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Analgesic effect of sacral erector spinae, penile and caudal block after hypospadias surgery: A randomized single blind controlled trial

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ABSTRACT

Background: Hypospadias surgery is associated with acute postoperative pain needing long-term analgesia. Regional anaesthesia is commonly used with general anaesthesia (GA). We aim to compare sacral erector spinae plane block (ESPB) caudal and penile blocks in pain management following hypospadias surgery.

Patients and methods: This randomized controlled single blind trial was established on 132 pediatric cases aged from 1 to 5 years, American Society of Anesthesiologists (ASA) physical status I-II, planned for hypospadias surgery. Cases were classified into three equal groups; group C: received caudal block (CB) (1 ml/kg bupivacaine 0.25%, maximum 20 ml), group P: received penile block (0.1 ml/kg bupivacaine 0.5%, maximum 2.5 ml) and finally, group E: received ultrasound guided sacral bilateral ESPB (1 mL/kg 0.25% bupivacaine, maximum 20 ml). The blocks were done after GA induction and before the surgical incision.

Results: Time to 1st rescue analgesia was significantly delayed in groups C and E than group P ($P < 0.001$) and was insignificantly different between groups C and E. Total pethidine consumption was significantly lower in groups C and E than group P ($P = 0.003$, and 0.028, respectively). FLACC scores were significantly lower in groups C and E than group P at 4, 6, 8 and 12 h ($p < 0.05$) and were insignificantly different between groups C and E. Penile engorgement was insignificantly different among the three groups.

Conclusion: Both ESPB and CB had better pain control and lower opioid consumption compared to penile block, but CB is associated with incidence with penile engorgement and hypotensiveness than other techniques.

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1. Introduction

Hypospadias are one of the most prevalent abnormalities that affect the external genitalia of males [1–3]. Hypospadias are the inadequate development of the urethral fold and ventral foreskin, with or without penile curvature [4]. In prior epidemiological research conducted in Egypt, the prevalence of genital abnormalities was found to be 1.8%. (Hypospadias 83.33%) [5]. Previous research has indicated that the surgical time and the kind of hypospadias repair affect surgical outcomes. The penile engorgement, patient age, postoperative inflammatory reaction and tissue edema were additional complicating variables [6–8].

The surgery of hypospadias is accompanied with acute postoperative pain and requires long-term analgesia [9]. In spite of the tremendous advance in the knowledge of mechanisms of acute post-surgical pain, management of pain after hypospadias surgery remains a challenging issue. The effective and safe analgesic approach for these children is still under research [10,11].

Regional anesthesia with general anesthesia (GA) is often used in children [10,12,13]. The benefits of regional anesthesia are associated with simple intraoperative pathway that reduced GA requirements, lower pain score with less impact on the respiratory system or hemodynamic stability [14].

The most common regional anesthesia methods used for pain management are the dorsal penile block and caudal block (CB) [15].

In pediatric surgery, CB is a low-cost, simple, and effective procedure for postoperative analgesia and as the only anesthetic strategy. CB is recommended for most surgical operations in the lower body, primarily below the umbilicus, including inguinal hernia repair, urinary and digestive system surgery [16].

Dorsal penile nerve block has been more commonly used in pediatric cases in penile surgeries such as circumcision, urethral dilation and hypospadias repair [17].

Erector spinae plane block (ESPB) is a potential interfacial plane block as it is a simple and safe alternative to a central block for postoperative analgesia [18]. 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

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paravertebral region, to both ventral and dorsal spinal rami. This spread has been proven by contrast-assisted imaging studies [19–21].

ESPB has been employed in pediatric surgery for several procedures ranging from thoracic, lumber to pelvic surgeries [12,22]. Several trials reporting the safety and efficacy of the ESPB in adults. However, few trials have discussed the role of ESPB for postoperative pain in pediatric cases [23,24]. Therefore, we aimed to compare sacral ESBP with CB and penile nerve block in pain management following hypospadias surgery.

2. Patients and methods

This randomized controlled single blind trial was established on 132 pediatric cases aged from 1 to 5 years, American Society of Anesthesiologists (ASA) physical status I-II, diagnosed with hypospadias (coronal, subcoronal, or distal types) scheduled for surgical repair with an intermittent non-dribbling urethral stent for 1 week or less.

After receiving approval from the ethics committee of the Faculty of Medicine, Tanta University Hospitals, Egypt, and registration at clinical trials.gov (NCT05307653) the study was conducted from April 2022 to August 2022. All patient guardians had given an informed written consent.

