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COMPARISON OF FENTANYL AND DEXAMETHASONE AS ADJUVANTS TO CAUDAL 0.25% ROPIVACAINE FOR ANALGESIC EFFICACY IN PEDIATRIC INFRA UMBILICAL SURGERIES: A RANDOMIZED CONTROLLED STUDY

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ABSTRACT:

Introduction: In paediatric patients, caudal anaesthesia has proven to be a dependable and efficient anaesthetic treatment. However, the short half-life of the local anaesthetic drugs used in caudal block has been addressed by the use of adjuvants in clinical settings.

Objectives: To compare the analgesic efficacy of Fentanyl and Dexamethasone as an adjuvant to caudal Ropivacaine in paediatric patients undergoing elective infra-umbilical surgery.

Methodology: Seventy patients were divided into two groups of 35 each. Group A was given 0.25% Ropivacaine along with Fentanyl at 2mcg/kg while Group B was given 0.25% Ropivacaine at along with Dexamethasone at 0.1mg/kg.

Results: In Group A, the mean duration of analgesia was 559.43 mins while in case of Group B it was 979.09 mins. The Face, Legs, Activity, Cry, Consolability (FLACC) score was always more in Group A compared to group B with it being significant at 2hr, 3hr, 4h, 5hr, 6hr and 8hr respectively with a p value of 0.04, 0.001, 0.05, 0.029, 0.012 and 0.062.

Conclusion: It can be concluded that 0.1 mg/kg of dexamethasone added to 0.25% ropivacaine concentration was more efficacious compared to fentanyl in prolonging the duration of analgesia.

Keywords: caudal anaesthesia, fentanyl, dexamethasone, ropivacaine

INTRODUCTION

The provision of adequate perioperative analgesia in children has improved recently due to increased awareness about the adverse effects of untreated pain as well as the availability of new drugs. However, inadequate treatment of children's pain can have long-term physical, psychosocial, and behavioural consequences (1). Single-shot caudal blockade continues to be one of the traditionally opted perioperative pain management strategies in paediatrics. The ease of performing a successful block that results in reliable analgesia in the immediate postoperative period has made single-shot caudal blockade a popular option (2). However, the length of the local anaesthetic's effect limits how long a caudal block can offer analgesia. To get around this problem, several adjuvants to local anaesthetics have been studied to enhance the block quality and duration of anaesthesia. (3–5)

Among LA, ropivacaine offers a higher margin of safety, less motor block, lower toxicity to the central nervous system and cardiovascular system, and an analgesic duration that is comparable to that of bupivacaine. To prolong caudal analgesia, a variety of adjuvants (opioids, ketamine agonists) have been added to the single-shot approach; nevertheless, their usage is restricted due to side effects such as nausea, vomiting, pruritis, respiratory depression, and urine retention (6). Bradycardia and extended sedation are linked to alpha-2 agonists such as clonidine and dexmedetomidine. Opioids are linked to a higher risk of respiratory depression, and there is ongoing debate regarding midazolam's neurotoxicity. The best adjuvant is still up for debate, and researchers are currently trying to find a medication that will give children caudal block the most analgesia with the fewest possible adverse effects (4).

Since it blocks the fibres that convey nociceptive impulses both pre and post-synaptically in the substantia gelatinosa in the dorsal horn of the spinal cord, fentanyl has been frequently utilized as an analgesic adjuvant to epidural analgesia. However, it has unwanted side effects such vomiting, itching, and respiratory depression (7). Dexamethasone is a long-acting corticosteroid with anti-inflammatory properties. It has been demonstrated that when given in conjunction with local anaesthetics in the epidural area, postoperative rescue analgesic intake after orthopaedic and abdominal procedures is decreased. Dexamethasone's natural strong anti-inflammatory properties increase its analgesic efficacy. This medication is a desirable option for additional research because it has fewer negative effects than other adjuvants (8).

