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A comparative study of preoperative ultrasound-guided lumbar erector spine plane block and preoperative ultrasound-guided caudal block for postoperative pain control in pediatric lower limb surgeries: A randomized controlled trial

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ABSTRACT

Background: Erector spinae plane block (ESPB) is a relatively new type of regional anesthesia that has demonstrated efficacy in pain management. The study uses ultrasound (US) guidance to perform the ESPB and evaluates its efficacy and safety compared to the traditional caudal block (CB) in managing postoperative pain in children undergoing lower limb surgeries.

Methods: This randomized controlled double-blind trial enrolled 50 pediatric cases aged 2–15 years planned for lower limb surgeries. Cases were classified into two equal groups that were administered 0.25% bupivacaine (0.5 ml/Kg) via CB (group C) or lumbar ESPB at the side of operation (group E). The blocks were US guided after induction of anesthesia before skin incision.

Results: Heart rate and mean arterial pressure at 45, 60, and 75 min, and at the end of surgery were reduced in group C contrasted to group E ($P < 0.05$). Pain scores at 6 h and 8 h were reduced significantly in group E ($P < 0.001$ and 0.049 respectively). The time of block performance was significantly lower in group C compared to group E. The number of patients who required intraoperative fentanyl was comparable between groups. Group E had prolonged analgesia and less postoperative pethidine doses. Neither group exhibited local anesthetic toxicity or hematoma with lower incidence of postoperative nausea and vomiting (PONV) in Group E ($P = 0.042$).

Conclusion: In pediatric cases undergoing lower limb surgeries, US-guided ESPB provided adequate analgesia (better pain score and prolonged analgesia with lower postoperative analgesic doses) with stable hemodynamic and lower incidence of PONV.

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1. Introduction

The lower limb surgeries are associated with acute postoperative pain and requires long-term analgesia [1]. Despite the tremendous advances in our understanding of acute post-surgical pain mechanisms, pain management after surgery remains a challenging issue. The effective and safe analgesic approach for these children is still under research [2,3].

Regional anesthesia is often used to prevent postoperative pain in pediatric surgery. Combined with general anesthesia (GA), ultrasound (US)-guided regional anaesthetic approaches provide simple intraoperative pathway that reduced GA requirements, lower pain score with less impact on the respiratory or cardiovascular system [2,4,5].

In paediatric surgery, caudal block (CB) is a low-cost, simple, and effective procedure for postoperative analgesia. CB is suggested for most surgeries in the lower body, primarily below the umbilicus [6]. Although the well-established anesthetic properties of CB, its action terminates early in the postoperative period and it has a number of restrictions, such as anatomical abnormalities or infection at the injection site, that can prevent its use [7,8].

Erector spinae plane block (ESPB) is a potential interfacial plane block as it is a simple and safe block approach for postoperative analgesia [9]. This regional approach has the advantage of local anesthesia (LA) spread in both cranial and caudal directions up to nine dermatomes. LA also spreads to the paravertebral region and to both ventral and dorsal spinal rami. This spread has been proven by contrast-assisted imaging studies [10–12].

ESPB has been employed for several surgeries ranging from thoracic, lumbar to pelvic surgeries [4,13–15]. Several trials have reported the safety and efficacy of

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ESPB in adults. However, fewer studies have studied the ESPB efficacy in pediatric postoperative pain with controversial results [8,16,17]. Therefore, this study was recruited to assess the efficacy and safety of US-guided ESPB versus US-guided CB in managing postoperative surgical pain through the investigations of pain score and total postoperative analgesic requirement, intraoperative hemodynamics, and adverse events in children undergoing lower limb surgeries.

2. Materials and methods

This randomized controlled double-blind trial enrolled 50 children aged 2–15 years, both sexes, with a physical status of I or II according to the American Society of Anesthesiology (ASA) planned for elective lower limb surgery.

The study was conducted after receiving approval from the Faculty of Medicine's Ethical Review Committee, Tanta University Hospitals, Egypt, and registration at clinicaltrials.gov (ID: NCT05369455) from May 2022 to July 2022. The patients' guardians had given signed consent.

Exclusion criteria were cases with spine or chest wall deformity, coagulation disorders, respiratory and cardiac disorders, renal or hepatic insufficiency, and known allergy to study drugs.

All cases were adequately evaluated preoperatively by history taking and clinical examination, in addition to routine laboratory investigation.