Cases with bleeding diathesis, allergy to LA medications, active infection at the injection area, developmental delay, or mental retardation (due to difficult pain assessment) were excluded.

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

3. Randomization and blindness

Cases were randomly divided equally into three groups by sealed opaque envelopes and a computer-generated sequence. Group C: were given CB, group P: were given penile block and finally, group E: were given bilateral sacral ESPB. An anesthesiologist carried out the block procedures and administered the necessary medication without subsequent participation in the trial. The care provider in this trial was blinded.

4. Intervention

ECG, pulse oximeter, non-invasive blood pressure, temperature probe, and capnogram were used to monitor children.

As a premedication, oral midazolam (0.5 mg/kg) was taken orally. Induction of GA was performed by sevoflurane 6% in oxygen: air (4:1). After the infant lost consciousness, intravenous (IV) access was acquired; then, fentanyl (1 ug/kg) and atracurium (0.5 mg/kg) were given through the IV route. Dextrose 5% in normal saline 7 ml/kg was started IV. The cases were mechanically ventilated (pressure-controlled mode) with parameters adjusted to maintain an end-tidal carbon dioxide of 36–40 mmHg using a suitable sized endotracheal tube.

Sevoflurane (0.5–1.5 MAC) was used to maintain anesthesia, along with incremental atracurium (0.1 mg/kg). Incremental doses of fentanyl 0.5 ug/kg were given after excluding other causes when the bispectral index (BIS) increased > 60 and/or their mean arterial pressure (MAP) or heart rate (HR) increased by more than 20% compared to their baseline values. These cases were deemed block failures and excluded.

In group C, the cases were resumed to the supine position following the completion of the procedure. Blocks were done under complete aseptic technique after induction of GA and before skin incision.

5. Caudal block

In the left lateral position, CB was done. Through the sacral hiatus, a 22 G needle was inserted. Resistance loss was employed to reach the caudal epidural space after passing through the sacrococcygeal membrane. Then, negative aspiration was carried out. When no cerebrospinal fluid or blood was detected, bupivacaine 0.25% (1 ml/kg, maximum 20 ml) was administered.

6. Penile block

Penile block was done in the supine position. After identifying the symphysis pubis (SP), a 22-gauge needle was inserted vertically about 1 cm lateral to the SP. After negative aspiration, and bupivacaine 0.5% (0.1 ml/kg, maximum 2.5 ml) was injected on every side after penetrating the Scarpa's fascia.

7. ESPB

Ultrasound guided ESPB was performed bilaterally in the prone position by Philips ® (CX50 Extreme edition). The superficial probe was positioned longitudinally at the midline just above the sacrum, and both erector spinae plane muscles and median sacral crests were identified. A 22-gauge needle was inserted in a craniocaudal direction till reaching the tip of the fourth median sacral crest by the in-plane approach. After negative aspiration (to avoid intravascular or intrathecal puncture), bupivacaine 0.25% (1 ml/kg, maximum 20 ml) was administered.

Sevoflurane was turned off at the surgery end. The muscle relaxation was reversed using atropine 0.01 mg/kg and neostigmine 0.04 mg/kg IV. After that, cases were awakened and transported to the post-anesthesia care unit (PACU). When their modified Aldrete's score reached 9, cases were discharged

Table 1. FLACC pain scale [41].

	0	1	2
Face	No particular expression or smile	Occasional grimace/frown withdrawn or disinterested	Frequent/constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless or tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	squirming, shifting back and forth, tense	Arched, rigid or jerking
Cry	No cry	Moans or Whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
Cancelability	Content or relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

Note: FLACC: The face, legs, activity, cry, consolability.

from PACU, and all children received 15 mg/kg IV infusion of paracetamol for analgesia every 6 h.

Postoperatively pain was assessed by FLACC pain scale (from 0 to 10) [Table 1]. FLACC was recorded in the ward every 2 h during the first 8 h, then every 4 h till the end of the first postoperative day. Pethidine 0.5 mg/kg IV rescue analgesia was used if FLACC was >3.

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, analgesic requirement, the incidence of penile engorgement and complications (bradycardia, hypotension, pruritis, hematoma, vomiting and infection). A result of at least 15% less than the usual mean value for the child's age was used to define hypotension and bradycardia.

