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Effect of ultrasound-guided erector spinae plane block on post-surgical pain in patients undergoing nephrectomy: a single-center, randomized, double-blind, controlled trial

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Abstract

Objective: Erector spinae plane (ESP) block is an alternative to neuraxial block for post-surgical pain in nephrectomy patients. However, no clinical trial has directly compared ESP block with a control group.

Methods: In a single-center, double-blind randomized comparative trial, patients undergoing nephrectomy with a subcostal flank incision under general anesthesia were divided into the following two groups: ESP block group (ESP block before anesthesia) and non-ESP (control) group (no intervention). The primary outcome measure was pain score (Numeric Rating Scale [NRS] 0 to 10). Secondary outcomes were postoperative opiate use, anesthetic and surgical complications, length of hospital stay, and patient-reported outcomes.

Results: Postoperatively (0 to 24 hours), the ESP block group experienced less pain and had lower NRS pain scores 0 to 24 hours postoperatively than the non-ESP group. Opioid consumption and the number of rescue analgesic doses decreased significantly in the ESP group compared with the non-ESP group. Patient-Reported Outcomes Information System (Quality of Recovery-15) scores significantly improved in the ESP group compared with the non-ESP block group.

Conclusions: Patients receiving an ESP block for intraoperative and postoperative analgesia during radical nephrectomies experienced less postoperative pain 0 to 24 hours compared with the non-ESP group.

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Regional anesthesia, ultrasound guidance, erector spinae plane block, nephrectomy, postoperative pain, opioid consumption

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Introduction

Open surgery is the most commonly used surgical method for nephrectomy.[1] Postoperative analgesia methods are essential to avoid respiratory and thromboembolic complications in radical or partial open surgical nephrectomy. A multimodal analgesic approach combining different analgesia modes with local or regional anesthesia to maximize effectiveness is essential.[2] Ultrasound-guided erector spinae plane (ESP) block, which was initially introduced by Forero et al.,[3] is a new trunk block.[3,4] There are many methods for post-surgical pain management after nephrectomy that are described in the literature. These methods include systemic opioid drugs, systemic nonsteroidal anti-inflammatory drugs (NSAIDs), epidural analgesia, surgical site analgesia, paravertebral block, and quadratus lumborum block.[5–7]

The erector spine muscle (ESM) is the complex of spinalis, longissimus thoracis, and iliocostalis muscles that are positioned vertically on the back. In ESP block, local anesthetic (LA) is stored in the profound fascial plane of the ESM at the transverse process of the vertebra. Therefore, LA is distributed craniocaucally in the fascial plane when a median of 3.4 mL of LA is injected per dermatome.[3] This stored LA also spreads to the paravertebral and epidural spaces and the intercostal space.[8] Direct evidence of the possible mechanisms for the ESP block was shown in studies focusing on the physical spread of the injected LAs. Both human and animal cadaver models were used in anatomical studies. LA spread has been demonstrated by anatomical dissection or sectioning, but radiocontrast studies using computed tomography (CT) or magnetic resonance (MR) imaging have also been used. The ESP block mechanism and its physical spread have been observed using CT or MR imaging in various clinical studies.[9–11]

In the literature, there are case reports involving both adult and pediatric patients that showed the postoperative analgesic effect of ESP block for nephrectomy, but there have been no clinical trials that evaluated ESP.[12–14] Therefore, this study aimed to evaluate the effect of ESP block on postoperative pain in nephrectomy, which leads to both visceral and somatic pain.

Epidural analgesia is the gold standard for perioperative analgesia in open surgery. Epidural analgesia-related significant complications can include epidural hematoma, postoperative neurologic deficit, and postdural puncture headache,[15] and anesthesiologists are searching for alternative analgesic modalities that have adequate analgesia and a lower complication risk. ESP block may be a good postoperative analgesia method in patients who have undergone laminectomy, have lumbar fusion, or have failed epidural intervention despite using a paramedian approach.[16] Our hypothesis is that ESP block can be a part of multimodal analgesia management in nephrectomy surgery with a subflank incision, and we investigated whether it will affect postoperative analgesic consumption. Because ESP block is an easy and safe method to use, we

believe that it is an essential part of anesthesia management for nephrectomy.

