

The Efficacy of Dexmedetomidine as Adjuvant in Caudal Block for Postoperative Pain Relief in Children

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Abstract

Introduction: In paediatric patients, optimum pain relief is a big challenge. An effective therapy to block or modify the physiological responses to painful stimulus is an essential. Hence, here is an attempt to study addition of dexmedetomidine, an alpha-2 adrenergic receptor agonist to bupivacaine with regards to analgesic potency and side effects. **Material and Methods:** After approval from institution ethics committee, the study was conducted to compare the effect of addition of dexmedetomidine to bupivacaine in caudal block for postoperative analgesia in paediatric infraumbilical surgeries. Written informed parental or guardian consent was obtained. 30 cases in the age group of 1 to 6 years were studied. They were randomly divided into two groups, Group N and Group D. • Group N (n=30) - 0.25% Bupivacaine 1 ml/kg+ 0.5 ml normal saline • Group D (n=30) - 0.25% Bupivacaine 1 ml/kg+Dexmedetomidine 1 µg/kg, making the volume to 0.5 ml. Total volume for caudal block being 1 ml/kg in both groups. • after giving general anaesthesia child was placed in left lateral position and caudal block was performed under sterile conditions. The postoperative pain relief was evaluated using FLACC score hourly for first 6 hours, 2 hourly upto 12 hours and then 4 hourly upto 24 hours. Sedation is evaluated by Ramsay sedation score. **Results and Conclusion:** Addition of dexmedetomidine in the dose of 1µg/kg to 0.25% bupivacaine for caudal blockade showed duration of analgesia for Group N was 5.86±1.21 hrs and Group D was 15.5±3.02 hrs, without any significant haemodynamic changes, safe for use in paediatric patients without any adverse effects.

Keywords: Caudal Block; Bupivacaine; Dexmedetomidine.

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Introduction

The International Association for the Study of Pain has defined pain as 'an unpleasant sensory and emotional experience, associated with actual or potential tissue damage' [1].

Children have been undertreated for pain because of the wrong notion that they neither feel

pain nor remember the painful experiences to the same degree that adult did. Pain experienced by infants and children often goes unrecognised, even neglected because they cannot express it [2]. An effective therapy to block or modify the physiological responses to painful stimulus is an essential component of paediatric anaesthesia practice [3]. Now, postoperative pain management is an integral part of paediatric anaesthesia.

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A caudal epidural analgesia has become one of the most popular and commonly performed regional blocks in paediatric anaesthesia after its first description by Campbell in 1933 [4]. It is relatively simple technique with good success rate [5]. Different additives have been used in order to improve the duration of action as well as the quality of analgesia of the local anaesthetic used in the single shot caudal block technique such as opioids, epinephrine, alpha 2 agonist, ketamine and neostigmine [6]. Dexmedetomidine is a potent as well as highly selective alpha 2 adrenergic agonist having a sedative, sympatholytic and analgesic effect and have been described as a safe and effective additive in many anaesthetic applications and analgesic techniques. Their stimulation decreases calcium entry in the nerve terminals resulting in an inhibitory effect on the neurotransmitter release thus facilitating analgesia [7]. It has an alpha2/alpha1 selectivity ratio of 1600:1, which is eight times more potent than clonidine (200:1) [8].

Hence here is an attempt to study addition of dexmedetomidine, an alpha-2 adrenergic receptor agonist to bupivacaine with regards to analgesic potency and side effects.

Material and Methods

Plan of study:

After approval from institution ethics committee, the present study was conducted to compare the effect of addition of dexmedetomidine to bupivacaine in caudal block for postoperative analgesia in paediatric infraumbilical surgeries. A written informed parental or guardian consent was obtained in vernacular language in each case.

Sample size:

Taking a significance level of 5%, power of 80% sample size was calculated using Winpepi Statistical Package. As per this the minimum sample size needed for study was 52. Considering dropouts, exclusions and loss for followup, we took a sample size of 60. They were randomly divided into two groups, Group N and Group D.

