Original Article

The impact of moderate versus deep neuromuscular blockade on the recovery characteristics following laparoscopic sleeve gastrectomy: A randomized double blind clinical trial

ABSTRACT

Background: Anesthesia with deep neuromuscular block for laparoscopic surgery may result in less postoperative pain with lower intra-abdominal pressure. However, the results in the existing literature are controversial. This study aimed to evaluate the effect of deep versus moderate neuromuscular block (NMB) on the postoperative recovery characteristics after laparoscopic sleeve gastrectomy (LSG) for weight loss surgery.

Methods: This is parallel-group, randomized clinical trial. The study was conducted at a tertiary care center. Patients undergoing LSG were included. Patients were randomly assigned to either deep (post-tetanic count 1–2) or moderate (train-of-four 1–2) NMB group. The primary outcomes were numeric rating scale scores of the postoperative pain at rest and postoperative shoulder pain. The secondary outcomes were the length of hospital stay (LOS) and postoperative complications. The statistics were performed using StatsDirect statistical software (Version 2.7.9).

Results: Two groups were identified: Group D (deep NMB), 29 patients, and Group M (moderate NMB), 28 patients. The BMI mean values for groups D and M were 44 and 45 kg/m2 respectively ($P > 0.05$). The mean durations of surgery for were 46.7 min and 44.1 min for groups M and D, respectively ($P > 0.05$). The mean train-of-four (TOF) counts were 0.3 and 0 for groups M and D, respectively ($P < 0.05$). The mean times from giving reversal agent to tracheal extubation (minutes) were 6.5 and 6.58 min for groups M and D, respectively ($P > 0.05$). In the recovery room, the means of pain scores were 3 and 4 for groups M and D, respectively ($P > 0.05$). Upon admission to the surgical ward, the median values of the pain score were non-significant ($P > 0.05$) (95% CI: 0.4–0.7). The opioid consumption in the recovery room was non-significant between both groups ($P > 0.05$) (95% CI: 0.3–0.6). Postoperative shoulder pain was non-significant between both groups ($P > 0.05$) (95% CI: 0.4–0.7). The median values of surgeon opinion of both groups were non-significant ($P > 0.05$). Regarding the LOS, the mean values of groups D and M were 1.20 and 1.21 days, respectively ($P > 0.05$).

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Conclusions: There was no significant difference between moderate and deep NMB techniques in terms of duration of the surgical procedure, postoperative pain, shoulder pain, and length of hospital stay. Further studies on a larger sample size are required to investigate the long-term recovery characteristics of patients with obesity undergoing LSG.

Key words: General anesthesia, laparoscopic sleeve gastrectomy, obesity

Introduction

Laparoscopic bariatric surgery sets distinct demands on the anesthesiologist and surgeon in terms of superior visualization of the surgical field to operate. Recent studies have confirmed improvement in surgical conditions during laparoscopy by applying deep NMB.[1] The evidence supporting this statement, however, is limited and inconclusive. Most published articles suggest that deep NMB is required for bariatric surgery with increased respiratory complications and risk for residual curarization.[2,3] There is a greater risk of postoperative respiratory complications (PPCs) in patients with obesity. Recent studies have confirmed the existence of at least one hypoxic event in 100% of patients following bariatric surgery (oxygen saturation <90% for more than 30 seconds).[4] According to Mulier and Dillemans, bariatric surgery has caused 12% of mortalities thus increasing the prominent role of NMB in surgeries.[5] NMB can enhance cannulization and surgical exposure, but it has also been associated with the risk of postoperative PPCs.[6] In contrast with moderate NMB, deep NMB is believed to have improved laparoscopic surgical conditions in the past while reducing involuntary movement.[7] Muscle relaxation is paramount for successful laparoscopic surgery; however, the optimal degree of NMB is not identified yet.[8] Previous studies showed conflicting results on the outcomes of laparoscopic surgical conditions when moderate NMB was compared to the deep blockade.[9] The evidences for the use of either modality are rather limited. In the recent literature, there is insufficient evidence to conclude that deep NMB improves surgical conditions during laparoscopic bariatric surgery. However, PPCs were decreased independently of the depth of the NMB regime.[10] Hence, there are limited data on the effect of such practices on postoperative outcomes. A previous study by Unterbuchner showed that deep NMB may improve surgical conditions during low-pressure capnoperitoneum.[11] However, it has also been reported by Bruintjes and his colleagues that routine-pressure capnoperitoneum improves surgical conditions independent of the level of muscular relaxation.[12] Torensma and his colleagues have reported that a previous pregnancy can affect the abdominal wall strength and eventually the degree of muscle relaxation.[13] Honing and his colleagues have previously showed that the rating of the quality of surgical conditions considerably varies between different surgeons when assessed through Leiden-surgical rating scale.[14]

