Caudal Epidural Analgesia in Paediatric Patients: Comparision Between Ropivacaine HCL (0.25%) and Bupivacaine Hcl (0.25%)

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ABSTRACT
BACKGROUND: To compare Ropivacaine HCL with Bupivacaine HCL for duration of peri-operative analgesia, haemodynamic parameters and complication in caudal epidural block in paediatric patients.

METHODS AND MATERIALS: In prospective randomized clinical study, 60 patients of ASA I or II, aged 3-8 years undergoing sub-umbilical surgeries were randomly allocated in two groups to receive 0.75 ml/kg of either (0.25%) Ropivacaine HCL (Group-R) or (0.25%) Bupivacaine HCL (Group-B) for caudal epidural block. Block was performed after induction of anaesthesia. Post-operatively, pain relief was assessed with the help of Hannallah’s subjective pain score. Requirement of first rescue analgesic and duration of peri-operative analgesia were monitored.

RESULTS: Total duration of peri-operative analgesia was significantly prolonged in Ropivacaine group compared to Bupivacaine group i.e. 455.16±45.13 minutes in Ropivacaine group patients as compared to 289±46.09 minutes in Bupivacaine group patients (p<0.001). Hannallah’s subjective pain score was significantly lower in Ropivacaine group patients compared to Bupivacaine group patients (p<0.001). There were no significant difference in haemodynamic parameters and no side-effects were noticed in both the groups.

CONCLUSION: Ropivacaine provides prolonged peri-operative analgesia with stable haemodynamics with wider margin of safety in comparison to Bupivacaine for caudal epidural analgesia in paediatric patients.

INTRODUCTION
Pain in paediatric age group has some additional problems compared to adults, like inability of the children to express pain properly, difficulty in assessing pain & its treatment, increase peri-operative morbidity and mortality and effects of unrelieved pain on child’s psychology, behaviour & development. Currently, paediatric pain relief is recognised as a very important issue all over the world. There is no place for minimal anaesthesia in paediatric age group. The selected technique should provide not only intra-operative analgesia but also post-operative analgesia which is now being considered as the 5th Parameter among the vital signs and without its treatment, it may cause significant increase in morbidity apart from personal discomfort. There have been various methods described for providing post-operative analgesia in paediatric age group like drugs like NSAIDS and opioids and regional anaesthetic technique like infiltration and neuroaxial block, each with its own advantages and disadvantages. Out of these, caudal epidural anaesthesia is a useful adjunct to general anaesthesia for lower abdominal surgery in children as it is safe, simple, effective technique, reduces intra-operative general anesthetic drugs and inhalational agent requirement, provides hemodynamic stability, early recovery of airway reflexes and contributes to comfortable awakening with post-operative analgesia. With these background, the study was carried out to evaluate and to compare Ropivacaine HCL with Bupivacaine HCL for duration of peri-operative analgesia, Hemodynamic parameters and complication in caudal epidural block for lower abdominal surgery in pediatric patients.

