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Comparative analysis of caudal ropivacaine with clonidine vs ropivacaine alone with regards to hemodynamic changes, analgesic potency and side effects in children

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ABSTRACT

Introduction: Pain management is an essential component of care provided by pediatric anaesthesiologists. That specially holds true due to inability of this group of patients to report their overall experience of surgical procedures like adults. Caudal analgesia is one of the most popular regional anaesthetic techniques employed in children undergoing surgery for lower abdominal, urological, and lower limb operations. Of all the major advantages that this technique has, there is one major disadvantage of short duration of anesthesia. In children it is observed that combination of ropivacaine and clonidine administered caudally has shown to prolong the effects of analgesia. The present clinical study is therefore undertaken to compare caudal ropivacaine with clonidine and ropivacaine alone with regards to hemodynamic changes, analgesic potency and side effects in children.

Materials and Methods: This study included 60 children of the age group 5-10 years ASA grade I and II, of either sex, coming for various elective infra-umbilical surgical procedures who were divided into two groups each comprising of 30 subjects. Group A received plain 0.20% Ropivacaine (1ml/kg) and Group B received 0.20% Ropivacaine (1ml/kg) with clonidine 1µg/kg and the effects were analysed on various parameters.

Results & Conclusion: In our study, we chose 0.20% ropivacaine which provides better quality of analgesia and clonidine 1.0µg/kg which prolongs the duration of analgesia significantly while avoiding the side effects like excessive sedation and bradycardia associated with higher doses. Other hemodynamic parameters did not differ significantly in both the groups.

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1. Introduction

The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”.¹ In children, even the definition of pain has been debated.² In fact, pain experienced by infants and children often goes unrecognized, even neglected, because of the operational

definition of pain that requires self-report.^{2,3}

Pain management is an essential component of care provided by pediatric anaesthesiologists. That specially holds true due to inability of this group of patients to report their overall experience of surgical procedures like adults. Unfortunately, one can argue that this has led to a considerable amount of unnecessary suffering on the part of these patients.⁴⁻⁶ Effective pain control in pediatric group has shown effect on pain perception but also on overall stress response during surgery, reduce the overall intra-operative requirement of both inhaled and intravenous

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anaesthetic agents and allow more rapid return of the conscious pre-operative state while providing effective post-operative pain relief with minimal sedation even in premature infants.^{7,8}

Caudal analgesia is one of the most popular regional anaesthetic techniques employed in children undergoing surgery for lower abdominal, urological, and lower limb operations. Of the many advantages of this technique including smooth recovery period and good amount of postoperative pain control; the major drawback with the single shot technique is the short duration of the analgesia.⁹ To overcome this, longer acting bupivacaine is used over traditional lignocaine which tends to increase the duration of the analgesia for many cases. Many other anesthetic agents including opioids, ketamine, epinephrine is being tried in combination which although are found to increase the duration and potency of the anesthetic agent have many side effects including respiratory depression, neurotoxic effects etc.^{9–12}

Clonidine, of lately, has shown very good results after systemic, epidural, or intrathecal administration without side effects of respiratory depression and neurotoxicity with bupivacaine in adults. In children it is observed that combination of ropivacaine and clonidine administered caudally has shown to prolong the effects of analgesia.⁹

The present clinical study is therefore undertaken to compare caudal ropivacaine with clonidine and ropivacaine alone with regards to hemodynamic changes, analgesic potency and side effects in children.

2. Aim of the Study

This study has been done to compare ropivacaine 0.20% (1ml/kg) and ropivacaine 0.20% (1ml/kg) with clonidine (1.0µg/kg) as a single shot caudal block and to assess its effects on hemodynamic changes, duration of post-operative analgesia and incidence of the side effects in infra-umbilical surgeries in children (5-10 years)

3. Materials and Methods

This study was conducted at Santokba Durlabhji Memorial Hospital, Jaipur from February 2013 to May 2014.

