International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Comparative Evaluation of Clonidine versus Dexamethasone as Adjuvants to Caudal Ropivacaine for Postoperative Analgesia in Paediatric Infra-Umbilical Surgeries: A Randomized Controlled Trial

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OPEN ACCESS

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Received: 20-01-2026
Accepted: 15-04-2026
Available online: 11-05-2026

ABSTRACT

Background: Caudal epidural block is one of the most commonly used regional anesthetic techniques for pediatric infra-umbilical surgeries because it provides effective intraoperative and postoperative analgesia. However, the short duration of analgesia following a single-shot caudal block remains a major limitation. Various adjuvants have been added to local anesthetics to prolong postoperative pain relief. Clonidine and dexamethasone are commonly used non-opioid adjuvants with favorable safety profiles.

Objectives: To compare the analgesic efficacy of clonidine and dexamethasone as adjuvants to ropivacaine for caudal epidural block in children undergoing infra-umbilical surgeries.

Methods: This prospective open-label randomized controlled trial was conducted in the operating theatres of Bangalore Baptist Hospital from August 2018 to June 2019. Seventy children aged 1–10 years, belonging to ASA physical status I and II, scheduled for elective infra-umbilical surgeries were enrolled and randomized into two groups. Group Clonidine received caudal ropivacaine 0.2% (1 mL/kg) with clonidine 1 µg/kg. Group Dexamethasone received caudal ropivacaine 0.2% (1 mL/kg) with dexamethasone 0.1 mg/kg. The primary outcome was duration of analgesia, defined as the time from caudal injection to first rescue analgesic requirement based on FLACC score ≥4. Secondary outcomes included postoperative sedation, perioperative hemodynamic stability, and adverse effects.

Results: Baseline demographic variables, ASA status, type of surgery, and duration of surgery were comparable between the groups. The mean duration of analgesia was significantly longer in the Dexamethasone group compared with the Clonidine group (10.43 ± 2.85 hours vs 7.93 ± 3.44 hours; $p < 0.05$).

In the Dexamethasone group, 71.43% of children required first rescue analgesia after 12 hours, whereas 42.86% of children in the Clonidine group required rescue analgesia within 6 hours ($p < 0.05$). Postoperative sedation scores were significantly higher in the Clonidine group at 1 hour and 1.5 hours ($p < 0.05$), but were comparable thereafter. Intraoperative hypotension occurred more frequently in the Clonidine group than in the Dexamethasone group (25% vs 3.57%; $p < 0.05$). Other adverse effects were infrequent and comparable between groups.

Conclusion: Dexamethasone (0.1 mg/kg) as an adjuvant to caudal ropivacaine provided significantly longer postoperative analgesia than clonidine (1 µg/kg) in children undergoing infra-umbilical surgeries. It was also associated with lower early postoperative sedation and a lower incidence of hypotension. Dexamethasone may be considered a superior non-opioid adjuvant for pediatric caudal epidural analgesia.

Keywords*: Caudal epidural block; pediatric anesthesia; clonidine; dexamethasone; ropivacaine; postoperative analgesia; infra-umbilical surgery.*

INTRODUCTION

Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." Pain assessment in children is particularly challenging because pain is a complex phenomenon, and it is often difficult to differentiate whether restlessness or crying is due to pain, hunger, fear, or anxiety.[1]

In the past, children were frequently undertreated for pain because of the mistaken belief that they neither suffered nor perceived pain, nor responded to or remembered painful experiences to the same extent as adults. Another reason for undertreatment was the lack of proven safety and efficacy data regarding opioid analgesics, along with concerns about opioid-induced respiratory depression. Undertreated postoperative pain in children and newborns can trigger biochemical and physiological stress responses, leading to impairment of pulmonary, cardiovascular, neuroendocrine, gastrointestinal, immunological, and metabolic functions.[1] Therefore, postoperative pain management in children requires special consideration because of their physical and psychological immaturity.[2]

Management of postoperative pain should be included in the anesthetic plan even before induction of anesthesia by adopting the concept of **preventive analgesia** or "managing pain before it occurs." Pain assessment in pediatric patients remains difficult, especially in preverbal children or those unable to self-report. In such cases, pain intensity is assessed using behavioral and physiological parameters. Clinical indicators such as increased heart rate, respiratory rate, blood pressure, sweating, and facial expressions are commonly used to evaluate pain in children.[2]

As multiple receptors and neurochemical pathways are involved in postoperative pain transmission, management should ideally be multimodal.[3] Effective postoperative pain relief in children is a major concern for anesthesiologists, as pain not only affects the child but also increases parental anxiety, which can be alleviated through adequate analgesia.

