The use of point of care ultrasound in detecting postoperative ileus – the GUILE study

Investigators

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Study Sites

St. Vincent's Hospital Melbourne

The Austin Hospital

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Introduction/Background

Post-operative Ileus (POI) is an important contributor to causes of prolonged hospital stay, delayed postoperative recovery, and increased postoperative morbidity (1,2,3).

The incidence of POI has been quoted as between 8.5% and 10% of surgical patients (1,2). The pathophysiology is complex and multifactorial, where the physiological stress of surgery, manual handling of the alimentary tract, anaesthetic and opiate analgesic administration leads to the failure of normal peristalsis and gastric motility in the days following surgery (3,4). It is defined as a transient cessation of coordinated bowel motility that prevents effective transit of intestinal contents or tolerance of oral intake (3), and clinically characterised by the absence of flatus and the passage of stool, abdominal distension, abdominal tenderness, nausea, vomiting and inability to tolerate oral feeds (2)**.**

POI can be classified into primary (occurs in the absence of an surgical complication) or secondary (in the presence of a post-surgical complication such as sepsis or an anastomotic leak), and additionally as recurrent, should there be an apparent resolution of POI that then reoccurs (3)**.** While a certain period of gastrointestinal paralysis in response to the stress of surgery is to be anticipated, components of the gastrointestinal tract should return to their normal function in stages (4).

Currently, the diagnosis of POI is based on clinical symptoms and observations of the treating clinician, and it would be desirable to have a more objective assessment tool in the identification of POI.

The primary aim of this study is to establish whether point of care ultrasound can identify and predict any markers of gastro-intestinal dysfunction and therefore help detect patients who go on to develop clinical post operative ileus.

Aims/Objectives

Primary Outcome:

- The use of point of care ultrasound to develop potential ultrasound markers of gastro-intestinal dysfunction in patients who go on to develop clinical post-operative ileus.

Secondary Outcome:

- The use of ultrasound of the small and large bowel
- To identify any associated biomarkers from routine post operative bloods

Methodology

This study will take the form of a prospective, non-randomised, observational cohort study. Patients presenting to participating hospital sites for non-emergency colorectal resection operations will be invited to be part of this study.

Ultrasound of participants will be undertaken, as outlined in the ultrasound protocol section below. A screening ultrasound scan will be performed with participant fasted on day of surgery. On post-operative day 1 and 2, a fasting scan and subsequent scans at 20 and 40 minutes after a 250mL oral water challenge. Patients will be classified as having abnormal gastric emptying if their gastric antrum is not empty at 40 minutes. If there is lack of gastric emptying at 40 minutes, a 60 minute scan will be performed. Quantitative measurements will include gastric antrum cross-sectional area and peristalsis of the small and large bowel will be categorised as absent or present. Should no view be attainable on ultrasound, this will be recorded.

All participants will undergo ultrasound scans on day of surgery and postoperative days one and two. In participants found to have normalised gastric emptying times, are tolerating oral intake, have re-established a diet, have normal peristaltic action o the small and large bowel, further scanning will be ceased. In those participants whose gastric emptying times have not normalised on postoperative day two, will continue to have the ultrasound scan on post-operative days 3 and 4. No further scans will be performed after post-operative Day 4. Participants who have been designated as nil by mouth by their treating team shall undergo the first ultrasound scan but no water oral challenge will be administered. At any point during the

ultrasound scan, if the participant is feeling sufficiently uncomfortable or are in pain, the scan will be abandoned.

I-FEED scores to be recorded at each ultrasound time point, with Intake, Feeling Nauseated, Emesis, Exam findings and Duration of symptoms being scored from 0 to 3 (5). The scores in each section, total score and categorisation of gastric function to be recorded. I-FEED scores of 0-3 denote normal gastric function, 4-7 defined as postoperative gastric intolerance and 8-10 defined as postoperative gastric dysfunction (5).

Ultrasound Protocol

1. Gastric Antrum will be imaged using a portable ultrasound machine and low-frequency probe with ultrasound gel on the abdominal wall. Participants will be placed in the right lateral decubitus position and the ultrasound probe placed in the epigastric area in a parasagittal orientation.
    a. The gastric antrum will be located using the left lobe of the liver and abdominal aorta as markers. Once the antrum has been located, the upper surface of the pool of liquid in the antrum will be located (moving the probe left laterally across the abdomen) and the anteroposterior and craniocaudal diameters should be recorded. Peristaltic waves will be recorded as present or absent. The cross-sectional area and gastric volume will be calculated using a validated formula (6).
        i. Cross-sectional Area (cm^2) = (Anteroposterior Length (cm) x Craniocaudal Length (cm) x π)/4
        ii. Gastric Volume (ml) = 27.0 + 14.6*CSA – 1.28*Age
2. The small and large bowel will be assessed using a low-frequency probe. This may be imaged in the right iliac fossa or periumbilical area. Once located, the luminal diameter and wall thickness will be measured. Peristaltic waves will be observed and categorised absent or present

