



Ultrasound-guided erector spinae plane block versus thoracic epidural block for postoperative analgesia in pediatric Nuss surgery: a randomized noninferiority trial

Yi Ren¹ · Xiaolu Nie² · Fuzhou Zhang¹ · Yangwei Ma¹ · Lei Hua¹ · Tiehua Zheng¹ · Zenghua Xu¹ · Jia Gao¹ · Jianmin Zhang¹

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Abstract

Purpose Thoracic epidural anesthesia (TEA) is often used for analgesia after thoracic surgery. Erector spinae plane block (ESPB) has been proposed to provide adequate analgesia. We hypothesized that ESPB would be noninferior to TEA as a part of multimodal analgesia in pediatric patients undergoing the Nuss procedure.

Methods Patients aged 7–18 years and scheduled for the Nuss procedure were randomly allocated to receive bilateral single-shot ESPB or TEA and a multimodal analgesic regimen including parent-controlled intravenous analgesia (PCIA). At 6 h, 12 h, 18 h, and 24 h postoperatively, pain was evaluated using the numeric rating scale (NRS) and opioid consumption was assessed by counting the number of PCIA boluses. The joint primary outcomes were the average pain score and opioid consumption at 24 h after surgery. The secondary outcomes were the NRS scores and the number of opioid boluses administered at different postoperative time points, adverse events, and recovery quality.

Results Three hundred patients underwent randomization, and 286 received ESPB (147 patients) or TEA (139 patients). At 24 h postoperatively, ESPB was noninferior to TEA in terms of the average NRS score (mean difference, -0.1 , 95% confidence interval [CI], -0.3 – 0.1 , margin = 1, P for noninferiority < 0.001) and the number of opioid boluses administered (mean difference, -1.1 , 95% CI, -2.8 – 0.6 , margin = 7, P for noninferiority < 0.001). Adverse events and patient recovery were comparable between groups.

Conclusions The results demonstrate that combined with a multimodal analgesia, ESPB provides noninferior analgesia compared to TEA with respect to pain score and opioid consumption among pediatric patients undergoing the Nuss procedure.

Keywords Erector spinae plane block · Postoperative analgesia · The Nuss procedure · Noninferior test · Pediatrics

Introduction

Pectus excavatum is the most common congenital chest wall deformity in children and adolescents, with an incidence of 0.1–0.3%, and it results in a concave anterior chest wall with cardiopulmonary compression and exercise intolerance [1]. The Nuss procedure is a surgical treatment for pectus excavatum that provides immediate correction of the chest wall defect by a convex bar placed under the sternum, which exerts outward pressure on the sternum [2]. The surgery is ‘minimally’ invasive and a short procedure, but it is associated with severe postoperative pain induced by the stimulation of nociceptive receptors, stretching of the chest wall, damage to the pleura and muscles, and injury to the intercostal nerves [3]. Thoracic epidural analgesia (TEA) has long been the gold standard for pain management after thoracic

Yi Ren and Xiaolu Nie have contributed equally.

✉ Jianmin Zhang
zhangjianmin@bch.com.cn

¹ Department of Anesthesiology, Beijing Children’s Hospital, National Center for Children’s Health, Capital Medical University, No. 56, South Lishi Road, Beijing 100045, China

² Center for Clinical Epidemiology and Evidence-Based Medicine, Beijing Children’s Hospital, National Center for Children’s Health, Capital Medical University, Beijing 100045, China

surgery [4], and it can be used as either single injection or continuous infusion [5]. However, TEA has shown certain difficulties regarding administration and side effects [6], thus sparking interest in alternative approaches to regional anesthesia.

Erector spinae plane block (ESPB) is a novel regional anesthesia in which local anesthetic (LA) injection is performed beneath the erector spinae muscle and superficial to the vertebral transverse process [7]. The sensory block of the thoracic wall in ESPB is attributed to the spread of LA on the dorsal and ventral rami of the thoracic spinal nerve [7], the coverage of LA on multiple dermatomal levels following its craniocaudal spread [8], and the possibility of its spreading into the paravertebral and thoracic epidural spaces [9]. Previous studies have proven that compared with patient-controlled intravenous analgesia only, single-injection ESPB without a catheter for continuous infusion can improve postoperative analgesia and reduce opioid demand [10]. However, its utility when compared with the gold standard remains unclear [11].

