



Comparison of two Different Doses of Dexmedetomidine as an Adjuvant to Ropivacaine in Caudal Block for Infraumbilical Surgery in Paediatric Patients

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Abstract

Introduction: Caudal block is widely used in children for analgesia. Adequate intra and post operative analgesia will not only modify the stress response but also has been shown to reduce morbidity and mortality. Hence, we have conducted a study by using two doses (1µg/kg & 2µg/kg) of Dexmedetomidine with 0.2% Ropivacaine to maintain stable hemodynamics and provide better analgesia with minimal complications.

Aim: The aim was to compare efficacy and safety of two Different doses of Dexmedetomidine in respect to the duration & quality of perioperative analgesia and sedation as adjuvant to Ropivacaine 0.2% in paediatric caudal anaesthesia.

Method: We performed a Double blind, prospective study in 60 patients aged 3-8 years scheduled for infraumbilical surgeries were randomly allocated into two groups. Group-I - 0.20% Ropivacaine 1ml/kg + 1µg/kg of Dexmedetomidine, Group-II - 0.20% Ropivacaine 1ml/kg + 2µg/kg of Dexmedetomidine. Patient's hemodynamics, duration of analgesia and four point sedation score were compared between the groups and analyzed.

Result: Mean Onset time of sensory and motor block was found earlier in group-RD2 (6.36 min & 9.06 min) than group-RD1 (11.76 min & 15.2min) (p value < 0.05). Hemodynamics was comparable at all stages of surgery except the MBP was higher in group-RD1. Mean duration of Analgesia was prolonged in Group-RD2 (906.17min.) as compared with Group-RD1 (587.27 min)(p value < 0.05). Surgeons were more satisfied in group-RD2.

Conclusion: Caudal dexmedetomidine 2 µg/kg with ropivacaine 0.2% for paediatric infraumbilical surgeries achieved significant postoperative pain relief up to 14 hours, which resulted in a better quality of sleep and a prolonged duration of arousable sedation upto 4 hours.

Keywords: Caudal Block, Ropivacaine, Dexmedetomidine, infraumbilical surgeries.

Introduction

Pain is an unpleasant subjective sensation which can only be experienced and not expressed, especially in children. Children have been under treated for pain because of the wrong notion that they neither suffer nor feel pain or respond to or remember the painful experiences to the same degree as adults' did¹.

In paediatric patients, optimum pain relief is always a big challenge, because it is really difficult to differentiate restlessness or crying due to pain from that of hunger or fear. An effective therapy to block or modify the diverse physiological responses to painful stimulus has become an essential component of modern day paediatric anaesthesia practice².

Caudal epidural block reduces the overall intra-operative requirement of both inhaled and intravenous anaesthetic with rapid return of consciousness and smooth recovery providing effective post-operative analgesia, reduces analgesic requirements and facilitates early discharge³.

Ropivacaine, a long-acting amide local anaesthetic related structurally to Bupivacaine, has been used for paediatric caudal anaesthesia. It provides pain relief with less motor blockade and is less cardio toxic than Bupivacaine, which makes it a more suitable agent for caudal epidural analgesia, especially following day care surgery⁴.

Alpha-2-adrenergic agonists were chosen for their sedative, analgesic, antihypertensive and antiemetic properties along with decreased requirement of local anaesthetic drugs⁵.

Dexmedetomidine has an eight-fold greater affinity for α_2 adrenergic receptors than Clonidine and much less α_1 effects. A major advantage of Dexmedetomidine is its higher selectivity compared with Clonidine for α_2A receptors, responsible for the hypnotic and analgesic effects of such drugs⁶. It also enhances the effects of local anaesthetics without increasing the incidence of side effects. It is a shorter-acting drug than Clonidine and it is unique that its sedative effect can be reversed by Atipamezole.

This study evaluates the sedo-analgesic efficacy and safety of two different doses of Dexmedetomidine added to Ropivacaine for caudal anaesthesia & analgesia in paediatric patients undergoing infraumbilical surgeries.

