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Original research

Use of chewing gum in children undergoing an appendectomy: A randomized clinical controlled trial

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HIGHLIGHTS

- If chewing gum is helpful, we could have a new tool to decrease ileus in children.
- Patients received a sugar free gum during the first 12 h after surgery.
- We assessed time to tolerate feedings, pass first flatus and bowel movement.
- There was no statistical difference between groups for any variable analyzed.

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ABSTRACT

Introduction: Post-operative ileus is a common condition among pediatric patients undergoing appendectomy. We aim to assess the feasibility, safety, and effectiveness of chewing gum to reduce ileus, and decrease time to oral tolerance.

Methods: A randomized trial was conducted in 5–18 year old patients that underwent an appendectomy. Subjects in the intervention group received sugar-free chewing gum within the first 12 h after surgery and control group received the usual therapy. We assessed the acceptability of the intervention, time to pass first flatus, present first bowel movement, and time to tolerate oral intake.

Results: A total of 41 patients were recruited, 21 in the intervention group and 20 in the control group. Mean time (SD) to first flatus in the intervention group was 17.18 h (8.18), and 24.37 h (17.53) in the control group (mean difference [MD] of −7.19 h; 95% CI, −15.7 to 1.38). Time to first bowel movement (MD, −4.6 h, 95%CI −18.5 to 9.3), time to tolerate oral intake (MD, 4.17 h; 95%CI −9.2 to 17.5), and length of hospital stay (MD, 6.9 h, 95%CI −19.1 to 33.1) appeared not to be affected by the intervention. Chewing gum was accepted, well tolerated, and without complications.

Discussion: The use of chewing gum in children undergoing an appendectomy was safe and well tolerated and might lead to a faster recovery of bowel function, more studies are needed to prove if length of hospital stay and other outcomes are improved.

1. Introduction

Post-operative ileus is the condition known as the time after surgery before the coordinated electro-motor bowel function is recovered [1].

Prevalence of this condition is difficult to establish due to the lack of standardized definitions. Several trials have demonstrated that most cases of ileus present after prolonged abdominal surgeries in which large bowel manipulation is involved. However, the range of cases goes from 3 to 32% of patients, according to some studies [2].

Multiple pharmacologic and non-pharmacologic resources (e.g., nasogastric tube insertion, administration of IV fluids, metoclopramide, cisapride, propranolol, etc.) are used to shorten this time in order to avoid many post-operative complications [3]. Most of them, mainly drugs, are effective in the adult population; unfortunately many of these pharmacologic agents are not approved for its use in pediatric patients; therefore its safety and effectiveness in children is unknown.

Recently, chewing gum has been suggested as a therapeutic alternative to reduce post-operative ileus in adults with bowel surgical resection, other types of gastrointestinal surgery and C-section

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in women. The mechanism proposed for its effectiveness is the stimulation of the cephalic phase of digestion [4]. Even though benefits of chewing gum in the adult population have been proven, there is only one study that involved pediatric patients who had intestinal resection with anastomosis. The authors of this study found no benefit from the addition of chewing gum to pharmacologic treatment but they found a reduction in the length of hospital stay [5].

Studies published until now state variables such as the time patients take to pass first flatus and time to present first bowel movement as markers of gastrointestinal function recovery; and discuss the reduction in the length of hospital stay as a benefit of the use of chewing gum [4,6,7,8]. However, none of them includes the time patients take to tolerate oral intake, which usually reflects clinical stability and wellness of the subject.

If benefits of the use of chewing gum in pediatric patients are proven, there could be a new, economic, effective and safe method to decrease the time of ileus in the patients involved; thus, a faster recovery of bowel function would allow children to stay for a shorter period of time in hospital [2]. We decided to conduct a randomized trial to evaluate the acceptability, feasibility, safety, and effectiveness of chewing gum to reduce post-operative ileus in pediatric patients with diagnosis of appendectomy.

2. Materials and methods

2.1. Study population

A randomized controlled trial was performed at two institutions of Tec de Monterrey School of Medicine, Multicentric Residency Program (Hospital San José Tec de Monterrey and Hospital Regional Materno Infantil); during April to August 2012. The protocol was approved by the Institutional Review Board of both institutions. Patients from 5 to 18 years of age with diagnosis of appendicitis and open or laparoscopic appendectomy were selected. Exclusion criteria for our study included: Patients out of the ages stated, children unable to chew or swallow, patients in the ICU, patients with gastrointestinal motility dysfunction not associated with the post-operative status; children unable to follow instructions about chewing gum.