The aim and objective of this study was to compare the analgesic efficacy of fentanyl and dexamethasone as adjuvants to caudal 0.25% ropivacaine in paediatric infra umbilical surgeries by evaluating the duration of analgesia (time to first rescue analgesia), total rescue analgesia, and Face, Legs, Activity, Cry, Consolability (FLACC) score at different times points.

METHODOLOGY

Study design:

The study was conducted as a prospective randomized, double-blinded clinical trial after getting Institutional Ethical Committee approval. The study design was thoroughly explained to the parents and written informed consent was obtained from them.

Study setting

It was conducted at Saveetha Medical College Hospital in Chennai over a year from January 2023 to January 2024.

Participants:

A total of 70 children were enrolled in the study and divided into two Groups A and B of 35 each. Group A was given 0.25% Ropivacaine along with Fentanyl at 2mcg/kg while Group B was given 0.25% Ropivacaine along with Dexamethasone at 0.1mg/kg.

Selection criteria

Children in the age group of 1-12 years, of American Society of Anaesthesiologist (ASA) physical status I and II scheduled for elective infra-umbilical surgeries were enrolled into the study after getting parental informed consent. Exclusion criteria included children belonging to ASA-3 and ASA-4, absence of parental consent, emergency surgeries, a history of back infection, allergy to study drugs, bleeding disorders, developmental delay, sepsis or infection at the site of caudal block, and sacral bone abnormalities.

Procedure:

The day before the procedure, a preanesthetic assessment was done. The sealed envelope method was used for randomization. In the preoperative holding area, all children received oral midazolam at a dose of 0.5 mg/kg thirty minutes before being put under anaesthesia. Preinduction monitors, such as non-invasive blood pressure monitoring, electrocardiograms, and pulse oximetry, were set up once the patient was moved into the operating room and documented the baseline values. Using 100% oxygen and 8% sevoflurane the patient was induced anaesthesia through inhalation and an intravenous line was secured.

Intravenous fentanyl (2 mcg/kg) was given. Depending on the attending anaesthesiologist's judgment, airway management techniques included face masks, laryngeal mask airways, or endotracheal tubes. Sevoflurane 2% and a combination of 40% O2:60% N2O were used to maintain anaesthesia. The caudal block was then given to the child when they were in the lateral position. Using sterile techniques, the caudal space was located using common landmarks, and the caudal epidural space was punctured with a 22 G short bevelled hypodermic needle. The correct placement of the caudal needle is determined by palpating the skin of the sacrum and quickly injecting 3 mL of saline through it. If no midline oedema was found, the needle is most likely in the right place. On the other hand, the needle was positioned wrongly and redirected again if there was midline oedema observed after the saline injection. An anesthesiologist who was not involved in the study prepared the medications to be administered in the caudal area. Another anaesthesiologist, blinded to the medication to be administered, carried out the caudal block in the lateral position. Five minutes after the research medicines were inserted caudally, the surgical incision was made. Any increases in heart rate, or mean arterial pressure increase that was 15% higher than baseline values were monitored in the patients, and the presence of any of these indicators was deemed indicative of a failed caudal block. These kids weren't included in the study and were given extra fentanyl intraoperatively.

Outcome measures

Heart rate, non-invasive blood pressure monitoring, pulse oximetry, and end-tidal capnography were among the intraoperative monitoring techniques used. Every five minutes during surgery, till awakening, the above mentioned parameters were recorded. Using the Face, Legs, Activity, Cry, Consolability (FLACC) scale, the pain score was determined following extubation at

intervals of 0 min, 30 min, 1h, 2h, 3h, 4h, 5h, 6h, 8h, 10h, 12h 18h and 24h. After 3 hours of observation in the postanaesthetic care unit, patients were sent to the ward. Every hour for the first 6 hours and every 2 hours till 12 hours and then every 6 hourly, the ward's pain scores were measured and recorded.