The combination of regional and general anesthesia in pediatric patients has been shown to reduce hospital stay and improve outcomes. Caudal epidural block is one of the most commonly used regional anesthetic techniques in pediatric anesthesia. It provides safe and effective intraoperative and postoperative analgesia for surgeries below the umbilicus.[3] It is a relatively simple technique and allows rapid recovery from anesthesia. However, the major disadvantage of caudal block is the relatively short duration of postoperative analgesia, even when long-acting local anesthetics are used. Therefore, several adjuvants have been investigated to prolong the duration and improve the quality of analgesia.[3,4]

Various drugs have been used as additives to local anesthetics for enhancing intraoperative and postoperative analgesia. Opioids are commonly used adjuvants for caudal analgesia; however, their use is limited by side effects such as nausea, vomiting, pruritus, and respiratory depression. Non-opioid adjuvants such as Midazolam, Clonidine, Dexamethasone, Magnesium, Adrenaline, and Ketamine have also been used, each with varying advantages and adverse effects.[5]

Dexamethasone is a well-known corticosteroid with potent anti-inflammatory properties. Although its precise mechanism of action when administered epidurally or perineurally is not fully understood, it may exert a local anesthetic effect through direct membrane action. Another possible mechanism is modulation of the transcription factor nuclear factor-kB (NF-kB). Epidural corticosteroid administration has been reported to inhibit the development of hyperalgesia with an associated reduction in NF-kB levels. These findings suggest that dexamethasone may prevent central sensitization after surgery and enhance the preventive analgesic effect of caudal block.[6]

Clonidine, an alpha-2 adrenergic agonist, produces analgesia primarily through central mechanisms. Although it can be administered via different routes, it is a potent analgesic with minimal side effects when used epidurally. Clonidine has been used as an adjuvant with local anesthetics such as lignocaine, bupivacaine, and ropivacaine in caudal block to improve intraoperative and postoperative analgesia and reduce the required dose of local anesthetic, thereby decreasing the risk of local anesthetic toxicity.[7] Hence, the present study is undertaken to compare the efficacy, safety, duration of postoperative analgesia, and adverse effects, if any, of adding dexamethasone or clonidine to ropivacaine in caudal epidural block.

MATERIALS AND METHODS

This study was conducted in the operating theatres of Bangalore Baptist Hospital. The study population consisted of children of either sex belonging to American Society of Anesthesiologists (ASA) physical status I and II who were scheduled for elective infra-umbilical surgical procedures.The research question of the present study was to determine

the comparative analgesic efficacy of caudal clonidine with ropivacaine versus caudal dexamethasone with ropivacaine in pediatric patients undergoing infra-umbilical surgeries. The aim of the study was to compare the analgesic efficacy of ropivacaine with clonidine or dexamethasone as adjuvants for caudal epidural block in pediatric infra-umbilical surgeries. The primary objective was to evaluate the duration of analgesia, defined as the time interval from caudal injection until the first requirement of rescue analgesia, with pain assessed using the FLACC score. The secondary objectives were to assess perioperative hemodynamic stability in both groups and to evaluate the incidence of adverse effects such as nausea, vomiting, sedation, bradycardia, hypotension, and wound infection.

Children aged between 1 and 10 years, weighing less than 30 kg, belonging to ASA physical status I and II, and posted for infra-umbilical surgeries of less than two hours duration such as herniotomy, urethroplasty, circumcision, orchidopexy, and lower limb orthopedic surgeries were included in the study. Children posted for emergency surgery, those with infection at the site of injection, coagulopathy or on anticoagulant therapy, congenital anomalies of the lower spine or meninges, active disease of the central nervous system, known allergy to local anaesthetics, clonidine, or dexamethasone, and surgeries requiring prone position were excluded from the study. The study endpoint was up to 12 hours postoperatively from the time of administration of the caudal block. The study was designed as an open-label randomized controlled trial and was conducted over a period from August 2018 to June 2019.

