



## Effects of caudal versus penile block on the incidence of hypospadias complications following primary repairs: A prospective, double-blind, randomized controlled trial

Fikret Salık<sup>a</sup>, Meral Erdal Erbatır<sup>a</sup>, Mehmet Ali Turgut<sup>b</sup>, Zülfü Savaş<sup>c</sup>, Ayhan Kaydu<sup>a</sup>, Mehmet Hanifi Okur<sup>d</sup>, Hakkari Aydogdu<sup>e</sup>, Mustafa Azizoglu<sup>f,g,\*</sup>

<sup>a</sup> Dicle University Faculty of Medicine, Department of Anesthesiology and Reanimation, Diyarbakır, Turkey

<sup>b</sup> Mardin Training and Research Hospital, Department of Anesthesiology and Reanimation, Mardin, Turkey

<sup>c</sup> Dicle University Faculty of Dentistry Department of Anesthesiology and Reanimation, Diyarbakır, Turkey

<sup>d</sup> Balıkesir University Faculty of Medicine Department of Pediatric Surgery, Balıkesir, Turkey

<sup>e</sup> Dicle University, Department of Pediatric Surgery, Diyarbakır, Turkey

<sup>f</sup> Basakşehir Cam and Sakura City Hospital, Department of Pediatric Surgery, Istanbul, Turkey

<sup>g</sup> Istinye University Department of Stem Cell and Tissue Engineering & 3D Bioprinting, Istanbul, Turkey

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### ABSTRACT

**Introduction:** This prospective, randomized, double-blinded study aimed to compare the incidence of postoperative complications and perioperative analgesic efficacy between caudal and penile block in children undergoing primary hypospadias repair.

**Methods:** Sixty-two boys aged 6–48 months were randomly assigned to receive either caudal block group (CB,  $n = 31$ ) or penile block group (PB,  $n = 31$ ) for preemptive analgesia before surgery. All patients underwent tubularized incised plate urethroplasty. The primary outcome was the incidence of postoperative complications, including urethrocuteaneous fistula and meatal stenosis, assessed at 3- and 6-months post-surgery. Secondary outcomes included total perioperative fentanyl consumption and the number of patients requiring rescue analgesia.

**Results:** There were no significant differences in the incidence of total complications (9.7 % vs. 16.1 %,  $p = 0.449$ ), fistula (6.5 % vs. 3.2 %,  $p = 0.554$ ), or meatal stenosis (3.2 % vs. 12.9 %,  $p = 0.162$ ) between the CB and PB groups. However, fistula rate was significantly higher in patients with midpenil compared to distal hypospadias (13 % vs. 0 %,  $p = 0.021$ ). Total perioperative fentanyl consumption and the number of patients requiring rescue analgesia were significantly lower in the CB group ( $p = 0.041$  and  $p = 0.01$ , respectively).

**Conclusion:** In conclusion, caudal block provides superior perioperative analgesia without increasing the risk of postoperative complications compared to penile block in children undergoing primary hypospadias repair.

**Level of evidence:** Level I.

### Introduction

Hypospadias repair, one of the most common urological procedures performed in boys, is associated with severe postoperative pain. Regional anesthesia has been used in addition to general anesthesia for years to provide adequate analgesia for this procedure. Caudal and penile blocks are preferred by pediatric anesthesiologists because of their ease of perform, effectiveness, and safety.<sup>1</sup> Especially, when caudal block is performed preemptively, it also contributes to protecting

patients from the undesirable effects of opioids by reducing intraoperative anesthetic agent consumption. Considering the neurotoxic effects of anesthetic drugs on the developing brain, the use of caudal block has retained its importance over the years.

Although the caudal block is considered safe and effective, recent findings present a confusing picture on its effect on surgical outcomes.<sup>2,3</sup> Some studies argue that the caudal block increases postoperative complications, while others blame other factors.<sup>4–7</sup> However, there is no clear evidence that caudal block increases the rate of complications after

\* Corresponding author at: Basakşehir Cam and Sakura City Hospital, Department of Pediatric Surgery, Istanbul, Turkey.

