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Prospective, Randomized, Controlled Study of Caudal Analgesia using 0.2% Ropivacaine with 1µg/kg Fentanyl and 0.2% Ropivacaine with 0.02ml/kg NS in Children Undergoing Infraumbilical Surgeries

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Abstract: ***Prospective, randomized, controlled study of Caudal analgesia using 0.2% Ropivacaine with 1µg/kg Fentanyl and 0.2% Ropivacaine with 0.02ml/kg NS in children undergoing infraumbilical surgeries. Introduction: Single shot caudal blocks provide post operative analgesia for limited duration. The addition of fentanyl as an adjuvant prolongs the duration of analgesia. Objectives: Primary: 1) Analgesic effect of caudal block. 2) Requirement of rescue analgesic. Secondary: 1) hemodynamic parameters. Methodology: 50 patients were divided into 2 groups, group F and S. Group F- 25 patients received 1ml/kg 0.2% ropivacaine with 1µg/kg fentanyl. Group S- 25 patients received 1ml/kg 0.2% ropivacaine with 0.02ml/kg NS. The analgesic effect of caudal block and sedation scoring was assessed. Post operative period of 24 hours was observed for rescue analgesic requirement, hemodynamic parameters and any complications. Results: There were no differences between the groups in terms of age, height, weight, duration of surgery or duration of anaesthesia. There were no differences between the groups in haemodynamic and respiratory parameters. . A trend towards more time to first analgesic rescue was observed in Group F compared with Group S, and it statistically significant. In addition, statistical differences were found in CHEOPS score and no statistical difference was seen in the Steward score. Conclusion: The addition of Fentanyl to Ropivacaine has considerably prolonged the duration of analgesia when compared to only Ropivacaine as assessed by CHEOPS scale and STEWARD scale.***

Keywords: paediatric anaesthesia, caudal block, analgesia

1. Introduction

Single shot caudal analgesia is commonly used for postoperative pain relief in paediatric population. The duration of surgical analgesia provided by single shot of ropivacaine or bupivacaine is of a short duration. Thus, addition of different adjuvants, such as clonidine, ketamine, adrenaline or opioids, to local anaesthetics have been used to prolong the pain-free period.

Fentanyl is one of the most common adjuvants available and used along with local anaesthetics and the effect of adding fentanyl has considerably prolonged the duration of postoperative analgesia in various studies. Caudal block with bupivacaine 0.25% and fentanyl 1 µg/kg provides further analgesic advantages when compared to the usage of bupivacaine alone. Also studies using the addition of fentanyl 1 µg/kg to the mixture of local anaesthetics (bupivacaine 0.25% with epinephrine and lidocaine 1% in equal parts) prolonged the duration of postoperative analgesia to a much larger extent. Vasoconstrictive property of epinephrine might contribute to prolong the duration of analgesia. It has been reported that ropivacaine produces vasoconstriction in contrast to vasodilation produced by bupivacaine. Thus, it is possible that additives to ropivacaine can provide further analgesic advantages compared with bupivacaine. In this prospective, randomized, double-blind study, we evaluated whether the addition of fentanyl 1µg/kg to ropivacaine prolonged the duration of analgesia when compared to the usage of ropivacaine alone after a single shot caudal block.

2. Methods

After obtaining Institutional Ethics Committee approval from Rangaraya Medical College, Kakinada and written informed parental consent, 50 patients of ASA grade I and II scheduled to undergo infraumbilical surgeries like inguinal hernia, hypospadias, colostomy closures were enrolled in the study. Patients were excluded if a history of allergic reactions to local anaesthetics was documented, bleeding diathesis, contraindications to caudal anaesthesia, or pre-existing neurological or spinal disease was present. The study design is a randomized, double binded controlled study.

