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A comparative study of levobupivacaine 0.25% with dexmedetomidine and dexamethasone as adjuvant in caudal block for pediatric patients undergoing infraumbilical surgeries

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ABSTRACT

Background: The caudal epidural block is one of the most commonly used regional techniques for post-operative pain management in pediatric age group patients undergoing infraumbilical surgeries. Adjuvants use increase the duration of analgesia and decrease local anesthetic dose requirement, thereby decreasing the risk of toxicity. **Aims and Objectives:** The aim of the present study was to compare the prolongation of the duration of analgesia, hemodynamic parameters, and side effects if any, provided by the addition of dexmedetomidine (DEX) or dexamethasone as an adjuvant to levobupivacaine in the caudal block. **Materials and Methods:** A total of 60 patients with the American Society of Anesthesiologists grade I/II scheduled for elective infraumbilical surgeries were randomly allocated into two groups of 30 each. Group 1 received levobupivacaine 0.25% 1 mL/kg + DEX 1 mcg/kg and Group 2 received levobupivacaine 0.25% 1 mL/kg + dexamethasone 0.1 mg/kg for caudal block. The duration of analgesia, hemodynamic parameters, and adverse events during the post-operative period were noted. **Results:** There was no statistically significant difference in hemodynamic parameters between Group 1 and Group 2. Post-operative face, leg, activity, cry, consolability, (FLACC) pain scores were significantly lower in Group 1 when compared with Group 2. The mean duration of analgesia was prolonged in Group 1 at 824.23 ± 53.53 min than in Group 2 with a mean duration of analgesia 480.50 ± 31.66 min which was statistically significant ($P < 0.005$). Adverse events were comparable between the two groups and were statistically not significant ($P > 0.05$). **Conclusion:** The addition of DEX to levobupivacaine in caudal block significantly prolongs the duration of analgesia in post-operative period in comparison to the addition of dexamethasone with levobupivacaine. It also provides more hemodynamic stability during the intraoperative and post-operative period, lower FLACC pain scores, and is associated with minimal side effects.

Key words: Levobupivacaine; Dexmedetomidine and dexamethasone; Caudal block

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INTRODUCTION

Pain states that it is an unpleasant sensory and emotional feeling accompanying existing or impending tissue damage or referenced to such damage.[1] Pain management is an integral part of anesthesia care in children. Regional anesthesia plus general anesthesia has advantages including decreased analgesic requirements, early extubation, decreased pulmonary complications, and early discharge.[2]

A caudal block is a popular reliable and safe technique for pediatric pain management for infra-umbilical surgical procedures. A single-shot caudal block as an additional technique to general anesthesia is commonly used for

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post-operative pain relief in pediatric lower abdominal, urologic, and lower limb surgery.[3]

Adjuvants use increases the duration of analgesia and decreases local anesthetic dose requirement decreasing the risk of toxicity.[4]

Levobupivacaine is a long-acting amide local anesthetic. Levobupivacaine is slightly less toxic to the central nervous system than bupivacaine, and it causes less myocardial depression and fatal arrhythmias.[5]

Dexmedetomidine (DEX) is a highly selective alpha-2 adrenergic receptor agonist.[6] It provides stable hemodynamic conditions and good quality of intraoperative and post-operative analgesia with minimal side effects.

Dexamethasone is very effective in prolonging the duration of peripheral nerve blocks and it also improves the quality of sensory blocks. Dexamethasone is commonly used for the management of post-operative pain, nausea, and vomiting.[7]

In this study, we evaluated the effect of DEX and dexamethasone as adjuvant to levobupivacaine in the caudal block for pediatric patients undergoing infraumbilical surgery.

Aims and objectives

1. To compare the prolongation of duration of analgesia.
2. To compare hemodynamic parameters
3. To compare side effects if any.

MATERIALS AND METHODS

We conducted a prospective, randomized, comparative, double-blind study in a cohort of 60 patients admitted to a super specialty hospital, GRMC Gwalior, belonging to the physical status of the American Society of Anesthesiologist (ASA) grade I and II, aged 1–8 years, undergoing infra umbilical surgeries, after obtaining approval from the Institutional Ethics Committee, informed and written consent from the parents of the patient.

Sample size calculated using the following formula, i.e.,

$$n = \frac{2S^2\left(Z_\alpha + Z_{1-\beta}\right)^2}{\left(\mu_1 - \mu_2\right)^2}$$

and we got a sample size of 60 (n=30).

