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Comparison of Caudal Block Using Ropivacaine with Clonidine and Ropivacaine with Fentanyl for Post Operative Analgesia

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Abstract

Aim: The aim of the study was to compare the postoperative analgesia provided by Clonidine and Fentanyl when given as additives with Ropivacaine for caudal block in children. *Methods:* After obtaining the approval of our Institutional Ethics Committee, the study was conducted in 60 pediatric patients undergoing elective infraumbilical surgeries. The patients were randomly divided into two study groups i.e. Group I and II. After inducing general anesthesia, patients in Group I received Ropivacaine 0.2% with Clonidine 2 mcg/kg whereas Group II received Ropivacaine 0.2% with Fentanyl 1 mcg/kg *via* caudal route. The parameters observed included heart rate, blood pressures, oxygen saturation, postoperative pain score, sedation score, motor blockade, time to rescue analgesia and adverse effects. Statistical analysis was done by applying Fishers exact test and unpaired *t*-test. *Results:* Demographic variables were comparable in both groups. Heart rate, blood pressures, peripheral capillary oxygen saturation values were significantly lower in the Clonidine group compared to the Fentanyl Group. The onset of pain and time to 1st dose of rescue analgesia was lesser in the Fentanyl Group (< 3 hours) when compared to Clonidine Group (3–5 hours) was statistically significant with *p* - value < 0.05. Sedation scores were significantly higher for the Clonidine Group. Motor blockade was not present in any patient. Adverse effects were comparable in both the groups. *Conclusion*: Addition of Clonidine to Ropivacaine in a single shot caudal block is more advantageous than Fentanyl for postoperative pain relief without increasing the incidence of adverse effects.

Keywords: Clonidine; Fentanyl; Ropivacaine.

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Introduction

Pain is an unpleasant subjective sensation and its emotional component is very pronounced in children.[1] Caudal epidural analgesia is one of the simplest and safest technique in pediatric anesthesia and also has a high success rate.[2] It is commonly used along with an adjuvant for both intraoperative and postoperative analgesia in children undergoing surgical procedures below the level of umbilicus.[3] Ropivacaine has less motor blockade and less cardio-toxic effects than Bupivacaine makes it a more suitable agent for caudal epidural analgesia, especially following day care surgeries.[4–8]

In this study, we assessed the efficacy of clonidine and fentanyl with Ropivacaine through caudal

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route with regard to the onset and duration of sensory and motor blockade and also to document any side effects .

Aims and Objectives

To compare the postoperative pain relief of Ropivacaine 0.2% with Clonidine (2 mcg/kg) *versus* Ropivacaine 0.2% with Fentanyl (1 mcg/kg) for pediatric patients undergoing infraumbilical surgeries.

Materials and Methods

Study Design

Prospective; Randomized: Double-blinded study.

Study Population

Total of 60 patients with 30 each in two study groups, all undergoing elective infraumbilical surgeries of age group 1–7 years of ASA I and II. Children with spine abnormalities, ASA more than III and those have contraindication for neuro axial block were excluded from the study.

Children were premedicated with oral Midazolam 0.4 mg/kg 20 minutes prior to shifting to the operating theatre and monitors such as electrocardiogram, pulse oximetry and noninvasive blood pressure were connected. Baseline heart rate, blood pressure and oxygen saturation were noted. Induction was done with stepwise inhalation of Sevoflurane 8% in 6L oxygen. After adequate depth of anesthesia, intravenous access was secured. Fentanyl of dose 2 mcg/kg was administered intravenously. Ventilation was controlled using a Jackson-Ree's modification of Ayre's T-piece and appropriately sized face mask. Anesthesia was maintained with 1–2% Sevoflurane and nitrous oxideoxygen mixture in a ratio of 1:1and inj. Atracurium 0.5 mg/kg for skeletal muscle relaxation. Intubated using an appropriate tracheal tube. Bilateral air entry was checked by auscultation and tube secured.

