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Ultrasound-guided vs Laparoscopic-asisted Transversus Abdominis Plane Block for Laparoscopic Cholecystectomy: A Randomized Prospective Study

Ultrason Kılavuzlu ve Laparoskop Yardımlı Transversus Abdominis Plan Bloklarının Analjezik Etkinliklerinin Laparoskopik Kolesistektomilerde Karşılaştırılması: Randomize Prospektif Bir Çalışma

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ABSTRACT

Objective: To compare the postoperative analgesic efficacy and side effects of ultrasound guided-Transversus Abdominis Plane block (USG-TAP) versus laparoscopic-guided Transversus Abdominis Plane block (LAP-TAP) in patients undergoing laparoscopic cholecystectomy.

Methods: This randomised, prospective, controlled study included 63 patients aged 18-65 years, classified as ASA I-III, and divided into three groups: Group USG-TAP (n=21) received postoperative TAP block under USG guidance, Group LAP-TAP (n=21) received postoperative laparoscopic-guided TAP block, and Group Control (n=21) received no additional procedure. Visual Analog Scale (VAS) scores and tramadol consumption were used to evalute postoperative pain.

Results: The changes in Visual Analog Scale (VAS) scores over time were statistically different in the groups (p=0.002). The change over time was similar in the USG and LAP groups (p=0.221), and the change in the control group was statistically different from that of the other two groups (p<0.05).

Conclusion: The analgesic efficacy of USG-guided and laparoscopic-guided TAP blocks was found to be similar.

Keywords: Laparoscopic cholecystectomy, transversus abdominis plane block, perioperative analgesic consumption

ÖZ

Amaç: Çalışmamızda laparoskopik kolesistektomi yapılan hastalarda ağrı kontrolünü optimize etmek için laparoskop kılavuzlu Transversus Abdominis Düzlem bloğu (LAP-TAP) ile ultrason eşliğinde uygulanan Transversus Abdominis Düzlem bloğunun (USG-TAP) postoperatif analjezik etkinliğini karşılaştırmak istedik.

Yöntem: Randomize kontrollü, prospektif, yapılan çalışmaya katılan 18-65 yaş, ASA I-III, 63 hasta 3 gruba ayrıldı. Grup USG-TAP'a postoperatif dönemde (n=21) USG eşliğinde TAP blok uygulandı. Grup LAP-TAP 'a (n=21) ise postoperatif laparoskopi yardımlı olarak TAP blok uygulandı. Kontrol grubuna (n=21) herhangi bir ek işlem uygulanmadı. Postoperatif dönemde Vizüel Analog Skala (VAS) skoru ve tramadol kullanımı ile ağrı değerlendirmesi yapıldı.

Bulgular: Gruplar arası VAS'taki zamana bağlı değişiklik istatistiksel anlamlı düzeyde farklıydı (p=0,002). Zamana göre değişim USG-TAP ve LAP-TAP gruplarında benzer iken (p=0,221), kontrol grubundaki değişimin diğer iki gruptan anlamlı farklı olduğu görüldü (p<0,05).

Sonuç: Çalışmanın sonucunda laparoskopik ve USG kılavuzluğunda yapılan TAP blokların analjezik etkinliği benzer bulunmuştur.

Anahtar sözcükler: Laparoskopik kolesistektomi, transversus abdominis plan bloğu, perioperatif analjezik tüketimi

INTRODUCTION

Although the postoperative pain of laparoscopic cholecystectomy operations is less than that of open surgery cholecystectomies, it remains the most common problem in the postoperative period. While parietal-type pain originating mainly from the abdominal wall is observed in laparotomy, after laparoscopic cholecystectomy, pain consists of various com-

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ponents such as parietal, visceral, and somatic and occurs at varying times and severity (1). Pain control can be achieved with methods such as intravenous analgesia application, local anesthetic infiltration to the wound site and Transversus Abdominis Plane block (TAP). The TAP block was first defined by Rafi in 2001 as local anesthetic injection made to the area between the transversus abdominis and the internal oblique muscles by determining the Petit triangle (2). The use of intraoperative opioids has been shown to be reduced with the application of TAP block in laparotomy, appendectomy caesarean section and laparoscopic cholecystectomy operations (3-7). Ruiz-Tovar et al. demonstrated that laparoscopically aided TAP block produces excellent analgesia in a research (8). Many surgeries have used laparoscopic assisted TAP block application for analgesia, and significant results have been obtained.

