World J Surg (2018) 42:3150–3157
https://doi.org/10.1007/s00268-018-4717-4

ORIGINAL SCIENTIFIC REPORT

Effects of Preoperative Oral Carbohydrates on Quality of Recovery in Laparoscopic Cholecystectomy: A Randomized, Double Blind, Placebo-Controlled Trial

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Published online: 18 June 2018

Abstract

Background While carbohydrate loading is an important component of enhanced patient recovery after surgery, no study has evaluated the effects of preoperative carbohydrate loading after laparoscopic cholecystectomy (LC) on patient satisfaction and overall recovery. Thus, we aimed to investigate the impact of preoperative oral carbohydrates on scores from the quality of recovery 40-item (QoR-40) questionnaire after LC.
Methods A total of 153 adults who underwent LC were randomized into three groups. Group MN-NPO was fasted from midnight until surgery. Group No-NPO received 400 mL of a carbohydrate beverage on the evening before surgery, and a morning dose of 400 mL was ingested at least 2 h before surgery. Group Placebo received the same quantity of flavored water as for group No-NPO. The quality of recovery after general anesthesia was evaluated using QoR-40 questionnaire. Intraoperative hemodynamics were also evaluated.
Results There were no significant differences among the groups in terms of the pre- and postoperative global QoR-40 scores ($P = 0.257$). Group MN-NPO had an elevated heart rate compared to patients who ingested a preoperative beverage (groups No-NPO and Placebo; $P = 0.0412$).
Conclusions The preoperative carbohydrate beverage did not improve quality of recovery using the QoR-40 questionnaire after general anesthesia for laparoscopic cholecystectomy compared to placebo or conventional fasting. However, the preoperative fasting group had a consistently increased heart rate during changes in body position that induced hypotension, which is likely a result of depletion of effective intravascular volume caused by traditional fasting over 8 h.
Trial Registration Clinical trial.gov identifier: NCT02555020.

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Introduction

Although fasting times recommended by anesthesiology guidelines have been reduced to 2 h before elective anesthesia prior to surgery [1–3], most Korean hospitals have routinely implemented longer fasting times to reduce the risk of aspiration during surgery. Therefore, the majority of patients suffer from preoperative discomfort, including anxiety, hunger, and thirst, after a long period of fasting. Although the effects of fasting depend on the type of surgery, "fasting after midnight" increases the incidence of insomnia and aggravates surgery-induced catabolic metabolism during and after surgery, which may lead to poor postoperative outcomes and longer hospital stays [4, 5].

Carbohydrate loading is an important component of enhanced patient recovery after surgery [6–8]. Compared to the traditional "fasting after midnight" principle used for various surgical procedures, preoperative carbohydrate loading has been shown to be associated with a more rapid recovery of bowel function, less muscle weakness, and less discomfort caused by hunger, anxiety, and thirst [9–11]. Patients undergoing laparoscopic cholecystectomy (LC) were also reported to benefit from preoperative oral carbohydrates in terms of preoperative discomfort and postoperative nausea and vomiting (PONV) [12–14]. However, no study has evaluated the effects of preoperative carbohydrate loading after LC on patient satisfaction and overall recovery. Thus, we aimed to investigate the impact of preoperative oral carbohydrates on scores from the quality of recovery 40-item (QoR-40) questionnaire after LC. Furthermore, we also sought to determine whether preoperative hydration would lead to preservation of intravascular volume, resulting in more stable hemodynamics during changes in body position compared to conventional fasting, and whether it might also positively affect the management of anesthesia.

Materials and methods

Patients characteristics

A total of 153 patients who underwent LC at Gangnam Severance Hospital, Yonsei University Health System, Seoul, Korea, between September 2015 and December 2016, were enrolled in this study. These patients were American Society of Anesthesiologists (ASA) class I–II adults who had a Karnofsky Performance Status Scale greater than 70 and provided written informed consent. Patients with the following characteristics were excluded from the study: (a) fasting glucose level greater than 120 mg/dL, (b) type I or II diabetes, (c) gastroesophageal reflux disease, or (d) history of previous upper gastrointestinal surgery. Patients with an ASA physical status of IV/V were also excluded. The study was approved from the Institutional Review Board (3-2015-0158) and registered to clinicaltrials.gov (NCT02555020).

