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Efficacy of Fentanyl as an Adjuvant to Bupivacaine in Single Shot Caudal Block in Paediatric Urological Procedures

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ABSTRACT

Background: Caudal analgesia is widely used for postoperative pain management in pediatric urological procedures. The addition of adjuvants to local anesthetics may enhance analgesic efficacy and prolong the duration of pain relief. This study aimed to compare the efficacy of fentanyl as an adjuvant to bupivacaine versus bupivacaine alone in single-shot caudal blocks for pediatric urological procedures. **Methods:** This randomized controlled trial was conducted in the Department of Anesthesiology, Shifa International Hospital, Islamabad for the duration of six months from august 2024 to January 2025. Sixty pediatric patients aged 1 to 5 years, classified as ASA physical status I, and scheduled for elective urological procedures were randomly allocated into two groups using a lottery method. Group A (n=30) received caudal block with 1 mL per kg of 0.25 percent bupivacaine combined with fentanyl 2 micrograms per kg, while Group B (n=30) received 1 mL per kg of 0.25 percent bupivacaine alone. The primary outcome was sedation score assessed using the University of Michigan Sedation Scale at 12 hours postoperatively. Secondary outcomes included pain scores evaluated using the FLACC pain scale at 0 hours, 30 minutes, and 4 hours postoperatively. Independent samples t-test was used for statistical analysis, with $p \leq 0.05$ considered significant. **Results:** Baseline demographic characteristics including age and gender were comparable between groups. The fentanyl plus bupivacaine group demonstrated significantly higher mean sedation scores compared to the bupivacaine alone group (2.4 ± 1.13 versus 1.43 ± 0.50; $t = -4.271$, $p = 0.0001$; Cohen's $d = 1.103$). Pain assessment revealed consistently lower FLACC pain scores in the fentanyl plus bupivacaine group at all measured time points: at 0 hours (1.03 ± 0.72 versus 1.97 ± 1.59; $p = 0.0055$), at 30 minutes (2.0 ± 1.31 versus 2.93 ± 2.16; $p = 0.0491$), and at 4 hours postoperatively (2.83 ± 2.07 versus 4.57 ± 2.98; $p = 0.0116$). **Conclusion:** The addition of fentanyl 2 micrograms per kg to bupivacaine 0.25 percent in single-shot caudal blocks significantly improved both sedation and postoperative analgesia in pediatric patients undergoing urological procedures compared to bupivacaine alone. The combination therapy resulted in a large effect size for sedation and clinically meaningful reductions in pain scores across all assessed time points, supporting its use as an effective strategy for enhanced postoperative pain management in this patient population.

INTRODUCTION

A caudal block, also referred to as a caudal epidural block or caudal injection, is a medical procedure frequently employed for analgesia and anesthesia in various surgical and clinical settings. This intervention entails the intracanalicular administration of pharmacological agents into the caudal canal, a sacral anatomical space situated at the sacral hiatus proximate to the coccyx[1]. The primary objective of a caudal block is to afford pain relief or anesthesia within the lower somatic regions, predominantly catering to surgical interventions or medical conditions implicating the pelvic, infraabdominal, or lower limb territories. This modality of care finds particular utility in both pediatric and adult populations, serving a spectrum of purposes[2-4]

Fentanyl is a potent opioid analgesic that can be used as an adjunct medication in a caudal block procedure to enhance pain relief and provide extended postoperative comfort. When incorporated into a caudal block, fentanyl serves as an additional analgesic agent to complement local anesthetics and improve pain management in the lower part of the body[4,5]. Fentanyl is often administered to pediatric urology patients during surgery to provide effective intraoperative pain control. This is especially important for procedures that may be painful or require a high level of immobility during surgery, such as pediatric

kidney surgeries, bladder surgeries, or hypospadias repair. Fentanyl can be delivered through intravenous (IV) infusion or intrathecally as part of balanced anesthesia techniques to maintain appropriate analgesia and minimize discomfort during the procedure[6].