This study included 60 children of the age group 5-10 years ASA grade I and II, of either sex, coming for various elective infra-umbilical surgical procedures such as herniotomies, circumcision, orthopaedic surgery, orchidopexy, perineal surgeries and minor lower extremity procedures. Children with ASA III and IV, infection at the site of injection, any coagulopathies or children on anticoagulants, Congenital abnormalities of lower spine and meninges or any other active CNS disease or history of allergy to local anaesthetics were excluded from the study. Armamentarium and equipments used for anesthesia are shown in Figure 1.



Fig. 1: Armamentarium for caudal anaesthesia

3.1. Pre-anaesthetic assessment

Patients were examined for general physical parameters including airway and spine along with vital parameters according to the pre surgical protocol.

After restriction of solid foods and clear fluids for 2-3 hours prior to the surgery, patients were pre medicated with syrup Promethazine on a night before and also 1 hour before the surgery.

3.2. Procedure

Induction of anesthesia was achieved with sevoflurane (2% - 4% - 6% - 8%) and oxygen after assessing the patients' vitals. A good i.v. line was secured and all patients were paralysed with injection atracurium 0.5mg/kg and injection xylocard (2%) 1.5 mg/kg given 90 sec prior to intubation with appropriately sized endotracheal tube. An infusion of ringer lactate was started and fluid was administered according to calculated requirements. No intravenous analgesia given.

3.3. Caudal block

After identifying the sacral hiatus, a 23G hypodermic needle with its bevel facing anteriorly was inserted at an angle of 60-70° to the skin till the sacro-coccygeal membrane was pierced, when a distinct "pop" was felt. The needle is now lowered to an angle of 20° and advanced 2-3 mm to make sure that the entire bevel is inside the space. Aspiration was done to exclude dural puncture or vessel puncture and the drug was injected.

The surgical incision was made 5 minutes after caudal placement of drug and duration of surgery noted. Procedure is being given in Figure 2.

3.4. Drug and dosage

The patients were randomly divided into 2 groups of 30 each. Group A received 0.20% ropivacaine (1ml/kg) and Group B received 0.20% ropivacaine (1ml/kg) with clonidine 1µg/kg.

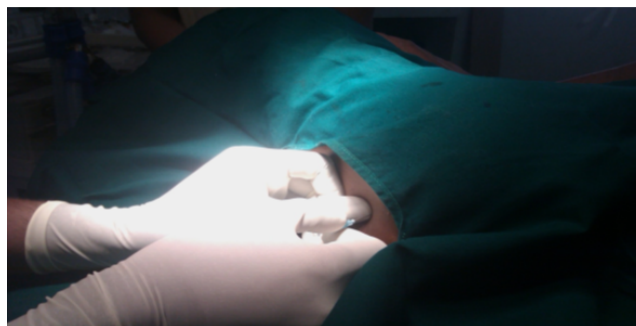


Fig. 2: Caudal anaesthesia technique

Along with monitoring of vital parameters, the time of caudal block and duration of surgery was noted.

3.5. Hemodynamic parameters

Patients were monitored for heart rate and blood pressure after administration of caudal block at 0,5,15,30,45,60,120 and 180 minutes and the values were recorded.

3.6. Duration of action

Duration of action of drug is defined as the time interval between the administration of caudal block and the first requirement of supplementary analgesia for the patient.

3.7. Post-operative analgesia

Post-operative analgesia is assessed by Paediatric Objective Pain Scale. The assessment was done for a period of 24 hours after caudal block. If the analgesia rated more than 6 on the scale at more than 2 intervals then supplementary analgesia with rectal Paracetamol (15mg/kg) was given. These assessments were made at 1,2,3,4,8,12 and 24 hours after caudal block. (Table 1)

3.8. Side effects

Patients were monitored for intra-operative and post-operative complications. These included nausea/vomiting, bradycardia, hypotension, respiratory depression and sedation which was measured on a 4-point scale. (Table 2)

4. Results

The results of continuous variables are given as mean $\pm$ SD and proportion as percentage. The difference between the two groups was assessed by student's *t* test and chi-square test. For all the tests a 'p' value of 0.05 and less was considered for statistical significance.