3. Randomization and blindness

Random computer-generated numbers were utilized to allocate patients through sealed opaque envelopes into two equal groups. Group E: received ESPB at the side of operation and group C: received CB. The number on the envelope was read by a nurse blinded to the study who was not participating in the research or data collection. The patient's parents and outcome assessors were blinded by group allocation.

Upon arrival in the operating room, an intravenous line was established. Non-invasive blood pressure, electrocardiogram (ECG), temperature probe, capnograph and pulse oximeter were used to monitor cases.

Anesthesia was induced in all patients with fentanyl 1 µg/Kg, propofol 2 mg/kg, and cis-atracurium 0.15 mg/kg IV to assist endotracheal intubation. Anesthesia was then maintained with isoflurane 1–2% in oxygen and air mixture and cis-atracurium 0.03 mg/kg.

In both groups, an expert anesthesiologist performed the block under ultrasound guidance who has no subsequent role in the study. The blocks were done guided by an ultrasound machine (Philips ® CX50). A longitudinal parasagittal transducer probe (6–12 MHz) was used under a complete aseptic technique after anesthesia induction and prior to skin incision.

4. Caudal block

The sacral hiatus was visualized using ultrasound while the patient was positioned at left lateral decubitus. The needle had pierced the skin at a 45° angle. Passive drainage or cautious aspiration was performed to rule out an inadvertent systemic or spinal needle location then 0.5 ml/kg of 0.25% bupivacaine (maximum 20 ml) for local anesthetic was injected between the two sacral cornu.

5. Espb

ESPB was performed on the side of operation at L1-L4. The individual was positioned in a given posture. In the sagittal plane, the probe was longitudinally positioned at the mid-vertebral line. To visualize the erector spinae muscle with the transverse process, the transducer was displaced 3.5–4 cm laterally from the midline to the surgery site. The precise placement of the needle point in the fascial plane proximal to the erector spinae muscle was verified by injecting 0.5–1 ml of saline and observing the fluid lifted the erector spinae muscle off the transverse process without stretching the muscle (hydro-dissection). As soon as the needle was positioned properly, a negative aspiration test was verified. The hyperechoic transverse process's shadow must lie superficial to the trapezius, erector spinae, and main rhomboid muscles. A 22 G needle was inserted with the level pointing cephalo-caudally, and 0.5 ml/kg of 0.25% bupivacaine (maximum 20 ml) was injected [18]. (Figure 1)

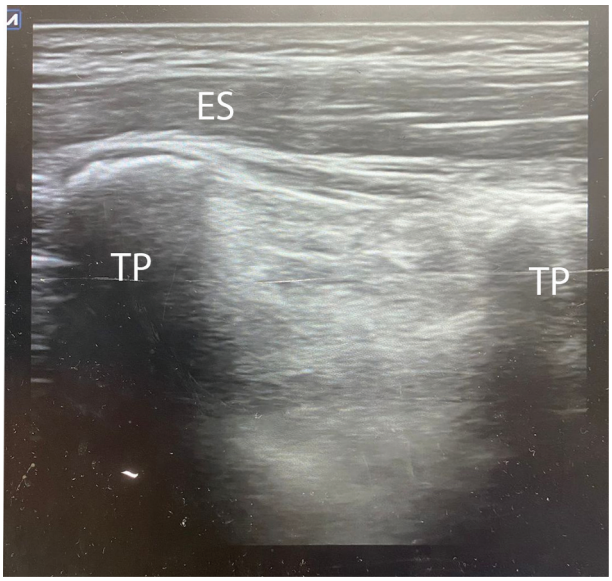

Figure 1. Ultrasound guided erector spinae plane block. ES: erector spinae muscle, TP: transverse process.

Then, the surgical incision was conducted. Intraoperatively, the administration of fentanyl 0.5 µg/Kg was used to control the elevation in hemodynamics of more than 20% of baseline values in response to surgical stimuli. The number of patients who required intraoperative fentanyl was recorded.

Mean arterial pressure (MAP) and heart rate (HR) were recorded at baseline before induction of GA and every 15 min during surgery.

After the surgery ended, the inhalational anesthetic was stopped and given IV atropine (0.02 mg/Kg) and neostigmine (0.05 mg/Kg) to reverse muscular relaxation. The anaesthetized patients were moved to the post-anesthesia care unit (PACU). Paracetamol 15 mg/kg/8 h IV was administered as routine analgesia in all patients postoperative.

