Original Research Paper

Volume - 11 | Issue - 10 | October - 2021 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Anaesthesiology

A COMPARATIVE STUDY OF 0.2% ROPIVACAINE AND 0.2% ROPIVACAINE WITH DEXAMETHASONE FOR CAUDAL BLOCK IN PEDIATRIC PATIENTS

Dr. Soujanya M R	Senior Resident, Department of Anaesthesiology, Hassan Institute of Medical Sciences, Hassan, Karnataka.
Dr. Vinay M S	Senior Resident, Department of Anaesthesiology, Shimoga Institute of Medical Sciences, Shimoga, Karnataka.
Dr. Sudha Shree P*	Senior Resident, Department of Anaesthesiology, Hassan Institute of Medical Sciences, Hassan, Karnataka. *Corresponding Author

ABSTRACT

Introduction: Pain is defined by international association for the study of pain (IASP) as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage." In pediatric patients, optimum pain relief is a huge challenge as it is difficult to differentiate restlessness or crying due to pain from that of hunger and fear. An effective therapy to block or modify the physiological responses to painful stimulus is an essential component of pediatric anesthetic practice.

Materials And Methods: 60 children posted for elective infraumbilical surgeries were randomly allocated according to computerized randomization chart into two groups: Group A (caudal ropivacaine) and Group B (caudal ropivacaine mixed with dexamethasone). After performing a safe surgery checklist child was transferred inside the operating room. In the operating room, standard monitors: ECG, noninvasive blood pressure (NIBP), pulse oximetry were connected and baseline values were noted.

Results: The mean age ± standard deviation in Group A was 37 ± 18.7 months and in Group B was 34 ± 17.9 months (Table 2).When subjected to statistical analysis "p" value was 0.45. The difference between the two groups was not significant. The mean duration of analgesia in group A was 7.67 hrs whereas in group B was 18.42hours with a "p" value of <0.001 (Fig 23). Thus the difference in the mean duration of analgesia among the two groups was statistically significant. Time interval from institution of caudal block to the time for requirement of first rescue analgesia was considered as duration of analgesia.

Conclusion: This study was conducted in 60children to compare the post-operative analgesic efficacy of caudal dexamethasone with 0.2% ropivacaine and 0.2% ropivacaine alone in our institute. The differences in the intraoperative vital parameters were 20% within the baseline limits in both the groups. We did not notice any difference in intraoperative vital parameters and postoperative recovery profile in both the groups. The mean duration of analgesia was significantly longer in caudal dexamethasone group as compared to ropivacaine alone. We conclude that caudal dexamethasone with ropivacaine has longer duration of postoperative analgesia as compared to ropivacaine alone.

KEYWORDS : Pain, dexamethasone, NIBH, IASP, ropivacaine.

INTRODUCTION

Pain is defined by international association for the study of pain (IASP) as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage." In pediatric patients, optimum pain relief is a huge challenge as it is difficult to differentiate restlessness or crying due to pain from that of hunger and fear. An effective therapy to block or modify the physiological responses to painful stimulus is an essential component of pediatric anesthetic practice.[1]

Caudal block is one of the most safe and popular technique in children as an adjunct to general anesthesia and for post-operative pain relief after infra-umbilical surgeries. Caudal anesthesia has been used for many years and is the easiest and safest approach to epidural space. It is usually placed after induction of general anesthesia and is used to provide adjunctive intraoperative anesthesia as well as post-operative analgesia in children undergoing infra umbilical surgeries.[2]

Ropivacaine, a long acting amide local anesthetic structurally related to bupivacaine has been used for pediatric caudal anesthesia. The concentrations used in caudal analgesia ranges from 0.1-0.5%.[3] Ropivacaine being less lipophilic in contrast to bupivacaine is less likely to penetrate large myelinated motor fibers, thus resulting inrelatively lower degree of motorblockade. The reduced lipophilicity is also associated with decreased potential for CNS toxicity and cardio toxicity. The quality and level of the block are dependent upon dose, volume and concentration of the local anesthetic solution.[4]

