

# Caudal Analgesia with Low Dose Levobupivacaine 0.25% Alone and In Combination with Low Dose Fentanyl or Dexmedetomidine In Paediatric Patients: Comparative Prospective Randomised Double Blind Study

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## ABSTRACT

**Introduction:** The utility of caudal anaesthesia occurs mainly in paediatric patients for sub umbilical surgeries. It can serve as a sole anaesthetic or can be an adjuvant to general anaesthesia and for that purpose levobupivacaine is an effective local anaesthetic agent due to reduced cardiac and CNS toxicity along with adjuvants. Fentanyl, dexmedetomidine and clonidine are promising additives to prolong post operative caudal analgesia as well as to reduce the dose of levobupivacaine.

**Aims and Objectives:** The purpose of this prospective randomised double-blind study was to compare the quality in terms of hemodynamic variables, pain score, level of sedation and duration of analgesia in caudal block using low dose 0.5ml/kg levobupivacaine 0.25% alone or in combination with low dose fentanyl (0.5µg/kg) or dexmedetomidine (0.5µg/kg).

**Materials and Methods:** Ninety children, aged 1 to 8 years of either sex, ASA I-II, posted for sub umbilical surgery received caudal block. The children were randomly allocated into three groups: Group L (control) received 0.5 ml/kg of 0.25% levobupivacaine diluted in saline, Group LD received 0.5 ml/kg of 0.25% levobupivacaine with dexmedetomidine 0.5µg/kg and Group LF received 0.5 ml/kg of 0.25% levobupivacaine with fentanyl 0.5µg/kg. Following the administration of the drugs - hemodynamic variables, FLACC- Face, Legs, Activity, Cry, Consolability scale, sedation score (Ramsay sedation score), duration of analgesia, and side effects were recorded and analysed statistically.

**Results:** The study groups were comparable with respect to age, sex, weight and duration of surgery. Preoperatively and intraoperatively hemodynamic parameters were comparable at all the time intervals throughout the study in all three groups. The mean pain score was significantly lower and the mean sedation score and duration of analgesia was significantly greater in group LD as compared to group L and group LF.

**Conclusion:** There is significant prolongation of duration of analgesia, better pain score and arousable sedation when low dose dexmedetomidine is added to low dose 0.25%levobupivacaine as compared to fentanyl or alone.

**Keywords:** Caudal Analgesia, Low Dose, Levobupivacaine, Dexmedetomidine, Fentanyl.

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## Article History:

Received: 08-12-2021, Revised: 02-01-2022, Accepted: 30-01-2022

Access this article online	
Website: <a href="http://www.ijmrp.com">www.ijmrp.com</a>	Quick Response code 
DOI: 10.21276/ijmrp.2022.8.1.005	

## INTRODUCTION

Historically, children have been under treated for pain because of the wrong notion that they neither suffer nor feel pain or respond to or remember painful experiences to the same degree as adults do.<sup>1</sup> Whereas, if a child's pain is not treated quickly and effectively, it can have long-term physical and psychological sequelae.<sup>2</sup>

In last two decades, various drugs oral, intravenous, suppositories, transdermal patches and techniques LA wound infiltration and regional techniques have been evolved.<sup>3</sup>

Among the various techniques of regional analgesia, caudal epidural analgesia alone or in combination with general anaesthesia provide safe, reliable and efficient analgesia for both high risk and general paediatric surgical patients.<sup>4</sup>

The major disadvantage of caudal analgesia with local anaesthetic alone is the short duration of analgesia.<sup>5</sup> The adjuvants added to local anaesthetics "Combination Wisdom", have brought a new era to regional anaesthesia. Adjuvants are the drugs which, when co-administered with local anaesthetic agents, may improve the

speed of onset and duration of analgesia and counteract adverse effects of local anaesthetics (hypotension, bradycardia, myocardial depression etc.) by decreasing their dose requirement.<sup>6</sup>

Bupivacaine and ropivacaine are the long-acting amide local anaesthetic used for paediatric caudal block with various concentration.<sup>7</sup> Levobupivacaine has been found to be equally efficacious as bupivacaine but with superior pharmacokinetic profile. In recent years, the reduced cardiotoxicity and central nervous system toxicity associated with the use of levobupivacaine rather than bupivacaine have been demonstrated.<sup>8,9</sup>

Fentanyl, a lipophilic opioid, is added frequently to local anaesthetics in children.<sup>10</sup> It acts on substantia gelatinosa on the dorsal horn of spinal cord by blocking fibres carrying nociceptive impulses both pre and postsynaptically.<sup>11,12</sup> It has some undesirable side effects like nausea, vomiting or respiratory depression.<sup>10</sup>

