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COMPARISON OF ANALGESIC EFFICACY OF CAUDAL DEXMEDETOMIDINE WITH ROPIVACAINE VERSUS ROPIVACAINE IN PEDIATRIC INFRAUMBILICAL SURGERIES

Anaesthesiology

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ABSTRACT

Introduction: Caudalanaesthesia is commonly practiced as regional block technique in children undergoing infraumbilical surgeries but has a short duration of action after single shot local anaesthetic injection. Many additives are being used in combination with local anaesthetics in caudal block to prolong the postoperative analgesia. The aim of this study was to compare analgesic efficacy and side effects of caudal Dexmedetomidine with Ropivacaine versus Ropivacaine in pediatric patients undergoing infraumbilical surgeries.**Materials and Method:** After approval from Institutional Ethical Research Committee, 60 ASA- I and II patients aged 1 and 7 years undergoing various elective infraumbilical surgical procedures were included in the study. The patients were randomly allocated into 2 groups of 30 patients each. Group RD (n=30) received 0.25% Ropivacaine 1ml/kg with Dexmedetomidine 1µg/kg and Group R (n=30) received 0.25% Ropivacaine 1ml/kg in normal saline. The various parameters studied were post-operative pain(FLACC pain score), mean duration of analgesia, rescue analgesic requirements, postoperative sedation score and side effects.**Results:** All the groups were comparable demographically and in block characteristics. The mean duration of analgesia was 624.72 ±60.28min in Group RD and 412.34 ±40.50 min in Group R.**Conclusion:** This study showed that the addition of Dexmedetomidine with Ropivacaine administered caudally significantly increase the duration of postoperative analgesia with minimal side-effects in children.

KEYWORDS

Ropivacaine, Caudal, Dexmedetomidine.

INTRODUCTION

The Society for Pediatric Anaesthesia, in its 15th annual meeting held at New Orleans in state of Louisiana (2001)[1] clearly stated that the alleviation of pain is a "basic human right" irrespective of age, medical condition and treatment. Langlade et al (1997)[2] suggested that post-operative analgesia must be included in the anaesthetic planning even before induction of anaesthesia, adopting the idea of "managing pain before it occurs". Caudal anaesthesia, a reliable and safe technique in pediatric patients, reduces the anaesthetic agent requirement, attenuates surgical stress and provides better intraoperative and postoperative analgesia. The drawback of caudal anaesthesia is the short duration of action after a single injection. Variety of adjuvants, such as epinephrine, ketamine, midazolam,opioids, and α-2 agonists have been used with local anaesthetics to prolong the duration of caudal analgesia. Dexmedetomidine is a stereoisomer of medetomidine and a highly selective α-2 adrenergic receptor agonist with eight times more specificity as compared to Clonidine[3]. Dexmedetomidine is conferred with anxiolytic, sedative, sympatholytic and analgesic properties and without significant respiratory depressant effect.

OBJECTIVES

The present prospective randomized controlled study was designed to compare analgesic efficacy of Caudal Dexmedetomidine with Ropivacaine versus Ropivacaine alone in pediatric infraumbilical surgeries.Objectives of the studywere: -

1)Primary objective-To compare Duration of Analgesia,
2)Secondary objective-
a)To assess pain intensity using FLACC[4] pain scale
b) To assess post-operative sedation by Ramsay Sedation scale
c) Haemodynamic changes with adverse effects

MATERIALAND METHODS

After obtaining permission from the Institutional Ethics Committee and consent from the parents, the prospective randomized controlled study was conducted at Department of Anaesthesiology, Jhalawar Medical College and Associated Hospitals, Jhalawar, Rajasthan. The study population included 60 patients of 1-7 years with ASA I or II, undergoing elective infraumbilical surgeries (lasting <60 min) with written informed consent, were enrolled in the prospective double-blind study.