E-mail address: [mdmazizoglu@gmail.com](mailto:mdmazizoglu@gmail.com) (M. Azizoglu).

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hypospadias surgery in children. Nevertheless, this uncertainty continues to cast doubt on the caudal block, which has been safely performed by pediatric anesthesiologists for many years now.

Given the postoperative benefits of regional blocks, it is extremely important to understand the effects on complications such as urethrocutaneous fistula formation. In the literature, it has been reported that urethrocutaneous fistula formation occurs in 5–10 % following hypospadias repair.<sup>8</sup> Identifying and controlling the factors affecting fistula development after hypospadias repair are critical for surgical success. Postoperative fistula formation may vary depending on many anatomic and surgical factors, rather than regional blocks (caudal or penile). However, the lack of clear evidence makes it difficult to establish this difference. Most studies on fistula development have been limited because they are either retrospective or observational.<sup>9</sup> Thus, recent meta-analyses have highlighted the conflicting results of caudal block on postoperative surgical outcomes, emphasizing the need for further research regarding efficacy and safety.

It is increasingly important to determine whether high rates of urethrocutaneous fistula are due to caudal block or other confounding factors. We hypothesize that caudal block does not increase the urethrocutaneous fistula formation compared the other technics after hypospadias surgery. This study aims to evaluate the impact of caudal block on the rate of postoperative complications, especially urethrocutaneous fistula formation, in children undergoing hypospadias repair (primary outcome). Intraoperative and postoperative opioid consumption was also analyzed (secondary outcome).

## Materials and methods

### Type of the study

This was a prospective, randomized, double-blind study.

### Masking

Blinding was maintained for patients (and their parents) as well as for physicians.

### Compliance and consent to participate

This manuscript adheres to the CONSORT guidelines. The study adhered to the principles of the Helsinki Declaration. Before the commencement of the study, informed consent was obtained from the legal guardians of each patient, ensuring that they were well informed about the nature of the study and its potential repercussions.

### Trial registration

The study was registered on [clinicaltrials.gov](https://clinicaltrials.gov), protocol, and results registration system (ID: NCT06667947).

### Ethical approval

This study was carried out at Dicle University Hospital and institutional ethics committee approval was obtained for the study (14.06.2023–332).

### Sample size calculation

Although the primary endpoint of the study was postoperative complications (fistula and meatal stenosis), their expected incidence is low (3–10 %), requiring an unrealistically large sample size for a randomized controlled trial. Therefore, consistent with previous anesthesia trials in hypospadias surgery, the sample size calculation was based on the key secondary endpoint, total perioperative analgesic consumption, using mean and standard deviation values reported in prior randomized

studies (Kundra et al.).<sup>4</sup> The G power version 3.1.9.4 (Universität Kiel, Germany) program was used for calculating the sample size based on a previous study.<sup>4</sup> Using an alpha error of 0.05, a power of 0.80, and an effect size of 0.77 (calculated based on the study by Kundra et al.), the required sample size was determined to be 28 participants per group. To account for potential withdrawals, loss to follow-up, and an anticipated 10 % dropout rate, we enrolled 32 patients in each group.

### Eligibility criteria

A total of 62 male patients aged 6–48 months diagnosed with distal or midpenil degree of hypospadias and ASA physical status I/II were included this study. Exclusion criteria were the patients who needed a two-stage hypospadias repair, those with a glans width <14 mm or preoperative testosterone stimulation, patients with a history of previous hypospadias repair, spinal deformity, local infection or skin lesions at the epidural site, failed caudal block, coagulopathies, history of allergic reactions to local anesthetics, chronic granulomatous disease, diabetes, or those on corticosteroid treatment.

### Randomization

The patients were randomly assigned to two groups using the envelope method: Group CB and Group PB, each consisting of 31 patients. The randomization results for the intervention technique to be employed were placed into envelopes by a person other than the anesthesiologist, and each envelope was opened by the researcher immediately before the intervention.

