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The effect of paravertebral block as a part of multimodal analgesia for laparoscopic cholecystectomy surgery

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ABSTRACT

Aim: In laparoscopic cholecystectomy surgery (LCS), for anesthesiologist and surgeons postoperative analgesia method is still problem. The aim of this study is to evaluate the effect of preoperative paravertebral block (PVB) application as a part of multimodal analgesia on postoperative pain management in this surgery.

Material and Method: In this prospective, randomized, single blinded study, over 18 years old, 70 (ASA I-II) patients who underwent elective LCS were included. In the control group, analgesia was managed with only traditional multimodal analgesia methods, while ultrasound- guided PVB (20 ml of 0.5% bupivacaine,T7 level) was added to multimodal anagesia in the study group. Postoperative pain reduction was evaluated using visual analog scale (VAS) at 1, 6, 12 and 24 hours postoperatively, and morphine consumption amount was calculated with IV patient-controlled analgesia in the postoperative period.

Results: Demographic data were similar in both groups. VAS scores at 1 and 6 hours were statistically significantly lower in the PVB group ($p<0.05$). When evaluated in terms of morphine consumption, it was observed that significantly less morphine was consumed in the PVB group compared to the control group in the first 24-hour period ($p< 0.001$). Shoulder pain was seen only in 3 patients in the control group.

Conclusion: In LCS, it was observed that PVB application under the guidance of US increased the effectiveness of multimodal anagesia and decreased postoperative morphine consumption. In addition, problems such as postoperative nausea, vomiting and shoulder pain were less common.

Keywords: Anesthesia, analgesia, paravertebral nerve block, ultrasound, laparoscopic cholecystectomy, postoperative pain

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INTRODUCTION

Although laparoscopic cholecystectomy surgery (LCS) is minimally invasive surgery, postoperative pain is an often encountered persistent problem. There are several components to pain following LCS, which are surgical manipulation, subdiaphragmatic irritation related to tension created by CO_2 gas, and visceral components of postoperative pain. The lesser somatic component of postoperative pain is created by abdominal wall trocars. Another complaint seen in 35%-60% of patients in the postoperative period is shoulder pain (1).

Paravertebral block (PVB) provides a great advantage in many surgical interventions as it is formed of high quality analgesia. In PVB applied with the blind technique, the dispersion of local anaesthetic is controversial and it has been reported that failure of close to 13% may be seen (2). In recent years the application of regional anaesthesia under ultrasound (US) guidance has increased in frequency and range as it is easy to use, non-invasive and safe (3).

To our knowledge, there are limited previous studies on the use of US-guided preoperative PVB in LCS (4-6). The aim of this study was to investigate the efficacy of the application of preoperative PVB in LCS on decreasing postoperative analgesia consumption.

MATERIAL AND METHOD

The study included 70 ASA I-II patients, aged 18-70 years, who were to undergo elective LCS surgery in our clinic. University Ethics Committee approval was obtained before study began. During the preoperative evaluation, from all the patients informed consent was obtained. The use of patient-controlled analgesia (PCA) to assess postoperative pain was explained to the patients and detailed information was given about the visual analog scale (VAS).

Study exclusion criteria were infection in the region where the block was to be applied, patients with tumours, those with known allergy to the local anaesthetic drugs, uncooperative patients and those with a change in the anatomic structure of the area where the block was to be applied because of trauma or previous surgery.

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The patients in this prospective, randomised and single-blind study were separated into 2 groups. Randomisation was applied with the closed envelope method. Patients in both groups were included in the study as a result of routine preoperative anaesthesia evaluation. Patients in the control group were administered with general anaesthesia only and patients in the study group were administered with TPVB before general anaesthesia induction. The block applications were administered to all patients by the same anaesthetist who was experienced in block application under US guidance.

Patients for whom block was planned were taken into the block application room of the operating theatre. A peripheral vascular route was opened with intravenous cannulation in the back of the hand. Premedication was administered before the block with 1-3 mg midazolam and 50-100 mcg fentanyl IV.

The paravertebral block was applied with the patient in a prone postion. All patients were monitored with ECG, non-invasive blood pressure, heart-rate and peripheral oxygen saturation. The skin and the US probe (Esaote LA435 Linear probe, 8-14 MHz, Florence, Italy) were cleaned with antiseptic solution (chlorhexidine), then PVB was applied by injecting 20ml 0.5% bupivacaine at T7 level (**Figure 1**).