Randomization and interventions

Patients were randomly assigned to the following three groups (group No-NPO, group Placebo, and group MN-NPO) by a computer-based randomization program (Fig. 1).

Patients in group MN-NPO were not allowed to drink any solution or fluid after midnight (MN) before surgery. Patients in group No-NPO received 800 mL of a clear carbohydrate beverage (12.8% carbohydrates, 50 kcal/100 mL, 290 mOsm/kg, NO-NPO®, Daesang WelLife Co., Ltd., Korea). Patients were instructed to ingest 400 mL of this beverage on the evening before surgery (8:00–10:00 p.m.) and on the morning of surgery (400 mL) 2 h before any anesthetic medication was administered (scheduled in advance). Patients in group Placebo received the same quantity of flavored water at the same times as those in the No-NPO group.

Anesthesia management

After administration with 0.02 mg/kg midazolam intravenously prior to surgery, anesthesia was induced with 2 mg/kg propofol and 1 μg/kg remifentanil, followed by 0.6 mg/kg rocuronium for muscle relaxation to facilitate tracheal intubation, and maintained by the administration of a volatile anesthetic and 0.1–0.3 μg/kg/min remifentanil. Hypertension (a mean arterial pressure $>$ 130% of basal mean arterial pressure) and hypotension (a mean arterial pressure $<$ 65 mmHg) were treated with medication. In the post-anesthesia care unit, patients received 1 μg/kg fentanyl or 10 mg metoclopramide for pain or nausea. In general ward, those who suffered from nausea and pain were given 10 mg metoclopramide or 0.3 mg ramosetron and 50 mg tramadol intravenously as needed. The number and doses of medication were recorded.

Patients were allowed to drink clear liquids immediately after transfer to the general ward and resume a normal diet one day after surgery.

Surgical management

All surgeries were performed at Gangnam Severance Hospital by one surgeon who had performed a minimum of 500 LCs. A standardized three-port laparoscopic approach using a 12-mm port placed above the umbilicus with two additional 5-mm ports in the right upper abdomen was

