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ORIGINAL ARTICLE

Modified Thoracoabdominal Nerve Block Through Perichondral Approach Versus Oblique Subcostal Transversus Abdominus Plane Block for Analgesia after Laparoscopic Cholecystectomy, a Non-inferiority Randomized Trial

Alrefaey K. Alrefaey, Mohamed A. Mamoun
Department of Anesthesia and Surgical Intensive Care, Mansoura University, Egypt.

Correspondence to *Alrefaey K. Alrefaey, Department of Anesthesia and Surgical Intensive Care, Mansoura University, Egypt.*
E-mail: Refa3ey2@yahoo.com

Background Patients suffer a considerable degree of pain after laparoscopic cholecystectomy (LC). Oblique subcostal transversus abdominis plane (OSTAP) block was frequently used for pain relief following LC. Recently, OSTAP block showed inadequate pain control and heterogeneous analgesia coverage. The M-TAPA block possesses analgesic properties that are adequate for pain control after LC.

Methods This prospective randomized trial enrolled 35 patients in each study group. After anesthesia induction and before skin incision, group M patients received bilateral M-TAPA block, while group S patients received bilateral OSTAP block.

Results The data recorded showed a statistically significant decrease of the NRS score for group M at rest at 6, 12, and 24 hours after surgery (p 0.047, p 0.001, p 0.011 consecutively) and on cough at 6 and 12 hours after surgery (p 0.038, p 0.002 consecutively). The NRS score at rest showed a statistically significant decrease in Group M (2.1±0.5 for group S, 1.8±0.5 for group M, p 0.007. The intraoperative requirement for fentanyl boluses, the mean postoperative rescue analgesia for the first day, times of postoperative analgesic requests, the mean NRS score at rest, and the mean NRS score on cough were comparable in both groups.

Conclusion Our study confirms the non-inferiority of M-TAPA block as an analgesic modality when compared to S-TAP block after LC surgeries. further studies are recommended in high-risk patients, like the morbidly obese and pediatric patients.

Keywords Analgesia, Cholecystectomy, Laparoscopic, Thoracoabdominal, Transversus abdominis.
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INTRODUCTION

Laparoscopic cholecystectomy (LC) is the definitive treatment for gallstone disease. Despite being a minimally invasive procedure, LC is followed by moderate to severe pain. A diversity of analgesic modalities are used for pain control after LC, with the merits and drawbacks of each option, including non-steroidal anti-inflammatory drugs (NSAIDs), port site infiltration, intraperitoneal medications, abdominal wall blocks, and neuraxial techniques [1,2].

The transversus abdominis plane (TAP) block is facial plane block with a well-known analgesic efficacy after laparoscopic surgeries [3,4]. The simplicity of the technique; especially when guided by ultrasound, and the fast learning curve has encouraged the addition of TAP block in many ERAS and PROSPECT guidelines [1]. Among the approaches for TAP block, the oblique subcostal technique results in a more suitable nerve block distribution and has been reported to reduce pain and consumption of analgesic medications after LC [5] However, the heterogeneity of analgesia distribution in the OSTAP block and the doubtful efficacy against visceral pain were raised in different studies [6,7] Also, applying OSTAP block can be technically demanding in morbidly obese patients, patients with stomas, and in the presence of previous abdominal incisions [8].

Based on the above limitations of the OSTAP block, Tulgar *et al.,* targeted the thoracolumbar nerves earlier in their course, toward the TAP space, by injecting the local anesthetic (LA) above and under the 10th rib. The traditional block was named the thoracolumbar nerve block through perichondrial approach (TAPA) [9]. Later, modified TAPA (M-TAPA) was performed by solely introducing the LA under the chondrium with a similar LA distribution [10]. The M-TAPA resulted in effective abdominal wall analgesia with a wider dermatomal distribution as a result of blocking the lateral and anterior divisions of thoracoabdominal nerves T5-T11 [11]. Such properties made the M-TAPA approach a potential choice for analgesia following LC.

This study investigated the analgesic impact of M-TAPA block compared to the OSTAP block after LC. We hypothesized that M-TAPA is equivalent to OSTAP, resulting in a comparable analgesia after LC. The primary outcome was the mean postoperative numeric rating scale (NRS) score on the 1st 24 hours after surgery. The secondary variables included the postoperative NRS scores at rest and on cough, the total morphine consumption in the first day after surgery, and the total incidence of postoperative nausea and vomiting (PONV).