The present study aims to investigate the impact of moderate versus deep NMB on the recovery characteristics following LSG for weight loss surgery under general anesthesia. We hypothesize that deep NMB is not superior to moderate NMB on the recovery characteristics following LSG.

Patients and Methods

An institutional review board (IRB) hospital ethics approval was obtained (**23.01.2020**, **Ref. No. 20/0033**). Patient consent was also obtained. The study was registered online (**ClinicalTrials.gov ID: NCT04466943).** This is parallel-group, randomized clinical trial. The study was conducted at a tertiary care center. The research team responsible of reporting and collecting data, surgeons, post anesthesia care unit (PACU) nurses as well as the ward staff, will be blinded for the study while providing treatment under the administration of an attending anesthesiologist and anesthesia assistant. Patient allocation was performed just before induction of anesthesia; the treating anesthesiologist gave the computerized randomization code before induction of anesthesia by an independent individual who is not involved in trial design, recruitment, or analysis. All patients undergoing elective LSG were seen in a preanesthesia clinic for evaluation and risk assessment according to the American Society of Anesthesiologists (ASA) scoring system. Patients who were booked under the participant surgeon will be approached for informed consent obtaining. Routine preoperative biochemical analysis was performed according to the hospital policies on preoperative evaluation of the bariatric population. Biochemical analysis included complete blood cell (CBC) count, urea and creatinine, sodium, potassium levels, international normalized ratio (INR), prothrombin time (PT), partial thromboplastin time (PTT) and pregnancy screening test, and urine human chorionic gonadotropin (HCG) for all female patients. The inclusion criteria included: 1. patients >18 years, 2. patients with BMI >35 (kg/m2), and 3. ASA classes II and III. While the exclusion criteria consisted of the following: 1. history of allergy to rocuronium; 2. history of allergy to dexamethasone, ondansetron, paracetamol, fentanyl, propofol, morphine, or tramadol; 3. current or previous pregnancy; 4. history of renal impairment (the Cockcroft–Gault equation as the gold standard for estimating renal function for drug dosing cut-off point: CrCl/GFR = 30 ml/min). The GFR