Patients and methods

Study design

This single-center, double-blind, randomized controlled trial was conducted at Namik Kemal University hospital in Tekirdag, Turkey. Written informed consent was obtained from all participants. The trial was registered at Clinicaltrials.gov before enrolling patients (NCT04703634; registration date, 2 February 2021, URL: https://www.clinicaltrials.gov). The patient enrollment date was 14 February 2021. This study conforms to the Consolidated Standards of Reporting Trials (CONSORT) and the CONSORT extension for trials reporting patient-related outcomes. The study was approved by the Republic of Turkey, Ministry of Health, Pharmaceuticals Institution Ethics Committee (approval number, 20-AKD-134; 12 November 2020). The study was conducted from 2 February 2021 to 20 May 2021.

The inclusion criteria were patients scheduled to undergo radical nephrectomy with subcostal flank incision, aged 18 years and older, with no contraindications for regional anesthesia, and who were able to provide informed consent and reliably report symptoms to the research team. The exclusion criteria were partial nephrectomy, inability to provide first-party consent due to cognitive impairment, not having an intellectual level to use a patient-controlled analgesia (PCA) device, or refused to participate.

Randomization, blinding, and study intervention

The patients were randomized into the ESP block group or the non-ESP block group. Randomization (1:1) was generated using an internet-based application (www.random.org). All patients were scheduled to undergo surgery using general anesthesia. ESP block group patients received an ESP block under ultrasound guidance before general anesthesia, while the non-EDP block (control) group did not receive this treatment. Surgery, anesthesia, study, and nursing staff were blinded to the intervention and patient information. The anesthesiologist who performed a preoperative block on the patient and the anesthesiologist who followed the block perioperatively were different to ensure blinding.

All patients participating in the study were brought from an inpatient service to a fully equipped block room 30 to 45 minutes before surgery. An anesthesiologist and an anesthesia technician performed the block procedure in accordance with the randomization scheme. Under ultrasound guidance, all blocks were performed using 30 mL of 0.25% bupivacaine at the T10 transverse process level.

Regardless of the study group, the patient was taken to the operating theater for anesthetic preparation. Three-way electrocardiography, peripheral oxygen saturation, and radial artery cannulation under topical anesthesia followed by invasive artery monitoring were performed after an Allen test. After obtaining intravenous access, an infusion of normal saline was started. After 3 minutes of pre-oxygenation with 100% oxygen, anesthesia was induced intravenously using 2 to 3 mg/kg of propofol, 1 μg/kg of fentanyl, and 0.6 mg/kg of rocuronium. After ensuring adequate muscle relaxation, orotracheal intubation was performed by an experienced anesthesiologist. All the patients were placed into a 30-degree modified lateral decubitis position. Anesthesia was maintained using 1% to 2% sevoflurane in 4 L of a 40%:60% oxygen and air mixture.

All patients received a tramadol-based patient-controlled analgesia regime postoperatively. A numeric rating scale (NRS) for pain was used, and pain scores ranging from 0 to 10 were recorded, where 0 was no pain and 10 was the worst pain imaginable. In the recovery unit after surgery, postoperative pain scores at hours 1, 2, 4, 8, 12, and 24 were recorded.

Outcome measures

The primary outcome was the NRS score upon emerging from the recovery unit (day 0).

Secondary outcomes were total opioid consumption; number of times postoperative rescue analgesic was used; postoperative complications such as nausea and vomiting; requiring surgical, endoscopic, or radiologic intervention; length of hospital stay; patient satisfaction; and patient-reported outcomes measures.