Therefore, we conducted a randomized trial using a joint hypothesis-testing framework to examine whether single-injection ESPB would be noninferior to TEA in terms of postoperative pain score and opioid consumption among pediatric patients undergoing the Nuss procedure.

Materials and methods

This single-center randomized noninferior trial was conducted in a university hospital after institutional ethics committee approval (2019–51) and clinical trial registration (ChiCTR2100046210, URL: <https://www.chictr.org.cn/showproj.html?proj=126366>, date of registration: May 10, 2021, date of recruitment of first patient: July 1, 2021). Written informed consent was obtained from the legal guardians of the patients before recruitment. This study was conducted based on the declaration of Helsinki and the manuscript was reported in accordance with the applicable consolidated standards of reporting trials (CONSORT) guidelines.

Participants and randomization

We included patients aged 7–18 years undergoing an elective Nuss procedure with an American society of anesthesiologists (ASA) physical status of I–II. Patients were excluded if they had contraindications to TEA or ESPB, severe spinal deformity, severe comorbidities such as Marfan's syndrome, allergy to medication used in the study, chronic pain characterized by opioid use for over 3 months preoperatively, mental illness or cognitive impairment rendering them unable to cooperate in the pain assessment, or did not have

a guardian able to use the parent-controlled intravenous analgesia (PCIA) pump.

The participants were randomized to either the ESPB or the TEA group at a 1:1 ratio according to computer-generated random numbers generated by a third party not involved in the study and received treatment according to the group allocation. Anesthesia and surgical procedures were performed by a specific team. The patients, parents, and investigators responsible for follow-up and data analyses were blinded to the group randomization.

Intervention

General anesthesia

All patients underwent standardized monitoring and induction of anesthesia with sufentanil (0.4–0.5 µg/kg), propofol (2.0–3.0 mg/kg) and cisatracurium (0.1 mg/kg) for intubation, followed by sevoflurane at 1–1.5 MAC in both groups for anesthesia maintenance to maintain a bispectral index between 40 and 60. The anesthetic, vasopressors, and fluid infusion were adjusted according to the hemodynamic monitoring conditions to maintain the parameters within 20% of the preoperative baseline values. Remifentanyl (0.1 µg/kg/min) was injected for intraoperative analgesia if necessary and titrated up to a dose of 0.3 µg/kg/min. Intraoperative hypotension was treated with boluses of lactated Ringer's solution (10–20 mL/kg) and/or phenylephrine (1–2 µg/kg). At the end of surgery, the patients received neostigmine to reverse neuromuscular blockade before being weaned from mechanical ventilation and extubated before being transferred to the postanesthesia care unit (PACU).

Erector spinae plane block

After intubation, the patients in the ESPB group received ultrasound-guided bilateral single-injection ESPB in the lateral position by experienced anesthesiologists. The erector spinae were identified using a high-frequency (4–15 MHz) linear transducer (Labat SP; Wisonic, Shenzhen, China) placed longitudinally 2–3 cm lateral to the T5 spinous process. Using an in-plane approach, a 21-gauge block needle (5 cm, Hakko disposable monopolar nerve blockage needle, Hakko Co., Ltd., Nagano, Japan) was inserted into the ultrasound beam from the cranial-to-caudal direction until the tip of the needle contacted the tip of the T5 transverse process. Once the correct location was confirmed, 0.3% ropivacaine in a volume of 0.5 ml/kg (maximum: 20 ml per side) was injected into the block. Successful injection is defined as a hypoechoic ellipsoid with a well-defined margin beneath the erector spinae muscle on ultrasound.

Thoracic epidural analgesia

The patients in the TEA group received single-dose thoracic epidural analgesia performed by experienced anesthesiologists using the conventional landmark-guided technique in line with currently accepted practice. Under strict aseptic precautions, an epidural was administered at the T6/T7 intervertebral space. After successful epidural insertion, an injection of 0.3% ropivacaine in a volume of 0.5 ml/kg (maximum: 20 ml) was administered.

