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Article

Comparison of analgesic efficacy of caudal and intravenous dexamethasone as an adjuvant to caudal block: A randomized, double-blind study

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Abstract: Background: The present study was performed to determine and compare the analgesic effect of dexamethasone as an adjuvant to caudal block when given intravenously and caudally.
Material and Methods: This interventional, double-blinded, randomized controlled study included 165 pediatric patients aged 1-5 years with anaesthesiology (ASA) physical status I and II admitted to the hospital for elective infraumbilical surgeries. Children were allocated randomly with the chit method to three groups such that subjects in group I received caudal Bupivacaine 0.25% (1ml/kg), along with caudal normal saline (NS) 0.025ml/kg and IV NS 0.075ml/kg; group II received caudal Bupivacaine 0.25% (1ml/kg) with caudal dexamethasone 0.1 mg/Kg (0.025ml/kg) and IV NS 0.075ml/kg; group III received caudal Bupivacaine 0.25% (1ml/kg) along with caudal NS 0.025ml/kg and IV dexamethasone 0.3mg/kg (0.075ml/kg) (dexamethasone sodium phosphate vial 4mg/ml). Patients 'intraoperative hemodynamic parameters were recorded every 10 minutes till the end of surgery. Postoperative pain was assessed hourly with a FLACC score until the score was>3, and the time was noted as analgesia duration. Total analgesic consumption during the first 24 hours was also noted down.
Results: In Group 1, the mean time to first rescue analgesia was 4.00±0.69 hours; in Group 2, it was 8.07±0.57 hours and in Group 3, it was 5.51±0.50 hours (p value<.05). In Group 1, mean total analgesic consumed in first 24 hours was 666.09±174.69 mg, in Group 2, it was 200.09±66.42 mg and in Group 3, it was 384.55±135.04 mg (p value<.05).
Conclusion: Dexamethasone as an adjunct to caudal Bupivacaine 0.25% (1ml/kg) provides effective postoperative analgesia.

Keywords: dexamethasone; Caudal block; Analgesia; Children; Post-operative pain.

1. Introduction

In the pediatric population, post-operative pain is of great concern as it is known that children, who experience pain in early life, show long-term changes in pain perception and related behaviors [1,2]. Post-operative pain greatly impacts children's psychological, physiological, and emotional well-being [3]. Utilizing an anesthetic approach that provides the flexibility of extending analgesia into the postoperative period without any risk of anesthetic neurotoxicity and ensuring optimal intraoperative sensory and motor blockade is crucial.

Single-shot caudal block is a traditionally opted perioperative pain management strategy in pediatrics and adults [4]. Evidence suggests that dexamethasone in epidural and caudal blocks prolongs the duration of action of the block [2,5]. Dexamethasone exerts some local analgesic effects through its anti-inflammatory action on intravenous administration. Dexamethasone is administered caudally with local anesthetic drugs in doses varying from 0.1–0.2mg/kg body weight [6]. Dexamethasone leads to the downregulation of prostaglandin synthesis via inhibition of synthesis of cyclooxygenase-2, reduction of proinflammatory chemokines, suppresses the bradykinin level, and alter the transmission of nociception at the level of nerve tissue and thus reduces pain [7,8]. It inhibits the transcription factor -nuclear factor-kB (NF-kB), which is responsible for pain and present in the nervous system [9,10]. Single dose of dexamethasone are safe, with minimal side effects expected from long-term use of corticosteroid administration [11]. When dexamethasone/steroids are administered in combination with local anesthetics in the epidural space, it has been shown to reduce postoperative rescue analgesic consumption following abdominal and orthopedic surgeries.12 However, little is known about administering a single dose of dexamethasone systemically and caudally in children.13 Thus, the present study has been performed to determine and compare the analgesic effect of dexamethasone as an adjuvant to caudal block when given intravenously and caudally.

