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Research Article

Modified thoracoabdominal nerve block with perichondrial approach in laparoscopic cholecystectomy surgery: a prospective, randomized, controlled, double-blind study

Laparoskopik kolesistektomi cerrahisinde perikondrial yaklaşımla modifiye torakoabdominal sinir bloğu: prospektif, randomize, kontrollü, çift kör bir çalışma

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Abstract

Aim: Although laparoscopic cholecystectomy (LC) is considered minimally invasive, it can cause moderate to severe pain in the postoperative period. This study investigates the effects of modified thoracoabdominal nerve block with perichondrial approach (M-TAPA) on postoperative analgesia after LC.

Material and Methods: The patients were divided into two groups: Group M (patients who received the M-TAPA block) and Group C (control group patients who did not receive the block). The primary outcome measures were the pain scores at 0, 2, 4, 8, 12, and 24 hours postoperatively. The secondary outcome measures included the total amount of rescue analgesic consumed, the time to first rescue analgesia, the occurrence of complications (nausea, and vomiting), and patient satisfaction.

Results: When the change over time of the numerical rating scale (NRS) scores at 24 hours postoperative was evaluated for both rest and movement, the time*group interaction was statistically significant for NRS scores during both rest and movement (p<0.001 and p<0.001, respectively). The total amount of tramadol consumed within the first 24 hours after surgery was higher in Group C (220 (170-260) vs 70 (0-80); P<0.001). Rescue analgesia was administered to all patien ts in Group C; in Group M, 8 patients did not receive rescue analgesic (p<0.005).

Conclusion: The use of M-TAPA as a component of a multimodal analgesia approach helps to reduce opioid consumption, thereby preventing opioid-related side effects and enhancing postoperative patient comfort.

Keywords: laparoscopic cholecystectomy; m-tapa; multimodal analgesia; numerical rating scale

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Öz

Amaç: Laparoskopik kolesistektomi (LC) minimal invaziv olarak kabul edilmesine rağmen, postoperatif dönemde orta ila şiddetli ağrıya neden olabilir. Bu çalışma, LC sonrası postoperatif analjezi üzerine modifiye torakoabdominal sinir bloğu ile perikondriyal yaklaşımın (M-TAPA) etkilerini araştırmaktadır.

Gereç ve Yöntemler: Hastalar iki gruba ayrıldı: Grup M (M-TAPA bloğu uygulanan hastalar) ve Grup C (blok uygulanmayan kontrol grubu hastalar). Birincil sonuç ölçütleri, postoperatif 0, 2, 4, 8, 12 ve 24 saatlerdeki ağrı skorlarıydı. İkincil sonuç ölçütleri, toplam kurtarıcı analjezik tüketimi, ilk kurtarıcı analjezik ihtiyacına kadar geçen süre, komplikasyonların (bulantı ve kusma) görülmesi ve hasta memnuniyetini içeriyordu.

Bulgular: 24 saatlik postoperatif dönemde hem istirahat hem de hareket halindeki numerik derecelendirme ölçeği (NRS) skorlarının zamana bağlı değişimi değerlendirildiğinde, zaman*grup etkileşimi hem istirahat hem de hareket halindeki NRS skorları için istatistiksel olarak anlamlıydı (p<0.001 ve p<0.001, sırasıyla). Ameliyattan sonraki ilk 24 saatte tüketilen toplam tramadol miktarı Grup C'de daha yüksekti (220 (170-260) vs 70 (0-80); P<0.001). Grup C'deki tüm hastalara kurtarıcı analjezi uygulanırken, Grup M'deki 8 hastaya kurtarıcı analjezik uygulanmadı (p<0.005).

Sonuçlar: Multimodal analjezi yaklaşımının bir bileşeni olarak M-TAPA kullanımı, opioid tüketimini azaltarak opioid kaynaklı yan etkilerin önlenmesine ve postoperatif hasta konforunun artmasına yardımcı olmaktadır.