Dexmedetomidine is a potent and highly selective alpha<sub>2</sub> adrenergic agonist that has been described as a safe and effective additive in many anaesthetic applications.<sup>13</sup> In contrast to other agents it has sympatholytic, analgesic and sedative effects, and is remarkably free from side effects except for manageable hypotension and bradycardia.<sup>14</sup>

While searching review of literature it was observed that in most of studies either higher volume (0.5-1.0ml/kg) or higher concentration 0.5% of levobupivacaine is used but in present study we have used low dose 0.5ml/kg of 0.25% levobupivacaine alone or in combination with low dose fentanyl (0.5µg/kg) or low dose dexmedetomidine (0.5µg/kg) for caudal analgesia in paediatric patients<sup>2,3,15-17</sup> posted for infra-umbilical surgery.

## MATERIALS AND METHODS

After institutional ethical approval and parental written informed consent this prospective randomised double-blind study was conducted from Nov 2018 to Oct 2020.

The sample size was estimated based on previous studies, the three independent groups to be compared were equal size n, and to be drawn from population. Sample size has been calculated by using the formula:

$$n = (r+1)/r \cdot SD^2 (Z\beta - Z\alpha)^2 / (d)^2$$

n = Sample size;

r = 1;

(r+1)/r = 2;

SD = 0.1; Z $\beta$  = 0.84;

Z $\alpha$  = 1.96; d = 0.25

Minimum 25.088 = 25 sample are required for each group in the study.

### Inclusion Criteria

ASA I & II paediatric patients of age group 1-8yrs of either sex posted for sub umbilical surgeries. Exclusion criteria -Patients with known allergy to studied drugs, ASA grading 3 or above, suspected coagulopathy or bleeding diathesis, local sepsis at the site of puncture, history of developmental delay and cases where consent was not given were excluded from the study. 90 children were randomly allocated into 3 groups Group L, Group LD and Group LF based on picking lots from a sealed bag.

For fasting clear fluid protocol was strictly followed. All children received 0.2mg/kg intranasal midazolam as premedication 30

minutes prior to induction of anaesthesia. The intraoperative monitors included electrocardiogram, pulse oximetry, non-invasive blood pressure and end tidal carbon dioxide. Intravenous access was secured. After induction with propofol, sevoflurane and muscle relaxant, the airway was secured with appropriate size laryngeal mask airway or endotracheal tube. Anaesthesia was maintained with 1-2% sevoflurane in oxygen nitrous mixture and with maintenance dose of muscle relaxant. No additional analgesic was given.

Before proceeding for caudal analgesia, adequate hydration with isolyte P was ensured. In lateral decubitus position, sacral hiatus was identified with help of landmarks under aseptic conditions. 22G hypodermic needle was advanced at a 45° angle cephalad until a pop was felt as the needle pierces the sacrococcygeal ligament. The angle of the needle was then flattened and advanced. Caudal epidural space was identified by using standard loss of resistance technique. The investigator who did not participate in the care of the enrolled children prepared all the study medications according to group assignment. Another investigator blinded to group assignments performed caudal blocks and administered drugs after negative aspiration for blood and CSF.

Group L received 0.25% levobupivacaine 0.5ml/kg diluted in normal saline.

Group LD received 0.25% levobupivacaine 0.5ml/kg with dexmedetomidine 0.5µg/kg.

Group LF received 0.25% levobupivacaine 0.5ml/kg with fentanyl 0.5µg/kg.

After 20 minutes of the procedure, surgery was allowed to proceed. The heart rate, spo<sub>2</sub>, blood pressure (systolic, diastolic, MAP) was observed before induction, after induction and then immediately after caudal analgesia, then every 5 min for first half an hour then every 10 minutes till completion of surgery. Pain Score was assessed by using face, legs, activity, cry, consolability scale (FLACC) and Level of sedation was assessed by Ramsay Sedation Scale. The pain score and level of sedation was noted at 30 min, 1 hour, 2 hours, 3 hours, 6 hours and 12 hours after surgery.

The duration of analgesia was defined as the time from caudal placement of drug to the first recording of a FLACC scale  $\geq$  4. Rescue analgesia was provided with syrup paracetamol 15mg/kg whenever the pain score was  $\geq$  4. All patients observed for any complication (hypotension, respiratory depression, vomiting, pruritus, retention of urine). If occurred managed accordingly.

