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ORIGINAL ARTICLE

A COMPARATIVE EVALUATION OF CLONIDINE & DEXMEDETOMIDINE AS ADJUVANTS TO ROPIVACAINE IN CAUDAL BLOCK IN CHILDREN

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ABSTRACT: BACKGROUND: Caudal analgesia has been successfully used in paediatric patients since 1933. Ropivacaine a stereo isomer of Bupivacaine was used to increase duration of analgesia. The present study is designed to compare clonidine and dexmedetomidine as adjuvants to Ropivacaine in caudal block in children. **METHODS:** A total of 60 patients of 3-10 years age, either sex, ASA I/II posted for infraumblical surgeries under GA with caudal analgesia were randomly allocated to receive 0.2% ropivacaine plain@1ml/kg+normal saline (1ml), 0.2% ropivacaine @1ml/kg+clonidine 1microg/kg (1ml), 0.2% ropivacaine @1ml/kg+dexmedetomidine 1microg/kg(1ml). The children were monitored postoperatively for duration of analgesia, sedation score and postoperative complications if any. **RESULTS:** Duration of analgesia was maximum in Group-III (Ropivacaine+ Dexmedetomidine)–14hrs., 12hrs. In Group-II (Ropivacaine+Clonidine) and 6-8 hrs. In Group-I (Ropivacaine Plain). Children were more sedated in early postoperative period in Group-II & III as compared to Group-I. **CONCLUSION:** Duration of analgesia was prolonged in Group-II & III, the same group children were more sedated and calm in postoperative period.
KEYWORDS: Ropivacaine, Clonidine, Caudal block.

INTRODUCTION: Pain is defined as an unpleasant sensory and emotional experience associated with the actual or potential tissue damage. (International Association for the study of Pain 1979)[1]. The main difference in perception of pain between children and adults is related to cognitive evaluative component that develops throughout childhood and adolescence. The younger the patient greater is the difficulty in communication.

Caudal route is simplest and safest way for infraumblical surgeries. It is placed after induction of general anaesthesia and is good for both intraoperative and postoperative analgesia. (Beyaz SG et al 2012)[2] Ropivacaine is amide local anesthetic and a stereo isomer of Bupivacaine. It is less cardiotoxic, has less CNS toxicity and less propensity for motor block as compared to Bupivacaine so postoperative mobilization is early. (Hodgson PS et al 2001)[3] It has greater margin of safety among all long acting local anaesthetics (Zink W et al 2008).[4]

Clonidine has been used as an adjunct to local anaesthetic in various regional techniques to increase duration of block (Murphy at el 2000).[5] It has partial agonist activity at α_2 receptors.

Dexmedetomidine is highly selective α_2 adrenoreceptor agonist with sedative, analgesic and sympatholytic properties (Gertler R et al 2001).[6]

AIMS AND OBJECTIVES: The aim of the present study will be;

i) To compare the efficacy, safety and hemodynamic parameters of clonidine and dexmedetomidine as adjuvants to ropivaciane in children in caudal block.
ii) To assess the duration of post-operative analgesia and to assess the sedation score and post-operative complications if any.

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METHODS: The present study was conducted in the Department of Anaesthesiology and Intensive Care, Government Medical College Jammu J&K, after obtaining approval from hospital ethical committee. The study was conducted on 60 children of ASA grade 1-2 in the age group of 3-10 years, of either sex, undergoing infraumblical surgery. The exclusion criteria were Parents refusal, Known or suspected Coagulapathy, H/o of known hypersensitivity to study drugs, any contraindication to neuraxial anaesthesia.

Preanaesthetic visit involved history taking, General Physical Examination, investigations, explaining the technique to parents, patient's weight and informed consent from parents.

In the operation theatre – monitors: Pulse oximeter, NIBP, ECG were attached and I/V line secured. Injection Glycopyrolate (4μg/kg), Ondansetron (0.1 mg/kg), Tramadol (1mg/kg) IV were given. Child preoxygenated with 100% O_2, induction done with propofol (2-2.5mg/kg) and suxamethonium 1.5mg/kg), patient intubated and maintained on O_2+N_2O+Halothane and Atracurium (0.5mg/kg) patient ventilated and put to lateral position.

The children taken up for study were randomly divided into 3 groups of 20 patients each.

- GROUP 1= RP = 20 children:
  Received 0.2%ropivacaine plain@1ml/kg+normal saline (1ml).
- GROUP 2 = RC =20 children:
  Received 0.2% ropivacaine @1ml/kg+clonidine 1microg/kg (1ml).
- GROUP 3 = RD = 20 children:
  Received 0.2% ropivacaine @1ml/kg+dexmedetomidine 1microg/kg (1ml).