Inclusion criteria

- Patient's guardian giving consent to participate in the study
- Pediatric age group (1–8 years)
- Patients of either sex
- ASA grades I and II
- Patients scheduled for infra umbilical surgeries.

Exclusion criteria

- Patient's guardian not giving consent to participate in the study
- ASA grade III and IV
- Patient with known hypersensitivity to local anesthetic
- Abnormal coagulopathy
- Pre-existing neurological disease
- Local sepsis or infection
- Mentally retarded child
- Abnormal sacral anatomy.

All parents were explained about the anesthetic technique during a pre-operative visit on the day before surgery.

Patients were randomly allocated into two groups by putting out a sealed envelope method undergoing elective infra-umbilical surgeries.

- Group 1: Levobupivacaine 0.25% 1 mL/kg+DEX 1 mcg/kg
- Group 2: Levobupivacaine 0.25% 1 mL/kg+ dexamethasone 0.1 mg/kg.

Technique

Standard ASA monitors were attached and all the children were pre-medicated with an injection of glycopyrrolate 0.005 mg/kg i/v and an injection of midazolam 0.05 mg/kg i/v before induction of anesthesia. Pre-oxygenation was done using 100% oxygen, and induction of anesthesia was done by injection of ketamine 2 mg/kg, injection of succinylcholine 2 mg/kg, and sevoflurane.

Intubation was done with the appropriate size of the endotracheal tube. Maintenance of anesthesia was done with 33% oxygen+67% nitrous oxide+sevoflurane+injection atracurium. The child was turned to the lateral decubitus position and under all aseptic precautions after localization of landmark, the sacral hiatus was punctured with a 22 gauge, 1½ inch short beveled needle. 1–2 mL of air was inserted (Whoosh test) for confirmation. If there was no wheal formation in the subcutaneous tissue, a study drug was injected that was loaded by the other anesthetist who was not involved in this study, and then, the child was made supine.

The surgical incision was made 10 min after the caudal placement of the study drug. Hemodynamic parameters were recorded every 10 min intraoperatively. Patients were observed for increase or decrease in heart rate and signs of respiratory depression, and the presence of any

of the above parameters was considered a failure of the caudal block. The children presented with signs of caudal block failure were excluded from the study and managed with additional doses of fentanyl intraoperatively. After extubation pain score was assessed using face, leg, activity, cry, and consolability (FLACC)[7] scale (0=no pain, 1–3=mild pain, 4–7=moderate pain, and 8–10=severe pain) at the interval of 0, 15, 30, 60, 90, 120, 150, and 180 min. The time from caudal block to the time when FLACC score was >4 was considered the duration of analgesia and at that time, rescue analgesia was given in the form of I/V diclofenac 2 mg/kg.

Pain scores were assessed and documented postoperatively every hour for the first 6 h, 2 hourly for 16 h, and 4 hourly till 24 h. We also recorded post-operative hemodynamic parameters till 90 min in the recovery room under observation.

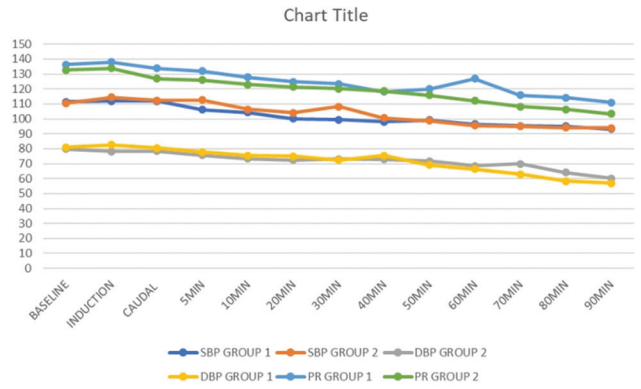
Any side effect or complication due to the drug or technique was noted including hypotension, bradycardia, tachycardia, nausea, vomiting, fever, shivering, respiratory depression, wound infection, etc.

Statistical analysis

All the observations and particulars of each patient were recorded in a pro forma. Data were composed in a suitable spreadsheet, i.e., EXCEL and Statistical Package for the Social Sciences (SPSS). After compilation data were analyzed statistically by SPSS software version 20.0. To compare the two groups either Chi-square test or unpaired t-test was applied. The significance level was 95% confidence level (P<0.05). Data were described as a frequency (percentage) distribution as well as in Mean±SD.

