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DEXAMETHASONE AS AN ADJUVANT TO CAUDAL ROPIVACAINE FOR POSTOPERATIVE ANALGESIA IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERIES

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ABSTRACT

Introduction: Caudal analgesia is one of the most popular regional blocks in paediatric patients undergoing infra-umbilical surgeries but with the drawback of short duration of action after single shot local anaesthetic injection. **Aims & Objectives:** We evaluated whether caudal Dexamethasone 0.1 mg/kg as an adjuvant to the Ropivacaine improved analgesic efficacy after paediatric infraumbilical surgeries. **Material & Methods:** This Prospective, randomized, double-blind study was conducted in the department of Anaesthesiology and Critical Care SKIMS Srinagar, J&K over a period of two years from june 2013 to june 2015 following approval from institutional ethical committee and written informed parental consent. The Sample size of 100 patients of 1–8 years age group, belonging to American Society of Anaesthesiologists (ASA) physical status I and II undergoing elective infraumbilical surgeries were randomly allocated into two groups in double-blind manner. Group A (control group, n =50) received 1 ml/kg of 0.2% ropivacaine caudally and Group B (study group, n = 50) received 1 ml/kg of 0.2% Ropivacaine, in which 0.1 mg/kg Dexamethasone was added for caudal analgesia. Post operative pain score, rescue analgesic requirement and adverse effects were noted for 24 hours. **Results:** Postoperative Pain scores by using Faces, Legs, Activity, Cry, and Consolability tool (FLACC & CHEOPS) measured at 0 minute, 30 minutes, 1, 2, and 3 hours post- surgery, were significantly lower in Group B (study group) as compared to Group A (control). Furthermore, the number of subjects who remained pain free up to 24 hours after operation was significantly greater in Group B (study group) than in Group A. Rescue analgesic requirement was less in Group B (Study group) as compared to Group A. The number of subjects who received oral analgesic was significantly lower in Group B (Study group), [12 out of 50 patients, than in Group A [26 of 50 patients], with significant P value = 0.004]. Mean time to first rescue analgesic administration after surgery was also significantly longer in Group B than in Group A, (10.17 ± 2.29 hours Vs 6.58 ± 1.63 hours with Significant P value of < 0.001. Adverse effects after surgery includes nausea and vomiting 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.

KEYWORDS: Caudal block, Dexamethasone, infraumbilical surgeries, Ropivacaine.

INTRODUCTION

Caudal block is the most popular and commonly used regional anaesthetic technique in children with a high success rate, for surgeries below the level of the umbilicus.[1] It reduces the requirement of inhaled and intravenous (IV) anaesthetic agents, attenuates the stress response to surgery, facilitates a rapid and smooth recovery and provides satisfactory post-operative analgesia[2] but with the limitation of relatively short duration of analgesia with single shot technique.[3] Use of caudal catheter for continuous infusion is usually not preferred due to high risk of catheter contamination from faecal soiling. To overcome this limitation, several adjuvants are added to local anaesthetic agent in a single shot technique.

Opioids, alpha 2 agonists and ketamine have been studied with local anaesthetics to increase the efficacy of caudal analgesia but are associated with adverse effects such as nausea, vomiting, pruritus, urinary retention and respiratory depression (in case of caudal opioids), hypotension, bradycardia (with caudal alpha 2 agonists) and more sedation with ketamine.[4,5,6,7] Among local anaesthetics, ropivacaine provides a greater margin of

safety, less motor blockade, less neurological and cardiac toxicity and similar duration of analgesia in comparison to bupivacaine.[8] Corticosteroids have a strong anti-inflammatory action[9] and have been used via epidural, intrathecal, caudal and perineural routes in adults for prolonging post-operative analgesia. This prospective double- blind study was designed to investigate whether dexamethasone as an adjuvant to 0.2% ropivacaine enhances the analgesic potency in paediatric herniotomies performed under caudal block.

MATERIAL AND METHODS

This Prospective, randomized, double-blind study was conducted in the department of Anaesthesiology and Critical Care Sher-I-Kashmir Institute of Medical Sciences, Srinagar, from june 2013 to june 2015 following institutional ethical committee approval and a written informed parental consent. The Sample size of 100 patients of 1–8 years age group, belonging to American Society of Anaesthesiologists (ASA) physical status I and II undergoing elective infraumbilical surgeries were included in the study. Patients having bleeding diathesis, Infection at puncture sites, Preexisting neurological disease, Diabetes mellitus)., allergy to ropivacaine or any other drug to be used were excluded from this study.

