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Original Research Article

Comparison Of Postoperative Analgesia Between Levobupivacaine And Ropivacaine In Caudal Anaesthesia In Paediatric Patients Undergoing Lower Abdominal Surgeries: A Prospective, Randomised, Blinded Study

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ABSTRACT

Levobupivacaine has also been evaluated as a less toxic substitute for bupivacaine and has been found to produce a quantitatively similar neural blockade. So far few data are available concerning the use of levobupivacaine in children. Ropivacaine, a recently introduced bupivacaine analogue drug, is less neurotoxic and cardiotoxic than bupivacaine. Ropivacaine is less lipophilic; hence, it is less likely to penetrate large myelinated motor fibers, resulting in a relatively reduced motor blockade and longer postoperative analgesia and has a greater degree of motor sensory differentiation, which could be useful when motor blockade is not desired. In this randomized, prospective, double blind, single hospital study ninety (90) paediatric patients aged 1 to 10 years undergoing lower abdominal surgery were enrolled. Twenty three patients were excluded as they did not meet the inclusion criteria and seven patients refused to participate. This study was conducted on 60 patients undergoing lower abdominal surgeries. The mean postoperative duration of analgesia was 321.37 ± 24.25 minutes in group L and 309.75 ±23.68 minutes in group R. The difference in the mean duration of analgesia was statistically insignificant (*p* -value was > 0.05 at all specified intervals).

Keywords: Postoperative analgesia, levobupivacaine, ropivacaine

INTRODUCTION

Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage [1]". Various methods have been evolved for providing post-operative pain relief in paediatric population. The regional anaesthetic techniques significantly decrease the postoperative pain and systemic analgesic requirements. Caudal route is one of the simplest and safest techniques in paediatric surgery with a high

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success rate [2]. Caudal analgesia can reduce the requirement of inhaled and intravenous anaesthetic administration and attenuate stress response to surgery. Caudal analgesia will facilitate a rapid and smooth recovery and provide adequate immediate postoperative analgesia. Single shot caudal block will provide adequate pain relief during the immediate postoperative period [2].

Levobupivacaine, the pure S-enantiomer of bupivacaine, has strongly emerged as a safer alternative for regional anaesthesia than its racemic sibling bupivacaine [3]. Levobupivacaine is cost effective and has been found to be equally efficacious as bupivacaine [4]. But with less cardiotoxic and less motor block profile. Clinically, levobupivacaine has been observed to be well-tolerated in regional anaesthesia techniques both after bolus administration and continuous post-operative infusion. Levobupivacaine provides good epidural anaesthesia and analgesia for surgical procedures with relatively longer postoperative analgesia and reduced motor blockade [5].

Levobupivacaine has also been evaluated as a less toxic substitute for bupivacaine and has been found to produce a quantitatively similar neural blockade. So far few data are available concerning the use of levobupivacaine in children.

Ropivacaine, a recently introduced bupivacaine analogue drug, is less neurotoxic and cardiotoxic than bupivacaine. Ropivacaine is less lipophilic; hence, it is less likely to penetrate large myelinated motor fibers, resulting in a relatively reduced motor blockade and longer postoperative analgesia and has a greater degree of motor sensory differentiation, which could be useful when motor blockade is not desired. Several studies in children have supported its efficacy for caudal anaesthesia [6].

Most adverse drug reactions are related to faulty administration technique (resulting in systemic exposure) or pharmacological effects of anaesthesia. However, allergic reactions can also occur rarely. The available literary evidence in anaesthesia practice indicates that levobupivacaine and ropivacaine produce comparable surgical sensory block with similar adverse side effect. To date, only few studies have been published comparing levobupivacaine and ropivacaine for the caudal block in children. Therefore, there is a need to study and compare the effectiveness of levobupivacaine and ropivacaine in the caudal block.

Methodology

Source of data

After approval from the institutional ethical committee and department this study was conducted under the department of Anaesthesiology and Critical Care.

Patient selection

Inclusion criteria

1. Children of either sex of the age 1-10 years posted for elective lower abdominal surgery.
2. ASA grade I and II.
3. Informed written consent.

Exclusion criteria

1. ASA grade III and IV.
2. Infection at the site of injection.
3. Coagulopathy or on anticoagulation therapy.
4. Congenital abnormalities of lower spine and meninges.
5. Active disease of the CNS.
6. History of allergy to local anaesthetics.

