Dressing and Securement of Peripheral Arterial Catheters: 
A Pilot Randomised Controlled Trial

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Abstract

Purpose
The purpose of this research was to assess the feasibility of the trial design and elements for future extensive study to provide evidence of the effectiveness of novel dressing/securement technologies to prevent catheter failure in peripheral arterial catheters in a larger research setting.

Background
Peripheral arterial catheters are a type of intravascular catheter that is widely used in the care of critically ill patients. The catheter insertion site is usually covered with a commercially produced transparent dressing to maintain the position of the catheter, as well as endeavouring to prevent microbial entry to the wound. Arterial catheters may accidentally fall out, become blocked, or become infected, causing catheter failure, interrupted therapy, painful reinsertion, and decreased patient satisfaction. The infection risks of arterial catheters have often been underestimated. Inadequate peripheral intravascular catheter securement remains a poorly researched area of patient care, with a paucity of quality studies. Improved securement would likely prevent many cases of catheter failure.

Aims and Objectives
The aim was 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. Specified feasibility objectives for this
pilot trial were to be considered successful if 90 out of 120 patients (75%) fulfilled
the feasibility criteria regarding recruitment, delivery and adherence, retention, and
patient/staff satisfaction with the study products. This would show that the research
methods were suitable for use in a larger trial.

**Design**

A four-arm, parallel, single site, superiority pilot trial of randomised controlled
design was performed to provide initial background research for a potential future,
larger randomised controlled trial. It was intended to function as a test to ensure that
the future larger trial was designed optimally, and able to be implemented in practice,
and that the novel interventions were feasible choices.

**Interventions**

Patients were randomised to three experimental groups of a bordered polyurethane
dressing, a sutureless securement device and tissue adhesive, and one control group
of a usual care polyurethane dressing.

**Population and sample**

The study population consisted of patients with arterial catheters inserted in the
operating theatre and admitted to the intensive care unit post-operatively at a
metropolitan, tertiary referral, teaching hospital. The study sample of 120, with 30 per
group, was drawn from all surgical patients for post-operative admission to the intensive care unit who met the inclusion criteria.

**Data collection and management**

A standardised data collection tool was developed and then adapted by Griffith University Information Technology Services for use 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 intensive care nurses. Arterial catheter failure and reason for unplanned removal (occlusion, dislodgement, loss of monitor trace, and pain), as well as staff satisfaction and timing for application, and patient and staff satisfaction for removal of the products were recorded. Predefined criteria for type of failure, time, and satisfaction were compared with observed results.

**Data analyses**

The statistical analyses of this pilot work were mainly descriptive, and reporting strategies used the confidence interval approach for estimation of sample size to establish feasibility. If 75% of patients received the study intervention and protocol correctly, and had ease and satisfaction scores for the study dressing and securement devices of $\geq 7$ on Numerical Rating Scale scores 1-10, future study would be feasible. Survival analyses were performed to assess the effect of study group on outcomes over time. Univariable and multivariable Cox proportional hazards regression models assessed independent relationships between explanatory variables and the
dichotomous outcome of device failure. Cost effectiveness analysis was performed by applying value of information analysis to avoiding catheter failure.

**Results**

There were 132 patients recruited over 32 weeks. Arterial catheter failure ranged from 2/32 (6.3%) for tissue adhesive, 4/30 (13.3%) for bordered polyurethane to 5/31 (16.1%) for the sutureless securement device, and 6/30 (20%) for the control usual care polyurethane dressing (Fisher’s exact test \( p = .14, .73, \) and .75 respectively). The effect sizes of bordered polyurethane, the sutureless securement device, and tissue adhesive were absolute reductions of 6.7%, 3.9%, and 14% compared to controls. Cox regression analysis confirmed non-significant differences between the control and all experimental group failure rates. However, being a current smoker, female, and skin colour “other than moderate brown” were significant predictors of failure \( (p = .05) \). Kaplan-Meier survival curves confirmed no difference in failure between all experimental groups and the control \( (\text{log-rank} \ p = .56) \). Research pre-study commencement workload was 151 hours, and mean total daily time over 12 days taken for all research tasks was 5.2 hours/day. All interventions had feasible numerical rating scale scores for patient product removal and overall patient satisfaction. Tissue adhesive and the sutureless securement device had statistically significant worse scores for staff ease of application compared to controls \( (\text{both} \ p < .05) \), although tissue adhesive still had a feasible score. Cost analysis suggested that tissue adhesive and bordered polyurethane were the most cost effective of the interventions and the control.
ARTERIAL CATHETER DRESSING AND SECUREMENT

Discussion

All three study interventions were shown to be feasible options. This 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.

Conclusion

This pilot study provides evidence that it is feasible to perform a larger randomised controlled trial comparing these dressing and securement methods for arterial catheters inserted in the operating theatre, and cared for in the intensive care unit.
Statement of Originality

This work has not previously been submitted for a degree or diploma in any university. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.

