

ORIGINAL ARTICLE

Comparison of Caudal Epidural Block Using Out-Of-Plane and In-Plane Techniques with Ultrasound in Pediatric Hypospadias Surgery: A Prospective Randomized Clinical Study

Pediatric Hipospadias Cerrahisinde Ultrason İle Out Of-Plane Ve In-Plane Teknikler Kullanılarak Kaudal Epidural Blok Karşılaştırması: Prospektif Randomize Klinik Bir Çalışma

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ABSTRACT

Aim: To compare the success rates and postoperative pain levels of caudal epidural block (CB) applications using ultrasound-guided out-of-plane technique and in-plane techniques in pediatric hypospadias surgery.

Methods: One hundred sixty-two patients who underwent pediatric hypospadias surgery were randomized to either the in-plane or out-of-plane ultrasound-guided CB. The primary outcome was the success rate of CB. Secondary outcomes included postoperative pain levels (FLACC score), the first analgesia requirement time, the total amount of paracetamol consumption, and complications. Procedural data were collected by blinded observers.

Results: There were differences in the primary outcome of the number of needle attempts (87.8% vs. 56.3%, $p<.001$), the success rate at the first entry (93.9% vs. 62.5%, $p<.001$), the visualization rate (90.2% vs. 31.3%, $p<.001$), a local anesthetic (LA) spread rate (87.8% vs. 46.3%, $p<.001$), and the duration of block application (41.44 ± 25.87 sec vs. 78.11 ± 43.13 sec, $p<.001$), respectively, between the in-plane and out-of-plane groups. There were also differences between out-of-plane and in-plane FLACC scores at the 12th and 24th hours ($p=.024$ and $p=.012$, respectively), the first analgesia requirement time ($p=.009$), and the total amount of paracetamol consumption ($p=.018$) in 24-hour pain ratings. There were no differences in complications.

Conclusion: Ultrasound-guided in-plane technique is an alternative technique that is superior to the out-of-plane technique for its success rate and postoperative analgesia.

Keywords: Caudal block, hypospadias surgery, pediatric, ultrasound

ÖZ

Amaç: Pediatrik hipospadias cerrahisinde ultrason kılavuzluğunda out of-plane ve in-plane teknikler kullanılarak yapılan kaudal epidural blok (CB) uygulamalarının başarı oranlarını ve postoperatif ağrı düzeylerini karşılaştırmak.

Yöntemler: Pediatrik hipospadias cerrahisi geçiren 162 hasta in-plane veya out of-plane ultrason kılavuzluğunda CB'ye randomize edildi. Birincil sonuç CB'nin başarı oranıydı. İkincil sonuçlar postoperatif ağrı düzeylerini (FLACC skoru), ilk analjezi gereksinim süresini, toplam parasetamol tüketim miktarını ve komplikasyonları içeriyordu. İşlem verileri kör gözlemler tarafından toplandı.

Bulgular: Birincil sonuçlarda, iğne denemelerinin sayısı (%87,8'e karşı %56,3, $p<.001$), ilk girişteki başarı oranı (%93,9'a karşı %62,5, $p<.001$), görüntüleme oranı (%90,2'ye karşı %31,3, $p<.001$), lokal anestezi (LA) yayılma oranı (%87,8'e karşı %46,3, $p<.001$) ve blok uygulama süresi ($41,44 \pm 25,87$ sn'ye karşı $78,11 \pm 43,13$ sn, $p<.001$) açısından sırasıyla düzlem içi ve düzlem dışı gruplar arasında farklar vardı. Ayrıca, 12. ve 24. saatlerdeki düzlem dışı ve düzlem içi FLACC skorları (sırasıyla $p=.024$ ve $p=.012$), ilk analjezi gereksinim zamanı ($p=.009$) ve 24 saatlik ağrı derecelendirmelerinde toplam parasetamol tüketimi miktarı ($p=.018$) arasında da farklar vardı. Komplikasyonlarda fark yoktu.

Sonuç: Ultrason rehberliğinde in-plane teknik, başarı oranı ve postoperatif analjezi açısından out of-plane tekniğe göre üstün olan alternatif bir tekniktir.

