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Original Research Article

Caudal Epidural Ropivacaine Versus Bupivacaine In Pediatric Patients For Infra-Umbilical Surgeries

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ABSTRACT

Aims and Objectives: 1. To assess the quality of sensory and motor blockade. 2. Duration of Sensory & motor blockade. 3. Duration of postoperative analgesia.
Material and Method: In a double blind study, 60 patients of (age 1-8 years) ASA grade I and II were randomly allocated in two groups to receive 1ml/ kg of either 0.25%Ropivacaine or 0.25% Bupivacaine via caudal epidural route. Group 'R' was Ropivacaine group = 30 patients and Group 'B' was Bupivacaine group = 30 patients. Caudal block was performed in all patients after induction of anesthesia with sevoflurane and oxygen. All the results were tabulated and analyzed statistically.
Results: There were statistically no significant difference between the groups, in respect of quality of sensory block and quality of motor block ($p > 0.05$). The duration of motor block in Group 'R' was 1.93±0.46 hours while in Group 'B' ,it was 5.1±1.09 hours ($p<0.05$).The mean duration of postoperative analgesia was 4.96±1.26 hours in group 'R' compared with 4.56 ± 1.26 hours in group 'B' ($p>0.05$). The mean pain score of patients in both groups were comparable.
Conclusion: Ropivacaine is a safe and effective local anesthetic agent which provides prolonged postoperative analgesia but significantly less motor blockade as compared with Bupivacaine following caudal block in pediatric patients undergoing infra-umbilical surgeries.

Keywords: Caudal epidural, Bupivacaine, Ropivacaine, Paediatric Infraumbilical surgeries.

INTRODUCTION

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. [1] It induces a metabolic, neuro-endocrinal and cardio-respiratory response, which has a negative impact on morbidity and mortality i.e. outcome of the surgery. Despite an understanding of importance of adequate analgesia in adults, the treatment has frequently been only a secondary consideration in pediatric patients suffering from surgical pain. Fortunately recent studies have completely changed the approach to pediatric pain. [2] Post-operative pain relief in children is of paramount important since emotional component of pain is very strong in children. As pain is very difficult to assess in pediatric

population mostly, post-operative pain is undertreated in this age group. [3]

The most commonly practiced pediatric epidural technique is caudal epidural block. First described for pediatric use in 1933, [4] caudal block is a well-accepted technique and proved to be a good alternative to general anesthesia in pediatric infra-umbilical surgeries. It provides excellent analgesia intraoperatively as well as during postoperative period. Usage of single local anesthetic agent via caudal route provides shorter duration of block [5] and requires often supplemental anesthetics. In order to decrease intra and postoperative analgesic requirements after single shot caudal epidural blockade, various additives, such as Morphine, Fentanyl, Clonidine and Ketamine with local anesthetics have been studied. [6] For surgeries below umbilicus, caudal epidural anaesthesia is the most commonly used procedure which is considered to be safe, simple and effective. [7-10] Single shot caudal analgesia is the most useful and popular paediatric regional block used today. [11] Various local anaesthetics like Lignocaine, Bupivacaine and Ropivacaine have been used for caudal analgesia in different concentrations. [12-16]

Bupivacaine is an amide local anaesthetic which has been used in clinical practice for more than 40 years. Due to prolonged motor blockade, higher incidence of cardiovascular side effects and neurotoxicity, researchers were searching for another safer local anaesthetic drug. Bupivacaine has proved its efficacy in producing long lasting analgesia when administered in caudal epidural space. [17]

Ropivacaine is another amide local anaesthetic recently introduced in clinical practice. It provides similar type of pain relief with less motor blockade. [18] Early report suggests that the agent is less cardio toxic than Bupivacaine.[19] Hence Ropivacaine may be more suitable agent for caudal epidural analgesia especially in cases of day care surgery. Ropivacaine has been extensively used for regional anaesthesia in adults and older children. [20] It has been used safely even in the younger age group as well for caudal epidural analgesia. [21-23] The lower incidence of cardiovascular side effects and neurotoxicity as well as the ability to produce lesser motor blockade has made the Ropivacaine a safer choice as compared to Bupivacaine for caudal epidural anaesthesia especially in day care paediatric surgeries. [20-24]

This is a prospective randomized double blind study to compare quality of sensory and motor blockade , duration of motor blockade and also quality as well as duration of post operative analgesia of Ropivacaine 0.25% Vs Bupivacaine 0.25% in pediatric patients undergoing infra-umbilical surgeries.

