Gastric Ultrasound in Tube Fed Intubated Patients

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PROTOCOL TITLE:

Utility of POC gastric ultrasound in confirming stomach is empty in intubated patients fed gastrically (NG) versus transpylorically (NJ) to ensure low risk of aspiration.

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	3/31/2021	Section 6 – clarifying what will happen if a patient can't be moved at all.	Yes
2	5/5/2021	Changing the inclusion criteria from PICU patients intubated < 7 days to < 14 days.	No
3	10/28/2024	Section 9 changing the study length, 10 adding inclusion age range, 11 adding description of protection of rights & welfare, 17.4 replaced study publication with study closure, 27.2 checking waiver of HIPAA, 27.3 removing "at least" before "6 years" and adding "after study closure".	No

1.0 Study Summary

Study Title	Utility of POC gastric ultrasound in confirming stomach is empty in intubated patients fed gastrically (NG) versus transpylorically (NJ) to ensure low risk of aspiration.
Study Design	Prospective study
Primary Objective	To compare gastric ultrasound (volume and quality of contents) in intubated patients receiving NG versus NJ feeds.
Secondary Objective(s)	
Research Intervention(s)/ Investigational Agent(s)	POC ultrasound of gastric contents.
IND/IDE #	N/A
Study Population	Intubated patients in the PICU.
Sample Size	200
Study Duration for individual participants	Maximum of 5 days
Study Specific Abbreviations/ Definitions	POC – point of care NG – nasogastric NJ – nasojejunal PICU – pediatric intensive care unit

2.0 Objectives

2.1 Intent of the study is to compare gastric ultrasound (volume and quality of contents) in patients receiving NG versus NJ feeds.

2.2 The hypothesis is patients that are NJ fed will not have gastric contents on POC gastric ultrasound despite rate and NPO time.

3.0 Background

3.1 Enteral nutrition support is essential in both medical and surgical patients cared for in intensive care units (ICUs). Upon admission to an ICU, up to 30% of patients are considered malnourished and that percentage can increase to 60% during an ICU stay due to a combination of increased metabolic demand and decreased delivery of nutrition. When compared to parenteral nutrition, enteral nutrition is associated with maintenance of gut integrity, improved immune function, decreased infection risk and overall lower cost. Gastric (NG) and post pyloric feeding tubes (NJ) can be placed at the bedside by credentialed practitioners in the ICU. Post pyloric placement is thought to allow for enteral feeds to be started in patients where aspiration risk is high (e.g. patients in respiratory failure on non-invasive ventilation) or in patients with

neurocognitive delays and subsequent aspiration risks due to impaired gastric emptying because food enters the digestive tract beyond the pylorus. Despite this, many ICU patients that have NJs have their vital nutrition interrupted or withheld for procedures for the same amount of time as those that are gastrically fed because so far, we are unable to prove that their stomachs are fully empty on post pyloric feeds. If they are trauma patients, this can often add up to days without nutrition that is needed for healing as they go back and forth from the OR for procedures. Currently, in our institution, burn patients are the only population allowed to continue NJ feeds during OR procedures as long as an abdominal radiograph on the day of the procedure confirms proper placement. This exposes the child to additional radiation.

3.2 Perioperative point of care gastric ultrasound has recently emerged as a method to evaluate patients coming to the OR when their prandial status is uncertain or when gastric emptying might be delayed. An ultrasound study at the bedside examines the gastric antrum and then quickly qualifies and quantifies gastric content, volume and transit time and stratifies the patient's risk of aspiration during a procedure. It has been validated in obese, pregnant and pediatric patients.

3.3 Our study will use POC gastric ultrasound to confirm that NJ feeds result in minimal to no gastric content and therefore are low risk for aspiration and should be allowed at the very least to decrease the time that enteral feeds need to be held prior to a procedure or if they need to be held at all. This would allow critically ill children to receive the nutrition that they need to heal for longer periods of time. Using ultrasound would also potentially eliminate the need for exposure to x-rays to confirm tube placement. Most ICUs have a POC ultrasound machine so this would be any easy tool to access to improve patient care.

4.0 Study Endpoints

4.1 Primary outcome is percentage of NJ fed patients that have scores of 0-1 on POC gastric ultrasound.

4.2 We would also like to observe changes, if any, of the gastric transit time while patients are sedated.

5.0 Study Intervention/Investigational Agent

5.1 PICU attendings and fellows will be trained in performing POC gastric ultrasounds by Anesthesiologists who are proficient in the procedure.

