Original Research Article

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A Randomized Prospective Double Blind Comparative Study of Caudal Ropivacaine 0.2% versus Caudal Bupivacaine 0.125% for Postoperative Analgesia in Pediatric Surgeries

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Abstract

Introduction: Pain relief is important for reduction of postoperative morbidity necessitating continuing search for safe and efficient method in pediatric patients due to difficulty in pain assessment and concern of potential side effects. Single dose caudal epidural block is simple, effective and easy technique to perform due to anatomy of sacrum of child. There are reports of ropivacaine/bupivacaine being used routinely for caudal anaesthesia (Bramwell, Kapsten) and the extension of its analgesic action in the postoperative period. *Aims & Objectives:* To study and compare the effects of caudal ropivacaine and caudal bupivacaine for postoperative analgesia in pediatric patients w.r.t. duration and quality of postoperative analgesia, duration of motor blockade, hemodynamic effects and adverse effects if any. *Methods:* Comparative double blind prospective study included 100 patients of ASA grade I/II in age group of 2 years to 12 years posted for elective surgeries (circumcision, herniotomy, hydrocoele repair etc). General anesthesia was given followed by a single shot caudal epidural in the left lateral position after completion of surgery. They were randomly divided into two groups of 50 each, Group B – 0.2% ropivacaine 0.75 ml/kg. Group A – 0.125% bupivacaine 0.75 ml/kg. *Results:* The mean duration of analgesia using caudal ropivacaine was 5.43 hrs and caudal bupivacaine was 5.38 hrs. The mean duration of motor blockade with caudal bupivacaine was prolonged 6.10 hrs and caudal ropivacaine was 3.16 hrs. No hemodynamic instability and adverse effects. *Conclusion:* 1. caudal ropivacaine showed quality and duration of postoperative analgesia comparable to that of caudal bupivacaine. 2. The duration of motor blockade with caudal ropivacaine was short as compared to that of caudal bupivacaine 3. Hemodynamic parameters were stable. 4. No any adverse effects.

Keywords: Postoperative Analgesia; Pediatric Surgery; Technique-Caudal Block; Drug-Bupivacaine/ Ropivacaine.

Introduction

Pain causes physical damage and fear. Pain relief is important for reduction of morbidity after surgery. Children have been neglected for effective postoperative pain relief due to difficulties in assessing their pain perception and concern of giving drugs with potential side effects.

Single dose caudal block is a simple, efficient and easy technique to perform due to the anatomy of the sacrum of the child. Caudal with local anesthetics after induction of general anesthesia prior to surgery has advantage of adequate intraoperative anesthesia, adequate postoperative analgesia, the presence of a tranquil recovery, calm child. There are reports of ropivacaine/ bupivacaine being used routinely for caudal anesthesia (Bramwell, Kapsten) and the extended analgesic action in the postoperative period.

This study was conducted to find out whether the caudal ropivacaine offers any advantage regarding duration of block and postoperative pain relief, compared with caudal bupivacaine.

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Aims and Objectives To study and compare, the effects of caudal ropivacaine 0.2% and caudal bupivacaine 0.125% w.r.t. 1. The quality and duration of postoperative analgesia. 2. Duration of motor block. 3. hemodynamic effects 4. Adverse effects.

Material and Methods

Study was prospective randomized comparative double blind clinical study. Approval from the institutional ethical committee was taken.

Inclusion Criteria

Hundred children, between the age group of 2 years to 12 years of either sex and ASA grade I/II who were posted for elective surgery involving the lower abdomen, genitourinary system and lower limbs.

Exclusion Criteria

The sacral hiatus pathology or deformity, neurological disease, obvious spine deformities, nutritional disorders, anaemia, known hypersensitivity to bupivacaine, coagulopathies, local infections, cardiorespiratory compromise, liver and renal dysfunction.

The children were selected by computer generated random numbers. The children were randomly assigned to two groups.

Group A: 50 patients, caudal plain bupivacaine (0.125%) 0.75 ml/kg.

Group B: 50 patients, caudal ropivacaine (0.2%) 0.75ml/kg

Informed parental consent was obtained in each case, after the procedure had been explained to them. Preoperatively thorough preanaesthetic evaluation was performed of all children. Detailed physical examination was done. Investigations haemogram, bleeding time, clotting time, urine examination were done.

