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Dexmedetomidine versus dexamethasone as an adjuvant in erector spinae plane block for postoperative pain management in open nephrectomy: A randomized controlled trial

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Abstract
Background: The management of acute postoperative pain is essential for improving patient satisfaction and achieving an improved outcome. The erector spinae plane block (ESPB) can potentially induce sensory blockage on both visceral and somatic levels. The efficacy of nerve block is enhanced, and opioid consumption is reduced by the addition of an adjuvant, such as dexmedetomidine (Dex) or dexamethasone (Dexa). The purpose of this research is to assess the efficacy of Dex and Dexa as adjuvants in ESPB for the management of postoperative pain in patients who underwent open nephrectomy.
Methods: A total of 60 patients participated in this randomized, controlled, double-blinded study, 18 to 65 years of age, both sexes and scheduled to undergo an open nephrectomy under general anesthesia. Each patient was assigned to one of three equal categories.: Group Dex: patients received ESPB with the addition of one µg/kg Dex to 29 ml bupivacaine 0.25% as a study group (total volume 30 ml), Group Dexa: patients received ESPB with the addition of 10 mg Dexa to 29 ml bupivacaine 0.25%, Group C: patients not received ESPB as a control group.
Results: Heart rate, mean arterial blood pressure and visual analog scale measurements were notably decreased in group Dex when contrasted with group Dexa and group C. The time to first rescue was substantially prolonged in group Dex compared to group Dexa and group C and in group Dexa in comparison to group C. The cumulative morphine consumption in the first 24 hours postoperatively was considerably lower in group Dex than in group Dexa and group C and group Dexa compared to group C.
Conclusion: As an adjuvant to bupivacaine in ESPB, Dex is superior to Dexa in hemodynamic stability, pain reduction, delayed time first to rescue, and total opioid consumption.

Keywords: Dexmedetomidine, dexamethasone, adjuvant, erector spinae plane block, pain, open nephrectomy

Introduction

The successful management of acute pain following open nephrectomy is a challenging endeavor due to the extensive severing of the musculature and the wide subcostal flank incision that is necessary to access a broad operative field [1, 2].

It is imperative to manage acute postoperative pain effectively to achieve a better outcome and ensure patient satisfaction [3]. Inadequate postoperative pain management can lead to acute effects and increase the likelihood of chronic postoperative pain [4, 5].

Constipation, respiratory depression, and postoperative nausea and vomiting (PONV) are among the adverse events associated with intravenous (IV) analgesics, which treatments are adopted most frequently to alleviate acute postoperative pain [6]. Consequently, it is imperative to implement alternative modalities, including multimodal analgesia, non-steroidal anti-inflammatory medications, and regional blocks, to reduce opioid consumption [7].

A recently defined interfascial regional anesthesia block for thoracic analgesia, the erector spinae plane block (ESPB) can be administered using either a superficial or deep injection approach [8]. The deep needle approach is the preferred method, as the substance is deeply deposited into the erector spinae muscle near the transverse process and at the origin of the dorsal and ventral rami [9].

In the past, studies have reported that the use of ordinary local anesthetic without adjuvants resulted in effective postoperative pain reduction and reduced postoperative opioid consumption following radical mastectomy surgery with ESPB [10-12].

A potent α2 agonist, dexmedetomidine (Dex), is being used more frequently as an adjuvant to regional anesthesia and analgesia. It has only a few adverse effects and can prolong the duration of nerve block anesthesia when used in conjunction with a local anesthetic [13, 14].

Dexamethasone (Dexa) is believed to function by inhibiting C-fibers' discharge through potassium channels and decreasing the release of inflammatory mediators. In human studies, the Dexa-treated group exhibited a prolonged sensory and motor blockade duration compared to the control group, as demonstrated by the results [14, 15].

The purpose of this research is to assess the efficacy of Dex and Dexa as adjuvants in ESPB for the management of postoperative pain in patients who underwent open nephrectomy.

