Title: The Role of a Nasal Bridle in the Frequency of Repeat Endoscopic Procedures for Endoscopic Naso-enteric Tube Placement

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Brief Summary:

In critically ill patients, nutrition is a major part of healing and recovery. In patients unable to tolerate oral feeding, nasoenteric tube feeding (a tube placed from the nose to the stomach or small intestine) provides a safe alternative for feeding. Some patients require these tubes to be placed endoscopically due to numerous patient factors including difficult anatomy, need for post-gastric feeding, among others). In patients that require endoscopically placed tubes, there is risk of perforation, infection, bleeding, aspiration, and rarely even death. In patients that have recurrent dislodgement of endoscopically placed tubes, the need for repeat endoscopy increases patient exposure to these risks. Traditional securing mechanism with adhesive tape to reduce dislodgment often fail in critically ill patients requiring patients to have repeat endoscopies to replace nasoenteric feeding tubes and subjects patients potentially to increased cumulative risks associated with each endoscopy.

The investigators propose to collect data for one year, the investigators will prospectively follow via chart review endoscopically placed nasoenteric tubes placed with a Standard AMT Bridle securement device and assess if there is a reduction in accidental tube removal requiring replacement endoscopically.

Outcomes:

Primary objective is to see if nasal bridles versus standard adhesive tape to secure nasoenteric tubes decreases the need for repeat endoscopy to replace dislodged nasoenteric tubes. The number of endoscopies and repeated nasoenteric tubes placed will be tracked at six and twelve months. Secondary objectives can assess if reduces tube dislodgement frequency. Hypothesis: We hypothesize that nasal bridles in endoscopically placed feeding tubes will reduce the number of unnecessary endoscopies reducing health care costs and complications.

Detailed Description:

Patients to be recruited are those who are scheduled to undergo routine upper endoscopy with nasoenteric tube placement. Patients will be randomized into two groups: control arm and device arm.

Control arm includes patients that will have nasoenteric tubes secured with standard protocol, adhesive tape. Device arm includes patients that will have nasoenteric tubes secured with Standard AMT Bridle. The nasal bridles will be placed by the endoscopist. Upper endoscopy will not be affected. Placement of nasal bridle will take 1-2 minutes after endoscopic procedure completed. No addition sedation, medication or exposure necessary.

Patients will be randomized by sealed envelope randomization. Clinicians are given randomly generated treatment allocations within sealed opaque envelopes. Once a patient has consented to enter the study

trial an envelope is opened and the patient is then offered the allocated treatment regimen. Patients will be consented by a member of the research team prior to endoscopy. Randomization will be singly blinded only to the patient prior to endoscopy. Endoscopist will not be blinded as they will be placing the securement device and in order to reduce selection bias.

In the event of tube dislodgment, the patient will receive same treatment.

Follow-up of patients will occur via chart review until the time of discharge, at 6 months and at 12 months after feeding tube placement via chart review. Data collected with include repeat EGD, length of endoscopy, length of hospital stay, and mortality. The number of endoscopies and repeated nasoenteric tubes placed will be tracked at six and twelve months.

Statical Analysis

Descriptive statistics (means, medians, percentage) will be used to define the patient characteristics. Chi-square will be used for categorical variables. T-test will be used to analyze continuous variables.