

“A Comparative Clinical Study Of 0.25% Bupivacaine with Dexmedetomidine And 0.25% Ropivacaine with Dexmedetomidine in Pediatric Caudal Block For Infra Umbilical Surgeries in Karpagavinayaga Medical College and Hospital, Maduranthagam”.

¹ Dr.P.Manohar, ² Dr.Yachendra.

¹ Assistant Professor, Department Of Anesthesia, Karpagavinayaga Medical College And Hospital, Maduranthagam.

² Associate Professor, Department Of Anesthesia, Karpagavinayaga Medical College And Hospital, Maduranthagam.

Abstract:

Background: Caudal epidural block is one of the most popularly used regional techniques in pediatric patients. Various drugs in different concentrations have been used for the technique. Local anesthetic like Ropivacaine produces differential neuraxial blockade with less motor block and reduced cardiovascular toxicity. To increase the duration of action of local anesthetics and thereby analgesia extending to the post-operative period, various adjuvants like Dexmedetomidine, α_2 agonist has been used. Lower concentration of local anesthetics can be used for the procedure as motor blockade is not much required. Hence we have compared Bupivacaine 0.25% combined with $1\mu\text{g}/\text{kg}$ of Dexmedetomidine and Ropivacaine 0.25% combined with $1\mu\text{g}/\text{kg}$ Dexmedetomidine at a volume of $1\text{ml}/\text{kg}$ in children undergoing infra umbilical surgeries.

Aims And Objectives: To assess the safety, efficacy, onset and duration of analgesia of 0.25% Bupivacaine and 0.25% Ropivacaine when equal volumes of Dexmedetomidine is added as an adjuvant in pediatric caudal block.

Material And Methods: The Current Study is a comparative randomized study where sampling method was purposive sampling. Statistical analysis was done using student's *t* test and chi square test. 60 children aged between 1 to 6 years weighing < 20 kgs posted for surgery were divided into two groups of 30 each. GROUP BD received 0.25% Bupivacaine $1\text{ml}/\text{kg}$ + $1\mu\text{g}/\text{kg}$ Dexmedetomidine and GROUP RD received 0.25% Ropivacaine $1\text{ml}/\text{kg}$ + $1\mu\text{g}/\text{kg}$ Dexmedetomidine. Intra-operatively, onset of analgesia was noted. Post-operatively, duration of analgesia was assessed using the observational pain scale, duration of sedation was assessed using sedation score and the duration of motor block was assessed using modified bromage scale.

Results: The onset of action in Group BD (Bupivacaine) and RD (Ropivacaine) was $7.06\pm 0.69\text{mins}$ and $6.5\pm 0.73\text{mins}$ respectively. The duration of analgesia was $532.67 \pm 47.12\text{ mins}$ in group BD (Bupivacaine) and $497\pm 23.21\text{mins}$ in group RD (Ropivacaine).

Conclusion: There was no significant difference in the onset of action, duration of sedation and vital parameters between the two groups. Bupivacaine with Dexmedetomidine produced longer duration of analgesia compared to Ropivacaine with Dexmedetomidine. Hence 0.25% Bupivacaine $1\text{ml}/\text{kg}$ with Dexmedetomidine $1\mu\text{g}/\text{kg}$ is a better choice than 0.25% Ropivacaine $1\text{ml}/\text{kg}$ with Dexmedetomidine $1\mu\text{g}/\text{kg}$.

Keywords: Caudal block, Dexmedetomidine, Bupivacaine, Ropivacaine.

I. Introduction

Historically, children have been under treated for pain because of the wrong notion that they neither suffer nor feel pain or respond to or remember the painful experiences to the same degree as adults did(1). It is now established that newborn infants, even preterm, can appreciate pain and react to it with tachycardia, hypertension and neuro endocrine response (2). Post-operative pain relief in children is challenging. Regional anesthetic techniques reduce the overall intra-operative requirement of both inhaled and intravenous anesthetic agents and allow more rapid return of consciousness while providing effective post-operative pain relief with minimal sedation (3).

Caudal epidural block is one of the oldest and the most popular regional block performed in pediatric anesthesia (4). It provides excellent intra-operative and post-operative analgesia in patients undergoing short surgical procedures below the umbilicus (5).

Bupivacaine and Ropivacaine are the long acting amide local anesthetics used for pediatric caudal block with various concentrations ranging from 0.125% to 0.5% and 0.2% to 0.75% respectively (6), Profound motor block and systemic toxicity are the problems encountered with higher concentrations and volumes of local anesthetics which can be minimized by reducing the concentration and dosage of the drugs.