Patients and Methods

We conducted this randomized, controlled, double-blinded study on 60 patients between the ages of 18 and 65, both sexes, belonging to physical status I-II of the American Society of Anesthesiology (ASA), with body mass index (BMI) from 20 to 35 kg/m^2, and scheduled for open nephrectomy under general anesthesia. The trial was conducted from 23th Augast 2023 to 1st septemper 2024 following approval from the Ethical Committee of Cairo University Hospitals. The patient provided written consent that was informed.

Exclusion criteria included a history of psychological disorders, local peritonitis, pre-existing peripheral neuropathies, coagulopathy, arrhythmia, infection at the injection site, pregnancy, advanced hepatic or renal disease, and severe respiratory or cardiac conditions. In addition, the study excluded individuals who had a known sensitivity or contraindication to the medications used.

Randomization and blindness

A random list was generated using an online randomization program (http://www.randomizer.org), and the codes of each patient were stored in an opaque sealed envelope. Each patient was concurrently assigned to one of three equal groups in a parallel manner, utilizing a 1:1:1 allocation ratio: Group Dex: patients received ESPB with addition of one µg/kg Dex to 29 ml bupivacaine 0.25% as a study group (total volume 30 ml), Group Dexa: patients received ESPB with the addition of 10 mg Dexa to 29 ml bupivacaine 0.25%, Group C: patients not received ESPB as a control group. Blinded to the patient group were both patients and outcome assessors. A pharmacist who would not be involved in the study prepared the interventional medications.

Medical and surgical histories of the patients were recorded, clinical examination was conducted, routine laboratory investigations were performed, and complete blood picture and coagulation studies were done.

Patients were instructed to evaluate their postoperative pain using the visual analog scale (VAS). VAS (0 represents “no pain” while 10 represents “the worst pain imaginable”) [16].

Standard monitoring, encompassing capnography, pulse oximetry, non-invasive arterial blood pressure (NIBP), electrocardiography (ECG), and temperature probe, was implemented upon patients' arrival in the operating room.

IV propofol and IV fentanyl were administered to induce general anesthesia at a rate of 2-2.5 mg/kg and 1-2 ug/kg, respectively. After administering 0.15 mg/kg of IV Cis-atracurium, endotracheal intubation was performed.

The maintenance of anesthesia is achieved by combining isoflurane (1-1.5%) with 50-100% oxygen. IV Cis-atracurium 0.03mg/Kg was administered in incremental quantities. Patients were ultimately mechanically ventilated to maintain an end-tidal carbon dioxide level of 35-45 mmHg.

Surgical technique

Through a ventral incision of 10-15 cm between the ninth and tenth ribcage, the same experienced surgeon performed surgical procedures on all patients. The external and internal oblique muscles are identified through the dissection of the intercostal muscle, transverse muscle, and ventrally opening of the peritoneum, the kidney, and Gerota's fascia, which were subsequently visible. After the ureter and lower pole of the kidney were isolated, the renal artery and vein were ligated and divided. The ureter was transected, the upper pole was segmented, and the adrenal gland was finally completed in the event of upper pole malignancies. Upon completion of the surgical procedure, the muscle layers, subcutaneous space, and epidermis were closed with flowing sutures, and in the retroperitoneal space, a drain was left.

Erector spinae plane block technique

A proficient anesthesiologist performed the block. The block was conducted using a linear transducer operating at 13-16 MHz. The probe was protected by a cover sheath and a substantial quantity of lubricant gel, and the participants were seated. Positioning the probe longitudinally, it was situated three centimeters lateral to the T7 spinous process. The hyperechoic transverse process shadow should reveal the primary rhomboid muscles, trapezius, and erector spinae. The epidermis was anesthetized with 3 ml of 1% lidocaine. The apex is situated in the deep (anterior) portion of the fascial plane of the erector spinae muscle; 20-gauge block needles were inserted into the plane from the cephalad to the caudal. In a subsequent phase, 20 ml of 0.25% bupivacaine was administered progressively. The erector spinae muscle was elevated from the bone shadow of the transverse process by the fluid spread, which confirmed the needle's placement.