- Group N (n=30) - 0.25% Bupivacaine 1ml/kg + 0.5 ml normal saline
- Group D (n=30) - 0.25% Bupivacaine 1 ml/kg + Dexmedetomidine 1 µg/kg, making the volume to 0.5 ml. Total volume for caudal block being 1 ml/kg in both groups, with maximum of drug volume 20ml was

used [9].

Inclusion Criteria:

- Children (age 1 to 6 years, ASA 1 and ASA 2) scheduled to undergo infraumbilical surgeries were included in this prospective, randomized, double blinded study.

Exclusion Criteria:

- Infection at the site of block, bleeding diathesis, pre-existing neurological, spinal disease or abnormalities of the sacrum, those with a history of allergic reactions to local anaesthetics and test drug. Children with history of developmental delay or mental retardation.

Procedure and Conduct of the Study:

The cases were selected after thorough preanaesthetic evaluation. Patients were randomly assigned to Group N and Group D using computer generated random number table. All children kept Nil by mouth for 6 hours. Patients were premedicated with inj Odansetron 0.1 mg/kg, inj Glycopyrrolate 0.004 mg/kg, inj midazolam 0.02 mg/kg and preoxygenated with 100% oxygen. Induction was done with inj Propofol 2 mg/kg and inj Atracurium 0.5 mg/kg. Patient were intubated with appropriate size of plain endotracheal tube and anaesthesia was maintained with oxygen, nitrous oxide and sevoflurane (1.5-2%). Child placed in left lateral position and caudal block was performed under sterile conditions using 22G hypodermic needle. Heart rate (HR), non-invasive BP(NIBP), ECG and peripheral oxygen saturation was recorded before anaesthesia, after intubation and immediate after caudal block and at 10 min interval till the end of surgery. Skin incision was performed after 15mins of caudal block. After surgery, patients were reversed using inj. Neostigmine 0.05 mg/kg + inj. Glycopyrrolate 0.008 mg/kg. After reaching extubation criteria patients were extubated. Patients were then shifted to recovery room and monitored for 6 hours. Later they were shifted to ward and monitored upto 24 hours. The postoperative pain relief was evaluated using FLACC score [10] [face, legs, activity, cry, consolability] with its 0-10 score range hourly for first 6 hours, 2 hourly upto 12 hours and then 4 hourly upto 24 hours. Sedation is evaluated by Ramsay sedation score [11] at same interval. If FLACC pain score \geq 4, syrup Paracetamol was

given 15 ml/kg as rescue analgesia. (If needed Paracetamol was repeated after 4 hours). Duration of analgesia (time from caudal block to FLACC ≥ 4) was noted and total number of doses of Paracetamol required in 24 hours was noted.

Following clinical parameters were monitored:

Intraoperative:

- Haemodynamic monitoring(HR, MAP)
- SpO₂
- ECG
- Duration of surgery

Postoperative:

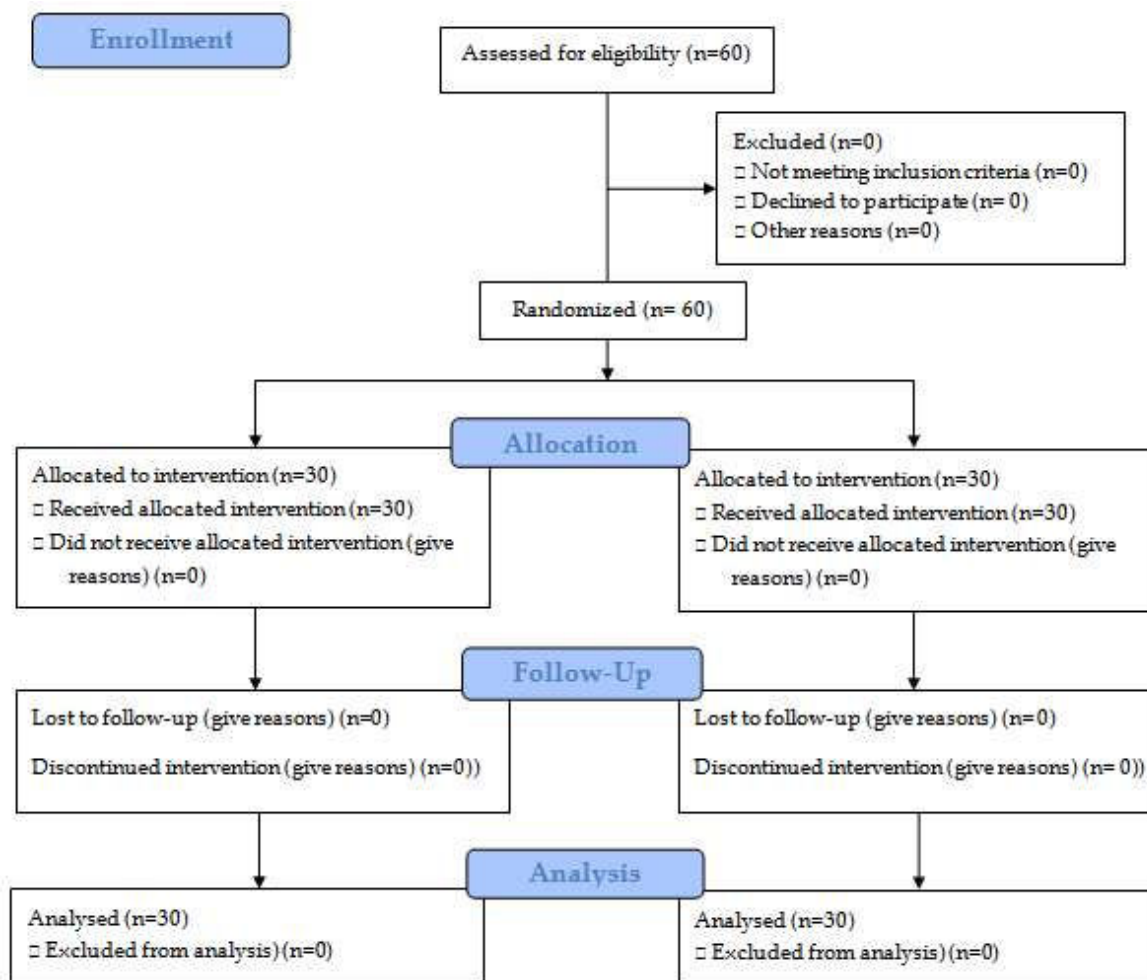
- Duration of analgesia (FLACC score).
- Analgesia requirement in 24 hours (number of doses of paracetamol).
- Side effects-

- Hypotension
- Bradycardia (HR<60).
- Sedation (Ramsay sedation score).
- Postoperative nausea vomiting.
- Urinary retention at 24 hours
- Respiratory depression (SpO₂ <95%)

Statistical analysis:

data analysis was done using the SPSS (Statistical Package for the Social Science) Version 17 for window. The t test, Mann Whitney test(MW), proportion test was used to find significant difference in age, weight, onset of analgesia, duration of analgesia, vital parameters, sedation score and side effects in study groups. A probability value of 0.05 or less was accepted as the level of statistical significance.

Consort 2010 Flow Diagram



Observation and Results

Table 1: Demographic Distribution

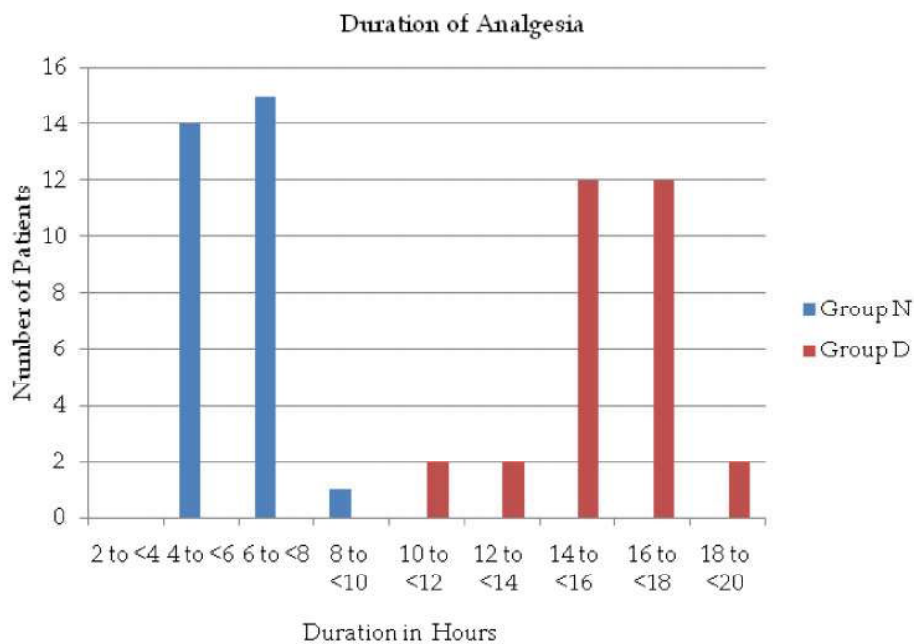
Parameters	Group N	Group D	p value	Significance
Age	3.8 ±1.46	3.2 ±1.37	0.10	NS
Male: Female Ratio	14:1	9:1	0.99	NS
Weight	12 ± 2.91	11.5 ± 2.78	0.50	NS
Duration of surgery (minutes)	58.12 ±7.20	58.12 ± 6.58	0.94	NS