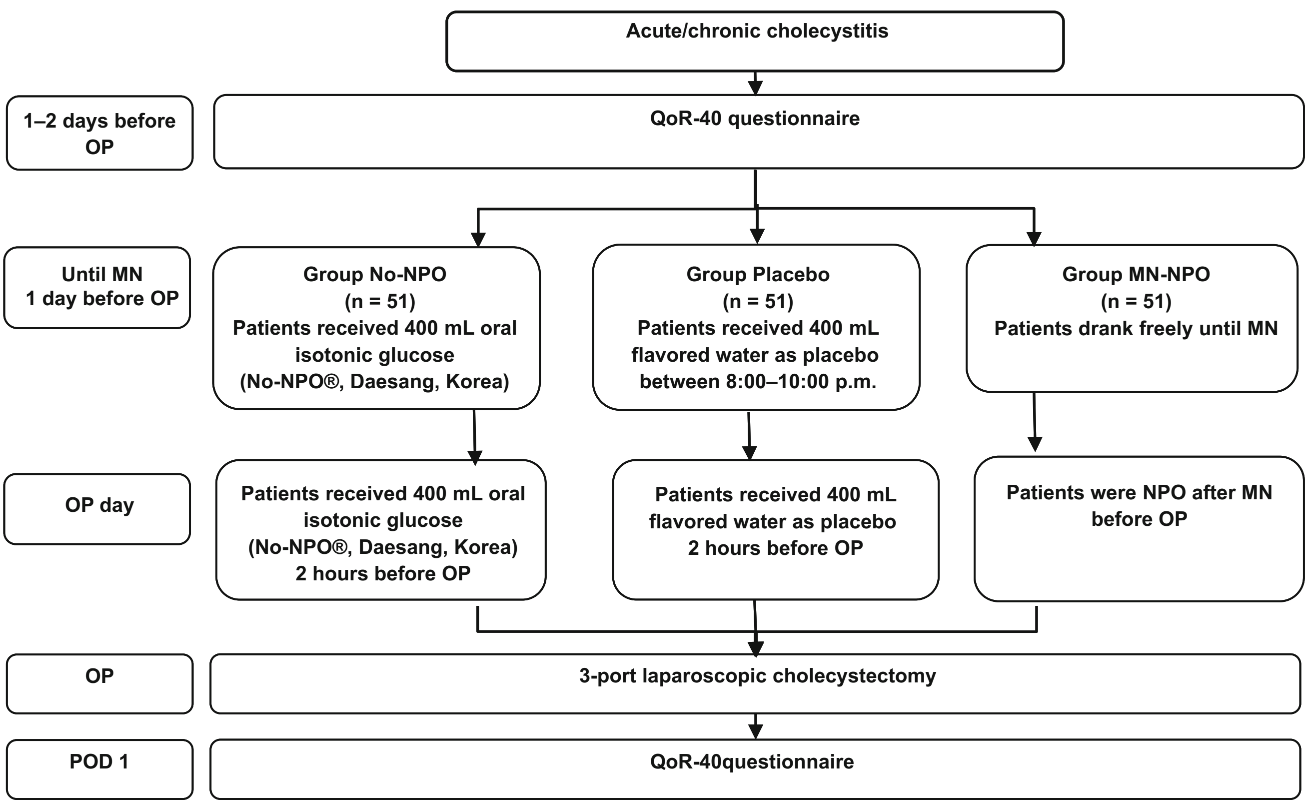

Fig. 1 Study outline. *OP* operation, *QoR*-40 quality of recovery 40 item, *MN* midnight, *NPO* nil per os, *POD* postoperative day

performed in all cases. The pneumoperitoneum pressure and CO_2 flow rate were set at 12 mmHg and 2 L/min, respectively. All specimens were removed through the 12-mm cannula into a disposable bag. The umbilical fascia was closed with 1–0 polyglactin sutures in all cases. All port-site skin was typically closed with a single subdermal polyglactin suture, applied with Histoacyl®.

Study endpoints

The primary endpoint was the quality of recovery after general anesthesia, as assessed using the QoR-40 questionnaire. The secondary endpoint was intraoperative hemodynamic changes induced by a pneumoperitoneum (12 mmHg) and reverse Trendelenburg position (15°). The heart rate and mean arterial pressure were recorded at nine time points: before and after induction of anesthesia, before positional changes during surgery, and five times after positional changes performed every 2 min.

Other assessments

The patient's basic characteristics and preoperative fasting time were recorded. Surgical details collected included time of surgery, fluid intake, and blood loss during surgery. Intraoperatively, the frequencies and doses of medication administered to treat hyper- or hypotension during surgery were recorded. Pain, PONV, and use of analgesics and antiemetics were evaluated for 24 h after surgery in the ward.

Sample size

This study was a three-arm, randomized-controlled trial. This definitive trial design used the quality of recovery after general anesthesia as the primary outcome variable. In existing QoR-40-related studies, a difference of ten points represents an actual difference of 15% [15]. In a study of 500 adult patients, the standard deviations of QoR-40 scores for males and females were 11 and 17, respectively [16]. To reduce gender bias, men and women were equally allocated to each group in this study, and the standard deviation was estimated to be 15. In this study, the average number of subjects required to have a power of 80% or more at the 5% significance level was 44 per group, assuming a difference between the MN-NPO, No-NPO, and Placebo groups of ten points. Finally, this study was designed to include 51 patients in each device considering a dropout rate of approximately 15%. Calculations were done using SigmaPlot 11.0 (Systat Software, Inc., Chicago, IL, USA).

Statistical analysis

Statistical analyses were performed by a medical statistician who was unaware of group allocations using SAS software 9.2 (SAS, Inc., Cary, NC, USA) and PASW statistics 23.0 Windows (SPSS, Chicago, IL, USA). All values were expressed as the number of patients (percentage), mean (SD), or median (interquartile range). Data were examined for a normal distribution of variance (ANOVA) and for an abnormal distribution of variance (Kruskal–Wallis test). Discrete variables between groups were compared using a Chi-square test or Fisher's exact test. Repeated measurements were taken using linear mixed models with a Bonferroni correction. Analysis of covariance (ANCOVA) for repeated measures was employed to examine differences in pre-/postoperative QoR-40 between groups with preoperative QoR-40 adjustment. Data with a P value less than 0.05 were considered statistically significant.