Data to be collected will include:

Pre-Operative Data

1. Demographic Data

    a. UR number, age, weight, height, BMI, gender.
2. Medical history and current medications
    a. History of postoperative nausea and vomiting
3. American Society of Anaesthesiologists (ASA) Classification

Intra-operative Data

1. Mode of anaesthetic.
2. Operation type
3. Operative access
4. Operative time
5. Presence or absence of drain tubes.

Post-operative Data

1. Ultrasound parameters as outlined in the ultrasound protocol.
2. Routine bloods collected during surgical admission including,
    a. FBE and Electrolytes
    b. 5-10mls of blood preoperatively and postoperatively for inflammatory biomarkers
3. Daily diary of oral intake, opening of the bowels or passage of flatus.
4. I-FEED score to be recorded at each ultrasound timepoint.
    a. Total score and characteristic scores to be recorded.
5. Additional information to be collected
    a. Complications
        i. Insertion of a nasogastric tube due to development of clinical postoperative ileus. Any aspiration or vomiting events to be recorded.
        ii. Surgical complications (hernias, anastamotic leak, perforation, infection, etc to be recorded using the Clavien-Dindo classification.
    b. Length of stay
    c. Pain score to be done each day
        i. Any ongoing pain management dosages and timings of doses to be recorded

Population/Participants

All patients undergoing elective colorectal resection surgery at St Vincent's Hospital will be invited to be part of this study.

Exclusion criteria

- Any patient unwilling to unable to give consent to be part of the study
- Any patient who is less than 18 years of age.
- Any patient who is currently pregnant or who has been pregnant in the last 3 month period.
- Any patient has undergone previous upper gastrointestinal tract surgery or has distorted upper gastrointestinal tract anatomy (i.e. hiatus hernia)

Sample size: 90 patients recruited over 12 months is expected to be sufficient to detect an incidence of delayed gastric emptying of 33% with an error of +/-10%.

Data Collection

Data will be collected using the hospital medical records and also patient's medical history files. All data will be collected using password protected excel spreadsheet and de-identified. De-identification process will be performed by creating a linking document to replace identifiable patient details with case number. Only the study investigators will have access to the data sheets. The de-identified linked dataset will be stored on St Vincent's Hospital password protected secure network server.

Data Analysis

Statistics will be presented using tables, graphs and descriptive statistics. The data will be described as medians, proportions and percentages. Continuous variables will be tested for normality, with data not being normally distributed, median and inter

quartile range will be presented. Categorical data will be analysed using Chi-squared analysis with Odds ratios and 95% CI presented.

Univariate logistic regressions will be used. A multivariate logistic regression will be used to determine predictors of peri-operative outcomes while controlling for other significant co-variables identified ion univariate analysis. Statistical analyses will be performed using SPSS 22.0 (IBM SPSS Statistics for Windows, Armonk, NY, USA)

Data Management

Data will be retained for a period of seven years from the date of collection.

Data will be destroyed in accordance with local St Vincent's Hospital policies. All storage media containing patient data will be disposed of securely and safely when the data is no longer required.

Ethical considerations

Ethical approval will be obtained from the Victorian State Government prior to beginning the research project. The study will be developed and carried out in accordance with the Declaration of Helsinki, 2013.

This study will be conducted whilst maintaining full confidentiality of patients. All data collected as part of this study will be stored as non-identifiable data. The data will be stored for 7 years on secure St Vincent's Hospital network server for a minimum of 7 years.

Data Safety and monitoring will be overseen by the Head of Clinical Research, Department of Anaesthesia, St Vincent's Hospital Melbourne.

Dissemination of Results

We would intend to publish the results in a peer reviewed journal and/or present the results at an anaesthesia or surgical conference. All data will be presented/published in non-identified manner.

Results of this pilot study may be combined with those from a larger prospective study in the near future for publication in academic journals and/or presentation in academic conferences. Data obtained from this pilot study may be used in the design and planning of a larger scale prospective study in the near future.

Study Timeline

Activities	Period of time from December 2020 to December 2021												
	Dec -20	Jan -21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sept-21	Oct-21	Nov -21	Dec -21
Development of research/project proposal													
Submit Ethics Application													
Recruitment and Data collection													
Data cleaning and Analysis													
External Conference Presentation													
Publication													

References

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