Effect of dexmedetomidine added to caudal ropivacaine for infra-umbilical surgery in children

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Abstract

Introduction: Dexmedetomidine, a potent, highly selective α_2 receptor agonist when added asan adjuvant to caudal local anaesthetics prolong analgesia in paediatric infra-umbilical surgeries. Present study is to assess the quality, duration of analgesia and safety profile of different concentrations of dexmedetomidine given caudally with ropivacaine and to see if a higher concentration has any added advantage.

Materials and Method: In this prospective, randomized, controlled, double-blind study, 90 children were allocated to three groups of 30 each. GpR (control) received 1ml/kg 0.2% ropivacaine +0.5ml normal saline. $GpRD_1$ and $GpRD_2$ (interventional) received 1mcg/kg and 2mcg/kg dexmedetomidine respectively (volume made to 0.5ml), in addition to ropivacaine. General anaesthesia was induced with 50% oxygen in nitrous oxide and sevoflurane and maintained on spontaneous ventilation via face mask. Once asleep, caudal block was performed. Primary end point of the study was the duration of analgesia. Complications, if any, were recorded.

Statistical Analysis: Data was analysed using SPSS version 22. One way ANOVA was used for comparison of numerical variables. If significant, Tukey's HSD -post-hoc analysis was employed for between group comparisons. P value of <0.05 was taken as significant, <0.01 as highly significant & <0.001 as extremely highly significant.

Results: Duration of analgesia was prolonged in $GpRD_1$ (854.67±199.98) and $GpRD_2$ (983.83±115.59) compared to GpR (329.33±140.33mins) (p=0.000). Between $GpRD_1$ and $GpRD_2$, analgesia showed highly significant prolongation in $GpRD_2$ (p = 0.005).There were no adverse effects.

Conclusion: Both 1mcg/kg and 2mcg/kg dexmedetomidine having comparable sedation, safely and effectively prolongs the duration of analgesia. 2µg/kg dexmedetomidine with its better analgesia and favourable safety profile can be recommended as an excellent adjuvant to caudal ropivacaine for infraumbilical surgeries in children.

Keywords: Dexmedetomidine, Ropivacaine, Caudal, Paediatric analgesia.

Introduction

With well identified pain pathways in children, they perceive pain in the same way as adults in physical and emotional respects. Caudal analgesia offers pain relief due to complete blockade of sensory transmission. Addition of adjuvants like dexmedetomidine to local anaesthetics given caudally can prolong analgesia. Dexmedetomidine, an alpha 2 agonist with hemodynamic, sedative, anxiolytic, analgesic, anaesthesia sparing and neuro protective effects.[1] Present study is to assess the quality, duration of analgesia and safety profile of different concentrations of dexmedetomidine given caudally with ropivacaine in the paediatric population and to see if a higher concentration has any added advantage.

Materials and Methods

A prospective, randomized, controlled, double blind study was conducted with the approval of Hospital Ethics Committee after obtaining written informed consent from parents of children included in the study. Ninety ASA I physical status children of either sex, aged 1–7 years scheduled for infraumbilical surgery were included. Exclusion criteria were infection at the injection site, coagulopathy, neurological diseases, skeletal deformities, developmental delay, allergy to the study drugs, parental denial. Children were randomly allocated to three study groups of 30 each using a computer generated randomization list. The study drug (same volume) was prepared and coded by an anaesthesia colleague. Caudal epidural block and subsequent assessment was done by the anaesthesiologist conducting the study to avoid individual variations. The anaesthesiologist conducting the study was blinded to the study drug.

Sample Size Calculation: Calculation of sample size revealed that at least 15 subjects in each group were needed to detect a difference in the average time to first analgesic as small as 1.5times its standard deviation with a power of 0.90 and a significance level (α) of 0.05. The sample size was doubled (i.e. 30 patients in each group) as the distribution of the primary outcome variable (time to first analgesic) was expected to be skewed (or generally not normally distributed) with the possibility of existence of censored data.