The patients selected for the study were kept fasting on solids and milk for 6 hours and clear liquids were allowed for up to 4 hours preoperatively. Patients were induced with standard doses of propofol (2 to 4 mg/Kg), or with inhaled halothane (up to 2 to 3%) with oxygen and nitrous oxide as inhalational agents. After induction of general anesthesia, caudal block was applied. The patients selected for the study were randomized into two groups (50 each) using a table of random numbers. After completion of the study, data was analyzed statistically using the student t- test, Mann Whitney U-test, π^2-test and Repeated Measurement Analysis to detect differences between two groups. A P value of <0.05 was considered statistically significant.

Group A (Control group):- Comprising of 50 patients who received normal saline 0.02mL/Kg added to ropivacaine 0.2% 1.0ml/kg.

Group B (Study group):- Comprising of 50 patients who received Dexamethasone 0.1mg/kg added to ropivacaine 0.2%, 1.0 ml/kg.

Anaesthesia was maintained by the same inhalational agents administered via laryngeal mask airway or the endotracheal tube. Muscle relaxation if necessary, was achieved by the use of Atracurium in a dose of 0.5mg/kg for insertion of LMA or endotracheal tube. The patients were monitored for heart rate, ECG and pulse oximetry during the operative procedure. Failure of caudal was diagnosed as an increase in baseline variables of heart rate and blood pressure by more than 20%. These patients received supplemental opioids for Intraoperative analgesia and were excluded from the study.

Postoperative pain was recorded at emergence, 30 min and 1, 2, and 3 hours by using Faces, Legs, Activity, Cry, Consolability tool, (FLACC)[10] and CHEOPS.[11] Postoperative pain was treated with rectal or oral paracetamol (30 mg per Kg as first dose and 20 mg per Kg for subsequent doses to a total dose of 90 mg per Kg per day). Participants were followed for the duration of hospital stay (typically 24 hours in our setting). Time to first analgesic administered after surgery was recorded and total analgesic consumption during the first 24 hours was recorded and compared between the two groups. Other adverse events such as nausea, vomiting, respiratory depression, bradycardia, hypotension, were also observed.

Table 1: The FLACC is a behavior pain assessment scale for use in patients unable to provide reports of pain.

FLACC SCALE (10) **(FACE, LEGS, ACTIVITY, CRY, CONSOLABILITY)**			
CATEGORIES	**Score**		
	0	**1**	**2**
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position Or relaxed	Uneasy, Restless, Tense	Kicking, Or Legs drawn up
Activity	Lying quietly Normal position Moves easily	Squirming Shifting back/forth Tense	Arched Rigid Or Jerking
Cry	No Cry (Awake or Asleep)	Moans or Whimpers Occasional Complaint	Crying Steadily Screams or Sobs Frequent Complaints
Consolability	Content, Relaxed	Reassured by occasional touching, hugging, or 'talking to.' Distractible	Difficult to console or comfort.

0 - Relaxed and comfortable , **1–3** - Mild discomfort , **4–6** - Moderate pain , **7–10** – Severe discomfort or pain or both.

CHEOPS (Children Hospital of eastern Ontario pain scale)

MODIFIED CHEOPS (11)

Observed Behavior	Score
Facial expression	
Positive (smiling)	0
Neutral	1
Negative (grimace)	2
Cry	
Laughing or giggling	0
Not crying	1
Moaning	2
Full-lunged cry or sobbing	3
Child verbal	
Positive	0
None/other complaints	1
Pain complaints	2
Movements	
Usual activities (relaxed)	0
Neutral, not moving, or rigid	1
Attempt to withdraw	2
Complex agitation (full body)	3
Restrained	3