RESULTS

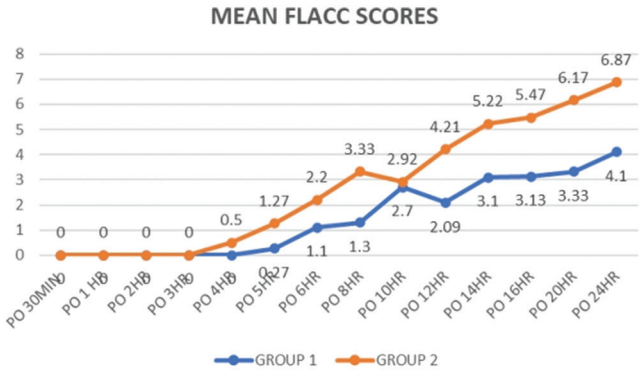
Levobupivacaine in combination with dexmedetomidine and dexamethasone in caudal analgesia.



Hemodynamic variables

There was no significant difference in demographic data, hemodynamic parameters, or duration of surgery between Group 1 and Group 2 (P>0.05). There were no significant changes in mean oxygen saturation (SpO_2) and mean end-tidal carbon dioxide between the two groups (P>0.05).

FLACC pain scores



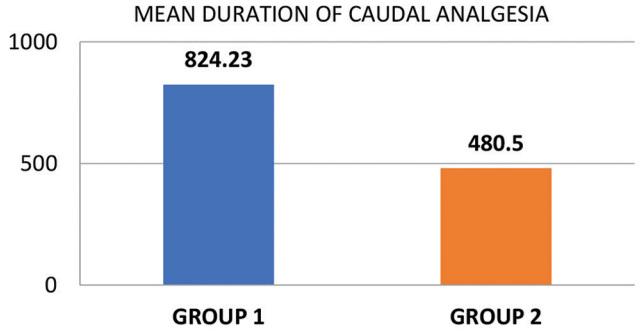
Postoperatively FLACC scores at 30 min, 1 h, 2 h, 3 h, 4 h, 5 h, 6 h, 8 h, and 10 h were <4 in both Group 1 and Group 2 indicating the child is pain-free, and analgesia is excellent. The mean FLACC pain scores at 12 h, 14 h, 16 h, 20 h, and 24 h were significantly lower in Group 1 than in Group 2 (P<0.005). Thereby, we can see that the duration of analgesia was significantly longer in Group 1 than in Group 2.

Mean duration of caudal analgesia

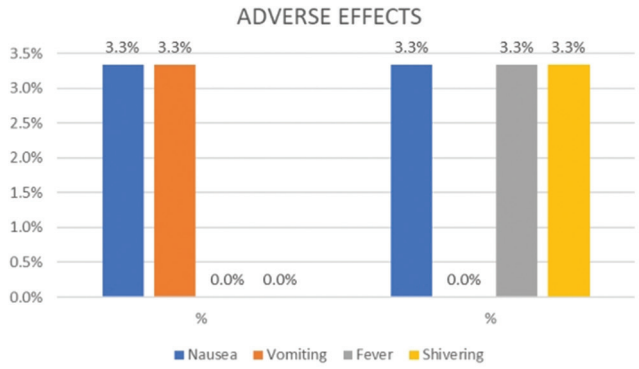
Comparison of mean duration of analgesia (minutes) between study groups

Groups	Mean±SD	"t" value	P-value
Group 1	824.23±53.53	−30.2723, df=58	0.000**
Group 2	480.50±31.66		

SD: Standard deviation, df=degree of freedom, P-value is 0.001



The mean duration of analgesia in Group 1 was 824.23±53.53 min and in Group 2, mean duration of analgesia was 480.50±31.66 min. Duration of analgesia



was statistically significant (P<0.005) and prolonged in Group 1 than in Group 2.

Adverse effects

Fewer adverse effects were seen in both groups and found to be statistically not significant (P>0.05) which shows that the adverse effects of both groups are comparable.