The sample size was calculated for comparison of two means with a confidence interval of 99% and a study power of 80%. Based on previous data, the required sample size was determined as 35 children in the clonidine group and 35 children in the dexamethasone group, making a total sample size of 70 participants.[3]

METHODOLOGY

During the pre-anesthetic evaluation, children fulfilling the inclusion criteria and scheduled for infra-umbilical surgeries were recruited into the study after obtaining written informed consent from their parents or guardians. Participants were randomized using a computer-generated block randomization method into one of two groups. Group Clonidine received caudal ropivacaine 0.2% at a dose of 1 mL/kg with clonidine 1 µg/kg. Group Dexamethasone received caudal ropivacaine 0.2% at a dose of 1 mL/kg with dexamethasone 0.1 mg/kg. Allocation concealment was ensured using sequentially numbered opaque sealed envelopes.

All children were kept fasting according to standard nil per oral guidelines. No child received premedication prior to surgery. General anesthesia was induced with oxygen and nitrous oxide in a ratio of 1:1 along with 5–6% sevoflurane inhalation. Standard intraoperative monitoring included pulse oximetry, electrocardiography, non-invasive blood pressure, and end-tidal carbon dioxide monitoring. After induction, an appropriately sized intravenous cannula was inserted and Ringer lactate infusion was started at 6 to 10 mL/kg/hour.

A deeper plane of anesthesia was achieved with intravenous propofol 1 mg/kg and fentanyl 0.5 µg/kg. An appropriately sized laryngeal mask airway was inserted, and anesthesia was maintained with oxygen and air in a ratio of 1:1 along with sevoflurane. Ventilation was maintained either spontaneously or with assistance as required.

The caudal epidural block was performed under strict aseptic precautions in the lateral decubitus position by an experienced anesthesiologist. The sacral hiatus was identified by palpation, and a 24-gauge short bevel needle was introduced into the caudal epidural space. After confirming negative aspiration for blood or cerebrospinal fluid, the allocated study drug was administered. The child was then turned supine immediately after the procedure. All children received paracetamol suppository 30 mg/kg immediately after caudal block placement.

Hemodynamic parameters were recorded every five minutes for one hour following the caudal block. If surgical incision was associated with an increase in heart rate or mean arterial pressure of more than 20% above baseline values, it was considered an inadequate or failed block and treated with intravenous fentanyl 0.5 µg/kg. At the completion of surgery, the laryngeal mask airway was removed in a deeper plane of anesthesia. Once regular spontaneous respiration and airway reflexes were restored, the child was shifted to the post-anesthesia care unit.

Pain was assessed using the FLACC score, while sedation was assessed using a five-point sedation score. In the post-anesthesia care unit, both scores were recorded every 30 minutes until discharge to the ward. Any FLACC score of 4 or more was treated with intravenous fentanyl 0.5 µg/kg. In the ward, FLACC and sedation scores were recorded every two hours for the first 12 postoperative hours. A pain score of 4 or more was managed with oral paracetamol syrup 10 to 15 mg/kg.

Duration of analgesia was defined as the time interval from administration of the caudal block until the first requirement of rescue analgesia. Time to first analgesic requirement was defined as the interval from caudal administration until the first complaint of pain or FLACC score of 4 or more.

Children were monitored intraoperatively for complications such as bradycardia and hypotension. Bradycardia was defined as a decrease in heart rate greater than 20% from baseline and was treated with intravenous atropine 0.02 mg/kg. Hypotension was defined as a decrease in mean arterial pressure greater than 20% from baseline and was treated with fluid bolus of 15 to 20 mL/kg. Persistent hypotension was managed with intravenous ephedrine 0.1 mg/kg. Postoperatively, children were observed for adverse effects such as nausea, vomiting, and sedation for up to 12 hours. Wound infection, if any, was assessed during follow-up in the outpatient department one week after discharge.

