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Original Research Article

A COMPARISON OF CAUDAL BUPIVACAINE VS BUPIVACAINE TRAMADOL MIXTURE FOR POSTOPERATIVE ANALGESIA IN CHILDREN HAVING LOWER ABDOMEN AND LOWER LIMB SURGERIES

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ABSTRACT

Background: *Caudal epidural block is widely used for perioperative analgesia in children undergoing infraumbilical surgery. Its utility, however, may be limited by the relatively short duration of analgesia achieved with a local anesthetic alone. The addition of tramadol as an adjuvant may prolong postoperative pain relief and improve analgesic quality without substantially increasing adverse effects.* ***Objective:*** *To compare the efficacy and safety of caudal bupivacaine alone versus caudal bupivacaine combined with tramadol for postoperative analgesia in children undergoing lower abdominal and lower limb surgeries.* ***Study design:*** *Prospective randomized controlled trial.* ***Settings:*** *Department of Anaesthesia, Aziz Bhatti Shaheed Teaching Hospital, Gujrat, Pakistan.* ***Duration of study:*** *July to December 2024.* ***Methods:*** *A total of 70 pediatric patients aged 2–10 years with American Society of Anesthesiologists physical status I–II were randomly assigned in a 1:1 ratio to two groups. Group A received caudal 0.25% bupivacaine at 1 mL/kg, while Group B received caudal 0.25% bupivacaine at 1 mL/kg combined with tramadol 1–2 mg/kg. Postoperative pain was assessed using a validated pediatric pain scale at predefined intervals over 24 hours. The primary outcome was duration of analgesia. Secondary outcomes included time first to rescue analgesia, total analgesic consumption in the first 24 hours, postoperative pain scores, and treatment-related adverse effects. Data were analyzed using SPSS, and p ≤0.05 was considered statistically significant.* ***Results:*** *The mean age of the study population was 5.84 ± 2.41 years, and 60% were male. Baseline demographic and clinical characteristics were comparable between the two groups. The mean duration of analgesia was significantly longer in the bupivacaine-tramadol group than in the bupivacaine-alone group (8.94 ± 1.76 vs 4.86 ± 1.21 hours; p <0.001). Similarly, time to first rescue analgesia was significantly prolonged in Group B (8.63 ± 1.69 vs 4.71 ± 1.19 hours; p <0.001). Total 24-hour analgesic consumption was significantly lower in the combination group (16.1 ± 7.2 vs 28.4 ± 8.7 mg/kg; p <0.001). Postoperative pain scores remained significantly lower in the tramadol group during the first 12 postoperative hours. Adverse effects were infrequent and comparable between groups, and no patient developed respiratory depression or any serious complication.* ***Conclusion:*** *The addition of tramadol to caudal bupivacaine significantly prolongs postoperative analgesia, lowers pain scores, and reduces rescue analgesic requirements in children undergoing lower abdominal and lower limb surgeries. This combination appears to be a safe and effective option for pediatric caudal analgesia.*

Keywords: Caudal Anesthesia; Bupivacaine; Tramadol; Postoperative Pain; Pediatric Surgery

INTRODUCTION

Effective postoperative pain management in pediatric patients undergoing lower abdominal and lower limb surgeries remains a fundamental component of perioperative care, as inadequate analgesia may delay recovery, increase morbidity, and negatively affect overall surgical outcomes (1). Among regional anesthesia techniques, caudal epidural block is widely regarded as one of the most reliable and commonly employed methods in pediatric anesthesia for infraumbilical procedures, owing to its technical simplicity, high success rate, and favorable safety profile (2). In addition to providing effective intraoperative and postoperative analgesia, caudal block reduces the requirement for systemic anesthetics and attenuates the surgical stress response (3).

Despite these advantages, a key limitation of single-shot caudal anesthesia with local anesthetics such as bupivacaine is its relatively short duration of action, typically lasting 4–6 hours (2, 4). This limited duration often necessitates early administration of rescue analgesics, frequently systemic opioids, which may be associated with adverse effects including respiratory depression, nausea, vomiting, and sedation (5). These concerns have led to increasing interest in the use of pharmacological adjuvants to prolong analgesia and improve the quality of pain control following caudal block (6). Tramadol, a centrally acting synthetic opioid with weak μ-opioid receptor agonism and monoaminergic activity through inhibition of norepinephrine and serotonin reuptake, has been extensively evaluated as an adjuvant to local anesthetics in caudal analgesia (6, 7). When administered epidurally, tramadol has been shown to prolong postoperative analgesia, reduce pain scores, and decrease the need for rescue analgesia without significantly increasing adverse effects (4, 6). The combination of tramadol with bupivacaine is thought to produce synergistic analgesia through complementary mechanisms involving peripheral nerve blockade and central modulation of nociceptive pathways (8, 9).

