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ORIGINAL ARTICLE

Effect of Dexmedetomidine as an Adjuvant to Caudal Ropivacaine for Postoperative Analgesia in Paediatric Patients Undergoing Subumblical Surgery

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Abstract

Caudal block is most popular regional anesthetic technique used in children. It provides excellent analgesia during surgery as well as in postoperative period in subumblical surgeries. In this study, we compared the analgesic efficacy and safety of caudal dexmedetomidine added to caudal ropivacaine for postoperative analgesia in children. 60 patients aged 1 to 8 years scheduled for subumblical surgeries were randomly allocated into two groups of 30 patients each. Group RD received 1ml/kg of 0.2% ropivacaine with dexmedetomidine 2ìg/Kg in normal saline 1 ml. Group R received 1ml/kg of 0.2% ropivacaine with normal saline 1ml.Hemodynamic parameters, duration of analgesia, pain scores using observational pain scoring (OPS), requirement of rescue analgesia, and various complications were recorded.The duration of analgesia in group R was 8.4± 1.4 hours while in group RD the duration was 10.4 ± 2 hours. Maximum OPS scores were lower in group RD compared to group R.It was concluded that caudal dexmedetomidine when added to ropivacaine as an adjuvant increases the efficacy and duration of analgesia, reducing the need of post operative rescue analgesia with no additional side effects.

Key Words

Caudal, Dexmedetomidine, Ropivacaine, Subumblical

Introduction

Pain after surgery is inevitable.The provision of adequate analgesia is necessary after any surgery and it is all the more important in children (1). The density of nociceptive nerve endings in the skin of newborn infants is similar to or greater than that in adultsCaudal block has become the most popular regional anaesthetic technique for use in children. It provides excellent analgesia during surgery as well as during postoperative period in subumblical surgeries in children (2). Ropivacaine hydrochloride is a member of the amide class of local anaesthetics and is supplied as the S-(-)-enantiomer. In vitro testing indicates that ropivacaine is comparable to (or slightly more potent than) bupivacaine in blocking sensory fibres and less active in blocking motor fibres.A number of non-opioid additives have been suggested to increase the quality and duration of analgesia by local anesthetics. The various non opioid additives include ketamine, midazolam, neostigmine, clonidine and more recently dexmedetomidine (3,4). Alpha 2 adrenergic receptor agonists like clonidine and dexmedetomidine have relevant physiological properties causing sedation and analgesia, reducing plasma catecholamine levels, attenuating the stress response to surgery and preventing shivering through alpha 2 adrenoreceptors in central nervous system (5). Dexmedetomidine is a highly selective á2 adrenergic agonist. It has a á2/á1 selectivity ratio of 1600:1 compared with clonidine which hasá2/á1 selectivity ratio of 200:1, making it a complete á2receptor agonist (6). The analgesic action of epidurally administered clonidine is due to stimulation of descending noradrenergic medullospinal pathways inhibiting the release of nociceptive neurotransmitters in the dorsal horn of spinal cord (7). The present study was undertaken to compare the analgesic efficacy of caudal

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dexmedetomidine added to caudal ropivacaine for postoperative analgesia in children undergoing subumblical surgeries.

Material and Methods

After obtaining approval from ethical committee of the institute and informed parental consent, 60 patients of physical status ASA I and II of either sex, aged 1 to 8 years scheduled for subumblical surgeries were prospectively enrolled in this study. During the preoperative visit, all patients were evaluated and assessed. No premeditation was given to any patient. In the operation theatre after connecting the patient to the monitors, an intravenous line was established. General anaesthesia was induced with standard doses of thiopental (4 to 6mg/kg) + Atracurium (0.5 mg/kg) to facilitate intubation and maintained with 0.5% to 1% of halothane and 66% Nitrous oxide in combination with 33% of oxygen, administered via laryngeal mask airway (LMA) or endotracheal tube. Muscle relaxation was achieved by the use of top up doses of atracurium. No intravenous or per rectal analgesic drugs were given to any patient intra operatively. Patients were randomly allocated into two groups of 30 patients each.

