Original article:

A comparison of the efficacy and safety of different doses of fentanyl as an adjuvant to bupivacaine for caudal analgesia in children undergoing lower abdominal surgery

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Abstract

Single dose caudal epidural anesthesia is a commonly performed regional technique in paediatric anesthesia. It supplements general anesthesia during surgery and provides analgesia in the post operative period for lower abdominal surgeries not exceeding 45 minutes.

Aims and Objectives: A comparative prospective interventional study was conducted to assess the duration, efficacy and safety of two different doses of fentanyl with bupivacaine administered via caudal route for postoperative analgesia in children. **Key words:** Paediatric anesthesia, Caudal blockade, Bupivacaine, Fentanyl, and Post operative analgesia.

Introduction

The Society for Paediatric Anesthesia, in its 15th annual meeting held at New Orleans in state of Louisiana in 2001¹ clearly stated that the alleviation of pain is a "basic human right" irrespective of age, medical condition and treatment. Langlade et al² suggested that post operative analgesia must be included in the anesthetic planning even before induction of anesthesia, adopting the idea of "managing pain before it occurs". Now post operative pain management is an essential part of paediatric anesthesia in all major hospitals. Commonly caudal block is given with a single dose of local anesthetic drug such as bupivacaine which provides adequate analgesia during surgery but is associated with early termination of analgesic effect in the postoperative period. Further, single dose caudal block has the drawback of having a relatively short duration of post operative analgesia.³ Although

increasing the concentration of the local anesthetic drug prolongs the period of analgesia, it raises the concentration of the drug thereby increasing the threat for toxicity. Reducing the amount of the local anaesthetic drug at a higher concentration, will reduce the dermatomal distribution of the caudal block. Placement of a catheter into the caudal epidural space has the possibility of infection due to its closeness to the anus and the potential of faecal contamination. It also prevents early mobilization.⁴ Attempts have been made by adding various drugs i.e. bupivacaine, opioids, clonidine, ketamine, prolong the post operative midazolam etc. to analgesia with variable results⁵. Fentanyl has been recommended as one such drug as it is an opioid which has the minimal possibility of causing the respiratory depression when given extradurally because of its high lipid solubility. It also does not

spread rostrally in CSF and more rapidly from CSF into the spinal cord. ⁶

The present comparative prospective interventional study was conducted to assess the duration, efficacy and safety of two different doses of fentanyl with 0.125 % bupivacaine administered via caudal route for postoperative analgesia in children undergoing infra abdominal surgeries. Any adverse hemodynamic effect due to use of these doses of fentanyl was studied.

Methods and material

After obtaining permission from the Institutional Ethics Committee and consent from the parents, this prospective interventional comparative study was conducted. The study population included 90 children belonging to American society of Anesthesiologists (ASA) grade I and II physical status, in the aged 2 to 8 years, selected for infra abdominal surgery. Patient below 2 year of age, co-existing medical (metabolic and endocrine) illnesses, coagulation disorders, anatomical defects of the spine, infection at the local site and children with known hypersensitivity to bupivacine were excluded from this study. These 90 children were randomly assigned in one of two groups consisting of 45 each. Group I received 1ml/kg of 0.125 % bupivacaine with fentanyl 0

 $.5\mu$ g/kg while Group II received 1ml/kg of 0.125 % bupivacaine with fentanyl 1 μ g/kg for caudal block.

After securing IV access with 22G size iv canula, premedication was given with oral Midazolam 0.5µg/kg, inj Glycopyrrolate 4µg/kg before induction. Preoperative Heart Rate (HR), Respiratory Rate (RR), Blood Pressure (BP) and Oxygen saturation (SPO₂) and were recorded using routine monitors. After pre oxygenation (100%) O_2 for 3 minutes, anesthesia was induced with IV Propofol 2-3mg/kg. Anesthesia was maintained by O₂,N₂O and Sevoflurane and spontaneous respiration with Jackson Ree's modification of Ayre's T-piece. Intravenous fluid administration was done using Holliday and Segar formula. Subsequently all children were given caudal block in the lateral position, before the start of surgery using appropriate drug depending on the group to which they were assigned. The duration and type of surgery was noted. Hemodynamic parameters like HR, Systolic BP, Diastolic BP, MAP, RR, and SPO₂ were noted at every 5 minutes for the first 30 minutes, every 10 minutes till the completion of 1 hour, followed by every 2 hours till 24 hours. Pain scores were noted using Modified Objective Pain Score (MOPS)⁷ Adverse effects in both groups, if any were recorded for24 hours.

Results

There were no differences between the two groups with respect to age, gender and weight as shown in table 1. [Table I]: Demographic Data.

| | Group I | Group II | P value |
|-------------|-----------------|-----------------|-----------|
| Age (years) | 4.28 ± 1.8 | 3.80 ± 1.4 | >0.05(NS) |
| Sex | M-38 F-7 | M-40 F-5 | >0.05(NS) |
| Weight (kg) | 14.7 ± 4.26 | 15.1 ± 2.58 | >0.05(NS) |

NS-Not Significant

Mean duration of analgesia was longer in group II than in group I which was statistically significant (P<0.05) as shown in table II. Comparison of Modified Objective Pain Scores (MOPS) between the two groups is shown in table III. There was a statistically significant lower pain score in group II as compared to group I (p<0.05).

