

The effects of laparoscopy-guided transversus abdominis plane (TAP) block in the sleeve gastrectomy procedure: a randomized double-blinded placebo-controlled trial

Ömer Faruk Bük¹, Sönmez Ocak¹, Mustafa Safa Uyanık¹, İlder Soytürk², Ahmet Burak Çiftci¹, Mehmet Alperen Avcı¹, Can Akgün¹

¹Department of General Surgery, Samsun Research and Training Hospital, Samsun, Türkiye

²Department of Anesthesiology, Ankara Mamak State Hospital, Ankara, Türkiye

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ABSTRACT

Aims: Laparoscopy-guided transversus abdominis plane (TAP) block is a novel postoperative analgesic modality. We aimed to explore the effect of TAP block in laparoscopic sleeve gastrectomy (LSG) procedures.

Methods: Forty patients were randomized into two groups: TAP block with bupivacaine and placebo. Visual analog scale scores at postoperative hours 1, 6, 12, and 24, total analgesic consumption and opioid doses, and postoperative nausea and vomiting (PONV) scores were evaluated between the groups.

Results: Postoperative first-hour VAS scores differed significantly between the groups ($p < 0.05$). PONV scores were also lower in the TAP block group ($p < 0.05$). The first rescue opioid requirement was later in the TAP block group than in the placebo group. Pain scores at postoperative hours 6, 12, and 24 and total analgesia doses were not significantly different between the groups.

Conclusion: Laparoscopy-guided TAP block reduced early postoperative pain and may also attenuate PONV in LSG.

Keywords: Sleeve gastrectomy, transversus abdominis plane block, postoperative pain management

Main points:

- Pain management after bariatric surgery is a challenge.
- TAP block with bupivacaine can decrease postoperative pain.
- TAP block can be performed by laparoscopy guidance.

INTRODUCTION

Laparoscopic sleeve gastrectomy (LSG) stands out as the bariatric procedure that is performed most often.¹⁻³ LSG has not only been found to be relatively easy to perform compared to other complex bariatric procedures, such as gastric bypass and duodenal switch, but it has also demonstrated effectiveness in achieving sustainable weight loss in prior studies.¹⁻⁴ However, despite the frequent performance of LSG, the management of postoperative pain and nausea-vomiting is still challenging. Paracetamol and non-steroidal anti-inflammatory agents are widely used for postoperative pain management, although opioid-based analgesia is usually required for rescue analgesia. However, opioids can also exhibit some severe adverse effects, including respiratory depression, nausea and vomiting, ileus, and even addiction.⁵⁻⁸

Achieving adequate analgesia is essential in bariatric surgery since early mobilization is mandatory for preventing thromboembolic events in these patients.⁹ Conventional analgesia modalities may not be sufficient, and other forms of analgesia are required for patients undergoing bariatric surgery. The transversus abdominis plane (TAP) block is a regional analgesia technique introduced by Rafi in 2001. It involves blocking the plane between the internal oblique muscle and transversus abdominis muscle through the infiltration of local anesthetic agents.¹⁰ Many studies have demonstrated the effectiveness of TAP block in reducing postoperative pain as well as postoperative nausea and vomiting (PONV) in a range of abdominal surgery procedures, including both laparoscopic and open surgeries.¹¹⁻¹⁶ Various authors have investigated TAP block anesthesia in LSG, and conflicting results have been reported in randomized controlled studies. Some studies have suggested adjusting TAP block into a multimodal analgesia procedure, but others found no significant improvement with the technique.¹⁷⁻²⁰

The aim of this study was to explore the impact of laparoscopy-guided TAP block on pain levels and other postoperative outcomes among patients undergoing primary LSG procedures.

Corresponding Author: Sönmez Ocak, sonmezdr@gmail.com



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METHODS

Trial Design

This prospective randomized, placebo-controlled single-blinded study was conducted at the Samsun Health Sciences University Training and Research Hospital General Surgery Department following the receipt of local ethical committee approval (Date: 27.08.2020, Decision No: 2020/7/2). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. Preoperative written informed consent was obtained from all participants, and the study was registered at www.clinicaltrials.gov (ID no. NCT05447429).

Patient Selection and Sample Size

Patients aged between 18 and 65 years who were scheduled for elective LSG were eligible for inclusion in the study. Exclusion criteria consisted of allergy to bupivacaine, presence of chronic pain or ongoing pain management, and an ASA classification of 4 or higher. Patients undergoing concurrent surgical procedures such as cholecystectomy, hiatal hernia repair, or abdominal hernia repair were also excluded. We also intended to remove patients experiencing postoperative complications requiring surgery or endoscopic interventions from the analysis. Using G-Power software power analysis, 40 participants were enrolled into the study (20 patients for each group) to achieve 95% power, a two-sided 5% significance level, and a 1.45 impact size.

