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CLINICAL INVESTIGATION

Randomised controlled trial comparing preoperative carbohydrate loading with standard fasting in paediatric anaesthesia

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Abstract

Background: Preoperative fasting is a major cause of perioperative discomfort in paediatric anaesthesia and leads to postoperative insulin resistance, thus potentially enhancing the inflammatory response to surgery. Addressing these problems by preoperative carbohydrate intake has not been a well-defined approach in children.

Methods: We randomised 120 children scheduled for gastroscopy under general anaesthesia to either a control group of standard preoperative fasting or a study group receiving a carbohydrate beverage (PreOpTM; Nutricia, Erlangen, Germany). Their stomach contents were aspirated endoscopically, and the volume and pH measured. Perioperative discomfort was evaluated using, among other parameters, an observational pain scale in \leq 4-yr-olds and a VAS in >4-yr-olds. The investigators doing the endoscopies and outcome evaluations were blinded to the study group allocation.

Results: Compared with fasting, carbohydrate loading was associated with significantly less gastric content (P=0.01), fewer patients experiencing postoperative nausea (P=0.028), with no significant difference in postoperative vomiting. High preoperative VAS scores (>5) were recorded for only one child in the carbohydrate group v five children in the fasting group. Bowel cleansing for simultaneous colonoscopies (v=61) made no difference to any of the intergroup findings.

Conclusions: Preoperative carbohydrates can reduce nausea and gastric content, the latter being a surrogate parameter for the risk and severity of gastric aspiration into the lungs during anaesthesia. Our study adds knowledge for preoperative fasting guidelines in paediatric anaesthesia.

Clinical trial registration: DRKS00005020.

Keywords: anaesthesia; children; gastric emptying; preoperative period; postoperative period

Editor's key points

- Preoperative fasting causes children additional stress and discomfort.
- Fasting also increases insulin resistance and may enhance the inflammatory response to surgery.
- In this randomised controlled trial, the authors studied the influence of oral carbohydrate intake 2 h before gastroscopy.
- Children who received a carbohydrate drink had less gastric content and less postoperative nausea than those undergoing routine fasting.

Children undergoing surgery are stressed as they are removed from their daily routine and are subjected to a number of perioperative procedures that cause anxiety and malaise. One major cause of discomfort is the requirement for preoperative fasting, which is accepted across the world as a precaution to minimise the risk of aspiration and regurgitation during induction of general anaesthesia. Based mainly on recommendations issued by anaesthesia societies,3 the current guideline for preoperative fasting in paediatric surgery is 6 h for solid foods, 6 h for formula milk or cow milk, 4 h for breast milk, and 2 h for clear fluids. $^{4-6}$ The strategy of preoperative fasting accounts for a significant share of postoperative nausea and vomiting, and other reactions such as postoperative pain and the inflammatory response to surgery may also be affected.

Preoperative oral intake of a carbohydrate fluid may decrease postoperative nausea and vomiting and reduces postoperative pain⁸ and the inflammatory response to surgery. Pagulation of carbohydrate metabolism responds by releasing insulin at similar concentrations to those seen after a normal meal, and perioperative insulin resistance is reduced. ¹⁰ In addition, such carbohydrate loading may help to reduce thirst, hunger, and anxiety. 11 Initial promising reports using high-carbohydrate beverages in children are published, 12 but investigations where gastric content is directly measured are not available. Therefore, we designed a randomised controlled trial to assess how a commercially available carbohydrate beverage, labelled as a dietary supplement for preoperative oral administration, would affect the gastric contents and various parameters of perioperative discomfort in children subjected to general anaesthesia.

