International Journal of Gynecology and Obstetrics xxx (2014) xxx–xxx

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

www.figo.org

CLINICAL ARTICLE

A randomized trial of chewing gum to prevent postoperative ileus after laparotomy for benign gynecologic surgery ☆

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ARTICLE INFO

Article history:
Received 23 January 2014
Received in revised form 3 June 2014
Accepted 14 July 2014

Keywords:
Chewing gum
Gynecologic surgery
Ileus
Laparotomy

ABSTRACT

Objective: To assess whether chewing gum prevents postoperative ileus after laparotomy for benign gynecologic surgery. *Methods:* A randomized study was conducted from December 1, 2010, to February 29, 2012. Patients scheduled to undergo laparotomy were randomly assigned to receive chewing gum or routine care after surgery. A chart review was performed to establish incidence of nausea and vomiting, use of antiemetics, cases of postoperative ileus (≥2 episodes of emesis of 100 mL or more, with abdominal distention and absence of bowel sounds), and time to discharge. Inpatient surveys recorded the time to specific events. *Results:* A total of 109 patients were randomly assigned to receive chewing gum (n = 51) or routine postoperative care (n = 58). Fewer participants assigned to receive chewing gum than routine care experienced postoperative nausea (16 [31.4%] versus 29 [50.0%]; $P = 0.049$) and postoperative ileus (0 vs 5 [8.6%]; $P = 0.032$). There were no differences in the need for postoperative antiemetics, episodes of postoperative vomiting, readmissions, repeat surgeries, time to first hunger, time to toleration of clear liquids, time to regular diet, time to first flatus, or time to discharge. *Conclusion:* Chewing gum after laparotomy for gynecologic surgery is safe and lowers the incidence of postoperative ileus and nausea.

ClinicalTrials.gov: NCT01579175

1. Introduction

Postoperative ileus is a transient state of abnormal bowel motility from the time of surgery until the return of normal gastrointestinal function [1,2]. Clinically, this condition ranges from a decreased appetite shortly after surgery to prolonged postoperative nausea, vomiting, and nutritional compromise. Postoperative ileus has been more specifically defined as at least two episodes of emesis of at least 100 mL each within a 24-hour period, with associated abdominal distention and absent bowel sounds [3]. Depending on the study and definition used, clinically severe postoperative ileus affects up to 14% of patients after laparotomy for gynecologic surgery [4]. After abdominal hysterectomy, postoperative ileus can increase the length of hospital stay by an average of 3.7 days [5]. An effective treatment or prophylaxis for postoperative ileus would save US$1.1 billion annually in healthcare costs in the USA [2].

Chewing gum hastens gastrointestinal recovery in several ways. Gum simulates sham feeding, which has been demonstrated to promote gut motility and function via the cephalic-vagal and cephalic-colic reflexes [6–9]. The gut does not readily absorb the stereoisomer sugars found in sugar-free gums, resulting in a laxative-like effect [10]. Meta-analyses and systematic reviews of randomized trials in colorectal surgery [11–13] show that chewing gum is pleasant, safe, and effectively decreases time to first flatus, bowel movement, and discharge from hospital. Similar results have been observed after cesarean [14]. Recently, two randomized controlled trials [15,16] used markers for intestinal recovery, such as flatus and bowel sounds, to demonstrate faster gastrointestinal recovery with the administration of chewing gum after gynecologic surgery. Neither trial defined or evaluated the clinical entity of postoperative ileus a priori. The aim of the present study was to test the hypothesis that the administration of chewing gum after laparotomy for benign gynecologic surgery would hasten gastrointestinal recovery and decrease the rate of postoperative ileus.

2. Materials and methods

This randomized study was conducted at Johns Hopkins Hospital at both the East Baltimore and Bayview campuses from December 1,

☆ Presented at the 39th Annual Society for Gynecologic Surgeons Meeting; April 8–10, 2013; Charleston, SC, USA.

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http://dx.doi.org/10.1016/j.ijgo.2014.06.008
0020-7292/

2010, to February 29, 2012. Patients were asked to participate if they were scheduled to undergo laparotomy for a benign gynecologic condition. They were excluded if they had an active intra-abdominal malignancy, bowel perforation, pre-existing bowel disease, or a history of abdominal or pelvic irradiation. Patients were also excluded if they were deemed unsafe for administration of chewing gum. The use of a preoperative bowel preparation and the advancement of diet postoperatively were at the discretion of the surgeon overseeing the patient. Approval from the Johns Hopkins Institutional Review Board was obtained. Participants provided written informed consent.

Patients were randomly assigned (1:1) to receive chewing gum or routine care after surgery using a random number generator (http://stattrek.com/Tables/Random.aspx). Opaque envelopes were labeled with the patient's unique study number and contained their assignment. If a patient declined to participate, this envelope was discarded and the next was selected for the next patient. A.M.J. approached patients while they were in the preoperative holding area before the administration of any analgesic or anesthetic agents. After consenting to participation, the study envelope was opened to reveal the assignment. Patients and providers were not masked to group assignment, but individuals reviewing charts were.

Participants in the chewing gum group received Wrigley's Sugar-free Extra Spearmint gum (William Wrigley Jr Company, Peoria, IL, USA). They were given a pack on arrival at the postoperative floor and were instructed to chew gum for 15 minutes every 4 hours while awake. Vital signs are measured every 4 hours on the postoperative floor, so participants were asked to use the measurements as a prompt.