Anahtar Kelimeler: laparoskopik kolesistektomi; m-tapa; multimodal analjezi; numerik derecelendirme ölçeği

Introduction

Laparoscopic cholecystectomy (LC) is a commonly performed surgery considered the gold standard for treating symptomatic gallstone disease [1]. Although LC is considered minimally invasive, it can cause moderate to severe pain in the postoperative period [2]. It has been observed that the majority of total abdominal pain following LC originates from the incision site, with the remainder resulting from visceral and referred pain [2, 3]. Multimodal analgesia, including opioids, is used to limit pain following LC [3]. However, opioid treatment can cause side effects such as postoperative nausea and vomiting, respiratory depression, and constipation [4]. The impacts of interfascial plane blocks on postoperative analgesia in LC surgery have been evaluated in various studies, and positive results have been obtained [5, 6]. The transversus abdominis plane block associated with perichondrium (TAPA) block, as described in the literature, is a novel regional anesthesia technique that provides analgesic effects to the anterior and lateral abdominal wall by injecting local anesthetics into the lower and upper parts of the perichondrium at the costochondral junction [7]. The modified thoracoabdominal nerve block through perichondrial approach (M-TAPA) block is defined as a modification of the TAPA block, in which local anesthetics (LAs) are applied only to the lower surface of the perichondrial area, creating a sensory block between T5 and T12 [8]. The M-TAPA block is thought to provide adequate analgesia in the anterior and lateral

thoracoabdominal walls, covering a wide dermatomal area. It has been used in various abdominal surgeries [5, 9].

Patients with an M-TAPA block during LC will have lower postoperative numerical rating scale (NRS) scores and use less pain medication overall. Our primary objective is to evaluate the postoperative NRS scores in patients undergoing LC with an M-TAPA block. Our secondary objectives are to assess the total amount of rescue analgesia consumed, the time first to rescue analgesia, patient satisfaction, and the occurrence of complications (nausea, and vomiting).

Material and Methods

This study was conducted with approval from the Ethics Committee of Harran University Faculty of Medicine (Date: 26 August 2024, Decision: 24.12.01). The experiment was carried out in accordance with the Declaration of Helsinki's ethical guidelines. Written and verbal informed consent was obtained from the patients. Patients were divided into two groups: Group M (patients who received the M-TAPA block) and Group C (control group patients who did not receive the block).

Patient Population and Inclusion/Exclusion Criteria

Patients aged 18–65 with American Society of Anesthesiologists physical status (ASA) I–III, undergoing laparoscopic cholecystectomy under general anesthesia, were included in the study. Patients with contraindications to regional anesthesia, those using anticoagulants, those with infection at the procedure site, those with allergies to LAs, pregnant women, and emergency cases were excluded from the study.

Randomization

The study was planned as a prospective, randomized, controlled, double-blind. At each clinic, an anesthesiologist randomly allocated patients to two significant groups using numbered opaque sealed envelopes: Group M (patients receiving M-TAPA) and Group C (patients getting just multimodal analgesia). The anesthesiologists responsible for the randomization process were not involved in any other sections of the trial, and the individuals executing the M-TAPA procedure were not engaged in other areas of the research. Additionally, the researcher who intervened, the participants, and the analyzer were blinded to the details of the study. After the surgery, two different anesthesia specialists recorded the primary and secondary results of the study.

Standard Anesthesia and Postoperative Analgesia Protocol

Routine monitoring (ECG, SpO2, non-invasive blood pressure, and EtCO2) and standard anesthesia management were applied to all patients. A 20-gauge intravenous (IV) cannula was placed, and isotonic fluid at 10 ml/kg/h was initiated. General anesthesia was induced with 1 mg IV midazolam, 2 mg/kg IV propofol, 15 mcg/kg IV fentanyl, and 0.6 mg/kg IV rocuronium. Patients were intubated, and anesthesia maintenance was achieved with a mixture of 50% O2 and 50% air containing 2% sevoflurane. The exact surgical procedure was applied to all patients. Under general anesthesia, after the surgery, an M-TAPA nerve block was applied to patients in Group M under ultrasound guidance. All patients received 3x1 g IV paracetamol and 2x1 20 mg IV tenoxicam. When the NRS scores were 4 or above, 1 mg/kg IV tramadol was administered as rescue analgesia.

