Evaluation of Caudal Dexamethasone as an Adjuvant for Ropivacaine 0.15% For Post-Operative Analgesia in Children Undergoing Elective Infra Umbilical Surgeries Under General Anesthesia: A Prospective Randomized Controlled Study

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Abstract:

Background and Aims: Caudal analgesia is one of the most popular regional blocks in pediatric patients undergoing infra-umbilical surgeries but with the drawback of short duration of action after single shot local anaesthetic injection, we evaluated the efficacy of dexamethasone 0.1mg/kg when combined with 0.15% ropivacaine for caudal analgesia.

Methods: Totally 60 patients of 1–5 years age group, American Society of Anesthesiologists physical status I and II undergoing elective infra umbilical surgeries were randomly allocated to two groups in double-blind manner. Group R received 1 ml/kg of 0.15% ropivacaine caudally and Group D received 1 ml/kg of 0.15% ropivacaine, in which 0.1 mg/kg dexamethasone was added for caudal analgesia. Post-

operative pain by faces, legs, activity, cry and CONSOL ability, tool score, rescue analgesic requirement and adverse effects were noted for 24h. **Results:** Results were statistically analyzed using Student's *t*-test. Pain scores measured at 1, 2, 4, and 6 h (for 24hrs) post-operative, were lower in Group D as compared to Group R. Mean duration of analgesia in Group R was 234.17 ± 61.37 min and in Group D was 447.13 ± 96.26 min with $P < 0.0001$. Rescue analgesic requirement was more in Group R as compared to Group D (p=0.001). Adverse effects after surgery were comparable between the two groups.

Conclusion: Caudal dexamethasone added to ropivacaine is a good alternative to prolong post-operative analgesia with less pain score compared to caudal ropivacaine alone.

Key words: Caudal block, dexamethasone, infra-umbilical surgeries, ropivacaine.

Introduction :

The alleviation of pain has been the focus of continuing human effort over centuries. Pain is a protective mechanism designed to alert the body to potentially injurious stimuli. The International Association for Study of Pain (IASP) defines pain as an "unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[1]

However, it has been recognized for some time that the management of acute pain, especially post-operative pain, has been consistently and systematically inadequate. Children are special in this regard as this complex phenomenon and the importance of pain relief is often underestimated in them.

Considering the facts that biology of pain, development of pain perception in infancy, assessment of pain, behavioral and psychological aspects of pain and pharmacology of analgesics are unique to this age group, the approach to a pediatric patient and the modalities to reduce pain should also be specialized. Under treatment of post-operative pain may trigger biochemical and physiologic stress response and cause impairments in pulmonary, cardiovascular, neuroendocrine, gastrointestinal, immunological, and metabolic function seven in the children and newborns.[2]

Assessment of pain is the most important and critical component of pain management. Assessing pain in children is a difficult task, mainly because so far no single reliable method of assessing and measuring child's pain is available.[3] Regional an aesthetic techniques decrease

the requirement of inhaled an aesthetics, opioids, attenuate the stress response to surgery, facilitate smooth recovery and provide good immediate postoperative analgesia with less systemic analgesic requirements.[4]

Caudal analgesia is a safe and reliable technique, easy to perform and has been found to be very effective in children, especially in infra-umbilical surgeries when combined with general anaesthesia.[5] It is one of the most popular, reliable and safe techniques in pediatric anesthesia that can be used for intra and postoperative analgesia. It is a relatively simple technique with a good success rate.[4]

The main disadvantage of caudal analgesia is the duration of action after a single injection which is limited by the duration of action of the local anesthetics used. Placement of a catheter has an inherent risk of infection.[6] Prolongation of caudal analgesia using a single-shot technique has been achieved by the addition of various adjuvants such as opioids, ketamine, neostigmine, midazolam and α2 agonists. Many of these adjuvants have side effects like respiratory depression, vomiting, pruritus etc.[7]

Recent research has focused on the addition of the glucocorticoid dexamethasone as an adjuvant to local anesthetics in regional anesthesia.[8] Although the exact mechanism of action is unknown, preliminary studies suggest its addition can impressively prolong the duration of analgesia with minimal adverse effects. Hence the present study is to find out the lower volume (1ml/kg) and lower concentration (0.15%) of ropivacaine along with dexamethasone in prolonging the post-operative analgesia in children undergoing infraumbilical surgeries.