Groups and Randomization

We randomly assigned the 40 patients into two groups: a TAP block group (TAP-B) and a placebo group, with each group comprising 20 patients. Randomization was carried out using the sealed envelope method. Forty small pieces of paper with either TAP-Block or Placebo written on them were prepared and placed into non-transparent envelopes. Before each operation, the sealed envelopes were shuffled and one was selected by a blinded resident (MSU) and given to the surgeons (SO, ÖFB). These opened the envelope and performed either TAP-B or placebo, accordingly. The patient and the resident who collected those data (SO) were blinded to which procedure was performed, and double-blinded randomization was thus achieved.

Surgical Procedure and TAP Block Intervention

All procedures were conducted by two experienced bariatric surgeons (SO and ÖFB). Initially, the patient was positioned supine. After insufflation using a Veress needle inserted into the left subcostal region, a 10-mm camera trocar was placed on the left side of the umbilicus. With direct visualization, 15 ml of 0.5% bupivacaine +5 ml of saline or 20 ml of saline (as a placebo) were bilaterally administered at a single point in the transversus abdominis plane. The needle puncture was made in the midaxillary line between the subcostal margin and iliac crest once the needle tip was identified just above the peritoneum, and then the syringe was retracted. The accurate injection site was confirmed by observing peritoneal bulging due to the injected agents (Doyle's bulge), which the surgeons observed in all cases (Figure 1).



Figure 1. Doyle's sign

After the TAP-B procedure, a 10-mm trocar was inserted into the left anterior axillary line, and the other trocars (5-mm and 12-mm) were placed in the right midclavicular line as shown in Figure 2. A liver retractor was used routinely to achieve a clear view of the hiatus. Bipolar energy devices (LigaSure™ Medtronic, Covidien product, Minneapolis, MN, USA) were utilized to devascularize the greater curvature of the stomach up to the left crus, approximately 4-6 cm away from the pylorus. Subsequently, a 36 F bougie was introduced, and sleeve gastrectomy was performed. Following the methylene blue leak test, the resected stomach was extracted from the abdomen. Trocars were removed under direct observation, and the procedure was concluded.

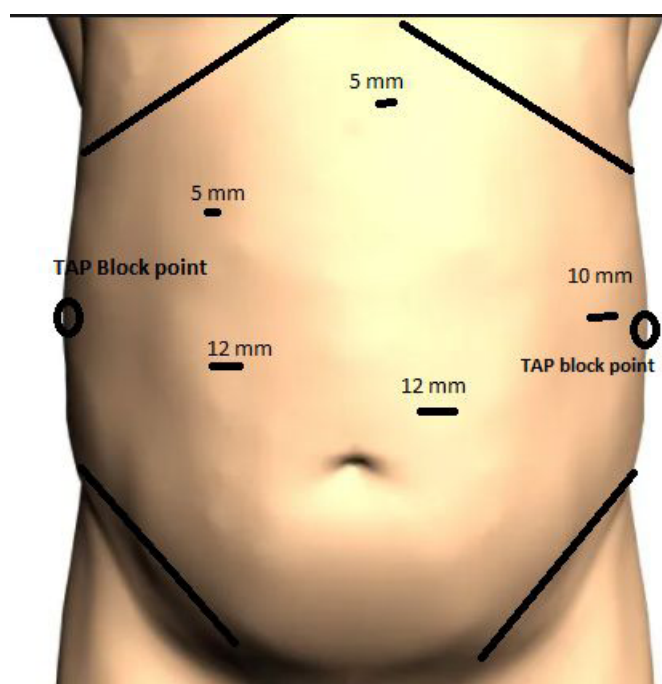


Figure 2. Trocar sites and TAP block injection site

Paracetamol 1000 mg was administered intravenously twice daily to both groups, and no opioids were administered during the perioperative course or in the postoperative

anesthesia care unit. Opioid-derived drugs (tramadol) were only given for rescue analgesia. Metoclopramide 10 mg was routinely administered three times per day to all patients as an antiemetic in the postoperative period. Patients were allowed to liquids on postoperative day 1 and were discharged on postoperative days 3 or 4.

Outcomes

The primary outcomes of this trial were to assess the patients' visual analog scale (VAS) scores at postoperative hours 1, 6, 12, and 24 together with postoperative analgesic doses.

Secondary outcomes included first mobilization and flatus times after surgery, nausea and vomiting scores, the times of first opioid administration, and operative times. PONV scores were calculated with the PONV scale as described in various previous studies. PONV scores were categorized as follows: 0 for no nausea or vomiting, 1 for mild nausea not requiring medication, 2 for moderate nausea requiring medication, and 3 for severe nausea and/or vomiting.²¹⁻²³

Statistical Analysis

SPSS software was utilized for statistical analysis. Chi-square tests were employed for categorical variables analysis, while either the Mann-Whitney U test or Student's t-test was applied to compare mean values between the groups following the Shapiro-Wilk normality test. p-values <0.05 were considered statistically significant.