Anahtar sözcükler: Kaudal blok, pediatrik, ultrason, hipospadias cerrahisi

Introduction

Caudal block (CB) is an easy and effective type of central neuraxial block that is widely used in the pediatric population to provide intraoperative and postoperative analgesia in sub-umbilical surgeries. Ultrasound (US)-guided CB was first used in 2003 by Klocke et al. (1). The sacrum, sacral cornua, sacrococcygeal ligament, and sacral hiatus can be easily distinguished with ultrasound. Within the caudal epidural space, the sacral roots can be seen as hypoechoic ellipses. With the sacrococcygeal

membrane in the middle of the image, the probe is rotated 90° out-of-plane and the exact position of the cornua is defined, which is especially useful in the presence of a fat pad (2). In addition, anatomic variations of the sacral hiatus and the process area can be observed clearly (3). In addition, with US, it is shown that the injection is performed correctly, the needle is advanced in the desired direction under ultrasound guidance, the sacral canal is enlarged with a local anesthetic (LA) injection, and turbulence

is observed in the sacral canal with color Doppler during the injection (4,5). In cases where the block is difficult, the in-plane technique may be preferred in the midline plane. The advantage of the in-plane technique is better needlepoint precision through real-time observation of the needle bar and tip. The advantage of the out-of-plane approach is that it involves a more consistent needle orientation with the long axis of the nerve and adjacent muscle/fascia (6). Success rates in ultrasound-guided CB applications vary between 92.8% and 97%. (3,6). However, there is no study in the literature comparing the two approaches in pediatric patients for the superiority of each technique.

This study aimed to compare the success rates and postoperative pain levels of CB applications with ultrasound-guided out-of-plane and in-plane techniques in pediatric hypospadias surgery.

Materials and Methods

This study with a prospective randomized design as a clinical trial was approved by the Institutional Review Board of Selçuk University (Decision No: 2019/241), and written informed consent was obtained from all subjects participating in the trial. The trial was registered before patient enrollment at clinicaltrials.gov (NCT04671992). The study was conducted under the principles of the Declaration of Helsinki and adheres to Consolidated Standards of Reporting Trials (CONSORT) guidelines. After obtaining written parental informed consent, 170 patients defined by the American Society of Anesthesiologists-physical status (ASA-PS) I-II aged 1-10 years and undergoing hypospadias surgery between January 1st, 2021, and December 31st, 2021, were included in the study. Children with a previous neurologic or spinal disorder, coagulation anomaly, known allergy to local anesthetics, local infection in the CB region, and a history of preterm birth were excluded from the study. The ethical rules specified in the Declaration of Helsinki were adhered to throughout the study. Basal levels were recorded through routine monitoring of electrocardiogram (ECG), peripheral oxygen saturation (SpO₂), and noninvasive blood pressure measurements of the patients admitted to the operating room. All patients received 0.5 mg.kg⁻¹ midazolam peroral for premedication. Anesthesia was induced using a face mask with 7-8% sevoflurane, and 50% medical air/50% oxygen until the patient lost consciousness. After the loss of consciousness, vascular access

was achieved; propofol 2-3 mg. kg⁻¹ and fentanyl 0.5 µg.kg⁻¹ IV were used for general anesthesia induction. After the eyelash reflex disappeared without any neuromuscular blocker drug administration, an appropriate laryngeal mask airway, supraglottic, was placed and the patient was connected to the anesthesia device for ventilation. For the maintenance of anesthesia, 2% sevoflurane and nitrous oxide were reduced, and a 50% oxygen + air mixture was used. The patients were randomized into the CP group with the out-of-plane technique (group OP) and the CP group with the US-guided in-plane technique (group IP) using a computer-generated random number table and were divided into the two groups using the closed opaque envelope method. After placing the patients in the lateral position for CB and providing asepsis of the perianal region, a sterile 7.5-10 MHz linear US probe (SONOHEALTH® Double Probes Handheld Ultrasound Scanners Highest Cost-effective D2CL-Linear) was applied transversely to the midline to obtain a transverse view of the sacral hiatus (out-of-plane technique) for group OP (Figure 1).

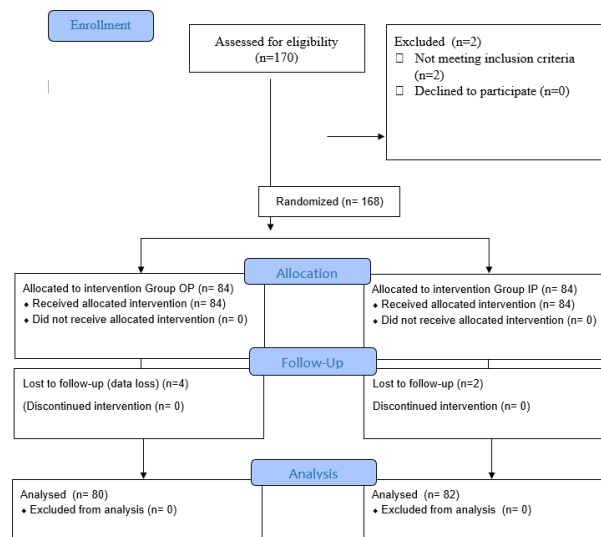


Figure 1. This randomization flow diagram displays the progress of all subjects throughout the study

The two sacral cornua were visualized as two hyperechoic structures, the sacrococcygeal ligament (SCL) as two band-like hyperechoic structures between the sacral cornua, the dorsal surface of the sacral bone as the deep structure and the sacral hiatus as the hypoechoic region between the 2 band-like hyperechoic structures

on US. The in-plane technique for group IP was obtained by rotating the US probe 90° from the transverse view of the sacral hiatus (Figure 2).