The mean age in group A was 7.1 ± 1.58 years and in group B was 6.86 ± 1.6 years. The two groups did not differ significantly ($p = 0.94$) with respect to their age. In group A there were 26 (87%) males and 4 (13%) females. Group B

Table 1: Paediatric objective pain scale

Observations	Criteria	Points
Blood pressure	$\pm 10\%$ pre-operative value	0
	$>20\%$ pre-operative value	1
	$>30\%$ pre-operative value	2
Crying	Not crying	0
	Crying but responds to tender loving care	1
	Crying with no response to tender loving care	2
Movement	None	0
	Restlessness	1
	Thrashing	2
Agitation	Asleep	0
	Mild	1
	Hysterical	2
Posture	No special posture	0
	Flexing legs and thighs	1
	Holding penis or groin	2

Table 2: Point patient sedation score

1	Asleep; not arousable by verbal contact
2	Asleep; arousable by verbal contact
3	Drowsy / not sleeping
4	Awake / alert

had 28 (93%) males and 2 (7%) females. The groups were comparable with respect to sex. The weight of the children in group A ranged from 12 to 22 kg with a mean weight of 16.3 ± 2.9 kg. In group B the weight ranged from 10 to 23 kg with a mean of 15.7 ± 3.4 kg. The two groups did not differ significantly with respect to weight ($p = 0.46$). The different surgical procedures performed during the study in the two groups are shown in Table 3.

Table 3: Types of surgical procedures

Types of surgery	Group A n (%)	Group B n (%)
Circumcision	6 (20%)	8 (26%)
Herniotomy	13 (43%)	14 (46%)
Orchidopexy	2 (7%)	2 (7%)
Anorectal surgeries	5 (16%)	4 (14%)
Others	4 (14%)	2 (7%)

4.1. Changes in heart rate

In group A, the mean baseline heart rate was 89 ± 5.6 per minute which increased to 98 ± 6.4 at 5 min. The heart rate gradually decreased to 87 ± 6.3 per minute at 180 minutes. The mean baseline heart rate in group B was 91 ± 8.6 per minute which increased to 97 ± 5.3 at 15 minutes and gradually decreased to 88 ± 7.8 at 60 min and remained so till 180 minutes.

Table 4:

Time interval (min)	Group A Mean±SD	Group B Mean±SD	Mean Difference	P* value	Significance
Baseline	89±5.6	91±8.6	1.1	0.48	NS
0	94±5.2	93±7.1	1.2	0.42	NS
5	98±6.4	96±6.1	1.5	0.32	NS
15	98±5.2	97±5.3	1.0	0.52	NS
30	90±6.3	93±6.0	2.1	0.15	NS
45	89±5.7	91±5.6	1.6	0.37	NS
60	87±5.9	88±7.8	1.6	0.37	NS
120	86±5.9	88±6.5	1.7	0.32	NS
180	87±6.3	88±6.6	1.0	0.52	NS

However, there was no significant difference in the heart rate between the two groups at any time interval ($p > 0.05$) as shown in Table 4.

4.2. Changes in systolic blood pressure

The mean systolic and diastolic blood pressure and the deviation range of both at 180 minutes is being displayed in Tables 5 and 6.

At all time interval, the p value was > 0.05 and hence the differences in the systolic blood pressure were insignificant at all time intervals.

There was no significant difference in the diastolic blood pressure ($p > 0.05$) at any of the time intervals, as depicted in Table 5.

4.3. Pain score

This distribution of subjects in the two study groups according to pain score < 6 at various monitoring intervals is shown in Figure 3.

The pediatric pain score was < 6 in both the groups during the first hour of anaesthesia. Statistically highly significant results were observed in at the end of 3rd and 4th hour of analgesia. Overall, the subjects with a pain score of ≥ 6 were significantly lower in group B compared to group.

4.4. Duration of analgesia

The mean duration of analgesia was 250.33 ± 41.4 min in group A with a range of 180 to 355 min. In group B, the mean duration of analgesia was 433.5 ± 60.2 min with a range of 265 to 530 min. The difference in the mean duration of analgesia was statistically highly significantly ($p < 0.001$) which is shown in Table 7.

4.5. Incidence of complications

The incidence of nausea and vomiting was among 3(9%) children in group A compared to 2(6%) in group B. This was not statistically significant. There was no incidence of hypotension, bradycardia, dural or vessel puncture and respiratory depression in the two groups.

