Archives of Anesthesiology and Critical Care (Autumn 2024); 10(Supplement 1): 422-429.

Available online at http://aacc.tums.ac.ir

Research Article

Post Operative Epidural Analgesia in Pediatric Abdominal Surgery: Comparison of Clonidine and Dexmedetomidine as an Adjuvant

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ARTICLE INFO

Article history:
Received 23 November 2023
Revised 16 December 2023
Accepted 31 December 2023

Keywords:
Clonidine;
Dexmedetomidine;
Adjuvant;
Epidural

ABSTRACT

Background: A Caudal epidural block is considered as one of the most common regional techniques in pediatric anesthesia. The latest addition to the group of adjuvants for caudal analgesia is α2 agonists namely Clonidine and Dexmedetomidine. This study includes a comparison of clonidine and dexmedetomidine as an adjuvant to bupivacaine in caudal epidural anesthesia for postoperative pain relief in the pediatric population.

Methods: This study was performed on 60 children, aged 1 year to 6 years, of ASA physical status I and II, undergoing elective infra-umbilical surgeries under general anesthesia. The patients were assigned randomly into two groups of 30 patients each, caudal epidural was given in all patients according to their group, after giving general anaesthesia. Group A (n=30) - patient received 0.125% bupivacaine (1ml/kg) with 0.5mcg/kg Dexmedetomidine. Group B (n=30)- patient received 0.125% bupivacaine (1ml/kg) with 0.5mcg/kg Clonidine. The patients were observed postoperatively for the duration and effect of caudal analgesia, (using the CHEOPS Score - Children's Hospital of Eastern Ontario Pain Scale), frequency and total dose of supplementary analgesic required, sedative effect (Modified Ramsay Sedation Score), perioperative hemodynamic parameters, and complications.

Results: The duration of Caudal analgesia without the need of supplementary analgesic is significantly higher in dexmedetomidine group (743 ± 73.6 min) than clonidine group (181.7 ± 53.60 min) and the total dose of supplementary analgesic (Inj. Paracetamol 15mg/kg i.v) required is significantly higher in clonidine group (491.5 ± 134.55 mg) as compared to dexmedetomidine group (236.5 ± 113.68 mg).

Conclusion: Addition of dexmedetomidine (0.5 mcg/kg) to caudal 0.125% bupivacaine (1ml/kg) produces a significantly longer duration of postoperative analgesia, less frequency, and dose of rescue analgesic required for postoperative analgesia in children, aged between 1 to 6 yrs as compared to a similar dose of clonidine used in caudal epidural for infra umbilical surgeries.

The authors declare no conflicts of interest.
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Introduction

Post surgical pain diagnosis and management in children remains one of the most challenging aspects of pediatric anesthesia. Poorly managed pain causes patient suffering and prolongs recovery. It is very difficult to differentiate between restlessness or crying due to pain from that of hunger or fear. One of the main reason is the inability of assessing the pain. Inadequate pain relief in children can produce long term negative effects in terms of harmful neuroendocrine responses that results in disrupted eating and sleep cycles. it also increases pain perception during subsequent painful experiences in future [1]. An effective pain therapy to modify the physiologic responses to stress has become an essential component of paediatric anaesthesia and surgical practice. Caudal epidural block is one of the most common regional techniques in paediatric anaesthesia as it is very safe, reliable and easy to perform, especially in infra-umbilical surgeries when combined with general anaesthesia. Caudal analgesia can reduce the amount of inhaled and intravenous anaesthetic agents, attenuate the stress response to surgery, facilitate a smooth recovery, and provide effective postoperative analgesia [2].

The latest addition to the group of adjuvants for caudal analgesia is α2 agonists namely clonidine and dexmedetomidine. In comparison to opioids, α2 agonists does not cause respiratory depression and there are many more advantages of them over opioids. Clonidine is partial α2 agonist and less protein bound than Dexmedetomidine. As compared to clonidine, Dexmedetomidine is highly selective α2 adrenergic agonist with sedative, sympatholytic and analgesic effect. Dexmedetomidine is eight times more potent for to α2 adrenergic receptors and lower affinity to α1 receptors than clonidine, besides its advantage of having higher selectivity to α2 adrenergic receptors, responsible for the analgesic effects [3-5]. Because of the advantages of Dexmedetomidine, we decided to use Dexmedetomidine as an adjuvant to bupivacaine for postoperative analgesia in infraumbilical surgery in paediatric population and its comparison with Clonidine.