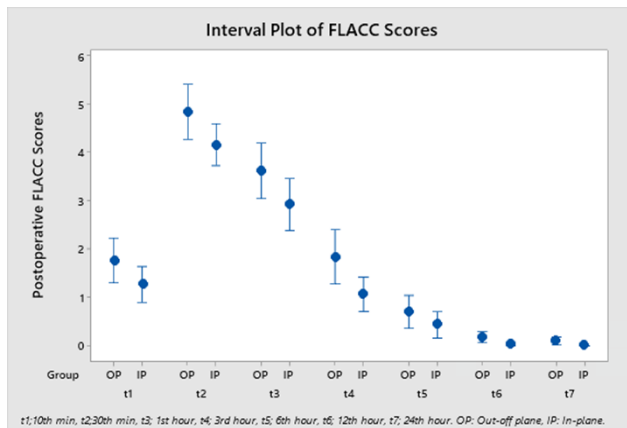


Figure 2. Comparison of Postoperative FLACC Scores in Both Groups

*p<0.001, compared to Group OP.

To obtain CP with both techniques, a 22-gauge caudal needle was inserted at the level of the sacral cornua. After observing that there was no blood or cerebrospinal fluid in aspiration, an LA injection was performed under hemodynamic and ECG monitoring, with a dose of 0.25% bupivacaine and a volume of 0.5 mL/kg. The block success rate was defined as the absence of significant motor movements after surgical induction or heart and respiratory rates exceeding 20% of baseline levels. In addition, the block application time, number of needle attempts, success at first entry, ease of visualization, and LA spread were recorded. The block application time was defined as the time between needle entry and termination of the LA application. The success rate at the first entry was defined as reaching the sacral canal or sacral hiatus with a single needle insertion at the first entry from the skin. Ease of visualization and the spread of LA visually in US were interpreted by evaluating US images.

In both groups, surgery started 10 minutes after CB administration. No intraoperative opioids or sedative drugs were used. Mean arterial pressures, heart rates, oxygen saturation, and end-tidal CO₂ values of the patients were recorded every 5 minutes.

The patients were extubated and followed up in the postoperative recovery unit face, legs, activity, crying, and consolability (FLACC) at the end of the surgery. Time to first analgesia requirement,

total analgesic type, amount of paracetamol consumption, and postoperative complications were recorded. In the evaluations made of the patients in both groups, if the FLACC scale was ≥ 4 , 15 mg.kg⁻¹ paracetamol was administered IV, and ibuprofen 10 mg.kg⁻¹ IV for rescue analgesia was administered and recorded.

Statistical analysis

All statistical analyses were performed using the R version 3.6.0 statistics package (The R Foundation for Statistical Computing, Vienna, Austria; <https://www.r-project.org>). The normality of the data was checked using the Shapiro-Wilk test of normality and Q-Q plots, and the homogeneity of group variances was checked using Levene's test. Descriptive statistics for numerical variables are presented as mean \pm standard deviation (minimum-maximum) and median, and descriptive statistics for categorical variables are presented as frequency (n) and percentage (%). The independent sample t-test, Welch's t-test, Fisher's exact test, and Mann-Whitney U test were used to compare the study groups (OP and IP) according to sociodemographic characteristics. The Mann-Whitney U test and Yates's continuity were used to compare CB details corrected Chi-square test. Fisher's exact test and Pearson's Chi-square test were used to assess CP complications. The Mann-Whitney U test was also used for postoperative pain clinical findings and postoperative FLACC scores. FLACC ratings are reported as medians with interquartile ranges. A p-value of <.05 was considered statistically significant.

Power analysis

The prior sample size was calculated with the "pwr" package in R version 4.0.1 software to test the success rate of CB using the two-proportion Z-test with an effect size of 0.45, and an alpha of 0.05. The results revealed that the required sample size in each group was 78 to achieve a power of 0.80. Considering the 10% dropout rate, we included 85 participants for each group.

