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Research Article

EXPLORING ANALGESIC EFFICACY OF DEXMEDETOMIDINE AND CLONIDINE AS ADJUVANTS IN CAUDAL EPIDURAL BLOCK WITH 0.2% ROPIVACAINE FOR PEDIATRIC LOWER ABDOMINAL SURGERIES

MANOJ KUMAR GUPTA[1], SANJAYA KUMAR GUPTA[2], VIKRAM SINGH RATHORE[3]*, DIVYA CHANDRA[4]

[1]Department of Anaesthesiology, Indian Naval Hospital Ship Sanjivani, Kochi, Kerala, India. [2]Department of Anaesthesiology, Military Hospital, Prayagraj, Uttar Pradesh, India. [3]Department of Anaesthesiology, Uttar Pradesh University of Medical Sciences, Etawah, Uttar Pradesh, India. [4]Department of Anaesthesiology, SMBT Institute of Medical Sciences and Research Centre, Nashik, Maharashtra, India. *Corresponding author: Vikram Singh Rathore; Email: vikram2012.mmc@gmail.com

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ABSTRACT

Objectives: Effective post-operative pain management is crucial in pediatric anesthesia. Challenges such as distinguishing pain from hunger or fear in younger children and concerns about respiratory depression with opioid use have often resulted in inadequate pain control in this population. Recent studies have highlighted the importance of addressing pediatric pain with the same seriousness as in adults, as pain in children can lead to similar physiological and psychological consequences. This prospective, randomized study aimed to compare the efficacy and safety of caudal ropivacaine with dexmedetomidine versus clonidine for post-operative analgesia in pediatric patients undergoing lower abdominal surgeries. In addition, we evaluated hemodynamic and respiratory changes in both treatment groups and monitored for any complications.

Methods: A comparative prospective study was conducted involving 100 American Society of Anaesthesiologists status I or II male patients aged 2–8 years undergoing lower abdominal surgeries from January 2012 to December 2013. Patients were randomly assigned to two groups and received caudal epidural analgesia following general anesthesia induction. Group A received 0.2% ropivacaine (1 mL/kg) plus clonidine 1 μg/kg, while Group B received 0.2% ropivacaine (1 mL/kg) plus dexmedetomidine 1 μg/kg. Intraoperative monitoring included heart rate (HR), mean arterial pressure (MAP), oxygen saturation, electrocardiogram, and end-tidal carbon dioxide levels. Post-operative sedation scores and Visual Analog Scale scores for pain relief were recorded.

Results: Statistical analysis using the Statistical Package for the Social Sciences release 12.0 showed a significant increase in HR and MAP at intubation, which declined after caudal block. There was a decrease in HR and MAP from baseline to minimum, but no intervention was required. Both groups exhibited similar post-operative sedation levels, with a significant increase in duration of post-operative analgesia in Group B.

Conclusion: In conclusion, as a caudal adjuvant to 0.2% ropivacaine, dexmedetomidine at a dosage of 1 μg/kg provided significantly longer post-operative analgesia and improved hemodynamic stability compared to clonidine 1μg/kg, without excessive sedation or major side effects.

Keywords: Analgesia, Pain management, Clonidine, Dexmedetomidine, Caudal anesthesia.

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INTRODUCTION

Effective perioperative pain management is essential for optimal anesthesia practice. Inadequate control of post-operative pain can lead to adverse acute effects such as physiological and psychological complications as well as long-term consequences such as delayed recovery and the potential development of chronic pain, particularly in pediatric patients [1]. Adequate relief of acute post-operative pain is now widely recognized as a fundamental aspect of pediatric anesthesia practice. However, achieving satisfactory post-operative pain relief in children can be challenging due to communication difficulties, especially with ill children, making pain assessment problematic. Distinguishing pain from other sensations like hunger or fear in younger children, coupled with concerns about the differing pain responses of children compared to adults and the potential for opioid-induced respiratory depression, has often resulted in suboptimal pain management in pediatric patients [2].