Groups studied were GpR (control)- 0.2% ropivacaine 1 ml/kg+0.5ml normal saline. $GpRD_1$ (intervention group) - 0.2% ropivacaine 1ml/kg+dexmedetomidine 1µg/kg made to 0.5 ml with normal saline. $GpRD_2$ (intervention group) - 0.2% ropivacaine 1ml/kg+dexmedetomidine 2µg/kg made to 0.5ml with normalsaline.

Detailed preoperative assessment was done using a pre tested structured questionnaire. Sex, age, weight and baseline vital parameters were recorded. Standard fasting guidelines were followed. Children were premedicated with oral midazolam 0.5mg/kg, 30 minutes prior to induction.

Anaesthesia was induced with 50% oxygen in nitrous oxide and sevoflurane. Once unconscious, intravenous access was secured and ringer lactate solution was infused as per calculated requirements and sevoflurane concentration was reduced. Caudal epidural block was performed with 23 gauge scalp vein needle in the lateral decubitus position observing all sterile precautions. The epidural space was confirmed by the feel of penetration of the sacrococcygeal membrane, loss of resistance to air and negative aspiration of blood and CSF. After injecting the study drug, patient was turned supine. General anaesthesia was maintained on spontaneous ventilation using face mask with 50% oxygen in nitrous oxide and sevoflurane. Surgical incision was performed only after ten minutes of caudal block to allow enough time for the block to act. An increase in heart rate and blood pressure from 20% of baseline, or any movement at the time of incision was considered as ineffective block. Oxygen, nitrous oxide and sevoflurane were continued till the completion of skin closure. No parenteral narcotics, analgesics or sedatives were used intra-operatively. ECG, pulse rate, oxygen saturation were monitored continuously and non-invasive blood pressure (NIBP), every five minutes. The occurrence of intraoperative hypotension (systolic blood pressure < 20% of base line values) requiring fluid bolus or bradycardia requiring intravenous atropine injection were noted. Hypoxia (SpO2< 94%) demanding increase in inspired oxygen concentration or respiratory inadequacy needing assisted ventilation were considered. Once the child was awake with stable vital parameters and normal oxygen saturation in room air, he/she was transferred to post anaesthesia care unit (PACU).

Behaviour during emergence was rated on a four point scale.[2] (1- Calm, 2- Not calm but could easily be calmed, 3- Not easily calmed, moderately agitated or restless, 4- Combative, excited or disoriented). Sedation was assessed using an objective score based on eye opening. (0-eyes open spontaneously, 1-eyes open to verbal stimulation, 2-eyes open only to physical stimulation). Pain intensity was assessed using the paediatric observational Face, Legs, Activity, Cry, Consolability scale (FLACC) with its 0 – 10 range, at the end of surgery and for 18 hours at four hourly intervals (2, 6, 10, 14, 18 hours post operatively).[3] (Table 1)

Table 1: FLACC score

Parameter	Finding	Points
Face (F)	No particular expression or smile	0
	Occasional grimace or frown, withdrawn, disinterested	1
	Frequent to constant quivering chin, clenched jaw	2
Leg (L)	Normal position or relaxed	0
	Uneasy / restless / tense	1
	Kicking or legs drawn up	2
Activity (A)	Lying quietly, normal position, moves easily	0
	Squirming, shifting back and forth, tense	1
	Arched, rigid or jerking	2
Cry (C)	No cry (awake or asleep)	0
	Moans or whimpers, occasional complaints	1
	Crying steadily, screams or sobs, frequent complaints	2
Consolability(C)	Content / relaxed	0
	Reassured by occasional touching, hugging or being talked to, distractable	1
	Difficult to console or comfort	2

FLACC score 4 was taken as mild pain. Once the FLACC score was ≥ 4, rescue analgesia was provided with paracetamol suppository 30 mg/kg body weight and FLACC scores were not recorded there after. Number of analgesic doses taken within 18 hours (the real time of discharge from hospital) was recorded. Motor block – Motor block was assessed using Bromage Scale.[4] Quality of surgical anaesthesia – Subjective score of quality of surgical anaesthesia was rated as poor, fair and good by the surgeons.[5] Children were observed 18 hours postoperatively for any untoward effects like hypotension, bradycardia, respiratory depression, pruritus, postoperative nausea and vomiting (PONV), urinary retention or any other complications. Time taken to first micturition after caudal was recorded.

