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Study and Compare Caudal Ropivacaine and Ropivacaine Plus Nalbuphine in Providing Better Post-Operative Analgesia in Pediatric Patients

[1]Sachin Pawar, [2]Abdul Rahman, [3]Dnyaneshwar Chavan, [4]Usha Badole, [5]Kiran Dhonnar and [6]Nishant Shankar Padvi

[1]Department of Anaesthesia District hospital Nashik, India
[2,3]NBEMS Anaesthesia, New Delhi District Hospital Nashik, India
[4]Department of Anaesthesia, Grant Medical College and JJ hospital Mumbai, India.
[5,6]District hospital Nashik, India.

ABSTRACT

A caudal epidural block is the most common technique for regional anaesthesia among paediatric patients. Present study was aimed to compare caudal ropivacaine and ropivacaine plus Nalbuphine in providing better post-operative analgesia in pediatric patients. Present study was prospective, double-blinded, randomized control study conducted in patients of Age between 1 to 9 years, ASA grade 1 and 2, undergoing elective infra umbilical surgery, parents willing to participate in present study. Children were randomly divided into two groups of 30 patients, as Group A (received 0.2% Ropivacaine 1 ml/kg with 1ml NS) and Group B (received 0.2% Ropivacaine 1 ml/kg with 0.1mg/kg Nalbuphine). Mean FLACC pain score at 30min, 60 min, 90 min, 120 min, 180 min and 240 min post op were statistically highly significantly less in group B as compared to group A. Mean FLACC pain scale at 15 min, 30 min, 1 hour, 2 hours, 4 hours, 6 hours, 12 hour and 24 hours was less in group B as compared to group A and difference was statistically highly significant ($p<0.001$). In group A 19 (63.33%) required rescue analgesia and only 3 (10%) required rescue analgesia, difference was statistically highly significant ($p<0.001$). The mean Modified Bromage scale score at 30 min, 1 hour, 2 hours, 4 hour and 6 hours were comparable in group A and group B, difference was not statistically significant. ($p>0.05$). Nalbuphine hydrochloride in the dose of 0.1mg/kg when added as an adjuvant to 1ml/kg of 0.2% of Ropivacaine in caudal block provides prolonged duration of analgesia, however it may cause early postoperative sedation without respiratory depression as compared to the group where only Ropivacaine was used without any side effect.

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Key Words
Nalbuphine hydrochloride, ropivacaine, analgesia, caudal, pediatric patients

Corresponding Author
Nishant Shankar Padvim,
District Hospital Nashik, India
drnishant.padvi@gmail.com

Author Designation
[1,4]Professor
[2,3]Senior Resident
[5,6]Consultant Anaesthetis

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INTRODUCTION

Pain has become the fifth vital sign and is now a critical focus of the patient[1]. The relief of pain has always been part of anaesthesiologists" role in the most immediate postoperative period and extends beyond post anaesthesia care unit. The various methods of providing pain relief have some side effects which prohibit their use in children, e.g., narcotics in children, because of their respiratory depression[2], the other analgesics which cannot be given for some time after general anaesthesia due to the fear of vomiting and aspiration. The regional anaesthetic techniques significantly decrease postoperative pain and systemic analgesic requirements[3]. Epidural space in children favors the rapid longitudinal spread of drugs and effectively treats postoperative pain. A caudal epidural block is the most common technique for regional anaesthesia among paediatric patients[4]. It is commonly used to augment general anaesthesia and to manage postoperative pain. Adequate postoperative pain relief from caudal analgesia has numerous benefits, including earlier ambulation, reduced time spent in a catabolic state, lowered circulating stress hormone levels and decreased need for postoperative analgesics, including narcotics[5]. Ropivacaine, a long-acting amide local anaesthetic related structurally to bupivacaine, has been used for paediatric caudal anaesthesia[6]. Many adjuvants to local anaesthetics. Clonidine, dexmedetomidine, Nalbuphine, buprenorphine, dexamethasone etc., have been developed to increase the quality of the nerve block as well as hastening the onset of the blockade and increasing the duration of blockade[7]. Present study was aimed to compare caudal ropivacaine and ropivacaine plus Nalbuphine in providing better post-operative analgesia in pediatric patients.

MATERIAL AND METHODS

Present study was prospective, double-blinded, randomized control study conducted in at department of Anesthesiology, at XXX medical college and hospital, XXX, India. Study duration was of 2 years (January 2020 to December 2021). Study approval was obtained from institutional ethical committee.