The aim of this study was to compare the postoperative analgesic efficacy of two different methods of application of TAP block, which is routinely used and has proven postoperative analgesic efficacy.

MATERIAL and METHOD

Approval for this randomized, prospective study conducted in our hospital was granted by the Clinical Research Ethics Committee of the hospital Medical Faculty. The study was registered on clinicaltrials.gov prior to patient enrollment (NCT 04634721). The study included 63 patients, aged 18-65 years, in the I-III risk group according to the American Society of Anesthesiologists (ASA) classification, who underwent a laparoscopic cholecystectomy operation (Figure 1).

Informed consent was obtained from all the patients. Patients with a history of anesthetic drug allergies, a history of abdominal surgery, coronary artery disease or cardiac block, chronic pain or having received pain treatment, a body mass index (BMI) greater than 35 kg m^2, emergency cases, pregnant women, and patients who had received analgesic treatment in the previous 48 hours were excluded. The patients were informed about the Visual Analog Scale (VAS) that was used for pain evaluation in the study. On a line marked from 0 to 10, patients were instructed to mark the severity of pain, where 0 = no pain and 10 = the most severe pain.

General anesthesia was applied to all the groups, and at 30 min before the end of the operation, tramadol and non-steroid anti-inflammatory drugs (NSAID) were administered for postoperative pain.

The patients were randomly divided into 3 groups using a computer randomisation method (http://www.graphad.com/quickcalcs/RandMenu.cfm). The patients in the Control Group (n=21) received local anesthetic infiltration at the trocar sites and tramadol and NSAID. Group USG-TAP (n=21) was applied with TAP block under USG guidance, and Group LAP-TAP (n=21) was applied with laparoscopic -guided TAP block. When the operation was completed, the procedure region, which was the lateral part of the abdominal wall in the subcostal and midaxillary line, was cleaned with antiseptic solution. For the TAP procedure applied to the USG-TAP group, first a linear ultrasonography probe was placed in a sterile sheath (Sonasite®, S-Nerve, USA). To be able to obtain the ideal view, the probe was moved up and down vertically or curved over the abdominal wall to the edge of the costa and the iliac crest. The probe was fixed when there was a clear image from external to internal of the skin-subcutaneous fatty tissue, external oblique muscle, internal oblique muscle, transversus abdominis muscle fascia, and peritoneum. A 20 mL solution was prepared of 10 mL 0.5% bupivacaine + 10 mL saline. A 21 G needle, 100 mm in length (Pajunk SonoPlex Stim cannula 21Gx100 Medizintechnik, Geisingen, Germany) was advanced with the in-plane technique under USG guidance. After careful aspiration to confirm placement of the needle tip between the fascia of the internal oblique muscle and the fascia of the transversus abdominis muscle, the prepared local anesthetic solution was injected as 10 mL to each side of the right subcostal-midaxilla under simultaneous USG imaging. For the LAP-TAP group, before removing the surgical trocars, first the needle course was traced on the intraabdominal image, then the prepared local anesthetic solution was injected as 10 mL to each side of the lateral area of the abdominal wall in the right subcostal-midaxilla line between the fascia of the internal oblique muscle and the fascia of the transversus abdominis muscle. Downward swelling from the transversus abdominis muscle to the internal oblique muscle was observed (Figure 2).

Postoperatively, all patients were routinely given paracetamol 1 g 3x1 and dexketoprofen 25 mg 2x1. The solution for intravenous administration with the PCA device was made by combining 10 mL of tramadol (500 mg) and 140 mL of physiological saline, for a total volume of 150 mL (3.3 mg mL^{-1}). All patients received patient controlled analgesia (tramodol 5 mg mL^{-1}, bolus of 5 mL, lock-out time of 20 minutes, without a basal infusion). When the VAS value was greater than 4 in the first 24 hours after surgery, an rescue analgesic agent (iv meperidine 100 mg) was administered, and the time, dose, and amount were recorded. All patients were transferred to the recovery room, and postoperative monitoring was applied. The VAS scores and potential side-effects (nausea and vomiting) were recorded at 0, 30^{th} minutes then at $1^{st,}$ 2^{nd}, 6^{th}, 12^{th}, and 24^{th} hours postoperatively by an independent observer.