Material & Methods

After approval by the Institute Ethics Committee & written informed consent from patient's parents or caretaker, the study was conducted as hospital based prospective randomized double blind observational study in 60 ASA Grade I & II patients, Age 3-8 yrs, performed in the year 2016-2017. In all cases duration of surgery (herniotomy) was upto 30 min.

Exclusion

Patient's with Pre-existing neuromuscular disorder, spinal disease and cardiovascular diseases, on anticoagulants, infection on injection site, having bleeding disorders, abnormalities of sacrum, allergic to the drugs used in the study, Patient's parents or caretaker's refusal were excluded from study.

On the day prior to surgery a thorough clinical examination of the patient was performed including general physical examination and systemic examination. All Parents or Caretakers were explained about the anaesthetic technique and written informed consent was taken. Patients were kept NBM for 6-8 hours prior to surgery.

On the of operation anaesthesia work station, equipment for caudal block and resuscitation was kept ready. After confirmation of fasting status patient was shifted to the operation room and connected to multipara monitor. Baseline heart rate, blood pressure and oxygen saturation was recorded and monitored throughout the procedure. An intravenous line with 22G/24G cannula was secured in the upper limb under inhalational anaesthesia if required and isolyte-P was started at the rate of 10ml/kg/hr. Premedication was done with injection atropine 0.01mg/kg, injection midazolam 0.03mg/kg. Under inhalational anaesthesia (O₂+N₂O+Sevoflurane), caudal block was performed with a 23-gauge epicaine needle

under aseptic conditions with the child in a left lateral position. After confirmation of caudal space (LOR technique), patients in Groups I (n=30) received injection Ropivacaine 0.20% 1ml/kg & injection Dexmedetomidine 1µgm/kg, Groups II (n=30) received injection Ropivacaine 0.20% 1ml/kg & injection Dexmedetomidine 2µgm/kg and child immediately turned supine position.

Anaesthesia was maintained with 0.5%-1% sevoflurane and 70% nitrous oxide in oxygen by face mask. Mean arterial pressure (MAP) and heart rate (HR) was observed 5 min before the induction with inhalational anaesthesia and every 5 min up to 30 min. After caudal block, patients were allowed to breathe spontaneously with manual assistance throughout the surgery. At the beginning of skin closure, inhalational anaesthesia was discontinued and patient was allowed to recover. Patient was observed for pulse rate, B.P. SpO₂, sedation and reflexes in recovery area & shifted to post operative ward when the sedation score =3.

An intra- or postoperative decrease of MAP or HR more than 30% from baseline values was defined as severe hypotension or bradycardia respectively, and treated with a rapid infusion of fluids or, if that was unsuccessful, the use of atropine 0.01 mg/kg, as appropriate. Respiratory depression was defined as a decrease of SpO₂ <93% that required supplemental oxygen via a mask in PACU.

Evaluation of sensory scores

Sensory block was assessed by the Observational pain scale at every 5 minute after completion of drug injection, in the dermatomal areas till complete sensory blockade.

Grade 0: Sharp pain

Grade 1: Touch sensation only

Grade 2: Not even touch sensation

The duration of analgesia was assessed by using the subjective pain scale in children more than 3 years of age who can verbally express pain and observational pain scale for rest of the children who cannot verbally express pain. If the child was complaining of pain or if the pain score was ≥ 3 ,

the child was given IM Paracetamol as a rescue analgesic.

Evaluation of motor scores

Motor block was assessed at each 5 minute till complete motor blockade after drug injection. Motor block was determined according to a modified Bromage scale for lower extremities on a 3-point scale.

Bromage 0- Patient is able to move the hip, knee and ankle.

Bromage 1- Patient is unable to move the hip but able to move the knee and ankle.

Bromage 2 - Patient is unable to move the hip and knee but able to move the ankle.

Bromage 3 - Patient is unable to move the hip, knee and ankle.

Definition of time points

Sensory onset: when there was a dull sensation to pin prick with a 23G needle in the dermatomal areas.

Complete sensory block: when there was complete loss of sensation to pin prick in the dermatomal areas.

Duration of sensory block: the time interval between caudal drug injection and the first analgesic requirement.

Onset of motor blockade: when there is Grade 1 motor blockade.