### Statistical Analysis

Analysis was conducted using IBM SPSS statistics (version 22.0). Numerical data was expressed as mean and standard deviation and statistically analysis was done using the Anova test to compare the three groups. For skewed data/scores Kruskal Wallis H-test was used. Gender and sex was compared using Chi square test. The p value of <0.05 was considered statistically significant and the p value of <0.001 was considered as statistically highly significant.

## RESULTS

The study groups were comparable with respect to age, sex, weight and duration of surgery. Preoperatively and intraoperatively HR, SBP, DBP, MAP, SPO<sub>2</sub> and RR were comparable at all-time intervals throughout the study in all the three groups [Fig-1, 2, 3].

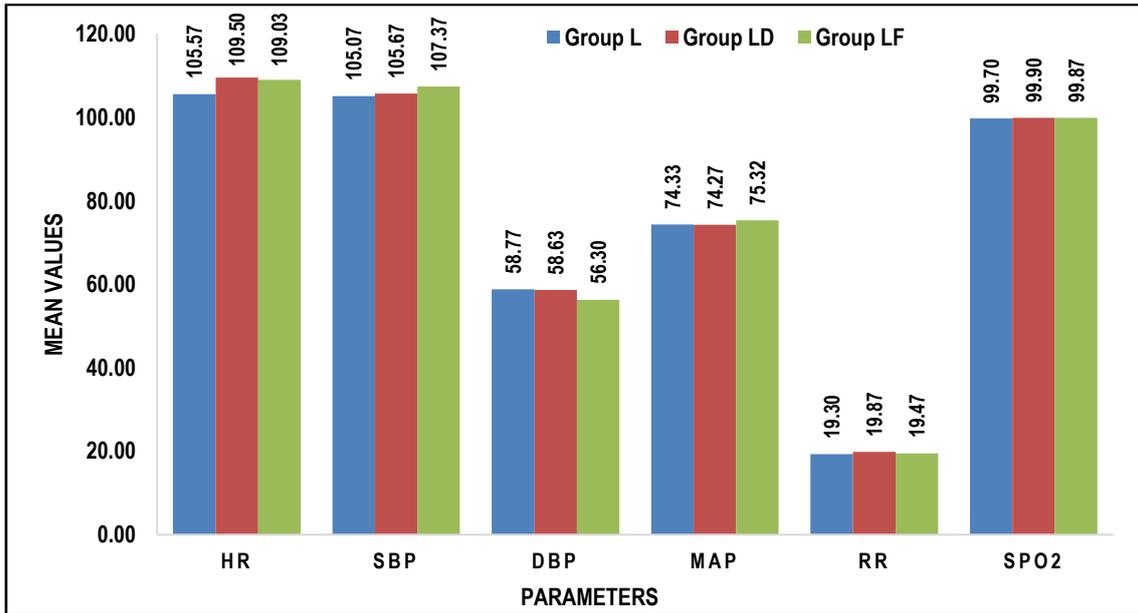


Fig 1: Mean preoperative vital parameters.

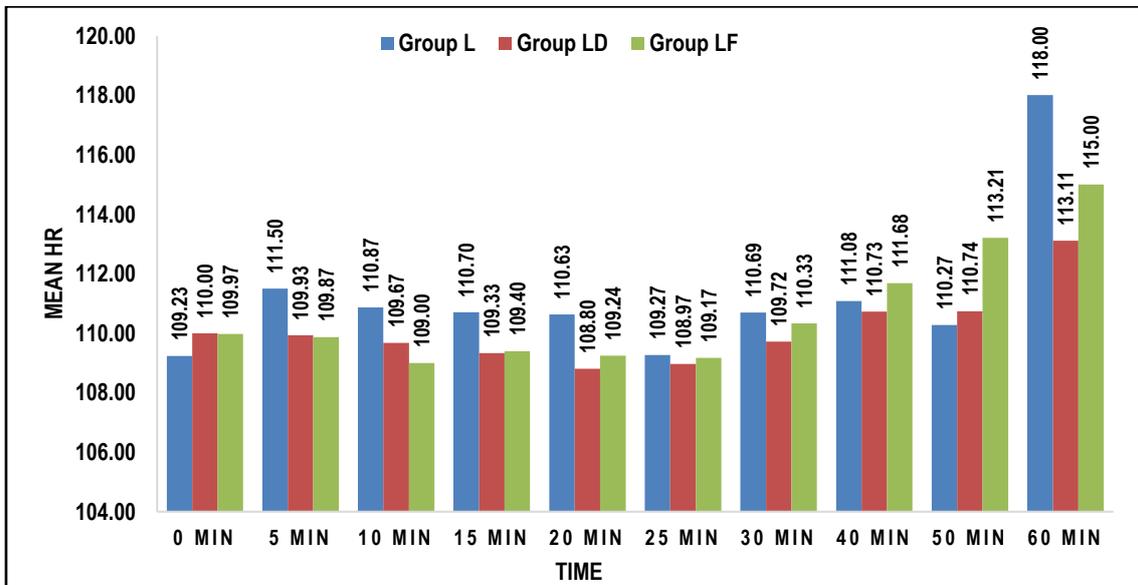


Fig 2: Mean Heart Rate at different time intervals during intra operative period.