Group RD received 1ml/kg of 0.2% ropivacaine with dexmedetomidine 2gì/Kg in normal saline 1 ml.

Group R received 1ml/kg of 0.2% ropivacaine with normal saline 1ml.

The study drugs were prepared by an anesthesiologist who was not involved in the study. All study drugs were kept at room temperature and used within 30 minutes of preparation.After induction of anaesthesia, patients were placed in lateral decubitus position. A short beveled 22 Gauge hypodermic needle was introduced in caudal epidural space under full aseptic precautions; single dose caudal block was performed. Skin incision was allowed after 15 minutes of caudal block.Heart rate (HR), Systolic and Diastolic blood pressure (SBP, DBP) and Oxygen saturation (SP02) were monitored and recorded just before induction of anesthesia, after induction of anesthesia, at ten minute intervals after caudal block till the end of surgery.An increase in the basal heart rate and blood pressure by 10% during the surgical procedure was considered as failure of caudal block. These patients were excluded from the study and rescue intraoperative analgesia was provided to them. After completion of the surgery, neuromuscular blockade was reversed with atropine 0.01mg/kg and neostigmine 0.05mg/kg and patients were send to recovery room after extubation/ removal of laryngeal mask airway.

In the recovery room patients were monitored for 1 hour and following parameters were recorded at 30 minute and 1 hour intervals:

- OPS
- Sedation score (SS)
- Heart rate (HR)
- SAP & DAP

After discharge from recovery room, patients were monitored 2 hourly until the administration of 1st analgesia dose. The maximum time being considered as 12 hours. No effort was made to stimulate or awaken the patient. Duration of motor block was assessed by noting when patients began to move legs.

Post operatively an observer, who was unaware of the patient groups, assessed the adequacy of analgesia using observational pain scoring scale (OPS).

Observer Pain Scale (OPS)

Item	Score
a. Laughing, Euphoric	1
b. Happy, contended	2
c. Calm or asleep	3
d. Crying, grimacing, restlessness	4
e. Severe pain, screaming, inconsolable	5

The duration of analgesia was calculated as time in minutes from performing the caudal block to the first administration of analgesic.

Assessment of sedation was made after operation on hour basis for 4 hours. Using an objective score based on eye opening.

Item	Score
1. Eye opening spontaneously	0
2. Eye opening in response to verbal stimulation	1
3. Eye opening in response to physical stimulation	2

The sedation score was used both to quantify sedation and to help identifying possible systemic effects of Dexmedetomidine

Rescue analgesia was given in the form of rectal paracetamol (20mg/kg/dose) or injection diclofenac (1mg/kg) if pain score were > 4. The number of doses required for analgesia in first 12 hours in both the groups was

recorded. Complications like Nausea, vomiting, pruritis, any prolonged sedation and urinary retention was recorded.

After completion of study the data was analyzed using SPSS version 17.0 computer software. Numerical variables were presented as mean and standard deviation (SD) and categorical variables were presented as percentages. One - way ANOVA was used for between – group comparisons of numerical variables. Chi square test was used for between – group comparisons of categorical variables. Student's't' test was also used for analysis of difference of means for quantitative data. The tests were referenced for p values for their significance. Any P-value less than 0.05 ($p < 0.05$) was taken as statistically significant.

