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Original Article

Anaesthesia Section

Comparing the Anaesthetic and Analgesic Efficacy of Caudal Levobupivacaine and Ropivacaine in Paediatric Patients

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ABSTRACT

Introduction: Introduction of S enantiomer of bupivacaine is a major breakthrough in the history of local anaesthesia as the pharmacodynamics of these drugs were favourable in reducing the occurrence of cardiotoxicity, neurotoxicity and unintended motor blockade.

Aim: To compare efficacy, postoperative analgesia and postoperative motor blockade of 0.25% levobupivacaine with 0.25% ropivacaine in caudal block for children, scheduled for lower abdominal and lowerlimb surgeries.

Materials and Methods: 80 children, ASA I–II, 1-10 years, weighing between 5-30 kg, scheduled for elective lower abdominal and lower limb surgeries were given single caudal injection of 1 mL/kg of either levobupivacaine or ropivacaine. Caudal block was given after general anaesthesia using sevoflurane as induction agent airway secured with laryngeal mask. Postoperative pain score was assessed using Children and Infants Postoperative Pain Scale (CHIPPS) scale in children less than 6 years and numerical scale for children more than 6 years. Motor recovery was assessed by modified Bromage scale.

Results: Onset of analgesia, duration of analgesia, postoperative pain and motor blockade were comparable between the two groups, of 40 each. Analgesia time was within 5 minutes in both the groups. Duration of analgesia was 404.8±67.6 minutes for levobupivacaine and 413.5±44.4 minutes for ropivacaine, which was not significant statistically. Postoperative analgesia was same between the two groups. It took 120 minutes for complete postoperative motor recovery. The motor recovery between the two groups was statistically not significant at immediate postoperative period (p=0.111), at 60 minutes (p=0.692).

Conclusion: We conclude that both 1 mL of 0.25% levobupivacaine and 0.25% ropivacaine provide similar effect caudal anaesthesia and analgesia with motor blockade for 120 minutes.

Keywords: Caudal block, Postoperative pain, Ropivacaine

INTRODUCTION

The effects of physical pain in children after recovery from general anaesthesia have negative psychological effect in their adulthood [1]. The management of perioperative and procedure related pain usually include regional anaesthesia techniques in children of all age groups. These techniques offer relief from postoperative pain and reduction in complications from medications especially opiates, that cause respiratory depression.

Caudal anaesthesia is the most popularly practiced regional block in paediatric age group in patients undergoing infra umbilical surgical procedures. It is considered a simple and safe technique, by providing excellent and prolonged analgesia during surgery as well as in the postoperative period. Caudal block minimises the perioperative stress response, requirement of intravenous narcotic and inhalational agent doses [2]. Pain relief provided by caudal is of higher quality with duration of action lasting for about 4 to 8 hours [3]. Postoperative pain relief increases patient satisfaction and reduces the duration of hospital stay.

However, there is an ever demanding need for lengthening the duration of analgesia after surgery with parental anxiety and restless child. To prevent these complications initially caudal catheters were inserted and repeated boluses were given, but they carry risk of drug overdose, infection at catheter site due to stool contamination, failure of adequate pain control due to displacement and complications in removal of catheter, particularly if catheter is tunnelled. Caudal block provides a calm and relaxed state in children with less chances of bleeding and dislodgement of dressing in recovery room due to pain or restlessness.

With the introduction of bupivacaine in 1963, it has been the choice of local anaesthetic agent for caudal block. Bupivacaine is a racemic mixture of R and S enantiomers, of which R enantiomer has been found to cause cardiotoxicity [4]. The introduction of S enantiomer, levobupivacaine was a major breakthrough because the pharmacodynamics of these drugs were favourable in reducing the occurrence of cardiotoxicity, neurotoxicity [5,6] and unintended motor blockade. Levobupivacaine is an amino-amide local anaesthtic drug with pKa 8.1 similar to racemic bupivacaine. It has a higher protein binding capacity (97%), resulting in less than 3% of free drug available in the circulation to cause inadvertent effects [5,7,8].