### Endpoints

The study aimed to evaluate primary outcomes, such as surgery-related complications, including urethrocutaneous fistula, and urethral stricture. The secondary outcomes were the determination of children who needed rescue analgesia and total fentanyl consumption.

### PICOT strategy

**Participant/Population(s):** Boys aged 6–48 months undergoing primary TIP hypospadias repair (distal or mid-shaft), ASA I–II.

**Intervention(s):** Preemptive caudal epidural block (0.25 % bupivacaine, 1 mg/kg).

**Comparator(s)/Control:** Preemptive penile/dorsal penile nerve block (0.25 % bupivacaine, 1 mg/kg; without epinephrine).

**Outcome(s):** Urethrocutaneous fistula, urethral stricture, rescue analgesia, and total fentanyl consumption.

**Time:** At least 6-month postoperative follow-up (assessments at 3 and 6 months).

### Techniques

All patients received 0.1 mg/kg midazolam (Dormicum® 5 mg/5 ml, Roche, Turkey) 15 min before induction in the preoperative area. The children were monitored with electrocardiogram, noninvasive blood pressure measurement and peripheral oxygen saturation at the operation theatre. The induction of anesthesia was done with 2–3 mg/kg propofol (Propofol 1 % Fresenius®; Fresenius Kabi Medicine, Istanbul, Turkey), 0.6–0.8 mg/kg rocuronium (Esmeron®, Merck Sharpoo Dohme (MSD) Pharmaceuticals Ltd., Germany) and 1–2 mg/kg fentanyl mcg/kg fentanyl (Talinat, Vem, Istanbul, Turkey). After orotracheal intubation, anesthesia was continued with sevoflurane gas during surgery. At the end of the surgery, the patients were extubated after administration of neostigmine 0,04 mg/kg and atropine 0,02 mg/kg. This protocol was used in both groups.

In the group CB, children were placed left lateral position. After the sterilization procedure, caudal block was performed with a 25–27 G

needle by injecting 1 mg/Kg of 0.25 % bupivacaine hydrochloride (0.5 ml/Kg). all caudal blocks were performed by the same pediatric anesthesiologist.

In the group PB children were placed supine position. After the sterilization procedure penil block was performed with 25–27 G needle by injecting 1 mg/Kg of 0.25 % bupivacaine hydrochloride without epinephrine. Penile block was performed by a pediatric urologic surgeon. The pediatric anesthesiologist was in charge of the case and not the surgeon chose the anesthesia method. All procedures were performed for preemptive analgesia before surgery.

An additional 0.5 mg/kg IV fentanyl was given in either group when the heart rate increased >20 % from baseline and noted. Total intra-operative fentanyl consumption and the patients who needed additional fentanyl were recorded. At the end of the procedure, 10 mg/kg intravenous paracetamol was given for postoperative analgesia, and all children received IV paracetamol 10-mg/kg 6 hourly until discharge. All patients underwent TIP urethroplasty according to previously published techniques by the same three pediatric surgeons.

**Data collection**

Patients age, weight and other demographic data were recorded. The operation time, surgeon, surgical technique, type of hypospadias (distal or midpenil), position of the urethral meatus (defined intraoperatively as distal [glanular, coronal, or distal shaft] or mid-shaft, and presence of chordee were noted.

**Follow-up**

All children were followed up for at least six months after surgery. Children in both groups were followed up monthly for 3-months, then at 6-months to assess the development of complications.

**Statistical analysis**

Statistical analyses were performed using Jamovi version 2.3.28 software. Descriptive statistics were presented as mean ± SD for continuous variables, numbers and percentages for categorical variables. Before the analysis, the Shapiro-Wilk test was used for normality. The Student’s t-test was used for normally distributed continuous variables. The Mann-Whitney U test was used for non-normally distributed continuous variables. The Chi-square test was used for categorical variables. Statistical significance was defined as a p-value <0.05.

**Results**

A total of 62 boys who underwent hypospadias repair surgery were included in this study. They were randomly assigned into two groups: Group CB (n = 31) who received caudal block, and Group PB (n = 31) who received penile block (Fig. 1).