Statistical Analysis

The statistical package “SPSS” (Statistical Package for Social

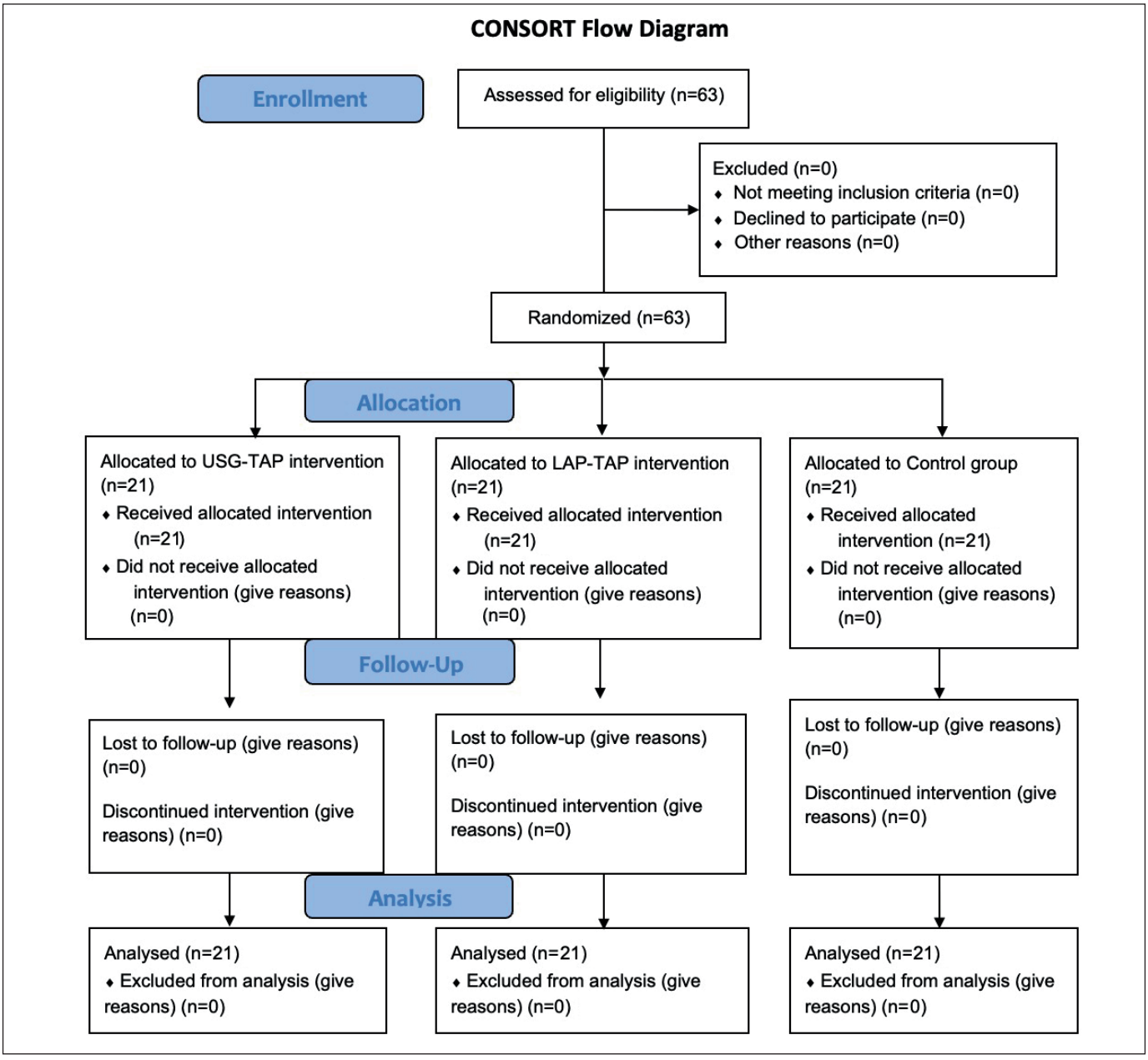

Figure 1. Consort flow diagram of the study.

Sciences, IBM Statistics Version 21.0 for Windows, IBM Corp. 2012, Armonk, NY, USA) was used to analyze the research data that was uploaded to the computer. Mean standard deviation, median (interquartile range), (minimum-maximum), frequency distribution, and percentage were used to present descriptive statistics. To examine categorical variables, the Pearson Chi-Square Test was used. To determine whether the variables fit the normal distribution, visual (histograms and probability graphs) and analytical methods (Shapiro Wilk Test) were used. For variables that did not fit the normal distribution, the Kruskall-Wallis Test was used to compare the three groups. When a significant difference was discovered, the Mann-Whitney U test with Bonferroni correction was used in post-hoc pairwise comparisons to determine the source of the difference.