Total opiate use as well as intraoperative opiate use on day 0 and from 0 to 24 hours postoperatively were reported. Quantities were converted to tramadol use via a PCA device.

On day 1, patient satisfaction, pain experienced, and quality of recovery parameters were evaluated using the Patient-Reported Outcomes Measurement Information System (PROMIS) (Table 1).

Complications were reported in accordance with the Clavien–Dindo classification[17] (Table 2).

Table 1. The PROMIS QoR-15 questionnaire.

How have you been feeling in the last 24 hours?
PROMIS Part 1. (0 to 10, 0 = none [poor] and 10 = all in the last 24 hours [excellent])
1. Able to breathe easily
2. Able to enjoy food
3. Feeling rested
4. Have had a good sleep
5. Able to look after personal toilet and hygiene unaided
6. Able to communicate with family and friends
7. Receiving support from hospital doctors and nurses
8. Able to return to usual activities
9. Feeling comfortable and in control
10. Having a general feeling of well-being
Have you had any of the following in the last 24 hours?
PROMIS Part 2. (0 to 10 to 0, 0 = all in the last 24 hours [poor] and 10 = none [excellent])
11. Moderate pain
12. Severe pain
13. Nausea or vomiting
14. Feeling worried or anxious
15. Feeling sad or depressed

PROMIS, Patient Reported Outcome Measurement Information System; QoR, Quality of Recovery.

Power analysis

Because no similar studies had been previously conducted, a preliminary study was performed with ten individuals in each group to determine the effect size (the amount of difference between the groups) so that we could conduct a power analysis. The effect size was estimated by calculating the descriptive statistics for the NRS score obtained at postoperative hour 1 in this study. The applied power analysis indicated that a sample size of ten individuals would be needed to show statistical significance for a 3.5-unit difference in the NRS score at postoperative hour 1 between the groups using 80% power and 5% type I error conditions, with at least five participants in each group. However, on the basis of the data collected, the power for our study with 30 individuals was 99% (Table 3).

PASS Software Trial version (PASS 15 Power Analysis and Sample Size Software (2017). NCSS, LLC. Kaysville, UT, USA, https://www.ncss.com/software/pass) was used to calculate the sample size.

Statistical analysis

Descriptive statistics were calculated as the mean ± standard deviation or as the median with the minimum and maximum values for continuous variables depending on their distribution. The number and percentage was used for categorical variables. The normal distribution of the numerical variables was analyzed using the Shapiro–Wilk, Kolmogorov–Smirnov, and Anderson–Darling tests.

Table 2. Clavien–Dindo classification for complications.

Degree	Definition
I	Any deviation from the ordinary course without requiring an intervention beyond the administration of anti-emetics, antipyretics, analgesics, diuretics, electrolytes, and psychical therapy
II	Complication requiring pharmacological treatment with other medicines beyond the ones used for complication of degree I
III	Complications requiring surgical, endoscopic, or radiological intervention
III-a	Intervention without general anesthesia
III-b	Intervention with general anesthesia
IV	Life-threatening complication requiring admission to the intensive care unit
IV-a	Uniorgan dysfunction (including dialysis)
IV-b	Multiorgan dysfunction
V	Death

An independent samples *t*-test was used to compare two independent groups where numerical variables had a normal distribution. The Mann–Whitney *U* test was used for variables without a normal distribution. The Pearson chi-square and Fisher's exact tests were used in 2×2 tables to compare the differences between categorical variables. The Fisher Freeman Halton test was used in rows×columns tables.

For the statistical analysis, Jamovi project (2020), Jamovi (Version 1.8.1) [Computer Software] (Retrieved from https://www.jamovi.org), and JASP (Version 0.14.1.0) (Retrieved from https://jasp-stats.org) were used. The significance level (p-value) was set at 0.05 for all statistical analyses.