Table 1 shows the demographic data and clinical characteristics of the patients. Age, weight and surgical time were statistically similar into two groups. Twenty-three boys had midpenil hypospadias (37.1 %) and 39 boys had distal hypospadias (62.9 %). There was no statistical difference in the frequency of midpenil or distal hypospadias in the groups. Forty-four (71 %) patients presented with concomitant penile chordee and seven of whom had severe penile chordee, and the groups were statistically similar in terms of chordee. There was no statistically significant difference between the frequencies of total complications, urethrocutaneous fistula and meatal stenosis in the two groups based on the penile chordee (p = 0.788, 0.256 and 0.854 respectively).

Patients were followed up for postoperative complications at regular intervals for 6 months after the operation. Eight patients (12.9 %) had complications in both groups. When the groups were compared in terms of the total complication rate, Group CB (9.7 %, n = 3) and Group PB (16.1 %, n = 5) were found to be similar (p = 0.449). The overall rate of

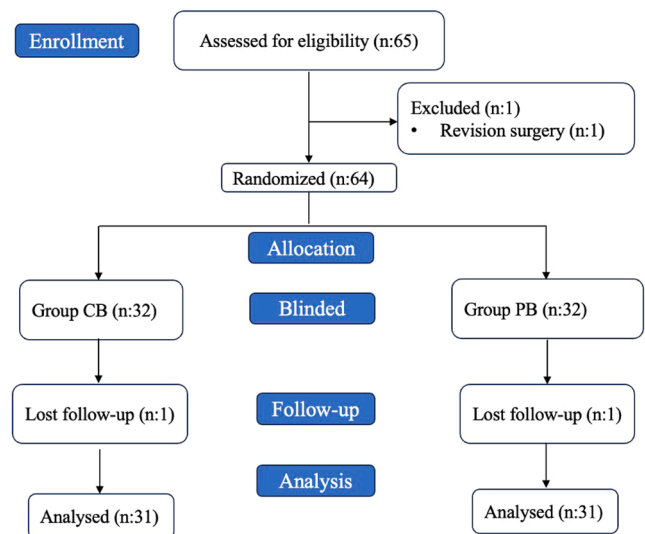


Fig. 1. Flow chart of patient’s selection.

**Table 1**  
Patient characteristics.

	Group CB (n = 31)	Group PB (n = 31)	p-value
Age (month)	26.1 ± 12.9	24.1 ± 12.2	0.578
Weight (kg)	11,371 ± 2745	11,606 ± 2682	0.734
Duration (minute)	83 ± 20	80 ± 21	0.414
Hypospadias Type, n (%)			0.793
Midpenil	11(35.5 %)	12(38.7 %)	
Distal	20(64.5 %)	19(61.3 %)	
Chordee, n (%)	22(71 %)	22(71 %)	1.000
Severity chordee, n (%)	4(12.9 %)	3(9.7 %)	0.688

Data are means±SD or n (%). P < 0.05 is considered statistically significant.

fistula was 4.8 % (3/62). The fistula rate was 6.5 % (n = 2) in Group CB and 3.2 % (n = 1) in Group PB. There was no significant difference in the fistula rates between the two groups (p = 0.554). In Group CB, one patient (3.2 %) had meatal stenosis and in Group PB four patients (12.9 %) had meatal stenosis. No significant difference was found between the two groups in terms of meatal stenosis (p = 0.162) (Table 2).

In the additional analysis, we compared the data according to the hypospadias type (midpenil/distal). The urethrocutaneous fistula rate was significantly higher in the midpenil hypospadias group than in distal hypospadias group (p = 0.021). All three fistulas were in the midpenil hypospadias (13.0 %) and there were no patients in the distal group. The rates of total complications were 21.7 % (n = 5) in the midpenil group and 7.7 % (n = 3) distal group. In the midpenil group, 8.7 % of patients (n = 2) had meatal stenosis and in the distal group, 12.9 % of patients (n = 3) had meatal stenosis. There were no significant differences between the frequencies of total complications and meatal stenosis in the two groups based on the type of hypospadias (distal/midpenil I) (p = 0.111 and 0.889, respectively) (Tables 3 and 4).