[Table II]: Duration of postoperative analgesia

| | Group I | Group II | P value |
|---------|-------------------|--------------|----------|
| Minutes | 392.6 ± 49.31 | 445.0± 49.62 | <0.05(S) |

S-Significant

[Table III]: Comparison of Pain Scores

| MOPS score 1-10) | G | roup I | Group | II | P value |
|------------------|-------|--------|-------|------|----------|
| | Cases | % | Cases | % | |
| 0-2 | 18 | 40 | 40 | 88.8 | <0.05(S) |
| 3-5 | 27 | 60 | 5 | 11.2 | <0.05(S) |
| Total | 45 | 100 | 25 | 100 | |

S-Significant

Hemodynamic parameters showed statistically significant (p<0.05) decrease in heart rate and mean arterial pressure in group II in comparison with group I as shown in figures 1, 2. There was no statistically significant difference in respiratory rate and oxygen saturation as shown in tables IV and V respectively (p>0.05). No adverse effects were observed in either group.

[Figure1]: Mean Heart rate in both groups. .







[Table IV]: Mean Respiratory rate (Min)

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|------------------------------------|------------------|-----------------|
| Preoperative | 23.2 ± 3.84 | 23.6 ± 3.90 |
| Intraoperative | 23.8 ± 3.88 | 24.0 ± 4.02 |
| Post operative | 24.26 ± 3.80 | 24.3 ± 4.12 |

[Table V]: Mean oxygen saturation (SPO₂).

| Preoperative | 98.8 ± 0.72 | 99.0 ± 0.74 |
|----------------|------------------|------------------|
| Intraoperative | 98.4 ± 0.69 | 97.01 ± 0.70 |
| Post operative | 97.08 ± 0.72 | 98.78 ± 0.66 |

Discussion

Caudal injection of bupivacaine is commonly used to provide anesthesia for lower abdominal surgeries in children. Various authors have used different concentrations of bupivacaine for intraoperative caudal supplementation from 0.25% to 0.175 %(Gunter et al⁸) for post operative analgesia. Wolf et al⁹ have shown that 0.125% bupivacaine administered caudally provides relief from post operative pain equivalent to that obtained from 0.25% bupivacaine but with less leg weakness and with reduced time until standing is possible. Therefore we have used 0.125 % bupivacaine in our study. The limitation with bupivacaine in its use as a single drug is that its analgesic effect finishes early and additional analgesics are needed for pain relief in postoperative period. Various additives to bupivacaine have been studied to prolong the analgesic effects. Attempts of combining bupivacaine with other non opioids such as clonidine, ketamine and neostigmine have met with different degrees of success in post operative pain free period.⁵ Addition of morphine to caudal bupivacaine has been found to improve both the efficacy and duration of analgesia but has the drawback of causing respiratory depression.⁹ Fentanyl has been explored as it is a synthetic opioid agonist. It affects its analgesic property by binding to µ receptors. It also binds to kappa and delta receptors within the spinal cord, producing spinal analgesia. However Gaitini LA et al¹⁰ has reported no improved efficacy of the combination of small dose fentanyl (1µ/kg) and bupivacaine 0.25 %, over bupivacaine 0.25 % alone when used for caudal anesthesia. Similarly Baris et al¹¹ reported that caudal block with 0.75ml/kg 0.25% bupivacaine and 50 μ /kg midazolam or 1 μ g/kg fentanyl provides no additional analgesic benefit to bupivacaine alone when administered in children operated for unilateral inguinal hernia..

However Aprodu GS et al¹² reported that caudal block with lidocaine 1% and bupivacaine 0.25 %; fentanyl 1µg/kg with 0.25% bupivacaine; plain bupivacine 0.25% with general anesthesia, is an effective method for both intra and post operative pain relief in children of age group 1-12 months and 1-6 years. Desai DJ et al⁶ concluded that 1µg/kg fentanyl added to 0.25 % bupivacaine for caudal produces prolonged blockade post-operative analgesia than 0.5 µg/kg fentanyl. Yaddanapudi et al^{13} reported that addition of 1µg/kg but not 0.5µg/kg of fentanyl to caudal bupivacaine prolonged the duration of postoperative analgesia in children posted for genitourinary surgery and herniotomy.

In the present study fentanyl produced postoperative pain relief in both doses but statistically significant analgesia was produced with doses of $1\mu g/kg$ (group II) when used with bupivacaine. Period of analgesia in group I was 392 ± 49.31 minutes and group II was 445.0 ± 49.62 . The difference in duration of analgesia in the two groups is statistically significant (p<0.05). These findings concur with the observations of the study conducted by Desai et al¹¹. Motor block was evaluated using modified Bromage scale.¹⁴ In the present study no motor blockade was observed in any child in either group. However Baris at al¹¹ encountered motor weakness in two children, one of whom had received 0.25% bupivacaine 0.75 ml/kg plus fentanyl 1µg/kg, the other child received 0.25% bupivacaine 0.75 ml/kg alone, whereas the study conducted by Gunter et al⁶ suggested that bupivacaine concentrations of 0.175 % are related with a lower incidence of complaints of leg weakness and paraesthesia.

Hemodynamic parameters showed more decrease in heart rate (HR) and mean arterial pressure (MAP) in group II in comparison with group I. Assessment of sedation was done by a three point sedation score (0awake, 1- drowsy, 2- sleep). Sedation was not observed in any child in both the groups.

Conclusion

We thus conclude that, both doses, 0.5μ g/kg and 1μ g/kg fentanyl with bupivacaine 0.125 % when administered caudally provide satisfactory surgical anesthesia and post operative analgesia with prolonged period of analgesia with fentanyl 1μ g/kg in comparison with 0.5μ g/kg without any major postoperative complications. However hemodynamic parameters showed more decrease in heart rate and mean arterial pressure in dose of 1 ug/kg fentanyl.

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