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ORIGINAL CONTRIBUTIONS

Impact of Ultrasound-Guided Transversus Abdominis Plane Block on Postoperative Pain and Early Outcome After Laparoscopic Bariatric Surgery: a Randomized Double-Blinded Controlled Trial

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Abstract

Background Based on the promising results of transversus abdominis plane (TAP) block in various abdominal procedures, this study aimed to investigate its effect on postoperative pain and early outcome after laparoscopic bariatric procedures.
Methods Patients with morbid obesity were randomly assigned to one of two equal groups; group I had US-guided TAP block upon completion of the bariatric procedure and before recovery from general anesthesia and group II did not have TAP block. All procedures were performed laparoscopically with a standardized five-trocar technique.
Results Ninety-two patients of a mean age of 34.7 years and mean BMI of 49.5 kg/m^2 were included. The mean pain score in group I was significantly lower than group II at 1 and 6 h postoperatively, whereas no significant differences in pains scores at 12 and 24 h between the two groups were observed. Eight patients in group I required rescue opioid analgesia within the first 24 h postoperatively, compared with 24 patients in group II ($P < 0.0001$). The postoperative nausea and vomiting (PONV) score at 24 h was significantly lower in group I than group II. Group I required a significantly shorter time to full ambulation and to pass flatus compared with group II. Hospital stay was similar in the two groups.
Conclusion Using US-guided TAP block in adjunct with laparoscopic bariatric surgery managed to achieve lower pain scores, lower opioid requirements, lower PONV scores, earlier ambulation, shorter time to pass flatus, and comparable hospital stay and complication rate to the control group.

Keywords Bariatric surgery · Postoperative pain · Transversus abdominis plane, TAP block, ultrasound-guided

Introduction

Morbid obesity has been recognized as a pandemic disease across the entire world. With proven efficacy of bariatric surgery in the treatment of morbid obesity, the rate of performing bariatric procedures has exponentially increased over the last few decades. Despite the minimally invasive nature of most bariatric procedures, moderate to severe pain can still be a problem in the immediate postoperative period [1]. Given the increased susceptibility of patients with morbid obesity

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to opioid-induced respiratory depression, adequate pain control can be challenging in this particular group [2, 3].

One of the most effective strategies in reducing postoperative pain after abdominal surgery is the transversus abdominis plane (TAP) block. TAP block is an afferent block of the anterior abdominal wall that can reduce pain and opioid use following lower abdominal surgery [4, 5].

From an anatomical perspective, the anterolateral abdominal wall is innervated by the thoracolumbar nerves (T6-L1) that give rise to both lateral and anterior cutaneous branches. These nerves run anteriorly through the TAP into the rectus sheath and then emerge as anterior cutaneous nerves [6]. Therefore, a locoregional nerve block such as TAP block has emerged as a promising approach to provide adequate relief of postoperative pain after abdominal procedures.

Viewing the current surgical literature, a remarkable reduction in postoperative opioid requirement in patients receiving TAP block has been observed [7–9]. TAP block has been demonstrated to improve pain-related outcomes after laparoscopic cholecystectomy [10, 11], open appendectomy [12], and cesarean section [13], in addition to other various upper and lower abdominal surgical procedures [14].

The impact of TAP block on immediate postoperative pain after bariatric surgery has been investigated by Wassef et al. [15] who concluded that ultrasound-guided TAP blocks are feasible in morbidly obese patients and result in satisfactory immediate postoperative analgesia following single-port laparoscopic sleeve gastrectomy (LSG). A randomized trial [16] also showed that ultrasound-guided TAP block is part of multimodal analgesic technique in morbidly obese patients undergoing laparoscopic gastric bypass. According to the trial, TAP block reduced opioid requirement, improved pain score, promoted early ambulation, and was associated with greater patient satisfaction.

Based on the promising results of TAP block in different abdominal procedures, we conducted the present study to investigate the effect of TAP block on postoperative pain after bariatric procedures in patients with morbid obesity. We presumed that TAP block will achieve better pain control, less need for postoperative analgesia, accelerated recovery, hence, decreasing the length of hospital stay, and improving the immediate and short-term outcome of bariatric surgery overall.