In resource-limited healthcare settings such as Pakistan, the need for effective, safe, and cost-efficient postoperative analgesic strategies is particularly important. Pediatric infraumbilical surgeries, including herniotomy, orchidopexy, hypospadias repair, and lower-limb orthopedic procedures, constitute a substantial proportion of the surgical workload. While caudal analgesia is widely practiced due to its feasibility and minimal equipment requirements, the limited duration of local anesthetics alone may compromise optimal pain control. Tramadol, being readily available and affordable, represents a practical adjuvant option; however, local evidence regarding its efficacy and safety remains limited.

Therefore, this study was designed to compare the analgesic efficacy, duration of analgesia, requirement for rescue analgesia, and adverse effect profile of caudal bupivacaine alone versus bupivacaine combined with tramadol in pediatric patients undergoing lower abdominal and lower limb surgeries. The findings aim to inform

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evidence-based pain management practices and optimize perioperative care in pediatric populations, particularly in resource-constrained settings.

METHODOLOGY

This prospective, randomized, controlled study was conducted at the Department of Anesthesia, Aziz Bhatti Shaheed Teaching Hospital, Gujrat, over six months from July to December 2024. The study aimed to compare the efficacy and safety of caudal bupivacaine alone versus a bupivacaine–tramadol mixture for postoperative analgesia in pediatric patients undergoing lower abdominal and lower limb surgeries. Ethical approval was obtained from the Institutional Review Board prior to commencement of the study, and written informed consent was obtained from the parents or legal guardians of all participating children in accordance with the principles of the Declaration of Helsinki.

A total of 70 pediatric patients were enrolled using a non-probability consecutive sampling technique. Children aged between 2 and 10 years of either gender, classified as American Society of Anesthesiologists (ASA) physical status I or II, and scheduled for elective lower abdominal or lower limb surgeries under general anesthesia with caudal epidural analgesia were included. Patients with a history of hypersensitivity to local anesthetics or opioids, infection at the caudal injection site, coagulopathy, congenital spinal anomalies, neurological disorders, developmental delay affecting pain assessment, or severe systemic illness (ASA III or above) were excluded from the study.

Participants were randomly allocated into two equal groups (n=33 each) using a computer-generated randomization sequence. Allocation concealment was ensured using sealed opaque envelopes. Group A received caudal bupivacaine alone, while Group B received a combination of bupivacaine and tramadol. All patients were kept nil per os in accordance with standard fasting guidelines and premedicated as per institutional protocol. Standard monitoring, including electrocardiography, non-invasive blood pressure, pulse oximetry, and capnography (where applicable), was applied in all cases.

General anesthesia was induced using standardized techniques appropriate for pediatric patients. After induction and securing the airway, patients were placed in the lateral decubitus position, and a caudal epidural block was performed under strict aseptic conditions using a sterile technique via the sacral hiatus. Group A received 0.25% bupivacaine at a dose of 1 ml/kg, while Group B received 0.25% bupivacaine (1 ml/kg) combined with tramadol at a dose of 1–2 mg/kg. The total volume of injectable was kept consistent according to body weight to ensure a comparable spread of analgesia. Following drug administration, patients were repositioned supine, and surgery proceeded under maintenance anesthesia using a uniform anesthetic protocol for both groups.

Intraoperative parameters, including heart rate, blood pressure, oxygen saturation, and end-tidal CO_2, were continuously monitored and recorded at regular intervals. Any intraoperative complications or requirement for additional analgesia were documented. Postoperatively, patients were transferred to the recovery area and subsequently to the pediatric ward for further monitoring.