The post-hoc power value was calculated based on the independent sample test of more than two groups in the G-Power (G*Power, Ver. 3.0.10, Universität Kiel, Germany). The achieved power was 96.62% with the 0.05 type I-error, 63 total sample size, and 0.76 effect size which was calculated for 24th hour VAS score.

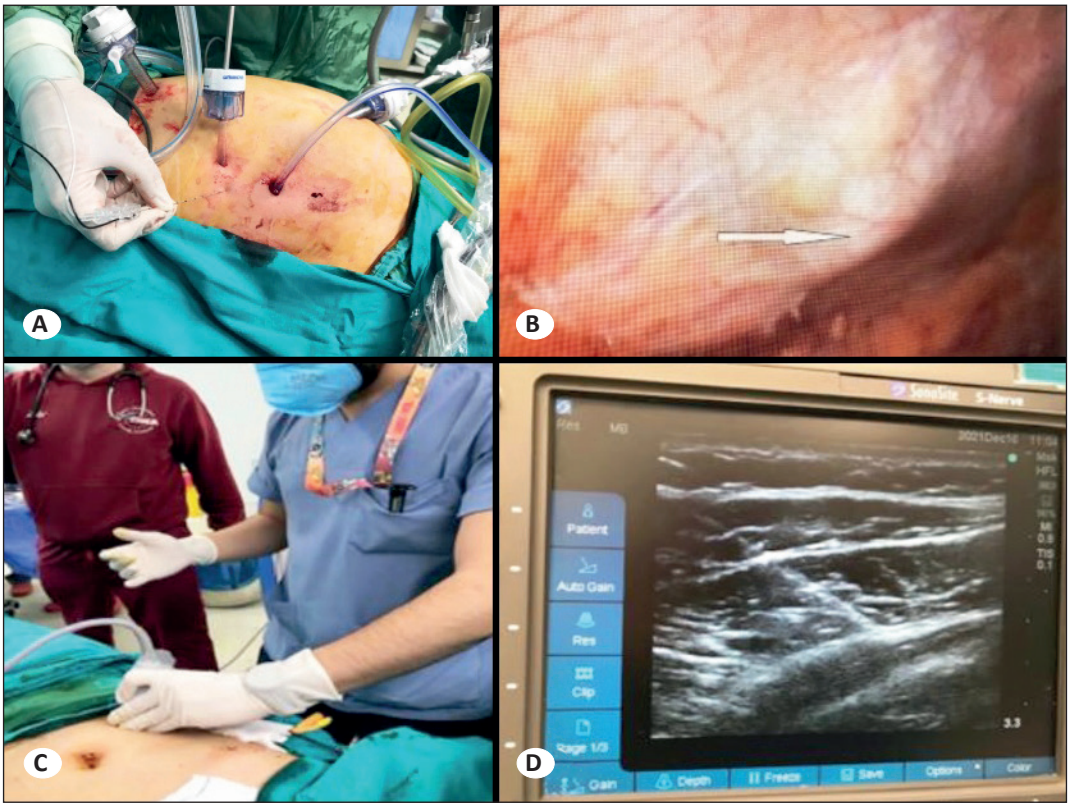

Figure 2. A) The infiltration was performed bilaterally **B)** Downward swelling from the transversus abdominis muscle to the internal oblique muscle was observed **C)** With the help of USG, TAP blocking **D)** USG picture during block TAP.

RESULTS

There was no statistically difference between the groups in respect of patient demographic data (Table I). There was no significant difference between the groups in terms of operation times. No difference was determined between the mean arterial blood pressure (MAP) values obtained at the time points measured in the USG-TAP and LAP-TAP groups. In the control group, a statistically difference was determined between at least two measurement time points ($p<0.05$). The first measured MAP values were higher in the control group.

The heart rate values were determined to be lower in the LAP and USG groups than in the control group. In the paired comparison of the 30th min and 1st hour values, the values of the LAP group were lower than those of the USG and control groups, but not to a statistically significant level.

No difference was found between the treatment groups (USG-TAP and LAP-TAP) in respect of the analgesic effect. Tramadol consumption was found to be decreased in both the block groups at 2nd, 4th, 6^{th,} and 24th hours compared to the control group (Table II).