Procedure: All children were kept nil by mouth for 6 hours prior to surgery. All children were given general anesthesia and the caudal block was then performed after completion of surgery.

Premedication: inj.Glycopyrrolate5ug/kgIV, Inj. Ondansetron 0.08mg/kgIV Inj.Midazolam 0.03mg/kgIV, Inj.Pentazocine 0.3mg/kg IV

Induction: Inj.Pentothal Sodium 5 mg/kg IV Inj. Suxamethonium2 mg/kgIV.

Intubation –plain PVC portex ETT of proper size using laryngoscope

Maintenance 50% O_2+50% N_2O on IPPV, Isoflurane as inhalational agent. Atracurium as muscle relaxant.

Caudal block was given using complete aseptic precautions after completion of surgery and before reversal of general anaesthesia by a short bevelled 22G 1" hypodermic needle. The correct placement of the needle into the epidural space was confirmed by using a smooth 2cc glass syringe and eliciting the 'loss of resistance' test. After negative aspiration for blood and CSF, the total calculated dose was given slowly. The needle was then withdrawn and a benzoin seal was placed and supine position given.

Recording - Heart rate, blood pressure, oxygen saturation, surgery duration recorded. The duration of motor blockade was charted as the time taken from the caudal block to the full return of muscle power in the lower limbs. Similarly duration of sensory blockade was also checked by pinprick. Pain assessment in the post operative period was done by using OPS score & duration of analgesia noted. If the OPS score more than 4 in 2 subsequent measurements or if patient showed obvious signs of pain they were given oral paracetamol 10 mg/kg as rescue analgesia.

Duration of motor block was assessed by using motor power scale. Complete motor recovery indicates score 10 (Table 2).

Table 1: Objective Pain Scale (OPS)

Sr. No.	OPS variable	Score
1	Crying	0-2
2	Facial expression	0-2
3	Verbal response	0-2
4	Position of torso	0-2
5	Motor restlessness	0-2

(0-none, 1-moderate, 2-severe)

Table 2: Motor power scale

Muscle Tone	Flaccid	Hypotonia	Normal
Muscle Power (Flexion)	0 Unable	1 Partial	2 Normal
Ankle	0	1	2
Knee	0	1	2
Thigh	0	1	2
Ability to stand	0	1	2

The occurence of complications were noted: *Immediate complications:* Dural puncture, Intravascular injection, Vasovagal attack, Severe hypotension. *Late complications:* Respiratory depression, Nausea, vomiting, Urinary retention.

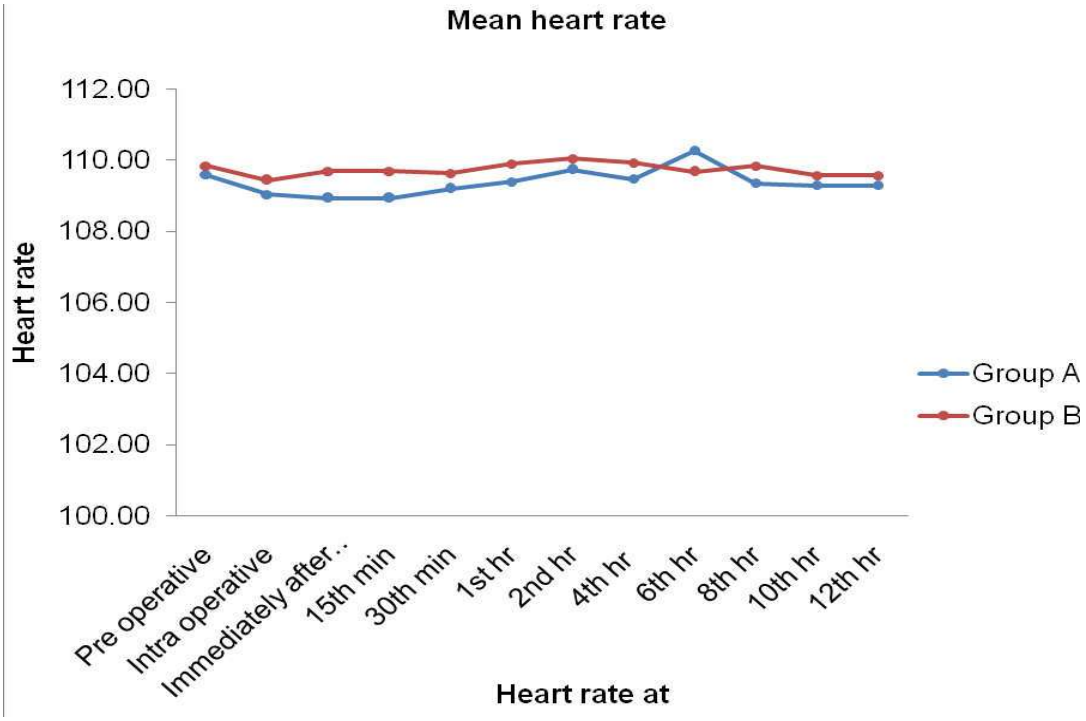
Statistical Analysis: ASA grade by chi-square test, gender by 2 sample proportion test. 2 independent sample t-test for age, weight, duration of surgery, heart rate, blood pressure, respiratory rate, duration of postoperative analgesia, duration of motor block. Mann-Whitney U test for Objective pain score, sedation score.

