



## **A randomised controlled trial to determine the effectiveness of a radial arterial catheter dressing**

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# A randomised controlled trial to determine the effectiveness of a radial arterial catheter dressing

Clare Healy, Ian Baldwin, Judy Currey and Andrea Driscoll

Arterial catheters are the most frequently used intravascular catheters in the intensive care unit (ICU), and have become crucial in the management of critically ill patients.<sup>1,2</sup> Despite their ubiquity, there are certain risks and complications that may occur associated with the insertion and ongoing management of arterial catheters; often resulting in premature removal.<sup>2,3</sup> Arterial catheter insertion is a routine practice in the ICU, but the catheters often fail,<sup>1</sup> resulting in unscheduled premature catheter removal. Recent evidence suggests that there is a correlation between inadequate dressing application or insufficient securing technique and arterial catheter failure.<sup>4-6</sup> The incidence of arterial catheter failure varies between 5% and 25% of patients.<sup>1,4,5</sup> Given the role critical care nurses have in assessing arterial catheter integrity and safety, failure may reflect suboptimal nursing care.<sup>1</sup>

There is little evidence available to guide clinical care for the more common complications associated with arterial catheters, particularly for care after insertion, including interventions aimed at reducing failure. Most of the research evaluating intravascular catheters focused on central venous catheters or combined studies that included multiple devices.<sup>7,8</sup> Studies focused on combined devices or central venous catheters make it difficult to reliably generalise to arterial catheter care as they are anatomically and functionally different. Since arterial catheters are the most heavily used intravascular catheters in the ICU,<sup>9</sup> with a clinically significant risk and cost associated with their failure, this lack of evidence is surprising. Where data do exist, the focus is on insertion and prevention of catheter-related blood stream infection — a somewhat rare event.<sup>10,11</sup>

An exploration of research investigating arterial catheter failure found three studies that had specifically investigated arterial catheter dressing techniques. These studies suggest that a large proportion of complications may be due to inadequate dressing application.<sup>1,4,6</sup> Given the paucity of research on securing arterial catheters, it was relevant and timely to further investigate arterial catheter safety and catheter failure.

The study reported here is the first randomised controlled trial of this size comparing the rate of arterial catheter failure using two different radial arterial dressing techniques. The aim of this study was to test the hypothesis that the polyurethane adhesive keyhole dressing (Veni-Gard)<sup>12</sup> in combination with a polyurethane semipermeable transparent dressing (OpSite Flexigrid, 10 cm × 12 cm)<sup>13</sup> would improve arterial catheter life.

## ABSTRACT

**Objective:** To reduce radial arterial catheter failure in patients admitted to an adult intensive care unit (ICU).

**Design:** A randomised controlled trial.

**Setting:** A single site, large metropolitan tertiary referral public hospital.

**Participants:** Three hundred participants admitted to an adult ICU were enrolled between 25 May and 13 September 2015.

**Interventions:** Participants were randomly assigned to one of two treatment groups (a polyurethane adhesive keyhole dressing or a polyurethane adhesive keyhole dressing together with a polyurethane semipermeable transparent dressing).

**Main outcome measure:** Arterial catheter failure.

**Results:** Data were complete for 289 of the 300 adult participants, who were randomised to one of the two groups. There were 179 men (62%) with a median age of 61 years (IQR, 48–74). Overall, there were 109 arterial catheter failures (38%). There was a significantly higher catheter failure rate in the usual care group (65, 60%) compared with the intervention group (44, 40%;  $P = 0.05$ ). Accidental catheter removal occurred in 87% of cases ( $n = 27$ ) in the usual care group and in 13% of cases ( $n = 4$ ) in the intervention group ( $P = 0.05$ ). There was no significant difference between the two groups for time to catheter failure ( $P = 0.06$ ). However, if patients were sedated, they were 54% less likely to experience arterial catheter failure (OR, 0.46; 95% CI, 0.31–0.67;  $P < 0.0001$ ).

**Conclusion:** This study showed a statistically significant reduction in arterial catheter failure using a radial arterial catheter dressing of a polyurethane adhesive keyhole dressing together with a polyurethane semipermeable transparent dressing. The nursing care technique of applying this dressing may improve dressing efficacy and patient safety and reduced costs.

