Pre-emptive caudal epidural analgesia with ropivacaine for lumbosacral spine surgery: A randomized case control study

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Abstract

**Background and Aims:** Pre-emptive analgesia using caudal epidural technique is an underutilized technique in lumbosacral spine surgery patients. We intend to study if pre-emptive analgesia with a single caudal epidural injection of ropivacaine is an effective method of postoperative analgesia by assessing the quality and duration of pain relief and intraoperative opioid requirement.

**Material and Methods:** Eighty patients undergoing lumbosacral spine surgeries by the posterior approach were randomized to ropivacaine (R) group (n = 40) and saline (S) group (n = 40). Patients in R group received caudal epidural injection of 20 ml of 0.2% ropivacaine for surgeries at or below L5 lumbar spine and 25 ml of 0.2% ropivacaine for surgeries between L2 and L5 lumbar spine. Patients in S group received similar amounts of normal saline. Patients were monitored in the immediate postoperative period and at 4, 8, 12, and 24 hours for pain using visual analogue scale (VAS) scale. Time to rescue analgesia and intraoperative fentanyl requirement were noted.

**Results:** The demographics, duration of anesthesia, and hemodynamic variables were comparable in both groups. The mean intraoperative fentanyl requirement (P = 0.001) and mean VAS scores were significantly lower in the R group in the immediate postoperative period, (P < 0.001), 4 hours (P < 0.001), 8 hours (P = 0.009), 12 hours (P = 0.007), and 24 hours (P = 0.046) postoperatively. The mean time to rescue analgesia was significantly longer in the R group (P < 0.001) compared to S group. No hemodynamic or neurological side-effects were observed in the groups.

**Conclusion:** Pre-emptive analgesia with caudal epidural injection of ropivacaine is a safe and effective method of postoperative analgesia.

**Keywords:** Analgesia, anesthesia, caudal, epidural, ropivacaine, spine, surgery

Introduction

Caudal epidural analgesia, as pre-emptive analgesia, is an underutilized technique in adult patients undergoing lumbosacral spine surgeries. Pain is transmitted through the peripheral nervous system causing plasticity of higher brain centres and resulting in pain perception that lasts even after the cessation of stimulus.[1] The exact mechanism of pre-emptive analgesia is not yet established. However, neuronal hyperexcitability mediated by upregulation of sensory neuron-specific sodium channels and vanilloid receptors, phenotypic switching of large myelinated axons, dorsal horn neuron sprouting, and loss of inhibitory neurons play a pivotal role in originating pain.[2] Epidural block before surgery acts by blocking sensory input at the spinal cord level.[3] Thus, pre-emptive analgesia has an important role in preventing the

Access this article online

Quick Response Code:  
Website: www.joaacp.org  
DOI: 10.4103/joaacp.JOACP_72_17

How to cite this article: Samagh N, Pai RK, Mathews TK, Jangra K, Varma RG. Pre-emptive caudal epidural analgesia with ropivacaine for lumbosacral spine surgery: A randomized case control study. J Anaesthesiol Clin Pharmacol 2018;34:237-41.
Single caudal epidural injection of bupivacaine with fentanyl given prior to the incision is known to be a safe and effective technique in controlling postoperative pain in lumbosacral spine surgeries. Epidural local anesthetics take approximately 20 min for fixation to spinal nerve roots and provide satisfactory pain relief for the first 24 h.

Ropivacaine is a newer, long-acting, amide local anesthetic agent which is less lipophilic than bupivacaine. There is lower penetration of ropivacaine in large myelinated motor fibres, resulting in lesser motor blockade compared to bupivacaine. This greater degree of sensory-motor differentiation could be useful in certain situations such as spine surgeries where motor blockade is unacceptable. There are various studies suggesting that ropivacaine is less cardiac and central nervous system toxic with similar duration of analgesia.

In this study, we intend to evaluate if pre-emptive analgesia with a single bolus dose of caudal epidural ropivacaine is a safe and effective method of postoperative analgesia. The primary outcome of the study was to assess the quality of pain relief [mean visual analogue scale (VAS)] with the use of ropivacaine. The secondary outcomes were duration of pain relief (time to rescue analgesia), intraoperative fentanyl requirement, and to assess the adverse events of this technique.