Methods

This prospective, randomized, double blinded, interventional, and open labelled study was conducted in a multispeciality operation theatre of ByramjeeJeejeebhoy Medical Hospital, Ahemdabad after the approval of institutional ethical committee (approval number IEC/2019/03) to compare Clonidine and Dexmedetomidine as an adjuvant to bupivacaine in Caudal epidural anaesthesia for postoperative pain relief in paediatric population. After thorough preanesthetic evaluation and necessary investigations, 60 patients of ASA physical status I and II, aged 1yr to 6yrs, undergoing infraumbilical surgeries were included in the study.

Inclusion and exclusion criteria

Inclusion criteria included Age between 1 year to 6 years, ASA physical status I - II, elective infraumbilical surgery.

Exclusion criteria included developmental delay or mental retardation, hypovolemia, increased intracranial pressure, infection at the site, allergy to local anaesthetics, coagulopathy, platelet count less than 1,00,000, spine abnormalities and unstable spine from trauma.

Patients fulfilling the inclusion criteria were randomly allocated to one of the two groups as following, using computer generated random number table.

Group A (n=30) - Patient received 0.125% bupivacaine (1ml/kg) with 0.5mcg/kg Dexmedetomidine caudally.

Group B (n=30) - Patient received 0.125% bupivacaine (1ml/kg) with 0.5mcg/kg Clonidine caudally.

Pre anesthetic preparation

After confirming the NBM (nill by mouth) status, monitoring consisting of H.R (ECG), NIBP, peripheral oxygen saturation (SpO2), temperature (Temperature probe) were attached and baseline parameters were recorded and an IV line with 22 or 24 gauge was also secured, in preanesthetic preparation room. Following premedication was given intravenously: Inj. glycopyrrolate 0.004mg/kg, Inj. ondansetron 0.16mg/kg.

Intra operative Management

Inside operation theatre, preoxygenation was done with 100% oxygen for 3-5 minutes. Induction of anaesthesia was done using inhalation method with 50% oxygen, 50% N2O and 6 to 8% Sevoflurane, along with I.V Propofol 2mg/kg. To facilitate insertion of an I-gel, succinylcholine 2 mg/kg was given intravenously. Caudal epidural was performed with a 22-gauze hypodermic needle with complete aseptic precautions with child in a left lateral position. The drugs to be given through caudal route were prepared by the anaesthesiologist who was excluded from further study. Procedure was done in double blind manner. The anaesthesiologist performing the Caudal block was blinded to the content of solution injected and the same person did the monitoring in perioperative period. After confirmation and negative aspiration for Blood and CSF, the drugs as per assigned group was injected. The patients were repositioned supine. Intra-operatively no analgesia was supplemented. Maintenance of anaesthesia was done with 50% O and 50% N2O mixture with 1.5%-2% sevoflurane and Inj. atracurium 0.5mg/kg intravenous. Patient's hemodynamic parameters i.e. HR, NIBP, SpO2, EtCO2 were recorded pre-operatively, after giving pre-medication, at the time of induction, laryngoscopy and intubation, then every five minutes after intubation till thirty minutes and then every 15 minutes till the end of surgery. Intraoperatively 0.45% DNS was given at the

rate of 10-15ml/kg/hour. During surgery adequate analgesia was evaluated by hemodynamic parameters like, change in HR and systolic blood pressure +/- 15% of baseline value. Any deviation in hemodynamic parameters >15% from baseline in either direction was considered significant. The occurrence of intraoperative hypotension requiring fluid bolus and bradycardia (fall in HR<80/min for age <1yr and <60/min for ages >1yr) requiring atropine was recorded. At the end of surgery, NM blockade was reversed with Inj. Neostigmine 0.05mg/kg intravenous and Inj. glycopyrrolate 0.008mg/kg intravenous. Patient was extubated, after checking protective reflexes with adequate tidal volume and hemodynamic stability after thorough oropharangeal suction. Duration of surgery, duration of anaesthesia and peri-operative complications like arrhythmia, hypotension/hypertension, nausea, vomiting, itching were recorded.