Standard postoperative pain treatment

For all patients, the multimodal analgesic regimen also included postoperative sufentanil parent-controlled intravenous analgesia (PCIA), acetaminophen, and dezocine given postoperatively. Electronic parent-controlled intravenous analgesia (PCIA) pumps (CPE-101, Fornia Medical Equipment Co., Ltd., Zhuhai, China) were connected to all participants. The PCIA infusate was sufentanil 4 µg/kg and tropisetron 0.1 mg/kg diluted in 100 ml of normal saline. The pump was programmed to deliver a bolus of 1 ml on demand with a 15 min lock-out interval. The researchers trained the parents to use the pump. The standard postoperative analgesic regimen also consists of 15 mg/kg acetaminophen orally four times daily (maximum dose of 2 g per 24 h). If rescue analgesia was required or the patient's NRS pain score was > 6, dezocine (0.1 mg/kg, maximum dose of 5 mg) was given.

Outcomes

The primary outcome was a joint endpoint of pain intensity and opioid consumption during the perioperative period of 24 h. The pain score at rest was measured using the 11-point NRS (0 means no pain and 10 means the worst pain) at 6 h, 12 h, 18 h and 24 h postoperatively. The average score of the four timepoints was calculated and recorded as the primary outcome, to better reflect the overall pain control during the early postoperative period of 24 h. Opioid consumption was measured as the number of sufentanil PCIA boluses that were used (in boluses, each bolus was 1 ml and contained 0.04 µg/kg sufentanil), which was extracted from the electronic PCIA pump records. The total number of boluses administered from 0 to 24 h postoperatively were recorded as the primary outcome.

The secondary outcomes included the NRS scores at rest at 6 h, 12 h, 18 h, and 24 h postoperatively and the amounts of PCIA boluses administered at 0–6 h, 6–12 h, 12–18 h, and 18–24 h postoperatively. The use of rescue analgesics within 24 h postoperatively was recorded. A more than 20% drop in blood pressure after ESPB or TEA operation compared with the blood pressure measured at the beginning of the

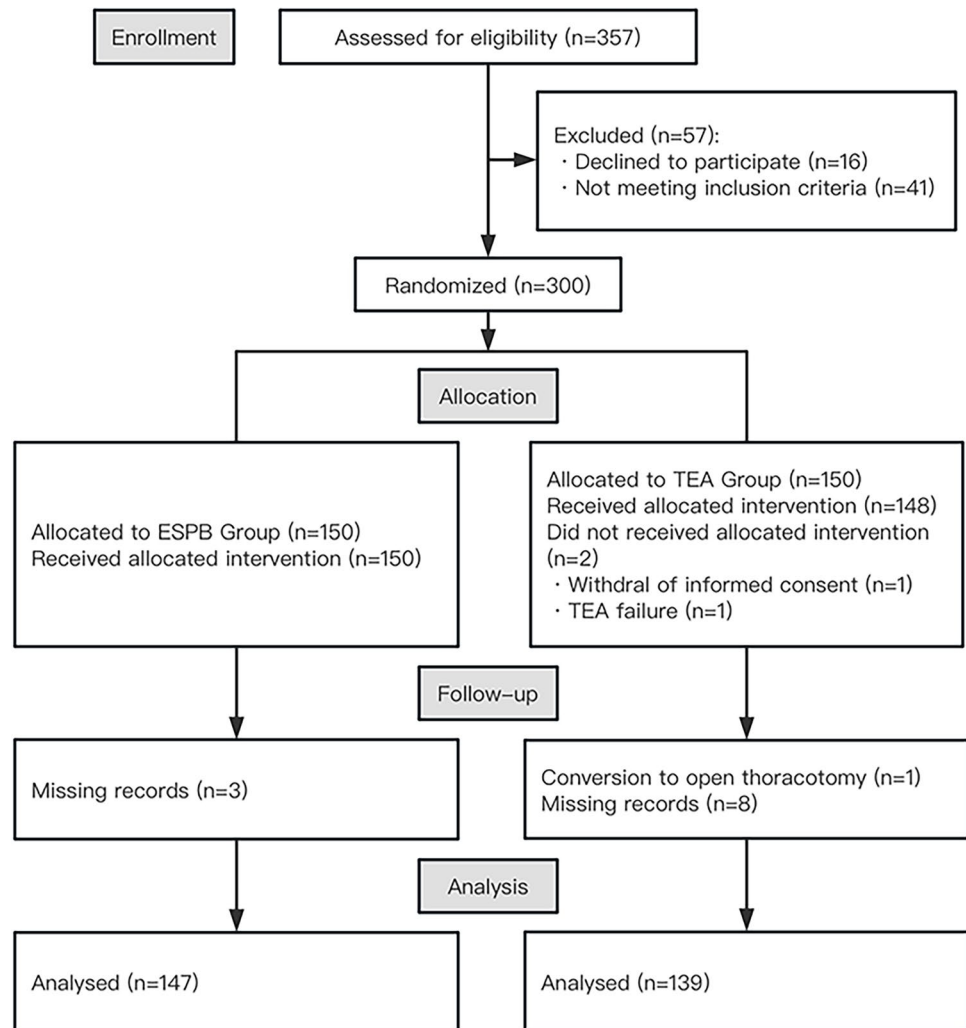
procedure was defined as an episode of hypotension and recorded. The failure at the first block attempt was also documented. Adverse events were recorded. Postoperative nausea and vomiting (PONV) at 24 h after surgery was assessed using a four-point numerical scale (0 = no PONV, 1 = mild nausea, 2 = severe nausea or vomiting once, and 3 = vomiting more than once) [12]. Time to out-of-bed activity, time to oral intake, time to flatus and defecation, and length of hospital stay were also recorded, with time 0 being arrival at the ward. Patient satisfaction (on a 1-to-10-point scale) with pain treatment was interviewed on the discharge day.