Results

Sixty-eight participants were included in the study and screened for eligibility during the study period. Five participants did not meet the criteria, as follows: LA allergy was detected while interviewing two participants; two participants had incomplete data; and one participant refused to participate in the study. To ensure equality in the groups, three participants were randomly excluded from the study. All participants completed the study and were included in the final analysis, and none were lost to follow-up (Figure 1).

Sixty participants with a mean age of 55.4 ± 7.9 years were included in the analysis, and 33 (55.0%) were men and 27 (45.0%) were women. Each group included

Table 3. Power and sample size calculation.

	Group		Difference		
	ESP-Group	Non-ESP Group	Between Means	α	$1-\beta$
NRS-1st hour	3.20 ± 1.55	6.70 ± 1.16	3.5	0.05	0.20
Calculated Sample Size (n)	*5*	*5*			

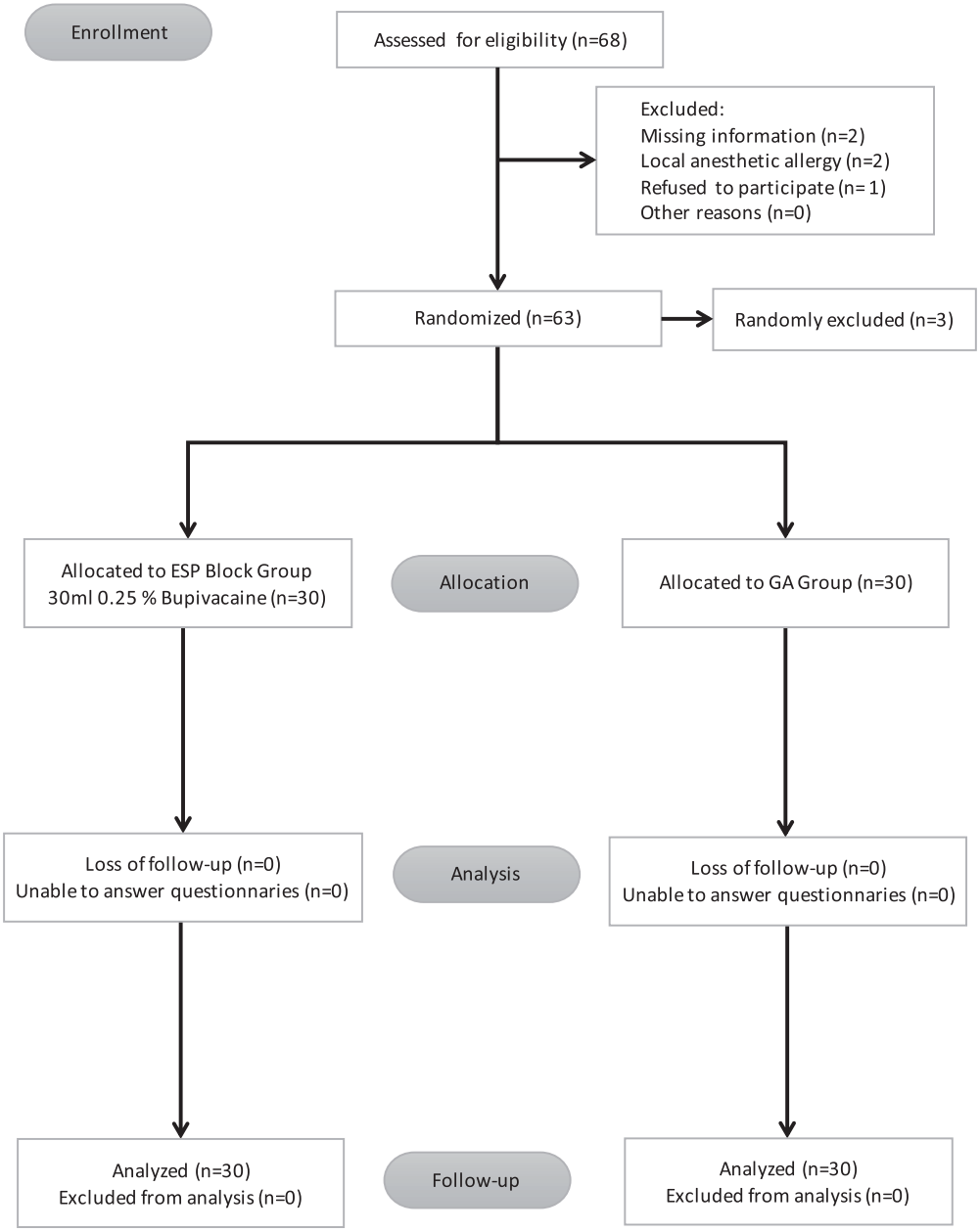

Figure 1. CONSORT study flowchart.
CONSORT, Consolidated Standards of Reporting Trials; ESP block, erector spinae plane block; GA, general anesthesia.

30 participants. The groups were similar in age (57.0 ± 6.5 vs. 53.8 ± 8.9 years for ESP and non-ESP block groups, respectively) and sex distribution (17 [56.7%] men and 13 [43.3%] women vs. 16 [53.3%] men and 14 [46.7%] women in the ESP and non-ESP block groups, respectively). However, the participants' mean BMI in the ESP block group was significantly higher in the ESP block group compared with that in the non-ESP block group (30.6 ± 4.9 vs. $27.6 \pm 3.3\ kg/m^2$, $p = 0.008$) (Table 4).