If the pain score was >3, oral paracetamol 15 mg/kg was administered as a rescue analgesic, and the total number of rescue doses received in a 24-hour period was noted. A pulse oximeter reading of < 93% or a respiration rate of < 10 breaths per minute that necessitates oxygen supplementation and assisted breathing were considered indicators of respiratory depression. Atropine 20 mcg/kg was administered intravenously to treat bradycardia, which was defined as a heart rate of less than 60 beats per minute or 20% below the baseline value, whichever was lower. Systolic blood pressure that was 20% below baseline and treated with fractionated doses of injection ephedrine was referred to as hypotension. The degree of sedation was also observed at hourly intervals using the Ramsay sedation score. The incidence of adverse effects like bradycardia, respiratory depression, nausea and vomiting was also recorded. Other potential risks included intravascular local anaesthetic infection and local anaesthesia toxicity.

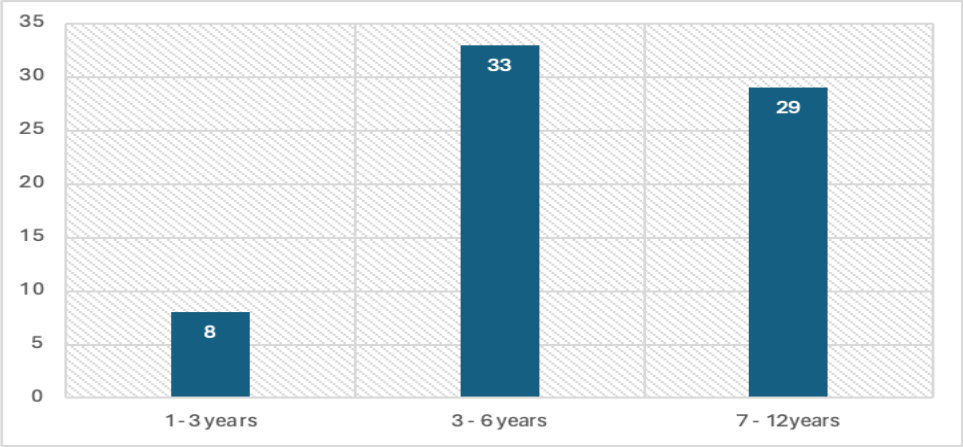
Statistical analysis

For analysis, the data was first transferred from the customized proforma into Microsoft Excel. P values were computed using Python 3 software. The means of the two groups were compared using the Mann Whitney U and independent T-tests depending on the normality of data distribution. Normality was analysed using Shapiro Wilke test and histograms. A presentation of descriptive statistics using percentages and counts was made. Statistical significance was defined as a p-value of less than 0.05. Tables and graphs were used to display the final data.

RESULTS

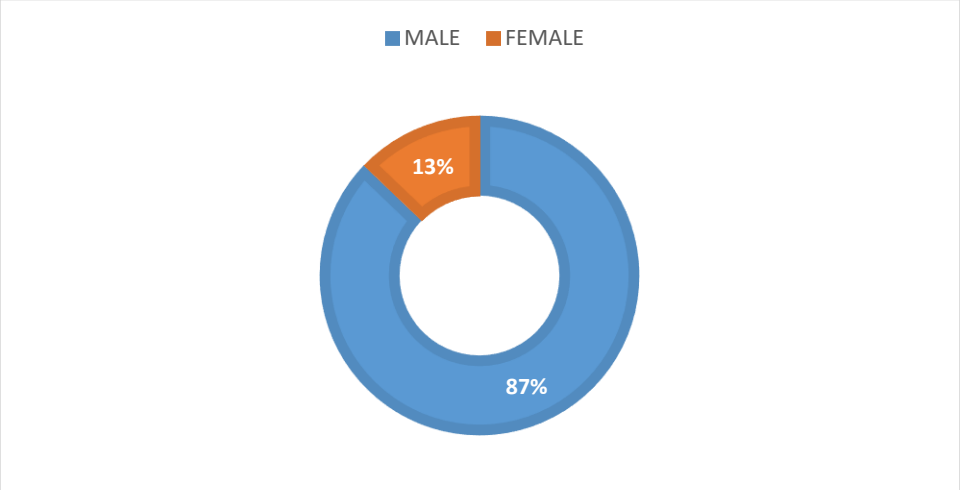
A total of 70 subjects were analysed for the analgesic effectiveness of fentanyl and dexamethasone as an adjuvant with 0.25% Ropivacaine. The majority of the subjects were 3-6 years of age (33/70) followed by 7-12 years (29/70) and least belonged to the 1-3 year age group (8/70) (Figure 1).