Time intervals taken were:-
Surgery time was taken as the time from incision to the end of surgical closure.
Anaesthesia time was from induction to the time when anaesthetic gases were discontinued.
Comparisons between groups were done on the following lines:-

Patient data		Gp. R (n = 30)	GpRD$_1$ (n = 30)	GpRD$_2$ (n=30)	p-value
Age (yrs)	1 yr – 2 yrs	11	10	11	0.990
	2 yrs – 3 yrs	3	3	4	
	3 yrs – 4 yrs	2	4	3	
	4 yrs – 5 yrs	6	5	3	
	5 yrs – 6 yrs	3	4	5	
	6 yrs – 7 yrs	5	4	4	
Sex	Male	24 (80%)	25 (83%)	26 (87%)	0.787
	Female	6 (20%)	5 (17%)	4 (13%)	
Weight (kgs) (mean±SD)		12.49±3.66	12.13±3.09	12.42±3.11	0.904
surgery	Herniotomy	19 (63%)	17 (57%)	19 (63%)	0.963
	Circumcision	6 (20%)	7 (23%)	5 (17%)	
	Orchiopexy	5 (17%)	6 (20%)	6 (20%)	
Duration of surgery (mean±SD)		31.86±8.47	31.83±6.36	31.66±7.11	0.994
Duration of Anaesthesia (mean±SD)		46.90±10.56	46.53±10.24	46.56±9.97	0.988

Intraoperative complications, emergence time (time taken from the end of anaesthesia to spontaneous eye opening), behaviour during emergence, sedation score, pain score at different intervals, duration of analgesia (time interval from administration of caudal to the first rescue analgesia), number of rescue analgesics, postoperative complications including interval to first micturition.

Statistical Analysis

Data was analyzed using SPSS version 22.0 computer software (Chicago, IL, USA). Numerical variables were presented as mean and standard deviation (SD) and categorical variables as frequency (%). One-way ANOVA was used for between-group comparisons of numerical variables. Tukey's HSD test was used whenever appropriate, as post-hoc tests. P value of <0.05 was taken as significant, <0.01 as highly significant and< 0.001 as extremely highly significant.

Results

Total of 90 children (30 in each group) completed the study.

Patients were comparable in age, sex, weight, type, duration of surgery and duration of anaesthesia (Table 2).

Table 2: Patient characteristics

Patient data		Gp. R (n = 30)	GpRD$_1$ (n = 30)	GpRD$_2$ (n=30)	p-value
Age (yrs)	1 yr – 2 yrs	11	10	11	0.990
	2 yrs – 3 yrs	3	3	4	
	3 yrs – 4 yrs	2	4	3	
	4 yrs – 5 yrs	6	5	3	
	5 yrs – 6 yrs	3	4	5	
	6 yrs – 7 yrs	5	4	4	
Sex	Male	24 (80%)	25 (83%)	26 (87%)	0.787
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By tenth hour, all the patients in the plain ropivacaine group had pain. By 18th hour, 83% of patients in the 1µg/kg dexmedetomidine group, and 50% in 2µg/kg group had pain (Fig 1).

