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Research Article

A Comparative Study Between Caudal Levobupivacaine and Levobupivacaine with Clonidine as An Adjuvant for Infraumbilical Surgery in Paediatric Patients at Tertiary Care center

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ABSTRACT

Background: Effective perioperative pain management in paediatric patients is essential to reduce physiological stress and improve postoperative recovery. Caudal epidural analgesia is widely used for infraumbilical surgeries; however, its duration is often limited when local anaesthetics are used alone. The addition of adjuvants such as clonidine may enhance analgesic efficacy and prolong duration.
Aim: To compare the efficacy of caudal levobupivacaine alone with levobupivacaine combined with clonidine for perioperative analgesia in paediatric patients undergoing infraumbilical surgeries.
Methods: This prospective randomized study included **60 ASA I and II paediatric patients** aged 1–12 years, divided into two groups (n=30 each). Group A received **0.25% levobupivacaine (1 ml/kg)**, while Group B received **0.25% levobupivacaine (1 ml/kg) with clonidine 1 µg/kg**. Hemodynamic parameters were monitored intraoperatively. Postoperative pain was assessed using the **FLACC scale**, and the time to first rescue analgesic, total analgesic requirement, and side effects were recorded.
Results: Baseline characteristics were comparable between groups ($p>0.05$). Group B showed significantly prolonged duration of analgesia, with a longer time to first rescue analgesic (**23.29 ± 2.67 hours**) compared to Group A (**11.0 ± 5.21 hours**) ($p<0.001$). Postoperative FLACC scores were significantly lower in Group B at 2, 6, 12, and 18 hours ($p<0.001$). Rescue analgesic requirement was reduced in Group B, with only 70% requiring analgesia compared to 100% in Group A ($p=0.001$). Hemodynamic parameters remained stable in both groups, although Group B demonstrated better attenuation of heart rate response.
Conclusion: The addition of clonidine to levobupivacaine in caudal analgesia significantly prolongs analgesic duration, reduces postoperative pain, and decreases analgesic requirements without causing significant adverse effects. It is a safe and effective adjuvant for paediatric infraumbilical surgeries.

Keywords*: Caudal analgesia, Levobupivacaine, Clonidine, Paediatric anaesthesia, FLACC score, Postoperative analgesia, Infraumbilical surgery.*

INTRODUCTION

Pain management in paediatric patients undergoing surgical procedures is a crucial component of perioperative care, as inadequate analgesia can lead to significant physiological and behavioural disturbances. Children often exhibit altered pain responses, including anxiety, irritability, and delayed recovery, which may adversely affect postoperative outcomes [1]. Effective pain control not only improves patient comfort but also reduces stress response, facilitates early mobilization, and enhances overall recovery [2].

Caudal epidural analgesia is one of the most commonly used regional anaesthetic techniques in paediatric patients for infraumbilical surgeries. It is widely accepted due to its simplicity, safety, and effectiveness in providing intraoperative

and postoperative analgesia [3]. However, one of the major limitations of caudal analgesia using local anaesthetics alone is the relatively short duration of analgesia, which may result in early postoperative pain and discomfort [4].

To overcome this limitation, various adjuvants have been added to local anaesthetics to prolong the duration and improve the quality of analgesia. Among these, clonidine, an α2-adrenergic agonist, has gained popularity due to its ability to enhance analgesic efficacy without causing significant respiratory depression [5]. Clonidine acts by inhibiting nociceptive transmission at the spinal cord level and has been shown to prolong the duration of caudal analgesia when combined with local anaesthetics [6].

Several studies have demonstrated that the addition of clonidine to local anaesthetics significantly increases the duration of postoperative analgesia and reduces the requirement of rescue analgesics in paediatric patients [7]. It also provides better haemodynamic stability and sedation without major adverse effects, making it a suitable adjunct in paediatric anaesthesia [8].

Levobupivacaine, a safer S-enantiomer of bupivacaine, is widely used in caudal blocks due to its favourable safety profile with reduced cardiotoxicity and neurotoxicity compared to racemic bupivacaine. It provides effective analgesia with minimal side effects, making it an ideal choice for paediatric regional anaesthesia [9].