Dexamethasone, a glucocorticoid is commonly used peri-operatively to manage postoperative pain, nausea and vomiting thus ensuring overall better recovery. Recently several studies have demonstrated that epidural administration of dexamethasone prolonged analgesic effects and reduced analgesic requirements in adults Additionally use of dexamethasone as an adjunct to local anesthetics during brachial plexus block effectively improved the quality of analgesia without side effects. Dexamethasone is thought to have a local anesthetic effect on nerve by direct membrane action; hence it potentiates the effect of ropivacaine and prolongs the duration of analgesia.[5]

After reviewing the recent scientific literature this study has been designed to compare the duration of post-operative analgesia in children scheduled for infra umbilical procedures when ropivacaine used alone or in combination with dexamethasone.

MATERIALS AND METHODS

After obtaining institutional ethical committee approval this study was conducted.

Study Design:
Prospective, randomised, controlled, single centre observational study

Study Period:
1st November 2017 to 30th April 2019 (18 months).

Source Of Data:
Patients posted for infraumbilical surgeries at Basaveshwara teaching and general hospital at Gulbarga after obtaining valid informed written consent.

Sample Size:
60 patients (30 patients in each group).
Group A (caudal ropivacaine)
Group B (caudal ropivacaine mixed with dexamethasone)

Selection Criteria For Patients:-
Inclusion Criteria:
1. Children in the age group of 1-6 years
2. Body weight <20kgs
3. Belonging to ASA-I & II
4. Posted for elective infraumbilical surgeries
5. Surgery lasting for less than 2hrs

Exclusion Criteria:
1. Children > 6years of age

2. Children weighing > 20kgs
3. Emergency surgery
4. Laparoscopic surgeries
5. Surgeries lasting for >2hrs
6. ASA grading > II
7. Refusal by parents
8. Contraindications to caudal anesthesia like:
   - ·Hypersensitivity to local anesthetics, steroid.
   - ·Bleeding diathesis
   - ·Infections at caudal site
   - ·Preexisting neurological disease
   - ·History of developmental delay, mental retardation, type-1 diabetes

Informed Consent:
For all the children fulfilling the selection criteria, before enrollment, an informed written parental/legal guardian consent was obtained after explaining the nature of the study.

METHODS:
60 children posted for elective infraumbilical surgeries were randomly allocated according to computerized randomization chart into two groups: Group A (caudal ropivacaine) and Group B (caudal ropivacaine mixed with dexamethasone). After performing a safe surgery checklist child was transferred inside the operating room. In the operating room, standard monitors: ECG, noninvasive blood pressure (NIBP), pulse oximetry were connected and baseline values were noted.

Children were induced with 100% oxygen and 8% sevoflurane. Intravenous access was secured and Ringer Lactate solution was administered as per calculated fluid requirement according to holliday-segar formula.

After securing intravenous access, Inj. Fentanyl 2µg/kg, Propofol 1mg/kg, Atracurium 0.5mg/kg were administered to patient to facilitate the induction of general anesthesia. Airway management was left to discretion of attending consultantanesthesiologist and the children were managed with laryngeal mask airway or endotracheal tube.

After induction, patients were placed to left lateral decubitus position to perform single shot caudal epidural block. Under strict aseptic precautions parts were painted and draped. Single shot caudal block was performed with 23G hypodermic needle after identifying the landmarks (Fig 11). After identifying the caudal epidural space 1ml/kg of 0.15%ropivacaine (GroupA) or 1ml/kg of 0.15% ropivacaine with 0.1mg/kg of dexamethasone (GroupB) were administered after negative aspirate for blood or CSF and checked for any subcutaneous swelling during the administration of the drug. Surgery was initiated 5minutes after administering caudal block.

Intraoperative vital parameters were measured at every 5minute intervals during the surgery. Heart rate variation at the time of incision was defined as 20% above or below the baseline heart rate. Blood pressure variability was described as 20% above or below the baseline blood pressure reading noted. Maintenance of anesthesia was done with oxygen, air in a ratio of 50:50 with2% sevoflurane. After extubation, patients were shifted to post anesthesia care unit.