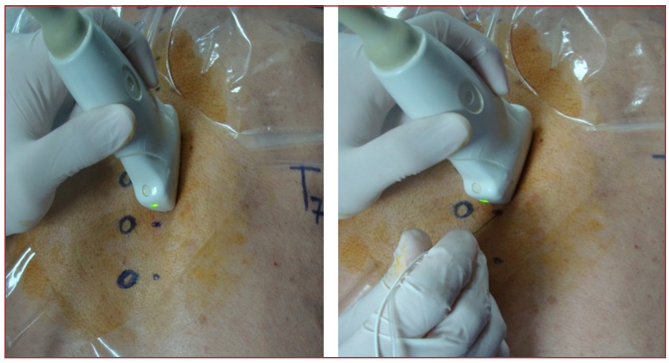

Figure 1. Placement of the US probe and needle in the application of thoracic paravertebral block (In-plane technique)

After application of the block in the preoperative period, the patients were transferred to the operating theatre. Routine monitoring including ECG, systolic/diastolic arterial pressure, peripheral oxygen saturation and Bispectral index (BIS) was performed in the operating theatre. Anaesthesia induction was achieved with 1 µg/kg fentanyl (Fentanyl-citrate, Abbott, USA), 2 – 2.5 mg/kg propofol (1% Fresenius), and 0.6 mg/kg rocuronium bromide. After intubation, all the patients were ventilated with volume-controlled mode mechanical ventilation. Anaesthesia was maintained with O_2+NO_2 and desflurane at the ratio of 1:2. At 15-minute intervals after induction, the values were recorded of BIS (Aspect Medical Systems, Newton, MA, USA) and end-tidal desflurane. The desflurane BIS values were set to be between 40-60. Surgery commenced 30 minutes after block application.

At 15 minutes before the end of surgery, 1µg/kg tramadol and 1 gr paracetamol were administered IV. In the postoperative period, IV morphine and PCA were applied (bolus: 1 mg, locked time: 8 mins, hourly limit: 6 presses). In the recovery unit and later on the ward, when patients had complaints of postoperative pain despite the use of PCA, 8 mg IV tenoxicam was administered according to need (VAS>3). The amount of additionaal analgesia used was recorded.

Statistical Analysis

In the evaluation of the findings obtained in the study, statistical analyses were applied with SPSS v.16.0 for Windows. Descriptive statistical methods were applied (mean, standard variation) and the conformity to normal distribution of numerical data was tested with the Kolmogorov -Smirnov test. In the evaluation of data with normal distribution, the Student's t-test was used and for data not showing normal distribution, the Mann Whitney U-test. For the calculation of the sample size, we have done in a pre-study in our clinic. According to this study, the mean morphine consumption of 20 patients administered with general anaesthesia was calculated as 20±12 mg and so to be able to achieve a 30% reduction, the number of patients necessary in each group was assigned as 32. It was considered that patients would be excluded for various reasons and to increase the power of the study, a total of 70 patients were included. Results were given in a 95% confidence interval and a value of $p<0.05$ was acceped as statistically significant.

RESULTS

The study enrolled 70 patients aged 18-70 years. In both the PVB application group and the control group, 2 of the 35 patients were excluded from the study; 1 due to discharge before 24 hours and 1 because of transfer to open cholecystectomy (**Figure 2**).