Children were premedicated 60 min before surgery with midazolam 0.5 mg/kg (mixed with sugar syrup or honey) orally. In the operating theatre, the patient was prepared for non invasive blood pressure, pulsoximetre saturation recordings (SpO2) and continuous electrocardiographic monitoring. A precordial stethoscope was attached. Anaesthesia was induced by facemask with sevoflurane and oxygen. After placement of an I.V. cannula, depolarizing muscle relaxant, succinylcholine was given at a dose of 2mg/kg body weight and the trachea was intubated with appropriately calculated sized endotracheal tube and the lungs were ventilated usine a modified Jackson Reyes breathing circuit. Anaesthesia was maintained with sevoflurane (0.6 MAC corrected for age) and nitrous oxide 66% and oxygen 34%. Caudal anaesthesia was performed in the lateral position with 23 gauge Needle and one of the two different mixtures described below was administered to the child.

Children were allocated randomly in one of two groups by opening a sealed envelope.

Group F received 1 ml/kg of ropivacaine 0.2% and fentanyl 1 µg/kg

Group S received 1 ml/kg of ropivacaine 0.2% and saline 0.02 ml/kg.

The maximum volume of ropivacaine 0.2% was 30 ml; patients >30 kg were excluded so that all subjects received an equivalent dose by weight. Caudal solution was prepared by another anaesthesiologist who was not involved in the study.

Heart rate (HR), mean arterial pressure (MAP) and SpO2 were recorded before induction, after induction and then 5 min after caudal anaesthesia. During surgery, adequate analgesia was defined by haemodynamic stability, as indicated by the absence of an increase in MAP or HR of more than 15% compared with baseline values obtained just before the surgical incision. If HR or MAP increased by more than 15%, analgesia was considered inadequate and subsequent data obtained from those children were no longer considered. During the surgery, children received ringer lactate solution at a rate of2-3 ml/kg/hr. Time from discontinuing the volatile anaesthetic to tracheal extubation were recorded.

MAP, HR and SpO2 values were recorded 30 min after extubation and at 1, 2, 4, 6, 12 and 24 h. The analgesic effect of caudal block was evaluated using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) 30 min after extubation and at 1, 2, 4, 6, 12 and 24 hours. When the CHEOPS score was greater than 6, analgesic was given in previous studies andin this study also. In the present study, if the patient's CHEOPS was greater than 6, or if the patient complained of pain at the surgical site, I.V Neomol (paracetamol) at a dose of 15mg/kg was administered. If no paracetamol was necessary within 24 h, the duration of analgesia was counted as 24 h. No analgesics other than I.V Paracetamol were given in the study period. In addition, sedation was assessed using Steward score, 1 hour after extubation and at hours 2, 4, 6, 8, 12 and 24 hours,. Recovery criteria were met when a Steward score of 6 was achieved. All measurements were recorded by the same anaesthesiologist who did not know which medication was administered. The incidence of side-effects (vomiting and pruritus) was recorded. Finally, global assessment of the duration of effective analgesia was performed by comparing the time from caudal block to administration of the first analgesic.

Statistical analysis

The statistical analysis was done using mean values for 50 patients. A p-value >0.05is not significant and a p-value of <0.001 is considered to be significant.

3. Results

No patient demonstrated signs of a failed block. Data from 50 children were analysed. There were no significant differences between the groups in terms of age, height, weight, duration of surgery or duration of anaesthesia. There were no large differences between the groups in terms of haemodynamic and respiratory parameters and the parameters were well maintained all throughout the surgery. However, there was no significant difference in time from discontinuation of the sevoflurane to tracheal extubation. A total of 10 patients in Group F and 15 patients in Group S received rescue analgesia which was IV 15mg/ml of paracetamol. A trend towards moretime to first analgesic rescue was observed in Group F compared with Group S however, it wasstatistically significant. In addition, statistical differences were found in CHEOPS score at 1 hour and 2 hours duration and no difference statistically was found in the steward score at any duration. The incidence of postoperative vomiting (4 patients in Group F and six patients in Group S) and pruritus (1 patient in both Groups F and S) was not significantly significant in both the groups.