Pain score was assessed in PACU using FLACC score.

FLACC score:
There are five parameters, each given a score of 0-2 and the total score is taken to assess the pain.

The severity of the pain was classified using total FLACC score as given here with:
0 = No pain
1-3 = Mild pain
4-7 = Moderate pain
8-10 = Severe pain.

Assessment of pain by FLACC scale was done by a second anesthesiologist who was not aware of the drug given at 1,2,4,6,8,12,18,24 hours post operatively. Patients were followed up until discharge. The time at which FLACC score> 4 was recorded. Duration of caudal analgesia was defined from the time of caudal drug administration to the time when FLACC score was > 4.

Rescue analgesics were administered when FLACC score > 4. Intravenous paracetamol was used as rescue medication with dosage of 15mg/kg every 6hours. Time of administration of first rescue analgesic was noted.

In the post-operative period, patients were also monitored for adverse effects like respiratory depression, nausea, vomiting, hypotension and bradycardia.

RESULTS
Continuous measurements are presented as Mean and SD and categorical measurements are presented as Number (%). Unpaired T test was used to compare the duration of analgesia in both the groups. The statistical software SPSS 16 was used for the analysis of the data. Microsoft excel have been used to generate the graphs.

DEMOGRAPHIC DATA:
Subjects:
A total of 60 children were included in the study. The demographics and characteristics of the study are given below:

Age Distribution:
The mean age ± standard deviation in Group A was 37 ± 18.7 months and in Group B was 34 ± 17.9 months (Table 2).When subjected to statistical analysis "p" value was 0.45. The difference between the two groups was not significant.

Table 1: Age Distribution

Age	Mean In Months	Standard Deviation
Group A	37	18.7
Group B	34	17.9

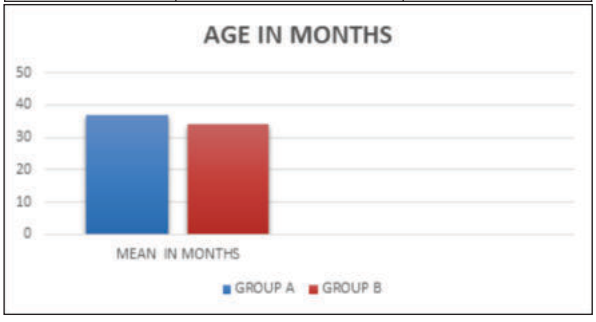

Figure 1: Age Distribution

Gender Distribution:
A total of 60 patients were included in the study with 30 children in each group. 26males and 4 females were included in Group A while 27males and 3 females were included in Group B.When subjected to statistical analysis "p" value was 0.69 (Table 3). Thus the difference with respect to gender among the two groups was not statistically significant.

Table 2: Gender Distribution

Group	Group A	Group A	Group B	Group B
Gender	Number	Percent	Number	Percent
Male	26	86.7	27	90
Female	4	13.3	3	10

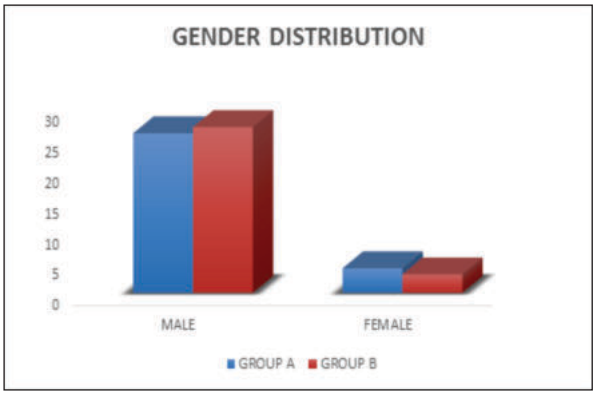

Figure 2: Gender Distribution

Weight:
The mean weight of children participating in group A was 12 ± 3.7 kgs while in group B was 12 ± 3.6 kgs (Table 4). "p" value was calculated to be 0.73. The difference among the two groups was not statistically significant with respect to weight.

