

Original research article

**A COMPARISON OF COMBINATION OF 0.25%
BUPIVACAINE WITH DEXMEDETOMIDINE AND 0.25%
ROPIVACAINE WITH DEXMEDETOMIDINE FOR
PAEDIATRIC CAUDAL BLOCK IN INFRAUMBILICAL
SURGERIES**

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Abstract

The first caudal epidural block first given in adults by Cathelin (1901). Pioneer in pediatric caudal epidural blocks Campbell (1933) He performed caudal blocks in 83 cases of endoscopic interventions for bladder and urethral procedures. No post-operative complications noted. 60 children were divided into two groups consisting of 30 children in each group. GROUP 1: received 0.25% bupivacaine 1ml/kg+ 1 µg/kg dexmedetomidine, GROUP 2: received 0.25% ropivacaine 1ml/kg+ 1 µg/kg dexmedetomidine (0.5% ropivacaine will be diluted to 0.25%). In our study the minimum time taken for surgery 15mins and the maximum time taken 30mins. The mean duration of surgery in group I 42±16mins and in group II 42.7±16.7mins. The duration of analgesia in both the groups. In our study in group I, the shortest duration of analgesia 405mins, longest 445mins and the mean duration of analgesia being 427±39.01mins, whereas in group II the shortest duration of analgesia 420mins, longest 490mins and the mean being 465±23.21mins.

Keywords: Bupivacaine, dexmedetomidine, ropivacaine

Introduction

Regional anesthetic techniques were in use since earlier times. For neonates, infants, and certain high-risk children, caudal epidural blocks were started as regional anaesthetic technique. It can be utilized for any procedure on the lower part of the abdomen and lower limbs. This procedure gained popularity due to the presence of clearly defined anatomical landmarks, safety, ease of performance. The availability of data on doses and pharmacokinetics of local anaesthetics in infants and older children is

also adequate ^[1].

The first caudal epidural block first given in adults by Cathelin (1901). Pioneer in pediatric caudal epidural blocks Campbell (1933) performed caudal blocks in 83 cases of endoscopic interventions for bladder and urethral procedures. No post-operative complications noted ^[2].

Poor-risk paediatric patients were managed by giving caudal analgesia by Fortuna (1963) in 38 cases without any complications. Caudal epidural blocks have surpassed all other techniques in pediatric anaesthesia. It is now the most performed procedure in paediatric regional anaesthesia

Pain is an unpleasant subjective sensation which can only be experienced and not expressed, especially in children, who rely completely on their parents or care-givers for their well-being. Pain described by Rene Descartes (1664) as “Fast moving particles of fire” the sensations passes along the nerve fibres and reaches the brain ^[3].

Earlier mobilization, shorter hospital stay and lower costs are the few benefits of appropriate pain management in postoperative patient. Post-operative analgesia in a child is a main concern to the anesthesiologists, pain not only affects the patient but also increases anxiety in the parents which can be relieved by good postoperative analgesia ^[4].

The caudal block is the most popular and commonly performed regional blocks in paediatric anaesthesia. In infraumbilical surgeries for intraoperative and postoperative analgesia caudal block is highly trusted and safe technique. Postoperative analgesia from caudal block has patient benefits like earlier ambulation, rapid weaning from ventilators, reduced time spent in a catabolic state and lowered circulating stress hormone levels.

Long acting local anaesthetics have been used for paediatric caudal block. Bupivacaine and Ropivacaine are the amide local anaesthetics used for paediatric caudal block with various concentrations ranging from 0.125% to 0.5% and 0.2% to 0.75% respectively.

The main disadvantage of this single shot caudal block is duration of action. despite with the use of longer acting local anaesthetic drugs. To avoid epidural catheter placement and yet prolong the duration and improve the quality of intra-operative and post-operative analgesia of local anaesthetics, various adjuvants like opioids, midazolam, ketamine, neostigmine, have been used as adjuvants ^[5].

Dexmedetomidine, an alpha 2 adrenergic agonist has been used as an adjuvant with different dosages in paediatric caudal block. Infra umbilical surgical procedures require post-operative analgesia without motor blockade. Therefore, lower concentrations and volumes of local anaesthetics with dexmedetomidine can be used, so that the side effects of these drugs can be reduced further ^[6].

In this study we assessed the duration of analgesia and motor blockade with low volumes and concentrations of local anesthetics with dexmedetomidine as an adjuvant for caudal block.

Methodology

Study design: Prospective double-blind randomized control study.

Study population: Children undergoing infraumbilical surgeries satisfying inclusion criteria.

Sample size: With 95% confidence interval, power of the study being 80% and

allocation ratio being 1:1 expecting a odd ratio of 4 (according to present reference), sample size in each group will be 30.

Sampling method: Universal sampling with randomization process. Patients were randomly assigned into two groups by computer generated table.