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## Methods

This study was a prospective, single site, randomised controlled trial with two separate groups (usual care or intervention group). This study was conducted in a large metropolitan tertiary referral public hospital with a 28-bed

mixed medical, surgical and specialist ICU. The proposed target population included all adult ICU patients who were admitted with radial arterial catheters or after subsequent catheter insertions that were expected to remain in situ for greater than 24 hours. The enrolment period was from 25 May until 13 September 2015. A total of 300 participants were recruited into this study; however, 11 participants had incomplete data and were excluded from the analysis.

### Inclusion criteria

The sample included patients over the age of 18 years and enrolled within the first 24 hours after radial arterial cannulation, and who were expected to have the radial arterial catheter in situ for greater than 24 hours.

### Exclusion criteria

Where an arterial catheter was inserted in an anatomical site other than the radial artery, if it was already in situ for greater than 24 hours or where the patient had a known or suspected allergy to polyurethane. Other exclusions were if the patient had burned or diseased skin at the insertion site or if they were undergoing organ donation, end-of-life care or withdrawal of active treatment.

### Randomisation

Participants were randomised to either the usual care or the intervention group on a 1:1 basis using a blinded web-based randomisation process (<http://www.randomizer.org>). Treatment allocation was concealed within opaque envelopes, with concealment maintained up until the point of study entry.

### Intervention

Patients randomised into the usual care treatment group had a polyurethane adhesive keyhole dressing (Veni-Gard).<sup>12</sup> Patients randomised into the intervention treatment group had an additional polyurethane semipermeable transparent dressing (OpSite transparent waterproof film, 10 cm × 12 cm)<sup>13</sup> placed over the top (Figure 1).

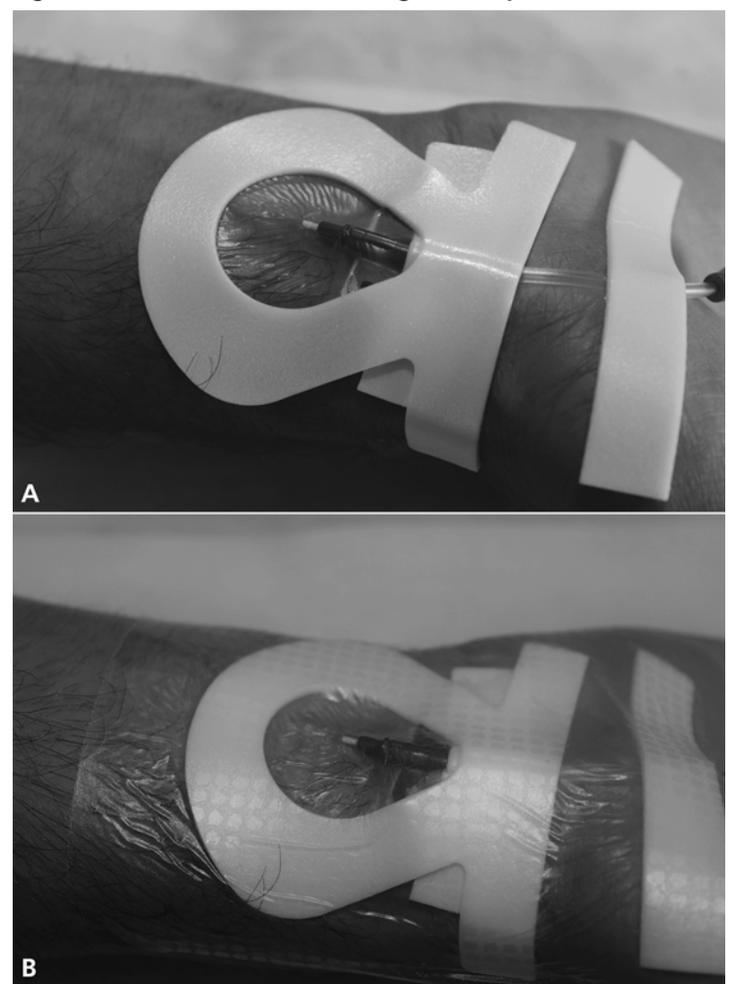
### Primary outcome measure

Arterial catheter failure was defined operationally as any circumstance or event that led to the premature unscheduled cessation of the arterial catheter.

### Data collection and statistical methods

Paper surveys were used to collect data and then entered into the statistical software program SPSS (v24.0, IBM

**Figure 1. Radial arterial dressing technique**



Usual care radial arterial dressing (A) and intervention radial arterial dressing (B).

