

A Comparative Study Between Dexmedetomidine (1mcg/Kg) And Dexamethasone (0.1mg/Kg) As Adjuvants To 0.25% Bupivacaine In Caudal Analgesia In Pediatric Patients Undergoing Lower Abdominal Surgeries - A Prospective Randomized Comparative Study

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Abstract: Background: Caudal analgesia is good, reliable and easy method to provide intra operative and postoperative analgesia in the lower abdominal surgeries in pediatric patients. Many additives were used in combination with local anaesthetics in caudal block to increase the quality of anaesthesia, to prolong the postoperative analgesia, to reduce the dose of local anaesthetics and to reduce side effects.

Aim of the study: This study is aimed to study and compare the effects of 1mcg/kg Dexmedetomidine and 0.1mg/kg Dexamethasone as adjuncts to 0.25%Bupivacaine on intra operative haemodynamics, prolongation of duration of postoperative analgesia, complications if any, in paediatric patients undergoing lower abdominal surgeries.

Material & Methods: This study was done in 100 patients of both the sexes, aged between 1-5 years, with ASA Status I, II posted for lower abdominal surgeries under general anaesthesia.

Group I: 0.25% Bupivacaine in a dose of 0.5ml/kg with Dexamethasone 0.1mg/kg caudally.

Group 2: 0.25% Bupivacaine in a dose of 0.5ml/kg with Dexmedetomidine 1mcg/kg caudally.

Parameters assessed were- Heart rate and Mean arterial pressure at base line, after induction, after caudal block, every 5min for first 15min and every 15min for 3hr from start of operation in operative room, Modified objective pain score (MOPS) at 30min, 1hr, 2hr, 3hr, 6hr, 12hr. Ramsay Sedation score at the time of pain, any side effects.

Results: Intra operative haemodynamics were comparable in both the groups, there was a marginal increase in the duration of post-operative analgesia and there was a sedation which is arousable in Dexmedetomidine group when compared to Dexamethasone group, no side effects were noted in both the groups.

Keywords: Adjuvant, Dexmedetomidine, Dexamethasone, Bupivacaine, Caudal Analgesia.

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I. Introduction

Pain is a protective mechanism designed to alert the body to potentially injurious stimuli. The international association for the study of pain has defined it as "an unpleasant sensory and emotional experience, associated with actual or potential tissue damage". However it has been recognized for some time that the management of acute pain, especially post-operative pain, has been consistently and systematically inadequate¹. Neonates and Children are special in this regard because in them, it is a complex phenomenon and the importance of pain relief is often underestimated².

Caudal block is one of the most reliable and commonly used regional analgesic techniques to provide intra- and postoperative analgesia in pediatric infraumbilical surgeries. It can be given as single-shot injection or continuous infusion through a caudal epidural catheter. Single-shot caudal was the most commonly preferred technique as the latter is associated with increased incidence of infection due to high risk of fecal contamination of catheter.³ However, the disadvantage of single-shot caudal is less duration of action of local anesthetics. Hence, to increase the efficacy of caudal analgesia, various adjuvants such as opioids, steroids, neostigmine, and α_2 agonists^{4,5,6} have been added to local anesthetics to provide prolonged postoperative analgesia.

Dexamethasone has synergistic effect when added to local anaesthetics epidurally reduce postoperative analgesic needs. One of the theory stated that dexamethasone might have a direct local anaesthetic effect on the nerve.^{7,8}

While dexmedetomidine is an alpha 2 agonist which has sedative, analgesic, and opioid-sparing effect.⁹ It prolongs the duration of analgesia by its local vasoconstrictive effect and by increasing the potassium conductance in A-delta and C-fibers.^{10,11} It also exerts its analgesic action centrally via systemic absorption or by diffusion into the cerebrospinal fluid and reaches alpha 2 receptors in the superficial laminae of the spinal cord and brainstem¹² or indirectly activating spinal cholinergic neurons.¹³ The sedative effects of dexmedetomidine are mostly due to stimulation of the alpha 2 adrenoceptor in the locus coeruleus.¹⁴

This study was conducted to see the efficacy of Dexmedetomidine and Dexamethasone as an adjunct to Bupivacaine in post-operative pain relief following caudal analgesia for subumbilical surgeries in pediatric patients (age 1- 10 years). We compare postoperative pain relief as well as the requirement of rescue analgesia and also look for postoperative complications as compared to local anaesthetics alone.

