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Preoperative liquid gastric emptying rate does not predict outcome after fundoplication☆,☆☆,★

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ABSTRACT

Aim of the study: Preoperative gastric emptying (GE) rate in patients with gastrointestinal reflux disease (GERD) was evaluated as a predictor of outcome after antireflux surgery.
Methods and patients: GE was assessed using radionuclide scintigraphy and a standardized meal with cow's milk. GE half time (T1/2), patient demographics and GERD symptoms including vomiting (>4 days/week), retching (>4 days/week), prolonged feeding time (>3 h/day), and discomfort after meals were recorded pre- and postoperatively. A standardized follow-up included a 24-h pH-monitoring and an upper gastrointestinal contrast study. Of 74 patients undergoing Nissen fundoplication between 2003 and 2009, 35 underwent a preoperative GE study. The remaining 39 patients were not examined owing to volume intolerance, cow's milk intolerance or allergy, inability to lie still, or parents refusing participation.
Main results: Median age at fundoplication was 4.9 [range 1.1–15.4] years, and follow-up time was median 4.3 [1.9–8.9] years. GERD recurred in 7 (20%) patients. Preoperative T1/2 in the seven patients with recurrent GERD was median 45 [21–87] min compared to 44 [16–121] min in the 28 patients without recurrent GERD ($p = 0.92$). There was no significant difference between the one third of patients with the slowest GE [T1/2 54–121 min] and the remaining patients [T1/2 16–49 min] regarding GERD recurrence or postoperative vomiting, retching, prolonged feeding time, or discomfort after meals.
Conclusion: Preoperative GE rate did not predict outcome after antireflux surgery, as slow GE was not associated with recurrent GERD or postoperative troublesome symptoms such as vomiting, retching, or meal discomfort.
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It is debated whether delayed gastric emptying (GE) is associated with or contributes to gastroesophageal reflux disease (GERD) [1]. Furthermore, it is controversial whether delayed GE affects outcome after fundoplication [2–9]. Some studies show that the recurrence rate of GERD after fundoplication is higher in patients with delayed GE [2,10,11]. There are also indications that patients with delayed GE more often experience postfundoplication problems such as early satiety, feeding difficulties, gas-bloat, and retching [4,11,12]. Some studies indicate that a pyloromyotomy or pyloroplasty concomitant with a fundoplication may reduce the recurrence rate in those with delayed GE [2,11]. On the other hand, other studies fail to show any major impact of GE rate on outcome after antireflux surgery [3,5–9]. To ensure that pediatric patients are offered the most optimal antireflux surgery if conservative GERD treatment fails, more knowledge on GE and how it may influence outcome after fundoplication is warranted. Therefore, we have examined if preoperative delayed GE in children is related to recurrence of GERD and symptoms of feeding difficulties, retching and bloating after fundoplication.

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1. Patients and methods

Children undergoing Nissen fundoplication from January 2003 to December 2009 at Oslo University Hospital, Rikshospitalet, a tertiary pediatric surgical center, were considered for inclusion. Criteria for undergoing fundoplication were troublesome symptoms of GERD despite conservative treatment including use of proton pump inhibitors. In addition, GERD had to be objectively verified by 24-h pH-monitoring (reflux index >4%) and/or upper gastrointestinal contrast study (massive gastroesophageal reflux (GER) and/or hiatal hernia). Exclusion criteria were previous antireflux surgery, major abdominal surgery within the last six months prior to referral, and parents that did not speak Norwegian. Of the 89 children undergoing fundoplication at Rikshospitalet during this time period, a total of 74 children fulfilled the criteria and were considered eligible for inclusion. The present study was part of a randomized trial comparing outcome after laparoscopic and open Nissen fundoplication [13,14].

Demographic data such as age, gender, neurological status, presence of a feeding tube, feed volume, duration of feeds during 24 h, and symptoms of GER were prospectively recorded. Presence of dysphagia, early satiety, and meal related discomfort was recorded as dichotomous variables. The frequency of retching, vomiting and regurgitation was scored on a 4-point scale: (0) never, (1) <1 per week, (2) 1–3 days per week, and (3) 4–7 days per week [13]. Frequent retching, vomiting and regurgitation were defined as occurring at least 4–7 days per week.

The methodology to examine GE has been described in detail previously [15]. Briefly, GE was assessed preoperatively and postoperatively after an overnight fast using radionuclide scintigraphy and a standardized meal with cow's milk. Children ≥4 years received 200 ml to finish, while younger children were given at least 100 ml or the amount they were willing to drink and/or able to tolerate. After intake of the test meal, patients were placed in the supine position under the gamma camera for 90 min. Half time of GE ($T_{1/2}$) and percentage of the meal retained after 30 (T_{30min}) and 60 (T_{60min}) min were recorded. In total, 24 healthy children were included as controls, receiving the same meal with similar test conditions as the patients. The patients' test meal was labeled with 10 MBq of 99Tc-DTPA, while the healthy children got a reduced dose of 2 MBq. The reduced radiation dose given to the healthy children had no significant impact on the measurement of GE rate [15], and the reduced dose has become standard in all patients after this study was completed. The median $T_{1/2}$ in the control group was 44 min (range 29–94 min). $T_{1/2}$ in the healthy child with the slowest gastric emptying was 94 min, and we therefore defined delayed GE as $T_{1/2} \geq 95$ min [15].