EXCLUSION CRITERIA

1. Parental refusal
2. History of developmental delay or mentally retarded
3. Known allergies to study drugs
4. Injection site infection
5. Spinal deformities
6. Coagulopathies
7. Neurological deformities
8. Congenital heart diseases
9. Co-existing medical (metabolic and endocrine) illnesses

SAMPLE SIZE

Sample size calculation was done on the basis of the previous studies. The primary outcome was taken as pain-free period and assuming 85% of study power and 5% α error. The minimum sample size was calculated to be 27 patients per group were required. Therefore, 30 patients in each group were planned.

Patients were allocated randomly by means of the closed envelope technique into two groups(Group RD and Group R) of 30 each.

Group RD (n=30) received 0.25% Ropivacaine 1ml/kg with Dexmedetomidine 1µg/kg

Group R (n=30) received 0.25% Ropivacaine 1ml/kg in normal saline.

METHOD

After completing pre-anaesthetic check-up, the patient received a conventional preoperative dose of oral midazolam (0.3 mg/kg) before induction.NBM was confirmed by parents & then the patient was taken to operative room.All standard monitors were connected & base line vitals(pulse, B.P, SpO2)were noted.

22/24 G IV cannula was secured, then induction was started with Sevoflurane 8% and a mixture of 60% N2O in 40% Oxygen and appropriate size I-GEL was inserted.The patient was turned to left lateral position, under aseptic precautions using a 23gauge sterile needle, the caudal space was identified using the loss of resistance technique. Once localization done successfully, the drug was injected following negative aspiration for cerebrospinal fluid or blood. The patient was turned back to supine position & anaesthesia was

maintained with a mixture of 1% Sevoflurane and 60% Nitrous oxide in 40% Oxygen.

Onset of block was assessed by applying mechanical stimulus at surgical site after 5, 10 and 15 minutes of the injection. The successful onset of the block is defined as the time in minutes between injection of local anaesthetic and the absence of motor response or absence of >20% increase in HR on application of mechanical stimulation. Patients with patchy and failed caudal block were excluded from the study. Side effect-hypotension, bradycardia etc. if any noted, treated accordingly. The occurrence of intraoperative hypotension requiring a fluid bolus,bradycardia requiring atropine, and nausea-vomiting etc. were recorded. Perioperative blood loss was replaced meticulously using crystalloids. At the end of the surgery-patient was awakened breathing spontaneously and transported to the post-anaesthesia care unit (PACU).

The patient was monitored postoperatively for pain using the Face, Leg, Activity, Cry and Consolability (FLACC)score at 15 min,30 min, 1 h, 2 h, 3 h, 4 h,5h,6h,7h,8 h,10h, 12 h, 16 h, and 24 h.FLACC score ≥4 was treated with rescue analgesia(syrup Paracetamol- 15mg/kg). Sedation was assessed at 1hr, 2hr,3hr,4hr using sedation score of 1 through 3 where 1 open eyes spontaneously, 2 open eyes on verbal commands, and 3 open eyes on painful stimulation.

STATISTICALANALYSIS

Intergroup comparisons of the data were done by T- test. For categorical data, Chi-square test was used as a test of significance. p value ≤ 0.05 was considered as significant. Statistical analysis wasdone using software SPSS 16 IBM, Armonk, NY, USA.

RESULTS

Table-1)Demographic data

Data/Parameter	GroupR(n=30)	GroupRD(n=30)	p
Age(years)	4.22±1.54	4.68±1.87	0.302
Sex(Male:Female)	22/8	23/7	0.388
Weight(kg)	13.7±2.55	14.03±2.99	0.644
Height(cms)	110.135.69	110.50±7.46	0.907
BaselineHR(/min)	103.56±5.52	102.92±8.67	0.734
BaselineMAP(mmHg)	76.45±4.23	78.32±3.92	0.088
Surgicalduration(min)	36.73±11.57	37.51±10.60	0.786

The current study showed no significant differences in demographic data including age, sex, weight, height, baseline vitals and surgical duration between the two groups. (p>0.05)(Table1)

