

Evaluating the utilization of central line-IV tubing sleeves in protecting and organizing central lines in a pediatric blood and marrow transplant population



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SIGNIFICANCE

- Patients admitted to the Pediatric Blood and Marrow Transplant (PBMT) Unit have double or triple lumen central venous lines connected to IV tubing for transplant medications
- Children often play with their lines, and inadvertently disconnect, tangle, chew, or spill fluids on the lines
- Children may also be scared or anxious at the sight of them
- These events increase risk of developing a Central Line Associated Blood Stream Infection (CLABSI) in a patient population already immunosuppressed
- Recently, a newly invented nursing product, a central line-IV tubing sleeve, has provided a means to protect lines from such contamination or entanglement as they are waterproof sleeves that cover the connection points between the IV tubing and central line lumens
- These central line-IV tubing sleeves are design patented and per the FDA 513(g) process, they are not considered a medical device

PURPOSE

- To evaluate the:
- clinical component
 - consumer satisfaction & convenience



of utilizing a central line-IV tubing sleeve in the PBMT population

INTERVENTIONS

Clinical component: This study assesses if the central line-IV tubing sleeves increase or harbor bacteria already present on the connected intravenous (IV) tubing.

- To determine clinical outcomes, subjects were enrolled after they completed the chemotherapy phase of transplant.
- After obtaining consent, the following procedures occurred:

Every subject served as their own control

Days 1-3

Control Phase

Bacterial growth was measured on Study Days 1 & 3 by ATP bioluminescence monitoring

Day 3

Line & Cap Change

Evening of Day 3, all lines and caps were changed per standard of care

Sleeve was applied to the lines after line change process was complete

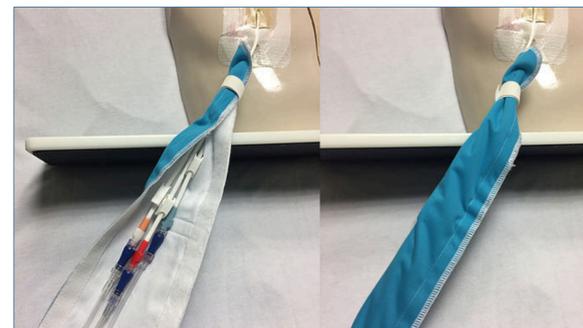
Days 4-6

Intervention Phase

Bacterial growth was measured on Study Days 4 & 6 by ATP bioluminescence monitoring

Satisfaction and Convenience of central line-IV tubing sleeves

- Parents or guardians were asked to complete a one-time online survey about consumer satisfaction and convenience at the completion of the study for their child.
- Staff are currently completing the survey regarding their experience using the central line-IV tubing sleeves



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Disclosures

MbT, RS, and DA are forming a LLC to bring these central line-IV tubing sleeves to market. AB has no relationships to disclose.

PRELIMINARY OUTCOMES (n=30)

Figure 1. Parent/guardian feedback regarding use of the central line-IV tubing sleeves is very positive and reflects a perception that the central line-IV tubing sleeves help protect children's lines

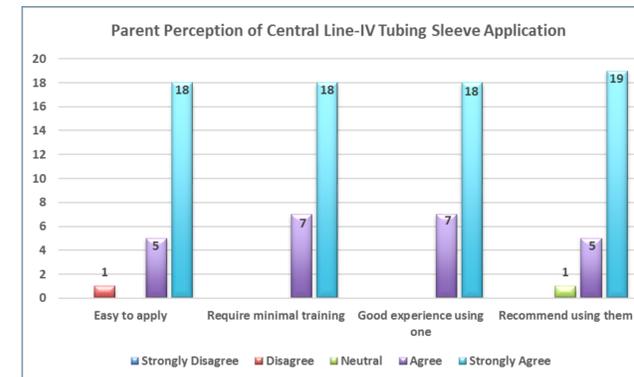
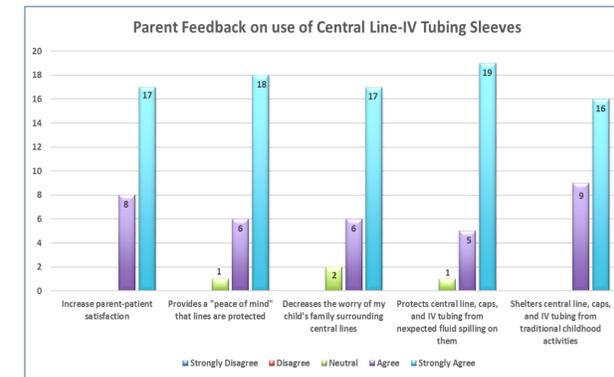


Figure 2. Parent/guardian perception on the central line-IV tubing sleeve application indicate ease of use, minimal training required, and an overall good experience.

Parent/guardian Survey Comments:

- "The sleeve protected my son's lines during two events that would have caused a need for complete line change and it being the middle of the night. It's safe and easy to use as a parent and gives perfect access for the nurses."
- "Once, our daughter's diaper leaked, which required cleaning everything that had been contaminated. Since we were using a sleeve, we could tell at a glance that since it wasn't dirty the 10+ lines running through it were also clean and didn't need to be cleaned or changed."
- "Our child is very particular about her lines and when they get tangled her anxiety increases. With the sleeve, she has not even been paying attention to her lines and if she wants or needs to, she can adjust it herself."
- "I love the sleeve. My grandson's lines were all over the place, even the floor, before using the sleeve. Now they are neatly wrapped and organized. I would recommend that they come in longer lengths. Thank you for such a great idea."

Next Steps

- Complete analysis of ATP data & staff responses
- Perform Phase 2 study in the adult population to assess utility
- Evaluate benefit for patients and healthcare staff