Results

A total of 153 patients who underwent LC between September 2015 and December 2016 were enrolled in this study (Fig. 2). In group No-NPO, five patients were excluded because of a prolonged fasting time (more than

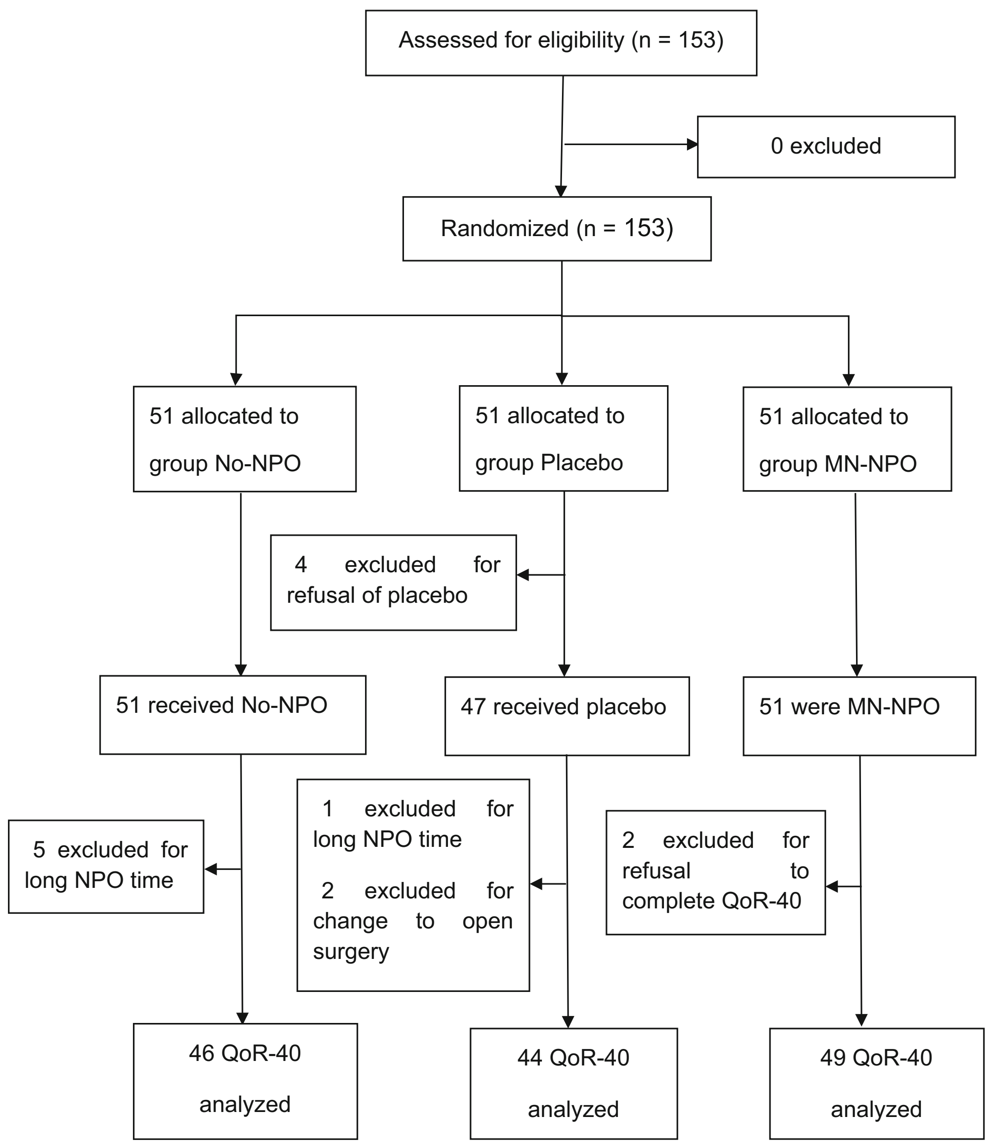

Fig. 2 CONSORT flow diagram. *MN* midnight, *NPO* nil per os, *QoR*-40 quality of recovery 40 item

