Preoperative gastric point-of-care ultrasound in non-elective surgical procedures in pediatric-aged patients

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PROTOCOL TITLE: Ultrasonographic evaluation of gastric volume and contents before surgery in children

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	11/18/2019	Addition of ultrasound scan of great vessels.	Yes – information sheet updated.
2	9/4/2020	Removal of initials of study investigators to perform scans as other investigators have been trained to complete scans. Alternative scan placement when preferred method not feasible.	No.

1.0 Study Summary

Study Title	Ultrasonographic evaluation of gastric volume and contents before surgery in children
Study Design	Prospective, non-blinded observational study
Primary Objective	The primary objective of this study is to evaluate gastric volume and contents in patients who are scheduled for elective, urgent, and emergent surgery
Secondary Objective(s)	None
Research Intervention(s)/ Investigational Agent(s)	There will be no change in anesthetic management or use of investigational agents.
IND/IDE #	Not applicable
Study Population	Patients who are scheduled for elective, urgent or emergent surgery
Sample Size	300 (100 in each group)
Study Duration for individual participants	Less than 10 minutes
Study Specific Abbreviations/ Definitions	CSA=cross sectional area POCUS=Point-of-Care Ultrasound RSI=Rapid Sequence Induction RLD=right lateral decubitus

2.0 Objectives

2.1 The primary objective of this study is to evaluate gastric volume and contents as well as gall bladder size in patients scheduled for routine, urgent, and emergency surgery.

2.2 The hypothesis is that patients with stress, pain and opioid administration will have delayed gastric emptying and therefore a larger gastric fluid volume than those scheduled for elective surgery. The patients who have an appropriate NPO time will have a larger gallbladder size than the patients with shorter NPO time.

3.0 Background

3.1 Point-of-Care Ultrasonography (POCUS) has been recognized as a powerful tool to evaluate critically ill patients. Using gastric ultrasonography, we can evaluate gastric volume and the types of contents as well as gall bladder size. The cross-sectional area of the gastric antrum is used to calculate the gastric volume. The full stomach state in pediatric patients scheduled for elective surgery is low at only 0-1%. However, it is unknown how lack of appropriate NPO time affects gastric volume and contents as well as gall bladder size. The gallbladder stores bile and starts to empty after the presence of fatty food in duodenum. Gallbladder emptying also

requires relaxation of the sphincter of Oddi, which may be disturbed by opioids. Therefore, it may be useful to evaluate patient NPO status. The diameter of great vessels has been used to evaluate patient volume status in pediatric patients.

3.2 Point-of-care gastric ultrasound had a sensitivity of 1.0 and a specificity of 0.975 to detect a "full stomach". [1] Using point-of-care gastric ultrasound, a previous study reported that 0-1 % of the healthy pediatric patients scheduled for elective surgery were at risk of pulmonary aspiration [2] [3] However, 35 % of the adult patients scheduled for unplanned surgery had a full stomach even after ≥ 6 hours of NPO time [4] The normal gallbladder sizes in healthy children has been evaluated after fasting in previous report. [5] There is no article which reports the relationship between NPO state and gallbladder size.

3.3 Rapid sequence induction (RSI) is widely used to avoid pulmonary aspiration during anesthetic induction. However, RSI is the risk factor for oxygen desaturation and other airway complications when compared to standard anesthetic induction techniques. The current study will help identify which trauma patients are truly at risk for aspiration and therefore require RSI.

4.0 Study Endpoints

4.1 The primary study endpoint is the number (percentage) of patients in the urgent, emergent group with a full stomach state as assessed by gastric volume and contents despite an appropriate NPO time.

4.2 The secondary endpoint will be to determine gall bladder size between fasted patients undergoing elective versus urgent/emergent surgery. The other endpoint will be to evaluate the preoperative volume status.

5.0 Study Intervention/Investigational Agent

1.1 The only novel intervention is the use of ultrasound to evaluate gastric volume and contents, gall bladder size, and diameter of great vessels. Ultrasound is a non-invasive device, used commonly in the perioperative setting for placement of vascular access and regional anesthesia. There will be no change in anesthetic care for the study. There is no risk added by the study and the use of ultrasound.

5.1 The only interventions being used that is not normally used in general clinical practice is ultrasonography. The technique is non-invasive and poses no risk. Ultrasonography will be performed by an

anesthesiologist who has significant experience with Point-of-Care Ultrasound.

6.0 Procedures Involved*

6.1 This is a prospective observational study that will be conducted in 300 patients, ranging in age from 2 to 18 years who are scheduled for routine, urgent or emergent surgeries. There will be no change in clinical practice regarding choice of anesthetic technique as a result of this research study. Before surgery in the pre-operating area, the ultrasonographer will evaluate the gallbladder size and volume. Procedure time will be recorded for the ultrasonography. Demographic data, including age, sex, height, weight, nil per os time, preoperative symptoms, administered opioids, and types of the surgery will be recorded.

