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Comparison between Ropivacaine and Ropivacaine with Dexmedetomidine in Caudal Analgesia in Pediatric Patients

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Abstract: **Aims of study:** ***To compare duration of caudal analgesia. To compare hemodynamic changes. To study the side effects of drugs if any during intraoperative and postoperative period. To compare degree of sedation.*** **Materials and methods:** ***Study was conducted in 60 children undergoing elective infraumbilical surgeries like herniotomy, orchidopexy, hypospadias repair etc. during the period 2014-2016. The patients were assigned randomly into two groups, 30 patients in each group. Group A: Control group- Ropivacaine 0.25% (1ml/kg) with 1ml normal saline. Group B: Dexmedetomidine group- Ropivacaine 0.25% (1ml/kg) with dexmedetomidine 1µg/kg in 1ml normal saline. The drugs were given in caudal block according to the groups after negative aspiration for blood and cerebrospinal fluid. Analgesia was assessed using FLACC pain scale and sedation was assessed by sedation score. Children who had a pain score of more than 4 were administered Acetaminophen 15mg/kg suppository.*** **Results and conclusions:** ***Addition of dexmedetomidine to caudal ropivacaine significantly prolongs the duration of post-operative analgesia. Degree of sedation is higher in dexmedetomidine group. Addition of dexmedetomidine does not produce significant hemodynamic fluctuations or major side effects. We find dexmedetomidine (1µg/kg dose) is safe and effective adjuvant to ropivacaine in caudal block.***

Keywords: Dexmedetomidine, ropivacaine, caudal block, post operative analgesia, pediatric

1. Introduction

Pain is one of the most misunderstood, underdiagnosed and untreated medical problems particularly in children. It is a likely reflection of myths like the child's lack of ability to perceive pain or remember painful experiences and relative lack of knowledge about age specific aspects of physiology and pharmacology and routine pain assessment. New JACHO (Joint Commission on Accreditation of Health Care Organization) regards pain as fifth vital sign and requires care givers to regularly address and assess pain.

IASP (International Association for Study of Pain) defines pain as "An unpleasant emotional and sensory experience associated with actual or potential tissue damage or described in terms of such damage".

Various multimodal techniques for paediatric pain relief have been designed. These involve regional anaesthesia with systemic analgesics, out of which the most commonly used regional block in paediatrics is caudal epidural block.Caudal block is a useful alternative/supplement to general anaesthesia and total I.V. anaesthesia as it provides effective post-operative analgesia. One of the main drawbacks of caudal technique is short duration of analgesia even with long duration local anaesthetics like bupivacaine and ropivacaine.

Various additives e.g. Ketamine, Neostigmine, Clonidine, Dexmedetomidine, Ephedrine, and opioids have been used to prolong the duration of analgesia provided by single injection. Ketamine has potential risk of neurotoxicity and opioids have side effects such as nausea, vomiting and respiratory depression. Clonidine, an alpha 2 agonist, widely used as an antihypertensive agent in 70s and 80s, is now used as sedation, premedication and as adjuvant analgesic. Dexmedetomidine, an alpha 2 agonist, has been used as an adjuvant to local anaesthetics in caudal block. It is highly selective for alpha 2 receptors and mediates its analgesic and sedative effects. Duration of analgesia is found to be prolonged with dexmedetomidine without any serious adverse effects.

2. Literature Survey

Caudal block was extensively studied by Kay in 1974.

1) In 1967, Fortuna reported a series of 170 infants and children operated upon under caudal analgesia. Lignocaine was used in concentration 0.5 - 2 percent.
2) M. J. Da Conceicao, Coelho L, Khalil M. et al9 1999 compared in a randomized double-blind study, the postoperative analgesia and degree of motor block produced by the new local anaesthetic ropivacaine, with bupivacaine, for caudal anaesthesia in children.
3) Mashallah Goodarzi, Gary Scott, Debby Jurry et al22 2000 compared the plain ropivacaine with ropivacaine-clonidine for caudal block. They studied 30 ASA I and II patients aged, 2-10 years in a randomized double blind study for hypospadias surgery. Patients were given 0.25 % ropivacaine 1ml/kg vs. 0.25% ropivacaine plus 1µg/ml clonidine in total 1ml/kg volume.
4) Saadawy I, Boker A, Elshahawy MA et al28 2008 evaluated Effect of dexmedetomidine on the characteristics of bupivacaine in a caudal block in paediatrics.

