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# COMPARATIVE STUDY OF CAUDAL CLONIDINE WITH ROPIVACAINE VERSUS DEXMEDETOMIDINE WITH ROPIVACAINE FOR POSTOPERATIVE ANALGESIA IN PEDIATRIC PATIENTS

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**ABSTRACT** **Background:** Regional anaesthesia reduces the intraoperative requirement of inhaled and intravenous anaesthetic agents and offers a faster return to the conscious preoperative state. The caudal epidural technique is very popular, safe and reliable in paediatric regional anaesthesia. **Objective:** To compare the duration of postoperative analgesia and hemodynamic stability in a caudal block using Clonidine 1mcg/kg with Ropivacaine (0.25%) versus dexmedetomidine (1mcg/kg) with Ropivacaine (0.25%) in paediatric age group. **Methods:** After taking valid written informed consent from parents, a prospective randomized double-blinded clinical study was conducted on 84 children over a period of 2 years. Subjects with ASA grade 1 and 2, aged 2-6 years scheduled for elective infraumbilical surgeries were randomized into two groups each with 42 subjects-group RC received caudal 0.25% Ropivacaine 1 ml/kg with Clonidine 1µg/kg and group RD received caudal 0.25 % Ropivacaine 1ml/kg with Dexmedetomidine 1mcg/kg. These were compared in terms of age, sex, duration, distribution and duration of surgery. The parameters studied were intraoperative hemodynamic changes, duration of postoperative analgesia and incidence of complications. **Conclusion:** 0.25% Ropivacaine 1ml/kg with Dexmedetomidine 1µg/kg in caudal block significantly prolongs the duration of analgesia compared to 0.25% Ropivacaine 1ml/kg with clonidine 1 mcg/kg, without adverse effects.

**KEYWORDS :**

## INTRODUCTION

Postoperative pain relief in paediatric patients has dramatically improved over time. Postoperative analgesia should be given prime importance in children. Oral analgesics often is inadequate for pain relief and parenteral opioids have better action on pain relief. But, it has certain side effects like nausea, vomiting, sedation, respiratory depression, and constipation, which prevent its usage[1]. Regional anaesthetic techniques, like spinal, caudal epidural, lumbar epidural, and peripheral nerve blocks have better advantage. Regional anaesthetic techniques minimize the intraoperative requirement of inhaled and intravenous anaesthetic agents and offers a faster return to the consciousness.[2]

In caudal epidural block, ropivacaine provides effective analgesia in paediatric patients. It produces less motor blockade with differential neural blockade and less cardiovascular and neurological toxicity, which makes it good option for daycare surgery in children.

Prolongation of the duration of caudal epidural analgesia is attained by using additives such as clonidine, and dexmedetomidine.[3,4,7]

**Clonidine** produces analgesia through a non-opioid mechanism, acting as an alpha-2 adrenergic receptor agonist[9]. **Dexmedetomidine** has a higher affinity of up to eight folds for alpha 2 adrenergic receptors than clonidine and much lesser alpha 1 effect[9].

## MATERIALS AND METHODS

After obtaining approval from CTRI (CTRI/2019/12/022479) and ethical committee clearance, 84 children of ASA grades 1 and 2, aged 2-6 years scheduled for elective below umbilical surgeries, were randomized into two groups-

- Group RC(n=42) received caudal 0.25% Ropivacaine 1 ml/kg with Clonidine 1µg/kg
- Group RD(n=42) received caudal 0.25 % Ropivacaine 1ml/kg with Dexmedetomidine 1mcg/kg.

These were compared in terms of age, sex, duration, distribution and duration of surgery. The parameters studied were intraoperative hemodynamic changes, duration of postoperative analgesia and incidence of complications.

Inclusion criteria include, ASA grade 1 and 2, Children between 1-6 years of age, Elective below umbilical surgeries and Exclusion criteria include Children with local infection over the caudal skin region, children with coagulopathies, Pre-existing neurological or other obvious spinal diseases, Congenital anomaly of lower back, Known allergy to the study drug, Refusal of parents to study

Written informed consent was obtained from the parents or guardians. The child's weight and pre-operative parameters such as heart rate, mean arterial blood pressure and oxygen saturation were monitored and recorded

