CLINICAL STUDY

A Pilot Randomized Controlled Trial of Novel Dressing and Securement Techniques in 101 Pediatric Patients

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ABSTRACT

Purpose: To evaluate feasibility of an efficacy trial comparing peripherally inserted central catheter (PICC) dressing and securement techniques to prevent complications and failure.

Materials and Methods: This pilot, 3-armed, randomized controlled trial was undertaken at Royal Children's Hospital and Lady Cilento Children's Hospital, Brisbane, Australia, between April 2014 and September 2015. Pediatric participants (N = 101; age range, 0–18 y) were assigned to standard care (bordered polyurethane [BPU] dressing, sutureless securement device), tissue adhesive (TA) (plus BPU dressing), or integrated securement dressings (ISDs). Average PICC dwell time was 8.1 days (range, 0.2–27.7 d). Primary outcome was trial feasibility including PICC failure. Secondary outcomes were PICC complications, dressing performance, and parent and staff satisfaction.

Results: Protocol feasibility was established. PICC failure was 6% (2/32) with standard care, 6% (2/31) with ISD, and 3% (1/32) with TA. PICC complications were 16% across all groups. TA provided immediate postoperative hemostasis, prolonging the first dressing change until 5.5 days compared with 3.5 days and 2.5 days with standard care and ISD respectively. Bleeding was the most common reason for first dressing change: standard care (n = 18; 75%), ISD (n = 11; 69%), TA (n = 4; 27%). Parental satisfaction (median 9.7/10; $P = .006$) and staff feedback (9.2/10; $P = .002$) were most positive for ISD.

Conclusions: This research suggests safety and acceptability of different securement dressings compared with standard care; securement dressings may also reduce dressing changes after insertion. Further research is required to confirm clinically cost-effective methods to prevent PICC failure.

ABBREVIATIONS

BPU = bordered polyurethane, BSI = bloodstream infection, CI = confidence interval, IQR = interquartile range, IR = incidence rate, ISD = integrated securement dressing, PICC = peripherally inserted central catheter, SSD = sutureless securement device, TA = tissue adhesive

The use of peripherally inserted central catheters (PICCs) in pediatric patients is increasing globally (1,2). However, 30% of PICCs fail before completion of treatment owing to infective, vascular, or mechanical (fracture, partial or total PICC dislodgment) issues (3). A recent meta-analysis of international observational studies (4) demonstrated high rates of failure (12.4 per 1,000 catheter-days), catheter-associated bloodstream infection (BSI) (3.1 per 1,000 catheter-days), thrombosis (0.2 per 1,000 catheter-days), and occlusion (2.2 per 1,000 catheter-days). Insertion of replacement devices is resource intensive and significantly reduces vessel health and preservation (5). The purpose of PICC dressing and securement is 3-fold: (*i*) stability to prevent gross movement of the catheter and maintain

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Table E1 is available online at www.jvir.org.

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central position; (*ii*) reduce micromotion, which may cause vascular injury; and (*iii*) protect skin puncture site from microbial entry and subsequent infection. PICC dressing and securement traditionally included sutures and a polyurethane dressing (6). A landmark randomized controlled trial in 170 adults demonstrated the superiority of a sutureless securement device (SSD) (StatLock; C.R. Bard, Inc, Covington, Georgia) over sutures to prevent catheter-associated BSI (7). SSDs have adhesive-backed foam anchor pads with hinged clamps for PICC wings and are used in addition to polyurethane dressings. Although this research has never been replicated in pediatric patients, SSDs are commonly used to secure PICCs in pediatric patients (8).

Two new PICC securement technologies might be superior to current strategies. First, integrated securement dressings (ISDs) combine dressing and securement in 1 product, providing a single product alternative. ISDs have a reinforced border with an absorbent barrier around the clear transparent polyurethane section to encourage movement of moisture away from the insertion site. A reinforced fabric "collar" aims to reduce movement of the external catheter extension, preserving dressing integrity. Manufacturers claim no additional securement (eg, tape) is necessary. Tissue adhesive (TA) is a medical-grade "superglue" (cyanoacrylate) commonly used as an alternative to sutures for wound closure (9) and more recently has been used to improve securement of peripheral intravenous catheters (10) and nontunneled central venous access devices (11). Simonova et al (12) additionally demonstrated tensile strength and bacteriostatic properties of TA to avoid dislodgment and penetration by gram-positive microorganisms in vitro. Despite the promise of these new PICC securement technologies, their clinical efficacy, cost-effectiveness, and acceptability by patients and staff have not been tested in the pediatric population.

The aim of this study was to pilot test feasibility aspects, including intervention acceptability, compliance, and recruitment of novel dressing and securement products for inpatient pediatric PICCs, before a full-scale efficacy randomized controlled trial. The secondary aim was to compare the effectiveness of products to prevent PICC complications and failure owing to infection, occlusion, dislodgment, thrombosis, or fracture.

MATERIALS AND METHODS

Design

An external, pilot, parallel, 3-arm, randomized controlled trial of PICC dressing and securement for pediatric patients was undertaken. The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12614001327673), and a protocol was published (13). The Children's Health Service District, Queensland (HREC/13/QRCH/181), and Griffith University (NRS/10/14/HREC) Human Research Ethics Committees provided ethics and governance approval. Informed consent was obtained from parents or legal guardians, with children providing Youth Assent when developmentally appropriate.

Study Setting

The study began in April 2014 at the Royal Children's Hospital, Brisbane, and owing to local hospital mergers, was completed at the Lady Cilento Children's Hospital, Brisbane, in September 2015. These are tertiary-level, specialist pediatric teaching hospitals in Brisbane, Australia, that provide full-spectrum health services to children from birth to 18 years of age.

Sample

The target sample size was 100 participants, allowing 30 per group, plus 10% for potential attrition, determined by standard pilot trial sample size recommendations (14). Inclusion criteria were PICC insertion, patient age < 18 years, anticipated inpatient stay for > 24 hours, and written informed consent by legal parent or guardian. Patients were excluded if they had a current (< 48 h) BSI; had diseased, burned, scarred, or extremely diaphoretic skin; had skin tears surrounding the PICC insertion site; had known allergy to the study products; or had previously been enrolled in the study within the current hospital admission.

Participant and PICC Characteristics

As described in **Table 1** and **Table E1** (available online at *www.jvir.org*), most participant, PICC, and insertion characteristics were balanced across the intervention groups. Most participants had a medical diagnosis ($n = 81$; 80%). Mean age was 7.5 years. There was some imbalance evident ($> 10\%$ difference between groups, not statistically significant) in skin integrity and number of insertion attempts required.

Interventions

Participants were randomly assigned to receive PICC dressing and securement (**Fig 1a–c**) as follows:

Group 1. Standard care: Bordered polyurethane (BPU) dressing (Tegaderm 1614 or 1616 [dependent on participant size]; 3M, St Paul, Minnesota) and SSD (StatLock VPPCSP)

Group 2. ISD: ISD (SorbaView SHIELD SV254; Centurion Medical Products, Williamston, Michigan)

Group 3. TA: BPU dressing (Tegaderm 1655 or 1616 [dependent on participant size]) and TA (Histoacryl; B. Braun Melsungen AG, Melsungen, Germany)

Outcomes

The primary outcome was feasibility of a full efficacy trial, established by composite analysis of elements of eligibility, recruitment, attrition, protocol adherence, missing data, parent and health care staff satisfaction, and effect size estimates to allow sample size calculations (14,15). Parent (or caregiver) and health care staff levels of satisfaction and acceptability of the study products were assessed using a 0-to-10 numeric rating scale at PICC insertion and removal