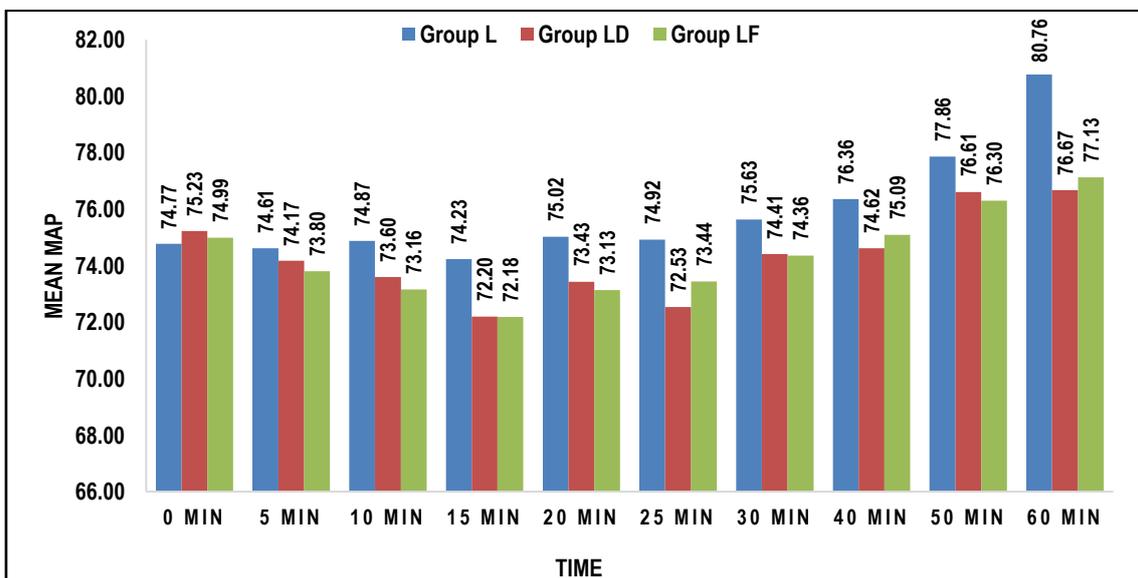


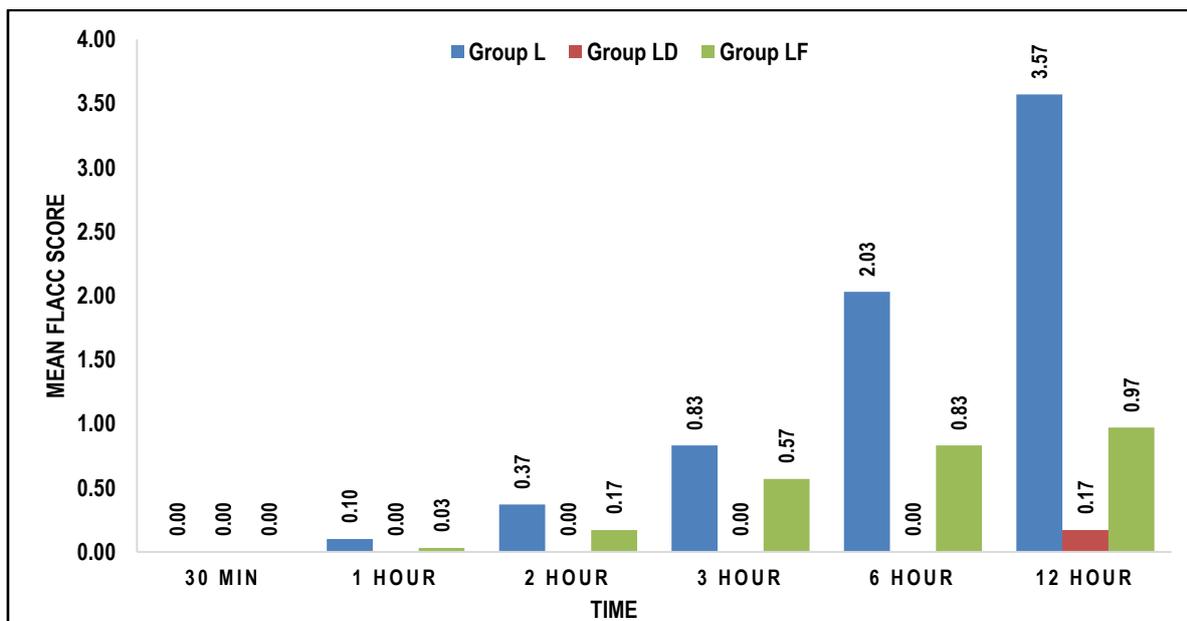
Fig 3: Mean MAP at different time intervals during intra operative period.