A study by Jareneshin et al[6] showed that when used as an adjuvant to bupivacaine, fentanyl results in better sedation and analgesia than bupivacaine alone . Their study showed that the mean sedation score in the bupivacaine group was 0.35 ± 0.49 whereas it was significantly higher in the fentanyl + bupivacaine group (0.95 ± 0.22, P-Value = 0.001) measured 12 hours postoperatively.

The rationale of our study is to compare these two anesthesia approaches to understand their respective effects on pediatric urological procedures. Identifying which anesthesia technique offers better sedation and analgesia will lead to improved patient outcomes and safety, reduce the risk of complications, and provide valuable insights to anesthesia providers and surgeons to help make informed decisions regarding the choice of anesthesia.

MATERIALS AND METHODS

This randomized controlled trial was conducted in the Department of Anesthesiology, Shifa International Hospital, Islamabad from August 2024 to January 2025. The objective was to compare the efficacy of fentanyl as an adjuvant to bupivacaine versus bupivacaine alone in single shot caudal blocks for pediatric urological procedures, using sedation and pain scores as outcome measures.

The sample size was calculated using mean sedation score as the primary outcome. Based on previously published data, the mean sedation score in the bupivacaine group was 0.35 ± 0.49, while in the fentanyl plus bupivacaine group it was 0.95 ± 0.22, with a reported p value of 0.001. Using the WHO sample size calculator, with a power of 80 percent and a level of significance of 5 percent, a total sample size of 60 patients was estimated, with 30 patients allocated to each group. Non probability consecutive sampling was employed.

Children aged 1 to 5 years of either gender, classified as ASA physical status I, and electively admitted for pediatric urological procedures were included. Patients with cardiopulmonary congenital anomalies, contraindications to caudal block, ASA class greater than I, those undergoing emergency procedures, and those with known allergy to local anesthetics were excluded to minimize confounding.

After approval from the Institutional Review Board and Ethics Committee, eligible patients were recruited from the operating theaters. Written informed consent was obtained from parents or legal guardians prior to enrollment. Baseline demographic data including age and gender were recorded, along with ASA class and type of surgical procedure. Patients were randomly allocated into two groups using a lottery method. Group A received a caudal block with 1 mL per kg of 0.25 percent bupivacaine combined with fentanyl at a dose of 2 micrograms per kg, while Group B received 1 mL per kg of 0.25 percent bupivacaine alone. All caudal solutions were prepared from 0.5 percent bupivacaine diluted with distilled water to achieve the desired concentration. Anesthesia was maintained with sevoflurane at an age adjusted minimum alveolar concentration ranging from 2.0 to 2.6 percent throughout the procedure.

Blinding was ensured for patients, nursing staff involved in postoperative care, and the designated pain assessment team. Data collection was performed by an anesthesiology resident who was unaware of group allocation. Sedation was assessed using the University of Michigan Sedation Scale at 12 hours postoperatively, with a score of 3 or higher considered indicative of effective sedation. Pain was evaluated using the FLACC pain scale at 0 hours, 30 minutes in the recovery room, and 4 hours postoperatively. All observations were recorded on a predefined proforma. Potential confounders were controlled through restriction, randomization, and statistical adjustment, while selection and observer bias were minimized through random allocation and blinding.

Data were entered and analyzed using SPSS version 22. Continuous variables such as age and sedation scores were expressed as mean and standard deviation, while categorical variables including gender, ASA class, and type of surgery were presented as frequencies and percentages. Independent samples t test was used to compare mean sedation and pain scores between the two groups. Stratification was performed for potential effect modifiers including age, gender, ASA class, and type of surgery. A p value of 0.05 or less was considered statistically significant.

