analysed in their original assigned groups on the basis of Intention

to Treat, and patient flow followed the Consolidated Standards of Reporting Trials (CONSORT) Guidelines (Altman et al., 2001) (see Figure 1). Mean values and standard deviations were reported for normally distributed data, while median values and the 25% and 75% percentiles were reported otherwise. The Kaplan-Meier curve was used to show the cumulative survival probability of arterial catheters over time. Arterial catheter failure over time was tested with the log-rank test for equality of survivor functions, comparing the three alternative interventions with the control group. Univariable and multivariable Cox proportional hazards regression models were used to assess for independent relationships between potential explanatory variables for catheter failure, and the dichotomous outcome of failure. The incident rate of catheter failure was expressed as the number of catheter failures per 1,000 catheter hours. In this study, if a NRS score of ≥ 7 was achieved for more than 75% of patients (90% CI) in all of the categories of ease of application, satisfaction on removal for staff, and satisfaction on removal and overall satisfaction for patients, then it would be accepted as feasible for a larger trial.

Research nurse workload was assessed by recording the total time taken to carry out all research tasks. The rate of recruitment, number of eligible patients who agreed to participate, number of patients who received the correct protocol, and completed the trial were also recorded.

Cost analysis was performed using the data from this pilot trial. The cost effectiveness of each of the interventions was considered, with a focus on the difference in the effect and cost. Cost effectiveness was determined by setting a threshold amount that society would be willing to pay for an incremental health gain. In this pilot study, the threshold was set at $AUD 100, which was the cost to replace an arterial catheter. The effect outcome was

the probability of catheter success. The economic concept of the net monetary benefit approach was used to perform the analysis. The net benefit which was calculated in terms of money with a ceiling ratio that was considered acceptable to pay, was estimated for the four catheter dressings/securements. The preferred option was the one with the maximum average net benefit (Tuffaha et al., 2014). Further, value of information analysis was used to estimate the value of additional research and to inform of optimal future trial design (Claxton and Posnett, 1996, Eckermann et al., 2010, Willan and Pinto, 2005).

3. Results

Consecutive eligible patients were recruited from September 1, 2012 to March 28, 2013. Over this 8 month period, 150 patients were screened for eligibility. Of these, 18 patients were excluded, 132 were randomised, and 123 completed the trial. Reasons for exclusion and not completing the trial following randomisation are listed in Figure 1.

3.1. Baseline demographics and characteristics of study participants

Demographic and clinical characteristics at baseline are presented in Tables 1 and 2. The median age of all randomised patients who progressed to trial was 62.0 years (25^{th} to 75^{th} percentile, 50.0 - 72.0). There were 72/123 (58.5%) males. The most frequently occurring surgery type was neurosurgery, performed on 64/123 (52.0%) patients. The most frequently reported comorbidity was malignancy. In addition, 30/123 (24.4%) patients were current smokers. Clinical characteristics (see Table 2) were considered similar at baseline for the three treatment group patients for most variables, including numbers treated with corticosteroids, antibiotics, and for median APACHE II scores and blood sampling events.

3.2. Intervention effect on primary and secondary outcomes

Primary and secondary outcome data were available for all patients (see Table 3). The primary outcome of arterial catheter failure prior to completion of therapy was analysed for incidence in control patients, compared with the three treatment groups. Arterial catheter failure was 6/30 (20%) for control polyurethane, compared with 4/30 (13.3%) for BPU, 5/31 (16.1%) for SSD, and 2/32 (6.3%) for TA. The effect size of TA was an absolute reduction of 14% compared to controls, with absolute reductions of 6.7% and 3.9% for BPU and SSD, respectively. The control group typically failed by blockage, 3/30 and accidental removal, 3/30, with 6/30 failures in total. BPU and SSD group arterial catheters most commonly failed through total monitor failure (loss of trace). The two failures of TA catheters were one blockage and one monitor failure.

The control catheter failure rate was 7.94 per 1,000 arterial catheter hours, (95% CI, 3.57- 17.68). The catheter failure rates for the interventions were BPU group, 5.09 per 1,000 catheter hours (95% CI, 1.91 - 13.56, $p = 0.51$), SSD group, 6.03 per 1,000 catheter hours (95% CI, 2.51 - 14.48, $p = 0.66$), and TA group, 2.33 per 1,000 catheter hours (95% CI, 0.58 - 9.31, $p = 0.13$) (see Figure 3). There were no statistically significant differences in outcomes of the study groups compared to controls. The secondary outcomes of individual types of failure and catheter dwell times were not significantly different in the treatment or control groups (see Table 3). No infection outcomes were observed in the study.