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All children that meet inclusion criteria will be randomized into two groups. (Group L and Group R)

Pre-anaesthetic assessment

All patients were visited on the pre-operative day and a detailed general physical examination, systemic examination including airway and spine examination was done. Baseline parameters like heart rate, blood pressure were noted. Relevant laboratory investigations were done. Informed consent was obtained from the parent. All children were secured with appropriate size intravenous cannula, a day prior to surgery.

Laboratory Investigations

Investigations included routine blood counts, Hb%, total count, differential count, random blood sugar, blood urea, serum creatinine, HIV, HbsAg, coagulation profile which included bleeding time, clotting time and platelet count.

Plan of study

In this randomized, prospective, double blind, single hospital study ninety (90) paediatric patients aged 1 to 10 years undergoing lower abdominal surgery were enrolled. Twenty three patients were excluded as they did not meet the inclusion criteria and seven patients refused to participate. This study was conducted on 60 patients undergoing lower abdominal surgeries.

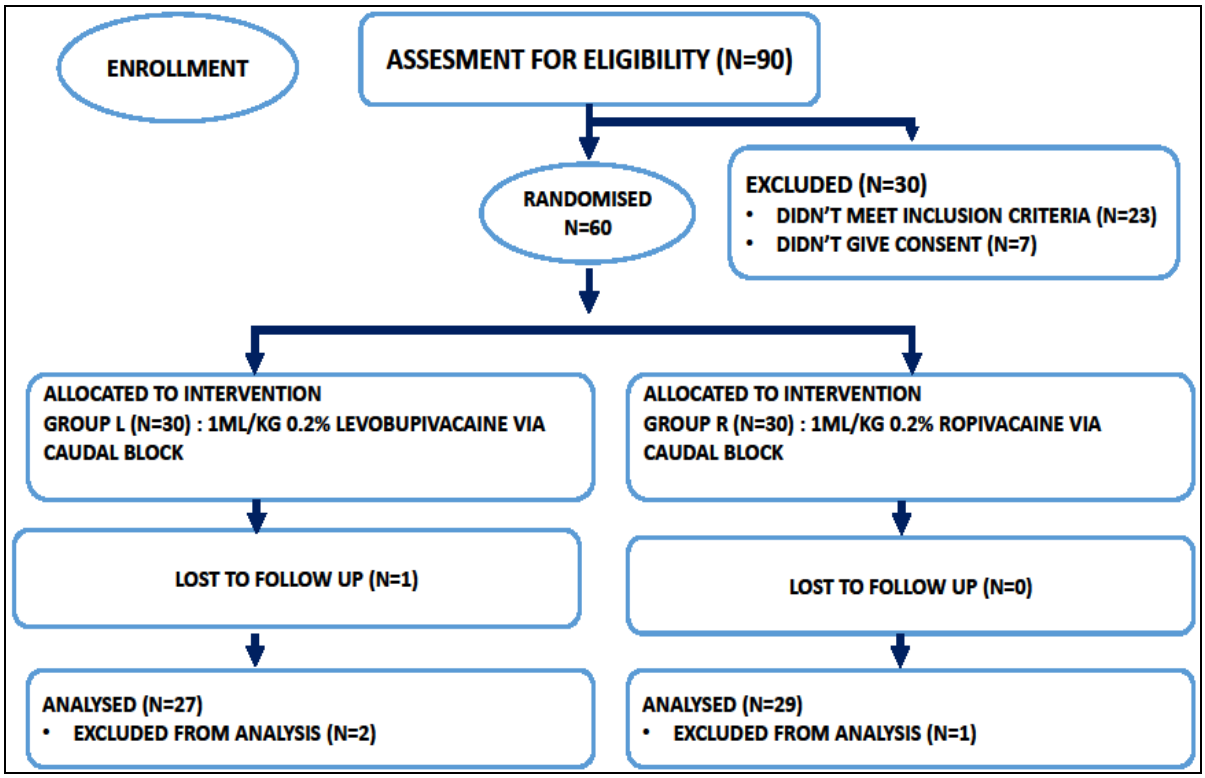

Fig 1: Consort Diagram of Study

Method of collection of data (including sampling procedures if any)

After institutional ethical committee approval, a double blind randomized prospective study

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was conducted on 60 patients including both sex, aged between 1 to 10 years undergoing elective lower abdominal surgeries. Study population was divided into two groups (Group L and Group R) using online block randomizer with 30 patients in each group and informed written consent of the guardian was taken. Details of group and the drug to be given were sealed within envelopes, which were randomly picked up and the drug was administered by the trained anaesthesiologist according to the randomization sequence. The randomization sequence was computer generated and prepared in double blind manner. If the child was enrolled and did not undergo surgery, the child and the randomization assignment were replaced. The study blinding was broken after statistical analysis.