2.2. Randomization and procedures

A randomization list was generated with the use of <http://www.randomization.com>, with 41 subjects randomized into 4 blocks. Investigators had access to the list only at the end of the trial. Report forms were stored in opaque sealed envelopes along with instructions for nurses and parents, and consent forms. Each envelope was numbered and stored at the surgery ward to be assigned to each new patient with diagnosis of appendectomy who fulfilled the inclusion criteria and whose parents accepted to participate in the trial.

Patients in the intervention group were given a sugar free chewing gum (Trident®) during the first 12 h after surgery at the moment the patient was able to chew and follow instructions. Chewing gum was given three times a day during 30–45 min; mothers or people in charge of taking care of the patients had written information about the use of chewing gum and the report of variables of interest for the trial; nurses (blinded to the child's group assignment) had written instructions at the patient's chart to report the time patients tolerated oral intake, had first bowel movement and passed first flatus. Hospitalization time was calculated from the moment surgery ended to the time the patient was discharged form hospital. Investigators and doctors at the surgery ward had no access to the information about which group of study patients were part of. Time to tolerate oral intake was defined as the time measured from the moment the surgical intervention was over to the time in which patients were able to drink liquids without symptoms associated (nausea, vomiting, abdominal distension or pain).

A sample of 40 patients was calculated, with a final number of 21 patients for the intervention group and 20 patients for the control group. Such sample was necessary to detect a difference of at least 24 h of hospital stay with a power of 80% and a significance level of 0.05. Variables such as age, gender, type of surgery (open or laparoscopic); use of analgesics, antibiotics; post-surgery signs and symptoms developed (i.e., abdominal pain, abdominal distension, fever, diarrhea, nausea, and vomiting) were analyzed for each group.

Variables of interest for the study were the overall acceptability as assessed by the mothers, time to tolerate oral intake, time to pass first flatus, time to first bowel movement and length of hospital stay; all of them measured in hours.

Medical treatment after surgery was similar in all patients. They received one or more of the following antibiotics: Cefotaxime, Ceftriaxone, Amikacin, Clindamycin and/or Metronidazole; Acetaminophen, Ketorolac and/or Metamizole were the most common analgesics used. Since medical treatment protocols are already established by the institutions and surgeons involved, the authors of this study had no influence on the decision about which drugs were used for each one of the patients.

2.3. Statistical analysis

Continuous variables were analyzed using mean differences and the 95% confidence interval (95% CI) with the Student *t*-test or Mann - Whitney *U* test; categorical variables were described in contingency tables and proportions compared using the χ^2 (chi-square) test. Time (used to describe length of hospital stay, time to pass first flatus, present first bowel movement and tolerate oral intake), measured in hours was also analyzed using the Kaplan – Meier survival test. The SPSS software version 20.0 for Mac iOS was used.

3. Results

A total of 41 patients were included, 21 of them in the intervention or chewing gum group and 20 of them in the control group. None of the patients had to be excluded from the protocol; just one of the patients from the intervention group accidentally swallowed the gum without any complication.

All of the patients had diagnosis of appendicitis (pathology diagnosis shown in Table 1) and classified in four categories according to the International Classification of Diseases-9 (ICD9; edematous, suppurated, perforated and gangrenous appendicitis).

Variables such as age, gender, diagnosis, type of surgery (open or laparoscopic), time of surgery, use of drugs and symptoms presented after surgical intervention, were similar in both groups (Tables 1 and 2). At least 85% of our appendicitis cases were treated by an open appendectomy; we decided to include this point since it has been proven that laparoscopic appendectomies are associated with a lower incidence of post-operative ileus compared to open appendectomies [9]. However, we did not perform a further analysis of this difference since our number of laparoscopic appendectomies was very low due to the lack of proper equipment in one of our institutions.

Post-operative ileus was measured by the time the surgical intervention ended to the time patients passed first flatus, had first bowel movement and tolerated oral intake; these were the variables of interest for our study, along with the length of hospital stay. There was no statistical significant difference between groups for any of these variables analyzed (Table 3).

4. Discussion

During the last few years, several studies have proposed