Table 1 Patient characteristics and surgical details

	Group No-NPO (n = 46)	Group Placebo (n = 44)	Group MN-NPO (n = 51[a])	P value
Gender (F/M)	23/24	21/24	25/25	NA
Age (years)	50 ± 13	48 ± 12	49 ± 12	NA
BMI (kg/m^2)	24.5 ± 4.8	25.4 ± 3.8	25.4 ± 4.0	NA
Smoking (yes/no)	7/40	12/32	7/43	NA
Hypertension (yes/no)	5/41	8/36	10/41	NA
Previous nausea/vomiting history[a]	6/39	3/39	7/43	NA
Diagnosis				
GB stone	35	33	42	NA
GB polyp/Adenomyosis	9	11	8	NA
Acute cholecystitis	2	0	1	NA
NPO time (min)	251 ± 101	245 ± 98	812 ± 250	<0.001
Operation time (min)	52 ± 20	44 ± 20	54 ± 24	0.043
Fluid intake during surgery (mL)	502 ± 167	462 ± 165	500 ± 190	0.386
Blood loss during surgery (mL)	4 ± 12	11 ± 60	22 ± 96	0.591
Hospital stay (days)	2.59 ± 1.61	2.13 ± 1.33	2.38 ± 2.05	0.064

Data presented as the number of patients or mean ± SD as appropriate.*MN* midnight, *NPO* nil per os, *BMI* body mass index, *GB* gall bladder

[a]Postoperative QoR-40 nonresponders included

8 h). In group Placebo, seven patients were excluded because of a prolonged fasting time (one patient), a change in the surgical procedure to open cholecystectomy (two patients), and a refusal to drink the placebo beverage (four patients). In group MN-NPO, two patients refused to complete the QoR-40 questionnaire after surgery. They were excluded from the analysis of the primary endpoint, but their characteristics and degree of hemodynamic stability during surgery were recorded.

Patient demographics were similar between the three groups (Table 1). Preoperative NPO time was statistically different among groups (group No-NPO 251 ± 101 min, group Placebo 245 ± 98 min, and group MN-NPO 812 ± 250 min, $P < 0.001$). There were no significant differences in age, body mass index, sex, or pathological findings between the three groups.

The preoperative QoR-40 as the baseline data also showed differences between the groups. Thus, analysis of covariance (ANCOVA) was employed to examine differences in pre-/postoperative QoR-40 between groups with preoperative QoR-40 adjustment (Table 2). However, the difference between the preoperative and postoperative QoR-40 scores with preoperative QoR-40 adjustment was not statistically significant.

The intraoperative hemodynamics are shown in Fig. 3. Group MN-NPO patients had elevated heart rates compared to patients in groups No-NPO and Placebo ($P = 0.0412$). There was no significant difference in mean arterial pressure between the three groups.

The incidence of ephedrine use had no statistical differences between the group MN-NPO (24%) and the other two groups (15% in group No-NPO and 20% in group Placebo; $P = 0.235$). Twenty-four hours after surgery, antiemetics were more frequently used in group MN-NPO than in the other two groups, but this result was not statistically significant [4 (8%) in group MN-NPO vs. 1 (2%) in the other two groups, $P = 0.532$]. There were no complications associated with preoperative hydration, such as perioperative aspiration or postoperative pneumonia.

Discussion

In this study, we were unable to show that preoperative oral carbohydrates improved the quality of recovery after general anesthesia in patients who underwent LC, as assessed by the QoR-40 questionnaire, compared to patients ingesting a placebo beverage or those who underwent conventional fasting.

Preoperative carbohydrate loading has been widely adopted as part of enhanced patient recovery after surgery and fast-track surgical protocols [7, 8, 17]. A meta-analysis published in 2013 and a Cochrane database review from 2014 both reported that the intake of carbohydrate beverages 2–4 h prior to surgery reduced the length of hospital stays [4, 6].

As reported by Dr. Myles, the QoR-40 questionnaire provides a patient-centered assessment of mental and physical recovery [15]. It includes questions about patient support, physical comfort, emotional state, physical independence, and pain, and score ranges from 40 to 200 points. It has been used as a method to evaluate the quality