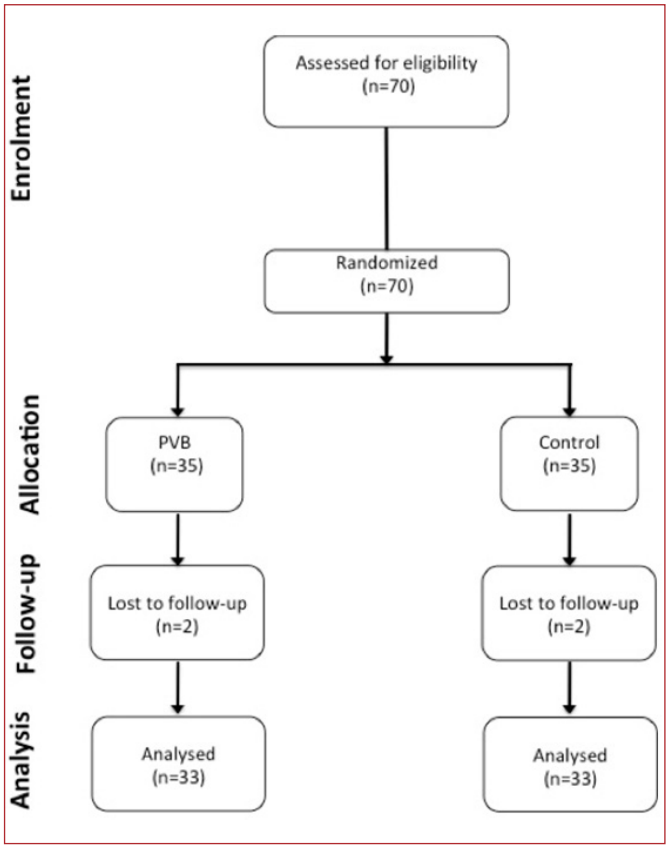

Figure 2. CONSORT statement flow diagram

The demographic data of the 66 patients evaluated in the study are shown in **Table 1**. The demographic characteristics of age, gender, body mass index (BMI) and ASA scores were similar in the 2 groups.

The end-tidal desflurane concentrations during the operation were found to be statistically significantly lower in the PVB patients than in the control group ($p<0.05$) (**Figure 3**).

Table 1. Demograhic data of patients undergoing LC			
	PVB GROUP (n=33)	CONTROL GROUP (n=33)	P
Gender (F/M)	21/12	20 /13	0.687
Age (years)	48 (36-56)	48 (35-55)	0.806
Height (cm)	1.65 (1.62-1.70)	1.65 (1.65-1.74)	0.281
Weight (kg)	79 (70-90)	80 (72-88)	0.674
BMI (kg/m²)	28.4 (25.7-32.1)	28.1 (25.7-31.2)	0.556
ASA (I/II)	15/18	17/16	0.138
Data are presented as number of patients (n) and median (25-75%).			

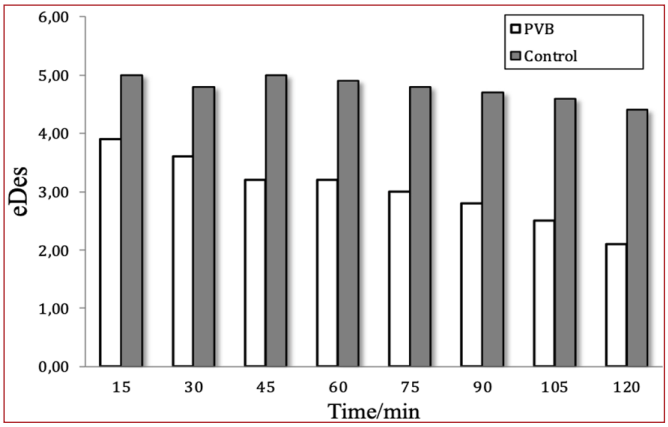

Figure 3. End-tidal Desflurane (eDes) scores during the operation. *p0.05 between groups

When the VAS scores were evaluated at the 1st, 6th, 12th and 24th hours postoperatively, the VAS values in the PVB group were found to be lower than the values of the control group at the 1st and 6th hours (Table 2). When the resting VAS values of the patients were examined, no significant difference was found between the groups at the 12th and 24th hours.

Table 2. Postoperative VAS Evaluations			
	PVB	Control	P
1. hour	2 (0-4)	4 (2-6)	0.003*
6. hour	1 (0-2)	4 (2-4)	0*
12. hour	0 (0-2)	0 (0-2)	0.09
24. hour	0 (0-0)	0 (0-0)	0.615
*The VAS values of the PVB group were found to be statistically significantly lower at the 1st and 6th hours (p<0.05).			

It was found that the 24-hour morphine consumption in the PVB group was statistically significantly lower than the morphine consumption in the control group (p< 0.001) (Table 3).

Table 3. Postoperative Morphine Consumption			
	PVB Group	Control Group	P
1. hour	1.0 (1.0-2.0)	4.0 (2.0-5.0)	0.587
6. hour	4.0 (2.0-6.0)	7.0 (5.0-9.0)	0 *
12. hour	6.5 (4.8-10.3)	12.0 (7.0-22.0)	0.121
24. hour	7.5 (6.0-13.0)	19.0 (13.0-32.0)	0 *
* 6th and 24th hour morphine consumption of the PVB group was found to be statistically significantly lower than that of the control group (p<0.05)			

At the postoperative 1st and 6th hours, the VAS values were found to be lower in the PVB group and the VAS values at the 12th and 24th hours were found to be similar in both groups (Table 4).

When the perioperative end-tidal concentrations were compared in the two groups, the volatile anaesthesia consumption of the PVB group was found to be statistically significantly low (p<0.05, Table 5).