8. Sample size calculation

The sample size calculation was done by G*Power 3.1.9.2 (Universitat Kiel, Germany). We performed a pilot study on 10 cases in each group and found that the mean (± SD) of 1st rescue analgesia (the primary outcome) was 8.6 (±2.50) h in group C, versus 7.2 (±1.4) h in group P and 6.6 (±2.67) in group E. 44 cases were enrolled in each group, based on the following: 0.38 effect size, 95% confidence limit, 95% power of the study, and seven cases were added to each group to overcome dropout.

9. Statistical analysis

Statistical analysis was performed using IBM SPSS (version 26). To check data normality, we used the Shapiro–Wilk test and histogram. Parametric parameters were presented as mean and standard deviation (SD) and were analyzed using the ANOVA test. Non-parametric parameters were presented as median (IQR) and were analyzed using Kruskal–Wallis test. Qualitative parameters were presented as frequencies and percentages were analyzed statistically using the Chi-square test. *P* values with two tails of 0.05 or less were considered significant.

10. Results

In the present trial, 147 cases were assessed for eligibility. Overall, 132 cases were allocated into three equal groups. Four cases in group C, three cases in group P and five cases in group E were dropped out (failed block). A total of 120 cases were followed-up and analyzed statistically (Figure 1).

Demographic data and duration of surgery were insignificantly different among three groups. Table 2

Intraoperative HR and MAP were comparable among the three groups. Figure 2

The mean ± SD of time to 1st rescue analgesia was 8.63 ± 4.35 h in group C, 5.12 ± 1.55 h in group P and 9.33 ± 4.14 h in group E. Time to 1st rescue analgesia was significantly delayed in group C and E than group P ($P < 0.001$) with no difference between groups C and E. Table 3

The mean ± SD of total pethidine consumption was 18.14 ± 9.66 mg in group C, 25.62 ± 9.02 mg in group P and 19.04 ± 11.22 mg in group E. Total pethidine consumption was significantly lower in group C and group E than group P with no difference C and group E. Table 3

FLACC score was significantly lower in group C and E than group P at 4,6, 8 and 12 h ($P < 0.05$) with no difference between group C and E and insignificantly different at 2, 16, 20 and 24 h among three groups. Table 4

Postoperative HR and MAP were significantly lower in groups C and E compared to group P at 4,6, 8 and 12 h ($p < 0.05$) with no difference between groups C and E and insignificantly different at 2, 16, 20 and 24 h among three groups. Figure 2

Penile engorgement occurred in 5% group C and 2.43% in group P and did not occur in group E. Intraoperative penile engorgement was comparable among the three groups. Table 5

Hypotension was significantly higher in group C than groups P and E and insignificantly different between group P and E. Bradycardia and vomiting were comparable among the three groups. Superficial infection occurred only in one patient in group P. No cases developed hematoma related to injection nor pruritis in the three groups. Table 5

