

The efficacy of oblique subcostal transversus abdominis plane block in laparoscopic cholecystectomy – a prospective, placebo controlled study

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Abstract

Introduction. Pain control after a laparoscopic cholecystectomy can represent a challenge, considering the side effects due to standard analgesia methods. Recently the transversus abdominis plane block (TAP Block) has been used as a part of multimodal analgesia with promising results. The subcostal approach (OSTAP Block), a variant on the TAP block, produces reliable unilateral supraumbilical analgesia. This study evaluated the efficacy of the OSTAP block with bupivacaine in laparoscopic cholecystectomy compared with the placebo OSTAP block. **Material and Methods.** Sixty ASA I/II adult patients listed for elective laparoscopic cholecystectomy were randomly allocated in one of two groups: Group A (OSTAP placebo) received preoperatively bilateral OSTAP block with sterile normal saline and Group B (OSTAP bupivacaine) received bilateral preoperatively OSTAP block with the same volumes of 0.25% bupivacaine. Twenty-four hours postoperative opioid consumption, the dose of opioid required during surgery, opioid dose in the recovery unit (PACU) and PACU length of stay were evaluated. The quality of analgesia was assessed by the Visual Analogue Scale (VAS) at specific interval hours during 24 h, at rest and with movement. **Results.** The mean intraoperative opioid consumption showed a significant difference between the two groups, (385 ± 72.52 mg in group A vs 173.67 ± 48.60 mg in group B, $p < 0.001$). The mean 24 h opioid consumption showed a statistically significant difference between groups (32 ± 26.05 mg vs 79 ± 16.68 mg, $p < 0.001$). PACU length of stay was significantly lower for group B patients compared with group A patients (20.67 ± 11.27 min vs 41.67 ± 12.41 min, $p < 0.001$). The OSTAP bupivacaine group had a statistically significant lower pain score than the OSTAP placebo group at 0, 2, 4, 6, 12, 24 h, both at rest and with movement. No signs or symptoms of local anaesthetic systemic toxicity or other complications were detected. **Conclusion.** OSTAP block with bupivacaine 0.25% can provide effective analgesia up to 24 hours after laparoscopic cholecystectomy when combined with conventional multimodal analgesia regimen.

Keywords: oblique subcostal transversus abdominis plane block, pethidine, laparoscopic cholecystectomy, analgesia

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Introduction

Laparoscopic cholecystectomy is a minimally invasive procedure that is widely used for symptomatic gall bladder lithiasis. Despite the minimally invasive

nature of this procedure, patients experience a considerable amount of pain in the first 24 h postoperatively. The analgesic regimen after laparoscopic cholecystectomy consists of intravenous patient-controlled analgesia with opioids (IV-PCA), patient-controlled thoracic epidural analgesia, intraperitoneal injection of local anaesthetics, low-pressure pneumoperitoneum, with specific side effects of opioids, a potential risk of dural puncture, infection, and epidural haematoma, as well as muscle weakness, insufficient pain control and short duration of analgesia [1-4].

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Transversus abdominis plane block (TAP Block) has become a popular component of postoperative analgesia after abdominal interventions. First described by Rafi et al. [5], this technique proved to be efficient in reducing perioperative opioid consumption in lower abdominal surgery [6, 7]. Hebbard et al. [8] described the achievement of this peripheral block by an ultrasound guided subcostal oblique approach, which allowed efficient analgesia in both the upper and lower abdomen, and a lower rate of complications due to the direct ultrasound visualization. Oblique subcostal transversus abdominis plane block (OSTAP block) is efficient in surgeries such as gastrectomy, laparoscopic bariatric procedure, liver transplant, open hepato-biliary or renal surgery [9-11]. Only a few studies have been published regarding the OSTAP block approach in laparoscopic cholecystectomy, being heterogeneous concerning the procedure or the postoperative analgesic regimen [12, 13]. These studies concluded the beneficial effects of the OSTAP block on 24 hours opioid consumption, but none of these studies compared the OSTAP block with a placebo-OSTAP block.