MATERIALS AND METHODS
After IRB approval and informed written consent from parents this prospective, randomized, double blinded study was conducted in sixty patients, aged 3-8 year of either sex with ASA physical status I & II.
scheduled for elective lower abdominal surgeries. After through pre anaesthetic evaluation, patients with hypersensitivity to local anesthetics, abnormal sacrum anatomy, bleeding diathesis, pre-existing neurological or psychological abnormalities, neuromuscular disease and local sepsis were excluded from the study. Patients were kept nil by mouth (6 hrs for solid foods and 2 hrs for clear fluids) prior to surgery. Monitoring consisting of heart rate, non invasive blood pressure and peripheral oxygen saturation was applied and baseline vitals were recorded in pre anaesthetic preparation room. Premedication in the form of glycopyrrolate-20microgram/kg and midazolam 0.5 mg/kg (added to 1-2 cc of 25% dextrose to make the drug palatable) was given orally 45 minutes before surgery. Patients were randomly allocated to one of the following two groups: Group- R : (n = 30) - Patients received Inj. Ropivacaine hydrochloride 0.25% (0.75ml/kg) and Group- B : (n = 30) - Patients received -Inj. Bupivacaine Hydrochloride 0.25%(0.75ml/kg). After 45 minutes of premedication, sedation was rated as per the sedation score (Table 1) and vital parameters were recorded. In operation theatre, after securing peripheral venous canulation and starting injection Isolyte P according to weight of the patient, anaesthesia was induced with Inj. Thiopentone sodium (2.5%) 5-7 mg/kg slowly intravenously till loss of eyelash reflex; followed by Inj. Succinyl choline 2mg/kg intravenously for intubation. Intubation was done with appropriate sized oral; PVC; endotracheal tube. After confirming the intubation and securing the tube in place, patients were placed in left lateral position. A short bevelled 24 G 1.5 inch hypodermic sterile needle was introduced in caudal epidural space under all aseptic precautions and0.75 ml/kg of local anaesthetic agent was injected as per the group assigned. After deposition of drug in caudal epidural space, patients were placed in supine position. Anaesthesia was maintained by oxygen+nitrous oxide + sevoflurane and top up doses of vecuronium bromide (0.1 mg/kg body weight loading dose followed by 0.025 mg/kg supplemented SOS). Vital parameters were monitored at the interval of 5 min. initially and then every 15 min throughout intra operative period. No additional analgesic medications were given during pre-operative; intra-operative or post operative period. At the end of surgery, residual neuromuscular blockade was reversed with Inj. Neostigmine (50ug/kg) and Inj. Glycopyrrolate (10ug/kg) and patients were extubated. Post operatively, patients were transferred to post anaesthesia care unit and observed for vital parameters at every 15 min. for 1st hour and then hourly till objective HANALLAH’S pain score was >4 (Table 2). When the score was 4 or more on the pain scale, rescue analgesia was administered in the form of Inj. PARACETAMOL 5 mg/kg intravenously; total duration of peri-operative analgesia (Time from caudal epidural drug administration to time of requirement of rescue analgesia.) was recorded and study was terminated. Patients were also observed peri-operatively for any complication like pyrexia, respiratory depression (RR<10), sedation, bradycardia, nausea/vomiting, hypotension, urinary retention and neurological deficit.

**Table 1: Sedation Score**

<table>
<thead>
<tr>
<th>Agitated</th>
<th>Patient clinging to parents and / or crying</th>
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<tbody>
<tr>
<td>Alert</td>
<td>Patient is aware but not clinging to parents may whimper but not cry</td>
</tr>
<tr>
<td>Calm</td>
<td>Sitting or lying comfortably with spontaneous eye opening</td>
</tr>
<tr>
<td>Drowsy</td>
<td>Sitting or lying comfortably with eye closed, but responding to minor stimulation</td>
</tr>
<tr>
<td>Asleep</td>
<td>Eyes closed,arousable but not responding minor stimulation</td>
</tr>
</tbody>
</table>
### Table 2: Hannallah’s Objective Pain Score (For post-operative pain assessment)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td>04.2±0.18</td>
<td>05.03±1.92</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Gender (Male:Female)</td>
<td>26:4 (86.66%:13.33%)</td>
<td>23:7(76.66%:23.33%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Weight (in kg)</td>
<td>12.06±3.72</td>
<td>13.98±4.27</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Duration of Surgery (min)</td>
<td>73.50±20.60</td>
<td>68.00±13.49</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

**Statistical Analysis**

The results of the study were statistically analyzed by using **CHI SQUARE TEST** for qualitative data and **PAIRED T TEST** for quantitative data. Difference between the group was significant when P value < 0.05.

**RESULTS**

**Graph 1(a): Hemodynamics Changes during Preoperative Period in Group R.**
Graph 1: Hemodynamics Changes During Perioperative Period In Group B

Graph 1A and 1B: The hemodynamics like pulse rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) and oxygen saturation were comparable to each other in both the groups (P > 0.05).