5) Neogi, Bhattacharjee DP, Dawn S et al26 2009 compared clonidine 1µg/kg and dexmedetomidine 1µg/kg as adjuncts to ropivacaine 0.25% for caudal analgesia in paediatricpatients .
6) M. El-Hennawy, A. M. Abd-Elwahab et al2 2009 evaluated comparison between clonidine and dexmedetomidine with bupivacaine in relation to duration of caudal analgesia.

3. Methods/Approach

This study was conducted in 60 children undergoing elective infraumbilical surgeries like herniotomy, orchidopexy, hypospadias repair etc. during the period 2014-2016

Inclusion Criteria
- Age of patient -6 months to 12 years
- Either gender
- Written & informed consent
- ASA grade I and II

Exclusion Criteria
- Patient with anatomical abnormalities-spina bifida or scoliosis
- Patient with bleeding disorder or coagulopathy
- Patient with known allergy to any of study drugs
- Any signs of infection at the site of caudal block
- Patients with history of developmental delay.

Following approval by the institutional ethics committee and written and informed parental consent, 60 patients scheduled for elective infraumbilical surgery under general anaesthesia were recruited for the comparative study. The patients were assigned randomly into two groups, 30 patients in each group.

Group A: Control group- Ropivacaine 0.25% (1ml/kg) with 1ml normal saline

Group B: Dexmedetomidine group- Ropivacaine 0.25% (1ml/kg) with dexmedetomidine 1µg/kg in 1ml normal saline.

The patients underwent a pre-anaesthetic check-up the day before surgery and all the routine and specific investigations were noted. Patients were kept fasting for 6 hours. After arrival in operating room, monitoring which included ECG, pulse oximetry, NIBP were applied and baseline values were recorded. Intravenous cannula was inserted into a suitable vein and inj. Isolyte P was started. Premedication was given in the form of Inj. Glycopyrrolate (4µg/kg) intravenously. Pre-oxygenation was done by a facemask and JR circuit with fresh gas flow of 6 L/min oxygen. Anaesthesia was induced with 4-5mg/kg Inj. Sodium thiopentone i.v. and Inj. Succinylcholine 1.5-2mg/ kg i.v. After intermittent IPPV, trachea was intubated with appropriate ET tube/ LMA. Maintenance of anaesthesia was done by Oxygen, Nitrous Oxide, Sevoflurane. Inj. Atracurium (0.5mg/kg) i.v. was given as a muscle relaxant. Intravenous fluid was given according to weight and estimated fluid loss depending on type of surgery. No other narcotics, analgesics, sedatives, or antiemetics were administered intraoperatively.

After induction, patients were placed in the lateral decubitus position, and a single dose caudal block was performed under aseptic and antiseptic conditions using a 23G hypodermic needle and standard loss of resistance technique. The drugs were given in caudal block according to the groups after negative aspiration for blood and cerebrospinal fluid.

Group A: Control group- Ropivacaine 0.25 % (1ml/kg) with 1ml normal saline

Group B: Dexmedetomidine group- Ropivacaine 0.25 % (1ml/kg) with dexmedetomidine 1µg/kg with 1ml normal saline.

Maximum volume limit was 20ml for all two study groups. The site of injection was dressed and the patient was turned supine.

Haemodynamic parameters (heart rate, ECG, blood pressure), respiratory rate and SPO2 were recorded before induction, after induction and then immediately after caudal anaesthesia, and every 10 minutes during surgery.

Duration of anaesthesia, defined as time from induction of anaesthesia to the time of extubation; duration of surgery; and duration of postoperative analgesia, defined as time from single shot caudal injection of drug to the FLACC pain score of more than 4, were also noted.