MATERIALS AND METHODS

This prospective, double-blinded, randomized study was conducted in a single University Hospital after the approval of the Institutional Review Board and Clinical Trial Registry. The study followed the Helsinki Declaration and the CONSORT reporting guidelines. Informed consent was obtained from eligible candidates, including adult patients scheduled for LC, with an American Society of Anesthesiologists (ASA) physical status classification of I and II. Patients with previous abdominal incisions, neuropsychiatric diseases, or known allergies to the study medications were excluded.

Randomization, allocation, and blinding technique:

A software-generated randomization list randomized the patients into two equal groups: (Group M; *n*= 35), (Group S; *n*= 35); in variable blocks of 6,8 in each group. On the day of surgery, an independent physician used opaque sealed envelopes, including generated codes, to allocate patients in each group. The health care workers involved in perioperative data retrieval were blinded to group assignment.

Anesthesia technique:

Upon arrival in the operating theatre, the patients were connected to basic monitors (heart rate [HR], noninvasive arterial blood pressure, and peripheral oxygen saturation [SpO2]). Intravenous access was secured, intravenous (IV) fluids started, and premeditations were administered (4mg of Ondansetron IV and 3mg of Midazolam IV). General anesthesia was induced using propofol at 1–2 mg/kg, fentanyl citrate at 1µg/kg, while Atracurium besylate at 0.5mg/kg was used to facilitate tracheal intubation. Anesthesia was maintained using sevoflurane in a 40% oxygen-air mixture. In our center, LC is performed through the 4-port standard approach "10-10-5-5". The 10-mm umbilical and epigastric ports were used for the camera and the operator instruments, while the 5-mm right hypochondrial and lumbar ports were used for fundal traction and the assistant instrument. After skin closure, patients were extubated upon achieving the required criteria and were subsequently shifted to recovery room.

Block techniques, Figure (1):

Both study blocks were performed bilaterally before the incision and after ensuring complete asepsis. For the M-TAPA, the ultrasound (US) probe (Toshiba Xario, Japan, PLT 805AT transducer, 12 MHz) was sagittally placed over the costochondral angle at the 10th rib. A slight compression was applied to the caudal end of the probe to facilitate the view of the transversus abdominis muscle (TAM), internal oblique (IOM), and external oblique (EOM) muscles. Using an in-plane or oblique alignment, a 22-G, 80mm block needle was introduced toward the posterior surface of the 10th costal cartilage inserted in the cranial direction. After confirming proper position using hydro-dissection, 20mLs of 0.25% bupivacaine were injected into the target area. In group S, the OSTAP block was performed while the US probe was obliquely placed in the subcostal region near to the midline. The probe was shifted obliquely and laterally the identify the TAM below the RAM. An 80mm, 22-gauge block needle was advanced and a 20mL of 0.25% bupivacaine was administered between the two muscles (in-plane technique).

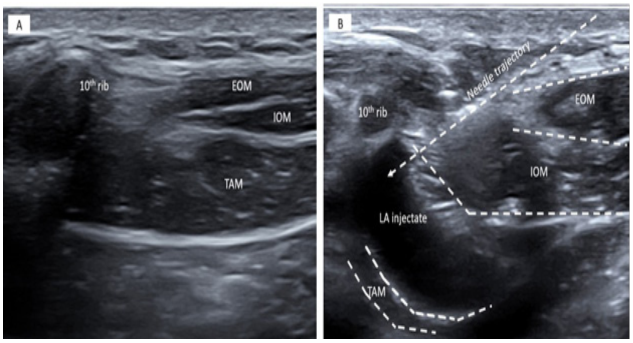

Figure 1: Ultrasound image of M-TAPA block (A): before injection, (B): after injection side). The dashed arrow line indicates the needle trajectory. EOM: external oblique muscle, IOM: internal oblique muscle, TAM: transversus abdominus muscle, LA injectate: Local anesthetic injectate.

Perioperative analgesia plan:

In both groups, 1g of paracetamol was given almost 30min before skin closure. A 50-μg bolus of fentanyl citrate was given IV when inadequate analgesia was diagnosed by a 20% increase in the hemodynamic measurements, in the absence of other causes. Postoperative analgesia orders included IV paracetamol in the dose of 1g/6h for all patients and ketorolac tromethamine 30mg IV each 12 hours. Rescue analgesia of 0.05mg/kg of IV morphine was administered if the postoperative NRS scale was ≥4. Postoperative morphine dose was titrated to a maximum daily dose of 20mg or when side effects appear; including sedation (Ramsey scale less than 2), respiratory depression (RR less than 12 or Spo2 less than 95 on oxygen support), severe allergy or persistent vomiting.