The patient was then placed in the left lateral decubitus position. The caudal space was identified and the assigned group drug was injected using a 23G beveled needle. The patients were selected to a particular group by computer generated randomization and prefilled syringes were provided containing the study drug combinations. Study drug was prepared by the third anesthetist who doesn't participate in the study. The patient was then turned back to supine position. Group I received 0.2% Ropivacaine with Clonidine 2 mcg/kg and Group II received 0.2% Ropivacaine with Fentanyl 1 mcg/kg. The volume of the drug was decided using the Armitage formula.[9] The vitals during caudal block were noted. The intraoperative hemodynamic parameters and oxygen saturation was monitored and documented every 5 minutes until awakening. The duration of surgery was noted. After closure of skin incision, nitrous oxide and Sevoflurane was discontinued. Neuromuscular blockade was reversed with intravenous Glycopyrolate 0.01 mg/kg with Neostigmine 0.05 mg/kg. Once the patient was awake and taking good respiratory efforts, thorough suctioning was done and trachea was extubated. Patient was then shifted to PACU for observation. The heart rate, blood pressure, oxygen saturation, pain score and sedation score was followed up for 24 hours. Pain score was assessed using Children's Hospital of Eastern Ontario Pain Scale and documented at 1, 2, 3, 4, 5, 6, 12, 24^{th} hour postoperatively. Adverse effects were also noted, if any. The follow up in the PACU was done by the PACU anesthesiologist.

An increase or decrease in HR > 20% of baseline value was considered as tachycardia or bradycardia respectively.[10] Hypotension was defined as a MAP < 25% of baseline value. Desaturation was taken as a decrease in SpO_2 < 95%. A Cheops more than 6 warranted the 1^{st} dose of rescue analgesia. Rescue analgesia was provided with 15 mg/kg of intravenous Paracetamol. The duration of postoperative analgesia was defined as the time interval between caudal anesthesia and the 1^{st} dose of rescue analgesia. Assessment of sedation was also done at 1, 2, 3, 4, 5, 6, 12 and 24^{th} hour postoperatively.

Spontaneous eye opening-3;

Eye opening to verbal command-2;

Eye opening physical shaking-1;

Not arousable-0.

Motor blockade was assessed using modified Bromage scale duration of motor blockade was documented by noting the time taken by the patient to have a modified Bromage score of 0.

Results

Data analysis

The patients were divided into two groups as Ropivacaine with Clonidine and Ropivacaine with Fentanyl. Descriptive statistics was done for all the data and were reported in terms of mean values and

percentages. Suitable statistical tests of comparison were done. Normality of the data was confirmed using Shapiro-wilk test. Continuous variables were analyzed with the unpaired *t*-test. Categorical variables were analyzed with Fisher Exact Test. Statistical significance was taken as p - value < 0.05. The data was analyzed using SPSS version 20 and Microsoft Excel.

Sample size calculation

Sample size was determined based on the study' Postoperative analgesia in children when using Clonidine or Fentanyl with Ropivacaine given caudally' authored by Usha Shukla, et al. and published in Journal of Anesthesiology Clinical Pharmacology. 2011 Apr–Jun; 27(2): 205–210. In this study, increased patient comfort with pain score significantly 18% higher in Group II (Fentanyl) than Group I (Clonidine) (p - < 0.05).

The confidence level is estimated at 95% with a z-value of 1.96 and the confidence interval or margin of error is estimated at ± 10.

Assuming p = 18% and q = 82%, $n = p \times q \times [z/e]^2$

$N = 18 \times 22 \times [1.96/12]^2$

$N = 56.70$

Therefore, 57 is the minimum sample size required for the study.

A sample size of 60 has been taken in this study:

N = 22 in Ropivacaine + Clonidine Group;

N = 38 in Ropivacaine + Fentanyl Group;

Both the groups were similar with respect to the distribution of age, weight ASA physical status, gender distribution and duration of surgery, (Table 1).