Patients were pre-medicated with iv Inj. Glycopyrrolate (0.005mg/kg) and Inj. Midazolam (0.05 mg/kg), induced on Inj. Propofol 2mg/kg, succinylcholine 2mg/kg, and intubated with appropriate size endotracheal tubes, Inj. Atracurium 0.5 mg/kg was given. After passing ETT, a caudal epidural block was given with a 23-gauge 1.5-inch hypodermic needle. The time of injection was noted. The patient was given a supine position immediately after the caudal block, HR and MAP and spo2 were recorded every 10 mins after the block. incision was taken 20 mins after administration of the caudal block. Intraoperative anaesthesia was maintained with oxygen (50%), Air (50%), the inhalational agent used was sevoflurane (1.5%) and neuromuscular blockade was maintained with Inj. Atracurium 0.1 mg/kg. Iv fluid, RL was given based on a calculation by Holliday Segar 4-2-1 formula as per body weight. The parameters HR, MAP and SPO2 were noted and recorded every 10 mins intraoperatively.

An increase in HR of > 20% from baseline heart rate at the time of incision was considered as a failure of caudal block and rescue analgesia was provided with Inj. Fentanyl 1mcg/kg of body weight and surgery was continued.

Intraoperatively any adverse effects such as bradycardia [less than 60 beats per minute for children more than 2 years] were treated with 20mcg per kg of Inj Atropine. All anaesthesia volatile maintenance gases were turned off at the end of the procedure and patients were reversed from neuromuscular blockade with Inj. Neostigmine 0.05 mg/kg and Inj. Glycopyrrolate 0.01 mg/kg on achieving spontaneous respiration.

Patients were monitored postoperatively to detect any complications like bradycardia, hypotension, nausea, vomiting, and urinary retention.

Post-operative HR and pain scores were recorded at 1, 2, 4, 6, 8, 10,12, 16, 20 and 24 hours.

The postoperative pain score was assessed based on the behaviour of the child. 1-Playing & laughing, 2-Happy, 3-Neutral, 4-Cries indicating pain, 5- Cries which cannot be distracted.

Ward staff were also trained to assess the pain score by the anaesthesia resident and an OPS pain chart was also provided to ward staff. The analgesic effect was evaluated by OPS score

Duration of postoperative analgesia is defined as the time interval between the administration of caudal block and the requirement of the first dose of postoperative analgesic. Patients who had a pain score of 4 & above were treated with analgesia in the form of paracetamol suppository 20mg/kg by the ward staff after confirmation with the anaesthesia resident telephonically. The time of administration of the first analgesic dose of paracetamol was noted.

Patients were monitored postoperatively to detect any complications like bradycardia (defined as a decrease in heart rate of >30% of the baseline heart rate), hypotension (defined as a decrease in the MAP of >30% from the baseline MAP), nausea, vomiting, urinary retention. Bradycardia was treated with Inj. Atropine 10 µg/kg iv, hypotension was treated with iv fluids, and nausea and vomiting were treated with Inj. Ondansetron 0.1 mg/kg.

## RESULTS

There were no statistically significant changes in haemodynamic parameters between group RC and group RD.

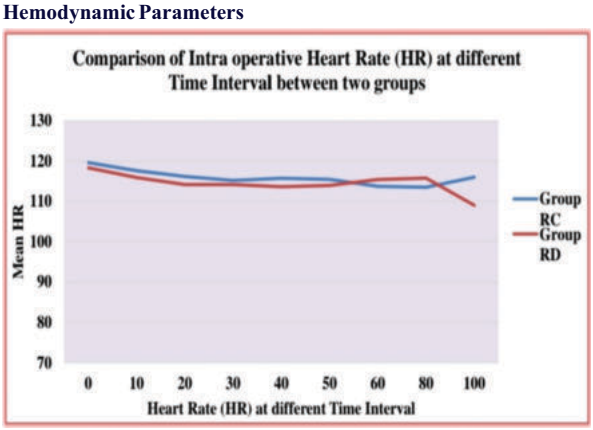
The duration of analgesia was significantly higher in patients receiving Dexmedetomidine (RD) than clonidine (RC)

No patients in group RC or RD, developed bradycardia, hypotension, nausea, vomiting or urinary retention in either group.

