Ultrasound Meal Accommodation Test for Enteral Feeding in the Critically Ill

STUDY DESCRIPTION

Brief Summary

Within the context of intensive care units (ICU), enteral nutrition (NE) is an essential tool in the management of critical patients. Gastrointestinal dysfunction causes significant difficulties in implementing enteral nutrition, and constitutes one of the main medical or non-avoidable causes to avoid enteral feeding in critically ill patients. Gastric ultrasound is a validated tool to non-invasively evaluate gastric volume and content. The purpose of this study is to evaluate the use of this test in critically ill patients for initiation and tolerance of the enteral feeding.

Condition or Disease: Enteral Feeding Intolerance

Intervention/treatment: Other: Ultrasound meal accommodation test

Phase: Not Applicable

DETAILED DESCRIPTION

Within the context of intensive care units (ICU), enteral nutrition is an essential tool in the management of critical patients, because it preserves the structure and function of the gastrointestinal mucosa, decreases the catabolic response to injury when it is administered early, and could also reduce the incidence of bacterial translocation. These factors could play an important role in reducing infectious complications, compared with parenteral nutrition. Current clinical practice guidelines, have agreed on the need to implement early enteral nutrition in the critically ill patient. Moreover, today it is considered one of the quality standards in the intensive care units. However, it is often not feasible to initiate early enteral nutrition due to the high incidence of gastrointestinal complications that act as a limiting factor. Within the gastrointestinal complications seen in the critically ill patient, gastroparesis is usually the most frequent caused in general by the delay of gastric emptying in the absence of mechanical obstruction, and is manifested by a high volume of gastric residue. It is a frequent problem and difficult to manage in ICUs, with a reported incidence of up to 50-60% in critical patients in mechanical ventilation (MV). Gastroparesis causes significant difficulties in implementing enteral nutrition, and constitutes one of the main medical or non-avoidable causes of its suspension; it can also cause hydroelectrolytic and acid-base disorders if the volume of gastric residue is of great magnitude. In addition, gastroparesis may favor gastroesophageal reflux and bacterial overgrowth, with increased risk of pulmonary aspiration, pneumonia and sepsis. Several factors have been implicated in the deterioration of gastrointestinal motility in critical patients. The most important are mechanical ventilation, the use of opioids, catecholamines (mainly dopamine), the presence of brain injury, sepsis, hyperglycemia, supine position, among others. However, there are aspects not yet defined with respect to their diagnostic criteria and their management.

Gastric ultrasound is a validated tool to non-invasively evaluate gastric volume and content and predict the risk of pulmonary aspiration. It has a high sensitivity and specificity that makes it a gold standard. Its implementation in the preoperative evaluation of emergency surgery has proven to be a cost-effective test, that allows reducing the morbidity and mortality of patients, establishing preventive measures and intubation techniques that limit or eliminate the risk of pulmonary aspiration, reducing the days of stay Hospital and mortality. Based on the knowledge generated by gastric ultrasonography, the concept of “risk stomach” was coined. Bouvet defines “stomach of risk” when the gastric volume exceeds 0.8 mL / kg of weight, measured by transverse ultrasound at the level of the gastric antrum. This model can predict volumes from 0 to 500 mL and is applicable to adult patients with a body mass index of less than 40 kg / m². The sensitivity and specificity of this model is 100%, which makes it the “gold standard” for non-invasive assessment of the stomach risk of lung gastric aspiration. The margin of error of the measurement is ± 6 mL.

In patients with dyspepsia, the Gastric Accommodation Test guided by ultrasound has given good results as a diagnostic method for gastrointestinal disorders. In critically ill patients the clinical assessment of gastrointestinal function is not recognized, which leads to poor evolution with an increase in mobility and mortality. The current recommendations in critical patient nutrition are the initiation of enteral diet when it is possible, however, we do not have a monitoring method or biomarkers of gastrointestinal dysfunction, so intolerance can lead to life-threatening complications, and even more so now that the gastric residue has been identified as a risk factor for malnutrition (by removing the caloric content before absorption) and is also considered a risk factor for pneumonia associated with mechanical ventilation.

The advantage of using ultrasound at the patient’s bedside is that it reduces the risk of Broncho-aspiration and malnutrition with a non-invasive, radiation-free and cheap method. The purpose of this study is to evaluate the use of this test in critically ill patients for initiation and tolerance of enteral diet.

Objectives.

