

BMJ Open Securing All intraVenous devices Effectively in hospitalised patients – the SAVE trial: study protocol for a multicentre randomised controlled trial

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ABSTRACT

Introduction: Over 70% of all hospital admissions have a peripheral intravenous device (PIV) inserted; however, the failure rate of PIVs is unacceptably high, with up to 69% of these devices failing before treatment is complete. Failure can be due to dislodgement, phlebitis, occlusion/infiltration and/or infection. This results in interrupted medical therapy; painful phlebitis and reinsertions; increased hospital length of stay, morbidity and mortality from infections; and wasted medical/nursing time. Appropriate PIV dressing and securement may prevent many cases of PIV failure, but little comparative data exist regarding the efficacy of various PIV dressing and securement methods. This trial will investigate the clinical and cost-effectiveness of 4 methods of PIV dressing and securement in preventing PIV failure.

Methods and analysis: A multicentre, parallel group, superiority randomised controlled trial with 4 arms, 3 experimental groups (tissue adhesive, bordered polyurethane dressing, sutureless securement device) and 1 control (standard polyurethane dressing) is planned. There will be a 3-year recruitment of 1708 adult patients, with allocation concealment until randomisation by a centralised web-based service. The primary outcome is PIV failure which includes any of: dislodgement, occlusion/infiltration, phlebitis and infection. Secondary outcomes include: types of PIV failure, PIV dwell time, costs, device colonisation, skin colonisation, patient and staff satisfaction. Relative incidence rates of device failure per 100 devices and per 1000 device days with 95% CIs will summarise the impact of each dressing, and test differences between groups. Kaplan-Meier survival curves (with log-rank Mantel-Cox test) will compare device failure over time. p Values of <0.05 will be considered significant. Secondary end points will be compared between groups using parametric or non-parametric techniques appropriate to level of measurement.

Ethics and dissemination: Ethical approval has been received from Queensland Health (HREC/11/QRCH/152) and Griffith University (NRS/46/11/HREC).

Strengths and limitations of this study

- This is the first large-scale, independent multicentre randomised controlled trial to investigate the efficacy and cost-effectiveness of peripheral intravenous device (PIV) dressing and securement methods to prevent PIV failure.
- The trial examines a novel tissue adhesive securement method for the first time in PIVs.
- This is a pragmatic trial, with PIVs inserted and cared for by general staff in two adult hospitals, not specialist teams or researchers.
- Microbiology end points will be analysed by blinded scientists, and infection outcomes assigned by a blinded infectious disease specialist outcome assessor. It will not be possible to blind the dressing and securement intervention/control from clinical staff, patients or research nurses.
- Patients with existing skin problems, severe diaphoresis or frail skin are excluded from the study, so results will not be generalisable to these groups.

Results will be published according to the CONSORT statement and presented at relevant conferences.

Trial registration number: Australian New Zealand Clinical Trial Registry (ACTRN); 12611000769987.

INTRODUCTION

Peripheral intravenous devices (PIVs) are the most commonly used medical device worldwide: almost all hospital patients need one or more to receive intravenous treatment.^{1 2} The failure rates of these devices are unacceptably high, affecting up to 69% of patients receiving therapy.^{3–7} Of these, 10%

simply fall out, despite having a dressing in place, with patients then unable to receive treatment.⁵ Other PIVs become painful or occluded and must also be replaced. Such failure rates for an essential device are unacceptable and indicate that current dressings and securement methods are inadequate, with much failure potentially preventable with improved effective dressing and securement.

Intravenous devices

About 90% of all vascular catheters are PIVs.⁸ Approximately 330 million PIVs are sold in the USA alone each year.⁹ The external component of PIVs require securement to the skin, with dressings and other securements used to ensure that PIVs do not dislodge and fall out, or move out of the vein and into surrounding tissue. Effective securement also minimises PIV micromotion within the vessel, which irritates the vein wall, causing inflammation presenting as pain, swelling and PIV occlusion/infiltration.^{6 10} Micromotion may also encourage skin bacteria to enter the PIV wound, causing infection risk.