Post operative management

After surgery, patients were shifted to PACU for monitoring and management. Postoperative pain was evaluated by using CHEOPS score (maximum score of 13) after arrival in PACU, at one-hour interval for first four hours and thereafter every two hours interval till twelve hours and then every six hours till twenty four hours. Rescue analgesic given in form of paracetamol 15mg/kg I.V. whenever score was greater than seven. Total dose and frequency of analgesic were also recorded

CHEOPS score is mentioned in the (Table 1).

Interpretation of CHEOPS score

Minimum score: 4

Maximum score: 13

Minimal pain: 4-6,

Mild pain: 7-9,

Severe pain: 10-13.

Post operative respiratory depression was defined as RR<10/min or fall in SPO2 <95% requiring supplemental oxygen. In post-operative period sedation was assessed by using Modified Ramsay Sedation Score as mentioned in (Table 2), at, fifteen minute interval till one hour after shifting to PACU, thereafter hourly until the Ramsay sedation score became two or less in all patients.

On awakening, post operative motor block was assessed with modified bromage scale that consisted of 4 points as mentioned in (Table 3).

Study end points

This study involves observation of analgesic efficacy of Caudal Bupivacaine with Clonidine and caudal bupivacaine with Dexmedetomidine in paediatric patients undergoing infraumbilical surgery.The end point of the study was twenty four hours after the completion of the surgery where postoperative pain was evaluated by using CHEOPS score (maximum score of 13) at one hour interval for first four hours and thereafter every two hours interval till twelve hour and then every six hour till twenty four hour.

Sedation was assessed by using Modified Ramsay Sedation Score, at, fifteen minute interval till one hour after shifting to PACU, thereafter hourly until the Ramsay sedation score became two or less in all patients.

Statistical analysis

The data received in the study for various parameters are mentioned in the tabulated form. Using software mean and standard deviation were calculated for the quantitative variables. Comparison among two groups was done by using unpaired t test. P value <0.05 was considered statistically significant.

Table 1- CHEOPS Score

Parameter	Finding	Points
cry	No cry	1
	Moaning	2
	Crying	2
	Screaming	3
facial	Smiling	0
	Composed	1
	Grimace	2
child verbal	Positive	0
	None	1
	Complaints other than pain	1
	Pain complaints	2
	Both pain and non-pain complaints	2
torso	Neutral	1
	Shifting	2
	Tense	2
	Shivering	2
	Upright	2
	Strained	2
touch	Non touching	1
	Reach	2

	Touch	2
	Grab	2
	Strained	2
legs	Neutral	1
	Squirming kicking	2
	Drawn up tensed	2
	Standing	2
	Restrained	2

Table 2- Modified Ramsay Sedation Score

Score	Description
Awake	
1	Anxious, agitated, restless
2	Cooperative, oriented, tranquil
3	Responsive to commands only
Asleep	
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 light glabellar tap or loud auditory stimulus

Table 3- Modified Bromage Scale

Bromage scale	Criteria
Grade I	Free movement of legs and feet.
Grade II	Just able to flex knees with free movement of feet.
Garde III	Unable to flex knees, but with free movement of feet.
Grade IV	Unable to move legs or feet.

Results

This prospective, randomized, double blinded, interventional open labelled study, comparing the analgesic efficacy and sedative effect of Caudal bupivacaine with Dexmedetomidine and bupivacaine with Clonidine, is conducted in paediatric patients undergoing infra umbilical surgery. This study was carried out in sixty patients, aged 1-6yrs, of ASA physical status I and II divided in 2 groups of thirty patients each. Group A - 1.0ml/kg of 0.125% bupivacaine + 0.5mcg/kg dexmedetomidine. Group B - 1.0ml/kg of 0.125% bupivacaine + 0.5mg/kg clonidine.

Demographic profile including age, gender, weight, ASA physical status was comparable in two groups ($p>0.05$).

The mean duration of analgesia was significantly prolonged in Dexmedetomidine group (743 ± 73.6min) as compared to Clonidine group (181.7 ± 53.60min) ($p<0.0001$).

Post-operative pain score of patients at different time interval After arrival in PACU in post-operative period in two groups, was statistically significant in favour of group A as compared to group B ($p <0.05$) as shown in (Table 4, Figure 1).

All the patient in dexmedetomidine had satisfactory analgesia till 6hrs postoperatively, while in clonidine group, patients started requiring supplementary analgesic from first hour itself (13 patients needed supplementary analgesic at one hr postoperatively).