Results

A total of 162 of 170 patients assigned for the study were included in this study. Eight patients from both groups (due to not meeting inclusion criteria, and data loss) were excluded. The remaining eligible patients were presented in the Consolidated

Reporting Standards (CONSORT) flowchart (Fig 1). There was no difference between the two groups in terms of patient and surgical characteristics (Table 1).

Table 1. Patient's demographics and clinical characteristics

	OP (n=80)	IP (n=82)	p-value
Age (years)	3.84±2.33 (1-10)	3.67 ± 2.54 (1-10)	.653 ¹
BMI (kg/m ²)	16.03±2.32 (11.41-22.91)	16.71±3.41 (12-27.78)	.135 ²
ASA I/II	76/4	80/2	.440 ³
Anesthesia time (min)	75.86±20.24 (50-130)	74.49±22.86 (40-135)	.811 ⁴
Operation time (min)	61.74±18.73 (39-115)	60.73±22.46 (30-120)	.618 ⁴

Data are presented as mean±standard deviation (minimum-maximum).

¹Independent sample t-test

²Welch's t-test

³Fisher Exact test

⁴Mann-Whitney U test

When the CB application details were compared according to the groups, the number of needle attempts (87.8% vs. 56.3%, respectively; $p<.001$), the success rate at the first entry (93.9% vs. 62.5%, respectively; $p<.001$), the visualization rate (90.2% vs. 31.3%, respectively; $p<.001$), and the LA spread rate (87.8% vs. 46.3%, respectively; $p<.001$) were significantly higher in group IP, compared with group OP. In addition, the duration of block application was significantly longer in the OP group than in the IP group ($p<.001$). (Table 2)

Table 2. Details of caudal epidural block application

	OP (n=80)	IP (n=82)	p-value
The time of block application (sec)	78.11±43.13 (29 – 195)	41.44±25.87 (15-135)	<.001 ¹
The number of needle attempts			<.001 ²
One time	45 (56.3)	72 (87.8)	
Multiple	35 (43.8)	10 (12.2)	
The success rate at first insertion	50 (62.5)	77 (93.9)	<.001 ²
The CB success rate	73 (91.3)	80 (97.6)	.097 ³
The ease of visualization			<.001 ⁴
Easy	25 (31.3) ^a	74 (90.2) ^b	
Middle	27 (33.8) ^a	5 (6.1) ^b	
Hard	28 (35) ^a	3 (3.7) ^b	
The spread of LA visually on US			<.001 ⁴
Good	37 (46.3) ^a	72 (87.8) ^b	
Middle	25 (31.3) ^a	7 (8.5) ^b	
Weak	18 (22.5) ^a	3 (3.7) ^b	

OP=Out-of-plane, IP=In-plane, CB=Caudal epidural block, LA=Local anesthetic; Data are presented as mean±standard deviation (minimum-maximum) or frequency (n) and percentile (%).

¹Mann-Whitney U test

²Yates continuity corrected chi-square test

³Fisher's exact test

⁴Pearson's chi-square test

For FLACC ratings at 12th and 24th hours, the in-plane technique was not superior to the out-of-plane technique, respectively (median FLACC 0; IQR, [0-0] vs. 0; IQR, [0-0], $p=.024$; Figure 1). There was no difference in median FLACC ratings at 10th (2.0; IQR, [0-3.0] vs. 0; IQR, [0-2.0]; $p=.106$), 30th min (5.0; IQR, [3.0-6.0] vs. 4.0; IQR, [3.0-5.0]; $p=.062$), 1st (3.0; IQR, [2.0-5.75] vs. 3.0; IQR, [0-4.25]; $p=.123$), 3rd (0; IQR, [0-3.75] vs. 0; IQR, [0-2.0]; $p=.068$) and 6th hours (0; IQR, [0-0] vs. 0; IQR, [0-0]; $p=.253$) respectively (Fig 1).

When comparing the postoperative pain of both groups according to clinical characteristics, the first analgesia requirement time was longer ($p=.009$) and the total amount of paracetamol consumption was higher in group IP compared with group OP ($p=.018$). The amount of rescue analgesia was similar between the groups ($p=.191$). (Table 3). Caudal epidural block complications were similar between the groups (Table 4).

Table 3. Characteristics of postoperative clinical pain

	OP (n=80) Median (min-max)	IP (n=82) Median (min-max)	p-value
The first analgesia requirement time (min)	30 (30-180)	60 (30-180)	.009 ¹
The total amount of paracetamol consumption (mg)	300 (150-1000)	150 (100-900)	.018 ¹
The amount of rescue analgesia (mg)	300 (200-400)	225 (100-300)	.191 ¹

Data are presented as median (minimum-maximum).

¹Mann-Whitney U test

Table 4. Complications of caudal block.

