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ORIGINAL RESEARCH REGIONAL ANESTHESIA

Ultrasound-guided erector spinae plane block in radical cystectomy: a randomized controlled study

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ABSTRACT

Background & Objectives: Radical cystectomy (RC) is usually performed under general anesthesia, with the management of postoperative pain being a big challenge. Various approaches have been tried, including epidural analgesia, or regional nerve blocks in addition to the intravenous patient-controlled analgesia (IV-PCA). We compared the efficacy and safety of bilateral single-injection erector spinae plane block (ESPB) with IV-PCA administered morphine to manage postoperative pain following RC.

Methodology: This prospective randomized controlled clinical study was performed on 60 participants ranging in age from 21 to 65 years, both sexes, BMI 20-40 kg/m^2, ASA physical status II-III, planned for elective RC. Participants were randomized into two equal groups. Group ESPB received ultrasound-guided single shot ESPB at T10 with 20 mL bupivacaine 0.25% bilaterally; IV morphine 3 mg bolus was used as rescue analgesia when the Numeric Rating Scale (NRS) pain score was ≥ 4. Group C (control group) received IV-PCA by morphine 3 mg IV when NRS pain score was ≥ 4 and repeated 1/2 mg if still pain score was recorded ≥ 4 for 15 min. Pain was measured on NRS at 2 , 4 , 8, and 12 h as well as the postoperative heart rate (HR) and mean arterial blood pressure (MAP). Complications were noted,

Results: Time to first analgesic request was substantially prolonged in Group ESPB compared to Group C ($P < 0.001$). Total postoperative consumption of morphine in 1st 48 h and postoperative nausea and vomiting were substantially reduced in Group ESPB compared to Group C ($P < 0.05$). NRS pain scores, postoperative HR and MAP measurements were substantially reduced at 2, 4, 8, and 12 h in Group ESPB than Group C ($P < 0.05$). Bradycardia and hypotension varied insignificantly different between both groups. Respiratory depression and urinary retention did not occur in any patient in both groups.

Conclusions: Compared with IV-PCA administered morphine, bilateral single-injection ESPB was associated with better hemodynamics and analgesic properties, as observed by lower pain scores, less postoperative opioid consumption, and longer time to first analgesic request with good safety profile after radical cystectomy.

Keywords: Ultrasound; Erector Spinae Plane Block; Radical Cystectomy; Patient-Controlled Analgesia

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1. INTRODUCTION

Radical cystectomy (RC) is a highly complex surgical procedure in urology.[1,2] The presence of intense pain following surgery often has a negative impact on a patient's healing process and quality of life.[3]

Intravenous patient-controlled analgesia (IV-PCA) is a highly utilized approach in medical procedures to manage postoperative pain. It entails the continuous delivery of a predetermined amount of pain-relieving medication while also permitting patients to get more doses as needed. It has made a significant contribution to enhancing the predictions of surgical outcomes and anesthesia by reducing postoperative pain and enhancing the satisfaction of patients.[4]

Morphine is the predominant opioid utilized for IV PCA and is often regarded as the gold standard for this technique. Furthermore, IV-PCA has its limitations due to the stimulation of μ-opioid receptors and the resulting adverse events, including postoperative nausea and vomiting (PONV), hypotension, bradycardia, respiratory depression and urinary retention.[5]

Erector spine plane block (ESPB) was initially introduced by Forero et al. in 2016.[6] While the exact mechanism of action of the ESPB remains unclear, one potential explanation is that it works by blocking the dorsal and ventral rami of thoracic/lumbar spinal neurons. ESPB has been utilized as a method of analgesia in cases of rib fractures, as well as other treatments involving the thoracic region and abdominal surgery.[7,8]

The purpose of the work was to compare the efficacy and safety of bilateral single-injection ESPB with IV-PCA in managing postoperative pain following RC.

2. METHODOLOGY

This prospective randomized controlled clinical study was performed on 60 participants, aged 21 to 65 y, both genders, BMI: 20-40 kg/m^2, American Society of Anesthesiologists (ASA) physical status II-III planned for elective RC. This research was performed following approval from the Ethics Committee of National Cancer Institute, Cairo, Egypt. All participants provided an informed written consent.