Figure 1: Age-wise distribution of the study participants



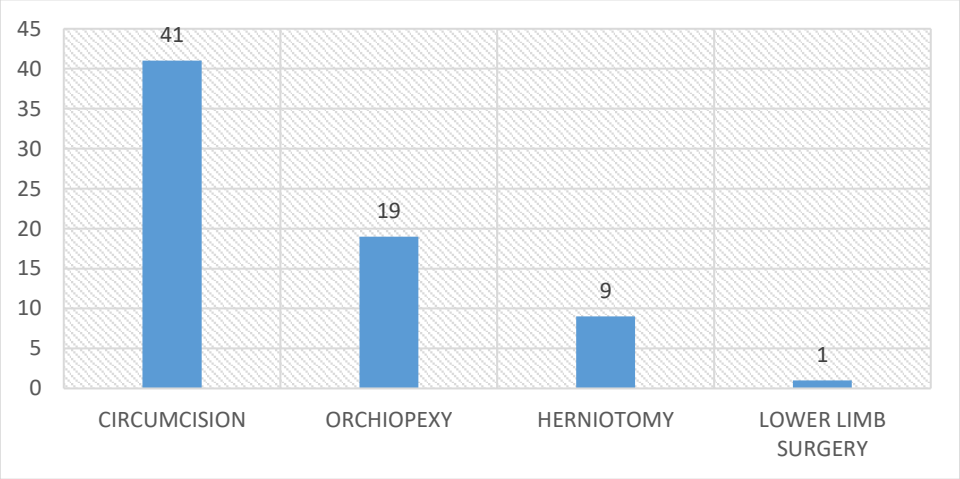
A male predominance was noted (87%) (Figure 2).

Figure 2: Gender distribution among the study subjects



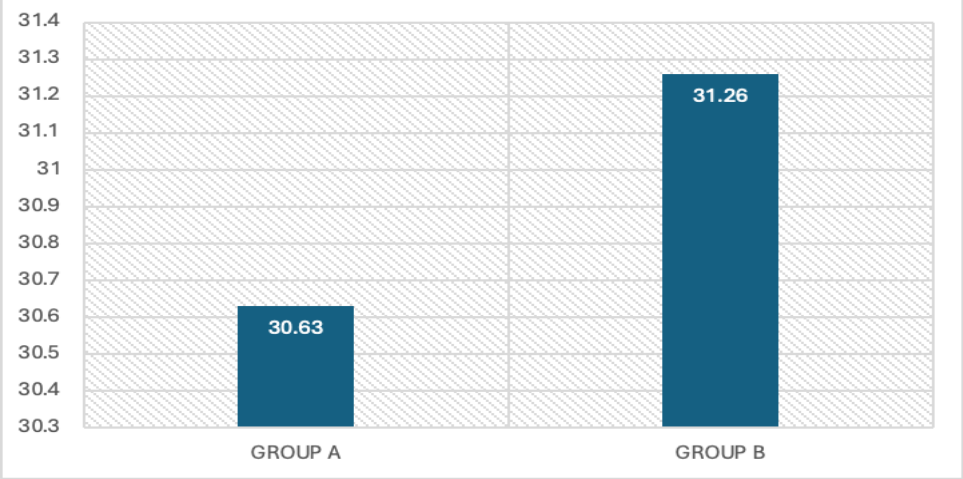
Circumcision was carried out in 41/70 cases followed by orchiopexy in 19/70 cases, herniotomy in 9/70 and lower limb surgery in 1/70 cases (Figure 3).