Table 4. VAS Evaluation			
	PVB	Kontrol	P
1. hour	2 (0-4)	4 (2-6)	0.003*
6. hour	1 (0-2)	4 (2-4)	0*
12. hour	0 (0-2)	0 (0-2)	0.09
24. hour	0 (0-0)	0 (0-0)	0.615

Table 5. Intraoperative End-tidal Desflurane Values			
	PVB	Control	p
5. min	4.6 (3.65-5.28)	5.4 (4.60-5.60)	0.003
15. min	3.9 (3.18-4.43)	5.0 (4.70-5.50)	0
30.min	3.6 (3.20-3.93)	4.8 (4.50-5.30)	0
45. min	3.2 (2.87-4.50)	5.0 (4.50-5.20)	0
60. min	3.2 (2.68-3.63)	4.9 (4.50-5.20)	0
75.min	3.0 (2.35-3.63)	4.8 (4.20-5.20)	0
90. min	2.8 (2.00-3.20)	4.7 (4.40-5.20)	0
105.min	2.5 (2.00-3.05)	4.6 (4.25-5.10)	0
120.min	2.1 (1.80-2.60)	4.4 (3.53-4.93)	0

In 1 patient in the PVB group, a single dose of ephedrine (5 mg/iv) was required due to perioperative hypotension. The other patients applied with block were seen to be haemodynamically stable.

Although shoulder pain was not seen in any of the patients in the PVB group, but it occured in 3 patients in the control group. When evaluated in terms of incidence of shoulder pain, the difference between the two groups was not statistically significant.

In the postoperative follow-up, there was a need for additional analgesia in 4 patients in the control group with a VAS score >3 despite the use of PCA, and in no patients in the PVB group.

DISCUSSION

Despite minimally invasive surgery, pain following cholecystectomy continues to be a frequently encountered problem. Several studies in literature have shown the efficacy of PVB on postoperative pain. Naja et al compared the effects on postoperative pain of general anaesthesia alone and general anaesthesia with additional PVB in LCS cases (4). Bilateral PVB was applied using nerve stimulator, which was different to the current study. The VAS values in the PVB group were found to be significantly low in the first postoperative 72 hours. Although better pain control and less nausea and vomiting was obtained in the patients applied with PVB together with general anaesthesia, these effects were not reflected in the total duration of hospital stay.

Dabbagh and Elyasi (7) compared the pain scores at 1, 3 and 6 hours after breast surgery in PVB and general anaesthesia groups and the VAS values in the PVB group were seen to be significantly lower. Hadzic et al. reported that the moderate and severe pain values in the PVB group were lower than those of the general anaesthesia group (8). However, no significant difference was seen between the groups in respect of the pain values at 24, 48 and 72 hours postperatively. Thus, these studies show that the technique of PVB combined with general anaesthesia is more successful in early postoperative pain control but in the late stage, there is no difference and the same success is not shown. Greengrass et al. showed that the analgesic effect of PVB applied to patients undergoing breast surgery was high in the first 24 hours (9). In the current study, the effect of PVB was more on acute pain and

when the duration of hospital stay was taken into account, it was found to be appropriate to monitor patients for the first 24 hours.

Agarwal et al. applied bilateral PVB using nerve stimulator to a patient group combined with general anaesthesia and compared the perioperative and postoperative analgesia requirement of that group with a group applied with general anaesthesia alone (5). The perioperative fentanyl consumption and the morphine requirement of the first postoperative 24 hours in the PVB group were found to be statistically significantly low. The resting VAS values immediately after waking were found to be higher in the control group (92%) than in the PVB group (44%). A study by Naja et al. showed that the requirement for additional analgesia and the rate of nausea and vomiting were lower in the PVB group. In the current study in which preoperative PVB intervention was made, the postoperative 24-hour morphine consumption in the PVB group was found to be at a significantly lower rate than the control group.

The reduced need for opioids reduces the frequency of side-effects related to potential opiod use. Postoperative nausea and vomiting, is one of the most discomforting complaints described by patients after LCS. In a study by Agarwal et al., the need for anti-emetic was seen to be 60% in the control group and 36% in the PVB study group (5). This was thought to be related to the lower use of opioids in the patients applied with PVB. In a study by Baumgarten et al. evaluating the efficacy of PVB in inguinal hernia repair, the postoperative nausea and vomiting rate was seen to be significantly lower in the PVB group (10). In this study, the low rate of nausea and vomiting seen in the PVB group was due to the reduced consumption of postoperative opioids but tthe difference between the groups was not statistically significant.

