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A comparative study of levobupivacaine alone and in combination with dexamethasone in caudal block for pediatric patient 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 increases the duration of analgesia and decrease local anesthetic dose requirement so decreasing the risk of toxicity. **Aims and Objectives:** The aim of present study was to evaluate and compare the efficacy of caudal block with 0.25% levobupivacaine 1 mL/kg and 0.25% levobupivacaine 1 mL/kg + dexamethasone 0.1 mg/kg for post-operative pain relief in pediatric patients undergoing infraumbilical surgeries. The secondary objective of the study was to compare hemodynamic parameters and side effects if any. **Materials and Methods:** A prospective, randomized, comparative, and double-blind study design was conducted in 60 patients in JAH super specialty group of hospitals. All patients belonging to physical status of American Society of Anesthesiologists Grade I and II, aged 1–6 years, were randomly allocated into two groups: Group 1 (n = 30) received levobupivacaine 0.25% 1 mL/kg in 0.5 mL saline and Group 2 (n = 30) received levobupivacaine 0.25% 1 ml/kg with dexamethasone 0.1 mg/kg for caudal block in pediatric patients undergoing infraumbilical surgeries. Primary outcome was duration of analgesia using face, legs, activity, cry, and consolability scale at interval of 0, 15, 30, 60, 90, 120, 150, and 180 min postoperatively. The secondary outcome of study included hemodynamic parameters and adverse events during the post-operative period. **Results:** The mean duration of analgesia in Group 1 (L) was 430.77 ± 16.71 min and in Group 2 (L + D) was 805.00 ± 36.71 min with statistically significant result. **Conclusion:** On adding dexamethasone to levobupivacaine in caudal block significantly prolongs duration of analgesia in post-operative period. It also provides more hemodynamic stability during intraoperative and post-operative period and associated with minimal side effects.

Key words: Levobupivacaine; Dexamethasone; Caudal block

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INTRODUCTION

The caudal epidural block is one of the most commonly used regional techniques for intraoperative and post-operative pain management in pediatric patients undergoing infraumbilical surgeries.[1,2]

The caudal epidural is safe and easy to administer with less complication and failure rate.[3] Long-term use of local anesthetic agents (xylocaine, bupivacaine, and ropivacaine) may result in toxicity so to avoid this problem, we use adjuvants.[4]

Use of adjuvants increases the duration of analgesia and decrease local anesthetic dose requirement so decreasing the risk of toxicity.[4]

In this study, we evaluated the effect of dexamethasone when added to levobupivacaine in a caudal block for pediatric patients undergoing infraumbilical surgeries.

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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]

Dexamethasone is very effective in prolonging the duration of peripheral nerve blocks, it also improves the quality of sensory blocks. Dexamethasone is commonly used for the management of post-operative pain, nausea, and vomiting.[6]

Aims and objectives

The aim of the study was to evaluate and compare the efficacy of caudal block with 0.25% levobupivacaine 1 mL/kg and 0.25% levobupivacaine 1 mL/kg+dexamethasone 0.1 mg/kg for post-operative pain relief in pediatric patients undergoing infraumbilical surgeries.

Primary objective

The primary objective of the study was to evaluate the prolongation of duration of analgesia.

Secondary objective

The secondary objectives of the study are as follows:

1. To study the intraoperative hemodynamics.
2. To record the side effects if any.

MATERIALS AND METHODS

We conducted a prospective, randomized, comparative, and double-blind study in a cohort of 60 patients admitted to super specialty group of hospitals, belonging to physical status of American Society of Anesthesiologists (ASA) Grade I and II, aged 1–6 years, undergoing infraumbilical surgeries, after obtaining approval from the ethics committee of the institute and informed and written consent from the parents of patient.

Sample size was calculated using formula $n = (S1^2+S2^2)(Z\alpha/2+Z_1-\beta)^2/(\mu_1-\mu_2)^2$, and we got sample size 60 (n=30).

Inclusion criteria

The following criteria were included in the study:

- Patient's guardian giving consent to participate in the study
- Age between 1 and 6 years
- Patient of either sex
- ASA Grade I and II
- Patient scheduled for infraumbilical surgeries.