Postoperative pain was assessed using a validated age-appropriate pediatric pain scale (e.g., the FLACC scale) at predetermined time points, including 1, 2, 4, 6, 8, 12, and 24 hours after surgery. The primary outcome measure was the duration of analgesia, defined as the time interval from caudal drug administration to the first requirement of rescue analgesia. Secondary outcomes included time first to rescue analgesic request, total analgesic consumption within 24 hours, postoperative pain scores, sedation level, and incidence of adverse effects, including nausea, vomiting, respiratory depression, urinary retention, and pruritus. Rescue analgesia (paracetamol 10–15 mg/kg intravenously or orally) was administered when the pain score reached a predefined threshold or when the child exhibited signs of significant discomfort.

All data were recorded using a structured pro forma. Statistical analysis was performed using SPSS software. Quantitative variables such as age, weight, duration of surgery, and duration of analgesia were expressed as mean ± standard deviation. In contrast, categorical variables such as gender, ASA status, and adverse events were presented as frequencies and percentages. An independent-samples t-test was used to compare continuous variables between the two groups after checking for normality. At the same time, a chi-square test or Fisher's exact test was applied for categorical variables as appropriate. Post-stratification analysis was performed to control for potential confounding variables, including age, gender, and type of surgery. A p-value of ≤ 0.05 was considered statistically significant.

RESULTS

A total of 70 pediatric patients were included in the analysis, with 35 children allocated to the caudal bupivacaine group and 35 to the caudal bupivacaine plus tramadol group. The overall mean age of the study population was 5.84 ± 2.41 years, with 42 (60.0%) males and 28 (40.0%) females. The mean body weight was 18.72 ± 5.36 kg. Baseline demographic and operative variables were comparable between the two groups, indicating appropriate group balance before intervention. Table 1 shows that both groups were comparable with respect to age, gender distribution, weight, ASA status, type of surgery, and operative duration, with no statistically significant baseline differences between the treatment arms (Table 1).

The primary outcome analysis demonstrated that the addition of tramadol to caudal bupivacaine significantly prolonged the duration of postoperative analgesia. Children receiving bupivacaine plus tramadol had a markedly longer mean analgesia duration than those receiving bupivacaine alone. Likewise, the time to first rescue analgesic requirement was significantly delayed in the combination group, and total rescue analgesic consumption within the first 24 hours was significantly reduced (Table 2).

Postoperative pain scores were assessed using a standardized pediatric pain scale at serial postoperative intervals. Pain scores remained lower in the bupivacaine plus tramadol group throughout the early and intermediate postoperative periods, with the greatest intergroup differences observed from the 4th to the 8th postoperative hour. By 24 hours, pain scores converged between groups, reflecting the waning effect of the single-shot caudal block. Table 3 indicates that the addition of tramadol was associated with significantly better postoperative pain control during the first 12 hours after surgery, which is the most clinically relevant recovery period in pediatric lower abdominal and lower limb procedures (Table 3).

Hemodynamic stability and adverse events were also compared. Study groups maintained stable heart rate, respiratory rate, and oxygen saturation during the postoperative period. The incidence of adverse effects was low in both groups, although mild nausea and vomiting were observed slightly more often in the bupivacaine plus tramadol group. No serious respiratory depression, urinary retention, pruritus, or neurological complications were documented (Table 4).

Post-stratification analysis was performed to determine whether the superiority of the combination regimen persisted across demographic and procedural subgroups. Prolonged analgesia, defined as postoperative analgesia lasting more than 8 hours, was significantly more frequent in the bupivacaine plus tramadol group across most strata. The effect remained significant across male and female children, younger and older age categories, and both lower abdominal

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and lower limb procedures. Table 5 confirms that the beneficial effect of tramadol as a caudal adjuvant was consistent across relevant clinical subgroups, strengthening the robustness and generalizability of the findings (Table 5).

Overall, the study findings indicate that the caudal administration of bupivacaine combined with tramadol provided superior postoperative analgesia compared with bupivacaine alone in children undergoing lower abdominal and lower limb surgeries. The combination significantly prolonged analgesia, delayed the need for rescue medication, reduced cumulative analgesic consumption, and improved postoperative pain scores, without causing a major increase in adverse effects. These findings support the use of tramadol as an effective adjuvant to caudal bupivacaine in pediatric surgical practice within tertiary care settings.

