IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 14, Issue 9 Ver. III (Sep. 2015), PP 50-54
www.iosrjournals.org

Comparative Evaluation of Caudal Ropivacaine and Ropivacaine with Clonidine for Postoperative Analgesia in Children

Ghulam Ali[1], Neha Kala[2], Mushtaq Ahmad Rather*[3], Arshi Taj[4], Shemaiel Maqbool[5], Khursheed Ahmad Bhat[6]

[1]*Associate professor Department of anaesthesiology and critical care GMC Srinagar, India*
[2]*Postgraduate Scholar Department of anaesthesiology and critical care GMC Srinagar, India*
[3,5,6]**Senior Resident Department of anaesthesiology and critical care GMC Srinagar, India*
[4]*Consultant Department of anaesthesiology and critical care GMC Srinagar, India*

Corresponding Author: mushtaqahmad767@gmail.com

Abstract:
Aim*: The aim of our study was to compare the duration of post-operative analgesia in children when clonidine is added to ropivacaine to that of plain ropivacaine following caudal analgesia.*
Materials and Methods: *Sixty healthy children of ASA I and II physical status of either sex, in the age group of 1-6 years undergoing elective sub umbilical procedures were randomlyallocated to three groups of 20 children each. Group A received 1 ml/kg of 0.1% ropivacaine, group B received 1 ml/kg of 0.1% ropivacaine with clonidine 1 mcg/kg, and group C received 1 ml/kg of 0.2% ropivacaine.Intraoperatively children were assessed for any haemodynamic changes and postoperatively children were assessed for sedation score, duration of analgesia and duration of motor block.*
Results:*The groups were comparable regarding demographic characteristics. The mean duration of analgesia was significantly prolonged in group B (589.1±39.64 min) compared to group A (248.4±17.39 min) and group C (384.4±22.75 min) with the P value of <0.001. At 8 h, all the 20 children in group A had received the first rescue analgesic compared to 18 children in group C and 3 children in group B. The mean duration of motor blockade (30.6 ± 7.8 min) after extubation was noted only in group C. Only one child in group B received two rescue medications compared to 15 (75%) children in group A and 8 (40%) children in group C. None of the groups were treated for bradycardia or hypotension and no significant sedation was noted in study groups.*
Conclusion*: clonidine ropivacaine mixture in caudal analgesia provided longer duration of analgesia requiring less doses of rescue analgesia compared to ropivacaine alone without causing any significant degree of post-operative sedation.*
Keywords*: Caudal analgesia, Ropivacaine, Adjuvant, Clonidine.*

I. Introduction

Postoperative analgesia in children is a challenging task before the anaesthesiologist. Good postoperative analgesia not only relieves pain in the children but also relieves anxiety in the parents. Caudal epidural block is a simple, safe, effective and reliable technique. Since Campbell first described caudal epidural analgesia in children in 1933, anaesthesiologists witnessed many advances in postoperative pain relief. Different techniques, drugs, drug combinations, doses and concentrations have been tried by many anaesthesiologists to increase postoperative analgesia. Ropivacaine produces differential neural blockade with less motor block and reduced cardiovascular and neurological toxicity compared to Bupivacaine. [1] Because ropivacaine has to be given in larger doses to achieve the analgesic and anaesthetic effects and this can increase toxic effects of ropivacaine. The addition of adjuvants like α-2 agonists, clonidine and dexmedetomidine can decrease the dose requirement and permit use of more diluted solutions for better analgesia and prevent side effects associated with larger doses of ropivacaine. [2, 3] But search for the ideal adjuvant along with local anaesthetic with wide margin of safety, minimal motor blockade, and prolonged period of analgesia continues till date. Therefore, we did a prospective, randomized, double-blind trial to investigate the role of clonidine as an adjuvant to ropivacaine through caudal route in children and we believe that clonidine will enhance the quality of analgesia and prolong the duration of pain relief as compared to plain ropivacaine.

