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COMPARISON OF CAUDAL BUPIVACAINE ALONE VERSUS BUPIVACAINE WOUND INFILTRATION PLUS RECTAL DICLOFENAC SUPPOSITORY FOR POSTOPERATIVE ANALGESIA AFTER PEDIATRIC INGUINAL HERNIOTOMY: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Effective postoperative analgesia is an important component of perioperative care in children undergoing inguinal herniotomy. Caudal bupivacaine is commonly used; however, local wound infiltration combined with a non-steroidal anti-inflammatory drug may provide an alternative multimodal strategy without neuraxial block.

Objective: To compare the duration of postoperative analgesia between bupivacaine wound infiltration combined with rectal diclofenac suppository and caudal bupivacaine alone in children undergoing elective inguinal herniotomy.

Methods: This single-center, parallel-group randomized controlled trial was conducted at the Department of Anesthesiology, Multan Institute of Kidney Diseases, Multan, Pakistan, from 20 January to 19 May 2026. Sixty male children aged 4–8 years, classified as ASA physical status I–II and undergoing elective inguinal herniotomy, were allocated equally to two groups using a draw/sealed-envelope method. Group A received rectal diclofenac 2 mg/kg (dose adjusted to 25 or 37.5 mg) plus preincisional infiltration with 0.25% bupivacaine 0.5 mL/kg. Group B received a caudal block with 0.25% bupivacaine 1 mL/kg, with a maximum dose of 2.5 mg/kg. Pain was assessed at 0, 15, 30, 45, and 60 minutes and every 30 minutes thereafter for up to 8 hours or until rescue analgesia was required. Data were analyzed using SPSS Statistics; continuous variables were compared using an independent-samples t test, and stratified analyses were performed. A p value ≤ 0.05 was considered statistically significant.

Results: The mean duration of postoperative analgesia was 149.23±9.61 minutes in Group A and 117.20±5.51 minutes in Group B. The between-group mean difference was 32.03 minutes (95% CI 27.98–36.08 minutes, calculated from the reported summary statistics), with a reported p value of 0.0001. The difference remained statistically significant in the reported stratified analyses by age, residential status, and BMI.

Conclusion: In this study population, bupivacaine wound infiltration combined with rectal diclofenac was associated with a longer duration of postoperative analgesia than caudal bupivacaine after pediatric inguinal herniotomy. Larger, prospectively registered trials using standardized pain assessment, explicit allocation and blinding procedures, adverse-event reporting, and clinically relevant secondary outcomes are warranted.

KEYWORDS: pediatric inguinal herniotomy; postoperative analgesia; bupivacaine; diclofenac; caudal block; wound infiltration; randomized controlled trial

INTRODUCTION

Postoperative pain is an important component of perioperative care in children undergoing inguinal herniotomy. Inadequate analgesia may increase physiologic stress and adversely affect recovery and the perioperative experience. Because pediatric inguinal hernia repair is commonly performed as an elective procedure, effective, safe, and practical analgesic strategies are particularly relevant.

Caudal analgesia is widely used for infraumbilical surgery in children. Although effective, neuraxial techniques require technical expertise and may be associated with procedural limitations or complications. Local anesthetic wound infiltration is less invasive and can be combined with systemic or rectal analgesics as part of a multimodal analgesic strategy.

Diclofenac is a non-steroidal anti-inflammatory drug that reduces prostaglandin synthesis through cyclooxygenase inhibition. Combining local anesthetic infiltration with diclofenac therefore provides analgesia through complementary mechanisms. A previous randomized study by Amminikutty et al. comparing caudal bupivacaine with bupivacaine infiltration plus rectal diclofenac in children undergoing herniotomy provided the principal rationale for the present trial.

The present study was designed to compare the duration of postoperative analgesia between bupivacaine wound infiltration plus rectal diclofenac and caudal bupivacaine in children undergoing elective inguinal herniotomy at a tertiary-care hospital.