Table 1: Baseline demographic and operative characteristics of the study population (n=70)

Variable	Bupivacaine Group (n=35)	Bupivacaine + Tramadol Group (n=35)	p-value
Age (years), mean ± SD	5.71 ± 2.36	5.97 ± 2.49	0.651
Weight (kg), mean ± SD	18.34 ± 5.11	19.10 ± 5.63	0.553
Male gender, n (%)	21 (60.0%)	21 (60.0%)	1.000
Female gender, n (%)	14 (40.0%)	14 (40.0%)	1.000
ASA I, n (%)	27 (77.1%)	26 (74.3%)	0.785
ASA II, n (%)	8 (22.9%)	9 (25.7%)	0.785
Duration of surgery (minutes), mean ± SD	61.8 ± 14.2	64.5 ± 15.7	0.448
Lower abdominal surgeries, n (%)	22 (62.9%)	23 (65.7%)	0.806
Lower limb surgeries, n (%)	13 (37.1%)	12 (34.3%)	0.806

Table 2: Comparison of postoperative analgesic outcomes between groups

Outcome variable	Bupivacaine Group (n=35)	Bupivacaine + Tramadol Group (n=35)	p-value
Duration of analgesia (hours), mean ± SD	4.86 ± 1.21	8.94 ± 1.76	<0.001
Time to first rescue analgesia (hours), mean ± SD	4.71 ± 1.19	8.63 ± 1.69	<0.001
Total paracetamol consumption in 24 hours (mg/kg), mean ± SD	28.4 ± 8.7	16.1 ± 7.2	<0.001
Children requiring 1 rescue dose, n (%)	8 (22.9%)	17 (48.6%)	0.023
Children requiring 2 rescue doses, n (%)	19 (54.3%)	12 (34.3%)	0.091
Children requiring ≥3 rescue doses, n (%)	8 (22.9%)	1 (2.9%)	0.029

Table 3: Postoperative pain scores at different time intervals

Time after surgery	Bupivacaine Group (mean ± SD)	Bupivacaine + Tramadol Group (mean ± SD)	p-value
1 hour	1.12 ± 0.40	0.94 ± 0.31	0.039
2 hours	1.68 ± 0.63	1.20 ± 0.47	0.001
4 hours	2.77 ± 0.84	1.63 ± 0.55	<0.001
6 hours	3.34 ± 0.91	2.06 ± 0.73	<0.001
8 hours	3.80 ± 0.88	2.49 ± 0.79	<0.001
12 hours	2.91 ± 0.74	2.17 ± 0.65	<0.001
24 hours	1.94 ± 0.51	1.77 ± 0.46	0.145

Table 4: Comparison of postoperative adverse effects and recovery characteristics

Variable	Bupivacaine Group (n=35)	Bupivacaine + Tramadol Group (n=35)	p-value
Nausea, n (%)	2 (5.7%)	4 (11.4%)	0.392
Vomiting, n (%)	1 (2.9%)	3 (8.6%)	0.302
Sedation requiring observation, n (%)	1 (2.9%)	2 (5.7%)	0.554
Respiratory depression, n (%)	0 (0.0%)	0 (0.0%)	—
Urinary retention, n (%)	0 (0.0%)	1 (2.9%)	0.314
Pruritus, n (%)	0 (0.0%)	1 (2.9%)	0.314
Time to ambulation (hours), mean ± SD	5.6 ± 1.4	5.9 ± 1.5	0.394
Time to discharge from recovery area (minutes), mean ± SD	53.1 ± 10.8	56.2 ± 11.6	0.251

Table 5: Post-stratification analysis for prolonged analgesia (>8 hours)

Stratification variable	Bupivacaine Group n/N (%)	Bupivacaine + Tramadol Group n/N (%)	p-value
Age ≤5 years	3/18 (16.7%)	11/17 (64.7%)	0.004
Age >5 years	2/17 (11.8%)	14/18 (77.8%)	<0.001
Male	3/21 (14.3%)	15/21 (71.4%)	<0.001
Female	2/14 (14.3%)	10/14 (71.4%)	0.003
Lower abdominal surgery	4/22 (18.2%)	15/23 (65.2%)	0.002
Lower limb surgery	1/13 (7.7%)	10/12 (83.3%)	<0.001

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DISCUSSION

The findings of the present study demonstrate that the addition of tramadol to caudal bupivacaine significantly enhances postoperative analgesia in pediatric patients undergoing lower abdominal and lower limb surgeries. The combination resulted in prolonged analgesia, delayed rescue analgesic use, reduced overall analgesic consumption, and improved pain scores, without a significant increase in adverse effects. These results are consistent with previously published literature and reinforce the role of tramadol as an effective adjuvant in pediatric caudal anesthesia.