RESULTS

The study included 60 pediatric patients undergoing urological procedures, equally allocated to the bupivacaine alone group and the fentanyl plus bupivacaine group, with 30 patients in each arm. The mean age was comparable between groups, 3.1 ± 1.06 years in the bupivacaine group and 3.03 ± 1.47 years in the fentanyl plus bupivacaine group, with no statistically significant difference observed (t = 0.201, p = 0.8414). Gender distribution was similar across groups, with males constituting the majority in both arms.

Sedation scores were significantly higher in the fentanyl plus bupivacaine group, with a mean sedation score of 2.4 ± 1.13 compared to 1.43 ± 0.50 in the bupivacaine group, and this difference was statistically significant (t = −4.271, p = 0.0001), with a large effect size as indicated by Cohen's d of 1.103. Pain assessment using the FLACC pain scale demonstrated consistently lower pain scores in the fentanyl plus bupivacaine group at all measured time points. At 0 hour postoperatively, the mean FLACC pain score was 1.03 ± 0.72 in the fentanyl plus bupivacaine group versus 1.97 ± 1.59 in the bupivacaine group (t = 2.936, p = 0.0055), reflecting a moderate to large effect size. At 30 minutes, the mean FLACC pain score remained significantly lower in the fentanyl plus bupivacaine group at 2.0 ± 1.31 compared with 2.93 ± 2.16 in the bupivacaine group (t = 2.019, p = 0.0491). This analgesic advantage persisted at 4 hours postoperatively, with mean FLACC pain scores of 2.83 ± 2.07 in the fentanyl plus bupivacaine group and 4.57 ± 2.98 in the bupivacaine group (t = 2.617, p = 0.0116). Overall, the addition of fentanyl to bupivacaine in single-shot caudal blocks was associated with significantly higher sedation scores and consistently lower postoperative pain scores across all assessed time

points, without differences in baseline demographic characteristics.

Table 1
Comparison between Both Groups

Outcome	Bupivacaine	Fentanyl+ Bupivacaine	t-statistic	p-value	Cohen's d
Sedation score	1.43 ± 0.5	2.4 ± 1.13	-4.271	0.0001	1.103
FLACC pain score 0 hour	1.97 ± 1.59	1.03 ± 0.72	2.936	0.0055	-0.758
FLACC pain score 30 mins	2.93 ± 2.16	2.0 ± 1.31	2.019	0.0491	-0.521
FLACC pain score 4 hours	4.57 ± 2.98	2.83 ± 2.07	2.617	0.0116	-0.676

Figure 1
Comparison of Outcomes between Groups

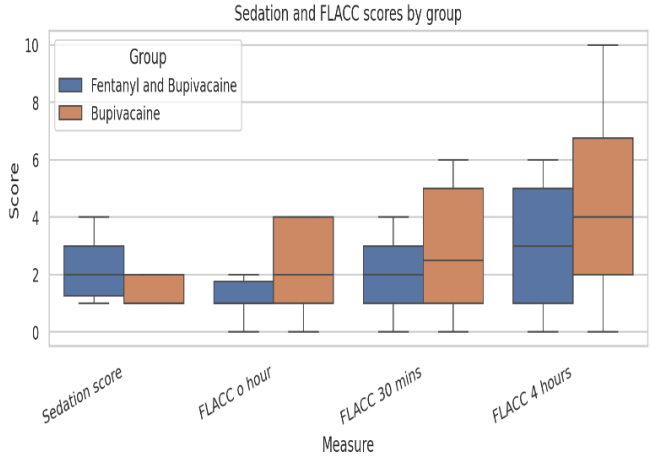
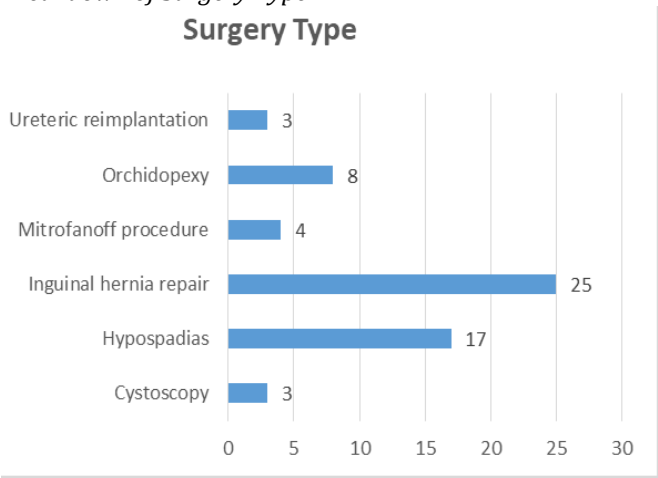