Ethical Considerations

This study involved children aged 1 to 10 years undergoing infra-umbilical surgeries under anesthesia. Standard general anesthesia techniques and approved adjuvants for postoperative pain relief were used. Dexamethasone was administered in doses not associated with significant adverse effects. Parents who declined participation for their child were offered standard care. The nature of the study was explained to parents or guardians, and written informed consent was obtained. Assent was obtained from children whenever appropriate.

Statistical Analysis

Descriptive and inferential statistical analyses were carried out in the present study. Continuous variables were expressed as mean ± standard deviation with range, while categorical variables were presented as number and percentage. Statistical significance was assessed at a 5% level of significance.

It was assumed that dependent variables were normally distributed and that samples drawn from the population were random with independent observations. Student's independent t-test (two-tailed) was used to compare continuous variables between the two groups. Chi-square test or Fisher's exact test was used for categorical variables. Fisher's exact test was applied when expected cell frequencies were small. Statistical analysis was performed using IBM SPSS Statistics.

RESULTS

It was observed that in the Dexamethasone group, the first analgesic requirement in 71.43% of children occurred after 12 hours, whereas in the Clonidine group, 42.86% of children required their first analgesic dose within 6 hours after caudal administration. Statistical analysis using the Chi-square test showed a significant association between the study groups and the timing of first analgesic requirement.

The mean duration of analgesia in the Dexamethasone group was 10.43 ± 2.85 hours, whereas in the Clonidine group it was 7.93 ± 3.44 hours. Statistical analysis using the independent samples t-test demonstrated that the mean duration of analgesia differed significantly between the two groups, with a longer duration observed in the Dexamethasone group.

The mean sedation scores of the Clonidine and Dexamethasone groups were recorded and compared at 1 hour, 1.5 hours, 2 hours, 4 hours, 6 hours, 8 hours, and 12 hours postoperatively. At the 1st postoperative hour, the mean sedation score in the Clonidine group was 2.18 ± 0.819, whereas in the Dexamethasone group it was 1.57 ± 0.742. This indicates that children in the Clonidine group were more sedated than those in the Dexamethasone group, and the difference was statistically significant ($p < 0.05$).

At 1.5 hours postoperatively, the mean sedation score in the Clonidine group was 1.68 ± 1.07, while in the Dexamethasone group it was 1.07 ± 0.267. This difference was also statistically significant ($p < 0.05$). Thereafter, at the 2nd, 4th, 6th, 8th, and 12th postoperative hours, the mean sedation scores were comparable between the Clonidine and Dexamethasone groups, and the differences were not statistically significant ($p > 0.05$).

The incidence of various intraoperative and postoperative side effects was compared between the two groups. Seven children in the Clonidine group (25%) developed intraoperative hypotension, whereas only one child in the Dexamethasone group (3.57%) developed hypotension. This difference was statistically significant ($p < 0.05$). Although other adverse effects were observed in both groups, the differences were not statistically significant ($p > 0.05$).