The mean heart rate was considered to be statistically significant between 3–6 hours. In the patients belonging to Group I, the heart rate decreased with a p - value of 0.0243, 0.0035, 0.0008 and 0.0016 at 3rd, 4th, 5th, and 6th hour respectively, (Fig. 1). There was significant difference of 3% reduction in systolic blood pressure in Group I compared to Group II with a p - value of 0.0448 and 0.0114 for 5th and 6th hour respectively, (Fig. 2). Diastolic blood pressure showed significant fall during 4th 5th 6th hours in Group I than in Group II with a p - value of 0.0056, 0.0007 and 0.0002 for the 4th, 5th and 6th hour respectively, (Fig. 3). Though Group I patients had significant fall in saturation during the 50 minutes and 5 hrs no patient had clinically significant desturation requiring intervention. On analyzing the values for the pain score, we found that the values were significant for 3rd, 4th, 5th and 6th hour, (Table 2). In Group I, the Cheops Pain Score showed an average of 6.34 whereas it was 8.09 in Group II, (Fig. 4). Group I had an average sedation score of 1.70 (more sedated) than Group II with an average of 2.54, (Fig. 5). It was observed that none of the patients in Group I required any rescue analgesia in the 1st 3 hours whereas 16 patients in Group II (53.33%) required it. Majority of the patients in Group I required rescue analgesia only during 5–7 hours postcaudal block. All the patients in Group II required rescue analgesia within 1st 5 hours difference was significant with a p - value of 0.0000, (Fig. 6). Majority of the Group I patients had no adverse effects (n = 26, 86.67%) followed by nausea (n = 3, 10.00%). Adverse effects between the groups was not statistically significant, (Fig. 7).

Table 1: Demography

Parameters	Group I	Group II	p - value
Mean Age in years	3.88 2 1.82	4.32 2.07	0.3409
Mean weight in Kgs	15.57 4.03	16.37 4.66	0.4924
Duration of surgery in minutes	38.83 16	38.33 18.35	0.9109
ASA			
I	29	29	> 0.999
II	1	1	
Gender			
Male	25	26	0.4178
Female	5	4	

Table 2: Cheops Pain score

Cheops Pain Score		PS 1 hr	PS 2 hr	PS 3 hr	PS 4 hr	PS 5 hr	PS 6 hr	PS 12 hr	PS 24 hr
Group I	N	30	30	30	30	30	30	30	30
	Mean	6.00	6.00	6.00	6.10	6.20	7.07	8.10	8.90
	SD	0.00	0.00	0.00	0.31	0.41	0.74	0.76	1.09
Group II	N	30	30	30	30	30	30	30	30
	Mean	6.00	6.00	6.70	8.07	9.03	8.57	8.47	8.10
	SD	0.00	0.00	0.79	0.74	1.16	1.33	1.22	1.16
p - value	Unpaired t-Test	> 0.9999	>0.9999	0.0000	0.0000	0.0000	0.0000	0.1696	0.1379