Patients &Methods

Study Design and Setting

This was a single-center, double-blinded, prospective, randomized control trial on patients with morbid obesity who underwent laparoscopic bariatric surgery in the General Surgery Department of Mansoura University Hospitals in the period of January 2018 to October 2018. Ethical approval for the trial was obtained from the institutional review board of Mansoura Faculty of Medicine. The clinical trial registration number in www.clincialtrials.gov is NCT03411772.

Eligibility Criteria

Patients of both genders with body mass index (BMI) > 35 kg/m^2 who underwent laparoscopic bariatric procedures within the study period were included in the study. Morbidly obese patients with type II diabetes mellitus were also eligible to be included.

We excluded the following patients:

- Patients unfit for general anesthesia (ASA Class IV and V)
- Patients with secondary obesity due to endocrine disorders
- Patients with psychiatric or neurological disorders
- Patients with drug abuse, history of opioid intake, or chronic pain disorder
- Patients with contraindication to peripheral nerve block such as allergy to local anesthetics and coagulopathy

Random Sequence Generation, Allocation Concealment, and Blinding

Patients were randomly assigned to one of two equal groups; group I (the study group) had ultrasound-guided TAP block upon completion of the bariatric procedure and before recovery from general anesthesia and received systemic analgesia in the form of intravenous infusion of paracetamol and group II (the control group) received systemic analgesia only.

Randomization was undertaken by online randomization software (www.randomization.com). Allocation concealment was conducted by sealed envelope method as randomly generated treatment allocations were placed within sealed opaque envelopes. The envelope was opened by a nurse in the operating room upon completion of the operation and the patient was then assigned to the allocated treatment group.

The study was double-blinded as both patients and operating surgeons were unaware whether TAP block was performed or not. Assessment of postoperative pain and other outcomes was performed by a surgical resident was also unaware of the group allocations and the nature of the study.

Preoperative Assessment

A detailed history was taken from the patients with regard to their complaint, its onset and duration, associated medical comorbidities, previous surgical operations, and previous diet regimens and attempts for weight loss. Thorough clinical examination was done for all patients. Abdominal examination was performed to detect any scars of previous operations or abdominal swellings. For each patient, the height in centimeter and the weight in kilogram were measured and the BMI was calculated.

Patients were subjected to abdominal ultrasonography to exclude associated gallbladder stones or any other abdominal pathology. Eventually, the general condition of patients was evaluated using the American Society of Anesthesiologists (ASA) score.

Technique of Ultrasound-Guided TAP Block

Procedures were performed under general anesthesia with endotracheal intubation. Induction was made using Propofol (1–2 mg/kg), Rucronium (0.5–1 mg/kg), Fentanyl (1 μg/kg), and Dormicum (0.05 mg/kg). Maintenance of anesthesia was done using Isoflurane (1–1.2 mac) with oxygen to air ratio of 1:2. Recovery from anesthesia was done by reversal of the effect of muscle relaxant using neostigmine (0.02–0.04 mg/kg). No reversal of opioid was used during recovery from anesthesia.

All bariatric procedures were performed laparoscopically by consultants of general and laparoscopic surgery. Pneumoperitoneum was created by insufflation of CO^2 at pressure of 15 mmHg. A standard five-trocar technique was employed in all patients regardless the type of procedure performed which included sleeve gastrectomy, mini-gastric bypass, gastric greater curvature plication, and single anastomosis sleeve ileal (SASI) bypass. Staple line reinforcement was not performed in any of the patients in both groups. Closure of 12-mm ports was done by absorbable polyglactin sutures in both groups in a standardized manner using fascial closure device.

Upon completion of the laparoscopic bariatric procedure and just before recovery from general anesthesia, an ultrasound-guided TAP block was performed in the operation theater by a consultant anesthetist with experience in performing TAP blocks for group I patients whereas group II was recovered from anesthesia without having TAP block.

The ultrasound probe (Philips® ClearVue 350, WA, USA) was placed on the lateral abdominal wall in the mid-axillary line between the lower costal margin and iliac crest. Using ultrasound allowed accurate deposition of the local anesthetic in the correct neurovascular plane. A spinal needle was advanced using in-plane technique between the aponeurosis of the internal oblique and transversus abdominis muscles. With intermittent aspiration, 20 mL of local anesthetic (0.25% bupivacaine) was deposited in the TAP on each side and seen as a hypoechoic shadow pushing the two layers apart (Fig. 1).