Exclusion criteria

The following criteria were excluded from the study:

- 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.
- Active infection at local site.
- Any anatomical abnormality.

All 60 patients satisfying the inclusion criteria randomly allocated into two groups, Group 1 and Group 2, using envelop method were investigated for routine baseline pre-operative complete blood count, random blood sugar, chest X-ray, and a 12 lead Electrocardiography. Parents were explained about the procedure and their consent were taken in written format. Patients were subsequently randomized into two groups of 30 each.

- Group 1 – Levobupivacaine 0.25% 1 mL/kg+Saline 0.5 mL
- Group 2 – Levobupivacaine 0.25% 1 mL/kg+dexamethasone 0.1 mg/kg.

Technique

Pre-anesthetic evaluation was done on the day before surgery. All the children were pre-medicated with inj. Glycopyrrolate 0.005 mg/kg i/v and inj. Midazolam 0.05 mg/kg i/v before induction of anesthesia.

Standard ASA monitors were attached and intravenous induction of anesthesia was done by using 100% oxygen, inj. Ketamine 2 mg/kg, inj. Succinylcholine 2 mg/kg and sevoflurane.

Airway management was done with use of endotracheal tube. Maintenance of anesthesia was done with 33% oxygen+67% nitrous oxide+sevoflurane+Inj. atracurium. The child was turned to the lateral decubitus position and under all aseptic precaution after localization of landmark, sacral hiatus was punctured with 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, study drug injected that was loaded by the other anesthetist who was not involved in this study and then child was made supine.

The surgical incision was made 10 min after caudal placement of study drug. 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, legs, activity, cry, consolability (FLACC)[7] scale (0=No pain, 1–3=Mild pain, 4–7=Moderate pain, and 8–10=Severe pain) at interval of 0, 15, 30, 60, 90, 120, 150, and 180 min. Time from caudal block to the time when FLACC score was >4 considered as duration of analgesia and at that time rescue analgesia was given in form of I/V diclofenac 2 mg/kg.

Table 1: FLACC scale

FLACC scale	0	1	2
1- Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chi
2 - Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
3 - Activity	Lying quietly, normal position, moves easily.	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
4 - Cry	No crying (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
5 - Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

FLACC: Face, legs, activity, cry, consolability

Pain scores were assessed and documented postoperatively every hour for first 6 h and second hourly for 16 h and fourth hourly till 24 h. We also recorded post-operative hemodynamic parameters till 90 min in 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, and wound infection.

FLACC scale

FLACC scale consist of 5 parameter Face, leg, activity, cry, consolability. Each parameter having minimum 0 and maximax 2 score. so total score will be from 0 to 10. This scale used for assessment of severity of pain in post operative patients [Table 1].

Statistical analysis

All the observations and particulars of each patient were recorded in a Proforma. Data were composed in a suitable spreadsheet, that is, EXCEL and 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 were applied. Significance level was 95% confidence level ($P<0.05$). Data were described as a frequency (percentage) distribution as well as in mean±standard deviation. All the observations and particulars of each patients were recorded in a proforma.

RESULTS

The 60 patients in two groups included in the study were compared with respect to demographic variables: Age, weight, and gender. The two groups were comparable and there was no statistically significant difference among the two groups with respect to these variables (Table 2).

There is a significant decrease in post-operative systolic blood pressure in Group 2 (L+D) compared to Group 1 (L) after caudal block (Figure 1).

Table 2: Demographic parameter

Demographic parameter	Group L (n=30)	Group L+D (n=30)	P value
Age (years)	4.38±1.29	4.90±1.17	0.112
Weight (kg)	14.73±4.78	16.28±3.42	0.154
Male:Female	29:1	27:3	0.301

The difference between the two groups was statistically insignificant (P>0.05). There were no significant difference in demographic profile between 2 groups (P>0.05)