The changes in the VAS scores of the groups over time were statistically different ($p<0.05$). The change over time was similar in the USG and LAP groups, and the change in the control group was statistically different from that of the other two groups ($p<0.05$). In the comparisons between the groups at each time point, the VAS scores of the control group were determined to be statistically higher than those of the other two groups at 6 different time points ($p<0.05$) (Table II).

In the evaluations of the change over time in each group, no difference was determined in the USG group in respect of the change in VAS score over time. A statistically difference was determined in the VAS score for at least two time points in the LAP group and control group ($p<0.05$). In the LAP group, the VAS scores at 12th hours and 24th hours were determined to be statistically different from the scores at 0, 30th min, 1st and 2nd hours. In the control group, the VAS score at 24th hours was found to be statistically different from the the scores obtained at all the other time points. The 12th hours score was significantly different from the values at all the other time points, and the difference between the 30th min and 2nd hour VAS scores was statistically significant. In the study, there was no difference between the groups in terms of nausea and vomiting in the postoperative period.

DISCUSSION

According to the findings of this study, which examined the analgesic effects of TAP block applied using two techniques to patients following laparoscopic cholecystectomy, the analgesic efficacy of both techniques was comparable in the postoperative period.

Table I. Demographic Data

	USG-TAP (n=21)	LAP-TAP (n=21)	Control (n=21)	X^2/F	p
Gender n (%)					
Male	10 (47.6)	10 (47.6)	7 (33.3)	1.167	0.558
Female	11 (52.4)	11 (52.4)	14 (66.7)		
Age (years)					
Min-Max	24-65	24-65	28-65		
Mean±SD	47.5±11.8	48.0±8.9	47.0±9.9	0.041	0.960
Median (Q1-Q3)	50 (38 - 57)	48 (43.5 - 53.5)	49 (38 - 51)		
Height (cm)					
Min-Max	155-181	156-189	149-189		
Mean±SD	166.2±9.3	170.4±9.5	163.0±11.3	2.908	0.062
Median (Q1-Q3)	160 (158 - 176.5)	171 (163.5 - 177.5)	159 (155 - 173)		
Weight (kg)					
Min-Max	50-93	57-118	49-99		
Mean±SD	77.7±12.0	77.6±16.6	71.7±13.5	1.216	0.304
Median (Q1-Q3)	82 (72 – 85)	76 (62 – 89.5)	73 (60.5 – 83.5)		
BMI					
Min-Max	19.5-34.9	20.5-34.1	21.8-33.6		
Mean±SD	28.2±4.5	26.5±3.6	26.8±3.2	1.196	0.309
Median (Q1-Q3)	28.4 (24.7 – 33.0)	25.4 (23.5 – 29.2)	26.4 (24.6 – 29.0)		
ASA n (%)					
I	7 (33.3)	5 (23.8)	5 (23.8)		
II	11 (52.4)	13 (61.9)	13 (61.9)	0.687	0.953
III	3 (14.3)	3 (14.3)	3 (14.3)		

n: Number of patient, **BMI:** Body mass index, **ASA:** American Society of Anesthesiologist physical status, **USG-TAP:** Ultrasound-guided transversus abdominis plane block, **LAP-TAP:** Laparoscopic-guided transversus abdominis plane block, **NSAID:** Non-steroidal anti-inflammatory drugs, **Min:** Minimum, **Max:** Maximum, **SD:** Standard deviation / **Q1-Q3:** Quartile 1-3 / **X^2:** Pearson Chi-square / **F:** One-way ANOVA.

Table II. VAS Values and Tramadol Consumption Between the Groups

	USG-TAP (n=21)	LAP-TAP (n=21)	Control (n=21)	p**
First				
Mean ± SD	3 ± 3.02	3.4 ± 1.8	7.2 ± 2.3	<0.001
Median (min-max)	2 (0-9)	3 (0-7)	8 (3-10)	
30th minute				
Mean ± SD	2.4 ± 1.9	3.1 ± 1.7	6.9 ± 1.5	<0.001
Median (min-max)	2 (0-7)	3 (0-6)	7 (4-9)	
1st hour				
Mean ± SD	2.4 ± 2.0	3.3 ± 1.1	6.0 ± 1.6	<0.001
Median (min-max)	2 (0-7)	3 (0-5)	6 (2-8)	
2nd hour				
Mean ± SD	2.5 ±1.9	2.9 ± 1.3	5.9 ± 1.4	<0.001
Median (min-max)	2 (0-6)	3 (0-5)	6 (3-8)	
12th hour				
Mean ± SD	2.3 ± 1.8	2.3 ± 1.4	4.6 ± 1.2	<0.001
Median (min-max)	2 (0-5)	2 (0-5)	4 (3-7)	
24th hour				
Mean ± SD	1.9 ± 1.9	2.0 ± 1.3	3.6 ± 0.9	<0.001
Median (min-max)	1 (0-5)	2 (0-4)	3 (3-6)	
Tramadol Consumption (mg)				
Mean ± SD	70.0 ± 15.1	65.0 ± 7.2	125.7 ± 37.2	<0.001
Median (min-max)	70 (50-90)	70 (55-75)	110 (100-250)	