Postoperatively, the pain score was assessed using Face, Legs, Activity, Cry, and Consolability (FLACC) for patients aged 2–7 years and Numeric Rating Scale (NRS) scores for patients >7 years after surgery at PACU, 2, 4, 6, 8, 12 and 24 h. Patients with pain score ≥4 received pethidine 1 mg/kg IV. Moreover, time to first analgesic request and postoperative pethidine consumption in first 24 h were recorded.

Adverse events (postoperative nausea and vomiting (PONV), local anesthetic toxicity, and hematoma) were recorded for all the studied groups.

The primary outcome was the analgesic duration (the time between the block and the first request for rescue analgesia). The secondary outcomes were pain score, total postoperative analgesic requirement, intraoperative hemodynamics, and adverse events.

6. Sample size calculation

G*Power 3.1.9.2 (Universitat Kiel, Germany) was used for sample size calculation. Our primary outcome was the duration of analgesia. According to previous study [19], the duration of analgesia in the caudal group was 4 ± 0.97 h. To detect a difference of at least 1 h in analgesia duration between the two groups, the sample size calculation required a minimum of 22 patients in each group at α error of 0.05, effect size 1.03 and 95% power of the study. So, we enrolled 25 patients in each group to compensate possible dropouts.

7. Statistical analysis

By using SPSS v26 (Inc., Chicago, IL, USA), the statistical analysis was performed. The Shapiro–Wilks test was applied to ensure the normal data distribution. Using T test, the quantitative data were compared and presented as mean ± SD where the data followed a normal distribution. Otherwise, the Mann–Whitney U test was used, and the data were presented as median (IRQ). The Chi-square test or Fisher's exact test was employed to ascertain the statistical significance of categorical data, which was presented as numbers and percentages. P value < 0.05 was considered significant.

8. Results

In this study, 71 patients were evaluated for suitability, 13 patients did not match the research criteria, and 8 patients' parents declined participation in this trial. The remaining children were randomly categorized into two equal groups. There were no dropout or excluded cases from analysis (Figure 2).

The demographic characteristics, surgical and anesthetic duration, and type of surgery were similar in both groups. Time of block performance was significantly lower in group C compared to group E. (Table 1)

HR measurements were comparable between both groups at baseline, 15 min, and 30 min and were statistically lower in group C than group E at 45 min, 60 min, 75 min, 90 min, and end of surgery (P value < 0.05) (Figure 3).

MAP measurements were similar between both groups at baseline, 15 min, 30 min, and 90 min and were significantly decreased in group C compared to group E at 45 min, 60 min, 75 min, and end of surgery (P value < 0.05) (Figure 4).

FLACC/NRS measurements were insignificantly different between the groups at PACU, 2 h,4 h, 12 h, and 24 h and were statistically decreased in group E than group C at 6 h and 8 h (P value < 0.001 and 0.049 respectively). (Table 2)

The number of patients who required intraoperative fentanyl was comparable between groups (12% in group E vs 8% in group C). The first analgesic request time and duration of the analgesia was remarkedly delayed in group E compared to group C (P value < 0.001). The mean number of doses and postoperative pethidine consumption in first 24 h were statistically lower in group E than in group C (P value < 0.001 and 0.026, respectively). (Table 3)

Incidence of was significantly reduced in group E compared to group C (4% vs 24%, respectively, P value = 0.042). Local anesthetic toxicity and hematoma did not occur in any patient in both groups.

9. Discussion

Pain after orthopedic surgeries may be severe and has a substantial influence on the postoperative outcome for patients of all ages [20]. Pain is one of the most complicated, underdiagnosed, and untreated medical problems, especially in pediatrics. A child suffering from postoperative pain may be uncooperative and restless [21].

Despite the wide use of caudal anesthesia for its proven effectiveness in providing postoperative analgesia after orthopedic surgery, there are some limitations. As a result of the bilateral sensory and