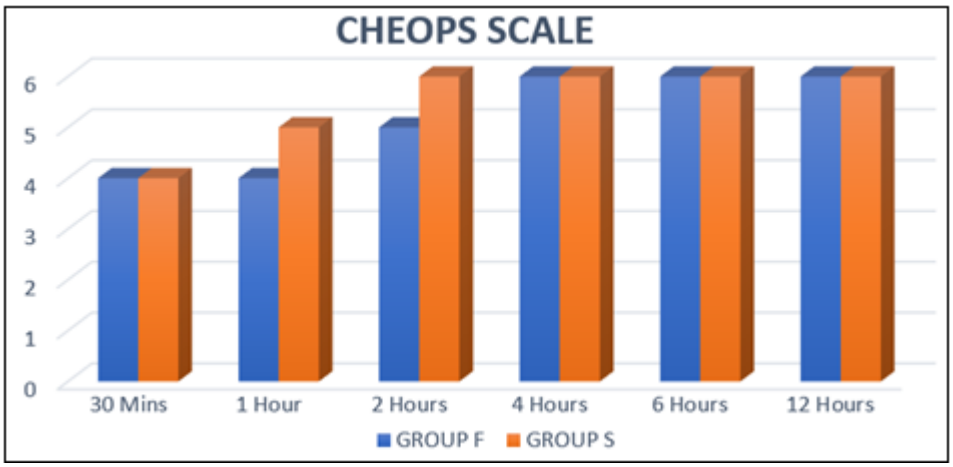
The duration for rescue analgesic was significantly prolonged in group F when compared to group S. Also there was significant difference in terms of CHEOPS scale in the grou F at 1 and 2 hours duration.

4. Results

4.1 Cheops Scale

The scores in Group F and Group S were found to vary significantly as p-value is <0.001 at 1st and 2nd hours postoperatively. These values have also correlated with with clinical assessment. The scores are 4 and 5 with a standard deviation of 0.2 and 0.3 in group F and group S respectively. The scores at all the other times were not significant either clinically or statistically.

	GROUP F	GROUP S	P value
30 min	4 (0.3)	4 (0.2)	>0.05
1 hour	4 (0.2)	5 (0.3)	**<0.001**
2 hours	5 (0.4)	6 (0.5)	**<0.001**
4 hours	6 (0.4)	6 (0.5)	>0.05
6 hours	6 (0.4)	6 (0.6)	>0.05
12 hours	6 (0.4)	6 (0.5)	>0.05

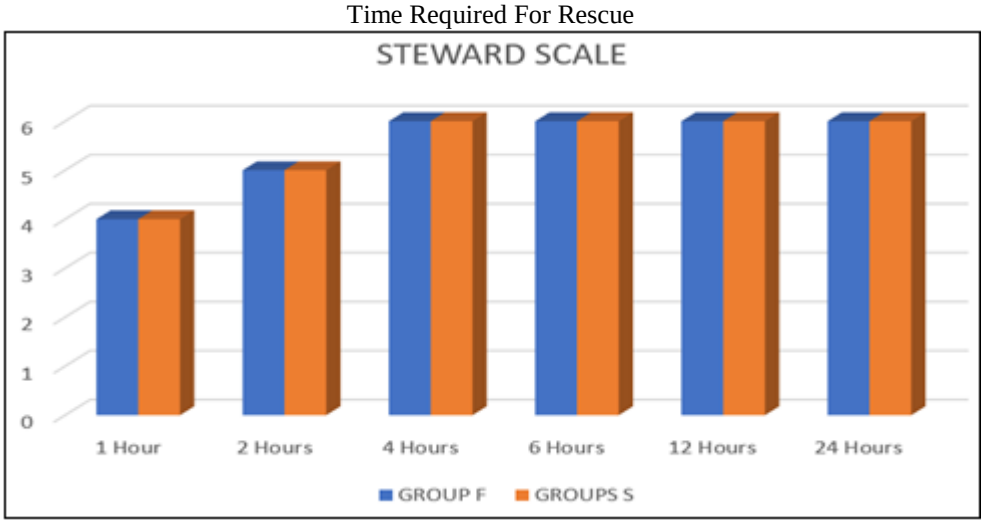


4.2 Steward Scale

There was no much clinical or statistical difference is the assessment of STEWARD scores at 1, 2, 4, 6, 12 and 24 hours. These scores are useful for postoperative hospital discharge.