Patients were monitored throughout the procedure and at completion of surgery, residual neuromuscular block was reversed with inj. glycopyrrolate 10microg/kg and inj. neostigmine 60microg/kg I/V and patient was extubated. In postoperative period patient was assessed for,

- Duration of analgesia.
- Sedation score.
- Postoperative complications if any.

Duration of analgesia was calculated from the time of caudal injection to the first dose of rescue analgesia given. Observer Pain Scale (Given by Attia J et al 1987)[7].

OPS	SCORE
Laughing, Euphoric	1
Happy contented	2
Calm or asleep	3
Crying, grimacing, restlessness but can be distracted with toys, food or parental presence	4
Crying, screaming, inconsolable	5

	PAIN SCORE
No pain	1 to 3
Mild to Moderate	4
Severe pain	5

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- Observations were made at 6 occasions: 30minutes, 1hour, 3hrs, 6hrs, 12hrs and 24hrs.
- Rescue analgesia was given with OPS score of 4 or more with intraveneous diclofenac sodium 1mg/kg for the first 24 hours.

SEDATION SCORE: 5 point sedation score (Given by Dsida R M et al, 1998)[8].

1. Asleep; not readily arousable.
2. Asleep; responds slowly to verbal commands.
3. Drowsy; readily responds to verbal commands.
4. Awake; calm and quiet.
5. Awake and active.

Measured at 6 occasions 30min, 1, 3, 6, 12 and 24 hours.

Sedation score of 1-3 reflect a sedative effect.

Post-operative complications or adverse effects if any, were noted and treated like Nausea, vomiting, Hypotension, Bradycardia, Motor weakness, Retention of urine.

Patients Characteristics	Group I	Group II	Group III
Age	5.70±2.43	6.80±3.09	5.55±2.21
Weight	19.55±4.76	21.85±6.67	19.75±5.09
Sex(M/F)	18/2	18/2	18/2

Table 1: Group comparison for demographic parameters

NS: Non-significant.

S: Significant.

The intergroup comparison between Group I & II, II & III and I & III were comparable in age, weight and sex distribution. The data was found to be statistically non-significant (P>0.05).

Time interval	Mean ± Standard Deviation			
	Group I	Group II	p-value	Remarks
0 minutes	93.30±4.78	91.45±5.73	0.27	NS
10 minutes	92.75±4.19	83.55±7.26	0.00	S
20 minutes	91.50±4.25	75.50±9.12	0.00	S
30 minutes	90.20±4.49	75.45±8.20	0.00	S
60 minutes	89.10±4.17	87.05±5.06	0.17	NS
90 minutes	88.80±4.37	86.90±4.03	0.16	NS
Grand mean	90.94±3.82	83.32±6.57	0.00	S

Table 2A: Group comparison (Group I & Group II) for heart rate (beats/min.)

NS: Non-significant.

S: Significant.

Intergroup comparison of Heart rate among three groups was done. Mean Heart rate comparison among Group I and Group II showed statistically significant variation at 10, 20 & 30 minutes ($P < 0.05$) and non-significant variation ($P > 0.05$) at 0, 60 & 90 minutes.

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Time interval	Mean ± Standard Deviation			
	Group I	Group III	p-value	Remarks
0 minutes	93.30±4.78	91.65±5.36	0.31	NS
10 minutes	92.75±4.19	91.00±6.33	0.31	NS
20 minutes	91.50±4.25	89.90±6.11	0.34	NS
30 minutes	90.20±4.49	89.20±6.16	0.56	NS
60 minutes	89.10±4.17	88.95±5.70	0.92	NS
90 minutes	88.80±4.37	88.45±5.32	0.82	NS
Grand mean	90.94±3.82	89.86±5.51	0.48	NS

Table 2B: Group comparison (Group I & Group III) for heart rate (beats/min.)

NS: Non-significant.

S: Significant.

The mean heart rate comparison among Group I and Group III showed non-significant variation (P > 0.05) and was comparable at 0, 10, 20, 30, 60 and 90 minutes.

Time interval	Mean ± Standard Deviation			
	Group II	Group III	p-value	Remarks
0 minutes	91.45±5.73	91.65±5.36	0.91	NS
10 minutes	83.55±7.26	91.00±6.33	0.00	S
20 minutes	75.50±9.12	89.90±6.11	0.00	S
30 minutes	75.45±8.20	89.20±6.16	0.00	S
60 minutes	87.05±5.06	88.95±5.70	0.27	NS
90 minutes	86.90±4.03	88.45±5.32	0.31	NS
Grand mean	83.32±6.57	89.86±5.51	0.00	S

Table 2C: Group comparison (Group II & Group III) for heart rate (beats/min.)