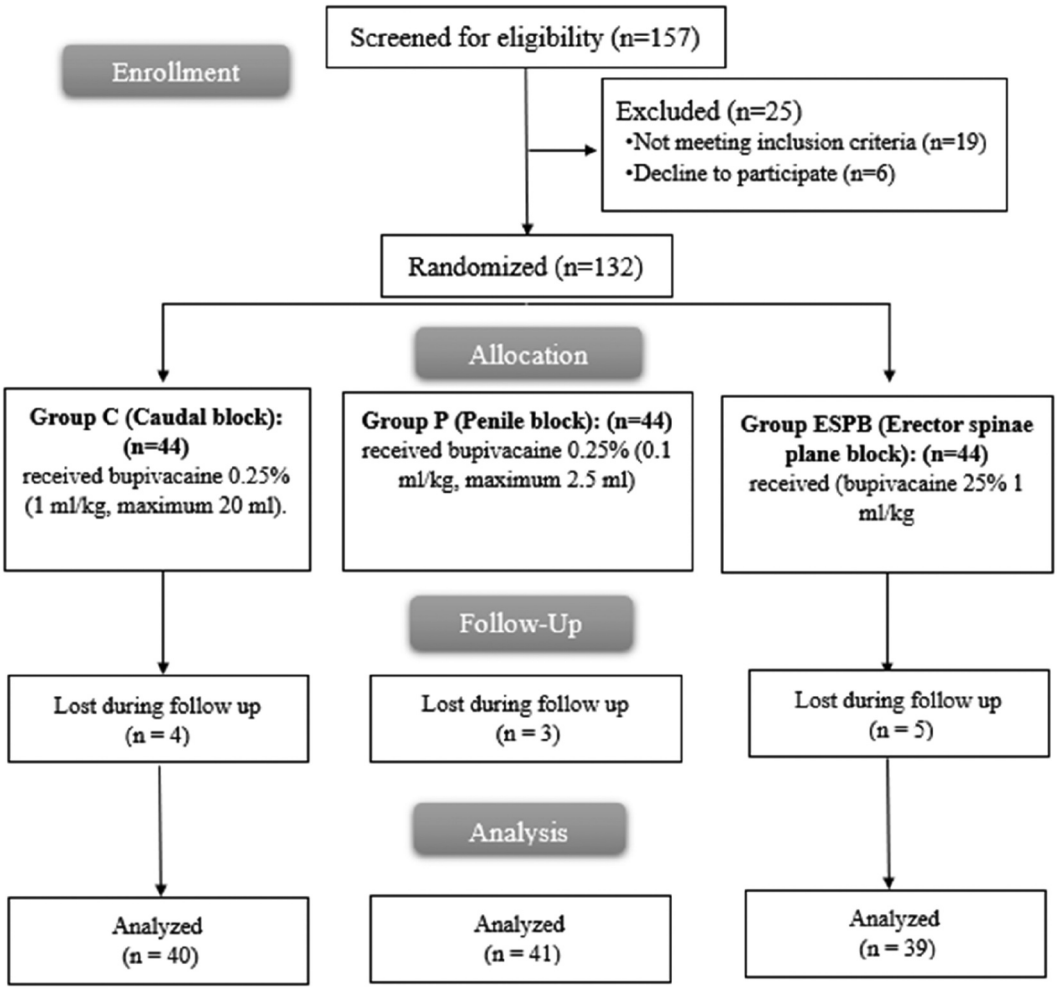

Figure 1. Consort flow diagram of the enrolled patients.

Table 2. Demographic data and duration of surgery of the three groups.

		Group C ($n = 40$)	Group P ($n = 41$)	Group E ($n = 39$)	P value
Age (years)		2.75 ± 1.35	2.95 ± 1.07	2.85 ± 1.29	.766
Weight (kg)		14.93 ± 2.37	15.9 ± 2.11	14.82 ± 2.33	.065
ASA physical status	I	38 (95%)	40 (97.56%)	37 (94.87%)	0.589
	II	2 (5%)	1 (2.44%)	2 (5.13%)	
Duration of surgery (min)		115.5 ± 33.36	111.9 ± 34.33	118.08 ± 35.59	.810

Note: Data are presented as mean ±SD or frequency (%), BMI: body mass index, ASA: American Society of Anesthesiologists, Group C: Caudal block, Group P: penile block, Group E: Erector spinae plane block.

11. Discussion

In children, pain is one of the most difficult, underdiagnosed, and neglected medical conditions [25]. A child suffering from postoperative pain may be uncooperative and restless [26].

Our findings showed sacral ESPB was effective and comparable to the CB. Sacral ESPB showed a longer analgesic period, lower FLACC, and lower opioid requirement than the penile group. Beneficial impacts of Sacral ESPB may be attributed to its anesthetic action for the posterior sacral nerves, along with epidural spread.

Aksu and Gürkan [27] published a case report about the effect of sacral ESPB in a six-month infant following hypospadias repair. Besides the normal regimen of postoperative systemic analgesics (paracetamol 15 mg/kg), no additional analgesics were needed. His pain scale (FLACC) was 0 for the early 24 h following the operation. Also, Kukreja et al. [28] case report confirmed the efficacy of sacral ESPB as an alternate regional method for gender reassignment surgeries.

According to a recent study [13], ESPB is considered an effective alternative to epidural and paravertebral blocks. It could be even applied in cases with coagulopathy, spinal deformities, anomalies, or low-weight cases.

In pediatrics undergoing lower abdominal procedures, Aksu et al. [26] reported that ESPB and quadratus lumborum block have similar impact on postoperative analgesia and the time for the first analgesic request.