Postoperative Care and Pain Assessment

Patients were monitored in the regular ward. Postoperative measures against venous thromboembolism including wearing elastic stocking, adequate hydration, and subcutaneous injection of low-molecular-weight heparin (Enoxaprin 40 IU) were taken. A single dose of prophylactic antibiotic (cefotaxime 1 g) was administered intravenously within 12 h of completion of the procedure. Early ambulation was advised for all patients.

Postoperative pain at rest was assessed by a surgical resident at 1, 6, 12, and 24 h postoperatively using the visual analogue scale of pain (VAS) which ranged from 0 that implied no pain to 10 which indicated the worst possible pain. Patients in both groups received systemic analgesia in the form of intravenous infusion of paracetamol (1 g every 8 h). When the pain VAS was 4 or higher, rescue analgesia in the form of intravenous opioids (0.2 mg/kg pethidine, maximum of 75 mg per day) was administered and recorded within the first 48 h.

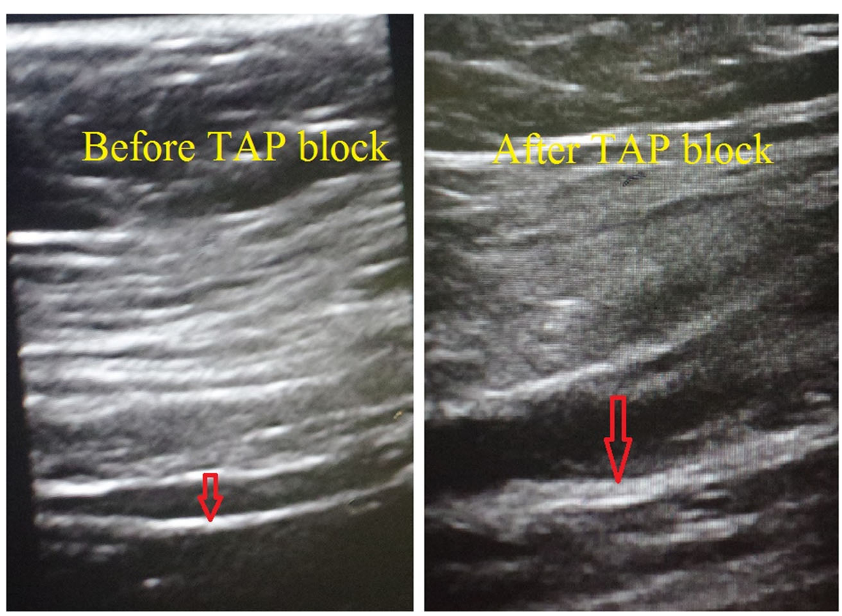

Fig. 1 Process of TAP block as seen on ultrasound examination

Postoperative nausea and vomiting (PONV) was assessed using PONV impact scale which grades the severity of vomiting from 0 to 3 and severity of nausea from 0 to 3 and then combines both scales in one scale from 0 to 6 [17, 18]. The requirement of antiemetic medications (Ondansetron 4 mg) and time to full ambulation were recorded in each group. TAP block-related complications as hematoma and pain necessitating local anesthetic injection and other postoperative complications were also recorded.

Outcomes of the Study

The primary outcome of the study was postoperative pain over the first 24 h after surgery as evaluated by the VAS score and opioids requirements. The secondary endpoints included PONV, need for antiemetic medications, time for full ambulation, hospital stay, rate of complications including TAP block-related morbidities, recovery of bowel functions as assessed by time to first flatus, and patients' satisfaction on discharge as assessed by simple questionnaire (completely satisfied, partially satisfied, and unsatisfied).

Sample Size Calculation and Statistical Analysis

Based on previous trials [15, 16], we assumed that the mean VAS of pain at 6 h postoperatively will range from 2 to 5 (median = 4) after ultrasound-guided TAP block (group I) and will range from 5 to 8 (median = 6) in the control group. Using sample size calculation software (www.powerandsamplesize.com), a minimum of 66 patients, equally divided into two groups, was needed to achieve a study power of 90% with alpha set at 5%.