Both the groups were comparable as there was no statistical significant difference between two groups with respect to age, sex, weight and duration of surgery (Table 1).

Table 2: Distribution of surgeries

Name of surgery	Group N	Group D
Herniotomy	18	15
Circumcision	5	12
Orchidopexy	4	1
Hypospadiasis	3	2

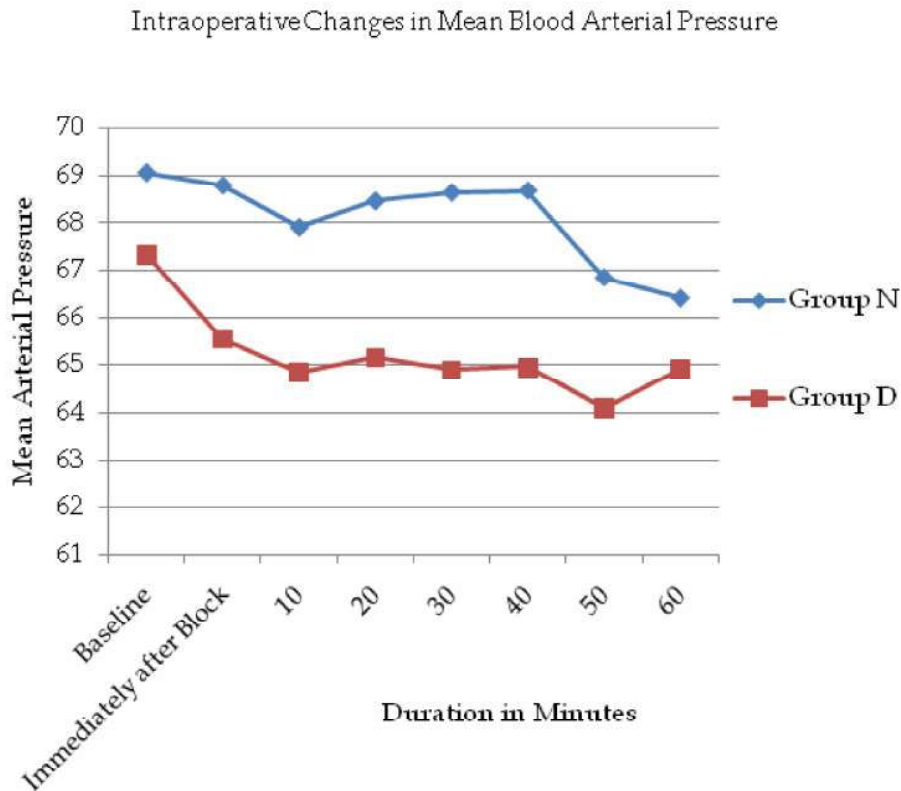
Above table 2 shows the different types of surgeries done in patients of both the groups.