AIMS AND OBJECTIVES

This is a prospective, randomised comparative study, to study and compare the effects of 1mcg/kg Dexmedetomidine and 0.1mg/kg Dexamethasone as adjuncts to 0.25%Bupivacaine on intra operative haemodynamics, prolongation of duration of postoperative analgesia, complications if any, in paediatric patients undergoing lower abdominal surgeries.

Our aims and objectives are to compare:

- 1) Intra operative hemodynamics.
- 2) Total duration of post-operative analgesia in both the groups.
- 3) Duration of motor block in both the groups.
- 4) Complications if any, intra and post operatively.
- 5) Total dose of rescue analgesic requirements.

II. Materials And Methods

STUDY DESIGN AND EQUIPMENT

After obtaining institutional ethical committee approval and informed consent from the parents, this prospective, randomised, comparative study was conducted in **Guntur medical college/ Govt. General Hospital, Guntur during June 2018 to April 2019.**

INCLUSION CRITERIA

- 1) Age 1-5 years
- 2) Elective cases
- 3) ASA status I, II physical status.

EXCLUSION CRITERIA

- 1) Patients with contraindications to caudal anaesthesia
- 2) Drug allergy to study drugs
- 3) Clotting disorders

III. Methods

100 patients belonging to both sexes, aged between 1-5 years, with ASA Status I, II who were posted for lower abdominal surgeries under general anaesthesia were included in the study. Clinical examination and routine investigations were done to all patients. Patients in the Operating room were monitored with Pulse Oximetry, ECG, NIBP. A 22-Gauge i.v cannula is inserted into peripheral vein. Patients were pre-medicated with 0.02mg/kg Atropine, 0.03mg/kg Midazolam.

All patients underwent general anaesthesia with 6%Sevoflurane, 3-5mg/kg Thiopentone Sodium and Endotracheal intubation was facilitated by Atracurium 0.5mg/kg. The patients were randomly allocated into two groups by picking random lots from a sealed bag.

Then patient is tilted on the lateral side and caudal anaesthesia was performed under complete aseptic conditions by using loss of resistance technique, in both the groups.

Group 1: 0.25% Bupivacaine in a dose of 0.5ml/kg with Dexamethasone 0.1 mg/kg caudally.

Group 2: 0.25% Bupivacaine in a dose of 0.5ml/kg with Dexmedetomidine 1mcg/kg caudally.

The block was given post intubation by a consultant anesthesiologist, and another anaesthesiologist who was blinded to the injection monitored post-operative pain score.

15min from the caudal block, the surgical procedure started, block considered failed if Heart rate or Mean arterial pressure were increased by 15% from the base line. The failed block patients were excluded from the study. Anaesthesia was maintained with O₂+N₂O+Atracurim and 2%Sevoflurane.

After completion of surgery, when extubating conditions were fulfilled Anaesthesia was reversed the

patients with 0.05mg/kg Neostigmine and 0.02mg/kg Atropine.

Parameters assessed were:

- 1) Heart rate and Mean arterial pressure at base line, after induction, after caudal block, every 5min for first 15min and every 15min for 3hr from start of operation in operative room.
- 2) Modified objective pain score (MOPS) at 30min, 1hr, 2hr, 3hr, 6hr, 12hr.
- 3) Ramsay Sedation score at the time of pain
- 4) Side effects like hypotension, bradycardia intra operatively, respiratory depression, nausea, vomiting and itching post operatively. The follow up in PACU and ward for MOPS was noted separately.

Modified Objective Pain Score (MOPS) Overview: Wilson and Doyle used a modification of the Objective Pain Score (OPS) to assess pain in children. It is intended for evaluation of post-operative pain and can be used by the child's parents.

Criteria	Finding	Points
Crying	None	0
	Consolable	1
	Non consolable	2
Movement	None	0
	Restless	1
Agitation	Thrashing	2
	Asleep	0
	Calm	0
Posture	Mild	1
	Hysterical	2
	Normal	0
Verbal	Flexed	1
	Holds injury site	2
	Asleep	0
Verbal	No Complaint	0
	complains but cannot localize	1
	complains and can localize	2

Ramsay sedation score was also assessed at the time of the pain (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, and 6 = asleep and not responsive to any stimulus).

The necessity for rescue medication was decided by the MOPS of > or = 4. Rescue medication was provided with Injection Paracetamol with a dose of 10-15mg/kg.