MATERIALS AND METHODS

After obtaining institutional ethical committee approval and parent's written informed consent, the study was conducted in 60 pediatric patients, aged 1–8 years of ASA grade I or II, scheduled for elective infraumbilical surgeries i.e. lower abdomen, genitourinary and perineal regions. This randomized double blind prospective comparative study was carried out in the department of anaesthesiology at tertiary care medical college hospital. Paediatric patients with known congenital abnormalities of spines, local infection at injection site, neuromuscular disorders, coagulopathies, congenital heart diseases, mental retardation and parent's refusal were excluded from the study. A detailed pre-anaesthetic evaluation including relevant laboratory investigations was done. The patients were kept nil by mouth as per ASA guidelines.

NBM PERIOD CHART

S. No.	Ingested Material	Minimum Hours of Fasting (Hrs.)
1	Clear liquids	2
2	Breast milk	4
3	Infant formula	6
4	Non breast milk	6
5	Light meal	6

The patients were randomly divided into two groups of 30 patients each to receive inj. 0.25% Ropivacaine (Group'R') or inj. 0.25% Bupivacaine (Group 'B') for caudal epidural block. In the operation theatre, Phillips MP20multipara monitor was attached to patient. Baseline vital parameters e.g. Heart Rate (HR), Respiratory Rate (RR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), SpO_2 were recorded. Each patient was premedicated with intravenous inj. Glycopyrrolate 4µg/kg and inj. Midazolam 0.05 mg/kg, then induced with O_2 + Sevoflurane (2-4%) on mask using Jackson Rees circuit. The dextrose normal saline (0.9%) was used as maintenance fluid during surgery. Caudal epidural block was given in left lateral position under all aseptic precautions with a hypodermic needle G-22. The placement of needle in caudal epidural space was confirmed by loss of resistance technique. The randomly allocated local anaesthetic drug was administered slowly in to the epidural space. All patients were randomized to receive caudal epidural drugs with 1 ml/ kg of either 0.25% Ropivacaine or 0.25% Bupivacaine. Zero time was considered from the time of completion of injection of drug in to epidural space. Thereafter general anaesthesia was maintained with Oxygen (50%) + Nitrous oxide (50%) + (0.5 -1%) Sevoflurane as per requirement.

Time from zero time to onset of sensory block at the site of surgery was noted as 'Onset time of sensory block'. It was evaluated by pin prick, abolition of superficial reflexes such as cremasteric reflex and abdominal reflex. Surgeon was allowed to operate on abolition of loss of sensory sensations, cremasteric & abdominal reflexes of the patient. Once surgery was started, response of child to painful stimulus (surgical incision) was noted in terms of tachycardia, tachypnea and limb movements.

Quality of sensory block was graded as:

a) 'Excellent'- If patient did not require more than Oxygen50% and Nitrous Oxide 50% by face mask) 'Good'- If patient needed supplement with Sevoflurane 0.8-1% in addition to Oxygen 50% and Nitrous Oxide 50% c) 'Inadequate'- If patient needed supplementation of Sevoflurane more than 1% or if heart rate increased more than 15% from baseline value.

Quality of Motor block was graded as:

a) 'Flaccid'- If no movements of lower limbs, b)'Hypotonic'- If movements of ankles present but no movements at hips and knees, c) 'Normal'- If movements of ankles and knees are present but no movements of hips. Monitoring of HR, SBP, DBP, RR and SpO_2every five minutes values were noted. Decrease in systolic blood pressure or heart rate of more than 30% from base line was defined as hypotension or bradycardia, and was treated with guarded infusion of saline 10-20ml/kg or IV atropine 10 µg/ kg respectively. The total duration of surgery and intraoperative complications 'if any' were noted.

Each patient was shifted to recovery room and monitored postoperatively for a period of 8-12 hours. In the postoperative period, hemodynamic parameters and SpO_2values were recorded at every 15 minutes till 2hrs. All patients were monitored for nausea, vomiting, urinary retention, bradycardia and hypotension and treated accordingly. **Pain score** were noted at ½ hr, 1 hr and then hourly till 8 hrs using the Broadman's objective pain score

(OPS) [5] which was based on behavioral objectives shown in following table.