Materials and Methods:

The present Randomized Control trail was conducted at Department of Anesthesia, JSS Medical College and Hospital, Mysuru from November 2015 to April 2017. Based on a previous study done by Santhi sree et al[9] and using the standard formula the minimum number of patients in each group was 25 considering the number of dropouts a sample size of 30 patients in each group was selected 60 children aged between 1 year to 5 years of age undergoing elective infraumbilical surgeries under general anesthesia were enrolled for the study

INCLUSION CRITERIA:

1. Age 1 year to 5 years
2. ASA PS I &II
3. Children scheduled for elective infraumbilical surgeries

EXCLUSION CRITERIA

1. All contraindications for caudal analgesia like:

a. Infection at the site of caudal injection

b. Any sacral bone abnormalities

c. Bleeding diathesis

2. Parental refusal to give consent

3. Allergy to local anaesthetics/dexamethasone

Methodology

60 children between the age group 1-5 years of ASA-PS I & II posted for elective infraumbilical surgeries were randomly grouped into two equal groups using shuffled sealed opaque envelope technique. Pre anesthetic evaluation was done and informed consent was obtained from the parents after explaining about the procedure and the drugs being used. The two groups were Group R (control group) and Group D (study group). Group R received 1 ml/kg of 0.15% ropivacaine with normal saline (1ml) and Group D received 1 ml/kg of 0.15% ropivacaine with dexamethasone 0.1 mg/kg in saline to make a total volume 1ml in the caudal epidural space.

All the children were premeditated with syrup midazolam 0.5mg/kg 1hr before surgery, the patients were then shifted to the operation room. Routine preinduction monitors were instituted which included pulse oximetry, electrocardiogram and noninvasive blood pressure monitoring. The baseline values were recorded and documented. Venous access (I. V) would have been secured by the pediatric surgeon in the ward which is routinely done in our hospital. Anesthesia was induced with injection thiopentone 5 mg/kg and intubation aided by administering injection atracurium besylate 0.5mg/kg after ensuring adequate chest rise with mask ventilation. Endotracheal (ET) intubation was done as per standard protocol of our hospital with appropriate size ET tube, position confirmed and ET tube secured in place, Anesthesia was maintained with 33% O_2: 67% N_2O mixture and sevoflurane 1-2%.

The recorded parameters were documented every 5 minutes intra operatively till awakening. The duration of surgery was noted down. Neuromuscular blocking drugs blockade was reversed with neostigmine (0.05 mg/kg) and glycopyrollate (0.01 mg/kg). After extubation, pain score was assessed using FLACC scale. Patients were then shifted to PACU. The heart rate, pulse oximetry, noninvasive blood pressure monitoring and pain score were monitored in the PACU and documented

at intervals of 0, 15, 30, 60, 90, 120, 150, 180 minutes.

Statistical analysis was done using the Statistical Package for Social Science (SPSS20.0 Evaluation version). Data are expressed as either mean and standard deviation or numbers and percentages. Continuous covariates were compared using analysis of variance (ANOVA). The comparison was studied using the Chi-square test or Fisher's exact test or Independent T-test as appropriate, with the P value reported at the 95% confidence interval, $P<0.05$ was considered statistically significant and $P<0.001$ was considered highly significant.

Results:

A total of 30 study subjects were enrolled in each group for the purpose of the study. The two groups were Group R (control group) and Group D (study group). Group R received 1 ml/kg of 0.15% ropivacaine with normal saline (1ml) and Group D received 1 ml/kg of 0.15% ropivacaine with dexamethasone 0.1 mg/kg in saline to make a total volume 1ml in the caudal epidural space.

The mean age of the two groups were compared using T tests and found to be insignificant with a p value of 0.20. Group R and D had a mean age of 3.2 and 2.8 years respectively The sex distribution between 2 groups were compared using Pearson Chi square test. There was no significant difference between the 2 groups with a p value of 0.16. The mean weight in Group R was 11.2 kgs, and in Group D was 12.2 kgs

The duration of surgery between 2 groups were compared using T test. The mean duration of surgery in group R was 22.90 minutes and group D 22.17 minutes with a p value of 0.6 which was not significant. The mean duration of analgesia between 2 groups were compared using Independent T test. The mean duration of analgesia was 234.17 ± 61.37 mins in Group R and 447.13 ± 96.26 mins in Group D with a p value <0.0001 which was highly significant. The number of rescue analgesics required by patients receiving only ropivacaine in their caudal block was compared to in patients receiving dexamethasone as adjuvant with ropivacaine and was found to be statistically highly significant with a p value of 0.001.