The adverse effects in PACU also were assessed: hypotension- decrease in mean arterial blood pressure by 20%, treated with i.v. fluid and incremental dose of Inj. Mephenteramine 0.12mg/kg, bradycardia- defined by decrease in basal heart rate by 20%, treated by i.v. atropine 0.01-0.02mg/kg, respiratory depression – SPO2 < 95%, need O2 supplementation.

From the time of arrival in PACU, to the first time the MOPS to be 4 or more was recorded as the duration of adequate caudal analgesia.

The numbers of doses of rescue medication required were recorded over 24hrs.

IV. Observations And Results

All the 100 patients enrolled completed the study. Both groups were similar in their demographic profile and baseline hemodynamic parameters like heart rate, mean arterial pressure, type of surgery and duration of surgery.

Data expressed as mean ± SD in both groups.

P> 0.05 considered as statistically not significant.

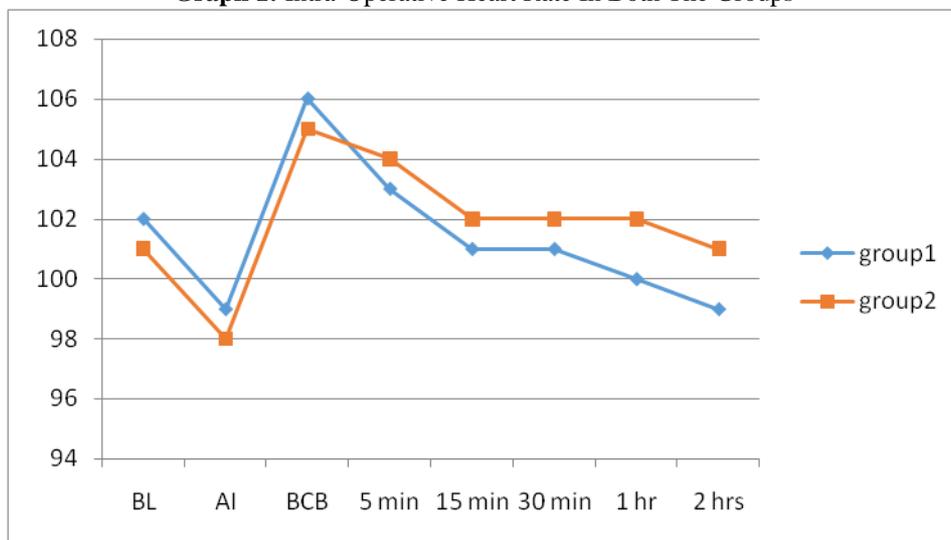
Table 1: Comparison of Intra-Operative Haemodynamics Between The Two Groups

	GROUP	HEART RATE (bpm) (mean±SD)	P VALUE	MAP (mm of Hg) (mean±SD)	P VALUE
After induction	Group 1	99.54±13.02	0.7080	57.82±4.38	0.5087
	Group 2	98.26±13.07		58.40±4.36	
Before caudal block	Group 1	105.96±13.15	0.8551	60.08±4.48	0.6565
	Group 2	105.48±13.07		60.48±4.49	
After 5min of caudal block	Group 1	103.38±11.75	0.8723	59.34±4.50	0.5295
	Group 2	103.78±13.03		59.90±4.38	
After 15 min	Group 1	101.32±11.33	0.5531	59.04±4.47	0.5261
	Group 2	102.76±12.82		59.60±4.33	
After 30 min	Group 1	100.90±10.90	0.5231	58.88±4.37	0.5121

	Group 2	102.42±12.75		59.46±4.44	
After 1hr	Group 1	100.10±11.39	0.4534	58.94±4.41	0.5892
	Group 2	101.94±13.00		59.42±4.45	
After 2hrs	Group 1	99.24±10.52	0.3293	58.74±4.27	0.4493
	Group 2	101.56±13.01		59.40±4.42	

Data expressed as mean ± SD in both groups. P value is not statistically significant. Intra op hemodynamics are comparable between 2 groups.

