Journal of Critical Care 36 (2016) 35–42

Contents lists available at ScienceDirect

Journal of Critical Care

journal homepage: www.jccjournal.org

A 4-arm randomized controlled pilot trial of innovative solutions for jugular central venous access device securement in 221 cardiac surgical patients

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ARTICLE INFO

Available online xxxx
Keywords:
Vascular access devices
Occlusive dressings
Randomized controlled trial
Securement device
Tissue adhesives

ABSTRACT

Purpose: To improve jugular central venous access device (CVAD) securement, prevent CVAD failure (composite: dislodgement, occlusion, breakage, local or bloodstream infection), and assess subsequent trial feasibility.
Materials and Methods: Study design was a 4-arm, parallel, randomized, controlled, nonblinded, pilot trial. Patients received CVAD securement with (i) suture + bordered polyurethane (suture + BPU; control), (ii) suture + absorbent dressing (suture + AD), (iii) sutureless securement device + simple polyurethane (SSD + SPU), or (iv) tissue adhesive + simple polyurethane (TA + SPU). Midtrial, due to safety, the TA + SPU intervention was replaced with a suture + TA + SPU group.
Results: A total of 221 patients were randomized with 2 postrandomization exclusions. Central venous access device failure was as follows: suture + BPU controls, 2 (4%) of 55 (0.52/1000 hours); suture + AD, 1 (2%) of 56 (0.26/1000 hours, $P = .560$); SSD + SPU, 4 (7%) of 55 (1.04/1000 hours, $P = .417$); TA + SPU, 4 (17%) of 23 (2.53/1000 hours, $P = .049$); and suture + TA + SPU, 0 (0%) of 30 ($P = .263$; intention-to-treat, log-rank tests). Central venous access device failure was predicted ($P < .05$) by baseline poor/fair skin integrity (hazard ratio, 9.8; 95% confidence interval, 1.2-79.9) or impaired mental state at CVAD removal (hazard ratio, 14.2; 95% confidence interval, 3.0-68.4).
Conclusions: Jugular CVAD securement is challenging in postcardiac surgical patients who are coagulopathic and mobilized early. TA + SPU was ineffective for CVAD securement and is not recommended. Suture + TA + SPU appeared promising, with zero CVAD failure observed. Future trials should resolve uncertainty about the comparative effect of suture + TA + SPU, suture + AD, and SSD + SPU vs suture + BPU.

1. Introduction

Central venous access devices (CVADs) are placed in the large veins of intensive care patients to deliver critical treatment and monitor central venous pressures. Central venous access devices are commonly used medical devices in hospitals, with 3 million used in the United States and 250 000 in the UK each year alone [1,2]. In total, 25% to 30% of CVADs are reported to fail via dislodgement, blockage, breakage, thrombosis, or infection, resulting in premature device removal [3,4]. This adversely impacts patients' care through interrupted treatment

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http://dx.doi.org/10.1016/j.jcrc.2016.06.006
0883-9441/

(eg, interruption of vasopressors, or sedatives) and requires additional CVAD insertion with inherent associated risks and procedural pain. Failure may involve localized or catheter-associated bloodstream infections (CABSIs) which lengthen stay by ~10 days, increase absolute risk of death by 1%, and increase costs by AUD$14 886 (2010) [5]. The placement of CVADs in the jugular vein increases this risk of CABSI and ultimately CVAD failure, when compared with subclavian vein placement [6]. All forms of CVAD failure significantly increase hospital costs and workloads.

Central venous access device securement is key to minimizing complications, yet CVAD failure rates suggest that current approaches do not adequately prevent dislodgement or the catheter micromotion which precipitates endothelial damage and occlusion, and facilitates the entry of skin microorganisms through the catheter insertion site [7,8]. Traditionally, sutures with either gauze and tape, or nonbordered, polyurethane dressings have been used for CVAD securement [9]. Clinical practice guidelines now recommend *against* the use of sutures due to needle-stick injury risks and significantly increased CABSI in one randomized controlled trial (RCT) [8,10]. Instead, sutureless securement devices (SSDs) are recommended [8,11]. These have a strong adhesive footplate affixed to the skin, with a plastic clip or velcro fabric clasp to secure the CVAD. Sutureless securement devices are designed to reduce movement, kinking, and flow impedance, yet to date, there has been no published RCT in short-term CVADs, and our experience is that uptake of SSDs in Australian intensive care units (ICU) is limited.

More recently, reinforced bordered polyurethane (BPU) dressings have emerged and are now used in many ICUs in place of traditional transparent dressings, but still in combination with sutures. No published RCT has yet reported on the effectiveness of BPU to prevent CVAD failure. Another alternative is absorbent dressings (ADs), some of which retain a degree of visibility of the site [12]. Developed for postsurgical wounds, these dressings may be beneficial, particularly in postcardiac surgical or other patients whose CVAD sites ooze hemoserous discharge; however, they are untested for CVAD securement.

