Study Protocol

Title: Innovative Central Line Securement Device: Line Complications and Quality of Life in the Pediatric Population as Compared to Traditional Securement Device

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Background

Central venous access devices (CVADs) are used in a wide variety of conditions to deliver medications, hydration, and intravenous feeding. CVADs are used in multiple conditions including cancer, short gut syndrome, chronic intestinal pseudo-obstruction, Crohn's disease, ulcerative colitis, mitochondrial disease, cystic fibrosis, just to name a few. Tunneled central lines are thin catheters inserted under the skin and into a large vein for long-term use and are particularly fragile in several locations including the thinnest part of the line and near the hub. Line repair is reported in as many as 33% of catheters (1) and there is a 3-fold increase in sepsis in the 30 days following line repair (2). Line trauma is a common cause for repair, especially in the pediatric portion population due to children's lack of safety awareness, nearly constant movement, and poor impulse control (3). Currently, pediatric tunneled CVADs have a failure rate of 29% prior to completion of therapy (4). This leads to a significant burden on the healthcare system by necessitating additional time in the hospital to place a new line, lost time receiving treatment or nutrition, loss of access site (only six available vessels), and the potential for further complications including death (5,6). Preventing line trauma directly impacts long-term outcomes by preserving central access, with clinicians seeking a safe, comfortable harness for CVAD securement to minimize line trauma and its resulting complications (7).

Objectives

This study will compare traditional central line securement methods to a novel central line securement device. Primary outcomes include rates of line breaks, line dislodgments and line infections. Secondary outcomes include changes to quality of life scores on a validated survey tool.

Design and Methods

Patients with central lines ages 0-18 years old (anyone <19 at time of recruitment) who have never worn Gus Gear will be eligible for the study. We will plan to recruit 200 patients. They will be block randomized based on age upon enrollment to either the securement device of traditional methods. Those in the device arm will be given Gus Gear devices and we will encourage continuous wear. The study will follow participants prospectively for approximately one year.

Patients will be recruited from an intestinal failure care clinic during care visits. Investigators JY and KA will introduce the study during the check in process. If families are interested they will be consented by researchers RS and MM.

Once consented patients were block randomized based on their age from between Birth < 12mo, between 12mo < 4 years and between 4 years < 18 years. Patients will be assigned to either receive a central line securement device or continue using the standard of care sterile dressing over their central line. If patients are randomized to receive the device, they will be fitted according to manufacturer protocols, which consists of a chest measurement.

After randomization and device securement if applicable, all families will fill out a baseline demographics form and a baseline quality of life survey. Patients will then be followed for 12 months from initial enrollment. At subsequent clinic visits patients and families will fill out

follow-up surveys detailing potential line related complications. They were also be given the same quality of life survey that they filled out at the time of initial enrollment. These follow-up surveys will be administered between 3-4 times throughout the year. Subjects' charts will be routinely reviewed over the study, monitoring for line related complications.

Eligibility Criteria

Patients eligible for inclusion were between the age of 0-18 with long term central line use for total parenteral nutrition in the setting of PIF.

Patients who were excluded from the study were those older than the age of 18, any patient who had used a central line securement vest before and any adolescent female with greater than Tanner 2 breast development. All females enrolled were monitored routinely for breast development, as patients with great than Tanner 1 breasts do not fit properly into the vest for safe line securement.

Statistical Consideration

Statistical Package for Social Sciences (SPSS Version 28.0, Armonk, NY) will be used for descriptive analysis of primary outcome data. Event rates were averaged for both cohorts before enrollment and after enrollment. Subjects will be compared to themselves pre and post intervention. A paired T-Test will be used to evaluate for treatment effect after enrollment.

Quality of life data will be recorded in RedCap using ordinal scales. Therefore, we will compare responses to individual questions between the dressing group and securement device group using ordinal logistic regression, adjusting for clustering of responses within a participant. We will present results as the ordinal odds ratio and 95% confidence intervals for a unit change in response level for each question. (analysis in STATA 16.1, College Station, TX).

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