A comparative study of ropivacaine and bupivacaine for caudal epidural anaesthesia in children undergoing lower abdominal surgery

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ABSTRACT

Background: Caudal epidural anaesthesia blocks dermatomes below the level of the umbilicus in children.

Objectives:This study intends to compareropivacaine and bupivacaine for caudal anaesthesia in children undergoing lower abdominal surgery.

Materials and methods: After the hospital ethics committee approval, 60 (ASA I–II) children scheduled for lower abdominal surgery were included in this study. Group A (n=30) patients received ropivacaine 0.25% and group B (n = 30) patients received bupivacaine 0.25% via the caudal route. We assessed the demographic and clinical characteristics, AIIMS pain score at 1, 2, 4, 8, 12, 16 and 24 hours after operation and level of residual motor block (Bromage Scale)immediately after surgery and at 1, 2 and 3 hours post operatively.Data analysis was performed using one way ANOVA test.P value less than 0.05 was considered significant.

Results and conclusion: There were no statistically significant differences in AIIMS pain scores between groups A and B at all postoperative time points –1hr, 2hr, 4hr, 8hr, 12hr, 16hr and 24hr($P < 0.00001$). The quality and duration of analgesia were comparable in both the groups. However, degree of motor block was significantly less in the ropivacaine group. After 3 hours there was no significant difference in the level of residual motor block.

The single shot caudal epidural block with 1ml/kg ropivacaine 0.25% is a safe and effective, long lasting dose for postoperative analgesia in paediatric lower abdominal surgery, producing less duration of motor block than bupivacaine 0.25%.

Keywords: analgesia,anesthesia, ropivacaine, bupivacaine, pediatrics

Introduction

Caudal anaesthesia is the oldest and most commonly used technique of epidural blockade in children. It produces dense perioperative anaesthesia and, when combined with simple analgesics, it provides excellent analgesia with minimal side-effects, making it suitable for day care surgery. [1]

First described for paediatric use in 1933-35, caudal epidural anaesthesia involves accessing the epidural space through the sacrococcygeal ligament via the sacral hiatus at the base of the sacrum. [2] Caudal block in children is most commonly performed in combination with general anaesthesia, but rarely may be the sole technique in some premature infants. [2,3]

Caudal blocks have been shown to reliably block dermatomes below the level of the umbilicus (T10–S5) in children <20 kg (~6 yr of age). Being a relatively safe technique with rare complications caudal anaesthesia is a technique of choice in groin, pelvic and lower extremity surgery. It also considerably decreases stress hormone response to surgery. The technique is relatively easy to perform and has a high success rate. [2]

Bupivacaine produces differential blockade that allows for good muscle strength and produces long lasting analgesia when administered in caudal epidural space. [4-6]It had originally been the drug of choice for postoperative epidural infusions in children. Bupivacaine has a narrower therapeutic index and cardiac and CNS complications may occur.

Ropivacaine, the *N*-propyl homologue of bupivacaine, a long-acting aminoamide local anaesthetic provides similar type of pain relief with less intense and shorter duration of motor blockade. [7,8] As it is safer than bupivacaine, with less risk for CNS and cardiac toxicity [9-11] it has been extensively used for regional anaesthesia in both adults and children. [7,8]It may be more suitable for caudal epidural analgesia especially following day case surgery as it has a quicker onset of action and provides more prolonged postoperative analgesia. [12]

This randomised controlled prospective study aimed to compare the perioperative haemodynamic response, duration of analgesia, time to rescue analgesia, degree of motor block, and side effects and complications if any, after a single shot caudal block with either bupivacaine or ropivacaine.

Materials and Methods:

After the hospital Ethics approval and parental written consent, 60 ASA I and II patients aged 1 to 8 years, scheduled for elective lower abdominal surgeries like inguinal hernia, undescended testis, hypospadias repair and circumcision were included in the study. Exclusion criteria included severe coagulation disorders, cutaneous or subcutaneous lesions at the contemplated site of puncture, hydrocephaly and intracranial space-occupying lesions, history of allergy to local anaesthetics and uncorrected hypovolemia.

All patients were randomly divided by a computer generated algorithm into two groups, Group A (n=30) received ropivacaine 0.25% 1ml/kg and Group B (n=30) received bupivacaine 0.25% 1ml/kg via the caudal route.