calculator is available at: http://clincalc.com/Kinetics/CrCl.aspx?example and 5. patient on oxygen therapy, namely continuous positive airway pressure (CPAP). Patients were randomly assigned to either deep (post-tetanic count 1 to 2) or moderate (train-of-four 1–2) NMB group. Group M (28 subjects): moderate NMB, defined by a 1–2 thumb twitch response to the train-of-four (TOF) stimulation of the ulnar nerve (rocuronium bolus and top-ups maintaining a train-of-four count of 1–2). Group D (29 subjects) deep NMB, defined by (0 twitch count in the train-of-four, 1–2 twitch responses in the post-tetanic count) (rocuronium bolus and top-ups maintaining a post-tetanic count of 1–2). Upon arrival to the operating room (OR), patients were connected to standard monitoring of vital signs (ASA guidelines). Consort flowchart is given in Figure 1. Neuromuscular function was recorded using the built-in neuromuscular testing module of the Drager-Primus® work station. The electrodes were applied conventionally to either the right or left wrist to stimulate the ulnar nerve. The module was activated after induction of anesthesia and prior to administration of muscle relaxants. Calibration and determination of proper current were done automatically in this module. The thumb-twitch response to four subsequent electrical stimuli (i.e., the train-of-four or TOF) at 20 seconds during induction until intubation then at 5-min intervals were recorded throughout the procedure. Induction of anesthesia was achieved with i.v. fentanyl 1 mcg/kg of the lean body weight (LBW) and propofol 2 mg/kg LBW after 3 minutes of preoxygenation (100%oxygen via face mask). Anesthesia was maintained with a mixture of air, oxygen, and sevoflurane at 1.0 MAC corrected for the participant's age. The lungs were ventilated with a tidal volume between 6 and 8 ml/kg ideal body weight (IBW) in addition to positive end-expiratory pressure (PEEP) of 5 cm H2O. Minute volume ventilation was adjusted to maintain end-tidal carbon dioxide between 35 and 45 mmHg. Pneumoperitoneum was achieved by CO2 insufflation to a maximum intra-abdominal pressure of 18 mm Hg. All patients received i.v. dexamethasone 8 mg and ondansetron 4 mg during at induction of anesthesia as prophylaxis of postoperative nausea and vomiting (PONV). The NMB was achieved with rocuronium 0.6 mg/kg to a maximum of 1.1 mg/kg corrected body weight (CBW) to facilitate tracheal intubation and with top-up doses of 0.1–0.2 mg/kg CBW to maintain a moderate NMB train-of-four count of 1–2 and deep NMB post-tetanic count of 1–2. Sugammade × 2 mg/CBW was given, and tracheal extubation was achieved after obtaining TOF >90. All subjects received intraoperatively a multimodal regime of analgesics consisting of i.v. paracetamol 1 gm, 16 mg of lornoxicam before skin incision, and another i.v. paracetamol 1 gm before tracheal extubation. The duration of