Corp, 2016). Descriptive and inferential statistics were used to analyse data. Nominal and ordinal variables were summarised as frequencies and percentages, and continuous variables were summarised as mean and standard deviation or median and interquartile range (IQR) based on distributions. Categorical variables were compared using  $\chi^2$  test; Student *t* tests were used to compare continuous variables. A univariate logistic regression analysis was performed on each variable with the primary endpoint of catheter failure. All variables with a *P* value of less than 0.05 were included in the multivariate logistic regression model. Multivariate logistic regression model analysis with odds ratio (OR) and 95% confidence intervals (CIs) were used to determine significant predictors of catheter failure. The models were adjusted for potential confounders: age, APACHE (Acute Physiology and Chronic Health Evaluation) III score, SAPS (Simplified Acute Physiology Score) II score, sedation, restraints and randomisation. A *P* value of  $\leq 0.05$  was used to determine statistical significance. A Cox

proportional hazards model with a log likelihood ratio was used for analysis of time of randomisation to catheter failure. Hazard ratio (HR), 95% CIs and *P* value ≤ 0.05 were used to determine significant predictors of catheter failure.

**Validity and reliability**

All arterial catheter care excluding the specific dressing was independent of this study. Every arterial catheter inserted at the study site was dressed with a polyurethane adhesive keyhole dressing (Veni-Gard)<sup>12</sup> as a minimum standard usual care, ensuring limits on policy variability. Decisions to include only one anatomical site and exclude catheters in situ for more than 24 hours were designed to minimise differences and increase the validity of comparisons of dressing outcomes between the two groups.

**Ethics**

Human research ethics committee approval was gained from the hospital and the university, with both sites waiving requirements for patient consent given the critically ill or unconscious status of participants.

**Results**

During the study, 621 patients were admitted to the ICU and screened for eligibility. Three hundred participants were eligible for enrolment and were subsequently randomised. Overall, 289 participants had complete data available for analysis. The usual care group had 151 participants (52%) and the intervention group comprised 138 participants (48%) (Figure 2).

**Demographic characteristics**

Overall, 179 participants (62%) were men with a median age of 61 years (IQR, 48–74) (Table 1). There were no significant differences of sex or age between the two groups. The most common ICU participant admission diagnoses were cardiac (71, 25%) and respiratory (57, 20%) related. Although there were minor differences in participants’ admission diagnoses in the two groups, these differences were not significant. The overall mean APACHE III score was 57.12 ± 23.07, with 57.52 ± 24.23 and 56.67 ± 21.78 in the usual care group and intervention group respectively. There was no significant difference between the groups suggesting that the groups were well matched for demographic characteristics.

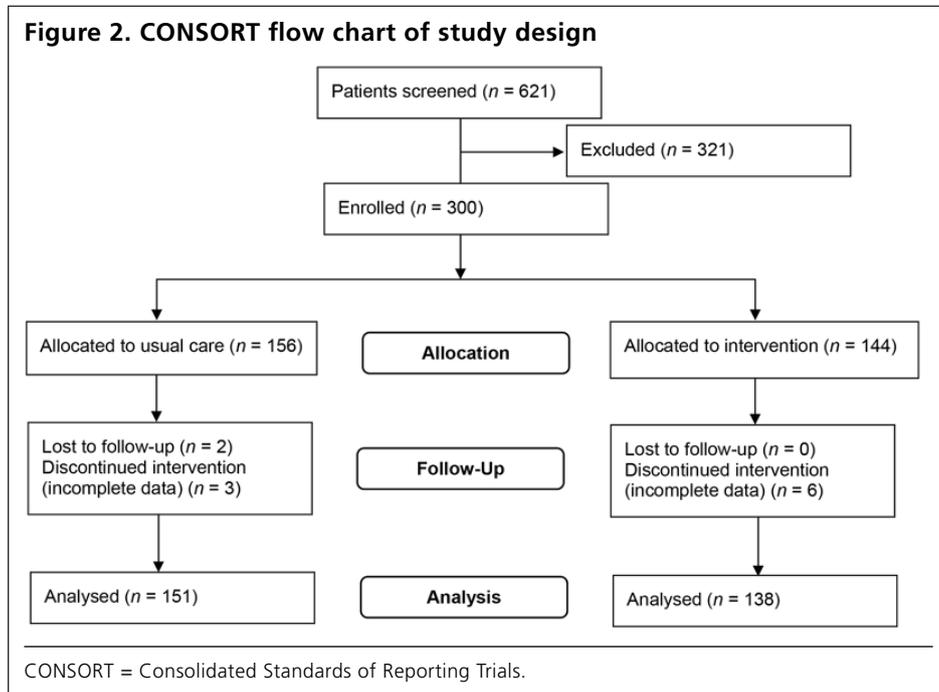
Aspects of care — other than radial arterial dressing technique — that may contribute to differences in the rates of arterial catheter failure were assessed to check the equivalence of the two groups. Assessments included dwell time, use of restraints, and type and amount of sedative infusions used. For both groups in this study, dwell time (ie, the number of days the radial arterial catheter was in situ) was recorded, with a median dwell time of 2 days (IQR, 1–3; *P* = 0.61).