This study aimed to evaluate the analgesic efficacy of the OSTAP block with bupivacaine in laparoscopic cholecystectomy compared with the placebo OSTAP block. The primary endpoints were the assessment of VAS in the first 24 postoperative hours. The secondary endpoints were intraoperative fentanyl consumption, opioid consumption in PACU, and opioid consumption in the first 24 hours postoperatively, discharge time from PACU.

Methods

After obtaining the Institutional Ethics Committee approval and the patients' written informed consent, 64 patients ASA I/II (American Society of Anesthesiologists physical status classification) scheduled for laparoscopic cholecystectomy were randomized, based on a computer generated program, into 2 groups: Group A (OSTAP Placebo) which received general anaesthesia and OSTAP block with saline solution, and Group B (OSTAP bupivacaine) which received general anaesthesia and OSTAP block with bupivacaine 0.25%. Sixty patients were finally analyzed, thirty in each group. The study was prospective, double blinded, randomized and placebo controlled.

Inclusion criteria were patients programmed for elective laparoscopic cholecystectomy, ASA I or II, age over 18 years old.

Exclusion criteria consisted of a patient's refusal to participate in the study, allergy to amino-amides local anaesthetics, infection at the puncture site, acute cholecystitis, documented severe cardiovascular, renal,

liver, neurological or psychiatric diseases, chronic pain syndrome.

Preoperative patients were informed regarding the visual analog scale (VAS) (0 no pain and 10 the strongest pain imaginable) and how to quantify the pain intensity between these two values.

All patients received a standard general anaesthesia regimen that included premedication with midazolam 7.5 mg orally 60 minutes before surgery, fentanyl 2 µg/kg, propofol 2 mg/kg, rocuronium 0.6 mg/kg or atracurium 0.5 mg/kg. Maintenance of anaesthesia was achieved with volatile sevoflurane 1-2 MAC in oxygen and air (FiO₂ 0.5). Mechanical ventilation was achieved in a controlled regimen maintaining EtCO₂ between 30-40 mmHg, and SpO₂ between 96-100%. Standard monitoring included 3 lead electrocardiography (ECG), noninvasive blood pressure (NIBP), pulse oximetry (SpO₂), capnography, temperature and train-of-four (TOF).

After oro-tracheal intubation and stabilization of vital signs, the transversus abdominis plane block was achieved by an ultrasound-guided subcostal oblique approach (Fig. 1).

To achieve the block, an ultrasound (Mindray DC-3 Biomedical Electronics, Shenzhen, China) with a high-frequency linear probe (6-10 MHz) was used. After skin preparation and isolation, the transducer was placed 2 cm subxiphoidian, then moved along the subcostal edge to identify the rectus abdominis muscle and the transversus abdominis. Once these structures were identified, a 21 G × 150 mm needle (SonoTap cannula, PAJUNK Medizintechnologie, Germany) was introduced in-plane 2-3 cm lateral to the transducer, under direct ultrasound visualization, and 1-2 ml of solution were injected between the rectus abdominis muscle and the transversus abdominis muscle. After confirming the correct placement of the needle and the negative aspiration probe, the rest of the anaesthetic substance was injected along the subcostal line in the transversus abdominis plane (20 ml saline solution in Group A, 20 ml 0.25% bupivacaine in Group B), and the dissection of the plane was observed. The block was performed bilaterally. All blocks were performed by the same anaesthetist who knew the type of the solution injected, but was not involved in the postoperative data collection.

The surgery commenced after 15 minutes of the completion of the block and consisted of the introduction of the 4 supraumbilically ports (two 5 mm ports and two 10 mm ports) and the achievement of cholecystectomy.