3.3. Statistical analyses

Cox regression was applied in univariate and multivariate models. This tested whether group, age, gender, skin type, comorbidities, smoker, dominant side, health care professional

who inserted the catheter, number of insertion attempts, sterile gloves worn, number of staff and which staff members applied the dressing/securement device, ease of application, time to apply, or number of securing devices used were explanatory variables for catheter failure. The results showed that compared with the control group, the hazard ratio of catheter failure was 0.32 (95% CI, 0.06 - 1.66) in the TA group, 0.64 (95% CI, 0.17 – 2.44) in the BPU group, and 0.78 (95% CI, 0.22 – 2.70) in the SSD group. None were statistically significant. Significant predictors of catheter failure in the multivariate model were *current smoker* and *female* ($p < 0.05$) (see Table 4).

Kaplan-Meier survival curves for the three treatment groups and the control were plotted to display failure of arterial catheters over time (see Figure 2). There was little difference between curves up until the average dwell time at the 24 hour mark, after which the TA group had the highest proportion in use of the three interventions. However, the difference was not statistically significant, $p = 0.562$, log-rank test. There were seven arterial catheters in place at 48 hours. This number was too small to make claims about difference.

3.4. Feasibility

The percentage of eligible people who agreed to participate was 100% and the average recruitment was 21 patients per month. Of the 146 patients recruited, 132 (90.4%) were randomised and timely performance of the protocol occurred for 123 (93.2%) of the randomised patients (see Figure 1). Satisfaction and ease of application Numerical Rating Scale scores were skewed, so they were transformed into dichotomous data for comparison of proportions in each group rating ≥ 7 for each item. TA and SSD had statistically worse scores for staff ease of application compared to controls, 25 (78.1%) and 22 (71.0%) respectively, (both $p < 0.05$). However, TA still met the feasibility cut-off for easy application of 75%, with

78% of ratings being ≥ 7. For the other ratings for staff ease of removal, patient ease of removal, and overall satisfaction, there were no significant differences between groups and controls (all $p > 0.05$). All groups met the feasibility criteria for patient removal ratings and overall patient satisfaction. The percentage of patient satisfaction with removal ratings ≥ 7 by group were 100% for BPU, SPU, and TA, and 93% for SPU control. Patient overall percentage satisfaction had feasible ratings of ≥ 7 by groups of 86.7% for BPU, 96.8% for SSD, 96.9% for TA, and 96.4% for SPU control. Other feasible Numerical Rating Scale scores of ≥ 75% were staff ease of application for BPU at 93.3% and control SPU at 100%, as well as staff ease of removal for BPU at 86.7%, and TA at 84.4%.

3.5. Workload of research activities

The total time taken to carry out pre-protocol implementation research activities, (before randomisation of the first patient) was 151 hours. Further, the Principal Investigator's daily research tasks were timed and collated for 12 consecutive days (Monday to Friday), after commencement of the recruitment phase. Each day's workload was categorised into nine tasks which included checking the OT lists for booked recruited patients, on-going recruitment, time to travel to and from recruitment areas, time to undertake randomisation, observation of device insertion in OT, spreadsheet data entry, database entry (laptop), ICU visits, and preparation of protocol packs for ICU. The mean total time per day for research tasks was 5.2 (1.67) hours, over 12 days from Monday to Friday.

3.6. Cost-effectiveness

Economic evaluation of the products was made with a calculation of the average net benefit for each of the dressing/securement options. With the willingness to pay threshold set

at $AUD 100 to gain the desirable outcome of catheter success, it was shown that the average net benefit was highest for tissue adhesive ($AUD 14.10). There was a probability of 35% of TA being the dressing/securement with the highest net benefit. A four-arm trial design was found to provide the highest net benefit, and was thus the most economical design for a large trial.

4. Discussion

The results fulfilled the study aims that the new dressing and securement technologies showed effectiveness to prevent arterial catheter failure compared with the control, but not to show a statistical difference, in accordance with the pilot methodology. It was shown that it would be feasible to undertake further study of the dressing and securement of peripheral arterial catheters with the interventions BPU, SSD and TA. It is encouraging for future studies that all three tested technologies had lower absolute incidence of arterial catheter failure than the control catheters, thus suggesting that all three tested interventions may reduce arterial catheter failure. The lowest was for TA with 2/32 (6.3%), followed by BPU with 4/30 (13.3%), and 5/31 (16.1%) for SSD, compared with 6/30 (20%) for control usual care polyurethane dressings. BPU dressings have not been well researched, with no previous randomised controlled trials to investigate the manufacturer's indications that BPU dressings minimise the risks of dislodgement and increase securement. This pilot study showed an accidental removal incidence of 2/30 (6.7%), which seemed to indicate a lack of suitability compared with the other interventions, which had no accidental removals. BPU dressings may have been more satisfying (presumably easier) to remove for nurses, than the controls (86.7% vs 65.5% scored ≥7 out of 10, $p = 0.072$). These results are difficult to

interpret, and may be coincidental findings, since the reinforced picture-frame design of the BPU would appear to require more work for nurses to remove.