Statistical analysis

Continuous data are presented as the mean (\pm standard deviation [SD]) or median (interquartile range [IQR]) as appropriate, according to normality distribution determined by the histogram and Kolmogorov–Smirnov test. Categorical variables were reported as numbers (percentages). The primary analysis of the study was to evaluate the noninferiority of ESPB to TEA on postoperative 24 h average pain score and opioid consumption by a joint hypothesis test: if noninferiority was detected for both NRS scores and PCIA boluses, then ESPB would be deemed to be noninferior to TEA. Otherwise, the presence of inferiority on any outcome indicated worse pain relief with ESPB than with TEA [13]. The noninferiority margin (Δ) for NRS was set to 1 on the 11-point scale, and for opioid consumption was defined as 30% of the amount of boluses in the TEA group at 24 h postoperatively [14]. We calculated the 95% confidence interval (CI) of the mean difference in the NRS score and number of PCIA boluses. If the upper limit of the CI was less than the margin, we defined ESPB as noninferior to TEA on that outcome. The per-protocol analysis was conducted as it was the most conservative test of noninferiority.

For the secondary outcomes, the repeated measurements of NRS scores and PCIA boluses were analyzed by linear mixed models (multilevel statistical models), in which time and group (ESPB or TEA) were treated as fixed effects, while individual was treated as a random effect. The treatment effect, time trend, and interaction effect between the treatment effect and time were tested using a random coefficient model. The between-group differences in NRS scores and number of opioid boluses were evaluated with the two-sample *t* tests. The Holm–Bonferroni method was used to justify the *P* values due to multiple comparisons. Block procedure duration, time of recovery, rescue analgesic (dezocine) consumption, length of stay and patient satisfaction between the two groups were compared using a two-sample *t* test or the Mann–Whitney U test based on the normality of the variable's distribution. Episodes of complications and adverse events were analyzed by the chi-square test or Fisher's exact test. For these analyses, a two-tailed *P* value less

Fig. 1 CONSORT participant flow chart. *CONSORT* consolidated standards of reporting trials, *ESPB* erector spinae plane block, *TEA* thoracic epidural anesthesia



than 0.05 was considered significant. The statistical analyses were performed with SAS 9.4 (SAS Inc., Cary, N.C., USA) and IBM SPSS Statistics for Windows, Version 27.0 (IBM Corp., Armonk, N.Y., USA).

Sample size calculation

The SDs of the NRS score were 2.4 for the ESPB group and 2.2 for the TEA group, and the difference in the mean NRS score was 0.2. To achieve 80% power with a significance level (α) of 0.05, 104 participants in each group were needed. For the number of PCIA boluses, the true difference between the groups was 2.0, and the SD was 17.0 in the ESPB group and 19.0 in the TEA group. The margin of noninferiority was 7.5. With an α of 0.05 (30% of the mean value of TEA group) and a power of 80%, 134 participants in each group were needed to detect noninferiority. Hence, a greater sample of 134 participants per group was used based on our primary hypothesis. To compensate for loss to follow-up, we decided to enroll 150 participants per group.