Rescue fentanyl doses of 100 µg were repeated depending on haemodynamic parameters (increase of MAP and HR with over 15% from baseline values). Intraoperative non-opioid analgesia was administered

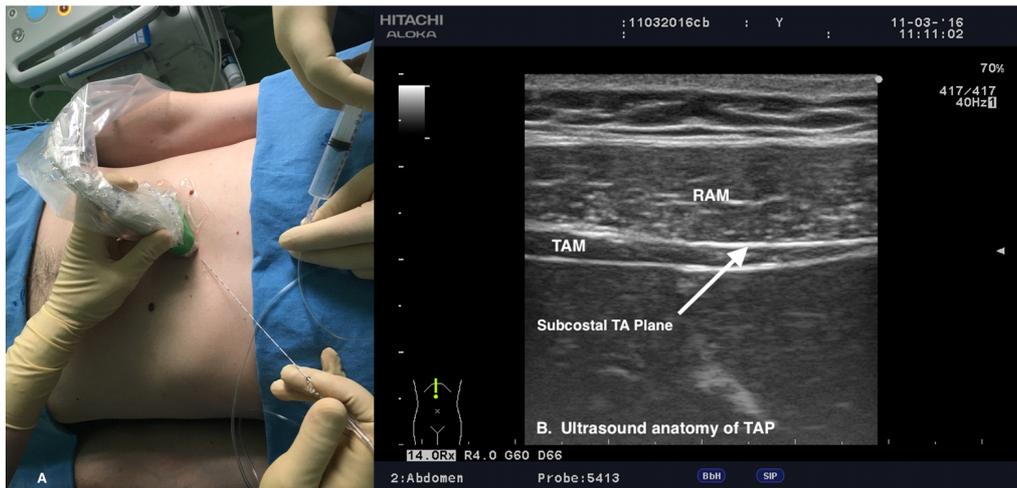


Fig. 1. A – Placement of ultrasound probe for subcostal TAP blocks; B – Ultrasound anatomy of TAP (transversus abdominis plane) at the fascia layer between TAM (transversus abdominis muscle) and RAM (rectus abdominis muscle)

with acetaminofen 15-20 mg/kg, 15 minutes before the end of the surgery.

At the end of the surgery, the neuromuscular block was reversed with neostigmine 0.04 mg/kg and atropine 0.01 mg/kg. Extubation was performed with the patient awake with TOF = 90%.

Postoperatively, patients were transferred to the post anaesthetic care unit (PACU), where pethidine boluses of 20-40 mg were administered if the pain was described as moderate or severe (the pain was considered mild for VAS = 1-3, moderate for VAS = 4-6, or severe for VAS = 7-9). Discharge criteria from the PACU were the absence of pain or mild pain (VAS between 1 and 3), the lack of nausea and vomiting, haemodynamic stability and an Aldrete score of at least 9.

In the surgery ward patients received standard acetaminophen 1 g i.v. at 8 h and in cases of moderate or severe pain, pethidine 20-40 mg i.v. every 3 hours or until VAS < 3. Antiemetic medication was made with ondansetron 4 mg i.v. in cases of nausea or vomiting.

Severity of pain was assessed using VAS, evaluation intervals being at 0 h (in the PACU), 2 h, 4 h, 6 h, 12 h, and 24 h. Pain evaluation was performed at rest and at movement (the patient was asked to cough and to flex the knees). Pain evaluation and data recording were made by an anaesthesiologist who was blinded regarding the two groups.

The primary outcome of the study was to assess the quality of postoperative analgesia between the 2 groups by comparing VAS in the first 24 postoperative hours at the mentioned intervals.

As a secondary outcome, we evaluated: intraoperative fentanyl consumption, opioid consumption in PACU, and opioid consumption in the first 24 hours postoperatively, discharge time from PACU.

