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Original article

Pulmonary recruitment maneuver reduces pain after laparoscopic bariatric surgery: a randomized controlled clinical trial

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Abstract

Background: Pulmonary recruitment maneuver (PRM) at the end of laparoscopic gynecologic surgery has been shown to reduce postoperative pain. This prospective, randomized, controlled clinical trial aimed to investigate postoperative pain (primary endpoint) and nausea when performing a ventilator-piloted PRM at the end of laparoscopic bariatric surgery.

Settings: A secondary-level public hospital in Sweden.

Methods: After giving written consent, patients undergoing elective laparoscopic bariatric surgery were randomized to receive routine exsufflation (control group) or a ventilator-piloted PRM to remove residual carbon dioxide from the abdomen at the end of surgery. Pain and nausea intensities were recorded at 4, 12, 24, 36, and 48 hours after surgery using a questionnaire with numeric rating scales. Postoperative consumption of analgesics and antiemetics was also evaluated.

Results: There were 150 randomly assigned patients recruited, 79 to PRM intervention and 71 controls. Pain intensity was significantly lower in the PRM group than in the control group 24 hours postoperatively (numeric rating scale 2 [1–3] versus 3 [2–5]; $P = .002$). Pain during the first 24 hours did not increase in the PRM group as it did in the control group ($P = .045$). Opioid requirements were significantly lower in the PRM group than in the control group (5.0 mg [2–10] versus 9.0 mg [5–15]; $P = .025$). The PRM did not affect incidence or intensity of nausea and vomiting.

Conclusions: A ventilator-piloted PRM reduced postoperative pain intensity and opioid requirement after laparoscopic bariatric surgery. The heterogeneity of the study population and the large number of hospital staff involved indicate good generalizability of the results. (Surg Obes Relat Dis 2017;▮:00–00.)

Keywords: Pulmonary recruitment; Laparoscopy; Postoperative pain; Postoperative nausea; Bariatric surgery

Patients undergoing a laparoscopic intervention usually experience postoperative pain. The pain may persist for several days and may be intense, not only in the abdomen but also in the shoulders. Other symptoms commonly affecting patients after laparoscopic surgery are nausea and vomiting [1–5].

Apart from the surgical trauma and the intra-abdominal pressure applied during the procedure, postlaparoscopic abdominal and shoulder pain are believed to be related to carbon dioxide (CO_2) trapped in the abdomen. This entrapment of gas may lead to direct irritation, local acidosis, and stretching of the diaphragm. The shoulder pain is believed to be caused by gas-induced irritation of the phrenic nerve, leading to referred pain in the shoulder. One method that seems to decrease postlaparoscopic pain is the removal of

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residual CO_2 by applying a pulmonary recruitment maneuver (PRM) at the end of the surgical procedure [1–4,6–8]. Inflation of the lungs and descent of the diaphragm during the PRM causes the intra-abdominal pressure to increase, mechanically facilitating exsufflation of intra-abdominal CO_2.

Pneumoperitoneum can result in systemic absorption of CO_2, especially in the morbidly obese, because the intra-abdominal gas pressure used when performing laparoscopy is higher than in patients with a normal body habitus [9]. In a recent study, mild intraoperative hypercarbia (end-tidal CO_2 43–45 mm Hg) was associated with a significant decrease in postoperative nausea and vomiting [10]. Could a PRM increase postoperative nausea and vomiting? Previous studies have not shown any correlation between PRM and incidence of nausea in patients with a normal body habitus [1–3,7].

To our knowledge, no previous study has been performed on the effect of PRM on postoperative pain and nausea in patients undergoing bariatric surgery. This study tests the hypothesis that PRM reduces the intensity of postoperative pain (primary endpoint) and investigates any effect on postoperative nausea (secondary endpoint) in the morbidly obese person undergoing laparoscopic bariatric surgery.

Methods

The study was designed as a prospective, randomized, controlled, blinded, parallel group, single-center, clinical trial. The participants, the postoperative staff, the doctor discharging the patients, and the investigator eventually collecting and registering data were all blinded to group allocation. Participants were recruited at Vrinnevi Hospital, Sweden. The Regional Ethical Review Board in Linköping, Sweden approved all study procedures (Dnr 2014/120-31). The trial was registered at www.clinicaltrials.gov, registration number: NCT03026530.

Patient recruitment and randomization

Inclusion criteria was as follows: adults (aged >18 yr); body mass index $\geq$35 kg/m^2; American Society of Anesthesiologists physical status classification I to II, including body mass index $\geq$40 kg/m^2; and undergoing elective laparoscopic bariatric surgery. Written consent was obtained. Criteria for exclusion from analysis were conversion to open surgery and complications classified as Clavien-Dindo grade $\geq$II [11].

Patients scheduled for elective laparoscopic bariatric surgery were consecutively enrolled into the study between November 2014 and May 2016. Using a computerized method, participants were randomized to 1 of 2 equally sized groups: intervention with PRM or control. An independent statistician at Forum Östergötland generated the randomization list in blocks of 2. The block size was kept secret to the researchers until the end of the study. After randomization, allocation instructions were placed in opaque, sealed, and numbered envelopes. As each participant was about to be transferred to theater, the next sealed envelope in turn was sent together with the patient's surgical notes. The anesthetic staff opened the envelope during the operation and, depending on group allocation, performed PRM or ordinary ventilation during the exsufflation process at the end of the surgical procedure.

Preoperatively, the participants filled out a form with information about age, weight, height, body mass index, sex, preoperative pain, and analgesic consumption, and whether they had prior abdominal surgery. Minimum 6 weeks of nonsmoking before surgery was a prerequisite for the operation. Registered operative and postoperative variables included type of surgery and anesthesia, duration of operation, amount of blood loss, complications, given medication, and the duration of postoperative hospital stay.

Surgery and study intervention

The surgical procedure (laparoscopic Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy) was performed according to routine clinical standards by 1 of 6 consulting surgeons skilled in the technique. CO_2 was introduced through a Veress needle placed under the left thoracic cage at the start of the operation and later through one of four 12-mm ports inserted in the upper abdominal area. A Nathanson liver retractor was used. The gas pressure was set to maximum 16 mm Hg. A total of 40 mL bupivacaine hydrochloride 5 mg/mL with epinephrine 5 ug/mL was infiltrated subcutaneously at the port sites before insertion of the trocars. General anesthesia was managed by a consultant anesthesiologist and a nurse specialized in anesthesiology. Induction was with remifentanil or alfentanil in combination with thiopental or propofol, and maintained with intravenous remifentanil and propofol or a combination of remifentanil and sevoflurane in oxygen-enriched air, the doses depending on the patient's requirements. The ventilator mode was set to pressure regulated volume control. Vital signs were monitored according to standard clinical practice. After surgery, the skin openings were adapted with staples. The fascia at the trocar sites was not sutured.

In the control group, residual CO_2 was evacuated by exsufflation through the open sleeve valves of 2 ports in the upper part of the abdomen, with the surgeon applying gentle abdominal pressure. Patients in the intervention group had CO_2 exsufflated in the same way, but also underwent a PRM before removal of the ports, using the ventilator (GE Datex-Ohmeda Aisys, Madison, WI, United States) according to a specific protocol developed by 2 of the hospital's consultant anesthesiologists (Fig. 1). During 1 minute, the ventilator mode was changed to pressure-controlled ventilation. The patient received 6 breaths with