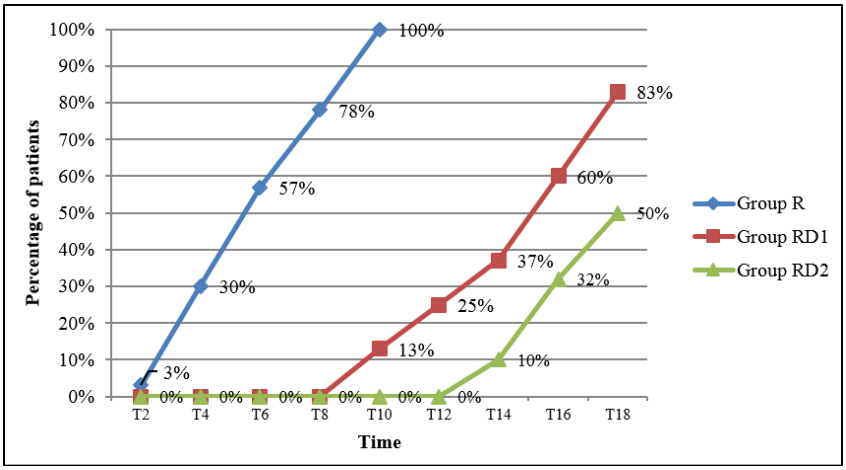

Fig. 1: Percentage of patients with FLACC – 4 at various intervals

Duration of analgesia was prolonged to an extremely high significant level in GP RD_1 (854.67±199.98) and Gp RD_2 (983.83±115.59) compared to Gp R (329.33±140.33mins) (p=0.000). Between Gp RD_1 and Gp RD_2, analgesia showed highly significant prolongation in Gp RD_2 (p = 0.005). The number of analgesic doses required was reduced to an extremely high significant level in Gp RD_1 and Gp RD_2 compared to Gp R (1.00±0.643, 0.53±0.507 vs 2.13±0.346)(p=0.000). Between Gp RD_1 and Gp RD_2, requirement of analgesic doses was reduced to a highly significant level in Gp RD_2 (p = 0.002). (Table 3)

Adding dexmedetomidine 1µg or 2µg significantly prolonged the emergence time (p=0.000) and made the sedation score significantly high (p=0.003). Between Gp RD_1 and Gp RD_2, emergence time and sedation score were not significantly different (Table 3). There was no significant difference between the groups in emergence behaviour scores (p=0.54). There was no motor block in any of the patients as assessed by Bromage score.

Table 3: Comparison between groups

	GpR&GpRD$_1$		**GpR&GpRD$_2$**		**GpRD$_1$&GpRD$_2$**	
	Difference	**P-value**	**Difference**	**P-value**	**Difference**	**P-value**
Duration of analgesia	-525.33	0.000	-129.57	0.000	-654.50	0.005
Number of analgesic doses	1.333	0.000	1.600	0.000	0.467	0.002
Emergence time	-26.46	0.017	-42.70	0.000	-16.23	0.206
Sedation score	-0.53	0.041	-0.73	0.003	-0.20	0.627

Table 4: Emergence time, emergence behaviour & sedation score

	Gp R (n = 30)	**Gp RD$_1$ (n = 30)**	**Gp RD$_2$ (n=30)**	**P-value**
Emergence time	16.20±13.96	42.66±34.85	58.90±51.25	0.000
Emergence behaviour	2.20±0.92	2.03±0.10	1.93±0.087	0.54
Sedation score	0.76±0.56	1.3±1.02	1.5±0.86	0.003

Quality of surgical anaesthesia was rated as good by the surgeons in near 75% of patients in the dexmedetomidine group (Fig. 2).

