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Efficacy of different local anaesthetic volumes during erector spinae block for postoperative pain management in patients undergoing open nephrectomy operations. A randomized controlled study

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ABSTRACT

Background: Pain control after surgery is of highest priority. Erector spinae plane block [ESPB] was reported to be a successful method to reduce pain scores and consumption of postoperative opioids. However, hardly any investigation has looked at the ideal volume of bupivacaine for ESPB. So, this work tried to fill this gap of literature in patients undergoing simple nephrectomy.

Methods: In this randomized double blinded control study, 100 cases undergoing simple nephrectomy were randomized into 4 groups with 25 patients per group. Group E1, 2, and 3 received ESPB with 2.5, 3.4, and 6.6 ml/segment of 0.25% bupivacaine, respectively, whereas there was no block given to the control group. Intraoperative fentanyl consumption, heart rate [HR] and the blood pressure [BP], Postoperative morphine consumption, time passed to first analgesic request, numerical rating score [NRS] of pain, the complications, HR and BP were documented for 24 hours after the operation.

Results: The reduction in intraoperative fentanyl consumption, postoperative morphine consumption and NRS were a significantly different between the block groups and control. Group E3 had significant difference from other groups with the longest time to first analgesia request. A lower HR was shown in block groups but within normal range. BP showed insignificant difference between groups. There were no reported complications in all study groups.

Conclusions: The volume of 6.6 ml/level was associated with the best pain control, without significant hemodynamic changes or adverse events as compared to other groups. This suggests that this volume may be the optimal for ESPB in patients undergoing simple nephrectomy.

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1. Background

The dorsal, lateral, and anterior cutaneous nerves of the abdomen and chest have been blocked by several fascial plane blocks that were identified in recent years. They included the Erector spinae plane (ESP), the transversus abdominis plane, the quadratus lumborum, the pectoralis nerve, and the serratus plane blocks [1].

The main benefit shared by these blocks is their simplicity to perform than neuraxial, paravertebral, and nerve blocks with a lower risk of significant adverse events as the injection is made into a tissue plane far from possibly dangerous structures [2].

Since Forero et al's original description of the erector spinae plane block (ESPB) [1], the local anaesthetic injections have been delivered into the tissue plane deep to the erector spinae muscle and superficial to the transverse processes and inter-transverse connective tissues. Many researches and case reports supported that the ESPB to be used for pain control and to reduce opioid consumption as in managing acute and chronic pain [1], fractured ribs [3], abdominal operations [4], hip arthroplasty [5], breast surgery [6], spinal surgery [7], and obstetric and gynaecological surgeries [8,9].

To our knowledge, however, very few studies have been done to identfy the ideal volume of bupivacaine for ESPB. Regarding a study of the medical literature conducted on 27 December 2017 [10], depending on the data acquired from 14 publications, the volume required to cover one dermatome varies greatly, ranging from 2.5 mL/per segment to 6.6 mL/per segment, with a median value of 3.4 mL/per segment. So, this study explored the analgesic ability of the lowest, highest, and median doses in patients undergoing unilateral simple nephrectomy.

2. Methods

This prospective randomized double blinded control trial was done on 100 patients undergoing open

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simple nephrectomy in the surgical theatre of urology of kasr Al-Ainy hospital of Cairo University at the duration between May 2020 to July 2021. The study was started after gaining the approval of the research ethics committee of the Faculty of medicine of Cairo University number (ID: MD−248-2019). Clinicaltrials.gov registration was done with (ID: NCT04371341 at 12 May 2020). Written informed consents were taken from all study applicants.

Inclusion criteria: Patients aging from 18–50 years with the American Society of Anaesthesiologists [ASA] physical status II presented for open simple nephrectomy were included in this study.