Boys in the group CB needed a total IV fentanyl of 15.2 ± 4.7 mg and 17.9 ± 5.1 mg in the group PB. The total perioperative fentanyl consumption and number of boys who needed additional fentanyl were

**Table 2**  
Complications according to received intervention.

	Group CB (n = 31)	Group PB (n = 31)	p-value
Total complications, n (%)	3(9.7 %)	5(16.1 %)	0.449
Fistula, n (%)	2(6.5 %)	1(3.2 %)	0.554
Urethral stenosis, n (%)	1(3.2 %)	4(12.9 %)	0.162
Reoperation, n (%)	2(6.5 %)	1(3.2 %)	0.554

Data are means n (%). P < 0.05 is considered statistically significant.

**Table 3**  
Patient characteristics according to hypospadias severity.

	Midpenil (n = 23)	Distal (n = 39)	p-value
Age (month)	23.3 ± 12.1	26.2 ± 12.7	0.358
Weight (kg)	11,491 ± 2721	11,487 ± 2713	0.995
Duration (minute)	93 ± 23	75 ± 16	0.002*
Block Type, n (%)			0.793
Penile	12(52.2 %)	19(48.7 %)	
Caudal	11(47.8 %)	20(51.3 %)	
Chordee, n (%)	19(82.6 %)	25(64.1 %)	0.121
Severity chordee, n (%)	6(26.1 %)	1(2.6 %)	0.005*

Data are means±SD or n (%). *p* < 0.05 is considered statistically significant.

**Table 4**  
Complications according to hypospadias severity.

	Midpenil (n = 23)	Distal (n = 39)	p Value
Total complications, n (%)	5(21.7 %)	3(7.7 %)	0.111
Fistula, n (%)	3(13.0 %)	0(0.0 %)	0.021*
Urethral stenosis, n (%)	2(8.7 %)	3(7.7 %)	0.889
Reoperation, n (%)	3(13.0 %)	0(0.0 %)	0.021*

Data are means n (%). *p* < 0.05 is considered statistically significant.

significantly statistically lower in Group CB (*p* = 0.041 and *p* = 0.010, respectively) (Table 5).

Sankey diagrams are essential for illustrate the relation between outcomes and groups.<sup>10</sup> Fig. 2 presents a sankey diagram linking hypospadias severity (distal vs midpenile), block technique (caudal vs penile), and outcomes (fistula, urethral stricture, reoperation, total complications, rescue analgesia).

We performed logistic regression to identify predictors of fistula formation, urethral stricture, overall complications, and reoperation; however, no variables emerged as significant predictors for any outcome.

**Discussion**

This prospective, single-center, double-blind, randomized controlled trial provides valuable insights into the potential impact of anesthesia type on hypospadias repair outcomes. The study found no differences in the rates of fistula and other complications between the caudal and penile blocks, suggesting that the choice of anesthesia may not influence surgical outcomes.

Caudal blocks are commonly preferred by pediatric anesthesiologists for hypospadias surgery because of their effectiveness and ease of perform. However, in recent years, studies have indicated that caudal block increases postoperative complications in hypospadias surgeries, leading to questioning the reliability of this block. Interestingly, despite the claims of higher complications, the caudal block was associated with lower postoperative pain scores. This finding highlights the effectiveness of the caudal block in controlling postoperative pain during hypospadias repairs.

