Innovative dressing and securement of tunneled central venous access devices in pediatrics: a pilot randomized controlled trial

AUTHOR(S);
Amanda J. Ullman, Tricia Kleidon, Victoria Gibson, Craig A. McBride, Gabor Mihala, Marie Cooke, and Claire M. Rickard

SOURCE:
BMC Cancer 2017

KEY TAKEAWAYS:
Tunneled central venous access devices (CVADs) incorporate a cuff designed to stimulate the ingrowth of tissue to anchor the device and to inhibit the migration of microbes from the skin into the insertion tract. Up to 29% of pediatric tunneled cuffed CVADs fail prior to completion of therapy (0.86 per 1,000 catheter days). Some of this failure can be attributed to the time it takes (up to 4 weeks) for the surrounding tissue to fully adhere to the cuff.

Tissue adhesives may improve the security and dressing integrity of tunneled CVADs by enhancing the securement strength of transparent film dressings and effectively sealing the catheter insertion and tunneling sites while the insertion tract heals and tissue grows into the CVAD cuff. This in turn leads to an overall reduction in the number of dressing changes required for tunneled CVADs.

STUDY OBJECTIVE(S):
To evaluate the feasibility of a statistically significant randomized control trial comparing various innovative dressing and securement modalities for use with pediatric tunneled CVADs to prevent complications and device failure.

METHODS:
A four-arm, randomized, controlled, pilot trial conducted in two large, tertiary referral pediatric hospitals in Australia between April 2014 and October 2014 and March 2015 and May 2016. Pediatric patients (n=48) receiving a tunneled CVAD were randomly allocated to one of four dressing/securement groups as follows:

1. Standard of Care (Control): Suture (Ethicon Prolene) + Bordered Polyurethane Dressing (3M Tegaderm)
2. Sutureless Securement Device (SSD): Suture (to close the tunneling wound) + Sutureless securement device (Bard Statlock or TIDI Griplok) + Bordered Polyurethane Dressing
3. Tissue Adhesive (TA): One to two drops of Histoacryl at exit wound and under catheter bifurcation + Bordered Polyurethane Dressing
4. Integrated securement dressing (ISD): Suture + ISD (Centurion SorbaView SHIELD)

OUTCOMES MEASURED:
The primary outcome was tunneled CVAD failure or cessation of function prior to completion of therapy and CVAD complication or a composite of CVAD-associated bloodstream infection, local infection, occlusion, dislodgement, venous thrombosis, and breakage. Secondary outcomes measured included securement dressing failure, time to first dressing change, skin complications, and direct product costs.

RESULTS:
CVAD failure from lowest to highest in the study groups was as follows: 0% for TA (0/12), 0% for the control (0/11), 8% for ISD (1/13), and 17% for SSD (2/12). One CVAD-associated bloodstream infection occurred, within the SSD group. Overall satisfaction was highest in the ISD group (mean 8.5/10; standard deviation 1.2). Improved dressing integrity was evident in the intervention arms, with the integrated securement-dressing associated with prolonged time to first dressing change (mean days 3.5). Tissue adhesive reduced total dressing changes per catheter day by 67.4% vs control, 45.2% vs ISD, and 62.2% vs SSD.

ADVERSE EVENTS:
One CVAD-associated blood stream infection in the SSD group. CVAD-associated skin injuries were a substantial issue within the study, with site complications identified in 9% of participants, with two additional participants (4%) withdrawing from the study due to skin irritation.

STUDY LIMITATIONS:

Due to the relatively small sample size the study results need to be confirmed in a larger trial. The study was only carried out in two sites and thus generalizability outside of this population is unknown. Participants, family members and the research staff were not blinded to the intervention allocation due to the visibility of the securement products.