

Comparison between Efficacy of Single Dose Caudal Ropivacaine and Levobupivacaine for Post-Operative Analgesia following Infraumbilical Surgeries in Paediatric Patients

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ABSTRACT

BACKGROUND

Caudal epidural is the most commonly used technique for post-operative pain management in paediatric age group, is virtually free of measurable hemodynamic effect, thus adding a new dimension to the evolving necessity of paediatric postoperative pain management. Though levobupivacaine, ropivacaine, bupivacaine are the safer drugs and the addition of fentanyl increases the effective duration of analgesia. Our present study was designed to compare the efficacy of single dose caudal ropivacaine and levobupivacaine for postoperative analgesia following infraumbilical surgeries in paediatric patient.

METHODS

Sixty children in total, aged between 1 yr. and 10 yrs. of ASA 1 & 2, posted for infraumbilical surgeries were included in the study. Written consent was obtained from parents of the children. Children were divided into 2 equal groups for the study. Group (R) received Ropivacaine 0.25%, 1 ml/kg and Group (L) received Levobupivacaine 0.25% 1 ml/kg. Assessment of pain was done using CHIPPS score and duration of motor blockade in term of modified Bromage scale was also noted and basic parameters like SBP, MAP, HR, SPO₂, were monitored intra-operatively.

RESULTS

The two groups were comparable in term of demographic characteristics. Haemodynamic status in patients in both groups was equally stable intra operatively, Duration of post-operative analgesia was almost similar in both the groups (R=306+-15.509 MIN, L=305+-18.633 MIN, P=.553). In both the groups no residual motor loss persisted postoperatively. Requirement of total dose of rescue analgesic was also similar in both groups. No group showed any significant side effects.

CONCLUSIONS

In children caudal administration of Ropivacaine and Levobupivacaine provides comparable postoperative analgesia., without motor paralysis, allows early ambulation and discharge following short infra umbilical surgeries in paediatric age.

KEY WORDS

Caudal Anaesthesia, Ropivacaine, Levobupivacaine

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BACKGROUND

The management of intraoperative and post-operative pain in paediatric patients can be accomplished by using multimodal approach. Various pharmacological methods to treat pain include Paracetamol, Nonsteroidal anti-inflammatory drugs (NSAIDS), Opioids, and Neuraxial or Regional local anaesthetics. Neuraxial blocks are particularly well tolerated in paediatric population and regional analgesia is now the preferred technique for postoperative pain management in this group. Caudal epidural is commonly used regional technique for infraumbilical surgery in children which provides pain relief both in intraoperative and postoperative period. Caudal block is one of the simplest and safest techniques in paediatric surgery with high success rate¹. Lower pain score has been observed with caudal block when combined with general anaesthesia than with general anaesthesia alone. Caudal block combined with general anaesthesia can reduce the amount of inhaled and intravenous anaesthetic agents, attenuate the stress response of surgery, facilitates rapid and smooth recovery with minimal postoperative vomiting providing good postoperative analgesia². Caudal block results in sensory analgesia, motor block and sympathetic block depending on the concentration, dose and volume of local anaesthetics. Complications are rare, about 1 case per 1000 procedures, and usually minor³. Single dose caudal block with local anaesthetics has been used safely and effectively in paediatric surgical procedures for provision of post-operative analgesia. Caudal epidural technique is well tolerated in paediatric population when combined with GA to suppress pain response in post-operative period.

Several local anaesthetic agents are in use to produce neuraxial block. Levobupivacaine is the pure S (-) enantiomer of Bupivacaine. Pharmacological studies demonstrated less affinity for and less degree of depressant effects on myocardium and vital centres in the brain having a superior pharmacokinetic profile. Clinically, levobupivacaine is well tolerated in a variety of regional anaesthesia technique after bolus administration.

Ropivacaine which is prepared from S(-) enantiomer also reported to have better safety profile than Bupivacaine, with less cardiotoxicity and less risk to CNS. Pharmacological studies have demonstrated the safety of caudal ropivacaine in children which have shown to be as effective as bupivacaine.^{4,5,6,7} Both the drugs have shown less extensive and shorter duration of motor block compared to racemic bupivacaine.^{5,8}

This present study was carried out to observe which one of the two local anaesthetic agents give prolonged analgesia with less residual motor block with same amount of drug of same concentration in paediatric patients undergoing infraumbilical surgeries.