Broadman'sobjective pain score (OPS)

Broadman's Objective Pain score	1 None	2 Moderate	3 Severe
Crying	None	Consolable	Not consolable
Motor restlessness	None	Restless	Thrashing
Position of torso	Normal	Mildly uncomfortable	Restless
Posture of legs	Normal	Flexed	Holds injury site
Facial expressions	Asleep/Calm	Hurts little bit	Grimacing

A score of 5 signifies 'Excellent analgesia' and a score of 15 signifies inadequate analgesia. An OPS score $\geq$ 8 was considered as the end of caudal analgesia and in such patients, rescue analgesia as intravenous Paracetamol (10mg/kg). The duration of postoperative analgesia was defined as time from zero time to the first rescue analgesic drug administration. **The duration of motor blockade** was defined as time from zero time to return of muscle tone to normal grade or ability to stand. All observed parameters of the study were recorded and subjected to statistical analysis.

Motor power scores [25,26] as per following table were noted postoperatively at 1/2, 1, 1½, 2, 2½, 3 hrs and then every hour for 8 hrs.

Motor Power Score

Muscle Tone/ Muscle Power (Flexion)	'Flaccid' Unable	'Hypotonia' Partial	'Normal' Normal
Ankle	0	1	2
Knee	0	1	2
Thigh	0	1	2
Ability To Stand	0	1	2

Statistical Analysis:

The data was collected and statistical analysis of parameters was presented as Mean ± SD. Categorical parameters were expressed in percentages. Demographic and hemodynamic variables were comparable between Group 'B' and Group 'R' by performing unpaired t-test. Changes in hemodynamic variables at different point of time from baseline in two groups by Wilcoxon rank sum test for non-normalized data. Categorical values were analyzed by Chi-square test. Fisher exact test was applied for small numbers. $p<0.05$ was considered as statistically significant. All the tests were two sided. Statistical analysis was done by STATA version 10.0 software.

RESULTS

Sixty patients were selected for the study, divided into Group 'R' and Group 'B'. In Group 'R' there were 6.6% females and 93.3% males whereas in the Group 'B'therewere3.3 % females and 96.7% males. The mean age of children in Ropivacaine and Bupivacaine group was 4.18±1.63 years and 4.20±1.83 years respectively. Maximum number of patients in the present study belonged to age group of 2-4 years (53.33%). The mean weight of patients in Group 'R' and Group 'B' was 10.43± 3.65 kg and 10.43 ± 3.73 kg respectively. The difference was statistically not significant.

The most common surgery performed in both the groups was circumcision, (Group 'R'= 80% & Group 'B'= 73.3%). Other type of surgery performed was herniotomy. The mean duration of surgery in Group 'R' was 36.16±5.52 minutes while 36.33±6.28 minutes in Group 'B'. In respect of demographic data, duration and type of surgery, there was no statistically significant difference between both the groups (Table 1, Table 2).

Table- 1 DEMOGRAPHIC DATA AND DURATION OF SURGERY

Variable	Group R	Group B	P Value
	Mean ±SD	Mean ± SD	
Age (yrs)	04.18 ± 01.63	04.20 ± 01.83	P = 0.9704
Weight (kgs.)	10.43 ± 03.65	10.43 ± 03.73	P = 1.000
Duration of surgery (min)	36.16 ± 05.52	36.33 ± 06.28	P = 0.9135

Demographic data i.e. age; weight and duration of surgery in Group B and Group R are statistically comparable (p > 0.05).

Table- 2-TYPES OF SURGERY

Type of Surgery	Group R N= 30	Group B N= 30	Chi^2	p value
Circumcision	24 (80%)	22 (73.3%)	0.3727	p = 0.542
Herniotomy	06 (20%)	08 (26.7%)		

The difference was not statistically significant (p =0.542). Both groups were comparable.

Table- 3- QUALITY OF SENSORY BLOCK

Grades of Sensory Block	Group R N=30	Group B N=30	total	Chi^2	p value
Excellent	07 (23.3)	04 (13.3%)	11	1.9015	0.386
Good	23 (76.7)	25 (83.3%)	48		
Inadequate	00	01 (3.3%)	01		
Total	30	30	60		

P> 0.05- Statistically not significant (NS).