Data were analyzed using SPSS version 23 (IBM Corp, Chicago, USA). Normally distributed data were presented as mean and standard deviation and non-normally distributed data as medians quartiles (interquartile range). Continuous data were processed using Student's *t* test and categorical data were processed using chi-square analysis or Fisher's exact test where applicable. *P* values less than 0.05 were considered significant.

Results

Patients' Characteristics and Procedures Performed

Ninety-eight patients with morbid obesity were initially assessed, 6 patients did not meet the inclusion criteria, thus were excluded and 92 patients were finally included to the study (Fig. 2). Patients were 85 (92.3) female and 7 (7.7%) male. The mean age of patients was 34.7 ± 9.4 (range, 21–56) years.

The mean preoperative BMI of patients was 49.5 ± 6.7 (range, 35.4–65.7) kg/m^2. Twenty-six (28.2%) patients had type II diabetes mellitus, 33 (35.8%) had hypertension, 51 (55.4%) complained of sleep apnea, and 49 (53.2%) complained of joint pain.

Sixty-four (69.5%) patients underwent laparoscopic sleeve gastrectomy, 8 (8.7%) underwent gastric greater curvature plication, 7 (7.6%) underwent mini-gastric bypass, and 13 (14.1%) underwent SASI. None of the patients in both groups required conversion to open surgery. There were no significant differences between the study group and the control groups regarding patients' age, gender, baseline BMI, associated comorbidities, ASA grade, and type of procedure performed as shown in Table 1.

Pain Scores and Analgesic Requirement in both Groups

The mean pain VAS in group I was significantly lower than group II at 1 hour (4.8 ± 1.3 vs 7.6 ± 0.7) and 6 hours (3.2 ± 1 vs 5.4 ± 0.9) postoperatively. The mean pain scores at 12 and 24 h after surgery were comparable in both groups with no statistically significant differences (2.3 ± 0.9 vs 2.5 ± 0.6) and (1.7 ± 0.6 vs 1.8 ± 0.8), respectively (Table 2). Eight (17.4%) patients in group I required rescue opioid analgesia within the first 24 h postoperatively, compared with 24 (52.1%) patients in group II ($P < 0.0001$).

Postoperative Nausea and Vomiting in both Groups

The PONV score at 24 h was significantly lower in group I than group II (2.1 ± 0.9 vs 3 ± 0.9; $P < 0.0001$). However, a comparable number of patients in both groups required antiemetic medications in the first 24 h postoperatively (19 in group I vs 23 in group II; $P = 0.53$) (Table 3).

Early Postoperative Outcome in both Groups

There was no significant difference between the two groups in regards the mean operation time (80.9 ± 16.9 min in group I vs 78.3 ± 14.5 min in group II, $P = 0.43$).

Group I attained significantly shorter time to full ambulation and to pass flatus than group II (Table 3). Hospital stay was similar in the two groups (1.76 ± 0.56 vs 1.74 ± 0.6; $P = 0.87$).

Regarding postoperative complications, three patients in group I experienced TAP block-related complications (two patients developed hematoma at the site of needle entry and one patient complained of severe pain at the site of injection), and two patients in group II experienced port site bleeding that was managed conservatively.