Graph 2: Hannallah’s Mean Objective Pain Score

Graph 2: Shows that Hannallah’s mean objective pain score was significantly lower in group R than group B. (P < 0.001)

Graph 3: No. of Patients Requiried Rescue Analgesia

Graph 3: Shows that requirement of rescue analgesia was much earlier in group B compared to group R.

DISCUSSION

Caudal epidural block is preferred technique for providing analgesia in paediatric patients for lower abdominal surgeries because sacral hiatus is easily palpable, cephalad spread of drug is more reliable as the epidural fat is loose and gelatinous up to 8 years of age. In our study a single shot pre operative caudal epidural block was given before surgical incision because it provides reliable and long lasting peri operative analgesia, reduces the general anaesthetic drugs requirement intra-operatively, provides early recovery of airway reflexes and comfortable awakening of paediatric patients with post operative analgesia following lower abdominal surgeries. We decided to compare the effect of 0.25% concentration of both the drugs as it appears to be the optimal concentration for paediatric caudal block as 0.5% concentration has peak plasma concentration very close to level associated with the toxicity and produce more motor block post operatively and 0.1% concentration is less effective and has shorter duration of action compared to 0.25% concentration of the drugs. The dose of the drug in our study was 0.75 ml/kg as it is adequate dose for lower abdominal surgery according to modified armitage formula. The demographic profile of the patients were comparable in both the groups. There were no statistically significant difference in both the groups with regards to ASA status of patient, duration and types of surgery and pre
operative sedation score. The technical difficulty in locating the caudal space was found in five patients but the block was performed successfully after second attempt. Other technical difficulty was subcutaneous insertion was encountered in two patients which was solved by changing the direction of needle resulted in successful block. The peri-operative hemodynamic changes, respiratory rate and mean oxygen saturation were statistically insignificant in both the groups in this study because paediatric patients have immature sympathetic system, less blood volume in lower limb capacitance vessels and splanchnic circulation with diminished autonomic adaptability of heart. These results were comparable with the result of Giorgio Ivani, Samia Khalil, Dr.Manjushree ray, Y.Gunes and J.S Tan.

The evaluation of post-operative analgesia was assessed by three parameters such as Hannallah’s objective pain score, duration of analgesia and requirement of first dose of rescue analgesia. In this study, Hanallah ’s mean objective pain score was significantly lower at 4th to 9th hours in group R compared to group B. These results were comparable with previous study done by Dr.Manjushree ray. The total duration of perioperative analgesia was 455.16 ± 45.13 min in group R and 289 ± 46.09 min in group B. Thus, ropivacaine provides prolonged duration of analgesia compared to bupivacaine in our study. These results were comparable with previous study done by Giorgio Ivani, Samia Khalil and Dr. Manjushree Ray. In group B, rescue analgesia was required from 4th hour and by the end of 6th hour all the patients received their rescue analgesic dose while in group R rescue analgesia was required from 6th hour and by the end of 9th hour all the patients received their rescue analgesic dose. Thus, the requirement of rescue analgesic dose was much earlier in group B as compared to group R in our study. These results were comparable with previous study done by Giorgio Ivani. Hence ropivacaine provides superior analgesia compared to bupivacaine. The reason for superior analgesic efficacy of ropivacaine is that it produces more profound and potent block of the A-delta and C fibers (mediating pain sensation) and has intrinsic Vasocostric activity compared to similar concentration of bupivacaine. Throughout the study, none of the patients had any significant complication like retention of urine, fever, bradycardia, hypotension sedation, neurological sequelae in both the groups. To conclude, Ropivacaine (0.25%) provides prolonged duration of analgesia and reduced requirement of rescue analgesic post operatively compared to equi concentration of Bupivacaine (0.25%). Thus, caudal Ropivacaine should be preferred over Bupivacaine for peri operative analgesia in paediatric patients.

REFERENCES