Criteria for exclusion were psychiatric and cognitive disorders, localized injection site infections, allergic reactions to the study drugs, anatomical anomalies, and an inability to understand or take part in the pain grading system.

Patients were randomized into two groups equally in a parallel way using computer-generated random numbers with closed envelopes. Group ESPB: ultrasound-guided bilateral single shot ESPB and Group C (Control group): received IV-PCA. The study was open label due to different techniques.

Each participant was subjected to history taking, physical examination, laboratory tests [full blood picture (CBC), coagulation profile, liver, and kidney function], 5 leads electrocardiogram (ECG) for patients above 40 y, and any other necessary investigations if required for high risk patients. Patient was informed about Numeric Rating Scale (NRS).

Patents were monitored by ECG, pulse oximetry, non-invasive blood pressure monitoring (NIBP), capnogram and temperature probe. natracurium 0.5 mg/kg to assist in tracheal intubation. The anesthesia was maintained using isoflurane at a concentration of 1.2 MAC in a mixture of 50% air and 50% oxygen. Increments of atracurium 0.1 mg/kg every 20 min. Extra doses of fentanyl 0.5 μg /kg were administered if the MAP or heart HR increased by more than 20% from the baseline. The patients were subjected to mechanical ventilation, and settings were adjusted to maintain end-tidal CO_2 levels within the range of 35-40 mmHg.

In Group ESPB, Following the surgery, the participant was lying in the lateral position in a completely sterile environment. A high-frequency linear transducer of ultrasound had been positioned in a longitudinal orientation 3 cm laterally to the T10 spinous process. The tip of a 22-G spinal needle was introduced into the fascial plane on the deep (anterior) portion of the ESM by inserting the needle in the plane from the cephalad to the caudad. After confirming the appropriate location using hydro dissection with 5 mL of saline solution (0.9%), the ESM was lifted away from the bony outline of the transverse process. Subsequently, 20 mL of bupivacaine 0.25% was administered. This was repeated on the other side. IV morphine (3mg) bolus was provided as rescue analgesia when the NRS score was ≥ 4.

In Group C, patients received IV-PCA by morphine (3 mg when NRS was ≥ 4 and 1/2 mg if still recorded pain for 15min).

Following the giving of neostigmine (0.05 mg/kg) and atropine (0.02 mg/kg) to reverse the effects of the neuromuscular blocking drug, participants were extubated in the operating theatre once they responded to verbal commands. Subsequently, they were relocated to the post-anesthesia care unit (PACU). Participants were transferred to the surgical ward once they met the modified Aldrete criteria of 9 or more. Pain assessment was done by NRS at PACU, 2, 4, 8, 12, 16, 24, 36, and 48 h postoperative.

The primary outcome was the total amount of morphine consumed within 48 hours.

Table 1: Patient characteristics and duration of surgery of the studied groups

Parameters		Group ESPB (n = 30)	Group C (n = 30)	P
Age (y)		48.27 ± 11.25	47.2 ± 8.6	0.681
Sex	**Male**	19 (63.33)	21 (70)	0.584
	Female	11 (36.67)	9 (30)	
Weight (kg)		71.33 ± 8.56	74.37 ± 5.42	0.106
Height (m)		1.67 ± 0.07	1.69 ± 0.07	0.249
BMI (kg/m^2)		25.62 ± 3.89	26.01 ± 2.66	0.649
ASA physical status	**II**	17 (56.67)	19 (63.33)	0.598
	III	13 (43.33)	11 (36.67)	
Duration of surgery (min)		161.5 ± 25.5	165.5 ± 22.72	0.524

Data are expressed as mean ± SD or n (%).ESPB: Erector Spinae Plane Block; P ≤ 0.05 considered as significant

Table 2: NRS measures of the groups under the study

Time	Group ESPB (n = 30)	Group C (n = 30)	P
PACU	1 (1 - 2)	2 (1 - 2)	0.153
2 h	2 (1 - 2)	4 (2 - 5)	< 0.001*
4 h	2 (1 - 3)	3 (2 - 4)	0.005*
8 h	2 (1.25 - 4)	4 (2 - 5)	0.035*
12 h	2 (1.25 - 4.25)	3 (2 - 5.75)	0.004*
16 h	4 (2 - 5)	3 (2 - 5)	0.875
24 h	3 (1 - 5)	3.5 (2 - 5)	0.428
36 h	3 (2 - 5)	3 (2 - 4)	0.137
48 h	3 (3 - 4)	3 (2.25 - 4.75)	0.431