Table 2 Quality of recovery (QoR-40) dimensions and global scores

QoR-40 dimensions	Group No-NPO (*n* = 46)	Group Placebo (*n* = 44)	Group MN-NPO (*n* = 49)	*P* value
Emotional state				
Postoperative	42.6 ± 3.9	41.7 ± 4.3	44.4 ± 1.1	0.001
Difference[a]	0.5 (0.4)	0.9 (0.5)	−0.3 (0.5)	0.241
Physical comfort				
Postoperative	50.5 ± 5.5	49.1 ± 6.1	52.8 ± 2.5	0.002
Difference[a]	7.0 (0.6)	7.4 (0.7)	6.2 (0.7)	0.230
Psychological support				
Postoperative	33.9 ± 2.5	33.4 ± 2.7	34.9 ± 0.8	0.005
Difference[a]	0.3 (0.3)	0.6 (0.3)	−0.4 (0.3)	0.053
Physical independence				
Postoperative	23.5 ± 3.1	23.5 ± 2.2	24.6 ± 1.3	0.047
Difference[a]	1.2 (0.3)	1.2 (0.4)	0.3 (0.3)	0.189
Pain				
Postoperative	31.3 ± 4.3	30.4 ± 3.7	32.9 ± 2.0	0.004
Difference[a]	2.2 (0.5)	2.8 (0.6)	1.0 (0.5)	0.680
Global QoR-40 score				
Postoperative	186.7 ± 17.5	182.8 ± 17.0	194.5 ± 5.6	0.001
Difference[a]	6.2 (1.9)	6.9 (2.2)	3.2 (2.0)	0.437

Data are presented as the mean ± SD or the estimated mean (SE)

MN midnight, *NPO* nil per os

Postoperative: assessed one day after surgery; Difference: difference between preoperative (within 2 days before surgery) and postoperative surveys

[a]Analysis of covariance (ANCOVA) was employed to examine differences in pre-/postoperative QoR-40 between groups with preoperative QoR-40 adjustment. *P* value of difference was for ANCOVA after preoperative QoR-40 adjustment

of recovery in surgical patients with excellent validity, reliability, responsiveness, and clinical utility [18]. In this study, we did not show the benefits of preoperative carbohydrate in the patients undergoing LC, in terms of quality of recovery after general anesthesia. From previous studies, one showed a reduction in PONV with oral carbohydrate compared to fasting [19], while neither showed a clear difference between carbohydrate and placebo [20]. The latter authors suggested that no difference between carbohydrate and placebo was caused by a relatively small decrease in insulin sensitivity after LC compared with major surgery. With the results of present study, it is also thought to be the results of low insulin resistance, caused by the relatively short fasting period and surgery time than major surgery. In addition, this result may be because of the failure of a sufficient NPO time during the study in this study. In No-NPO and Placebo patients, who aimed to fast for 2 h before surgery, the actual mean fasting time before surgery was about 4 h. In terms of standard deviations, a lot of patients in group No-NPO and Placebo were fasted longer than 4 h. This result may be reflected in the postoperative QoR-40 surveys, because of patient dissatisfaction with not undergoing surgery at the prescribed time and decreased patient expectations regarding the surgery.

Even though the frequency of medications administered for PONV and pain was not significantly different between the three groups, reduced PONV was observed in the No-NPO group. In the general ward, the frequency of medications administered for pain or PONV was slightly higher in group MN-NPO compared to the other groups, but this finding was not statistically significant. This result corresponded with a study conducted by Sing et al., which found that preoperative oral carbohydrates reduced preoperative discomfort and PONV in patients with LC [13].

During LC, changes in the patient's position are inevitable. Both the reverse Trendelenburg position and a pneumoperitoneum result in a hypotensive state due to the temporary shortage of effective circulating blood volume [21]. These changes are closely related to the vascular capacity of the patient, which declines with prolonged fasting times, especially in elderly and hypertensive patients with poor vascular reactivity. When hemodynamic stability during the positioning of a patient that subsequently induces hypotension during surgery was analyzed, a high heart rate was observed consistently in group MN-NPO patients. Although mean arterial pressure or usage of a vasopressor did not significantly differ in these patients, a high heart rate was maintained, both before and during the