Material and Methods

This double-blind, case-control study was conducted among 80 patients who were randomly divided into two equal groups of 40 patients each. Sample size was determined based on the previous study and calculated on the basis of VAS Score. We expected to find the difference of 10% between the groups, and to achieve a power of 95% and confidence interval of 95%, sample size was calculated to be 35 in each group. It was decided to include additional participants for possible dropouts and for a reasonable number; finally, 40 participants were included in each group. The study was commenced after obtaining Institutional Ethics Committee approval (Reference no. STD-1/09) and written informed consent from the patients.

We enrolled patients undergoing surgeries of lumbosacral spine by the posterior approach, including discectomy, laminectomy, and laminotomy with or without instrumentation. Patients who had hypersensitivity to ropivacaine and those with anomalies of sacral anatomy were excluded. Patients were randomly enrolled into two groups; ropivacaine (R) group (received 20 ml of 0.2% ropivacaine for surgeries at or below L5 lumbar spine and 25 ml of 0.2% ropivacaine for surgeries between L2 and L5 lumbar spine based on the formula provided by Southworth et al.) and saline (S) group (received 20 ml of normal saline for surgeries at or below L5 lumbar spine and 25 ml of normal saline for surgeries between L2 and L5 lumbar spine). Randomization was done using computer-generated random number table. The random numbers were then kept in opaque sealed envelopes numbered sequentially which were opened by the attending anesthesiologist just before shifting the patient inside the operation theatre. The drugs were prepared in identical syringes and infused with the label of the test drug. The anesthesiologist who prepared and administered the drug was not involved in data collection. A blinded investigator, who was not part of intraoperative patient care, collected the data during the postoperative period.

All patients were made familiar with the VAS for pain assessment during the preoperative visit. The standard American Society of Anesthesiologists (ASA) monitoring, including electrocardiography, noninvasive blood pressure, pulse oximetry, and endtidal carbon dioxide, were applied and measurements were noted intraoperatively at various steps, including preinduction, induction, postintubation, time of incision, and then at 15-min intervals till the time of completion of surgery. Patient’s vitals were monitored for half an hour after the surgery. Anesthesia was induced with injection fentanyl 2 mcg/kg, injection propofol in titrated dosages till loss of consciousness, and injection vecuronium 100 mcg/kg or injection atracurium 0.5 mg/kg was used to facilitate intubation. Patients were given caudal epidural analgesia after they had been positioned for surgery in the prone position. Position of needle 21-Guage Quincke’s spinal needle in the epidural space was confirmed using Swoosh test (injection of 5 ml of normal saline or local anesthetic through the needle in caudal space and auscultation over the thoracolumbar spine with a stethoscope). Accurate placement of the needle was also confirmed with fluoroscopy or image intensifier by locating the tip of the needle with respect to bony landmarks and the drug was injected into the epidural space. The time elapsed between caudal epidural injection and surgical incision was kept more than 20 min in both the groups to allow adequate fixation of the drug. Patients were maintained on oxygen, nitrous oxide (50:50), isoflurane, and intermittent boluses of muscle relaxants. Injection paracetamol 1 g was given 1 h before the anticipated completion of surgical procedure. Neuromuscular blocking agent was reversed with the neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg, and patients were extubated after the return of consciousness and muscle power. Patients were monitored for postoperative pain during the immediate postoperative period, and subsequently at 4, 8, 12, and 24 hours. All patients having VAS of more than 3 were given rescue analgesic in the form of 75 mg of
injection diclofenac as an intravenous infusion. The time to the demand of first dose of supplemental analgesic medication by the patient during the postoperative period was recorded. Any complications and adverse drug reactions were noted.

**Statistical analysis**

Statistical Package for Social Sciences (SPSS, V 10.5) was used to analyze the data. Continuous data and numbers were averaged (mean ± standard deviation) and percentage for dichotomous data were presented in Tables and Figures. Proportion was compared using Chi-square test of significance. The parameters of the R and S Groups were compared using Student’s t-test. P values of less than 0.05 were considered statistically significant.

**Results**

The demographics, type of surgery, and duration of anesthesia between the two groups were comparable. The mean heart rate, mean systolic and diastolic blood pressure, and oxygen saturation were comparable among the two groups at different time periods [Figures 1-3].