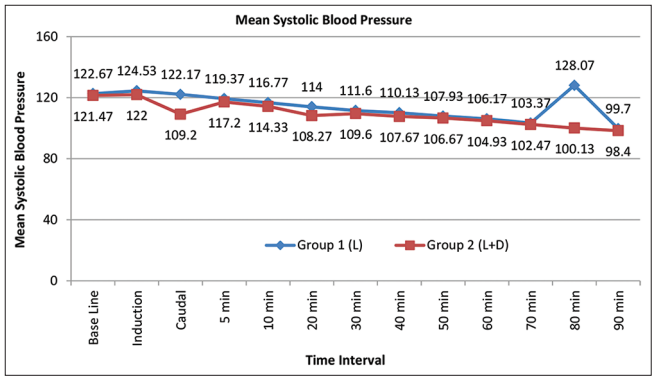

Figure 1: Mean systolic blood pressure. P<0.05. There is significant decrease in mean systolic blood pressure after 20 minutes of caudal block in group 2

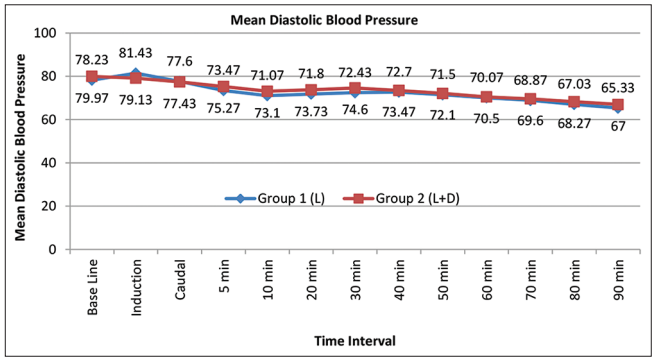

Figure 2: Mean systolic blood pressure. P<0.05. There were no significant difference in diastolic blood pressure between two groups(P>0.05)

There were no significant changes in diastolic blood pressures between the two groups (P>0.05) (Figure 2).

There is a significant decrease in post-operative mean pulse rate in Group 2 (L+D) as compared to Group 1 (L)

at induction, at 40 min, 80 min, and 90 min (P<0.05), and there is highly significant decrease in postoperative pulse rate at 5 min, 10 min, 20 min, 30 min, 50 min, and 60 min (P<0.005) (Figure 3).

There were no significant changes in mean SPO2 between the two groups (P>0.05) (Figure 4).

Postoperatively, FLACC score at 3 h, 4 h, 5 h, 6 h, 8 h, 14 h, 16 h, 20 h, 24 h was highly significantly lower (P<0.005) and at 10 h, it was significantly lower (P<0.05) in group 2 (L+D), so we can see that duration of analgesia was significantly longer (Figure 5).

The mean duration of analgesia in Group 1 (L) was 430.77±16.71 min and in Group 2 (L+D) was 805.00±36.71 min. Duration of analgesia was statistically highly significant (p<0.005) and prolonged in Group 2(L+D) (Figure 6).

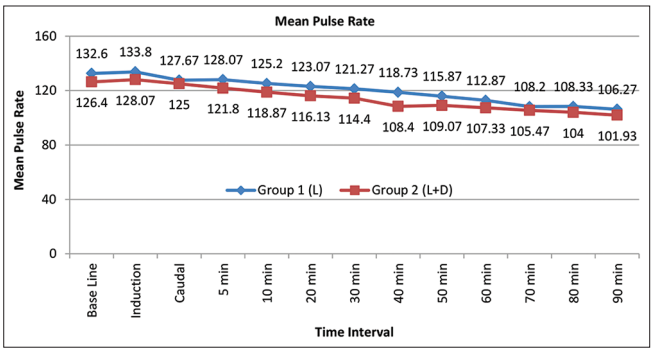

Figure 3: Mean pulse pressure. P<0.05. There is significant decrease in mean pulse rate in group 2 at induction, 40 min, 80 min, 90 min (<0.05) and highly significant decrease in group 2 at 5 min, 10 min, 20 min, 30 min, 50 min, 60 min (P<0.005)