The sample size was estimated by PASS 15.0 (NCSS PASS, UT, USA).

Results

A total of 357 patients were screened for eligibility from July 2021 to January 2023. Fifty-seven patients were excluded because of parental refusal (16 patients) or failure to meet the inclusion criteria (41 patients). Three hundred eligible patients consented to participate in the study and were randomly allocated to the ESPB or TEA group. After randomization, one patient in the TEA group was excluded after withdrawing informed consent, and one patient was excluded because the anesthesiologist decided not to perform TEA for him after two unsuccessful attempts. During the follow-up, three patients in the ESPB group and three in the TEA group were excluded due to nonfunctional electronic pumps and missing records on PCIA boluses. One patient in the TEA group who underwent conversion to open thoracotomy

Table 1 Patients' demographic characteristics and intraoperative variables

Variables	ESPB (<i>n</i> = 147)	TEA (<i>n</i> = 139)
Age, median [IQR], y	13 [9–14]	12 [9–13]
Male, number (%)	120 (82)	106 (76)
Height, median [IQR], cm	163 [142–172]	162 [142–172]
Weight, median [IQR], kg	44 [30–52]	43 [31–52]
BMI, mean (\pm SD), kg/m ²	16 (\pm 3)	17 (\pm 3)
ASA physical status, I/II	22/125	28/111
Diagnosis, PE/PE with pectus carinatum	119/28	119/20
Haller index, mean (\pm SD)	3.8 [3.3–4.5]	3.6 [3.3–4.1]
Number of Nuss bars, 1/2/3	79/65/3	86/51/2
Anesthesia induction		
Propofol, mean (\pm SD), mg/kg	2.6 (\pm 0.3)	2.6 (\pm 0.3)
Sufentanil, mean (\pm SD), μ g/kg	0.4 (\pm 0.0)	0.4 (\pm 0.0)
Cisatracurium, mean (\pm SD), mg/kg	0.1 (\pm 0.0)	0.1 (\pm 0.0)
Anesthesia maintenance		
Propofol, mean (\pm SD), mg/kg/min	0.12 (\pm 0.04)	0.13 (\pm 0.04)
Remifentanyl, mean (\pm SD), μ g/kg/min	0.11 (\pm 0.04)	0.12 (\pm 0.04)
Surgery duration, median [IQR], min	50 [37–70]	54 [40–70]

ASA american society of anesthesiologists, ASD absolute standardized difference, BMI body mass index, ESPB erector spinae plane block, IQR interquartile range, PE pectus excavatum, SD standard deviation, TEA thoracic epidural analgesia

and transfer to the intensive care unit with tracheal intubation after surgery was excluded. In total, 147 patients in the ESPB group and 139 patients in the TEA group finished the study according to the protocol and completed the primary outcome measures (Fig. 1). The baseline characteristics in terms of patient, anesthetic, and surgical procedure were comparable between the two groups (Table 1).

Test of noninferiority for the primary outcome

At 24 h postoperatively, the mean \pm SD average NRS scores at rest in the ESPB group and TEA group were 2.3 ± 0.7 and 2.4 ± 0.7 , respectively. The mean difference was -0.1 , with a 95% CI of -0.3 to 0.1 , which was within the noninferiority margin of 1 (P for noninferiority < 0.001). The mean \pm SD 24 h opioid consumption for the ESPB group was 22.5 ± 7.1 boluses compared to 23.6 ± 7.7 boluses for the TEA group, with a mean difference of -1.1 (95% CI, -2.8 – 0.6 , P noninferiority < 0.001). Noninferiority was concluded on 24 h opioid boluses, as the upper limit of the CI was less than the noninferiority margin of 7 (Fig. 2).