Comparison of the postoperative outcomes in the study groups is summarized in Table 5. We detected significant differences in NRS scores, total PCA consumption, the number of rescue analgesic doses, and PROMIS Part 1 and Part 2 scores,

Table 4. Demographic and clinical characteristics in the study groups.

		Groups		
	Overall (n = 60)	ESP block group (n = 30)	Non-ESP block group (n = 30)	p-value
Age (years)†	55.4 ± 7.9	57.0 ± 6.5	53.8 ± 8.9	0.124*
Sex‡				
Male	33 (55.0)	17 (56.7)	16 (53.3)	0.999**
Female	27 (45.0)	13 (43.3)	14 (46.7)	
BMI (kg/m^2)†	29.1 ± 4.4	30.6 ± 4.9	27.6 ± 3.3	0.008*

†: mean ± standard deviation, ‡: n (%).
ESP, erector spinae plane; BMI, body mass index.
*Independent samples *t*-test.
**Pearson chi-square or Fisher's exact test.

Table 5. Comparison of the postoperative pain outcomes between the study groups.

	Groups		
	ESP block group (n = 30)	Non-ESP block group (n = 30)	p-value
Number of patients in PACU‡	4.0 [0.0–7.0]	6.0 [4.0–9.0]	<0.001**
NRS hour 1‡	3.0 [0.0–6.0]	5.5 [3.0–9.0]	<0.001**
NRS hour 2‡	3.0 [0.0–5.0]	5.0 [3.0–8.0]	<0.001**
NRS hour 4‡	3.0 [1.0–5.0]	5.0 [2.0–8.0]	<0.001**
NRS hour 8‡	3.0 [1.0–5.0]	5.0 [2.0–8.0]	<0.001**
NRS hour 12‡	3.0 [1.0–7.0]	5.0 [2.0–8.0]	0.001**
NRS hour 24‡	4.0 [2.0–.0]	4.5 [2.0–8.0]	0.020**
Total PCA dosing (mg)†	114.7 ± 40.0	212.0 ± 26.6	<0.001*
Number of rescue analgesic doses‡	1.0 [0.0–3.0]	4.0 [2.0–5.0]	<0.001**
Number of PONV attacks	0.0 [0.0–1.0]	0.0 [0.0–1.0]	0.999*
PROMIS score Part 1†	94.7 ± 2.9	73.2 ± 8.7	<0.001*
PROMIS score Part 2†	44.5 ± 3.2	21.4 ± 5.5	<0.001*