Exclusion criteria: Patients with cardiovascular diseases (hypertensive uncontrolled, ischemic heart disease, atria fibrillation, cardiomyopathic with ejection fraction < 50%), cerebrovascular diseases (transient ischemic attacks, stroke, intracranial haemorrhage), coagulation abnormalities with INR > 1.5 platelets < 80000 per microliter blood, liver dysfunction with ALT and AST > 2 times normal, total-bilirubin >1.5, allergy to the drugs of the study and pregnancy.

Randomization: Patients were divided into 4 groups, each with 25 patients, and randomized using generated computer numbers hidden within sequentially numbered, sealed opaque envelopes. ESPB with 2.5 ml/segment of 0.25% plain bupivacaine was given to group E1. The ESPB administered to Group E2 included 3.4 ml/segment of 0.25% plain bupivacaine. ESPB with 6.6 ml/segment of 0.25% plain bupivacaine was administered to Group E3. The control group was Group C, which did not get any blocks.

Blinding: the records were taken by an anaesthesiologist other than the one who performed the block and was blinded to the patients' groups.

The day before surgery, every patient was ordered to fast for 6 to 8 hours prior to the operation. On the procedure day, the patient arrived in the preparation room an hour prior to the procedure to give time for the block procedure and at least thirty minutes after performing the block. An 18 G cannula was inserted, an IV fluid was started, and premedication with 0.02–0.03 mg/kg intravenous (IV) midazolam were administered. Electrocardiogram (ECG), heart rate (HR), oxygen saturation (SpO_2), non-invasive blood pressure (NIBP), and baseline readings for SPO_2, diastolic pressure (DBP), mean pressure (MAP), and systolic pressure (SBP) were recorded every five minutes until the patient arrived in the operation room.

A line was drawn on the patient back joining the tips of the scapulae which is at the level of spinous process of T7; accordingly, the spinous process of T8 was identified as the next one caudal to that of T7. Then the targeted level (T8), the spinous processes and 3 cm from them (injection points) were marked. While the patient is sitting and supported by staff members, iodine was used for field preparation. Under ultrasound imaging with a 6–10 MHz linear probe (Mindray- DP−10/6N−64009884), anatomical landmarks were identified including the T8 transverse process and the trapezius & erector spinae muscles.

Following skin infiltration with 2% lidocaine, a 22-G spinal needle was placed with ultrasound guidance in plane, targeting the transverse process. The probe was positioned for the long axis view in a paramedian sagittal plane at the T8 level to locate the posterolateral border of the transverse process and the interfacial space between the intertransverse ligaments and the erector spinae muscle.

Following a light contact with the transverse process, a volume of 2.5, 3.4, and 6.6 ml, respectively, of 0.25% bupivacaine was administered according to groups. The local anaesthetic's spreading (separating the erector spinae muscles from transverse process) was noticed (Figure 1)

Onset of the block was tested every 10 minutes by pin-brick after performing the block up to a maximum of 30 minutes after which it was considered failed, while dermatomal spread was tested by pin-brick test thirty minutes after the start of the block and recorded for each group, aiming for blockage of segments from T6 to T10 as minimum.

Then the patient was transferred to the operation room. ECG-HR-SpO_2-NIBP were applied, and HR, SPO_2, $ETCO_2$, SBP, DBP, and MAP were recorded at base line then, every five minutes until the end of the operation.

General anaesthesia was inducted with 2 mg/kg propofol, 1mic/kg fentanyl and 0.5 mg/kg atracurium-besylate. After intubating the trachea, mechanical ventilation was started to maintain the ETCO2 35–40 mmHg. Then the patient was positioned in the lateral position. Maintenance of anaesthesia was done by isoflurane keeping its endtidal concentration at 1–2%.