Study drugs were then injected according to group allocation, and the distribution of drugs in both cranial and caudal direction was observed (patients received ESPB with the addition of 10 mg Dexa to 29 ml bupivacaine 0.25% in group Dex and with the addition of 10 mg Dexa to 29 ml bupivacaine 0.25% in group Dexa).

Atropine (0.02 mg/kg) and neostigmine (0.08 mg/kg) were administered to reverse residual neuromuscular blockade after the anesthesia was terminated after the surgery, and extubation was performed. When the patients were completely conscious, they were transferred to the post-anesthesia care unit (PACU).

Postoperative

In the postoperative period, a standardized analgesic regimen was prescribed. Routine analgesia involves

administering 1 milligram of paracetamol every 6 hours to all patients. If the VAS was more significant than 3, rescue analgesia of morphine was administered as a 3 mg bolus. If the pain persisted until the VAS was less than 4, the bolus was repeated after 30 minutes. VAS was evaluated at 0, 2, 4, 6, 8, 10, 12, and 24 hours postoperatively.

The following adverse effects were evaluated: hypotension (a 20% decrease in basal mean arterial blood pressure), bradycardia (a 20% decrease in basal heart rate), respiratory depression (a SpO_2 level below 95% requiring oxygen supplementation), and postoperative nausea and vomiting (PONV) were all treated with IV ondansetron 0.1 mg/kg.

The degree of patient satisfaction was evaluated using a five-point Likert scale: (1, extremely dissatisfied; 2, unsatisfied; 3, neutral; 4, satisfied; 5, extremely satisfied) [17].

The primary outcome was the time to the 1st rescue analgesia. The secondary outcomes were total morphine consumption in the 1st 24hr, pain intensity, intraoperative hemodynamics, patient satisfaction, and adverse events.

Sample Size Calculation

G*Power 3.1.9.2 (Universitat Kiel, Germany) was employed to calculate the sample size. A pilot study was conducted, with five cases in each cohort, and we discovered that the mean (±SD) time to the 1st rescue analgesia was 9.60±2.40 in group Dex, 5.40±2.07 in group Dexa, and 2.80±1.48 in group C. The sample size was determined based on the following criteria: a group ratio of 1:1, an effect size of 0.510, a 95% confidence limit, 90% power of the study, and adding two cases to each group to overcome dropout. Therefore, we recruited 20 patients for each group.

Statistical analysis

SPSS v27 (IBM©, Chicago, IL, USA) was employed to conduct the statistical analysis. The Shapiro-Wilks test and histograms were employed to evaluate the normality of the data distribution. The quantitative parametric data were analyzed using the ANOVA (F) test with a post hoc test (Tukey), which was presented as the mean and standard deviation (SD). Quantitative non-parametric data were used the Kruskal-Wallis test to analyze the data, with Mann-Whitney test to compare each group, representing the median and interquartile range (IQR). The Chi-square test was employed to analyze the qualitative variables, which were presented as frequency and percentage (%). A two-tailed P value that was less than 0.05 was considered statistically significant.

Results

The eligibility of 76 patients was evaluated in this investigation; 11 patients did not satisfy the criteria, and five declined to participate. The remaining patients were randomly assigned to one of three categories, each consisting of twenty patients. The statistical analysis and follow-up of all allocated patients were conducted.