Graph 1: Intra-Operative Heart Rate In Both The Groups



Graph 2: Intra-Operative Mean Arterial Pressures In Both The Groups

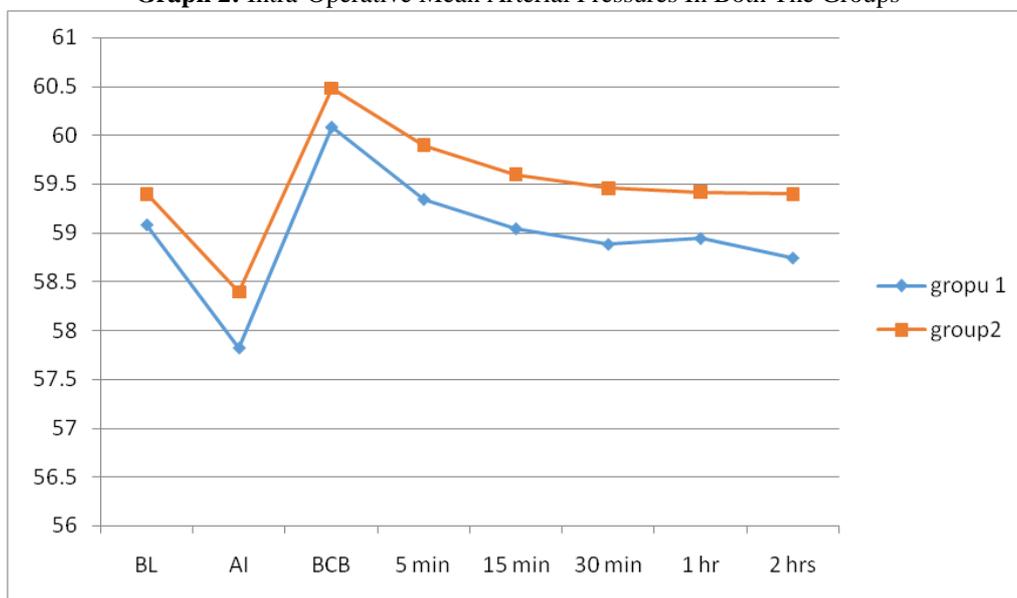


Table 2: Total Duration of Postoperative Analgesia In Both The Groups

GROUP	DURATION OF ANALGESIA (min)
GROUP 1	449.48±5.98
GROUP 2	484.94±2.85

Data expressed as mean±SD. P value is < 0.0001. **p value is statistically significant.**

Graph 3: Total Duration Of Postoperative Analgesia In Both The Groups

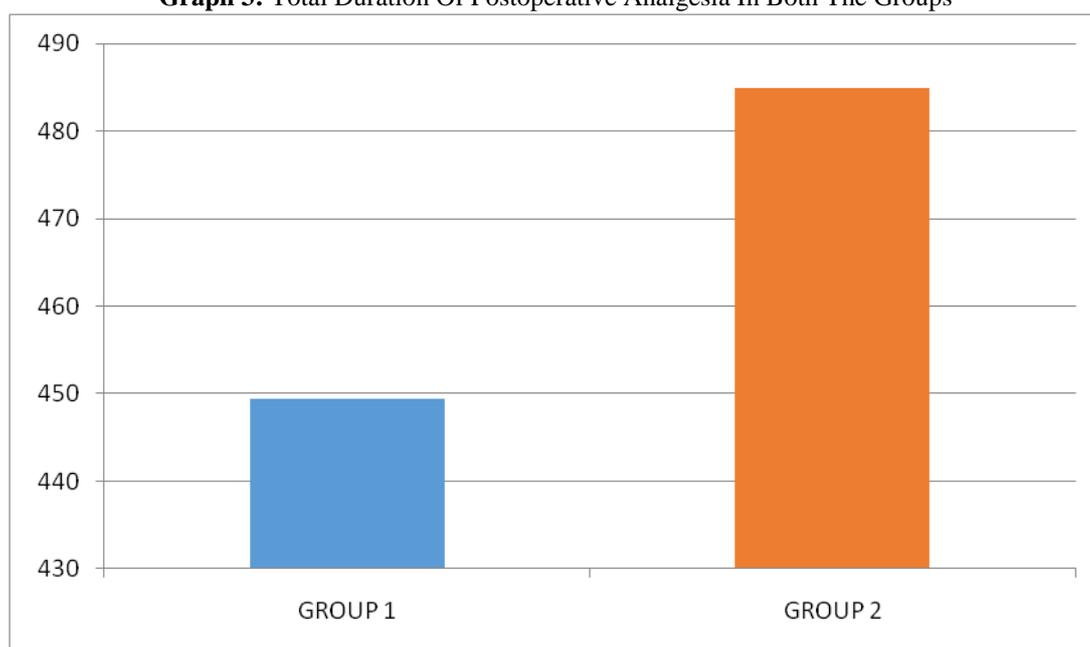


Table 3: Duration of Motor Block

	GROUP 1	GROUP 2
MOTOR BLOCKADE	129.42±27.13	143.02±23.58

Data expressed as mean±SD. P value is 0.486, considered statistically insignificant.