†: mean ± standard deviation, ‡: median [minimum–maximum].
ESP, erector spinae plane; PACU, postoperative anesthesia care unit; NRS, numerical rating scale for pain; PCA, patient-controlled analgesia; PONV, postoperative nausea and vomiting; PROMIS, the Patient-Reported Outcomes Measurement Information System.
*Independent samples *t*-test.
**Mann–Whitney *U* test.

which were all higher in the non-ESP block group compared with those in the ESP block group ($p < 0.05$) (Table 5). The median number of patients who were followed-up in the postoperative anesthesia care unit (PACU) was significantly lower in the ESP block group compared with that in the non-ESP block group (4 vs. 6, $p < 0.001$). The NRS score for pain during the postoperative follow-up between hours 1 and 24 were significantly higher in the non-ESP block compared with those in the ESP-block group ($p < 0.05$) (Figure 2). The total PCA consumption was 114.7 mg in the ESP block group and 212 mg in the non-ESP block group, which was a significant difference ($p < 0.001$). The number of rescue analgesic doses was higher in the non-ESP block group compared with that in the ESP-block group ($p < 0.001$). The PROMIS Part 1 and Part 2 scores were significantly higher in the ESP block group compared with those in the non-ESP block group ($p < 0.001$ and $p < 0.001$, respectively) (Figure 3).

Table 6 presents the distribution of the complications in accordance with the Clavien–Dindo classification and the parameters that evaluated patient satisfaction. Adequate preoperative assessment and preparation, including coagulation tests and the use of the ultrasound guidance as well as no ESP block complications such as bleeding, LA toxicity, and pneumothorax, were reported. The distribution of the complications in both groups was similar. There was one death in the non-ESP block group. Additionally, 93.3% of the patients in the ESP block group reported that they would have an ESP block again. Patients were more satisfied with the analgesia in the ESP block group; 28 patients (93.3%) were satisfied, while two patients (6.7%) were ambivalent, and no patient was dissatisfied. In the non-ESP block group, 181 patients (60%) were satisfied, four patients (33%) were ambivalent, and eight patient (27%) was dissatisfied. The median length of hospital stay was 3.5 days in the ESP block group and 4 days in the non-ESP block group, which was not significantly different.

Discussion

Regional anesthesiologists have been searching for alternative methods that are

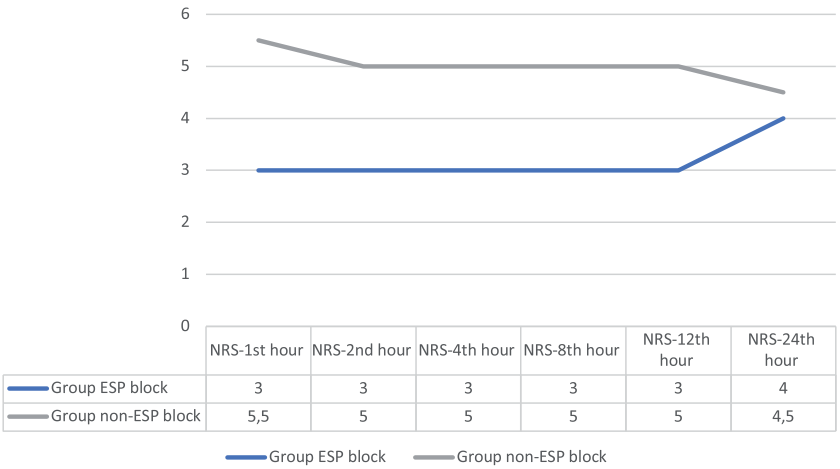

Figure 2. Numerical rating scale scores for pain in the ESP block and non-ESP block groups. ESP, erector spinae plane.

