ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 05 | May - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A RANDOMIZED DOUBLE BLIND CONTROL STUDY OF EFFICACY OF DEXMEDETOMIDINE AS AN ADJUVANT WITH LEVOBUPIVACAINE V/S LEVOBUPIVACAINE ALONE IN CAUDAL BLOCK IN PAEDIATRIC PATIENTS

Anaesthesiology

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ABSTRACT

This study aims to compare the efficacy of caudal analgesia using levobupivacaine alone versus levobupivacaine combined with dexmedetomidine in pediatric patients undergoing subumbilical surgeries. This study was designed as a prospective, randomized, double-blind clinical trial conducted on 50 pediatric patients aged 1-8 years with American Society of Anesthesiologists (ASA) physical status I and II. This study demonstrates that the addition of dexmedetomidine to levobupivacaine in caudal blocks significantly enhances postoperative analgesia, prolongs pain relief, and improves sedation while maintaining hemodynamic stability in pediatric patients undergoing subumbilical surgeries.

KEYWORDS

Caudal Anesthesia, Dexmedetomidine, FLACC Scale, Levobupivacaine, Pain Score, Post-operative Pain, Ramsay Sedation Scale, Rescue Analgesia

INTRODUCTION

Postoperative pain is a critical concern in pediatric patients, often leading to significant discomfort, stress responses, and delayed recovery if not managed effectively. Caudal epidural anesthesia is a commonly used regional anesthesia technique for children undergoing lower abdominal and lower limb surgeries. While local anesthetics such as levobupivacaine provide effective pain relief, their duration is limited, requiring additional analgesic strategies. Dexmedetomidine [1], an alpha-2 adrenergic agonist, has gained attention as a potential adjuvant due to its sedative, analgesic, and sympatholytic properties. This study aims to compare the efficacy of caudal analgesia using levobupivacaine alone versus levobupivacaine combined with dexmedetomidine in pediatric patients undergoing subumbilical surgeries.

MATERIALS & METHODS

This study was designed as a prospective, randomized, double-blind clinical trial conducted on 50 pediatric patients aged 1-8 years with American Society of Anesthesiologists (ASA) physical status I and II. Patients scheduled for elective subumbilical surgeries were randomly assigned to one of two groups:

- Group L (n=25): Received caudal levobupivacaine (0.25%) 0.5 ml/kg.
- Group LD (n=25): Received caudal levobupivacaine (0.25%) 0.5 ml/kg with dexmedetomidine (0.5 µg/kg).

Pain scores assessed using the FLACC (Face, Legs, Activity, Cry, Consolability) scale, sedation levels using the Ramsay Sedation Scale, and adverse effects were recorded at baseline, postoperatively at regular intervals. The primary endpoint was the duration of analgesia, defined as the time from caudal drug administration to the first requirement of rescue analgesia (FLACC score ≥ 4). The secondary endpoints included hemodynamic stability, sedation levels, and incidence of adverse effects such as nausea, vomiting, respiratory depression, or urinary retention.

Data was analyzed using computer software, statistical package for social sciences (SPSS) version 10. Mean value and standard Deviation was used for quantitative data. Frequency and percentage were used for the qualitative data. Chi-square test was employed for the comparison of two independent qualitative normally distributed variables. Student t- test was employed for the comparison of two independent quantitative normally distributed variables. P- value > 0.05 was considered statistically non- significant. P-value < 0.05 was considered statistically significant and p-value <0.001 was considered statistically highly significant.

RESULTS

The study results demonstrated that Group LD (levobupivacaine with dexmedetomidine) exhibited significantly prolonged analgesia compared to Group L (levobupivacaine alone). The total duration of analgesia was 537.60 ± 199.36 minutes (table 1) in Group LD, significantly longer than 205.20 ± 129.81 minutes in Group L ($p < 0.001$).

Table 1 Comparison Of Duration Of Analgesia And Time Of First Rescue Analgesia

Category	Group L (Mean ± SD)	Group LD (Mean ± SD)	F value	p-value
Total duration of analgesia (min)	205.20 ± 129.81	537.60 ± 199.36	48.81	<0.001
Time of First Rescue Analgesia (min)	720.00 ± 0.00	720.00 ± 0.00		
Number of rescue analgesic doses	1.00 ± 0.00	1.00 ± 0.00		

Group LD showed better pain control, with significantly lower FLACC scores (table 2) at 2 and 3 hours postoperatively compared to Group L ($p = 0.004$ and $p = 0.009$, respectively). The requirement for rescue analgesia was delayed in Group LD, reflecting superior and prolonged pain relief.