6.2

Ultrasound protocol

All ultrasound scans will be performed by study investigators by using Sonosite X-porte (Sonosite Inc. USA) machine and 3-8 MHz curved linear probe with abdominal setting. The investigators have enough experiences of POCUS.

All patients will be lying supine, followed by RLD position. Patients were placed in the supine position, followed by the right-lateral decubitus (RLD) position. In cases where it is not feasible to place the patient in the right lateral decubitus position, the patient can be placed in a 45 degree head up position with a bump placed under the left hip. The gastric antrum is identified in a sagittal plane between the left lobe of the liver and the pancreas at the level of the descending aorta and supra mesenteric artery or inferior vena cava, as previously reported. [6] One video clip will be recorded for each patient in the supine and RLD positions. The qualitative measurements (empty versus nonempty) will be reported to the attending anesthesiologist. The quantitative measurements will be performed at later time. The quantitative exam is performed using the cross-sectional area of the gastric antrum. The CSA of the antrum will be measured with a free-tracing method to follow the outer margin of the antrum corresponding to the serosa. [7] The gastric volume will be calculated using the following formula. [8]

Gastric volume ($ml.kg^{-1}$) = [$-7.8+0.035\times$CSA (mm2) + $0.127\times$ age (months)]/body weight (kg).

The qualitative measurements will be performed using 3-point grading scale. [9]

Grade 0: no fluid visible in the antrum in either the supine or RLD position.

Grade 1: antral fluid visualized only in the RLD position.

Grade 2: antral fluid visualized in both the supine and RLD position.

"Full stomach is defined by the visualization of solid contents or frost-grass pattern and/or by a calculated gastric fluid volume >1.5 $ml.kg^{-1}$.

The gallbladder size and volume will be evaluated as previously reported. [5]

The gallbladder volume was calculated as following formula.

Volume = 0.52×L (the greatest length) ×W (anterior posterior dimension) ×W (transverse width)

B and C are assumed to be equal.

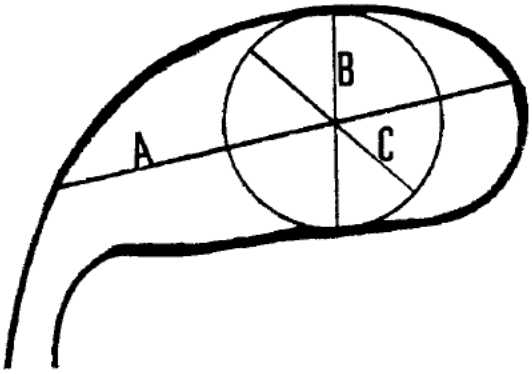

FIGURE 1. Method of sonographic measurement of gallbladders. The gallbladder volume was measured using the prolate ellipsoid volume formula: V = 0.52 × L × W × W. A is the greatest length (L), B is the anteroposterior dimension (W) and C is the transverse width (W). B and C were assumed to be equal.

The diameter of great vessels will be measured in supine position.

Demographic data, including age, sex, height, weight, nil per os time, preoperative symptoms, administered opioids, and types of the surgery will be recorded.

6.3 There are no foreseeable risks associated with the use of ultrasound.

6.4

Ultrasound data will be stored in the ultrasound machine. The research team will transmit the data to the password-secured server and store as MP4 file and JPEG file. The data will then be deleted from the ultrasound machine.

7.0 Data and Specimen Banking*

N/A

8.0 Sharing of Results with Subjects*

8.1 Results will not be shared with subjects.

9.0 Study Timelines*

An individual study subject's participation in the study should last approximately 10 minutes total.

All study subjects should be enrolled within 1 year of study start.

The study should be completed within 18 months of study start.

10.0 Inclusion and Exclusion Criteria*

10.1 Potential subjects will be identified by reviewing the surgery schedule in Epic and will be recruited from the main OR pre-operative area the day of their surgery.

10.2 Inclusion criteria: ASA 1-3 patients aged 2-18 years of scheduled for elective, urgent, or emergent surgery under general anesthesia.

Exclusion criteria: History of upper gastro-intestinal surgery.

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

11.0 Vulnerable Populations*

11.1 This study presents no more than minimal risk as it only involves ultrasound which is non-invasive, and written consent is normally not required.

12.0 Local Number of Subjects

12.1 300 (100 in each group of routine, urgent, and emergent cases).

13.0 Recruitment Methods

13.1 Potential subjects will be recruited in surgical preoperative area on the day of the surgery. The research team will contact the guardian/parents and obtain verbal consent. Verbal assent will also be obtained from age appropriate patients.