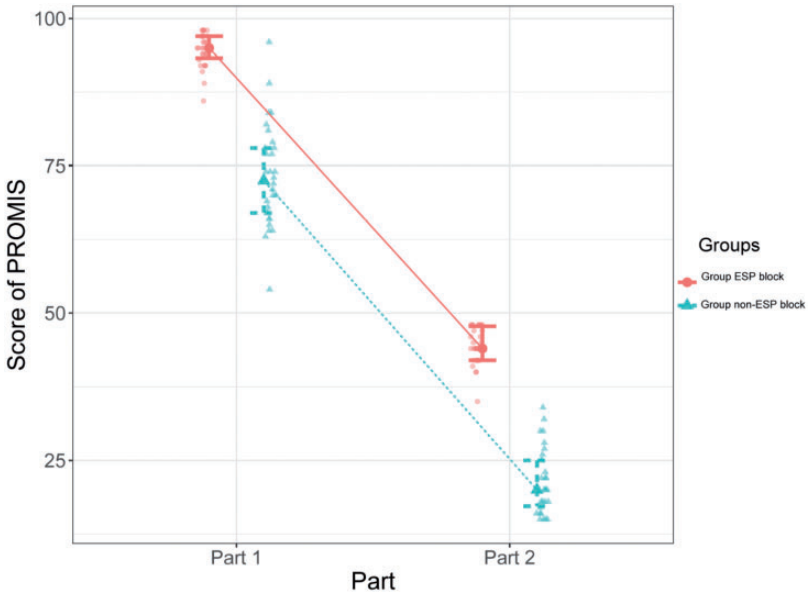

Figure 3. PROMIS Part 1 and Part 2 scores in both groups.
PROMIS, the Patient-Reported Outcomes Measurement Information System.

Table 6. Comparison of the complications and the patient satisfaction between groups.

	Groups		
	ESP block group (n = 30)	Non-ESP block group (n = 30)	p-value
Clavien–Dindo grades°			
0	11 (36.7)	3 (10.0)	0.154**
I	8 (26.7)	9 (30.0)	
II	6 (20.0)	9 (30.0)	
III	5 (16.7)	7 (23.3)	
IV	0 (0.0)	1 (3.3)	
V	0 (0.0)	1 (3.3)	
Would have the block again°			
No	2 (6.7)	–	–
Yes	28 (93.3)	–	
Patient satisfaction°			
Unsatisfied	0 (0)	8 (27)	<0.001*
Satisfied	28 (93.3)	18 (60)	
Ambivalent	2 (6.7)	4 (13)	
Length of hospital stay (days)°	3.5 [2.0–6.0]	4.0 [2.0–7.0]	0.059*

‡: n (%), °: median [minimum–maximum].
*Mann–Whitney *U* test.
**Fisher Freeman Halton test.
ESP, erector spinae plane.

as effective as possible but have fewer complications and that are easy to use instead of neuraxial blocks. Postoperative pain control creates a comfortable anesthesia experience for the patient, a short mobilization duration, a shorter hospital stay, and professional satisfaction among regional anesthesiologists.

This is the first randomized, double-blind controlled trial comparing ESP block with routine systemic analgesia. Previous publications on ESP block for nephrectomy have been limited to case series. This randomized controlled trial shows that the ESP block provides better perioperative analgesia than that in the non-ESP control group. Additionally, postoperative pain scores were significantly improved in the ESP group compared with those in the control group.