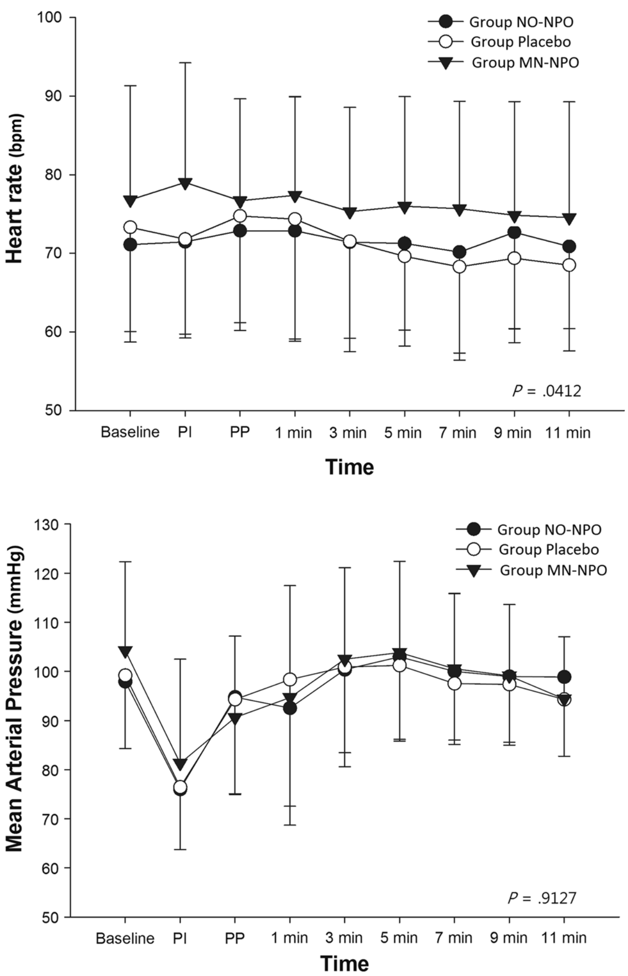

Fig. 3 Hemodynamic changes during intraoperative change in position. *PI* post induction, *PP* before position change with pneumoperitoneum

administration of anesthesia (opioids) that induced a slow heart rate; this finding may reflect volume depletion in patients who underwent preoperative fasting. Considering that the primary response to volume depletion is an increase in heart rate [22, 23], an increased heart rate in group MN-NPO may be the indirect result of volume depletion because of preoperative fasting. Twelve group MN-NPO patients were administered ephedrine to correct hypotension, which was slightly higher than in the other groups, but was not statistically significant.

LC is a typical day surgery in many countries, but in case of Korea it's different. This is considered to be a characteristic of South Korea where study has been conducted. Patients undergoing surgery with general anesthesia prefer hospitalization after surgery due to the low burden on patients with National Health Insurance. There was no difference in hospital stay caused by complications after surgery between groups.

There were some limitations in the present study. First, the timing of the QoR-40 questionnaire was not appropriate to assess the primary endpoint. The postoperative QoR-40 questionnaire was given on the day after surgery. After LC, all patients were allowed to drink clear water after moving to the general ward. The day after surgery, patients began a regular diet. Thus, the QoR-40 scores in this study were unable to fully reflect the discomfort caused by fasting and the effects of preoperative oral hydration. In addition, the baseline results of the preoperative evaluation were significantly different among groups that included patients at varying stages of acute cholecystitis progression, which biased the patient-reported effects of the preoperative beverage. Second, the degree of position change may have been insufficient to compare the hemodynamic instabilities among groups. The surgeon in the present study preferred a low intraabdominal pressure (< 12 mmHg) and reverse Trendelenburg position (< 15°), which are lower than those reported for the general LC procedure [24]. Third, the study sample size calculation was based on the analysis of QoR-40. Thus, with a sample size 141, the present study was underpowered to definitely assess the benefits of preoperative carbohydrate in LC as secondary outcomes, such as PONV or pain control. Despite these facts, there was a significant difference in heart rate, which may benefit high-risk patients with hemodynamic instability. Further research on heart rate is therefore needed in patients undergoing major surgical procedures during which hemodynamic instability is frequently observed.

Administration of a preoperative carbohydrate beverage did not improve quality of patient recovery after general anesthesia for LC, according to the results of the QoR-40 questionnaire, compared to patients ingesting a placebo beverage or those who underwent conventional fasting. Further investigations of patient satisfaction after preoperative oral carbohydrates are needed. However, patients in the preoperative fasting group had consistently elevated heart rates during changes in body position, which induced hypotension, and may reflect the depletion of effective intravascular volume caused by traditional fasting over 8 h. Additionally, preoperative hydration up to 2 h prior to surgery was not associated with additional complications.

Acknowledgement Nos-NPO® and Placebo beverages were provided by the Daesang Corporation, Korea.

Compliance with ethical standards

Conflicts of interest The authors declare no competing interests.

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