M-TAPA Block Technique

Patients in Group M were placed in the supine position. After skin antisepsis with 5% povidone-iodine, a sterile drape was placed. The high-frequency (8–13 MHz) linear ultrasound (USG) probe (MyLabFive; Esaote Europe BV Philipsweg 1 6227 AJ Maastricht Netherlands) was covered with a sterile sheath, and the transversus abdominis, internal oblique, and external oblique muscles were identified at the 10th costal margin in the sagittal plane at the costochondral angle. The probe was angled sagittally to visualize the costochondral angle at the edge of the 10th rib and to display the posterior surface of the rib cartilage in the midline. Using an in-plane technique, a 22-gauge, 100-millimeter (mm) Stimuplex A (B.Braun Melsungen AG Germany) peripheral nerve block needle was advanced cranially, and the needle tip was directed towards the posterior surface of the 10th costal cartilage. After negative aspiration, 20 ml of 0.25% bupivacaine was injected under the lower surface of the costal cartilage. The same procedure was repeated on the opposite side.

Outcome Measures

The primary outcome measures were the NRS pain scores (0-10, 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, 7-10 = severe pain) at 0, 2, 4, 8, 12, and 24 hours postoperatively. The secondary outcome measures included the total amount of rescue analgesic consumed, the time to first rescue analgesia, the occurrence of complications (nausea, and vomiting), and patient satisfaction. The age, gender, weight, height, surgery duration, and ASA classification of patients in both groups were recorded. A Likert scale (1 = not satisfied at all, 2 = not satisfied, 3 = neutral, 4 = satisfied, and 5 = very satisfied) was used to assess patient satisfaction.

Statistical Analysis

The study's sample size was calculated using the G*Power program (V.3.1.9.7). We conducted a preliminary study with 10 patients in our clinic. The power analysis was based on the NRS scores (the static NRS scores in the PACU at two hours), which were the primary outcomes of this study. We considered a reduction of two points in the mean pain scores clinically meaningful and important based on a previous study [10]. The mean of the NRS scores in the preliminary study was 5.9 points, with the SD=2.5. We were assuming an α error of 0.05 (two-tailed) with a power of 0.85; at least 27 patients per group were required to obtain a statistically significant value. Therefore, we included 30 patients in each group to anticipate possible dropouts.

The IBM-Statistical Package for Social Sciences (IBM-SPSS Inc., Chicago, IL, USA) 26.0 program was used to analyze the data obtained in the study. The conformity of the data to the normal distribution was examined by the Shapiro-Wilk test. Continuous variables were expressed as mean, standard deviation, or (median (25-75 percentile) according to their distribution status, and categorical variables were expressed as numbers and percentages. In the analysis of continuous variables, the independent sample Student's t-test was applied when parametric test assumptions were met. Otherwise, the Mann-Whitney U-test was applied. The Fisher exact test and Chi-square test were used in the analysis of categorical variables. Analysis of Variance (ANOVA) was utilized for repeated measurements between groups at different times. The statistical significance level was accepted as p<0.05.

Results

Of the planned 65 enrolled patients were first assessed for eligibility in this study; however, five were excluded because they refused participation. The remaining 60 cases were allocated, randomized, and treated according to the protocol (Group C, n=30; Group M, n=30) (Figure 1).



Figure 1. Consolidated Standards of Reporting Trials flow study diagram describing patients progress through the study. M-TAPA, Modified thoracoabdominal nerve block with perichondrial approach. The patient characteristics and time of surgery were similar between groups (Table 1).

Table 1. Baseline characteristics by groups			
Factors	Group C (n=30)	Group M (n=30)	P value
Age (yr)	44±13	44±14	0.907
Female	24 (80%)	20 (66.7%)	0.243
ASA			0.342
1	11(36.7%)	6 (20%)	
2	16 (53.3%)	21 (70%)	
3	3 (10%)	3 (10%)	
Smoking	6 (20%)	12 (40%)	0.091
Coronary artery disease	3 (10%)	5 (16.7%)	0.706
Hypertension	7 (23.3%)	4 (13.3%)	0.317
Lung disase	5 (16.7%)	3 (10%)	0.706
Height (cm)	165.5±6.1	168.6±7	0.089
Weight (kg)	70.3±8.6	73.7±8.2	0.115
BMI (kg m-2)	25.6±3,1	25.9±2.7	0.700
Surgery time (min)	74.1±14	68.5±14.7	0.129

Data presented as mean±standart deviation, median (Q1-Q3), or n(%). Kg, kilogram; cm, centimeter; min, minutes; ASA, American Society of Anesthesiologists physical status.