On entry to the postoperative floor from the postoperative acute care unit, all patients were given a survey to complete. They were asked to record the date and time of first hunger, toleration of clear liquids, toleration of a regular diet, passage of flatus, and bowel movement. Participants were also asked to record their satisfaction with their own gastrointestinal recovery on a Likert Scale. Nursing staff collected the surveys when the patient was discharged. A chart review was conducted 30 days after surgery to record intraoperative details and events, complications, episodes of nausea and vomiting, the use of postoperative antiemetics, time to discharge, and postoperative readmissions or complications. Additionally, attempts were made to contact the patient to capture additional details regarding postoperative events that might have occurred outside the hospital.

The primary outcomes were time to the passage of first flatus and incidence of postoperative ileus (defined a priori as at least two postoperative episodes of emesis of 100 mL or more, accompanied by abdominal distention and absence of bowel sounds on physical examination [3]). Secondary outcomes were patient satisfaction and time to first toleration of clear and regular diets, time to hunger, and bowel movement.

A total of 63 patients were needed in each group to detect an 18-hour difference in time to passage of first flatus with a power of 80%. Assuming a 5% dropout rate, the goal was to accrue 132 patients. In February 2012, the Johns Hopkins Hospital Institutional Review Board performed a random internal audit. At this point, more than half the patients had been accrued. An interim analysis was performed for the Institutional Review Board and, although the planned numbers needed to analyze the primary outcome had not been attained, there were significant differences in more clinically compelling outcomes—rates of postoperative ileus and nausea. The trial was halted at this point.

Statistical analysis was performed using STATA 10 software (StataCorp, College Station, TX, USA). Descriptive statistics are presented for continuous and categorical variables. Continuous variables were analyzed by t test and linear regression, and categorical variables by χ^2 analysis, simple logistic regression, and multiple logistic regression. Some continuous variables were transformed into categorical variables for analysis—e.g. age was divided into categories by decade, and body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters) was divided into categories according to the WHO BMI classification [17]. $P < 0.05$ was considered statistically significant.

3. Results

Of the 110 patients who consented, one was excluded after assignment to the chewing gum group because she was found to have metastatic colorectal cancer at the time of her laparotomy. Of the remaining 109 participants, 51 were assigned to receive chewing gum and 58 routine postoperative care (Fig. 1). Overall, 29 (26.6%) surveys were returned: 12 (20.7%) were returned from patients in the routine care group, and 17 (33.3%) from those in the chewing gum group. Complete data were collected from chart reviews for surgical details, length of stay, use of antiemetics, rates of nausea and vomiting, and frequency of postoperative ileus for all 109 participants.

Participants' ages ranged from 17–76 years (mean 47.1 ± 9.7). Mean BMI was 31.3 ± 9.0. Age did not differ significantly by group, but participants assigned to routine postoperative care were more likely to be African American ($P = 0.039$) and have a higher BMI ($P = 0.037$) than were those assigned to chewing gum (Table 1).

The most common type of incision was Pfannenstiel (used in 77 [61.5%] participants), and the most common procedure was a hysterectomy (done in 66 [60.6%] participants). Most patients received general endotracheal anesthesia alone (83 [76.1%] participants); 19 (17.4%) had general endotracheal anesthesia with an epidural. There were intraoperative complications in 5 (4.6%) patients: three patients had hemorrhages and were admitted to an intensive care unit (one also had a bilateral ureteral injury), one had a denuded small bowel mesentery requiring surgical consultation intraoperatively, and an incidental cystotomy occurred in one patient. Surgical variables were similar between groups, although significantly more patients in the routine postoperative care group received an epidural than in the chewing gum group ($P = 0.026$) (Table 2).

Postoperatively, 70 (64.2%) patients required antiemetics. Progress notes showed postoperative nausea in 45 (41.3%) patients. Postoperative emesis was reported in the charts of only 16 (14.7%) patients. Postoperative ileus was noted in 5 (4.6%) patients, and 2 (1.8%) required a nasogastric tube for symptomatic relief. Readmission was necessary in 5 (4.6%) patients. Fewer participants assigned to receive chewing gum experienced postoperative nausea ($P = 0.049$) and postoperative ileus ($P = 0.032$) (Table 3). Compared with the routine care group, patients who were assigned to chewing gum had log odds ratios of –0.49 (95%

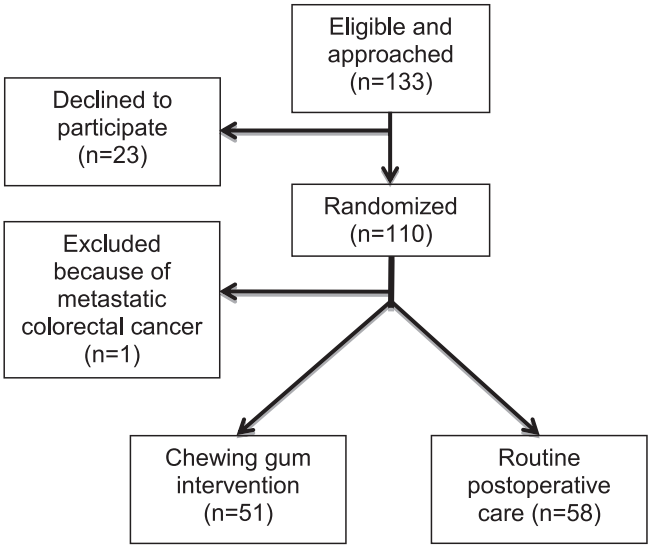

Fig. 1. Flow of participants through the study.

Please cite this article as: Jernigan AM, et al, A randomized trial of chewing gum to prevent postoperative ileus after laparotomy for benign gynecologic surgery, Int J Gynecol Obstet (2014), http://dx.doi.org/10.1016/j.ijgo.2014.06.008