Recent studies have highlighted that pain can induce similar psychological and physiological complications in children as it does in adults. Regional anesthesia techniques, particularly in combination with general anesthesia (GA), have become integral to multimodal pain management strategies in children, offering excellent post-operative pain relief. Among these techniques, caudal epidural analgesia stands out as one of the most commonly used, safe, and reliable regional blocks in pediatric anesthesia, providing expected levels of blockade [3]. Caudal epidural analgesia effectively delivers intra- and post-operative analgesia for procedures involving lower abdominal, urological, and lower limb surgeries. Its gradual offset typically extends analgesia beyond the surgical duration, facilitating smooth recovery and effective post-operative pain control [4]. In ambulatory surgery settings, caudal epidural analgesia is particularly advantageous, reducing analgesic requirements and enabling early discharge.

However, the efficacy of caudal epidural analgesia hinges on the duration of action of the local anesthetic used. While the use of ropivacaine through the caudal route is established in pediatric anesthesia practice, its main drawback is its short duration of action after a single injection [5]. Indwelling caudal catheters, though effective in prolonging analgesia, are not widely favored due to the risk of infection and catheter migration. Prolonging caudal block duration through a single-shot technique can be achieved by adding various adjuncts such as epinephrine, ketamine, and opioids [4]. Alpha-2 adrenergic agonists, a recent addition to the list of adjuvants, have shown promise. Clonidine, an alpha-2 adrenergic agonist, when used

epidurally, extends sensory block more than motor block, possibly through potassium channel opening and subsequent hyperpolarization rather than its alpha-2 agonist effect [6]. It also mitigates the immune stress and cytokine response to pain [7]. However, epidural clonidine can lead to undesirable side effects such as bradycardia, hypotension, dry mouth, and sedation [8]. Dexmedetomidine, a newer centrally acting alpha-2 selective agonist, offers enhanced selectivity compared to clonidine and has demonstrated reduced intraoperative anesthetic and post-operative analgesic requirements, along with prolonged sensory and motor blockade in adult studies [9].

We conducted a prospective, randomized study to compare the efficacy and safety of caudal ropivacaine with dexmedetomidine versus clonidine in providing post-operative analgesia in children undergoing lower abdominal surgeries. In addition, we assessed the hemodynamic and respiratory changes in both groups while monitoring for complications.

METHODS

This prospective, randomized, double-blind comparative study was conducted between January 2012 and December 2013 after obtaining approval from the Institutional Ethics Committee and written informed consent from the parents or legal guardians of all participants. A total of 100 male pediatric patients, aged 2–8 years, with American Society of Anaesthesiologists (ASA) physical status I or II, scheduled for elective lower abdominal surgeries under GA with caudal epidural analgesia, were enrolled.

Inclusion criteria comprised male children aged 2–8 years, ASA physical status I or II, undergoing elective lower abdominal surgeries. Exclusion criteria included known hypersensitivity or allergy to study drugs, coagulopathy, local infection at the caudal injection site, and developmental delays or neurological conditions affecting the reliability of pain assessment.

A pilot study was conducted before the main trial to estimate the required sample size. Based on the pilot data, it was determined that a minimum of 50 patients per group was required to detect a clinically significant difference in the duration of post-operative analgesia between groups, with a power of 80% and a significance level of 5% (α=0.05). Therefore, a total of 100 patients were included, with 50 patients allocated to each group. Randomization was carried out using a computer-generated random number table, and allocation concealment was ensured using sealed opaque envelopes.

Participants were randomly assigned into two equal groups: Group A received 0.2% ropivacaine combined with clonidine 1 μg/kg and Group B received 0.2% ropivacaine combined with dexmedetomidine 1 μg/kg, with the total volume standardized to 1 mL/kg [10]. All personnel involved in perioperative care, data collection, and outcome assessment were blinded to group allocation.