Despite the known benefits of both levobupivacaine and clonidine, there is a need to evaluate their combined efficacy in terms of analgesic duration, pain control, and side effect profile in comparison to levobupivacaine alone. Previous studies using various α2 agonists as adjuvants have shown improved analgesic outcomes, but variability exists depending on drug combinations and dosages [10].

Hence, the present study was undertaken to compare the efficacy of caudal levobupivacaine alone with levobupivacaine combined with clonidine in paediatric patients undergoing infraumbilical surgeries, with emphasis on intraoperative and postoperative analgesia, haemodynamic stability, and requirement of rescue analgesics.

The present study was undertaken with the aim of comparing the efficacy of caudal levobupivacaine alone and levobupivacaine with clonidine as an adjuvant for perioperative analgesia in paediatric patients undergoing infraumbilical surgeries. The objectives were to evaluate and compare intraoperative and postoperative analgesic efficacy of both regimens, assess the duration of effective analgesia, determine the time to first rescue analgesic and total analgesic requirement, analyse haemodynamic parameters, and identify any associated side effects. The justification for this study lies in the need for prolonged and effective postoperative pain relief in children, as caudal analgesia with local anaesthetics alone often has limited duration, leading to early postoperative discomfort. The addition of clonidine may enhance and prolong analgesic effects without significant adverse outcomes, thereby improving patient comfort and recovery. The findings of this study are expected to provide evidence for optimizing analgesic protocols in paediatric anaesthesia, promoting safer and more effective pain management strategies. In the future, the results may contribute to the development of standardized guidelines for the use of adjuvants in caudal blocks, encourage wider clinical adoption of combination techniques, and support further large-scale studies to establish long-term safety and efficacy in diverse paediatric populations.

MATERIALS AND METHODOLOGY

This study was conducted as a **prospective randomized comparative study** after obtaining approval from the Institutional Ethics Committee and written informed consent from the parents or guardians of the participating children. The study included a total of **60 paediatric patients** aged between **1 year and 12 years**, belonging to **American Society of Anaesthesiologists (ASA) physical status I and II**, who were scheduled for **infraumbilical surgeries** at a tertiary care centre.

The patients were randomly allocated into two equal groups of **30 patients each** using a randomization method.

- **Group A** received **0.25% levobupivacaine (1 ml/kg) with 1 ml normal saline**.
- **Group B** received **0.25% levobupivacaine (1 ml/kg) with clonidine 1 µg/kg diluted with normal saline to make a total volume of 1 ml**.

Inclusion Criteria: Patients aged 1–12 years of either sex, belonging to ASA grade I and II, undergoing infraumbilical surgeries, and whose parents provided written informed consent were included in the study.

Exclusion Criteria: Patients with infection at the site of caudal block, sacral anomalies, bleeding disorders, known allergy to study drugs, pre-existing neurological diseases, mental retardation, or those whose parents did not consent were excluded.

A detailed **pre-anaesthetic evaluation** was performed one day prior to surgery, including history, clinical examination, and relevant investigations such as haemoglobin, blood sugar, blood urea, platelet count, and ECG when indicated. All patients were kept **nil per oral for 6 hours** prior to surgery.

In the operating theatre, standard monitoring including **electrocardiography (ECG), non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), and heart rate (HR)** was instituted. An intravenous line was secured, and Ringer lactate solution was administered according to the Holliday-Segar formula. Premedication was given with **glycopyrrolate 0.004 mg/kg intravenously**.

General anaesthesia was induced with **propofol (2–3 mg/kg)** and **atracurium (0.5 mg/kg)** to facilitate airway management, which was achieved using either a laryngeal mask airway or endotracheal tube as per the anaesthesiologist's discretion. Anaesthesia was maintained with **100% oxygen, sevoflurane, and intermittent doses of muscle relaxant** with controlled ventilation.

The **caudal block** was performed in the **left lateral decubitus position** using a **22G short bevel needle** by the loss-of-resistance technique. After confirming negative aspiration for blood and cerebrospinal fluid, the study drug was administered as per group allocation.