Patients were kept nil per orally for 6 hrs before the operation, except for clear fluid which was allowed up to 3 hrs before the procedure. Premedication was done with midazolam 0.5 mg/kg intramuscularly (IM) 15-20 minutes before surgery and glycopyrrolate 10 μg/kg intravenously (IV). All 60 patients were induced with 1% propofol2.5 mg/kg and

increasing concentrations of halothane via Jackson-Rees modification of Ayre's T-piece. Atracurium0.5 mg/kg was injected and endotracheal intubation was done with adequate size PVC ETT or LMA.Pressure controlled ventilation was done by providing oxygen 50% and N_2O 50% at the flow rate of 2 L/min. Maintenance of anaesthesia was done by halothane at 0.5 - 1 MAC.

The caudal block was performed after the induction of general anaesthesia. Patients were placed in left lateral position and sacral cornua were palpated by moving the left thumb up and down across base of sacrum, which forms the base of an isosceles triangle whose apex points cephalad. This apex coincides with the sacral hiatus. A 23-gauge needle was inserted immediately caudad to the thumb and at right angle to the skin. After penetrating the skin and subcutaneous fat, the tip of the needle passes through the resistance of the sacrococcygeal ligamentand into the sacral canal when a distinct loss of resistance is felt and then the needle was advanced 2-3 mm, after 20-30° cephalic redirection, to ensure that it lies freely within the cavity. Care was taken not to advance the needle any more as dural sac and epidural vessels may be as low as S3 – S4 in younger children. After confirmation by injecting air and auscultating with a stethoscope and negative aspiration of blood or CSF, the calculated amount of drug was administered slowly to avoid excessive cephalad spread.

During surgery, just before and after surgical incision, and in 5 minute intervals we monitored the heart rate, ECG (Electrocardiogram), end tidal CO_2, arterial oxygen saturation and non-invasive blood pressure (Dräger Fabius).

Block was considered successful with adequate intra-operative analgesia if there was haemodynamic stability, indicated by absence of an increase in heart rate or non invasive blood pressure or both of greater than 15% compared with baseline values obtained just before surgical incision.

The postoperative pain assessment was done in the recovery room by an anaesthesiologist (independent observer) at 1, 2, 4, 8, 12, 16, and 24 h after surgery. AIIMS Pain Discomfort Scale (minimum pain – 0, maximum pain - 10) was used for pain assessment. (Table 1) During the first post operative day, a rescue analgesic paracetamol 10mg/kg orally was given to patients if their AIIMS pain score was ≥4.

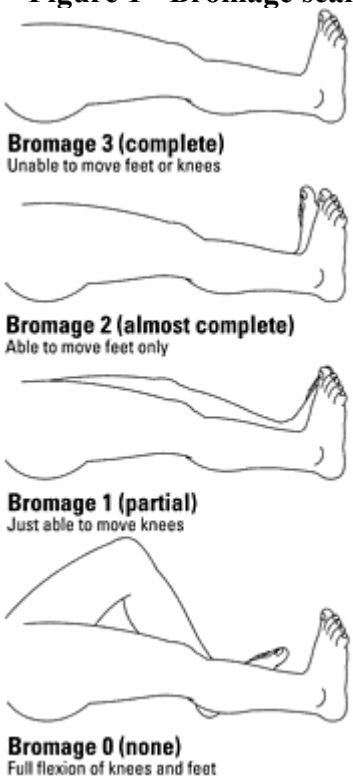
Table 1: AIIMS pain discomfort scale

Observation	**Criteria**	**Points**
Respiratory rate	+ 10% preoperative + 20-50% preoperative > 50% preoperative	0 1 2
Heart rate	+ 10% preoperative + 20% preoperative + 30% preoperative	0 1 2
Cry	No cry, responding to water, food, parental presence Cry responding to tender loving care Cry not responding to tender loving care	0 1 2

Discomfort	Calm Restless Agitated	0 1 2
Pain at the site of operation	No pain States vague pain Can localize pain	0 1 2

Residual motor block was assessed immediately after the operation and at 1, 2 and 3 h after surgery, using the Bromage scale (maximum score 3).(Figure 1). Significant residual motor block was defined as a motor block score of >1 point at wake-up and 180 min after caudal block. In case of asymmetrical block, the highest numerical value was recorded.

Figure 1 - Bromage scale



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Data analysis was performed using one way ANOVA test. Data was expressed as mean ± standard deviation. ANOVA assumes that the data are sampled from populations with identical SDs. This assumption was tested using the method of Bartlett. Post test i.e. Tukey - Kramer Multiple Comparison Test was performed only in case where a statistically significant difference was obtained ($P < 0.05$) using one way ANOVA. P value less than 0.05 was considered significant and P value less than 0.001 was considered extremely significant.