DISCUSSION

We assessed the effect of caudal block in our study in terms of prolongation of the duration of analgesia, hemodynamic changes intraoperatively and postoperatively, and side effects if any. There was no statistically significant difference in demographic data, ASA grade, type of surgery, or duration of surgery distribution in both groups (P>0.05). There is no significant difference in hemodynamic parameters between both groups (P>0.05). Meghani et al.,[8] found that the systolic blood pressure and heart rate were statistically insignificant between Group A (bupivacaine+normal saline) and Group B (bupivacaine+clonidine+normal saline) during surgery. Ali et al.[9] found that mean systolic blood pressures between Group A (1 mL/kg of 0.1% ropivacaine), Group B (1 mL/kg of 0.1% ropivacaine with clonidine 1 mcg/kg), and Group C (1 mL/kg of 0.2% ropivacaine) were insignificant. Laha et al.[10] found that intraoperative diastolic blood pressure was not statistically significant between Group A (plain ropivacaine) and Group B (ropivacaine+clonidine). Mahendru et al.[11] compared the heart rates between three groups who received intrathecal fentanyl, clonidine, and DEX in lower limb surgeries and found that the mean values of heart rate were comparable between the studied groups during both intraoperative and post-operative periods. EI-Rahman Ali et al.[12] noted a comparison of intraoperative and post-operative SpO_2 between three study groups showed that there was no significant difference, Group C (0.25 and bupivacaine+NS), Group D (0.25% bupivacaine+DEX 1 mcg/kg), and Group M (0.25% bupivacaine+50 mg magnesium sulfate).

Abu Elyazed et al.[13] did a study in which Group I received plain 0.25% bupivacaine, Group II received bupivacaine with dexamethasone, and Group III received bupivacaine with neostigmine who underwent ultrasound-guided caudal block in which they found that mean arterial pressure changes among three groups were comparable.

Postoperatively FLACC scores at 30 min, 1 h, 2 h, 3 h, 4 h, 5 h, 6 h, 8 h, and 10 h were <4 in both Group 1 and Group 2 indicating the child is pain-free, and analgesia is excellent. The mean FLACC pain scores at 12 h, 14 h, 16 h, 20 h, and 24 h were significantly lower in Group 1 than in Group 2 (P<0.005). Thereby, we can see that the duration of analgesia was significantly longer in Group 1 than in Group 2. Sanwatsarkar et al.[13] observed that FLACC pain scores never reached >4 during the first 3 h in any groups, however, by the end of 4th, 8th, and 12th h, the number of patients with FLACC pain scores >4 was significantly more in Group B (received 1 mL/kg 0.25% bupivacaine in normal saline) than Group BC (received 1 mL/kg 0.25% bupivacaine+1 mcg/kg clonidine in normal saline) and Group BM (received 1 mL/kg 0.25% bupivacaine+30 mcg/kg midazolam in normal saline) with 46%, 56%, and 72%, respectively. Goyal et al.[14] found that the mean FLACC score was less in patients of Group B (who received 0.25% bupivacaine 1 mL/kg+1 mcg/kg in 1 mL NS) throughout the initial 12 h of the post-operative period when compared with Group A. The mean FLACC pain score of Group A was 7.21±1.76, and that of Group B was 6.49±1.72. The results are comparable and statistically significant.

The mean duration of analgesia in Group 1 was 824.23±53.53 min. In Group 2, the mean duration of analgesia was 480.50±31.66 min. The duration of analgesia was significantly prolonged in Group 1 than in Group 2. Badoke and Hooli[15] found that the mean duration of post-operative analgesia was found significantly longer in Group D, i.e., ropivacaine+DEX (718.00±100.06 min) as compared to Group T, i.e., ropivacaine+tramadol (467.33±68.94 min) with P<0.001. Gupta and Sharma,[16] observed that Group RD (0.25% ropivacaine with DEX) had a prolonged mean duration of analgesia of 780.29±71.21 min when compared with Group RT with a mean duration of analgesia of 654.20±78.36 min (P=0.0001).

Fewer adverse effects were seen in both groups and found to be statistically not significant (P>0.05) which shows that the adverse effects of both groups are comparable. Goswami et al.,[7] found that the incidence of side effects such as vomiting and urinary retention was equal between Group B (bupivacaine) and Group BD (bupivacaine+DEX). Gupta

and Sharma[16] found that the incidence of side effects such as shivering (P=1.0), post-operative nausea and vomiting (P=0.642), and hypotension (P=1.0) was not statistically significant.

Limitations of the study

Lack of standardization: The success rate of the block was not fully assessed since it was given after general anesthesia.

CONCLUSION

Based on the present study, we have concluded that adding DEX to levobupivacaine in caudal block significantly prolongs the duration of analgesia in post-operative period when compared with the group receiving levobupivacaine with dexamethasone. It also provides more hemodynamic stability during the intraoperative and post-operative periods and is associated with minimal side effects.

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NT- Concept and design of the study, prepared the first draft of the manuscript; **BS**- Interpreted the results; reviewed the literature and manuscript preparation; **SS**- Concept, coordination, statistical analysis, and interpretation; **JMM**- Preparation of manuscript and revision of the manuscript.

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