Duration of motor block: the time interval between the end of drug administration and the recovery of complete motor function of the leg and foot.

The block was considered incomplete when increase of MAP or HR more than 30% from baseline values on incision and patient was able to move the hip, knee and ankle even after 30 min of drug injection. In this case, general anaesthesia was given and patient was excluded from the study.

Sedation was assessed by the 4 Point Sedation Score. The rescue analgesia was given in the form of IM Paracetamol. All patients was observed for any side-effects like nausea, vomiting, dryness of mouth and complications like hematoma &

Ropivacaine toxicity and treated with appropriate measures.

Statistical Analysis

The obtained data was tabulated and analyzed using one-way analysis of variance (STUDENT t-test). STUDENT t-test is used to determine whether there are any statistically significant differences between the means of two independent (unrelated) groups. Results were expressed as mean ± standard deviation. STUDENT t-test was applied for onset and duration of sensory and motor blockade and duration of analgesia, demographic data, and hemodynamic parameters. The INDO-STAT software was used. P-value was considered significant if more than 0.05.

Sample size:- Study sample size was estimated based on the pilot study ($n = 15$) for mean time to first demand bolus of 420 min in Dexmedetomidine group and 310 min in control group. With SD of 23.5, our sample size came out to be 29 per group at a power of 80% and confidence interval of 95%. For possible dropouts, it was decided to include 30 patients per group.

Scores Were Recorded

Observation Pain Scale (For Sensory block assessment)

Parameter	Criteria	Score
HEART RATE	>10% to < 20% of preoperative	0
	20% to 30% of preoperative level	1
	>30% of preoperative level	2
BLOOD PRESSURE	>10% to < 20% of preoperative	0
	20% to 30% of preoperative level	1
	>30% of preoperative level	2
CRYING	Not crying	0
	Crying but responds to tender loving care	1
	Crying and does not respond to tender loving	2

Four Point Sedation Score

Score	Criteria
1	Asleep, not arousable by verbal contact.
2	Sleep, arousable by verbal contact.
3	Drowsy not sleeping.
4	Alert/ awake.

Likert scale (for surgeon satisfaction)

Score	Criteria
1	Extremely dissatisfied
2	Dissatisfied
3	Somewhat dissatisfied
4	Undecided
5	Somewhat satisfied
6	Satisfied
7	Extremely satisfied

Results

Statistical analysis shows no significant difference in average taken for age, weight and duration of surgery among two groups. Male predominance was seen in both groups. (table 1).

The mean pulse rate decreased in both the group after caudal block (T5). This decrease was more in group RD2, which was statistically significant ($P < 0.05$) (figure. 1).

The mean arterial pressure decreased in both the groups after caudal block (T5). But intergroup comparison was statistically insignificant at each time interval ($P > 0.05$) (figure 2).

Mean oxygen saturation was comparable in both the groups at each time interval. ($p > 0.05$) (figure. 3).

Mean Onset time of sensory and motor block was found earlier in group RD2 (6.36 min & 9.06 min) than group RD1 (11.76 min & 15.2min), which is significant statistically (p value < 0.05) (table 2).

The duration of sensory block and motor block was found to be longer in Group RD2 as compare to Group RD1. Which is statistically significant (p value < 0.05). (table 3).

Mean duration of Analgesia was prolonged in Group RD2 (906.17min.) as compared with Group RD1 (587.27 min). Which is statistically significant (p value < 0.05).

Mean duration of sedation was longer in Group RD2 (256.40 min.) as compared with Group RD1 (138.33 min.). Which was statistically significant (p value < 0.05).

Surgeons were more satisfied in Group RD2 as compared with Group RD1. Which is statistically significant (p value < 0.05).