2. Material and methods

2.1. Study design, study population, sample size, sampling technique, randomization, blinding

This interventional, double-blinded, randomized controlled study was conducted over a period of 1 year in the Department of Anaesthesiology, MGM Medical College and M.Y. Hospital, Indore, India. The study included 165 pediatric patients aged 1-5 years with anaesthesiology (ASA) physical status I & II admitted to the hospital for elective infraumbilical surgeries. Patients with ASA grades III and IV were excluded. Patients already on steroids, with conditions contradicting caudal anesthesia, cardiovascular diseases, drug allergy, bleeding disorders, infection at the site of block, and pre-existing neurological or spinal disease, were also excluded from the study.

Sample size calculation was done using G-power software 3.1.9.2 version and 95% confidence level and 80% power for three groups using ANOVA (fixed effect one-way model) effect size 0.435. The participants were allocated randomly to the three groups using simple random sampling. Randomization was done by pulling out the chits from a partially sealed box. Subjects in group I received caudal Bupivacaine 0.25% (1ml/kg), along with caudal normal saline (NS) 0.025ml/kg and IV NS 0.075ml/kg; group II received caudal Bupivacaine 0.25% (1ml/kg) with caudal dexamethasone 0.1 mg/Kg (0.025ml/kg) and IV NS 0.075ml/kg; group III received caudal Bupivacaine 0.25% (1ml/kg) along with caudal NS 0.025ml/kg and IV dexamethasone 0.3mg/kg (0.075ml/kg) (dexamethasone sodium phosphate vial 4mg/ml). The double blinding allocation concealment was practiced. The observer and the participants were blinded to the treatment they received.

2.2. Methodology

2.2.1. Pre-anesthetic check-up

The patient's age, weight, and baseline vital parameters, such as pulse, blood pressure, temperature, pallor, cyanosis, and edema, were recorded during the preoperative visit. Detailed history, including general physical and systemic examinations, was recorded. The systemic examination included an assessment of the respiratory system, cardiovascular system, central nervous system, and physical assessment.

2.2.2. Administration of anesthetic agents

All standard monitors were attached in the operating room, and baseline heart rate, mean arterial pressure, and oxygen saturation were recorded. Pre-medication was done with an injection of glycopyrrolate 0.008mg/kg and midazolam 0.05mg/kg injection through already secured venous access. Anesthesia was induced with an injection of ketamine 2mg/kg and maintained with a 40% O_2: 60% N_2O mixture and sevoflurane 0.8% to 1% with a face mask. The anesthesia was induced using Drager Narkomed GS Anaesthesia Workstation. Study drugs were prepared by an anaesthesiologist not participating in the study. The caudal block was performed in the lateral position by other anesthesiologists blinded to the drug injected caudally and intravenously. After waiting for 10 minutes to allow for the block to work and after ensuring the adequate effect of the caudal block reduction in heart rate and tone of the anal sphincter, the surgeon proceeded with the surgery. If the child showed lower limb movement, increased heart rate, or increased mean arterial pressure by 20% from the baseline values, it was considered a failed caudal block and was excluded from the study. Intra-operatively, the assessment of heart rate, non-invasive blood pressure, respiratory rate, and SPO_2 was done every 10 minutes till the end of the surgery. At the end of the surgery, the anesthetics were discontinued. The total time of surgery was recorded. Occurrences of any side effects, such as desaturation, hypotension, bradycardia, and nausea/ vomiting, were noted and managed accordingly. After surgery, patients were shifted to the post-anesthesia care unit for further observation and monitoring. Patient's hemodynamic parameters, post-operative pain status, and duration of analgesia were evaluated and recorded hourly till FLACC >3. Pain score was assessed using the Face, Legs, Activity, Cry, Consolability (FLACC) scale at hourly intervals till the score was>3.[14] At this time, the first rescue analgesia was given, and time was noted as the duration of analgesia. In patients with pain scores of more than 3, rescue analgesia was achieved with IV paracetamol (15mg/kg). Total analgesic consumption in the first 24 hours was recorded. All the information was collected in a pre-designed proforma.