Kruskal Wallis test results, Bonferroni adjustment was used for pairwise comparison. p<0.001 Control versus USG-TAP and LAP-TAP. **VAS: Visual Analog scale, **USG-TAP:** Ultrasound-guided transversus abdominis plane block, **LAP-TAP:** Laparoscopic-guided transversus abdominis plane.

The risk of chronic postoperative pain following laparoscopic or open cholecystectomy has been reported to be 10-40% (9,10). Although laparoscopic cholecystectomy is a minimally invasive procedure, postoperative pain management remains important (11). There are several reasons for the pain, including visceral pain associated with resection of the gall bladder, pain associated with the gas applied to the abdominal wall, and pain in the site of the incision made for the trocar. However, despite these reasons, the main cause is not clear (12). Pain control can be achieved with methods such as intravenous analgesic application, local anesthetic infiltration to the wound site, epidural anesthesia and TAP block (13). In this study, comparisons were made of the postoperative analgesic efficacy of USG-guided TAP block and laparoscopic-asisted TAP block applied to patients after general anaesthesia for laparoscopic cholecystectomy.

A prospective study which evaluted 150 patients undergoing laparoscopic cholecystectomy, demonstrated a correlation between the severity of acute postoperative pain and the likelihood of experiencing debilitating chronic pain in the follow up period (10). The TAP block has been used in recent years as a component of multimodal analgesia in the postoperative period. In several previous studies, TAP block has been shown to reduce the analgesia requirement following cholecystectomy operation. El-Dawlatly et al. reported that TAP block applied to patients undergoing laparoscopic cholecystectomy operation reduced perioperative sufentanil use and the need for postoperatve morphine (6). Ra et al. showed that TAP block reduced pain scores in the first 24 hours after laparoscopic cholecystectomy and reduced the use of ketolorac and fentanyl (7). When block performed under USG guidance, the time taken to apply the block, the time to onset of the effect, and the number of entries were reduced (14). Another advantage is the lower risk of gastrointestinal organ punction (15). Although there are known to be several parameters for the evaluation of postoperative pain after laparoscopic cholecystectomy, in the current study, it was decided to use the VAS score.

Laparoscopic-guided TAP is a block technique which has recently started to be used, and has been recommended as a perioperative recovery method following laparoscopic gastric tube operations in bariatric patients (14). The use of LAP-TAP is supported by The Society of American Gastrointestinal and Endoscopic Surgeons (15). It seems to be a block that can be applied by surgeons without depending on ultrasound (16). The efficacy of LAP-TAP block has been shown in colorectal surgery gynaecological, and bariatric operations (14-18). As far as we know, LAP-TAP block has only been used in a small number of laparoscopic cholecystectomy studies. The results of this study showed that it can be an alternative to the more common USG-TAP block.

There were some limitations of our study. One of the limitations, the use of intraoperative remifentanil, which may affect the postoperative pain score, was ignored. Also, the level of the sensory block was not assessed. Another limitation was that the pneumoperitoneal insufflation pressure was not recorded. There is known to be some evidence that maintaining low insufflation pressure during laparoscopy can reduce postoperative pain.

CONCLUSION

The results of this study in which the analgesic effects were compared of TAP block applied with different methods to patients undergoing laparoscopic cholecystectomy demonstrated that the analgesic efficacy of both methods was similar in the postoperative period. Nevertheless, there is a need for further studies with larger patient groups to confirm these results.

AUTHOR CONTRIBUTIONS

Conception or design of the work: MS, HG
Data collection: MS
Data analysis and interpretation: MS
Drafting the article: MS, MSA, AB
Critical revision of the article: AB, AY
Other (study supervision, fundings, materials, etc): MS
All authors reviewed the results and approved the final version of the manuscript.

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