1. To evaluate the ULTRASOUND GUIDED GASTRIC DYNAMICS TEST FOR TOLERANCE OF ENTERAL DIET IN CRITICAL PATIENTS Hypothesis The ULTRASOUND GUIDED GASTRIC DYNAMICS TEST FOR ENTERAL DIET TOLERANCE IN CRITICAL PATIENTS (UMATI PROTOCOL) is useful for evaluating the initiation of enteral diet in critically ill patients with gastrointestinal dysfunction.

Standardization of the ultrasound test All patients admitted to intensive therapy who present risk for gastrointestinal dysfunction grade I to III (tolerance to enteral diet should be assessed but not contraindicated) to observe their tolerance will be passed 500 mL of solution with glutamine, OR Casenate and the protocol will be carried out. (Table 2) performing ultrasonographic measurements and observing changes in cross sectional area of the gastric antrum of the first measurement at the time after administration. Gastric residue will be measured. All risk factors for known gastrointestinal dysfunction and relevant data of the clinical history, age, gender, BMI, time of initiation of enteral nutrition will be recorded. The latter will be evaluated individually for each patient according to known risk factors (mainly absolute contraindications for the onset of enteral nutrition in critical patients.

The gastric volume by ultrasound will be calculated according to the model of Pearls GV (ml) = 27.0 + 14.6 × right-lateral cross sectional area (cm²) - 1.28 × age (yr)
Study Type: Interventional

Estimated Enrollment: 61 participants

Intervention Model: Single Group Assignment

Masking: None (Open Label)

Primary Purpose: Other

Official Title: Ultrasound Meal Accommodation Test for Enteral Feeding in the Critically Ill

Actual Study Start Date: April 2019

Actual Primary Completion Date: November 2019

Actual Study Completion Date: December 2019

ARMS AND INTERVENTIONS

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<th>Arm</th>
<th>Intervention/treatment</th>
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<tr>
<td>Other: Ultrasound meal accommodation test, ultrasound guided gastric dynamics test for tolerance of enteral feeding, 500 ml of water with protein (glutamine or casein) will be administered</td>
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<tr>
<td>Other: Ultrasound meal accommodation test, to observe their tolerance a 500 ml of solution with glutamine, or Casein and the protocol will be carried out will be given. Ultrasound measures will be performed and observing changes in Cross Sectional Area of the gastric antrum of the first measurement at the time after administration. Gastric residue will be measured</td>
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OUTCOME MEASURES

Primary Outcome Measures: 1. GASTRIC CROSS SECTIONAL AREA DIAMETER CHANGE [ Time Frame: 1 hour ] measure the diameter of the gastric cross sectional area change in time to evaluate enteral feeding tolerance

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 80 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Patients diagnosed with gastrointestinal dysfunction who enter the intensive care unit grade I to III
- That they agree to participate in the study and sign informed consent
- Haven’t eat for more than 36 hours

Exclusion Criteria:
- Patients with grade IV gastrointestinal dysfunction
- Patient with absolute contraindication for the start of the enteral diet

CONTACTS AND LOCATIONS

Contacts

Locations

Mexico, Queretaro
- Hospital de Especialidades Del Niño Y La Mujer
- Querétaro City

Sponsors and Collaborators

Grupo Mexicano para el Estudio de la Medicina Intensiva

Investigator

Principal Investigator: Angel Augusto Perez-Calatayud, MD

Head ICU

MORE INFORMATION


Responsible Party: Grupo Mexicano para el Estudio de la Medicina Intensiva

ClinicalTrials.gov Identifier: NCT03851354
**Other Study ID Numbers:** DI1711203047

**First Posted:** February 22, 2019

**Last Update Posted:** January 27, 2020

**Last Verified:** January 2020

**Individual Participant Data (IPD) Sharing Statement:**

- **Plan to Share IPD:** Yes
- **Plan Description:** No plan has been developed
- **Supporting Materials:** Study Protocol, Statistical Analysis Plan (SAP), Informed Consent Form (ICF), Clinical Study Report (CSR), Analytic Code
- **Time Frame:** Data will be available as soon as the statistical analysis is finished
- **Access Criteria:** Open
- **Studies a U.S. FDA-regulated Drug Product:** No
- **Studies a U.S. FDA-regulated Device Product:** No
- **Keywords provided by Grupo Mexicano para el Estudio de la Medicina Intensiva:** enteral feeding, gastric ultrasound
- **Additional relevant MeSH terms:** Critical Illness, Pathologic Processes, Disease Attributes