2.3. Statistical analysis plan

Data were analyzed using SPSS (Statistical Package for Social Sciences) 21.0 version, IBM, Chicago. Data were analyzed for probability distribution using Kolmogorov- smirnov test. Descriptive statistics were performed. Inter-group comparison of continuous variables was made using One-way ANOVA followed by post hoc analysis. A comparison of categorical variables was made using chi-square test. p value<0.05 was considered statistically significant.

3. Results

Results of the study revealed that mean weight, duration of surgery, pre-operative diastolic and systolic blood pressure, and oxygen saturation were non-significantly different between the groups. [Table 1]

Table 1. Comparison of mean weight, duration of surgery, pre-operative diastolic and systolic blood pressure and oxygen saturation between subjects of three groups.

	Mean±standard deviation			F value	P value
	Group 1 (n=55)	Group 2 (n=55)	Group 3 (n=55)		
Weight (Kg)	14.82±3.89	13.06±4.62	13.36±4.39	2.62	0.076
Duration of surgery (in minutes)	39.73±9.93	39.55±9.34	37.73±7.12	0.853	0.428
Pre-operative diastolic blood pressure (mmHg)	54.62±2.73	54.58±2.78	54.87±2.65	0.187	0.83
Pre-operative systolic blood pressure (mmHg)	105.38±3.46	106.58±2.79	106.18±2.47	2.378	0.096
Pre-operative respiratory rate (per minute)	24.51±1.73	25.27±2.19	24.62±1.84	2.518	0.084
Pre-operative mean oxygen saturation (%)	99.44±0.57	99.62±0.56	99.64±0.52	2.213	0.113

One-way ANOVA

Table 2. Comparison of time to first rescue analgesia and total analgesic consumed in first 24 hours between subjects of three groups.

	Mean±standard deviation			F value	P value
	Group 1 (n=55)	Group 2 (n=55)	Group 3 (n=55)		
Time to first rescue analgesia (hours)	4.00±0.69	8.07±0.57	5.51±0.50	657.45	0.001*
Total analgesic consumed in first 24 hours (mg)	666.09±174.69	200.09±66.42	384.55±135.04	168.802	0.001*

One-way ANOVA. *p value<.05 was considered statistically significant.

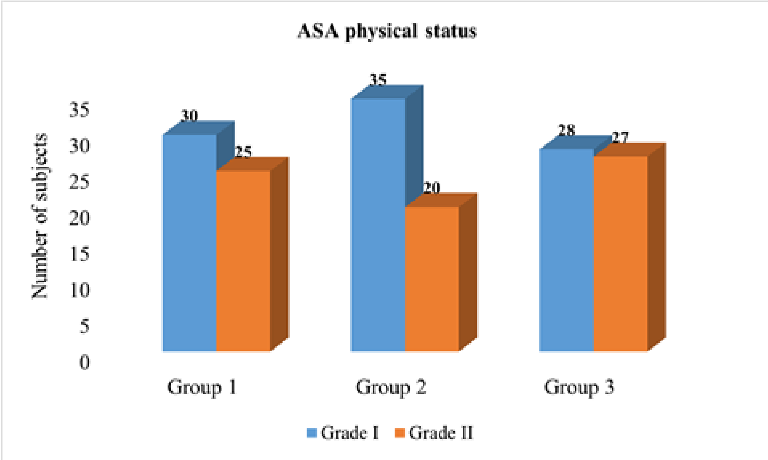

Figure 1. ASA physical status of the subjects belonging to three groups.

