

To evaluate the analgesic efficacy of intravenous dexamethasone as an adjuvant to caudal block: A prospective, randomized, double-blind study



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ABSTRACT

Background: Post-operative pain is of great concern in pediatric age group. Intravenous dexamethasone has been found to be promising in reducing post-operative pain when administered as an adjuvant to epidural anaesthesia in abdominal and orthopedic surgeries. However, little is known about its efficacy in children receiving caudal block for post-operative pain relief. **Aims and Objectives:** This study aimed to evaluate the analgesic efficacy of intravenous dexamethasone as an adjuvant to caudal block in children posted for infraumbilical surgeries. **Materials and Methods:** This interventional, double-blinded, randomized controlled study included 110 children aged 1–5 years with American Society of Anesthesiologists Grade I and II undergoing elective infraumbilical surgeries. To test our hypothesis, the superiority of intravenous dexamethasone was compared with the control group. All children received caudal bupivacaine 0.25% (1 mL/kg). Children were randomly allocated to two groups to receive: normal saline 0.075 mL/kg (Group C) and IV dexamethasone 0.3 mg/kg (0.075 mL/kg) (Group D). Post-operative pain scores (Face, Legs, Activity, Cry, and Consolability [FLACC] score), duration of analgesia, post-operative analgesic consumption, and intraoperative hemodynamics were compared. **Results:** FLACC score was found to be higher in Group C than Group D at all times. The mean FLACC score was significantly less with the study drug compared to the control group ($P < 0.001$). The time to request for first rescue analgesia was significantly less in Group C as compared to Group D (4.01 ± 0.69 h vs. 5.51 ± 0.50 h, $P = 0.019$). The mean total analgesic consumed in the first 24 h was significantly higher in Group C than in Group D (666.09 ± 174.69 mg vs. 384.55 ± 125.04 mg, $P = 0.015$). Hemodynamic parameters were comparable in both the groups. **Conclusion:** Intravenous administration of dexamethasone 0.3 mg/kg as an adjunct to caudal bupivacaine 0.25% provides significantly longer duration of post-operative analgesia and lesser total analgesic consumption compared to the use of caudal bupivacaine 0.25% alone.

Key words: Post-operative pain; Caudal block; Analgesic efficacy; Duration of analgesia

INTRODUCTION

In children, utilizing an anesthetic approach which provides the flexibility of extending analgesia into the post-operative period without any risk of anesthetic neurotoxicity is crucial. Caudal block is one of the most common regional

anesthetic techniques in pediatric practice for infraumbilical surgeries. However, its analgesic effect has limited duration of action after single-shot injection.¹⁻⁵

Dexamethasone has seen much interest in the field of regional anesthesia as an adjuvant for peripheral nerve

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blocks and epidural anesthesia. Perineural as well as intravenous dexamethasone is thought to function by altering the inflammatory response and may have a direct effect on nociceptive fibers.^{6,7} Efficacy of dexamethasone as an additive to local anesthetic agent for caudal block has been extensively studied.⁸⁻¹⁰ Nevertheless intravenous dexamethasone as an adjunct to caudal block provides an exciting option to prolong post-operative analgesia in children, and there is limited literature related to the same.

Hence, we designed a study to evaluate the effect of intravenous dexamethasone as an adjunct to caudal block on post-operative analgesia.

Aims and objectives

The primary objective of the study was to compare the duration of post operative analgesia in patients receiving intravenous dexamethasone with the control group. The secondary objectives were to calculate the total dose of rescue analgesia in each group and to compare intraoperative hemodynamics.

MATERIALS AND METHODS

The present study is a prospective, randomized, double-blinded study conducted in a tertiary care teaching institute in Central India over a period of 1 year from the date of approval of the Institutional Ethics Committee (letter no. EC/MGM/Sept-21/06).

One hundred and ten patients aged 1–5 years with American Society of Anesthesiologists (ASA) Grade I and II were enrolled in the study after written informed consent from the parents/legal guardians. Patients posted for infraumbilical surgeries formed the study population. Patients with known allergy to amide local anesthetics, coagulopathy, or injection site skin infection were excluded from the study. The patients were randomly allocated into one of the two study groups (55 patients each) using sealed envelope technique. A day before surgery detailed pre-anesthetic checkup was done including general physical examination along with proper systemic examination, assessment of airway, and local examination of lumbosacral spine.

On the day of surgery, patients were shifted to the operation theater. Baseline heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate, and peripheral oxygen saturation were recorded, and continuous monitoring was conducted.

The patient was induced with injection ketamine 2 mg/kg and maintained with a 40% O₂:60% N₂O mixture and sevoflurane 0.8–1% with face mask.