First, Kundra et al. reported that caudal block increased the fistula rate after hypospadias repair.<sup>4</sup> The proposed mechanism is that the caudal block causes anatomical changes in the penile tissue due to vasodilation, venous congestion, and tissue edema. It has been supposed

**Table 5**  
Outcome data.

	Group CB (n = 31)	Group PB (n = 31)	p Value
Fentanyl (mcg)	14.5 ± 3.5	15.8 ± 3.4	0.169
Total Perioperative Fentanyl (mcg)	15.2 ± 4.7	17.9 ± 5.1	0.041*
Rescue analgesic, n (%)	2(6.5 %)	10(32.3 %)	0.010*

Data are means±SD or n (%). *p* < 0.05 is considered statistically significant.

that penile edema may increase tension on surgical sutures and thus be associated with urethral fistula formation. However, definitive evidence and the underlying etiology remain unclear. Further research is required to understand the underlying mechanisms of this phenomenon. When the study by Kundra et al. is examined, it is seen that postoperative complications and fistula formation were not the primary outcomes of this study, and other important factors, such as surgical technique and experience were not clearly evaluated. Furthermore, the patient population had a high average age. Therefore, their study may not have sufficient power to detect this difference. Indeed, they reported that they did not have sufficient objective data to blame the caudal block for fistula formation and that further trials were needed to prove this role.

Following Kundra et al., other studies have evaluated this issue and supported their findings.<sup>11-13</sup> However, most of these are retrospective and observational studies in which potential confounding factors cannot be excluded from the results. The lack of a sufficient number of randomized controlled trials on this issue causes uncertainty. Although other studies have reported that caudal block increases penis volume, this increase has not been definitively proven to contribute to fistula formation.<sup>14</sup> In one of the limited numbers of randomized controlled trials, Koul et al. compared patients receiving caudal block with those receiving only general anesthesia and found that although there was a 26.8 % increase in penile volume, this increase had no effect on fistula development.<sup>14</sup> In another randomized controlled trial, Alizadeh et al. compared 60 patients who received general anesthesia+caudal block and those who received only general anesthesia and found no association between caudal block and fistula development.<sup>15</sup> We compared the effects of caudal and penile blocks. Additionally, while they performed the caudal block postoperatively, we performed the block preoperatively to provide intraoperative analgesia and reduce opioid consumption.

In a prospective study, Ngoo et al. compared caudal block with penile block and found that penile block increased the rate of revision surgery in hypospadias repair.<sup>16</sup> They concluded that the caudal block may reduce the rate of revision surgery after hypospadias repair by having positive effects on bleeding and wound healing. In one of the studies with a large series, Fischer et al. evaluated 1008 patients and found no difference in postoperative fistula development between the caudal and penile blocks.<sup>17</sup> However, their study was retrospective and included only distal hypospadias repair. In our study, we found results that support previous studies reporting that caudal block has no effect on postoperative fistula formation.

It has been reported that the risk of surgical complications following hypospadias repair is mainly due to the severity of hypospadias rather than the regional block. Adler et al. stated that the most important factor in fistula formation is the position of the meatus (midpenil versus distal). They found that fistula formation increased 3.85 times in midpenil hypospadias compared with distal hypospadias.<sup>18</sup> Braga et al. also stated that the most effective factor for fistula formation is the severity of hypospadias, which represents only the location of the urethral meatus and the degree of ventral curvature.<sup>19</sup> Similarly, Zaidi et al. found that postoperative fistulas developed in most proximal hypospadias cases.<sup>1</sup> In our study, all three children with postoperative fistula had midpenil hypospadias. This finding confirms that the severity of hypospadias, rather than the type of regional block, may be an effective factor in the development of postoperative complications.

As indicated by Braga et al., many biased and confounding factors were not excluded from the studies, indicating that the caudal block affects fistula development.<sup>20</sup> The results of our randomized controlled trial, in which many of these confounding factors were excluded, further demonstrate the value of these findings. In a meta-analysis, Xia et al. included only three randomized controlled trials in the subgroup analysis and found that the caudal block had no effect on fistula development, which is similar to the findings of our study.<sup>7</sup>

It has been reported that age, surgical time, presence of chordee, surgical technique and surgical experience are important factors