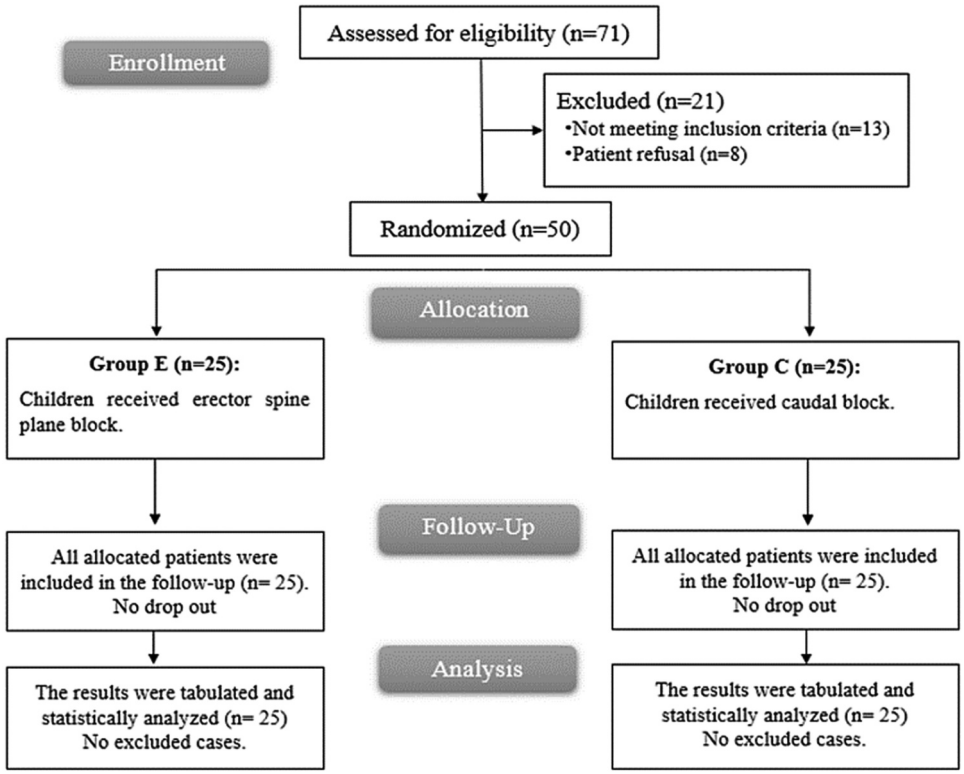

Figure 2. CONSORT flowchart of the enrolled patients.

Table 1. Patient characteristics, surgical and anesthetic duration, time of block performance, and type of surgery of the examined groups.

		Group E (*n*=25)	Group C (*n*=25)	P value
Age (years)		7.96 ± 3.55	7.36 ± 3.49	0.550
Sex	Male	12 (48%)	15 (60%)	0.395
	Female	13 (52%)	10 (40%)	
Weight (Kg)		27.8 ± 11.52	26.2 ± 11.02	0.618
ASA physical status	I	21 (84%)	19 (76%)	0.480
	II	4 (16%)	6 (24%)	
Surgical duration (min)		134.4 ± 26.43	138.2 ± 25.57	0.608
Anesthesia duration (min)		153.6 ± 25.72	158.2 ± 27.57	0.545
Time of block performance		6.5 ± 2.33	3.7 ± 1.17	<0.001*
Type of surgery	Fracture shaft femur (closed reduction+ percutaneous fixation with gliding nails)	11 (44%)	10 (40%)	0.767
	Fracture shaft tibia (closed reduction+ percutaneous fixation with gliding nails)	4 (16%)	7 (28%)	
	Genu varum (High tibial osteotomy)	7 (28%)	6 (24%)	
	Genu valgum (Distal femur osteotomy)	3 (12%)	2 (8%)	

Data are presented as mean ± SD or frequency (%). BMI: Body mass index, ASA: American society of anesthesiologists. *: Significant when *P* value ≤0.05.

motor block caused by CB, patients may have difficulty in walking soon after surgery and have longer recovery period. Urinary retention is another common and potentially serious side effect [22].

Ultrasound-guided ESPB is a recent regional anesthetic approach that is designed to have epidural spread and block the ventral and dorsal rami of the abdominal and thoracic spinal nerves, therefore blocking the lateral, posterior, and anterior thoracic and abdominal walls and promoting visceral analgesia [23,24]. ESPB is preferred as a regional anesthetic technique owing to its relative simplicity and probable safety in comparison to neuraxial procedures [25,26].

In our study, HR and MAP were statistically higher in group E than in group C at 45 min, 60 min, 75 min, and end of surgery. Pain scores at 6 h and 8 h were reduced significantly in group E. Group E had prolonged analgesic effect with lower postoperative pethidine doses compared to group C. Neither group presented with local anesthetic toxicity or a hematoma with lower incidence of in Group E.

