COMPARISON OF CAUDAL ANALGESIC EFFICACY BETWEEN FENTANYL AND DEXAMETHASONE AS ADJUVANTS TO ROPIVACAINE IN CHILDREN FOR SUBUMIBILICAL SURGERIES

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Abstract

Background: Caudal Anesthesia has becomed a reliable and effective anesthetic technique in pediatric patients but the drawback is the limited duration of action of local anesthetic agents used in caudal block, has now overcome by using adjuvants in the clinical settings.
Aim: We compare the analgesic effects and side effects of Fentanyl and dexamethasone added to ropivacaine with ropivacaine alone in paediatric patients undergoing subumibilical surgeries.
Setting & design: This was a prospective, randomized Double-blinded study, involving 111 no of ASA I & II pediatric patients.
Material & Methods: one hundred eleven patients (3- 10 years) were evenly and randomly assigned into 3 groups in double-blind manner. Group R received 1mg/kg of 0.25% ropivacaine diluted in saline. Group D received 1mg/kg of 0.25% ropivacaine with 0.1mg/ kg of dexamethasone . Group F received 1mg/kg of 0.25% of Ropivacaine with 1u/kg Fentanyl.
Result: The duration of postoperative analgesia and pain score was less in dexamethasone group and less number of patients required analgesia in dexamethasone group as compared to Fentanyl and ropivacaine groups. More sedation and significant number of adverse effects was present in the Fentanyl group.
Conclusion: Addition of dexamethasone and Fentanyl to caudal ropivacaine significantly prolongs analgesia and are good alternatives, but dexamethasone have superior analgesia and less adverse effects as compare to Fentanyl.

Keywords: Dexamethasone, Caudal block, Ropivacaine Fentanyl.

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1. Introduction

Pain is a unpleasant subjective experience with a strong emotional component attached to it especially in paediatric age group, as they can't express the actual intensity of pain verbally. Caudal block is one of the most emerging, safe and commonly used regional anaesthetic procedure in paediatric patients for most subumibilical surgeries.[1] The primary advantage of caudal block is decrease requirement of anaesthetic agent and reduced stress response to surgery and smooth recovery[2] Block is mostly done by single shot injection of local anesthetic agent[3] but it may not last long and would still depend on dose, volume and concentration of local anesthetic agent an excess of this could lead to unintended motor block , hemodynamic disturbances and systemic side effects to over come this problem, adjuvant in local anesthetic are being used in clinical practices .

Among LA, ropivacaine provides greater margin of safety, less motor block, less CNS and CVS toxicity and similar duration of analgesia in comparison to bupivacaine[8]. Various adjuvant (opioids ,ketamine) agonist has been added to single shot technique for prolongation of caudal analgesia, but there use is limited by adverse effects such as nausea, vomiting, pruritis, respiratory depression, urinary retention[4, 5,6,7]. Fentanyl has been widely used as analgesic adjuvants to epidural an and it act on substantia gelatinosa on dorsal horn of spinal cord by blocking fibers carrying nocieptive impulses both pre and post synaptically. Corticosteriod have strong intravenous anti-inflammatory[9], analgesic and anti emtic effects, thereby has been mostly used for prophylaxis &and treatment of postoperative nausea, vomiting and also reducing airway oedema in all age groups. Also used epidurally[10,19,26], caudal[20, 28,29] peri neural[24] routes in adults, for prolonging analgesia as shown by no. of studies.

2. Material and Methods

After obtaining approval of Institutional ethical committee and informed & written consent from parents before surgery, this prospective randomized double blinded study was conducted in the department of anesthesia. 111 ASA grade I & II patients aged 3- 10 years scheduled for subumibilical surgeries were enrolled for the study with exclusion criteria

1. Allergy to local anesthetic or any of the study drug.
2. Coagulation disorder.
3. Spine deformity, sepsis.
4. Neurological disorder.

According to randomization, 111 patients, were equally and randomly allocated into 3 groups, and blinding was assured by drug preparation by consultant anaesthesiologist not involved in further follow up of study.

Preanesthetic evaluation was done at least one day prior to surgery, which includes, history, general physical & systemic examination, investigation, blood grouping, CBC, serum electrolytes, PTI and others relevant investigation are done. On the day of surgery adequate fasting -6 hrs for solid, 4 hrs for breast milk and 2hrs for clear fluids was ensured. Baseline values of heart rate (HR), respiratory rate, mean blood pressure (MBP) were recorded. Intravenous access was secured. Premedication with inj. glycopyrrolate 0.4ug/kg, inj. ondansteron 0.1mg / kg & inj. tramadol 1mg/kg was given to all children. Preoxygenation was done using 100% O_2 .Induction was done with inj. propofol 1-2mg / kg and Inj. suxamethonium chloride 1.5mg /kg by i.v route .intubation was done with appropriate size PVC ETT.