Results:

Demographic variables and operative characteristics were similar in both the groups. There were no statistically significant differences in age (years), sex (F/M), ASA (I/II), body weight (kg), operative time (minutes) and discharge time after the surgery between groupsA and B.
There were no statistically significant differences in mean blood pressure, heart rate and oxygen saturation among measurement times intraoperatively within both groups.
There was no statistically significant differences in AIIMS pain discomfort scores between group A and group B at all postoperative time points i.e.,1h, 2h, 4h, 6h, 12h and 24h. The duration of analgesia was found to be within the range of 3.1 - 6.1 hours in group A (mean duration 4.69 h) and 3.2 - 5.9hours in group B (mean duration 4.37h). (Table 2)

Table 2 : Showing the duration of post-operative analgesia (in hours) in the two groups:

Group	Duration of post-operative analgesia (in hours)		
	Number	Range	Mean ± SD (hours)
A	30	3.1 - 6.1 hrs	4.69 ± 0.85
B	30	3.2 - 5.2 hrs	4.18 ± 0.59

There was however a significant difference in the pain scores of 1 hour compared to 4, 8 and 12 hours post operative, though there was no significant difference between the two groups. (Table 3)

Table 3: Average pain score in post-operative period

Time of assessment	Group A		Group B	
	Mean	SD	Mean	SD
0	0.00	0.00	0.00	0.00
1 hr	0.20	0.41	0.20	0.41
2 hr	0.73	0.69	1.13	0.78
4 hr	1.87	1.01	2.60	0.93
8 hr	3.57	1.07	3.67	0.84
12 hr	4.77	0.94	4.93	1.08
Total	1.86	1.94	2.09	1.97
P	P<0.001		P<0.001	

Preoperative heart rates were comparable in both the groups with P values of >0.05. There was an increase in heart rate in all the groups in the post-operative period after 4 hours.
There was decrease in MAP 1 hour post operatively but after 2 hours, the MAP increased in both the groups.
There is no significant difference (P>0.005) in the preoperative respiratory rate among the two groups. Postoperatively, there was an increase in respiratory rate after 4 hours.
Bupivacaine produced significant residual motor block at wake up. (Table 4) After 3 hours there was no significant difference in the residual motor block between the two groups.

Table 4: Residual motor block in two groups

Residual motor block at wake-up.		
Motor block scale	**Ropivacaine**	**Bupivacaine**
0	15	3*
1	11	12
2	3	9
3	1	6
Residual motor block 180 min after caudal block.		
Motor block scale	**Ropivacaine**	**Bupivacaine**
0	27	22
1	3	5
2	0	3

Data are number of children.
* $P < 0.001$
Bupivacaine produced a significant incidence of residual motor block at wake up. After 3 hours there was no significant difference in the residual motor block between the two groups.

There were no major intra or postoperative complications related to caudal block. Nausea/vomiting was seen in 3% patients in both groups.

Discussion

The demographic characters of the patients in our study were comparable.We limited our study to lower abdominal surgeries only so that the groups were comparable from surgical point of view. Premedication and anaesthetic techniques were kept constant in order to avoid variation in our observation that may occur due to the variable effects of drugs and techniques. The patients received sedative premedication and no analgesic during the intraoperative period. The preoperative mean heart rate, MAP and respiratory rate were comparable in both groups.

There have been differentopinions as to whether pain can be measured subjectively i.e., by patients or objectively by a trained observer, but in the case of infants and children, it is very difficult to assess pain because in them crying may be due to some other reason like hunger, thirst or anxiety. [1] Subsequently, in our study postoperative pain was assessed by an objective pain scale, All India Institute of Medical Sciences (AIIMS) pain discomfort scale. This scale uses five criteria: ventilatory frequency, heart rate, discomfort, cry and pain at site of operation, each of which scores from 0 to 2 to give a total score of 0–10. (Table 1) This score was found to be suitable because it provides allowance for thirst and hunger, avoids duplication of behaviour, and includes physiological factors such as heart rate and respiration, which can be easily measured without causing discomfort to the child. [13] For this reason, it is a clinically relevant scoring system and has been validated for use in children. [14-17]Patients received rescue analgesia when AIIMS score was ≥ 4.