**Table 1: Pain score was assessed by using face, legs, activity, cry, consolability scale (FLACC)**

FLACC Scale			
Parameter	0	1	2
Face	No Expression	Occasional grimace	Frequent to constant quivering chin.
Legs	Normal or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quiet	Squirming, shifting back and forth, tense	Arched, rigid or jerking
Cry	No cry	Moans and whimpers	Crying seadily
Consolability	Content, relaxed	Reassurance, hugging	Difficulty to console

**Table 2: FLACC Score During Postoperative Period In Three Groups**

FLACC	Group L		Group LD		Group LF		P Value	Significance
	Mean	S.D	Mean	S.D	Mean	S.D		
30 min	0.00	0.00	0.00	0.00	0.00	0.00	-	-
1 Hour	0.10	0.31	0.00	0.03	0.03	0.18	0.163	NS
2 Hour	0.37	0.49	0.00	0.00	0.17	0.38	0.001	HS
3 Hour	0.83	0.65	0.00	0.00	0.57	0.68	<0.001	HS
6 Hour	2.03	1.16	0.00	0.00	0.83	0.83	<0.001	HS
12 Hour	3.57	1.30	0.17	0.46	0.97	1.54	<0.001	HS



**Fig 4: FLACC Score During Postoperative Period In Three Groups**

**PAIN SCORE:**

Pain score was assessed by using face, legs, activity, cry, consolability scale (FLACC)

FLACC Scale.

Score:

- 0 No pain
- 1-3 Mild pain
- 4-7 Moderate pain
- 8-10 Severe pain

It was observed that mean FLACC score was significantly lower in group LD as compared to group L and group LF. The difference in the pain scores were statistically highly significant after 2 hours and continued to remain same till 12<sup>th</sup> and the patients in group L and LF started showing increase in pain score (mean ± SD) after 3 hours and 6 hours respectively [Table 2/ Fig 4].

**LEVEL OF SEDATION**

Level of sedation was assessed by Ramsay Sedation Scale

0- arousable

1-arousable to voice

2-arousable to pain

3-unarousable

It was observed that Ramsay sedation score was significantly greater in group LD as compared to group L & LF. Sedation score was highly significant till 2 hours in group LD as compared to L & LF [Table 3/ Fig 5].

**DURATION OF ANALGESIA**

The duration of analgesia was defined as the time from caudal placement of drug to the first recording of a FLACC scale ≥ 4. The mean duration of analgesia in group LD was significantly longer as compared with group L & LF [Fig 6].

**COMPLICATIONS**

Post operative vomiting significantly occurred in group LF as compared to other groups. The other adverse effects were comparable among studied group. [Fig 7]

**Table 3: Sedation Score During Postoperative Period In Three Groups**

SS	Group L		Group LD		Group LF		P Value	Significance
	Mean	S.D	Mean	S.D	Mean	S.D		
30 min	0.60	0.50	2.07	1.01	1.07	1.08	<0.001	HS
1 Hour	0.33	0.48	1.93	1.01	0.57	0.82	<0.001	HS
2 Hour	0.07	0.25	1.43	1.07	0.57	0.50	<0.001	HS
3 Hour	0.07	0.25	0.57	0.86	0.33	0.61	0.010	S
6 Hour	0.00	0.00	0.23	0.50	0.03	0.18	0.603	NS
12 Hour	0.00	0.00	0.13	0.43	0.00	0.00	0.368	NS

