Cover page

Title: Safety and Efficacy of CO2 for Endoscopy

NCT 03287687

1/1/2020

Study Protocol:

The current literature in pediatric endoscopy does not include evidence on effectiveness and safety of CO2 insufflation in procedures besides colonoscopy and does not include children in the younger age range. Esophagogastroduodenoscopy procedures (EGDs) are much more commonly performed procedures in children so it is important to assess these clinical scenarios before adopting CO2 insufflation as the main mode of practice.

Our study aimed to address these knowledge gaps by enrolling younger children, including infants, and a wide variety of endoscopic procedures, including EGDs and percutaneous endoscopic gastrostomy (PEG) tube placement.

Study Design

This is a double-blinded, prospective, randomized study comparing CO_2 and air for insufflation during endoscopic procedures in pediatric patients performed in the Pediatric Endoscopy Unit at the University of Iowa Children's Hospital. The study was approved by the Institutional Review Board (IRB) at the University of Iowa

Subjects and Randomization

Patients aged 6 months to 21 years undergoing diagnostic or therapeutic endoscopic procedures were offered participation. These procedures included EGD, colonoscopy, PEG tube placement, and endoscopic PEG tube exchange. Exclusion criteria included non-English-speaking families needing an interpreter and patients with significant chronic lung disease, such as bronchopulmonary dysplasia, severe asthma, or cystic fibrosis. Consents and assents were obtained proper to enrollment.

Both the patient and endoscopist were blinded to the arm of study. Randomization was done by the procedure suite nurse using a sealed envelope system. To maintain allocation concealment, the nurse set up the equipment to deliver CO2 or air then covered the relevant equipment settings

to assure complete blinding of the endoscopist and others in the room. The equipment was adjusted to deliver CO2 or air at a similar flow rate.

Data Collection

Collected data included patient demographics (age, sex, growth parameters), procedure indication, patient's overall health status based on the American Society of Anesthesiologists (ASA) classification, endoscopy-related characteristics (duration, trainee vs faculty endoscopist and complications) and anesthesia-related parameters (duration, medication dosing, and complications). Vital signs, including EtCO2, heart rate, respiratory rate, oxygen saturation, and blood pressure were monitored and automatically recorded continuously throughout the procedure, according to the anesthesia protocol. EtCO2 was monitored and continuously sampled by nasal prong or via capnography for intubated patients.

Outcome Measures

Patient discomfort was assessed using 3 scales:

1. Face, Legs, Activity, Cry, and Ability to be Consoled (FLACC) behavioral assessment score

2. Global Parent Perception of Pain (PPP) scale

3. FACES scale; for neurodevelopmentally appropriate children 5 years and older.

Pain

FLACC at baseline, within 15 minutes of return to recovery area, when awake. FLACC scores categorized as no pain, mild pain, moderate to severe pain, very severe pain or worst pain ever

PPP at baseline, when awake and 4 hours post discharge. PPP scores categorized as no pain, mild pain, moderate to severe pain, very severe pain or worst pain ever

VAS at baseline, when awake and 4 hours post discharge. VAS scores categorized as no pain, mild pain, moderate to severe pain, very severe pain or worst pain ever

Abdominal girth at baseline, after procedure, at discharge, and 4 hours post discharge

Endoscopist assessment

Perceived ease of inflation: easy or average, mild difficulty, very difficult

Perceived patient discomfort: comfortable or average discomfort, above average discomfort

Endoscopist guess of inflation gas

Abdominal girth was measured by the same nurse at the level of the umbilicus before the procedure, immediately upon arrival in the recovery area after the procedure, and again just before discharge. Patients were sent home with a tape measure and a postage-prepaid response card on which they recorded the abdominal girth four hours after completion of the procedure. Parents were also asked to indicate if the patient had experienced belching, bloating or flatulence.

Sedation for all procedures was provided by an anesthesia team lead by a pediatric anesthesiologist, who was also blinded to the study group allocation. For most patients, anesthesia consisting of a continuous propofol infusion without an advanced airway such as endotracheal intubation was used. When indicated, based on the patient and procedure characteristics, general anesthesia with endotracheal intubation was occasionally used.

Data were entered into Redcap software. Adverse events defined as any undesired event occurring during endoscopy, and sedation-related complications such as hypoxia and aspiration were reported at regular intervals to the IRB during enrollment.