Data was presented as mean, standard deviation or median and qualitative data as frequency and percentage. Data was compared by paired t test and Man- Whitney U test for independent continuous variables.

Study groups

- 60 children were divided into two groups consisting of 30 children in each group.

Group 1: Received 0.25% bupivacaine 1ml/kg+ 1 µg/kg dexmedetomidine.

Group 2: Received 0.25% ropivacaine 1ml/kg+ 1 µg/kg. dexmedetomidine (0.5% ropivacaine will be diluted to 0.25%).

Inclusion criteria

- ASA Physical status I and II patients.
- Patients between 6 months to 6 years.
- Patients coming for infraumbilical surgeries.

Exclusion criteria

- Parental refusal.
- Patients with known allergy to the study drugs.
- Coagulopathies.
- Infection at the site of injection.
- History of developmental delay.
- Neurological diseases.
- Skeletal deformities.
- Anticipated difficult airway.
- Surgeries in prone position.

Study procedure

- A detailed history, complete physical examination and routine investigations were done for all the patients.
- Informed consent was taken.
- The patient was premedicated with syrup Triclofos 30 mg/kg and oral atropine 0.3mg if wt is <10 kg and 0.6 mg if wt is >10 kg 45 minutes before the surgery.
- Patient was shifted to OT and pre-induction monitors were connected (ECG, pulse oximeter, non-invasive blood pressure).
- Patient was induced with oxygen and nitrous oxide at 1:1 ratio and sevoflurane 1-3%.
- Intravenous (IV) access was secured with 22G IV cannula.
- Appropriate size Proseal Laryngeal Mask Airway (PLMA) was inserted after deepening the plane of anaesthesia with Inj. Propofol 2mg/kg.
- Anaesthesia was maintained with oxygen, nitrous oxide in 1:1 ratio with 0.6%

sevoflurane with patient on spontaneous ventilation.

- Study drug was calculated according to the weight of the patient and loaded using insulin syringe.
- The drug was rounded off to the closest unit in the insulin syringe. It will be diluted to 1ml with normal saline.
- The caudal block was performed under aseptic precautions in lateral decubitus position by a trained anaesthesiologist.
- 25-G needle was inserted through the sacro-coccygeal membrane until loss of resistance is obtained.
- After confirming the absence of cerebrospinal fluid or blood in the aspirate, one of the following drug combinations was injected into the caudal space.
- Group 1 received 1ml/kg of 0.25% bupivacaine with 1µg/kg dexmedetomidine in caudal block.
- Group 2 received 1ml/kg of 0.25% ropivacaine with dexmedetomidine 1 µg/kg in caudal block.

Results

Age of the children ranged from 6 months-6 years. The youngest being 6 months and the eldest being 6 years Patients were uniformly distributed among three categories.

Table 1: Age distribution of patients studied

| Age years | Group 1 | | Group 2 | |
|-----------------|---------|------------|---------|------------|
| | Number | percentage | Number | percentage |
| 6 month-2 years | 13 | 43.3 | 10 | 35.1 |
| 2-4 years | 10 | 33.3 | 8 | 27.0 |
| 4-6 years | 7 | 23.3 | 12 | 38.9 |
| Total | 30 | 100% | 30 | 100% |

Samples are age matched with P value = 0.448 which means that there no statistical significance (i.e. there is no difference in the age among the two groups).

The mean age of patients studied in group I and group II 3.2±1.71 years and 3.8±1.5years respectively.

Table 2: Mean age distribution

| Study groups | Mean age in years |
|--------------|-------------------|
| Group 1 | 3.2+_1.7 |
| Group 2 | 3.8+_1.5 |

40% of the children in group I were in the weight group of 1-10kgs, 36.67% were 11-15 and 23.3% were >15. 32.4% of the children in group II were in the weight group of 1-10kgs, 29.7% were>11-15kgs and 18.9% were 11-15kgs. The least weight studied 6 kgs and the highest 21kgs.

Table 3: Weight Distribution

| Weight (KG) | Group 1 | | Group 2 | |
|-------------|---------|------------|---------|------------|
| | Number | percentage | Number | percentage |
| 1-10 | 12 | 40.0 | 10 | 32.4 |
| 11- 15 | 11 | 36.7 | 9 | 29.7 |
| > 15 | 7 | 23.3 | 11 | 18.9 |
| Total | 30 | 100% | 30 | 100% |

Samples are weight matched with P=0.181 Samples are weight matched with P value =0.226 which means that there is no statistical significance (i.e. there is no difference in the weight among the two groups).

The mean weight of patients studied in group I and group II 13.46±3.35 kgs and 13.26±3.66kgs respectively.