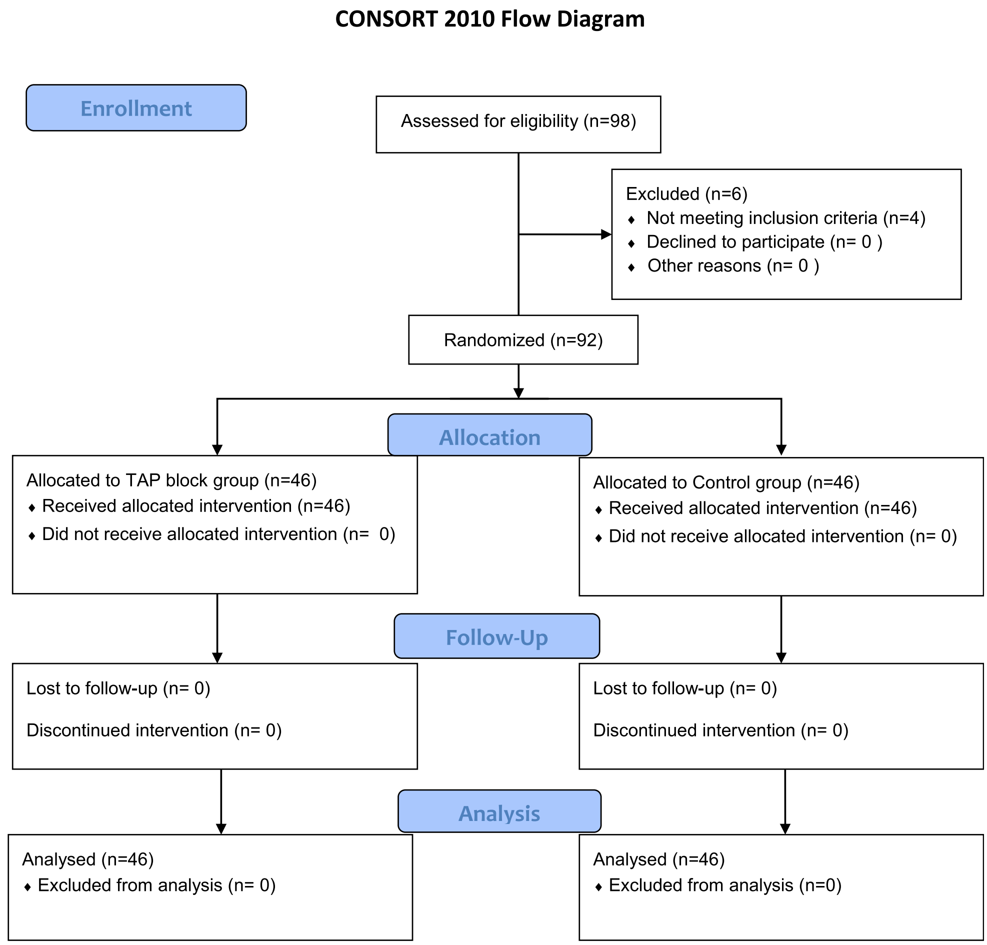

Fig. 2 Consort flow chart of the study

Eighty-seven percent of patients in group I were completely satisfied with the early outcome of their procedure, compared with 30.5% of group II (Table 3). One patient in group I and three in group II were unsatisfied with the early outcome of their surgery, particularly the degree of postoperative pain and PONV.

Table 1 Preoperative characteristics and procedures performed in both groups

Variable		Group I (study group) [$n = 46$]	Group II (control group) [$n = 46$]	P value
Mean age in years		35.8 ± 8.9	33.6 ± 9.8	0.26
Male/female		3/43	4/42	1
Mean preoperative BMI in kg/m^2		50.4 ± 7.9	48.6 ± 5.3	0.2
ASA grade	I	21 (45.6)	18 (39.1)	0.61
	II	23 (50)	24 (52.2)	
	III	2 (4.4)	4 (8.6)	
Associated comorbidities	D.M. (%)	12 (26.1)	14 (30.4)	0.82
	Hypertension (%)	15 (32.6)	18 (39.1)	0.66
	Sleep apnea (%)	24 (52.2)	27 (58.7)	0.67
	Joint pain (%)	28 (60.8)	21 (45.6)	0.21
Bariatric procedures performed	Sleeve gastrectomy (%)	29 (63)	35 (76.1)	0.26
	Greater curvature plication (%)	6 (13)	2 (4.3)	0.27
	Mini-gastric bypass (%)	3 (6.5)	4 (8.6)	1
	SASI (%)	8 (17.4)	5 (10.8)	0.55

BMI, body mass index; *SASI*, single anastomosis sleeve ileal bypass; *D.M.*, diabetes mellitus

Table 2 Pain scores at different time points in both groups

Variable	Group I (study group)	Group II (control group)	*P* value
Mean pain VAS at 1 h	4.8 ± 1.3	7.6 ± 0.7	< 0.0001
Mean pain VAS at 6 h	3.2 ± 1	5.4 ± 0.9	< 0.0001
Mean pain VAS at 12 h	2.3 ± 0.9	2.5 ± 0.6	0.21
Mean pain VAS at 24 h	1.7 ± 0.6	1.8 ± 0.8	0.49

VAS visual analogue scale

Discussion

Management of postoperative pain after abdominal procedures is an important and integral component of postoperative care. Improper control of postoperative pain can be associated with delayed ambulation and recovery, higher rate of complications, longer opioid usage, higher health care costs, functional impairment, and lower quality of life [17].