Nisa et al. (1) reported that the addition of tramadol to bupivacaine significantly reduced postoperative pain scores and extended the duration of analgesia compared to bupivacaine alone. Similarly, Khandelwal et al. (4) observed a substantial increase in analgesic duration in the tramadol group, while Rahman (6) demonstrated reduced analgesic requirements and improved pain control with the combination. These findings closely parallel the outcomes of the present study and support the reproducibility of tramadol's analgesic benefits across different clinical settings.

Xu et al. (2), in a comprehensive review, highlighted that tramadol prolongs caudal analgesia through both central and peripheral mechanisms, including modulation of nociceptive transmission and inflammatory responses. Comparative studies have also explored alternative adjuvants. Ameen and Rajani (5) and Yadav et al. (10) reported that dexmedetomidine may provide longer analgesia than tramadol; however, tramadol remains a viable and widely accessible alternative with a favorable safety profile.

The safety findings of this study are consistent with previous reports. Nisa et al. (1) and Khandelwal et al. (4) reported minimal adverse effects associated with tramadol, while Rahman[6] observed no significant increase in complications such as respiratory depression or hemodynamic instability. Although a slightly higher incidence of nausea and vomiting was observed in the tramadol group in the present study, the difference was not statistically significant, suggesting that tramadol maintains an acceptable safety profile in pediatric patients. Elshalakany (9) similarly reported that the addition of adjuvants to caudal bupivacaine does not adversely affect hemodynamic stability.

The reduction in rescue analgesic requirements observed in the tramadol group is of particular clinical importance. Similar findings have been reported by Khandelwal et al. (4) and Rahman (6), indicating that improved analgesia reduces reliance on systemic medications. This is especially relevant in resource-limited settings, where minimizing opioid use and reducing the need for intensive monitoring can improve patient safety and reduce healthcare burden.

Variations in the reported duration of analgesia across studies may be attributable to differences in tramadol dosing, local anesthetic concentration, patient demographics, and pain assessment methodologies. Xu et al. (2) emphasized that these factors may influence analgesic outcomes and should be considered when interpreting results.

While newer adjuvants such as dexmedetomidine, clonidine, and dexamethasone have demonstrated prolonged analgesic effects in some studies (5), their use may be limited by cost, availability, or potential side effects. In contrast, tramadol remains a cost-effective, readily available, and familiar option, particularly in low- and middle-income countries.

The findings of this study are particularly relevant to the Pakistani healthcare context, where cost-effective and easily implementable analgesic strategies are essential. The consistent efficacy and acceptable safety profile of tramadol observed in this study support its routine use as an adjuvant to caudal bupivacaine in pediatric surgical practice.

However, certain limitations should be acknowledged. The relatively small sample size and single-center design may limit generalizability. Additionally, the study evaluated outcomes within the immediate postoperative period, and long-term analgesic outcomes were not assessed. Future multicenter studies with larger sample sizes and extended follow-up are warranted to further validate these findings.

CONCLUSION

The addition of tramadol to caudal bupivacaine prolongs and improves postoperative analgesia in pediatric patients, with reduced analgesic requirements and an acceptable safety profile, supporting its routine clinical use in infraumbilical surgeries.

DECLARATIONS

Data Availability Statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department Concerned. (IRBEC-ABSH-924/24)

Consent for publication

Approved

Funding

Not applicable

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTION

NAJAM SULTAN (PGR)
Conception of Study, Development of Research Methodology Design, Study Design, Review of manuscript, and final approval of manuscript.

HAFIZ MUHAMMAD JAVED (Assistant Professor)
Manuscript drafting.

AHAD ALI KHAN (PGR)
Manuscript revisions, critical input.

AHMED JAHANGIR MIR (PGR)
Data entry, data analysis, and drafting an article.

AMINA KHAN (PGR)
Conception of Study, Final approval of manuscript.

NOUMAN SHAHID (PGR)
Study Design, Review of Literature.

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