Inclusion Criteria:

- Patients of Age between 1 to 9 years, ASA grade 1 and 2, undergoing elective infra umbilical surgery, parents willing to participate in present study

Exclusion Criteria:

Patients with:

- Infection at the site of caudal block
- Sacral bone abnormalities
- Bleeding diathesis
- Allergy to any of the study drugs
- Pre-existing neurological or spinal diseases
- Mental retardation
- Parents / Guardian refusal to give consent for procedure

Study was explained to parents in local language and written consent was taken for participation and study. A detailed history and pre-anaesthetic evaluation were made on the previous day of the surgery with the help of the child's parents. Routine investigations like blood grouping, hemoglobin, blood urea, blood sugar and platelet count were done. ECG, whenever indicated, was taken to rule out the presence of any active cardiac disease. Written informed consent was taken before the scheduled operation from the patient's parents. Patients were kept nil oral for 6 hours before the surgery. Patients were shifted to the operation theatre and Pulse oximeter, non-invasive blood pressure and electrocardiography monitors were connected. Inhalation induction of anaesthesia was done using 100% oxygen and sevoflurane 8% and intravenous lines were secured. According to Holliday Segar Formula, premeditation was done with injection glycopyrrolate 0.008 mg/kg through already secured venous access. Anaesthesia was induced with 2-3 mg kg-1 of propofol or injection ketamine 2 mg/kg and injection atracurium 0.5mg/kg. Airway management was done using a laryngeal mask airway or endotracheal tube and was left to the discretion of the attending anaesthesiologist. Maintenance of anaesthesia will be with 33% O2:67%N2O mixture and sevoflurane 1.0-1.2minimum alveolar concentration by controlled ventilation Children were randomly divided into two groups of 30 patients, by a computer-generated table of random numbers:

- Group A received 0.2% Ropivacaine 1 ml/kg with 1ml NS
- Group B received 0.2% Ropivacaine 1 ml/kg with 0.1mg/kg Nalbuphine in saline to make the volume of 1ml

Investigator, who was blinded to group assignments, performed caudal blocks in all patients. After securing the airway, under all aseptic precautions, the caudal block was performed in left lateral decubitus position using 22G short beveled needle by loss of resistance technique and the study drug was deposited after confirming negative aspiration for Blood and CSF. Continuous monitoring of vital parameters-heart rate (HR), ECG, respiratory rate, NIBP, SpO2-was done and values were recorded before premeditation (baseline), at the time of the caudal block, 3min, 6 min, 10 min after caudal block and after

that every 10 min till the surgery was over. The surgical incision was taken approximately 10 minutes after the caudal block. After surgery, all anaesthetic drugs were discontinued, reversal given and the patient was extubated or LMA removed. After extubation, patients were shifted to the post-anaesthesia care unit (PACU) for further observation and monitoring. Any side effects like breath-holding/apnoea, hypotension, involuntary movement and nausea/vomiting were noted. Pain score was assessed using face, Legs, Activity, Cry, Consolobility (FLACC) scale on the emergence and 1,2,4,6,12,24h until the first dose of rescue analgesia. The level of sedation was assessed by Ramsay sedation scale at 30min, 1hr, 2hr, 4hr and 6 hr postoperatively. Motor blockade was assessed using Modified Bromage Scale at 15min, 30min, 1hr,2hr 4hr, 6hr, 12hr and 24hr postoperatively. Sensory blockade was assessed with Hollmens scale at 30min,1hr, 2hr, 4hr and 6hr postoperatively. Data was collected and compiled using Microsoft Excel, analyzed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi- square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

RESULTS AND DISCUSSIONS

In this study total 60 patients were enrolled among which 30 were in the group A and 30 in the group B. The mean age among group A was 4.44±2.78 and 5.27±2.63 among group B and the difference was not statistically significant. (P value 0.176). Majority of the patients were male in both the groups, there was no significant difference between both the group. Mean weight among the group A was 13.25±4.45 and it was 15.00±5.16 among group B and the difference was not statistically significant. (P value 0. 510). Mean duration of surgery among the group A was 88.67±39.63 and it was 86.33±33.98 among group B, and the difference was not statistically significant. (P value 0. 413). We measured hemodynamic parameters (mean heart rate, mean systolic blood pressure, mean diastolic blood pressure, mean SPO2, mean respiratory rate) at various intervals such as before premeditation (baseline), at caudal block, 3 min, 6 min, at incision (10 min), 20 min, 30 min, 40 min, 50 min, 60 min, 70 min, 80 min, 90 min, 100 min, 110 min, 120 min and 130 min. On applying the Mann Whitney U test, the p-value showed no significant difference between the two groups throughout the study.

