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# Comparative evaluation of fentanyl and dexamethasone as an adjuvant to bupivacaine for caudal analgesia in children undergoing infra-umbilical surgery

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**Abstract**
**Background:** Caudal analgesia is the most commonly used technique providing intra and postoperative analgesia for various infra-umbilical surgeries for paediatric patients. Main disadvantage of single dose caudal block with local anesthetic alone is its short duration of action. To overcome this limitation, several adjuvants have been added to local anaesthetic agent to prolong the duration of analgesia.
**Aims and Objectives:** To compare the effectiveness of caudal Bupivacaine, Bupivacaine + Fentanyl and Bupivacaine + Dexamethasone for intraoperative hemodynamic stability, duration of analgesia, total analgesic requirement in first 24 hours, postoperative sedation and side-effects.
**Materials and Methods**: The study was conducted on 150 children of ASA I and II physical status aged 1 to 6 years undergoing elective infra-umbilical surgeries. The patients were randomly allocated into 3 groups of 50 patients' each and the following were given in the caudal epidural space after the induction of anesthesia. In Group B, patients received 0.25% Bupivacaine 1ml/kg in normal saline caudally. Group BF patients received 0.25% Bupivacaine 1ml/kg + inj Fentanyl 1µg/kg in normal saline caudally. Group BD patients received 0.25% Bupivacaine 1ml/kg + inj Dexamethasone 0.1mg/kg in normal saline caudally.
**Results:** Group BD had prolonged mean duration of analgesia (10.80 ± 0.755) hr, reduced mean total analgesic requirement in first 24 hour (1.90 ± 0.404), minimum sedation and adverse effects.
**Conclusion:** Group BD shows prolonged duration of analgesia, reduced total analgesic requirement in first 24 hour with minimum sedation and adverse effects as compared to Bupivacaine alone or Bupivacaine with Fentanyl.

**Keywords:** Caudal, bupivacaine, fentanyl, dexamethasone, paediatric, analgesia

## Introduction
Pain is most commonly misunderstood, under diagnosed and untreated medical problem particularly in children. Inadequately and inappropriately managed pain in children can lead to long-term physical, psychosocial and behavioural sequelae [1]. Under treatment of pain in children is common because of the difficulty in pain assessments in very small children [2].
The most commonly used regional technique in pediatric patient is caudal epidural block. Advantages of the caudal block are early extubation, decreased risk of chest infections, decreased postoperative analgesic requirements, early ambulation and early discharge from hospital. Caudal analgesia can be administered either through a single shot technique or as a continuous infusion through caudal catheter. Use of caudal catheter for continuous infusion is usually not preferred due to high risk of contamination of catheter with faecal material.
Single-shot caudal blockade continues to be one of the traditionally opted perioperative pain management strategies in paediatric patients. The ease of performing a successful block and reliable analgesia in the immediate postoperative period has made it a popular and most accepted technique in paediatric age Group [3]. Main disadvantage of a single dose caudal block with local anesthetic alone is its short duration of action and need for immediate administration of analgesics postoperatively.
To overcome this limitation, several adjuvants like Clonidine, Dexmedetomidine, Neostigmine, Ketamine, Midazolam have been added to local anaesthetic agent in a single shot technique. The use of these adjuvants improves the quality of block and duration of analgesia but most of these adjuvants are associated with various side effects [4, 5].

Fentanyl has been widely used as an adjuvant to local anaesthetics in caudal block. It acts on substantia gelatinosa on the dorsal horn of spinal cord, by blocking fibers carrying nociceptive impulses both pre- and post synaptically [22].

Dexamethasone is a long-acting corticosteroid with anti-inflammatory action. The mechanism of analgesic effect of Dexamethasone is due to the local anesthetic action of corticosteroids, and also it inhibits the transcription factor - nuclear factor - kB (NF-kB) which is responsible for pain and present in the nervous system [17, 18].

When administered in combination with local anesthetics in the epidural space, it has been shown to reduce postoperative rescue analgesic consumption following abdominal and orthopaedic surgeries [15].

This study is designed to evaluate the inherent intense anti-inflammatory effects of Dexamethasone which promotes it's analgesic effectiveness. The added advantage of minimal side effects when compared to other adjuvants makes Dexamethasone an attractive choice for further evaluation.

In this study, we compared the caudal Fentanyl 1µg/kg and Dexamethasone 0.1mg/kg as an adjuvant to 0.25% Bupivacaine in respect to their analgesic effects and adverse effects in paediatric patients undergoing infra-umbilical surgeries.

## Aims and Objectives

**Primary Objective:** To compare Fentanyl and Dexamethasone as an adjuvant to caudal Bupivacaine in pediatric patients undergoing elective infra-umbilical surgery for intraoperative hemodynamic stability, duration of analgesia. (Time to first rescue analgesia)

**Secondary Objective:** Total analgesic requirement in first 24 hours, postoperative sedation, postoperative side effects.