Aksu and Gurkan performed ESP block on two pediatric patients who underwent nephrectomy for Wilms' tumor, and no rescue analgesic was needed during the first 48 hours after surgery.[14]

Canturk performed an ESP block at the L1 level and showed effective post-surgical pain control in patients who underwent radical nephrectomy with a subcostal flank incision. Furthermore, the NRS scores did not change even after the same patient underwent a revision operation due to bleeding.[18]

Tanaka et al. performed a combined quadratus lumborum block with an ESP block in another case report involving a robot-assisted partial nephrectomy. There were multiple portholes starting at the xiphoid process and continuing to below the umbilicus, and the NRS score was 5 on movement 48 hours after surgery.[13]

Our preliminary results showed that the PACU and the NRS scores from postoperative hours 1 to 24 were lower in the ESP block group than those in the non-ESP block group. Additionally, the total PCA consumption was significantly lower in the ESP block compared with the non-ESP block group. Thus, as stated in our hypothesis, NRS scores were lower in the ESP block compared with the non-ESP block group, but we did not detect low NRS scores, such as 0 or 1, which was shown in previously published case reports. However, there was still a significant difference compared with the control group.

The ultrasound-guided ESP block is a myofascial plane block that provides analgesia for thoracic or abdominal segmental innervation in conjunction with the injection site.[19] Cadaver research showed that the injection involves both the ventral and dorsal rami of the spinal nerves and creates a sensory block on both the posterior and anterolateral thorax.[3] Although 20 mL of LA diluted 1:1 was used in previously performed thoracic ESP blocks, we used 30 mL in our study.[20,21] Before starting this study, pilot cases showed that analgesia was not sufficient for radical nephrectomy patients using 20 mL of 0.25% bupivacaine.

Rescue analgesic use was significantly higher in the non-ESP group compared with that in the ESP group. Adverse events related to LA were not observed in any patient.

Patient satisfaction was significantly better in the ESP group compared with that in the non-ESP group ($p < 0.001$). The Quality of Recovery (QoR-15) score is recognized as an international method of patient assessment after hospital treatment.[22] The PROMIS QoR-15 questionnaire includes ten questions that are divided into two parts, with the first part containing five questions about emotional distress and the second part containing five questions about pain relief. PROMIS QoR-15 scores were significantly higher in the ESP block group compared with the non-ESP block group. In the ESP block group, 93.3% of the patients stated that they would have the block again. In the questionnaire for analgesia, patient

satisfaction was significantly higher in the ESP block group compared with the non-ESP block group. Nausea and vomiting did not occur in any patient in either group.

Based on the Clavien–Dindo classification, complications and the length of hospital stay were similar in both groups. One patient died in the non-ESP block group, and they had been previously followed-up in the intensive care unit for 15 days because they had a COVID-19 infection. This patient died due to myocardial infarction on day 3 after surgery.

Only patients with a subcostal flank incision were included in our study. This increased the homogeneity of the patients in our study, but it was also a study limitation. Because all ESP blocks were performed on a sedated patient in a separate block room, a formal dermatome assessment of block function was evaluated.

ESP block seems to be easy to perform, and it is associated with few side effects.[23] However, alternative techniques such as epidural and paravertebral anesthesia are more challenging to use and are associated with significant complications such as epidural hematoma or pneumothorax.[24,25]

Conclusion

Ultrasound-guided ESP block reduced pain scores and postoperative tramadol consumption more effectively compared with that in the control group in the first 24 hours after nephrectomy. Thus, ESP block positively affected the quality of the patient's recovery and reduced their postoperative opioid use. Additionally, ESP block can be used to reduce postoperative pain after radical nephrectomy with a subcostal flank incision.

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Author contributions

Dr. Ayhan Sahin: This author conceived the presented idea, wrote the manuscript, and coordinated the research in the operating room, including implementing the ESP blocks.
Dr. Onur Baran: This author verified the analytical methods, performed the analysis, and contributed to the final manuscript.

Declaration of conflicting interests

None to declare.

Ethics approval

The Republic of Turkey, Ministry of Health, Pharmaceuticals Institution Interventional Ethics committee approved this study (approval number 20-AKD-134; 12 November 2020).

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Registration

This trial is registered at Clinicaltrials.gov (NCT04703634; Registration Date, 2 February 2021, URL: https://www.clinicaltrials.gov).

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