Consideration needs to be taken of which AC failures can be directly attributable to securement technique. The reason of monitoring failure as a cause of AC failure needs to be investigated further, to establish a link with the securement method. Further study of the contribution of thrombotic complications to monitoring failure and blockage would contribute to our current knowledge (Salmon et al., 2010).

Several studies in IV catheters have shown superior performance of the StatLock® SSD over usual care polyurethane dressings or tape (Frey and Schears, 2006, Royer, 2003, Schears, 2006, Smith, 2006). There has only been one large prior study of StatLock® in arterial catheters (Stephenson, 2005). In our study, the SSD catheter failure incidence was 5/31 (16.1%) which was not significantly different to incidence in the control group. In Stephenson's study of 995 patients (2005) the SSD failure incidence was 12.8%. This is not largely dissimilar to the observed SSD failure of 16.1% in the current study, thus supporting the validity of the findings. Stephenson (2005) reported a lower incidence of failure in the SSD group than in their control group (25%) as statistically significant, while our study failed to find the same difference. However, we had the advantage of a robust randomised design, adding to the quality of the body of knowledge on the SSD approach.

There were only 22 (71%) of SSD patients whose Numerical Rating Scale scores were ≥ 7 for ease of application, compared with 100% in the control group, and this difference was statistically significant at $p = 0.002$. This score was lower than our feasibility criteria of 75% of scores being ≥ 7. Thus, staff clearly found application less easy. This SSD required a multistep procedure to apply, with the first step to prepare the skin, prior to applying the

adhesive pads, and then the arterial catheter and tubing to be inserted into the SSD itself. This likely contributed to a longer application time compared with the other interventions, and led to lower satisfaction ratings for application. In contrast, satisfaction with removal for patients and staff, and for overall satisfaction ratings were similar for patients in the SSD and control groups and these results were feasible. Further education and experience with the SSD may increase the ease of application ratings.

All dressing and securement methods were used until the conclusion of the pilot trial, with no reasons found to exclude their use. All clinical staff were familiar with application and removal of usual care polyurethane, and somewhat familiar with BPU, but were usually not familiar with SSD or TA. It is possible that this may have introduced an attitude of bias against the more unfamiliar products. To counter this, product information and educational sessions provided support and guidance to use the study products according to the protocol and manufacturers' guidelines.

The sample size of 30 per group was used to guide calculations for the proposed larger randomised controlled trial. On the basis of this pilot study, sample size calculations could be made for a larger study. Thus, calculations were performed to compare the observed proportions with 90 per cent power and $p = 0.05$ (two-sided) (University of British Colombia, 2014), and revealed that a future trial would need group sizes of 983 patients for SSDs (16% failure), 589 for BPU (13% failure) and 61 patients TA patients (14% failure). The 983 required for SSDs corresponds with Stephenson's (2005) number of 995.

The use of skin glue (TA) was a novel inclusion in this randomised controlled pilot trial in response to concerns in the literature regarding lack of effective securement of arterial catheters (Carrión et al., 2000, Durie et al., 2002), and the potential risk of infection which

may be underestimated (Koh et al., 2008, Lucet et al., 2010, Traore et al., 2005, Wittekamp et al., 2013). The glue was associated with the lowest number of arterial catheter failures as the primary outcome, at 2/32 (6.3%), however this was not statistically different, $p = 0.14$, in comparison with controls. However, there were two patients with TA who remained in ICU for four days, and their arterial catheters were secured successfully. If effectiveness could be confirmed in a larger trial, this would be of great benefit. Wilkinson and Fitz-Henry (2008) and Wilkinson et al. (2007) also reported positive findings in a case study and case series of TA use for central venous catheters and epidural catheter securement. However, this trial has provided the first research data on the use of TA in arterial catheters in general surgical patients, and provides new information regarding its use. Economic evaluation using value of information analysis to inform of an optimal future trial design showed that the new method of TA was most effective of the three interventions in comparison with control polyurethane, indicating that it was the preferred intervention. The probability of TA being the most cost effective of 35% was low, but was sufficient to justify further research. A four-arm trial design with 220 patients provided the highest expected net benefit of sampling, and was more economical than the sample size calculated on type 1 and type 11 errors and the smallest clinically significant difference. These findings were different from the recent pilot randomised controlled trial, similarly comparing dressing/securement effectiveness of BPU, SSD and TA with a control polyurethane dressing to investigate dressing/securement of arterial catheters, but in cardiac surgical intensive care patients (Edwards et al., 2014). In this pilot trial there was significantly less incidence of catheter failure with BPU dressings. However, TA has been shown in our study to have the potential to have a worthwhile impact on developing methods for effective securement of arterial catheters, while offering proven