Anesthesia was maintained with O_2: N_2O, Holathane 0.5-1% muscle relaxation was achieved by .inj atracurium beslayte 0.5mg/ kg. Caudal block was given in lateral position under all aseptic precautions with 22G small short beveled needle. Sacral hiatus is landmark, needle is inserted at 45, after a pop is felt indicating its progession through sacrococcyeal ligament and enterening into the epidural space ,following careful negative aspiration, drug were administrated acc. to 3 group allocation randomly by sealed envelope (37

patients in each group) and the anesthesiologist was blinded for each solution.

Group R (Ropivacaine group) patients received 1mg/ kg of 0.25 % of Ropivacaine diluted in saline caudally.

Group D (Dexamethasone group) patients received 1mg/ kg of 0.25 % Ropivacaine +0.1mg / kg of dexamethasone caudally.

Group F (Fentanyl group) patients received 1mg/ kg of 0.25% of Ropivacaine + 1μg / kg of Fentanyl caudally.

After performing block, the patients were turned back to supine position, & surgery was allowed to proceed after 10 mints. The demographic data such as age, weight, ASA status, duration of surgery were noted for all patients. Hemodynamic parameters -HR, and MBP were recorded as follows- at baseline (0 mint), 10 mints after caudal block, every 10 mints there after till end of surgery and immediately postoperatively. After the completion of surgery, the patients were extubated when adequate spontaneous ventilation was established, patients were shifted to the post anesthesia care unit (PACU) for further observation.

Hypotension was defined as fall in BP>20% from baseline (to be treated with fluid blous)and bradycardia as fall in heart rate >20% from the baseline (to be treated with atropine).

In the postoperative Anesthesia care unit (PACU) the modified objective pain score (MOPS) was assessed at 30 min 1, 2, 3, 6, and 12 hr.(Table 1)

Table: 1

Criteria	Finding	Points
Crying	none consolable not consolable	0 1 2
Movement	none restless thrashing	0 1 2
Agitation	asleep/calm mild hysterical	0 1 2
Posture	normal flexed holds injury site	0 1 2
Verbal	asleep/no complaint complains/cannot localize complains/can localize	0 1 2

If the MOPS > 4, the patient was given supplementary paracetamol i.v. injection in a dose of 15mg/kg as analgesia. The first time to require analgesia was calculated (the time from caudal block to the first time to paracetamol injection), and also the number of patients who don't require analgesia in the first 12h postoperative was calculated.

Degree of Sedation by Ramsay sedation score was also observed at 30 mint, 1hr, 2,3,6,and 12 hr in (PACU).

Table 2. Sedation Score

1	Anxious and agitated or restless or both
2	Co-operative, oriented and tranquil
3	Responding to commands only
4	Brisk response to light glabellar tap or loud auditory stimulus
5	Sluggish response to light glabellar tap or loud auditory stimulus
6	No response to stimulus

Statistical Analysis:
All the collected data was initially entered into the Microsoft excel. SPSS -26 software was used for calculating the p value. The number of sample size was adequate (111 patients) with α=0.05 and a power of 0.8. Statistical Analysis of data was carried out as for all comparisons P < 0.05 was considered significant. ANOVA (f) test used for numerical values as data expressed in mean and standard deviation and chi -square test used for categorical values as data expressed in number of patients. ANOVA (f) test used for postoperative pain and sedation score.

3. Result

A total 111 patients who were scheduled for elective subumibilical surgeries were included in this study. Patients in all the groups were comparable with respect to demographic characteristics such as age, weight, ASA groups, duration of surgery as shown in table 1. The means of heart rate and means blood pressure changes among the studied groups were comparable from start of surgery until 90 mint ,with no statistical significant difference between them (p> 0.05), as shown in Fig. 1 & 2.

Table 1: Distribution demographic data of the subjects studied.