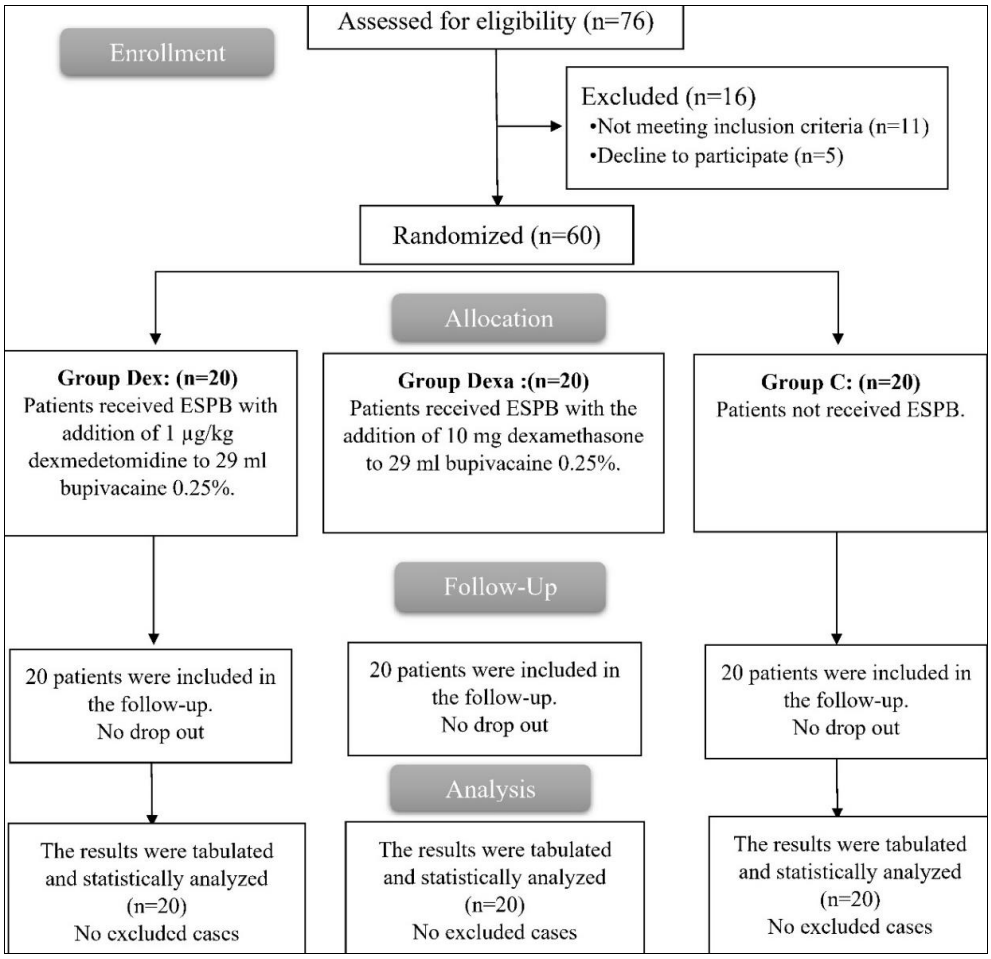

Fig 1: CONSORT flowchart of the enrolled patients

The three groups exhibited no notable variations in demographic data or surgical duration.

Table 1: Demographic data and duration of surgery of the studied groups

		Group Dex (n=20)	Group Dexa (n=20)	Group C (n=20)	P value
Age (years)		42.4±15.14	38.9±14.25	40.3±11.87	0.717
Sex	Male	12 (60%)	13 (65%)	11 (55%)	0.812
	Female	8 (40%)	7 (35%)	9 (45%)	
Weight (kg)		77.1±8.72	72.9±7.88	74.9±9.03	0.299
Height (m)		1.68±0.07	1.66±0.07	1.67±0.06	0.808
BMI (kg/m^2)		27.6±4.22	26.5±3.93	26.9±3.92	0.689
ASA physical status	I	14 (70%)	15 (75%)	12 (60%)	0.583
	II	6 (30%)	5 (25%)	8 (40%)	
Duration of surgery (min)		97.5±15.52	99.8±17.81	90.8±18.73	0.243

Data are presented as mean ± SD or frequency (%), BMI: Body mass index, ASA: American society of anesthesiologists

HR and MAP measurements at preoperative and before block performed insignificantly differed between the three categories. HR and MAP measurements after 15 min, 30 min, 45 min, 60 min, 75 min, 90 min, and end of surgery showed a more substantial decrease in group Dex than in group C (p<0.05). They were not markedly distinct between the Dexa and Dex groups, while at 45 min, 60 min, 75 min, and 90 min were notably lower in group Dex compared to group Dexa (p<0.05).