antimicrobial benefits (Simonova et al., 2012). This provides an important step forward into knowledge in this area.

Our study provides new information on the most common types of arterial catheter failure. Regardless of group, the overall study failure rate was 17/123 (13.8%) for this vital and ubiquitous medical device, which is in agreement with the Stephenson (2005) study. This seems to be high, especially given that devices in this study were only required for a short (approximately 24 hour) period. The study of arterial catheter failure rates does not command discussion in the current literature. Therefore, this study is extremely important.

The pilot trial was designed according to the feasibility objectives, with a view that a future multi-centre, randomised controlled trial would replicate and extend the approach with a larger sample. It is appropriate to build upon this pilot, and perform a larger, definitive randomised controlled trial.

All patients who were assessed as eligible gave written informed consent to participate in the trial. Thus, 100% of eligible patients commenced the recruitment process. This result could not be bettered, suggesting the process was effective. Mean daily work time for the research nurse for a 12 day period was 5.2 (1.6) hours. Therefore, the estimated daily research nurse requirements for the larger trial were approximately 5.5 to 8 hours per day, Monday to Friday, with the recommended work hours between 0600 and 1630. A senior research nurse would be required full-time for eight months. This can assist with budgeting for future studies, providing valuable information regarding the cost of the research nurse in relation to seniority and skill mix. An estimate of up to nine full-time research nurses would be required for a larger trial with these interventions and control, over the same time frame of eight months.

5. Limitations

This pilot trial had the limiting factor of lack of evidence of a known effect size to test statistical difference in the analyses of primary and secondary outcomes. Thus, pilot methodology was required to be utilised, which allows for its being underpowered. It was also limited in that it was a single site trial, with only short-term arterial catheters studied. One research nurse provided continuity of practice, consistency of education, and a thoroughness of follow-up, and this may not be possible with multiple research personnel in a larger, multi-centre trial. This positive limitation may have been the key to the lack of missing data, and total adherence to the protocol.

6. Conclusion

The benefits of the study have been recognised with the evidence of proven feasibility of performing further research with a large number of patients. More work needs to be undertaken to achieve a better understanding of arterial catheter failure in relation to dressing and securement types, so as to inform decisions about the most useful and cost-effective choices that optimise the care and comfort for patients. An important research priority for future study of dressings and securement of arterial catheters is that the current catheter failure rate is unacceptably high after only short-term arterial catheter use. This pilot research makes an original contribution to knowledge by providing initial information on the effectiveness of the tested novel technologies to secure arterial catheters, together with a thorough investigation of pilot methodology to verify the feasibility of future extensive use of these products in randomised testing. This approach decreases the risk of novel therapies being

included in practice without evidence. Thus, the trial has contributed to optimising care of patients with peripheral arterial catheters, which has previously attracted little research attention.

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8. Conflict of Interest

There were no conflicts of interests.

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Table 1. Baseline Demographics of Study Participants by Group.