Sample size and Statistical analysis

The sample size was estimated using the formula: $n = f(\alpha, \beta) \times 2 \times \sigma^2/d^2$ [12]. We assumed a minimum increase in the postoperative NRS score of 1.5 (ε= 1) to be clinically significant. According to a meta-analysis by Wang *et al.,* [13]. The NRS score at 6 hours after LC in patients receiving OSTAP was 1.6±1.3. Enrollment of sixty patients was required to demonstrate the non-inferiority of the M-TAPA block compared to the OSTAP block after LC (with an alpha error of 0.05, a beta error of 0.10, and an SD (σ) of 1.3). The study included a total of 70 patients to compensate for possible dropouts.

The study data were statistically analyzed using the IBM SPSS Statistics program, version 22, USA. The numerical variables were shown as means±standard deviation, median (minimum, and maximum). The normality of quantitative data distribution was examined using the Shapiro-Wilk test. The qualitative variables were shown as numbers and percentages. Microsoft Excel software 2016 was used to generate descriptive figures. We used the unpaired *t*-test and the Mann-Whitney *U* test for evaluating the numerical variables. Pearson's Chi-square or Fisher exact test were applied in independent group comparisons of qualitative variables, as appropriate. A *p*-value less than 0.05 were considered statistically significant in all statistical tests.

RESULTS

Of the 74 patients recruited for the study from January 2024 to December 2024, 70 were enrolled and randomly allocated into two equal groups, see Figure (2). Table (1) shows the basal characteristics, with no statistically significant differences. In Table (2), the intraoperative hemodynamic measurements (HR, MAP) for groups S and M showed statistical similarity.

The box and whisker graph in Figure (3) illustrates the NRS for both groups at rest and on cough. The data recorded at 1, 2, 4, 6, 12, and 24 hours did not exhibit any statistically significant variation between the two study groups except for a statistically significant decrease of the NRS score for group M at rest at 6, 12, and 24 hours after surgery (*p* 0.047, *p* 0.001, *p* 0.011 consecutively) and on cough at 6 and 12 hours after surgery (*p* 0.038, *p* 0.002 consecutively).

The intraoperative requirement for fentanyl boluses, the mean postoperative rescue analgesia (milligrams of morphine) for the first postoperative day, times of postoperative analgesic requests, the mean NRS score at rest, and the mean NRS score on cough were recorded in Table (3). Among the aforementioned variables, the NRS score at rest significantly decreased in Group M when compared to group S. Also, the mean incidence of PONV was statistically similar in the two study groups see Table (3).

No complications related to the block technique (ecchymosis, hematoma, local infection) were recorded in either of the study groups.

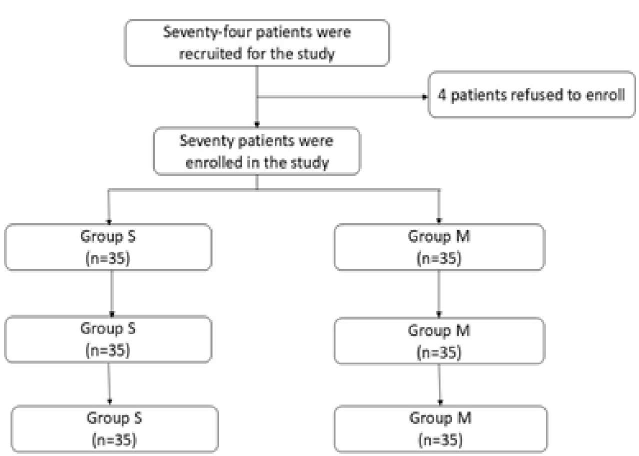

Figure 2: Study flow chart.

Table 1: Basal characteristics in the two studied groups. Data are presented as mean±SD, or absolute numbers:

	Group S (*n*= 35)	Group M (*n*= 35)	*P* value
Age (years)	45.9±13.5	43.4±14.8	0.460
Weight (Kg)	78.3±14.9	76.2±10.9	0.501
Height (cm)	170.1±5.6	171.7±5.9	0.242
BMI (kg/m^2)	27.1±5.5	25.9±3.8	0.272
Gender (M/F)	13/22	7/28	0.112
DM	9(25%)	4(11%)	0.218
HTN	11(31%)	7(20%)	0.274
ASA physical status	3(8.6%)	3(8.6%)	1
Duration of surgery (min)	77.0±12.4	81.2±10.5	0.134

BMI: Body mass index; M: Male; F: Female; DM: Diabetes mellitus; HTN: Hypertension; ASA: American Society of Anesthesiologists; Independent Samples *T*-test for parametric quantitative data between the two groups; Chi-square test or Fisher exact test for qualitative data between the two groups.