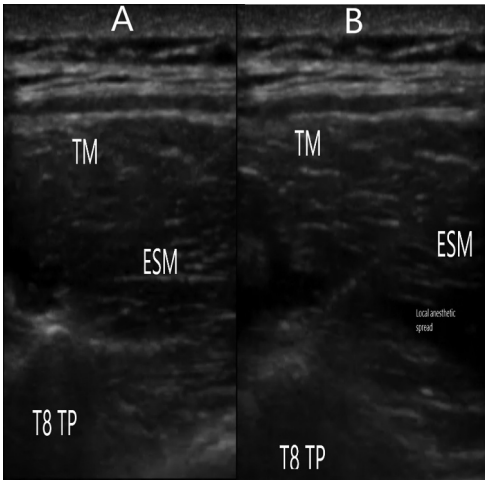

Figure 1. Ultrasound guided erector spinae plane block after needle contact to T8 transverse process in image (A) and after injection of local anaesthetic showing its spread in the erector spinae plane in image (B). TM: Trapezius muscle, ESM: Erector spinae muscle, T8 TP: Transverse process of T8.

Atracurium-besylate doses of 0.1 mg/kg were given every 30 minutes. Added intravenous fentanyl of 0.5 mic/kg was given if HR and/or SBP was > 20% from baseline as a response to surgical stimulus for a highest dose of 2 mic/kg and the total fentanyl dose was reported.

The Numerical Rating Score (NRS) for pain was used to measure the patient's pain at rest at intervals of zero, thirty minutes, first, second, fourth, sixth, eighth, tenth, twelfth, and twenty-fourth hours. The point at which the patient arose from general anaesthesia was the "zero" point in time. The time span from the zero point until the NRS was four or greater was reported as the time to the first analgesia request.

One gram intravenous paracetamol was specified at fixed intervals for whatever the NRS value was. The rescuing analgesia as intravenous 5 mg morphine was given on request if NRS was > or = 4 while the highest dose was 0.1 mg/kg every six hours and the total dose consumed of these medications was documented.

Adverse events were recorded as haematoma formation, local anaesthetic toxicity, pneumothorax, neuraxial block, severe hypotension (<50% of the baseline), or bradycardia.

3. Primary outcome

The goal was to compare morphine consumed in the 3 groups for up to 24 hours postoperatively.

4. Secondary outcome parameters

Intraoperative fentanyl consumption, NRS, the start time of the block, Dermatomal spread assessment, number of failed blocks, intraoperative and postoperative HR and SBP, the time for first analgesic request, complications in the form of toxicity of local anaesthesia, injuring nearby structures (Pleura, dura, vessels).

5. Statistical analysis

Data were reported by the mean, standard deviation (SD), median or number of incidences, and percentages. The Kolmogorov-Smirnov test was adopted to identify if numerical data supported the normal assumption. A one way analysis of variance (ANOVA) test was used to compare normally distributed numerical variables between the research groups. The Kruskal-Wallis test was employed for contrasting numerical variables that were not normal. Categorical data were compared by the Chi-square test. When the expected frequency is < 5, an exact test was adopted instead. Statistically significance was considered when the 2-sided p value was < 0.05. IBM SPSS (Statistical Program for the Social Science; IBM Corp., Armonk, NY, USA) was used to do the statistical computations.

The sample size was estimated with G power software 3.1.92. A minimum of 80 patients were calculated for all groups. A sample size was raised to 25 in each group compensating for dropouts; this was designed as follows: power analysis is done on the ability of different volumes of local anaesthetic administered during erector spinae block to decrease postoperative consumed morphine up to 24 hours postoperatively after open simple nephrectomy as the primary outcome for independent samples using F test. A pilot study on ten patients in each group has reported that the mean morphine consumption in the first 24 hours for local anaesthetic volumes of 6.6, 3.4, and 2.5 ml/segment after surgery was 17.9 ± 8.6, 19.4 ± 8.4 and 18.2 ± 6.5 mg, respectively. The necessary sample size was calculated to find a 25% difference in means. 5% type I error, a P value of less than 0.05, and an 80% power of study were achieved.

6. Results

One hundred and twenty patients were enrolled in this work, but only one hundred completed the investigation. Four were excluded due to failed block, 10 refused to participate, and six did not meet the inclusion criteria. Patients' demographics are shown in Table 1.