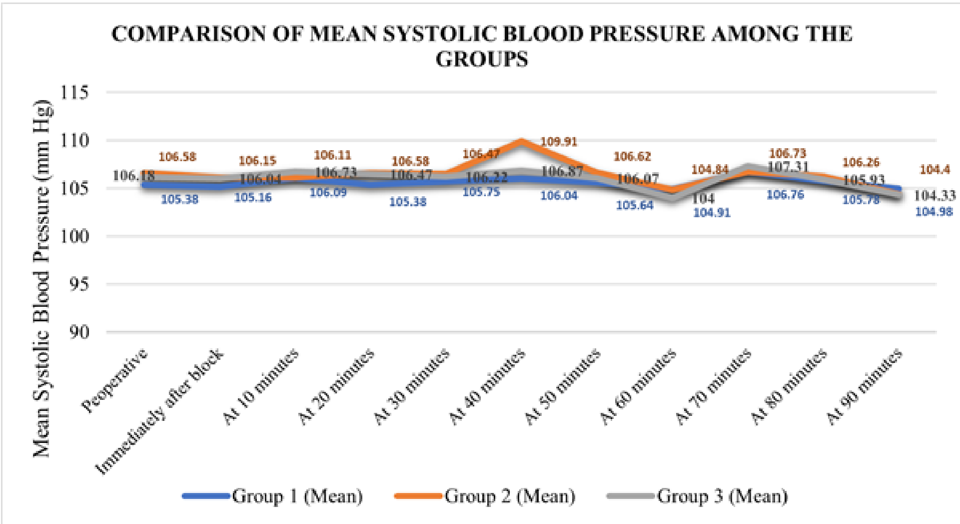

Figure 2. Diastolic blood pressure at different time intervals of the children belonging to three groups.

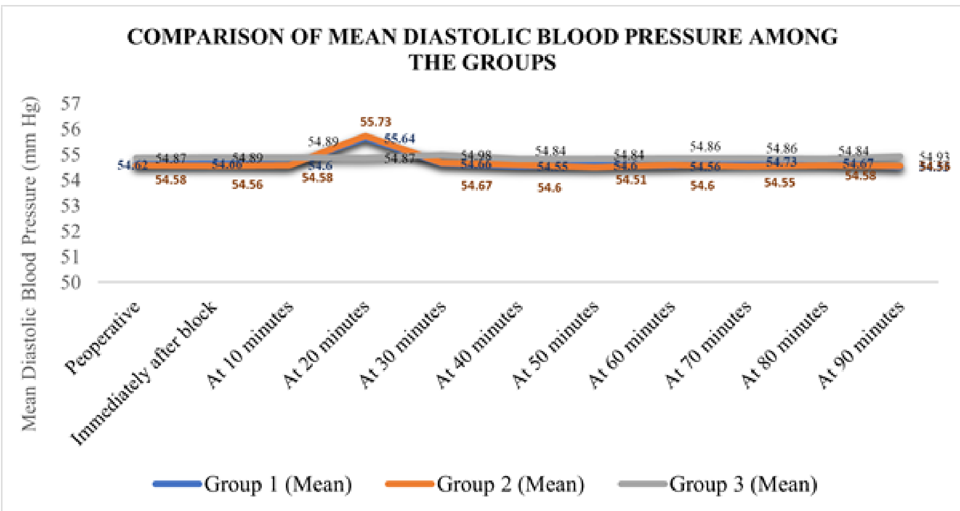

Figure 3. Systolic blood pressure at different time intervals of the children belonging to three groups.

During the procedure, mean SBP & DBP remained stable in all three groups and at any point of time, there was no significant difference between mean SBP and DBP of subjects belonging to 3 groups (p value>.05). [Figure 1,2]

After the procedure, FLACC score was non-significantly different between the groups at 1 hour and 2-hour time interval (p value>.05). However, after 2 hours the FLACC score was significantly different between the groups at all the time intervals till 24 hours (p value<.05). The shortest time to request first rescue analgesia was seen in Group 1 and the longest in Group 2. Mean time to request or first rescue analgesia was significantly shorter in Group 1 than Group 2 (P=0.001) and Group 3 (P=0.001) and it was significantly longer in Group 2 than Group 3 (P=0.001). The highest analgesic consumption was seen in Group 1 patients and lowest in Group 2 patients. [Table 2] Mean total analgesic consumed in first 24 hours was significantly higher in Group 1 than Group 2 (P=0.001); it was significantly higher in Group 1 than Group 3 (P=0.001) and it was significantly lower in Group 2 than Group 3 (P=0.001). [Table 2] Three patients in group 1 developed nausea and vomiting.