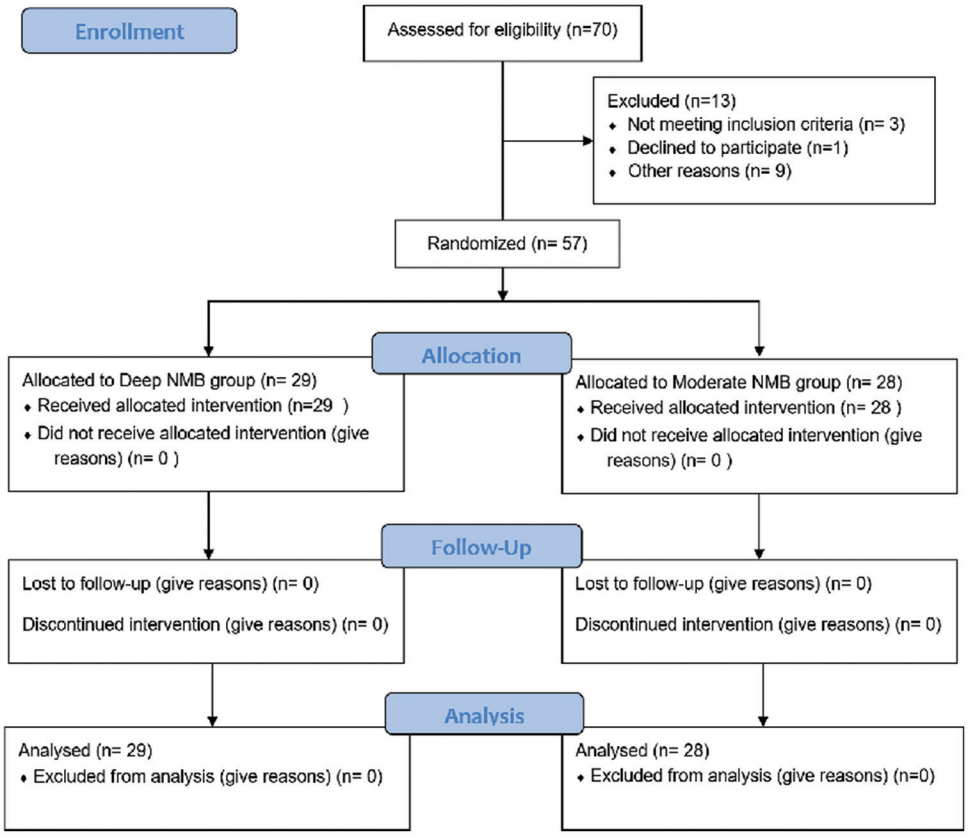

Figure 1: Consort flowchart

surgery was defined from the skin incision till last suture taken. The primary outcome measurements were numeric rating scale (NRS) of the postoperative pain at rest and shoulder pain after surgery. Secondary outcome measurements were the length of hospital stay (LOS) and postoperative complications. Surgeon opinion was evaluated using the Leiden-surgical rating scale (L-SRS) [Table 1]. Patients were monitored in the PACU for at least 30 minutes before discharge to the surgical ward with Aldrete score of >9. The postoperative pain was assessed with NRS from 0 to 10. Pain relief in PACU consisted of titrated doses of i.v. morphine every 5 minutes until the pain is relieved or a total of 6 mg was reached. In the surgical ward, i.v. paracetamol 1 gm 6 hourly was prescribed in addition to i.v. tramadol 50 mg as rescue analgesic given when needed. Statistical analysis was performed using StatsDirect statistical software (Version 2.7.9). Student's *t*-test was used for parametric variables and Mann–Whitney U-test for non-parametric variables. Sample size was calculated using Epi Info CDC. Assuming population size 85 patients undergo LSG in one-year period, power is 80% with confidence limits of 5%, and a total of 56 patients were calculated. The study was performed during the COVID-19 era that was the reason of small sample size.

Surgical technique

Upon arrival at the operating room, the patient was placed in the supine position on the bed with both arms secured to the footboard. Pneumoperitoneum was achieved via a Veress needle at the Palmer's point. A camera incision was made 16 cm from the xiphoid process and 1 cm to the left midline. An 11 mm port trocar was inserted; a 5 mm camera size was used to explore the abdomen. With the guidance of the camera, the second skin incision was made for 15 mm port, 1 cm proximal, and 5 cm to the right of the first incision. The third incision (5 mm) was made 1 cm proximal and 5 cm to the left side of the patient. The fourth incision (5 mm) was made 1–3 cm to the left of the xiphoid process. After skin incisions were made, a Veress needle was inserted until it reached the preperitoneal space under laparoscopic guidelines with bupivacaine 0.5% (10 ml) infiltration. The periperitoneum space was infiltrated adequately from all the quadrants around each trocar with bupivacaine 0.5% (5 ml). Only the camera port was infiltrated after the trocar placement with bupivacaine 0.5% (5 ml). The infiltration takes 20–30 seconds for each port. The fascial wounds were closed by sutures via a fascial closure device under laparoscopic guidance. This was followed by closure of the skin. After tracheal extubation, all the patients were transferred to the PACU.

Table 1: Leiden-surgical rating scale (L-SRS)

Grade	Description
Extremely poor conditions	The surgeon is unable to work because of coughing or because of the inability to obtain a visible laparoscopic field because of inadequate muscle relaxation. Additional neuromuscular blocking agents must be given
Poor conditions	There is a visible laparoscopic field, but the surgeon is severely hampered by inadequate muscle relaxation with continuous muscle contractions, movements, or both with the hazard of tissue damage. Additional neuromuscular blocking agents must be given
Acceptable conditions	There is a wide visible laparoscopic field, but muscle contractions, movements, or both occur regularly causing some interference with the surgeon's work. There is a need for additional neuromuscular blocking agents to prevent deterioration
Good conditions	There is a wide laparoscopic working field with sporadic muscle contractions, movements, or both. There is no immediate need for additional neuromuscular blocking agents unless there is a fear of deterioration
Optimal conditions	There is a wide visible laparoscopic working field without any movement or contractions. There is no need for additional neuromuscular blocking agents