Methods

Preparation and patient enrolment

We obtained approval of the study protocol from the institutional review board (ethics committee) at the Medical University of Vienna (ref. 1622/2013), Vienna, Austria, and registered the study in the German Clinical Trial Register (DRKS00005020). Registration with the Austrian Medicines and Medical Devices Agency was not required, as the carbohydrate beverage under study (see next paragraph) is labelled as a dietary supplement. All parents and all >8-yr-olds gave their written informed consent 1 day before surgery to participate after having received comprehensive information about the nature and scope of the study, and about the procedures to be conducted.

Patient selection and study groups

We included 120 patients (2-18 yr old) from the Department of Paediatrics and Adolescent Medicine (Medical University of Vienna, Austria). Children <2 yr were not included in this study as the product information of PreOpTM (Nutricia, Erlangen, Germany) indicates that it is not suitable for infants. In addition, endoscopic procedures in children <2 yr is extremely rare. All children between 2 and 18 yr of age were scheduled for elective endoscopic examinations (gastroscopy with or without colonoscopy) under general anaesthesia. Indications for endoscopic procedures were suspected gastritis, gastroduodenal ulcus, portal hypertension, chronic bowel inflammation, Crohn's disease, or suspected bowel adenoma. All patients undergoing colonoscopy received additional gastroscopy. Patients at risk for aspiration (related to their underlying disease), on H₁ antagonist or corticoid therapy, or those refusing $\mathsf{PreOp^{\scriptscriptstyle TM}}$ were excluded. Using a computerised randomisation protocol, each patient was assigned to one of two groups: a control group managed by a standard protocol of preoperative fasting [6 h for solid foods, 4 h for breast milk, 2 h for clear fluids (water, tea)] or a study group in which 5 ml kg⁻¹ of a lemon-flavoured carbohydrate beverage (PreOp $^{\text{TM}}$) was administered on the evening and exactly 2 h before the scheduled endoscopic procedure. The nutrition value of PreOpTM per millilitre is 0.5 kcal (=2.15 kJ) and 0.126 g carbohydrate. It does not contain protein or fat.

The compliance regarding preoperative fasting times were monitored by one of the authors of this study (B.A.T.).

General anaesthesia

Vascular access having been established on the ward, general anaesthesia was induced with remifentanil 0.5 μg kg⁻¹ min⁻¹, propofol 4–6 mg kg $^{-1}$, and rocuronium 0.6 mg kg $^{-1}$. This was followed by tracheal intubation, using an appropriately sized cuffed tube, and maintenance of general anaesthesia with remifentanil 0.25 $\mu g \ kg^{-1} \ min^{-1}$ and propofol 6 $mg \ kg^{-1} \ h^{-1}$. Elo-Mel Isoton (Fresenius Kabi; Friedberg, Germany) 10 ml $\rm kg^{-1}$ $\ensuremath{h^{-1}}$ was used for i.v. fluid administration. Then, the endoscopic procedure was performed (see below). Before the ensuing extubation, we assessed the degree of muscle relaxation by relaxometry and, if indicated, administered sugammadex 1 mg kg⁻¹ to antagonise rocuronium.

Endoscopic procedure (gastroscopy with or without colonoscopy)

A gastric endoscope (Q180 or H180; Olympus, Hamburg, Germany) was inserted through the oesophagus into the stomach and the entire gastric content aspirated to measure its volume (primary outcome parameter of the study; see below) and to analyse its pH using non-bleeding indicator strips (MColorpHast™; Merck, Darmstadt, Germany). An additional colonoscopy was performed in about half of all patients (n=61). These patients had received a bowel cleanse (PicoprepTM; Ferring Arzneimittel, Kiel, Germany) dissolved in an agedependent fashion in 50-150 ml of water 18 and 12 h before induction of anaesthesia. At the end of the examination, care was taken to evacuate all air from the gastrointestinal tract before removing the endoscope. The investigators performing the endoscopies (with gastric-content extraction) and the perioperative outcome evaluations were blinded to the (carbohydrated vs fasting) group assignment.

Outcome parameters

Volume and pH of each patient's stomach content were used and evaluated as the primary outcome parameters of this

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