Frequency of supplementary analgesic required in postoperative period was significantly higher in Clonidine group as compared to Dexmedetomidine group ($p<0.05$). In dexmedetomidine group, 76% of the patients required only single dose of supplementary analgesic while, 66% of patients from clonidine group required three doses.Total dose of paracetamol as rescue analgesic required in post operative period was significantly more in clonidine group (Group B) as compared to dexmedetomidine group (Group A) ($p<0.05$).

None of the patients in either group had developed residual motor blockade in post-operative period.

Sedation score was higher in Group A as compared to Group B and this difference was statistically significant till 2hrs postoperatively ($p <0.05$) as shown in table 5 and (Figure 2). After two hours, patients of both the group had achieved sedation score ≤2 (i.e awake, cooperative, oriented, and tranquil).

Hemodynamic parameters

Heart rate remained stable and comparable in two groups intraoperatively. There was increase in SBP at two hours in postoperative in clonidine group because of early wearing off of caudal analgesia as compared to Dexmedetomidine and the difference was statistically significant. DBP remained stable and comparable in two groups intraoperatively. There was increase in DBP at two hours in post- operative period in clonidine group because of early wearing off of caudal analgesia as compared to dexmedetomidine group and the difference was statistically significant wearing off of caudal

analgesia as compared to dexmedetomidine group and the difference was statistically significant ($p<0.05$). There were no perioperative complications in either group. Respiratory rate remained stable and comparable in both the groups in post-operative period and none of the patients in either group developed R.R < 10/min at any time which is the criteria of respiratory depression in this study. SpO2 remained stable and comparable in post-operative period in two groups and none of the patient in either had SpO2 < 95% which is the criteria of respiratory depression in this study.

Table 4- Comparison of CHEOPS score in both groups

Time (hr)		Group A Mean ± S.D.	Group B Mean ± S.D.	P value
After Arrival in PACU	0	06.00 ± 00	06.00 ± 00	-
	1	06.00 ± 00	08.00 ± 02.95	0.0005
	2	05.70 ± 0.45	07.53 ± 03.01	0.0018
	3	05.10 ± 0.53	06.26 ± 02.11	0.0015
	4	05.03 ± 0.48	06.03 ± 01.53	0.2218
	6	05.23 ± 0.76	05.83 ± 0.93	0.1120
	8	06.06 ± 01.65	08.16 ± 03.01	0.0195
	10	07.70 ± 02.39	08.60 ± 02.70	0.1434
	12	09.96 ± 02.50	06.46 ± 01.78	0.0001
	18	06.43 ± 0.49	06.83 ± 02.13	0.3203
	24	06.90 ± 1.01	09.16 ± 02.69	0.0001

Table 5- Ramsay Sedation Score in both groups

Time		Group A Mean ± S.D.	Group B Mean ± S.D.	P value
After Arrival in PACU	0 min	06 ± 00	05.67 ± 2.12	0.3974
	15 min	60 ± 00	04.70 ± 0.45	0.0001
	30 min	06 ± 00	03.93 ± 0.24	0.0001
	45 min	06 ± 00	02.96 ± 0.83	0.0001
	1 hr	06 ± 00	01.83 ± 0.89	0.0001
	2 hr	04.06 ± 1.12	01.63 ± 0.48	0.0001
	3 hr	02.20 ± 0.54	02.13 ± 0.61	0.6397