At the time of arterial catheter removal or failure, the use of restraints and the type and amount of sedative infusions were documented to assess whether these factors affected the number of arterial catheter failures (Table 2). There was no significant difference between the groups for wrist restraints or sedation at the time of arterial catheter failure. To assess arterial catheter failures, the scheduled removal for arterial catheters was also separated for analysis.

Scheduled removal refers to the catheter being removed at the intended time, that is, at the end of therapeutic use.

The most common reason for arterial catheter removal was scheduled removal, which occurred overall in 180 participants (62%), with 86 patients (48%) in the usual care group and 94 participants (52%) in the intervention group; leaving a total of 109 (38%) cases that were considered catheter failures across both groups (Table 3).

The most common reason for arterial catheter failure was a blocked catheter, that is, the clinician being unable to aspirate or flush the arterial catheter or a damped arterial waveform trace. Overall 70 catheter failures



**Table 1. Demographic characteristics**

	Usual care ( <i>n</i> = 151)	Intervention ( <i>n</i> = 138)	Overall ( <i>n</i> = 289)
Randomised < 24 hours	142 (94%)	127 (92%)	269 (93%)
Males	92 (61%)	87 (63%)	179 (62%)
Age (years), median (IQR)	60.50 (46–73)	63.00 (49–76)	61.00 (48–74)
Admission diagnosis	151 (52%)	138 (48%)	289 (100%)
Neurology	17 (11%)	18 (13%)	35 (12%)
Cardiac	32 (21%)	39 (28%)	71 (25%)
Respiratory	33 (22%)	24 (17%)	57 (20%)
Sepsis	18 (12%)	16 (12%)	34 (12%)
Liver failure	19 (13%)	14 (10%)	33 (11%)
Gastrointestinal	14 (9%)	14 (10%)	28 (10%)
Renal	1 (1%)	2 (1%)	3 (1%)
Overdose	2 (1%)	2 (1%)	4 (1%)
ENT/maxillofacial/ plastics	7 (5%)	6 (4%)	13 (4%)
Endocrinology/vascular	4 (3%)	0	4 (1%)
Other	4 (3%)	3 (2%)	7 (2%)
APACHE III score, mean ± SD	57.52 ± 24.23	56.67 ± 21.78	57.12 ± 23.07
SAPS II score, mean ± SD	33.67 ± 13.92	34.43 ± 13.32	34.03 ± 13.62

Numbers are *n* except where specified. APACHE = Acute Physiology and Chronic Health Evaluation. ENT = ear, nose and throat. IQR = interquartile range. SAPS = Simplified Acute Physiology Score. SD = standard deviation.

**Table 2. Wrist restraints and sedation at the time of catheter removal**

	Usual care ( <i>n</i> = 151)	Intervention ( <i>n</i> = 138)	Overall ( <i>n</i> = 289)	<i>P</i>
Restraints	17 (11%)	8 (6%)	25 (9%)	0.14
Sedated	58 (38%)	41 (30%)	99 (34%)	0.14
Agitation	15 (10%)	10 (7%)	25 (9%)	0.53

Numbers are *n* except where specified.

**Table 2. Reasons for arterial catheter failure**

	Usual care ( <i>n</i> = 151)	Intervention ( <i>n</i> = 138)	Overall ( <i>n</i> = 289)	<i>P</i>
Catheter failure	65 (60%)	44 (40%)	109 (38%)	0.05
Reasons among the failures				0.001
Blocked	35 (50%)	35 (50%)	70 (64%)	
Accidental	27 (87%)	4 (13%)	31 (28%)	
Suspected infection	3 (38%)	5 (63%)	8 (7%)	

Numbers are *n* except where specified.

(64%) were associated with blockage, with no significant differences between the two groups (35, 50%, in each group). The second most common reason for arterial catheter failure was accidental removal, which occurred overall 31 times (28%), with 27 (87%) in the usual care group compared with four (13%) in the intervention group. Suspected catheter-related blood stream infection numbers were low. Overall, suspected infections occurred eight times (7%), with three patients (38%) in the usual care group and five patients (63%) in the intervention group. There was a significant difference between the groups in reasons for catheter failure ( $P = 0.001$ ).