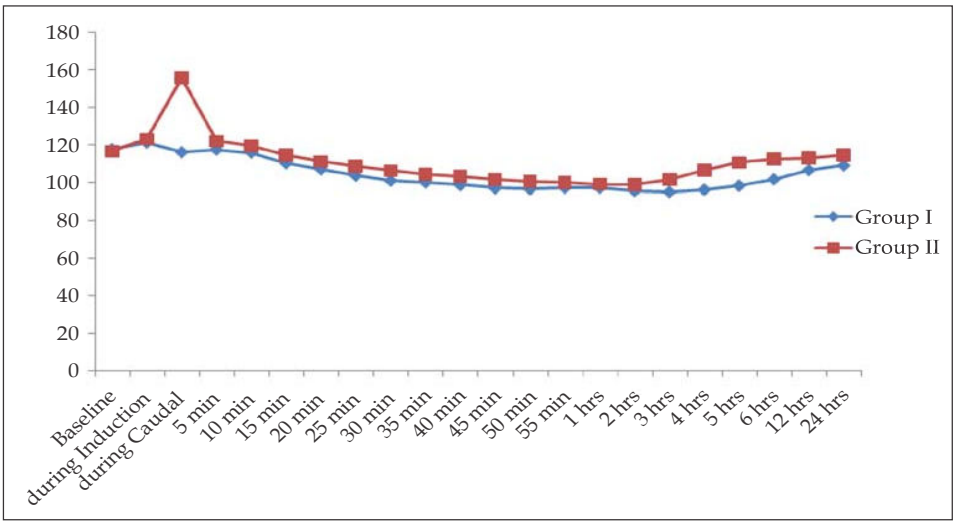

Fig. 1: Mean Heart rate

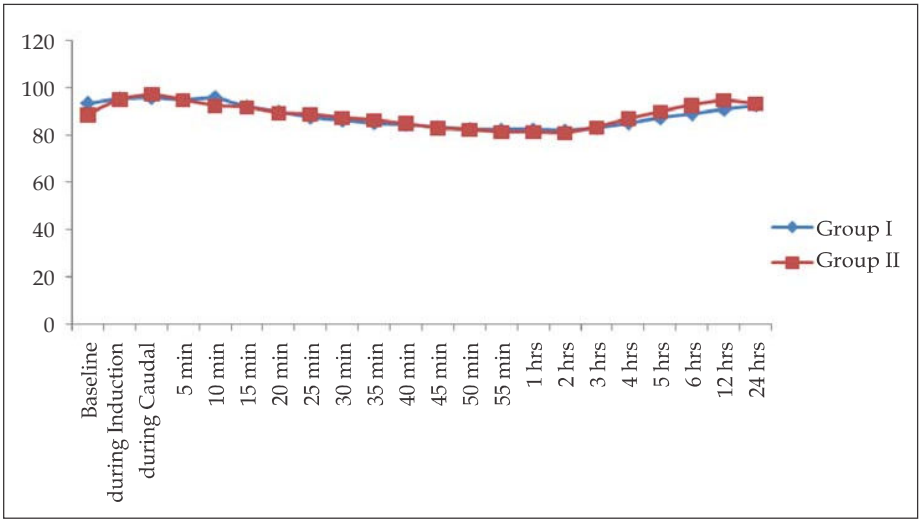

Fig. 2: Mean Systolic blood presure

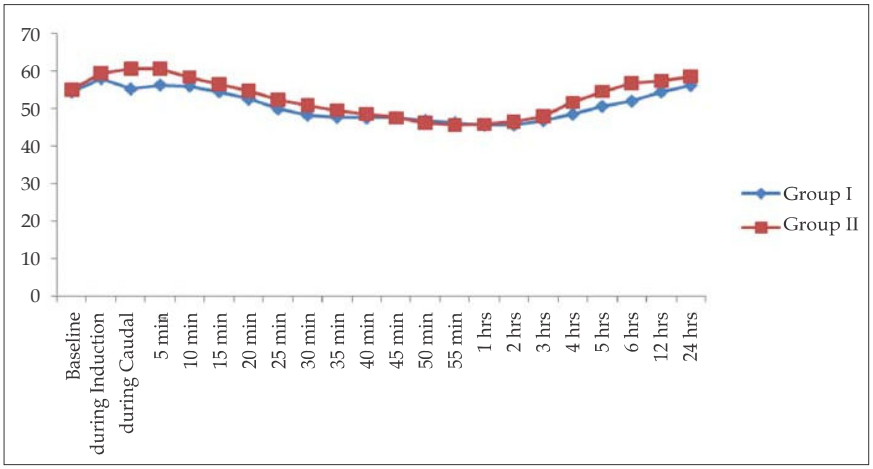

Fig. 3: Mean Diastolic blood presure

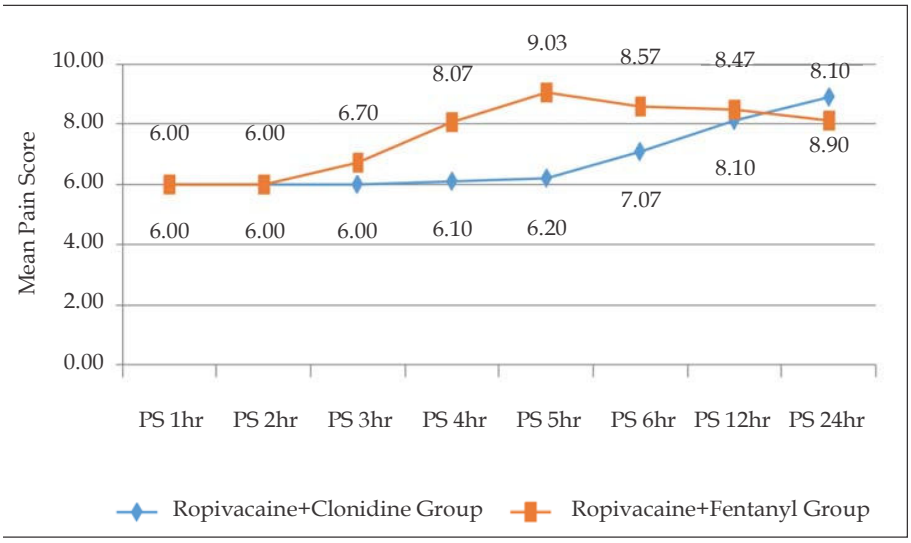

Fig. 4: Cheops Pain score

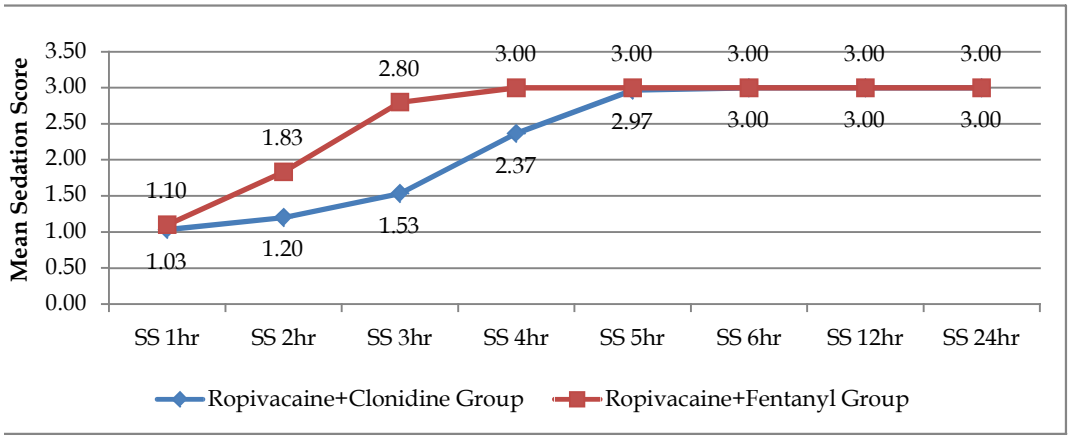

Fig. 5: Sedation score

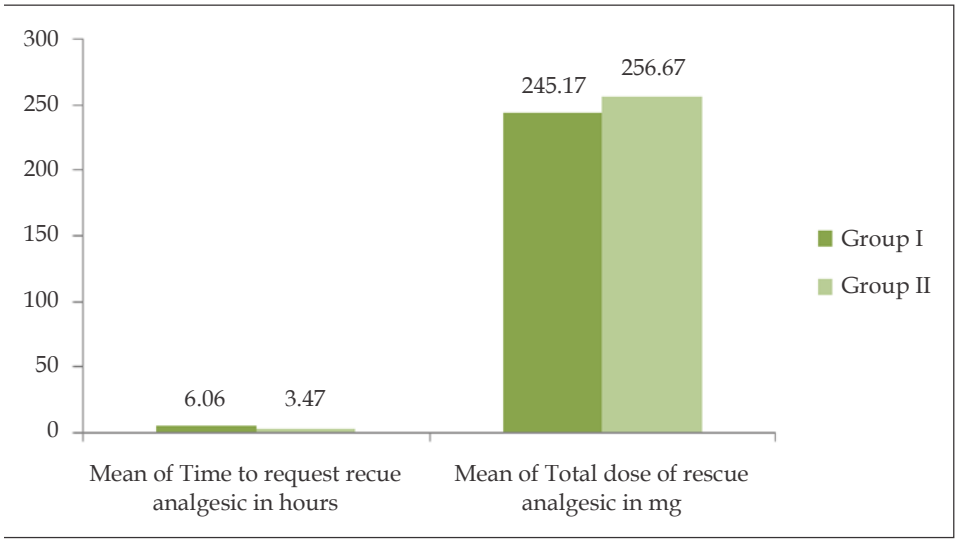

Fig. 6: Rescue analgesic

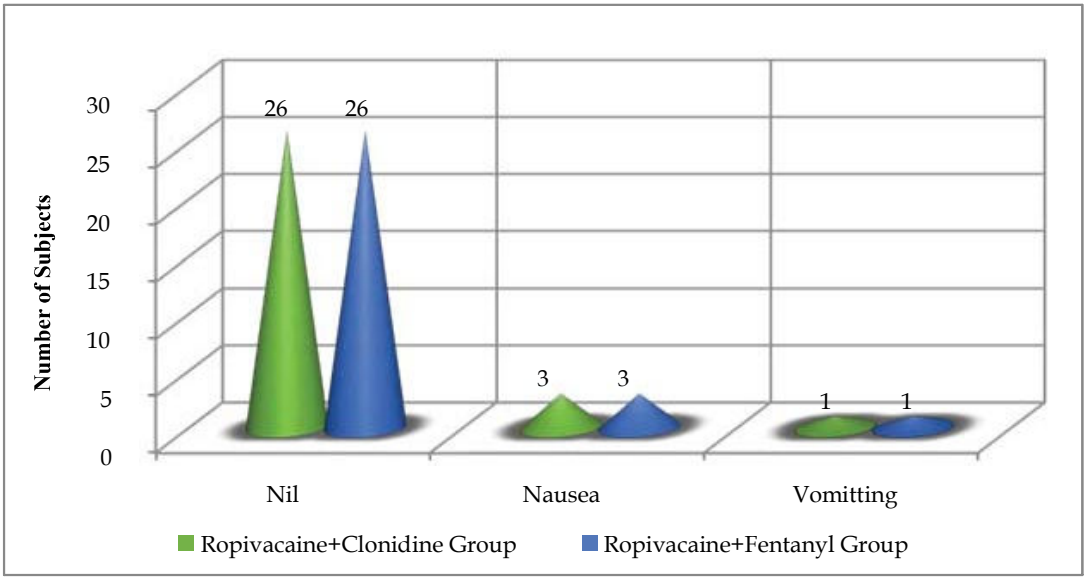

Fig. 7: Adverse effects

Discussion

Caudal block is a popular and routinely used technique to provide intra and posoperative analgesia in children. Ropivacaine and Bupivacaine are the most widely used local anesthetics in caudal blocks. In our study, we evaluated the effect of two additives— Clonidine and Fentanyl to Ropivacaine in prolonging postoperative analgesia. A limitation of a single shot caudal block is its short duration of action. A study was done by Samuel et al.