Table- 4-QUALITY OF MOTOR BLOCK

Grades of Motor Block	Group R N=30	Group B N= 30	Total	Chi^2	p value
Flaccid (1)	01 (3.3%)	03 (10%)	4	1.0741	0.584
Hypotonic (2)	28 (93.33%)	26 (86.7%)	54		
Normal (3)	01 (3.3%)	01 (3.3%)	2		
Total	30	30	60		

The mean time of onset of sensory block was found to be 9.56± 1.05 minutes in Group 'R' while 9.76± 1.07 minutes in Group 'B'. When onset of sensory blockade was compared in both the groups, difference was statistically not significant (p>0.05), (Table 5).When compared for quality of sensory block and quality of motor block (p > 0.05), (Table 3 and Table 4), there was no statistically significant difference between the groups. The duration of motor block in Group 'R' was 1.93±0.46 while in Group 'B' it was 5.1±1.09 (Figure No.2).

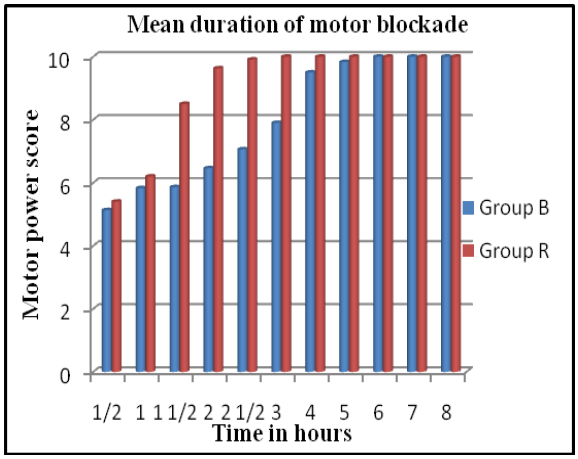

FIGURE- 1 MEAN DURATION OF MOTOR BLOCK

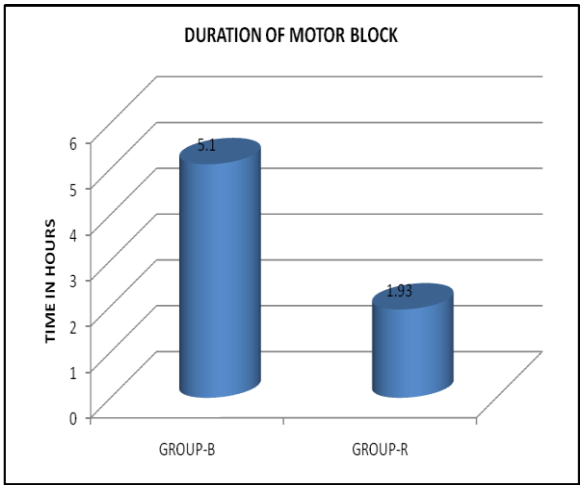

FIGURE- 2 TOTAL DURATION OF MOTOR BLOCK

This shows that motor block in Group 'R' was significantly less than that in Group 'B'. The duration of motor block was statistically significant (p<0.05). The difference in postoperative motor power score in both the groups at ½ hour and 1 hour were not significant. The motor power recovery in both the groups at intervals of ½ hour and 1 hour were comparable.

The motor power recovery difference was statistically significant in Group B' and Group 'R' at intervals of 1½, 2, 2½, 3, 4,5 and 6 hour (fig.1).

The baselines values of all hemodynamic parameters were comparable;

there were no statistically significant difference in both the groups. When both groups were compared in respect of heart rate and change in heart rate from baseline to intraoperative period, the difference was statistically insignificant except at 5 min, 10min and 15min which showed statistically significant difference but insignificant clinically. Thus heart rate remained stable throughout intraoperative period in both groups. Systolic blood pressure was stable and within normal limits in all patients. Although statistically significant difference was noted in diastolic blood pressure (Group 'R' or 'B') at 10 min and 20 min and in respiratory rate at15 min and 20min, difference was clinically insignificant, (fig.3). SpO_2 was within normal range of 98%-100% throughout intraoperative period in both groups. Haemodynamic parameters were comparable in both groups and remained stable in the postoperative period.