- **Group L** received 1ml/kg of 0.2% levobupivacaine through caudal block
- **Group R** received 1ml/kg of 0.2% ropivacaine through caudal block.

These children were subjected to various surgical procedures like herniotomy, circumcision hypospadias repair, cystoscopy assisted fulguration and orchidopexy. Depending upon the type and duration of procedure, the assessment of post-operative pain was done by a blinded person in paediatric surgery ward using Children's and Infant's Postoperative Pain Scale (CHIPPS) as per Breschan C *et al*.

Results

When mean pain scores (assessed by CHIPPS) between the two groups were compared in postoperative period, scores were comparable in groups till 24 hours and hence differences in pain scores were insignificant at all time intervals as shown below in table no 9.10 and graph 9.10, (*p*-value > 0.05).

Table 1: Pain scores at different time intervals in group L and Group R

Time interval in hour	**Group L**	**Group R**	***p* value**
	Mean ± SD	**Mean ± SD**	
1hr	**5±0**	**5±0**	
2hr	5.07±0.26	5.27±0.45	0.05
3hr	6.22±0.57	6.17±0.92	0.81
4hr	7.55±0.64	7.41±1.21	0.59
5hr	9.29±0.77	9.65±0.85	0.10
6hr	11.22±0.93	11.65±0.85	0.07
9hr	12.07±0.87	12.27±0.75	0.35
12hr	12.51±1.01	12.93±0.65	0.07
18hr	12.44±1.21	12.86±0.99	0.16
24hr	12.44±0.93	12.58±0.98	0.58

As postoperative pain is assessed by ordinal pain scale we also compared median pain scores between two groups at all intervals and they were comparable. Median *p*- value >0.05 which is statistically insignificant.

Table 2: Median pain scores of group L and group R

Time interval	**Group L**	**Group R**	**Median *p*- value**
1HR	5	5	0.89
2HR	5	5	
3HR	6	6	
4HR	7	8	

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5HR	9	9	
6HR	11	11	

9HR	12	12	
12HR	13	13	
18HR	12	13	
24HR	13	13	

The mean postoperative duration of analgesia was 321.37 ± 24.25 minutes in group L and 309.75 ±23.68 minutes in group R. The difference in the mean duration of analgesia was statistically insignificant (*p* -value was > 0.05 at all specified intervals).

Table 3: Rescue Analgesia

	Group L	**Group R**	***p* -value**
	Mean ± SD	**Mean ± SD**	
Rescue analgesia	321.37 ±24.25	309.75±23.68	0.076

Sedation scores

Mean postoperative sedation scores were comparable in both the groups at all-time intervals.

Table 4: Sedation score of both the groups

Time interval	**Group L**	**Group R**	***p*-value**
	Mean ±SD	**Mean ± SD**	
1 HR	1.92±0.26	1.86±0.35	0.449
2 HR	2.14±0.36	2	0.032
3 HR	3	2.37±0.56	<0.001
4 HR	3.92±0.26	3.79±0.49	0.219
5 HR	4	3.86±0.35	0.046
6 HR	4	4	
9 HR	4	4	
12 HR	4	4	
18 HR	4	4	
24 HR	4	4	

Median postoperative sedation scores were compared between both the groups. The *p*- value > 0.05 which is statistically insignificant.

Table 5: Median postoperative sedation scores of group L and group R

Time interval	**Group L**	**Group R**	**Median *P-value***
1HR	2	2	0.80
2HR	2	2	
3HR	3	2	
4HR	4	4	
5HR	4	4	
6HR	4	4	
9HR	4	4	

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12HR	4	4	
18HR	4	4	
24HR	4	4	