Table 2: Intraoperative hemodynamic data in the two studied groups. Data are presented as mean±SD:

		basal	15min	30min	60min	End surgery
HR (bpm)	Group S	82.7±9.9	77.4±9.8	75.5±9.6	76.5±10.3	77.7±10.2
	Group M	84.1±10.7	78.3±10.2	77.1±9.8	77.6±9.7	80.4±11.7
	P value	0.565	0.703	0.510	0.662	0.301
MAP (mmHg)	Group S	90.3±8.2	82.7±13.8	80.3±12.7	82.7±12.3	84.9±12
	Group M	86.7±12.7	81.7±11.8	80.6±10.0	80.5±11.1	81.6±10.1
	P value	0.163	0.746	0.917	0.436	0.229

HR: Heart rate; bpm: beats per minute; MAP: Mean arterial pressure; mmHg: millimeters of mercury Independent Samples *T*-test for parametric quantitative data between the two groups.

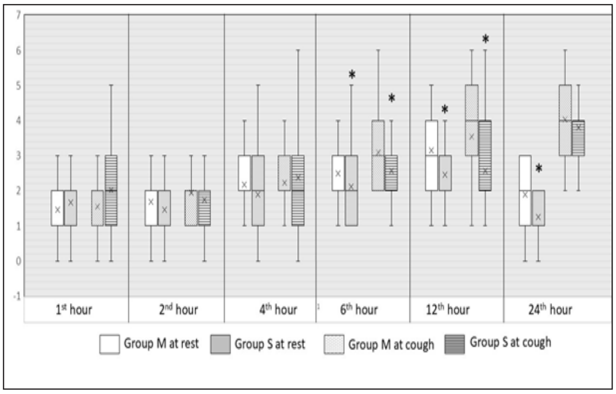

Figure 3: Box and whisker graph of the postoperative Numerical Rating Scale scores at rest and on cough in the two studied groups. Mann-Whitney test for non-parametric quantitative data between the two groups: * Indicates a significant p level when less than 0.05.

Table 3: Postoperative characteristics in the two studied groups. Data are presented as median (min-max), mean±SD, or numbers (%):

	Group S (*n*= 35)	Group M (*n*= 35)	*P* value
Intraoperative bolus analgesia *n* (%)	6(17%)	5(14%)	*0.743*
Postoperative rescue analgesia requests	0(0-2)	0(0-1)	*0.610*
Postoperative morphine consumption (mg)	0(0-8.5)	0(0-4.5)	*0.653*
Mean NRS score at rest	2.1±0.5	1.8±0.5	*0.011**
Mean NRS score on cough	2.7±0.8	2.5±0.7	*0.268*
The incidence of PONV *n* (%)	8(11%)	6(8.6%)	*0.550*

NRS score: Numerical rating scale score; PONV: Postoperative nausea and vomiting. Mann-Whitney test for non-parametric quantitative data between the two groups. Pearson Chi-square test for qualitative data between the two groups. *: Indicates a statistical significance when the *p*-value is less than 0.05.

DISCUSSION

This study investigated the M-TAPA block in comparison to the OSTAP block regarding their analgesic profiles in the first postoperative day after LC. The postoperative analgesic properties of the M-TAPA block matched the OSTAP block at the first 4 hours. Afterward, the M-TAPA group showed a statistically significant reduction in the NRS scores at 6, 12, 24 hours after LC. The mean NRS score at rest was statistically lower in group M, while the mean NRS on cough and the mean postoperative rescue analgesia consumption were similar in both study groups. Our results support the non-inferiority of the M-TAPA block as an analgesic modality after LC, when compared to the OSTAP block.

LC is a commonly performed surgery and is considered the definitive treatment for calcular cholecystitis. Despite the minimally invasive nature, pain scores after LC can significantly affect the patients' perioperative experience and pose a management challenge [14] Pain after LC includes a parietal component originating from port site incisions, and a visceral component, resulting from the diaphragmatic and peritoneal stretching, increased peritoneal acidity, peritoneal irritation by the insufflating gas, the release of pro-inflammatory mediators, and dissection of the gall bladder from its bed in the liver [15]. A diverse range of analgesic techniques have been applied after LC, like Paracetamol, NSAIDs, Gabapentinoids, Dexamethasone, and Opioids [1]. With the emergence of enhanced recovery protocols, regional blocks were utilized to improve patient satisfaction and facilitate recovery, including intrathecal injections, erector spinae block, TAP block, and local wound infiltration [16].

