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**Original work**

# COMPARISON OF CAUDAL CLONIDINE VERSUS CAUDAL DEXMEDETOMIDINE WITH BUPIVACAINE FOR PROLONGATION OF POSTOPERATIVE ANALGESIA IN CHILDREN UNDERGOING INFRA-UMBILICAL SURGERIES.

## (CAUDAL ANALGESIA)

*Nilesh M Solanki, Nirmal Mistry, Jay Solanki, Liza Jalu, Amit Pandit*

BJMC, Gujarat, India

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***Summary***

***Introduction:*** *Caudal analgesia is considered a safe, simple and common procedure in children. As bupivacaine alone has short duration of action, addition of clonidine and dexmedetomidine has been shown to increase the duration of caudal analgesia. We aimed to evaluate caudal clonidine and caudal dexmedetomidine with bupivacaine in terms of the analgesic efficacy and sedation in children scheduled for infra-umbilical surgeries.* ***Methods:*** *We conducted a prospective, randomized, and interventional study. We randomized sixty patients into two groups aging 1 to 8 years belonging to ASA grade I and II posted for infra- umbilical surgeries. Group C was administered 0.25% bupivacaine (1 ml/kg) + clonidine 1 μg/kg, maximum total volume of 12 ml for caudal block, while Group D was administered 0.25% bupivacaine (1 ml/kg) + dexmedetomidine 1 μg/kg, maximum total volume of 12 ml for caudal block. Hemodynamic variables were monitored. Postoperative analgesia was assessed using FLACC score, sedation using the Ramsay Sedation Scale, and total analgesic requirements and side effects were recorded during the first 24 hour.* ***Results:*** *A significant difference in duration of postoperative analgesia was observed between the two groups. In Group D, the mean duration was 742 min ± 247.38 min, whereas in Group C, it was 608.87 min ± 251.16 min (p value < 0.043). The mean sedation score in the immediate postoperative period was lower in Group D compared to Group C. The rescue analgesic requirement in the first 24 hours in Group D was also lower than in Group C. Hemodynamic changes and adverse effects were comparable between the two groups.* ***Conclusions:*** *Dexmedetomidine was a safe and more effective adjuvant to bupivacaine as compared to clonidine for prolonging caudal in children undergoing infraumbilical surgeries, without an increase in adverse effects.*

***Key words:*** *Caudal analgesia; Clonidine; Dexmedetomidine*

## *Introduction*:

There is inevitability of postoperative pain following surgery in children. The main responsibility of the anaesthesiologist in modern paediatric anaesthesia lies in providing postoperative pain relief. The most common technique for perioperative analgesia following infra-umbilical surgeries in children is caudal block[1]. The major drawback of single shot caudal injection with bupivacaine alone is that it has short duration of action. But the use of caudal catheter for infusion of local anaesthetics drugs is associated with chances of infection[2].The various adjuvants like opioids, ketamine and α2 agonists with local anaesthetics has been added to prolong caudal analgesia effects[3]. The mechanism for caudal analgesia by α2 adrenergic agonists is through activation of spinal cholinergic neurones which results in release of acetylcholine[4].

The higher affinity of dexmedetomidine for α2A adrenergic receptors is responsible for more analgesic and hypnotic effects than clonidine[5]

**Corresponding author:** Dr Nilesh M Solanki, Associate Professor, Address: Department of Anesthesia, BJMC, Civil Hospital, Asarwa, Ahmedabad.380016, Gujarat, India, Phone Number: 079 2680074, E-mail: nmscbaps@gmail.com, Mobile Number: 9998991716

This study was done to determine the postoperative analgesic efficacy, sedation, total rescue analgesic requirement and safety of clonidine and dexmedetomidine as adjuvant to caudal bupivacaine for postoperative pain relief in children undergoing infra-umbilical surgeries.

### *Objective:*

The primary objective of our study was to compare postoperative analgesia in both the groups.

The secondary objectives were to compare intraoperative hemodynamic parameters, level of sedation score, need of total rescue analgesics and any complications related to drug and technique.