Results

Table 3: Demographic data

Variables	Group A	Group B	P Value	Statist. Signi.
Age (yrs) Mean ± SD	4.35 ± 1.02	4.38 ± 1.05	0.885	>0.05-NS
Gender (M/F)	34/16	33/17	0.804	>0.05-NS
Weight (kg) Mean ± SD	15.06 ± 2.08	14.42 +1.88	0.110	>0.05-NS
Asa grade (i/ii)	21/29	20/30	0.999	>0.05-NS
Surgery Duration Mean ± SD (min.)	46.40 ± 6.23	46.90 ± 5.61	0.110	>0.05-NS

(SD- Standard Deviation, NS- Not Significant)



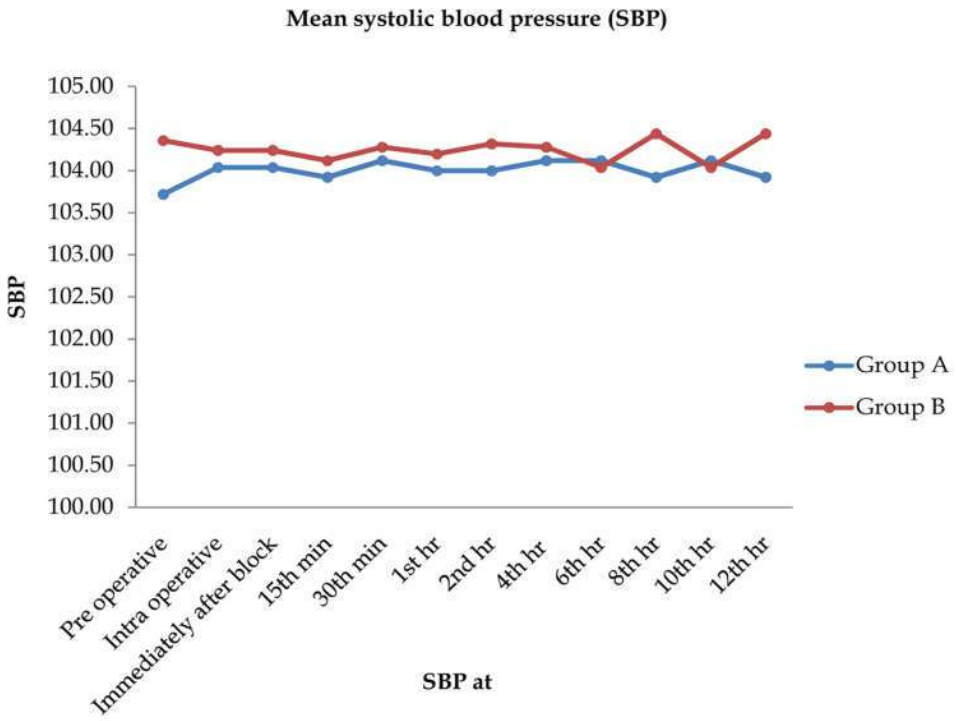
Graph 1: Comparison of mean heart rate in group A and group B at pre operative, intra operative, immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr

(SD- Standard Deviation, NS- Not Significant)

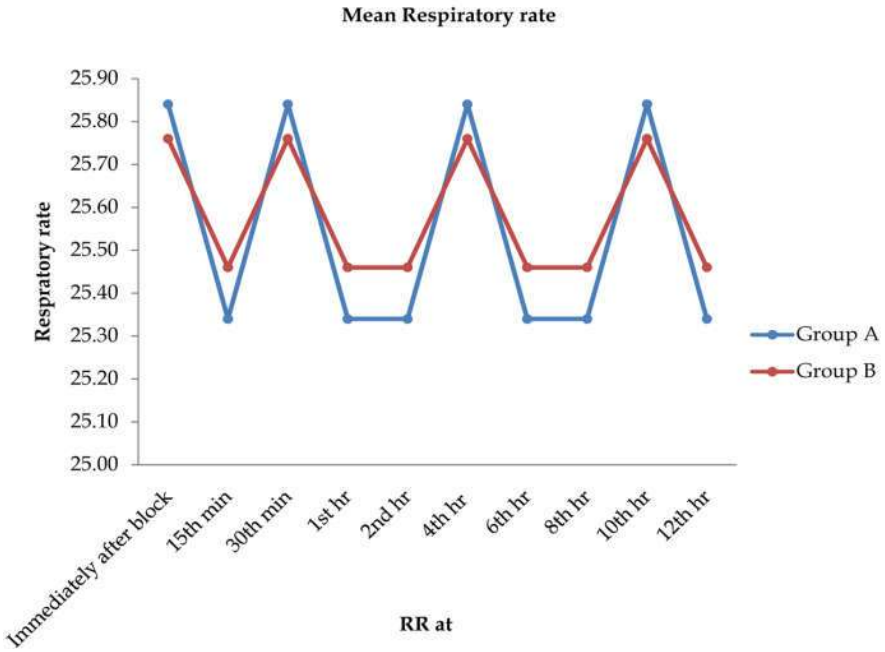
Graph 1: By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between mean heart rate in group A and group B immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr.

Graph 2: By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between mean SBP in group A and group B immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr.

Table 4: By using Mann-Whitney U test p-value >0.05 therefore there is no significant difference between median pain score immediately after block to 8th hr.



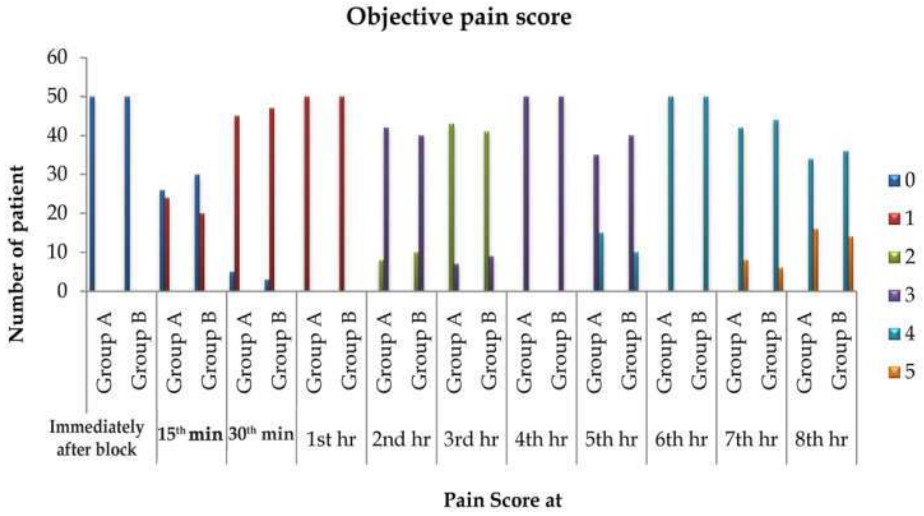
Graph 2: Comparison of mean systolic blood pressure (SBP) in group A and group B at pre operative, intra operative, immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr.