A statistically significant difference in the mean fentanyl consumption in the intraoperative period was revealed between the block groups and control. The lowest consumption was in E3 group (Table 2).

Number of affected dermatomes increased as local anaesthetic volume increased with a statistically significant difference between group E3 and other block groups. Onset time was lowest in E3 group showing and was significantly different between E3 and other groups. (Table 3).

The postoperative morphine dose decreased as local anaesthetic volume increased with statistically significant difference in contrast to control and a significant difference between E3 and the other groups. Also, the first analgesia request time was

Table 1. Patients' demographic data.

Variable		Group E1	Group E2	Group E3	Control group
Age [years]	Mean (Sd)	46.36 (4.25)	46.36 (5.96)	45.72 (4.34)	47.0 (4.18)
BMI [Kg/M^2]	Mean (Sd)	27.3 (2.3)	26(3.3)	27.7 (1.9)	27.1(1.4)
Gender (Male/Female)		21/4	20/5	20/5	20/5
Operative duration [min]	Mean (Sd)	126.5 (31.6)	115(28.5)	113 (24.4)	118.5(27.5)

Note: Data is exhibited as mean and standard deviation(Sd). P value < 0.05 is considered significant.

Table 2. Comparison of total intraoperative fentanyl consumption between groups.

	E1 Mean (Sd)	E2 Mean (Sd)	E3 Mean (Sd)	Control group Mean (Sd)	P value
Fentanyl dose (mcg)	126(48.1)	112(41.5)	100(0.0)	232(37.8)	*0.24 **0.01 ***0.16 ****<0.001

Note: Data is exhibited as mean and standard deviation(Sd). *P* value < 0.05 is significant * for *P* value between E1 and E2, ** for *P* value between E1 and E3, *** for *P* value between E2 and E3 and **** for *P* value between all block groups and control.

Table 3. Comparison of study groups as regards number of affected dermatomes and block onset time.

	E1 Mean (Sd)	E2 Mean (Sd)	E3 Mean (Sd)	P value
Number of dermatomes	4.56 (0.65)	5.20 (0.57)	8.44 (1.58)	*0.001 **<0.001 ***<0.001
Block Onset time (min)	27.2(4.58)	25.6(5.06)	18.8(6.0)	*0.29 **<0.001 ***<0.001

Note: Data is exhibited as mean and standard deviation(Sd). *P* value < 0.05 is significant. * for *P* value between E1 and E2, ** for *P* value between E1 and E3, *** for *P* value between E2 and E3.

Table 4. Comparison of four groups as regard postoperative morphine dose and time to first analgesic request.

	E1 Mean (Sd)	E2 Mean (Sd)	E3 Mean (Sd)	Control group Mean (Sd)	P value
Morphine dose (mg)	12(6.12)	10.6(7.68)	1.8(4.05)	21(5.77)	*.035 **<0.001 ***<0.001 ****<0.001
Time to first analgesic request (min)	9.14(7.1)	12.6(7.3)	21.2(5.45)	4.04 (4.98)	*.045 **<0.001 ***<0.001 ****<0.001

Note: Data is exhibited as mean and standard deviation. *P* value < 0.05 is significant. * For *P* value between E1 and E2, ** for *P* value between E1 and E3, *** for *P* value between E2 and E3 and **** for *P* value between all block groups and control.

more in the block groups in contrast to control with statistically significant difference (Table 4).

The HR intraoperatively was significantly different ($P < 0.001$) between all groups, which was lowest in E3 group (Figure 2 &amp ; Table 5). Also, the HR over the 24 hours postoperative period showed significant difference between all groups ($P < 0.001$) (Figure 2) .

The systolic blood pressure measurements in the preoperative and intraoperative period were lower in study groups as in contrast to control group but with no significant difference ($P = 0.0558$) (Figure 2). SBP readings over the 24 hours after the operation were lower in the study groups in contrast to control group with statistically significant difference ($P = 0.03$); however, no statistical significance was shown between the three block groups (Figure 2).