The SPSS statistical package version 15 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis, using the Chi square test for parametric values, or the Man Whitney Test for nonparametric data analysis. Data was expressed as mean \pm standard deviation, median and interquartile range (IQR) and a p value of < 0.05 was considered significant. Allowing for a 20% drop-out rate, we planned to recruit a total of 66 subjects. A post-hoc analysis with alpha set at 0.05 showed a power of 90% for this study. 46 patients are required to have a 90% chance of detecting, as significant at the 5% level, an increase in the primary outcome measure from 50% in the control group to 90% in the experimental group.

Results

Sixty-six patients were scheduled and data from 60 patients were included for analysis. Two patients refused inclusion in the study; four patients were excluded due to protocol violation (Fig. 2).

Patient characteristics were similar between groups (Table 1).

In terms of the quality of postoperative analgesia there were statistically significant differences between the 2 groups. The OSTAP bupivacaine group had a statistically significant lower mean pain score than the placebo at 0 h, 2 h, 4 h, 6 h, 12 h, and 24 h both at rest and at movement (Table 2, Table 3).

Intraoperative opioid consumption was significantly lower in the OSTAP group with bupivacaine than in the OSTAP placebo group ($p < 0.001$). Opioid consumption in PACU and 24 h opioid consumption were also lower in the OSTAP group with bupivacaine. PACU stay time was significantly less in the OSTAP with bupivacaine group than in the OSTAP placebo block (Table 4).