[11], where they analyzed the effect of double caudal technique by injecting drug into the caudal space a second time at the end of the surgery. This gave way to concerns about the safety of injecting such high volumes in a short period of time. Bosenberg et al. conducted a study where they demonstrated that Ropivacaine 0.2% provided satisfactory postoperative pain relief where, 0.1% was less effective and 0.3% was associated with a higher incidence of motor block with minimal improvement in pain relief. In our study, we have used 0.2% Ropivacaine in both the study groups and no motor blockade was recorded in any patient.

In this study, our aim was to study about the postoperative analgesia and side effect profile provided by Clonidine and Fentanyl when used along with Ropivacaine. Shukla et al. conducted a similar study and concluded that the analgesic properties in both groups were comparable but the side effects were significantly lesser in the Clonidine Group but they had avoided muscle relaxant and analgesic dose and the route was different.[12]

Our study showed that the heart rates, blood pressures, and peripheral capillary oxygen saturation values were significantly lower in the Clonidine Group but none of the patient required clinically significant changes.

Clonidine is said to cause sedation in the postoperative period as stated in a study done by Lee et al.[13] In our study too, it was observed that the sedation scores were higher in the Clonidine Group which could be the cause for a decreased peripheral capillary oxygen saturation in them.

Clonidine is known to have antiemetic properties whereas Fentanyl and other opioids usually cause postoperative nausea and vomiting.[14] The adverse effects in both our study groups were comparable with equal number of patients having nausea or vomiting postoperatively.

Conclusion

We conclude that addition of Clonidine to Ropivacaine in a single shot caudal block is more advantageous than Fentanyl for postoperative pain relief without increasing the incidence of adverse effects.

Key messages: None.

Conflict of Interest: None.

Source(s) of support: Nil

Presentation at a meeting: Nil

Conflicting Interest (If present, give more details): Nil

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