At end of surgery, neuromuscular block was reversed with Inj. Glycopyrrolate 8µg/kg and Inj. Neostigmine 0.05mg/kg. Trachea was extubated after oral and endotracheal suction/ LMA removed. Pulse, blood pressure, SpO2, respiratory rate, sedation score, FLACC score were recorded postoperatively at 0 minutes, 15 minutes, 30 minutes and every 30 minutes for next 6 hour and then every 1 hour for next 6 hours in PICU. Postoperative respiratory depression, defined as oxygen saturation less than 95% was treated by oxygen with ventimask at the rate of 4 L/minute. Post operative nausea and vomiting were treated with i.v.ondansetron 0.06 mg/kg. Postoperative pruritus was treated with i.v. diphenhydramine 0.2mg/kg. Patients were assessed for 24 hours postoperatively.

Analgesia was assessed using FLACC pain scale and sedation was assessed by sedation score. Children who had a pain score of more than 4 were administered Acetaminophen 15mg/kg suppository. Time of first micturation and time of administration of rescue analgesia were also noted.

FLACC score

The Face, Legs, Activity, Cry, Consolability scale or FLACC scale is a measurement used to assess pain for children between the ages of 2 months and 7 years or individuals that are unable to communicate their pain. The scale is scored in a range of 0–10 with 0 representing no pain. The scale has five criteria, which are each assigned a score of 0, 1 or 2.

Patients who are awake: Observe for at least 2-5 minutes. Observe legs and body uncovered. Reposition patient or

observe activity, assess body for tenseness and tone Initiate consoling interventions if needed.

Patients who are asleep: Observe for at least 5 minutes or longer. Observe body and legs uncovered. If possible reposition the patient. Touch the body and assess for tenseness and tone.

Each category is scored on the 0-2 scale which results in a total score of 0-10.
Assessment of Behavioural Score:
0 = Relaxed and confortable
1-3 = Mild discomfort
4-6 = Moderate pain
7-10 = Severe discomfort/pain.

Sedation score
0 Eyes open spontaneously 1. Eyes open in response to verbal command 2. Eyes open in response to physical stimulation 3. Unarousable

4. Results & discussion

Demographic Data

Variables	*Group A N=30*	*Group B N=30*	*P Values*
Age (Mean + SD)	3±1.5	3.24±1.6	0.625
Weight (Mean + SD)	11.066 ± 3.591	11±2.924	0.08
Sex Ratio (M:F)	29:1	29:1	

As per the table, all two groups were comparable in respect to age, weight and sex ratio without any significant difference ($p > 0.05$).

Types of surgery

Surgery	*Group A (No of Patients)*	*Group B (No of Patients)*
Inguinal hernia	2	4
Hypospadias&urethral fistularepair	20	16
Orchidopexy	2	4
Cystolithotomy	3	3
Extrophy bladder repair	3	3

As per the table, all two groups were comparable in respect to number of patients for given type of surgery without any significant difference ($p > 0.05$).

Duration of surgery

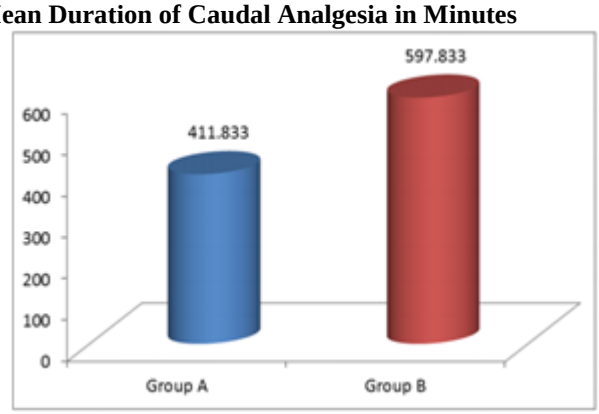
Duration(min)	*Group A*	*Group B*	*P value*
Mean±sd	57.833±26.053	60.83±24.32	0.697