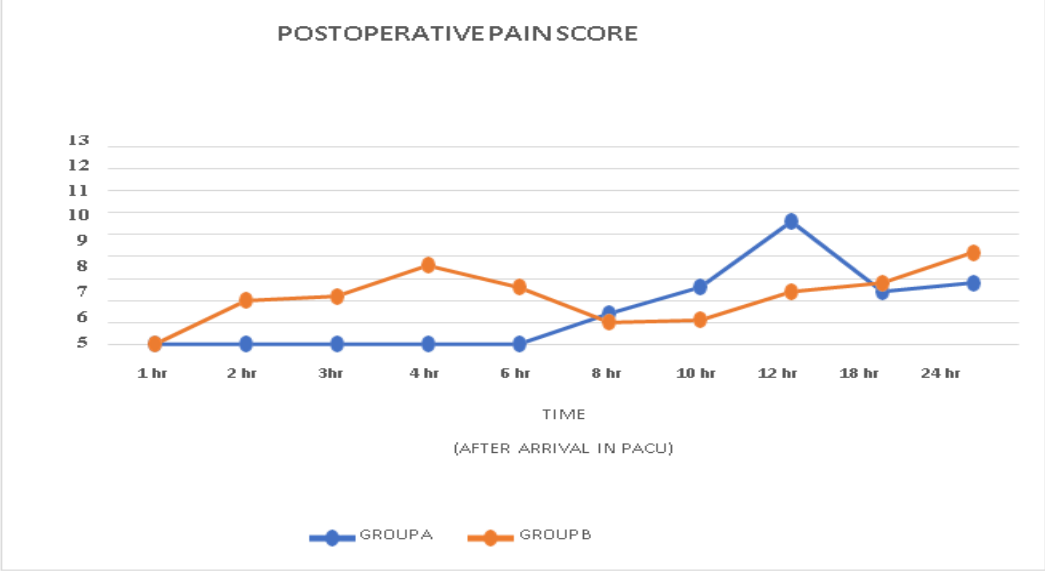

Figure 1- Post operative CHEOPS pain score in both groups

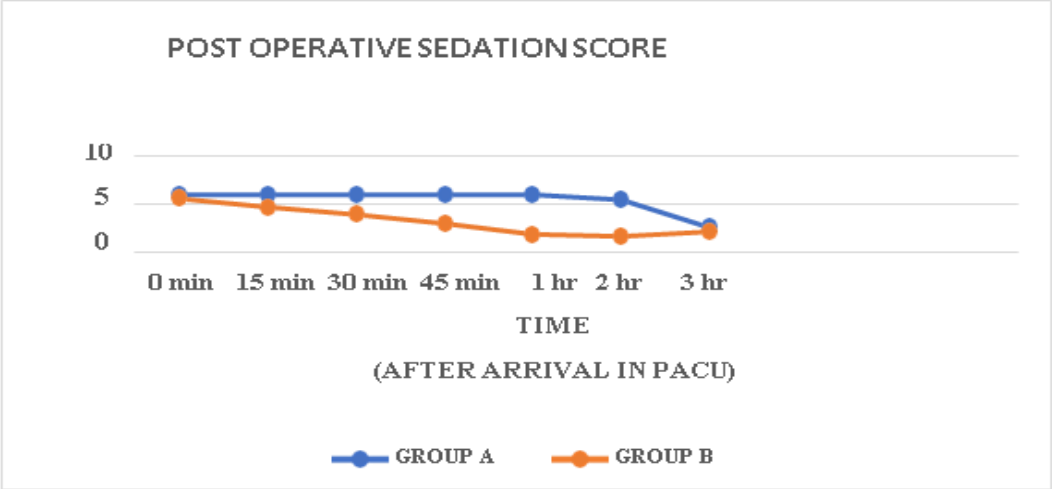

Figure 2- Post operative sedation score in both groups

Discussion

Children with significant postoperative pain may demonstrate anxiety, fright, insomnia, rendering the postoperative recovery period unpleasant and a traumatic experience [6]. Regional anaesthesia provides an extended pain free period and reduces stress response to surgery. Caudal block is an excellent and safe technique for providing postoperative analgesia in paediatric population with a high success rate.Placing the block before the surgical incision provides excellent preemptive analgesia, intraoperative pain relief, reduces the general anaesthetic requirement, and offers earlier recovery of airway reflexes [7].

Adjuvants like opioids (morphine, butorphanol), midazolam, ketamine increase the duration of analgesia and decrease the individual dose of drug and thereby decreasing the side effects. The latest addition to the group of adjuvants is α2 agonists.

α2 agonist and its interaction with local anaesthetics have been explained by three possible mechanisms. α2 agonist blocks Aδ and C fibres in isolated neurones, thus intensifying local anaesthetic conduction block [8]. α2 agonist cause local vasoconstriction, thus decreasing local anaesthetic spread and removal around neural structures. This effect is mediated by drug action on post-synaptic α2 receptors, although there is little evidence of this mechanism with clinical doses [9-10]. α2 agonist combined with spinal local anaesthetics or used in peripheral blocks intensifies and prolongs analgesia. The assessment of pain in paediatric population below five years of age is challenging task, as they cannot express there subjective feeling of pain. Given the subjective and personal nature of pain, self-report has generally been considered as gold standard of measurement. Despite of recognition of its importance, self-report may not be feasible, possible or the best choice for this paediatric population. The CHEOPS (Children's Hospital of Eastern Ontario Pain Scale), FLACC (Face Leg Activity Cry and Consolability scale), CFCS (Child Facial Coding System), TPPPS (Toddler Preschool Postoperative Pain Scale), OPS (Objective Pain Scale) are few of the behavioural pain scoring system devised for paediatric population [11-12]. Use of the κ statistic indicated that CHEOPS yielded the best agreement with the routine decision to treat pain.