*Data presented as median (IQR). * P ≤ 0.05 considered as significant; PACU: Post-anesthesia care unit.*

Table 3: Intraoperative fentanyl consumption, time to first analgesic request, total postoperative consumption of morphine in 1st 48 h of the studied groups

Variable	Group ESPB (n = 30)	Group C (n = 30)	P
Intraoperative fentanyl consumption (µg)	193.53 ± 44.27	200.8 ± 37.76	0.497
Time to first analgesic request (h)	8.53 ± 2.11	1.53 ± 0.51	< 0.001*
Total postoperative morphine consumption in 1st 48 h (mg)	20.9 ± 6.33	31.7 ± 9.78	< 0.001*

*Data displayed as mean ± SD. *Significant as P value ≤ 0.05. ESPB: Erector Spinae Plane Block.*

2.1. Sample size calculation

The sample size was calculated by G* Power 3.1.9.4. Based on the results of a pilot study (five cases per group), the mean difference in the total amount of morphine consumed between the ESP block group and the PCA group was 1.4, with a standard deviation of 1.3. A sample size of 25 individuals was required in each group to detect a significant difference in means between groups at 1.14 effect size. α error of 0.05 and power of 80%. This number was increased by 15 % to compensate for expected losses. The total required sample size was 30 cases per group.

2.2. Statistical analysis

Statistical analysis had been conducted utilizing SPSS v26 (IBM Inc., Chicago, IL, USA). The Shapiro-Wilks test and histograms were utilized to evaluate the normality of the distribution of data. Quantitative parametric data were displayed as mean and standard deviation (SD) and compared between both groups by employing an unpaired Student's t-test. Quantitative non-parametric data had been displayed as median and interquartile range (IQR) and had been analyzed by Mann Whitney-test. Qualitative parameters were displayed as frequencies and percentages (%) and were analyzed employing the Chi-square test or Fisher's exact test when appropriate. A two-tailed $P < 0.05$ was considered statistically significant.

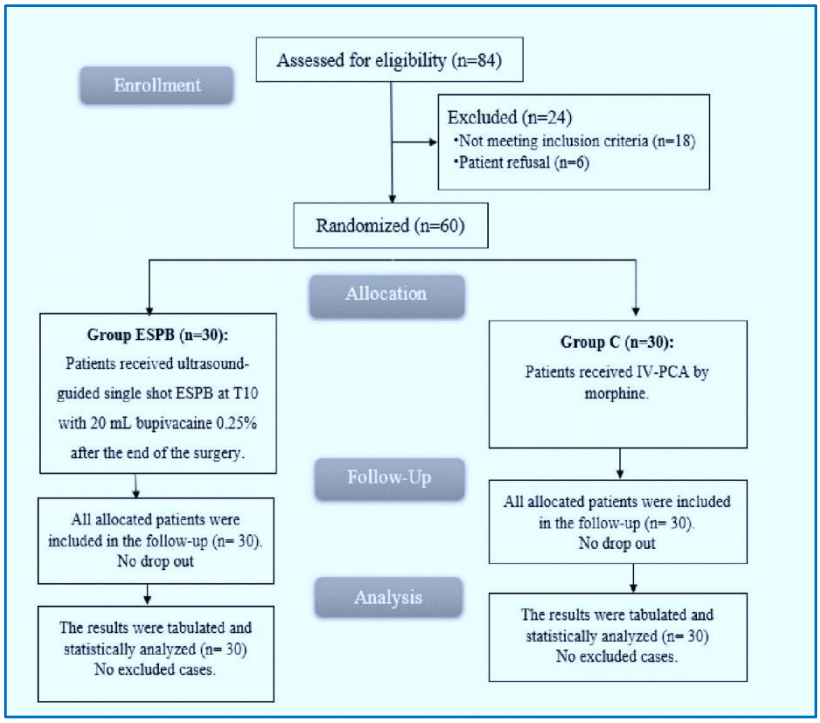

Figure 1: CONSORT flow diagram of the subjects through each stage of the work.

