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Original Research Article

Comparison of Analgesic Efficacy of Caudal Dexmedetomidine versus Caudal Tramadol with Ropivacaine in Paediatric Infraumbilical Surgeries: A Prospective, Randomised Study

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Conflict of interest: Nil

Abstract

Background: Inadequate postoperative pain management in paediatric patients can lead to adverse physiological and psychological outcomes. Caudal epidural block is a widely accepted regional anaesthetic technique providing effective intraoperative and postoperative analgesia in infraumbilical surgeries. Adjuvants added to local anaesthetics prolong the duration and quality of caudal blockade.

Aims: To compare the postoperative analgesic efficacy, sedation levels, hemodynamic stability, and rescue analgesic requirements of caudal dexmedetomidine versus caudal tramadol when added to 0.25% ropivacaine in paediatric patients undergoing infraumbilical surgeries.

Settings and Design: A hospital-based, prospective, randomized, double-blind comparative study conducted at a tertiary care medical college hospital.

Materials and Methods: Seventy paediatric patients aged 1–8 years of ASA physical status I and II scheduled for elective infraumbilical surgeries were randomly assigned into two groups of 35 each: Group RD (n=35) received caudal 0.25% ropivacaine (1 mL/kg) plus dexmedetomidine (2 µg/kg), and Group RT (n=35) received caudal 0.25% ropivacaine (1 mL/kg) plus preservative-free tramadol (2 mg/kg). Postoperative pain was assessed using the Face, Legs, Activity, Cry, Consolability (FLACC) score, and sedation was evaluated using the Ramsay Sedation Scale (RSS). Rescue analgesia (paracetamol suppository 15 mg/kg) was administered when the FLACC score reached ≥ 4.

Statistical Analysis: Data were analyzed using R software and Microsoft Excel. Continuous variables were evaluated using Student's t-test or Mann-Whitney U test depending on normality, and categorical data were analyzed using the Chi-square test. $P < 0.05$ was considered statistically significant.

Results: Demographic profiles and surgical durations were comparable between the groups ($P > 0.05$). The mean duration of postoperative analgesia was significantly longer in Group RD (613.88 ± 39.28 min) compared to Group RT (462.55 ± 25.35 min; $P < 0.0001$). The mean total number of rescue analgesic doses required in 24 hours was significantly lower in Group RD (2.85 ± 0.36) compared to Group RT (3.28 ± 0.45; $P < 0.0001$). Postoperative Ramsay Sedation Scores were significantly higher in Group RD during the first postoperative hour ($P < 0.05$), representing mild, arousable sedation. Perioperative hemodynamics were stable in both groups without significant adverse effects.

Conclusion: Caudal dexmedetomidine (2 µg/kg) added to 0.25% ropivacaine provides significantly longer duration of postoperative analgesia, superior pain control, lower rescue analgesic consumption, and favourable early postoperative sedation compared to caudal tramadol (2 mg/kg), with a comparable safety profile.

Keywords: Caudal block, Dexmedetomidine, FLACC scale, Infraumbilical surgery, Paediatric analgesia, Ropivacaine, Tramadol.

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Introduction

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. The Society of Paediatric Anaesthesia (SPANA) highlights pain alleviation as a basic human right, regardless of age or treatment setting. Inadequate management of postoperative pain in children can lead to acute physiological distress, disturbed eating and sleep patterns, exaggerated stress responses, and long-term physical or behavioural complications.

Caudal epidural block, introduced by Campbell in 1933, remains the most popular regional technique in paediatric anaesthesia for infraumbilical, lower abdominal, and perineal surgeries. When combined with general anaesthesia, caudal block provides robust analgesia, reduces inhalational anaesthetic and systemic opioid requirements, attenuates surgical stress response, and facilitates smooth emergence. However, single-shot caudal injection with local anaesthetic alone yields analgesia of limited duration.