Postoperative follow-up was standardized and included a clinical examination including symptom registration, a 24-h pH-monitoring, scintigraphy, and an upper gastrointestinal series six months postoperatively. Furthermore, symptoms of GERD, gas-bloat, retching, and feeding difficulties were registered by phone-interviews 1, 2 and 4 years after the fundoplication using the same questions and scoring as preoperatively. Symptoms 1 year postoperatively were used to assess outcome related to GE in the present paper, while recurrent GERD was assessed at the end of follow-up. The persons interviewing the parents had not been involved in the medical or surgical treatment of the children. To be diagnosed as having recurrence, the child had to present both clinical symptoms of GERD and objective verification of gastroesophageal reflux (either reflux index >4% and/or GER and/or herniation of the wrap by upper gastrointestinal contrast study) [16].

Of the 74 eligible patients, 35 underwent a preoperative GE test and were included in the study. The remaining 39 eligible patients were not examined with a GE study preoperatively owing to known volume intolerance; parents reporting any form of cow's milk intolerance or allergy, inability to cooperate, or because the parents refused participation.

1.1. Statistics

Results are presented as median [min–max] or mean [SD] with 95% confidence intervals. Data were compared with chi-squared test, Students t-test or Mann–Whitney-U test, as appropriate.

As only one of the patients had slower GE than healthy controls [15], symptomatic outcome after fundoplication was compared by dividing patients into two groups: the one third with the slowest GE and the remaining two-thirds with the fastest GE. Comparison of change in GE rate from pre- to postoperatively was performed using paired sample t-test. Analyses were performed using SPSS version 20.0. A p-value <.05 was considered statistically significant.

1.2. Ethics

Participation in the study was voluntary and informed written consent was obtained from all parents. The trial was approved by the Medical Regional Ethical Committee and registered at ClinicalTrials.gov, number NCT01551134.

2. Results

Thirty-five patients with a median age of 4.9 [1.1–15.4] years were included. The preoperative reflux index was median 11.6% [4.5–49.1]. Nineteen (54%) children were neurologically impaired, which was defined as a static or progressive, central or peripheral neurological condition associated with intellectual disability and/or functional impairment [17]. More than half of the patients had frequent regurgitation and vomiting, and approximately one-third of the patients reported discomfort after meals, prolonged feeding time and tube feeding dependency. An overview of preoperative GERD symptoms and symptoms possibly related to delayed GE is outlined in Table 1.

In 20 children a laparoscopic fundoplication was performed, whereas 15 had an open operation. Median follow-up was 4.3 [1.9–8.9] years. All parents (n = 35) reported improved well-being of their child 12 months postoperatively and that their expectations of outcome were fulfilled. The effect of fundoplication on various GERD symptoms is described in Table 2. Seven (20%) patients (4 with and 3 without neurological impairment) experienced recurrent GERD, and all had been operated laparoscopically.

There was no significant difference in preoperative $T_{1/2}$ in the seven patients with recurrent GERD compared to those without recurrent GERD (Fig. 1). Furthermore, there was no significant difference in retained volume after 30 min in patients with and without recurrent GERD (median 46% [31–88] vs median 56% [15–87]) p = .36, respectively. Similarly, retained volume after 60 min did not differ between those with recurrence (31%, [20–65]) and not (median 36% [4–73]), p = .63. Lastly, the recurrence rate between the one third of patients (n = 12) with the slowest GE [$T_{1/2}$ 54–121 min] was not significantly different to the recurrence rate in the two thirds of patients (n = 23) with the fastest GE [$T_{1/2}$ 16–49 min] (Table 2).

When comparing symptomatic outcome after fundoplication, we found no significant difference between the one third of patients with the slowest GE and the remaining patients with faster GE with regard to discomfort after meals, prolonged feeding time, or frequent retching (Table 2). Among the 39 excluded patients who did not undergo scintigraphy, 12 (31%) patients had recurrent GERD. Their recurrence rate was not significantly different compared with the included patients (p = .32).

In 24 children, a GE study was performed both pre- and postoperatively. There was no significant difference between the preoperative and postoperative GE rate (Table 3).

3. Discussion

The main result of the present study is that the preoperative GE rate of a liquid caloric meal did not predict outcome of fundoplication. We found no significant difference in the preoperative GE rate between patients with and without recurrent GERD, and the preoperative GE rate was not related to postoperative problems such as vomiting, retching, prolonged feeding time, or discomfort after meals.

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