METHODS

The present study was conducted at M.K.C.G. Medical Collage and Hospital after obtaining clearance from institutional ethical committee & scientific committee. This randomized double blind study is having 60 children of either sex, aged

between 1 year to 10 years of American Society of Anaesthesiologists physical Status (ASA) I and II, posted for infraumbilical surgeries the procedures include inguinal hernia repair, orchidopexy, hypospadias correction, urethroplasty, any orthopaedic surgeries in lower limbs with an anticipated duration of less than 90 minutes. Written informed consent was taken from the parents of the children. Children were divided into two equal groups for the study. Children having known hypersensitivity to amide local anaesthetics, known active co-morbid conditions like cardiorespiratory, renal, hepatic, neurological, neuromuscular disorder, cutaneous infection at the site of caudal injection, blood clotting disorders & blood dyscrasias, platelet count < 100000/ cumm. and all emergency surgeries were excluded.

By using double blind randomized control design these children were divided into two groups as group R and L. Group (R) with 30 children received Ropivacaine 0.25% 1 ml/kg and Group (L) with 30 children received Levobupivacaine 0.25% 1 ml/kg.

Children were administered general anaesthesia and after intubation caudal anaesthesia was administered with either of the study drugs. Patients were received at operation theatre, patients NPO status and Consent was verified and general anaesthesia was induced by 100% O₂ and increasing dial concentration of Sevoflurane up to 4- 6 MAC through the appropriate paediatric mask using Jackson-Rees modification of Ayre's T-piece. All the monitor attachments were made subsequently to record vital parameters. Intravenous access was secured using a 22G or 24G I.V. cannula as appropriate for the child's and baseline hemodynamic parameters were noted. Injection Glycopyrrolate 10 µg/kg and inj. Pentazocine 0.5 mg/kg was given intravenously and tracheal intubation was done with appropriate size of uncuffed PVC endotracheal tube by increasing dial concentration of Sevoflurane up to 5-8 MAC. Anaesthesia was maintained by using N₂O:O₂=3:2 and intermittent Sevoflurane of 0.2-3 MAC using IPPV through-Jackson Rees modification of Ayre's T-piece. Caudal block was then performed under strict aseptic condition. Patient was turned to left lateral position. After confirming the sacral hiatus, the puncture was performed with a sterile disposable hypodermic needle of size 22G or 23G. The syringe filled with the calculated dose of study drug was then attached to the hub of the needle and gentle aspiration was performed, if no blood or CSF was aspirated, then only either of the study drugs was injected in small increments with repeated aspiration test random numbers. Group R received Inj. Ropivacaine 0.25% 1 ml/kg and group L received Inj. Levobupivacaine 0.25% 1 ml/kg. The anaesthesiologist who performed the procedure was unaware of the drug he/she administered. At the end of the procedure the point of puncture was covered with antiseptic dressing. The end point of administering caudal block was noted as 0 min. Patient was turned supine and positioned for surgery. Anaesthesia was maintained using N₂O:O₂ =3:2 ratio and intermittent Sevoflurane of 0.2-3MAC using IPPV through-Jackson Rees modification of Ayre's T-piece. The hemodynamic parameters were continuously monitored during intraoperative period. After completion of the procedure child was reversed from general anaesthesia by discontinuing inhalation agent Sevoflurane, after thorough suctioning of oral cavity and oropharynx was done and the child was extubated when

protective airway reflexes returned. Patients were observed postoperatively in post anaesthesia care area with monitoring of HR and SpO₂ before sending to ward. In the ward the degree of pain was assessed by CHIPPS scale hourly till score was >4 or first requirement of rescue analgesic. The motor blockade was assessed by Bromage Scale till it is 0. Inj. Fentanyl 1.5-2 µgm/kg was administered intravenous as rescue analgesic at dose of 0.5 µ/kg body weight once pain score >4. Time of requirement of 1st rescue analgesic and total dose of analgesic consumption were noted.