## Patients and Methods

This study was conducted in the Department of Anaesthesiology, M.G.M. Medical College & M.Y. Hospital, and Indore after taking approval from Ethics and Scientific Review Committee. A total of 150 children aged 1 to 6 years of ASA grade I and II of either sex posted for infra-umbilical surgery under caudal block were included in our study. 50 patients who qualified the inclusion criteria were enrolled in each group. Written informed consent was obtained from all patients' parents who were enrolled in the study. Patients were divided into Group B, Group BF and Group BD equally (50 patients in each group).

In Group B, patients received 0.25% Bupivacaine 1ml/kg in normal saline caudally. Group BF patients received 0.25% Bupivacaine 1ml/kg + inj Fentanyl 1µg/kg in normal saline caudally. Group BD patients received 0.25% Bupivacaine 1ml/kg + inj Dexamethasone 0.1mg/kg in normal saline caudally.

After shifting to operation theatre, premedication was done with intravenous Glycopyrrolate 0.008 mg/kg and intravenous Midazolam 0.05 mg/kg through already secured venous access. Baseline vitals were recorded.

Anaesthesia was induced with injection Ketamine 2mg/kg and maintained with 40% $O_2$: 60% $N_2O$ mixture and Sevoflurane 0.8% to 1% with face mask till the end of surgery.

The child was turned to the lateral position for administration of the caudal block. Under sterile technique, the caudal space was identified using standard landmarks and a 22 G short bevelled needle was inserted into the caudal epidural space. Once the needle was placed in epidural space, after negative aspiration for blood and cerebrospinal fluid, the study drug was injected slowly according to the group assigned in the chit.

The drugs for administration in the caudal space were prepared by an anaesthesiologists not participating in the study. The caudal block was performed in the lateral position by another anaesthesiologists who was blinded to the drug that was injected.

After the block, if any child showed lower limb movement, increase in heart rate or mean arterial pressure by 15% more than the baseline values, it was considered as a failed caudal block and they were excluded from the study.

After ensuring adequate effect of caudal block, surgeon was allowed to proceed with the surgery.

All patients were monitored intraoperatively for Pulse rate, MAP, $SpO_2$ respiratory rate. The parameters were documented every 10 min interval upto 90 min. At the end of surgery all anaesthetics were discontinued and total time of surgery was recorded.

After the completion of surgery, patients were shifted to the postanaesthesia care unit for further observation.

The pain was assessed using FLACC scale (face, legs, activity, cry, consolability) postoperatively at hourly intervals till the score was > 3. At this time rescue analgesia was given with oral Paracetamol 15mg/kg and time to first rescue analgesia was noted as duration of analgesia. Total analgesic consumption in first 24 hours was also recorded.

**FLACC score to assess post operative analgesia**

| Parameter | Finding | Points |
|---|---|---|
| Face | No particular expression or smile | 0 |
| | Occasional grimace or frown withdrawn, disinterested | 1 |
| | Frequent to constant quivering chin, clenched jaw | 2 |
| Leg | Normal position or relaxed | 0 |
| | Uneasy, restless, tense | 1 |
| | Kicking or legs drawn up | 2 |
| Activity | Lying quietly, normal position, moves easily | 0 |
| | Squirming, shifting back and forth, tense | 1 |
| | Arched, rigid or jerking | 2 |
| Cry | No cry (awake or sleep) | 0 |
| | Moans or whimpers occasional complaints | 1 |
| | Crying steadly, screames or sobes, frequent complaints | 2 |
| Consolability | Content relaxed | 0 |
| | Reassured by occasional touching hugging or being to, distractable | 1 |
| | Difficult to console or comfort | 2 |

Total range 0-10

0 = No pain, 1-3 =Mild pain, 4-7 =Moderate pain, 8-10 =Severe pain

Degree of sedation (Ramsay sedation score) was also observed at hourly intervals upto 3 hours postoperatively.

**Ramsay Sedation Scor**

| | Score |
|---|---|
| 1 | Anxiety and completely awake |
| 2 | Completely awake |
| 3 | Awake but drowsy |
| 4 | Asleep but responsive to verbal commands |
| 5 | Asleep but responsive to tactile stimulus |
| 6 | Asleep and not responsive to any stimulus |

Patients were also observed for any adverse effects like bradycardia, hypotension, nausea, vomiting, respiratory depression in the postoperative period.

1. If there was any respiratory depression (the SPO2 <95%) than children were given supplemented O2.
2. If bradycardia (defined by decrease in basal heart rate by 20%) occurred then treated with i.v. atropine .01–.02 mg/kg.
3. If hypotension (decrease in basal mean arterial blood pressure by 20%) occurred than treated with i.v. fluid.
4. If nausea/ vomiting occurred than treated with i.v. ondansetron 0.15 mg/kg.
5. Other.

**Statistical Data Analysis**

The data was initially entered into the Microsoft excel from the customized proforma for analysis. SPSS software was used for calculating the P values. Comparison of means between the two Groups was done using ANOVA test, unpaired‘t’ test & paired‘t’ test. Descriptive statistics was presented in the form of numbers and percentages. A p value of <0.05 was taken as statistically significant. The final data was presented in the form of tables and graphs.

**Observation and Result**

- **Demographic Data: -** All patients in three groups were comparable according to age, sex, weight, duration of surgery, type of surgery with no significant statistical difference ($p$>0.5).