Graph 3: Respiratory Rate

Table 4: Median Pain Score

	Median pain score		p-value
	Group A	Group B	
Immediately after block	0	0	0.423
15th min	0	0	0.423
30th min	1	1	0.463
1st hr	1	1	0.999
2nd hr	2	2	0.604
3rd hr	2	2	0.622
4th hr	3	3	0.999
5th hr	3	3	0.251
6th hr	4	4	0.999
7th hr	4	4	0.586
8th hr	4	4	0.664



Graph 4: Comparison of objective pain score in group A and group B at immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 4th hr, 6th hr, 8th hr, 10th hr and 12th hr.

Table 5: Comparison of motor power scale in group A and group B at immediate after block, 15th min, 30th min, 1st hr, 2nd hr, 3rd hr, 4th hr, 6th hr, 7th hr

	Median MPS		p-value
	Group A	Group B	
Immediately after block	0	0	0.999
15th min	2	2	< 0.001
30th min	3	4	< 0.001
1st hr	3	6	< 0.001
2nd hr	4	8	< 0.001
3rd hr	5	10	< 0.001
4th hr	6	10	< 0.001
5th hr	8	10	< 0.001
6th hr	10	10	0.002
7th hr	10	10	0.999

Table 6: Comparison of duration of analgesia and motor blockade

Group	Group A	Group B	p-value	Statistical significance
Duration of analgesia (Mean± SD)	5.38 ± 0.33	5.43 ± 0.32	0.430 (>0.05)	Not significant
Duration of motor blockade (Mean± SD)	6.10 ± 0.80	3.16 ± 0.19	<0.001 (<0.05)	Statistically significant

Discussion

In our study, we found this technique to be a simple, safe and easy to perform. Dalens Bernard [3] studied 750 patients using both lidocaine and bupivacaine and found a success rate of 96.5%. Most of the failures occurred in an older age groups. No respiratory or neurological problems were noted.

Fortuna [4] reported on 170 children in the age group of 1 day to 10 years and found an incidence of 91.5% of successful analgesia.

Mc grown [5] studied 500 cases upto the age of 10 years and found a success rate of 86.8%. He described it to be a technically simple and safe procedure. In our study, caudal block was performed in the left lateral position using a 22G hypodermic short, beveled needle, No failures were noticed in our study. Pediatric age group is a suitable age group as regards the caudal block because of anatomic peculiarities.

Arthur D.S. [6] documented that sacrum in children is straighter and the sacral cornu are more prominent making identification of the hiatus easier.

Murat [7] attributed the success of caudal block to incomplete ossification of the sacral vertebrae and more fluid in epidural fat thereby allowing local anesthetic agent to diffuse freely.

In our study, we have randomly chosen 100 children in the age group between 2 year to 12 years belonging to ASA I or ASA II grade. The two groups were comparable in age, sex, ASA grading and weight (Table 3). Proper patient selection is an important aspect of success of a caudal block. Children below the age of 6 months are more prone for toxicity of local anesthetic agents because of incomplete myelinization of the nervous system, lower plasma proteins and higher elimination half life and thus were excluded from our study.

Both sexes were included in this study. However the number of male children far outnumbered the number of females. This was because the majority of the operations for which caudal anesthesia was given were commoner in males (Table 3). The various surgeries performed were herniotomies, hydrocoelectomy, cystolithotomy, circumcision, repair of hypospadias and orchidopexy.

General anesthesia was induced which ensured that the child is motionless during the block, thereby minimizing the chances of complications like dural puncture, intravascular puncture or breakage of needle, resulting in high success rate, proper painting of the area thus reducing the risk of sepsis as well as failure to identify the hiatus.

Kay B [8] has used the technique of general anesthesia with caudal epidural using O_2 (33%), N_2O (66%), Halothane (1% to 0.5%) by mask, while Cook, Crubb have used the laryngeal mask airway to secure the airway and O_2, N_2O and halothane to maintain light anesthesia.

Arthur D.S. advocated the combined use of caudal epidural with general anesthesia as it also produced amnesia as regards the caudal block and surgery

In our study all the blocks were performed in the left lateral position after completion of surgery and before reversal of general anaesthesia. A short, 22G beveled hypodermic needle was used for the block. Since the distance between the skin and epidural space in children is much less thus a short needle (1") had been used to effectively enter the epidural space and also prevent dural puncture, after negative aspiration for blood and CSF, the volume of anesthesic solution was injected slowly.