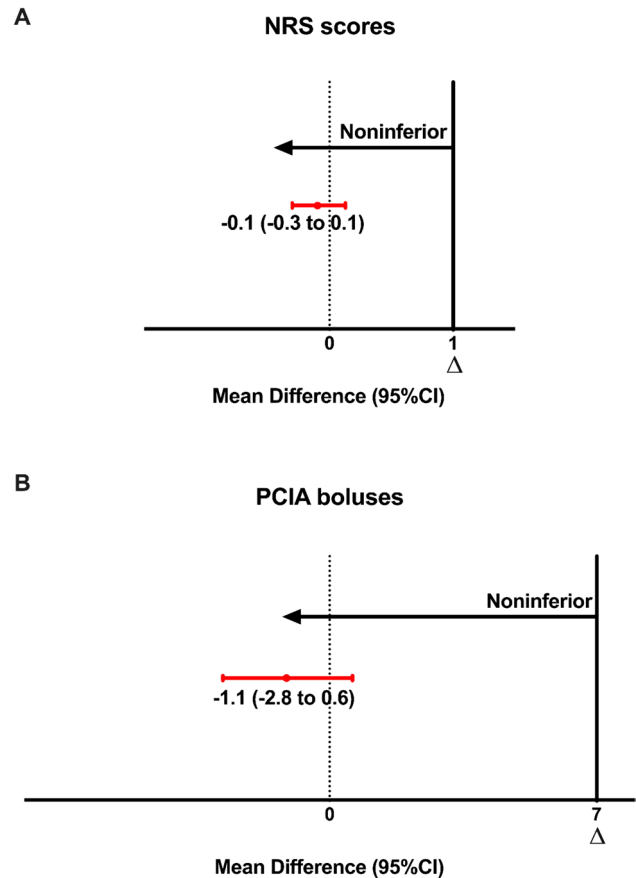


Fig. 2 Noninferiority analysis of the mean difference in the average NRS scores within 24 h (**A**) and in the number of PCIA boluses administered within 24 h (**B**). The data are plotted as differences in the means of ESPB minus TEA with 95% CI. The dashed lines designate the noninferiority margins. CI confidence interval, NRS numerical rating scale, ESPB erector spinae plane block, TEA thoracic epidural analgesia

Secondary outcomes

The NRS scores and the amounts of PCIA boluses of the randomized groups at the 4 time points after surgery are shown in Fig. 3. Between-group differences were not observed at any time point ($P > 0.0125$ for comparisons at all time points). Multilevel statistical models showed that the NRS scores had a significant interaction effect between group and time at 18 h ($P = 0.003$) and 24 h after surgery ($P = 0.033$). Regarding the number of PCIA boluses, the group-time interactions were significant at 18 h ($P = 0.004$). Other secondary outcomes are summarized in Table 2. The duration of block performance was shorter in the ESPB group than in the TEA group (16 [10, 23] vs. 22 [15, 28] min, $P = 0.002$). Eight patients in the TEA group and 1 patient in the ESPB group received a second puncture because of failure at the first attempt ($P = 0.014$). Five patients in the TEA group had

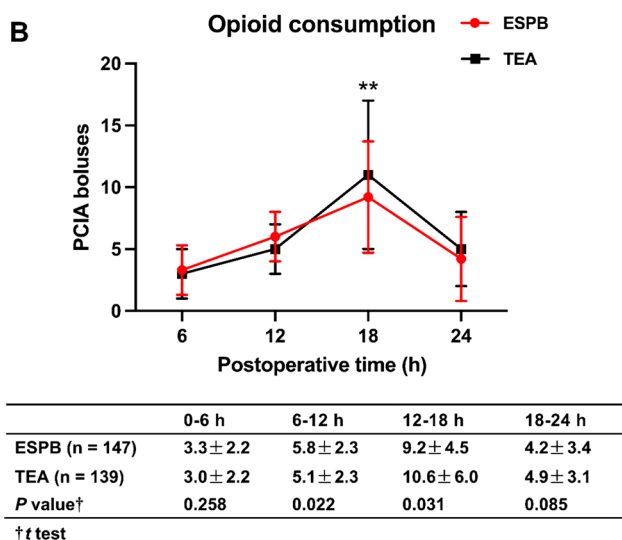
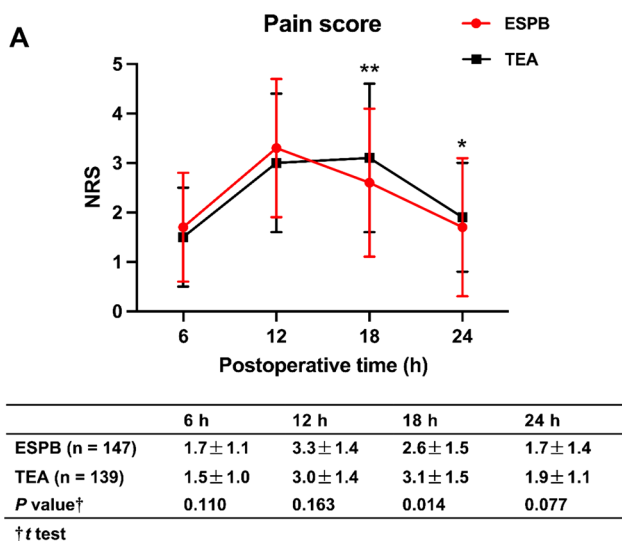