Heather Reynolds
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<th>Description</th>
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<tbody>
<tr>
<td>AC</td>
<td>Arterial Catheter</td>
</tr>
<tr>
<td>ACIPC</td>
<td>Australasian College for Infection Prevention and Control</td>
</tr>
<tr>
<td>AICA</td>
<td>Australian Infection Control Association</td>
</tr>
<tr>
<td>AIMS-ICU</td>
<td>Australian Incident Monitoring Study in Intensive Care</td>
</tr>
<tr>
<td>ANOVA</td>
<td>Analysis of Variance</td>
</tr>
<tr>
<td>ANZICS</td>
<td>Australian and New Zealand Intensive Care Society</td>
</tr>
<tr>
<td>AVATAR</td>
<td>Australian Vascular Access Teaching and Research Group</td>
</tr>
<tr>
<td>BP</td>
<td>Blood Pressure</td>
</tr>
<tr>
<td>BPU</td>
<td>Bordered Polyurethane</td>
</tr>
<tr>
<td>CABSI</td>
<td>Catheter Associated Blood Stream Infection</td>
</tr>
<tr>
<td>CDC</td>
<td>Centres for Disease Control</td>
</tr>
<tr>
<td>CEAC</td>
<td>Cost Effectiveness Acceptability Curve</td>
</tr>
<tr>
<td>cfu</td>
<td>colony forming units</td>
</tr>
<tr>
<td>CHRISP</td>
<td>Centre for Healthcare Related Infection Surveillance and Prevention</td>
</tr>
<tr>
<td>CONSORT</td>
<td>Consolidated Standards for Reporting Trials</td>
</tr>
<tr>
<td>CRBSI</td>
<td>Catheter Related Blood Stream Infection</td>
</tr>
<tr>
<td>CRI</td>
<td>Catheter Related Infection</td>
</tr>
<tr>
<td>EBP</td>
<td>Evidence Based Practice</td>
</tr>
<tr>
<td>ESD</td>
<td>External Stabilisation Device</td>
</tr>
<tr>
<td>ENBS</td>
<td>Expected Net Benefit of Sampling</td>
</tr>
<tr>
<td>EVPI</td>
<td>Expected Value of Perfect Information</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drugs Administration</td>
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<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
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<tr>
<td>HIES</td>
<td>Hospital infection Epidemiology and Surveillance Unit</td>
</tr>
<tr>
<td>HICPAC</td>
<td>Healthcare Infection Control Practices Advisory Committee</td>
</tr>
<tr>
<td>HISWA</td>
<td>Health Infection Surveillance Western Australia</td>
</tr>
<tr>
<td>HR</td>
<td>Hazard Ratio</td>
</tr>
<tr>
<td>ICH</td>
<td>International Conference of Harmonisation</td>
</tr>
<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
</tr>
<tr>
<td>IDSA</td>
<td>Infectious Diseases Society of America</td>
</tr>
<tr>
<td>INS</td>
<td>Infusion Nurses’ Society</td>
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<tr>
<td>ITT</td>
<td>Intention to Treat</td>
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<td>IV</td>
<td>Intravenous</td>
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<td>LCBSI</td>
<td>Laboratory Confirmed Blood Stream Infection</td>
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<td>MID</td>
<td>Minimal Importance Difference</td>
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<tr>
<td>NB</td>
<td>Net Monetary Benefit</td>
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<td>NC</td>
<td>Needleless Connector</td>
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<tr>
<td>NEAF</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>NHSN</td>
<td>National Health and Safety Network</td>
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<tr>
<td>NICE</td>
<td>National Guidelines for Health and Clinical Excellence</td>
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<tr>
<td>NRS</td>
<td>Numerical Rating Scale</td>
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<tr>
<td>OR</td>
<td>Odds Ratio</td>
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<tr>
<td>OT</td>
<td>Operating Theatre</td>
</tr>
<tr>
<td>PFGE</td>
<td>Pulsed-Field Gel Electrophoresis</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>PICC</td>
<td>Peripherally Inserted Central Catheter</td>
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<tr>
<td>QCAT</td>
<td>Queensland Civil and Administrative Tribunal</td>
</tr>
<tr>
<td>RBWH</td>
<td>Royal Brisbane and Women’s Hospital</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>RR</td>
<td>Relative Risk</td>
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<tr>
<td>SID</td>
<td>Sufficiently Important Difference</td>
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<tr>
<td>SD</td>
<td>Standard Deviation</td>
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<td>SPU</td>
<td>Standard Polyurethane</td>
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<td>SSA</td>
<td>Site Specific Approval</td>
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<td>SSD</td>
<td>Sutureless Securement Device</td>
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<tr>
<td>SSI</td>
<td>Surgical Site Infection</td>
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<tr>
<td>TA</td>
<td>Tissue Adhesive</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
</tr>
<tr>
<td>VOI</td>
<td>Value of Information</td>
</tr>
<tr>
<td>VICNISS</td>
<td>Victorian Healthcare Associated Infection Surveillance System</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WTP</td>
<td>Willingness to Pay</td>
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Invited oral presentation and poster

Reynolds, H., Mihala, G., Taraporewalla, K., Tower, M., & Rickard, C.M.

Oral presentation and poster

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Poster: Awarded best poster

Reynolds, H., Mihala, G., Taraporewalla, K., Tower, M., & Rickard, C.M.
Poster


Oral presentation


Publication