Bradycardia was seen in 2 patients & Urinary Retention occurred in 1 patient in Group RD2

Table 1 (Demographic characteristics of patients with caudal block)

	Group RD1		Group RD2		P value
	Mean	SD	Mean	SD	
Age	5.12	1.68	4.9	1.66	0.026
Weight	14.43	2.81	14.56	2.71	0.427
Duration of Surgery (Min.)	26.67	4.15	26.33	3.39	0.38
	Group RD1		Group RD2		
Gender	Male=28	Female=2	Male=30	Female=0	

Table 2 (Statistical analysis of different parameters among two groups in patients with caudal block)

		Group RD1		Group RD2		P value
		Mean	SD	Mean	SD	
Onset Time (in min.)	Sensory block	11.76	2.47	6.36	0.91	0.0001
	Motor block	15.2	2.73	9.06	1.09	0.0001
Duration of block (in min.)	Sensory Block	446.66	27.36	806.5	26.89	0.0001
	Motor Block	139.66	25.39	246.20	14.23	0.0001
Duration of Analgesia (in min.)		587.27	15.86	906.17	27.22	0.0001
Duration of sedation (in min.)		138.33	9.06	256.40	9.32	0.0001
Surgeon satisfaction score		5.43	0.76	5.80	0.74	0.03

Table 3 (Distribution of cases according to complications)

Complications	Group RD1		Group RD2	
	No.	%	No.	%
Nil	30	100.0	28	93.33
Bradycardia	-	-	2	6.67
Urinary Retention	-	-	1	3.33

Figure. 1 (Graphical representation of intraoperative Mean Pulse Rate (bpm))

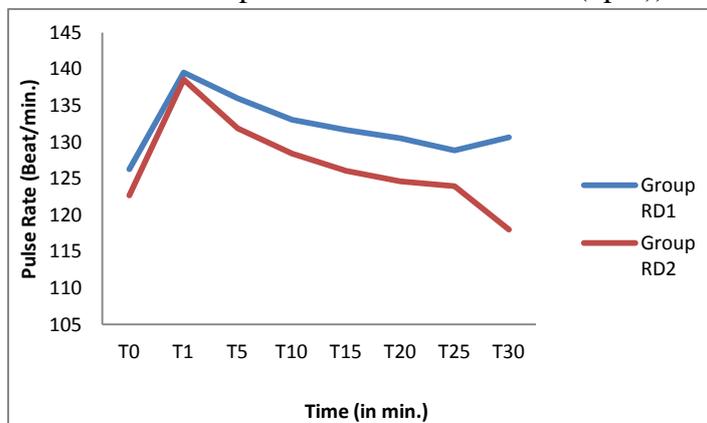


Figure 2 (Graphical representation of intraoperative Mean Arterial Pressure)

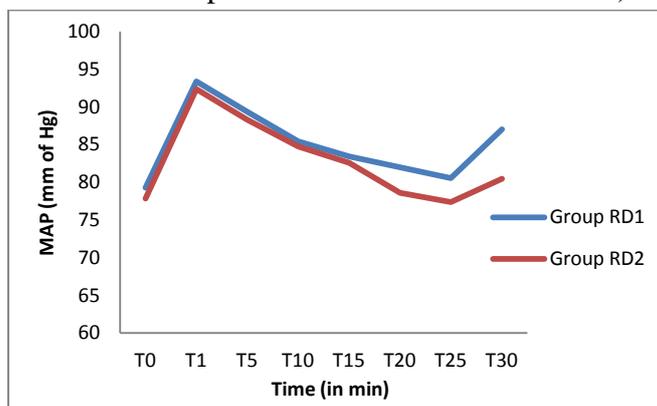
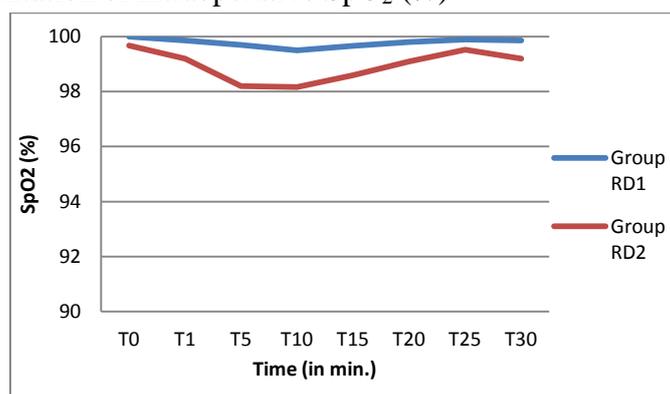


Figure. 3 Graphical representation of intraoperative SpO₂ (%)

Discussion

Caudal block is easy to perform and has been found to be very effective in children, especially in infra-umbilical surgery like herniotomy.