Fig. 3 NRS scores (A) and number of PCIA boluses (B) over time. The data are expressed as the means and SDs. The group-time interaction was significant regarding the NRS scores at 18 h (***P* = 0.003) and 24 h after surgery (**P* = 0.033) and the number of PCIA boluses at 18 h (***P* = 0.004). Between-group differences were not observed at any time point (all *P* > 0.0125). ESPB erector spinae plane block, NRS numeric rating scale, PCIA, parent-controlled intravenous analgesia, SD standard deviation, TEA thoracic epidural anesthesia

a more than 20% drop in blood pressure after the epidural operation, while no patient in the ESPB group had hypotension after the block (*P* = 0.020). The incidence of postoperative complications, length of PACU stay, time to recovery, rescue dezocine consumption, length of hospital stay, and patient satisfaction score did not differ significantly between the two groups (all *P* > 0.05).

Discussion

This randomized controlled study found that in pediatric patients undergoing the Nuss procedure, bilateral ultrasound-guided single-injection ESPB could be considered as effective as TEA when used as a part of multimodal analgesia for postoperative pain management with respect to pain score and opioid consumption. Based on our primary hypothesis, we assessed both postoperative 24 h pain and opioid consumption using a joint noninferiority test, as major surgery causes greater pain in the first 24 postoperative hours [15], and based on how long ESP block combined with multimodal intravenous analgesia can provide analgesia [16, 17]. To better reflect the overall pain control during the 24 h postoperative period, the cumulative PCIA boluses at 24 h and the average NRS score were analyzed as the primary outcome.

The results of our study are similar to those of controlled trials reporting that patients who received an ESPB had comparable pain scores to those who received an epidural [18, 19]. In terms of opioid sparing, a meta-analysis of controlled trials demonstrated that ESPB was comparable to TEA in reducing total opioid consumption during the first 24 h after surgery [20]. A randomized trial on adult patients undergoing total hip replacement did not demonstrate that lumbar ESPB improved analgesia [21]. One possible reason was that the complex structure of the thoracolumbar fascia in the lumbar region made the LA inconsistently travel to the ventral ramus at the level of injection. In our study, the erector spinae muscle of pediatric patients is thinner and narrower at the thoracic level [22], possibly facilitating more uniform spread of the LA through the intervertebral foramina and nerve sheaths and leading to a favorable result. However, since the dose of local anesthetic differed between the two groups in our study, we could only conclude that ESPB was noninferior to TEA in our trial setting.

Additionally, we found that ESPB did not increase the incidence of opioid-related adverse events, nor did the two groups have differences in clinical outcomes that could be affected by pain, such as time to ambulation, which was consistent with previous studies [23]. Notably, ESPB also provided several advantages, including fewer episodes of hypotension after the block procedure than TEA, which is similar to previous studies [24], and a higher one-time success rate of puncture and shorter operating time, suggesting the opportunity for increased operating room utilization.