Figure 3: Type of surgery conducted on the subjects



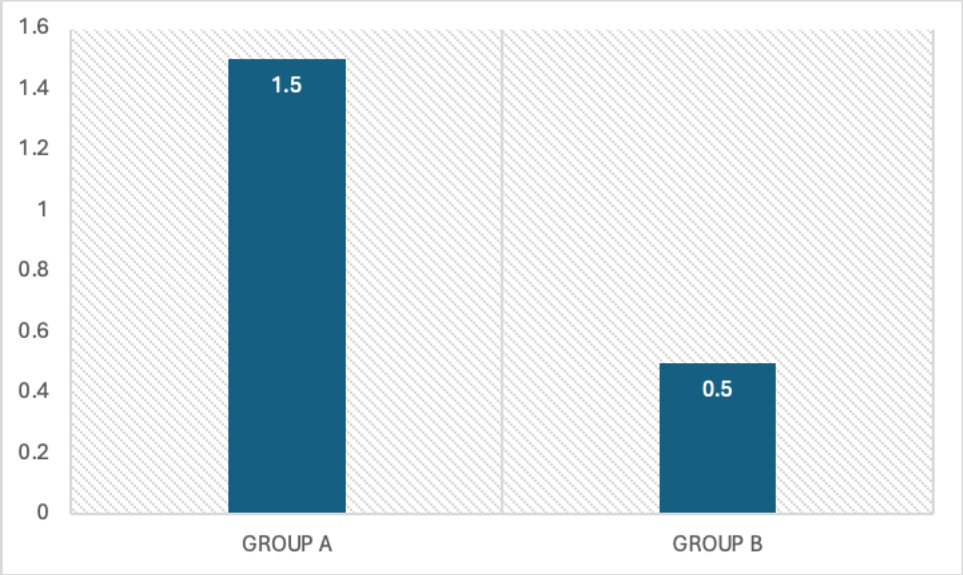
The duration of surgery in group B (31.26) was more than that of group A (30.63) (Figure 4).

Figure 4: Duration of surgery conducted on both the groups



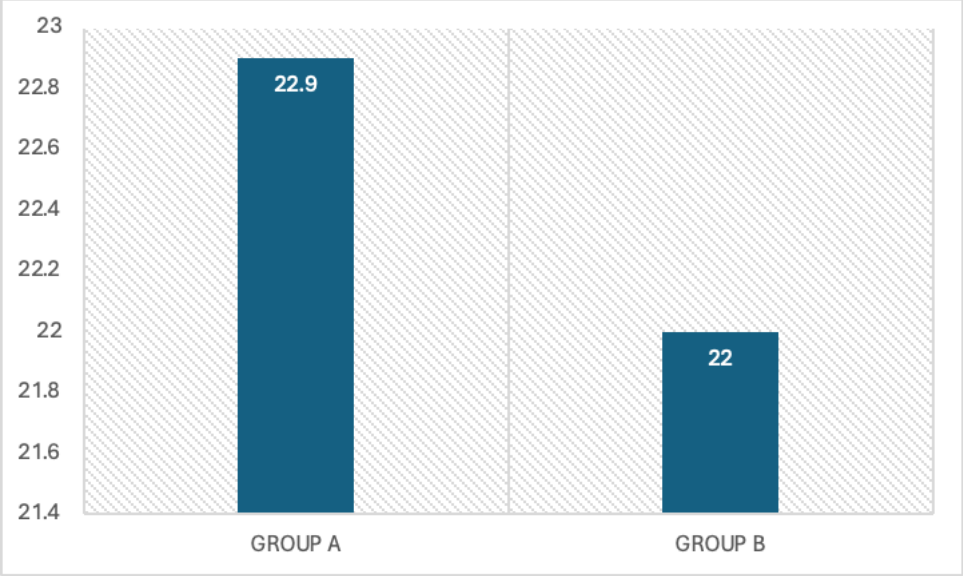
The number of rescue analgesia was more in group A compared to B (1.5 vs 0.5) (Figure 5).