Caudal block was performed in the lateral position using a short beveled 22G needle. Group 1 patients received caudal bupivacaine 0.25% (1 mL/kg volume) and iv normal saline 0.075 mL/kg as placebo. Group 2 received caudal bupivacaine 0.25% (1 mL/kg) along with intravenous dexamethasone 0.3 mg/kg which was equivalent to 0.075 mL/kg of dexamethasone sodium phosphate from a vial containing 4 mg/mL of dexamethasone. Both the patient and the investigator were unaware of the group allocation. The anesthesiologist giving the study drug did not participate in data collection/analysis.

Postoperatively, the pain score was assessed using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale at hourly interval for the first 24 h. When the pain score was recorded to be more than or equal to 4, rescue analgesia with intravenous paracetamol (15 mg/kg) was given. Duration of analgesia was taken as time from giving the block to the request for the first dose of rescue analgesic (FLACC \geq 4). The total analgesic consumption in the first 24 h was recorded on an hourly basis.

Any post-operative adverse event including shivering, vomiting, and sedation in the first 24 h was recorded and treated accordingly.

Sample size calculation was done using G*Power software version 3.1.9.2 at 95% confidence interval, alpha error of 5%, and power of 80%. Previous data suggested that the mean time to the first dose of rescue analgesia after caudal block with 0.25% bupivacaine was 4.33 ± 0.98 h. We calculated that at least 52 patients in each group would be required to show a difference of 20% in this time interval. Sample size of 110 (55 patients in each group) was assigned to account for dropouts, as shown in the consort diagram (Figure 1).

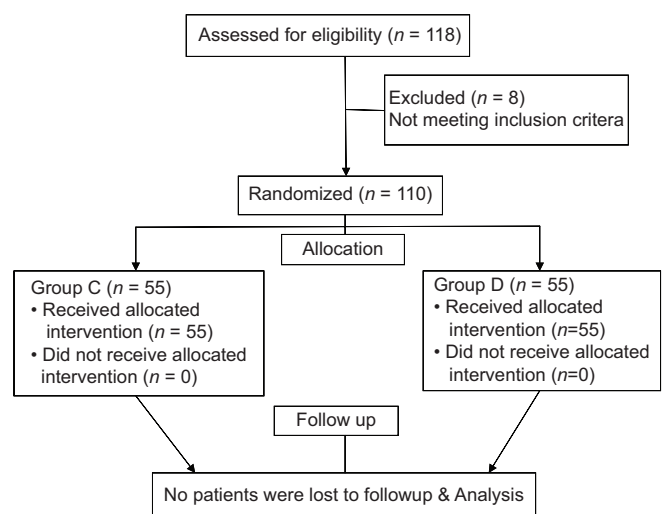


Figure 1: Consort diagram

The data were entered into the Microsoft Excel sheet from the customized pro forma for analysis. Minitab 17.0 was used for calculating the P-values. Comparison of means between the two groups was done using unpaired t-test. The categorical data were analyzed using the Chi-square test. Descriptive statistics was presented in the form of numbers and percentages. $P < 0.05$ was taken as statistically significant. The final data were presented in the form of tables and graphs.

RESULTS

Data from 110 patients were analyzed. There were no significant differences between the two groups with regard to their weight, height, ASA grade, and mean duration of surgery, as shown in Table 1.

Vital parameters were comparable between the two groups throughout the surgery (Table 2).

The mean time to request or first rescue analgesia was significantly shorter in Group C than Group D (4.01 h vs. 5.51 h, $P < 0.05$). The total analgesic consumption in Group C was considerably more than in Group D (666 mg vs. 384 mg, $P < 0.05$), as shown in Table 3.

The FLACC pain score was less in patients receiving intravenous dexamethasone than the control group at all time intervals. The mean FLACC score of Group C was

5.19 ± 1.74 whereas that of Group D was 4.48 ± 1.69 and the difference was found to be significant ($P < 0.001$), as shown in Figure 2.

DISCUSSION

This randomized controlled trial was conducted to evaluate the efficacy of intravenous dexamethasone (0.3 mg/kg) as an adjuvant to caudal block with 0.25% bupivacaine in children aged 1–5 years. The present study demonstrated significantly increased duration of post-operative analgesia with the study drug as compared to the control group who received caudal block alone (approximately 5.5 h vs. 4 h). The total analgesic requirements were also found to be significantly reduced in the study group compared to the control group (385 mg vs. 666 mg).

Hong et al.,¹¹ demonstrated similar findings with the use of intravenous dexamethasone in children aged 1–5 years posted for day-case orchiopexy. However, they used a higher dose of dexamethasone (0.5 mg/kg up to a maximum dose of 20 mg). Many studies have established the role of steroids for post-operative pain relief.^{12–15}

Glucocorticoids have powerful anti-inflammatory and immune-modulating effects. They modulate several components of inflammatory response to surgery including nociception.^{11,16} They have shown to reduce post-operative pain and swelling in a variety of otolaryngological, dental, and spine surgeries. At cellular level, dexamethasone suppresses the tissue levels of immunoreactive bradykinin^{17,18} and the release of neuropeptides from nerve endings resulting in analgesic effects. It also inhibits cyclooxygenase isoform 2 in tissues and nerve fibers resulting in suppression of prostaglandin synthesis. Moreover, dexamethasone also inhibits other pro-inflammatory mediators such as tumor necrosis factor- α , interleukin-17 β , and interleukin-6. These varied mechanisms might explain decreased morbidity and better pain management with the perioperative use of steroids.