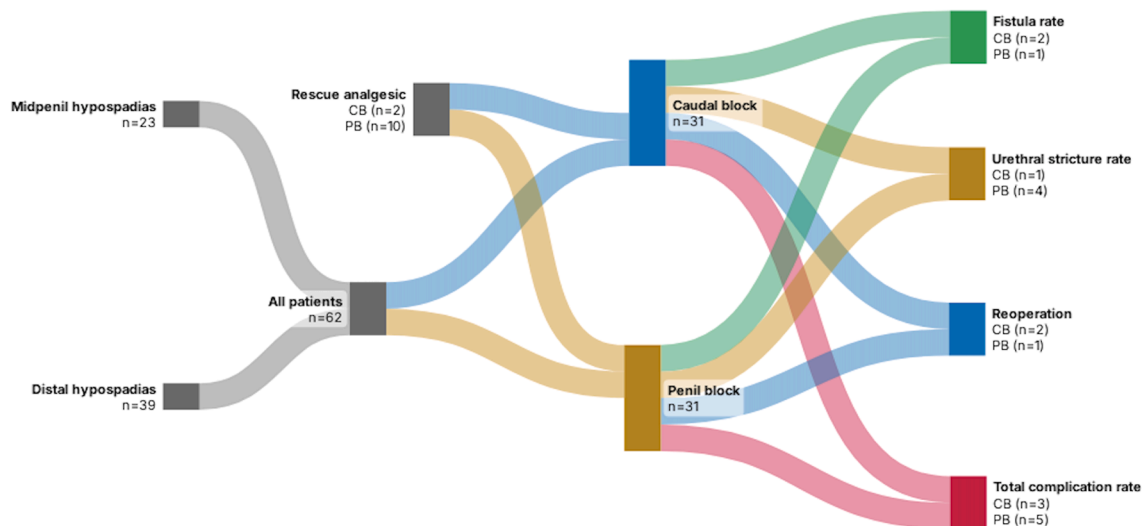


Fig. 2. Sankey diagram.

affecting fistula development after hypospadias surgery.<sup>12,14,21–23</sup> Storm et al. found that every 1-year increase in age increased the complication rate by 26 % and every 15-minute extension in surgical time increased the complication rate by 5 %.<sup>24</sup> Taicher et al. also reported that surgical time was effective in fistula formation.<sup>13</sup> Splinter et al. stated that surgical techniques impact the development of postoperative complications.<sup>25</sup> In our study, we did not find any factors that affected fistula formation in terms of age, surgical time, presence of chordee, surgical technique, or surgical experience.

Caudal block has been proven to be superior to penile block in terms of postoperative analgesia.<sup>14</sup> Furthermore, it has been observed that anesthetic agent consumption, particularly opioids, is reduced in patients receiving caudal block during the intraoperative and postoperative periods.<sup>4</sup> In today's world, where the adverse effects of anesthetic drugs on the brain are more widely discussed, caudal block is gaining popularity due to its ability to reduce anesthetic drug consumption and contribute more to opioid-free anesthesia. In our study, consistent with the literature, we found lower intraoperative opioid consumption and fewer patients requiring rescue analgesia in patients receiving caudal block compared to those receiving penile block.

### Limitations

Our study has several limitations. First, the study was a single center and had small sample size. Second, the changing of penile size after regional blocks was not measured. Third, the study included children with both midpenil hypospadias and distal hypospadias. However, our study conducted the same three surgeon who had 15 years experiences and used the same surgery technique. This removed the more conflicting factors and bias.

### Conclusions

Our findings suggest that caudal block provides effective postoperative pain control and is not associated with an increased risk of complications following hypospadias repair. This information can inform decision-making regarding the anesthetic management of pediatric patients undergoing this procedure. While our study provides valuable data to the ongoing debate regarding the use of caudal block in hypospadias repair, further research is necessary. Future studies should aim to confirm these findings in larger cohorts and explore possible

strategies to reduce the risks associated with caudal blocks. More prospective randomized controlled trials are needed to confirm all this.

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This research received no external funding.

### Institutional review board statement

The study adhered to the principles of the Declaration of Helsinki and received approval from the Medical Faculty of Dicle University Ethics Committee (approval date and number: 14.06.2023–332).

### Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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### Data availability

Data will be made available on request.

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