In our study we used bupivacaine as local anesthetic agent in a concentration of 0.125% and ropivacaine 0.2%. Bupivacaine is a potent, highly lipophilic drug with a long duration of action.

Hemodynamic Stability

A feature of caudal anesthesia in children below 5 years of age is the hemodynamic stability observed postoperatively. By using 2 independent sample t-test p-value > 0.05 therefore there was no significant difference between mean heart rate and systolic blood pressure in group A and group B, immediate after block, 15^{th} min, 30^{th} min, 1^{st} hr, 2^{nd} hr, 4^{th} hr, 6^{th} hr, 8^{th} hr, 10^{th} hr and 12^{th} hr , with no case of bradycardia or hypotension (Graph 1,2).

Bromage too noted this hemodynamic stability despite higher mg/kg dosage of local anesthetic. Several reasons have been put forward for this beneficial effect (Murat, Dalens) - Reduced size of the lower part of the body, Low level of systemic vascular resistance, Effectiveness of the sympathetic system in the non blocked areas to compensate for vasodilatation in the blocked area.

Pain Score Method: In this study we used OPS pain score system and duration of analgesia was noted post operatively. Each variable (Crying, facial expressions, verbal response, position of torso & motor restlessness) scored between 0-2 (0-None, 1 moderate, 2-severe) to give cumulative score of 0-10. If the OPS score is more than 4 in two subsequent measurement or if patients showed obvious signs of pain they were given oral paracetamol 10 mg/kg as rescue analgesia.

Aruna Parameswari [9] and her colleagues have used FLACC pain score, which includes assessment of face, leg, activity, cry, consolability. Five parameters were given score of 0-2 each and total score was taken to assess pain.

Hannalah [10] and his colleagues used a 5 point pain assessment chart which included cry, pulse, BP, movement, posture.

Lunn J [11]. N used a visual analogue scale 10 cm long with asleep at one end and violently restless at the other.

Pain Score: The difference in pain score indicating quality of pain relief was statistically not significant when median pain score was compared between Group A & Group B. (Table 4).

P value of median pain score at 8th hr after block was 0.664. It is >0.05, therefore there is no significant difference between median pain score in both groups. This means that children receiving caudal ropivacaine had comparable quality of pain relief as that of caudal bupivacaine.

Duration of Postoperative Analgesia: The mean duration of postoperative analgesia using bupivacaine caudally in our study was 5.38 hrs. and using caudal ropivacaine was 5.43 hrs. This was comparable in both groups (Table 6). Warner using 0.25% bupivacaine 1 ml/kg. found postoperative analgesia to be between 4-8 hours and Hannalah reported it to be 4 hrs 40 mins. Vater et al using 0.25% bupivacaine 0.5 ml/kg found analgesia lasting between 4-6 hrs.

The Mean Duration of Motor Blockade: The mean duration of motor blockade with caudal bupivacaine was 6.10 hrs.and with caudal ropivacaine was 3.16 hrs. which was for less time, helps in early ambulation of children. By using 2 independent sample test p-value < 0.05 therefore there was significant difference between mean duration motor blockade (Table 6).

Adverse Effects: There was no case of dural puncture, intravascular puncture, transient apnea, severe hypotension or urinary retention. This was possible with scrupulous attention to technique and proper patients selection. No toxic reactions to the local anaesthetic drugs were noticed which was due to our utmost care of dose calculation.

Conclusion

1. Ropivacaine provided the quality and duration of analgesia comparable to that of bupivacaine.
2. The duration of motor blockade was short with caudal ropivacaine as compared to that of bupivacaine.
3. Hemodynamic parameters remained stable.
4. No any adverse effects occurred.

We observed the effectiveness of caudal ropivacaine in providing postoperative analgesia with less duration of motor blockade as compared to caudal bupivacaine in pediatric patients with no occurance of adverse effects. We feel that child undergoing lower abdominal surgery would definitely benefit from postoperative caudal analgesia using caudal ropivacaine. The reward of pain free, happy child and appreciative parents would definitely be a guiding point in the use of this technique in pediatric anesthesia.

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