Graph 1: Duration of Analgesia

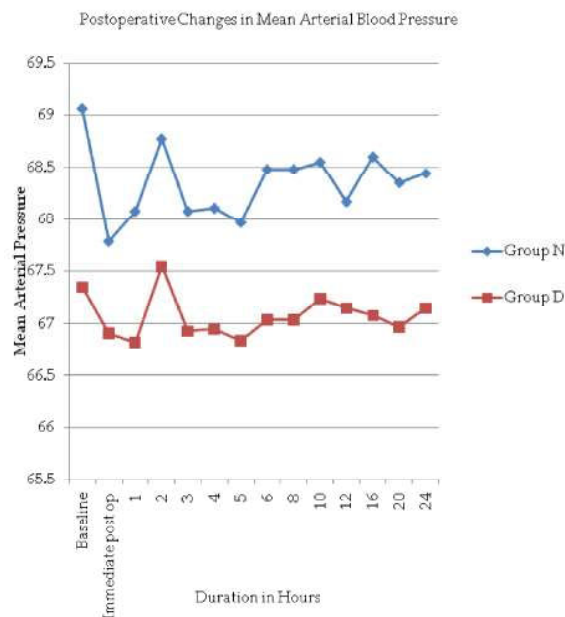
The above graph shows the total duration of analgesia from the time of caudal block to FLACC ≥ 4 . The average duration of analgesia for Group N was 5.86 ± 1.21 hours. The average duration of analgesia for Group D was 15.5 ± 3.02 hours.

Statistically the difference between two groups is highly significant ($p < 0.001$), indicating that duration of analgesia was more in Group D than Group N. (Graph 1).



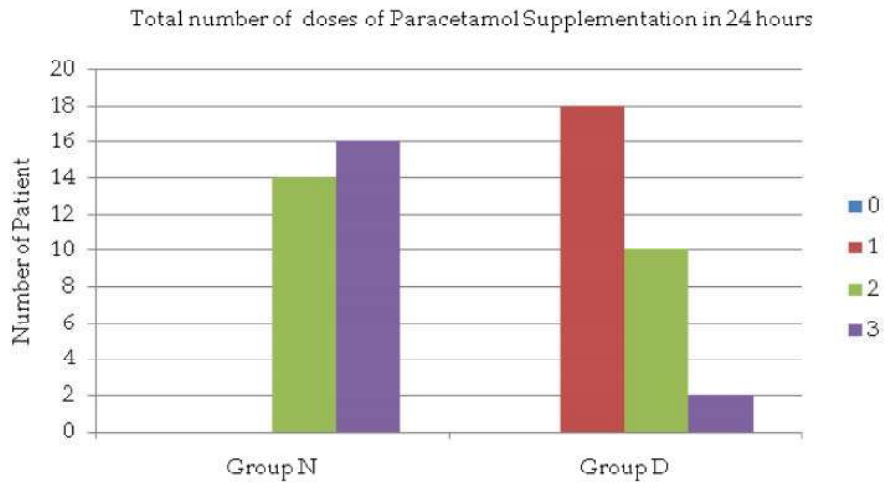
Graph 2: Intraoperative Changes in Mean Arterial Blood Pressure

There was fall in Mean Arterial Blood Pressure in both the groups. Fall in Mean Arterial Blood Pressure was more in Group D than Group N. The difference between both the groups is statistically significant. However, none of the patients required ionotropic support for hypotension from any of the groups (Graph 2).