II. Materials And Methods

After approval from the institutional ethical committee and written consent from parents, this randomized prospective comparative hospital based study was conducted in Government Medical College Srinagar. A total of 60 patients of American Society of Anaesthesiologist (ASA) grades I and II of either sex,

aged 1-6 years scheduled for elective subumblical surgery were enrolled for the study. Patients were divided into three groups. Each group consisted of 20 patients and received the drug as follows: Group A: received 1ml/kg of 0.1% ropivacaine, Group B: received 1ml/kg of 0.1% ropivacaine with clonidine 1µg/kg and Group C: received 1ml/kg of 0.2% ropivacaine. Patients with bleeding disorders, neuromuscular disorders, bony abnormality of the spine, and infection at the site of caudal analgesia were excluded from the study. All children were evaluated at least 24 hours before the expected surgical procedure and instructed to remain fasting for at least 6 hours before surgery. All children received 0.5mg/kg of midazolam orally as a premedication 30 minutes prior to induction. ECG, pulse oximetery, non-invasive blood pressure and end tidal carbon dioxide monitors were applied for intraoperative monitoring and baseline heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) and SPO2 recorded. Inhalational induction was done with increasing concentration of halothane and intravenous access was secured. Fentanyl 2µg/kg was administered intravenously for base line analgesia. After securing the airway the children were placed in lateral decubitus position. The caudal space identified and the appropriate drug injected in the caudal epidural space as per the group using a 22 gauge needle. The surgical incision made 5 minutes after caudal placement of the drug. The intraoperative heart rate, SBP, DBP and SPO2 monitored and documented every 10 minutes till awakening. Motor blockade noted at the time of extubation and then every 15 minutes upto 2 hours. The degree of motor blockade was assessed by Bromage scale. Sedation Score was assessed by as:- 0-arousable; 1-arousable to voice; 2-arousable to pain ; 3-unarousable . The heart rate, SBP, DBP respiratory rate, motor block and sedation score were assessed in the postoperative period for two hours. Pain Score were assessed by using face, legs, activity, cry, consolability scale (FLACC)

Table 1: FLACC Scale

Parameter	**0**	**1**	**2**
Face	No expression	Occasional grimace	Frequent to constant quivering chin.
Legs	Normal position 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 or whimpers	Crying steadily
Consolability	Content, relaxed	Reassurance, hugging	Difficulty to console
Score: 0 = no pain; 1-3 mild pain; 4-7 moderate pain; 8-10 severe pain			

The pain score noted at 0, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22 and 24 hours postoperatively. The time from caudal placement of drug to the first recording of a FLACC scale > 3 was taken as duration of analgesia. Rescue analgesia was provided with paracetamol suppository 20mg/kg whenever the pain score was > 3. The number of rescue analgesia required within 24 hours was noted. Respiratory depression is defined as decrease of SpO_2< 93%. Hypotension is defined as mean arterial blood pressure 30% less than baseline value and was treated with a bolus of 10ml/kg crystalloid. Bradycardia is defined as heart rate less than 15% from the baseline value and was treated with atropine 0.02mg/kg.

The data were collected, tabulated and analyzed using appropriate statistical tests Statistical software SPSS (version 16.0). Data was analyzed by means of descriptive statistics viz., means, standard deviations and percentages. The inter group comparison of quantitative data was done by applying analysis of variance (ANOVA) test and for multiple comparisons, least significant difference (LSD) test was applied. For qualitative data, Chi-square test or Fisher's exact test, whichever appropriate, was applied. P-value less than 0.05 were considered statistically significant.