As regards to NRS, a statistically significant difference between the block groups and control was revealed all-over the studying times. A significant difference was shown between E3 and other groups in most of measurements postoperatively (Table 5).

With regards to the occurrence of complications, there were no complications reported in the three block groups.

7. Discussion

This randomized control study was done to investigate the optimal local anaesthetic volume to be used in ESPB in simple nephrectomy. The optimal volume was defined as that with the best analgesic properties and with the least hemodynamic compromise and least incidence of complications.

According to metanalyses done by different authors on the efficacy of the ESPB in abdominal and thoracic operations, the block was found to be a valuable option for postoperative pain, and it significantly reduced the consumed opioids and prolonged the time to first analgesia request [11–13]. There is no study that has explored the ideal volume of local anaesthetic for ESPB. This study compared 3 volumes of local anaesthetic (2.5 mL, 6.6 mL, and 3.4 mL/level) for ESPB based on the volumes stated by the previous literatures [10]. However, in this study, the

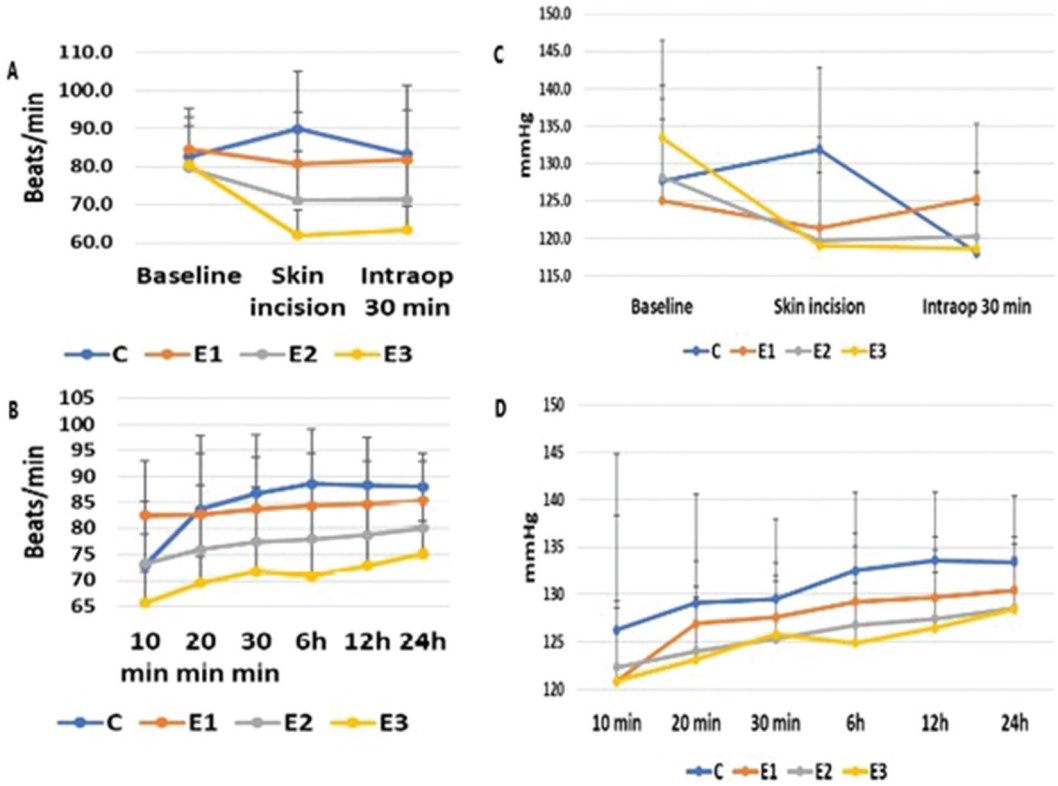

Figure 2. HR and SBP in the study groups (A) Mean preoperative and intraoperative HR (B) Mean postoperative HR (C)mean preoperative and intraoperative SBP (D) Mean postoperative SBP.

investigators adopted fixed concentration, technique, site of injection, and the same operation.