The mean pain scores at different time intervals in between 2 groups were compared using Independent t test and was found to be statistically highly significant with a p value of <0.0001.

Table 1: Social Profile of the study subject

		Group		P value
		R	D	
Mean Age in years		3.2±1.4	2.8±1.3	0.2
Gender	Male	23	27	0.16
	Female	7	3	
Mean weight in kg		11.2±.2.8	12.2±3.1	0.2

Table 2: Profile of Surgery Performed among subjects in both the groups

		Group				
		R		D		
		Count	Column N %	Count	Column N %	
SURGERY	HERNIOTOMY	13	43.3	11	36.6	
	ORCHIDOPEXY	10	33.3	11	36.6	
	CIRCUMCISION	7	23.3	8	26.7	
Mean Duration of Surgery (minutes)		22.90±4.67		22.17±5.97		0.6
Mean duration of Analgesia **(minutes)**		234.17±61.37		447.13±96.26		<0.0001
Number of rescue analgesics	0	0 (0%)		3 (10%)		0.001
	1	8 (26.7%)		18 (60%)		
	2	15 (50%)		9 (30%)		
	3	7 (23.3%)		0(0%)		

Table 3:– **Mean pain scores at different time intervals in the two groups**

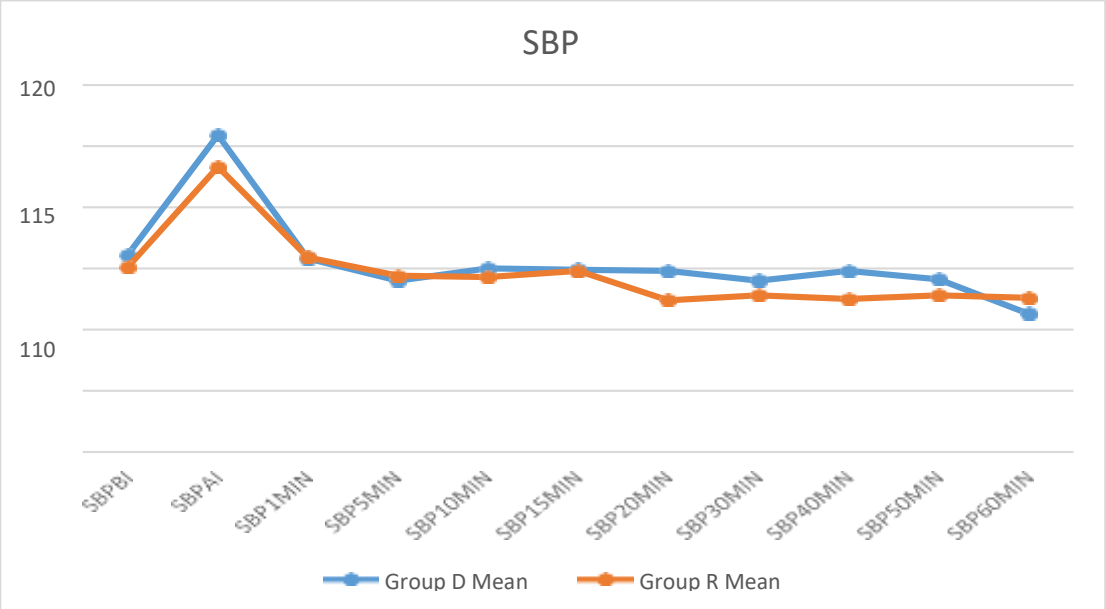
	Group				P value
	D		**R**		
	Mean	**SD**	**Mean**	**SD**	
FLACC PAIN SCORE At 0 Min	.0	.0	.0	.0	-
FLACC PAINSCORE 30min	.0	.0	.0	.2	-
FLACC PAINSCORE 1hr	.0	.0	1.0	.7	-
FLACC PAINSCORE 2hr	.5	.5	1.7	.7	<0.001
FLACC PAINSCORE 3hr	1.1	.7	2.7	1.0	<0.001
FLACC PAINSCORE 4hr	1.7	.7	1.7	1.6	<0.001
FLACC PAINSCORE 6hr	2.1	.9	1.1	1.6	<0.001
FLACC PAINSCORE 7hr	1.8	1.4	.8	1.0	<0.001
FLACC PAINSCORE 9hr	1.4	1.7	1.7	1.1	<0.001
FLACC PAINSCORE 12hr	.8	1.3	1.6	1.2	<0.001
FLACC PAINSCORE 15hr	.6	1.0	1.4	1.0	<0.001
FLACC PAINSCORE 20hr	.8	.9	1.4	.9	<0.001
FLACC PAINSCORE 24hr	.8	.8	1.6	.9	<0.001