Table 4: Mean weight of patients

| Study groups | Mean weight in kg |
|--------------|-------------------|
| Group 1 | 12.2+_5 |
| Group 2 | 12.8+_4 |

The onset of action in the study as early as 5mins and as late as 9mins. The mean onset of action in group I 8.56±0.69mins and in group II 6.5±0.73mins.

Table 5: Mean Onset of action

| Onset of action in minutes | Group1 | Group 2 | P value |
|----------------------------|-----------|-----------|---------|
| Mean | 8.56+0.69 | 6.5+_0.73 | 0.246 |

In our study the minimum time taken for surgery 15mins and the maximum time taken 30mins. The mean duration of surgery in group I 42±16mins and in group II 42.7±16.7mins.

Table 6: Mean duration of surgery

| Duration of surgery in min | Group1 | Group 2 | P value |
|----------------------------|---------|-----------|---------|
| Mean | 42.0+16 | 42.7+16.7 | 0.358 |

The mean duration of sedation in group I and group II 137.03±14.22mins and 136.03±13.21mins respectively.

Table 7: Duration of sedation

| Duration of sedation | Group1 | Group 2 | P value |
|----------------------|--------------|--------------|---------|
| Mean | 137.03+14.22 | 136.03+13.21 | 0.139 |

The duration of analgesia in both the groups. In our study in group I, the shortest duration of analgesia 405mins, longest 445mins and the mean duration of analgesia being 427±39.01mins, whereas in group II the shortest duration of analgesia 420mins, longest 490mins and the mean being 465±23.21mins.

Table 8: Duration of analgesia

| Duration of analgesia | Group1 | Group 2 | P value |
|-----------------------|-----------|------------|---------|
| Mean | 427+39.01 | 465+_23.21 | |

The difference in duration of analgesia between the two groups is statistically significant (p<0.001).

Discussion

The onset of action is defined as the time in minutes between local anaesthetic deposition and the absence of gross movements or absence of significant increase in heart rate on application of the mechanical stimulus. The onset of analgesia varies with different local anaesthetics used and adjuvants added and different induction methods used.

In 1998 G. Ivani *et al.* did a double-blind study in 245 children aged 1-10 years undergoing elective minor surgery were randomly allocated to receive a single caudal extradural injection of 1 ml/kg of either 0.25% Bupivacaine or 0.2% Ropivacaine. They were given oral midazolam as premedicant and were induced with Halothane or Sevoflurane and Propofol and maintained on spontaneous ventilation with Sevoflurane or Isoflurane with oxygen. They observed the onset of action as 9.7mins with 0.2% Ropivacaine 1ml/kg and as 10.4mins with 0.25% Bupivacaine 1ml/kg^[7].

The onset of action observed by Locatelli *et al.* in 2004 8mins in those given caudal Bupivacaine 0.25% and Levobupivacaine 0.25%, 7 mins in those given Ropivacaine 0.25%. All the children were premedicated with Midazolam 0.5mg/kg and induced with Propofol 2mg/kg and Fentanyl 2mg/kg and maintained with Propofol infusion and the airway controlled with a facial mask or LMA.

Ivani *et al.* 91 in 2000 observed the onset of action as 10min for those given caudal Ropivacaine 0.2% without adjuvant and 9 min for those given Clonidine 2µg/kg as adjuvant. They were given oral midazolam as premedicant and were induced and maintained on spontaneous ventilation with Sevoflurane, Oxygen and Nitrous oxide^[8].

Adjuvants, when added to local anaesthetic agent will shorten the time of onset of action. In our study the mean onset of action 8.5 mins in group I and 6.5mins in group II. The earliest onset of action 5mins and the latest 9mins. This is almost similar to the onset of action observed by Locatelli *et al.* in 2004^[8].

The duration of analgesia is defined as the time of onset of analgesia to the time of

appreciation of pain. Several pain assessment scales are available to provide a quantitative and qualitative information about pain in children.

In 1998 Klimsha *et al.* documented analgesic efficacy by an observational pain/discomfort scale and by the duration of analgesia after caudal blockade. They used the OPS to assess behavioral objective variables (crying, facial expression, position of torso, position of legs, motor restlessness). Each variable scored 1-3 (1 = none, 2 = moderate, 3 = severe) to give a cumulative score of 5-15 with which to qualify analgesia (e.g., 5 = excellent, 15 = ineffective) ^[9].

In our study we have chosen the modified objective pain scale to assess the duration of analgesia. If the child complained of pain or if the pain score is ≥ 3 the child received Paracetamol suppository 15mg/kg as a rescue analgesic.

In 2005 Locatelli *et al.* evaluated the postoperative pain using the children and infants postoperative pain scale (CHIPPS) which includes: crying, facial expression, posture of the trunk, posture of the legs and motor restlessness ^[8].