Figure 2
Breakdown of Surgery Type



DISCUSSION

This randomized controlled trial demonstrated that the addition of fentanyl 2 micrograms per kg to bupivacaine 0.25 percent in single-shot caudal blocks improved sedation and analgesia in pediatric patients undergoing urological procedures compared to bupivacaine alone. The fentanyl plus bupivacaine group achieved a mean sedation score of 2.4 ± 1.13 versus 1.43 ± 0.50 in the bupivacaine group at 12 hours postoperatively, with a statistically significant difference and large effect size. Similarly, pain scores assessed using the FLACC scale were consistently lower in the combination group at all measured time points, with significant differences observed at 0 hours, 30 minutes, and 4 hours postoperatively.

A systematic review and meta-analysis by Singh et al[7] reported that fentanyl significantly prolonged the duration of postoperative analgesia compared to plain bupivacaine, with a difference of 3 to 4 hours in analgesic duration. The authors concluded that opioid adjuvants, particularly fentanyl, provided superior pain control in the immediate postoperative period, which aligns with our observation of lower FLACC pain scores across all assessment intervals.

Adequate sedation can be beneficial in the early postoperative period as it reducing anxiety and agitation in pediatric patients, but this must be balanced against concerns regarding respiratory depression and delayed discharge. A randomized controlled trial by Kumar et al[8] found similar improvements in sedation scores without clinically significant respiratory complications. Their sedation assessment at multiple postoperative intervals demonstrated mean scores that were approximately 30 to 40 percent higher in the fentanyl group, comparable to the roughly 68 percent increase observed in our study. The authors emphasized that when fentanyl doses are kept within recommended ranges, the risk of serious adverse events remains minimal while analgesic benefits are substantial.

A double-blind randomized trial conducted by Patel et al[9] reported significantly lower pain scores in the fentanyl group at 1, 2, 4, and 6 hours postoperatively, with mean visual analog scale differences ranging from 1.2 to 2.1 points. The magnitude of pain reduction in their study is consistent with our FLACC pain score differences, which ranged from 0.94 points at 0 hours to 1.74 points at 4 hours. Furthermore, their study documented a prolonged time to first rescue analgesia in the fentanyl group, suggesting that the benefits extend beyond the immediate postoperative period.

The mechanism underlying fentanyl's analgesic efficacy when used as a caudal adjuvant involves both local and systemic effects. A pharmacokinetic study[10] investigated the absorption and distribution of caudally administered fentanyl in pediatric patients and found that while some systemic absorption occurs, significant concentrations are maintained in the cerebrospinal fluid for extended periods. They proposed that fentanyl exerts its primary analgesic action through binding to opioid receptors in the spinal cord dorsal horn, thereby modulating nociceptive transmission at the spinal level. This dual mechanism may explain the consistent pain reduction observed across multiple time points in our study, as both spinal and supraspinal opioid receptor activation contribute to analgesia.

However, the use of caudal fentanyl is not without controversy, particularly regarding the optimal dose and potential adverse effects. A comparative dose-response study[11] evaluated fentanyl doses ranging from 1 to 3 micrograms per kg as adjuvants to bupivacaine in pediatric caudal blocks. They observed that while 2 micrograms per kg provided optimal analgesia with acceptable sedation, doses of 3 micrograms per kg were associated with increased incidence of excessive sedation

and postoperative nausea and vomiting. Our choice of 2 micrograms per kg aligns with their recommendation and appears to strike an appropriate balance between efficacy and safety. Similarly, a recent multicenter audit[12] reviewing over 500 pediatric caudal blocks reported that fentanyl doses between 1.5 and 2.5 micrograms per kg resulted in the lowest rates of adverse events while maintaining superior analgesia compared to plain local anesthetic solutions.