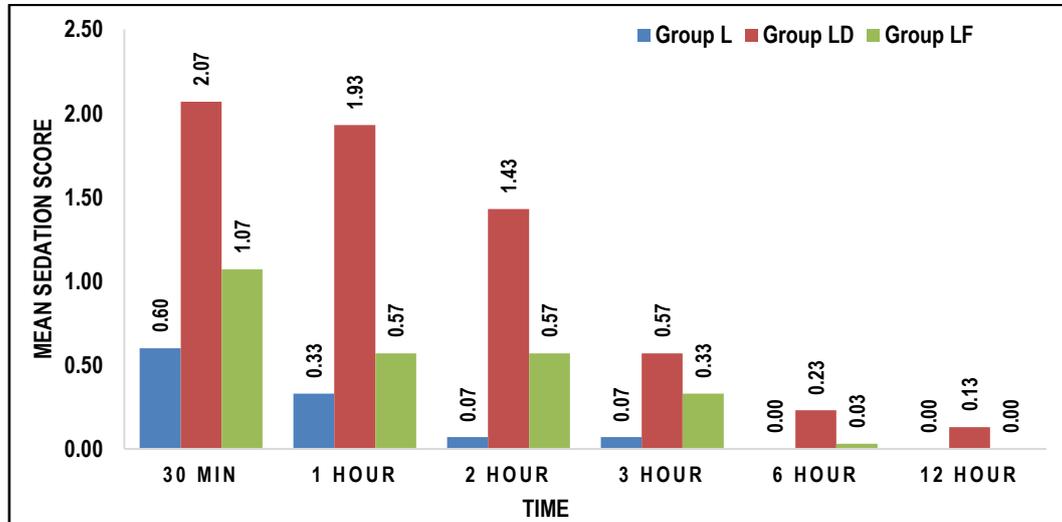


Fig 5: Mean sedation score (SS) at different time intervals during postoperative period in recovery room.

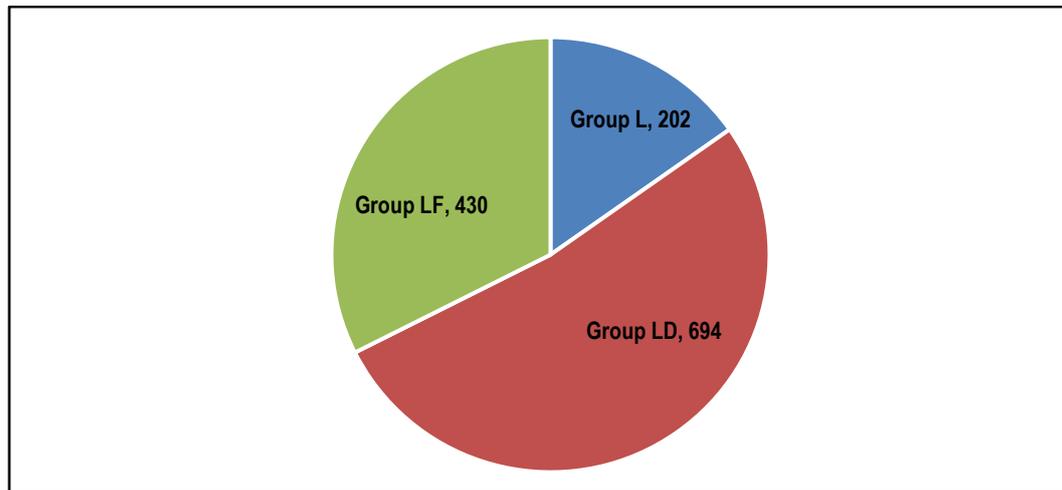


Fig 6: Mean Duration of Analgesia (Minutes) In The Postoperative Period

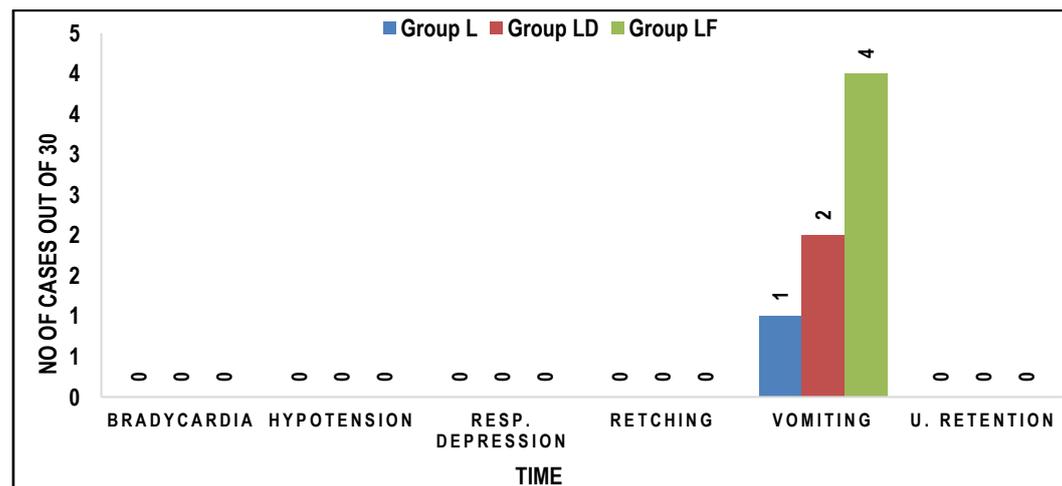


Fig 7: Complications.