There were 109 radial arterial catheter failures in total, representing 38% of all catheters inserted across both groups. There was a statistically significant higher rate of catheter failure in the usual care group (65, 60%) compared with the intervention group (44, 40%;  $P = 0.05$ ). However, there was no significant difference between groups for time to catheter failure (HR, 0.70; 95% CI, 0.48–1.03,  $P = 0.07$ ).

SAPS II (OR, 1.01; 95% CI, 1.00–1.03;  $P = 0.05$ ) and sedation (OR, 0.46; 95% CI, 0.31–0.67;  $P < 0.0001$ ) showed significant associations with catheter failure. Participants who were sedated were 54% less likely to experience arterial catheter failure than those participants who were not sedated.

## Discussion

The major finding of this study suggests that the intervention arterial dressing technique resulted in a statistically significant reduction in radial arterial catheter failure compared with usual care (44, 40%, *v* 65, 60%, respectively;  $P = 0.05$ ). Moreover, sedated patients were 54% less likely to have an arterial catheter failure (95% CI, 0.31–0.67;  $P < 0.0001$ ). The overall rate of arterial catheter failure of 38% found in this study is high when compared with other results.<sup>1,4,6</sup> Rates of failure have been reported between 13%<sup>4</sup> and 14%.<sup>1</sup> Another study<sup>6</sup> used a surrogate measure of failure, the “restart” rate (ie, the number of arterial catheters that needed to be reinserted due to catheter failure), and reported a restart rate of 13–25%. The use of different primary outcome measures for the study<sup>6</sup> makes it difficult to compare data; however, the current study calculated a “restart” rate of 15%, which is comparable. The relatively high rates of failure in the current study warrants further consideration.

Given that increased patient agitation or confusion may increase the risk of catheter failure,<sup>14</sup> participant sedation and agitation, measured by the Sedation-Agitation scale,<sup>15</sup> was recorded to determine whether this affected the rate of failure. The current study reported 9% of participants as agitated and 34% as sedated at the time of catheter failure. Agitation has only been reported in two other studies and

was experienced by 2% of participants,<sup>1,4</sup> but it is unclear whether the same tool was used to measure agitation. Sedated patients were 54% less likely to experience arterial catheter failure in the current study; however, while sedation may decrease arterial catheter failure, reducing conscious state for this benefit alone is clinically inappropriate. Statistical analysis involving sedation was not reported in other studies of catheter failure.<sup>1,4,6</sup> Without further detail, it is difficult to assess the contribution of agitation or sedation to the increased rate of arterial catheter failure in the current study.

It is noteworthy that the current study site specifically involves a hospital that is the state-wide service for liver transplantation,<sup>16</sup> with 11% of ICU participants being admitted with liver dysfunction. These patients may have increased confusion due to hepatic encephalopathy — a serious complication of liver failure which features high serum urea and ammonia resulting in delirium.<sup>17,18</sup> Two of the three previously noted study sites<sup>4,6</sup> do not appear to perform liver transplantation,<sup>19</sup> and the other study reports gastrointestinal surgery but not specifically liver dysfunction.<sup>1</sup> These differences in patient characteristics may account for some increase in agitation and possibly increase arterial catheter failure.

Other possible explanations of difference in catheter failure rates include the anatomical site used in the studies. Similar Australian studies<sup>1</sup> have either not specified which arteries were used for cannulation or, in one study, included brachial or femoral arteries (3%).<sup>2</sup> Although 9% of participants were restrained at the wrist in the current study, none of the relevant studies<sup>1,4,6</sup> had specifically comparable data, and it is not possible to say if the site of cannulation made a difference or whether the use of wrist restraints contributed to arterial catheter failure. The use of the radial artery as the anatomical site for arterial cannulation is the preferred site both locally and in the literature,<sup>11,9,20</sup> suggesting the need to ameliorate these catheter failures.

Further, intrinsic reasons for the higher incidence of failure were not explored during the study phase and aspects of this study design, local care standards or other unknown variables may have contributed to the higher rates of failure; for example, arterial catheters are not routinely sutured in place at the study site, consistent with international guidelines.<sup>11</sup> Other studies appear to be consistent with these current recommendations, with one using a sutureless securement device,<sup>6</sup> and the only Australian comparison study to provide this detail,<sup>4</sup> not suturing arterial catheters in situ.