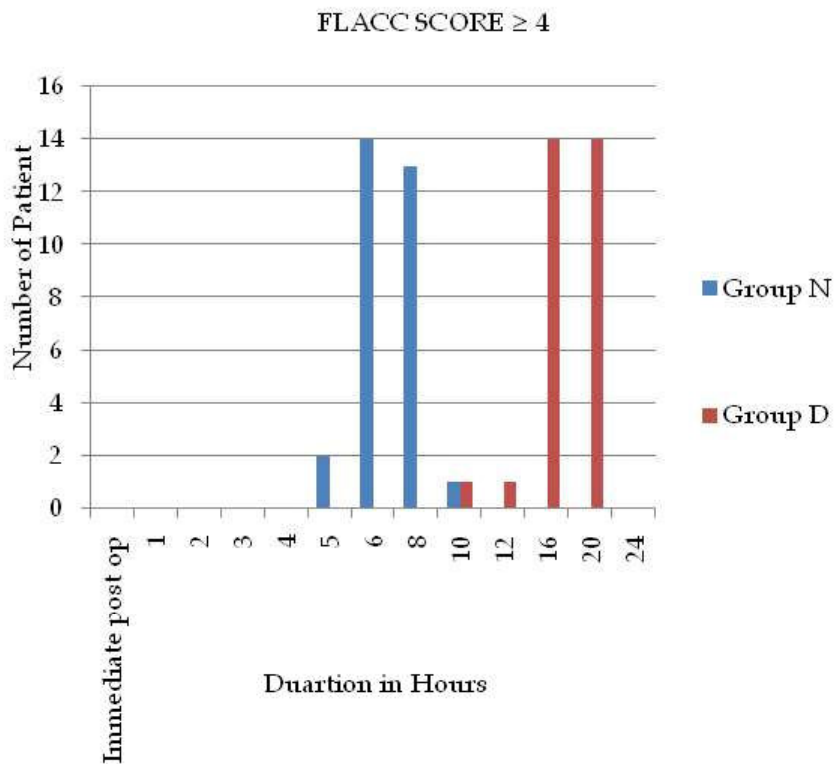
Graph 3: Postoperative changes in Mean Arterial Blood Pressure

Above graph shows the changes in Mean Arterial Blood Pressure in the recovery room in both the groups. There is no statistical difference between both the groups (Graph 3).



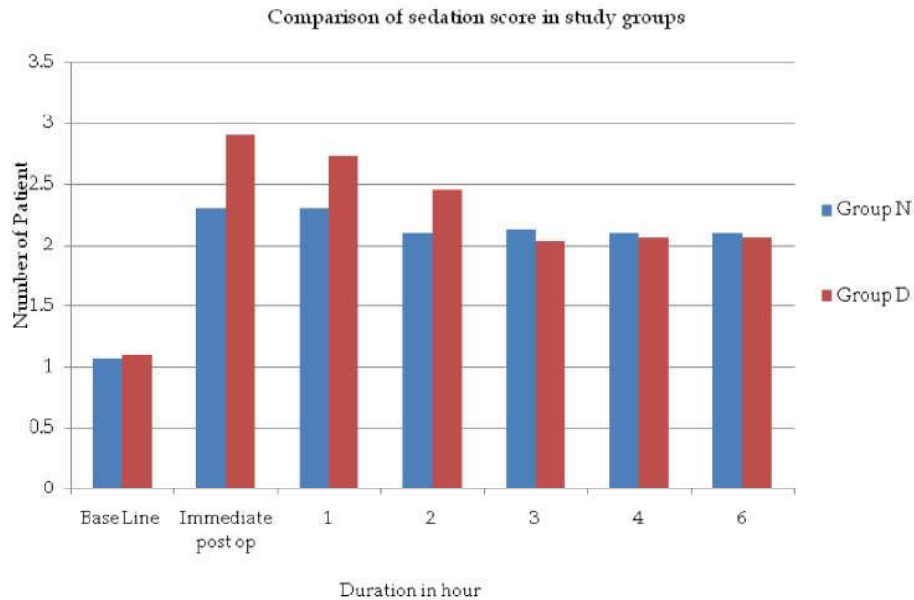
Graph 4: Total number of doses of Paracetamol Supplementation in 24 hours

Above graph 4 shows the supplementation of doses required in both the groups. The difference between both the groups is statistically significant (Graph 4).



Graph 5: FLACC Score ≥ 4

Above graph 5 shows the distribution of patients in the two groups according to FLACC Score ≥ 4 at various time intervals postoperatively (Graph 5).



Graph 6: Comparison of sedation score in study groups

Above graph 6 shows Ramsay sedation score. Group D had a better sedation score in the immediate postoperative period, at 1 hour and 2 hours as compared to Group N. The *p* value was statistically significant ($p < 0.05$). After 6 hours there was no sedation in both the groups. The patients were calm and easily arousable (Graph 6).