To prolong the duration of action and to improve the quality of intra-operative and post-operative analgesia of local anesthetics, various adjuvants have been used.

Dexmedetomidine is a highly selective α_2 receptor agonist with sedative and analgesic properties. Dexmedetomidine has a higher affinity for α_2 adrenergic receptors than clonidine, which is responsible for its hypnotic and analgesic effects (7). Various studies are being done to evaluate the use of Dexmedetomidine in regional anesthesia to improve quality and duration of analgesia. Very few studies have been done to evaluate the effect of Dexmedetomidine as an adjuvant to Bupivacaine in caudal anesthesia in children (8).

Post-operative analgesia is achieved with lower concentrations and volumes of local anesthetics with additives can be used for intra operative and post-operative analgesia.

Hence, we have compared Bupivacaine 0.25% combined with 1 μ g/kg of Dexmedetomidine and Ropivacaine 0.25% combined with 1 μ g/kg Dexmedetomidine at a volume of 1ml/kg in children undergoing infra umbilical surgeries.

II. Aims And Objective

1. To assess the safety and efficacy of 0.25% Bupivacaine and 0.25% Ropivacaine when Dexmedetomidine is added as an adjuvant in pediatric caudal block.
2. To compare the onset and duration of analgesia between the two study groups.

III. Methods

Patients' Selection: The study protocol was approved by the Institutional Ethics' Committee. This prospective, double-blind, randomized study took place in the Department Of Anesthesiology, Karpaga Vinayaga Medical College Hospital, Maduranthagam and included 60 patients. Study was done over a period of 18 months from Jan 2014- June 2015. This is a comparative randomized study where sampling method was purposive sampling. Written informed consent was obtained from the parents or legal guardians. Patients aged 1-6 years, ASA I-II, undergoing lower abdominal surgeries were included. They were divided into 2 groups; Group BD (n=30) received 0.25% Bupivacaine 1ml/kg + 1 μ g/kg Dexmedetomidine and Group RD (n=30) received 0.25% Ropivacaine 1ml/kg + 1 μ g/kg Dexmedetomidine.

Exclusion criteria were patients with ASA physical status III-IV, known history of hypersensitivity to any of the drugs used, infection at the site of block, bleeding diathesis, pre-existing neurological or spinal disease and abnormalities of the sacrum.

On admission, a thorough preoperative evaluation of the patient was done. A written informed consent was taken from the parents after explaining the procedure, its advantages and disadvantages. Basal vital parameters like heart rate, blood pressure and Oxygen saturation and ECG were recorded. Inj. Atropine 0.01mg/kg IV and Inj. Midazolam 0.03mg/kg IV were given as premedication. Patients were induced with Propofol 2mg/kg IV and maintained on spontaneous ventilation with Oxygen, Nitrous Oxide and sevoflurane.

The child was put in the left lateral position and under aseptic precautions the sacral hiatus was identified. Caudal epidural space was identified by using the loss of resistance technique and Whoosh test and the study drug was deposited after confirming negative aspiration for blood and CSF.

Intra-operatively, the onset of action of the study drug and duration of surgery were noted. Heart rate, blood pressure and SPO₂ were recorded before and after induction and every 5 mins thereafter till the surgery was over. Doses of Propofol if needed were noted.

Post-operatively, the vital parameters were recorded every 15 mins and also the duration of sedation, duration of analgesia, any complications like bradycardia, hypotension, dry mouth, retention of urine, respiratory depression, nausea, vomiting etc. were noted in each group.

The duration of analgesia was assessed by using the subjective pain scale in children more than 3years of age who can verbally express pain and observational pain scale for rest of the children who cannot verbally express pain. If the child complained of pain or if the pain score is ≥ 3 , the child received Paracetamol suppository 15mg/kg as a rescue analgesic. Sedation was assessed using Sedation score. Motor block was assessed by Modified Bromage scale.

Observation Pain Scale

CRITERION		SCORE
HEART RATE	>10% to < 20% of preoperative	0
	20% to 30% of preoperative level	1
	>30% of preoperative level	2
BLOOD PRESSURE	>10% to < 20% of preoperative level	0
	20 % to 30% of preoperative level	1
	>30% of preoperative level	2
CRYING	Not crying	0
	Crying but responds to tender loving care	1
	Crying and does not respond to tender loving care	2

Four Point Sedation Score:

1. Asleep, not arousable by verbal contact.
2. Sleep, arousable by verbal contact.
3. Drowsy not sleeping.
4. Alert/ awake.