The necessity of epidural analgesia may need reevaluation, considering the up to 30% failure rate [25], the incidence of severe complications [4], and the conflicting evidence regarding its efficacy [26]. Singhal et al. [27] stated that epidural analgesia might result in unilateral instead

Table 2 Secondary outcomes

Outcome	ESPB N/Total		TEA N/Total		P value*
First-attempt success	146/147		131/139		0.014
Hypotension after block	0/147		5/139		0.020
Local anesthetic toxicity	0/147		0/139		–
Infection	0/147		0/139		–
Neurological deficits	0/147		0/139		–
PONV score					0.689
0	125/143		123/136		
1	16/143		12/136		
2	2/143		1/136		
3	0/143		0/136		
4	0/143		0/136		
Pruritus	2/144		1/136		0.595
Fever	6/147		4/139		0.580
Pulmonary infection	2/147		6/139		0.130
Atelectasis	0/147		2/139		0.144
Hypoxemia	1/147		1/139		0.968
Pneumothorax	15/147		23/139		0.114
Pleural effusion	2/147		1/139		0.595
Respiratory failure	0/147		0/139		–
Wound discharge	2/147		2/139		0.955
Extrapulmonary infection	0/147		0/139		–
Sepsis	0/147		0/139		–
Cardiac arrest	0/147		0/139		–
Outcome	N	Median [IQR]	N	Median [IQR]	P value†
Block procedure, min	147	16 [11–24]	139	22 [4, 16–29]	0.002
Length of PACU stay, min	147	18 [15–24]	139	20 [15–25]	0.939
Time to ambulation, h	142	16 [12–20]	138	17 [12–21]	0.398
Time to oral intake, h	139	12 [8–18]	132	14 [9–19]	0.636
Time to flatus, h	117	9 [8–11]	109	9 [8–11]	0.549
Time to defecation, h	119	36 [24–42]	119	36 [26–44]	0.319
Rescue analgesia consumption, mg	147	0 [0–3.0]	139	0 [0–3.5]	0.295
Time of first rescue analgesia, h	147	14.0 [10.2–19.8]	139	16.5 [10–19.2]	0.847
Length of hospital stay, d	147	5 [5, 6]	139	5 [5, 6]	0.566
Patient satisfaction score	147	8 [8, 9]	139	8 [8, 9]	0.841

ESPB erector spinae plane block, IQR interquartile range, PACU post anesthesia care unit, PONV postoperative nausea and vomiting, POD postoperative day, TEA thoracic epidural analgesia

* χ^2 test

†Mann–Whitney *U* test

of bilateral analgesia, requiring the administration of supplemental opioids intravenously or through a PCIA pump. Patients receiving TEA as the primary analgesic method may have difficulty transitioning from epidural analgesia to intravenous opioid analgesia, further resulting in increased postoperative pain scores [28]. The indications for epidural analgesia in thoracic surgery, especially in children, have become narrower to comprise open thoracic surgery [29]. Video-assisted thoracoscopic surgeries are better managed

with regional analgesic techniques [30], and a single injection of ESPB might be a safe, simple alternative for pain control [31].

The current study should be viewed with the following limitations. First, for medical and logistic reasons, double blinding was not performed. Second, in the ESPB group, all the blocks were given under ultrasound, but in the TEA group, we did not use ultrasound to confirm placement of the epidural needle. Third, in our study, patients in both

groups showed the highest NRS scores at 12 h postoperatively, indicating that single shot ESPB or TEA may not be sufficient to sustain the analgesic effect for longer period without the use of supplement analgesia. Under the condition of ensuring the quality of technology and not causing additional damage, continuous catheterization might be considered for providing protracted postoperative analgesia, and extending the duration of the study might be more informative. Forth, for noninferiority trials, a more conservative α -level of 0.025 is recommended as opposed to 0.05 we used, which can be considered a limitation of our study. At last, ropivacaine concentration in the plasma was not assayed in our study. Although local anesthetic systemic toxicity or other complications related to ESPB was not observed during our study, the patients in the ESPB group received ropivacaine closed to the maximum dose, which should be optimized. Further studies are needed to document the pharmacokinetics of LA absorption, and to investigate the optimal dose for ESPB.

In summary, analgesia for the Nuss procedure was similar after ESPB and TEA when combined with a multimodal analgesic regimen in terms of pain score and opioid consumption. ESPB could serve as a promising alternative for managing pain in pediatric patients after the Nuss procedure.

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Data availability The data that support the findings of this study are available from the corresponding author, upon reasonable request.

Declarations

Conflict of interest All authors disclose that there are no conflict of interest.

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