The rationale for replacing racemic bupivacaine with the S enantiomers levobupivacaine and ropivacaine is to provide a wide margin of safety with the same analgesic efficacy and less postoperative motor block [8]. Ropivacaine and levobupivacaine have been shown to be effective and well tolerated by caudal route in children [9-11].

In the present study, we used 0.25% levobupivacaine and 0.25% ropivacaine which were found to be relatively safe with fewer side effects in children. We considered prospective observational study to compare the effect of caudal block with 0.25% levobupivacine versus 0.25% ropivacaine for analgesia onset time, alleviation of postoperative pain and motor recovery in children undergoing lower abdominal and lower limb surgeries. The present study aim to compare the efficacy of a single dose of caudal 0.25% levobupivacaine with 0.25% ropivacaine, in children undergoing lower abdominal and lower limb surgeries.

MATERIALS AND METHODS

After availing approval from the Institutional Ethical Committee, this observational study was conducted, in the hospitals associated with Kasturba Medical College, Mangalore, India (from year 2015 to July 2017). The study participants included 80 children under going lower abdominal and lower limb surgeries.

Inclusion Criteria

1. Age between 1-10 years.
2. ASA Grade I and II.
3. Patients posted for elective lower abdominal and lower limb surgery.

Exclusion Criteria

1. ASA Grade III and IV.
2. History of allergy to any study drugs.
3. History of cardiac disease, liver and renal diseases.
4. History of seizures.
5. Neurological and neuromuscular disorders.
6. Blood dyscrasias.
7. History of chronic pain and analgesic drug in use.
8. Clotting disorders, platelet count <100,00/cumm.
9. Anatomical malformation at puncture site.
10. Active cutaneous infection at puncture site.

The study was carried out in 80 paediatric patients who were divided into 2 groups:

1. Group A (Levobupivacaine) 1 mL/kg body weight (n=40);
2. Group B (Ropivacaine) 1 mL/kg body weight (n=40).

Sample size was calculated by using the following formula:

$$n = \frac{2\,(Z\alpha+Z\beta)^2\sigma^2}{d}$$

1. $Z\alpha$=1.96 at 95% confidence level.
2. $Z\beta$=1.28 at 90% power.
3. σ=Combination of SD.
4. D=Mean difference between groups.

The study was explained to the parents in detail and written informed consent was taken from the parents. All the children (1-10 year age group, 5-30 kg weight) were scheduled for elective lower abdominal and lower limb surgery with an expected duration of less than 90 minutes. Preoperative assessment was done for all the patients.

The selected patients were divided into two groups of 40 each based on drug given. Once the patient was shifted to operating theatre, nil per oral status was confirmed. Peripheral IV access was secured using either sevoflurane inhalation agent. Monitors were connected and patient pre-medicated with Injection atropine 0.02 mg/kg IV, Inj fentanyl 2 ug/kg. They were induced with propofol 2 mg/kg and then airway was secured with appropriate size LMA. Anaesthesia was maintained with mixture of nitrous oxide, oxygen (50:50) and sevoflurane was titrated to reach MAC 0.9 and connected to the ventilator after securing the airway. Patient was then turned to the left lateral position. Under all aseptic precautions, caudal block was performed by using 22 SWG needle.

Immediately after the caudal block, patient was turned supine position for surgery. No intravenous or per rectal analgesia drugs were given intraoperatively. The time of onset of analgesia was studied with a modified Allis clamp by giving mechanical stimulus for every 5 minutes for a total of 15 minutes. The mechanical stimulus given with Allis clamp stimulates both A and C nervefibers, and detects the pain threshold within physiological limit [12] without causing tissue damage. Surgical incision was started 15 minutes after the block. Onset and duration of block was calculated from the time of caudal injection of the study drug.