4. Discussion

The regional anaesthetic used in this study was Bupivacaine. Choice of Bupivacaine was based on the fact that it is the most commonly used local anaesthetic for this technique and is known to provide postoperative analgesia for 4-8 hours.15 Caudal anaesthesia has a limitation that it provides analgesia for a shorter duration. Therefore, adjuvants such as fentanyl, dexamethasone, neostigmine, morphine, magnesium sulphate, clonidine, dexmedetomidine, midazolam and ketamine are administered along with the caudal block to prolong the post-operative analgesia.3 Use of the adjuvants as mentioned above is associated with some adverse effect. Therefore, in this study adjuvant analgesic effects of dexamethasone has been studied.

Age, weight, ASA grade, duration of surgery, pre-operative diastolic and systolic blood pressure

Mean weight, duration of surgery, pre-operative diastolic and systolic blood pressure and oxygen saturation were non-significantly different between the groups making them comparable.

Intra-operative blood pressure and respiratory rate

In our study, mean diastolic and systolic blood pressure, respiratory rate and oxygen saturation remained stable throughout the study period in all the three groups. Mean diastolic and systolic blood pressure was comparable between the three groups at all intervals (P>0.05). Similar to our study, Gandhi M et al. (2021) also reported no significant variation in the mean arterial blood pressure, respiratory rate on administration of Dexamethasone in the dose of 0.1mg/kg as an adjuvant to 0.25% Bupivacaine for caudal analgesia in children [2]. Larousse E et al. (2002) studied the hemodynamic effect of 1 ml/kg of 0.25% bupivacaine with 1/200,000 epinephrine when administered as caudal anaesthesia. They found that caudal anaesthesia does not influence mean arterial blood pressure. All these findings from our study and previous research indicated that Bupivacaine provides stable hemodynamic parameters during surgery and co-administration of Dexamethasone either caudally or intravenously to bupivacaine does not hamper hemodynamic parameters.

Post-operative pain

In the present study, FLACC pain scale was used to evaluate postoperative pain as it is easy to use, is validated and gives an objective evaluation [18]. In this study, till 2 hours post-operatively the pain score was not found to differ significantly between three groups (p value>.05). However, at 3 hours onwards, significant differences in pain score were observed between the groups which suggested that pain score were significantly less in group 2 compared to group 1 and 3. Similar to our findings, Choudhary S et al. (2016) in their study to assess the effects of caudally administered dexamethasone, reported that Pain score in first 2 hours were not found to differ significantly between the groups however, at 4, 6, 12 hours, the pain score in group A (Control) was significantly greater than that in group B subjects (Dexamethasone) [19]. Similarly, Gandhi M et al. (2021) also reported significantly lower pain scores on caudal administration of dexamethasone as an adjunct to Bupivacaine than bupivacaine alone [2]. Bishnoi A et al. (2020) reported significantly less FLACC score amongst patients in which dexamethasone had been administered as adjuvant to caudal block [20].

El-Feky EM et al. (2014) reported significant reduction in pain score on use of Dexamethasone ad adjuvant to Bupivacaine [21].