Postoperative pain after bariatric procedures can be particularly challenging because this patient population is more amenable to both pain-related complications and opioid-related morbidities, especially respiratory depression [19]. Given the current implications of the opioid crisis [20], alternative pain-control measures were suggested, one of which is the TAP block. TAP block has proved effective in control of postoperative pain after a multitude of upper and lower abdominal procedures, including cesarean section [10–14].

The aim of the present randomized trial was to assess the efficacy and safety of TAP block after various laparoscopic bariatric procedures. Although previous trials [15, 16, 21, 22] evaluated the impact of TAP block after individual bariatric procedures including sleeve gastrectomy and Roux-en-Y-gastric bypass, our trial aimed to assess this impact after a variety of bariatric operations to verify whether the beneficial effect of TAP block is generalizable over a wide spectrum of bariatric procedures.

We included 92 patients, more than 90% of whom were female in concordance with the female predominance of patients undergoing bariatric procedures as reported in the literature [23]. Around 70% of patients underwent laparoscopic sleeve gastrectomy which became the most popular bariatric procedure in our community, and one of the most frequently performed bariatric surgery across the world [24].

Patients were randomly assigned to one of two equal groups, only patients in the first group received TAP block before recovery from anesthesia. The two groups were comparable with regard patients' demographics, ASA score, associated comorbidities, and type of procedure performed which reflects the absence of selection bias in the study, most probably due to proper randomization of patients to each group as Akobeng [25] implied.

Patients in the TAP block group had significantly lower pain scores than the control group up to 6 h after surgery. However, pain scores at 12 and 24 h were similar in both groups which can be explained that the reported duration of action of TAP block after single shot injection is between 6 and 8 h [26]. This finding was in the line with Wasef and colleagues [15] who also found the pain-relieving effect of TAP block was limited to 6 h after bariatric surgery with no significant difference to the control group at 24 h.

On the other hand, other studies [21, 22] that assessed the impact of TAP block after sleeve gastrectomy and Roux-en-Y-

Table 3 Early postoperative outcomes in both groups

Variable		Group I (study group)	Group II (control group)	*P* value
Mean operation time in minutes		80.9 ± 16.9	78.3 ± 14.5	0.43
Number of patients that required opioid analgesia (%)		8 (17.4)	24 (52.1)	0.001
Mean PONV score		2.1 ± 0.9	3 ± 0.9	< 0.0001
Number of patients that required antiemetic medications (%)		19 (41.3)	23 (50)	0.53
Mean time to ambulate in hours		6.3 ± 1	7.3 ± 1.2	< 0.0001
Mean time to first flatus in hours		9.5 ± 1.9	10.5 ± 2.2	0.02
Complications (%)		3 (6.5)	2 (4.4)	1
Hospital stay in days		1.76 ± 0.56	1.74 ± 0.6	0.87
Patients' satisfaction	Completely satisfied (%)	40 (87)	14 (30.5)	< 0.0001
	Partially satisfied (%)	5 (10.8)	29 (63)	< 0.0001
	Unsatisfied (%)	1 (2.2)	3 (6.5)	0.61

PONV postoperative nausea and vomiting gastric bypass found the analgesic effect of TAP block extends up to 24 h postoperatively. Nonetheless, since these studies [21, 22] used a different anesthetic agent (ropivacaine) than the one we used in the current trial, the difference in the duration of action of TAP block may be explained. As Said et al. [27] highlighted in their trial, continuous infusion of bupivacaine through laparoscopically placed epidural catheters in the transversus abdominis plane may help achieve the sustained analgesic effect of TAP block, up to 24 h after sleeve gastrectomy.

The tangible analgesic effect of TAP block was echoed by a significantly lower rate of patients who required rescue opioid analgesia within the first 24 h postoperatively, compared with the control group. In contrast, Wasef et al. [15] found no statistically significant difference between the two groups in cumulative opioid consumption at 24 h; however, the small sample size (total number = 35) in their study may be the cause of this insignificant difference. Similarly, Albrecht et al. [1] found comparable cumulative opioid consumption in the two groups; however; since the authors infiltrated the trocar sites in both groups with local anesthetic, this confounding factor may explain the difference in outcome to our trial.

