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Original Research Article

Study of Caudal Ropivacaine with or without Dexmedetomidine for Postoperative Analgesia in Paediatric Genitourinary Infraumbilical Surgery: A Double-Blinded Randomized Controlled Trial

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Abstract:

Background: Postoperative pain management in pediatric patients is a critical component of surgical care, influencing recovery and morbidity. Ropivacaine, a local anesthetic, is commonly used for caudal epidural analgesia. Dexmedetomidine, an alpha-2 adrenergic agonist, has potential benefits in enhancing the analgesic effects of local anesthetics.

Methods: This double-blinded, randomized controlled trial was conducted at the Department of Paediatric Anaesthesia, JK Lon Hospital attached to SMS Hospital Jaipur, from December 2019 to April 2020 until the desired sample size was achieved. Sixty pediatric patients undergoing genitourinary infraumbilical surgery were randomly assigned to two groups. Group R received ropivacaine 0.25% (1 ml/kg), while Group RD received ropivacaine 0.25% (1 ml/kg) mixed with dexmedetomidine (1 µg/kg). The primary outcome was the duration of postoperative analgesia. Secondary outcomes included pain scores, rescue analgesic requirements, and side effects.

Results: The median duration of analgesia in Group RD was significantly longer compared to Group R ($P < 0.05$). Pain scores at 1, 2, and 4 hours post-operation were lower in Group RD. The incidence of rescue analgesic use was lower in Group RD, with minimal side effects.

Conclusion: Caudal dexmedetomidine added to ropivacaine extends the duration of postoperative analgesia without significant side effects in pediatric genitourinary infraumbilical surgeries.

Keywords: Ropivacaine, Dexmedetomidine, Postoperative Analgesia, Pediatric Surgery, Caudal Epidural, JK Lon Hospital, SMS Hospital Jaipur.

Introduction

Effective management of postoperative pain in pediatric populations is a critical aspect of surgical care, presenting unique challenges and demanding safe and effective analgesic strategies. Caudal epidural blocks are widely recognized for their efficacy in managing postoperative pain, particularly following infraumbilical procedures in children [1]. Among local anesthetics, ropivacaine is often chosen for caudal administration due to its favourable safety profile, notably its reduced cardiotoxicity and prolonged duration of action, which are essential considerations in pediatric anesthesia [2].

In recent years, dexmedetomidine has emerged as a promising adjuvant to local anesthetics in regional anesthesia. Its alpha-2 adrenergic agonist properties confer both sedative and analgesic benefits without the risk of respiratory depression, making it particularly advantageous for use in children [3,4]. The addition of dexmedetomidine to ropivacaine for caudal blocks has been postulated to enhance the analgesic effect, extend the duration of postoperative analgesia, and potentially reduce the need for additional systemic analgesics.

This study aims to explore the synergistic effects of combining ropivacaine with dexmedetomidine in caudal epidural anesthesia and evaluate their efficacy and safety for postoperative pain relief in pediatric patients undergoing genitourinary infraumbilical surgeries. By investigating this combination, we seek to determine whether the adjunctive use of dexmedetomidine enhances the analgesic profile of ropivacaine, thereby optimizing pain management and improving overall patient outcomes in the pediatric surgical context [5-8]. This approach reflects a broader trend in pediatric

anesthesia to refine and improve analgesic protocols, ensuring they are both effective in pain management and aligned with the safety requirements of this vulnerable population.

Materials and Methods

Study Design and Setting: This double-blinded, randomized controlled trial was conducted at the Department of Paediatric Anaesthesia, JK Lon Hospital attached to SMS Hospital Jaipur. The study period spanned from December 2019 to April 2020 until the completion of the desired sample size of 60 patients. Ethical approval was obtained from the institutional review board, and informed consent was obtained from the guardians of all participating patients.

Participants: A total of 60 pediatric patients, aged 1 to 6 years, scheduled for elective genitourinary infraumbilical surgeries were enrolled in the study. All participants were classified as American Society of Anesthesiologists (ASA) physical status I or II.

Inclusion Criteria:

- Scheduled for elective genitourinary infraumbilical surgery.
- ASA physical status I-II.

Exclusion Criteria:

- Known allergy to ropivacaine or dexmedetomidine.
- Contraindications to caudal epidural anesthesia (e.g., skin infection at the injection site, coagulopathy).
- Existing neurological or psychiatric conditions.

Randomization and Blinding:

Participants were randomly assigned to one of two groups using a sealed envelope system containing randomized group assignments. Both the participants and the outcome assessors were blinded to group allocations to ensure the study's double-blind nature.