PIV failure

PIV failure occurs when the PIV can no longer be used for treatment. Failure can be mechanical (dislodgement, occlusion, infiltration), vascular (phlebitis) or infectious (localised or bloodstream infections). PIV failure is an important detrimental patient outcome that causes: (1) interruptions to medical treatment and compromised patient safety from lost vascular access; (2) painful phlebitis lasting for days or weeks at the PIV site, even after removal; (3) potentially increased hospital length of stay and mortality from PIV-associated bloodstream infection; (4) additional needlesticks for replacement of PIV insertions; and (5) replacement of PIVs in poorer quality veins with exponentially higher risk of device failure and need for central venous catheter insertion with even greater infectious and other complication risks.^{11 12} Studies have reported high PIV failure rates, up to 69%.³⁻⁷ Inadequate dressing and securement is most likely a factor in most PIV failures, with one study reporting that 71% of PIVs are inadequately secured.¹³

PIV dressing and securement

Despite its obvious importance, the study of effective approaches to PIV dressing and securement has received little attention.^{10 14} The earliest PIV dressing and securement was with simple tape or gauze and tape, with plastic film dressings becoming prominent in the 1980s.^{15 16} An early systematic review found plastic films to have higher infection risk than gauze and tape¹⁷ and this spurred the development of the modern standard polyurethane dressings (SPU) which are transparent and semipermeable to oxygen, carbon dioxide and water vapour.¹⁸ SPUs (eg, Tegaderm, 3M, St Paul or IV3000, Smith & Nephew, Hull) have been standard care for many years.¹⁹ In contrast with gauze and tape

dressings that are generally limited to short-term use, SPUs allow visualisation of the insertion site and can be left in place for up to 7 days if not soiled, loose or wet.^{18 20} Suturing is not recommended as this increases infection.²⁰

Two new approaches to PIV dressing and securement are bordered polyurethane (BPU) and sutureless securement devices (SSDs). BPUs retain the central polyurethane component of SPUs with an added adhesive border of foam or cloth (eg, Veni-Gard I.V. stabilization Dressing, CONMED, Utica). One BPU manufacturer (Tegaderm IV Advanced Securement Dressing, 3M, St Paul, Minnesota, USA) reports that it has nearly twice the pull-out force of SPU; however, there are scant independent data on the effectiveness of BPUs.^{21 22} For example, Needham and Strehle²² studied four different BPU and SPUs, but the small sample size of 78 precluded statistical comparisons. BPU use is not yet widespread, most likely due to increased costs over SPU and lack of convincing data to support its implementation.

SSDs are used in conjunction with SPUs. They have a large adhesive padded footplate with a PIV locking or gripping clasp (eg, StatLock, Bard Access Systems, Murray Hill; Grip-Lok, Vygon, Ecouen; Hubguard, Centurion, Williamston). They are designed to reduce movement, dislodgement, kinking and flow impedance.¹⁰ A manufacturer-initiated, non-randomised study reporting data from 10 164 patients in 63 hospitals observed that PIV failure reduced from 71% to 17% ($p < 0.001$) when securement was with SSD (and SPU) compared with tape (and SPU), with significant estimated cost savings.²³ A manufacturer-sponsored and analysed randomised controlled trial (RCT; $N = 302$) reported BPU to have a 25% lower purchase price than SSD, and PIV failure rates at 96 h of 52% for SSD, and 62% for BPU.¹ It remains unclear whether BPU or SSD has more benefit over traditional less expensive SPU dressings.