13.2 The patients to be recruited are those who are scheduled for surgery under general anesthesia in NCH operating rooms.

13.3 Using Epic, the research team will check the patients scheduled for unplanned surgery in the NCH operating rooms.

14.0 Withdrawal of Subjects*

N/A

15.0 Risks to Subjects*

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

15.2 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. Subject PHI will be stored in a locked cabinet, and will be stored and maintained in password protected computer files.

16.0 Potential Benefits to Subjects*

16.1 The qualitative finding will be given to the attending anesthesiologists. This information may impact subsequent anesthetic induction.

17.0 Data Management* and Confidentiality

17.1 Summary statistics will be described by using means and standard deviation for parametric variables and median with interquartile ranges (IQRs) for nonparametric variables. The Kolmogorov-Smirnov test will be used to assess the normality of data. Bivariate analysis for paired continuous variables will be conducted using the paired t test and Wilcoxon signed-rank test, and for independent continuous variables it is conducted using the independent samples t-test and Wilcoxon rank-sum test. Bivariate analysis for categorical variables will be conducted using the Chi-square test or Fisher's exact test, where appropriate. P value less than 0.05 is considered to indicate statistical significance. Statistical analysis will be done using SAS 9.4 and G*Power version 3.1.9.2.

Primary Outcome: The primary outcome is the proportion of full stomach state.

17.2 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

17.3 Following publication of study results, research records will be stored for a period of 3-5 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*

The study will only be monitored by the study investigators.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 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.

20.0 Compensation for Research-Related Injury

N/A

21.0 Economic Burden to Subjects

N/A

22.0 Consent Process

22.1 We are requesting a waiver of informed consent documentation. Subjects will receive a complete explanation of the study and will be asked to consent verbally. Subjects will receive a written summary of the research as outlined in the attached written Study Information Sheet. Subjects will not be asked to sign a consent form.

23.0 Process to Document Consent in Writing

N/A

24.0 Setting

The research team will identify the potential subjects in anesthesia office by Epic and recruit them in the preoperative area. Research procedures will be performed in the pre-operating room.

25.0 Resources Available

25.1 We will need approximately 20 minutes per patient to explain the research protocol, obtain consent, and enroll patients. The Department of Anesthesiology and Pain Medicine has 2 research coordinators/RNs and 2 research associates that will be enrolling subjects for this study. All study staff will be trained on the study procedures.

Before the study start, the study protocol, the research procedures, research member's duties, and functions will be informed by e-mail. After the e-mail is sent, the research meeting will be held.

26.0 Multi-Site Research*

N/A

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.

***Find the HIPAA forms in the IRB Website Library, Templates.**

Attach the appropriate HIPAA form on the "Local Site Documents, #3. Other Documents", page of the application.

3.0 How long will identifying information on each participant be maintained?

Following publication of study results, research records will be stored for a period of 3-5 years 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.
N/A

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.)

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. Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

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.

Demographics need to be recorded to describe patient characteristics. Diagnosis and procedures need to be assessed for inclusion criteria. Names of medications need to be recorded to clarify the standardized management.

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

References:

1. Kruisselbrink R, Gharapetian A, Chaparro LE, et al. Diagnostic Accuracy of Point-of-Care Gastric Ultrasound. Anesthesia & Analgesia 2019;128:89-95.
2. Desgranges FP, Gagey Riegel AC, Aubergy C, de Queiroz Siqueira M, Chassard D, Bouvet L. Ultrasound assessment of gastric contents in children undergoing elective ear, nose and throat surgery: a prospective cohort study. Anaesthesia 2017;72:1351-6.
3. Bouvet L, Bellier N, Gagey-Riegel AC, Desgranges FP, Chassard D, De Queiroz Siqueira M. Ultrasound assessment of the prevalence of increased gastric contents and volume in elective pediatric patients: A prospective cohort study. Paediatric anaesthesia 2018;28:906-13.
4. Dupont G, Gavory J, Lambert P, et al. Ultrasonographic gastric volume before unplanned surgery. Anaesthesia 2017;72:1112-6.
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6. Engelhardt T. Rapid sequence induction has no use in pediatric anesthesia. Paediatric anaesthesia 2015;25:5-8.
7. Kruisselbrink R, Arzola C, Endersby R, Tse C, Chan V, Perlas A. Intra- and interrater reliability of ultrasound assessment of gastric volume. Anesthesiology 2014;121:46-51.
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9. Perlas A, Davis L, Khan M, Mitsakakis N, Chan VW. Gastric sonography in the fasted surgical patient: a prospective descriptive study. Anesth Analg 2011;113:93-7.