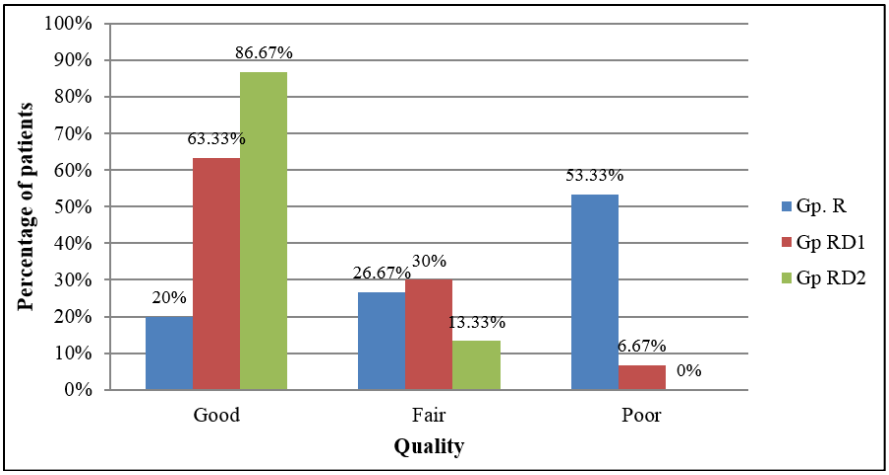

Fig. 2: Quality of surgical anaesthesia

Intra Operative Complications: Intra operative complications like hypotension, bradycardia, and respiratory inadequacy were not present in any patients. No episodes of clinically significant post-operative complications such as hypotension, bradycardia, respiratory depression or urinary retention were observed. PONV occurred in 6.6% of the patients and was equally distributed among the groups. The mean time interval to first micturition after caudal was similar among the groups.

Discussion

The concept of postoperative pain relief in the paediatric age group has improved dramatically with the recognition that premature and term neonates, infants and children are capable of responding to noxious stimuli and that long and short term morbidity can result from inadequate analgesia. Caudal analgesia reduces the amount of inhaled and intravenous anaesthetic administration, attenuates the stress response to surgery and facilitates a rapid, smooth recovery while providing good postoperative analgesia. Its main disadvantage is its relatively short duration of action when given as a single shot, even when long acting local anaesthetics like bupivacaine or ropivacaine is used. Employing caudal catheters for prolonging analgesia is deferred for fear of infection. Various drugs have been tried as adjuvants to caudal local anaesthetics to be administered as single shot for prolonged postoperative analgesia.

Ropivacaine, with its wider margin of safety, less motor blockade, less cardiovascular, neurological toxicity and similar or slightly prolonged duration of analgesia has mostly replaced bupivacaine as the local anaesthetic. Ropivacaine 0.2% was chosen, as higher concentration of ropivacaine (0.3%) was associated with prolonged motor block.[6] The dose of local anaesthetic, ropivacaine (1ml/kg), was calculated using the Armitage formula.[7] Dexmedetomidine, a second generation alpha 2 adrenergic receptor specific pharmacologically active d-isomer of medetomidine is chosen as the adjuvant. It is claimed to possess anxiolytic, sedative, sympatholytic and analgesic properties without respiratory depression and undesirable cardiovascular effects which is in contrast to opioids given caudally which can cause nausea, vomiting, pruritus and late respiratory depression. Pharmacodynamics effects of dexmedetomidine have been studied thoroughly in adults whereas in children, initial publications were anecdotal in the form of case reports.

In our study, we were attempting to assess the quality and duration of analgesia of different concentrations of dexmedetomidine given caudally in combination with ropivacaine and to see if higher concentration of dexmedetomidine had any added advantage and also to confirm the safety profile of the same. Only children aged one to seven years were included in the study, as the spread of analgesia is more predictable and failure rate less in children up to 7 years.[8] Premedication with oral midazolam made parental separation smoother.

Analgesia: Assessment of pain proved difficult in the paediatric age group because of limited cognitive and language skills. Our study also included preverbal children, so self-report measures could not be relied upon for pain assessment in all the children. The FLACC behavioural scale was used for assessment as it includes behavioural categories and a variety of descriptors that are reliably associated with pain in children, adults with cognitive impairment and critically ill adults.[2,3] The number of patients having pain (FLACC score ≥4) increased rapidly in the ropivacaine group (by tenth hour all the patients had pain). In the dexmedetomidine 1mcg/kg group, by the 18th hour, 83% of patients had pain while in the 2mcg/kg group, only 50% of patients had pain.