In 2006 Y. Kawaraguchi *et al.* evaluated the analgesic effect of caudal block using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS12) 30 min after extubation and at 1, 2, 4, 6, 12 and 24 h. CHEOPS includes cry, facial expression, verbal response, torso and leg position.

El Hennawy *et al.* in 2009 used the observational FLACC pain scale to assess the duration of analgesia which includes face, legs, activity, cry and consolability ^[10].

Though different authors have adapted different scales, some methods are easy to assess and some are difficult. Hence we have chosen 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 varies with use of different local anaesthetics with varying concentrations. Some studies have reported that there is no difference between Ropivacaine and Bupivacaine in the duration of analgesia whereas some have reported that the duration of analgesia is more with Bupivacaine compared to that of Ropivacaine. Duration of analgesia increases significantly on addition of Clonidine to different local anaesthetics in paediatric caudal block.

In our study in group I, the shortest duration of analgesia 405mins, longest 445mins and the mean duration of analgesia being 427 ± 39.01 mins, whereas in group II the shortest duration of analgesia 420mins, longest 490mins and the mean being 465 ± 23.21 mins.

Ivani *et al.* conducted a double blinded for caudal block on 245 patients aged 1-10 years, they compared duration of analgesia. Duration which significantly higher in ropivacaine group. In our study also duration in ropivacaine + dexmedetomidine group is more.

Gupta *et al.* compared ropivacaine with saline (group A) and with dexmedetomidine (group B) among 60 pediatric patients. First analgesic requirement time statistically prolonged in group B (17.6 ± 2.9 h) when compared to group A (10.1 ± 3.2 h) ($P < 0.05$). The concentration of the drug used higher as compared to our study.

Different local anaesthetic agents used, concomitant use of adjuvant used for caudal block, various drugs used for premedication, drugs used for rescue analgesia, different methods used to assess pain and statistical analysis may all account for the variability in the duration of analgesia.

Dexmedetomidine causes sedation due to its action on the locus coeruleus ⁵⁴. There are

several methods like Ramsay sedation scale, Richmond agitation sedation scale etc., to assess the duration of sedation.

In our study we have assessed sedation using an objective score based on eye opening which includes 0= eyes open spontaneously, 1= eyes open in response to verbal commands and 2= eyes open in response to physical stimulation.

Cook *et al.* in 1995 assessed sedation using an objective score based on eye opening. The duration of sedation 4hrs where, they have used 2microgram/kg of clonidine with bupivacaine 0.25% 1 ml/kg.¹¹

Sedation assessed using a three-point sedation score by Constant *et al.* in 1998 where 0= awake, 1= drowsy and 2= asleep^[12].

In 2005 Upadhyay *et al.* assessed sedation using a four-point sedation score where, 1= asleep, not arousable by verbal command, 2= asleep, arousable by verbal command, 3= drowsy/not sleeping and 4=alert/aware.

In our study the mean duration of sedation in group I is 137.03+/-14.22mins and group II is 136.03 +/- 13.21mins.

Sedation made the child look more comfortable and it actually appreciated by the parents and hence not regarded as an adverse effect.

Degree of motor blockade depends on the concentration of the local anaesthetics used. Among the amide local anaesthetics Ropivacaine produces a lesser degree of motor blockade^[37].

Bupivacaine 0.25% and Ropivacaine 0.25% produces analgesia and a mild to moderate degree or no motor blockade.

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

Our results match with works of G. Ivani, *et al.* who compared Ropivacaine 0.2% and Bupivacaine 0.25% for caudal analgesia in children in 1998 and demonstrated no motor blockade in either group.

Khalil *et al.* in 1999 also found no significant differences in degree of motor blockade in their study, where they compared Ropivacaine 0.25% with Bupivacaine 0.25%, 1ml/kg.

Omar elsafty *et al.* in the year 2002 did a comparative study of Ropivacaine versus Bupivacaine 0.375% for Paediatric caudal block. Motor weakness assessed according to modified Bromage scale and it observed that Ropivacaine showed a significant lesser degree of motor blockade than Bupivacaine.

In 2004 Hansen *et al.* did not observe motor blockade, where they used 0.25%, 0.5ml/kg of Bupivacaine and Clonidine 2microgram/kg. They observed no motor blockade in both the groups where, they compared Bupivacaine alone with Bupivacaine and Clonidine 2 microgram/kg.

Conclusion

- Both Bupivacaine and Ropivacaine along with Dexmedetomidine as an adjuvant produced good postoperative analgesia in children.
- There 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.

- Pertaining to the duration of analgesia Ropivacaine with Dexmedetomidine produced longer duration of analgesia compared to Bupivacaine with Dexmedetomidine. Hence 0.25% Ropivacaine 1ml/kg with Dexmedetomidine 1microgram/kg is a better choice than 0.25% Bupivacaine 1ml/kg with Dexmedetomidine 1microgram/kg for infraumbilical surgeries.

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