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Official title: 8.4% Sodium Bicarbonate Locks in Intestinal Failure

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Study Protocol and Statistical Analysis Plan

Study design

This was an open-label prospective cohort study on pediatric patients with IF followed by the Pediatric Intestinal Rehabilitation program at a tertiary medical center assessing the rates of CRBSI and CVC replacement. The study was approved by the institutional review board.

Consent was obtained from caregivers. This trial was registered on Clinicaltrial.gov (NCT05813535). The study covered a period between January 1, 2021, and March 1, 2025. Baseline (preintervention) period covered January 1, 2021, until start of $NaHCO_3$ locks while patients were on heparin locks. The intervention period covered the start of $NaHCO_3$ lock use until the end of the study period or until discontinuation of $NaHCO_3$ locks, whichever occurred earlier. Data from baseline period (while on heparin locks) were reviewed retrospectively. In our practice, we primarily use a single lumen silicone CVC for PN delivery for patients with IF but may use a polyurethane peripherally inserted central catheter line for few weeks as a bridge.

Inclusion criteria for the study included the following:

- Diagnosis of IF, leading to PN dependence based on published guidelines
- Use of heparin locks in preintervention period followed by use of $NaHCO_3$ locks
- Age <18 years old at time of starting $NaHCO_3$ locks

Lock solutions

During baseline period, the CVC was flushed with sterile normal saline followed by heparin 10 unit/ml flush syringe. At time of PN initiation, heparin was flushed with sterile normal saline.

During the intervention period, the CVC was flushed with sterile normal saline after PN delivery, followed by placing 8.4% $NaHCO_3$ lock 0.5–1.5 ml daily (to fill luminal volume determined based on the catheter's priming volume from manufacturer and adjusted per individual patient). This was left to dwell for a minimum of 4 h daily. Before starting PN, the next day, $NaHCO_3$ locks were aspirated and discarded.

Data collection and outcome measures

A CRBSI was defined as a documented positive blood culture from the CVC in patients showing signs and/or symptoms of infection, including fever, irritability, or hypotension in

the absence of an alternative source of infection. A CRBSI occurring within 1 month of a prior CRBSI with the same organism documented on central blood culture was considered a single CRBSI event. A CRBSI-related CVC replacement event was defined as a replacement procedure because of a documented CRBSI including failed salvage. Event rates were expressed as number of events per 1000 CVC days. Data collected included patient demographics, underlying conditions leading to IF, dates and types of CVC lock use, dates of CRBSI events and CVC placement, and blood culture results.

The primary aim was to compare CRBSI rates between heparin vs $NaHCO_3$ locks. Both per-protocol analysis, which excluded nonadherent patients, and intent-to-treat (ITT) analysis were conducted and reported for the primary outcome. Secondary outcomes included comparing CVC replacement and repair rates from CRBSIs between groups. The number of catheter days and rates were expressed as medians with interquartile ranges. Event rates were compared using the Wilcoxon signed rank test for paired nonparametric data, with each patient used as their own control, with a significance level set at $P < 0.05$. Statistical analysis was performed using SAS 9.4 (SAS Institute, Cary, NC).