**Table 1:** Demographic data

| | Group B | Group BF | Group BD | P value |
|---|---|---|---|---|
| Age (years) | 2.82 ±1.782 | 2.52±1.741 | 2.72±1.642 | 0.4249 |
| Sex (male/female) | 48/2 | 48/2 | 46/4 | 0.5897 |
| Weight (Kg) | 14.26 ± 4.606 | 13.4 ± 4.716 | 14.52 ± 4.101 | 0.4270 |
| Duration of surgery (minutes) | 36.6 ± 7.85 | 37.7 ± 11.25 | 38.6 ± 12.61 | 0.4215 |
| **Type of surgery** | | | | |
| Circumscision | 12 (24%) | 18 (36%) | 13 (26%) | 0.7845 |
| Herniotomy | 30 (60%) | 25 (50%) | 26 (52%) | |
| Orchidopexy | 4 (8%) | 3 (6%) | 6 (12%) | |
| Urethroplasty | 4 (8%) | 4 (8%) | 5 (10%) | |

Data expressed as mean and standard deviation (Mean ± SD)

The mean of pulse rate changes among the studied groups were comparable at all time and until 90 minutes from the start of surgery in Fig.1

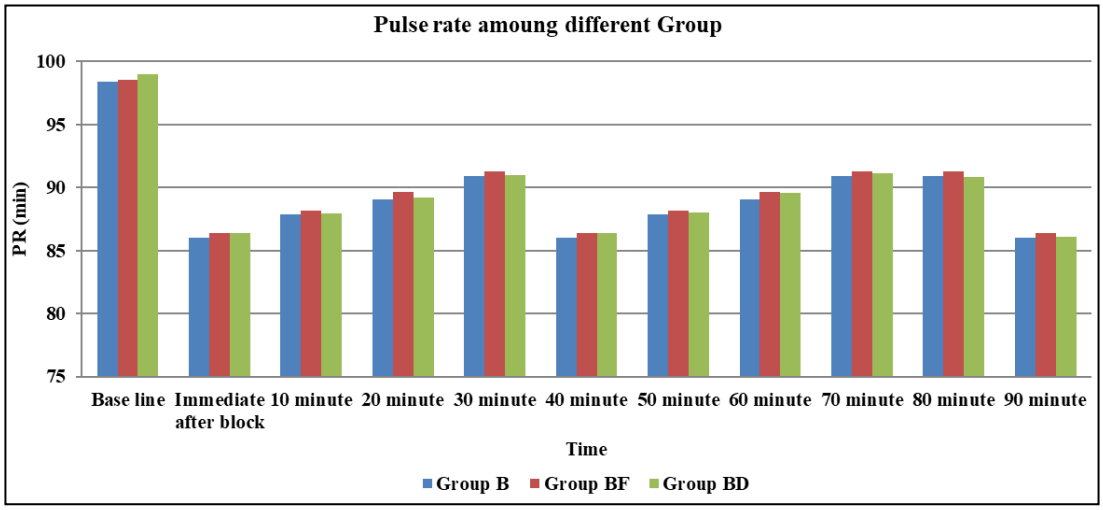


**Fig 1:** Pulse rate changes among the studied groups, data expressed by mean and standard deviation

The mean of mean arterial blood pressure changes among the studied groups were comparable at all time and until 90 minutes from the start of surgery in Fig.2

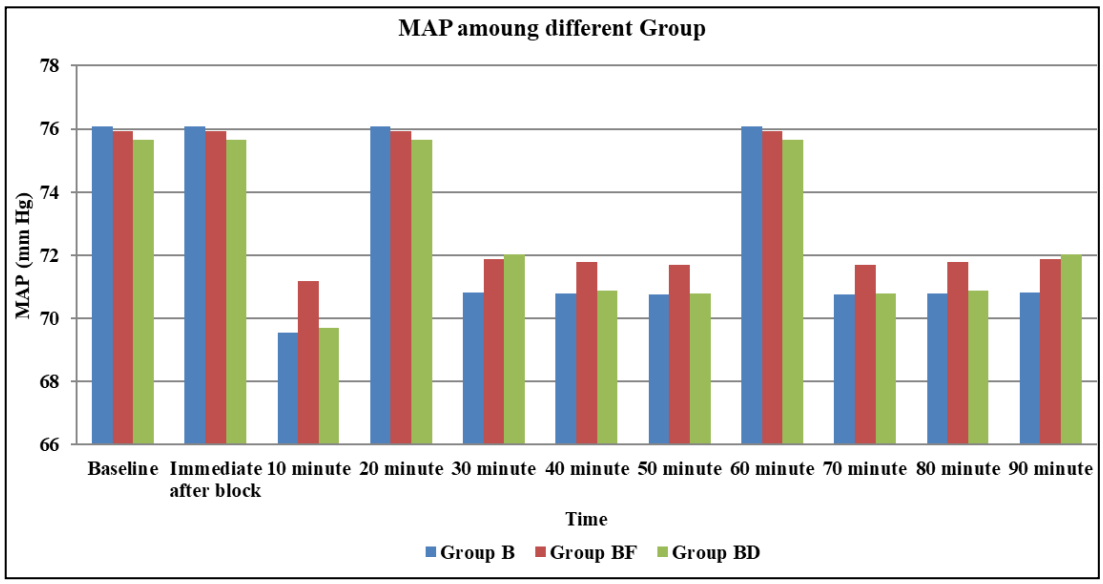


**Fig 2** MAP changes among the studied groups, data expressed by mean and standard deviation

The mean of $SpO_2$ changes among the studied groups were comparable at all time and until 90 minutes from the start of surgery in Fig.3