RESULTS

The study flowchart is shown in Figure 3. The 40 patients were randomly assigned into two equal groups. All the participants were subjected to analysis, and no patients were excluded from the study. Preoperative variables including age, BMI, and sex were similar between the groups and exhibited no significant differences. The groups' preoperative data are summarized in Table 1. No intraoperative complications developed, and all patients were transferred to the surgery ward, as expected. Postoperative courses were uneventful, and no major complications occurred.

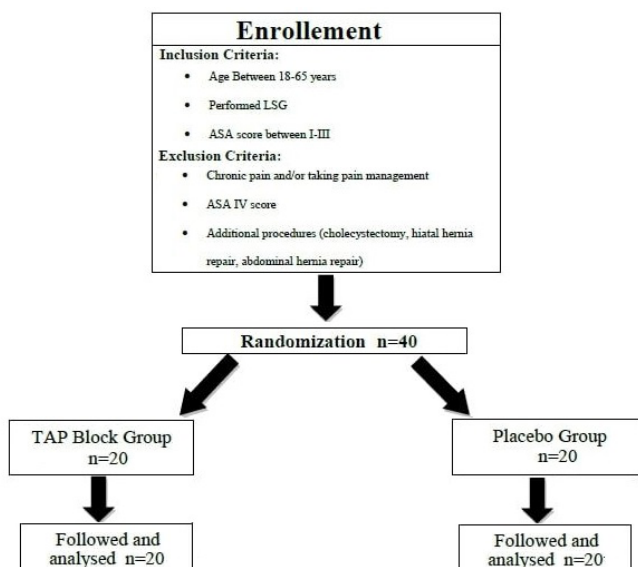


Figure 3. Study flowchart

Table 1. Patients' preoperative characteristics

	TAP-B	p	Total	p value
Age±SD (Min-Max)	33±9 (21-56)	30.9±9.14 (19-52)	31.95±9.03 (19-56)	0.409
BMI±SD (Min-Max)	44.6±3.37	46.12 ±6.24	45.36±5.01	0.776
Sex				
Male (%)	2 (10%)	5 (25%)	7 (17.5%)	
Female (%)	18 (90%)	15 (75%)	33 (82.5%)	0.212
Total	20	20	40	

TAP-B: Transversus abdominis plane block, p: Placebo, SD: Standart deviation, BMI: Body mass index, Min: Minimum, Max: Maximum

A statistically significant difference was observed in terms of pain scores between the two groups during the first hour after surgery (p<0.05). However, pain scores at hours 6, 12, and 24 exhibited no significant differences. Mean and p values are shown in Table 2. The total doses of postoperative paracetamol or opioids did not differ significantly between the groups. Times to the first opioid administration differed significantly between the groups (p<0.05), with patients in the TAP-B group receiving rescue opioids later than the placebo group (286.25 minutes vs 217.22 minutes, respectively). Additionally, two patients in the TAP-B group did not require opioids. Nausea-vomiting scores were significantly lower in the TAP-B group compared to the placebo group (p<0.05). There were no significant differences observed in first flatus times, first mobilization times, or operative times between the groups. The findings of the groups are summarized and compared in Table 2.

Table 2. Postoperative data for the study groups

	TAP-B	p	p value
Operation time-min (SD)	68 (18.73)	71.8 (15.11)	0.485 [†]
Time till the first opioid administration-min (SD)	286.25 (117.67)	217.22 (83.22)	0.046 [†]
VAS Score-1. hour (SD)	8.25 (1.11)	9.2 (1.19)	0.009 [‡]
VAS Score-6 (SD)	5.8 (1.98)	6.15 (1.78)	0.562 [‡]
VAS Score-12 (SD)	3.75 (2.02)	4.05 (2.03)	0.591 [‡]
VAS Score-24 (SD)	2.10 (1.25)	2.05 (1.46)	0.723 [‡]
Nausea-vomiting score (SD)	2.15 (0.67)	2.70 (0.57)	0.006 [‡]
Total tramadol dose-mg (SD)	170 (47.01)	195 (123.43)	0.431 [‡]
Total parasetamol dose-mg (SD)	2000 (324.44)	2350 (745.16)	0.085 [‡]
Flatus time-hour (SD)	13.95 (5.68)	13.50 (5.73)	0.828 [‡]
Mobilization time-hour (SD)	14.90 (8.67)	19.20 (7.11)	0.119 [‡]

TAP-B: Transversus abdominis plane block, p: Placebo, SD: Standart deviation, [†]Student t-test, [‡]Mann-Whitney U test, VAS: Visual analog scale