Heart rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP) were recorded at regular intervals (Before Incision (BI), immediately After Incision (AI), 30 minutes, 60 minutes and 90 minutes after incision). If any patient responded to the incision with gross movements or by increase in HR of more than 20 beats/minute; this was considered as failure of the caudal and additional analgesia with fentanyl 1 microgram/kg were given and plane of anaesthesia was deepened by increasing the sevoflurane concentration. After completion of surgery LMA was removed, and patient was shifted to postoperative room. The children were kept in postoperative room for 12 hours before sending to ward. Postoperative pain score was assessed accordingly by using CHIPPS [13] in patients less than 6 years age [Table/Fig-1].

Crying
None-0
Moaning-1
Screaming-2
Facial expression
Relaxed/smiling-0
Wry mouth-1
Grimace (mouth and eyes)-2
Posture of the trunk
Neutral-0
Variable-1
Rear up-2
Posture of the legs
Neutral-0
Kicking-1
Tightened legs-2
Restlessness
None-0
Moderate-1
Restless-2

[Table/Fig-1]: Children and infants postoperative pain scale.

Children more than six years, pain score was assessed accordingly by numerical pain score [14].

If the CHIPPS scale or the numerical scale was more than 3, rescue analgesia in the form of rectal paracematol (20 mg/kg) was given. Duration of block was calculated from the time of caudal injection of drug till the requirement of rescue analgesia i.e., paracetamol. Side effects/complications during the study period like bradycardia, hypotension, arrhythmias, nausea and vomiting were noted. Residual motor block was evaluated immediately after recovery and every hour till total motor power was regained by using modified Bromage scale (motor block scale) [Table/Fig-2].

0-No motor block, able to stand unassisted or complete flexion of ankle, knee and thigh in non-walking child
1-Unable to stand unassisted or partial knee flexion, with complete thigh flexion in non-walking child
2-Unable to flex the knee but can flex the ankle
3-No movement or complete motor blockade in a fully awake child

[Table/Fig-2]: Motor block scale.

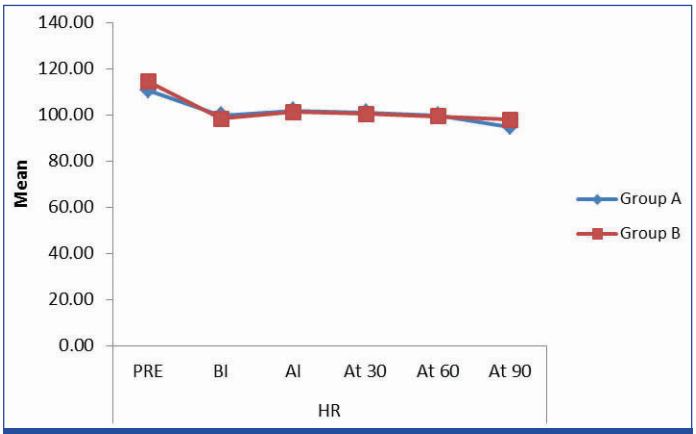
STATISTICAL ANALYSIS

Statistically analysis was done with students paired t-test and chi-square (χ^2) test. A statistical package SSPS version 17.0 was used to do the analysis. A p-value of <0.05 was considered significant.

RESULTS

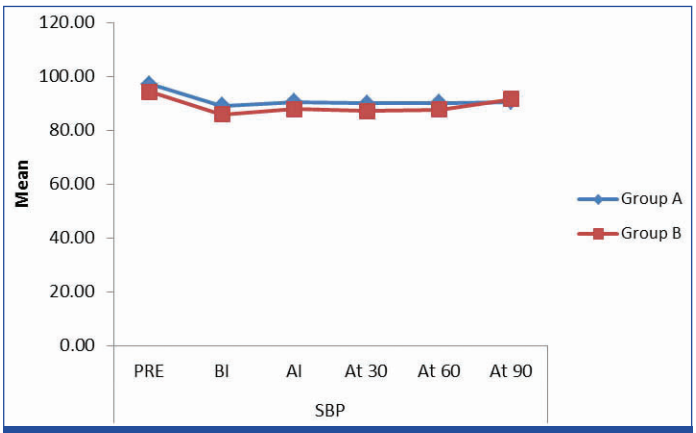
The patients were comparable in age among both the groups; (with a p-value of 0.960). Out of 80 patients, 30 (75%) were males and 10 (25%) were females in Group A, where as 32 (80%) were males and 8 (20%) were females in Group B (p-value of 0.592). The type and duration of surgery was similar in both the groups. (Student t-test, p-value 0.727).