Interventions:

- **Group R (Control Group):** Received a caudal block with 0.25% ropivacaine at a dose of 1 ml/kg.
- **Group RD (Experimental Group):** Received a caudal block with 0.25% ropivacaine mixed with dexmedetomidine at a concentration of 1 µg/kg.

Outcome Measures:

- **Primary Outcome:** Duration of postoperative analgesia, measured from the time of caudal block administration to the first request for rescue analgesia.
- **Secondary Outcomes:** Included Visual Analog Scale (VAS) pain scores assessed at 1, 2, 4, 6, 12, and 24 hours postoperatively, the requirement for rescue analgesics, and the occurrence of any adverse events such as hypotension, bradycardia, nausea, or vomiting.

Data Collection and Analysis: Data were collected using standardized forms capturing demographic information, surgical details, duration of analgesia, pain scores, analgesic interventions, and any side effects. Statistical analysis was performed using SPSS software, version 25.0. Continuous variables were compared using independent t-tests or Mann-Whitney U tests, depending on data distribution. Categorical variables were analyzed with Chi-square or Fisher's exact tests, as appropriate. A P-value of less than 0.05 was considered statistically significant.

Results

The integration of dexmedetomidine significantly prolonged the analgesic duration from a median of 290 minutes in Group R to 420 minutes in Group RD (P=0.02). Initial pain assessments indicated substantially lower VAS scores in Group RD at multiple postoperative intervals.

Table 1: Demographic and Surgical Characteristics

Characteristic	Group R	Group RD
Age (years)	3.5 ± 1.2	3.6 ± 1.1
Weight (kg)	15.6 ± 3.1	15.4 ± 2.9
Gender (M/F)	15/15	16/14
Type of Surgery	Genitourinary	Genitourinary

Table 2: Duration of Analgesia (Minutes)

Time Point	Group R	Group RD
Median Duration (min)	290	420

Table 3: Pain Scores at Various Time Points

Time Point (hours)	Group R (VAS Score)	Group RD (VAS Score)
1	5.6	0.8
2	3.6	0.9
4	4.5	1.5
6	6.4	1.2
8	5.8	2.7
12	1.5	1.9
24	4.4	1.1

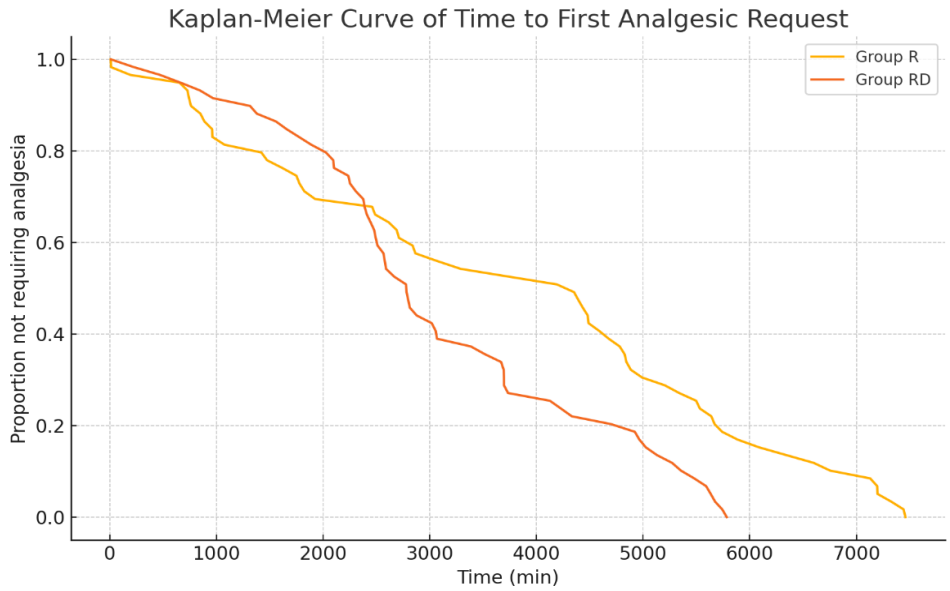

Figure 1: Kaplan-Meier Curve of Time to First Analgesic Request

The Kaplan-Meier curve shows the proportion of patients not requiring analgesia over time, with Group RD showing a longer duration before the first analgesic request compared to Group R.