METHODS

This was a single-center, parallel-group randomized controlled trial conducted in the Department of Anesthesiology, Multan Institute of Kidney Diseases (MIKD), Multan, Pakistan, between 20 January and 19 May 2026.The study included 60 male children aged 4–8 years undergoing elective inguinal herniotomy. Eligible participants were classified as ASA physical status I or II. Exclusion criteria were known drug allergy, bleeding disorders, infection at the injection site, valvular heart disease, spinal deformity, and patient or parental refusal. Written informed consent was obtained from the patients

A total sample of 60 participants (30 per group) based on previously reported estimates of analgesia duration, with 80% power, a 95% confidence level, and α=0.05.Participants were allocated equally to two groups using a draw/sealed-envelope method. Group A received rectal diclofenac 2 mg/kg, adjusted to 25 mg or 37.5 mg, together with infiltration using 0.25% bupivacaine at 0.5 mL/kg according to the hospital protocol. Group B received a caudal block using 0.25% bupivacaine at 1 mL/kg, with the dose limited to 2.5 mg/kg according to the hospital protocol.The primary outcome was duration of postoperative analgesia, defined as the time in minutes from administration of the assigned analgesic intervention to the first administration of rescue analgesia in response to a clinical complaint of pain. Pain was assessed at 0, 15, 30, 45, and 60 minutes and then every 30 minutes until 8 hours after surgery or until rescue analgesia was required, whichever occurred first.

Data were summarized using means and standard deviations for continuous variables and frequencies and percentages for categorical variables. The mean duration of analgesia was compared between groups using an independent-samples t test. Stratified analyses were performed for age, residential status, and BMI. A p value ≤0.05 was considered statistically significant. The manuscript materials provided report analysis using SPSS using software 25 version.

RESULTS

Sixty participants were included, with 30 in each treatment group. The overall mean age was 6.62±1.50 years. Mean age was 6.50±1.53 years in Group A and 6.67±1.42 years in Group B. Nineteen participants (31.67%) were aged 4–6 years and 41 (68.33%) were aged 7–8 years. The overall mean BMI was 19.71±3.42 kg/m²; 28 participants (46.67%) had a BMI ≤20 kg/m² and 32 (53.33%) had a BMI >20 kg/m².

Table 1. Baseline age distribution

Age	Group A (n=30)	Group B (n=30)	Total (n=60)
4–6 years	9 (30.0%)	10 (33.33%)	19 (31.67%)
7–8 years	21 (70.0%)	20 (66.67%)	41 (68.33%)
Mean±SD, years	6.50±1.53	6.67±1.42	6.62±1.50

Table 2. Baseline BMI distribution

BMI (kg/m²)	Group A (n=30)	Group B (n=30)	Total (n=60)
≤20	15 (50.0%)	13 (43.33%)	28 (46.67%)
>20	15 (50.0%)	17 (56.67%)	32 (53.33%)
Mean±SD, kg/m²	19.80±3.36	19.70±3.60	19.71±3.42

Primary outcome

The mean duration of postoperative analgesia was 149.23±9.61 minutes in Group A compared with 117.20±5.51 minutes in Group B. The mean between-group difference was 32.03 minutes. Based on the reported group means, standard deviations, and sample sizes, the approximate 95% confidence interval for the mean difference is 27.98–36.08 minutes. The reported p value was 0.0001.

Table 3. Primary outcome: duration of postoperative analgesia

Outcome	Group A	Group B	Between-group comparison
Duration of analgesia, mean±SD (min)	149.23±9.61	117.20±5.51	Mean difference 32.03 min; reported p=0.0001; approximate 95% CI 27.98–36.08 min

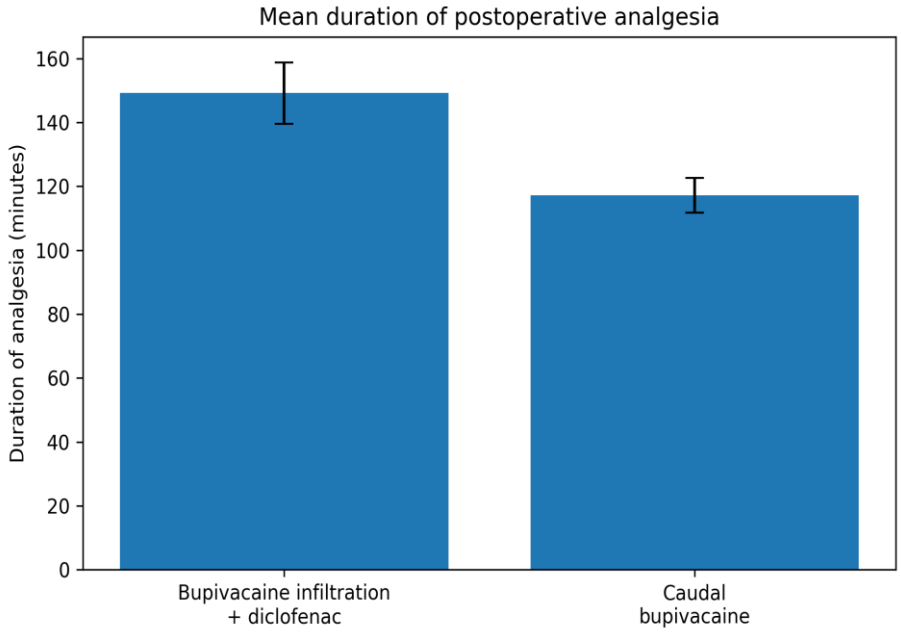


Figure 2. Mean duration of postoperative analgesia. Error bars represent standard deviations.