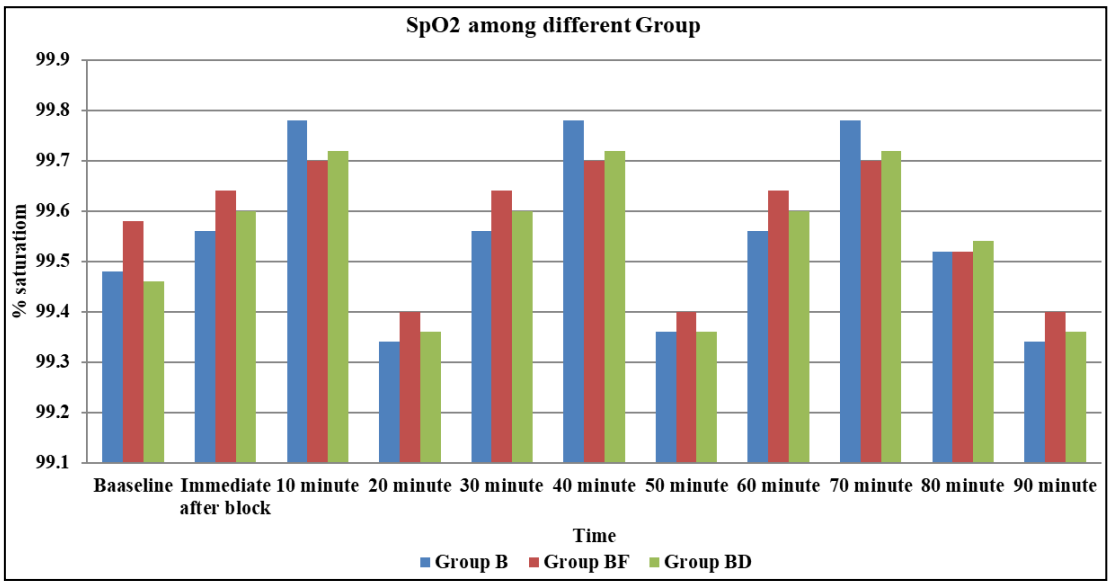


**Fig 3:** $SpO_2$ changes among the studied groups, data expressed by mean and standard deviation

The mean of respiratory rate changes among the studied groups were comparable at all time and until 90 minutes from the start of surgery in Fig.4

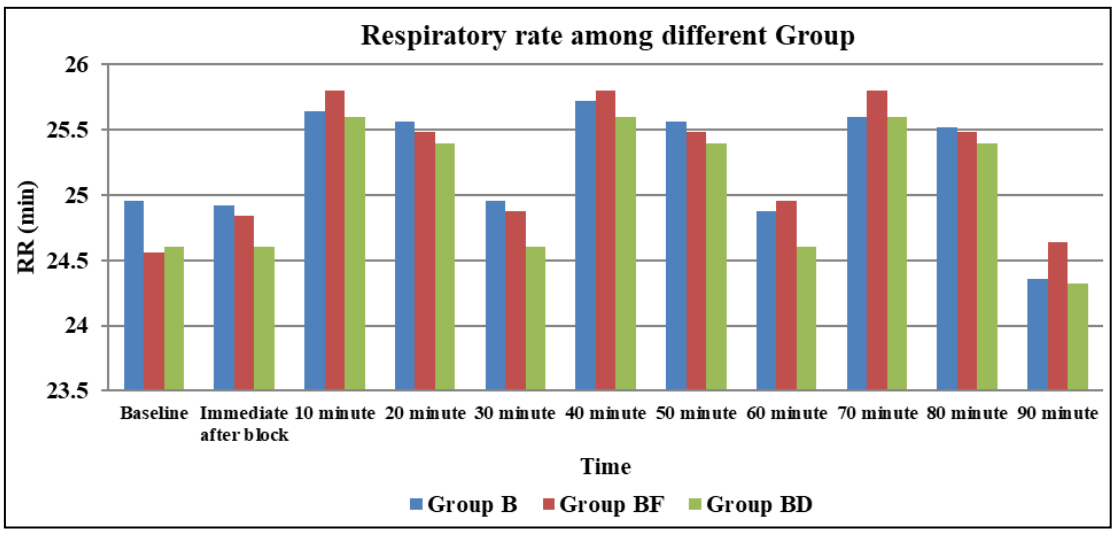


**Fig 4:** Respiratory rate changes among the studied groups, data expressed by mean and standard deviation

Post operative pain score (FLACC score) was a significant difference among the Groups in the FLACC score measured hourly in the post operative period. Group B achieved FLACC score more than 3 at 5th hr, Group BF achieved FLACC score more than 3 at 7th hr and Group BD achieved FLACC score more than 3 at 11th hr. Fig 5