### *Methods:*

This study was approved by Institutional Ethical Committee ((Reference number 118/2024/25/07/24) and CTRI (Ref No CTRI/2024/08/090480). The duration of study period was January 2024 to August 2024. After written informed consent from parents, this prospective, randomized, controlled study included total 60 children for elective infraumbilical surgeries under general anaesthesia.

Inclusion criteria: Age 1-8 years
Either sex
ASA I or II
Elective infraumbilical surgeries

Exclusion criteria: Allergic reaction to local anaesthetics
Local infection at the caudal site
Any neurological disorder
Sacral/vertebral abnormalities
History of bleeding disorder

After securing intravenous peripheral line, injection glycopyrrolate (0.004 mg/kg) and injection ondansetron (0.15 mg/kg) were given. Standard monitors were applied including: electrocardiogram (ECG), non-invasive blood pressure (NIBP), pulse oximetry, capnography, and temperature. Patients were induced with injection propofol 2-2.5 mg/kg intravenously and injection succinylcholine 2 mg/kg intravenously for insertion of an I-gel.

Caudal block was given under full aseptic precaution in the left lateral position with the use of 22-gauge Touhy epidural needle. The study drugs were injected into the caudal space slowly with continuous ECG monitoring after confirmation of negative aspiration for blood and cerebrospinal fluid. The randomization was done by using computer generated numbers and divided into two groups:

Group C: 0.25% bupivacaine 1 ml/kg with 1 µg/kg of clonidine in normal saline (maximum volume 12 ml)
Group D: 0.25% bupivacaine 1 ml/kg with 1 µg/kg of dexmedetomidine in normal saline (maximum volume 12 ml)

The person performing the caudal block was not aware about the study drug identity. After giving caudal block, the patients were turned to supine. Maintenance of anaesthesia was done with injection atracurium (0.5 mg/kg) with mixture of oxygen 50% and air 50% along with sevoflurane (1-2 %). No other analgesic was given intraoperatively. Intraoperative iv fluid was administered using glucose/saline solution as per need.

During surgery, adequacy of analgesia was considered when hemodynamic changes like increase in heart rate and systolic blood pressure were within 15% of baseline values.

In intraoperative period, recording of Heart rate, NIBP, $SpO_2$, $EtCO_2$, and temperature were done at every 15 min interval until the end of the surgery. At the end of the surgery, injection glycopyrrolate 0.008 mg/kg and injection neostigmine 0.05 mg/kg were given intravenously to antagonize the residual neuromuscular block.

Anaesthesia duration and surgical duration were noted with perioperative complications like hypo/hypertension, brady/tachycardia, vomiting, and urinary retention.

Duration of analgesia was noted, and it was defined as "the time from the administration of caudal block to need of first rescue analgesic." When the FLACC pain score ≥ 4, inj paracetamol 15mg/kg IV was given as rescue analgesic. Number of total rescue analgesics required in 24 hours period were recorded.

Hemodynamic parameters, sedation, and pain score in the postoperative room were recorded at 1 hour and thereafter every 2 hourly up to 12 hours

followed by every 3 hours interval for 24 hours. Ramsey sedation score was used for assessment of postoperative sedation (1 -Anxious and agitated or restless or both, 2- Co-operative, oriented and tranquil, 3- Responding to commands only, 4- Brisk response to light glabellar tap or loud auditory stimulus, 5- Sluggish response to light glabellar tap or loud auditory stimulus, 6- No response to stimulus), and FLACC score was used for pain evaluation (F = Face, L = Leg, A = Activity, C = Cry, C = Consolability), maximum score of 10.

The sample size calculation was done by using formula $n = 4pq/E2$ where p is the prevalence of infra-umbilical paediatric surgery at our institute. It is based on Hardy–Weinberg principle. Sixty patients were included (30 patients in each group).

Data were presented in the form of mean ± standard deviation, numbers, and percentages. Chi-square with Yate's correction and Fisher's exact test (two-tailed) were used for analysis of Categorical variables and an unpaired Student's *t*-test was used for testing continuous variables. Microsoft Office Excel 2010 and GraphPad Prism 6.05 (GraphPad Software, Inc., La Jolla, CA, USA) (QuickCalc) Software were used for statistical analysis. When P value was < 0.05, it was considered as statistically significant.