The analgesic effect of TAP block was also associated with significantly lower PONV scores, in line with Mittal et al. [21] and other studies [28, 29] that have linked lower pain scores after TAP block in patients undergoing abdominal and pelvic surgeries with lower opioid consumption and PONV scores. Nevertheless, we could not detect a significant difference in the amount of antiemetic medications required in both groups, in agreement with the findings of Saber et al. [22].

Further, beneficial effects of TAP block were demonstrated by a shorter time to ambulate and to pass flatus in the study group. Time taken for the patient to fully ambulate is highly related to the degree of postoperative pain as patients with marked abdominal pain are usually unable to ambulate freely. Patients who received TAP block were able to ambulate 1 hour earlier than the control group, in agreement with other investigators [16, 21, 27] who reported that TAP block was associated with significantly shorter time to ambulate. Conversely, Saber et al. [22] reported no significant impact of TAP block on pain control and subsequently no impact on PONV scores or time to ambulate.

Earlier return of bowel function after TAP block was noted by shorter time to pass flatus. It has been reported that adequate pain control can prevent sympathetic activation, hence is associated with minimal sympathetic inhibition of gastrointestinal motility and earlier recovery of bowel function after surgery [30]. The impact of TAP block on the return of bowel function after bariatric surgery has not been investigated in previous randomized trials. On the other hand, studies that assessed the effect of TAP block in colorectal surgery documented that it was associated with expedited recovery of bowel function [31].

The two groups were comparable in terms of hospital stay and postoperative complications which were all of minor degree. More patients in the TAP block group were completely satisfied with their procedure on discharge, most probably due to better pain control and lower PONV scores in this group.

The mean operation time in both groups was comparable; hence, the impact of the duration of anesthesia on PONV was similar in the two groups. Similarly, all procedures in both groups were performed under the same pressure pneumoperitoneum and the port sites were closed in a standardized manner; thus, the impact of pressure and abdominal wall closure on postoperative pain is comparable in both groups.

Finally, it is important to note that TAP block relieves postoperative parietal pain related to the abdominal wall, nonetheless, it does not address visceral pain due to gut and stomach contractions. Therefore, systemic analgesia is mandatory, even when TAP block is performed, to alleviate visceral pain and that is why we used intravenous infusion of paracetamol in all patients in the study.

Limitations of the present trial included being a single-institution trial, short follow-up, and inclusion of different bariatric procedures which may render the methods used in both groups heterogeneous. However, since all procedures were performed by a standard 5-port technique, the impact of surgery on the parietal abdominal wall would have been similar. Furthermore, no significant difference between the two groups regarding the type of surgery performed was observed, thus the impact of the type of surgery on postoperative pain and recovery may be minimal. The study was not placebo-controlled which may be considered another limitation of the study; however, since the patients were under anesthesia when they received the TAP block, they were unaware of the intervention performed and could not identify whether they had TAP block or not postoperatively; therefore, the placebo effect would be minimal in such case. Moreover, previous trials [1, 15, 21] that compared TAP block versus no block reported similar findings to the studies [16, 22] that were placebo-controlled by injecting normal saline in the transversus abdominis plane which may imply that the impact of omitting placebo on the outcome of the trial may be minimal.

Conclusion

Ultrasound-guided TAP block after laparoscopic bariatric surgery achieved lower pain scores, lower opioid requirements, lower PONV scores, earlier ambulation, shorter time to pass flatus, and comparable hospital stay and complication rate to the control group.

Authors' Contributions Sameh Emile and Khaled Elbahrawy designed the study. Khaled Elbahrawy performed the US-guided TAP block for patients and contributed to data analysis and revision of the manuscript. Sameh Emile, Mohamed Abdel-Razik, Ayman Elshobaky, Waleed Gado, and Hosam Elbanna performed the surgical procedures, followed the patients, and shared in data analysis and writing of the manuscript. Mostafa Shalaby and Samy Elbaz participated in patient follow-up, data interpretation, and drafting and critical revision of the manuscript.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Statement of Informed Consent Informed consent was obtained from all individual participants included in the study.

Statement of Human and Animal Rights This study was conducted in accordance with the declaration of Helsinki. Ethical approval for the study was obtained from the Institutional Review Board (IRB) of Mansoura Faculty of Medicine.

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