Discussion

In our study, we found that the mean postoperative duration of analgesia was 321.37 ± 24.25 minutes in group L and 309.75 ± 23.68 minutes in group R (*p value*-0.076). Thus, there is no differences in duration of analgesia between both these drugs at the concentration used by us. Our study results are similar to that of Breschan C *et al*. [7] wherein they studied the analgesic duration of levobupivacaine, ropivacaine in 182 paediatric patients aged 1-7 years undergoing caudal block for lower abdominal surgeries using same concentration and dose of drugs as in our study. They also used bupivacaine in another group. Children received caudal epidural either with 1 ml/kg levobupivacaine 0.2% (Group L) or 1 ml/kg ropivacaine 0.2% (Group R) or 1 ml/kg bupivacaine 0.2% (Group B) and the duration of postoperative analgesia was 345 ± 39 min in Group L, 342 ± 48 min in Group R and 321 ± 78 in Group B. It is noted that the duration of postoperative analgesia of all these three agents were similar. Cardio toxicity and neurotoxicity of bupivacaine has led to more use of ropivacaine and levobupivacaine in clinical practice. Although, earlier investigators have used bupivacaine, we used levobupivacaine and ropivacaine. The motor blocking property of bupivacaine is more than that of ropivacaine and levobupivacaine at equipotent dosage. As postoperative residual motor blockade is not desirable in general, both levobupivacaine and ropivacaine are gaining popularity. This was the reason behind using levobupivacaine and ropivacaine in our study.

Our study also concurs with the studies done by Ivani G *et al*. [8] and Praveen P *et al*. [5] for various types of lower abdominal surgeries under caudal epidural block, where the authors found that the mean duration of analgesia was similar between patients receiving either levobupivacaine or ropivacaine.

Although the duration of analgesia was comparable between levobupivacaine and ropivacaine, the duration of analgesia observed in our study was higher than that of Uma Soujanya S *et al*. [9] and Astuto M *et al*. [10] In both of these studies, authors have used 0.25% levobupivacaine and ropivacaine in a dose of 1 ml/kg via caudal epidural for children aged less than 10 years undergoing elective lower abdominal surgeries.

The duration of postoperative analgesia observed by Uma Soujanya S *et al*. [9] was 273.5 ± 48.53 min with levobupivacaine and 255.50 ± 41.89 min with ropivacaine. As authors have used a concentration that is higher than that used by us, the shorter duration of analgesia is a striking finding. It is noteworthy that Uma Soujanya *et al*. [9] used FLACC scale (score >4) to define duration of analgesia, whereas we used CHIPPS (score >10) scale. Even after extensive literature search, we could not retrieve any study that compared both these scales. Therefore, the intensity observed by one scale may not be extrapolated to the other. We postulate that, this may be one of the reasons for this observed discrepancy in duration of analgesia.

Astuto M *et al*., reported that the duration of postoperative analgesia was 302 ± 29 min in group L and 230 ± 38 min in group R. Similar to the study by Uma Soujanya *et al*., they used 1ml/kg of 0.25% levobupivacine and ropivacaine via caudal epidural. This difference may be due to use of CHEOPS (Children's Hospital Eastern Ontario Pain Scale) for postoperative pain assessment.

However, in contrast to the study done by Locatelli *et al*. [11], in which the authors found lesser duration of postoperative analgesia with 1ml/kg of 0.25% levobupivacaine and 1ml/kg of 0.25% ropivacaine (150 ± 5.8 min levobupivacaine group and 142 ± 6.2 min ropivacaine group). The reported duration of analgesia in the study by Locatelli *et al*. [11] is substantially shorter than those in Breschan C *et al*. [7] and Praveen P *et al*. [5], Uma Soujanya S *et al*. [9] and our study despite using the similar pain assessment scale (CHIPPS). It is noted that Astuto and colleagues have used different volumes of local anaesthetic for different surgeries like

circumcision (0.5 ml/kg), orchidopexy (1 ml/kg) and inguinal hernia repair (1 ml/kg). So the differences of volume of local anaesthetics used for different surgeries may be the cause of decreased duration of postoperative analgesia. Further studies are needed to clarify this issue [12].

Conclusion

Postoperative pain scores of the children receiving levobupivacaine and ropivacaine were comparable at all pre-specified time intervals in the study. No significant difference was noted in both the study groups in terms of haemodynamics.

Also the postoperative sedation scores and motor scores were comparable at all time intervals between the levobupivacaine and the ropivacaine group. Other side effects like nausea, vomiting and urinary retention were comparable in both the study groups.

We, therefore, conclude that both levobupivacaine 0.2% and ropivacaine 0.2% are comparable in terms of duration of postoperative analgesia in paediatric patients who have undergone lower abdominal surgeries.

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