Ropivacaine, an S-enantiomer amide local anaesthetic, offers distinct advantages for paediatric regional anaesthesia including differential neural block (sensory predominant with minimal motor block) and reduced cardiotoxicity and central nervous system toxicity relative to bupivacaine. To extend the analgesic spectrum of single-shot caudal ropivacaine, various adjuvants have been investigated, including opioids, benzodiazepines, ketamine, neostigmine, and α2-adrenergic agonists.

Dexmedetomidine is a highly selective α2-adrenoceptor agonist with an 8-fold higher affinity for α2-receptors compared to clonidine (α2:α1 ratio 1620:1 vs 220:1). When administered neuro axially, it produces antinociception via spinal dorsal horn hyperpolarization and central locus coeruleus modulation, along with local vasoconstrictive effects that slow systemic drug absorption. Tramadol is a synthetic centrally acting analgesic with a dual mechanism: weak μ-opioid receptor agonism combined with inhibition of neuronal reuptake of norepinephrine and serotonin at the spinal level.

While both drugs are established caudal adjuvants, direct comparative evaluations in paediatric Indian populations regarding their relative analgesic duration, rescue analgesic demand, and sedative/side-effect profiles remain pertinent. Therefore, this prospective, randomized, double-blind study was designed to compare the analgesic efficacy and safety of caudal dexmedetomidine versus caudal tramadol co-administered with 0.25% ropivacaine in children undergoing infraumbilical surgeries.

Materials and Methods

Study Design and Ethical Approval: This hospital-based, prospective, randomized, double-blind comparative study was conducted in the Department of

Anaesthesiology and Critical Care, Jawahar Lal Nehru Medical College and Associated Group of Hospitals, Ajmer, Rajasthan, India. Ethical clearance was formally granted by the Institutional Ethics Committee (IEC Approval No: 04215/Acad-III/MCA/ 2024, dated 28/10/2024). The trial was prospectively registered with the Clinical Trial Registry-India (CTRI/2025/07/090175).

Written informed consent was obtained from parents or legal guardians of all enrolled patients prior to surgery.

Study Population & Sample Size: Seventy paediatric patients aged 1 to 8 years, of American Society of Anaesthesiologists (ASA) physical status I or II, scheduled for elective infraumbilical operations (e.g., herniotomy, orchidopexy, hypospadias repair, and circumcision) were recruited. Sample size was calculated using the formula for comparison of two independent means based on prior published literature:

$$n = 2(Z + Z)^2 \times SD^2 / \Delta^2 \alpha/2 \beta p$$

Assuming a pooled standard deviation (SD) of 78.3 minutes and a clinically meaningful mean difference (Δ) of 55.14 p minutes in block/analgesic duration between groups, a sample size of 32 patients per group was calculated for 80% power and $\alpha = 0.05$. To account for dropouts or protocol deviations, 35 patients per group (total N = 70) were enrolled.

Inclusion Criteria: Children aged 1–8 years, ASA physical status I or II, undergoing elective infraumbilical surgical procedures under general anaesthesia with caudal block.

Exclusion Criteria: Parental refusal, infection at the sacral site, known allergy to study drugs, bleeding/coagulation disorders, developmental delay, pre-existing neurological or spinal disorders, or systemic sepsis.

Randomization and Blinding: Patients were randomly assigned into two equal groups of 35 each using a computer-generated random number table:

- **Group RD (n = 35):** Received caudal 0.25% ropivacaine (1 mL/kg) with dexmedetomidine (2 μg/kg), bringing total volume to 1 mL/kg.
- **Group RT (n = 35):** Received caudal 0.25% ropivacaine (1 mL/kg) with preservative-free

tramadol (2 mg/kg), bringing total volume to 1 mL/kg.

An anaesthesiologist not involved in clinical management or data recording prepared the weight-based drug mixtures in identical syringes. The operating anaesthesiologist performing the block, the surgical team, and the post-anaesthesia care unit (PACU) nursing personnel evaluating pain/sedation were completely blinded to group allocation.