	GROUP F	GROUP S	P value
1 hour	4 (0.2)	4 (0.3)	>0.05
2 hours	5 (0.3)	5 (0.4)	>0.05
4 hours	6 (0.4)	6(0.5)	>0.05
6 hours	6 (0.5)	6(0.5)	>0.05
12 hours	6 (0.4)	6(0.6)	>0.05
24 hours	6 (0.5)	6(0.6)	>0.05

Time Required For Rescue



4.3 Analgesic

The time required for the need of rescue analgesic was significantly prolonged in group F when compared to Group S both clinically and statistically as the p value is <0.05. The values for Group F are 5.2 hours± 1.5 hours and for that of group S are 4.3 hours ± 1.3 hours.

Group F	Group S	P value
5.2 ± 1.5 hours	4.3 ± 1.3 hours	<0.05

5. Discussion

The present study found that adding fentanyl 1 µg/kg to ropivacaine 0.2% for a single shot caudal analgesia altered the mean time to usage of first analgesic and the postoperative pain scores (CHEOPS) were found to be better in Group F when compared to Group S.

Fentanyl is one of the most commonly used adjuvants with local anaesthetics in caudal blocks. However, only a few studies have addressed the benefit of fentanyl-local anaesthetic mixture. Constant and Colleagues have demonstrated that the addition of fentanyl to bupivacaine and lidocaine with epinephrine prolonged the duration of surgical analgesia for caudal block undergoing bilateral vesicoureteral reflux. In contrast, other studies have reported that there is no beneficial effect to the mixture of fentanyl 1 µg/kg and bupivacaine 0.25% compared with bupivacaine alone on pain score and plasma catecholamine concentration.

It has also been reported that ropivacaine is less cardiotoxic and there is a greater separation of sensory and motor effects than with bupivacaine. Therefore, ropivacaine is increasingly used for caudal blocks in children. A previous report demonstrated that ropivacaine 0.2% provided satisfactory postoperative pain relief and 0.1% was

less efficacious, whereas 0.3% was associated with a more frequent incidence of motor block with minimal improvement in postoperative pain relief. Thus, we chose ropivacaine 0.2% in the present study. In addition, it has been reported that ropivacaine produces vasoconstriction in contrast to vasodilation produced by bupivacaine. Thus, we hypothesized that additives to ropivacaine can provide further analgesic advantages compared with bupivacaine.

The effects of adding fentanyl to ropivacaine on single caudal block in children has proven to be more efficacious when compared to the usage of ropivacaine alone.

In the study, the need for higher concentration of sevoflurane at extubation in Group F was significantly lower than in Group S as assessed by the hemodynamic variability and the increase or decrease in trends of heart rate. In a previous report, Katoh and colleagues demonstrated the MAC_{awake} reduction of sevoflurane by constant plasma fentanyl concentrations.

The limitation of the study is the difficulty in differentiating between pain response and agitation on emergence, especially in younger children. Among the patients administered analgesics, there might be the ones exhibiting agitations rather than pain complaint. Furthermore, type of surgical procedure is varied in the study. The intensity of postoperative pain may vary depending on the typeand the level of surgical procedure and the duration for completion of the surgery.

In conclusion, the addition of fentanyl 1 μg/kg to ropivacaine 0.2% for caudal analgesia provides further analgesic advantages to ropivacaine 0.2% alone when used in children undergoing surgical procedures below the umbilicus.

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