Modified Bromage Scale:

- Bromage 0- Patient is able to move the hip, knee and ankle.
- Bromage 1- Patient is unable to move the hip but able to move the knee and ankle.
- Bromage 2 - Patient is unable to move the hip and knee but able to move the ankle.
- Bromage 3 - Patient is unable to move the hip, knee and ankle.

IV. Statistical Analysis

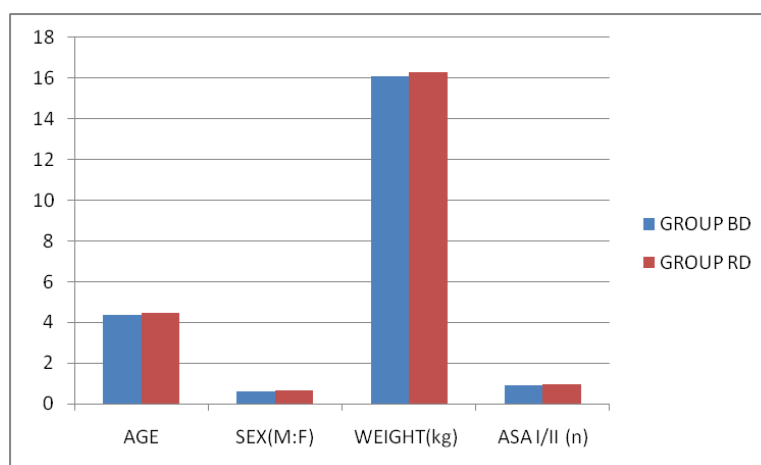
Numerical data were expressed as mean with a standard deviation and categorical data were put into tables. Statistical analyses were carried out using the statistical package for the social sciences 16.0 statistical software packages. Using Student's t test and chi-square test. P< 0.05 was considered statistically significant.

V. Results

In this randomized comparative study, the demographic parameters were comparable between the two study groups. (Table 1)

PARAMETER	GROUP BD	GROUP RD	p value
AGE	4.37±1.10	4.48±1.18	0.69
SEX(M:F)	14:16	15:15	
WEIGHT(kg)	16.07±3.69	16.31±3.44	0.93
ASA I/II (n)	22:8	23:7	0.90
DURATION (mins)	73.62±9.81	76.17±9.35	0.31

Table 1. Demographic Parameters.



Picture 1. Demographic Parameters

Onset Of Action: The mean onset of action in group BD was 7.06±0.69mins and in group RD was 6.5±0.73mins

ONSET OF ACTION IN MINUTES	GROUP BD	GROUP RD	p VALUE
Mean	7.06 ± 0.69	6.50 ± 0.73	0.284

Table 2. Onset of action.

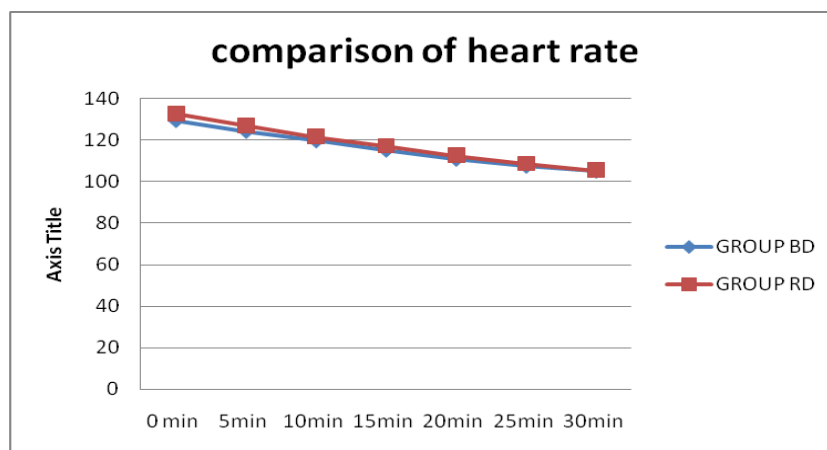
Statistically **NOT** significant.