### Patient Characteristics And Clinical Parameters

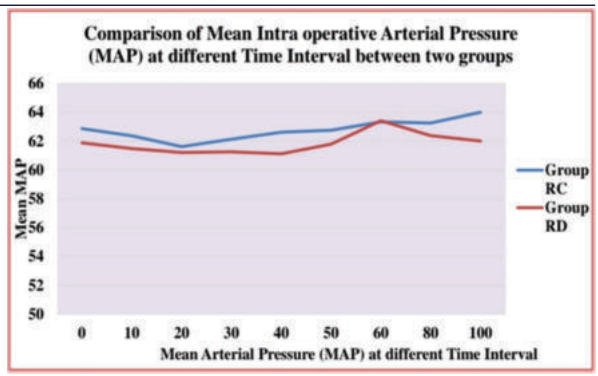
| Parameter | Group RC | Group RD | P value |
|---|---|---|---|
| Age (Years) | 3.93±1.49 | 3.98±1.42 | 0.881 NS |
| Gender- Male: Female | 12:30 | 9:33 | |
| Duration of surgery (minutes) | 50.2±17 | 51±19 | 0.856 NS |
| Duration of postop analgesia (in minutes) | 511.5±50.9 | 556.2±75.6 | 0.002 S |
| Total dose of paracetamol (mg) | 289.5±78 | 285±75.7 | 0.788 NS |
| Baseline HR (per minute) | 123.19±8.82 | 122.33±7.84 | 0.639 NS |
| Mean Arterial Pressure (mmHg) | 63.29±3.64 | 62.48±2.89 | 0.262 NS |
| Mean heart rate | 117.07±8.05 | 115.96±7.72 | 0.520 NS |
| Baseline SpO2 | 100±0.00 | 99.97±0.0238 | - |

### Hemodynamic Parameters

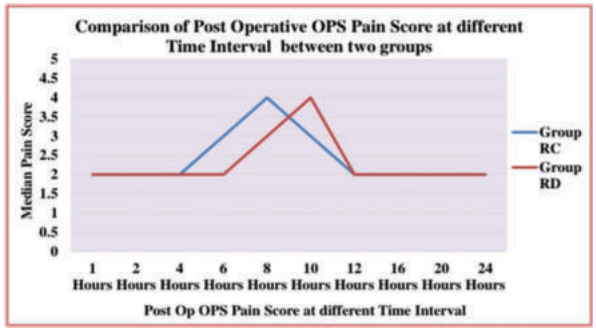



The Mean±SD Comparison of mean intraoperative heart rate at different intervals between group

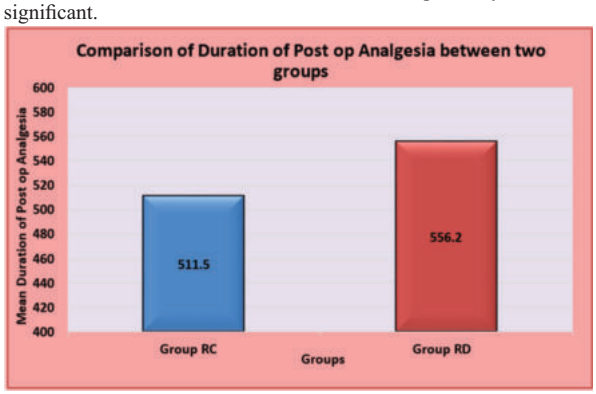
RC and RD did not vary significantly. P>0.05 is not significant.



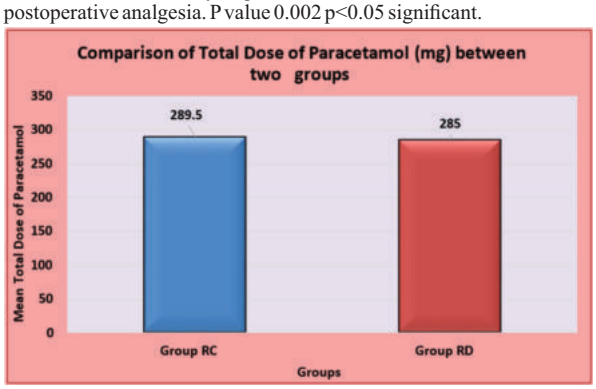

All patients remained hemodynamically stable throughout the surgery with no statistically significant difference between the groups.




The Mean±SD Comparison of postoperative ops pain score at different time intervals. The two groups showed statistically significant differences at 6, 8, 10, 12 and 24-hour intervals respectively. P is <0.05 significant.




The Mean±SD duration of post-operative analgesia in group RC is 511±50.9 mins and in group RD is 556±75.6 mins. The two groups did not show a statistically significant difference in the duration of postoperative analgesia. P value 0.002 p<0.05 significant.