Table 3: Weight

Group	WEIGHT	SD
GROUP A	12	3.7
GROUP B	12	3.6

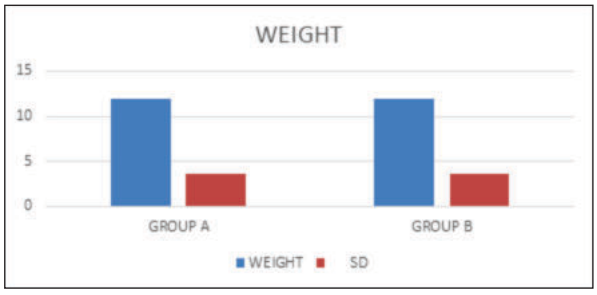

Figure 3: Weight

Type of Surgery:
Infraumbilical surgeries performed were included (Table 5). Type of surgeries are as follows:

Table 4: Type Of Surgery

Surgery	Group A Number	Group A Percent	Group B Number	Group B Percent
Chordee Repair	0	0%	1	3.30%
Circumcision	8	26.70%	9	30%
Herniotomy	14	46.70%	17	56.70%
Hypospadiasis	3	10%	1	3.30%
Orchidectomy	2	6.70%	1	3.30%
Orchidopexy	3	10%	1	3.30%

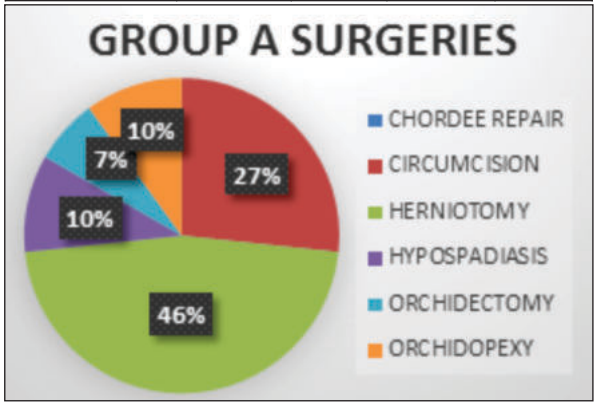

Figure 4A: Group A surgeries

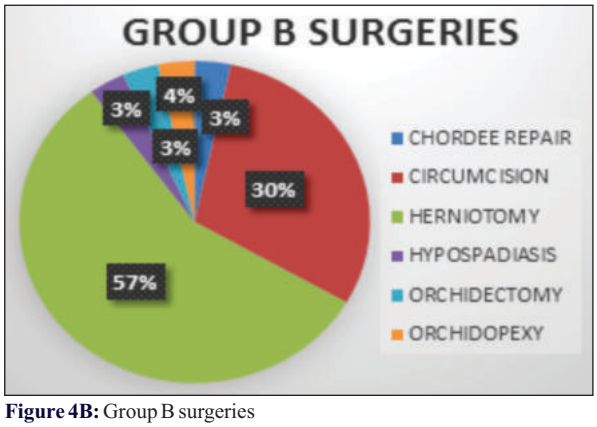

Figure 4B: Group B surgeries

Duration Of Surgery:
The mean duration of surgery in group A was 29 ± 5.2 min and group B was 28 ± 6 min (Fig 17). "P" value was calculated to be 0.21. The difference between the two groups was not statistically significant.

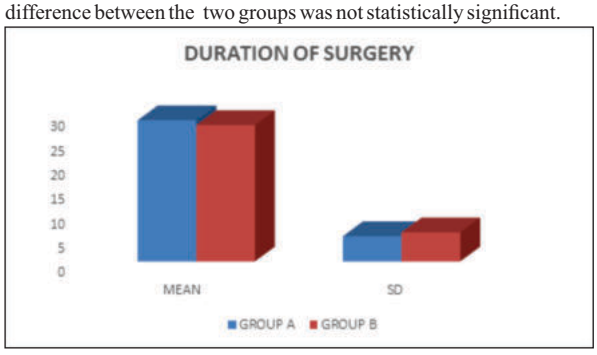

Figure 5: Duration of Surgery

Vital Parameters:
There was no significant difference in the intraoperative heart rate and blood pressure between the two groups.