Parameters	Ropivacaine (37)	Fentanyl (37)	Dexamethasone (37)	Test statistic value	P-value
Age (in years)	6.31± 2.56	6.51 ± 2.32	6.29 ± 2.73	0.0847	0.919
Weight (in Kgs)	22.12 ±5.71	21.84 ± 4.93	20.98 ± 5.53	0.4477	0.640
ASA (I/II)	26/11	24/13	25/12	0.2467	0.884
Duration of surgery (in minutes)	116±10.73	112.45± 9.97	113.14± 10.13	1.4504	0.239

Data express as a mean and standard deviation (Mean±SD), ANOVA (F) test used or data expressed as Chi-square test used (X) (ASA status)

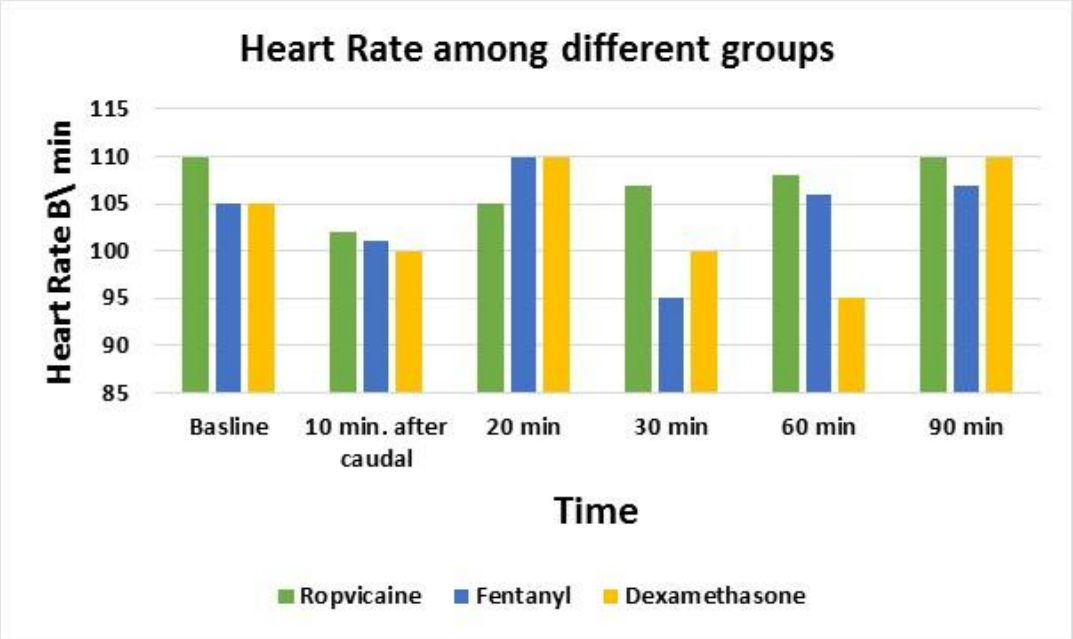

Fig. 1 Heart Rate changes among studied groups, data expressed as M±SD

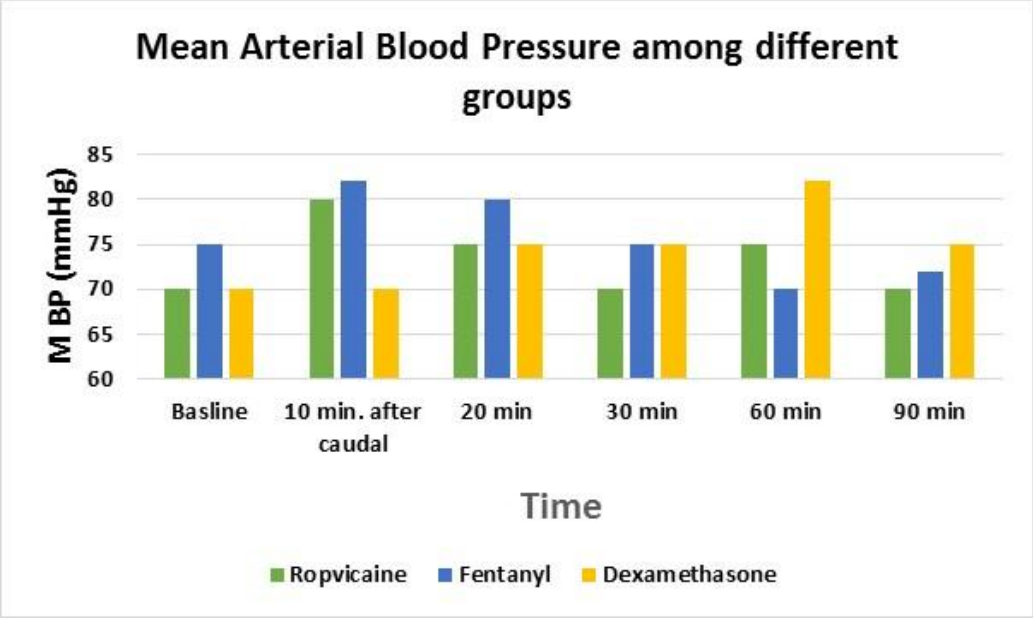

Fig. 2 MAP changes among studied groups, data <expressed as M±SD

Table 2: Comparison of Modified objective pain score (MOPS) among three groups.