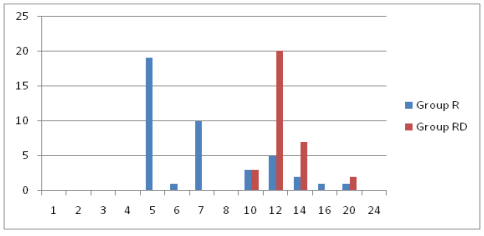

Figure-1) Incidence ofFLACC Pain Score At Various Time Intervals

Patients in Group R achieved significantly higher FLACC pain score compared with patients in Group RD. No patient had pain score 4 till first 4 hours in both the groups. 19(63.33%)patients,1 (3.33%) patients and 10 (33.33%)patients at the end of 5th, 6th and 7th hour while none of the patients in Group RD had a pain score of ≥4 at these intervals. However, in Group RD 20 out of 30 patients had FLACC pain score ≥4 at 10th hr after the caudal block which was statistically significant,p<0.05.(Figure 1)

Table-2 Duration of Analgesia & Rescue Analgesia Required In 24 hrs.

Parameters	Group R	Group RD	p-value
Duration of Analgesia(in mins)	412.34 ±40.50	624.72 ±60.28	<0.001
Number of doses of Rescue Analgesia Required(%)			
1	19	25	
2	8	5	
3	3	0	

The mean duration of analgesia was longer in Group RD (624.72±60.28 min) compared to Group R (412.34±40.50min) that was statistically highly significant, p<0.0001(Table 2). The total number of doses of rescue analgesic required were lesser in Group RD as compared to group R. In Group R, 3(10%) patients required 3 doses of rescue analgesic, whereas none of the patients required 3 doses of rescue analgesic in Group RD. In Group R, 8(26.66%) patient required 2 doses whereas 19(63.33%) patients required 1 dose of rescue analgesic. However, in Group RD 5(16.66%) patients required 2 doses and 25 (83.33%)patients required only one dose of rescue analgesic that was statisticallysignificant,(p<0.05)(Table 2).

Table 3 -Post-Operative Sedation Score (Ramsay Sedation Scale)

Time interval(hours)	RSS	GROUP R (n=30)	GROUP RD (n=30)
At 1 hr.	3	8	27
	2	22	3
At 2 hr.	3	2	21
	2	28	9
At 3 hr.	3	0	5
	2	30	25
At 4 hr.	3	0	0
	2	30	30

The patients in Group RD achieved higher sedation scores than Group R. At the end of first hour, the patients in Group RD had higher sedation scores, in comparison to patients in Group R which was highly significant, (p < 0.0001). 27 out of 30 patients (90%)had sedation score equal to 3 as compared to 8 patients (26.66%) in Group R which was highly significant, (p < 0.001). At the same time 22 patients (73.33%) in Group R have a sedation score of 2. Similarly, at the end of 2nd hour, 21 patients (70%) in Group RD had a sedation score of 3, while at the end of 3rd hr, 2 patients (6.66%) in Group R had a sedation score of 3. However, in Group R, none of the patients had a sedation score of 3, at the end of 3rd and 4th hrs. At the end of 4th hour, none of the patients in both groups had RSS of 3 (Table 3).

Figure 2 depicts the comparative incidence of side-effects in both the groups. Two patients in Group R had episode of nausea and vomiting and one patient in Group R had episode of hypotension and post-op agitation which is not significant on statistical analysis (p>0.05).No any other untoward side-effects were observed in either of the groups