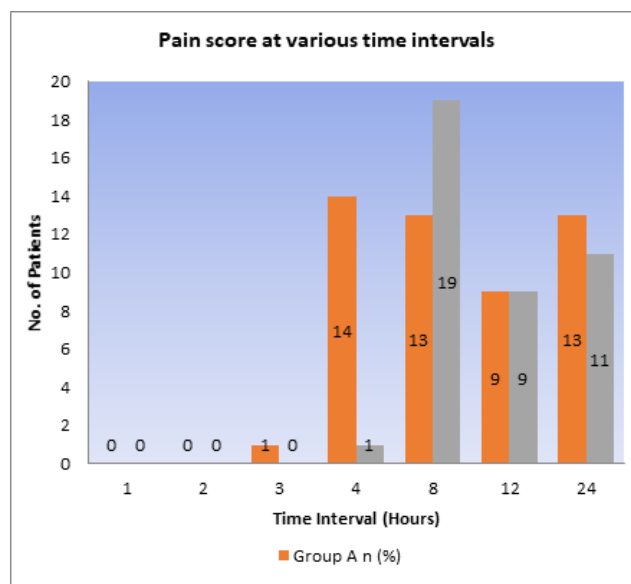


Fig. 3: Shows pain scores in pediatric patients at various intervals

5. Discussion

Caudal epidural blockade is one of the most popular regional blocks used in paediatric anaesthesia due to its reliability and safety. The only major drawback of shorter duration of analgesia is being tackled by using many combinations of drugs specially to avoid extradural catheter placement, which carries the risk of infection especially in single shot caudal anesthesia.¹⁰ Though opioids were in use, the major side effects associated them led to the advent of the use of alternative drugs such as clonidine have been administered to improve analgesia in the postoperative period while avoiding the side-effects.¹³

In this study, caudal epidural block using ropivacaine alone and ropivacaine with clonidine combination was conducted in 60 children in the age group of 5 to 10 years of ASA grade I and II coming for various elective infra-umbilical surgeries.

In the present study, there was no significant difference in the two groups with regard to age, weight and sex. In

Table 5: Changes in systolic blood pressure

Time interval (min)	Group A Mean±SD	Group B Mean±SD	Mean Difference	P* value	Significance
Baseline	98±7.4	100±6.9	1.57	0.40	NS
0	99±7.0	101±6.9	2.00	0.27	NS
5	107±7.7	105±6.0	1.93	0.28	NS
15	104±8.4	103±4.6	1.20	0.49	NS
30	100±7.0	101±3.3	1.73	0.22	NS
45	97±7.03	99±2.7	1.20	0.39	NS
60	96±7.2	97±3.7	0.13	0.93	NS
120	94±6.7	96±3.0	0.93	0.49	NS
180	97±9.1	96±3.3	1.33	0.29	NS

Table 6: Changes in diastolic blood pressure

Time interval (min)	Group A Mean±SD	Group B Mean±SD	Mean Difference	P* Value	Significance
Baseline	63±4.8	63±6.9	0.07	0.97	NS
0	63±4.8	63±6.8	0.073	0.98	NS
5	69±4.8	67±6.7	2.33	0.13	NS
15	69±5.4	68±4.0	0.93	0.53	NS
30	63±5.9	65±6.3	2.13	0.18	NS
45	63±6.1	64±6.3	0.87	0.59	NS
60	61±6.2	60±7.1	1.13	0.51	NS
120	60±5.0	61±6.6	1.33	0.38	NS
180	60±5.8	62±6.6	1.87	0.25	NS

Table 7: Duration of analgesia

Duration of analgesia (min)	Group A	Group B
Mean duration±SD	250.33±41.4	433.5±60.2
Range	180-355	265-530

p<0.01, student's unpaired 't' test.

both the groups males were more (> 80%). This could be due to inclusion of surgeries like herniotomy, orchidopexy and circumcision in our study. Ivani G. et al.¹⁴, Neogi M et al.¹⁵ Arpita et al.⁹ have reported that patients in the 2 groups were comparable regarding age, weight, sex distribution and duration of surgery. HR, SBP and DBP as noted intra-operatively did not vary significantly between the 2 groups. Motor blockade was comparable between the 2 groups. Analgesia persisted for a longer duration in clonidine group, in comparison to ropivacaine only group, which is statistically significant. In plain group, rescue was needed after average 8 hrs post operatively whereas rescue was needed after average 16 hrs in ropivacaine plus clonidine group.