3. RESULTS

Eighty- four individuals had been evaluated for eligibility; 18 individuals didn't fulfil the criteria, and six individuals refused to take part in the work. The remaining individuals were assigned at random into two equal groups (30 patients in each). All allocated participants received follow-up and had been analyzed statistically (Figure 1).

Patient characteristics and the duration of surgery varied insignificantly between the two groups. Table 1

Table 4: Comparative adverse events in the studied groups

Adverse events	Group ESPB (n=30)	Group C (n=30)	P
PONV	4 (13.33)	11 (36.67)	**0.037***
Hypotension	5 (16.67)	7 (23.33)	0.519
Bradycardia	3 (10)	4 (13.33)	0.688
Respiratory depression	0 (0)	0 (0)	---
Urinary retention	0 (0)	0 (0)	---

*Data are presented as frequency (%). * Significant as P value≤0.05. ESPB: Erector Spinae Plane Block, PONV: Postoperative nausea and vomiting.*

Postoperative HR and MAP measurements were substantially reduced at 2 h, 4 h, 8 h, and 12 h in Group ESPB compared to Group C ($P < 0.05$) and had been insignificantly various at PACU, 16 h, 24 h, 36 h, and 48 h between both groups (Figure 2).

NRS measurements were significantly lower at 2 h, 4 h, 8 h, and 12 h in Group ESPB compared to Group C ($P < 0.05$) and were insignificantly different at PACU, 16 h, 24 h, 36 h, and 48 h between the two groups (Table 2).

Intraoperative fentanyl consumption had been insignificantly varied between the two groups. Time to first analgesic request had been substantially prolonged in Group ESPB compared to Group C ($P < 0.001$). Total postoperative consumption of morphine in 1st 48 h had been substantially reduced in Group ESPB compared to Group C ($P < 0.001$) (Table 2).

Postoperative nausea and vomiting were substantially decreased in Group ESPB compared to Group C ($P = 0.037$). Bradycardia and hypotension varied insignificantly between both groups. Respiratory depression and urinary retention did not occur in any patient in Group ESPB and Group C (Table 3).

4. DISCUSSION

RC is surgery to remove the bladder to prevent cancer from spreading. It may also involve removing lymph