The mean±SD total dose of paracetamol in group RC is 289.5±78.0 mg and in group RD is 285.0±75.7mg. The two groups did not show any statistically significant difference in the requirement of paracetamol. P is 0.788 p>0.05 not significant

## DISCUSSION

In the paediatric regional anaesthetic technique, the caudal epidural block is a very common and popular technique. It is commonly used

for many surgical procedures along with general anaesthesia and is safe and reliable. The short duration of action with local anaesthetic agents is a major disadvantage for caudal block. Various additives are added to local anaesthetics, that can effectively help in lowering the dose and increasing the duration of analgesia. Opioids prolong the duration of analgesia but have also been associated with severe side effects, particularly in paediatric patients. Some non-opioid adjuncts with more favourable outcomes are used for the same.

This study assessed the duration of postoperative analgesia and the safety of caudally administered clonidine compared to dexmedetomidine and ropivacaine in paediatric patients undergoing below umbilical surgeries.

**Concentration and Dosage Used:**

**Koinig et al**[5] studied the dose-response of caudal ropivacaine in children and found that a higher concentration of 0.5% ropivacaine (0.75 ml/kg) is associated with prolonged duration of analgesia when compared to 0.25% ropivacaine (0.75 ml/kg) ($p<0.0001$). They found that ropivacaine 0.5% is more effective as analgesic but is associated with side effects like motor blockade. Hence, we decided to use 0.25% ropivacaine 1ml/kg

**Manickam et al**[6] studied the duration of analgesia with different doses of ropivacaine with the addition of clonidine. Children were divided into 3 groups, group A received 0.1% ropivacaine 1ml/kg, group B received 0.1% ropivacaine 1ml/kg with clonidine 1µg/kg, group C received 0.2% ropivacaine 1ml/kg. The mean duration of analgesia in group A was (243±99.29) min, in group B was (590±83.93) min in and group C was (388±82.35) min. Hence, we decided to use clonidine 1mcg/kg with 0.25% ropivacaine

**Keshari et al**[4] used clonidine 1µg/kg along with 0.25% ropivacaine 0.75 ml/kg and compared to plain 0.25% ropivacaine 0.75 ml/kg. The duration of analgesia was (13.4±3.4 hr) significantly higher with the addition of clonidine.

**Shobhana C et al**[7] studied the duration of postoperative analgesia in children by comparing clonidine 2mcg/kg and dexmedetomidine 2mcg/kg with 0.2% ropivacaine 1 ml/kg and found that the duration of postoperative analgesia was prolonged in ropivacaine with dexmedetomidine (17± 2.9) hours when compared to ropivacaine with clonidine (10.1 ± 3.2) hours.

Based on the above reports, we decided to use 0.25% ropivacaine 1ml/kg, with 1µg/kg clonidine, and 1mcg/kg dexmedetomidine because ropivacaine 0.5% is more effective in terms of analgesia but is associated with side effects like motor blockade and 0.1% ropivacaine has associated with less duration of postoperative analgesia. Keshari and Manickam used 1mcg/kg of clonidine as an additive to 0.25% ropivacaine 0.75ml/kg, resulting in a good post-operative analgesia duration.

**Duration Of Analgesia In Caudal Clonidine:**

The duration of postoperative analgesia is calculated by the time of caudal injection to the time of administration of the first dose of postoperative analgesic. In our study, the mean duration of analgesia in group RC was (511±50.9) mins .

**Manickam et al**[6] in their study, observed the mean duration of analgesia in 3 groups. Group 1 had (0.1% ropivacaine 1 ml/kg) and the duration was 243.7±99.29 mins. Group 2 had (0.1% ropivacaine 1ml/kg with clonidine 1µg/kg) and duration of analgesia was (590±83.93) min. in group 3 (0.2% ropivacaine 1 ml/kg) duration was (388.25±82.35) mins. He concluded increasing the concentration of ropivacaine increased the mean duration of analgesia, but the addition of clonidine made it significantly longer ($p=0.001$). This is correlating with our study of (0.25% ropivacaine 1ml/kg addition of clonidine 1mcg/kg) prolonged the duration of analgesia because they have also used a similar concentration of ropivacaine 0.2%.