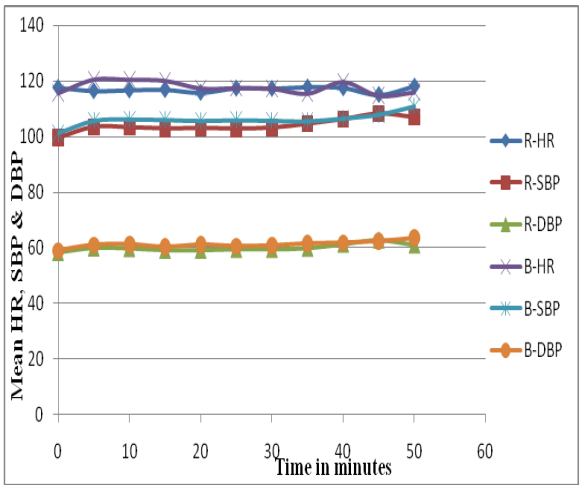

FIGURE- 3-SHOWING INTRA-OPERATIVEHEART RATE (HR), SYSTOLIC BLOOD PRESSURE (SBP), DIASTOLIC BLOOD PRESSURE (DBP)

The mean duration of postoperative analgesia was 4.96± 1.26 hours in Group 'R' as compared with 4.56 ± 1.26 hours in Group 'B', the difference was statistically insignificant (p>0.05), (Table 5).

Table- 5 DURATION OF POST-OPERATIVE ANALGESIA,SENSORYMOTOR BLOCK AND MEAN PAIN SCORE

VARIABLE	Group R	Group B	P-value
	Mean ± SD (N=30)	Mean ± SD (N=30)	
Onset of sensory blockade (mins)	9.56 ±1.05	9.76 ± 1.07	P = 0.4660
Mean pain score	6.69 ±0.27	6.84 ± 0.31	0.516
Mean duration of (hrs.) postoperative analgesia	4.96 ± 1.26	4.56 ± 1.26	0.2292
Duration of motor block (hrs.)	1.93 ± 0.46	5.1 ± 1.09	0.00

P> 0.05 – statistically not significant (NS).

The mean pain score in Group 'R'& Group 'B' was 6.69± 0.27 and 6.84±0.31 respectively. It was statistically insignificant (p value >0.05), (Table 5). The pain relief was equal in both groups.

In Group 'R', 3 (10%) patients had nausea and vomiting while 4 (13.3%) patients in Group 'B' had complaints of nausea vomiting postoperatively. The difference was statistically not significant (p>0.05).

DISCUSSION

Regional analgesia techniques are commonly used in paediatric patients for intraoperative analgesia and postoperative pain relief. Regional techniques are advantageous as there is little requirement of systemic narcotics and resumption of early feeding as well as early ambulation. For surgeries below umbilicus, caudal anaesthesia is the most commonly used procedure which is safe, simple and effective. It provides excellent analgesia during surgery as well as during

postoperative period in sub- umbilical surgeries in children. [27-29]

Local anaesthetics like Lignocaine, Bupivacaine and Ropivacaine have been used for caudal anesthesia in different concentrations. Single shot caudal anaesthesia with Bupivacaine is commonly used with good success. Ropivacaine has been extensively used for regional anaesthesia in adults and children. It has been used safely even in the younger age group for paediatric caudal epidural analgesia.

In the present study, both drugs produced comparable and satisfactory quality of sensory and motor blockade which was consistent with observations of Ray M et al [25] when they used 0.75 ml/kg drug. Ivani G et al [30] also reported that 0.2% Ropivacaine was sufficient to obtain sensory block for lower abdominal or genital surgery in children but dose of drug used was quiet high i.e. 2 mg/kg.

Throughout perioperative period, haemodynamic parameters were clinically stable and none of patient required treatment for bradycardia and hypotension in both groups. Although Group 'R' showed statistically significant decrease in heart rate at 5-15 min and decrease in DBP at10 to 20 min intraoperatively, clinically these changes in HR and DBP were insignificant.

Locatelli B. et al (2005) [31] found two episodes of sinus bradycardia in Bupivacaine group which might be due to intravascular absorption of drug. Ahmad S et al (2012) [26] found no significant difference with respect to mean heart rate and mean systolic arterial pressure during perioperative period between Bupivacaine and Ropivacaine groups. Ray M et al (2003) [25] and Da Conceicao and Coelho (1999) [32] also reported no difference between heart and arterial pressure between the Groups Ropivacaine 0.25% compared with Bupivacaine 0.25% by caudal route. Our findings were consistent & comparable with the findings stated by above authors.

Habre et al [33] reported that maximum plasma concentration of Ropivacaine was achieved at 2 hours following caudal block which is much later than for Bupivacaine in children**.** Another reason of using 0.25% Ropivacaine is to avoid prolonged motor blockade in postoperative period which may occur with higher concentrations. However Da Conceicao and Coelho [32] reported a significantly shorter duration of motor block with 0.375% Ropivacaine as compared to Bupivacaine. This observation was consistent with our findings though we used 0.25% Ropivacaine and Bupivacaine.