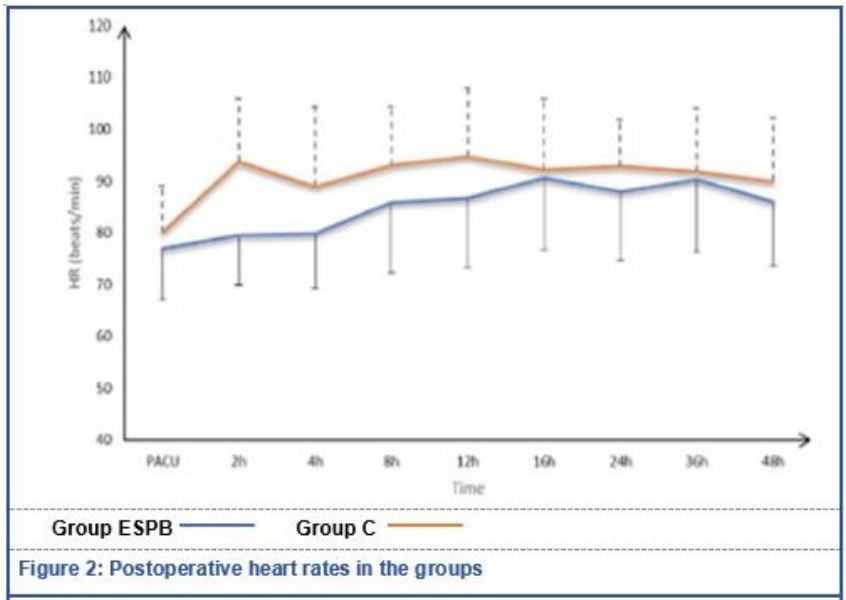

Figure 2: Postoperative heart rates in the groups

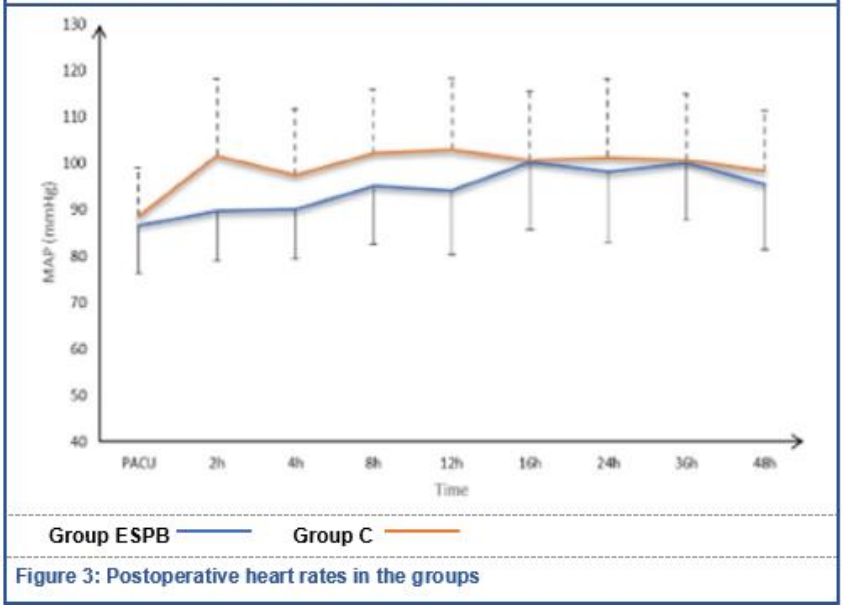

Figure 3: Postoperative heart rates in the groups

nodes and some, or all, of the urethra. Acute postsurgical pain often hurts an individual's recovery and overall quality of life.[9,10]

Time to first analgesic request has been substantially prolonged in Group ESPB compared to Group C. Similar to the current results, Dubilet et al. showed an increase in postoperative opioid and non-opioid analgesic consumption in the control group compared to the ESPB group.[11] Various other authors agreed with the present results as they showed that postoperative consumption of morphine was a statistically substantial decrease in the ESPB group compared to the control group, and the time to first analgesic request had been significantly prolonged in the ESPB group compared to the control group.[12,13] In disagreement with our findings, Kang et al. stated that postoperative opioid consumption was significantly greater in the ESPB group compared to the ITM group.[14] This difference can be explained by the use of intrathecal administration of morphine and the difference in the surgery.

The current study showed that postoperative HR and MAP measurements were significantly lower at 2 h, 4 h, 8 h, and 12 h in Group ESPB than in Group C, as stated by other researchers.[13,14] Elshrazly et al. compared the impact of postoperative analgesia and the feasibility of both the transverse abdominal plane (TAP) and ESPB between individuals with obesity undergoing bariatric surgeries. There was a statistically substantial rise in MAP and HR in the TAP group, which compared with the ESPB group.[15]

In the current work, postoperative NRS measurements were significantly lower in Group ESPB than in Group C, in addition to substantially reduced HR as well as diastolic and systolic blood pressure when compared with the control group (P ranging from 0.03 to < 0.001).[11] VAS measurements were substantially greater in the control group than the ESPB group post-operatively.[13] In disagreement with the present findings, Aksu et al. showed no difference in the NRS measurements of the ESPB and control group. The variations in the surgical technique and demographics might explain this.[12] ESPB has also been used for the treatment of acute pain in acute pancreatitis.[16]

The control group was significantly associated with a higher incidence of PONV compared to the ESPB group.

5. LIMITATIONS

The sample size was relatively small, the work was in a single center, and there was no comparison between different anesthetic techniques.

6. CONCLUSION

On the basis of the results of our study, we conclude that compared with IV-PCA, bilateral single-injection ESPB is associated with better hemodynamics and analgesic properties, observed as lower pain scores and less

postoperative opioid consumption, and longer time to first analgesic demand with good safety profile after RC.

7. Data availability

The numerical data generated during this research is available with the authors.

8. Acknowledgement

We gratefully thank Faculty of Medicine, National Cancer Institute, Cairo University, Cairo

9. Conflict of interest

The study utilized the hospital resources only, and no external or industry funding was involved.

10. Authors' contribution

AMA, AMT: developed the original idea and the protocol, abstracted, and analyzed data, wrote the manuscript, and is a guarantor.

EM, TEA: contributed to the development of the protocol, abstracted data.

ASA, TEA: prepared the manuscript.

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