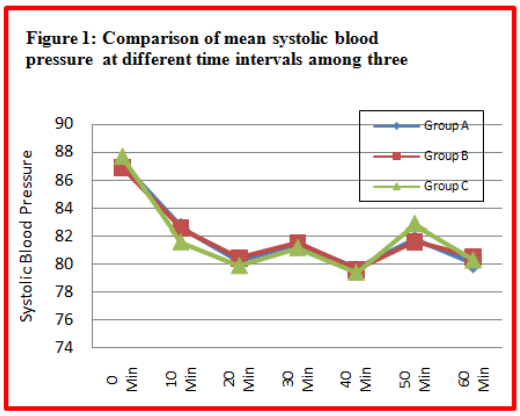
III. Results

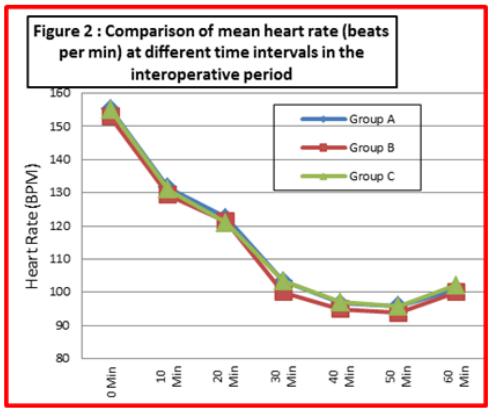
The demographic characteristics, age, male/female ratio and weight were comparable in both the groups (Table 2).

Table 2: Demographic characteristics:-

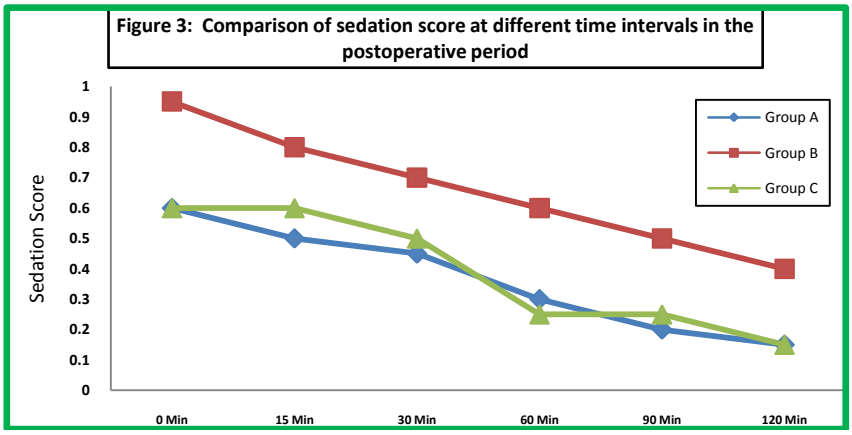
Parameter	Group A (n=20)	Group B (n=20)	Group C (n=20)	P value
Age (years)	3.22±1.46	3.18±1.45	2.95±1.18	0.803
Gender (M/F)	16/4	17/3	16/4	0.895
Weight (kgs)	14.75±2.73	15.45±2.56	14.9±2.15	0.648
Duration of surgery (min)	52.1±4.82	52.9±5.03	54.1±6.41	0.530
Data are given as mean or absolute numbers. M=male, F=female				

Comparing the hemodynamic parameters statistically, the difference was found to be insignificant (Figure 1 and 2).





The mean duration of analgesia was significantly prolonged (248.4 ± 17.39 min) in group A compared to groups B (589.1±39.64) and C (384.4±22.75) with p value of <0.001 (Table 3). The doses of rescue analgesia were more in group A and in group C than in group B. 95% of patients in group B required rescue analgesia only once and 5% required rescue analgesia twice in 24 hours whereas in group A 10% received one dose , 85% received two doses and 5% received three doses of rescue analgesia in 24 hours and in group C 60% patients received one dose and 40% received two doses of rescue analgesia in 24 hour duration (p< 0.001) (Table 3) . There were a significant difference in the pain score of children in group B at 2, 4, 6, and 8 h postoperatively when compared to group A and group C. At 8 h, only 3 children in group B had pain score more than 3 compared to 18 children in group C and all 20 children in group A. At 2 hours the mean sedation score was 0.15±0.36 in group A, 0.40±0.50 in group B and 0.15±0.36 in group C (Figure 3).The three groups did not vary in respect to sedation or other adverse effect (>0.005) The motor blockade in different groups observed postoperatively for 2 hours and statistically significant difference was found in group C with p value of <0.001.