The distribution of PVB has been the research subject of several studies. In cadaver and patient studies, distribution to more than one segment has been shown from PVB applied at a single level. Conacher injected contrast dye into an epidural catheter placed in the paravertebral area in 5 patients undergoing thoracic procedures and radiolgically the contrast dye was seeen to have spread along the lateral and intercostal cavity and above and below the paravertebral area (11). In a study by Marhofer et al., bilateral PVB was applied to 10 patients at T6 level under ultrasound guidance and after the procedure, the 3-D spread of LA was investigated with MRI (12). At 4 vertebral levels from the punction site, craniocaudal, primarily caudal dispersion was seen of the LA. In 40% of the cases, dispersion was determined outside the PVB area to epidural, intercostal, and contralateral paravertebral areas. In accordance with the aforementioned studies, a single level block was preferred in the current study and it was shown to have dispersed at 4 levels craniocaudally to intercostal and epidural areas.

The application of regional anaesthesia together with general anaesthesia is known to reduce the requirement for general anaesthesia. Several studies in literature have shown that local anaesthetics applied epidurally have decreased perioperative anaesthesia consumption, but to the best of our knowledge, there are limited previous studies on the use of US-guided preoperative PVB in LCS (4-6). In a study by Marley et al., 50 patients with planned abdominal hysterectomy were divided into 2 groups, with Group 1 given combined general +epidural anaesthesia and Group 2, general anaesthesia only (13). The patients were monitored with similar BIS values and it was determined that 21% less isoflurane was used in the group applied with combined general + epidural anaesthesia and as this dose was a more superficial anaesthesia, the recovery time was reported to be shorter. Lu et al. attached an epidural catheter after general anaesthesia induction in patients undergoing colorectal surgery and 2% lidocaine was adminstered to the study group and physiological saline to the control group via the catheter, then perioperative desflurane consumption was monitored (14). The end-tidal desflurane concentration of the group administered with epidural lidocaine was found to be significantly low compared to the group administered with general anaesthesia alone. In the current study, when the perioperative end-tidal concentrations were compared in the two groups, the volatile anaesthesia consumption of the PVB group was found to be statistically significantly low.

Second to diaphragmatic irritation, shoulder pain is often seen following laparoscopic operations. Local anaesthetics given to the sub-diaphragmatic area may block the nociceptive stimuli formed in the diaphragmatic peritoneum. In a study by Ng et al., intraperitoneal levobupivacaine was applied and shoulder pain was reported to be seen in statistically significantly fewer patients compared to the placebo group (15). In the current study with intraperitoneal local anaesthetics application, no shoulder pain was seen in any patient of the PVB group and in 3 patients of the control group, but there was no significant difference between the groups in respect of postoperative shoulder pain. Therefore, the application of PVB at T6-7 can be considered effective in the elimination of shoulder pain. However, the effect of TPVB on shoulder pain is a subject open to investigation as to the best of our knowledge there have been no previous studies.

As there have been no studies comparing the efficacy of unilateral and bilateral PVB, it is not known which is more effective. In the current study, right-side unilateral PVB was applied at T6-7 level. Laparoscopic cholecystectomy is itself a surgical procedure which shortens hospital stay. However, there is no objective system which could reveal the effect of the anaesthesia technique applied in our clinic on the time of discharge. Therefore, in the current study, the time to discharge was not compared between the groups.

The incidence of side-effects has been reported as generally low in paravertebral blocks. In PVB applications, pneumothorax has been reported at 0.5%-1%, severe hypotension at 4%-6% and vascular injury at 2.4% (16). In the current study, hypotension was seen in the perioperative first half hour in only 1 of the 33 patients applied with PVB. The haemodynamics of the patient recovered with intravascular fluid replacement and 10mg IV ephedrine.

In this application, there is a risk of intrathecal dispersion. When the needle tip is advanced too far, there is a high probability of passing into the epidural or intrathecal space. Epidural dispersion has been reported in single injectionsof 15 ml or more at a single level (17).

CONCLUSION

The results of this study have shown that PVB applied with an injection of 20 ml 0.5% bupivacaine at T7 level under US guidance before general anaesthesia reduced the need for perioperative anaesthetic and postoperativve opioids in LCS. Complaints of postoperative nausea, vomiting and shoulder pain were seen at a lower rate in the PVB group.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Institutional Review Board of University of Kocaeli, Türkiye, Local Ethics Committee (protocol number: 2013/8).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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

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