Intraoperative Hemodynamic Variations:

Heart Rate: The mean basal heart rate in group BD was 129.37±9.16/min and in group RD was 132.72±11.86/min as shown in Table 3. At the end of 30 mins the mean heart rate in group BD was 105.16±7.44/min and in group RD was 105.25±6.36/min. There was a minimal fall in heart rate which was not statistically significant.

HR(bpm)	GROUP BD	GROUP RD	p value
0 min	129.37±9.16	132.72±11.86	0.235
5min	124.23±8.52	126.86 ±10.40	0.344
10min	119.66±8.57	121.58± 9.47	0.325
15min	115.23±8.83	117±9.25	0.428
20min	110.86±8.47	112.44±8.46	0.567
25min	107.56±7.81	108.44± 8.21	0.315
30min	105.16±7.44	105.25 ±6.36	0.364

Table 3. Comparison Of Heart Rate In Two Groups

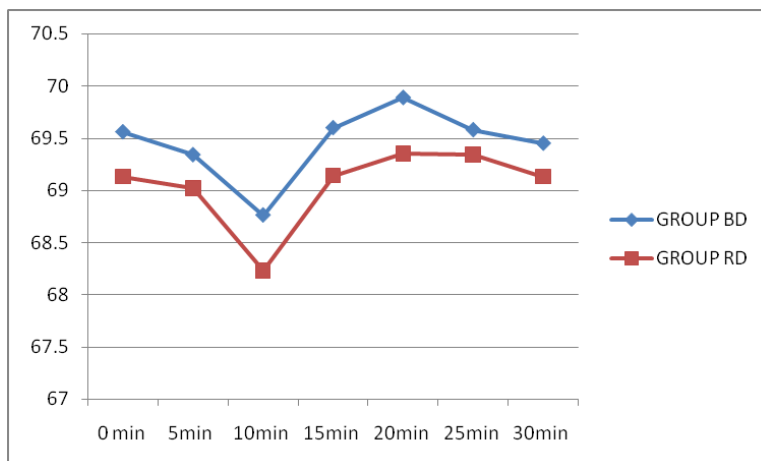


Picture 2. Heart Rate Comparison.

Mean Arterial Blood Pressure: The basal mean arterial pressure in group BD was 69.56±3.52mmHg and in group RD was 69.13±3.16mmHg. After 30mins it was 69.45±3.12mmHg and 69.13±3.54mmHg respectively (Table 4). This was not statistically significant.

MAP (mm Hg)	GROUP BD	GROUP RD	p value
0 min	69.56 ±3.52	69.13 ±3.16	0.362
5min	69.34 ±3.75	69.02± 3.24	0.343
10min	68.76 ±2.89	68.23 ±2.68	0.635
15min	69.60± 3.24	69.14± 3.25	0.346
20min	69.89± 2.51	69.35 ±3.27	0.641
25min	69.58 ±2.87	69.34± 3.68	0.451
30min	69.45 ±3.12	69.13± 3.54	0.678

Table 4. Map Comparison Between Two Groups.



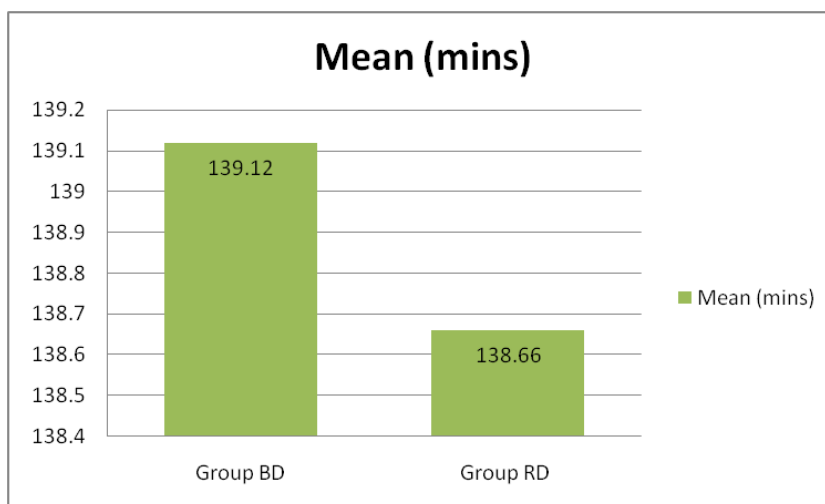
Picture 3. Map Comparison

Post-Operative Hemodynamic Parameters: Post operatively, there were no statistically significant variations in hemodynamic parameters in both the study groups.