Figure 5: Number of rescue analgesia for both the groups



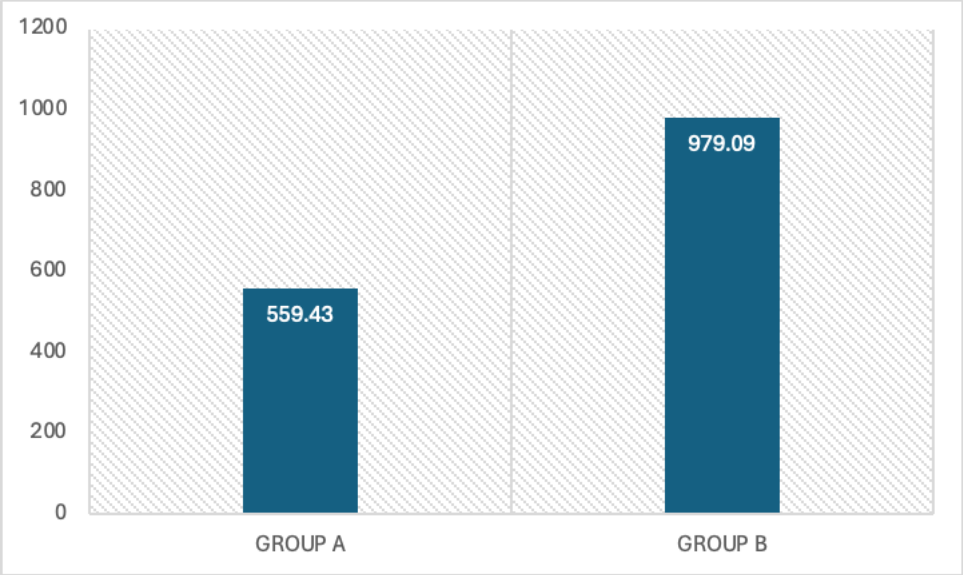
The mean weight of the subjects in Group A (22.9 kg) was slightly more compared to Group B (22 kg) (Figure 6).

Figure 6: Weight of participants belonging to both groups



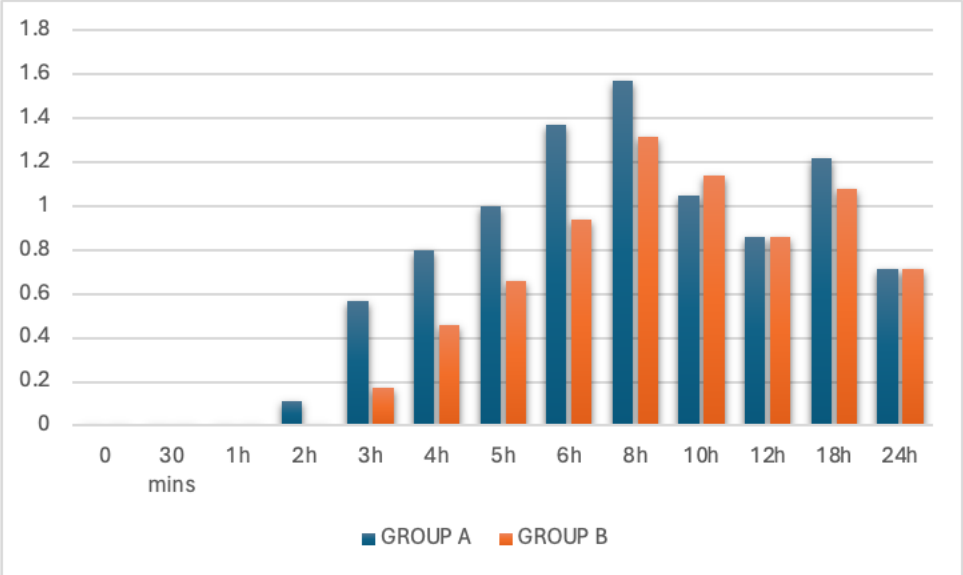
In Group A, the minimum duration of analgesia was 401 mins while the maximum was 779 mins with a mean of 559.43 mins while in the case of Group B the minimum and maximum time was 717 mins and 1462 mins respectively with a mean of 979.09 mins (Figure 7).