6.0 Procedures Involved*

6.1 We will conduct a prospective study of patients who receive NG feeds (control group) and compare them to those who receive NJ feeds (test group). The ultrasound will be taken while the patient is in the supine position - 30° head up and right lateral decubitus. If the patient cannot be moved in lateral decubitus position, we will scan with head up and bump under left hip In the case that a patient cannot be moved at all, we will perform the ultrasound in the supine position as long as they are 30-45° head up. This will be noted in our findings.

6.2 The patients will have POC ultrasounds taken one time per day, for up to five days.

6.3 We will record the following data at time of ultrasound:

- Gastric antrum volume (if applicable): cross sectional area and estimated volume.
- NPO time (if applicable) or feeding rate and formula.
- Current sedation.

7.0 Data and Specimen Banking*

7.1 Data will not be banked for future use.

8.0 Sharing of Results with Subjects*

8.1 Results will not be shared with subjects or others.

9.0 Study Timelines*

9.1 Each subject's participation in the study will last a maximum of 5 days. Each ultrasound should take 15-30 minutes.

9.2 We anticipate study completion by December 31, 2026.

9.3 The study data should be analyzed and a manuscript written and submitted for publication within 12 months of the completion of the study.

10.0 Inclusion and Exclusion Criteria*

10.1 PICU study staff will review the daily census for eligible patients.

10.2 We would include all PICU patients, aged 0-18 years, intubated < 14 days that are receiving NJ or NG feeds, especially interested in > 50% goal feeds.

10.3 Exclusion criteria would be patients that cannot be moved, patients with significant GI conditions affecting motility, and patients intubated for more than 14 days.

11.0 Vulnerable Populations*

11.1 We will include children, and will not include adults, pregnant woman, and prisoners as they are not part of our usual patient population.

11.2 The research involves no greater than minimal risk to children. Permission will be obtained from one parent/guardian after thorough explanation of the study. Assent will be obtained from children 9 years of age and above who have the capacity to understand the study . Wards of the state or county will not be included in the research study.

12.0 Local Number of Subjects

12.1 200.

13.0 Recruitment Methods

13.1 Potential subjects will be recruited from the PICU by the study staff who work there.

13.2 PICU study staff will review the daily census for potential subjects and then will approach the family about participating in the study.

13.3 Subjects will not be paid to participate.

14.0 Withdrawal of Subjects*

14.1 There are no anticipated circumstances under which subjects will be withdrawn from the research without their consent.

14.2 Subjects may withdraw from the research at any time.

15.0 Risks to Subjects*

15.1 Although not likely, there may be a potential risk for breach of confidentiality. There is no study related physical risk to study subjects associated with this study. All study related procedures are non-invasive.

16.0 Potential Benefits to Subjects*

16.1 There is no direct benefit to participants

17.0 Data Management* and Confidentiality

17.1 Demographics and basic clinical data will be analyzed using descriptive statistics. We will compare the two groups t-tests and chi-squared tests as necessary.

17.2 Covariates:

- Age (date of birth)
- Weight
- Gender
- Growth curve percentile
- Race
- Goal feeds in mL/hour
- Comorbid conditions, PRISM score

- Cause of respiratory failure
- Current sedation
- Other medications
- Feeds – NG or NJ, type of formula, volume (ml/hour)
- NG or NJ confirmed on morning radiograph
- Changes to feeds in the last 8 hours

17.3 Research records will be stored in a locked cabinet and password protected computer. Only certified research personnel will be given access to identifiable subject information.

17.4 Following study closure, research records will be stored for a period of at least 6 years and then will be destroyed by placing in a secure shredding bin.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

18.1 This is a minimal risk study and will be monitored by the study investigators.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Potential patients will only be approached by PICU study staff who are already familiar with the patients.

19.2 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study.

19.3 The PICU study staff are the same people who are treating patients clinically and have access to their medical records.

20.0 Compensation for Research-Related Injury

20.1 This is a minimal risk study.

21.0 Economic Burden to Subjects

21.1 None.

22.0 Consent Process

22.1 The consent process will take place in the PICU by the PICU study staff. The families will be able to take as much time as they'd like to review the protocol and have their questions answered before signing the consent form.

22.2 We will be following SOP: Informed Consent Process for Research (HRP-090) and SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).