## DISCUSSION

Postoperative pain is an annoying subjective sensation for both children and their parents and postoperative pain relief in children is challenging. Various methods have evolved for providing pain relief in children.<sup>3</sup> Caudal epidural block remains the standard of care for providing postoperative analgesia in children. The search for the ideal adjuvant and a local anaesthetic with wide margin of safety, minimal motor blockade and prolonged period of analgesia continues till date.

The present study was conducted to compare quality in terms of haemodynamics, pain score, level of sedation and duration of analgesia with low dose levobupivacaine (0.25% 0.5ml/kg) alone and in combination with low dose fentanyl (0.5µg/kg) or low dose dexmedetomidine (0.5µg/kg) for caudal block in paediatric patients. In our study the haemodynamic parameters heart rate, systolic and diastolic blood pressure, mean arterial pressure, respiratory rate and peripheral oxygen saturation measured preoperatively and intraoperatively at various time intervals in all 3 study groups were comparable and statistically non- significant as the p value was >0.05.

Similarly, Dutt B et al<sup>18</sup> in their study concluded that haemodynamics were comparable at all times in ropivacaine (0.2%) plus fentanyl (2µg/kg) group and in ropivacaine (1ml/kg of 0.2%) plus dexmedetomidine (2µg/kg) group for caudal block in paediatric patients posted for lower abdominal and lower limb surgeries. Our observation also mirrored the study conducted by El Shamaa et al<sup>16</sup> comparing the effect of caudal dexmedetomidine (2µg/kg) versus morphine (30µg/kg) added to bupivacaine (0.25%, 1ml/kg) for infra-umbilical surgery in paediatric patients where it was concluded that the vital signs and haemodynamics MAP, HR and the SPO2 showed no statistically significant difference between 2 groups.

## QUALITY OF ANALGESIA

### 1. PAIN SCORE (FLACC Scale)

In our study the difference in the pain scores were statistically highly significant from 2nd hour to 12th hour. The patients in group L, LF and LD started showing increase in pain score (mean ± SD) after 3 hours, 6 hours and at 12 hours respectively. [Table 2/ Fig 4] Similarly, Tandale SM et al<sup>17</sup> found higher FLACC scores at second, third, fourth and sixth hour in postoperative period in Group L (0.25% levobupivacaine alone) as compared to Group LD (0.25% levobupivacaine and dexmedetomidine 1 µg/kg) which was highly significant.

Furthermore, study done by Elfawal SM et al [3] concluded that the mean FLACC score was significantly lower in Group LD (0.75ml/kg levobupivacaine 0.25% with dexmedetomidine 1ug/kg) as compared to Group LF (0.75 ml/kg levobupivacaine 0.25% with fentanyl 1µg/kg) and Group L (0.75 ml/kg levobupivacaine 0.25% diluted in normal saline).

Thus, our study is supported by Elfawal SM et al<sup>3</sup> and Tandale SR et al<sup>17</sup> study where it was observed that addition of dexmedetomidine to levobupivacaine resulted in better quality of sleep, prolonged duration of analgesia and arousable sedation with significantly lower mean FLACC score.

### 2. LEVEL OF SEDATION

In the present study the mean sedation score remained statistically significant till 6 hrs. [Table 3/ Fig 5].

Similarly, Elfawal SM et al<sup>3</sup> concluded that caudal dexmedetomidine 1µg/kg with 0.75ml/kg of 0.25% levobupivacaine for paediatric lower limb orthopaedic surgeries achieved significant postoperative pain relief that resulted in a better quality of sleep and a prolonged duration of arousable sedation as mean sedation score was significantly greater in group LD (2.53 ± 0.681) as compared to group LF (2 ± 0.525) and control group L (1.61 ± 0.413).

In addition, Tandale SR et al<sup>17</sup> studying efficacy and safety of dexmedetomidine as an adjuvant to caudal levobupivacaine in paediatric patients used 4 Point sedation score which showed low sedation scores till 3<sup>rd</sup> hour postoperatively in group LD (0.25% levobupivacaine and dexmedetomidine 1µg/kg) as compared to group L (0.25% levobupivacaine).

Thus, the conclusion of present study was in close agreement with Elfawal SM et al<sup>3</sup> and Tandale SR et al<sup>17</sup> studies.