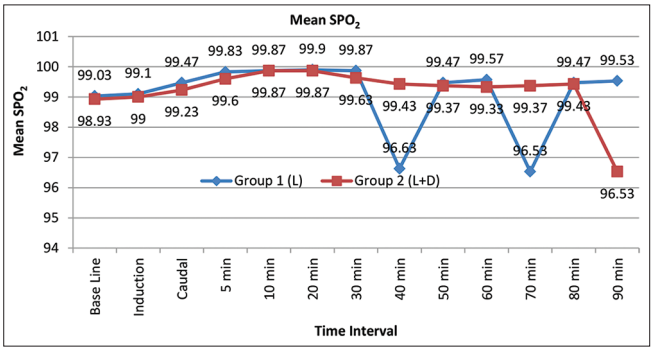

Figure 4: Mean SPO_2. P<0.05. There were no significant changes in mean SPO_2 between the two groups (P>0.05)

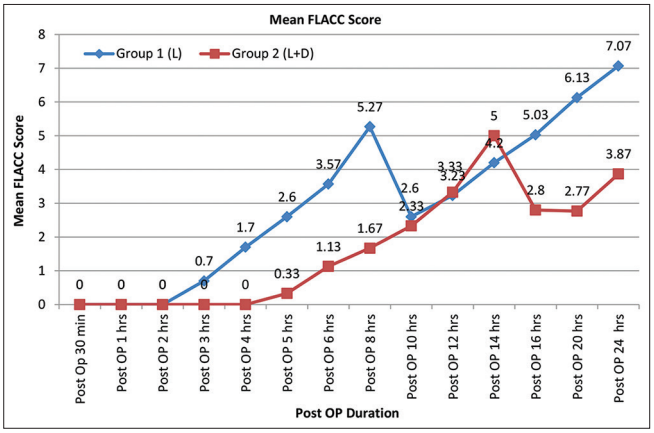

Figure 5: Mean FLACC score. P<0.05. Postoperatively in group 2, FLACC score at 3 hr, 4 hr, 5 hr, 6 hr, 8hr, 14 hr, 16 hr, 20 hr, 24 hr was highly significantly lower (P<0.005)

DISCUSSION

In the present study, we have studied intraoperative and post-operative analgesia and see the effect of an adjuvant added to levobupivacaine in caudal block**.** In our study, levobupivacaine was used along with an adjuvant dexamethasone in caudal block. After institutional ethical committee clearance, patients were randomized into two groups, that is, Group L received 0.25% levobupivacaine 1mL/kg with NS 0.5 mL and Group L+D received 0.25% levobupivacaine 1 mL/kg with dexamethasone 0.1 ml/kg. We assessed the effect of caudal block in our study in term of prolongation of duration of analgesia, hemodynamic changes intraoperatively and postoperatively, and side effects if any were noted. There was no statistically significant difference in demographic data, ASA grade, type of surgery, and duration of surgery distribution in both group (P>0.05). There is a significant decrease in post-operative systolic blood pressure in Group 2 (L+D) compared to Group 1 (L) because levobupivacaine does sympathetic blockade and dexamethasone synergizes with levobupivacaine on blockage of impulse conduction in nerve fibers.[8,9] There was no significant difference in diastolic blood pressure from baseline value between the two groups (P>0.05) because levobupivacaine has no effect on parasympathetic system. There is a highly significant (P<0.005) decrease in post-operative pulse rate in Group 2 (L+D) at 5 min, 10 min, 20 min, 30 min, 50 min, 60 min, and significant decrease (P<0.05) at 80 min, 90 min as compared to Group 1 (L) because of sympathetic blockade

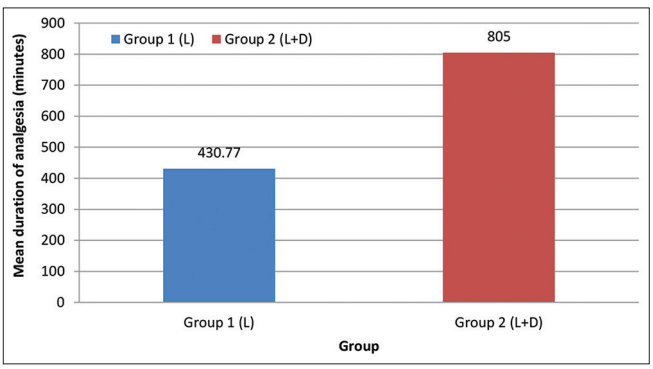

Figure 6: Mean duration of analgesia (minutes). Mean duration of analgesia in group 2 was 805±36.71 min while in group 1 was 430.77±16.71 min which was highly significant (P<0.005) in group 2