***Results:***

Both the groups were comparable for demographical data with ASA gradings and duration of surgery (Table 1).

Type of surgeries performed on children were hypospadias, hernia repair, circumcision and orchidopexy. (Table 2)

There was no difference in baseline heart rate, systolic blood pressure and diastolic blood pressure before induction of general anaesthesia. No statistically significant difference in heart rate, systolic blood pressure and diastolic blood pressure were observed in either group. (Table 3, 4, 5)

A significant difference in duration of analgesia was found between two groups with average post-operative analgesia of 742 min ± 247.38 min in Group D and 608.67 min ± 251.16 min in Group C (p value < 0.043). (Figure 1)

There were comparable mean hourly FLACC pain scores in both groups up to eight hours in the postoperative room. After that the mean pain

**Table 1.** Demographic data

| | Group C (N = 30) | Group D (N = 30) | P Value |
|---|---|---|---|
| Age (year) | 4.27 ± 2.39 | 3.12 ± 2.34 | 0.065 |
| Sex (male/female) | 27 / 3 | 28 / 2 | 0.640 |
| Body Weight (kg) | 14.30 ± 4.91 | 13.37 ± 5.59 | 0.510 |
| ASA* grade I/II | 14 / 16 | 16 / 14 | 0.670 |
| Duration of Surgery(min) | 72.67 ± 18.46 | 76.10 ± 15.16 | 0.434 |

*ASA-American Society of Anesthesiologist
Data presented as mean ± SD or Number: *P value < 0.05 is considered significant

**Table 2.** Types of surgery

| Surgical Procedures | Group C (N = 30) | Group D (N = 30) | P Value |
|---|---|---|---|
| Hypospadias | 9 (30%) | 6 (20%) | 0.9772 |
| Inguinal Herniotomy | 14 (47%) | 16 (53%) | |
| Circumcision | 4 (13%) | 5 (17%) | |
| Orchidopexy | 3 (10%) | 3 (10%) | |

Data presented as Number (%): *P value < 0.05 is considered significant

Table 3. Comparison of Pulse Rate per minute

| | Group C (N = 30) | Group D (N = 30) | P Value |
|---|---|---|---|
| Basal | 114.67 ± 15.84 | 114.60 ± 14.98 | 0.987 |
| 5 min after caudal | 110.20 ± 15.33 | 106.27 ± 13.94 | 0.303 |
| 15 min | 111.93 ± 16.00 | 112.53 ± 15.22 | 0.882 |
| 30 min | 108.27 ± 15.31 | 106.23 ± 15.25 | 0.608 |
| 45 min | 105.23 ± 15.03 | 102.77 ± 14.75 | 0.524 |
| 60 min | 103.26 ± 14.88 | 102.46 ± 14.63 | 0.513 |

**Data presented as mean ± SD or Number: *P value < 0.05 is considered significant**

**Table 4.** Comparison of Systolic Blood Pressure mmHg

| | Group C (N = 30) | Group D (N = 30) | P Value |
|---|---|---|---|
| Basal | 113.33 ± 3.84 | 111.87 ± 4.73 | 0.192 |
| 5 min after caudal | 111.67 ± 5.66 | 110.20 ± 7.07 | 0.379 |
| 15 min | 108.17 ± 6.09 | 110.40 ± 6.27 | 0.167 |
| 30 min | 106.27 ± 6.05 | 108.10 ± 5.72 | 0.233 |
| 45 min | 105.13 ± 6.96 | 107.13 ± 6.98 | 0.271 |
| 60 min | 104.60 ± 6.13 | 105.47 ± 6.17 | 0.587 |

Data presented as mean ± SD or Number: *P value < 0.05 is considered significant

**Table 5.** Comparison of Diastolic Blood Pressure mmHg

| | Group C (N = 30) | Group D (N = 30) | P Value |
|---|---|---|---|
| Basal | 72.07 ± 5.77 | 70.00 ± 5.56 | 0.163 |
| 5 min after caudal | 69.80 ± 5.52 | 69.20 ± 5.74 | 0.681 |
| 15 min | 69.27 ± 5.37 | 70.67 ± 7.09 | 0.392 |
| 30 min | 66.07 ± 4.68 | 68.23 ± 6.64 | 0.150 |
| 45 min | 66.10 ± 5.06 | 68.17 ± 5.84 | 0.148 |
| 60 min | 66.60 ± 4.76 | 66.73 ± 5.26 | 0.148 |