The children in group A had a mean intraoperative heart rate of 116.93± 14.96 beats/min while children in group B had mean intraoperative heart rate of 112.48 ± 16.01 beats/min. The difference was not statistically significant.

The children in group A had an intraoperative mean systolic blood pressure of 98.33 ±7.06 mm Hg. The mean diastolic blood pressure of 60.9 ± 5.63 mm Hg while the children in group B had an intraoperative mean systolic blood pressure of 95.66 ± 7.3 mm Hg and mean diastolic blood pressure of 60.21 ± 5.42 mm Hg.

POST OPERATIVE PAIN SCORE:
Pain scores were calculated using FLACC scale (Table 5).

Table 5: Post Operative Pain Score

		A		B	
PAIN SCORE	FLACC SCALE	NUMBER	PERCENT	NUMBER	PERCENT
AT 0 HRS	<3	28	93.30%	30	100.00%
	≥4	2	6.70%	0	0.00%
AT 2 HRS	<3	28	93.30%	30	100.00%
	≥4	2	6.70%	0	0.00%
AT 4 HRS	<3	28	93.30%	30	100.00%
	≥4	2	6.70%	0	0.00%
AT 6 HRS	<3	28	93.30%	30	100.00%
	≥4	2	6.70%	0	0.00%
AT 8HRS	<3	20	66.70%	30	100.00%
	≥4	10	33.30%	0	0.00%
AT 12 HRS	<3	0	0.00%	30	100.00%
	≥4	30	100.00%	0	0.00%
AT 16 HRS	<3	0	0.00%	26	86.70%
	≥4	30	100.00%	4	13.30%
AT 24 HRS	<3	0	0.00%	4	13.30%
	≥4	30	100.00%	26	86.70%

DURATION OF ANALGESIA:
30 children in each group were taken of which for 2 children of Group A were excluded as analgesia was inadequate from 0hrs.

Percentage Of Patients Comfortable At 2hrs, 4hrs, 6hrs And 8hrs In Group A And Group B:-

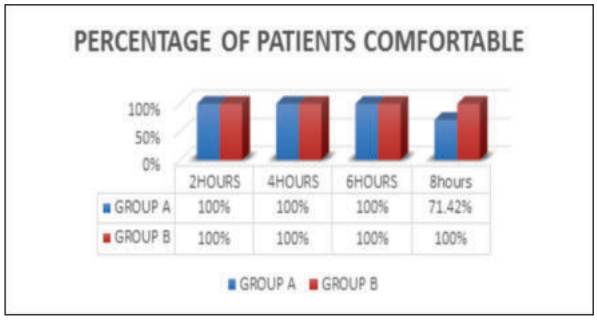

Figure 6: Percentage of Patients Comfortable

2 children of group A were excluded from the study as analgesia was inadequate at 0 hours. At the end of 2hrs, 4hrs and 6hrs all children of group A and group B were comfortable. "p" value was calculated to be 0.49 at 2, 4 and 6hrs. The difference among the groups was not statistically significant. At 8hours 71.42% of children of group A required rescue analgesics while all children of group B were comfortable. "p" value was calculated to be < 0.001 . The difference among the groups was statistically significant at 8hrs.

At the end of 12hours all the children in group A required rescue analgesics while all the children were comfortable in group B. At the end of 16hrs 86.7% children in group B were comfortable. "p" value was calculated to be <0.001. Thus the difference among the two groups was statistically significant.

At the end of 24hrs 13.3% of children in group B were comfortable. "p" value was calculated to be 0.11. The difference among the two groups was statistically significant.

MEAN DURATION OF ANALGESIA:

The mean duration of analgesia in group A was 7.67 hrs whereas in group B was 18.42hours with a "p" value of <0.001 (Fig 23). Thus the difference in the mean duration of analgesia among the two groups was statistically significant.

Time interval from institution of caudal block to the time for requirement of first rescue analgesia was considered as duration of analgesia.