Vital parameters including **heart rate, blood pressure, respiratory rate, and SpO_2** were recorded at baseline, during caudal block, at **3, 6, and 10 minutes**, and subsequently at **10-minute intervals** until completion of surgery.

At the end of surgery, neuromuscular blockade was reversed using **neostigmine 0.05 mg/kg and glycopyrrolate 0.008 mg/kg intravenously**, and patients were extubated after meeting standard criteria.

Postoperative pain was assessed using the **FLACC (Face, Legs, Activity, Cry, Consolability) scale** at **0, 10 minutes, 2, 4, 6, 12, 18, and 24 hours**. Rescue analgesia in the form of **intravenous paracetamol (10–15 mg/kg)** was administered when the FLACC score indicated significant pain.

The **primary outcome measure** was the duration of effective analgesia, defined as the time interval between administration of caudal block and the requirement of first rescue analgesic. Secondary outcomes included haemodynamic parameters, postoperative pain scores, and incidence of side effects.

All data were recorded in a structured proforma and analysed statistically using appropriate methods. Continuous variables were expressed as **mean ± standard deviation**, and categorical variables as **frequency and percentage**. Statistical significance was considered at **$p < 0.05$**.

RESULT

A total of 60 paediatric patients were included in the study and were equally distributed into two groups: Group A (levobupivacaine alone) and Group B (levobupivacaine with clonidine), with 30 patients in each group. The baseline characteristics were comparable between the two groups. Age distribution showed that the majority of patients were in the 4–7 years age group (48.3%), followed by <4 years (35%) and 8–11 years (16.7%), with no statistically significant difference between groups ($\chi^2 = 1.958$, $p = 0.376$). Gender distribution was also similar, with 35 males (58.3%) and 25 females (41.7%) ($\chi^2 = 0.069$, $p = 0.793$). Most patients belonged to ASA grade I (91.7%), while only 8.3% were ASA grade II, and the distribution was comparable between groups ($\chi^2 = 1.964$, $p = 0.161$). The mean age was 4.48 ± 2.03 years in Group A and 5.18 ± 2.89 years in Group B ($p = 0.283$), while the mean weight was 19.30 ± 6.91 kg and 19.38 ± 8.32 kg respectively ($p = 0.971$), indicating homogeneity of the study population.

Intraoperative hemodynamic parameters showed that heart rate was consistently lower in Group B compared to Group A at multiple time points, with statistically significant differences observed at 6 minutes (103.6 ± 9.16 vs 95.97 ± 11.84, $p = 0.007$), 10 minutes (100.13 ± 9.23 vs 91.97 ± 10.99, $p = 0.003$), 20 minutes (97.47 ± 8.19 vs 89.77 ± 10.67, $p = 0.003$), 30 minutes (96.2 ± 8.39 vs 89.43 ± 9.99, $p = 0.006$), and several later time intervals, indicating better hemodynamic attenuation with clonidine. However, systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) remained comparable between the two groups at all time points ($p > 0.05$), suggesting overall hemodynamic stability in both groups. Oxygen saturation (SpO_2) was well maintained in both groups throughout the study period, with a statistically significant difference only at 120 minutes (99.14 ± 0.80 vs 97.77 ± 1.41, $p < 0.001$), though clinically within acceptable limits.

The analgesic profile demonstrated a marked difference between the two groups. The mean time to first rescue analgesic was significantly prolonged in Group B (23.29 ± 2.67 hours) compared to Group A (11.0 ± 5.21 hours), which was highly statistically significant ($p < 0.001$). Postoperative pain assessment using the FLACC score revealed significantly lower scores in Group B at multiple time intervals. At 2 hours, the FLACC score was 0.5 ± 0.86 in Group A compared to 0 in Group B ($p = 0.002$). At 6 hours, the scores were 2.87 ± 1.41 vs 0 ($p < 0.001$), at 12 hours 3.2 ± 1.54 vs 0.57 ± 0.90 ($p < 0.001$), and at 18 hours 3.3 ± 1.75 vs 1.63 ± 1.19 ($p < 0.001$). At 24 hours, the difference was not statistically significant (3.3 ± 1.84 vs 3.77 ± 1.19, $p = 0.249$), indicating that the analgesic benefit of clonidine was most pronounced in the early postoperative period.