In our study also, we have used a single dose of 0.20% ropivacaine (1ml/kg). Higher concentration can produce motor blockade in the immediate post-operative period and delay discharge. Since all the patients are monitored for 24 hours postoperatively in our hospital, 0.20% ropivacaine was used for post-operative analgesia.

A number of papers on the use of caudal clonidine have been published over the past years. However, most

of them have focused on the use of bupivacaine and clonidine combination including the studies of Jamali S and colleagues,¹⁶ Cook B et al,¹² Lee JJ et al¹⁷ and Klimscha and colleagues¹⁸ demonstrated that in small children undergoing infraumbilical surgeries the addition of clonidine to bupivacaine significantly prolonged the mean duration of analgesia and reduced the post-operative analgesic requirement within the first 24 hours.

In our study, we chose 0.20% ropivacaine which provides better quality of analgesia and clonidine 1.0µg/kg which prolongs the duration of analgesia significantly while avoiding the side effects like excessive sedation and bradycardia associated with higher doses.

In the present study, heart rate and blood pressure of all the patients were monitored at regular intervals. It was observed that heart rate and blood pressure both systolic and diastolic were more or less similar in both the groups. After an initial rise in both these parameters owing to the commencement of intubation and surgical procedure, the values returned to baseline normalcy or just minor decrease after the administration of the caudal block. There was no incidence of bradycardia or hypotension in both the groups.

Motsch and colleagues¹⁹ found that children receiving high dose clonidine ($5\mu\text{g/kg}$) had lower systolic pressures and heart rate during the first 3 hours after surgery compared with the control group. However, apart from one of the 20 children who received atropine to treat a heart rate of less than 70 beats per minute, no additional measures were necessary with this relatively high dose clonidine.

In the present study, no significant difference in the respiratory rate between the two groups was observed. There were no cases of respiratory depression in patients of either group.

Some studies Narchi P et al.²⁰ have reported no respiratory depression at the dose of about $150\mu\text{g}$, however, higher doses $300\mu\text{g}$ of clonidine was frequently associated with marked sedation, obstructive apnoea and arterial oxygen desaturation.

Breschan C et al²¹ reported a case of life-threatening apnoea following herniorrhaphy and orchidopexy in a 2-week-old term neonate.

No such respiratory distress was present in the present study.

The post-operative pain which is one of the most important parameters of the present study was observed on a pain scale (Table 2). There was no pain in both the groups during the first hours post surgery; however, statistically significant values for pain were observed at around 3-4th hour where only 1 (3%) patients with clonidine reported pain. The duration of analgesia was significantly prolonged in ropivacaine-clonidine group (433.5 ± 60.2 min) compared to ropivacaine alone group (250.33 ± 41.4 min) in our study. This is in agreement with a study by Arpita et al.⁹ and Jamali and colleagues¹⁶ which found that addition of clonidine to local anaesthetic prolongs the duration of analgesia after a single shot caudal block.

There was no significant sedation in the post-operative period leading to respiratory depression. In our study, a child with a sedation score of ≤ 3 was considered sedated. The sedation score was either 2 or more in all the patients at all times. There was a confusion although regarding analgesia and sedation and it was concluded that the patients were sleeping well, comfortably because of less postoperative pain and discomfort rather than sedation. J J Lee et al¹⁹ also found that the duration of sedation was very similar to the respective duration of caudal analgesia in both the groups.

The only side effect that was comparable in the present study was the incidence of vomiting (9% in group A and 6% in group B) which was well managed. No other side effects/complications including bradycardia, hypotension, respiratory distress and sedation warranting treatment occur.

6. Conclusion

The present study demonstrated that caudal administration of ropivacaine 0.20% (1 ml/kg) with clonidine ($1.0\mu\text{g/kg}$) resulted in superior analgesia with longer duration of action

compared with 0.20% ropivacaine (1 ml/kg) alone, without any significant difference in the hemodynamic parameters and the incidence of side-effects.