Data presented as mean ± SD or Number: *P value < 0.05 is considered significant

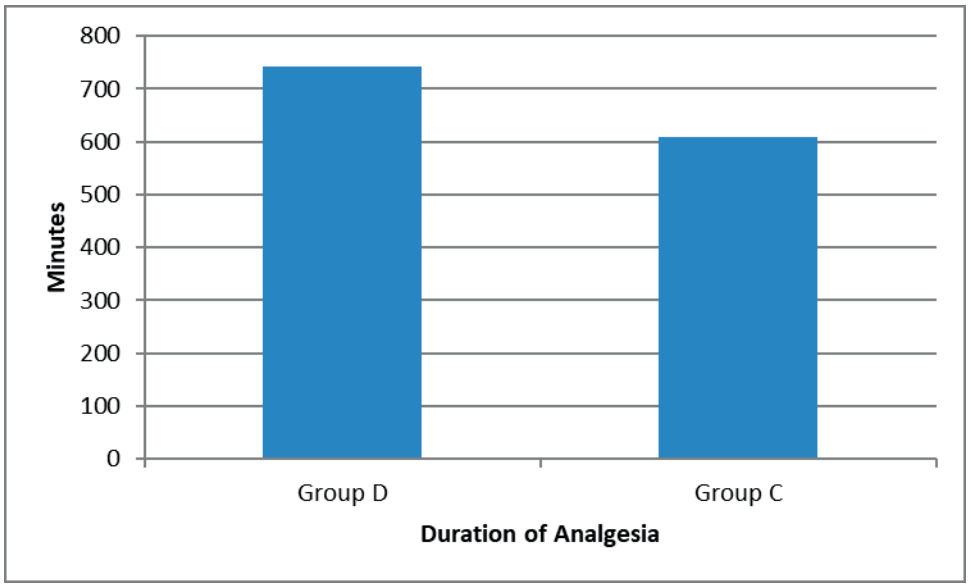


**Figure 1.** Comparison of duration of analgesia in both groups

score in group C was on higher side as compared to group D with statistical significance (Figure 2).

The mean Ramsey sedation score was lower in group D in comparison to group C in immediate postoperative period and it was found to be statistically significant (p value < 0.048). (Figure 3)

A significant difference was observed for requirement of rescue analgesia between two groups.