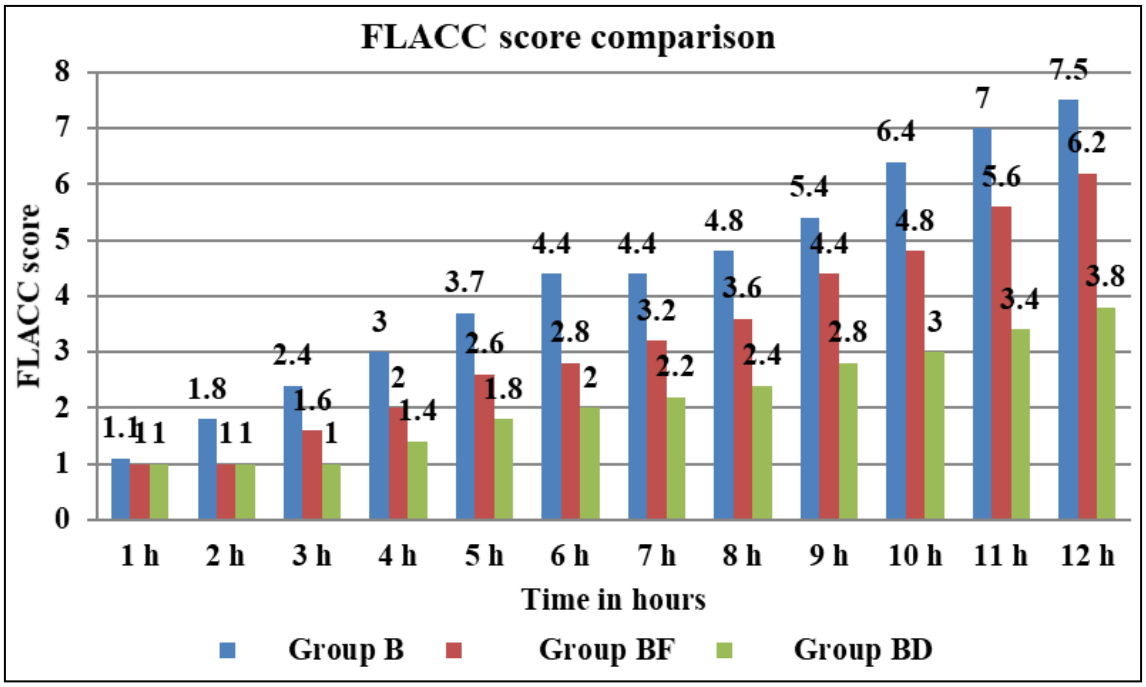


**Fig 5:** Post operative pain score (FLACC score) changes among the studied groups, data expressed by mean and standard deviation

The mean duration of analgesia (time to first rescue analgesia) of the Group B was 5.08± 1.010 hr, Group BF was 7.20 ± 0.755 hr and Group BD was 10.80 ± 0.755 hr. Fig 6

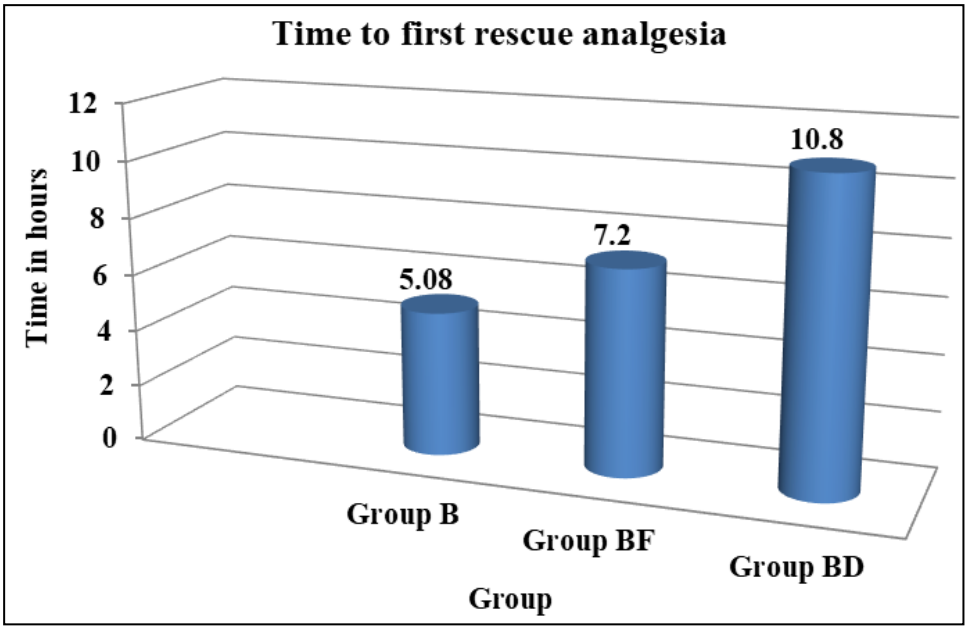


**Fig 6:** Duration of analgesia (time to first rescue analgesia) in Group B, BF and BD patients, data expressed by mean and standard deviation