Interpretation: Minimum score: 0, Maximum score : 10

OBSERVATIONS AND RESULTS

The result of this study shows the difference in age, weight, duration of surgery, mean heart rate, mean oxygen saturation, systolic BP and diastolic BP was statistically insignificant [Table 1-6]. A statistically significant difference ($p < 0.001$) was observed in CHEOPS pain scores between the two groups at 0 minutes, 30 minutes, 60 minutes, 120 minutes and 180 minutes, pain scores being less in study group compared to control group [Table 7]. A statistically significant difference ($p<0.001$) was observed in FLACC pain scores between the two groups at 0 minutes, 30 minutes, 60 minutes, 120 minutes and 180 minutes, pain scores being less in study group compared to control group [Figure 8]. In our study the mean time to First acetaminophen was 10.17±2.29 hours in the study group while it was 6.58±1.63 hours in control group. Statistically a significant difference ($p<0.001$) was observed in both the groups [Table 9].

Table 1: Comparison of mean age between study and control group.

Age (Years)	No.	Mean	SD	P-value	Remarks
Study Group	50	4.10	1.49	0.411	NS
Control Group	50	3.88	1.15		

Table 2: Comparison of mean weight between study and control group.

Weight (Kgs)	No.	Mean	SD	P-value	Remarks
Study Group	50	15.82	4.63	0.497	NS
Control Group	50	15.30	2.77		

Table 3: Comparison of duration of surgery between study and control group.

Duration of Surgery (Minutes)	No.	Mean	SD	P-value	Remarks
Study Group	50	58.8	4.55	0.386	NS
Control Group	50	59.6	4.16		

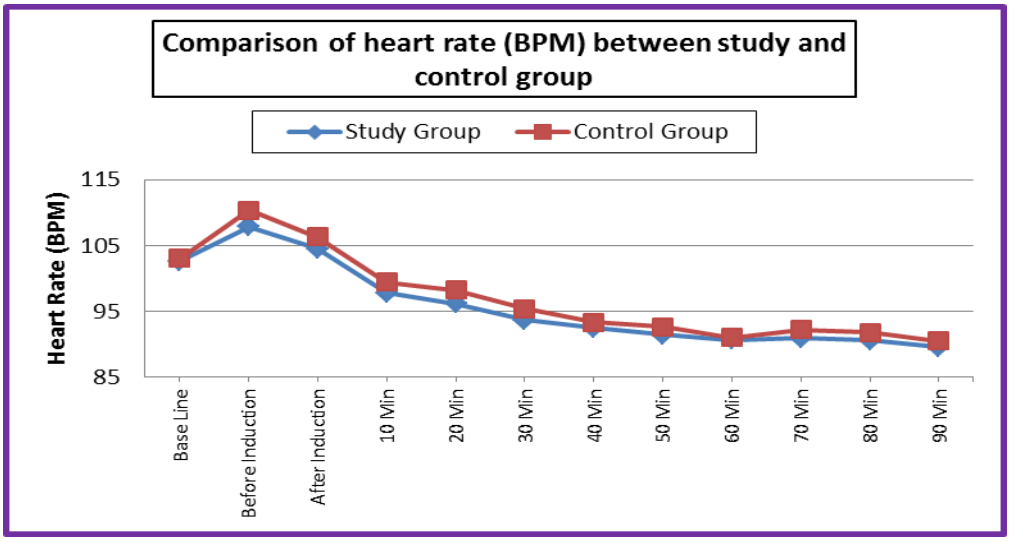

Figure 4: Line diagram showing comparison of mean heart rates (beats/min) between the two groups.

The difference in mean heart rates between the two groups was statistically insignificant ($p > 0.05$).