None of the children had nausea, vomiting, respiratory depression, blood pressure drop, bradycardia or urinary retention. None of the under study subjects required any type of therapeutic intervention.

Table 3 : Comparison of block characteristics:-

Variables	Group A (n=20)	Group B (n=20)	Group C (n=20)	P value
Duration of Analgesia (min)	248.4±17.39	589.1±39.64	384.4±22.75	<0.001
Degree of Motor Block:				
0 (No blockade)	20	20	0	<0.001
1(Partial blockade)	0	0	1	
2(Almost complete blockade)	0	0	10	
3(Complete blockade)	0	0	9	
Duration of Motor Blockade (min)	-	-	29.05±8.01	
No. of Rescue Medications in 24 hrs				
1 dose	2 (10%)	19 (95%)	12 (60%)	<0.001
2 doses	17 (85%)	1 (5%)	8 (40%)	
3 doses	1 (5%)	0	0	
Data are given as mean with standard deviation (SD) , percentage (%) or absolute numbers.				

IV. Discussion

Caudal epidural block is one of the most common regional anaesthetic techniques used in children. It is generally considered a simple and safe procedure but its main disadvantage is its relatively short duration of action, even with the use of long-acting local anaesthetic agents. Adjuvants are drugs that increase the efficacy or potency of other drugs when given concurrently. In addition to their dose sparing effects, neuraxial adjuvants are also utilised to increase the speed of onset of neural blockade, improve the quality and prolong the duration of neuraxial blockade. Neuraxial adjuvants include opioids, sodium bicarbonate, vasoconstrictors, alpha-2 adrenoceptor agonists, cholinergic agonists, N-methyl-d-aspartate (NMDA) antagonists and γ-aminobutyric acid (GABA) receptor agonists. However, a "gold standard" drug has not been defined. Among the drugs, opiates are most potent; however, the opiates are associated wide-ranging and unpredictable side effects. In various studies it has been shown that when Clonidine used as a neuraxial adjunct, prolongs the duration of analgesia and anaesthesia. During the last decade the use of clonidine has become increasingly popular in paediatric anaesthesia, particularly when administered caudally with a local anaesthetic agent. **[4]** Clonidine has been shown to produce analgesia without causing significant respiratory depression after systemic, epidural or spinal administration. Although epidural clonidine may also cause hypotension, bradycardia and sedation in higher doses, serious adverse effects are uncommon in the dose range (1-2 µg/kg body weight) normally used in children. **[5]** A number of studies on the use of caudal clonidine have been carried out over the past 10 years focusing primarily on the quality of analgesia obtained with local anaesthetics. **[6, 7, 8, 9, 10]** The results of these studies vary widely. The duration of analgesia achieved has been reported to vary between 5.8hrs and 16.5hrs, for which there are variety of causes. The majority of studies used non-standardized surgery and non standardized anaesthetic techniques both within and between treatment groups. Moreover, differences in the dose of clonidine and the local anaesthetic agents used, concomitant use of premedication, indications for rescue analgesia, type of drugs used for rescue analgesia, and different methods of assessment of pain and statistical analysis may all account for this variability. In this study, we were unable to detect any significant differences in the mean heart rate and blood pressure at 0, 10, 20, 40 and 60 min in the intraoperative period between three groups. No patient required drug therapy to treat hypotension or bradycardia. No episode of oxygen saturation <95% was recorded. However, the mean heart rate and blood pressure were lower in group B at different intervals compared to group A and group C but that was statistically insignificant. Similar haemodynamic results were obtained in various studies in patients who received either ropivacaine (0.2% 1ml/kg) or ropivacaine (0.2% 1ml/kg) with clonidine (2ug/kg) in caudal block. **[11, 12, 13]**