NS: Non-significant.

S: Significant.

The mean heart rate comparison among Group II and Group III showed statistically significant variation at 10, 20 & 30 min (P < 0.05) and non-significant variation (P > 0.05) at 0, 60 & 90 min.

Time interval	Mean ± Standard Deviation			
	Group I	Group II	Group III	Remarks
0 minutes	100.90±4.46	101.45±7.10	100.25±5.56	NS
10 minutes	100.50±4.89	100.80±6.58	99.60±5.51	NS
20 minutes	100.45±4.50	101.40±5.44	98.30±5.49	NS
30 minutes	100.40±4.15	101.50±5.37	98.60±5.77	NS
60 minutes	100.50±3.53	101.05±5.57	98.75±5.97	NS
90 minutes	100.75±3.65	100.90±5.51	99.15±5.33	NS
Grand mean	100.58±3.83	101.18±5.79	99.12±5.46	NS

Table 3A: Group comparison for SBP

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Mean systolic BP in Group I, Group II and Group III were comparable and data was found to be statistically non-significant (P>0.05).

Time interval	Mean±Standard Deviation			
	Group I	Group II	Group III	Remarks
0 minutes	63.50±3.25	64.05±4.64	64.70±3.40	NS
10 minutes	63.65±3.41	63.85±3.98	63.75±2.71	NS
20 minutes	59.65±3.15	63.50±3.53	64.00±2.68	NS
30 minutes	62.70±3.66	63.60±3.59	63.55±2.24	NS
60 minutes	62.70±2.18	63.90±3.04	63.85±2.91	NS
90 minutes	63.35±2.08	64.20±3.29	63.75±2.51	NS
Grand mean	63.06±2.75	63.85±3.41	63.93±2.47	NS

Table 3B: Group comparison for DBP

Intergroup comparison of mean Diastolic BP between Group I, II and III were comparable and was found to be statistically non-significant (P > 0.05).

Groups	Observer pain scale (Mean±SD)	p-value	Remarks
Group I & II			
Group I	2.76±0.22	0.32	NS
Group II	2.70±0.19		
Group I & III			
Group I	2.76±0.22	0.02	S
Group III	2.61±0.20		
Group II & III			
Group II	2.70±0.19	0.13	NS
Group III	2.61±0.20		

Table 4: Group comparison for observer pain scale

NS: Non-significant.

S: Significant.

The mean observer pain scale was compared among the three groups. Mean observer pain scale in group-I was 2.76±0.22, group-II was 2.70±0.19 and group-III was 2.61±0.20.

Comparison of mean observer pain scale among group-I & II and II & III was statistically non-significant (P > 0.05) but among group-I & III was found to be statistically significant (P < 0.05).

Groups	Duration of post-operative analgesia (hrs) Mean ± Standard Deviation	p-value	Remarks
Group I & II			
Group I	7.25±0.71	0.00	S
Group II	12.01±0.27		

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Group I & III			
Group I	7.25±0.71	0.00	S
Group III	14.03±0.25		
Group II & III			
Group II	12.01±0.27	0.00	S
Group III	14.03±0.25		

Table 5: Group comparison for duration of analgesia (hrs)

NS: Non-significant.

S: Significant.

Mean duration of analgesia in Group I was 7.25±0.71 min, Group II was 12.01±0.27 and Group III was 14.03±0.25.

Intergroup comparison of duration of analgesia among three Groups I & II, I & III and II & III was found to be statistically significant (P< 0.05).

Groups	5 Point sedation score (Mean±SD)	p-value	Remarks
Group 1&2			
Group 1	4.33 ± 0.29	0.02	S
Group 2	4.12 ± 0.22		
Group 1&3			
Group 1	4.33 ± 0.29	0.00	S
Group 3	3.84 ± 0.29		
Group 2&3			
Group 2	4.12 ± 0.22	0.01	S
Group 3	3.84 ± 0.29		

Table 6: Group comparison for 5 point sedation score

NS: Non-significant.

S: Significant.

Mean sedation score in Group I was 4.33±0.29, Group II was 4.12±0.22 and Group III 3.84±0.29. Intergroup comparison of 5 point sedation score was done among Group I & II, I & III and II & III and was found to be statistically significant (P < 0.05).

It is very difficult to assess pain in young children. Different methods and scores are in use to estimate pain induced behaviour changes in children but their reliability depends upon the familiarity of the investigators with the scoring system. Pain management modalities for children are intravenous route, oral preparations, rectal route and regional blocks.