Statistical Analysis

Statistical analysis was done using statistical package for social sciences (SPSS) software version 22. Sample size calculation was done with PS power and sample size calculations version 3.1.2. Haemodynamic variables were compared between two groups by Mann Whitney U test. Unpaired Students' t-test was used to compare normally distributed numerical variables such as age and body weight. Categorical variables were compared with Chi-square test or Fishers' exact test, wherever applicable. A p<0.05 was taken to be statistically significant.

RESULTS

Parameters	Group R	Group L	p Value	Significance
Age (months)	33.00±17.147	34.50±16.387	.684	NS
Sex	M	22	.347	NS
	F	8		
Weight (kg)	14.73±3.047	14.43±2.242	.665	NS

Table 1. Demographic Data

Type of Surgery	Group R	Group L
Urethroplasty	5	4
Herniotomy	11	8
Orchidopexy	7	7
Orthopaedic Operations in Lower Limbs	3	3
Circumcision	2	5
Eversion of Sac of Hydrocele	2	3

Table 2. Distribution of Type of Surgery Performed

CHIPPS Score	Group R	Group L	p Value
C60	1.5±0.878	1 ±0.798	0.992
C120	2±0.379	2±0.479	0.992
C180	2±0	2±0	0.992
C240	3±0	3±0	0.833
C300	4±0.498	4±0.479	0.896

Table 3. Post-Operative Pain Scoring

Parameters	Group R	Group L	p Value	Significance
Time of First Rescue Analgesia	306 ± 15.509	305 ± 18.633	.553	NS
Total Dose of Fentanyl	14.73 ± 3.307	15.5 ± 2.596	.652	NS

Table 4. Time of First Rescue Analgesia

	Nausea & Vomiting	Bradycardia	Hypotension	Respiratory Depression	Urinary Retention
Group R	4	0	0	0	2
Group L	4	0	0	0	3

Table 5. Side Effects Observed

The two groups were comparable with respect to age, sex and weight (Table 1).The types of surgery and the duration of surgeries in both the groups were comparable (Table 2). The postoperative pain (table 3) use of rescue analgesia as fentanyl for the first time and the total dose of fentanyl used as analgesia (table 4) were comparable in both the groups without any significant changes. Only few children had nausea and vomiting, some had retention of urine (table 5).

No other complications seen in either of the groups. Table 3 shows changes in Children & Infants Postoperative Pain Scale score in postoperative periods in two groups. CHIPPS scores were almost similar in both the groups at different times in postoperative period. The differences in mean scores after 60 minutes following caudal injection up to 300 minutes following caudal injection were not statistically significant (Students independent t-test, P>0.05)

DISCUSSION

Pain is one of the most unpleasant sensations experienced by human beings. As children have well developed pain pathways & are more vulnerable to adverse physiological effect of pain, postoperative pain relief in paediatric patients is as important as in adults. Various medications & techniques are used to control postoperative pain. The advent of regional anaesthesia has added a new dimension to the postoperative pain management even in paediatric populations. Caudal epidural is one of the regional techniques that have been widely accepted over the last few years in the field of paediatric anaesthesia.⁴ The wide acceptance of this procedure is due to easier administration of the technique and extent of safety and tolerance⁵ The sympathetic immaturity, diminished autonomic adaptability of the heart and smaller vascular bed in the lower extremities provide excellent hemodynamic stability during neuraxial block in paediatric patients. Usually preloading with fluid and use of vasoactive agent are not required. So caudal epidural block is commonly used to supplement general anaesthesia with reduced requirement of anaesthetic agents along with good postoperative pain relief.

Similarly, the discovery of newer generation of highly efficacious and relatively safe group of local anaesthetic agents has begun a new era in the domain of postoperative analgesia. Though bupivacaine is the most widely used local anaesthetic since its discovery, it is associated with cardiac and central nervous system toxicity. Newer

Drugs like ropivacaine and levobupivacaine are gaining popularity due to lesser cardiotoxicity, lesser motor blockade & similar degree of analgesia with equipotent dose of bupivacaine.^{5,6,7} Previous studies published compared caudal bupivacaine with either levobupivacaine or ropivacaine.^{5,6,7} Till date only few studies have been published comparing analgesic efficacy of two new drugs levobupivacaine with ropivacaine

