Trial protocol

Title: Effect of chewing gum on anxiety in women undergoing elective cesarean section: a randomized controlled study

Trial registration:

Registry name

Clinical Research Information Service

https://cris.nih.go.kr/cris/info/introduce.do?search_lang=E&lang=E

Trial identifier

KCT0006602

Study Type: Interventional Study

Study Purpose: Treatment

Trial design: Parallel group

Intervention Type: Other products

Eligibility criteria:

Full-term pregnant women undergoing elective cesarean section (CS) were included.

Subjects who are with American Society of Anesthesiologists physical status more than III, age under 19 years old, unstable vital signs, increased risk of pulmonary aspiration, medication affection gastrointestinal motility, and refusal to participates were excluded.

Interventions:

1. Participants were required to complete the Amsterdam Preoperative Anxiety and Information Scale (APAIS) questionnaire to evaluate baseline anxiety as they were provided written informed consent, a day before surgery.

2. For pre-anesthetic fasting, all participants were instructed to stop solid food ingestion 6 h before surgery and encouraged to drink clear liquid until 2 h before surgery.

3. In the gum group, the participants were provided a pack of xylitol gum (Sweetory xylitol, Daeyoung Foods Co., Korea) by other investigator (YJB) and instructed to chew a piece of gum for at least 10 min/h regardless of fasting unless they are sleeping. Chewing duration for each hour was logged on a self-reported form. In the control group, participants were requested to follow fasting guidelines without further instructions.

4. The patients were allocated into control group or gum group with a ratio of 1:1.

3. On the day of surgery, participants completed their second APAIS questionnaire and rated their subjective sense of discomfort using a numeric rating scale (NRS; 0 to 10, 0 = no suffering, 10 = worst imaginable suffering) immediately before entering the operating room. After the patient entering the operation room, standard ASA monitoring devices (EKG, NIBP, SpO2)

were applied and CSE induction was performed by an independent anesthesiologist in the usual manner on the lateral decubitus position with 8mg 0.5% hyperbaric bupivacaine and 20 μg fentanyl. We also asked the participants to rate their pain during induction using the NRS.

4. Baseline characteristics including age, gestational age, cause of CS, past medical history, and level of education were collected from medical records. Intraoperative variables including fluids, anesthetics, urine output, estimated blood loss, and any complications during the hospital stay were also collected from anesthetic records.

5. In both groups, the recovery satisfaction score was recorded 24 h after surgery. Postoperative nausea and vomiting (PONV) during the 3 postoperative days were collected. The time to flatus and resume feeding, recovery satisfaction score, and length of hospital stay were collected

Outcomes:

Primary outcome

preoperative anxiety using the APAIS score immediately before surgery.

Secondary outcome

The subjective discomforts in NRS, pain score during the anesthetic procedure, postoperative nausea and vomiting for the 3 postoperative days

Statistical analysis

Continuous variables were presented as the mean ± standard deviation (SD) or medians [inter-quartile ranges (IQR)] according to normality of distribution as checked by the Shapiro–Wilk test. Categorical variables were presented as the number (percentage). Differences between groups were assessed using Student's t-tests or Wilcoxon's rank sum test for continuous variables, and the chi-squared test or Fisher's exact test for categorical variables as appropriate.

Statistical significance was defined as a p-value < 0.05. The individual p value of multiple testing was adjusted using Bonferroni post corrections. All analyses were performed using SPSS software (version 27.0; SPSS Inc., Chicago, IL).

Sample size:

Opioid consumption for 24 hours postoperative was reported to be 58. 3 ± 18.5 mg (morphine equivalent dose) in a previous gynecologic laparotomy study. We deemed a 30% decrease in the opioid consumption for 24 hours postoperative to be clinically significant. The calculated sample size was 31 participants in each group with a power of 95% and an alpha error of 5%. Total planned recruitment was 68 participants to account for dropout of 10%.

Allocation:

Randomization was performed using random permuted block design with a block size of two generated by the web service (www.randomizer.org). Allocation information was sealed in an opaque envelope numbered with a randomization sequence and stacked in labor and delivery units. YJB opened the envelope in sequence and gave gum with instructions of chewing protocol to parturient in gum group. The anesthetic provider, obstetrician and outcome assessor were blinded to the group allocation.

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