Anaesthesia Protocol and Caudal Injection Technique: All children received intravenous premedication with midazolam (0.05 mg/kg) and glycopyrrolate (0.005–0.01 mg/kg). Anaesthesia was induced with 8% sevoflurane in 100% oxygen. Airway was secured with an appropriate endotracheal tube, and muscle relaxation was maintained with atracurium (0.5 mg/kg loading, 0.1 mg/kg maintenance) under controlled mechanical ventilation using 50% nitrous oxide in oxygen with 1% sevoflurane. Patients were placed in the lateral position, and strict aseptic preparation of the sacral area was performed. The sacral hiatus and cornua were identified by palpation. A 25-gauge short-bevel needle was advanced at a 60° angle to the skin until penetrating the sacrococcygeal ligament ("pop" sensation), then redirected to 30° and advanced 2–3 mm into the sacral canal. After negative aspiration for blood or cerebrospinal fluid (CSF) and confirmation with a positive "whoosh" test (0.5 mL air), the study solution was injected slowly. Surgery was allowed to commence 10 minutes post-block.

Monitoring and Outcome Measures: Vital parameters including heart rate (HR), non-invasive blood pressure (SBP, DBP, MAP), SpO2, and ETCO2 were monitored continuously and recorded at baseline, post-induction, post-block, immediately at incision, and every 10 minutes intraoperatively.

At surgical completion, neuromuscular block was reversed with neostigmine (0.05 mg/kg) and glycopyrrolate (0.008 mg/ kg), and extubation was performed. Patients were transferred to the PACU and evaluated for 24 hours.

Primary Outcome: Duration of analgesia, defined as the time interval from caudal injection to the first instance of FLACC score ≥ 4.

Postoperative Pain: Evaluated using the Face, Legs, Activity, Cry, Consolability (FLACC) observational pain scale (0–10) hourly for 8 hours, then 2-hourly up to 24 hours.

Rescue Analgesia: Paracetamol suppository (15 mg/kg) was administered whenever FLACC score was ≥ 4. Total rescue doses in 24 hours were recorded.

Sedation Score: Evaluated using the Ramsay Sedation Scale (RSS) at extubation (0 min), 30 min, 1 h, 2 h, 3 h, and hourly up to 8 hours.

Adverse Events: Bradycardia, hypotension, respiratory depression, PONV, shivering, urinary retention, or fever were recorded.

Results

All 70 randomized patients successfully completed the study protocol without any block failures or technical dropouts. The two groups were statistically comparable regarding baseline demographic parameters and surgical durations (P > 0.05, Table 1).

Table 1: Baseline Demographic Profile and Duration of Surgery

Parameter	Group RD (n = 35)	Group RT (n = 35)	P-value
Age (years) (Mean ± SD)	4.07 ± 1.56	3.52 ± 1.62	0.1525 (NS)
Gender (Male / Female) [n (%)]	27 (77.14%) / 8 (22.86%)	30 (85.71%) / 5 (14.29%)	0.3600 (NS)
Body Weight (kg) (Mean ± SD)	12.95 ± 3.09	12.33 ± 3.08	0.4034 (NS)
Duration of Surgery (min) (Mean ± SD)	40.57 ± 12.99	40.43 ± 12.03	0.9628 (NS)

Hemodynamic Parameters: Baseline and intraoperative vitals including Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure, and Oxygen Saturation (SpO2) remained stable throughout the surgical procedure. No statistically significant differences were noted between Group RD and Group RT at any time point (P > 0.05, Table 2).

Table 2: Comparison of Preoperative and Baseline Vitals

Vital Parameter	Group RD (Mean ± SD)	Group RT (Mean ± SD)	P-value
Heart Rate (beats/min)	104.03 ± 12.59	102.54 ± 7.23	> 0.05 (NS)
Systolic Blood Pressure (mmHg)	94.86 ± 6.53	94.60 ± 9.02	> 0.05 (NS)
Diastolic Blood Pressure (mmHg)	58.86 ± 8.43	58.83 ± 8.82	> 0.05 (NS)
Mean Arterial Pressure (mmHg)	70.83 ± 7.34	70.71 ± 8.50	> 0.05 (NS)
Oxygen Saturation SpO2 (%)	99.40 ± 0.65	99.71 ± 1.05	> 0.05 (NS)

Postoperative Analgesia and Pain Scores: The primary endpoint—mean duration of postoperative analgesia—was significantly longer in Group RD (613.88 ± 39.28 minutes; range 510–665 min) compared to Group RT (462.55 ± 25.35 minutes; range 402–525 min) (t = 20.473, P < 0.0001, Table 3).