Figure 7: Duration of analgesia in both the groups



The FLACC score was always higher in Group A compared to Group B with it being significant at 2h, 3h, 4h, 5h 6h and 8h respectively with a p-value of 0.04, 0.001, 0.05, 0.029, 0.012 and 0.062. (Figure 8).

Figure 8: FLACC score at different time frames in both the groups



Sedation was more in Group A as compared to Group B, which was statistically significant. The incidence of adverse effects like bradycardia, respiratory depression, nausea and vomiting was higher in Group A as compared to Group B. All hemodynamic and intra-operative parameters were within normal range in both groups.

DISCUSSION

The conventional method of giving children intra and postoperative analgesia for surgery involving the abdomen, pelvis, and lower leg is known as caudal analgesia. When given as a single-shot injection, the caudal block's efficacy is only constrained by the local anaesthetic's duration of action. As a result, several adjuvants are now used to extend the local

anaesthetic's duration of action. The perioperative usage of dexamethasone and fentanyl has grown in the past few years, encompassing its application in peripheral and central nerve block and intravenously during surgery. (4)

Dexamethasone given caudally lengthens the analgesic effect's duration. Its analgesic effect could be attributed to corticosteroids' direct membrane action, which acts as a local anaesthetic on the nerve (9). Dexamethasone may therefore enhance the effects of ropivacaine and increase the length of analgesia (10). Dexamethasone increases the duration of analgesia by inhibiting the transcription factor nuclear factor-kB (NF-kB) (9,11). These results imply that dexamethasone may increase the preventative analgesia of caudal block and avoid central sensitization following surgery.

Fentanyl is a synthetic opioid agonist which acts as an analgesic by attaching to mu, kappa, and delta receptors in the spinal cord, resulting in spinal analgesia. It avoids central nervous system depression of the respiratory and cardiovascular systems by rapidly passing through the lumbar dura and penetrating the lipid phase of the underlying cord tissue with little opioid migration in a rostral direction (12).

In the present study, majority of the subjects were 3-6 years of age followed by 7-12 years and least belonged to the 1-3 year age group with a mean age of 6.67 years. (Figure 1) A male predominance was observed with 87% of the subjects being males. (Figure 2). Circumcision was carried out in 41/70 cases followed by orchiopexy in 19/70 cases, herniotomy in 9/70 and lower limb surgery in 1/70 cases. (Figure 3). However in a study by **Gandhi et al.,**(5) it was seen that herniotomy was the most common procedure performed followed by circumcision with a mean age of 2.52±1.741 years in fentanyl group and 2.72±1.642 years in dexamethasone group with a male predominance. **Mattoo et al.,**(3) observed a mean age of 6.51 ± 2.32 years in the fentanyl group while a mean age of 6.29 ± 2.73 years in the dexamethasone group which was very much similar to that obtained in our study.

The duration of surgery in group B (31.26) was more than that of group A (30.63). (Figure 4) Similar results were obtained in a study by **Gandhi et al**., (5) with the fentanyl group having a lower duration (37.7 ± 11.25 mins) compared to the dexamethasone group. However, in a study by **Mattoo et al.,** (3) it was observed that there was hardly any difference in the two groups in terms of time taken for surgery with it being 112.45± 9.97 mins in the fentanyl group and 113.14± 10.13 mins in the dexamethasone group (38.6 ± 12.61 mins).