Time to rescue analgesia

In the present study, mean time to rescue analgesia differed significantly between the groups (P=0.001). The shortest time to request for first rescue analgesia was seen in Group 1 and longest was seen in Group 2. These findings showed that administration of dexamethasone as an adjunct significantly prolongs the time to first rescue analgesia and the results are significantly better administered caudally compared to IV. Hong JY et al. (2010) had also reported that single IV dose of dexamethasone in combination with caudal block significantly prolongs the time to rescue analgesia. In their study, time to rescue analgesia in dexamethasone group was 646 minutes and in control group was 430 minutes [22]. Similarly, Khafagy HF et al. (2010) reported significantly prolonged time (4.8 times) to first rescue analgesia in experimental group (use of dexamethasone as an adjunct) compared to control group [23]. Bishnoi A et al. (2020) reported d significantly long duration of analgesia amongst patients in which dexamethasone had been administered ad an adjuvant to caudal block.20 Similar findings were reported by Girgis K (2014) [24], Almajali Z et al. (2014) [25], Kim EM et al. (2014) [26]. According to the findings of Girgis K (2014), bupivacaine in combination with dexamethasone prolongs the duration of postoperative analgesia [24]. Almajali Z et al. (2014) postoperative mean pain free period was significantly less in group I (plain bupivacaine 0.25%) than in group II (bupivacaine 0.25% mixed with dexamethasone 0.1mg/kg) (186 minutes vs 272 minutes) [25]. Mohamed GS et al. (2020) compared the effect of caudal and IV administration of dexamethasone as an adjunct to caudal bupivacaine. They also found that caudal administration of dexamethasone significantly prolongs the duration of the postoperative analgesic effect of caudal block compared to when given intravenously [27].

Total analgesic consumed

Out study showed that the total analgesic consumed significantly differed between the groups (P=0.001). The highest analgesic consumption was seen in Group 1 patients and the lowest in Group 2 patients. These findings showed that administration of dexamethasone as an adjunct significantly reduces the analgesic consumption and the results are significantly better when dexamethasone is administered caudally compared to IV. Similar to our study, Gandhi M et al. (2021) also reported that caudal administration of dexamethasone as an adjunct to Bupivacaine significantly reduces the total analgesics consumed [2]. In agreement to our findings, Obsa M et al. (2020) reported that caudal IV administration of dexamethasone as an adjunct to caudal Bupivacaine significantly reduce the amount of total analgesics consumed [28]. Similarly, Gashaw A et al. (2020) reported that analgesic consumption was significant lower in patients receiving dexamethasone compared to those not receiving dexamethasone (55 (0-250)mg vs 402(95-812)mg) as an adjunct to bupivacaine [29]. El-Feky EM et al. (2014) and Kim EM et al. (2014) also reported significantly less consumption of analgesics in patients receiving dexamethasone caudally along with Bupivacaine.21,26 Kim EM et al. (2014) reported that significantly lesser number of subjects receiving dexamethasone consumed oral analgesics compared to those not receiving dexamethasone as adjuvant to caudal block [28.9% vs 54.1%] [26].

5. Limitations of the study

This was carried out amongst patient of a single centre. The sample size is comparatively small and included children aged 1-5 years only with ASA grades I and II only. The blood sugar levels of the children were not studied in this study.

6. Conclusion

1. Caudal administration of dexamethasone 0.1mg/Kg (0.025ml/kg) and IV administration of dexamethasone 0.3mg/kg (0.075ml/kg) as an adjunct to caudal Bupivacaine 0.25% (1ml/kg) provides significantly longer duration of post-operative analgesia and lesser total analgesic consumption compared to use of caudal Bupivacaine 0.25% (1ml/kg) alone.
2. Caudal administration of dexamethasone 0.1mg/Kg (0.025ml/kg) as an adjunct to caudal Bupivacaine 0.25% (1ml/kg) provides significantly longer duration of post-operative analgesia and lesser total

analgesic consumption compared to IV administration of dexamethasone 0.3mg/kg (0.075ml/kg) as an adjunct to caudal Bupivacaine 0.25% (1ml/kg).

3. Dexamethasone when administered caudally 0.1mg/Kg (0.025ml/kg) or intravenously 0.3mg/kg (0.075ml/kg) as an adjunct to caudal Bupivacaine 0.25% (1ml/kg) provides hemodynamic stability and is not associated with any adverse effects.

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Conflicts of Interest: The authors declare that they do not have any conflict of interests.

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