Tissue adhesive

Another potential product to assist with PIV securement is tissue adhesive (TA) which is medical grade 'super-glue' (cyanoacrylate). TA is used mainly to close skin lacerations and wounds as an alternative to sutures or staples, but also to repair gastric varices, inguinal hernias, bones, tendons and retinal detachments.^{24 25} TA has haemostatic properties that may reduce postinsertion bleeding, haematomas and associated infection risk. The use of TA to secure vascular access devices has only been reported in two case reports.^{26 27} In these, TA was completely successful in securing approximately 100 epidural and central venous devices with no skin reactions or mechanical problems reported.^{26 27} Epidural fallout was reduced from 12% to 4%, but little data were provided on study methods or sample characteristics.²⁶

The pull-out force required to dislodge PIVs secured with SPU, BPU, SSD, TA or no dressing (control) was tested in an experimental model.²⁸ Compared with no dressing, neither SPU nor BPU significantly increased

the pull-out force required to dislodge the PIV, although this may have been an underpowered comparison. In contrast, TA and SSD significantly increased the pull-out force, and TA resulted in a bond which was four times as strong as an SPU dressing.²⁸ The bactericidal properties of TA include inhibition of all Gram-positive organisms, including methicillin-resistant *Staphylococcus aureus*, the predominant organisms in PIV infections.²⁹ We demonstrated that TA inhibits *S. aureus* and *S. epidermidis* both under the TA, and down the PIV tunnel at 18 and 72 h dwell time.²⁸ Given the strong results from non-controlled clinical reports and in vitro work, TA may assist in avoiding PIV failure by reducing pistoning and accidental removal, with additional benefits being infection prevention and comfort for patients.

PIV dressing and securement remains a poorly researched area of patient safety and has been identified as a priority area for improvement.²³ Previous research is limited by small samples, non-randomised designs and the manufacturer's involvement. Moreover, there has been no specific study comparing the cost-effectiveness of different PIV dressing and securement approaches, which vary widely in purchase price but may be more cost-effective if they reduce PIV failure. This study will test the efficacy, cost-effectiveness and acceptability to patients and professionals of TA (used with SPU), BPU and SSD (used with SPU), against current care (SPU alone) to assist policy-makers with decision-making about the best dressing and securement choice for patients with PIVs.

METHODS AND ANALYSIS

The study will be a multicentre, parallel group superiority RCT with four arms: three experimental groups (TA, BPU and SSD) and one control (SPU). There will be a 3-year recruitment of 1708 adult patients from two large teaching hospitals in south-east Queensland, Australia. Comprehensive assessment of effectiveness, cost-effectiveness and acceptability will be performed in line with the Medical Research Council model for evaluating complex interventions.³⁰ This will include smaller qualitative components including staff survey and focus groups. The protocol is V.1 dated 6 October 2011.

Outcome measures

Primary outcome

1. PIV failure: composite of any unplanned PIV removal, prior to completion of therapy. This includes: dislodgement (complete), occlusion (PIV will not infuse, or leakage occurs when fluid infused), phlebitis (score of 2 or more of pain/tenderness, redness, swelling, purulence and/or a palpable cord) or infection (laboratory-confirmed local or bloodstream infection).^{20 31}

Secondary outcomes

1. PIV and dressing/securement dwell time: Time in hours from insertion/application until removal.

2. Costs: Direct costs to the hospital for device management, including costs of PIV replacement in addition to the effects of dressing choice (randomised product and any additional tape or reinforcements).
3. Types of PIV failure will be analysed as secondary outcomes (dislodgement, occlusion, phlebitis and infection).
4. PIV colonisation (>15 colony forming units (cfu)) from a purposive 10% subset of devices.³²
5. Skin colonisation (>15 cfu) from a purposive 10% subset of patients.³²
6. Patient (overall with product) and staff satisfaction (with removal) ranked on a 10-point scale.