By using ultrasound, we were able to detect minor structural features in addition to a real-time visualization of the nerve/needle interaction with identifying the target nerve(s) and their relationship to adjacent structures as well as visualization of the longitudinal distribution of local anesthetic. This is especially helpful when injecting near the lumbar spine as it increases accuracy and decreases the likelihood of complications [27].

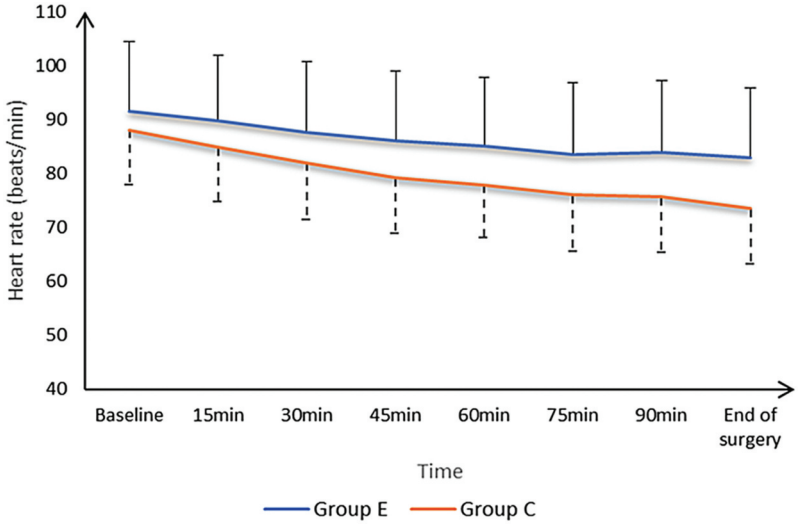

Figure 3. Heart rate measurements of the studied groups.

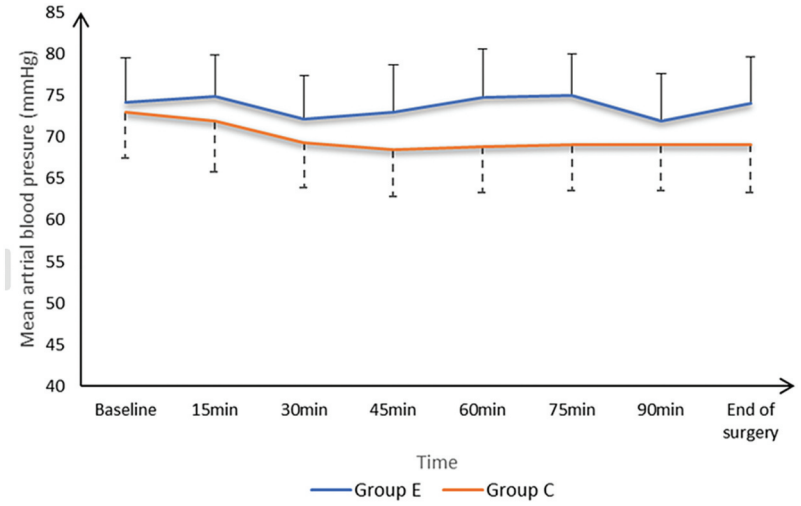

Figure 4. Mean arterial blood pressure measurements of the studied groups.

Table 2. FLACC/NRS measurements in both groups.

	Group E (*n*=25)	Group C (*n*=25)	P value
PACU	1 (0–1)	1 (0–1)	1.000
2h	0 (0–1)	0 (0–1)	0.780
4h	1 (1–2)	1 (1–2)	0.400
6h	2 (1–3)	3 (2–6)	**<0.001***
8h	3 (2–4)	4 (3–6)	**0.049***
12h	4 (2–6)	4 (3–5)	0.766
24h	4 (3–5)	4 (3–5)	0.856

Data are presented as median (IQR), *: Significant when *P* value ≤0.05.
PACU: Post anesthesia care unit.

In accordance with our results, Abdelrazik et al. [7] revealed that the ESPB at T10 had a lower FLACC score in the early postoperative period and longer analgesic duration with decreased rescue analgesic doses than in the CB group in children undergoing unilateral lower abdominal surgeries. Our study had different blocking sites (L1-L4) compared to (T10) in Abdelrazik et al. study. Also, we had a wider range of age (2–15 years) with multiple types of lower limb surgeries.