In present study, pain scores were evaluated using FLACC scale in the recovery room at every 2 hours for first 24 hours postoperatively. In our study we found that pain scores at 4, 6, 8, 10 and 12 hours were significantly lower in group B and Group C compared to Group A . We also found in our study that the mean duration of analgesia after caudal block and number of doses for supplemental analgesia in postoperative period were significantly lower in group B than in group A and group C. Our observation correlate with Akilandeswari et al**,** who also observed prolonged duration of analgesia in group of children who received ropivacaine 0.1%(1ml/kg) with clonidine 1µg/kg than plain ropivacaine of 0.1% (1ml/kg) and 0.2%(1ml/kg) concentration. [12] Our study also correlates with the study done by ArpitaLaha et al, in which they observed that caudal analgesia in children with ropivacaine 0.2% (1ml/kg) and clonidine (2µg/kg) group resulted in longer duration of post operative analgesia and reduced frequency of rescue medication. [11]No significant difference was found regarding post-operative sedation between the three groups in our study, which correlates with other studies. [11, 13, 14]

In conclusion, this study shows that the clonidine-ropivacaine mixture in caudal block provided superior quality and longer duration of postoperative analgesia compared to ropivacaine alone without causing any significant degree sedation or prolongation of motor blockade.

References

[1]. N S Morton. Ropivacaine in children. British Journal of Anaesthesia 2000; 85(3): 344-346
[2]. Mariann AH. Dexmedetomidine:A useful adjunct to consider in some high risk situations. AANA 2008;76(5):335-340
[3]. Bajwa SJ, Bajwa SK, Kaur J, Singh G, Arora V, Gupta S .Dexmedetomidine and clonidine in epidural anaesthesia: A comparative evaluation. Indian J Anaesth 2011; 55:116-21.
[4]. Nishina K, Mikawa K. Clonidine in paediatric anaesthesia. CurrOpinAnaesthesiol2002;15(3): 309-16
[5]. Jamali S, Monin S, Begon C, Dubousset AM, Ecoffey C. Clonidine in pediatric caudal anesthesia. Anaesthesia and Analgesia 2009 78(4):663-6
[6]. Lee JJ and Rubin AP. Comparison of bupivacaine – clonidine mixture with pain bupivacaine for caudal analgesia in children. British Journal of Anesthesia 1994; 72: 258-262
[7]. Cook B, Dayle E. The use of additives to local anaesthetic solution for caudal epidural analgesia. Pediatric Anesthesia 1996; 6:353–359
[8]. Klimsha W, Chiari A, Michalek-Sauberer. The efficiency and safety of Clonidine-Bupivacaine combination in caudal blockade for pediatric hernia repair. Anesthesia Analgesia 1998; 6: 54-61
[9]. Sharpe P, Klein JR, Thompson JP. Analgesia for circumscision in pediatric population: comparison of caudal bupivacaine alone with bupivacaine plus two doses of clonidine. PeadAnesth 2001;11:695-700

[10]. Tsui BC, Berde CB. Caudal analgesia and anesthesia techniques in children. CurrOpinAnaesthesiol. 2005; 18(3): 283-8
[11]. AkilandeswariManickam, Mahesh Vakamudi, ArunaParameshwari, ChetanaChetan. Efficacy of clonidine as an adjuvant to ropivacaine for caudal analgesia in children undergoing subumblical surgery. Journal of Anaesthesiology Clinical Pharmacology 2012; 28: 185-189
[12]. ArpitaLaha, SarmilaGhosh, Haripada Das. Comparison of caudal analgesia between ropivacaine and ropivacaine with clonidine in children: a randomized controlled trial. Saudi Journal of Anaesthesia 2012; 6: 197-200
[13]. UshaShukla, (Brig) T Prabhakar, KiranMalhotra. Postoperative analgesia in children when using clonidine or fentanyl with ropivacaine given caudally. Journal of Anaesthesiology Clinical Pharmacology 2011; 27: 205- 10
[14]. Shobhana Gupta, VirendraPratap. Addition of clonidine or dexmedetomidine to ropivacaine prolongs caudal analgesia in children. Indian Journal of Pain 2014; 28: 36-41