Primary Outcome

Pain Scores

During the 24 hours postoperatively, both the NRS scores at rest and during movement were consistently higher in Group C at all time points, this difference was statistically significant for the 0th, 2nd, 4th, 8th, 12th, and 24th hours (Figures 2 and 3). In addition, when the change over time of the NRS scores at 24 hours postoperative was evaluated for both rest and movement, the time*group interaction was statistically significant (p<0.001 and p<0.001, respectively) (Figures 2 and 3).



Figure 2. Postoperative numerical rating scores at rest. NRS, numerical rating scale.



Figure 3. Postoperative numerical rating scores at motion. NRS, numerical rating scale.

Secondary Outcomes

Rescue analgesia requirement, and First rescue analgesic time

Rescue analgesia was administered to all patients in Group C; in Group M, 8 patients did not receive rescue analgesic (p<0.005). The postoperative rescue analgesic requirement among groups is displayed in Table 2. The number of patients requiring rescue analgesia was significantly higher in the control group at all time intervals. The difference between the groups was statistically significant for the "0-8", "8-12", "12-24", and "0-24" time intervals (p<0.001, p=0.026, p=0.002, and p=0.005 respectively (Table 2). The total amount of tramadol consumed within the first 24 hours after surgery was higher in Group C (220 (170-260) vs 70 (0-80); P<0.001) (Table 2). The median time for administering rescue analgesics across groups was as follows: 2 (0-2) hours in Group C and 12 (8-12) hours in Group M (p<0.001) (Table 2). Patients in the control group requested analgesia earlier compared to Group M, and this difference was statistically significant (p<0.001) (Table 2).

Table 2. Postoperative rescue analgesic characteristics amongst groups.			
Factors	Group C (n=30)	Group M (n=30)	P value
First rescue analgesic time (h)	2 (0-2)	12 (8-12)	<0.001
Tramadol consump- tion (mg)	220 (170- 260)	70 (0-80)	<0.001
Rescue analgesic usage, time frame (h)			
0-8	30 (100%)	1 (3.3%)	< 0.001
8-12	29 (96.7%)	22 (73.3%)	0.026
12-24	9 (30%)	0 (0%)	0.002
0-24	30 (100%)	22 (73.3%)	0.005
Data are presented as n (%), h=hour, mg=milligram.			

Adverse events, Need for antiemetic drug, and the Likert scale In the postoperative 24-hour period, PONV was observed in 19 (63.3%) patients in Group C and 5 (16.7%) patients in Group M (p<0.001). The need for antiemetic drugs was significantly lower in Group M (5 vs. 19 patients, p<0.001). The patient satisfaction Likert scale scores were significantly higher in Group M (5 (5-5) vs 3 (2-3); p<0.001) (Table 3).

Table 3. Comparison of incidence of adverse effects, anti-emetic drug usage, and the Likert scale			
Factors	Group C (n=30)	Group M (n=30)	P value
PONV	19 (63.3%)	5 (16.7%)	< 0.001
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Likert	3 (2-3)	5 (5-5)	< 0.001
Data presented as median (Q1-Q3) or n (%). PONV= postoperative nause and vomiting.			

Discussion

This study was conducted with a prospective randomized controlled design. The analgesic efficacy of M-TAPA

was compared with multimodal IV analgesia in patients undergoing LC. The results showed that the M-TAPA group had lower postoperative pain scores during rest and movement. Additionally, the need for rescue analgesia was significantly less, and the time to first rescue analgesia was more extended in this group. Side effects such as nausea and vomiting were also rarely observed in patients who received M-TAPA. Furthermore, patient satisfaction was higher in the M-TAPA group. These findings suggest that M-TAPA could be an effective option for postoperative pain management.