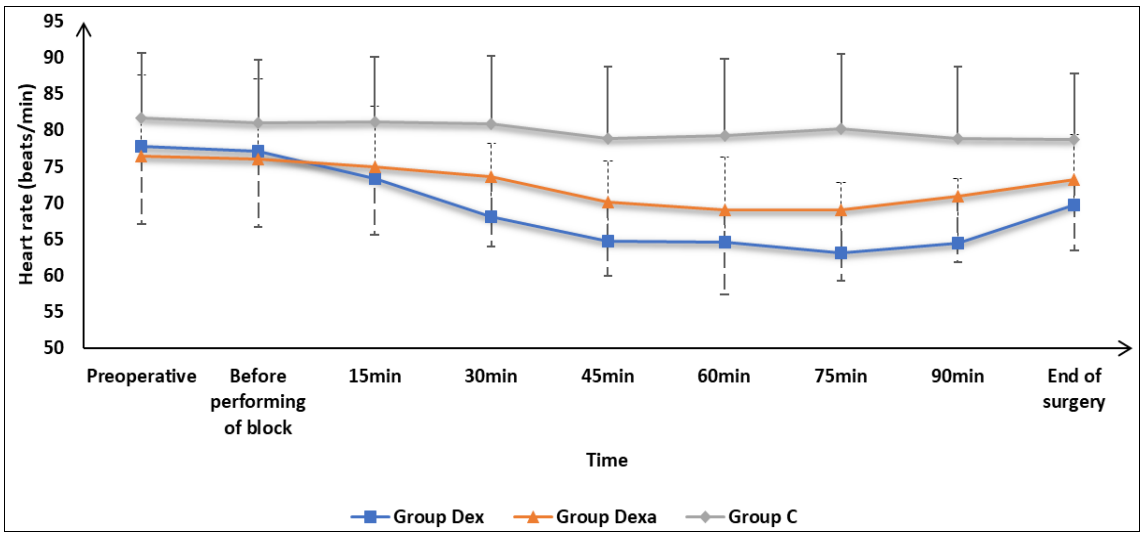

Fig 2: Heart tare of the studied groups

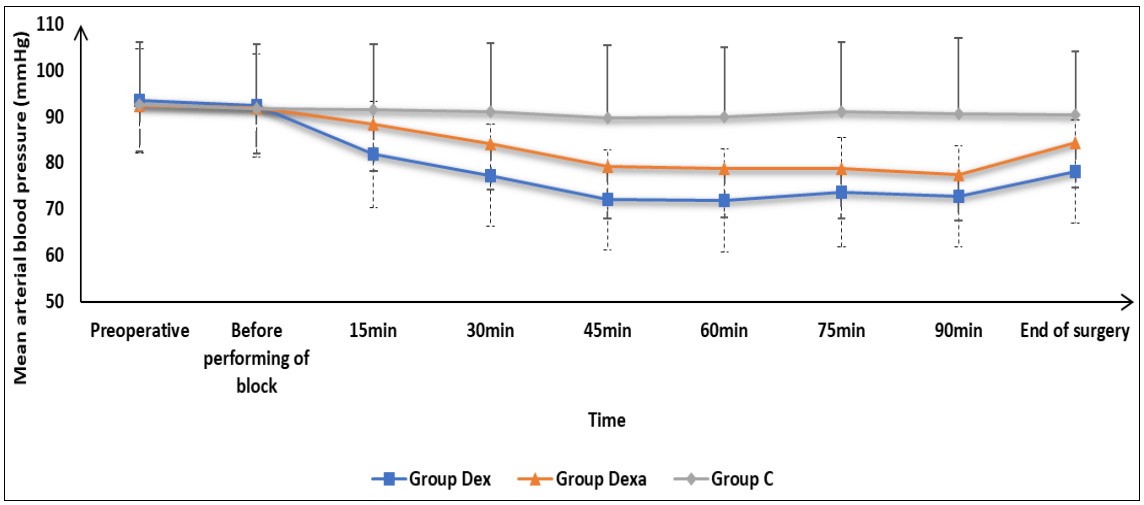

Fig 3: Mean arterial blood pressure of the studied groups

VAS score measurements at 0h**,** 10h, 12h, and 24h were not substantially different among the three categories. VAS score measurements at 2h were decreased significantly in group Dex and group Dexa in contrast to group C (p<0.05) and were markedly reduced in group Dex than group Dexa (P=0.019) and were substantially decreased at 4h and 6h in group Dex in contrast to group Dexa and group C and were not significantly different between group Dexa and group C. VAS score measurements showed a substantial decrease at 8h in group Dex compared to group C (P=0.013). There was no statistically considerable disparity between group Dex and (group Dexa, and group C).

Table 2: VAS score of the studied groups

	Group Dex (n=20)	Group Dexa (n=20)	Group C (n=20)	P value	Post hoc
0h	1(0 - 1)	0.5(0 - 1)	0.5(0 - 1)	0.936	
2h	1(1 - 1)	2(1 - 2)	3(2 - 4.25)	<0.001	P1=0.019 P2<0.001 P3=0.001
4h	1(1 - 2)	2.5(1.75 - 3.25)	3(2 - 4.25)	<0.001	P1=0.002 P2<0.001 P3=0.175
6h	2(1 - 2)	2.5(2 - 4.25)	3(2 - 3)	0.006	P1=0.011 P2=0.003 P3=0.688
8h	2(1 - 4)	2(2 - 3.25)	4(2 - 5.25)	0.036	P1=0.514 P2=0.013 P3=0.067
10h	2(1 - 4)	2(2 - 3.25)	4(2 - 5.25)	0.172	
12h	3(1 - 4)	3(2 - 4)	3(1.75 - 4)	0.723	
24h	4(2 - 4)	4(1 - 4)	4(3 - 4)	0.577	

Data are presented as median (IQR), P1: P value between group Dex and group Dexa, P2: P value between group Dex and group C, P3: P value between group Dexa and group C.