Results

Two groups were identified: Group M, 28 patients, and Group D, 29 patients. The BMI mean values for groups M and D were 45 and 44 kg/m^2 respectively ($P > 0.05$). The mean duration of surgery was 46.7 (7.3) min and 44.1 (6.4) min for groups M and D, respectively ($P > 0.05$). The mean train-of-four (TOF) counts intraoperatively were 0.3 and 0 for groups M and D, respectively ($P < 0.05$). The mean times from giving reversal agent to tracheal extubation (minutes) were 6.5 and 6.58 min for groups M and D, respectively ($P > 0.05$). In the recovery room, the means of pain scores were 3 and 4 for groups M and D, respectively ($P > 0.05$). Upon admission to the surgical ward, the median values of the pain score were non-significant ($P > 0.05$) (95% CI: 0.4–0.7). The opioid consumption in the PACU was non-significant between both groups ($P > 0.05$) (95% CI: 0.3–0.6). Postoperative shoulder pain was non-significant between both groups ($P > 0.05$) (95% CI: 0.4–0.7). The median values of surgeon opinion of both groups were non-significant ($P > 0.05$). Regarding PONV, only three patients in each group had PONV which spontaneously resolved. Regarding the LOS, the mean values of groups D and M were 1.21 (0.5) and 1.20 (0.7) days, respectively ($P > 0.05$).

Discussion

The opioid consumption in the PACU as well as the shoulder pain and the LOS were non-significant between both groups. In relation to previous reports, the results of this study align with the study by Kopman and Naguib, which showed that the optimal degree of NMB during general anesthesia for a surgical patient has not been yet identified.[15] In some surgical procedures like laparoscopic hysterectomy, it was

found that deep NMB provided good surgical conditions.[16] That can be understood due to the deep pelvic structures unlike LSG procedure.

The same applied for laparoscopic colorectal surgery where deep NMB was found to improve the surgical conditions.[17] Current studies have not identified whether a deep NMB can improve the recovery characteristics following general anesthesia for LSG. In a meta-analysis on the effect of deep NMB on surgical workspace conditions in laparoscopic bariatric surgery, it was found that deep NMB helps improve surgical space conditions, whereas it fails to shorten procedure duration.[18] Over the years, the technique of deep NMB to create more surgical working space has gained popularity. Recent studies showed that deep NMB can also be a promising technique for metabolic procedures. However, the optimal combination of depth of NMB and amount of intra-abdominal pressure (IAP) in metabolic surgery has not yet been determined. As fast-track protocols are becoming more popular in metabolic surgery, it is important to determine the most optimal combination of IAP and NMB for this specific patient population.[19] In a recent study by Fuchs-Buder *et al*.[20] on whether deep NMB improves surgical conditions during bariatric surgery showed that the transition from a moderate to a deep NMB improves surgical conditions. The most important findings of their study were that, even at a moderate level of NMB, surgical conditions were good to excellent in the majority of patients, but they were just acceptable or poor in one-third of them. In a recent study by Baete *et al*.[21] on whether deep NMB could improve the quality of surgical conditions for laparoscopic bariatric surgery compared with moderate NMB and investigated whether deep NMB puts patients at risk for postoperative respiratory impairment compared with moderate NMB, the authors concluded that compared with a moderate NMB, there was insufficient evidence to conclude that deep NMB improves surgical conditions during laparoscopic bariatric surgery. Postoperative pulmonary function was substantially decreased after laparoscopic bariatric surgery independently of the NMB regime that was used. The limitation of the present study was the small sample size.

In conclusion, there was no significant difference between moderate and deep NMB techniques in terms of duration of the surgical procedure, postoperative pain, shoulder pain, and length of hospital stay; thus, the researchers accept the null hypothesis. Further studies from different centers on a larger sample size are required to investigate other long-term recovery characteristics of patients with obesity undergoing LSG.

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Conflicts of interest
There are no conflicts of interest.

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