**Akbas et al**[8] in the study compared the analgesic quality and duration of 0.2% ropivacaine with the addition of clonidine (1 µg/kg) with that of 0.2% ropivacaine and the addition of ketamine (0.5 mg/kg), Group R received 0.2% ropivacaine 0.75 ml/kg in, Group RC received 0.2% ropivacaine 0.75 ml/kg plus clonidine 1 µg/kg, Group RK received 0.2% ropivacaine 0.75 ml/kg pl. The duration of analgesia was significantly higher in group RC (14±3.1 h) and group RK (10±4.32 h) than in group R (4±3.23 h). This is following our study that the addition of clonidine to ropivacaine increases the duration of postoperative analgesia as they have used a similar dose of 0.2% ropivacaine and clonidine 1mcg/kg

**Bajwa et al**[9] in the study found analgesic requirement time was statistically prolonged in (0.25% ropivacaine 0.5 ml/kg+ clonidine 2µg/kg) group which was (13.4±3.4 h) in comparison to plain (0.25% ropivacaine plain 0.5 ml/kg) (8.5±3.4 h) ($p<0.005$). This is similar to our study of 0.25% ropivacaine with clonidine 1mcg/kg increased the duration of postoperative analgesia the longer duration of analgesia compared to our study could be due to a higher dose of clonidine (2µg/kg) in their study.

**Duration of Analgesia In Caudal Dexmedetomidine:**

In our study duration of analgesia in group RD (0.25% ropivacaine 1ml/kg with dexmedetomidine 1mcg/kg) was (556.2±75.6.) mins.

**Monica Gandhi et al**[10] observed that the duration of analgesia in group RD 0.25% ropivacaine with Dexmedetomidine 2mcg/kg was 884 mins (14.7±5) hours when compared to group R 0.25% ropivacaine to 339 mins (5.6±2.4). This is following our study of (0.25% ropivacaine 1ml/kg with dexmedetomidine 1mcg/kg) addition of dexmedetomidine prolongs the duration of analgesia, the longer duration of analgesia may be due to a higher dose of additive dexmedetomidine 2mcg/kg.

**Preeti Goyal et al**[11] in their study the mean duration of analgesia in group RD 0.2% ropivacaine 1ml/kg with dexmedetomidine 2mcg/kg was (795.06±39.02) mins, in comparison to group R 0.2% ropivacaine 1ml/kg to (279. ±46.26) mins. This is again following our study of 0.25% ropivacaine 1ml/kg with dexmedetomidine 1mcg/kg addition of dexmedetomidine to caudal ropivacaine prolongs the duration of postoperative analgesia, but the increased duration of postoperative analgesia in their study could be due to a higher dose of dexmedetomidine 2mcg/kg

**Vijay g anand et al**[12] found that duration of analgesia was prolonged in group RD ropivacaine 0.25% 1ml/kg + dexmedetomidine 2mcg/kg was (13.90 ± 15.09) hours when compared to group R ropivacaine 0.25% + 0.5 ml NS (4.97±6.03). this is following our study of 0.25% ropivacaine 1ml/kg with dexmedetomidine 1mcg/kg addition of dexmedetomidine to caudal ropivacaine prolongs the duration of postoperative analgesia.

**Comparison Of Duration Of Analgesia Between Caudal Clonidine And Caudal Dexmedetomidine**

In our study, the mean duration of analgesia in group RC was 511±50.9 mins and in group RD was (556.2±75.6.) mins. The duration of analgesia was significantly higher in patients receiving Dexmedetomidine than clonidine, which was statistically significant ($p=0.002$).

**Shobhana c et al**[7] their study found that the duration of analgesia using ropivacaine 0.2% 1ml/kg with clonidine 2µg/kg was (10.1±3.2h) and ropivacaine 0.2% 1ml/ kg with dexmedetomidine 2µg/kg was (17.6±2.9h). The duration of analgesia in our study RC (0.25% ropivacaine 1ml/kg with clonidine 1mcg) was (511±50.9) mins and group RD (0.25% ropivacaine with dexmedetomidine 1mcg/kg) (556.2±75.6) mins because they have used a higher dose of clonidine 2mcg/kg and dexmedetomidine 2mcg/kg which was higher than our dosage of clonidine 1mcg/kg and dexmedetomidine 1mcg/kg the results were dissimilar and duration of postoperative analgesia was prolonged in comparison to our study concerning the duration of analgesia

**Comparison of Hemodynamic Parameters In Caudal Clonidine:**

The heart rate, ECG, mean arterial pressure, and spo2 were monitored pre-operatively, intraoperatively, and post-operatively at regular intervals. Any adverse intraoperatively events such as Bradycardia [less than 60 beats per minute for children over 2 years - PALS]. Hypotension (systolic arterial blood pressure less than 70 + twice the age in years- Picu handbook) was monitored vigilantly.