The [Table/Fig-3] shows the comparison of heart rate preoperative, before incision, after incision at 30 minutes, at 60 minutes and 90 minutes with standard deviation between the groups which revealed statistically no significant difference between the groups. (p-values are 1.226, 0.66, 0.83, 0.81, 0.92, and 0.57 respectively).



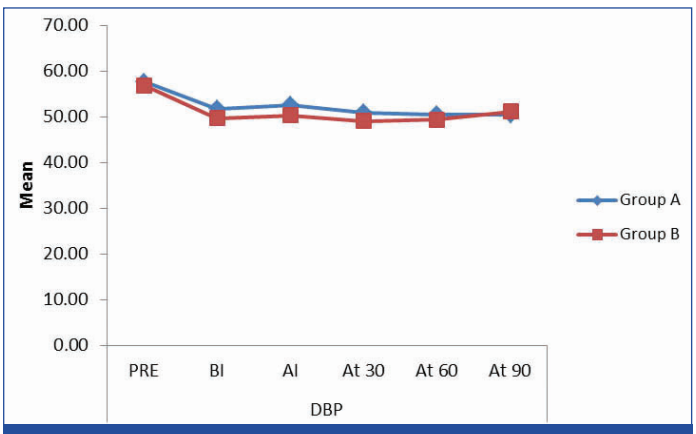
[Table/Fig-3]: Heart rate variation.

The [Table/Fig-4] shows the comparison of mean systolic blood pressure in preoperative, before incision, after incision, at 30 minutes, 60 minutes, 90 minutes with standard deviation between the groups.



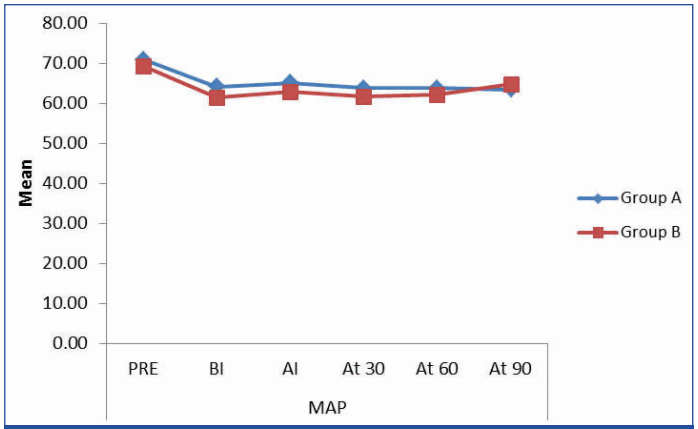
[Table/Fig-4]: Systolic blood pressure variations.

The [Table/Fig-5] shows the comparison of mean diastolic blood pressure with standard deviation preoperative, before incision, after incision, at 30 minutes, at 60 minutes and 90 minutes between the groups which revealed statistically no variation.



[Table/Fig-5]: Diastolic blood pressure variation.

The [Table/Fig-6] shows the comparison of mean of mean arterial blood pressure with standard deviation between the groups had not showed any variation statistically. (p-values were 0.251, 0.057, 0.061, 0.068, 0.205, and 0.586 respectively).



[Table/Fig-6]: Mean arterial blood pressure variation.

Onset and Duration of Analgesia

Each of the forty (100%) patients in Group A showed no response to stimuli given by Allis forceps within 5 minutes of indicating no further requirement of analgesia in intraoperative and postoperative period. In the Group B, 37 (92.5%) showed no response to stimuli given by Allis forceps within 5 minutes whereas 3 (8.5%) in Group R responded to stimuli implying no analgesia and requirement of further additional analgesics.