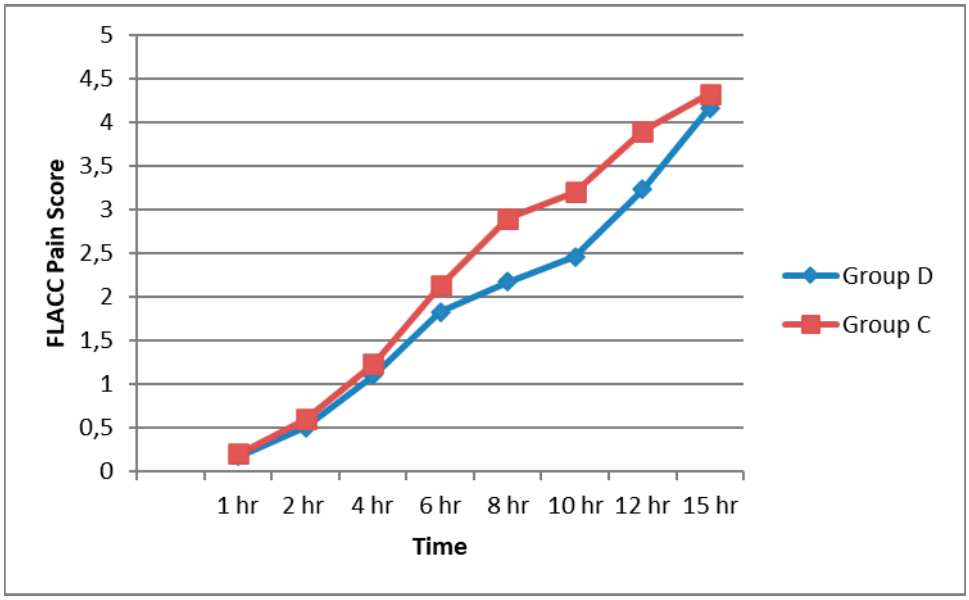


**Figure 2.** Comparison of FLACC pain score in both groups

In group C, 23(76%) patients required rescue analgesic while in group D, 12(40%) patients required rescue analgesic. Eighteen patients (60.0%) were given single dose, and 5(17%) patients were given two doses of supplemental (rescue) analgesic in group C. While eleven patients (37%) were administered one dose of rescue analgesia and one patient (3%) was administered two doses of rescue analgesia in group D. (Figure 4)

Postoperatively no complications like respiratory depression, nausea, vomiting, and urinary retention were observed in any of the group.

## *Discussions:*

The most popular and commonly used regional anaesthetic procedure in children is found to be caudal block. But short duration of analgesia even with bupivacaine is main drawback[6]. So as Caudal