No significant variation was noticed in either of the groups with respect to heart rate. The p values at all the various time intervals was >0.05.There is no significant statistical difference between the systolic blood pressure between the two groups. There is no difference which is statistically significant between the diastolic blood pressures of the two groups.

Table 4- Heart Rates at different time intervals in the two groups

	Group				
	D		R		
	Mean	SD	Mean	SD	
HRBI	124.0	11.7	125.7	14.8	> 0.05
HRAI	137.0	11.9	137.9	13.3	> 0.05
HR1MIN	133.0	13.8	133.9	14.2	> 0.05
HR5MIN	130.2	12.9	132.7	14.4	> 0.05
HR10MIN	129.2	12.0	129.7	14.1	> 0.05
HR15MIN	127.7	12.8	129.5	13.3	> 0.05
HR20MIN	127.4	12.1	128.2	13.7	> 0.05
HR30MIN	126.2	12.3	126.7	13.8	> 0.05
HR40MIN	124.9	12.0	125.7	12.7	> 0.05
HR50MIN	124.2	11.7	125.3	11.4	> 0.05
HR60MIN	121.8	15.7	122.4	15.5	> 0.05

Figure 1- Systolic blood pressure variation at different time intervals in the two groups



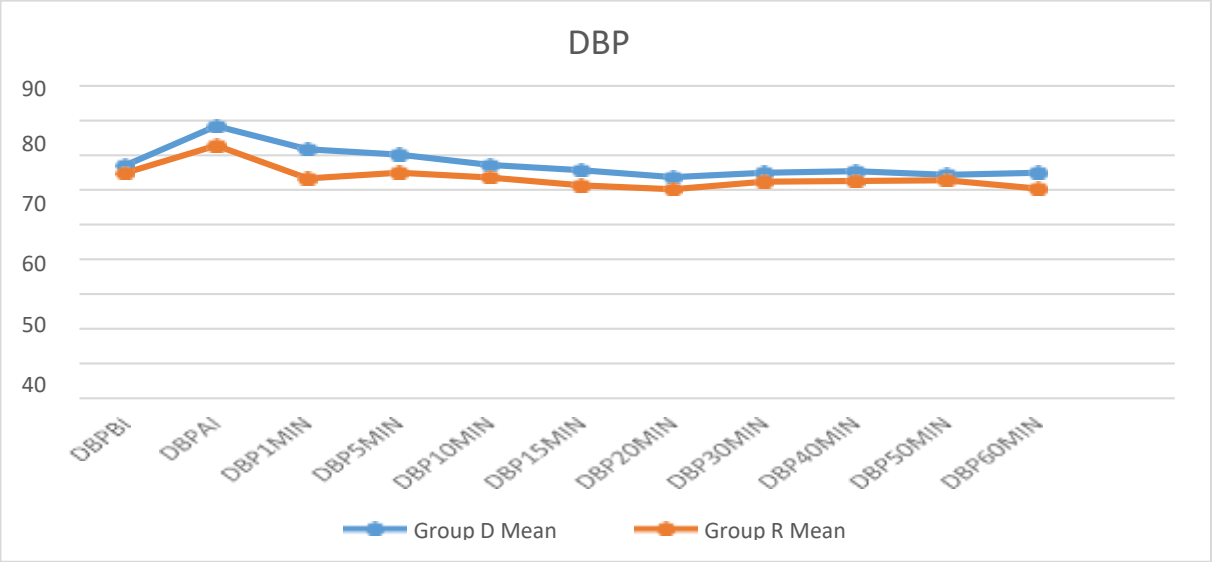


Figure 2– Diastolic pressure variation at different time intervals in the two groups