Three overarching categories for failure were used to investigate the efficacy of the different dressing techniques: blocked catheter, accidental removal and suspected infection. Overall, the most common reason for failure was a blocked catheter (64%), followed by accidental catheter removal

(28%) and, lastly, suspected infection (7%) ( $P = 0.001$ ).

The accidental removal of arterial catheters is potentially the most preventable reason for failure and readily amenable to change through a safe, nursing specific intervention. This category of failure showed the greatest difference between the two treatment groups. Accidental removals were responsible for 28% of arterial catheter failures; of these, most were from the usual care group (87%), with the intervention group only contributing to 13% ( $P = 0.001$ ).

Australian comparisons of accidental removal range between 1% and 4%,<sup>4</sup> with a study from the United States<sup>6</sup> stating that most of their 25% of arterial catheter failures were due to accidental removal.<sup>6</sup>

Results of this current study have provided evidence that the intervention radial arterial catheter dressing technique reduced rates of arterial catheter failure, most particularly reducing accidental removals. Given that central venous catheters and arterial catheters are anatomically and functionally different, guidelines for each should not be combined or assumed to be comparable. Individually written, clear guidelines specific to arterial catheters need to be thoughtfully developed. There is disproportionate available evidence regarding the more common complications of arterial catheters when compared with less common occurrences — mostly catheter-related blood stream infections.

In considering what constitutes routine care and management for securing an arterial catheter, there is very little information pertaining to arterial catheter dressing management. The most frequent reference is the use of a sterile, transparent, semipermeable, polyurethane dressing to allow for observation, or sterile gauze dressing if there is bleeding around the insertion site or if the patient is diaphoretic.<sup>11,21-24</sup> However, most available articles do not differentiate guidelines for arterial catheters in detail.<sup>21-24</sup> Where additional information relating to arterial catheters is provided,<sup>11</sup> it is usually focused on solutions recommended for cleaning and preparing the skin either before insertion or during a dressing change, avoiding both moisture and sutures. All appear to consistently recommend the use of a sterile, transparent, semipermeable dressing. A narrative review of the literature assessing arterial catheter dressing and securement techniques suggests there is limited robust evidence specific to arterial catheter dressings.<sup>5</sup> There have only been three pilot studies investigating arterial catheter dressing techniques — one in the US<sup>6</sup> and two in Australia,<sup>1,4</sup> — and although this current study only used two proprietary dressing components, it appears that these or similar dressings are used in other Australian ICUs.

There were several limitations to our study. The trial was conducted in a single site and there was no historical data audit to compare rates of failure before the start of the trial. The inability to blind clinicians to the intervention was

another limitation. Every effort was made to standardise the two dressing protocols and to ensure clinicians adhered to them.

It should be noted that there are some instances of arterial catheter failure which are not clinically associated with increased risk for patients, and intravascular devices are often left in longer than clinically indicated; however, other scenarios of arterial catheter failure may lead to serious consequences. These situations may include patients who are haemodynamically unstable or are in an acute post-operative period, where reducing arterial catheter failure is of the utmost importance.

It is worth considering that an insertion of an arterial catheter is an invasive procedure requiring financial and human resources with each new insertion, while also increasing patient vulnerability to further complications.<sup>21</sup> Each new insertion not only increases the clinically significant risk for the patient but also causes the patient discomfort.<sup>1,10,21</sup>

The addition of the polyurethane semipermeable transparent dressing (intervention group) to the usual polyurethane adhesive keyhole dressing alone significantly lowered the rate of arterial catheter failure. The maintenance of arterial catheter care after insertion is primarily a nursing intervention that may provide an opportunity to improve arterial catheter care and reduce arterial catheter failure, particularly accidental removal. These results suggest that clear individual guidelines pertaining to arterial catheters should be developed, implemented and further evaluated.

## Competing interests

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## Author details

Clare Healy<sup>1,2</sup>

Ian Baldwin<sup>2,3,4</sup>

Judy Currey<sup>2,5</sup>

Andrea Driscoll<sup>2,5</sup>

1 Department of Intensive Care, Alfred Health, Melbourne, VIC, Australia.

2 School of Nursing and Midwifery, Deakin University, Geelong, VIC, Australia.

3 School of Health and Biomedical Sciences, RMIT University, Melbourne, VIC, Australia.

4 Department of Intensive Care, Austin Hospital, Melbourne, VIC, Australia.

5 Centre for Quality and Patient Safety Research, Deakin University, Geelong, VIC, Australia.

**Correspondence:** clarel.healy@alfred.org.au

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