22.3 Since this is a minimal risk study, parental permission will be obtained from just one parent/legal guardian.

22.4 We will attempt to obtain assent from those patients that are able, but since our study population is intubated patients they will most likely be sedated and unable to provide assent.

23.0 Process to Document Consent in Writing

23.1 Even though our research presents no more than minimal risk of harm to subjects, we will be following "SOP: Written Documentation of Consent (HRP-091).

24.0 Setting

24.1 All recruitment and study procedures will take place in the PICU.

25.0 Resources Available

25.1 The study staff include 2 PICU attendings, an anesthesia attending, 2 fellows, a PICU research nurse, an anesthesia research nurse, and an anesthesia data analyst.

25.2 All study staff will be properly trained on the protocol, the research procedures, and their duties and functions.

26.0 Multi-Site Research*

26.1 Not Applicable

27.0 Protected Health Information Recording

1.0 Indicate which subject identifiers will be recorded for this research.

☒ Name
☐ Complete Address
☐ Telephone or Fax Number
☐ Social Security Number (do not check if only used for ClinCard)
☒ Dates (treatment dates, birth date, date of death)
☐ Email address , IP address or url
☒ Medical Record Number or other account number
☐ Health Plan Beneficiary Identification Number
☐ Full face photographic images and/or any comparable images (x-rays)
☐ Account Numbers
☐ Certificate/License Numbers
☐ Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
☐ Device Identifiers and Serial Numbers
☐ Biometric identifiers, including finger and voice prints
☐ Other number, characteristic or code that could be used to identify an individual
☐ None (Complete De-identification Certification Form)

2.0 Check the appropriate category and attach the required form* on the Local Site Documents, #3. Other Documents, page of the application. (Choose one.)

☒ Patient Authorization will be obtained. (Include the appropriate HIPAA language (see Section 14 of consent template) in the consent form OR attach the HRP-900, HIPAA AUTHORIZATION form.)

☒ Protocol meets the criteria for waiver of authorization. (Attach the HRP-901, WAIVER OF HIPAA AUTHORIZATION REQUEST form.)

☐ Protocol is using de-identified information. (Attach the HRP-902, DE-IDENTIFICATION CERTIFICATION form.) (Checked "None" in 1.0 above)

☐ Protocol involves research on decedents. (Attach the HRP-903, RESEARCH ON DECEDENTS REQUEST form.)

☐ Protocol is using a limited data set and data use agreement. (Contact the Office of Technology Commercialization to initiate a Limited Data Use Agreement.

3.0 How long will identifying information on each participant be maintained? Identifying information will be stored for a period of 6 years after study closure and then will be destroyed by placing in a secure shredding bin.

4.0 Describe any plans to code identifiable information collected about each participant. None

5.0 Check each box that describes steps that will be taken to safeguard the confidentiality of information collected for this research:

☒ **Research records will be stored in a locked cabinet in a secure location**

☒ **Research records will be stored in a password-protected computer file**

☐ **The list linking the assigned code number to the individual subject will be maintained separately from the other research data**

☒ **Only certified research personnel will be given access to identifiable subject information**

6.0 Describe the provisions included in the protocol to protect the privacy interests of subjects, where "privacy interests" refer to the interest of individuals in being left alone, limiting access to them, and limiting access to their information. (This is not the same provision to maintain the confidentiality of data.)

Potential patients will only be approached by PICU study staff who are already familiar with the patients. Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study.

Confidential Health Information

1.0 Please mark all categories that reflect the nature of health information to be accessed and used as part of this research.

☒ Demographics (age, gender, educational level)
☒ Diagnosis
☐ Laboratory reports
☐ Radiology reports
☐ Discharge summaries
☒ Procedures/Treatments received
☒ Dates related to course of treatment (admission, surgery, discharge)
☐ Billing information
☒ Names of drugs and/or devices used as part of treatment
☐ Location of treatment
☐ Name of treatment provider
☐ Surgical reports
☒ Other information related to course of treatment
☐ None

2.0 Please discuss why it is necessary to access and review the health information noted in your response above.
It is necessary to review the above health information in order to evaluate the primary outcome of this study and assess for covariates.

3.0 Is the health information to be accessed and reviewed the minimal necessary to achieve the goals of this research? ☒ Yes ☐ No

4.0 Will it be necessary to record information of a sensitive nature? ☐ Yes ☒ No

5.0 Do you plan to obtain a federally-issued Certificate of Confidentiality as a means of protecting the confidentiality of the information collected? ☐ Yes ☒ No