Discussion:

Since even long acting local anesthetics like ropivacaine have a limited duration of analgesia of about 4-6 hours, several adjuvants have been used to prolong the duration of analgesia of caudal block. Extended duration of analgesia can be achieved by using caudal additives, however an ideal agent is still not available, alpha-2 agonists, ketamine and midazolam are some of the commonly used drugs as additives.[10,11,12] In a previous study regarding the analgesic effect of epidural dexamethasone in adults which showed that effective analgesia was provided by 5 mg of epidural dexamethasone but not 5mg of i.v. dexamethasone in patients undergoing laparoscopic cholecystectomy, which implied that epidural dexamethasone has greater analgesic efficacy than i.v. dexamethasone at the same dose.[13,14]

In our study, patients in Group R who received caudal block with 0.15% ropivacaine alone had a mean duration of analgesia was 234.17 ± 61.37 mins. The minimum duration of analgesia was 120 minutes and the maximum duration of analgesia observed was 960 minutes.

Patients in Group D received 0.15% ropivacaine with 0.1mg/kg dexamethasone had a mean duration of analgesia of 447.13 ± 96.26 mins. The minimum duration of analgesia was 300 minutes and maximum was 24 hours, beyond which monitoring was not done.

In a study by Kim Lee et al, [15] the

number of subjects who remained pain free up to 48 h after operation was significantly greater in the group who received Dexamethasone (0.1 mg/kg) in caudal block [19 of 38 (50%)] as compared to patients in the control group who received 0.15% ropivacaine alone four of 37 (10.8%); P<0.001. Time to first oral analgesic administration after surgery was also significantly longer in Group D than in Group C (P=0.014).

Girgis et al demonstrated the analgesic efficacy of dexamethasone (0.2 mg/kg) added to bupivacaine (1ml/kg 0.25%) in caudal blocks. The duration of analgesia was11.2 ± 3.5hrs with dexamethasone vs. 7.1 ± 3.2 hrs with plain bupivacaine. (P<0.001, statistically significant).[16]

Yousef et al observed that addition of magnesium or dexamethasone to caudal ropivacaine significantly prolonged analgesia duration to 8 hours (5-11hours) and 12hours (8-16 hours), respectively compared with 4 hours (3-5 hours) with the use of ropivacaine alone. The time to first analgesic dose was significantly longer in groups with Magnesium and Dexamethasone (500 ± 190 and 730 ± 260 min) respectively compared with Ropivacaine alone (260 ± 65 min).[17]

In a study by Naghipouretal, the duration of analgesia was significantly longer in the group receiving dexamethasone in the epidural space (372±58.1) than with plain bupivacaine (234.6 ±24.3min).[18] Overall, the mean pain scores were found to be lower in subjects who received dexamethasone as a caudal additive as compared to patients who received local anesthetic alone. Naghipour et al showed in their study that pain score and rescue analgesia use wereless in the Dexamethasone group than the control group (37.1+/-19.7mg v.s.73.1+/- 17.6 mg, respectively; p=0.001).[18]

In a study by Kim Lee et al, the number of subjects who received oral analgesic was significantly lower in Group D (28.9%) than in Group C (54.1%) P=0.027.[15] Dexamethasone with local anaesthetic has been shown to prolong peripheral nerve block in animals and humans. It has been found to be superior than other adjuvants in terms of duration of analgesia, requirement of rescue analgesia, and lesser motor block.

There was no significant decrease in heart rate and blood pressure from the base line with the use of dexamethasone with ropivacaine in caudal epidural analgesia, and all patients maintained hemodynamic stability with no episodes of hypotension or bradycardia being

reported in our study.

Conclusion:

In our study, we compared the analgesic efficacy of dexamethasone (0.1mg/kg) added to 0.15% ropivacaine as compared to plain ropivacaine for caudal block in children undergoing infraumbilical surgeries. From our study it is concluded that adding dexamethasone to ropivacaine (0.15%) for caudal block resulted in longer duration of analgesia, lesser requirement of rescue analgesics and without any significant side effects.

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