The mean weight of the subjects in Group A (22.9 kg) was slightly higher compared to Group B (22 kg) (Figure 6). In a study by **Mattoo et al.,** (3) a mean weight of 21.84 ± 4.93 kg was observed in the fentanyl group while that in the dexamethasone group was 20.98 ± 5.53 kg. In Group A, the minimum duration of analgesia was 401 mins while maximum was 779 mins with a mean of 559.43 while in case of Group B the minimum and maximum time was 717 mins and 1462 mins respectively with a mean of 979.09 mins (Figure 7). **Gandhi et al**., (5) observed the mean duration of analgesia to be higher in the dexamethasone group (10.80 ± 0.755 hr.) as compared to the fentanyl group (7.20 ± 0.755 hr) which was similar to the results obtained in the current study. According to **Doctor et al.,** (13) the length of analgesia did not differ in patients receiving ropivacaine, but there was reduced motor blockade in those receiving 0.25% bupivacaine and 0.2% ropivacaine when fentanyl [1µg/ml] was used for caudal block during infra umbilical procedures in children.

The FLACC score was always more in the fentanyl group compared to the dexamethasone group with it being significant at 2h, 3h, 4h, 5h 6h and 8h respectively with a p value of 0.04, 0.001, 0.05, 0.029, 0.012 and 0.062. The fact that there was no difference in the pain scores between the groups throughout the first hour is likely because both groups continued to experience the analgesic effects of ropivacaine during this time. Following this time, a difference in the pain scores between the two groups was noted, with the dexamethasone group exhibiting lower mean pain scores. Additionally, the statistically significant increase in the mean duration of analgesia further emphasizes the advantages of adding dexamethasone or fentanyl. The score kept increasing till 8h and then reduced at 24h (Figure 8) Similar results were obtained in a study by **Gandhi et al**., (5)

Our findings concurred with research conducted by **Kim et al.,** (14) which assessed the addition of Dexamethasone 0.1 mg/kg to caudal Ropivacaine 0.15% in paediatric patients having orchidopexy ranging in age from 6 months to 5 years. In their study, compared to Ropivacaine 0.15% alone, there was a reduction in pain severity, an increase in the duration of caudal block analgesia, and a decrease in the amount of analgesics used. Yousef et al., (15) assessed caudal analgesia of children aged 1-6 years undergoing inguinal hernia repair, and noted that the addition of Dexamethasone 0.1 mg/kg or magnesium sulphate 50 mg to Ropivacaine 0.15% 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. **Choudhary et al.** (2017) assessed the efficacy of caudal Dexamethasone 0.1 mg/kg as an adjuvant to Ropivacaine in children aged 1-5 years and discovered that caudal Dexamethasone combined with Ropivacaine was an effective substitute to prolong postoperative analgesia with a lower pain score than caudal Ropivacaine alone.(16)

The study is not without limitations. Children from 1-12 year age group were included which could have led to variation in the pain scores as they could have varying pain thresholds and communication skills. The study also included patients undergoing a broad range of sub-umbilical procedures. The degree of pain may vary depending on how invasive the various surgeries are. The study did not assess the side effects of the drugs used such as adrenal suppression and hyperglycaemia, because these are uncommon after a single dosage. Additionally, it raises the expense and causes the child to receive unnecessary needle pricks for recurrent blood collection. Our post-operative follow-up ended after 24 hours, and we are unsure if simple opioid administration as intermittent boluses or infusion would have produced comparable or better results.

CONCLUSION

It can be concluded that 0.1 mg/kg of dexamethasone added to 0.25% ropivacaine concentration was more efficacious compared to fentanyl in prolonging the duration of analgesia, reducing the need for rescue analgesia and showing a lower FLACC score.

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