An existing systematic review confirmed the significant beneficial effect of ESBP on acute post-

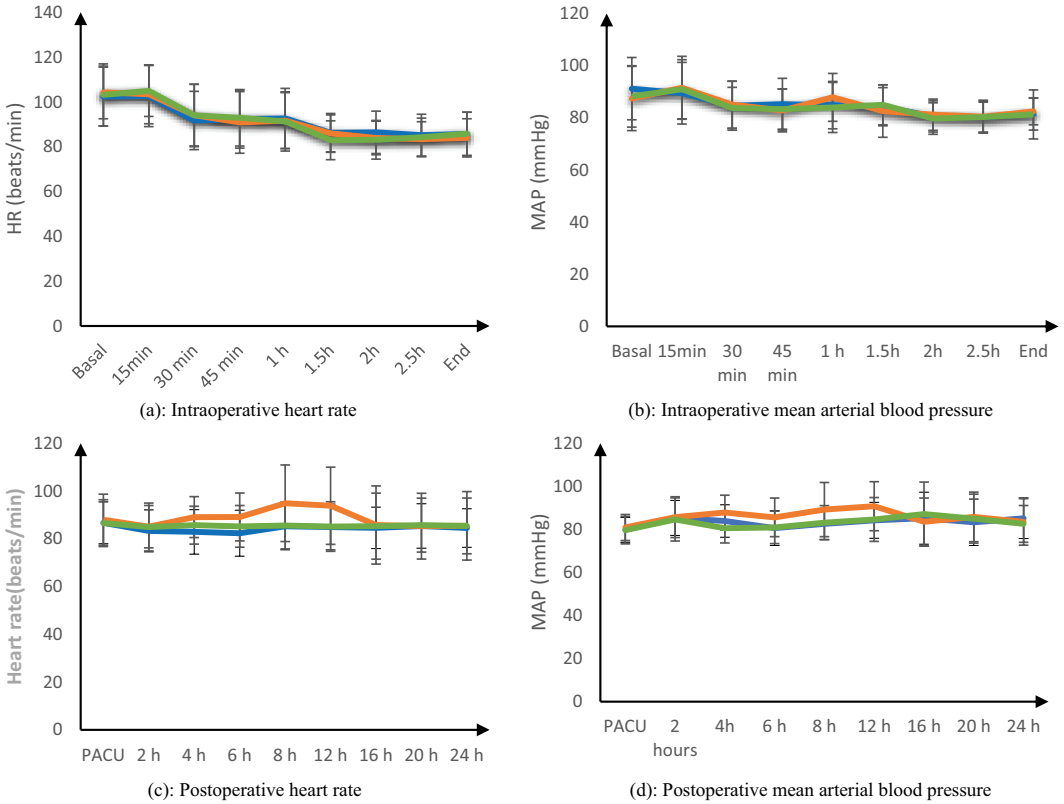

Figure 2. Intraoperative and post operative heart rate and mean arterial blood pressure among the studied groups. PACU: postoperative care unit

Table 3. Post-operative analgesic profile of the three groups.

	Group C($n = 40$)	Group P ($n = 41$)	Group E ($n = 39$)	P	
Time to 1st rescue analgesia(h)	8.63 ± 4.35	5.12 ± 1.55	9.33 ± 4.14	<0.001	P1 < 0.001 P2 = 0.375± P3 < 0.001
Total pethidine consumption (mg)	18.14 ± 9.66	25.62 ± 9.02	19.04 ± 11.22	0.001	P1 = 0.001 P2 = 0.848 P3 = 0.003

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

Table 4. FLACC score follow-up among the three groups.

	Group C ($n = 40$)	Group P ($n = 41$)	Group E ($n = 39$)	P value	
2 h	1 (1–2)	2 (1–2)	1 (1–2)	.200	
4 h	2 (2–3)	4 (3–4)	2 (2–3)	<.001	P1 < 0.001 P2 = 0.722 P3 < 0.001
6 h	3 (2–3.25)	3.5 (3–5)	3 (3–3)	.001	P1 < 0.001 P2 = 0. 552 P3 = 0.005
8 h	3.5(3–4)	5(3–6)	4 (3–4)	.008	P1 = 0.006 P2 = 0.911 P3 = 0.009
12 h	3 (3–4)	4 (3–4)	3 (3–4)	.008	P1 = 0.008 P2 = 0.936 P3 = 0.007
16 h	4 (3–4.25)	3 (3–5)	4 (3.5–4)	.380	
20 h	3 (3–4)	3 (3–4)	3 (3–4)	.824	
24 h	3 (2–4)	3 (2–5)	3 (2–4)	.789	

Data are presented as median (IQR), Group C: Caudal block, Group P: penile block, Group E: Erector spinae plane block, P1: between group C and group P. P2: between group C and group E. P3: between group P and group E.

surgical pain after different pediatric surgeries including hypospadias, inguinal hernia repair, varicocelectomy, cholecystectomy, nephrectomy and thoracotomy [12].