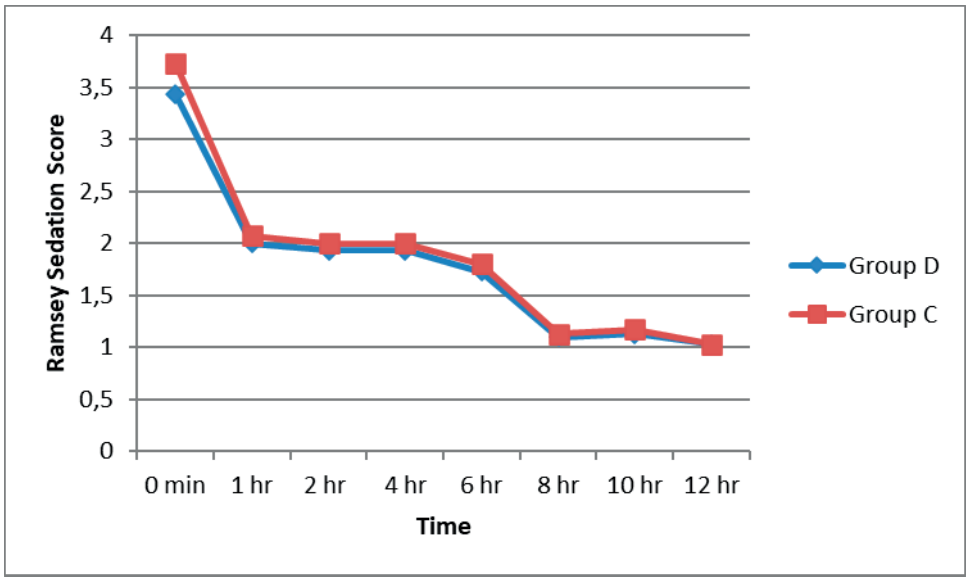


**Figure 3.** Comparison of Ramsey sedation score in both groups

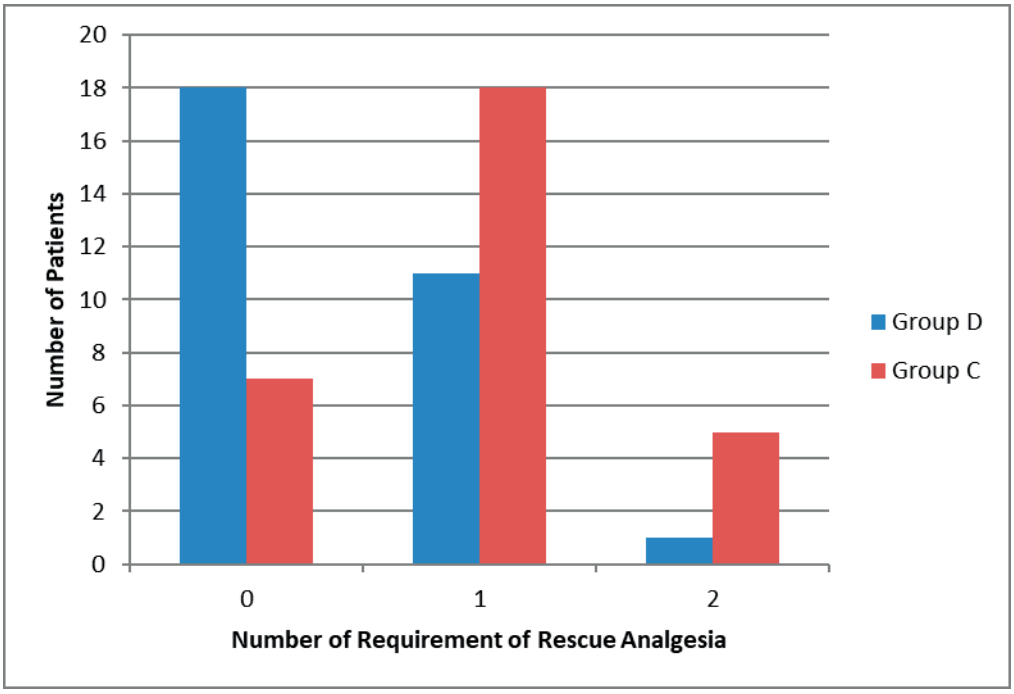


**Figure 4.** Requirement of rescue analgesia in both groups

bupivacaine alone terminates its analgesic effects early, adjuvants like clonidine, dexmedetomidine, tramadol and fentanyl have been added to increase the duration of analgesia for caudal block[7].

In our study, we used 1 ml/kg of 0.25% bupivacaine with addition of 1 µg/kg clonidine or 1 µg/kg dexmedetomidine to a maximum volume of 12 ml as a single shot caudal epidural to compare the prolongation of analgesia in children undergoing infraumbilical surgeries.

The α2 adrenergic receptor agonist action on central or peripheral receptor causes analgesic effect. Dexmedetomidine has higher affinity to bind selective α2 adrenergic receptor agonist than to α1 adrenergic receptors. So dexmedetomidine has more analgesia effect than clonidine[5].

In a study using 1 µg/kg clonidine with 0.25% caudal bupivacaine for postoperative analgesia in children undergoing subumbilical surgeries and observed that caudal bupivacaine with clonidine prolonged the duration of caudal analgesia with minimum need of supplemental analgesic drug without any adverse effects in comparison to bupivacaine alone[8].

The study with 0.1 % and 0.2 % caudal ropivacaine alone and with clonidine 1 μg/kg added to 0.1% caudal ropivacaine and concluded that 0.1% ropivacaine with clonidine (1 μg/kg) had longer duration of analgesia (590.25 ± 83.93 minutes) with adequate motor power and no sedation postoperatively, while 0.2% ropivacaine alone (388.5 ± 82.35 minutes) and 0.1% ropivacaine alone (243.7 ± 99.29 minutes) had shorter duration of analgesia[9].

Other study was also found that dexmedetomidine at doses of 1 μg/kg had been an effective adjuvant to ropivacaine for epidural anaesthesia when compared to clonidine as it provides faster onset, prolonged duration of action with better sedation[6].

This study with caudal dexmedetomidine (2 μg/kg) plus bupivacaine (0.25%) and bupivacaine (0.25%) alone and reported that increased the duration of caudal analgesia and better quality of sleep with bupivacaine plus dexmedetomidine than bupivacaine alone[10].

In Group C, a mixture of clonidine 1 μg/kg and 0.25% bupivacaine 1 ml/kg was used, while in Group D, dexmedetomidine 1 μg/kg was combined with 0.25% bupivacaine 1 ml/kg for caudal anaesthesia/analgesia in children. It was observed that postoperative analgesia was significantly longer in Group D (14.16 ± 1.65 hours) compared to Group C (11.24 ± 2.48 hours). Additionally, the requirement for rescue analgesics was lower in Group D. Hemodynamic stability was maintained in both groups, and no other adverse effects were reported[11].

In our observations we reported that Group D had average post-operative analgesia of 742 min ± 247.38 min and in group C it was 608.67 min ± 251.16 min. which was found to be statistically significant (p value < 0.043).