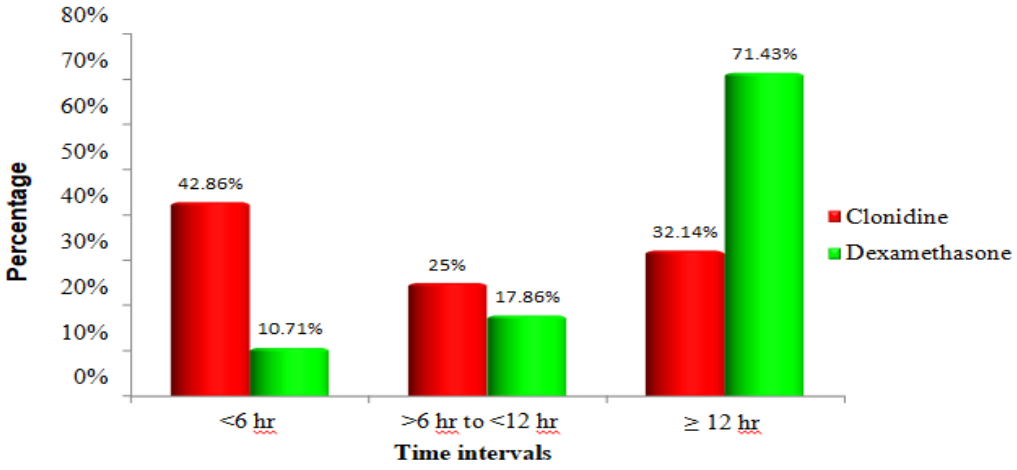

Figure 1: First analgesia requirement

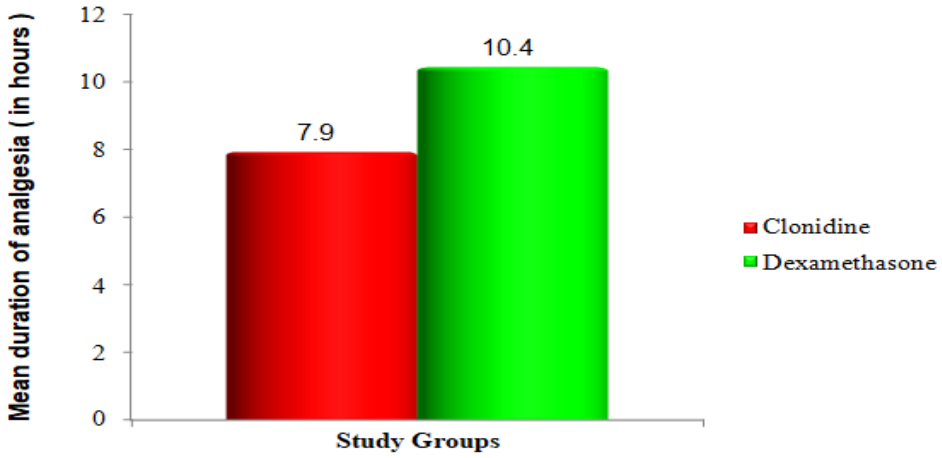

Figure 2: Mean duration comparison

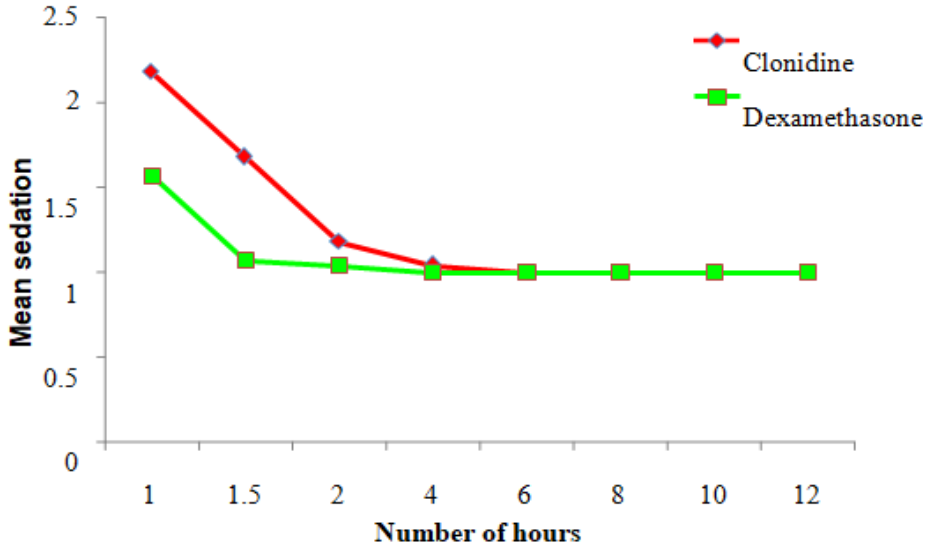

Figure 3: Mean Sedation Scores

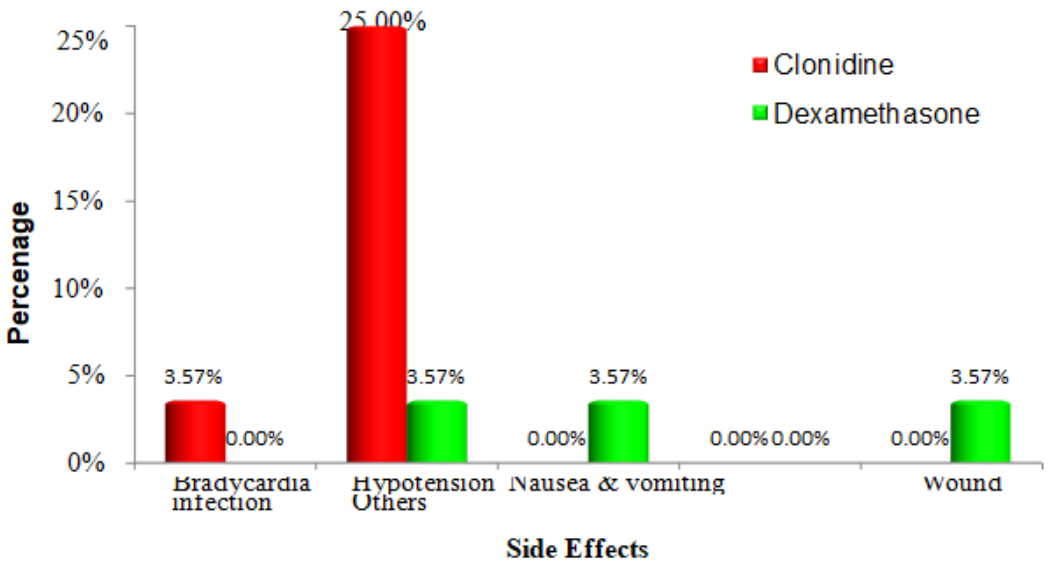

Figure 4: Side effects comparison

DISCUSSION

Effective postoperative pain management in children remains a fundamental component of perioperative care. Inadequately treated pain may result in physiological stress responses, delayed recovery, behavioral disturbances, increased parental anxiety, and the potential for long-term alterations in pain perception. Caudal epidural block is one of the most frequently used regional anesthetic techniques in pediatric patients undergoing infra-umbilical surgeries because it is technically simple, reliable, and provides excellent intraoperative and postoperative analgesia. However, the principal limitation of a single-shot caudal block is the relatively short duration of analgesia. Consequently, several adjuvants have been investigated to enhance and prolong the analgesic effect of local anesthetics.[8]

The present study compared clonidine and dexamethasone as adjuvants to caudal ropivacaine in children undergoing infra-umbilical surgeries. The principal finding was that dexamethasone produced a significantly longer duration of postoperative analgesia than clonidine, while clonidine was associated with greater early postoperative sedation and a higher incidence of intraoperative hypotension.[9]

Baseline demographic and perioperative characteristics, including age, sex, weight, ASA physical status, type of surgery, and duration of surgery, were comparable between the two groups. This suggests that the observed differences in postoperative outcomes were unlikely to be attributable to confounding baseline variables.[10,11]

The most clinically relevant outcome in the present study was duration of analgesia. Children receiving dexamethasone had a significantly longer mean duration of analgesia (10.43 ± 2.85 hours) compared with those receiving clonidine (7.93 ± 3.44 hours), with a mean difference of approximately 2.5 hours. Furthermore, 71.43% of children in the dexamethasone group did not require rescue analgesia within the first 12 postoperative hours, whereas 42.86% of children in the clonidine group required rescue analgesia within 6 hours. These findings indicate a more sustained analgesic profile with dexamethasone when used as a caudal adjuvant.[12,13]

The prolonged analgesic effect of dexamethasone may be explained by several mechanisms. Corticosteroids reduce local inflammatory responses, suppress ectopic neuronal discharge, inhibit nociceptive C-fiber transmission, and attenuate central sensitization. Dexamethasone has also been proposed to prolong the action of local anesthetics through modulation of potassium channel activity and reduction of perineural inflammation. These mechanisms may collectively explain the superior duration of analgesia observed in the present study.[14]