Table 3: Comparison of Duration of Analgesia and Breakthrough Pain Distribution

Outcome Metric	Group RD (n = 35)	Group RT (n = 35)	P-value
Mean Duration of Analgesia (min)	**613.88 ± 39.28**	**462.55 ± 25.35**	**< 0.0001 (S)**
Patients with FLACC > 4 at 6th Hour [n (%)]	0 (0.0%)	3 (7.5%)	0.239 (NS)
Patients with FLACC > 4 at 7th Hour [n (%)]	0 (0.0%)	13 (32.5%)	0.0003 (S)
Patients with FLACC > 4 at 8th Hour [n (%)]	6 (15.0%)	21 (52.5%)	0.0009 (S)
Patients with FLACC > 4 at 10th Hour [n (%)]	29 (72.5%)	4 (10.0%)	0.0001 (S)

No child in Group RD experienced pain (FLACC > 4) up to the 7th postoperative hour.

In contrast, breakthrough pain in Group RT commenced at 6 hours (7.5%) and rose sharply to 32.5% at 7 hours and 52.5% at 8 hours (P < 0.001). Group RD showed peak pain occurrence at 10 hours (72.5%).

Rescue Analgesic Requirements: The overall demand for postoperative rescue analgesics over 24 hours was significantly lower in Group RD compared to Group RT. The mean total number of doses required was 2.85 ± 0.36 in Group RD versus 3.28 ± 0.45 in Group RT (P < 0.0001, Table 4).

Table 4: 24-Hour Rescue Analgesic Consumption

Rescue Analgesic Doses	Group RD (n = 35)	Group RT (n = 35)	P-value
Patients requiring 2 doses [n (%)]	6 (15.0%)	0 (0.0%)	0.039 (S)
Patients requiring 3 doses [n (%)]	34 (85.0%)	29 (72.5%)	0.274 (NS)
Patients requiring 4 doses [n (%)]	0 (0.0%)	11 (27.5%)	0.0001 (S)
Total Cumulative Doses (24 h)	114 doses	131 doses	—
Mean Doses per Patient ± SD	**2.85 ± 0.36**	**3.28 ± 0.45**	**< 0.0001 (S)**

Postoperative Sedation Profile: Mean Ramsay Sedation Scores (RSS) were significantly higher in Group RD compared to Group RT during the initial post extubation period: 1.80 ± 0.99 vs. 1.13 ± 0.33 at 0 min (P = 0.0001), 1.33 ± 0.76 vs. 0.88 ± 0.56 at 30 min (P = 0.0035), and 0.65 ± 0.74 vs. 0.28 ± 0.51 at 1 hour (P = 0.0110). Sedation in the dexmedetomidine group was easily arousable, comfortable, and resolved fully by 3 hours without causing airway obstruction or delayed recovery.

Adverse Effects: Incidence of postoperative adverse effects was minimal and non-significant between groups (P > 0.05). Fever was reported in 1 patient (2.86%) in Group RD and 2 patients (5.71%) in Group RT (P = 0.558). Postoperative nausea and vomiting (PONV) occurred in 1 patient (2.86%) in Group RT and 0 in Group RD (P = 0.315). No patient in either group developed bradycardia, hypotension, respiratory depression, pruritus, or urinary retention.

Discussion

Effective management of postoperative pain in paediatric surgical patients is crucial for promoting physiological recovery, reducing stress hormone activation, and preventing emergence agitation. Single-shot caudal epidural blockade using longacting local anaesthetics such as ropivacaine is widely employed for infraumbilical surgeries. However, plain ropivacaine provides analgesia lasting only 4 to 6 hours. Co-administration of adjuvants significantly enhances the quality and duration of caudal neural block.