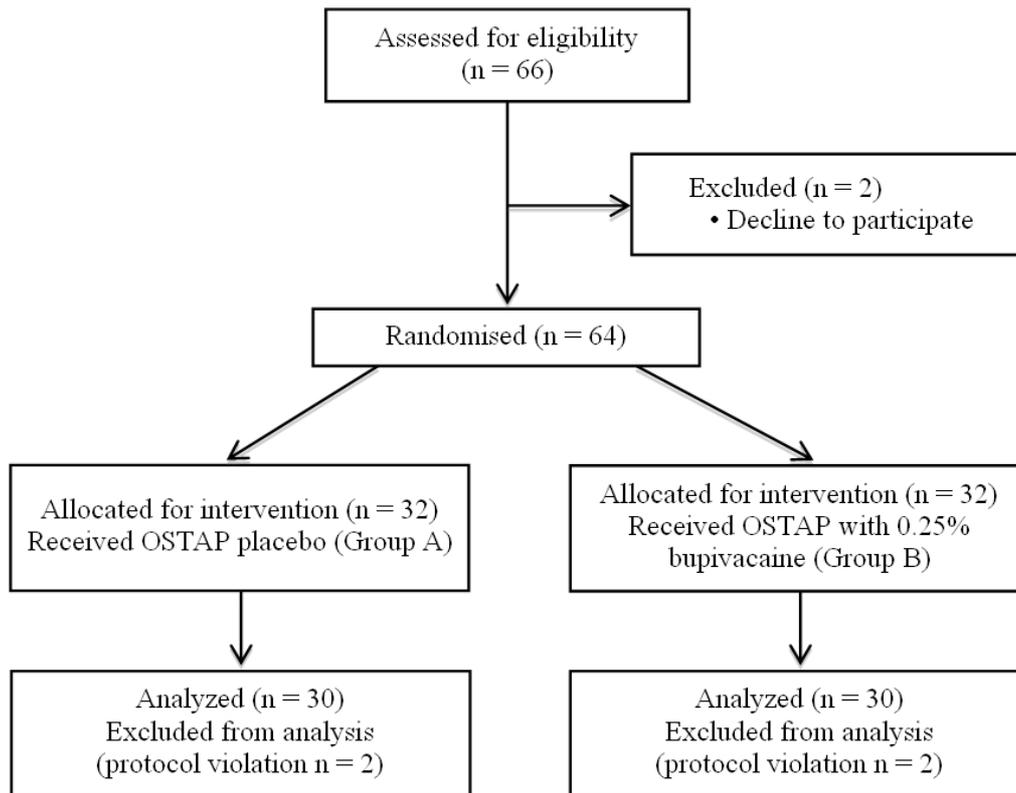


Fig. 2. Flowchart of participants through the study

Table 1. Demographic data

	Group OSTAP placebo (n = 30)	Group OSTAP 0.25% bupivacaine (n = 30)	p value#
Age (years)*	51.5 (26-68)	50 (24-78)	0.978
Sex (F/M)**	20/10	18/12	0.789
ASA I/II**	14/16	20/10	0.192
Weight (kg)***	74.13 ± 16.66	73.57 ± 11.29	0.878
Surgery time (min)***	48.83 ± 18.55	44.33 ± 10.31	0.250

OSTAP – ultrasound-guided oblique subcostal transversus abdominis plane block

* values are given as median (IQR); ** analysis done by using the chi square test; *** values are given as mean ± standard deviation; # p value > 0.05 = insignificant

Table 2. VAS pain scores at rest

	Group OSTAP placebo (n = 30)	Group OSTAP 0.25% bupivacaine (n = 30)	p value**
VAS 0 h*	2.93 ± 1.17	1.33 ± 1.09	U = 143, p < 0.001
VAS 2 h*	3.83 ± 1.76	1.73 ± 1.04	U = 143, p < 0.001
VAS 4 h*	3.27 ± 1.50	1.23 ± 1.006	U = 128, p < 0.001
VAS 6 h*	2.50 ± 0.86	0.67 ± 0.711	U = 56, p < 0.001
VAS 12 h*	1.70 ± 0.98	0.33 ± 0.60	U = 106, p < 0.001
VAS 24 h*	1.27 ± 0.69	0.23 ± 0.43	U = 115, p < 0.001

OSTAP – ultrasound-guided oblique subcostal transversus abdominis plane block

VAS – visual analog scale

* results are expressed as mean ± SD; ** statistical analysis was performed with the Mann-Whitney U-test for nonparametric data; p < 0.05 was considered statistically significant

Table 3. VAS pain scores with movement

	Group OSTAP placebo (n = 30)	Group OSTAP 0.25% bupivacaine (n = 30)	p value**
VAS 0 h*	3.13 ± 1.25	1.37 ± 1.06	U = 131, p < 0.001
VAS 2 h*	4.00 ± 1.66	1.90 ± 1.26	U = 140, p < 0.001
VAS 4 h*	3.53 ± 1.50	1.47 ± 1.25	U = 126, p < 0.001
VAS 6 h*	2.57 ± 0.89	0.70 ± 0.83	U = 67, p < 0.001
VAS 12 h*	1.83 ± 1.02	0.53 ± 0.73	U = 140, p < 0.001
VAS 24 h*	1.27 ± 0.69	0.27 ± 0.52	U = 128, p < 0.001

OSTAP – ultrasound-guided oblique subcostal transversus abdominis plane block

VAS – visual analog scale

* results are expressed as mean ± SD; ** statistical analysis was performed with the Mann-Whitney U-test for nonparametric data; p < 0.05 was considered statistically significant

Table 4. Comparison of the analgesic efficacy of OSTAP with bupivacaine 0.25% and OSTAP placebo in laparoscopic cholecystectomy

	Group OSTAP placebo (n = 30)	Group OSTAP 0.25% bupivacaine (n = 30)	p value**
Intraoperative opioid consumption (µg)*	385 ± 72.52	173.67 ± 48.60	p < 0.001
Opioid consumption in PACU (mg)*	36 ± 16.52	12 ± 14.94	p < 0.001
PACU length of stay (min)*	41.67 ± 12.41	20.67 ± 11.27	p < 0.001
Opioid consumption / 24 h (mg)*	79 ± 16.68	32 ± 26.05	p < 0.001

OSTAP – ultrasound-guided oblique subcostal transversus abdominis plane block

* results are expressed as mean ± SD; ** p value < 0.05 is considered statistically significant

Discussion

Pain causes after laparoscopic cholecystectomy are multifactorial: visceral pain due to gall bladder dissection, abdominal pain due to peritoneal cavity distention and abdominal wall incision [14]. Efficient pain control after surgery permits rapid mobilization, decreases the postoperative complication rate, and allows early hospital discharge.