	OP (n=80)	IP (n=82)	p-value
Vascular puncture	1	0	.494 ¹
Subcutaneous bulging	1	3	.620 ¹
Dural puncture	1	0	.494 ¹
Local anesthetics toxicity	0	0	>.999 ¹
Respiratory depression	0	0	>.999 ¹

Values are presented as numbers.

¹Fisher's exact test

Discussion

Ultrasound-guided OP versus IP techniques in pediatric hypospadias surgery resulted in a decrease in FLACC scores, total paracetamol consumption amounts, and prolongation of the first analgesia requirement in the first 12 hours postoperatively. In addition, CB shortened the application time, decreased the number of needle attempts, increased the success rates at the first entry, provided easy visualization, and provided

good LA dissemination.

Caudal anesthesia is often preferred for pain control during and after surgery in pediatric surgery. The introduction of ultrasonography into anesthesia practice affects block success and its use may reduce complications associated with blind blocks. Ultrasonographic guidance ensures the precise delivery of LA drugs around targeted peripheral nerves (7). Visualization of anatomic landmarks and nerves increases the success of the block while also preventing possible complications related to critical structures. US guidance is even more important in regional anesthesia procedures because critical structures are located closer to target tissues in children than in adults (8). Although there is no study comparing IP and OP techniques for CP, these techniques have been compared in various anesthesia procedures such as peripheral nerve block and central vascular access (9-11). In this study, OP and IP techniques were examined in terms of the determination of anatomic points using US, visualization of BP, and visualization of LA distribution, which Abukawa et al. (12) also noted. It has been revealed that the IP technique can be advantageous in terms of visualization of the anatomic structure and monitoring of LA distribution. In this study, it was thought that when the IP technique could follow along the caudal longitudinal axis and the needle's progression to the desired anatomic region was simultaneously observed, the desired place of injection could be visualized optimally, and the LA injection would be followed more clearly from beginning to end. Considering the difficulty in visualization and the disadvantage in following the LA spread in OP applications performed with the OP technique, local anesthetic has been shown to spread in a wider region in the epidural area, since it is difficult to determine the proximity of the needle to the target area. Thus, we believe that the amount of LA penetrating the nerve in this OP technique is less than in the IP technique. Although there is no statistical difference between the two techniques in terms of block success rates, it is thought that this may explain the lower success of the OP technique in terms of the shortening of the first analgesia requirement time, the increase in the total amount of paracetamol consumption, and the increase in the postoperative FLACC scores at the 12th hour and later in postoperative follow-ups.

In the study conducted by Ahiskalioglu et al. on 140 patients (ASA I-II) aged 5-12 years in which they compared US-guided CP applications and the conventional method, the use of US was recommended because it reduced complications in caudal injections and increased the success rate of the first punctures (7). In our study, considering the advantages of US use in CP, when OP and IP techniques used in US-guided CP applications were compared in terms of postoperative complications, it was determined that the two techniques were not superior to each other in terms of complications. In a study by Karaca et al.(13), in which the authors compared US-guided and conventional caudal block in children (ASA-I) and 266 children aged 6 months to 6 years, it was found that as the patient's age decreased, the anatomic signs could not be well defined; therefore, it might be more difficult to perform the block in younger children. It has been shown that there is always a risk of dural puncture or other complications such as vascular puncture, soft tissue swelling, intraosseous injections, and systemic toxicity as the needle passes through the sacral canal (13). As a result of the study, although the success rate between the groups was not different, it was observed that the use of US during pediatric CP procedures was effective in reducing complications and increasing the success rate of the first puncture, and it was recommended to use US guidance, especially in children aged <6 years or those weighing <16 kg. In addition to this study, although there were no significant differences in complications in our study, it was concluded that the IP technique was more appropriate in increasing the success rates of the first punctures.

There were several limitations in the study. CB is used at various dermatome levels of pediatric surgery. However, only BP comparisons were made for hypospadias surgery in this study. Another limitation was that the duration of the motor block in the postoperative period was not taken into account.

Conclusion

It was concluded that the ultrasound-guided OP versus IP technique in pediatric hypospadias surgery was better in terms of FLACC scores, total paracetamol consumption, and time to the first analgesia in the first 12 hours postoperatively. In addition, in the IP technique, the CB application time was shortened, the number of needle attempts decreased, first entry success rates

increased, visualization was easier, and it provided good LA dissemination. Therefore, the ultrasound-guided IP technique should be considered an effective alternative technique for CB, which is more commonly used for the CB success rate and postoperative analgesia.

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Conflict of interest

No author has a conflict of interest that relates to the content discussed in this article.

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