The mean total analgesic requirement in first 24 hours of the B Group was 4.8± 0.756, BF Group was 3.4 ± 0.495 and BD Group was 1.80 ± 0.404. Fig 7

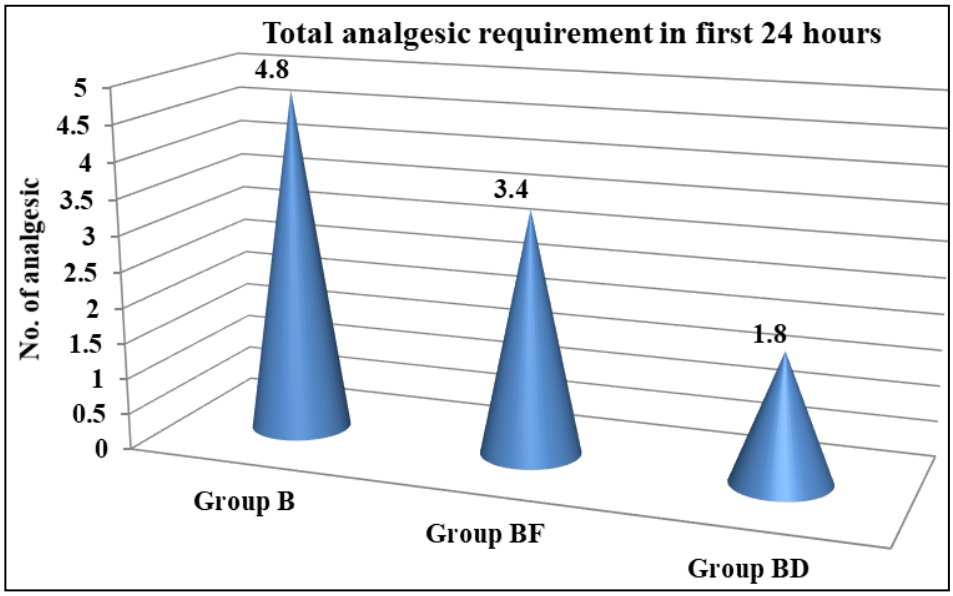


**Fig 7:** Total analgesic requirement in first 24 hours in Group B, BF and BD patients, data expressed by mean and standard deviation

Sedation was more in Group BF 1st hour (3.90± 0.303), 2nd hour (2.80± 0.756), 3rd hour (1.90± 0.707) as compared to Group B and Group BD was statistically significant and the sedation score was comparable between Group B and Group BD. Fig 8

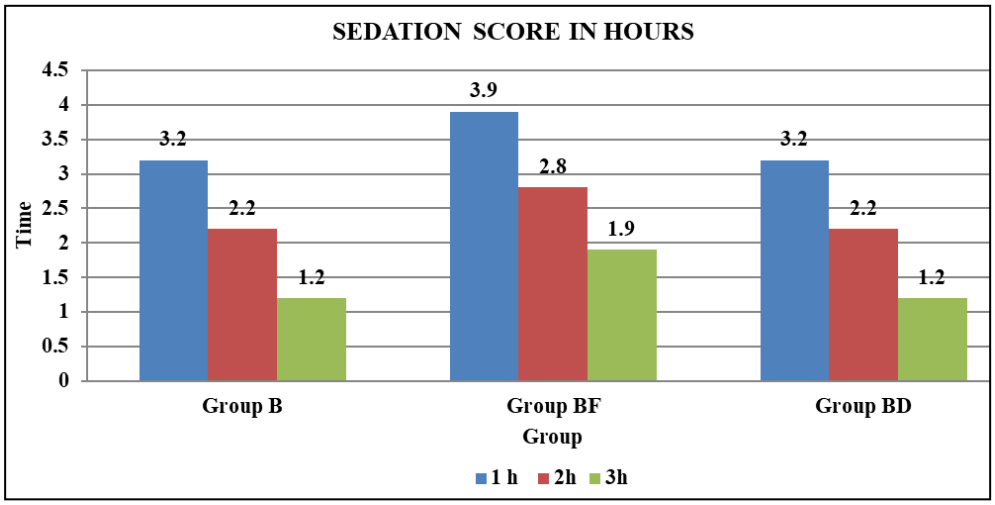


**Fig 8:** Sedation score in Group B, BF and BD patients, data expressed by mean and standard deviation

Incidence of adverse effect like bradycardia, respiratory depression and nausea vomiting was higher in Group BF as compared to Group B and Group BD