Duration of anesthesia

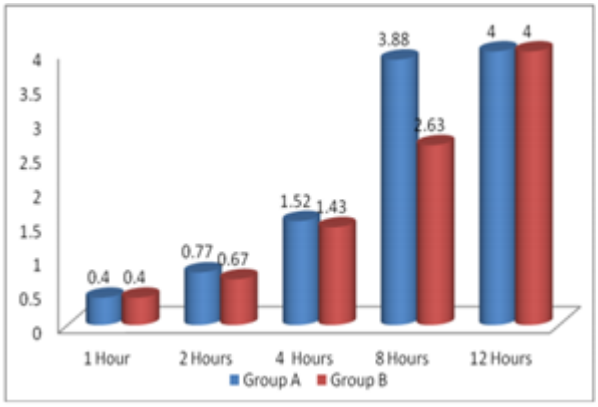
duration	*Group A*	*Group B*	*P value*
Mean±sd	71.333±26.93	74.166±23.784	0.73

There was no statistically significant difference in duration of surgery and in duration of anaesthesia in all two groups. ($p > 0.05$)

Mean Duration of Caudal Analgesia in Minutes

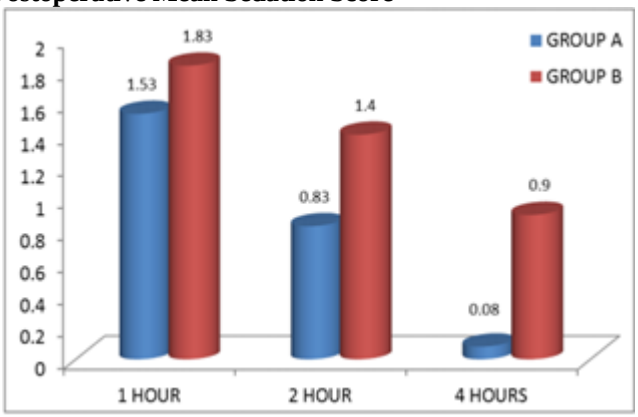


This duration was significantly prolonged by addition of Dexmedetomidine to Ropivacaine (Group B) in comparison to Ropivacaine alone (Group A). There was statistically significant difference in duration of caudal analgesia between Group A & Group B ($p < 0.05$).



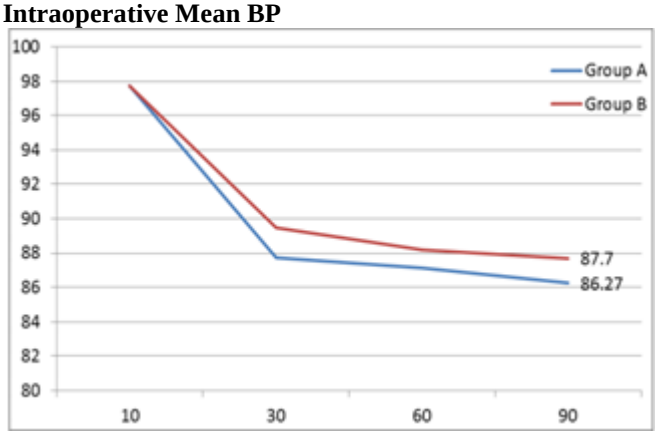
FLACC at 1, 2, 4, 8 and 12 hours
There is no statically significant difference in mean FLACC score at postoperative 1 hour, 2 hours, and 4 hours between the two groups ($p>0.05$). However statistically significant difference was seen in mean FLACC score at 8 hours which was lower in test group as compared to control group.

Postoperative Mean Sedation Score



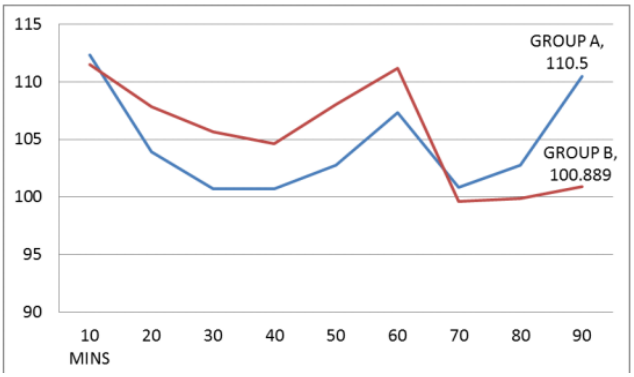
Mean sedation score immediately after postoperative period was higher in Group B. There was slightly prolonged sedation in Dexmedetomidine Group (Group B) ($p < 0.05$).