Several local anaesthetic agents (eg. bupivacaine, ropivacaine etc.) have been used for caudal block. Adjuvant⁷ like opioids (morphine, butorphanol etc.), clonidine, midazolam and ketamine 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.

α 2 Adrenergic receptor agonists⁸ (dexmedetomidine) could prolong the duration of action of ropivacaine⁹ and improve the quality of analgesia, by causing local vasoconstriction and increasing the potassium conductance in A δ and C fibres. They may also potentiate the action of local anaesthetic by entering the central nervous system either via systemic absorption or by diffusion into the cerebrospinal fluid and reach α 2 receptors in the superficial laminae of the spinal cord and brainstem or indirectly activating spinal cholinergic neurons.

The sedative effects of dexmedetomidine are mainly attributable to stimulation of the α 2 adrenoceptor in the locus coeruleus.

El-Hennawy et al¹⁰ administered dexmedetomidine and clonidine, both in a dose of 2 μ g/kg as adjuvant with 0.25% bupivacaine caudally and found that the duration of analgesia was significantly higher in the group receiving bupivacaine–dexmedetomidine mixture or

bupivacaine–clonidine mixture than the group receiving bupivacaine alone.

Neogi et al¹¹ compared clonidine 1 μ g/kg and dexmedetomidine 1 μ g/kg as adjuncts to ropivacaine 0.25% for caudal analgesia in paediatric patients and concluded that addition of both clonidine and dexmedetomidine with ropivacaine administered caudally significantly increases the duration of analgesia.

Saadawy et al¹² compared caudal bupivacaine 0.25% administered with dexmedetomidine 1 μ g/kg and caudal bupivacaine alone and showed that the incidence of agitation following sevoflurane anaesthesia was significantly lower with dexmedetomidine ($P < 0.05$). The duration of analgesia was significantly longer with dexmedetomidine administration ($P < 0.001$). No statistically significant difference in haemodynamics was found between both the groups. Dexmedetomidine produced better quality of sleep and a prolonged duration of sedation ($P < 0.05$).

Manohar and Yachendra et al¹³ used 1 μ g/kg dexmedetomidine with 0.25% bupivacaine and 0.25% ropivacaine caudally and found the duration of analgesia to be 532.67 (493.66–571.68) min in BD group and 497 (473.79–520.21) min in RD group. The lower duration of analgesia noted in this study was probably due to the use of lower dose 1 μ g/kg of dexmedetomidine.

Arpita laha et al¹⁴ in the year 2012 compared the quality of analgesia between Ropivacaine 0.2% 1ml/kg alone and Ropivacaine 0.2% 1ml/kg with

Clonidine 2microgram/kg for pediatric caudal block. They did not observe any significant difference in mean heart rate, SBP, DBP between the two groups.

Xiang et al¹⁵ have also demonstrated that supplementation of caudal bupivacaine with dexmedetomidine (1 µg/kg) reduced the hemodynamic response to hernial sac traction in children undergoing inguinal hernia repair.

In our study Dexmedetomidine¹⁶ (2µg/kg) as adjuvant to Ropivacaine has faster onset and prolonged duration of sensory and motor blockade and increased duration of analgesia compared to Dexmedetomidine (1µg/kg) without any significant side effects.

Most of the studies show that α2 agonists prolong the the effects of local anaesthetic and improves the quality of block.

Conclusion

Dexmedetomidine when added to Ropivacaine 0.20% prolong the duration of sensorimotor blockade and duration of analgesia in caudal block. We concluded that Dexmedetomidine (2µg/kg) is better adjuvant than Dexmedetomidine (1µg/kg) in caudal block for infra umbilical surgeries.

Limitations

We did not biochemically analyze the blood concentration of Ropivacaine and Dexmedetomidine The population enrolled was in the age group of 3-8 years which were otherwise healthy patients of ASA Grade I and II, so the effect of Dexmedetomidine as an adjuvant in older patients with cardiovascular co morbidities is yet to be investigated.

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