Table 2 Comparison Of Postoperative For Pain {Face, Legs, Activity, Cry And Consolability (FLACC) Score During Post-operative Period}

Time Period	Group L (Mean ± SD)	Group LD (Mean ± SD)	F	Sig.
FLACC 30 min	0.00 ± 0.00	0.00 ± 0.00		
FLACC 1 hr	0.12 ± 0.33	0.00 ± 0.00	3.273	0.077
FLACC 2 hr	0.28 ± 0.46	0.00 ± 0.00	9.333	0.004
FLACC 3 hr	0.32 ± 0.48	0.04 ± 0.20	7.350	0.009
FLACC 6 hr	0.92 ± 0.91	0.72 ± 0.84	0.651	0.424
FLACC 12 hr	3.28 ± 0.74	3.40 ± 0.82	0.298	0.588

Patients in Group LD demonstrated more stable hemodynamic parameters intraoperatively and postoperatively. The addition of dexmedetomidine led to lower heart rates and blood pressures at various time intervals, indicating its sympatholytic effect. Heart rate was consistently lower in Group LD, with a significant reduction from 5 minutes post-caudal administration and continuing throughout the intraoperative and postoperative periods ($p < 0.001$).

The sedation scores (figure 1) in Group LD were significantly higher than in Group L, ensuring improved postoperative comfort and reduced agitation without excessive sedation. Patients in Group LD exhibited better sedation scores at 30 minutes, 1 hour, and 2 hours postoperatively, which contributed to smoother recovery without delayed emergence from anesthesia.

No significant adverse effects such as respiratory depression,

hypotension, nausea, vomiting, or urinary retention were observed in either group. Both groups tolerated the anesthesia well, with no reported complications.

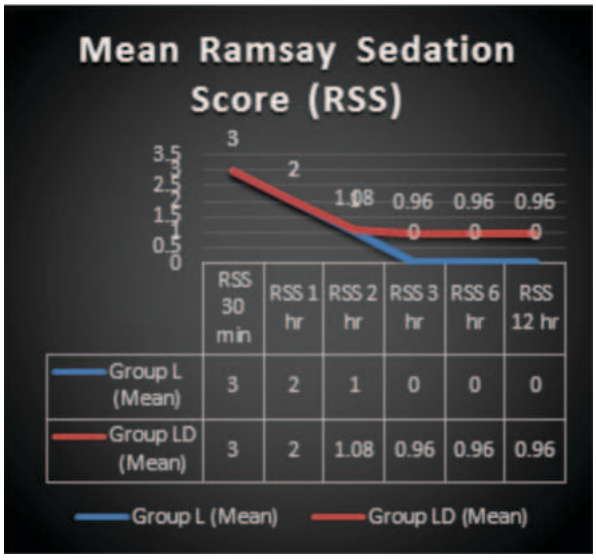

Figure 1: Mean Ramsay Sedation Score (RSS) at Different Time Intervals During Postoperative Period

DISCUSSION

Caudal epidural analgesia is most common, dependable, and safe method in pediatric anesthesia that can provide satisfactory analgesia for a variety of infra-umbilical surgeries. The main drawback of caudal block is the shorter duration of analgesia after a single injection. The use of repeated doses or infusions of local anesthetics through caudal catheter is not common in clinical practice due to risk of infection. So, prolongation of single shot caudal analgesia technique has been accomplished by the use of different adjuvants with local anesthetics. The findings of this study are discussed below, in comparison with similar research studies conducted by Indian authors and other international studies.

FLACC Score During Postoperative Period

The outcomes are analyzed in three main categories: Face, Legs, Activity, Cry, and Consolability (FLACC) score during the postoperative period, total duration of analgesia, time of first rescue analgesia, number of rescue analgesic doses, and Ramsay Sedation Score (RSS).

At 30 minutes, there was no significant difference between the two groups, with both groups having a FLACC score of 0.00 ± 0.00, suggesting that both treatments provided equivalent immediate postoperative pain relief. This is consistent with previous studies where the addition of dexmedetomidine to local anesthetics did not show immediate improvement in pain scores immediately after surgery (Verma et al., 2019) [2]. The immediate absence of pain may be attributed to the aesthetic effect of levobupivacaine, which could mask the need for additional analgesia.

At 1 hour, Group L had a slightly higher FLACC score (0.12 ± 0.33), while Group LD had a FLACC score of 0.00 ± 0.00, with a p-value of 0.077 (F = 3.273). The difference, though not statistically significant, suggests a trend toward better pain control with the addition of dexmedetomidine. A study by Kumar et al. (2020) [3] observed that the addition of dexmedetomidine to a local aesthetic provided a more sustained analgesic effect, which may explain the lower FLACC score observed in Group LD at this time point.

At 2 hours, there was a significant difference between the groups (p = 0.004, F = 9.333), with Group LD having a FLACC score of 0.00 ± 0.00 compared to 0.28 ± 0.46 in Group L. This result aligns with findings from Bharti et al. (2018) [4], who reported that dexmedetomidine significantly prolonged analgesia in paediatric patients when added to levobupivacaine in caudal block. The significant reduction in pain scores in Group LD at this interval supports the hypothesis that dexmedetomidine prolongs the effects of local anaesthetics.