The present study was designed to determine & compare the duration of analgesia with single dose caudal 0.25 ropivacaine at 1 ml/kg body weight to same dose of 0.25% levobupivacaine in infraumbilical surgeries in children. Caudal block administered after induction of general anaesthesia with Sevoflurane with endotracheal intubation without muscle relaxant. Anaesthesia was maintained with O₂, NO₂ and sevoflurane. Postoperative pain was assessed by CHIPPS scale and duration of analgesia was obtained by noting the time of first rescue analgesia. Perioperative haemodynamic changes, residual motor block and any obvious side effects like nausea-vomiting, respiratory depression, retention of urine were also taken into consideration.

Clinically the demographic parameters were almost similar with no statistically significant difference between the groups in terms of age, sex, and body weight. Hence the groups were comparable with respect to demographic characteristics & the effect of these parameters on drug effect were equal in both groups. Difference in duration of surgery between the two groups were not statistically significant. It is evident that the intraoperative hemodynamic profile, which is an indirect indicator of intra and postoperative pain, is well maintained with ropivacaine as compared to levobupivacaine.

Children and Infants Postoperative Pain Scale score in postoperative periods in two groups. CHIPPS score were almost similar in both the groups at different times in postoperative periods. The differences in mean score after 60 minutes following caudal injection up to 300 minutes following caudal injection were not statistically significant.

The use of first rescue analgesia after caudal block as inj. fentanyl in both the groups is also not significant. We also noted that only few children had nausea and vomiting, and some had retention of urine in both the groups.

Ingelmo P et al in 2009⁽⁹⁾ performed a study to determine the minimum local analgesic concentrations of a caudal single shot of ropivacaine and levobupivacaine in children and to describe the upper dose response curve. CHIPPS scores assessed at 10 min intervals up to 60 min after awakening were not significantly different between drugs (Kruskal-Wallis rank test $P = 0.34, 0.78, 0.57, 0.45, 0.67, 0.57$ respectively).

M. Astuto et al.¹⁰ compared the onset, intra operative tolerance, post-operative analgesic effect, motor blockade & any adverse reaction produced by single dose of Levobupivacaine with Ropivacaine by caudal route. During the first 4 hour after placement of caudal block, the pain assessment score according to the Children Hospital Eastern Ontario Pain Scale (CHEOPS) was comparable for the two groups.

Christian Breschan et al.¹¹ compared postoperative analgesic efficacy, analgesic duration and motor blockade of levobupivacaine, ropivacaine and bupivacaine administered caudally in equal concentrations to children undergoing elective minor surgery in a study. Postoperative pain scoring evaluated with Children's and Infant's Postoperative Pain Scale (CHIPPS) scale showed no statistical difference between groups.

Biswas S, et al.⁽¹²⁾ in 2013 compared post-operative analgesic efficacy of a single dose administration of caudal Levobupivacaine (0.25%) vs Ropivacaine (0.25%) in children undergoing elective infra umbilical surgeries with anticipated duration of surgery of less than 90 minutes and they found both the drugs having same efficacy. B. Locatelli et al.¹³ compared post-operative analgesic efficacy of 0.25% Levobupivacaine, 0.25% Ropivacaine & 0.25% Bupivacaine by caudal route and post-operative pain was evaluated using the Children and Infants Postoperative Pain Scale (CHIPPS) which was comparable. G. Ivani et al.¹⁴ investigated the issue comparing equal concentrations (0.2%) of ropivacaine and 0.2% of levobupivacaine in children undergoing minor subumbilical surgery. During the 24-h observation period CHIPPS scores were almost identical for the two study groups. In our study the time period for first rescue analgesia was approximately equal in both the groups. The present

study thus corroborates the findings of previous studies, that ropivacaine has equipotent analgesic activity as levobupivacaine, when given caudally. No residual motor block was observed in our study in any of the groups in immediate postoperative period. Thus, present study corroborates the findings of previous studies.

CONCLUSIONS

In children caudal administration of Ropivacaine and Levobupivacaine provides similar and comparable postoperative analgesia, without motor paralysis, allowing early ambulation & discharge following short infra-umbilical surgeries. Further studies are needed to establish these facts.

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