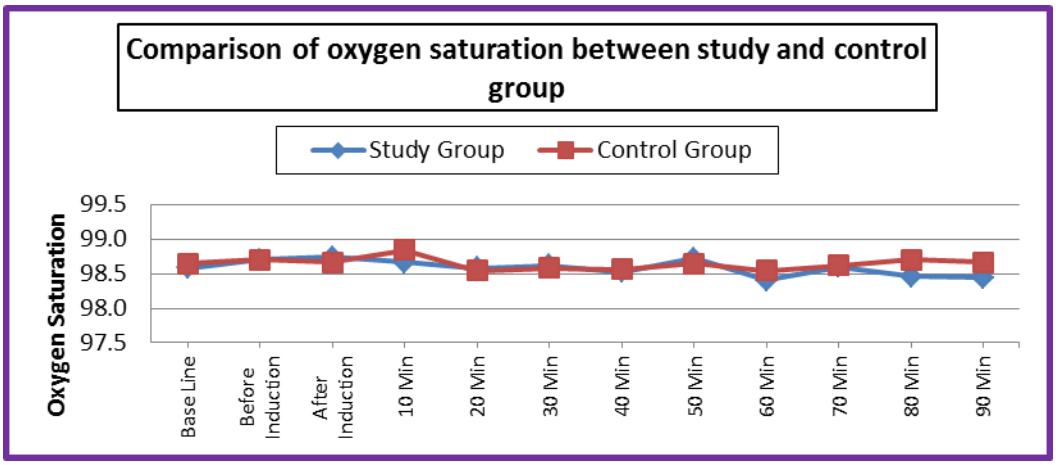

Figure 5: Line diagram showing comparison of mean Oxygen saturation (SpO_2%) in study and control group.

There was no Significant difference in mean Oxygen saturations at various times between the two groups intraoperatively ($P > 0.05$).

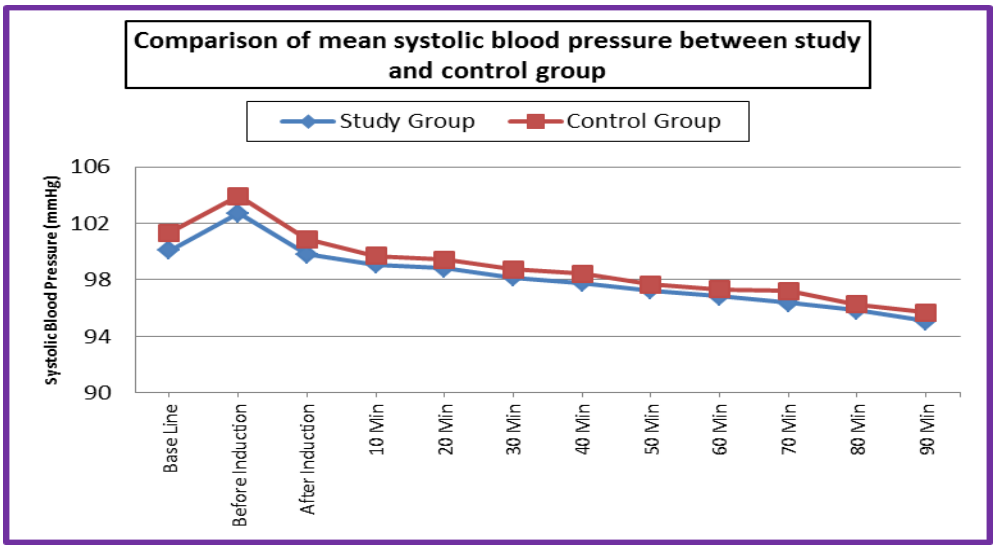

Figure 6: Line diagram showing comparison of systolic blood pressures between the two groups intraoperatively.

The difference between the two groups was statistically insignificant ($p>0.05$).

Table 7: Showing comparison of mean CHEOPS scores between the study and control group at various times postoperatively in PACU.

Table 8: Comparison of mean CHEOPS score between study and control group.						
Time Interval	Study Group		Control Group		P-value	Remarks
	Mean	SD	Mean	SD		
0 Min	1.16	0.65	1.68	0.74	<0.001	Sig.
30 Min	1.98	0.79	2.34	0.63	0.014	Sig.
60 Min	1.88	1.00	2.52	0.79	<0.001	Sig.
120 Min	1.22	0.42	2.08	0.49	<0.001	Sig.
180 Min	0.96	0.35	1.48	0.65	<0.001	Sig.
Overall	1.45	0.51	2.02	0.49	<0.001	Sig.

There was a statistically significant difference in mean CHEOPS scores between the two groups, postoperatively in PACU at all times ($p < 0.05$), scores being less in study group compared to control group.