Effective control of postoperative pain in LC, a surgical procedure that causes moderate pain, is of great importance. Most of the pain following LC originates from the incision sites, while a smaller portion arises from intraperitoneal gas insufflation and gallbladder dissection [3, 11]. Multimodal analgesia methods, including peripheral nerve blocks, can reduce analgesic consumption and the side effects associated with analgesics [12]. The effects of interfascial plane blocks on postoperative analgesia in LC surgery have been evaluated in various studies, and positive results have been obtained [5-7]. The M-TAPA block is a novel thoracoabdominal nerve block that provides a wide range of analgesic effects. This technique can affect both the anterior and lateral branches of the thoracoabdominal nerves from T5-6 to T11-12 and is achieved by injecting local anesthetics into the lower and upper parts of the perichondrium at the costochondral junction [7, 8,13-15]. The application of interfascial plane blocks, such as erector spinae plane block and paravertebral block, may have certain disadvantages due to the higher risk of potential complications. These risks have led to the preference for safer alternatives like the M-TAPA block. With its low complication risk and broad analgesic coverage, the M-TAPA block stands out as an advantageous option for postoperative pain management [16, 17].

Research has shown that the M-TAPA block provides effective analgesia for postoperative pain management. Studies have reported that patients receiving M-TAPA have significantly lower postoperative pain scores, which enhances patient comfort [18-22]. The effectiveness of M-TAPA is particularly notable for its ability to control pain at rest and during movement in the postoperative period. Similarly, in our study, NRS pain scores measured in patients who received the M-TAPA block were significantly lower during rest and movement than in the control group. This finding demonstrates the superior performance of M-TAPA in pain control. The results of our study are consistent

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The effects of the M-TAPA block on postoperative analgesia have been supported by various studies, which have highlighted that this block method significantly reduces the need for rescue analgesia. Additionally, it has been reported that the time to the first requirement for rescue analgesia is prolonged following M-TAPA application [5, 7, 18-22]. The analgesic effect achieved with regional anesthesia techniques is generally known to last for 36 to 48 hours. This prolonged analgesia offers a significant advantage in postoperative pain management and reduces the need for analgesic medications [23]. These findings demonstrate that M-TAPA provides longlasting and effective analgesia. Similar results were obtained in our study; patients who received M-TAPA had a significantly reduced need for tramadol, and the time to the first requirement for rescue analgesia was markedly extended. Our study's findings support the potential of M-TAPA to minimize the use of rescue analgesics, particularly in postoperative analgesia management. This makes M-TAPA a valuable option in analgesic management, especially in the current context where strategies to reduce opioid use are gaining importance.

Patient satisfaction in the postoperative period is essential to effective pain management. Various studies in the literature have highlighted the positive effects of the M-TAPA block on patient satisfaction. For example, one study reported that the M-TAPA group's satisfaction scores were higher than other treatment methods [22]. Similar findings were observed in our study; the Likert satisfaction scale results were significantly higher in patients who received M-TAPA, reflecting their satisfaction with this analgesic method. Additionally, postoperative nausea and vomiting incidence was notably low in the M-TAPA group, which can be considered another significant factor contributing to patient comfort. The reduction in postoperative nausea and vomiting can be associated with decreased opioid requirements and the effective analgesic block provided by M-TAPA. These results suggest that M-TAPA not only ensures effective pain control but also enhances patient comfort and satisfaction in the postoperative period, making it an effective method for overall postoperative care.

The limitations of our study include the fact that only the first

24 hours postoperatively were evaluated. Therefore, no data were obtained regarding the long-term effects of the M-TAPA block. Additionally, this study was limited to laparoscopic surgeries and M-TAPA's effectiveness in open surgical procedures was not assessed. If the study had the opportunity to use patient-controlled analgesia, more detailed data on opioid consumption and pain management could have been obtained. Lastly, our study did not evaluate the quality of recovery in patients, indicating the need for further detailed studies on postoperative recovery quality.

Conclusion

The M-TAPA block can safely provide postoperative analgesia in abdominal surgeries such as LC. Its low risk of complications and long-lasting analgesic effect make it an ideal option for multimodal analgesia protocols. The use of M-TAPA as a component of a multimodal analgesia approach helps to reduce opioid consumption, thereby preventing opioid-related side effects and enhancing postoperative patient comfort.

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Conflicts of interest

None declared by the authors. The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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Declaration that the article has not been submitted for publication elsewhere

We hereby declare that the material presented in this work, either in whole or in part, has not been previously published, and is not currently under consideration for publication in any other journal.

Authors' contributions

Author Muhammed Halit SATICI, study's concept and design, data collection, analysis, interpretation, drafting, review, funding, research, methodology, project management, resources, software, supervision, verification, visualization, roles/writing original draft and writing – review contributed to the stages.

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