In contrary in terms of analgesic impact, a recent randomized controlled study conducted by Elshazly et al. [8] on lumbar ESPB at the L3 level and it was not superior than CB in children following hip or proximal femur surgery. They observed that CB provided

Table 3. Analgesia in the studied groups.

	Group E (*n*=25)	Group C (*n*=25)	P value
Number of patients required fentanyl	3 (12%)	2 (8%)	1
Time to first analgesic request (h)	10.1 ± 2.04	7.1 ± 1.01	**<0.001***
Duration of the analgesia (min)	729.6 ± 124.57	565.4 ± 68.57	**<0.001***
Number of doses of postoperative pethidine in 1st 24 h	1.6 ± 0.58	2.2 ± 0.72	**<0.001***
Postoperative pethidine consumption in 1st 24 h (mg)	43.4 ± 22.53	62 ± 33.55	**0.026***

Data are presented as mean ± SD, *: Significant when *P* value ≤0.05.

a greater analgesic impact that was evidenced by delayed time to initial rescue analgesia and lower pain levels in the early postoperative period. In general, hemodynamics was similar between the groups from skin incision until early postoperative care in PACU. This could be explained by the different age groups of the two studies and different types of surgeries in our study. Our study was strengthened by the use of ultrasound guidance in both blocks, as well as the broad range of ages and surgical procedures performed.

Ultrasound-guided ESPB is a recent regional anesthetic approach that is designed to have epidural spread and block the ventral and dorsal rami of the abdominal and thoracic spinal nerves, therefore blocking the lateral, posterior, and anterior thoracic and abdominal walls and promoting visceral analgesia [23,24]. ESPB is preferred as a regional anesthetic technique owing to its relative simplicity and probable safety in comparison to neuraxial procedures [25,26].

Pinar et al. [9] observed that ESPB resulted in comparatively longer duration of analgesia and significant decrease in pain score during the postoperative 24 h.

Abduallah et al. [28] reported comparable results: US-guided ESPB in pediatric hip surgery showed decreased postoperative pain scores at 2, 4, and 6 h after the surgery ($p < 0.05$) and prolonged analgesia with lower analgesic doses compared to the control group. The incidence bradycardia, hypotension, and PONV were statistically insignificant between both groups.

Holland et al. [4] established a systematic review that confirmed the significant beneficial effect of ESBP on acute post-surgical pain after different pediatric surgeries, including hypospadias, inguinal hernia repair, varicocelectomy, cholecystectomy, nephrectomy, and thoracotomy.

Moreover, Singh et al. [29] reported that the FLACC score in the ESPB group was significantly low at 3 h and 6 h, resulting in a prolonged duration of analgesia with no intra- or postoperative hypotension, tachycardia, or anaphylactic response occurred.

Our results are supported by Mostafa et al. [30] who reported that the MAP and HR were comparable between control and ESPB in pediatric patients undergoing open midline splenectomy with no complications associated to ESPB group and lower pain score.

Also, El-Emam and Abd El Motlb [31] concluded that US-guided ESP block provided superior postoperative analgesia than that provided by an ilioinguinal nerve block, as evidenced by lower FLACC score, and for a longer analgesic duration.

Moreover, Karaca and Pinar [32] reported that using 0.5% bupivacaine for ESPB in children undergoing laparoscopic cholecystectomy results in lower pain scale with no need for rescue analgesia.

Supporting our results, Aksu et al. [33] found low pain scores after pediatric lower abdomen surgery suggest that ESPB offered sufficient perioperative analgesics; no patients required rescue analgesia during follow-up.

Our results are confirmed by Tulgar et al. [34] who observed that ESPB had lower pain score at the 1st, 3rd, and 6th h and lower rescue analgesic doses compared to control in patients undergoing hip and femur surgeries.

In agreement with our results, Aksu and Gürkan [35] experienced no pain or need for analgesia after using ESB, even 24 h after surgery.

Our study has some limitations as it was a single-center study with a relatively small sample size and there was no control group without any block. The study lacked the estimation of motor block and satisfaction of patients and their parents. Additionally, more studies using different additives with different doses and concentrations of these blocks and the effect of different block techniques on the postoperative outcome are recommended. Also, further trials for longer follow-up periods are needed.

10. Conclusion

In pediatric cases undergoing lower limb surgeries, the US-guided ESPB produced adequate analgesia with more stable hemodynamic as well as better pain control and prolonged analgesia with lower postoperative pethidine doses and lower incidence of PONV than those received CB.

Disclosure statement

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

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