The findings of the present study are consistent with prior literature demonstrating improved analgesic duration when dexamethasone is added to regional anesthetic techniques. Previous pediatric caudal studies and peripheral nerve block meta-analyses have reported prolonged analgesia and reduced rescue analgesic requirements with dexamethasone as an adjunct. Our results support the growing evidence favoring dexamethasone as an effective non-opioid adjuvant in pediatric regional anesthesia.[15]

Clonidine has been widely used as a caudal additive because of its well-established analgesic effects mediated through alpha-2 adrenergic receptor agonism at spinal and supraspinal levels. It reduces nociceptive neurotransmitter release, hyperpolarizes dorsal horn neurons, and enhances the action of local anesthetics. Although clonidine significantly improves caudal analgesia compared with local anesthetic alone, its duration of effect in the present study was inferior to dexamethasone.[16]

Pain assessment in preverbal and younger children remains challenging. The FLACC score is a validated and widely accepted observational pain tool in pediatric postoperative care. In the present study, higher proportions of children in the clonidine group demonstrated FLACC scores requiring rescue analgesia at later postoperative intervals, particularly from the 6th postoperative hour onward. This supports the primary finding of shorter analgesic duration with clonidine.[17]

Hemodynamic stability is an important consideration when selecting caudal adjuvants in children. In the present study, heart rate and mean arterial pressure were generally stable and comparable between groups throughout surgery. However, intraoperative hypotension occurred significantly more frequently in the clonidine group (25%) than in the dexamethasone group (3.57%). Although all episodes responded to fluid bolus and no child required vasopressor therapy, this finding is clinically relevant. Clonidine decreases sympathetic outflow through central alpha-2 receptor stimulation, predisposing susceptible children to hypotension and bradycardia. In contrast, dexamethasone does not exert sympatholytic effects and therefore demonstrated a more favorable hemodynamic profile.[18]

Sedation is another recognized effect of clonidine. In the present study, children receiving clonidine had significantly higher sedation scores at 1 and 1.5 hours postoperatively. However, sedation was mild, transient, and children remained easily arousable. Thereafter, sedation scores were comparable between groups. While mild early sedation may be acceptable or even desirable in some clinical contexts, delayed recovery room discharge or reduced oral intake may be concerns in ambulatory settings. Dexamethasone, by contrast, was associated with lower sedation scores and a more alert recovery profile.[17,18]

The overall adverse effect profile in both groups was favorable. Apart from hypotension in the clonidine group, no major complications were observed. Incidences of nausea, vomiting, bradycardia, wound infection, or clinically significant respiratory events were low and comparable. These findings support the safety of both agents when used at the studied doses.

The present study has important clinical implications. In pediatric infra-umbilical surgeries where prolonged postoperative analgesia is desired, dexamethasone may be preferable to clonidine as an adjuvant to caudal ropivacaine because it extends analgesia, reduces early rescue analgesic requirements, avoids significant sedation, and is associated with lower rates of hypotension. This may be particularly valuable in day-care surgery, resource-limited settings, and where opioid-sparing multimodal analgesia is prioritized.

Several limitations should be acknowledged. First, the study was open-label in design, which may introduce observer bias despite standardized outcome measures. Second, the sample size was adequate for the primary outcome but may be underpowered to detect uncommon adverse effects. Third, pain and sedation assessment in children, although standardized using validated tools, remains inherently subjective. Fourth, follow-up was limited to the early postoperative period, and long-term outcomes were not assessed. Finally, only single doses of clonidine and dexamethasone were evaluated; dose-response relationships remain to be defined.

Future randomized double-blind multicenter trials with larger sample sizes are warranted to confirm these findings, evaluate optimal dosing strategies, compare combinations of adjuvants, and assess long-term safety. Comparative cost-effectiveness and discharge readiness outcomes may also provide valuable information for routine clinical practice.

CONCLUSION

Dexamethasone (0.1 mg/kg) as an adjuvant to caudal ropivacaine provided significantly longer postoperative analgesia than clonidine (1 µg/kg) in children undergoing infra-umbilical surgeries. It was also associated with less early postoperative sedation and a lower incidence of hypotension. Both agents were effective and generally safe; however, dexamethasone demonstrated a more favorable overall clinical profile in the present study.

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