Time to first rescue was markedly prolonged in group Dex in contrast to group Dexa and group C (p<0.001) and in group Dexa than group C (p<0.001). Total morphine consumption in 1st 24h postoperative was substantially decreased in group Dex than group Dexa and group C (p<0.001) and in group Dexa than group C (p<0.001).

Table 3: Time of first rescue analgesia and total morphine consumption in 1st 24h postoperative of the studied groups

	Group Dex (n=20)	Group Dexa (n=20)	Group C (n=20)	P value	Post hoc
Time of first rescue analgesia (h)	9.5±1.79	5.7±1.57	2.8±1.2	<0.001	P1<0.001 P2<0.001 P3<0.001
Total morphine consumption in 1st 24h postoperative (mg)	4.8±1.51	7.4±1.81	9.8±1.92	<0.001	P1<0.001 P2<0.001 P3<0.001

Data are presented as mean ± SD. P1: P value between group Dex and group Dexa, P2: P value between group Dex and group C, P3: P value between group Dexa and group C

Bradycardia, hypotension, PONV, and patient satisfaction were not substantially different among the three categories.

Table 4: Adverse effects and patient satisfaction of the studied groups

		Group Dex (n=20)	Group Dexa (n=20)	Group C (n=20)	P value
Adverse effects	Bradycardia	3 (15%)	2 (10%)	1 (5%)	0.573
	Hypotension	5 (25%)	3 (15%)	2 (10%)	0.431
	PONV	1 (5%)	3 (15%)	4 (20%)	0.364
	Pneumothorax	0 (0%)	0 (0%)	0 (0%)	---
	Respiratory depression	0 (0%)	0 (0%)	0 (0%)	---
	LAST	0 (0%)	0 (0%)	0 (0%)	---
Patient satisfaction	Extremely satisfied	8 (40%)	5 (25%)	4 (20%)	0.506
	Satisfied	6 (30%)	7 (35%)	6 (30%)	
	Neutral	5 (25%)	6 (30%)	4 (20%)	
	Unsatisfied	1 (5%)	2 (10%)	5 (25%)	
	Extremely dissatisfied	0 (0%)	0 (0%)	1 (5%)	