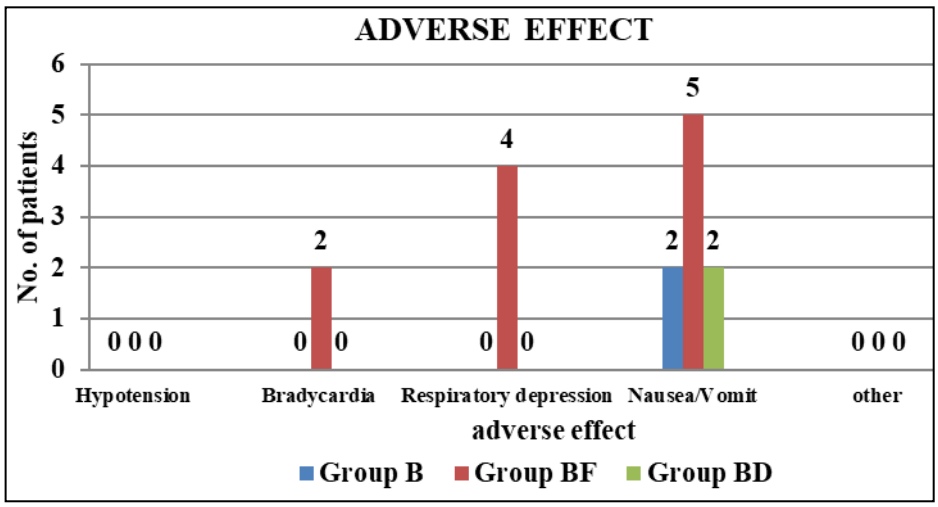


**Fig 9:** Adverse effects in Group B, BF and BD patients

## Discussion

Pain is the most dreaded symptom of disease, which man is always trying to alleviate and conquer since ages. In this regard, children are special because it is a complex phenomenon in them.

Caudal block is an efficient method of providing intraoperative and postoperative analgesia in children undergoing infra-umbilical surgeries. Caudal analgesia decrease the amount of intra venous and inhaled anaesthestic administration, reduce the stress response to surgery and helps in a rapid, smooth recovery and provides good postoperative analgesia.

In this study, we compared Fentanyl 1 µg/kg and Dexamethasone 0.1mg/kg as an adjuvant to 0.25% Bupivacaine for caudal analgesia in children undergoing infra-umbilical surgeries.

The present study was assessed under following heading and compared with relevant studies supporting the result of our study.

### Demographic data (age, sex, weight), duration of surgery and type of surgery

Table 1 shows distribution of age, sex, weight, duration of surgery and type of surgery in all three Groups.

### Hemodynamic variables

Figure (1, 2, 3, 4) show comparison of hemodynamic variables (Pulse rate, MAP, Spo2, Respiratory rate) in all three Groups (Group B, BF and BD).

Pulse rate, MAP, SpO2 and respiratory rate was assessed every 10 minutes for 90 minutes after the caudal block. There was no statistical significant difference in hemodynamic variable up to the observation period.

### Our results were supported by the studies done by

El-Feky *et al*. [8] compared Fentanyl, Dexmedetomidine, and Dexamethasone as additives to caudal mixture of Linocaine 1% and Bupivacaine 0.25% in paediatrics patients who underwent lower abdominal surgeries. They concluded that the means of HR and MAP changes among the studied Groups were comparable at all times and until 3 h from the start of surgery.

El-Abdein Mohamed *et al*. [10] evaluated the analgesic effect of caudal Dexamethasone 0.1 mg/kg combined with 1 ml/kg of 0.25% Bupivacaine in children and they found that there were no significant differences between the two Groups with regards to heart rate, blood pressure, and oxygen saturation.

Choudhary *et al*. [12] evaluated caudal Dexamethasone 0.1 mg/kg as an adjuvant to Ropivacaine in children 1-5 years and they found that intraoperative haemodynamic parameters were maintained within 20% of base value in both the Groups having no significant variation.

### Postoperative pain score, duration of analgesia, and total analgesic requirement in first 24 hours

Figures (5, 6 and 7) show the comparison of postoperative pain score, duration of analgesia and total analgesic requirement for 24 hours.

### Our results were in agreement with the studies done by

Kim *et al.* [6] evaluated the addition of Dexamethasone 0.1 mg/kg to caudal Ropivacaine 0.15% in children aged between 6 months and 5 years undergoing orchidopexy. In their study, there was increased duration of analgesia of caudal block with Ropivacaine-Dexamethasone, reduced pain severity and analgesic consumption when compared with Ropivacaine 0.15% alone.

Yousef *et al*. [7] found that the addition of Dexamethasone 0.1 mg/kg or magnesium sulfate 50 mg to Ropivacaine 0.15% in caudal analgesia of children aged 1–6 years undergoing inguinal hernia repair prolonged postoperative analgesia, increased the time to the first rescue analgesic dose, and decreased the need for postoperative rescue analgesics without an increase in the side effects.

El-Feky *et al.* [8] found that both Dexamethasone and Dexmedetomidine when combined with local anesthetics in the caudal analgesia prolonged the postoperative analgesia with less pain score compared to caudal local anesthetic alone or when added to caudal Fentanyl.

Solanki *et al*. [9] Compared Dexamethasone 0.2 mg/kg and Clonidine 1 µg /kg as additives to caudal 1ml/kg of 0.25% Bupivacaine in children 1-12 years old scheduled for subumbilical 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*. [10] found that adding Dexamethasone 0.1 mg/kg to the caudal Bupivacaine significantly prolonged the duration of postoperative caudal analgesia and decreased the intensity of postoperative pain during hypospadias repair surgery.