The regional anesthetic technique significantly decreases the post-operative pain and systemic analgesic requirements. Caudal route is one of the simplest and safest way in pediatric surgery with a high success rate.

To improve the quality of caudal block and prolong the duration of post-operative pain relief, numerous adjuncts have been added to anaesthetic agent. Adjuvants like opioids (Morphine, Butorphenol Tramadol etc.) as used by Demiraran Y et al (2005)[9] in their study where they compared

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single shot epidural administration of Tramadol versus Morphine in children undergoing urological surgeries. Non-opioids like Midazolam, Ketamine, Clonidine and Dexmedetomidine are added to local anaesthetic agents to increase the duration of analgesia, decrease the individual dose of the drug and thereby decreasing the side-effects. Hager H et al (2002),[10] evaluated preservative free S(+)–Ketamine 1ml/kg alone or in combination with Clonidine 1 or 2μg/kg for caudal blockade in children for post-operative analgesia. Kumar P et al (2005)[11] assessed and compared the efficacy of Ketamine, Midazolam and Neostigmine co administrated with Bupivacaine in caudal epidural to provide intra-operative & post-operative pain relief. El Hennawy et al (2009)[12] studied the effect of Clonidine and Dexmedetomidine to Bupivacaine in prolonging the caudal analgesia in children.

The results of the study were analyzed and compared with those reported in literature and are discussed below.

PATIENTS CHARACTERISTICS: The mean age, weight and sex of the children in all the 3 Groups were comparable.

HEART RATE: In the present study, heart rate of patients was observed intra-operatively at 0 min, 10 min, 20 min, 30 min, 60 min and 90 min.

At 0 min, mean heart rate was 93.30±4.78 in Group I, 91.45±5.73 in Group II & 91.65±5.36 in Group III. This data was statistically non-significant (P > 0.05).

At 10 min, mean heart rate was 92.75±4.19 in Group I, 83.55±7.26 in Group II & 91.00±6.33 in Group III. Intergroup comparison showed statistically significant difference in mean heart rate between Group I & II and group II & III (P > 0.05) but mean heart rate in Group I and Group III was comparable.

At 20 min, mean heart rate was 91.50±4.25 in Group I, 75.50±9.12 in Group II and 89.90±6.11 in Group III. Intergroup comparison showed statistically significant (P <0.05) difference between Group I & II and Group II & III but Group I & III was statistically non-significant (P > 0.05).

At 30 min, mean heart rate was 90.20±4.49 in Group I, 75.45±8.20 in Group II and 89.20±6.16 in Group III. The data was again found to be statistically significant (P <0.05). Intergroup comparison showed significant differences between Group I & II and II & III but Group I & III was statistically non-significant (P > 0.05).

At 60 min, mean heart rate was 89.10±4.17 in Group I, 87.05±5.06 in Group II and 88.95±5.70 in Group III. Intergroup comparison showed non-significant differences between Group I & II, I & III and II & III. Mean heart rate in all the three groups was comparable at 60 minutes.

At 90 min, mean heart rate was 88.80±4.37 in Group II, 86.90±4.03 in Group II and 88.45±5.32 in Group III. This data was found to be statistically non-significant (P > 0.05). Mean heart rate in all the three groups was comparable at 90 minutes.

In present study we found mean heart rate decreased about 10-15% below baseline in Group II at 10, 20 and 30 minute after administration of caudal block with 0.2% Ropivacaine+1μg/kg Clonidine. This observation was in accordance with the study done by Eisenach et al (1993),[13] they also reported decrease in mean arterial pressure and heart rate within 15-30 min after injection of Clonidine in the caudal epidural space.

At 60 and 90 minutes, however the heart rate returned to baseline in Group II and thus mean heart rate was comparable in all the three Groups at 0, 60 and 90 minutes. This was in accordance

with the study done by Manickam A et al (2012),[14] they found in their study that the mean arterial pressure and heart rate in the Clonidine group was less as compared to plain Ropivacaine. However, none of the children required intervention as hemodynamic parameters were not below the defined criteria. Bajwa S et al (2010)[15] reported in their study the fall in Mean Arterial Pressure and 3-5% decrease in heart rate in children receiving caudal Ropivacaine 0.25%+Clonidine 2μg/kg as compared to plain Ropivacaine 0.25% but it got stabilized to normal within 20-30 min of caudal injection.