Bromage Scale was used to assess any residual motor block immediately after surgery and at 1, 2 and 3 hours post operatively. A qualitative measure of spread and intensity of motor block, it is easy to apply in a clinical setting. (Table 2)
Clinically seen, an injection of 0.5ml/kg of local anaesthetic gives a lumbosacral block and 1ml/kg gives a thoracolumbar block (T10). Since we wanted to avoid different responses to different concentrations of drug in different types of surgeries studied here, we decided to stick to 1ml/kg in our study.The volume and concentration of local anaesthetic solution used in the current study are comparable to those in the literature.[18]
Bupivacaine provides reliable and long lasting post operative analgesia when given via the caudal route. However, previous reported data showed that a single shot caudal injection of 0.25% bupivacaine caused more frequent incidence of motor blockade than 0.25% ropivacaine. [19]Unfortunately, motor block produced by caudal block may be a cause of distress to children in the post operative ward.
Ropivacaine, on the other hand, offers a greater sensory effect, less motor blockade and less cardiotoxicity than bupivacaine. In paediatric patients, this could allow for more rapid mobilization after surgery.
As we had performed the caudal block only after induction of general anaesthesia we could not assess the onset of block by pinprick test or by any other sophisticated means. But it has been shown in the literature that onset time is faster in ropivacaine than in bupivacaine. [18]
Regarding motor block, higher concentration of local anaesthetic can increase the incidence after caudal epidural anaesthesia.One studyfound no difference in the quality and duration of analgesia produced by caudal ropivacaine 0.375% (1 ml/kg) and bupivacaine 0.375% (1 ml/kg)but found a significant difference in the degree of motor block with ropivacaine producing lesser motor block. [20]
Lesser doses don't cause much significant motor block as has been shown inone study.The authors found no significant difference in quality and duration of post operative pain relief after 1 ml/kg of 0.25% ropivacaine and bupivacaine. Theyalso found no significant difference in motor and sensory effects after both ropivacaine and bupivacaine. [21] In another study, the authors found that 0.375% of ropivacaine 1ml had a shorter duration of motor block than similar dose of bupivacaine, although duration of postoperative analgesia was almost equal in both. [22]
*J. S. Tanet al*did not observe any significant motor block after 0.5ml/kg of caudal ropivacaine 0.2% or bupivacaine 0.2% (modified Bromage score = 0). [23]In another study by Ivani G et al 0.7ml/kg of bupivacaine 0.25% or ropivacaine 0.2% showed similar onset time to sensory blockade and duration of analgesia and there was no occurrence of motor block. [24]
D'Angelo R found that only 23% of studies demonstrated a statistical reduction in motor block with caudal ropivacaine compared to similar concentrations of bupivacaine. [25]
Regarding analgesic effect, many investigators found no difference between equivalent doses of local anaesthetics when given via the caudal route. [19] *Ray Manjushree et al* found no significant difference in the quality and duration of post operative pain relief between 0.75ml/kg of 0.25% bupivacaine and 0.25% ropivacaine. [26] *Pasquale De Negri, Giorgio Ivani et al* found that postoperative analgesia was almost identical after giving a smalldose (0.125%; 0.2 mg/kg/h) of bupivacaine, levobupivacaine, and ropivacaine (Group R; $n = 26$) in postoperative epidural infusions in children after hypospadias repair. [27]*Christian Breschan, Robert Jost, et al*, found no statistically significant difference in the level of the caudal block between 1ml/kg of levobupivacaine 0.2%, ropivacaine 0.2% and bupivacaine 0.2%. [28] Another study found that ropivacaine 0.1% is less effective and had shorter duration of analgesia than ropivacaine 0.2%, whereas ropivacaine 0.2% provides pain relief

similar to bupivacaine 0.2%. Motor block in the early postoperative period is less with ropivacaine than with bupivacaine. [29]
Karmakar M K, Aun C S T, found that 2 mg/kg of 0.2% ropivacaine has a quicker onset of action and provides more prolonged post operative analgesia than 0.2% bupivacaine (2mg/kg) in 1-7 year old children undergoing elective hypospadias repair. [30]

Conclusion

The single shot caudal epidural block with 1ml/kg ropivacaine 0.25%, is a safe and effective, long lasting dose for postoperative analgesia in paediatric lower abdominal surgery, producing lesser duration of motor block than bupivacaine 0.25%.

The awareness of adequate pain relief in paediatric patients is increasing in both neonates and small children. In the last decade, pain among paediatric patients has received considerable attention and reliable age-related pain scales have been developed to evaluate both the severity and efficacy of pain management. A better knowledge of the pathophysiology of pain, the pharmacology of local anaesthetic substances in infants and children, the development of regional techniques, as well as the availability of better equipment specifically designed for children have all allowed the implementation of safe regional anaesthesia in paediatric surgery.

The sacral hiatus is usually very easy to palpate in infants and children, which makes this technique much easier and more predictable in them. Consequently, in many institutions with a large number of paediatric patients, caudal epidural block is an integral part of the intra- and postoperative pain management for children undergoing varied surgical procedures both below and above the diaphragm.

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