The conventional methods for analgesia after laparoscopic cholecystectomy consist of opioid administration, which causes respiratory depression and late bowel movements [15]. Another conventional method is thoracic epidural analgesia, difficult to perform and with potential severe side effects such as spinal haematomas or abscess, dural puncture [16].

Recent literature data argue for TAP as an efficient component in multimodal analgesia after laparoscopic cholecystectomy [12, 14, 17, 18]. The first description of TAP block was done in 2001 by Rafi et al. [5] using the ‘Petit’ triangle, and performed with so-called “pop” or “double-pop” method (also called posterior approach), suitable for subumbilical abdominal interventions. In order to minimize potential local side effects, Hebbard et al. [7] described the ultrasound-guided block that enables direct visualization of all anatomical structures, the needle, and the spread of local anaesthetic by ultrasonographic guidance. The subcostal approach

(OSTAP) is a variation on the TAP block that produces reliable unilateral supraumbilical analgesia [7].

The first use of the TAP block for laparoscopic cholecystectomy was described by El-Dawlatly in 2009 using the posterior approach. To date, 20 original studies have addressed this technique in laparoscopic cholecystectomy. The methodology used in these studies is not homogeneous. Controversial results were reported among these studies. Ra et al. [14], Peterson et al. [12] and El-Dawlatly [18] reported efficient analgesia after TAP, but Ortiz et al. [13] did not find any statistical significance in postoperative pain and analgesic consumption in patients who received a TAP block, compared to those who received port-site local infiltration with ropivacaine. These contradictory results might be explained by differences in the methodology used in these studies regarding the type of block (subcostal approach, posterior approach, blind technique or ultrasound guided TAP), the timing of the block (before or after surgery), the medication and the doses of local anesthetics used, and the placebo group (cholecystectomy without placebo TAP, analgesics infiltration of the port sites)

Only 3 studies reported the effect of the OSTAP block in laparoscopic cholecystectomy and none of them used a placebo controlled OSTAP block, our study being the first to address this issue.

El-Dawlatly [18] et al. compared the effect of TAP block for laparoscopic cholecystectomy vs no intervention and demonstrated a lower consumption of intraoperative opioids (8.6 µg vs 23 µg; $p < 0.01$), and of morphine in the first 24 h (10.5 mg vs 22.8 mg; $p < 0.05$). Ra et al. [19] demonstrated that TAP in laparoscopic cholecystectomy reduced the numeric verbal pain score in the first 24 h ($p < 0.001$) and also the intraoperative and postoperative opioids consumption was lower in TAP with bupivacaine ($p < 0.001$). Shin et al. [17] compared OSTAP with TAP and conventional care in laparoscopic cholecystectomy and concluded that OSTAP block provided more efficient analgesia than the TAP block for 24 h postoperatively and also that the OSTAP block reduced the postoperative opioid requirement.

Our results are consistent with those studies and sustain the efficiency of OSTAP block using bupivacaine 0.25% for intraoperative and postoperative analgesia in laparoscopic cholecystectomy.

The pre-incisional OSTAP block was efficient in reducing the intraoperative opioid consumption as well as the 24 h opioid consumption. Also OSTAP block with bupivacaine shortened the PACU stay. We consider that PACU stay time correlates with the amount of opioid used (intraoperative and postoperative as well), patients needing less opioid reached an Aldrete score of 9, quicker than those who needed larger quantities. The VAS scores were significantly reduced in our study at 0, 2, 4, 6, 12 and 24 hours. This efficient analgesia might be explained by the subcostal approach, as laparoscopic cholecystectomy is performed above the umbilicus level.