Data are presented as frequency (%), PONV: Postoperative nausea and vomiting

Discussion

ESPB is a balanced anesthesia technique component and is intended to provide extended postoperative analgesia. To enhance the efficacy of local anesthetic compounds, they are typically combined with a variety of adjuvants [15]. The efficacy of a nerve block is enhanced and opioid consumption is reduced by the addition of an adjuvant, such as Dex or Dexa [14]. We aimed to evaluate the efficacy of Dex and Dexa as adjuvants to ESPB in patients undergoing open nephrectomy.

In our study, HR and MAP measurements after 15 min, 30 min, 45 min, 60 min, 75 min, 90 min, and end of surgery were notably lower in group Dex than group C and were not significantly different between group Dex and group Dexa while at 45 min, 60 min, 75 min, 90 min was a substantial decrease in group Dex in comparison to group Dexa.

In concurring with our finding, Kumari *et al.* [18] showed that the HR and MAP were notably decreased in Dex than in the control group for modified radical mastectomy surgery.

In contrast, Ahmed *et al.* [15] reported that there was no significant difference in HR and MAP between Dex and Dexa for patients undergoing modified radical mastectomy. This difference may be due to different type of surgery.

In our study, VAS score measurements at 2h were substantially reduced in group Dex and group Dexa than group C and were significantly decreased in group Dex than group Dexa and were markedly decreased at 4h and 6h in group Dex than group Dexa and group C and were not significantly different between group Dexa and group C. VAS score measurements were substantially lower at 8h in group Dex than in group C and were not markedly distinct between group Dex and (group Dexa and group C). The time to first rescue was substantially prolonged in group Dex compared to group Dexa and group C and was significantly prolonged in group Dexa compared to group C. The total morphine consumption in the first 24 hours postoperatively was substantially decreased in group Dex compared to group Dexa and group C and was substantially decreased in group Dexa compared to group C.

Consistent with our findings, Kumari *et al.* [18] showed that a significantly lower pain score reduces postoperative rescue analgesic requirements and prolongs postoperative analgesia in the Dex group than in the control group. In the same line, Ahmed *et al.* [15] discovered that the VAS scores of Dex were notably lower than those of Dexa. Similarly, Sinha *et al.* [19] exhibited that VAS scores were substantially lower and time to first analgesia was markedly prolonged in Dex than Dexa in patients undergoing total abdominal

hysterectomies. Moreover, Gao *et al.* [14] revealed that the VAS score was significantly reduced, and the first-time request was delayed in Dex compared to Dexa and the control group for video-assisted thoracoscopic lobectomy surgery. Furthermore, Ali *et al.* [20] showed that In comparison to the Dexa and control group, the VAS score of the Dex group was the lowest at various postoperative time intervals, and time to first rescue was notably prolonged in Dex than Dexa and control group and was prolonged in Dexa than the control group in total abdominal hysterectomy.

Our result revealed that Patient satisfaction and adverse effects were not substantially different among the three categories. They were concerned with Sinha *et al.* [19] and Ahmed *et al.* [15], who found an insignificant distinction in patient satisfaction between Dex and Dexa. Similarly, Ali *et al.* [20] concluded that there was no discernible difference in adverse effects among Dex, Dexa, and the control group. Ahmed *et al.* [15] and Gao *et al.* [14] found that PONV was insignificantly different between Dex and Dexa. Also, Sinha *et al.* [19] showed that adverse events were not significantly different between Dex and Dexa.

Our trial has limitations, including a relatively limited sample size, and was conducted at a single center. Further studies are required using various additives, concentrations, volumes, and blocks in different types of surgery.

Conclusion

As an adjuvant to bupivacaine in ESPB, Dex is superior to Dexa in hemodynamic stability, pain reduction, delayed time to first rescue, and total opioid consumption.

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Conflict of Interest: Nil.

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