Baseline parameters including age, weight, heart rate (HR), mean arterial pressure (MAP), respiratory rate (RR), oxygen saturation (SpO_2), and findings from systemic examination were recorded. Pre-operative investigations were conducted, and intravenous premedication was administered upon arrival in the operating theater. Intraoperative monitoring included continuous electrocardiogram, HR, MAP, SpO_2, and end-tidal CO_2, with measurements taken at baseline, after induction, after intubation, after the caudal block, and every 10 min thereafter. Bradycardia and hypotension, defined as a >30% fall from baseline, were managed with intravenous fluids and/or pharmacological agents as needed. Post-operative monitoring included HR, MAP, RR, and SpO_2 at defined intervals. Sedation and pain scores were recorded using validated, age-appropriate scales, and rescue analgesia was administered for Visual Analog Scale scores >3. Any complications, such as respiratory depression, nausea, vomiting, and urinary retention, were documented.

Statistical analysis

The Statistical Package for the Social Sciences version 12.0 was employed for analysis, with numerical variables presented as mean and standard deviation. Student's unpaired t-test was used for normally distributed continuous outcome variables, with $p<0.05$ considered significant.

RESULTS

Demographic characteristics were comparable between groups (Table 1).

HR and MAP increased at intubation but decreased post-caudal, with no significant between-group differences (Table 2).

Post-operative sedation scores were similar, with no significant group differences observed (Table 3).

There is no significant difference in post-operative respiratory rate in both the groups (Fig.1). Group B exhibited significantly longer post-operative analgesia duration compared to Group A (Fig. 2).Incidence of complications was minimal and comparable between groups (Fig. 3).

DISCUSSION

Caudal epidural analgesia remains one of the most commonly employed regional techniques for pediatric lower abdominal surgeries due to its relative safety and simplicity. However, its primary limitation lies in the relatively short duration of action of local anesthetics, such as ropivacaine. Although ropivacaine is preferred over bupivacaine because of its lower cardiotoxicity and motor block incidence, its analgesic effect wears off within a few hours postoperatively. The incorporation of adjuvants into caudal blocks has been explored extensively to overcome this limitation, with α2-adrenoceptor agonists such as clonidine and dexmedetomidine emerging as valuable adjuncts.

Our study aimed to evaluate and compare the efficacy and safety of clonidine and dexmedetomidine as adjuvants to 0.2% ropivacaine in pediatric patients aged 2–8 years undergoing elective lower abdominal surgeries. The study was designed as a prospective, randomized, and double-blinded clinical trial to eliminate bias and ensure accurate assessment. The results demonstrated that dexmedetomidine significantly prolonged the duration of post-operative analgesia without increasing the incidence of side effects or compromising hemodynamic stability, suggesting that it may be a superior adjuvant to clonidine in this context.

We enrolled 100 male patients in this study, with the aim of maintaining homogeneity, as most surgical procedures involved pathologies specific to the male genitourinary system (e.g., hydrocele, orchidopexy, and hypospadias repair). This choice also helped reduce confounding variables related to gender differences in pain perception and hormonal influence.

The hemodynamic responses in both groups followed a similar pattern. An initial rise in HR and MAP was observed following intubation, which subsequently decreased after the administration of the caudal block. The lowest HR was recorded around 33–35 min postoperatively in both groups, and the lowest MAP values were observed at approximately

Table 1: Demographic variables and duration of surgery

Variables	Group A (n=100)	Group B (n=100)	p-value
Age (years) mean±SD	5.12±1.95	4.78±1.72	0.18
Weight (kgs) mean±SD	16.97±5.67	17.81±4.39	0.91
ASA PS (I/II)	51/49	48/52	-
Duration of surgery (minutes)	112.65±23.47	106.92±26.75	0.14

Data expressed is in mean±standard deviation. *P*<0.05=significant

Table 2: Comparison of hemodynamic variables at different periods

Timeline	Variable	Group A (n=100) Mean±SD	Group B (n=100) Mean±SD	p-value
Baseline	Heart rate (Per Mins)	108.21±12.02	105.87±9.81	0.18
	Mean atrial pressure (in mm Hg)	81.92±7.15	82.13±6.97	0.92
After intubation	Heart rate (Per Mins)	123.94±13.27	122.11±11.02	0.45
	Mean atrial pressure (in mmHg)	87.21±5.12	86.97±4.75	0.91
After caudal	Heart rate (Per Mins)	120.35±15.12	121.91±13.78	0.43
	Mean atrial pressure (in mmHg)	86.38±4.68	85.99±4.25	0.31
Lowest value intraoperatively	Heart rate (Per Mins)	89.67±6.21	92.01±7.09	0.29
	Mean atrial pressure (in mmHg)	75.68±11.83	78.02±8.57	0.21