Parameters MOPS at	Ropivacaine (37)	Fentanyl (37)	Dexamethasone (37)	Test statistic (F) value	P-value
	Mean±SD	Mean±SD	Mean±SD		
30min	3.15±1.31	3.12±1.32	3.13±1.34	0.0049	0.995

1h	3.27±1.30	3.24±1.33	3.43±1.31	0.2237	0.799
2h	3.26±1.31	3.19±1.32	3.23±1.34	0.0261	0.974
3h	4.76±1.92	4.43±1.56	3.34±1.93	6.2263	<0.003
6h	4.74±2.09	4.47±1.49	3.39±1.96	5.4309	<0.005
12h	5.83±2.11	4.53±1.72	4.46±1.89	6.0166	<0.003

Data express as a mean and standard deviation (Mean±SD), ANOVA (F) test used.
Statistically significant ($p<0.05$)

Table 3: Comparison of time of first analgesia and number of patients require analgesia in first 6 hours among three groups.

Parameters	Ropivacaine (37)	Fentanyl (37)	Dexamethasone (37)	Test statistic (F) value	P-value
Time of 1st analgesia (Minutes)	325.92±11.39	332.45±15.09	493.41±13.93	1811.6	<0.0001
Does not require analgesia	28(75.68%)	18(48.65%)	10(27.03%)17.59	17.59	<0.0002

Data express as a mean and standard deviation (Mean±SD), ANOVA (F) test used or data expressed as Chi-square test used (X)
Statistically significant ($p<0.05$)

Table 4: Comparison of Ramsay sedation score among three groups.

Sedation Score in	Ropivacaine (37)	Fentanyl (37)	Dexamethasone (37)	Test statistic (F) value	P-value
	Mean±SD	Mean±SD	Mean±SD		
30min	4.92±1.87	4.23±1.28	4.141.14	3.141	0.047
1h	2.94±1.44	4.47±1.47	3.871.56	10.17	<0.001
2h	2.18±2.11	4.53±1.72	3.461.89	18.04	<0.001
3h	2.26±0.36	2.14±0.42	2.130.39	1.268	0.285
6h	1.39±0.34	1.34±0.33	1.43±0.31	0.704	0.497
12h	1.76±0.61	1.57±0.72	1.69±0.54	0.867	0.423

Data express as a mean and standard deviation (Mean±SD), ANOVA (F) test used
Statistically significant ($p<0.05$)

Table 5: Comparison of adverse effects among three groups.

Adverse effects	Ropivacaine (%)	Fentanyl (%)	Dexamethasone (%)	Test statistic (F) value	P-value
Hypotension	1(2.7%)	3(8.11%)	0(0)	3.631	0.163
Bradycardia	0(0)	3(8.11%)	0(0)	6.167	0.046
Respiratory depression	0(0)	12(32.43%)	0(0)	26.91	<0.001
Itching	0(0)	9(24.32%)	0(0)	19.59	<0.001
Vomiting	1(2.7%)	9(24.32%)	3(8.11%)	9.061	0.011

Data expressed as number (%), Chi-square test used
Statistically significant ($p<0.05$)

4. Discussion

Caudal analgesia **decrease the amount of** intra venous and inhaled anesthetic agents ,causes early extubation, decrease risk of chest infection ,reduce postoperative analgesic requirement, early ambulatory and early discharge from hospital. We compare Fentanyl 1ug/ kg and Dexamethasone 0.1mg/ kg as an adjuvant to 0.25% of Ropivacaine for caudal analgesia in children undergoing subumibilical surgeries. Apart from analgesic potential, we also investigate any significant post-operative side effects.

The demographic data includes age, weight, ASA grading, duration of surgery were comparable between the groups.

Postoperative pain score, duration of analgesia and number of patients who don't required analgesia in the first 6 hr were analyzed. Our results were in agreement with the studies done by El- Feky et al[13] found that both Dexamethasone and dexmedomidine when combined with local anesthetic in the caudal analgesia prolonged the postoperative analgesia with less pain score as compared to caudal local anesthetic alone or when added to caudal Fentanyl.

Choudhary et al[17] also evaluated caudal Dexamethasone 0.1mg/ kg as an adjuvant to Ropivacaine in children 1- 5 years and they found that caudal Dexamethasone added to Ropivacaine was a good alternative to prolong postoperative analgesia with less pain score compared to caudal ropivacaine alone.