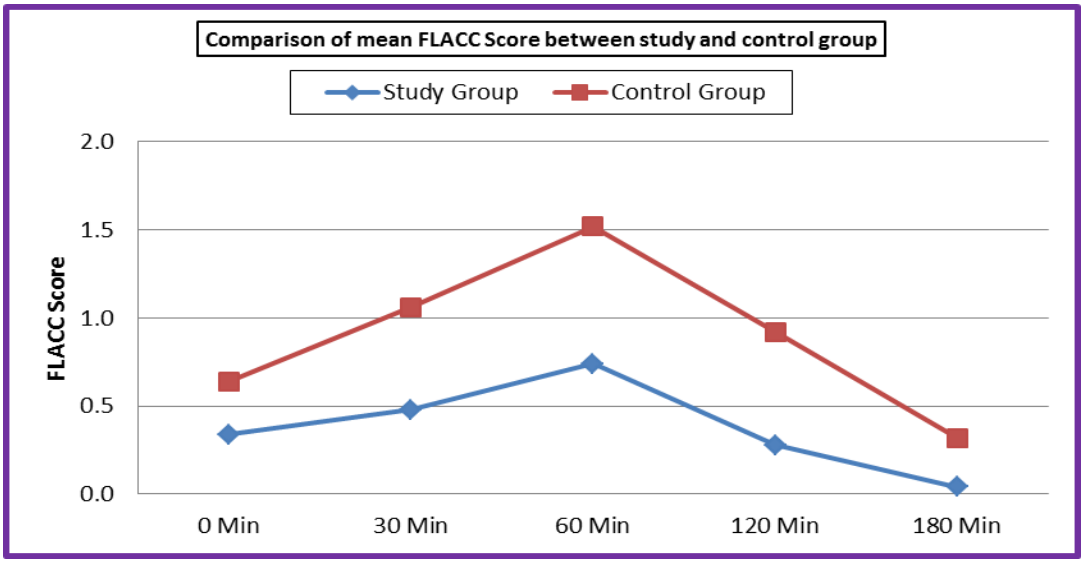

Figure 8: Line diagram showing comparison of mean FLACC scores between the two groups.

The difference between the two groups was statistically significant ($p<0.05$).

Table 9: Time to first rescue analgesia.					
	Study Group		Control Group		P-value
	Mean	SD	Mean	SD	
Time to first rescue analgesia (Hours)	10.17	2.29	6.58	1.63	<0.001 (Sig.)

Table 10: Comparison of number of subjects who received analgesia in study and control group.					
Analgesia Received	Study Group		Control Group		P-value
	No.	%age	No.	%age	
Yes	12	24	26	52	0.004 (Sig.)
No	38	76	24	48	
Total	50	100	50	100	

Table 11: Comparison of number of doses received in two groups.					
No. of Doses	Study Group		Control Group		P-value
	No.	%age	No.	%age	
0	38	76	24	48	0.006 (Sig.)
1	10	20	15	30	
2	2	4	5	10	
3	0	0	3	6	
≥4	0	0	3	6	
Total	50	100	50	100	

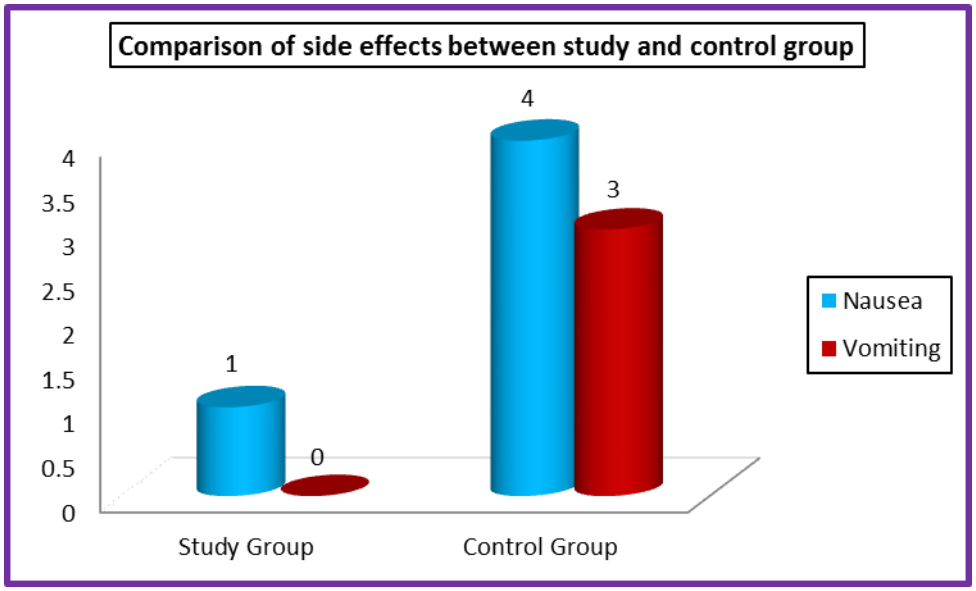

Figure 12: Showing comparison of side effects between the two groups.