The mean duration of analgesia in Group A was 404.8 minutes (±67.66) with median 420 compared with Group B was 413.5 minutes (±44.47) with median 420 implying no much difference in duration of analgesia (p=0.514) between the groups [Table/Fig-7].

Onset of analgesia	Group A	Group B
5 min response	40 (100%)	37 (92.5%)
Duration of analgesia	404.8±67.66 minutes	413.5±44.47 minutes

[Table/Fig-7]: Onset and duration of analgesia.

The [Table/Fig-8] shows comparison of mean postoperative pain score immediately, at 60 minutes, 120 minutes, 180 minutes, 240 minutes, 300 minutes, 360 minutes, 420 minutes with standard deviation between the groups which revealed no variation statistically, implying similar postoperative pain score between the groups.

	Group	N	Mean±SD	Median	Mannwhitney test z-value	p-value
POSTOP PAIN IMME	Group A	40	1.28±0.751	1.00	0.07	0.947 NS
	Group B	40	1.48±1.414	1.00		
At 60	Group A	40	1.70±0.608	2.00	1.48	0.138 NS
	Group B	39	1.59±0.785	2.00		
At 120	Group A	40	1.95±0.552	2.00	0.69	0.493 NS
	Group B	37	1.86±0.481	2.00		
At 180	Group A	39	2.18±0.556	2.00	0.49	0.626 NS
	Group B	37	2.14±0.419	2.00		
At 240	Group A	38	2.47±0.647	2.50	1.49	0.136 NS
	Group B	37	2.30±0.463	2.00		
At 300	Group A	36	2.61±0.494	3.00	0.99	0.321 NS
	Group B	36	2.72±0.454	3.00		
At 360	Group A	27	2.59±0.501	3.00	1.44	0.138 NS
	Group B	36	3.00±0.414	3.00		
At 420	Group A	9	2.89±0.333	3.00	1.15	0.248 NS
	Group B	12	3.00±0.000	3.00		

[Table/Fig-8]: Postoperative pain score.
SD: Standard deviation

The [Table/Fig-9] shows motor recovery from immediate postoperative period to full recovery in which during immediate postoperative recovery in Group A 16 (40%), Group B 24 (60%) had no motor blockade with score 0. 23 (57.5%) in Group A, 16 (40%) in Group B had pain score 1 indicating partial flexion of knee with

complete flexion of hip. At 60 minutes children belonged to Group A 36 (90%), Group B 37 (92.5%) had motor score 0 indicating they were able to move legs. At end of 120 minutes children belonged to the groups had 100% motor recovery. Comparing motor recovery between the groups showed no variation statistically with p-value of (p=0.111) at immediate postoperative recovery and (p=0.692) at 60 minutes.

		Group					
		Group A		Group B		Total	
		Count	Column N %	Count	Column N %	Count	Column N %
Motor recovery immediately	0	16	40.0%	24	60.0%	40	50.0%
	1	23	57.5%	16	40.0%	39	48.8%
	2	1	2.5%	0	.0%	1	1.3%
At 60 minute	0	36	90.0%	37	92.5%	73	91.3%
	1	4	10.0%	3	7.5%	7	8.8%
	Total	40	100.0%	40	100.0%	80	100.0%
At 120 minute	0	40	100.0%	40	100.0%	80	100.0%
	Total	40	100.0%	40	100.0%	80	100.0%

[Table/Fig-9]: Motor recovery blockade-variation.

DISCUSSION

The present study attempted to assess the efficacy of two local anaesthetics, ropivacaine and levobupivacaine given caudally. Some factors which might have an influence on the postoperative analgesia, such as the age, sex, duration of surgery were comparable in the present study.

In the present study haemodynamic parameters (HR, SBP, DBP and mean arterial blood pressure) did not show any variation statistically, which is comparable to a study by Praveen P et al., who compared the same concentration and volume of 1 mL/kg of 0.25% levobupivacaine with 0.25% ropivacaine and showed no significant effect on the haemodynamic parameters [15]. Similar results were also observed by Astuto M et al., [11].