Intraoperative Mean BP



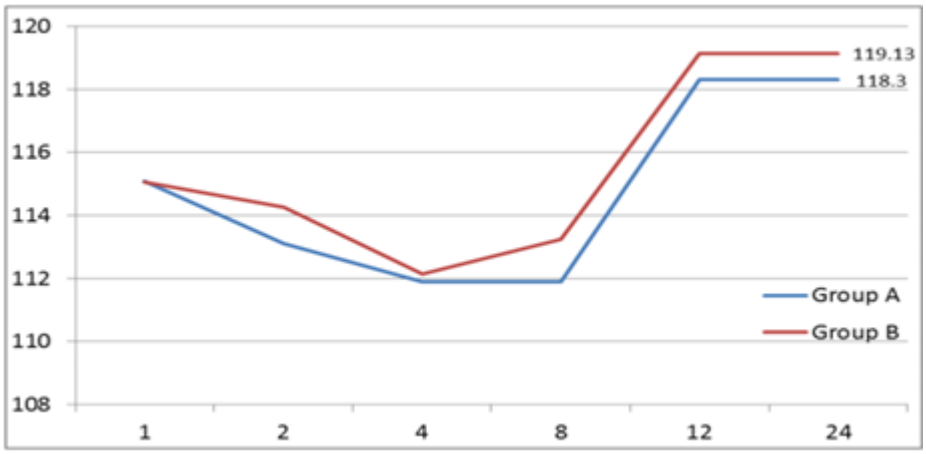
X axis=Time Y axis=mean Bp

Comparison between Intra-op Mean Pulse Rate



Intra-operative mean pulse values are shown in the graph. There was no statistically significant difference in fall in pulse rate between Group A and Group B ($p<0.05$)

Comparison between Post-Op Pulse Rate



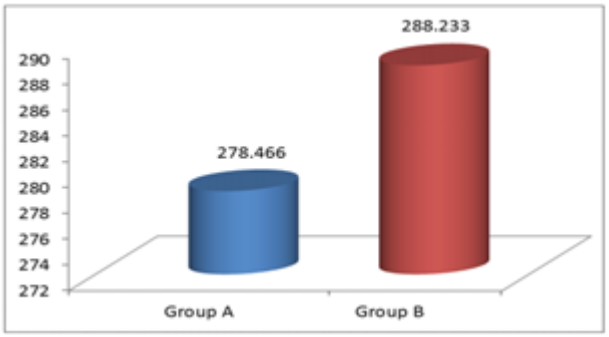
In the postoperative period, the pulse rate was stable in both groups. Pulse rate increased as the effect of caudal analgesia decreased. There was no statistically significant difference in pulse rate between both the groups ($p>0.05$)

Postoperative Complications

Sr no	Complications	Group A	Group B
1	Nausea	0	2
2	Vomiting	1	1
3	Bradycardia	0	0
4	Hypotension	0	0
5	Respiratory depression	0	0

Above table shows that there was higher incidence of nausea and vomiting in group B as compared to group A but difference was not statistically significant ($p=0.23$). No episodes of respiratory depression, hypotension or bradycardia were observed in any of two groups.

Mean Time of First Micturition



Mean time to first micturation was recorded in all two groups. There was no statistically significant difference in mean time of first micturation among two groups ($p > 0.05$).

5. Conclusion

- Addition of dexmedetomidine to caudal ropivacaine significantly prolongs the duration of post-operative analgesia.
- Degree of sedation is higher in dexmedetomidine group.

- Addition of dexmedetomidine does not produce significant hemodynamic fluctuations or major side effects.

Hence, we find dexmedetomidine (1µg/kg dose) is safe and effective adjuvant to ropivacaine in caudal block.

6. Future Scope

In this study we found that dexmedetomidine is a good adjuvant for caudal analgesia without any major complications. We provide a good adjuvant to compare other adjuvant with use dexmedetomidine as a base.

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