There is no consensus on the use of steroids in pediatric age group. Dexamethasone has been used in a variable dose ranging from 0.2 mg/kg to 1 mg/kg for analgesia. The optimum dose, however, remains unknown.

The difficulty in assessment of pain in children poses an obstacle to post-operative pain management in them.

Table 1: Patient data and intraoperative characteristics

Characteristic	Group C	Group D	P-value
Weight (kg)	14.82 \pm 3.89	13.36 \pm 4.39	0.3770
Height (cm)	82.7 \pm 11.1	81.3 \pm 12.2	0.4898
ASA grade (1/2)	30/25	35/20	0.383
Mean duration of surgery (min)	39.73 \pm 9.93	37.73 \pm 9.97	0.9765

ASA: American Society of Anesthesiologists

Table 2: Comparison of intraoperative hemodynamic and respiratory parameters

Parameter	Group C	Group D	P-value
Systolic blood pressure	105.38 \pm 4.26	106.18 \pm 4.57	0.6075
Diastolic blood pressure	54.62 \pm 2.73	54.87 \pm 2.65	0.8278
Respiratory rate	24.51 \pm 1.73	24.62 \pm 1.84	0.6522
Oxygen saturation	99.44 \pm 0.57	99.64 \pm 0.52	0.5022

Table 3: Duration of analgesia and analgesic consumption (intravenous paracetamol) expressed as mean \pm SD

Characteristic	Group C	Group D	P-value
Time to first rescue analgesia (h)	4.01 \pm 0.69	5.51 \pm 0.50	0.019
Total analgesic consumed in the first 24 h (mg)	666.09 \pm 174.69	384.55 \pm 125.04	0.015

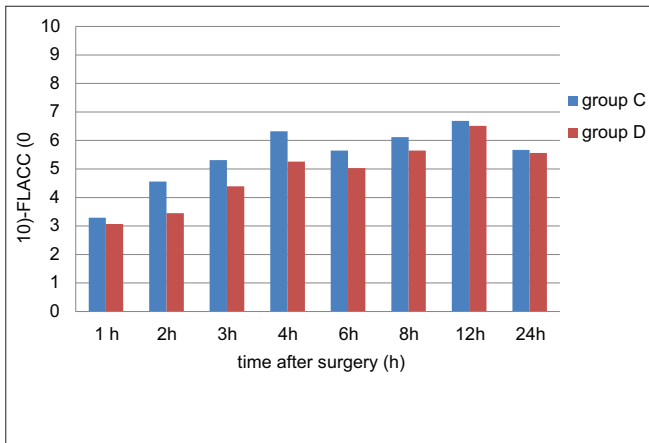


Figure 2: Post-operative pain scores (mean FLACC score for each group)

FLACC score employed for this study is a validated tool for pain assessment, but it can lead to subjective variations. The Children's Hospital of Eastern Ontario Pain Scale¹⁹ and the Wong-Baker Faces Pain Rating Scale²⁰ are other popular tools. Nevertheless, accurate and reliable assessment of pain remains burdensome in children.

In the present study, there were no significant hemodynamic alterations or adverse effects with the use of intravenous dexamethasone. This establishes the safety of the study drug.

Limitations of the study

There were certain limitations of the study. The type of surgery was not specified. We could not measure the plasma levels of dexamethasone or cortisol to explain the pharmacodynamic effects of the study drug. Blood glucose level monitoring was also missing. Further multicentric studies need to be conducted to substantiate and generalize our results. The optimum dose of intravenous dexamethasone as an adjunct to caudal anesthesia remains to be determined.

CONCLUSION

In children posted for infraumbilical surgeries, intravenous administration of dexamethasone 0.3 mg/kg as an adjunct to caudal bupivacaine 0.25% results in significantly longer duration of post-operative analgesia and considerably lower total analgesic consumption in the first 24 h compared to the use of caudal bupivacaine 0.25% alone.

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Authors' Contributions:

NG - Definition of intellectual content, literature survey, concept, design of study, and clinical protocol; **YD** - Literature survey, implementation of study protocol, data collection, data analysis, and preparation of figures; **KB** - Literature survey, data collection, and data analysis; **AS** - Statistical analysis and interpretation, manuscript preparation, manuscript revision, and submission of article; **KKA** - Literature survey, prepared first draft of manuscript, review manuscript, and coordination.

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