The end point of the study was the duration of analgesia. Addition of 1µg/kg, 2µg/kg dexmedetomidine prolonged the mean duration of analgesia to an extremely high significant level as compared to ropivacaine alone(854.67 ± 199.98 min, 983.83 ± 115.59 min vs. 329.33 ± 140.33 min, p=0.000). Between the dexmedetomidine groups, duration of analgesia was significantly prolonged in the 2µg/kg group (p=0.005). Studies by Neogi et al[9] and Saadawy[10] et al using 1µg/kg caudal dexmedetomidine; El-Hennawy[11] et al. and Anand et al[1] using 2µg/kg caudal dexmedetomidine also demonstrated significantly higher mean duration of analgesia with dexmedetomidine

administration, supporting our findings. As expected, analgesic requirement in the dexmedetomidine groups was decreased to an extremely high significant level because of prolonged analgesia. Between the dexmedetomidine groups, analgesic requirement was significantly less in the 2µg/kg dexmedetomidine group. The subjective score of quality of anaesthesia was rated good by the surgeons in near 75% patients in the dexmedetomidine group. Alpha2 Adrenergic receptor agonists could prolong the duration of action of local anaesthetics and improve the quality of analgesia by causing local vasoconstriction and increasing the potassium conductance in Aδ and C fibres.[12,13]

Emergence time, sedation, emergence behaviour: Addition of dexmedetomidine 1µg/kg and 2µg/kg prolonged the emergence time and sedation score to a significant level which is similar to the studies by Sadaawy et al[10] and Anand et al[1] respectively. But between the dexmedetomidine groups, there was no difference in emergence time or sedation score. Patients were responsive, cooperative and calm when aroused, but promptly went back to sleep when not stimulated. This contributed to reducing parent's anxiety. Dexmedetomidine is documented to cause sedation by the stimulation of G_2 receptors in the locus ceruleus.[14] Emergence agitation is a frequent side effect of sevoflurane anaesthesia. The incidence of the excitatory behaviour is documented to be reduced by the perioperative use of sedative and analgesic drugs.[15,16] The alpha 2 receptor agonist, similarly is thought to prevent emergence agitation due to its analgesic and sedative properties.[2] We did not find any significant difference in the emergence behaviour scores between the study groups. But all our patients were calm and co-operative and responded to gentle stimuli. This was contrary to the observation made by Saadawy et al[10] who showed lower incidence of emergence agitation with dexmedetomidine in sevoflurane anaesthesia.

Post-operative Complication: Hemodynamic and respiratory parameters were within normal limits and there were no complications like pruritus or urinary retention. The excellent safety profile and stable respiratory and hemodynamic profile observed were in concordance with the reports published by other authors.[17,18] Postoperative nausea and vomiting (PONV) occurred in 6.6% of the patients which was equally distributed among the groups. The favourable safety profile associated with dexmedetomidine is in concurrence with the reports published in other studies[1,19]

The caudal administration of dexmedetomidine (1µg/kg and 2µg/kg) to ropivacaine (0.2%) achieved good quality and prolonged intra and post-operative analgesia, with a favourable safety profile. It resulted in prolonged duration of arousable sedation. The quality and duration of analgesia was even better with 2µg/kg dexmedetomidine.

Limitations

Age group selection - Pain assessment in the younger age group was difficult because of lack of adequate communication and cognitive skills. We could not effectively assess the time of onset of analgesia in our study, as our patients were given general anaesthesia before administering the caudal block. There was no alternative as the patient had to be put to sleep before performing the block as is the case in paediatric population. However, we waited for ten minutes after caudal block to place the surgical incision on the assumption that it takes nearly ten minutes for the caudal block to be effective. The primary aim of our study was to compare the effect on postoperative analgesia and not intraoperative analgesia. Pain assessment was done using FLACC score 0 – 4, first at the 2nd hour and then at 4 hourly intervals till 18 hrs. Assessing the scores more frequently would have provided finer details of change of FLACC scores from 0-4.

Conclusion

Both 1mcg/kg and 2mcg/kg dexmedetomidine having comparable sedation, safely and effectively prolongs the duration of analgesia. 2µg/kg dexmedetomidine with its better analgesia and favourable safety profile can be recommended as an excellent adjuvant to caudal ropivacaine for infra umbilical surgeries in children.

Conflict of Interest: None.

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