Among the regional blocks used for pain after LC, the OSTAP block has shown a significant potency in decreasing pain scores and analgesic requirements [17]. LA infiltration into the TAP plane will soak the thoracoabdominal nerves, and result in analgesia over the anterolateral abdominal wall. The PROSPECT guidelines recommend the OSTAP as a second-line analgesic strategy after LC, especially in the presence of an experienced anesthetist. [1]. Yet, the possible complications of the OSTAP include LA toxicity, wrong-site injection, and visceral injury [18]. Also, the technical difficulty increases in the morbidly obese patients and patients with previous abdominal incisions. Even thin patients can have a higher possibility of needle-induced visceral injury. Also, the TAP block is highly affected by the non-homogeneous spread of the LA in the interfacial TAP plane [19]. and the lateral cutaneous branches of the thoracoabdominal nerves may not be blocked effectively in either the lateral or subcostal approach [20]. The rise of other regional and facial plane blocks with more solid landmarks was expected to have a higher success rate, a better safety profile, and a lower technical demand.

Based on the above limitations of the different approaches available for TAP blocks [19]. Tulgar *et al.,* targeted the thoracolumbar nerves earlier in their course, before entering the TAP space. The goal of the new technique was to target the anterior and lateral cutaneous divisions above and below the costal cartilage Later, Tulgar *et al.,* improved their initial block by infiltration of the LA to the lower surface of the costal cartilage which was found to effectively block the thoracoabdominal nerves during their course to the TAP space including the lateral cutaneous branches. The dermatomal spread of the Modified block extends between T5 and T11 levels, which provides a consistent sensory loss and acts as analgesia for abdominal surgeries [8,21]. The extent beyond the T11 level is not supported in many anatomical and clinical studies [22,23].

The efficacy of M-TAPA after LC was explored in different abdominal surgeries. In a study comparing bilateral M-TAPA block to no block in the control group, Bilge *et al.,* concluded that M-TAPA decreased the pain scores, analgesic requirements, and improved quality of recovery after LC [24]. Similar results were published by Ertürk *et al.,* for both TAPA and M-TAPA blocks [25]. Likewise, in a retrospective case-control study of LC patients, the authors recommended integrating the M-TAPA block in the perioperative protocols of LC, especially in middle-income countries, because of the improved analgesia, earlier mobilization, and faster oral intake [26]. Also, when the M-TAPA block was compared to local infiltration after LC, it decreased the NRS scores, analgesic requirements, and the incidence of PONV [20,27]. Parallel to our results, the meta-analysis by Park *et al.,* [20]. indicated that the analgesic efficacy and M-TAPA, including NRS scores and rescue analgesic requirements, were similar in other analgesic modalities with a lower incidence of postoperative adverse events, especially PONV [20].

The M-TAPA block was also compared to other novel abdominal wall blocks in the setting of LC. After the assessment of sensory block over the ventral abdominal wall using cold sensation, the M-TAPA produced a comparable block to that of the external oblique block (EOB), with a more superior midabdominal distribution. This pattern of distribution indicates a more reliable spread around the anterior cutaneous branches of the T6-T12 fibers [28].

Even in surgeries other than LC, the M-TAPA block could prove its analgesic efficacy. In laparoscopic inguinal hernia repair surgery, the M-TAPA block improved the patients' recovery and pain scores [29]. Also, the M-TAPA block provided a sufficient analgesia in a case series of sleeve gastrectomy patients [22]. Conversely, when the M-TAPA block was applied in laparoscopic gynecological surgeries, the lack of consistent spread beyond T11 resulted in weak evidence to support the use of in lower abdominal surgeries [30]. A similar conclusion of inconsistent analgesia in open gynecological surgeries was adopted by Tanaka *et al.,*[23].

Our study has some limitations. The exclusion of patients with expected difficult sonographic views will limit the generalization of the results and warrant the requirement for future studies in these groups. The quality of recovery should be compared between the two groups using a recovery score system like QOR-15, which would be more informative about the patient outcome and satisfaction, which was not used in our study. Also, the addition of adjuvants to bupivacaine would increase the efficacy and the duration of analgesia, however, this is not believed to affect the results.

Our study confirms the non-inferiority of M-TAPA block as an analgesic modality when compared to S-TAP block after LC surgeries. Based on our results, the M-TAPA block can offer a preferable analgesic option after LC. We believe that further studies are required to confirm the safety and efficacy of M-TAPA block, especially in high-risk patients like the morbidly obese and pediatric patients.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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