Discussion

Postoperative pain is an acute pain and should be treated adequately to decrease morbidity and hospital stay. Postoperative analgesia provides not only pain relief but also inhibits trauma-induced nociceptive impulses so as to blunt autonomic reflexes. In the present study 0.25% bupivacaine in the dose of 1 ml/kg alone and in combination with dexmedetomidine 1 μ g/kg was used caudally and compared for the duration of analgesia and any adverse effects. Dexmedetomidine 1 μ g/kg was selected based on studies by Fares KM [14].

Clinical parameters noted were haemodynamic variations in operation room and recovery room, assessment of pain by FLACC Score, sedation score, number of doses of Paracetamol supplementations required, duration of analgesia and postoperative complications if any.

Demographic profile

Both the groups were comparable in respect to age, weight, sex, duration of surgery and distribution of surgeries.

Duration of analgesia

The average duration of analgesia for Group N and Group D was 5.86 ± 1.21 and 15.5 ± 3.02 hours respectively. Statistically the difference between two groups is highly significant ($p < 0.001$), indicating that duration of analgesia was more in Group D than Group N. Similar prolongation of postoperative analgesia was seen in different studies. Saadawy et al [12] showed that the duration of analgesia was significantly longer with dexmedetomidine administration 1 μ g/kg with bupivacaine 0.25% 1 ml/kg (18.5 hr) than plain bupivacaine 0.25% 1 ml/kg (6.2 hr) ($p < 0.001$) and the incidence of agitation following sevoflurane anaesthesia was significantly lower with dexmedetomidine ($p < 0.05$).

Hemodynamic parameters

There was no significant change in pulse rate in any of the groups intraoperatively and postoperatively. The difference between both the groups is statistically insignificant.

There was a fall in Mean Arterial Blood Pressure in both the groups intraoperatively. Fall was more in Group D than in Group N. The difference between

both the groups is statistically significant. Similar findings were obtained in a study conducted by Schnaider et al. [13]. However, none of the patients required ionotropic support for hypotension from any of the groups.

Total number of doses of Paracetamol Supplementation in 24 hours

Number of patients requiring single dose of Paracetamol supplementation was significantly higher in Group D ($p < 0.001$) where as those requiring two and three doses was higher in Group N.

Fares KM et al. [14] concluded addition of dexmedetomidine ($1 \mu\text{g}/\text{kg}$) to caudal bupivacaine 0.25% ($1 \text{ mL}/\text{kg}$) in paediatric major abdominal cancer surgeries achieved significant postoperative pain relief for up to 19 hours with less use of postoperative analgesics and prolonged duration of arousable sedation.

Flacc Score ≥ 4

Difference in FLACC score between two groups were statistically significant at 6th, 8th, 16th and 20th hour ($p < 0.01$). Anand V G et al (2011) randomly assigned 60 patients to two groups. Group R received ropivacaine 0.25% $1 \text{ mL}/\text{kg}$ caudally and group RD received ropivacaine 0.25% $1 \text{ mL}/\text{kg}$ with dexmedetomidine $2 \mu\text{g}/\text{kg}$. They concluded that Group R patients achieved a statistically significant higher FLACC score compared with Group RD. The difference was statistically significant ($p < 0.001$) [15].

Sedation score

Sedation was higher with group D. Patients were calm, quite but easily arousable. This was supported by studies from Koroglu et al [16].

Koroglu et al (2005) evaluated dexmedetomidine ($1 \mu\text{g}/\text{kg}$) in 80 children undergoing magnetic resonance imaging concluded dexmedetomidine provided adequate sedation in most of the children aged 1-7 years without haemodynamic or respiratory side effects [16].

Adverse effects

The adverse effects were noted in both the groups. Two patients from Group N had vomiting and retention of urine where as one patient from Group D had vomiting and two patients had urinary retention which was statistically

insignificant. This was supported by studies conducted by El-Hennawy et al. They concluded that addition of dexmedetomidine or clonidine to caudal bupivacaine significantly promoted analgesia in children undergoing lower abdominal surgeries without increase in side effect [17].

Conclusion

Hence, we conclude that addition of dexmedetomidine in the dose of $1 \mu\text{g}/\text{kg}$ to 0.25% bupivacaine for caudal blockade-

- Significantly prolongs the duration of analgesia
- Without any significant haemodynamic changes
- Safe for use in paediatric patients without any adverse effects.

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