Variable	Control SPU n = 30	BPU n = 30	SSD n = 31	TA n = 32	Total n = 123
Gender – Male n (%)	18 (60.0%)	12 (40.0%)	20 (64.5%)	22 (68.0%)	72 (58.5%)
Gender – Female n (%)	12 (40.0%)	18 (60.0%)	11 (35.5%)	10 (31.3%)	51 (41.5%)
Age: Median (25^{th} to 75^{th} percentile)	62.0 (49.0, 72.0)	63.0 (50.0, 73.0)	56.0 (42.0, 70.0)	63.0 (55.5, 74.0)	62.0 (50.0, 72.0)
Current Smoker:					
Yes	9 (30.0%)	8 (26.7%)	5 (16.1%)	8 (25.0%)	30 (24.4%)
No	21 (70%)	22 (73.3%)	26 (83.9%)	24 (75%)	93 (75.1%)
Type of Surgery n (%)					
Neurological (Brain)	16 (53.3%)	15 (50.0%)	17 (54.8%)	16 (50.0%)	64 (52.0%)
Gastrointestinal	6 (20.0%)	7 (23.3%)	7 (22.6%)	9 (28.1%)	29 (23.6%)
Vascular	4 (13.3%)	2 (6.7%)	5 (16.1%)	4 (12.5%)	15 (12.2%)
Urological/Renal	2 (6.7%)	3 (10.0%)	0 (0.0%)	0 (0.0%)	5 (4.1%)
Neurological (Spine)	1 (3.3%)	3 (10.0%)	0 (0.0%)	0 (0.0%)	4 (3.3%)
Other General	0 (0.0%)	0 (0.0%)	1 (3.2%)	2 (6.3%)	3 (2.4%)
Orthopaedic	1 (3.3%)	0 (0.0%)	1 (3.2%)	0 (0.0%)	2 (1.6%)
Otolaryngological	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.1%)	1 (0.8%)
Comorbidities n (%)					
• None	11 (36.7%)	5 (16.7%)	7 (22.6%)	6 (18.8%)	29 (23.6%)
• 1	8 (26.7%)	13 (43.3%)	14 (45.2%)	16 (50%)	51 (41.5%)
• 2	7 (23.3%)	6 (20.0%)	9 (29.0%)	6 (18.8%)	28 (22.8%)
• > 3	4 (13.3%)	6 (20.0%)	1 (3.2%)	4 (12.5%)	15 (12.2%)

Table 2. Clinical Characteristics of Study Participants by Group.

Variable	SPU control n=30	BPU control n=30	SSD n=31	TA n=32	Total n=123
Corticosteroids n (%)	18 (60%)	20 (66.7%)	18 (58.1%)	21 (65.6%)	77 (62.6%)
Antibiotics n (%)	29 (6.7%)	29 (96.7%)	31 (100%)	32 (100%)	121 (98.4%)
ICU APACHE II scores					
Median (25th to 75th percentile)	11.0 (8.0-12.0)	12.0 (8.0-15.0)	10.0 (8.0-14.0)	11.0 (9.0-15.0)	_____
ICU Blood glucose mmol/L					
Median (25th to 75th percentile)	7.9 (6.3-8.8)	6.4 (5.9-7.8)	5.8 (5.3-7.8)	5.9 (5.3-7.2)	_____
ICU Confusion n (%)	3 (10%)	2 (6.7%)	1 (3.2%)	1 (3.1%)	7 (5.7%)
Agitation n (%)	3 (10%)	0 (0%)	0 (0%)	0 (0%)	3 (2.4%)
Drowsiness n (%)	2 (6.7%)	5 (16.7%)	4 (12.9%)	5 (15.6%)	16 (13%)
ICU Blood sampling events (25th to 75th percentile)	2 (2-4)	2 (1-3)	2 (1-4)	2 (1-3.5)	_____
ICU Patient mobility n (%)					
* Unable to mobilise	21 (70%)	16 (53.3%)	19 (61.3%)	19 (59.4%)	75 (61%)
* Turn independently	6 (20%)	8 (26.7%)	8 (25.8%)	7 (21.9%)	29 (23.6%)
* Sit out/walk with assistance	3 (10%)	5 (16.7%)	4 (12.9%)	6 (18.8%)	18 (14.6%)

Table 3. Primary Outcome and Secondary Outcomes by Group.

Outcome variable	SPU control n = 30	BPU n = 30	SSD n = 31	TA n = 32
Hours till removal				
Median	24.3	24.9	25.0	24.3
(25% to 75%)	(21.5-25.5)	(21.3-27)	(21.4-26.8)	(21.9-26.5)
p value[a]		0.34	0.26	0.55
Primary				
Failure				
n (%)	6 (20%)	4 (13.3%)	5 (16.1%)	2 (6.3%)
*p v*alue[a]		0.73	0.75	0.14
Catheter hours	755	786	829	859
Failure rate				
per 1,000 AC days	7.94	5.09	6.03	2.33
95% CI	(3.57-17.68)	(1.91-13.56)	(2.51-14.48)	(0.58-9.31)
Failure rate ratio		0.64	0.76	0.29
95% CI		(1.13-2.70)	(0.18-2.98)	(0.03-1.64)
p value[a]		0.51	0.66	0.13
Secondary[b]				
Blocked Catheter	3 (10.0%)	1 (3.3%)	3 (9.7%)	2 (6.3%)
Total Monitor Failure	1 (3.3%)	4 (13.3%)	4 (12.9%)	2 (6.3%)
Accidental Removal	3 (10.0%)	2 (6.7%)	0 (0.0%)	0 (0.0%)
Painful	1 (3.3%)	0 (0.0%)	2 (6.5%)	0 (0.0%)
Local Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Suspected BSI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note. CI = confidence interval.