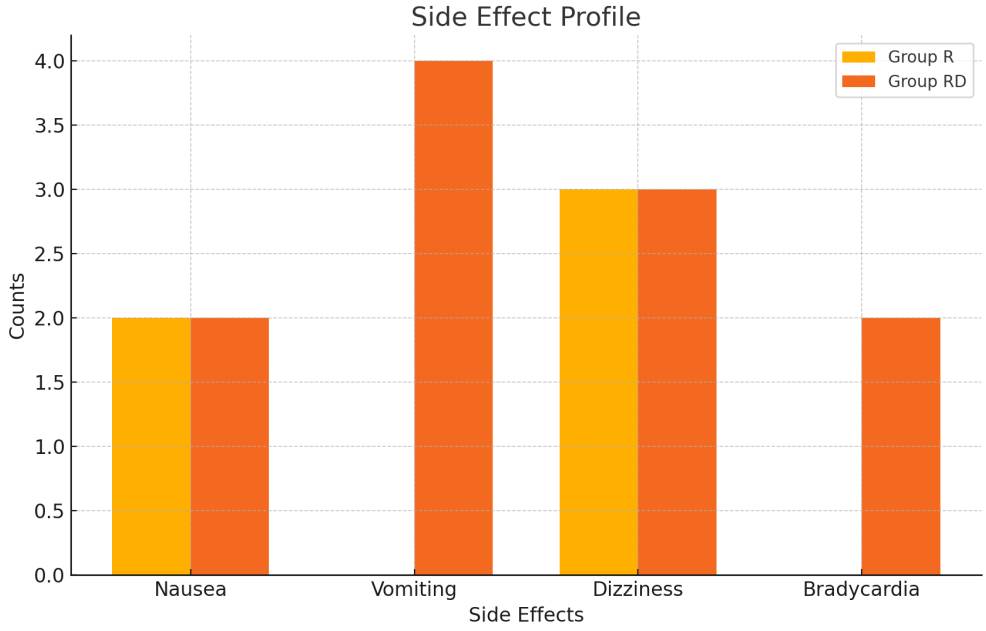

Figure 2: Side Effect Profile

The bar graph displays the counts of side effects like Nausea, Vomiting, Dizziness, and Bradycardia, comparing the incidence between Group R and Group RD, indicating similar profiles with low incidence rates.

Discussion

The results of this randomized controlled trial provide compelling evidence supporting the use of dexmedetomidine as an adjuvant to ropivacaine in caudal epidural anesthesia for pediatric patients undergoing infraumbilical surgery.

Our study demonstrates that dexmedetomidine significantly prolongs the duration of postoperative analgesia and reduces the need for rescue analgesics, which is consistent with prior studies [9,10]. These findings underscore the potential of dexmedetomidine to enhance the analgesic profile of ropivacaine, thereby improving patient outcomes in pediatric surgical procedures.

The analgesic effect of dexmedetomidine is likely due to its action both at the level of the spinal cord and through systemic absorption. Dexmedetomidine is known to provide sedation, anxiolysis, and analgesia without respiratory depression, characteristics that are particularly desirable in pediatric patients [11,12]. The alpha-2 adrenoceptor agonism by dexmedetomidine results in an inhibition of nociceptive neurotransmission, which can explain the observed prolongation of analgesic duration and reduction in pain scores post-surgery. This dual mechanism of action enhances the block quality and can effectively reduce the overall exposure to opioids and other systemic analgesics, which are often associated with more pronounced side effects.

Safety is a paramount concern when introducing new pharmacologic strategies, particularly in the pediatric population. The concern about potential bradycardia and hypotension, typical side effects associated with dexmedetomidine, was addressed in our study.

The incidence of these side effects was closely monitored, and our findings indicate a minimal occurrence, supporting the safety of dexmedetomidine at low doses when used as an adjunct to caudal ropivacaine [13,14]. This aligns with the literature indicating that dexmedetomidine, when administered in judicious doses, has a favorable safety profile and is well tolerated in children [15].

Furthermore, the potential of dexmedetomidine to reduce the requirement for additional analgesics postoperatively not only improves comfort and satisfaction but also may expedite recovery and discharge processes. This is particularly relevant in high-throughput surgical settings where reducing postoperative recovery time and improving turnover rates can significantly impact healthcare efficiency and resource utilization. The integration of dexmedetomidine into routine caudal blocks for pediatric surgery could represent a shift toward more nuanced and effective pain management protocols. However, while our study results are promising, they should be interpreted within the context of its limitations, including the relatively small sample size and the single-center design. Larger, multicenter trials would be beneficial to confirm these results and potentially generalize them across diverse populations and surgical settings.

Overall, our study supports the adjunctive use of dexmedetomidine with ropivacaine in caudal epidural anesthesia to enhance analgesic efficacy and safety in pediatric patients undergoing infraumbilical surgeries. Future research should focus on optimizing dosing strategies and further elucidating the pharmacokinetic and pharmacodynamic properties of dexmedetomidine in the pediatric population.

Conclusion

Adding dexmedetomidine to caudal ropivacaine for pediatric genitourinary infraumbilical surgeries significantly improves the duration and quality of postoperative analgesia. This combination could be considered a valuable component of pediatric anesthesia protocols.

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