At 3 hours, the difference between the two groups remained significant (p = 0.009, F = 7.350), with Group LD having a FLACC score of 0.04 ± 0.20 compared to 0.32 ± 0.48 in Group L. These results suggest that dexmedetomidine not only prolongs analgesia but also reduces the need for additional analgesic interventions during the early postoperative period. The findings corroborate those of Choudhury et al. (2017) who reported similar effects in a cohort of paediatric patients receiving a combination of levobupivacaine and dexmedetomidine in caudal blocks.

However, at 6 hours, the FLACC scores between the two groups (0.92 ± 0.91 for Group L and 0.72 ± 0.84 for Group LD) were not significantly different, as indicated by the p-value of 0.424 (F = 0.651). This finding suggests that the prolonged analgesic effect of dexmedetomidine diminishes over time, and at later intervals, the difference in pain relief between the groups becomes less pronounced. Vats et al. (2016) [5] similarly found that while dexmedetomidine prolonged analgesia at earlier intervals, its effect wore off after a few hours.

At 12 hours, the pain scores were very similar in both groups, with Group L showing a FLACC score of 3.28 ± 0.74 and Group LD showing a score of 3.40 ± 0.82, and the p-value was 0.588 (F = 0.298). This indicates no significant difference in pain levels between the two groups at this later stage, supporting the notion that the benefits of dexmedetomidine as an adjuvant in the caudal block wear off within a day after surgery. This finding is consistent with Jaiswal et al. (2017) [6] who found that the advantage of adding dexmedetomidine to levobupivacaine gradually diminished after the first few hour's post-surgery.

Total Duration of Analgesia, First Rescue Analgesia, and Number of Rescue Analgesic Doses.

The total duration of analgesia was significantly longer in Group LD, with a mean of 537.60 ± 199.36 minutes compared to 205.20 ± 129.81 minutes in Group L, with an F-value of 48.81 and a p-value of <0.001. This data supports the efficacy of dexmedetomidine in prolonging the duration of analgesia in pediatric patients, as previously demonstrated by Hossain et al. (2019) [7] , who observed that dexmedetomidine significantly prolonged the analgesic effect of levobupivacaine in pediatric caudal blocks. The prolonged analgesia in Group LD is likely due to the synergistic effect of dexmedetomidine, which not only enhances local aesthetic effects but also provides additional central analgesic effects through its action on the α2-adrenergic receptors in the spinal cord (Eldor et al., 2020) [8].

Both groups had identical times of first rescue analgesia (720.00 ± 0.00 minutes), suggesting that both treatments delayed the need for rescue analgesia until the maximum time duration (12 hours). This may be due to the long-lasting effect of the drugs used in both groups, especially in paediatric patients where the pharmacokinetics may be prolonged due to developmental factors. Furthermore, the number of rescue analgesic doses was identical in both groups (1.00 ± 0.00), indicating that no additional doses of analgesics were required within the observed period. This further suggests that both caudal blocks were effective in managing postoperative pain for the duration of the study.

Ramsay Sedation Score (RSS)

The Ramsay Sedation Score (RSS) was used to assess the sedation levels of patients after surgery. For 30 minutes, the scores were identical in both groups (3.00 ± 0.00), indicating no sedation at this early stage. However, at 1 hour, there was no significant difference in sedation between the two groups, as indicated by the identical RSS scores (2.00 ± 0.00) in both groups.

At 2 hours, there was a slight difference between the groups (1.00 ± 0.00 in Group L and 1.08 ± 0.28 in Group LD), but the difference was not statistically significant (p = 0.155; F = 2.087). The results suggest that dexmedetomidine, though effective in prolonging analgesia, does not significantly alter sedation levels in pediatric patients.

At 3, 6, and 12 hours, the RSS scores remained identical in Group L (0.00 ± 0.00) and were slightly elevated in Group LD (0.96 ± 0.20). The significant increase in sedation in Group LD compared to Group L, especially at the later time points, suggests that dexmedetomidine may have a mild sedative effect that persists over time. This is consistent with studies by Gholipour et al. (2018) [9] who found that the addition of dexmedetomidine to local anesthetics in pediatric caudal blocks resulted in increased sedation scores without causing any adverse effects.

CONCLUSION

This study demonstrates that the addition of dexmedetomidine to levobupivacaine in caudal blocks significantly enhances postoperative analgesia, prolongs pain relief, and improves sedation while maintaining hemodynamic stability in pediatric patients undergoing subumbilical surgeries. The combination of dexmedetomidine with levobupivacaine proves to be a safe and effective approach for caudal analgesia in pediatric anesthesia. Further large-scale, multicenter studies are recommended to confirm these findings and establish optimal dosing strategies.

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