Results

Sixty patients selected for this study were randomly divided into two groups of 30 patients each. The two groups were matched with regard to their age, gender, body weight and duration of surgery. *(Table 1)*

Table 1: Demographic Characteristics and Duration of Surgery of Studied Patients

Parameters	Group R	Group RD	P value	Remarks
Age (years) Mean ± SD	5.4 ± 2.5	5.0 ± 2.7	0.592	NS
Weight (Kgs) Mean ± SD	18.9 ± 5.6	16.8 ± 6.0	0.170	NS
Sex Male: Female	28:2	30:0	0.150	NS
Duration of surgery(min) (Mean ± SD)	52 ± 32.5	49 ± 27.0	0.320	NS

NS=Not Significant

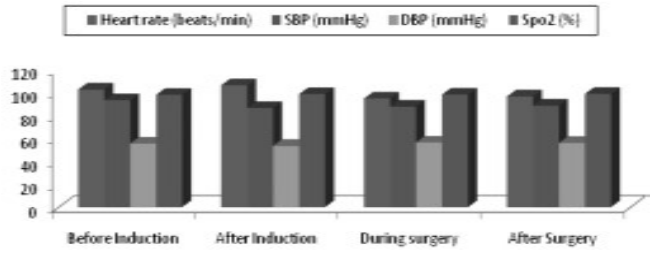

Fig. 1: Bar chart depicting mean heart rate, blood pressure (systolic and diastolic), and oxygen saturation at various stages in Group RD

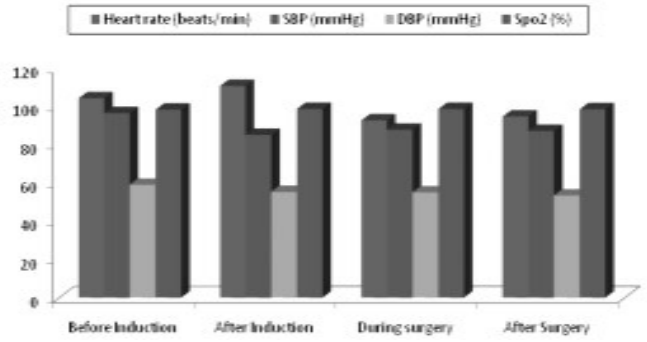

Fig. 2: Bar chart depicting main heart rate, blood pressure (systolic and diastolic) and oxygen saturation at various stages in Group R

In the study, hemodynamic effects with regards to heart rate, systolic blood pressure, diastolic blood pressure as well as oxygen saturation showed a benign profile and no clinically relevant change were observed in these variables at various stages. *(Figure 1&2)*

The mean pain scores were higher in group R as compared to group RD at all stages postoperatively till 12 hours. *(Table 2)*

Table 2: Comparison of Pain Scores (Mean ±SD) at Various Intervals Between Two Groups.

Time	Pain Scores (Mean ± SD) Group R	Group RD
30 minutes	3.03 ± 0.183	3.07 ± 0.254
1 hour	3.43 ± 0.679	3.07 ± 0.254
2 hour	3.53 ± 0.681	3.10 ± 0.305
4 hour	3.43 ± 0.626	3.10 ± 0.305
6 hour	3.50 ± 0.630	3.10 ± 0.305
8 hour	3.40 ± 0.563	3.17 ± 0.531
10 hour	3.77 ± 0.774	3.37 ± 0.615
12 hour	4.23 ± 0.774	3.47 ± 0.730

Sedation was assessed using an objective scoring system based on eye opening ranging from 0 to 2. At 4 hours 70% children in group R and 66.7 % in group RD were fully conscious (sedation score of 0) and none of the children in the two groups had a sedation score of 2.The difference in the sedation scores for 4 hours in post operative period in both the groups was statistically

Table 3:Comparision of Sedation Score Between Two Groups.

Time	Sedation score	Group R No. of patients (%)	Group RD No. of patients (%)	P value	Remarks
1 hr	0	7 (23.30)	7 (23.30)	1.000	N.S
	1	11 (36.70)	11 (36.70)		
	2	12 (40.00)	12 (40.00)		
2 hr	0	5 (16.70)	5 (16.70)	0.647	N.S
	1	22 (73.30)	22 (73.30)		
	2	3 (10.00)	5 (16.70)		
3 hr	0	14 (46.70)	15 (50.00)	0.808	N.S
	1	15 (50.00)	14 (46.70)		
	2	1 (3.30)	1 (3.30)		
4 hr	0	21 (70.00)	20 (66.70)	0.783	N.S
	1	9 (30.00)	10 (33.30)		
	2	0	0		

insignificant. (p >0.05). *(Table 3)*

Duration of analgesia was the time interval from the caudal block to the first request for rescue analgesia.Although the duration of analgesia was longer in group BC, but difference between the two groups was not found statistically significant. (P>0.05). *(Table 4)*

Table 4: Comparison of Duration of Analgesia Between Two Groups.