The difference was statistically insignificant between the two groups ($p>0.05$).

DISCUSSION

Our Observations correlate with with a study conducted in 2012 from Severance Hospital, Yonsie University, Korea with Eun Mi Kim being its Principal Investigator. They have compared Dexamethasone 0.1 mg per kilogram (Kg) of body weight added to 0.15% Ropivacaine 1.5 ml per Kg to Ropivacaine 0.15% alone in single shot caudal anaesthesia in infraumbilical surgery in children aged 6 months to 6 years. The results of this study have found that pain score in patients who received caudal dexamethasone with ropivicaine were significantly low ($p<0.001$) as compared to patients who received caudal ropivicaine alone and time to first request for analgesia was significantly longer in study group than control group.[12]

Our results are also similar to results of Ahmed Abdalla Mohammad et al. (2012) who in their study to cauda "Dexamethasone as adjuvant l ropivacaine as analgesic for labour pain" evaluated the analgesic yield of dexamethasone (DEX) as adjuvant to caudal ropivacaine (ROP) for labor pain. DEX group patients experienced significantly earlier onset of analgesia in association with significantly prolonged duration of analgesia and postpartum perineal pain scores were also significantly lower in DEX group.[13]

Our results are also similar to results of Bayazit Dikmen et al. (2005) in their study "Dexamathasone: Can it be an analgesic after lumbar laminectomy?" evaluated the effects of epidural dexamethasone as an analgesic agent for postoperative analgesia after lumbar laminectomy. 31 patients were allocated to two groups receiving either 2mg morphine or 8mg dexamethasone epidurally. It was found that the total analgesic consumption over 48 hours was lower in patients receiving dexamethasone.[14]

Our observations correlate with Siji Thomas et al. (2006) who in their study *"Epidural dexamethasone reduces postoperative pain and analgesic requirements*" evaluated the efficacy of epidurally administered dexamethasone in reducing postoperative morphine requirements as a measure of analgesia following laproscopic cholecystectomy. They found that total morphine consumption for the first 24 hours following surgery was lower in dexamethasone group compared to the control group, being reduced to 53%.[15]

Our observations are also consistent with the observations of Zekiye Bigat et al. (2006) who in their study "*Does dexamethasone improve the quality of intravenous regional anaesthesia and analgesia*" concluded that the addition of dexamethasone to lidocaine for intravenous regional anaesthesia improves postoperative analgesia during the first postoperative day.[16]

Our observations also correlate with Chun C. et al. (2007) who in their study "*Dexamethasone prolongs the effective duration of ropivacaine for sciatic nerve blockade in total knee arthroplasty"* evaluated the effectiveness of local and systemic use of dexamethasone in prolonging the effective duration of sciatic nerve blocks. The results showed that the addition of dexamethasone, directly to the nerve block, or given intravenously, prolonged the duration of ropivacaine induced sciatic nerve blockade.[17]

Our observations also correlate with K.C. Cummings et al. (2011) who in their study "*Effect of dexamethasone on the duration of interscalene nerve blocks with ropivacaine or bupivacaine*" studied the effect of dexamethasone as an adjunct to ropivacaine and bupivacaine in interscalene nerve blocks. The results revealed that dexamethasone prolonged analgesia from

interscalene blocks using ropivacaine or bupivacaine, with the effect being stronger with ropivacaine.[18]

Our observations also correlate with Youn Yi Jo et al. (2011) who in their study "*The effect of epidural administration of dexamethasone on postoperative pain: a randomized controlled study in radical subtotal gastrectomy*" found that the administration of 5 mg of dexamethasone epidurally, before or after operation, reduces the analgesic requirement after radical subtotal gastrectomy.