Table 4: Rescue Medication

	GROUP 1	GROUP 2
ONE	4	36
TWO	25	14
THREE	21	0

Two or more rescue medications were used in Dexamethasone group than Dexmedetomidine group in first 24 hrs.

V. Discussion

Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in paediatric anaesthesia. It is a reliable and safe technique that can be used with general anaesthesia for intra and postoperative analgesia in patients undergoing infraumbilical surgeries.

The present study was designed to compare the effectiveness of Dexamethasone versus Dexmedetomidine as an adjuvant to Bupivacaine for caudal analgesia in children. A total of 100 patients were randomized into two groups 1 and 2. Group 1 received Dexamethasone 0.1mg/kg with 0.5 ml/kg of 0.25% Bupivacaine, while Group 2 received Dexmedetomidine 1mcg/kg with 0.5ml/kg of 0.25% Bupivacaine. Both the groups were then monitored for intra operative hemodynamics, duration of postoperative analgesia, complications like sedation, respiratory depression if any.

Caudal Dexamethasone prolongs the duration of analgesia. The mechanism of analgesic effect may be due to the local anaesthetic action of corticosteroids, also it inhibits the transcription factor nuclear factor-kB (NF-kB) which is expressed in the nervous system and causes pain^{15,16}.

Dexamethasone reduces stimulus transmission in unmyelinated c-fibers by inhibiting the activity of the potassium channels on these fibers. Secondly, it is thought that Dexamethasone causes a degree of vasoconstriction to the tissues and local anesthetic will have a slower uptake and absorption thus, prolonging its duration and amount of comfort felt by the patient. Thirdly, Dexamethasone exhibits a potent anti-inflammatory effect and inhibits the release of inflammatory mediators like interleukins and cytokines; it promotes the release of anti-inflammatory mediators leading to decreased postoperative pain.

Dexamethasone might have a local anaesthetic effect on nerve by direct membrane action. Therefore, dexamethasone might potentiate the effect.

When Dexmedetomidine is added to caudal bupivacaine as adjuvant, it enters the central nervous system either via systemic absorption or by diffusion into the cerebrospinal fluid and reach α_2 receptors in the superficial laminae of the spinal cord and brainstem or indirectly activating spinal cholinergic neurons^{17,18,19,20}.

Dexmedetomidine is a highly selective α_2 adrenoceptor agonist. Dexmedetomidine exerts its analgesic action at α_2 receptors in the locus ceruleus and spinal cord. In spinal cord activation of α_2 'c' receptor subtype seems to accentuate the analgesic actions of opioids. Dexmedetomidine enhances the effects of local anesthetics without increasing the incidence of side effects.

Administration of an α_2 -agonist via an intrathecal or epidural route provides an analgesic effect in postoperative pain without severe sedation. This effect is due to the sparing of supraspinal CNS sites from excessive drug exposure, resulting in robust analgesia without heavy sedation. Although bradycardia and hypotension are considered to be the most prominent adverse effects of α_2 -adrenoreceptor agonists, these side effects appear to be less pronounced in children than in adults. Dexmedetomidine has a favorable safety profile and stable hemodynamics, which are in concordance with the reports published by several other authors²¹.

The two groups were comparable with respect to demographic details like age, sex and weight and type of surgeries.

Intra and post-operative heart rate and MAP:

Intra-operative and post-operative haemodynamics were comparable in both the groups in our study. The hemodynamic parameters such as HR and systolic, diastolic, and mean blood pressure were similar among the groups studied which is similar to Saadawy *et al.*, where no statistical difference between Dexmedetomidine and Bupivacaine groups¹⁸ exist.

Dutt *et al.* compared the addition of Fentanyl or Dexmedetomidine to caudal Ropivacaine in paediatric patients who underwent lower abdominal and lower limb surgeries and concluded that hemodynamics were comparable between the two studied groups²².

Duration of analgesia:

In our study, the postoperative analgesia was evaluated using the MOPS for the first 24 hours. In our study, as assessed with MOPS the postoperative analgesia was found to be marginally higher in the Group 2 which received Dexmedetomidine as an adjuvant to Bupivacaine than Group 1 which received Dexamethasone as an adjuvant to Bupivacaine. The duration of analgesia in group 1 is 449.48 ± 5.98 min and in group 2 is 484.94 ± 2.85 min, expressed in (mean \pm SD).