Duration Of Sedation: The mean duration of sedation in group BD and group RD was 139.12±14.22mins and 138.66±13.21mins respectively as shown in Table 5.

Duration of sedation	Group BD	Group RD	p value
Mean (in mins)	139.12±14.22	138.66±13.21	0.147

Table 5. Duration Of Sedation

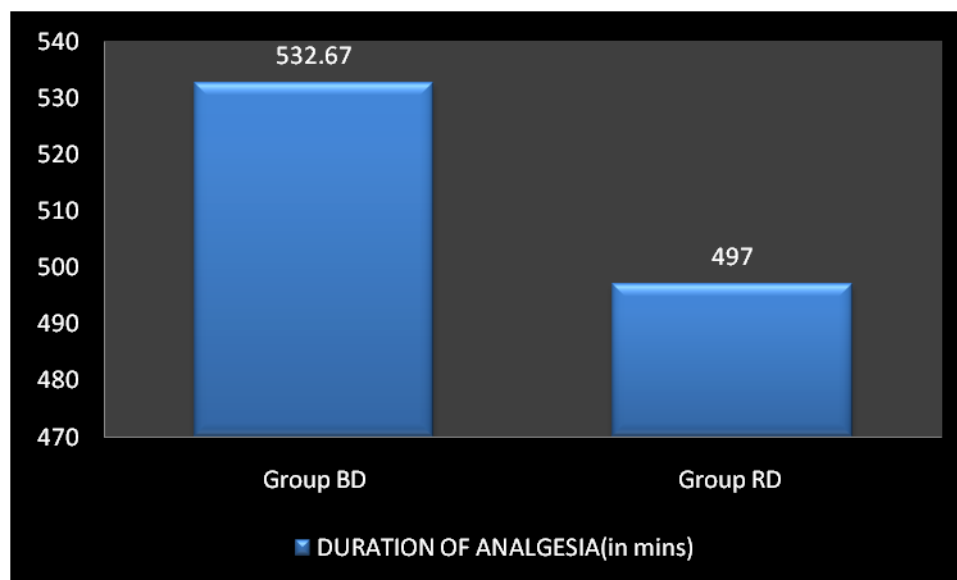


Picture 4. Duration Of Sedation

Duration Of Analgesia: Table 6 represents the duration of analgesia in both the groups. In our study the mean duration of analgesia in group I was 477.5±39.01mins, whereas in group II the mean duration of analgesia was 437±23.21mins which was statistically **highly significant. (p< 0.001).**

Duration of Analgesia	Group BD	Group RD	p value
Mean (in mins)	532.67 ±39.01	497±23.21	<0.001

Table 6. Mean Duration Of Analgesia



Picture 5. Mean Duration Of Analgesia

Complications: In our study, only one case (3.3%) in Group BD had retention of urine for >12hrs which was not statistically significant.

VI. Discussion

The origin of pediatric regional anesthesia goes back to 1899 when August Bier, the father of regional anesthesia, studied the Cocainization of spinal cord in a 11 year old boy (9). Regional anesthesia produces excellent postoperative analgesia and attenuation of the stress response in infants and children.

The advantages of regional anesthesia are that it provides complete block of sensory transmission, hence offers complete pain relief and it can be extended to the post-operative period (10). In our study, we included children between 1- 6 years of age as there is difficulty in identifying caudal epidural space in children greater than 7 years due to the fusion of sacral vertebrae and reduction in the size of sacral hiatus (11).

Bernard et al (12) in 1989 observed high failure rates in children above 7 years of age.

The volume of local anesthetic required is directly proportional to the weight, larger volume of the drug increases the cephalad spread leading to higher levels of block (12) Hence we have included children weighing less than 20 kgs in our study. Our study can be correlated with Constant.et.al (13) 1998 who studied the efficacy of caudal blockade in children weighing less than 25 Kgs.

Onset of analgesia differs with various local anesthetics, adjuvants and different induction methods used. In our study the mean onset of action was 7.1mins in Group BD and 6.5mins in Group RD.

The onset of action observed by Locatelli et al(14) in 2004 was 8mins in those given caudal Bupivacaine 0.25% and Levobupivacaine 0.25%, and 7 mins in those given Ropivacaine 0.25% which is in par with our study.