Solanki et al[14] also compare Dexamethasone 0.2mg / kg and clonidine 1ug /kg as additives to caudal 1mg / kg of 0.25% Bupivacaine in children 1- 12 years old scheduled for subumibilical surgeries and found that adding Dexamethasone to caudal Bupivacaine significantly prolonged the duration of postoperative caudal analgesia without any side effects.

El– Abdein Mohamed et al[28] also found that adding Dexamethasone 0.1mg / kg to the caudal Bupivacaine significantly prolongs the duration of postoperative caudal analgesia and decreased the intensity of postoperative pain during hypospadias repair surgery.

The duration of analgesia was significantly longer in dexamethasone D group than ropivacaine alone, which was similar to study conducted by Kim *et al.*[29], found that number of patients who remain pain free upto 48 hr postoperatively was significantly greater in D group than in ropivacaine R alone.

As regards sedation score, there was a significant increase in the 1st 2hr in sedation score which was more pronounced in the Fentanyl group, compared to the Ropivacaine and dexamethasone. Our results were supported by study done by El – Feky et al[13], they found that sedation score was significantly more in Ist & 2nd hour in caudal Fentanyl than in Dexamethasone group. Solanki et al[16], compared caudal tramadol versus caudal Fentanyl with bupivacaine for prolongation of postoperative analgesia in paediatric patients. They found that in the postoperative period up 1½ hr group Fentanyl had higher sedation score compared to other Groups. In the dexamethasone group the sedation score is little but in the level which is acceptable to the parents as there was no crying.

As regards, the postoperative adverse effects (Respiratory depression, vomiting and Itching) they were increased significantly in the Fentanyl group, result was similar as studies done by

Constant et al[32] compared caudal clonidine and caudal Fentanyl and consulted that the adverse effects especially vomiting occurred mainly in the Fentanyl group.

Bajwa et al[33] found that addition of either Fentanyl or dexmetomidine to epidural analgesia in lower limb Surgeries and revealed that the incidence of postoperative nausea and vomiting was significantly occurred in the Fentanyl group.

This study clearly shows the potentiation of sensory block of ropivacaine by addition of adjuvant, which in our study was dexamethasone, which was similar to study done by Kopacz *et al.*, who also study steroids have analgesic effect in neuraxial and peripheral block .
Another important observation made during the course of this study was that excellent analgesia was produced with minimal (0.1mg/kg) dose of dexamethasone by caudal route where i.v dose (0.5-1mg/ kg)[12,21,22] is high and has been studied in child mainly in ENT procedure in decreasing post operative pain as similar to study conducted by Thomas and Beevi *et al.*[19] Found that epidural dexamethasone is significant more effective than iv route to decrease postoperative pain after laproscopic cholecystectomy.

Dexamethasone is commonly used as iv antiemtic and anti-inflammatory, but analgesic effects is believed because of membrane stabilizing and local anesthetic effects on nerves[30]. Use of dexamethasone is more common because it is a clear liquid steroids & we use it with preservatives, methyl paraben and propylene paraben, their safety for internal injection has been proven in human and animal models[31]. The effect of steroids on spinal cord is due to presence of transcription factor Nuclear factor -kappa B (NF-kB), present throughout the nervous system[32,33]. Dexamethasone by regulating NF-kB, inhibits central sensitation after surgery and potenitates analgesia of caudal block and has been safely and commonly used in treatment radicular pain of lower back.

High dose of dexamethasone is associated with complications such as hyperglycemia, wound infection, post-operative bleeding & transient adrenal suppression therefore low dose of steroid is preferred in our study. Also there is no significant hemodynamic changes in any patients, this can be partly due to caudal route which causes deposition of drug in caudal space a which limits systemic absorption and partly due to gradual onset of sympathetic block .

Our study were similar to Choudhary *et al*[20] , who compared the analgesic effects of ropivacaine alone and with dexamethasone in paediatric patients posted for inguinal herninotomy. Girgis *et al*. studied the effects of addition of dexamethasone to bupivacaine in paediatric caudal anesthesia of age (1-6 years), posted for inguinal herintomy, they also found dexamethasone prolongs post operative analgesia.

El-Feky et al[13] who studied the effects of addition of dexamethasone versus dexmetomidine versus fentanly to paediatrics caudal anesthesia, confirm that dexamethasone as an adjuvant has significant analgesic effects

5. Conclusion

In our study, we concluded that addition of dexamethasone to ropivacaine prolongs the duration of post operative analgesia with less pain score compared to caudal local anesthetic alone or added to caudal Fentanyl. Also they showed less side-effects as compare to caudal Fentanyl.

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Nil

Conflicts of Interest
There are no conflicts of interest.

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