Data are expressed in mean±SD. *P*<0.05=Significant

Table 3: Comparison of post-operative sedation score

Time line	Group A (n=100) Mean±SD	Group B (n=100) Mean±SD	p-value
1 h	2.07±0.62	2.33±0.48	0.19
2 h	1.55±0.13	1.57±0.30	0.19
3 h	1.49±0.09	1.54±0.25	0.36
4 h	1.01±0.17	1.05±0.15	0.14
6 h	1.02±0.05	1.01±0.03	0.08

Data are expressed in mean±SD. *P*<0.05=Significant

41–43 min, indicating the onset of the peak pharmacological effects of the alpha-2 agonists. However, the decrease in HR and MAP from baseline was <30% in both groups and did not warrant any active intervention. These results are consistent with the findings of Gupta and Pratap [11], who also noted that caudal administration of 2 μg/kg clonidine or dexmedetomidine with ropivacaine induced mild but manageable bradycardia and hypotension, particularly within the first 15 min after injection. Their study attributed the early peak of cardiovascular depression to the higher doses of alpha-2 agonists used, which may explain the relatively more stable readings observed in our study with the lower 1 μg/kg dose. The pharmacodynamic properties of alpha-2 agonists explain the observed hemodynamic changes. Both clonidine and dexmedetomidine exert their action by inhibiting the sympathetic nervous system through presynaptic and central alpha-2 receptor stimulation. When administered neuraxially, these agents reduce sympathetic outflow by inhibiting norepinephrine release at the spinal and medullary levels. This results in bradycardia and decreased blood pressure, although without a significant impact on tissue perfusion when used in clinically appropriate doses.

Post-operative sedation is a concern when using alpha-2 agonists due to their central nervous system (CNS) depressant effects. However, in our study, the sedation scores remained within an acceptable range in both groups throughout the initial 6-h observation period. Children were either calm and alert or drowsy but easily arousable. No episodes of excessive sedation, irritability, or respiratory depression were observed. Similar findings were reported by Gupta and Pratap [11], who found that dexmedetomidine offers a unique sedative profile characterized by ease of arousability and lack of respiratory compromise. In addition, Anand *et al*. [12] also concluded that dexmedetomidine provided a high quality of sedation without deep unresponsiveness, which is desirable in pediatric patients for easier post-operative assessment and faster recovery.

From a mechanistic perspective, the analgesic effects of α2-agonists are attributed to their action on inwardly rectifying G-protein-gated potassium channels and inhibition of voltage-gated calcium channels. This leads to neuronal hyperpolarization and reduced excitability of afferent nociceptive fibers. Moreover, the decreased neurotransmitter release impairs the propagation of pain signals in the spinal cord, thereby enhancing analgesia. Notably, these effects are achieved without significant interference with higher CNS functions, especially at the doses used in our study, thereby sparing the child from excessive sedation.