El-Feky *et al* used MOPS to evaluate pain in 120 children of 3-10 years who received Fentanyl, Dexmedetomidine or Dexamethasone as caudal additive to Bupivacaine scheduled for lower abdominal surgeries found that both Dexamethasone and Dexmedetomidine extended the postoperative analgesia significantly with mean duration of 490.4 ± 13.6 min and 498.2 ± 15.4 min similar to our study with almost no side effects²³.

Our study is also in agreement with Sridhar RB *et al* where they compared Dexmedetomidine, Dexamethasone, and Magnesium as adjuvants to Ropivacaine caudal analgesia in pediatric patients undergoing infraumbilical surgeries. They randomly allocated to four groups to receive Normal saline, Dexmedetomidine 1 μ g/kg, Dexamethasone 0.1 mg/kg, and Magnesium sulphate 50 mg with injection Ropivacaine 0.2% in the dose 0.5 ml/kg caudally. Modified Objective Pain Score and Ramsay Sedation Score, duration of analgesia, hemodynamic changes, and side effects were assessed. There was a significant prolongation of duration of analgesia in all study groups, Dexmedetomidine (406.2 ± 45.5 min). They had no excess or prolonged sedation. No side effects were encountered²⁴.

This is in agreement with Goyal *et al.* as they randomized 100 children aged 2–10 years undergoing infraumbilical surgeries to either receive Dexmedetomidine with Bupivacaine or Bupivacaine alone caudally. They observed that postoperative analgesic duration was significantly prolonged in Dexmedetomidine group with 9.88 ± 0.90 h versus 4.33 ± 0.98 h in Bupivacaine alone group²⁵.

Choudhary *et al* where they enrolled 128 patients of 1-5 years who underwent inguinal herniotomy into Group A and Group B randomly to receive either Ropivacaine or Ropivacaine with Dexamethasone for caudal analgesia. Postoperative pain scores measured at 1, 2, 4, and 6 h were lower in Group B as compared to Group A. The mean duration of analgesia in Group A was 248.4 ± 54.1 min and in Group B was 478.046 ± 104.57 min, with $P < 0.001$ as seen in our study²⁶.

VI. Sedation

Ramsay Sedation Score monitored in this current study inferred that none of the adjuvants resulted in either excessive or prolonged sedation.

Afonso and Reis.²⁷ found that sedation caused by dexmedetomidine can be easily reversed with slight stimulation and do not cause respiratory depression even at high doses. In our study, also no child had respiratory depression in the post-operative period which is in agreement with his study.

These results come with agreement of the study done by Anand *et al.* who evaluated the effects of

Dexmedetomidine added to caudal Ropivacaine in paediatric lower abdominal surgeries, and found that Dexmedetomidine group achieved significant postoperative pain relief with better quality of sleep and prolonged duration of arousal sedation²⁸.

Saadawy et al. studied the addition of Dexmedetomidine to Bupivacaine in caudal block in children concluded that the Dexmedetomidine group had better quality of sleep and a prolonged duration of sedation¹⁸.

Motor block

The definition of motor block duration included time to first movement; ability to abduct the arm 2 in.; ability to overcome gravity; or complete motor recovery. The overall estimate of the effects of Dexamethasone on the prolongation of motor block is 129min and Dexmedetomidine 143min with a p value of 0.486, considered insignificant.

Rescue analgesics in the first 24 h postoperative period

In our study, the Dexmedetomidine group required significantly less number of rescue analgesics as compared to Dexamethasone group. In Dexamethasone group, all patients required 2 or more than 2 rescue analgesic within first 24hrs. In Dexmedetomidine group, 82% patients required single rescue analgesic and 18% required two rescue analgesic. This is in agreement with a study conducted by Saadawy *et al*¹⁸.

Postoperative complications

At no time in this study, there was a decrease in RR and fall in SpO₂ requiring oxygen supplementation. Similar findings were demonstrated by Afonso and Reis.²⁷

VII. Conclusion

To conclude, in our study, we found that **Dexmedetomidine** (1 µg/kg) as an adjuvant to Bupivacaine 0.25% (0.5mL/kg) in caudal analgesia for paediatric infraumbilical surgeries, had marginally prolonged the duration of post-operative analgesia and had an arousable sedation which is needed in paediatric patients, when compared with Dexamethasone (0.1mg/kg).

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