Mean FLACC pain score at 30 min, in group A was 0.20±0.4 and in group A was 0±0 (p = 0.001) Mean pain score at 60 min in group A was 0.57 ±0.7 and in group B was 0±0 (p<0.001). At 90 min mean pain score in group A was 1.03±0.89 and in group B was 0±0. (p<0.001). At 120 min mean pain score in group A was 1.70±1.02and in group B was 0±0 (p<0.001) At 180 min mean pain score in group A was 2.50 ±1.28 and in group B was 0.17±0.53 (p<0.001) At 240 min mean pain score in group A was 3.48±1.43 and in group B was 0.40±1.22 (p<0.001). Thus, the difference in mean pain score at 30min, 60 min, 90 min, 120 min, 180 min and 240 min post op were statistically highly significant. Mean FLACC pain scale at 15 min, 30 min, 1 hour, 2 hours, 4 hours, 6 hours, 12 hour and 24 hours was less in group B as compared to group A and difference was statistically highly significant (p<0.001).

In group A 19 (63.33%) required rescue analgesia and only 3 (10%) required rescue analgesia, difference was statistically highly significant (p<0.001). In our study both the group didn't have any side effect. On comparing the Ramsey sedation score between both the group. The mean score at 30 min was 1.20± 5.2 in group A and 2.00±0.00 in group B difference was statistically highly significant (p<0.001). Similarly, there has been significant difference at 1 hour, 2 hours and 4 hours. when compared at 6th hour there was no statistical difference between both the group. The results show that the sedation score is more in the Nalbuphine and it is statistically significant. The mean Modified Bromage scale score at 30 min, 1 hour, 2 hours, 4 hour and 6 hours were comparable in group A and group B, difference was not statistically significant. (p>0.05). Sensory block using Hollamans score at 30 min, 1 hour, 2 hours, 4 hour and 6 hours were comparable in group A and group B, difference was not statistically significant. (p>0.05).

Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in pediatric anaesthesia. It is a reliable and safe technique that can be used with general anaesthesia for intra operative and postoperative analgesia. The main disadvantage of caudal anaesthesia is the short duration of action after a single injection of local anaesthetic solution. The use of caudal catheters to administer repeated doses or infusion of local anaesthetic solutions is not widespread because of concerns about infection. So prolongation of caudal analgesia using a „single shot" technique has been achieved by adding various adjuvants. In our study, nalbuphine has been used as an adjuvant. Nalbuphine hydrochloride is a mixed μ antagonist and ? agonist opioid. It has been found to cause prolongation of the effects of local anaesthetics in intrathecal, epidural and peripheral nerve blocks with the advantages of minimal respiratory depression and better hemodynamic stability[7].

In our study on comparing the Ramsey sedation score, there has been significant difference at 30 min,

Table 1: General characteristics

	GROUP A Mean ± SD	GROUP B Mean ± SD	p-value
Mean age (in years)	4.44 ±2.78	5.27±2.63	0.176
Gender			
Male	23 (76.67%)	28 (93.33%)	X^2 = 3.268 0.145
Female	7 (23.33%)	2 (6.67%)	
Mean weight (in kgs)	13.25±4.45	15.00±5.16	0.510
Mean duration of surgery (in minutes)	88.67±39.63	86.33±33.98	0.413

Table 2: Mean postoperative FLACC score

Postoperative FLACC score	GROUP A Mean ± SD	GROUP B Mean ± SD	p-value
15MIN	0	0	
30MIN	0.20±0.4	0	0.001
60MIN	0.57±0.7	0	<0.001
90MIN	1.03±0.89	0	<0.001
120MIN	1.70±1.02	0	<0.001
180MIN	2.50±1.28	0.17±0.53	<0.001
240 MIN	3.48±1.43	0.40±1.22	<0.001

Table 3: Comparison of mean FLACC pain scale between two (N = 60)

FLACC pain scale	GROUP A Mean ± SD	GROUP B Mean ± SD	p-value
15 min	3.39±2.15	2±0	<0.001
30 min	4.29±4.7	2.03±0.18	<0.001
1 hour	4.00±0.45	2.33±0.47	<0.001
2 hour	4.47±0.50	2.80±0.40	<0.001
4 hour	5.13±0.50	3.10±0.30	<0.001
6 hour	6.03±0.66	3.47±0.50	<0.001
12 hour	6.77±0.43	3.90±0.30	<0.001
24 hour	7.20±0.40	4	<0.001

Table 4: Comparison of rescue analgesia between two group

Rescue analgesia	Group AN (%)	Group BN (%)	p-value
Required	19 (63.33%)	3 (10%)	<0.001
Didn't required	11 (36.67%)	27 (90%)	