We did not find any significant differences in postoperative nausea and vomiting (PONV) and also we did not record any complications due to the OSTAP technique.

This study has some limitations. Firstly, the block was performed after induction of general anaesthesia, so we were unable to appreciate block installation time or its extension. Secondly, the recommended doses and volumes of local anaesthetics during the OSTAP block are not yet established. We used 20 ml of bupivacaine 0.25% bilaterally based on the description of Dhouib et al. [19]. Transversus abdominis plane is not highly vascular, so we considered safe the volume of local anaesthetic used.

Conclusion

OSTAP with bupivacaine 0.25% can provide effective analgesia up to 24 h after laparoscopic cholecystectomy when combined with a conventional multimodal analgesia regimen. The block is easily

performed using ultrasound guidance, it is safe, and provides effective analgesia with significant opioid sparing effect.

Conflict of interest

Nothing to declare

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Eficacitatea blocului planului mușchiului transvers abdominal prin abord oblic subcostal în intervențiile de colecistectomie laparoscopică

Rezumat

Introducere. Managementul durerii după intervențiile laparoscopice pentru colecistectomie poate constitui o provocare, având în vedere efectele secundare ale tehnicilor standard de analgezie postoperatorie. Recent, blocul planului mușchiului transvers abdominal (TAP block) a fost folosit ca parte a analgeziei multimodale, cu rezultate promițătoare. Abordul oblic subcostal (OSTAP block) este o variantă a TAP block, care produce analgezie supraombilicală unilaterală. În acest studiu am evaluat eficacitatea OSTAP block cu bupivacaină în intervențiile de cole-

cistectomie laparoscopică prin comparare cu blocul placebo.

Material și metodă. Șaizeci de pacienți ASA I/II programați pentru intervenția de colecistectomie laparoscopică au fost alocați aleator într-unul din cele două grupuri: grupul A (OSTAP placebo), la care s-a realizat TAP block prin abord oblic subcostal cu ser fiziologic steril, și grupul B (OSTAP bupivacaină), la care s-a realizat TAP block prin abord oblic subcostal cu bupivacaină 0,25%. Au fost evaluate consumul de opioid per 24 h, doza de opioid necesară în timpul intervenției chirurgicale, doza de opioid necesară și durata staționării în unitatea de trezire postanestezică (PACU). Calitatea analgeziei a fost evaluată prin Visual Analog Scale (VAS) timp de 24 h în repaus și în mișcare.

Rezultate. Consumul mediu de opioid intraoperator a arătat o diferență semnificativă între cele două grupuri ($385 \pm 72,52$ mg grup A vs $173,67 \pm 48,60$ mg grup B, $p < 0,001$). Consumul de opioid per 24 h a fost semnificativ statistic mai scăzut la grupul B ($32 \pm 26,05$ mg vs $79 \pm 16,68$ mg, $p < 0,001$). Durata staționării în unitatea de trezire postanestezică a fost semnificativ statistic mai scăzută la grupul B comparativ cu grupul A ($20,67 \pm 11,27$ min vs $41,67 \pm 12,41$ min, $p < 0,001$). Grupul B a avut un scor de durere semnificativ statistic mai scăzut decât grupul A la 0 h, 2 h, 4 h, 6 h, 12 h, 24 h atât în repaus, cât și în mișcare. Nu am înregistrat semne și simptome de toxicitate sistemică a anesteziicelor locale sau alte complicații datorate realizării blocului.

Concluzii. Blocul planului mușchiului transvers abdominal prin abord oblic subcostal realizat cu bupivacaină 0,25% combinat cu un regim de analgezie multimodală asigură o analgezie eficientă postoperator timp de 24 h, în intervențiile de colecistectomie laparoscopică.

Cuvinte cheie: blocul planului mușchiului transvers abdominal, petidină, colecistectomie laparoscopică, analgezie