In contrast to our findings, Elshazly et al. [29] reported that in pediatric hip surgery, FLACC score at 15 and 30-min postoperative was increased in ESPB compared to CB. The time to first rescue analgesia was

Table 5. Side effects of the three groups.

	Group C ($n = 40$)	Group P ($n = 41$)	Group E ($n = 39$)	P value	
Penile engorgement	2(5%)	1(2.43%)	0 (.0%)	.363	
Bradycardia	2 (5%)	1 (2.4%)	3 (7.69%)	.559	
Hypotension	8 (20%)	1(2.4%)	2 (5.13%)	.013	P1 = 0.002 P2 = 0.046 P3 = 0.526
Vomiting	4 (10%)	5(12.2%)	3 (7.69%)	.729	
Hematoma	0 (.0%)	0 (.0%)	0 (.0%)	—	
Infection	0 (.0%)	1 (2.3%)	0 (.0%)	.365	
Pruritis	0 (.0%)	0 (.0%)	0 (.0%)	—	

Note: Data are presented as frequency (%), P1: Caudal group vs Penile block group. P2: Caudal group vs. Erector spinae group. P3: Penile block group vs Erector spinae group.

earlier in the ESPB than CB. Different sample sizes and types of surgery may be an appropriate explanation for this difference from our findings.

Also, in children who underwent lower abdominal surgery, Abdelrazik et al. [30] concluded that the early postoperative FLACC score and total amount of analgesia were decreased in ESPB than CB. ESPB had a longer duration of analgesia than CB.

Our findings showed CB was better than penile by providing longer analgesic duration, lower pain scores, and pethidine consumption.

In agreement with our results, previous studies [17,31] showed that caudal tended to be more effective in lowering postoperative pain scores with lower rescue analgesic requirements when compared to penile block for postoperative pain management in children undergoing hypospadias repair.

Furthermore, Ekstein et al. [10] confirmed our findings regarding the superiority of CB compared to penile block in pediatric cases undergoing hypospadias repair. Cases in the caudal group reported significantly lower pain scores and morphine consumption compared to the penile group. Similarly, Canakci et al. [32] found that CB decreased postoperative pain more than the penile block.

In disagreement with our findings, Wang et al. [33] reported comparable pain scores between both caudal and penile block groups. This could be explained by applying the penile block via the perineal approach under ultrasound guidance, which may increase its efficacy to be comparable to the caudal technique.

Moreover, Ashrey et al. [34] found that penile block is more effective than the CB for postoperative pain management in pediatric penile surgery cases, with greater surgeon and parent satisfaction and no substantial increase in the incidence of side effects. This may be due to different doses of blocks.

On the other hand, Ozen et al. [35] reported a better analgesic profile with the penile block under ultrasound guidance compared to the caudal technique for pediatric distal hypospadias surgery.

Our results showed that penile engorgement occurred in 5% in CB group and 2.43% in penile block group and did not occur in sacral ESPB, and this could be explained by the fact that caudal anesthesia leads to vasodilatation and pooling of blood in the venous sinuses of the penis. Engorgement is problematic for the surgeon and can negatively impact surgical success.

A study by Kundra et al. [36] showed that CB resulted in intraoperative penile engorgement with 27% increase in penile volume from baseline.

In another study by Koul et al. [37] observed that the caudal group had 26.8% increase in penile volume from baseline after distal hypospadias repair.

Also, hypotension incidence was significantly higher in groups C as occurred in 20% compared to group E (5.13%) and (2.4%) case in group P.

CB has been shown to decrease either sympathetic activity, decrease vascular resistance or cardiac output [38–40]. This could explain the higher incidence of hypotension in association with that form of block. In ESPB, the epidural spread of the anesthesia agent could also explain the incidence of that complication in this group [27].

Our study has some limitations as it is a single-center study with a relatively small sample size to prove our secondary outcomes. Additionally, the different doses and concentrations of these blocks and the effect of these different block techniques on the postoperative outcome (like the incidence of postoperative fistula). Therefore, further trials for longer follow-up periods are needed.

12. Conclusion

Both CB and ESPB are associated with better pain control compared to the penile block. Despite their advantages and comparable complication profile with the penile block and ESPB, the hypotension incidence was significantly higher in caudal than other techniques and penile engorgement occurred with CB and penile block. Therefore, children must be closely monitored to prevent the occurrence of such a complication.

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