[a] Fisher's exact 2-sided test.

[b] Do not add to 100% due to multiple possible outcomes.

Table 4. Predictors of Catheter Failure Using Cox Regression.

Predictors including referent levels	Coding	Cox regression					
		Univariable			Multivariable[a]		
		HR[b]	95% CI		HR[b]	95% CI	
Treatment arm 0 = SPU	1 = BPU	0.64	0.17	2.44	0.74	0.19	2.93
	2 = SSD	0.78	0.22	2.70	1.26	0.32	4.91
	3 = TA	0.32	0.06	1.66	0.33	0.06	1.80
Age (years)	Centered over mean	1.01	0.97	1.04	1.04*	1.00	1.09
Gender 0 = male	1 = female	2.88**	1.00	8.26	5.99**	1.51	23.75
Skin type 0 = moderate brown	1 = other	0.76	0.28	2.04	3.97**	1.04	15.15
No. of comorbidities 0 = one	1 = none	1.39	0.38	5.02			
	2 = two	0.79	0.20	3.16			
	3 = three or more	1.61	0.40	6.47			
Smoker 0 = never	1 = current smoker	2.63*	0.92	7.53	4.87**	1.32	17.93
	2 = past smoker	1.51	0.30	7.51	2.32	0.42	12.74
Device on non-dominant side 0 = yes	1 = no	0.91	0.31	2.61			
Catheter inserted by 0 = registrar	1 = consultant	0.81	0.25	2.61			
	2 = senior registrar	1.68	0.36	7.76			
Number of insertion attempts 0 = none	1 = two	1.60	0.57	4.51			
	2 = three or more	0.66	0.08	5.27			
Gloves worn 0 = yes, sterile	1 = no or non-sterile	1.84	0.66	5.09			

Predictors including referent levels	Coding	Cox regression				
		Univariable			Multivariable[a]	
		HR[b]	95% CI		HR[b]	95% CI
Number of staff to apply securing device 0 = one	1 = two	1.47	0.55	3.98		
Securing device applied by (0 = registrar, consultant, senior registrar)	1 = other	1.65	0.61	4.47		
Ease of securing device application (< 0 difficult, > 0 easy)	Centered over mean	0.98	0.71	1.34		
Time required to apply securing device (seconds)	Centered over means by groups[c]	0.99	0.98	1.01		
No. of sec. devices used 0 = one	1 = two or more	0.53	0.12	2.37		

[a] All predictors were entered into the multivariable models. Blank cells indicate that the variable was removed during the manual stepwise backward deletion of variables at a $p > 0.2$ level. Hazard ratios (HRs) in the multivariate model indicate adjusted values.

[b] HR < 1 indicates lower hazard (risk) of catheter failure than at the referent level, and HR > 1 indicates higher hazard.

[c] Centered by groups, as the levels were considerably different in the various groups.