Our observations are consistent a study conducted in 2012 from Severance Hospital, Yonsie University, Korea with Eun Mi Kim being its Principal Investigator. They have compared Dexamethasone 0.1 mg per kilogram (Kg) of body weight added to 0.15% Ropivacaine 1.5 ml per Kg to Ropivacaine 0.15% alone in single shot caudal anaesthesia in infraumbilical surgery in children aged 6 months to 6 years. The result of this study shows that the incidence of side effects (nausea, vomiting, urinary retention) were statistically insignificant between study and control group.

Our observations also correlate with a study Hong et al. (2010) who in their study "*Effect of dexamethasone in combination with caudal analgesia on postoperative pain control in day-case paediatric orchidopexy*" studied the effects of a single i.v. dose of dexamethasone in combination with caudal block on postoperative analgesia in children. They found that the dexamethasone associated adverse effects were not noted with single i.v. dose of dexamethasone 0.5mg/kg and overall there were no significant differences in the incidence of adverse effects including vomiting (7.7% vs 10.5%), sedation (25.6% vs 31.6%), and shivering (2.6% vs 0%) between the study and control groups.[19]

Our observations also correlate with T.Bisgaard et al. (2003) in their study "*Preoperative Dexamethasone Improves Surgical Outcome After Laparoscopic Cholecystectomy*" determined the effects of preoperative dexamethasone on surgical outcome after laparoscopic cholecystectomy (LC). Their results showed that preoperative dexamethasone (8 mg) reduced fatigue, nausea and vomiting.[20]

SUMMARY AND CONCLUSION

1. Age and weight were comparable in both the groups.
2. There were no statistically significant differences in the intraoperative hemodynamic parameters (mean heart rate and mean blood pressure) and oxygen saturation by pulse oxymetry, at various time intervals amongst the two groups (P >0.05).
3. The pain scores CHEOPS and FLACC assessed postoperatively in PACU in study group were less as compared to control group. The differences were statistically significant ($p<0.05$).
4. The total number of patients who required rescue analgesia (oral acetaminophen) in ward was less in study group compared to control group and the difference was statistically significant ($p<0.05$). Comparison showed that adding a caudal dexamethasone decreased the overall requirement of rescue analgesia postoperatively.
5. The mean time to first rescue analgesia (oral acetaminophen) in study group was 10.17±2.29 hours compared to control group where it was 6.58±1.63 hours. Comparison between the two revealed that adding caudal dexamethasone to patients who received caudal block significantly increased the duration of analgesia compared to patients who received caudal block alone ($p<0.05$).
6. There was decreased incidence of complications like nausea and vomiting in the study group, but the inter group variation was statistically insignificant ($P>0.05$).

LIMITATIONS OF OUR STUDY

1. First, we cannot completely exclude the possibility that caudal dexamethasone exerts analgesic effects through systemic absorption because i.v. dexamethasone has been reported to have analgesic effects. The dose of caudal dexamethasone (0.1 mg/ kg) in our study was selected based on a previous study regarding the analgesic effect of epidural dexamethasone in adults. In the previous study, effective analgesia was provided by 5mg of epidural dexamethasone but not 5 mg of i.v. dexamethasone in patients undergoing laparoscopic cholesystectomy, which implied that epidural dexamethasone has greater analgesic efficacy than i.v. dexamethasone at the same dose. Although the effect of caudal dexamethasone through systemic absorption on analgesia cannot be excluded in this design, our study clearly demonstrates that caudal dexamethasone can provide clinically relevant analgesia even at a low dose in children undergoing infraumblical surgeries.

2. Secondly, We did not evaluate some potential adverse effects of dexamethasone such as hyperglycemia and adrenal suppression because the children for paediatric infra umbilical surgeries did not require postoperative laboratory testing and we did not want to introduce invasive techniques for further blood sampling. However previous studies have demonstrated that caudal dexamethasone is not associated with significant side-effects.

CONCLUSION

Thus we concluded that a caudal dexamethasone in combination with ropivacaine augmented the intensity and duration of postoperative analgesia after paediatric infra umbilical surgeries and a single dose of caudal 0.1mg/kg of dexamethasone was not associated with adverse effects.

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