Table 5: Comparison of Side effect between two group (N=60)

SIDE EFFECT	GROUP A	GROUP B
YES	0	0
NO	30	30

Table 6: Comparison of Ramsey sedation score

Ramsey sedation score	GROUP A Mean ± SD	GROUP B Mean ± SD	p-value
30 MIN	1.20±5.2	2.00±0.00	<0.001
1 HOUR	1.00±0.00	2.00±0.00	<0.001
2 HOUR	1.00±0.00	1.50±0.50	<0.001
4 HOUR	1.00±0.00	1.03±0.18	0.326
6 HOUR	1.00±0.00	1.00±0.00	1

Table 7: Comparison of Modified Bromage Scale

Modified bromage scale	GROUP A Mean ± SD	GROUP B Mean ± SD	p-value
30 min	1.98±5.20	2.00 ±0.00	0.091
1 hour	1	1.03±0.50	0.891
2 hour	1	1±0.25	0.161
4 hour	1	1.03±0.18	0.326
6 hour	1	1	1

Table 8: Comparison of Hollamans score

Hollamans score	GROUP A Mean ± SD	GROUP B Mean ± SD	p-value
30 min	1.94±5.20	1.98±4.80	0.317
1 hour	1	1	1
2 hour	1	1	1
4 hour	1	1	1
6 hour	1	1	1

1 hour, 2 hours and 4 hours. when compared at 6th hour there was no statistical difference between both the group. The results show that the sedation score is more in the Nalbuphine and it is statistically significant. Our study was in concurrence to the study conducted by Mohamed *et al.*[8]. and Riham Hussein Saleh *et al.*[9].where there was significant difference in the sedation score on addition of Nalbuphine as an adjuvant in early postoperative period. The mean Modified Bromage scale score at 30 min, 1 hour, 2 hours, 4 hour and 6 hours were comparable in group A and group B, difference was not statistically significant. (p>0.05). Our study was in concurrence to the study conducted by Mohamed *et al.*[8]. and Riham Hussein Saleh *et al.*[9]. where there is no significant difference in the motor blockage in both the group.

Pain assessment was done using FLACC score. In our study the difference in mean pain score at 30min, 60 min, 90 min, 120 min, 180 min and 240 min post op were statistically highly significant. Atef Kamel *et al.*[10].

found that the postoperative FLACC pain score was significantly (P<0.05) less in the group where the Nalbuphine was added. It indicated that Nalbuphine has a significant effect on postoperative analgesia. This observation correlates with observation in our study. Similarly, our study was in concurrence to the studies conducted by Mohamed *et al.*[8]. and Riham Hussein Saleh *et al.*[9]. where the addition of Nalbuphine has a significantly prolonged postoperative analgesia compared to the groups without Nalbuphine. In our study on comparing the rescue analgesia between two groups. 19 (63.33%) required rescue analgesia in group A and only 3 (10%) required rescue analgesia. On applying the Chi-square test, there was a significant (P<0.001) difference between both groups concluding that the addition of Nalbuphine has reduced the requirement of rescue analgesia.

Atef Kamel *et al.*[10]. found that the rescue analgesia was required earlier 202±23.42 in group A with plain Levobupivacaine compared to the dose required was less in group B where Nalbuphine was added 384.9±23 and the dose required was also less than 200.5±75.65 compared to the other group where 355.25±69.9 mg of paracetamol was used. The study concluded that the addition of Nalbuphine has delayed and reduced the dose of rescue analgesia, on analyzing it was found to be statistically significant. A study conducted by Mohamed *et al.*[8]. found that the time required for the first administration of rescue analgesia was longer (10.1±1.5hr). in the group where Bupivacaine was combined with Nalbuphine compared to Group B (6.2±1.4hr). Where Bupivacaine was given alone and it was statistically significant. There were no side effects in our study like hypotension, bardycardia, nausea, vomiting, shivering, respiratory depression, or pruritis in both groups. In concurrence with the study conducted by Riham Hussein Saleh *et al.*[9]. and Atef Kamel *et al.*[10]. in our study, there were no side effects like hypotension, bardycardia, nausea, vomiting, shivering, respiratory depression, pruritis in both the groups.

CONCLUSION

Nalbuphine hydrochloride in the dose of 0.1mg/kg when added as an adjuvant to 1ml/kg of 0.2% of Ropivacaine in caudal block provides prolonged duration of analgesia, however it may cause early postoperative sedation without respiratory depression as compared to the group where only Ropivacaine was used without any side effect.

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