* $p < 0.01$; ** $p < 0.05$

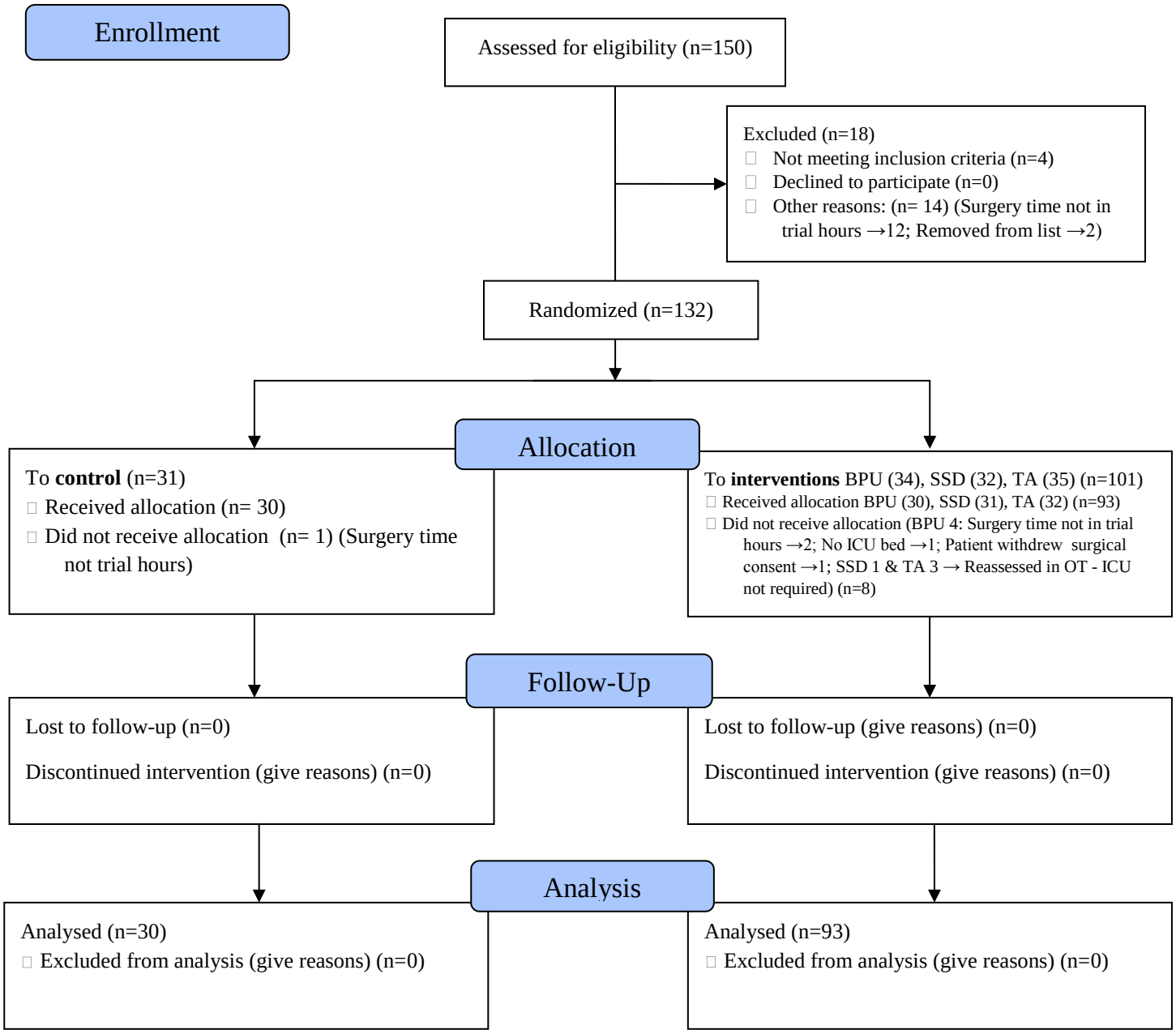
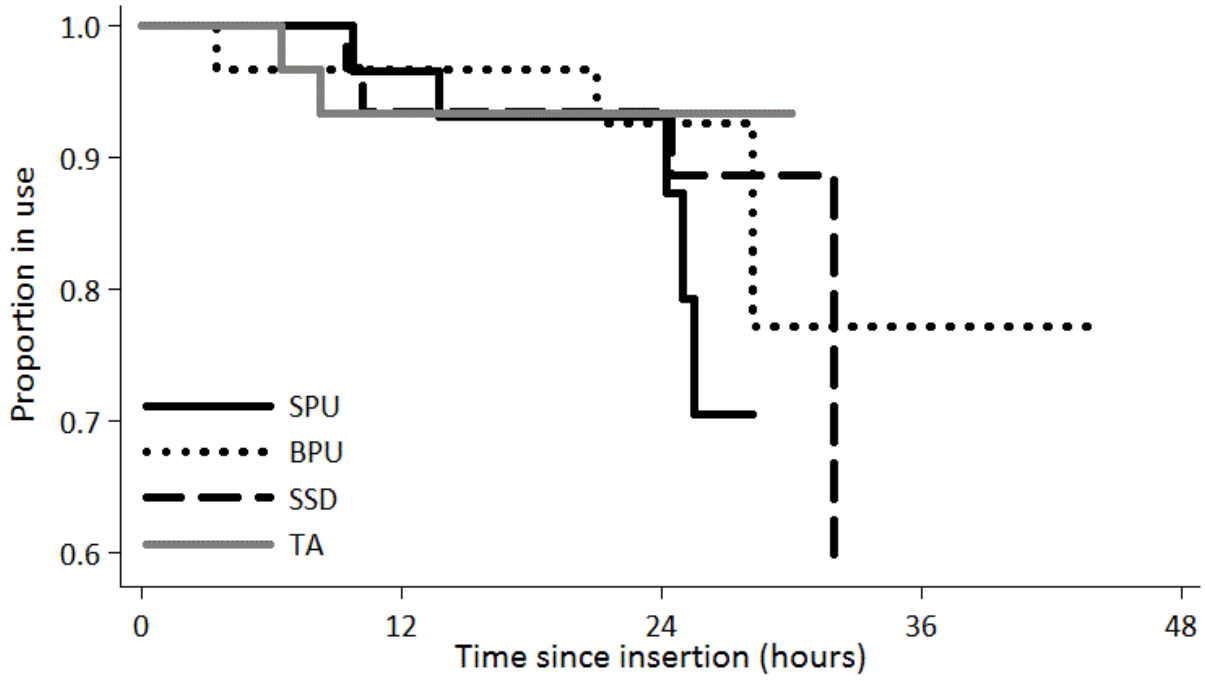


Figure 1. CONSORT Flow Chart of Participants (Altman et al., 2001).