Setting and sample

Patients will be recruited from the medical and surgical areas, and critical care departments at the Royal Brisbane and Women's Hospital and the Princess Alexandra Hospital, Queensland, Australia. Only one PIV will be studied per patient. The study hospitals together have approximately 500 000 separations per annum. Inclusion criteria are: ≥ 18 years of age; requires a PIV for clinical treatment; and the duration of clinical treatment with the PIV is expected to be longer than 24 h. Exclusion criteria will be: non-English speaking patients without interpreter; PIV to be inserted through burnt or diseased skin (eg, blisters, sunburn, bruising, rash or skin infections); severe diaphoresis; known allergy to any study product; terminal/palliative care patients; current skin tear or clinician believes patient is at high risk of a skin tear; or previously enrolled in the study.

Sample size and study power

We hypothesise a difference (reduced failure rate) for each of the three alternative treatments against control. For each, we will measure difference in outcomes for pairs of treatments (ie, group (G)1 (SPU—controls) vs G2 (TA); G1 vs G3 (BPU); G1 vs G4 (SSD)—that is, in turn the three alternatives versus the control). Sample sizes were calculated for three inequality tests of two proportions. Our recent trial of 3283 patients in the same study hospitals showed failure rates of 40% using SPU.³³ We hypothesise that TA, BPU and SSD will each reduce failure by an absolute proportion of 10%, therefore to 30%. A 10% absolute difference in PIV failure incidence was also observed in a previous study of SSD and BPU, and would be clinically important to detect.^{1 23} PASS (Power Analysis & Sample Size system, NCSS, Utah) was used to calculate the sample required to reduce the 40% device failure rate (controls) to 30% in each of the three experimental groups with 90% power at $p=0.05$. This results in each group requiring 388 patients, that is, a total of 1552 PIVs. We will add 10% to allow for potential attrition, therefore 1708 patients in total.

Recruitment, randomisation, allocation concealment and blinding

Research nurses (ReNs), not clinicians, will screen patients on a daily basis, gain informed consent and

perform randomisation for each patient at the time of study entry. Randomisation will be via a centralised web-based service provided by Griffith University. This will ensure full compliance with best practice standards for computerised randomisation generation and allocation concealment until study entry. Randomisation will be stratified by hospital site, and in a 1:1:1:1 ratio between the four study groups. Block randomisation will be used with random variation in block sizes to further ensure allocation concealment. PIV dressings are not amenable to blinding of patients, clinical staff or ReNs. However, there is no suggestion in the literature or our practice that clinical staff or patients would sabotage medical devices to favour one group. This is an independent academic study, with no product manufacturer having any involvement in the research.

Insertion and care of the PIV dressings and securements

PIVs will be inserted, and dressing and securements applied by clinical nurses, medical staff or the ReNs using standard policies in place throughout Queensland Health. The study sites do not have dedicated intravenous teams to perform insertions, although there are a small number of intravenous nurse consultants who provide education and undertake surveillance. Extensive education will be delivered to staff on how to apply, care for and remove the study products. All study products will be changed weekly or earlier if they are not clean, dry and intact, as recommended by the Centres of Disease Control (CDC).²⁰ Strips of non-sterile tape on the intravenous tubing will be permitted in all groups as per usual practice, and this will be documented.

Data collection

The ReNs, all of whom have had study-specific database training, will directly enter data in the clinical areas using portable password-protected electronic devices with a purpose-built RedCAP database and form-based interface. All data are de-identified at this point and only identifiable within the database by specific study number. The master list of participants will be kept separately from the study database in a different password-protected computer program at the hospital sites. Patient characteristics collected by ReNs at baseline will be: age, sex, estimated weight category, diagnostic group, dominant limb, comorbidities, length of stay, immunodeficiency, current infection, intravenous therapy (including antimicrobial), skin integrity, skin type, and the presence of a wound, drain, tracheostomy or intestinal stoma. PIV characteristics collected will be: device type, insertion site, PIV gauge, side of insertion, clinical area/ward, inserter discipline, insertion difficulty, initial/subsequent PIV, skin preparation (including disinfectants and clipping), use of gloves for insertion, and the addition of extension tubing and injection ports. After PIV removal, the following data will be collected: reason for PIV removal, dwell time, infusates given, oral antibiotic therapy, number of additional vascular access