The requirement of rescue analgesia further supported these findings. All patients in Group A (100%) required rescue analgesia, whereas only 70% of patients in Group B required it, with 30% not requiring any rescue analgesia ($\chi^2 = 10.588$, $p = 0.001$). The total number of rescue doses was significantly higher in Group A, where 86.7% of patients

required two or more doses, compared to only 3.3% in Group B ($\chi^2 = 42.608$, $p < 0.001$). In contrast, the majority of patients in Group B required either no dose or only one dose of rescue analgesia.

Overall, the addition of clonidine to levobupivacaine resulted in significantly prolonged duration of analgesia, reduced postoperative pain scores, decreased requirement of rescue analgesics, and better hemodynamic stability in terms of heart rate, without clinically significant adverse effects, demonstrating superior analgesic efficacy compared to levobupivacaine alone.

Table 1: Baseline Characteristics (Comparability of Groups) (n = 60)

Variable	Group A (Levobupivacaine) (n=30)	Group B (Levo + Clonidine) (n=30)	p-value
Age (years) Mean ± SD	4.48 ± 2.03	5.18 ± 2.89	0.283 (NS)
Weight (kg) Mean ± SD	19.30 ± 6.91	19.38 ± 8.32	0.971 (NS)
Male n (%)	17 (56.7)	18 (60.0)	0.793 (NS)
Female n (%)	13 (43.3)	12 (40.0)	—
ASA I n (%)	29 (96.7)	26 (86.7)	0.161 (NS)
ASA II n (%)	1 (3.3)	4 (13.3)	—

Table 2: Hemodynamic Parameters (Combined Mean ± SD with Single p-value)

Time (min)	HR (Mean ± SD)	SBP (Mean ± SD)	DBP (Mean ± SD)	MAP (Mean ± SD)	SpO_2 (Mean ± SD)	p-value
0	111.27 ± 12.2	113.10 ± 11.1	73.37 ± 8.5	86.61 ± 8.6	98.17 ± 1.16	0.063
3	105.93 ± 12.1	105.12 ± 15.5	68.39 ± 7.9	80.63 ± 8.3	98.25 ± 1.19	0.051
6	99.79 ± 10.8	101.65 ± 14.8	64.10 ± 7.8	76.62 ± 8.0	98.22 ± 1.31	**0.007***
10	96.05 ± 10.2	100.44 ± 8.7	62.34 ± 9.6	75.04 ± 8.4	98.27 ± 1.22	**0.003***
20	93.62 ± 9.6	99.42 ± 8.5	61.14 ± 9.6	73.90 ± 8.5	98.30 ± 1.25	**0.003***
30	92.82 ± 9.3	95.07 ± 15.4	61.45 ± 6.9	72.65 ± 7.9	98.28 ± 1.08	**0.006***
40	92.35 ± 9.6	96.47 ± 13.8	60.83 ± 11.6	72.55 ± 10.2	98.13 ± 1.31	**0.007***
50	92.03 ± 8.8	97.61 ± 8.6	59.92 ± 7.8	72.49 ± 7.5	98.35 ± 1.14	**0.033***
60	90.49 ± 13.2	97.45 ± 7.6	59.86 ± 7.3	72.39 ± 6.7	98.38 ± 1.20	0.488
80	90.35 ± 9.9	98.08 ± 8.2	60.87 ± 7.8	73.28 ± 7.2	97.98 ± 1.27	**0.011***
90	90.23 ± 9.8	98.19 ± 8.1	62.72 ± 9.7	74.53 ± 8.0	97.93 ± 1.22	**0.036***
100	89.50 ± 10.5	99.01 ± 10.6	63.44 ± 9.2	75.29 ± 8.6	97.96 ± 1.15	**0.025***
120	88.50 ± 10.9	102.50 ± 13.8	63.00 ± 6.8	76.14 ± 8.8	98.46 ± 1.10	0.173