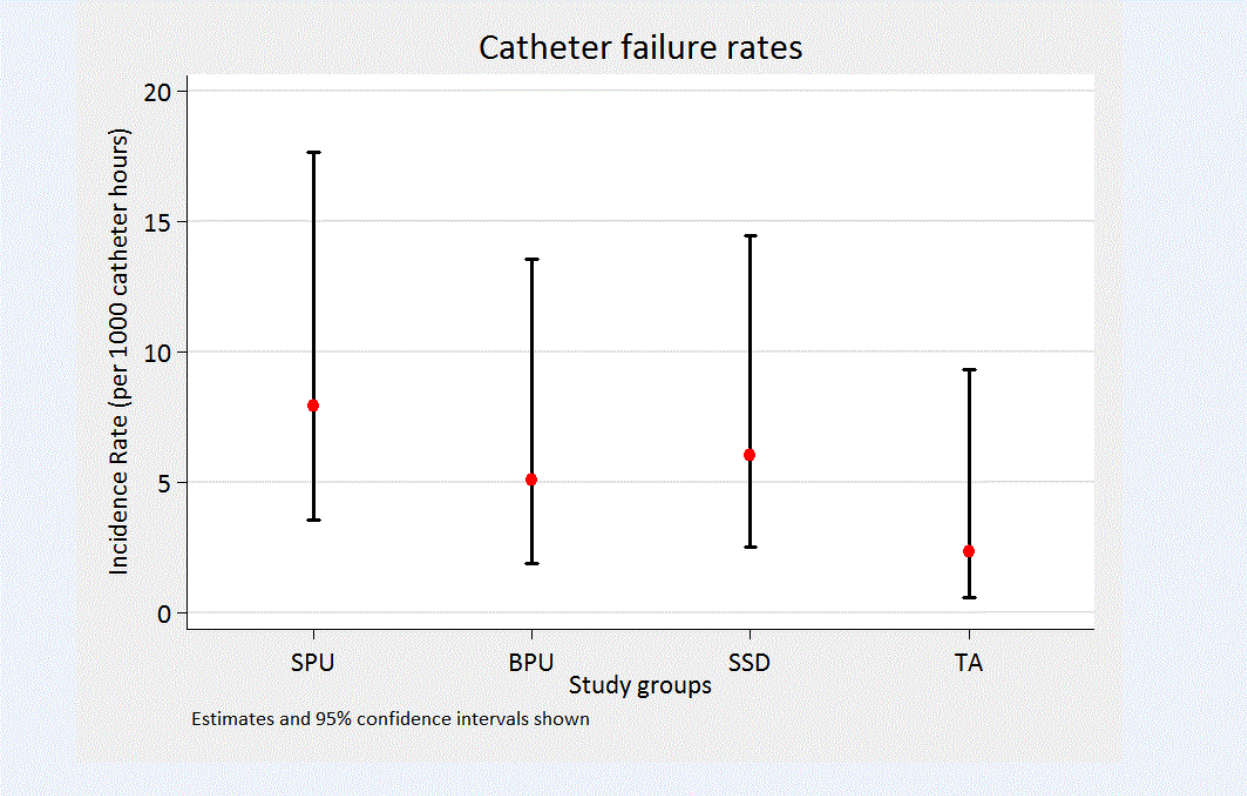


Number at risk

SPU	30	28	17	1	1
BPU	30	28	17	5	2
SSD	31	29	20	2	2
TA	32	28	18	2	2

SPU = Usual care standard polyurethane; BPU = Bordered Polyurethane; SSD = Sutureless Securement Device; TA = Tissue Adhesive.

Figure 2. Kaplan-Meier survival curve to show differences between groups for time to AC failure in hours.



SPU = Usual care/standard polyurethane; BPU = Bordered Polyurethane; SSD = Sutureless Securement Device; TA = Tissue Adhesive.

Figure 3. Catheter failure rates by group per 1,000 catheter hours.