BLOOD PRESSURE: Mean systolic blood pressure in Group I was 100.58±3.83, Group II was 101.18±5.79 and Group III was 99.12±5.46. Mean diastolic blood pressure in Group I was 63.06±2.75, Group II was 63.85±3.41 and Group III was 63.93±2.47. The systolic and diastolic blood pressure in all the three groups was recorded intra operatively at 0, 10, 20, 30, 60 & 90min. It was found to be statistically non-significant ($P > 0.05$).

DURATION OF ANALGESIA: In the present study, duration of analgesia is the time from the caudal block administration to the time when the child needed first rescue analgesia.

Pain was evaluated using observer pain scale (OPS) at 30 min, 1hr, 3hrs, 6hrs, 8hrs, 12hrs and 24 hours.

Rescue analgesia was given with OPS score of 4 or more (OPS ≥ 4) with I/V diclofenac sodium 1mg/kg for the first 24 hours.

MEAN DURATION OF ANALGESIA: Mean duration of analgesia in Group I was 7.25±0.71, in Group II was 12.01±0.27 and in Group III was 14.03±0.25. Intergroup comparison showed statistically significant difference between Group I & II, I & III and II & III.

The increase in the duration of analgesia with clonidine and dexmedetomidine is explained on the basis that α_2 agonists inhibits the release of glutamate and substance P from primary afferent terminals and G-protein mediated activation of potassium channels causes hyper-polarisation of inter-spinal neurons, which decreases the pain transmission. This finding is consistent with the study conducted by Gupta S et al (2014),[16] they also found that the addition of Dexmedetomidine or Clonidine to caudal Ropivacaine significantly promoted analgesia time with significant advantage of Dexmedetomidine over Clonidine without an increase in the incidence of side effect.

But the study done by Neogi M et al (2010)[17] concluded that the addition of Dexmedetomidine or Clonidine to caudal Ropivacaine significantly increases the duration of post-operative analgesia without any significant advantage of Dexomedetomidine over Clonidine.

POST-OPERATIVE SEDATION: The sedation score used in the present study was a 5 point sedation score given by D Sida R M et al (1998).

It was measured at 6 occasions: 30 min, 1, 3, 6, 12 and 24 hours.

Sedation score of 1-3 (≤ 3) reflect a sedative effect.

At 30 min, sixteen children had a sedation score of ≤3 in Group I, twenty children had a sedation score of ≤3 in Group II and twenty children had a sedation score of ≤3 in Group III. Intergroup comparison showed statistically significant difference between Group I & II and Group I & III but non-significant difference was seen between Group II & III.

At 1 hour, six children had a sedation score of ≤3 in Group I, eleven children has a sedation score of ≤ 3 in Group II and nineteen children has a sedation score of ≤3 in Group III. This was found to be statistically significant (P <0.05).

At 3 hours, two children has a sedation score of ≤3 in Group I, four children had a sedation score of ≤ 3 in Group II and nine children had a sedation score of ≤3 in Group III. This was found to be statistically significant (P < 0.05).

At 6, 12 and 24 hours, none of the children had a sedation score of ≤ 3 in all the three group and sedation score was comparable in them at 6, 12 & 24 hours.

The mean sedation score was found to be statistically significant (P < 0.05) in all the three groups. Thus indicating that more number of the children were sedated in the early post-operative period who received either Ropivacaine with Clonidine or Ropivacaine with Dexmedetomidine as compared to those who received plain Ropivacaine which is in accordance with the study of Lee J J et al (1994).[18] They demonstrated longer duration of sedation in children receiving Bupivacaine-Clonidine mixture for caudal analgesia. In Dexmedetomidine group more sedation is seen in the early post-operative period which is also consistent with the finding of the study done by Saadawy et al (2009)[19]. They demonstrated in their study that not only there is significantly longer duration of analgesia with Dexmedetomidine administration in caudal route but it also produces better quality of sleep and a prolonged duration of sedation (P <0.05).

INCIDENCE OF SIDE EFFECTS AND COMPLICATIONS: Children in all the three groups were observed for complications like Nausea, Vomiting, Hypotension, Bradycardia, motor weakness and urinary retention. In this study, one patient each in Group I, II and III had nausea and vomiting. The difference was statistically non-significant. This finding of our study is consistent with finding in study conducted by Bajwa S et al (2010) and Laha A et al (2012).[20]

Therefore in the present study, we have found that addition of Clonidine 1μg/kg and Dexmedetomidine 1μg/kg to 0.2% Ropivacaine (1ml/kg) produces a better and prolonged duration of analgesia, with a better quality of sleep and prolonged duration of arousable sedation with significant advantage of Dexmedetomidine in terms of prolonged duration of analgesia and calm postoperative period over Clonidine. There were no significant side-effects or complications in caudal block in children undergoing sub-umbilical surgeries.

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