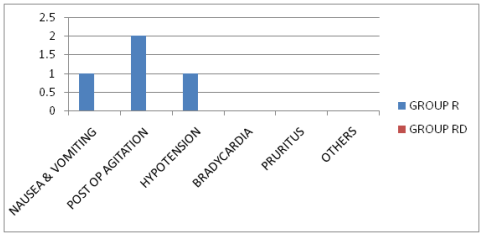

Figure 2-Incidence of Complications

DISCUSSION

Caudal epidural anaesthesia is one of the most common regional techniques used in the pediatric age group. But the disadvantage for single-shot caudal anaesthesia is the relatively limited duration of postoperative analgesia. Alpha-2 adrenergic receptors like Dexmedetomidine 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 A-δ and C fibres[5].They may also potentiate the action of local anaesthetics by entering the central nervous system either via systemic absorption or by diffusion into the cerebrospinal fluid and reach alpha-2 receptors in the superficial laminae of the spinal cord and brainstem[6],or indirectly activating cholinergic neurons. The present study demonstrated that addition of Dexmedetomidine is safe and efficacious in prolonging the duration of postoperative analgesia when administered with Ropivacaine as an adjuvant via the caudal route in children undergoing lower abdominal surgeries. In our study, the mean duration of analgesia was 412.34±40.50 mins in Group R,while in Group RD, the mean duration of analgesia was 624.72 ±60.28 mins, which was significantly longer in Group RD as compared to Group R, (p<0.05).In similar study conducted by Jain K et al (2018)[7], Dexmedetomidine in a dose of 1 µg/kg with 0.25% Ropivacainewas used caudally, and the duration of postoperative analgesia was significantly longer in the group receiving Ropivacaine-Dexmedetomidine mixture than the

group receiving Ropivacaine alone. The results of our present study also supportwith the results of Kamal M et al(2016)[8], whoconcluded that addition of Dexmedetomidine (2 μg/kg) to caudal Ropivacaine 0.25% at 1 ml/kg significantly prolonged analgesia after anesthetic recovery in children, undergoing lower abdominal surgeries without increasing the incidence of side effects.

In the present study, the patients in Group RD achieved higher sedation scores than in Group R, which was highly significant ($p<0.05$). Similarly,Anand VG et al (2011)[9]also concluded thatCaudal Dexmedetomidine (2 μg/kg) with 0.25% Ropivacaine (1 ml/kg) for pediatric lower abdominal surgeries achieved significant postoperative pain relief that resulted in a better quality of sleep and a prolonged duration of arousable sedation and produced less incidence of emergence agitation following sevofluraneanaesthesia.

In our study, if the FLACC pain score was ≥4, the syrup paracetamol (15mg/kg) was given as a rescue analgesic in the post-operative period. Patients in Group R required a greater number of doses of rescue analgesic as compared with Group RD, which was highly significant($p<0.05$). Gupta S et al (2017)[10]also concluded that caudal Ropivacaine 0.25% with Dexmedetomidine 2 μg/kg provided longer duration of analgesia and reduced requirement for rescue analgesic in the post-operative period compared to caudal Ropivacaine 0.25% with tramadol 2 mg/kg. Thus,Dexmedetomidine with Ropivacaine can be used as an alternative to tramadol with Ropivacaine for paediatric infraumbilical surgeries through the caudal route as a safe and effective agent.Mavuri G et al(2017)[11] concluded that addition of Clonidine (1 μg/kg) and Dexmedetomidine (1 μg/kg) to 0.2% caudal Ropivacaine significantly prolongs the duration of analgesia without an increase in the incidence of adverse effects. They found that the longest duration of analgesia with Dexmedetomidine when compared to the other groups. The addition of Clonidine and Dexmedetomidine also caused statistically significant sedation.

LIMITATIONS:

Our study has been limited by a small sample derived from a single institution. Other limitations of our studyare, as for alladditives in regional anaesthesia, the analgesic roleof Dexmedetomidinethrough systemicabsorption cannot be completely excluded from ourstudy design. Hence, comparing the potential localeffects to a systemic administration particularly whenadditives are used is difficult since we did not havea control group with IV Dexmedetomidine.Ultrasound guidance for caudalblock administration should be considered in caseswhere the detection of sacral anatomy is difficult,especially by palpation.The study could notstabilize the severity of surgical trauma which may lead to variability in pain severity.

CONCLUSION:

The addition of Dexmedetomidine (1μg/kg) to caudal Ropivacaine 0.25% at 1 mL/kg significantly prolonged postoperative analgesia in children undergoing infra-umbilical surgeries without notable side effects.Hence Dexmedetomidine may be used as a safe and effective adjuvant for caudal analgesia in paediatric patients.

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