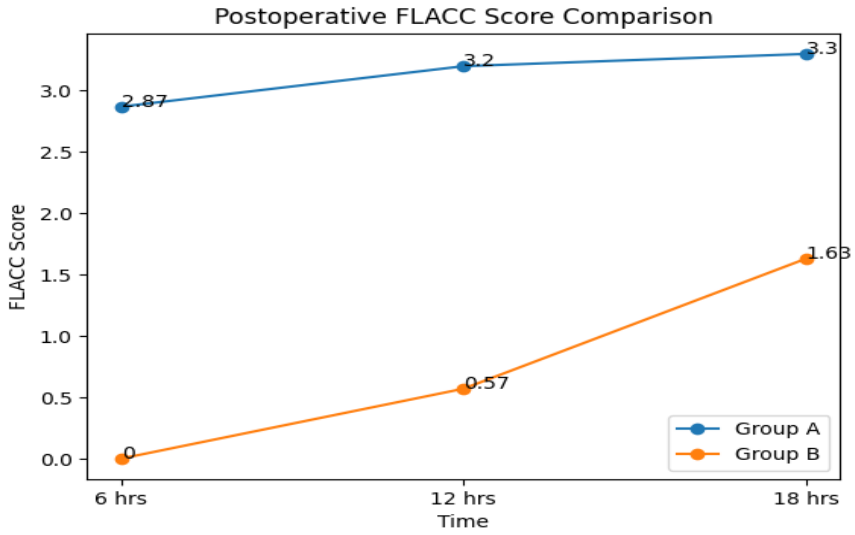
Table 3: Analgesic Profile and Duration of Analgesia

Parameter	Group A	Group B	p-value
Time to First Rescue Analgesic (hrs) Mean ± SD	11.0 ± 5.21	23.29 ± 2.67	<0.001*
Post-op FLACC Score (6 hrs)	2.87 ± 1.41	0 ± 0	<0.001*
Post-op FLACC Score (12 hrs)	3.2 ± 1.54	0.57 ± 0.90	<0.001*
Post-op FLACC Score (18 hrs)	3.3 ± 1.75	1.63 ± 1.19	<0.001*

Table 4: Rescue Analgesic Requirement and Total Doses

Parameter	Group A n (%)	Group B n (%)	p-value
Rescue Analgesic Required	30 (100%)	21 (70%)	0.001*
No Rescue Required	0 (0%)	9 (30%)	—
Total Doses (≥2 doses)	26 (86.7%)	1 (3.3%)	<0.001*
0–1 dose	4 (13.3%)	29 (96.7%)	—

Figure 2: Post-Operative FLACC Score Comparison



DISCUSSION

The present study compared caudal levobupivacaine alone with levobupivacaine plus clonidine in paediatric patients undergoing infraumbilical surgeries. Both groups were comparable at baseline with respect to age, gender, ASA grading, mean age, and mean weight, as the differences were statistically non-significant. This comparability indicates that the later differences in analgesic profile were likely due to the addition of clonidine rather than baseline variation.

In this study, heart rate was significantly lower in Group B at multiple intraoperative time points, including 6 minutes, 10 minutes, 20 minutes, 30 minutes, 40 minutes, 50 minutes, 80 minutes, 90 minutes, and 100 minutes. This suggests that clonidine provided better sympatholytic effect and haemodynamic attenuation. Similar findings were reported in studies where clonidine used as a caudal adjuvant provided stable intraoperative haemodynamics without clinically significant adverse events [14,16]. In the present study, SBP, DBP, and MAP remained comparable between groups at almost all time intervals, indicating that addition of clonidine did not cause clinically significant hypotension.

The postoperative analgesic effect was markedly better in Group B. The time to first rescue analgesic was significantly prolonged in Group B compared to Group A (**23.29 ± 2.67 hours vs 11.0 ± 5.21 hours; p < 0.001**). This finding is consistent with El-Hennawy et al., who observed that addition of clonidine to caudal local anaesthetic significantly prolonged postoperative analgesia in children [14]. Gogoi et al. also reported prolonged duration of caudal analgesia when clonidine was added to bupivacaine in children undergoing infraumbilical surgery [15]. Similarly, Bonisson et al. found that clonidine-bupivacaine combination improved postoperative analgesic duration in paediatric caudal block [16]. Postoperative FLACC scores also supported the superior analgesic efficacy of clonidine. In the present study, FLACC scores were significantly lower in Group B at 2 hours (**0 vs 0.5 ± 0.861; p = 0.002**), 6 hours (**0 vs 2.87 ± 1.408; p < 0.001**), 12 hours (**0.57 ± 0.898 vs 3.2 ± 1.54; p < 0.001**), and 18 hours (**1.63 ± 1.189 vs 3.3 ± 1.745; p < 0.001**). These findings are comparable with previous paediatric caudal analgesia studies, where α2-agonists such as clonidine and dexmedetomidine reduced postoperative pain scores and delayed requirement of rescue analgesia [14,15].