In a novel approach to various vascular device securement, we have previously investigated in vitro use of tissue adhesive (TA; ie, medical grade "superglue"), finding it potentially beneficial to avoid dislodgment and microbial growth [13]. In short peripheral arterial and venous lines, TA securement led to absolute reductions in catheter failure ranging from 11% to 24% compared with traditional non-BPU films [14-16]. We hypothesized that TA could also improve CVAD securement, although only case series have to date reported its use for this indication with mixed results [17-20].

A lack of rigorous data on effective interventions for CVAD dressing and securement has seen practice change little for decades [21]. Given the large number of CVADs used globally each year and frequent CVAD complications, this is a high priority area for research. With this in mind and in preparation for a large multisite study, we undertook a pilot RCT to consider the feasibility, safety, and acceptability of a study protocol [22], and to prioritize products for a planned large-scale RCT.

2. Materials and methods

2.1. Study design and participants

After hospital and university ethical approval (HREC/11/QRCH/152; NRS/10/14/HREC), this randomized controlled pilot trial was commenced. Written informed consent was obtained before scheduled cardiac surgery. The study design was a 4-arm, parallel trial. The single-center setting was in the operating theaters and a 21-bed ICU at The Prince Charles Hospital—a tertiary referral hospital in Queensland, Australia, with a large cardiac surgical cohort. The target sample size was 220, 50 per group, plus 10% for potential attrition, determined by recommendations for pilot trial sample sizes [22]. The study was registered with the Australian Clinical Trials Registry: ACTRN12613001103752.

From 2nd September 2013 to 8th April 2014, Monday to Friday, clinical research nurses (CRNs) screened elective cardiac surgical patients preoperatively. Only 1 CVAD per patient was studied. Inclusion criteria were as follows: written informed consent, aged ≥18 years, and a CVAD expected to be in use for at least 24 hours. Patients were excluded if they had an existing bloodstream infection (<48 hours), were non–English-speaking without an interpreter, had burned or diseased skin at the entry site, had extreme diaphoresis at enrollment, had existing skin tears or "papery" poor quality skin, or had a known allergy to any study product.

2.2. Randomization and masking

The CRN performed randomization using an independent Web-based service (https://www151.griffith.edu.au/) to ensure allocation concealment until study entry. Patients were randomly assigned in a 1:1:1:1 ratio with computer-generated and randomly varied block sizes of 4 and 8 to prevent prediction of allocation. Urn randomization was not used and the groups could potentially have more than 55 patients allocated to them, with recruitment to be continued until a minimum of 55 per group were enrolled. Dressing and securement interventions could not be blinded because clinical staff needed to be able to continuously monitor that they were clean, dry, and intact for purposes of patient safety, and research staff needed to check the adherence of the study products and inflammation/discharge. All infection and microbiological end points were blinded through the use of blinded scientists.

2.3. Study interventions

Central venous access devices (quadruple-lumen 8.5F 8-in./20-cm, or triple-lumen 7F 6-in./16-cm chlorhexidine impregnated ARROWg^{+}ard Blue Plus CVC, Teleflex, Research Triangle Park, NC) were inserted into the internal jugular vein using landmark/ultrasound technique by anesthetic registrars or anesthetists, at the inserter's discretion. Preinsertion, skin preparation was with chlorhexidine 0.5% in 70% alcohol (PharmAust, Welshpool, Western Australia), or Riodine Povidone Iodine 10% (PharmAust), at the inserter's discretion.

Group 1. Suture + BPU (controls): CVADs were sutured with an Ethicon 3-0 Prolene 30-in. (75-cm) SH needle 26-mm 1/2c Taper (Johnson & Johnson, North Ryde, NSW, Australia), and the catheter entry site was secured with a BPU (Tegaderm I.V. 1650 Dressing 10 × 15.5 cm; 3M, St Paul, Minn). This is a polyurethane adhesive film with a reinforced fabric border Fig. 1A.

Group 2. Suture + AD: CVADs were sutured as for group 1 and the catheter entry site was secured with an AD (OpSite Post-Op Visible 10 × 8 cm; Smith & Nephew, Hull, United Kingdom). This has a low adherent wound contact layer, a "criss-cross" lattice-shaped absorbent pad, and a waterproof, bacteria-resistant polyurethane film with adhesive coating Fig. 1B.

Group 3. SSD + SPU: CVADs were not sutured. Instead, an SSD (Grip-Lok CVC 3601 Securement Device; TIDI, Neenah, Wis) was used to anchor the hub near the catheter entry site, with the "tails" anchored to the skin with a second Grip-Lok. A simple polyurethane (SPU) borderless dressing (IV3000™ 10 × 14 cm; Smith & Nephew) was used to cover the catheter entry site Fig. 1C.

Group 4. TA + SPU: CVADs were not sutured. Instead, Histoacryl Blue TA (BBraun #1050044, Ann Arbor, Mich) was applied at the insertion site, and under each CVAD wing (see Fig. 2). Approximately a half to three quarters of a 0.5 ml vial was used to secure the CVAD. After allowing the TA to dry, an SPU (as in group 3) was used to cover the catheter entry site. This combination was used for 24 patients. After CVAD dislodgement in 3 of these patients, we ceased randomization to this arm midtrial, and instead created a fifth intervention group for the remaining 30 patients Fig. 1D.