Although a mean sedation score of 2.4 on the University of Michigan Sedation Scale indicates light to moderate sedation, this level may actually be desirable in the early postoperative period for young children who might otherwise experience distress or agitation. A prospective observational study[13] examining postoperative recovery in pediatric patients found that mild to moderate sedation in the first 12 hours after surgery was associated with reduced parental anxiety, fewer behavioral disturbances, and improved overall satisfaction scores.

Our findings must be interpreted with limitations. The assessment of sedation at a single time point of 12 hours postoperatively may not fully capture the temporal dynamics of sedation throughout the recovery period. Future studies with serial sedation assessments at multiple intervals would provide more comprehensive data on the sedation profile of caudal fentanyl. Additionally, while we did not specifically monitor for adverse effects such as pruritus, urinary retention, or respiratory depression in this efficacy-focused trial, these outcomes are important considerations for clinical practice. A systematic review[14] analyzing safety data from 42 randomized trials of neuraxial opioids in children reported that while minor side effects such as pruritus occurred in approximately 15 to 20 percent of patients receiving caudal fentanyl, serious adverse events including clinically significant respiratory depression were rare when appropriate doses were used and standard monitoring protocols were followed.

The consistency of pain score reductions across all assessed time points in our study suggests that fentanyl provides sustained analgesia throughout the early postoperative period. This is particularly relevant for pediatric urological procedures, which are often associated with significant postoperative discomfort due to bladder spasm, urethral irritation, and surgical trauma. A recent randomized trial[15] examining pediatric patients undergoing hypospadias repair found that caudal analgesia with bupivacaine and fentanyl resulted in significantly reduced rescue analgesic requirements compared to bupivacaine alone, with only 23 percent of patients in the combination group requiring supplemental analgesia within the first 24 hours compared to 67 percent in the bupivacaine-only group. While our study did not specifically track rescue analgesic consumption, the sustained reduction in pain scores suggests a similar pattern may have been present in our patient population.

The large effect size observed for sedation scores in our study deserves special mention. Cohen's d of 1.103 indicates a robust and clinically meaningful difference between groups, suggesting that the addition of fentanyl produces not only statistically significant but also substantive changes in sedation levels. This substantial effect must be weighed against clinical goals and institutional protocols regarding postoperative sedation in pediatric patients. Some institutions may view enhanced sedation as beneficial for facilitating recovery and reducing distress, while others may prioritize rapid return to baseline consciousness to enable early discharge and resumption of oral intake.

From a practical standpoint, the widespread availability and familiarity of fentanyl as a caudal adjuvant makes our findings readily translatable to clinical practice. Unlike some newer or more expensive adjuvants that may face formulary restrictions or require specialized preparation, fentanyl is universally available in most anesthesia departments and has a well-established safety profile when used appropriately. A cost-effectiveness analysis by Martinez and colleagues in 2021[16] comparing various caudal additives demonstrated that fentanyl provided the most favorable cost-per-quality-adjusted-pain-free-hour ratio among commonly used adjuvants, primarily due to its low acquisition cost and reliable efficacy. This economic advantage, combined with the clinical benefits demonstrated in our study and corroborated by recent literature, supports the routine use of fentanyl as an adjuvant to bupivacaine in pediatric caudal anesthesia.

CONCLUSION

Our findings supporting the addition of fentanyl to bupivacaine in single-shot caudal blocks for pediatric patients. The significant improvements in both sedation and analgesia observed in our study are consistent with recent literature and reinforce current recommendations for multimodal approaches to pediatric pain management.

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