In the present study, the onset of analgesia in both the groups was within five minutes. In Group R, out of 40 patients, 3 (7.5%) patients developed pain and rescue analgesics were required in the intraoperative and postoperative period. Frawley G et al., conducted a study on comparison of levobupivacaine versus bupivacaine for caudal anaesthesia in children [16]. A 94% showed the mean onset of block within five minutes when 1 mL/kg of 0.25% levobupivacaine was given. Astuto M et al., compared 0.25% levobupivacaine with ropivacaine 0.25% administration for caudal block in 60 children [11]. They inferred that the mean onset of block was 8.2±2 minutes for levobupivacaine and 8.5±2 minutes for ropivacaine (p=0.66). Ingelmo PM et al., conducted central blocks with levobupicaine in children in 2005 suggested that the onset time may be less than five minutes in a patients receiving volatile anaesthesia [12], as it exerted a direct action at the spinal cord level to block noxious stimuli, which correlates with surgical immobility [17]. As a result volatile anaesthesia may reduce the observed minimum local anaesthetic concentration and modify nociceptive response to initial surgical stimulus which might be the reason of early onset of analgesia in present study group.

The duration of analgesia in present study Group L was 404.8±67.66 minutes in comparison with Group R which was 413.4±44 minutes with not much difference in the duration of analgesia (p=0.514) in both groups and no requirement of early analgesia. Ray M et al., compared 0.75 mL/kg of 0.25% bupivacaine with 0.75 mL/kg of 0.25% ropivacaine and found to have a mean duration of analgesia of 405±18 minutes, similar to present result for 1 mL/kg of 0.25% ropivacaine 413±44 minutes [18]. Ivani G et al., inferred that 2 mg/kg of 0.2% ropivacaine is sufficient to obtain sensory blockade for infraumbilical surgeries in children [19]. In order to achieve the similar analgesic effect in children a same or even lower concentration of ropivacaine is required in comparison with the same amount of levobupicavaine or bupivacaine. Taylor R et al., studied efficacy and safety of caudal injection of 0.25% levobupivacaine in children below two years noted that duration of analgesia 7.95 hours correlating with present study [10]. Regarding postoperative pain score is same in both the groups in the present study which correlates with study done by Brechan C et al., with 0.2% levobupicaine, 0.2% bupivacaine, 0.2% ropivacaine assessed by using CHIPPS scale have similar efficacy [20].

Postoperative motor blockade was seen in the present study, it took 120 minutes for complete postoperative motor recovery. The motor recovery between the two groups was statistically not significant at immediate postoperative period (p=.111), at 60 minutes (p=0.692). Similar results were observed by Kumar M et al., who compared caudal 0.2% ropivacaine with 0.2% bupivacaine in 60 children and showed complete motor recovery in two hours in children with 0.2% ropivacaine group [21]. In another study, Ivani G et al., compared 0.2% ropivacaine with 0.25% levobupivacaine and 0.25% bupivacaine found that postoperative analgesia was similar, but the use of ropivacaine was associated with a significant reduction in early postoperative motor blockade when compared with racemic bupivacaine and levobupivacaine as well [22]. Also, Astuto M et al., did not observe motor blockade following surgery with 0.25% ropivacaine or 0.25% levobupivacaine which differs from the results of our study, wherein a significant number of patients had motor blockade [11]. But our findings correlate well with a prior study by Praveen P et al., more than half their subjects receiving levobupicaine 0.25% and ropivacaine 0.25% had the same duration of motor block at 2 hours [15].

LIMITATION

Ours was an observational study which was not blinded. There were no control groups to compare with the drugs. A double blind randamonised control study would be better one. Also, anticipated duration of surgery was not achieved in some the cases, which could have alter the results.

CONCLUSION

Both levobupivacaine and ropivacaine have a similar onset time of analgesia after caudal block. They have a similar duration of postoperative analgesia as well as motor recovery. They delayed the requirement of rescue analgesia and provided a stable haemodynamic status without additional side effects like hypotension, bradycardia, arrythmias, nausea and vomiting.

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