### 3. DURATION OF ANALGESIA

The duration of analgesia has been taken as the time from caudal placement of drug to the first recording of a FLACC scale ≥ 4.

In present study the mean duration of analgesia was prolonged in group LD as compared to group L and LF. [Fig 6]

Similarly, Goyal V et al<sup>19</sup> studied the effects of dexmedetomidine 1µg/kg as an adjuvant to bupivacaine 1ml/kg of 0.25% in caudal analgesia in paediatric patients posted for infra-umbilical surgeries and concluded that the mean duration of postoperative caudal analgesia in Group A (bupivacaine + normal saline) was 4.33 ± 0.98 hrs while in Group B (bupivacaine + dexmedetomidine) was 9.88 ± 0.90 hrs. This shows that the duration was significantly prolonged by the addition of dexmedetomidine to bupivacaine (P < 0.0001) thus supporting the findings of our study.

In addition, El -Feky EM et al<sup>20</sup> added three adjuvants (dexmedetomidine, dexamethasone and fentanyl) to local anaesthetic and observed that caudal dexmedetomidine (490.4 ± 13.6) added to local anaesthetic is a good alternative in prolongation of postoperative analgesia with less pain score.

In another comparative study by Elfawal SM et al<sup>3</sup> mean duration of analgesia was 321.8 ± 10.8 minutes in group L (0.75ml/kg levobupivacaine 0.25% diluted in normal saline), 330.4 ± 14.7 minutes in group LF (levobupivacaine + fentanyl 1µg/ml), 490.4 ± 13.6 minutes in group LD (levobupivacaine + dexmedetomidine 1µg/ml). The first time to rescue analgesia was significantly prolonged in LD group as compared to control and fentanyl groups thus showing similar results as our study.

Similar findings as in our study was seen by Tandale SR et al<sup>17</sup> where the safety and efficacy of levobupivacaine 0.25% (Group L) and levobupivacaine 0.25% and dexmedetomidine 1µg/kg (Group LD) in caudal analgesia in paediatric patients was compared and concluded that the mean duration of analgesia in minutes in Group L and LD was 440 ± 53.240 and 769.66 ± 86.859 respectively (p value <0.001). So, duration of analgesia was prolonged (statistically highly significant) in group LD compared to group L. Thus, the results of our study were in close agreement with Goyal et al<sup>19</sup>, El-Feky EM et al<sup>20</sup>, Elfawal et al<sup>3</sup> and Tandale et al<sup>17</sup> studies.

### COMPLICATIONS

It is a well-known fact that narcotics induce nausea and vomiting, which is due to direct stimulation of CTZ in floor of 4<sup>th</sup> ventricle.<sup>21</sup>

And in our study 4 patients out of 30 in group LF, 2 out of 30 in group LD, 1 out of 30 in group L developed episodes of vomiting which was statistically significantly in fentanyl group. [Fig 7]. Similar observation was supported by Gupta P et al<sup>22</sup> who compared fentanyl with ropivacaine and ropivacaine alone for caudal analgesia in paediatric patients and reported that 1 patient in ropivacaine group and 4 patients in ropivacaine fentanyl group had vomiting.<sup>20</sup> Similarly Constant et al<sup>23</sup> and El Shamaa et al<sup>16</sup> used  $\alpha 2$  agonist and narcotic and observed vomiting in narcotic group. All the patients were observed for other complications (bradycardia, hypotension, respiratory depression, retching and urinary retention) and none of our patients show any other adverse effect.

Our results are in close agreement with El Hennawy et al<sup>24</sup>, Sengupta et al<sup>25</sup> and Tandale et al<sup>17</sup> studies. They also did not observe clinically significant postoperative respiratory depression, urinary retention, retching, hypotension, or bradycardia etc.

## CONCLUSION

Our study revealed that the addition of dexmedetomidine to levobupivacaine provided significant pain relief, better quality of sleep and prolong duration of arousable sedation and also decreased the need of rescue analgesia in the postoperative period as compared to fentanyl.

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**Source of Support:** Nil.

**Conflict of Interest:** None Declared.

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**Cite this article as:** Balwinder Kaur, Tejinderpal Kaur, Mandeep Kaur, Kajal Nohria. Caudal Analgesia with Low Dose Levobupivacaine 0.25% Alone and In Combination with Low Dose Fentanyl or Dexmedetomidine In Paediatric Patients: Comparative Prospective Randomised Double Blind Study. *Int J Med Res Prof*. 2022 Jan; 8(1): 20-26. DOI:10.21276/ijmrp.2022.8.1.005