The reported between-group difference remained statistically significant across the prespecified descriptive strata available in the study materials. For participants aged 4–6 years, mean analgesia duration was 157.10±7.31 minutes in Group A versus 115.44±5.00 minutes in Group B. For participants aged 7–8 years, the corresponding values were 145.30±8.17 and 117.95±5.66 minutes. By residential status, the means were 147.65±8.85 versus 118.65±5.38 minutes for rural participants and 152.40±10.74 versus 115.31±5.28 minutes for urban participants. By BMI, the means were 153.86±9.57 versus 117.40±5.65 minutes for BMI ≤20 kg/m² and 145.19±7.86 versus 117.00±5.56 minutes for BMI >20 kg/m². The reported p value for each comparison was 0.0001.

Table 4. Stratified duration of postoperative analgesia

Stratum	Group A mean±SD (min)	Group B mean±SD (min)	Reported p value
Age 4–6 years	157.10±7.31	115.44±5.00	0.0001
Age 7–8 years	145.30±8.17	117.95±5.66	0.0001
Rural residence	147.65±8.85	118.65±5.38	0.0001
Urban residence	152.40±10.74	115.31±5.28	0.0001
BMI ≤20 kg/m²	153.86±9.57	117.40±5.65	0.0001
BMI >20 kg/m²	145.19±7.86	117.00±5.56	0.0001

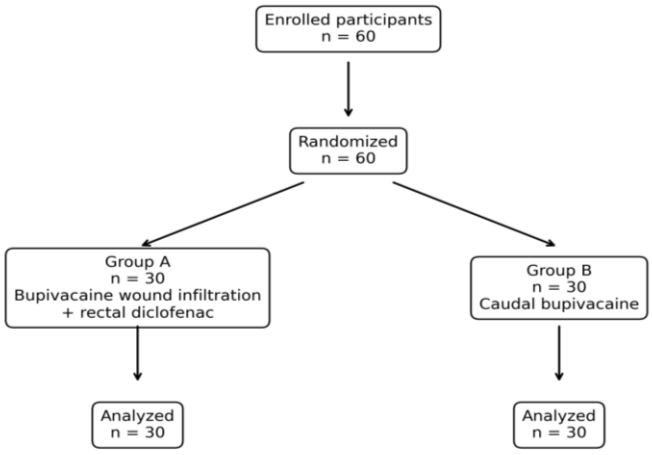


Figure 1. Participant allocation and analysis

DISCUSSION

The principal finding of this randomized trial was a longer duration of postoperative analgesia with bupivacaine wound infiltration combined with rectal diclofenac than with caudal bupivacaine in children undergoing elective inguinal herniotomy. The observed mean difference was 32.03 minutes.

This finding is relevant to multimodal pediatric analgesia because both strategies are practical components of perioperative pain management, while wound infiltration avoids the need for a neuraxial technique. The combination of local anesthetic and a non-steroidal anti-inflammatory drug also provides analgesia through complementary pharmacologic mechanisms.

The present findings are consistent with the randomized study by Amminnikutty et al., which compared caudal bupivacaine with bupivacaine infiltration plus diclofenac suppository in children undergoing herniotomy. The current study also aligns with the broader literature describing caudal analgesia as an established technique for pediatric infraumbilical surgery and the use of alternative regional and multimodal approaches.

The stratified analyses showed that the observed difference remained statistically significant across the reported age, residential-status, and BMI categories. These analyses should, however, be interpreted cautiously because the sample size was small and the available analysis does not establish prespecified interaction effects or demonstrate that treatment effects differ between subgroups.

CONCLUSION

Among children aged 4–8 years undergoing elective inguinal herniotomy at a single tertiary-care center, bupivacaine wound infiltration combined with rectal diclofenac was associated with a longer duration of postoperative analgesia than caudal bupivacaine alone. Further adequately powered, prospectively registered randomized trials with standardized pediatric pain assessment, explicit allocation concealment and blinding procedures, systematic adverse-event reporting, and clinically relevant secondary outcomes are warranted.

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