Groups	Minimum (hrs)	Maximum (hrs)	Mean ± SD	P value	Remarks
R	6	12	8.5 ± 4.4	0.309	NS
RD	8	12	10.3 ± 1.8		

The need for rescue analgesia was less in group RD as compared to group R and the difference was found to be statistically significant. (P<0.05). *(Table 5)*

Vomiting was observed in 3 patients each in groups B and BC, whereas urinary retention in 3 and 2 patients respectively in groups B and BC. 1 patient in each group had pruritis. 23 children in group B and 24 children in group BC had no complications. The difference in incidence of complications in both the groups was statistically insignificant. (P<0.05).

Discussion

Caudal block is one of the most common regional anaesthetic technique used in children. It is considered safe and simple procedure but its main disadvantage is its relatively short duration of action even with use of long acting agents such as bupivacaine (8). The successful use of epidural clonidine in adults leads to its evaluation in paediatric caudal block.Dexmedetomidine is highly

Table 5: Comparison of Post Operative Rescue Analgesic Dose in 12 Hours in Two Groups.

No of doses	Group B No. of patients (%)	Group BC No. of patients (%)	P value	Remarks
0	13 (43.30)	23 (76.70)	0.009	Sig
1	14 (46.70)	6 (20.00)		
2	3 (10.00)	1 (3.30)		

selective á$_2$ adrenoreceptor agonist, the analgesic action of intrathecal or epidural dexmedetomidine results from direct stimulation of pre- and post-synaptic á$_2$ adrenoreceptors in the dorsal grey matter of spinal cord thereby inhibiting the release of nociceptive neurotransmitters (9). This effect correlates with the concentration of dexmedetomidine in the cerebrospinal fluid but not that in the plasma (10).

Both the groups were homogenous with reference to age, sex, weight of patients, duration of anesthesia and surgery. Although males overall dominated in group R with no females in group RD, yet the male female ratio among groups did not reveal any statistical significance ($p = 0.150$).

Mean weight (kg) of patients (18.9 ± 5.6 kg) was more in group R (18.9+5.6 kg) as compared to group RD (16.8 ± 6.0). Mean age of patients in group R (5.4 ± 2.5 years) was more than in group RD (5.0 ± 2.7 years).

Heart rate,systolic and diastolic blood pressures, oxygen saturation were monitored and recorded just before induction ,after induction of anesthesia and at 10 minute interval after caudal block till the end of surgery. All the caudal blocks were taken as successful. We were unable to detect any significant hemodynamic differences between our groups of patients. No patient required drug therapy to treat hypotension or bradycardia. No episode of oxygen saturation < 95% was recorded. The mean heart rate was 99.45 ± 25.25 beats/minute in group RD and 97.61± 24.70 beats/ minute in group R. The mean oxygen saturation in group RD was 98.49 ± 1.29% and 98.48± 1.16 % in group R. The mean systolic blood pressure was 88.15±8.25 mmHg in group RD and 87.06± 10.30 mmHg in group R. The mean diastolic blood pressure was 55.45± 9.29 mmHg in group RD and 54.55± 9.86 mmHg in group R. Comparing the hemodynamic parameters statistically, the difference was found to be insignificant.($p < 0.05$).