Dexmedetomidine is a potent alpha 2 agonist which acts by binding to central nervous system alpha 2 receptor which in turn causes, decreased release of catecholamine. Its specificity for alpha2 receptors helps in minimizing side effects associated with alpha 1 blockade (15)

The clinical effects of Dexmedetomidine by any route result in bradycardia, hypotension and reduced stress response to surgery. Various adjuvants to caudal local anesthetics are used to improve the quality of block but the hunt for ideal agent continues in view of safety profile of these agents in pediatric age group.

Dexmedetomidine is widely used and has proven benefits in ICU sedation, spinal anesthesia and peripheral nerve blocks. These observations encouraged the understanding of wider areas of action of dexmedetomidine. Dexmedetomidine enhances the action of local anesthetics by acting on peripheral alpha-2A adrenergic receptors and when used in spinal anesthesia it enhances local anesthetic action by virtue of its spinal alpha 2 receptors (16, 17).

Neogi et al. compared clonidine 1 µg/kg and Dexmedetomidine 1 µ/kg as adjuncts to Ropivacaine 0.25% for caudal analgesia in pediatric patients and concluded that addition of both clonidine and Dexmedetomidine with Ropivacaine administered caudally significantly increases the duration of analgesia (18).

Prolongation of sensory blockade in caudal anesthesia by Dexmedetomidine can also be attributed to its vasoconstrictor effect on blood vessels which in turn prevents its systemic uptake (19). This vasoconstrictor property also helps in minimizing local anesthetic toxicity chance in caudal anesthesia.

Different authors have adopted different scales to assess pain. Some methods are easy and some are difficult to assess. We have chosen the subjective pain scale for children aged more than three years of age who can verbally express pain and observational pain scale for children less than three years of age who cannot verbally express pain.

The duration of analgesia depends on the type of local anesthetics used and the concentration of the adjuvant used.

In our study, the mean duration of analgesia was 532.67 ±39.01 mins in group BD, whereas in group RD the mean duration was 497.0±23.21mins.

In 2005 Upadhyay et al (20) studied 50 children undergoing elective lower abdominal and lower limb surgeries who received 0.25% Bupivacaine 0.75ml/kg alone and in combination with low dose Clonidine 1µg/kg caudally. The duration of analgesia was 10.3hrs in the Clonidine group. This is in contrast to our study, where the duration of analgesia is comparatively less even though the dose of Clonidine used is same.

Different local anesthetics and adjuvants with different concentrations and volumes used for caudal block, drugs used for pre medication and rescue analgesia, various methods to assess pain and statistical analysis may all account for the variability in the duration of analgesia.

In our study, sedation was assessed using an objective score based on eye opening. In our study the mean duration of sedation in group BD was 139.12±14.22mins and group RD was 138.66 ±/ 13.21mins.

In our study, we found no motor blockade in both the groups which was assessed by using the Modified Bromage scale.

Our results correlated with the work of G.Ivani, et al (21) who compared Ropivacaine 0.2% and Bupivacaine 0.25% for caudal analgesia in children in 1998 and demonstrated no motor blockade in either group. Arpita laha et al (22) in the year 2012 compared the quality of analgesia between Ropivacaine 0.2% 1ml/kg alone and Ropivacaine 0.2% 1ml/kg with Clonidine 2microgram/kg for pediatric caudal block. They did not observe any significant difference in mean heart rate, SBP, DBP between the two groups.

In our study, there was a marginal fall in mean heart rate intra operatively which was not statistically significant. No significant difference in heart rate, SBP, DBP was noted between the two study groups post operatively.

El Hennaway (23) in 2009 observed postoperative nausea and vomiting and urinary retention as side effects in those given caudal Clonidine as an adjuvant. Archna et al (24) in 2009 observed no side effects with the use of Bupivacaine 0.25% and 2µg/kg of Clonidine caudally as an adjuvant. In our study, we observed 1 case of urinary retention (3.3%) in group I, as complication. The complications observed in many studies are within the acceptable range.

VII. Conclusion

Our Observations From The Study Are: There was no significant difference in the onset of action, duration of sedation and vital parameters between the two groups. With the doses and concentrations of the drugs we used, no motor blockade and no significant complications were observed. Bupivacaine with Dexmedetomidine produced longer duration of analgesia compared to Ropivacaine with Dexmedetomidine.

Hence 0.25% Bupivacaine 1ml/kg with Dexmedetomidine 1µg/kg is a better choice than 0.25% Ropivacaine 1ml/kg with Dexmedetomidine 1µg/kg in caudal block for infra umbilical surgeries in pediatric age group.

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