The hypothesis of this study was that the larger used dose of local anaesthetic would have the optimal analgesic effect of ESPB required in simple nephrectomy operation. This hypothesis was supported by our results, although the block groups had significant difference from control with regards to the analgesic efficacy; yet, group E3 (the group of the largest dose) had significant reduction in intraoperative fentanyl and postoperative morphine consumption and NRS compared to the other study groups. Dermatomal coverage was highest in group E3 with the fastest block onset. Time to first analgesia request was longest in E3 group. Group E3 had a lower heart rate but within normal range while the systolic blood pressure was not significantly different between the block groups. Finally, there were no reported complications in all study groups.

Based on cadaveric and contrast investigations, on the ESPB, it is thought to function at the spinal nerves' origins. When dye was administered bilaterally, injected into the inter-fascial plane under the erector spinae muscle, the para-spinous gutter showed craniocaudal spread from C7 to T8 on the right and T1 to T8 on the left, with lateral spreading up to the transverse processes at all levels. At levels T3 to T6 on the right and T4 to T8 on the left, the injectate was also seen just beyond the costotransverse junction [1]. According to cadaveric investigations, a block at the T5 level is all that is necessary to cause a unilateral multidermatomal sensory block affecting the range of T1 to L3 [14].

The anterior spreading of the injectate to the ventral and dorsal rami of the spinal nerves and through the inter-transverse tissue to enter the paravertebral and epidural spaces are perceived as the main advantages of the ESPB over other inter-fascial blocks for abdominal procedures.

This would relieve visceral discomfort by blocking sympathetic fibers that are transmitted through rami communicants as well as spinal nerve roots. This was underlined in the short case series by Chin et al, who found that three bariatric patients having laparoscopic abdominal operations experienced a considerable reduction in visceral discomfort following the administration of ESPB [15]. This spread can explain why the higher doses of our study were most effective.

An analysis of the medical research was carried out by De Cassai et al. In fact, the amount required to cover one dermatome following a injection of local anaesthetic varied greatly, ranging from 2.5 mL [1,2] to 6.6 mL [7], with a median value of 3.4 ml. Moreover, a single loading of thirty ml in ESP might reach a maximum of nine dermatomes [16]. The author came to the conclusion that further investigations might be planned using the volume of 3.4 mL as the volume necessary for covering one dermatome.

Consistent with our results, a research done by Tuglar et al. [5], on the use of ESPB at L4 transverse process level

Table 5. NRS for up to 24 hours postoperatively.

	E1 Mean (Sd)	E2 Mean (Sd)	E3 Mean (Sd)	Control group Mean (Sd)	P value
NRS 0 min	0.68 (0.69)	0.72 (0.84)	0.40 (0.57)	1.88 (0.83)	*0.86 **0.11 ***0.08 <0.001
NRS 30 min	1.04 (1.06)	0.68 (0.53)	0.40 (0.57)	2.24 (1.33)	*0.58 **<0.06 ***0.02 ****<0.001
NRS 1 h	1.6 (0.86)	1.28 (0.84)	0.52 (0.65)	3.2 (1.6)	*0.22 **<0.001 ***0.03 ****<0.001
NRS 2 h	2.36 (1.28)	1.84 (0.89)	0.76 (0.83)	3.28 (1.06)	*0.12 **<0.001 ***<0.001 ****<0.001
NRS 4 h	2.68 (0.9)	2.8 (1.19)	1.28 (0.84)	3.64 (1.28)	*0.64 ** <0.001 ***<0.001 ****<0.001
NRS 6 h	3.08 (0.99)	2.76 (0.87)	1.36 (0.90)	3.2 (0.70)	*0.23 ** <0.001 *** <0.001 ****<0.001
NRS 8 h	3.16 (0.55)	3.32 (1.10)	1.60 (1.1)	3.68 (0.9)	*0.49 **<0.001 *** <0.001 ****<0.001
NRS 10 h	3.36 (0.95)	3.22 (1.03)	2.0 (0.70)	3.72 (1.02)	*0.9 **<0.001 ***<0.001 ****<0.001
NRS 12 h	3.36 (0.75)	3.12 (0.60)	2.36 (0.99)	3.32 (0.98)	*0.22 **<0.001 ***0.007 ****<0.001
NRS 18 h	3.28 (0.67)	3.64 (1.11)	2.56 (0.71)	3.64 (1.18)	*0.17 **<0.001 ***<0.001 ****<0.001
NRS 24 h	3.28 (0.67)	3.16 (0.89)	2.60 (0.50)	3.64 (0.90)	*0.52 **<0.001 ***0.016 ****<0.001