A comparative study by Dipak L Raval etal., (11) where group D received 1ug/kg Dexmedetomdine while group C received 1ug/kg Clondine both with Bupivacaine plain 0.25% 1ml/kg. Mean duration of of prostoperative analgesia in group D was 14.16 ± 1.65 hours and in group C it was 11.24 ± 2.48 hours. This observation was similar to our study where in Dexemedetomidine group it was 10.4 ± 2 hours. Also incidence of adverse effects were statistically insignificant in both the studies.

Our observations correlate with Kamal M et al., (12) who found no significant hemodynamic effects in their patients receiving either dexmedetomidine 2 ìg/kg in normal saline 1 ml, or corresponding volume of normal saline according to group assignment.

In our study, the quality of analgesia postoperatively was assessed using observer pain scale at 30 minutes intervals while in recovery room and thereafter 2 hourly for 12 hours. We found patients in group R had overall higher pain scores during 12 hour study period as compared to group RD and the difference was statistically significant ($P<0.05$).The mean duration of analgesia in group B was 8.5 $\pm$ 4.4 hours while the mean duration of analgesia in group BC was 10.3 $\pm$ 1.8 hours. Although the duration of analgesia was longer in group BC, but difference between the two groups was not found statistically significant. ($P>0.05$)

Our results correlate with the study of Gupta S and Sharma R, (13). Children given a combined administration of caudal dexmedetomidine and ropivacaine resulted in significantly better and longer post operative analgesia when compared to ropivacaine alone. This was confirmed by longer time of interval to first request of analgesic and by lower number of analgesic requests. Contrarily to above studies the statistical significance in the duration of analgesia was not observed in our study,although the rescue analgesic requirement was significantly lower in group RD.One of the reasons for this could be small sample size. Alternatively the differing evaluating tools for pain assessment and statistical analysis may also account for this variability.

Comparing the post operative sedation scores between the two groups at 1 hour, 2hour, 3hour and 4hour there was no statistical significance observed between group R and RD. At 4 hours 70% children in group R and 66.7 % in group RD were fully conscious (sedation score of 0) and none of the children had sedation score of 2.Similar to our study, Gupta et al. (13) observed that there was no prolonged sedation and respiratory depression in children receiving caudal dexmedetomidine - ropivacaine combination compared with ropivacaine alone. Comparing the post operative complications, there was no statistically significant difference observed between the 2 group ($p= 0.750$).Kamal M (12) also observed that no significant increase in incidence of pruritis, urinary retention after administration of caudal dexmedetomidine with ropivacaine 0.2%.

Our study correlates with study of Gonapa et al. (14), where children were given Dexmedetomidine (1mcg/kg) and Dexamethasone (0.1mg/kg) as adjuvants to 0.25% Bupivacaine in caudal analgesia in pediatric patients undergoing lower abdominal surgeries. Total duration of

Post operative analgesia was 484.94 ± 2.85 (minutes) in Dexmedetonidrue group & 449.48 ± 5.98 (minutes) in Dexamethsone group. Although this were comparable to our study, but in this study they used Dexemedetomide 1mcg/kg instead of 2mcs/kg used by our study. Intraoperative haemodynamics were comparable in both the studies. And also side effects were insignificant in both the groups.

In a comparative study by Grewal et al. (15), where they compared Ropivacaine 0.2% alone & in Combination with Fentanyl for caudal anaesthesia in pediatric patients undergoing infra umbilical surgeries in age group of 3-8 years. In their study Mean duration of analgesia in Ropivacaine group was 7.35 hours & in Ropivacaine Fentanyl group was 14.86 hours. When compared to our group of Ropivacaine it was 8.4 ± 1.4 hours & in Ropivacaine Dexmedetomidine group it was 10.4 ± 2 hours. So Fentanyl as adjuvant had longer duration of analgesia as compared to Dexmedetomidine.

In conclusion we found that dexmedetomidine when added to caudal ropivacaine provided superior quality and longer duration of analgesia requiring less doses of rescue analgesia in post operative period compared to ropivacaine alone at no additional risk.

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