Choudhary *et al*. [12] evaluated caudal Dexamethasone 0.1 mg/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.

Parameswari *et al*. [13] in their prospective, double-blind trial, found that the addition of Dexamethasone 0.1mg/kg to 1 ml/kg of 0.125% bupivacine in caudal analgesia of children aged 6 months–6 years undergoing infra-umbilical surgeries prolongs the postoperative analgesia without any side effects.

Caudal Dexamethasone increases the duration of analgesia. The mechanism of analgesic effect of Dexamethasone may be due to the local anesthetic action of corticosteroids on nerve by direct membrane action [21]. Hence, Dexamethasone might potentiate the effect of Bupivacaine and prolong the duration of analgesia [19]. Another possible mechanism involves the effect of dexamethasone on the spinal cord. The transcription factor nuclear factor-k B (NF-kB) is expressed throughout the nervous system and plays an important role in the development of pathological pain.. Dexamethasone inhibits this transcription factor nuclear factor-kB (NF-kB) and prolongs the duration of analgesia. [17, 18].

These findings suggest that dexamethasone might prevent central sensitization after surgery and strengthen the preventive analgesia of caudal block.

### Sedation score

Sedation was more in Group BF; 1st hour (3.90± 0.303), 2nd hour (2.80± 0.756), 3rd hour (1.90± 0.707) as compared to Group B and Group BD and was statistically significant. Fig.8.

**Our results were supported by studies done by**

El-Feky *et al*. [8] found that sedation score was significantly more in the 1st and 2nd hour in the caudal Fentanyl and Dexmedetomidine Groups. Sedation score in the 3rd, 6th and 12th hours was comparable.

Solanki *et al*. [11] Compared caudal Tramadol versus caudal Fentanyl with Bupivacaine for prolongation of postoperative analgesia in paediatric patients. They found that in the postoperative period up to 1½ h, Group Fentanyl had higher sedation scores compared to other Groups.

As regards sedation score, there was a significant increase in sedation score in first 2 hours in the Fentanyl group(Group BF) as compared to the control( Group B) and Dexamethasone group (Group BD). The sedation score in Dexamethasone group was little and the level was acceptable to the parents as there was no crying.

**Postoperative adverse effects**

Figure: 9 Show the comparison of adverse effects (hypotension, bradycardia, respiratory depression, nausea/vomiting and other) in all the three Groups.

**Our results were supported by studies done by**

El-Feky *et al*. [8] found that caudal Fentanyl 1 µg/kg produced postoperative vomiting, itching and significant respiratory depression in the Fentanyl Group as compared to other Groups. The other adverse effects were comparable in studied Groups.

El Hamamsy *et al*. [16]. observed that caudal Fentanyl 2 µg/kg produced analgesia for up to 4.5 h. However, the addition of Fentanyl to local anesthetics increased the incidence of vomiting and desaturation as compared with other Groups who did not receive Fentanyl.

Shukla *et al*. [14]. observed a transient decrease of oxygen saturation to 91% in 5 cases and vomiting in 8 patients out of 45 who received Fentanyl 1 µg/kg with Ropivacaine caudally.

Dexamethasone is known to reduce nausea and vomiting in the perioperative period [46]. The antiemetic effect could be due to the inhibition of prostaglandins, prevention of serotonin release in the gut, reduction in neural 5HT levels or release of endorphins.

Fentanyl is a synthetic opioid agonist. The analgesic action of Fentanyl is by binding to mu receptor, as well as to kappa and delta receptors within the spinal cord, producing spinal analgesia. It crosses the lumbar dura and penetrates quickly the lipid phase of the underlying tissue of the cord with minimal migration of opioids in rostral direction, hence, avoiding central nervous system depression of respiratory and cardiovascular system [20].

The results of our observation shows that in addition to prolonged post-operative analgesia, Dexamethasone has a favourable safety profile and stable hemodynamics, which are in concordance with the studies published by several other authors.

**Limitations**

**This study has few limitations**

Firstly, the inclusion of children in the age Group of 1 to 6 years of age with varying thresholds for pain and ability to communicate pain could have led to variability in the pain scores.

Secondly, patients coming for a wide variety of subumbilical surgeries were chosen for the study. The varying degree of invasiveness of the different surgeries could have varying degrees of pain. However, the different types of surgeries were equally distributed in the three Groups.

**Conclusion**

We concluded that addition of 0.1 mg/kg of Dexamethasone as an adjuvant to 0.25% Bupivacaine for caudal block and administered as a 1 ml/kg mixture in children undergoing infra-umbilical surgeries showed a prolonged duration of analgesia (time to 1st rescue analgesia) with hemodynamic stability, significant reduction in total analgesic requirement in first 24 hour, minimal sedation and adverse effects as compared to 0.25% Bupivacaine alone or 0.25% Bupivacaine with Fentanyl 1 µg/kg.

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Nil

**Conflicts of Interest**

There are no conflicts of interest.

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