Single shot of caudal dexmedetomidine 2 μg/kg or clonidine 2 μg/ kg with bupivacaine 0.25% (1 ml/ kg) and concluded that there was significantly prolonged duration of analgesia with caudal bupivacaine plus dexmedetomidine as well as caudal bupivacaine plus clonidine in children undergoing lower abdominal surgeries. No significant benefit of dexmedetomidine was observed over clonidine and no difference was seen for any adverse effects[12].

The decrease in the heart rate after giving epidural clonidine or dexmedetomidine was because of the predominance of parasympathetic system and the decrease of blood pressure may be due to inhibition of preganglionic sympathetic fibres.

We monitored the mean heart rate and mean systolic blood pressure at different time intervals perioperatively. and found that the difference was comparable in both groups (p value > 0.05). There was not any incidence of bradycardia (heart rate < 60/min) or hypotension (systolic arterial pressure < 70 mm of Hg) in any patients in both the groups. We did not observe respiratory depression or hypoxia in any patient in this study.

Our findings were similar with some other authors[11]. There was no significant difference found in the hemodynamic parameter with addition of clonidine 1 μg/kg or dexmedetomidine 1 μg/kg with bupivacaine 0.25% (1 ml/kg) for caudal analgesia in children undergoing infraumbilical surgeries.

Some authors had added dexmedetomidine 2 μg/kg or clonidine 2 μg/kg to caudal bupivacaine 0.25%. However, the difference in incidence of hemodynamic changes or side effects in paediatric patients undergoing subumbilical surgeries were not significant[12].

In our study, addition of 1 μg/kg of clonidine or 1 μg/kg of dexmedetomidine with 0.25% caudal bupivacaine had been chosen for postoperative analgesia. Many studies had depicted that the dose is increased from 1 to 2 μg/kg of clonidine or dexmedetomidine with caudal bupivacaine, it did not make any difference in prolongation of the duration of analgesia[12].

We used FLACC pain scale score for assessment of quality of postoperative pain relief.

The FLACC score was used for postoperative analgesia in similar type of study population[12].

In our study, adequate caudal analgesia (FLACC score < 4). was found up to 8 hours of postoperative period in all the patients in both groups. After that there was decline in the number of patients with adequate caudal analgesia in group C showing significant higher FLACC score in comparison to group D.

We found that in immediate postoperative period, there was significantly less mean Ramsey sedation score in group D when compared to group C. Some authors were compared bupivacaine (0.25%) plus dexmedetomidine (2 μg/kg) versus bupivacaine (0.25%) alone and observed better sleep quality when dexmedetomidine was added to caudal bupivacaine[10].

In our study we found that the number of patients who required rescue analgesic doses were more in group C (23 patients) as compared to in group D (12 patients). It was also seen that number of doses of postoperative rescue analgesic were significantly higher in group C as compared to group D.

Findings of one study were in accordance to our study findings. They reported less requirement of syrup paracetamol 15 mg/kg as a rescue analgesic in dexmedetomidine group in comparison to clonidine group during postoperative study period of 24 hours[11].

In our study, the incidence of nausea, vomiting, and urinary retention in the postoperative period was not significant between the groups ($p > 0.05$).

Many authors had used caudal clonidine or dexmedetomidine with bupivacaine 0.25%. and observed no significant increase in incidence of vomiting, pruritus, and urinary retention in any group[8,11,12].

This study had few limitations. Firstly, the sample size of 60 subjects is relatively small which could affect the generalizability of the study. Secondly, since it is single centred study, it has potential for selection bias. Future studies with larger sample size might be beneficial with multicentre involvement.

## *Conclusion:*

Mixture of dexmedetomidine (1 μg/kg) with caudal bupivacaine 0.25% in comparison to that of clonidine (1 μg/kg) with caudal bupivacaine 0.25% significantly prolonged the duration of postoperative analgesia along with less need of rescue analgesic and less sedation also in immediate postoperative period in children undergoing infraumbilical surgeries with no side-effects.

### *Acknowledgment*

### *Conflict of interest*

The author declares there is no conflict of interest.

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