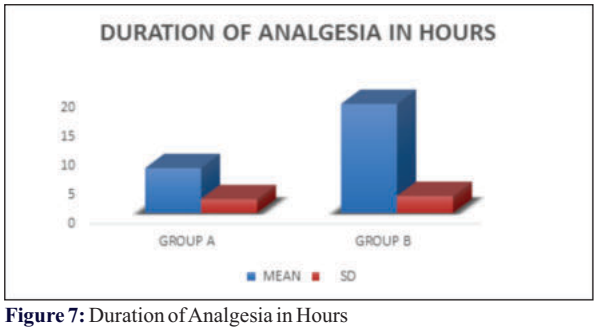

Figure 7: Duration of Analgesia in Hours

When subjected to "unpaired T test" to find the significance of the duration of analgesia "p" value was <0.001 which was statistically significant.

Observations:

This study compares ropivacaine alone and ropivacaine with dexamethasone for duration of post-operative analgesia in children undergoing infra umbilical surgeries.

Sixty children were studied of whom 30 were administered ropivacaine alone and the other were administered ropivacaine with dexamethasone. 2 children from group A were excluded as their analgesia was inadequate at "0" hours. There were no significant differences between the two groups with regard to age, weight, duration of anaesthesia and surgery.

No statistical significance could be associated with regards to the intraoperative vital parameters.

In PACU there were no significant differences in the recovery profiles between the two groups. There were no patients who required rescue analgesics in the PACU.

Both the groups did not have any undue complications in the postoperative period. No motor blockade was noted in both the groups as expected with drug profile and also since we used a lesser concentration of ropivacaine.

The mean duration of analgesia between the two groups at 2,4,6,8,12,16hrs was comparable. When subjected to "T" test to find the significance of the duration of analgesia "p" value was <0.001 which was significant.

DISCUSSION

Caudal block is the most popular and commonly used regional anaesthetic technique in children with a high success rate. This technique is a useful adjunct during general anesthesia and for providing postoperative analgesia after infraumbilical operations. It reduces the requirement of inhaled and intravenous (IV) anaesthetic agents, attenuates the stress response to surgery, facilitates a rapid and smooth recovery and provides satisfactory post-operative analgesia.[6] Although it is a versatile block, one of the major limitations of the single-injection technique is the relatively short duration of postoperative analgesia. The most frequently used method to further prolong postoperative analgesia following caudal block is to add different adjunct drugs to the local anesthetic solution.[7]

E. M. Kim, J.R Lee et al did a study comparing analgesic efficacy of caudal dexamethasone combined with ropivacaine and ropivacaine alone in children undergoing orchiopexy. This randomised study included 80 children aged 6months to 5years undergoing unilateral orchiopexy. They either received 1.5ml/kg of 0.15% ropivacaine alone (Group C) or 1.5ml/kg of 0.15% ropivacaine mixed with 0.1mg/kg dexamethasone (Group D). They confirmed that postoperative pain scores were significantly lower in the group who received caudal dexamethasone (Group D). The number of subjects who remained pain free up to 48hrs was significantly greater in Group D [19 of 38 (50%)] than in Group C [4 of 37 (10.8%); P<0.001]. Our study was consistent with this study and our children who received caudal dexamethasone had significantly lowerpost-operative pain scores. However the mean duration of analgesia in our study in Group A (ropivacaine alone) was 7.67 hours and in Group B (ropivacaine with dexamethasone) was 18.42 hrs with a significant "p"value of <0.001while in their study 50% of children in Group D were comfortable after 48hrs as compared to 10.8% of Group C. although the mean duration of analgesia was lesser than their's, this difference could be attributed to other surgical procedures like herniotomy, circumcision, chordee repair and orchiopexy which were included in our study where as their study included only children undergoing orchiopexy and higher volume being used in their study.[8]