which is accentuated by dexamethasone. There were no significant changes in mean SPO_2 from the baseline value between the two groups (P>0.05). The mean duration of analgesia in Group 1 (L) was 430.77±16.71 min. In Group 2 (L+D) was 805.00±36.71 min which was highly prolonged in Group 2 because dexamethasone alters the function of potassium channels in excitable neurons[9] and it occupies the glucocorticoid receptors in the endothelium of cutaneous blood vessels which leads vasoconstriction.[10]

Laha et al.,[11] found that intraoperative systolic blood pressure was not statistically significant between Group A (Plain ropivacaine) and Group B (ropivacaine+clonidine). Saini et al.,[12] compared systolic blood pressure intraoperatively at different intervals between the Group RC (0.25% ropivacaine 1 mL/kg+2 μg/kg clonidine) and Group RF (0.25% ropivacaine 1 mL/kg + 1 μg/kg fentanyl), but the difference was statistically insignificant (P>0.05). Imani et al.,[13] noted that diastolic blood pressure postoperatively was significantly lower in Group DR (0.2% ropivacaine 1 mL/kg+2 μg/kg dexmeditomedine) than in Group R (0.2% ropivacaine 1 mL/kg). Meghani et al.,[14] found no significant difference in heart rate between Group A and Group B during surgery. Children receiving high dose clonidine (5 μg/kg) had lower heart rates during the first 3 h after surgery compared with the control group. El Shamaa and Ibrahim[15] noted that intraoperative heart rate was not significant between the Group A (bupivacaine + dexmedetomidine) and Group B (bupivacaine + morphine). Intraoperative SpO_2 was not statistically significant between the Group A and Group B (P>0.05) according to El Shamaa and Ibrahim.[15] Hassan et al.,[5] observed FLACC scores from 30 min to 12 h postoperatively. There was a significant difference between the group N(0.25% levobupivacaine 0.75 mL/kg+0.2 mg/kg nalbuphine+normal saline), Group F (0.25% levobupivacaine 0.75 mL/kg+1 μg/kg fentanyl) and Group D (0.25% levobupivacaine 0.75 mL/kg+0.1 mg/kg dexamethasone+normal saline) at 2, 6, and 8 h postoperatively; otherwise, no significant difference was found. Badole and Hooli[16] found that postoperatively up to 90 min FLACC score was < 4. However, after 90 min, adequate analgesia declined rapidly in Group T (ropivacaine + tramadol) as compared to Group D (ropivacaine + dexmeditomedine) and the difference was statistically significant. Kumar and Kadam et al.,[17] observed that the mean duration of analgesia in Group B (bupivacaine) was 288.1 min and in the Group BD (bupivacaine+dexmedetomidine) was 541 min. Duration of analgesia was significantly prolonged when dexmedetomidine was used along with bupivacaine (P<0.001). Meghani et al.,[14] found that the duration of analgesia was significantly longer in Group B (bupivacaine+clonidine+normal saline), that is, 9.98±0.86 h. than Group A (bupivacaine+normal saline), that is, 4.3±1.12 h. Gupta and Sharma[18] 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.

Scope

Comparing other drugs to find out the most effective, feasible, and optimum drug for caudal block in pediatric patients I.

Limitations of the study

Limitations of our study were the small sample size. Often a larger trail testing selected gives greater differences and more significant results.

CONCLUSION

From the present study, it is concluded that on adding dexamethasone to levobupivacaine in caudal block significantly prolongs duration of analgesia in post-operative period. It also provides more hemodynamic stability during intraoperative and post-operative period and associated with minimal side effects.

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Author's Contribution:
EB- Concept and design of the study and prepared first draft of manuscript; **SS-** Interpreted the results; reviewed the literature, and manuscript preparation; **SS-** Concept, coordination, statistical analysis and interpretation, and preparation of manuscript; and **NT-** Revision of the manuscript.

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