In this study, demographic profile of the patients was comparable in two groups ($p>0.05$) and we found that, the time of caudal analgesia without the need of supplementary analgesic is significantly higher in dexmedetomidine group (743 ± 73.6min) than clonidine group (181.7 ± 53.60min) and the total dose of supplementary analgesic (Inj.Paracetamol 15mg/kg i.v) required is significantly higher in clonidine group (491.5± 134.55mg) as compared to dexmedetomidine group (236.5± 113.68mg). Also, in dexmedetomidine group 76% of the patients required only single dose of supplementary analgesic while, 66% of patients from clonidine group required three doses. All the patient in dexmedetomidine group had satisfactory analgesia till 6hrs post operatively, while in clonidine group patients started requiring supplementary analgesic from first hour itself.

The addition of Dexmedetomidine or Clonidine to bupivacaine in this study did not change the magnitude of hemodynamic changes between two groups in perioperative period and was comparable. None of the patients in either group developed hypotension and bradycardia as per the defined criteria in present study (hypotension is defined as fall in systolic blood pressure >20% from baseline and bradycardia as fall in HR <80/min for age <1yr and <60/min for ages> 1yr). And this shows the safety of both the drugs used.

This study is not exactly similar to any other study in terms of, dose of bupivacaine, dexmedetomidine and clonidine used. Hence, we are not in position to copmare

the results of present study with any other study. So we are highlighting the result of those studies who have used higher doses of these above mentioned drugs for our clinical interest.

In study [13], 60 paediatric patients, aged 6 months to 6 years, undergoing infraumbilical surgery, where dexmedetomidine 1mcg/kg with 0.25% bupivacaine was compared with 1mcg/kg clonidine with 0.25% bupivacaine, administered caudally. The duration of analgesia was significantly prolonged in dexmedetomidine group (17.6 ± 2.9 hr) as compared to clonidine group (10.1 ± hr). Total analgesic consumption was statistically lesser in dexmedetomidine group (60 ± 47 mg) when compared to clonidine group (100 ± 76 mg).

In another study [14], 60 patients aged 6 months to 6 years, undergoing infraumbilical surgery, 30 patients were administered 1mcg/kg dexmedetomidine with 0.25% bupivacaine caudally and another 30 patients received 1mcg/kg clonidine with 0.25% bupivacaine caudally. They found that analgesia time was significantly higher in dexmedetomidine group (14.16 ± 1.65 hr) than clonidine group (11.24 ± 2.48 hr). Also, the number of analgesic doses required in 24 hrs post operatively, was significantly higher in clonidine group as compared to dexmedetomidine group.

The study [15], conducted in 60 patients, aged 6months to 6 years, undergoing infraumbilical surgery, were recruited in two groups: Group RD(n=30) received 0.25% ropivacaine with 2mcg/kg dexmedetomidine and Group R(n=30) received 0.25%ropivacaine, for caudal. The duration of postoperative analgesia was 5.5 hours in Group R and 14.5 hours in Group RD They also found that the difference of mean sedation score between both the groups was statistically very significant ($p<0.0001$). RD group had significant sedation compared to R group, which means that RD group children were asleep.

Limitations

There is no prospective study without limitations. The limitations of our study is as follows. Patients with only ASA physical status I and II were selected for study. The participants were a local population with low sample size. Therefore, large clinical trials are mandatory to validate implication of the above findings.

Conclusion

The result of present study allowed us to conclude that, addition of Dexmedetomidine (0.5mcg/kg) to caudal 0.125% bupivacaine (1ml/kg) produces significantly longer duration of postoperative analgesia, less frequency and dose of rescue analgesic required for postoperative analgesia in children, aged 1 to 6 yrs as compared to similar dose of Clonidine used in caudal epidural for infra umbilical surgeries. Inspite of higher sedation score found in Dexmedetomidine group as compared to Clonidine group, no incidence of respiratory depression requiring supplemental oxygen, shows its safety comparable to clonidine. Both the drugs used were stable and had comparable hemodynamics.

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