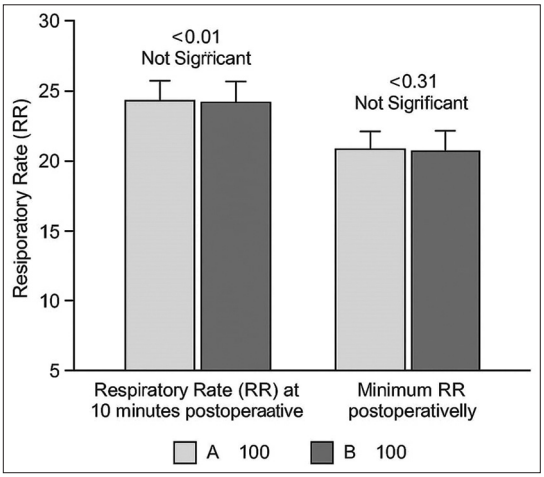

Fig. 1: Post-operative respiratory rate

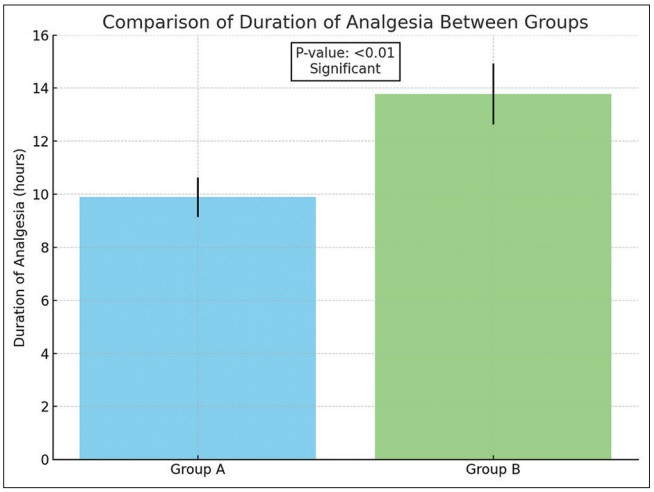

Fig. 2: Comparison of post-operative analgesia between both groups

The most significant finding of our study was the prolonged duration of post-operative analgesia observed in the dexmedetomidine group compared to the clonidine group. The mean duration of analgesia was 13.78±1.15 h in Group B versus 9.57±0.86 h in Group A, a statistically significant difference. These results are in concordance with multiple previous studies. Hennawy *et al*., [13] compared 1 μg/kg doses of both clonidine and dexmedetomidine added to 0.25% bupivacaine for caudal block in children and found significantly longer analgesia in the dexmedetomidine group (14.16±1.65 vs. 11.24±2.48 h), similar to Koul *et al*. [14] on addition, clonidine to bupivacaine in caudal analgesia increases post-operative analgesia. Similarly, Neogi *et al*. [15] and Gupta and Pratap [11] also reported superior analgesic durations with dexmedetomidine, even at higher doses. These findings reinforce the

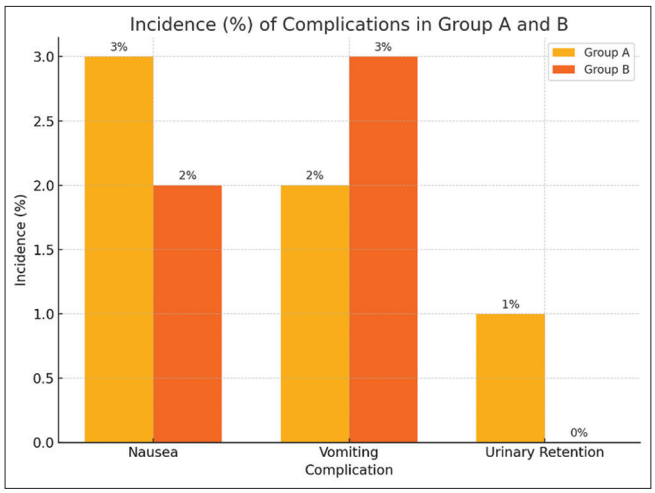

Fig. 3: Comparison of complications

efficacy of dexmedetomidine in providing extended post-operative comfort. Joshi *et al.* [16] show the incidence of vomiting is increased in the clonidine group, but in our study incidence of vomiting is higher in the dexmedetomidine but nausea is more in the clonidine group. In contrast to Sagar *et al.* [17] in which no difference in the mean duration of analgesia in both dexmedetomidine and clonidine group.

CONCLUSION

Our study demonstrates that the addition of dexmedetomidine (1 µg/kg) to 0.2% ropivacaine in caudal epidural blocks provides significantly longer post-operative analgesia compared to clonidine (1 µg/kg), while maintaining similar hemodynamic and respiratory stability. Dexmedetomidine produced no additional sedation or complications compared to clonidine, suggesting that it is not only effective but also safe for use in the pediatric population.

AUTHORS' CONTRIBUTION

All authors contributed to manuscript preparation.

CONFLICTS OF INTEREST

No conflict of interest.

AUTHORS FUNDING

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