7. Source of Funding

None.

8. Conflict of Interest

The author declares no conflict of interest.

References

1. International association for study of pain, Subcommittee on Taxonomy. Pain terms: a list with definitions and notes on usage. *Pain*. 1979;6:249–52.
2. Anand KJ, Craig KD. New perspectives on the definition of pain. *Pain*. 1996;67:3–6.
3. Walco GA, Cassidy RC, Schechter NL. Pain, hurt, and harm. The ethics of pain control in infants and children. *N Engl J Med*. 1994;331:541–4.
4. Twycross A, Mayfield C, Savory J. Pain management for children with special needs: A neglected area? *Paediatr Nurs*. 1999;11:43–5.
5. Sahler O, Frager G, Levetown M. Medical education about end-of-life care in the pediatric setting: Principles, challenges, and opportunities. *Pediatrics*. 2000;105:575–84.
6. Eland JM. Children's communication of pain. Educational Psychology. Iowa City; 1974.
7. Anand KJ, Hickey PR. Pain and its effects in the human neonate and fetus. *N Engl J Med*. 1987;317:1321–9.
8. Markakis DA. Regional anaesthesia in paediatrics. *Anesthesiol Clin North Ame*. 2000;18(2):355–9.
9. Laha A, Gosh S. Howpada Das: Comparison of caudal analgesia between ropivacaine and ropivacaine with clonidine in children. *Saudi J Anaesth*. 2012;6(3):197–200.
10. Cook B, Doyle E. The use of additives to local anaesthetic solutions for caudal epidural blockade. *Paediatr Anaesth*. 1996;6:353–9.
11. Valley RD, Bailey AG. Caudal morphine for post-operative analgesia in infants and children: a report of 138 cases. *Anaesth Analg*. 1991;72:120–4.
12. Cook B, Grubb DJ, Aldridge LA, Doyle E. Comparison of the effects of epinephrine, clonidine and ketamine on the duration of caudal analgesia produced by bupivacaine in children. *Br J Anaesth*. 1995;75:698–701.
13. Baskar S, Singh G, Jacob R. Clonidine in paediatrics - a review. *Indian J Anaesth*. 2009;53(3):270–80.
14. Ivani G, Negri PD, Conio A, Amati M, Roero S, Giannone S, et al. Ropivacaine/clonidine combination for caudal blockade in children. *Acta Anaesthesiol Scand*. 2000;44(4):446–9.
15. Neogi M, Dhurjoti PB, Satrajit D, Chatterjee N. A comparative study between clonidine and dexmedetomidine used as adjuncts to ropivacaine for caudal analgesia in pediatric patients. *J Anaesth Clin Pharmacol*. 2010;26(2):149–53.
16. Jamali S, Monin S, Begon C, Dubousset A, Ecoffey C. Clonidine in paediatric caudal anaesthesia. *Anaesth Analg*. 1994;78:663–6.
17. Lee JJ, Rubin AP. Comparison of a bupivacaine-clonidine mixture with plain bupivacaine for caudal analgesia in children. *Br J Anaesth*. 1994;72:258–62.
18. Klimscha W, Chiari A, Michalek-Saubere A, Wilding E, Lerche A, Lorber C. The efficacy and safety of caudal clonidine/bupivacaine combination in caudal blockade for pediatric hernia repair. *Anesth Analg*. 1998;86(1):54–61.
19. Motsch J, Bottiger BW, Bach A, Bohrer H, Skoberne T, Marin E. Caudal clonidine and bupivacaine for combined epidural and general anaesthesia in children. *Acta Anaesthesiol Scand*. 1997;41:877–83.

20. Narchi P, Benhamou D, Hamza J, Bouziz H. Ventilatory effects of epidural clonidine during the first 3 hours after caesarean section. *Acta Anaesthesiol Scand*. 1992;36:791–796.
21. Breschan C, Krumpholz R, Likar R, Kraschl R, Schalk H. Can a dose of 2 µg/kg caudal clonidine cause respiratory depression in neonates? *Paediatr Anaesth*. 1999;9:81–3.

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