In this prospective randomized trial, we demonstrated that adding dexmedetomidine (2 μg/kg) to 0.25% ropivacaine prolonged the mean duration of postoperative analgesia to 613.88 ± 39.28 minutes (~10.2 hours), compared to 462.55 ± 25.35 minutes (~7.7 hours) with caudal tramadol (2 mg/kg) (P < 0.0001). This represents a highly significant clinical extension of analgesia exceeding 2.5 hours. Our findings are consistent with several previous clinical investigations. Badole et al. reported a mean analgesic duration of 718.00 ± 100.06 min with caudal dexmedetomidine versus 467.33 ± 68.94 min with caudal tramadol (P < 0.001). Senthamizh et al. observed durations of 750.29 ± 71.29 min in the dexmedetomidine group versus 674.2 ± 78.38 min in the tramadol group (P = 0.0002). Similarly, Gupta et al. (780.29 ± 71.21 min vs 654.20 ± 78.38 min), Yadav et al. (718 ± 31.88 min vs 653 ± 33.59 min), and Kapadia et al. (792 ± 168 min vs 414 ± 72 min) established the clear analgesic superiority of caudal dexmedetomidine over caudal tramadol.

The neurobiological basis for dexmedetomidine's prolonged efficacy lies in its high α2-adrenoceptor selectivity. Neuraxial α2-agonists suppress nociceptive neurotransmission in the superficial spinal dorsal horn (lamina II, substantia gelatinosa) by hyperpolarizing postsynaptic interneurons and inhibiting presynaptic release of Substance P and

glutamate. Furthermore, local α2-mediated vasoconstriction delays local anaesthetic vascular clearance, while direct inhibition of hyperpolarization-activated cation currents in C-fibres enhances sensory blockade. In contrast, tramadol acts via weak μ-opioid receptor agonism combined with spinal serotonin and norepinephrine reuptake inhibition, yielding effective but shorter-lasting analgesia.

In our study, total 24-hour rescue analgesic consumption was significantly lower in the dexmedetomidine group (mean 2.85 doses) compared to the tramadol group (mean 3.28 doses; $P < 0.0001$). Furthermore, 27.5% of patients in the tramadol group required 4 rescue doses, whereas no patient in the dexmedetomidine group required more than 3 doses.

Dexmedetomidine also produced a distinct, favorable sedation profile during the early postoperative period (first 1 hour). This sedative effect—mediated by central α2-adrenoceptors in the locus coeruleus—produces a tranquil, easily arousable sleep state mirroring natural non-REM sleep. This significantly reduces emergence delirium following sevoflurane anaesthesia without depressing respiratory drive or delaying emergence time.

Both study drug regimens demonstrated high hemodynamic stability. No patient developed clinically significant bradycardia, hypotension, or respiratory depression. Adverse effects such as fever and PONV were rare and comparable between groups, proving the clinical safety of both adjuvants.

Study Limitations

1. Sample size was limited to 70 patients, which may obscure low-frequency adverse events.
2. The study population was restricted to children aged 1–8 years undergoing elective infraumbilical surgeries.
3. Single fixed weight-based doses were evaluated without comparative dose-ranging analysis.
4. Observational FLACC scale, while validated, relies on observer scoring.

Conclusion

Caudal administration of dexmedetomidine (2 μg/kg) with 0.25% ropivacaine provides significantly longer postoperative analgesia, delayed onset of breakthrough pain, lower 24-hour rescue analgesic requirements, and superior early postoperative sedation compared to caudal tramadol (2 mg/kg) with 0.25% ropivacaine in paediatric infraumbilical surgeries. Both adjuvants demonstrate excellent safety and hemodynamic stability. Therefore, caudal dexmedetomidine is a highly effective and desirable adjuvant to ropivacaine for paediatric postoperative pain management.

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