enhancement of ropivacaine caudal analgesia using dexamethasone or magnesium in children undergoing inguinal hernia repair was studied by Yousef GT, Ibrahim TH et al[49] This study included 105 children aged 1-6years. This cohort was divided into three groups who received single caudal dose of ropivacaine 0.15% 1.5 mL/kg combined with either magnesium 50 mg in normal saline 1 mL (group RM), dexamethasone 0.1 mg/kg in normal saline 1 mL (group RD), or corresponding volume of normal saline (group R) according to group assignment. They concluded that the addition of dexamethasone or magnesium to 0.15% ropivacaine significantly prolonged the duration of analgesia in children undergoing inguinal hernia repair with significant advantage of dexamethasone over magnesium.[9] They showed that postoperative analgesia persisted for a longer duration in groups RM and RD, 8 (5-11) h and 12 (8-16) h, respectively compared with 4 (3-5) h in group R, with a (P < 0.001) and also the need for rescue postoperative analgesic was reduced with fewer incidences of emergence agitation and without prolongation of motor blockade or an increase in incidence of side effects. Our results are in line with this study showing children who received caudal dexamethasone had significantly prolonged duration of post-operative analgesia. However the mean duration of analgesia in our study showed 7.67 hours in Group A and 18.42 hours in Group B while this study showed 4hours in group which received ropivacaine alone and 12hours in group which received ropivacaine with dexamethasone. This difference again can be attributed to other surgical procedures like circumcision, chordee repair, orchiopexy, herniotomies which were included in our study while this study only included children undergoing herniotomies. CHEOPS and FLACC score was used to assess post-operative pain score in this study while we used FLACC score alone to assess the post-operative pain scores.[10]

There were few limitations to our study. Firstly the mean age of children included in our study was 34 months. Thus the children in this study might not be able to express their pain accurately. Although FLACC score was used to assess the post-operative pain score itself has its own limitations.

CONCLUSION

This study was conducted in 60children to compare the post-operative analgesic efficacy of caudal dexamethasone with 0.2% ropivacaine and 0.2% ropivacaine alone in our institute. The differences in the intraoperative vital parameters were 20% within the baseline limits in both the groups. We did not notice any difference in intraoperative vital parameters and postoperative recovery profile in both the groups. The

mean duration of analgesia was significantly longer in caudal dexamethasone group as compared to ropivacaine alone. We conclude that caudal dexamethasone with ropivacaine has longer duration of postoperative analgesia as compared to ropivacaine alone.

REFERENCES

1. Silvani P, Camporesi A, Agostino MR, Salvo I. Caudal anesthesia in pediatrics: An update. Minerva Anestesiol. 2006;72:453–9
2. Wolf AR. Tears at bedtime: A pitfall of extending paediatric day-case surgery without extending analgesia.Br J Anaesth. 1999;82:319–20
3. Dalens B, Hasnoui A. Caudal anesthesia in pediatric surgery: Success rate and adverse effects in750 consecutive patients. AnesthAnalg. 1989;68:83–9
4. De Beer DA, Thomas ML. Caudal additives in children – Solutions or problems? Br J Anaesth 2003;90:487-98
5. Verghese ST, Hannallah RS.Postoperative pain management in children. Anesthesiol Clin North America.2005;23:163–84
6. Ansermino M, Basu R, Vandebeek C, Montgomery C. Nonopioid additives to local anaesthetics for caudal blockade in children: A systematic review. Paediatr Anaesth 2003;13:561-73
7. Engelman E, Marsala C. Bayesian enhanced meta-analysis of post-operative analgesic efficacy of additives for caudal analgesia in children. Acta AnaesthesiolScand 2012;56:817-32
8. Singh R, Kumar N, Singh P. Randomized controlled trial comparing morphine or clonidine with bupivacaine for caudal analgesia in children undergoing upper abdominal surgery. Br J Anaesth 2011;106:96-100
9. Ivani G, Lampugnani E, Torre M et al. Comparison of ropivacaine with bupivacaine for paediatric caudal block. Br J Anaesth 1998; 81: 247–8
10. Constant. I, O. Gall, L. Gouyet, M. Chauvin, I. Murat: Addition of clonidine or fentanyl to local anaesthetics prolongs the duration of surgical analgesia after single shot caudal block in children, Br J Anaesth 1994; 80: 294-8.