Patients were monitored postoperatively to detect any complications such as bradycardia (defined as a decrease in heart rate of >30% of the baseline heart rate), hypotension (defined as a decrease in the MAP of >30% from the baseline MAP), nausea, vomiting, urinary retention. Bradycardia was treated with Inj. Atropine (NEON TROPINE) 10

µg/kg iv, hypotension was treated with iv fluids, and nausea and vomiting were treated with Inj. Ondansetron 0.1 mg/kg.

The mean perioperative heart rate was similar in both the groups, being (117.07±8.05) per minute in group RC and (115.96±7.72) per minute in group RD (p=0.520) not significant. There was no significant difference in the heart rates between both groups during surgery, the maximum duration of surgery was 100 mins. The postoperative heart rate did not show significant differences at any point.

The mean arterial pressure was monitored pre-operatively, intraoperatively and postoperatively at regular intervals.

The mean intraoperative MAP was (62.38±3.24) mmHg in group RC and (61.61±2.01) mmHg in group RD. (P = 0.192) not significant. There was no difference between the two groups significantly in the MAP at any duration of time.

**Keshari et al**[4] reported that the mean perioperative heart rate in group R (0.25% ropivacaine 1 ml/kg) was 103.4±8.2 and that in group C (0.25% ropivacaine 1 ml/kg+ 1µg/kg clonidine) was 101.5±5.03 per minute(p=0.28). They did not find any significant decrease in heart rate between two groups the with the use of clonidine in the caudal block. We have used 0.25% ropivacaine 1ml/kg with clonidine 1mcg/kg similar to their study and did not find any difference between heart rates in both groups which is following our study

**Bajwa et al**[9] observed that the mean perioperative HR in group I (0.25% ropivacaine 0.5 ml/kg) was 109.16±7.94 per minute and the mean arterial pressure was (65.74±8.32) and that in group II (0.25% ropivacaine 0.5 ml/kg + 2µg/kg clonidine) heart rate was 107.20±8.02 per minute(p=0.74) and mean arterial pressures were (63±8.16). we have used (0.25% ropivacaine 1ml/kg + Clonidine 1mcg/kg) and did not find any significant difference in heart rate, mean arterial pressures and spo2 between both the groups. This was similar to our results as we used a similar dose of (0.25% ropivacaine 1ml/kg)

### Comparison Of Hemodynamic Parameters In Caudal Dexmedetomidine

**Vijay g anand et al**[12] in a study among 2 groups, Group RD had (0.25% ropivacaine 1ml/kg + dexmedetomidine 2mcg/kg) and group R had 0.25% ropivacaine 1ml/kg) observed that mean pre-operative, perioperative and post-operative haemodynamic changes between both the groups were comparable to each other and there was no statistically significant difference in perioperative and postoperative mean arterial pressures between two groups.

Similar to their concentration of (0.25% ropivacaine 1ml/kg with dexmedetomidine 1mcg/kg) we did not find any significant difference between mean heart rates pre-operatively, perioperatively and post-operatively in group RD

**Monica Gandhi et al**[10] in their study among 2 groups, group RD had (0.25 ropivacaine 1ml/kg + 2mcg/kg dexmedetomidine) and group R had (0.25% ropivacaine + 0.5ml normal saline) observed that pre-operative, intraoperative and post-operative hemodynamic variables between both groups were comparable and statistically insignificant and therapeutic interventions were not required. This is in accordance with our study as we have used (0.25% ropivacaine 1ml/kg with dexmedetomidine 1mcg/kg) similar to them.

### Comparison of hemodynamic parameters between caudal clonidine with ropivacaine and dexmedetomidine with ropivacaine

**Shobhana C et al**[7] observed that there was no difference in the heart rate and mean arterial pressure in RC (0.2% 1 ml/kg ropivacaine+ clonidine 2mcg/kg) and RD (0.2% 1 ml/kg ropivacaine+ 2 mcg/kg Dexmedetomidine) did not differ significantly at any point. We have used a lower dose of additives clonidine 1mcg/kg and dexmedetomidine 1mcg/kg with ropivacaine 0.25% 1ml/kg which is approximately similar to our study and we did not find any difference in heart rate between the two groups. This was similar to our study RC (0.25% ropivacaine 1ml/kg with clonidine 1mcg/kg) and RD R (0.25% ropivacaine 1ml/kg with dexmedetomidine 1mcg/kg).

## CONCLUSION

In our study, we conclude that 0.25% Ropivacaine 1ml/kg with Dexmedetomidine 1µg/kg in caudal block significantly prolongs the duration of analgesia compared to 0.25% ropivacaine 1ml/kg with clonidine 1 mcg/kg, without any adverse effects.

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