devices in place, phlebitis signs and symptoms, level of consciousness, mobility level, delirium status, hospital length of stay and hospital mortality. Clinical staff will order blood and PIV cultures from patients suspected of PIV-related infection as per usual practice and the ReNs will access the results. Clinically instigated cultures will be performed by blinded scientists in the hospital laboratories. Routine culturing is unnecessary and leads to comparable infection rates as those performed on clinical suspicion.¹⁰ The ReNs will visually inspect PIVs daily and assess for phlebitis (redness, pain/tenderness, swelling, purulence, palpable cord or vein streak); dressing integrity (including any dressing change and/or addition of secondary securement products) and any residue, rash, blister, itchiness or tearing of skin on dressing removal (adverse event). At device removal, the ReN will ask the patient (if able) about their satisfaction with the dressing and securement on a 10-point scale (0=completely dissatisfied, 10=completely satisfied). The person removing the dressing will be asked to rate the difficulty of removing the product (0=very difficult, 10=very easy). A study manager (reporting to the chief investigator) will audit data quality, completeness and protocol adherence with site visits for initial training and then for monitoring at least bimonthly. Since trial participation is relatively short (approximately 1 week) and participants will remain hospitalised, high rates of retention and follow-up are expected. A purposive sample of 150 clinical staff (about 10% of staff involved in the trial) will be invited to participate in a brief researcher-developed survey about study products and trial involvement. Further, 10–15 key clinical and policy staff will be invited to participate in a brief semistructured interview about perceived barriers/enablers of implementation of the results, using a nominal group technique.

Data analysis

The principal investigator, study manager and trial statistician will have access to the final data set. All randomised patients will be analysed by intention to treat, regardless of the treatment received. The patient will be the unit of measurement, with only one PIV studied per patient. Comparability of groups at baseline for risk of device failure will be assessed. Relative incidence rates of device failure per 100 devices and per 1000 device days with 95% CIs will summarise the effectiveness of each dressing and securement, and test for differences between groups. Kaplan-Meier survival curves (with a log-rank Mantel-Cox test) will compare device failure over time. Secondary end points will be compared between groups using parametric or non-parametric techniques as appropriate. In addition to group, multivariate regression (Cox) models will test the association between patient and device characteristics and device failure (eg, age, PIV insertion site). Missing data will be modelled for best-case and worst-case outcomes to assess for potential effect on overall results. A per-protocol analysis will assess the effect of protocol violations. p Values

of <0.05 will be considered significant. We do not expect effect sizes to vary between sites; however, variability will be assessed and, if necessary, adjustment made in the model, with consideration of potential institutional differences in practice variables. Survey data will be described and interview data thematically analysed for issues that provide contextualisation of the RCT results, and inform implementation of findings into practice.

Estimating cost parameters and cost-effectiveness analysis

Direct costs to the hospital for device management will be captured including purchase costs of dressings and securements, any additional tape or reinforcements, and the costs incurred by PIV failure (eg, PIV replacement or antibiotics to treat PIV infections). Adverse event costs will be obtained from hospital cost centres for precise estimates, given the likely variability in costs between participants, reasons for admission and hospitals. Detailed resource use for dressing and securement replacement will be recorded for 100 replacements selected at random (25 per device per group). Resources to be recorded include nurse/doctor time for replacement, waiting times for treatment and equipment (eg, dressings). The study will determine the hours of nursing and medical time required for replacement, wage costs per minute and the cost of treatments. These data will be used to estimate total resource use and costs for each of the groups over the study period. A cost analysis using analysis of covariance or non-parametric bootstrapping techniques (dependent on the distribution of the cost data) will be undertaken from the public hospital perspective to compare mean total costs for the four treatment groups. Explanatory clinical and demographic variables (in addition to group) will be explored. A cost-effectiveness analysis will also be undertaken to estimate the incremental cost of each study product alternative per additional PIV failure avoided, compared with SPU. This will indicate the device securement that would provide the best value for money if implemented more widely in clinical practice.