The requirement of rescue analgesia was significantly reduced with clonidine. In Group A, all 30 patients required rescue analgesia, whereas in Group B, only 21 patients required rescue analgesia and 9 patients did not require it (**p = 0.001**). Similarly, total rescue doses were markedly lower in Group B, where most patients required 0–1 dose, while Group A patients commonly required multiple doses (**p < 0.001**). This is in agreement with studies showing that clonidine as an adjuvant reduces postoperative analgesic consumption in paediatric caudal blocks [14–16].

Regarding the choice of levobupivacaine, previous studies have supported its role as an effective and safer local anaesthetic in paediatric regional anaesthesia. Breschan et al. compared levobupivacaine, ropivacaine, and bupivacaine for caudal blockade in children and reported good analgesic efficacy with levobupivacaine [11]. Glaser et al. and Athar et al. also demonstrated favourable clinical efficacy and safety of levobupivacaine compared with other local anaesthetics in regional anaesthesia settings [12,13]. These findings support the use of levobupivacaine as the baseline drug in the present study.

Overall, the present study findings are consistent with existing literature and show that clonidine is an effective adjuvant to levobupivacaine in caudal block. It significantly prolonged analgesia, reduced FLACC pain scores, decreased rescue analgesic requirement, and maintained haemodynamic stability. Thus, levobupivacaine with clonidine appears superior to levobupivacaine alone for perioperative analgesia in paediatric infraumbilical surgeries.

CONCLUSION

The present study demonstrates that the addition of clonidine to caudal levobupivacaine significantly enhances perioperative analgesic efficacy in paediatric patients undergoing infraumbilical surgeries. Patients receiving levobupivacaine with clonidine exhibited a markedly prolonged duration of analgesia, with a significantly longer time to first rescue analgesic (**23.29 ± 2.67 hours vs 11.0 ± 5.21 hours**), lower postoperative FLACC pain scores at multiple time intervals, and reduced requirement for rescue analgesics. Hemodynamically, both groups remained stable; however, the clonidine group showed better attenuation of heart rate response without clinically significant hypotension or oxygen desaturation. These findings indicate that clonidine is a safe and effective adjuvant to levobupivacaine, providing superior analgesia and improved postoperative comfort compared to levobupivacaine alone.

LIMITATIONS

This study has certain limitations. The **sample size was relatively small (n = 60)**, which may limit the generalizability of the findings. The study was conducted at a **single centre**, which may not reflect broader population variability. Only **ASA I and II patients** were included, limiting applicability to higher-risk patients. The **follow-up period was restricted to 24 hours**, and long-term analgesic outcomes were not assessed. Additionally, variability in surgical procedures and individual pain perception in children may have influenced the results. The study also did not evaluate sedation scores or biochemical markers, which could provide additional insight into the effects of clonidine.

RECOMMENDATIONS

Further studies with **larger sample sizes and multicentric designs** are recommended to validate these findings. Inclusion of **high-risk paediatric populations** and evaluation across different types of surgeries would enhance applicability. Future research should consider **longer follow-up periods** to assess sustained analgesic benefits and safety. Comparative studies with other adjuvants such as dexmedetomidine may help establish the most effective adjunct for caudal analgesia. Standardization of dosing protocols and inclusion of additional outcome measures such as sedation scoring and recovery profiles are also suggested. Routine use of clonidine as an adjuvant in caudal blocks may be considered to improve postoperative analgesia and reduce analgesic requirements in paediatric anaesthesia.

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