For assessment of postoperative motor power recovery, we assessed motor power as per motor power scale by Ray M. et al (2003) [25] and Ahmad S et al (2012). [26] They found that all patients showed some amount of motor weakness in Bupivacaine and Ropivacaine groups immediately after surgery but after two hours almost normal motor power was recorded in Ropivacaine group. Khalil et al (1999) [34] also reported significant motor block initially which almost recovered to normal power within three hours in Ropivacaine group. Motor recovery was significantly slow in Bupivacaine group in their series. We observed that difference in postoperative motor power recovery in Ropivacaine and Bupivacaine groups at intervals from 1½ hour to 6 hour. By the time of 2 ½ hour all patients in Ropivacaine group regained full motor power. However some studies indicated that Ropivacaine produces less motor impairment than Bupivacaine is probably a potency-related rather than a drug-specific effect. [35,36] Ropivacaine administered by caudal route is reported to be 40% less potent than Bupivacaine at equal doses, [35] implying that when higher concentrations of

Ropivacaine are used for central neuraxial blockade, significant motor block and delayed hospital discharge may ensue. The present study observations are contradictory to that of Tan et al (2000) [37] which showed that there was no significant difference in pain intensity & degree of motor blockade between Ropivacaine and Bupivacaine on comparison in pediatric caudal block.

Broadman's Objective Pain Score (OPS) was used to assess postoperative analgesia. This scale combines the physiological and behavioral parameters. It was developed by Broadman and Hannallahand has demonstrated both reliability and validity in pain assessment. OPS has been very useful in measuring pain in infants and non-verbal children. It is a reliable scale for assessment of pain in children. This scoring system is easy to use, validated, widely used in children and gives an objective evaluation of pain.

Although there was equal duration postoperative pain relief in both groups, range of first rescue analgesic requirement in Bupivacaine group was 2-8 hours while in Ropivacaine group it was 3-7.5 hours. Mean duration of analgesia in Bupivacaine group and Ropivacaine group was 4.56 hrs and 4.96 hrs respectively. Our observations are consistent with findings of Da Conceicao MJ et al (1999) [32] where average duration was 5 hrs for both the drugs. Although, Ray M. (2003) [25] found duration of analgesia of 6.63 hrs in Bupivacaine group and 6.75 hours in Ropivacaine group in 0.75 ml/ kg, the longer duration in their study might be due to higher concentration of drugs. However Ahmad S. et al (2012) [26] reported the duration of analgesia of 7.4 hrs in Bupivacaine group and 7.6 hrs in Ropivacaine group by using 0.25% and 0.2% concentration respectively in dose of 1ml/kg. Our findings correlates with the study of Da Conceicao MJ et al (1999), [32] Ray M (2003)[25] and Ahmad S. et al (2012). [26] We observaed4.56 hrs and 4.96 hrs duration of analgesia in 0.25 % Bupivacaine group and 0.25% Ropivacaine group respectively.

In our study we have noted the complications in relation to caudal epidural Bupivacaine 0.25% and Ropivacaine 0.25% for dural puncture, hypotension, bradycardia, nausea, vomiting and convulsions. In Bupivacaine group 4(13.33%) patients and 3(10%) patients in Ropivacaine group had nausea and vomiting. The difference was statistically not significant ($p>0.05$). Vomiting may be attributed to residual effect of anaesthetic agents, early ambulation and was treated with IV Inj. Ondansetron 0.08mg/kg.

The main purpose of the study was to assess the suitability of Ropivacaine in day care surgery patients. Absence of any major side effect with comparable quality of sensory block and post operative analgesia with short duration of motor blockade goes in favor of using Ropivacaine in day care surgery under regional anesthesia; Ropivacaine is less cardiotoxic and neurotoxic than Bupivacaine.

CONCLUSION

- From the observations of the present study, it may be concluded that 0.25% Ropivacaine (1 ml/ kg) compared to 0.25% Bupivacaine (1 ml/kg) was safe and effective for caudal analgesia in pediatric patients undergoing infra-umbilical surgeries.
- It provided comparable postoperative analgesia and quality of sensory block with stable haemodynamics and significantly less postoperative motor blockade without any major complications.

- Ropivacaine seems to be suitable local anaesthetic drug for caudal anaesthesia and analgesia in day care setting surgeries.
- As our study group sample size was smaller, to confirm the observations, the study on larger sample size is recommended.

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