Microbiological testing and end points

To further inform the infection outcomes, a substudy (purposive 10%) will have ReNs take PIV tip and skin cultures (from under the dressing) immediately after PIV removal.¹³ These specimens will be transferred to the laboratory, with skin swabs streaked onto non-selective agar, and PIV tip segments roll-plated.³² After 24 h of incubation, plates will be examined for bacterial colony counts. The plates will then be reincubated for 72 h to enable growth of slow-growing species. Species identification will be determined morphologically, biochemically and, if required, genetically (eg, PCR and sequencing). Samples will be scored for the presence of bacteria, the total cfu and species present. The added workload and cost mean this is not feasible for the entire sample. For patients who consent, we will store

recovered microorganisms for use in potential future infection control studies.

In vitro antimicrobial properties

We will also investigate the antimicrobial properties of each dressing.³⁴ These tests are similar to the minimum inhibitory concentration evaluations for antibiotics. A confluent bacterial monolayer on the surface of solid agar will be produced by plating liquid bacterial suspensions. An aliquot of TA will be dropped onto one point of the agar plate. We will do this for unpolymerised, semipolymerised and fully polymerised TA. For SPU, BPU and SSD, a 0.5 cm disc will be cut and laid on the plate, incubated and the zone of inhibition determined. We will also examine growth under each specimen. Bacteria associated with PIV infection will be used (*S. epidermidis*, *S. aureus*, *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*).^{35 36} A modification of this method will also be used to investigate bacterial migration between the dressing and securement products and the agar surface, modelling bacterial migration at the skin/PIV interface. Proportions colonised between study groups will be compared with non-parametric techniques.

ETHICS AND DISSEMINATION OF RESULTS

Ethical and safety considerations

The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12611000769987). Written informed consent will be obtained from participants or representatives to participate in this trial, with an additional option to consent for the data and specimens collected to be stored and used in future infection control studies. Consent can be withdrawn from the trial participation for use of the study products and/or data collection if participants change their mind. In these cases, the trial products would be removed (if the participant requests) and replaced with SPU dressings. Serious adverse events (deaths, ICU admissions, PIV-related bloodstream infections) will be monitored and reported to the Human Research and Ethics Committees (HREC). Owing to the rapid recruitment expected in the trial, there are no plans for interim analyses or safety data monitoring beyond that reported to the HREC. The study manager will communicate important protocol modifications or clarifications to relevant parties (investigators, ReNs, HREC, trial registry).

Dissemination of results

The prevention of medical device failure, improved well-being, hospital patient satisfaction and responsible use of the health dollar are all of high interest to stakeholders, including the general community. To disseminate results widely, the investigators will present results locally and at relevant international meetings. The study can be expected to be published in an influential medical journal and rapidly translated into clinical policies. Additional processes to promote research

translation into practice will be sought, for example, brief practical articles in professional newspapers.

DISCUSSION

PIV failure is a common problem and affects millions of people each year. Improved dressing and securement is likely to prevent many cases of PIV failure. However, despite a high clinical need and the high costs to hospitals for products given the significant volume of use, there is a paucity of studies reporting the efficacy of alternative dressing and securement methods. Rigorous assessment of the efficacy and cost-effectiveness of PIV dressing and securement methods is therefore needed to guide clinical decision-making. If failure rates can be reduced by 10%, this would prevent more than 30 million PIV failures and reinsertions in the USA each year alone, with phenomenal associated reductions in health costs and nursing/medical time.⁹ The results from this large RCT will have a significant impact on international health policies, decrease hospital budgets, reduce nursing/medical workloads and improve patient experiences.

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Ethics approval Queensland Health (HREC/11/QRCH/152) and Griffith University (NRS/46/11/HREC).

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