Note: Data presented as mean and standard deviation(Sd). *P* value < 0.05 is statistically significant. * For *P* value between E1 and E2, ** for *P* value between E1 and E3, *** for *P* value between E2 and E3.

using a dose of 6 ml/level. The NRS was < 3 for 18 hours postoperatively. Ueshema et al. [7], used a volume of 6.6 ml/level in ESPB at the level of the T5. No added analgesic was required for perioperative control of pain.

Hamilton et al. [2], performed the ESPB with 2.5 ml/dermatome and showed NRS of 0–1 and the distribution of block extended from T1 to T9 with limited block of the C7 and C8 dermatomes. However, a catheter was used, and it was performed at T5 level. In Forero et al., study [1] ESPB was performed at the T5 level for neuropathic pain. They used a local anaesthetic volume of 2.5 ml/dermatome and reported full liberation of pain. The dermatomal distribution involved T2 to T9, and from 3 cm lateral to the spine to the mid-clavicular line.

Ahiskalioglu et al. [17], used continuous ESP block at the level of T5 with a volume of 3.3 ml/dermatome. The visual analog score was reduced in seconds after the block from 9 to 2 and the dermatomes covered were from T2 – T7. Another Forero et al., study [16] used ESPB with a volume of 3.3 ml/segment for post-thoracotomy pain. All the patients had a satisfactory relief of pain after ESPB. By comparing different volumes and concentrations of local anesthetic agents, Nicholas et al. [18] found that 0.2% ropivocaine to be similar to greater doses of local anesthetic while theoretically reducing the risk of local anesthetic toxicity. Nevertheless, they employed various concentrations and concentrated on the dosage rather than the volume.

Because the precise LA concentration to be utilized in ESPB has not yet been defined, in this trial, bupivacaine concentration of 0.25% was chosen. Although using a large volume of a low LA concentration is advised from a safety standpoint, authors of some case reports have employed a lower to moderate volume of a high concentration [19].

8. Limitations

This work is better to be done on a greater patients' sample to approve the findings. Pain was assessed at

rest so it would be better to be assessed in both rest and coughing for better evaluation. The insertion of a catheter with continuous local anaesthetic infusion appears to give potentially substantial postoperative analgesia. The use of PCA may be advantageous in pain control in addition to the block. The spread of local anaesthetic under ultrasound imaging would be a valuable tool to determine the optimal volume. However, these limitations did not affect the outcome of the study. Finally, we did not investigate the effect of different dose in blunting the markers of the surgical stress response. These limitations may be taken into considerations for future studies.

9. Conclusion

The use of a volume of 6.6 ml/level during ESPB was associated with the lowest intraoperative fentanyl and postoperative morphine consumption, lowest NRS scores, and longest time to first analgesic request largest covered area. Additionally, this volume was not associated with significant systolic blood pressure changes than other groups and it was not associated with adverse events. This suggests that this volume may be used for ESPB as the optimal volume for pain control in patients undergoing nephrectomy operations.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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