DISCUSSION

Postoperative pain management in bariatric surgery continues to pose a challenge for surgeons. Effective pain control allows earlier mobilization, which plays a crucial role in preventing venous thromboembolism, as reported in previous studies.^{9,24} Opioids are commonly used in postoperative pain management regimens in almost all types of surgery.²⁵ However, despite their analgesic efficacy, they also cause a number of adverse effects, including nausea and vomiting, respiratory depression, constipation, and hypotension.²⁶ Opioid addiction is another problem, with up to 10% patients exhibiting opioid addiction after bariatric surgery, meaning that their use should be as limited as possible.²⁷⁻²⁹

We set out to investigate whether the TAP-B procedure can reduce pain and opioid consumption following LSG. While a

notable distinction was observed in the VAS scores between the two groups at the initial postoperative hour, no significant variances were noted at 6, 12, or 24 hours. The total opioid and paracetamol doses showed no significant differences as well, although the TAP-B group experienced a longer interval before the first opioid administration compared to the placebo group. Additionally, two patients in the TAP-B group did not require any opioid administration. However, these data did not support the idea that TAP block with bupivacaine exhibits a favorable effect on postoperative pain management. Previous research has investigated the impact of TAP block on pain management in bariatric surgery, with several authors noting reduced postoperative pain, decreased analgesic needs, shorter hospital stays, and earlier resumption of daily activities as a result of this block.^{18,19,30-35} In contrast, however, Wong et al.²⁰ and Saber et al.¹⁷ observed no significant reduction of postoperative pain or opioid consumption after bariatric surgery. The variation in these studies may be attributed to several factors. Firstly, differences in the TAP Block application can vary among practitioners. Variances in the application site and doses of administered anesthetic agents may have influenced the outcomes. Another reason is the disparity in analgesia protocols applied during the perioperative period and diverse practices in Laparoscopic Sleeve Gastrectomy (LSG), such as changes in the number of ports, materials or techniques used to reinforce the stapler line (e.g., omentopexy, suturing to reinforce the stapler line), may lead to alterations in postoperative pain levels. Lastly, variations in patients' pain thresholds can also impact the results of the studies. Also the ineffectiveness of the intervention was attributed to enhanced recovery after surgery already improving postoperative pain, with the TAP block procedure therefore producing no additional benefit.²⁰

The TAP block procedure can be conducted using either ultrasound guidance (USG) or laparoscopy. Several previous studies, along with a recent meta-analysis, have indicated that laparoscopy-guided TAP block is equally effective compared to USG-guided TAP block.^{11,12,14,36-38} Laparoscopy-guided TAP block provides a clear field of vision through direct visualization of the peritoneum, thus avoiding the risk of intra-abdominal organ injury. In addition, USG-guided TAP block entails a longer operative time and requires expensive equipment and advanced radiological skills. It can be particularly difficult to identify true anatomical landmarks using USG in obese patients due to a thick layer of subcutaneous adipose tissue, and laparoscopy-guided TAP block may therefore be safer in these cases. Although Mittal et al.³⁰ concluded that USG-guided TAP block is a practicable and effective technique, other authors suggest that obesity poses a challenge for that technique.^{19,39,40} We therefore prefer the laparoscopy-guided TAP block in obesity surgery at our clinic.

PONV represents another challenge in bariatric surgery and can be seen in approximately half of patients.⁴¹⁻⁴³ In agreement with previous studies, the current study observed lower postoperative nausea and vomiting (PONV) scores in the TAP-B group.^{30,31}

Limitations

There are two major limitations to this study that need to be addressed. First, the number of patients was quite low,

despite the sample size being calculated using power analysis. The effects of TAP Block application on pain management during Laparoscopic Sleeve Gastrectomy (LSG) can be better understood through the planning of advanced studies involving a larger number of patients. Second, although the VAS scale is a well-validated pain assessment tool, pain is a subjective phenomenon based on self-evaluation. Furthermore, in this study, only the immediate postoperative effects of TAP Block application were investigated, and no conclusive findings regarding its long-term outcomes were reached. However, the fact that the patients and assessors were blinded in this study that enhances the power of the trial.

CONCLUSION

Laparoscopic-guided TAP-B with bupivacaine resulted in a small decrease in pain at the postoperative first hour after LSG and improved PONV. The study recommends incorporating TAP block into the postoperative analgesia protocol after LSG. However, further trials with larger sample sizes are necessary to better understand its effects on pain management and postoperative nausea and vomiting (PONV).

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of Samsun Health Sciences University Training and Research Hospital Clinical Researches Ethics Committee (Date: 27.08.2020, Decision No: 2020/7/2).

Informed Consent

All patients signed and free and informed consent form.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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