The mean intraoperative fentanyl requirement per kg body weight was significantly lower in the R group (2.07 ± 0.54 mcg/kg) compared to the S group (2.59 ± 0.77 mcg/kg) \((P = 0.001)\) [Table 1]. We found significantly lower values of mean VAS in the R group during the immediate postoperative period \((P < 0.001)\), 4 hours \((P < 0.001)\), 8 hours \((P = 0.009)\), 12 hours \((P = 0.007)\), and 24 hours \((P = 0.046)\) after the surgery [Figure 4]. The mean time elapse to the first demand of rescue analgesia was significantly longer in the R group (8.15 ± 4.73 h) compared to the S group (1.65 ± 2.51 h) \((P < 0.001)\).

All patients as per our hospital protocol were mobilized at 24 h postoperatively. No procedure-related complication was observed. No neurological side effects were observed during the follow-up period.

![Comparison of mean heart rate at different time points between ropivacaine and saline groups](image1)

![Comparison of mean systolic blood pressure at different time points between ropivacaine and saline groups](image2)

![Comparison of mean diastolic blood pressure at different time points between ropivacaine and saline groups](image3)

![Comparison of mean visual analogue scale at different time points between ropivacaine and saline groups](image4)
Table 1: Demographic data and analgesia requirement

| Parameters                        | Ropivacaine group (mean±SD) | Saline group (mean±SD) | P  |
|-----------------------------------|-----------------------------|------------------------|----|
| Age (years)                       | 47.30±13.87                 | 44.15±13.65            | 0.31|
| Height (in cm)                    | 167.23±6.36                 | 165.70±6.68            | 0.30|
| Weight (in kg)                    | 66.05±10.10                 | 64.53±11.27            | 0.51|
| Fentanyl requirement per kg of body weight (µg) | 2.07±0.54                  | 2.59±0.77              | 0.001*|
| Duration of Anesthesia (min)      | 170.63±41.37                | 176.58±47.59           | 0.55|
| Time to Rescue Analgesia (h)      | 8.15±4.732                  | 1.65±2.507             | <0.001*|

* P < 0.05 was considered statistically significant

Discussion

In our study, the use of ropivacaine in caudal epidural block resulted in significantly lower mean intraoperative fentanyl requirement per kg body weight and mean VAS score in the immediate postoperative period, 4, 8, 12, and 24 h after the surgery compared to the S group. The mean time to the first demand of rescue analgesia was also significantly longer in the R group as compared to the S group (P < 0.001).

Epidural analgesia by placing a catheter preoperatively is difficult in spine surgeries. On the other hand, blood in epidural space after surgery might affect the action of drugs resulting in an unpredictable response. Other problems may be inadequate retention of drugs in the epidural space due to the presence of drain tubes, catheter malposition, and blockade.[12] However, all these problems can be addressed by pre-emptive administration of local anesthetic agents or opioids via epidural route allowing sufficient time for the fixation of drugs prior to surgically opening the epidural space.

The caudal epidural route is an ideal route for lumbosacral spine surgeries. Moreover, caudal epidural space can be conveniently accessed in prone position that is commonly used during these surgeries. Image intensifiers are also readily available during such surgeries aiding in accurate placement of needle in caudal space, and thus, decreasing the chances of block failure.[13]

Ropivacaine being less lipophilic has a lower penetration in large myelinated Aβ fibres that are involved in motor function. This action is desirable in spine surgery patients where early postoperative neurological assessment is very important.[7]

Sekar et al. in their study administered a single bolus injection of caudal epidural with 20 ml of 0.375% bupivacaine and 50 mg of tramadol hydrochloride in lumbosacral spine surgery patients and found that the VAS and verbal rating score (VRS) were significantly lower (P < .0001) in the bupivacaine-tramadol group compared to the control group during the study period, as seen in our study. Similarly, the time elapsed to first rescue analgesia was also significantly prolonged in the study group (P = 0.0041).[10] Kakiuchi et al. studied patients undergoing posterior interbody fusion and laminotomy for spinal stenosis and found that patients who received pre-incisional caudal epidural injection of a mixture of bupivacaine and buprenorphine had a significantly lower VAS score and lower requirement of rescue analgesics compared to the control group.[11] In another study, Khalil et al. compared ropivacaine and bupivacaine in caudal epidural space in children undergoing elective, ambulatory procedures such as lower abdominal, lower limbs, and urological surgeries, concluding that postoperative analgesia was adequate with ropivacaine (0.25%, 1 ml/kg) and was comparable to bupivacaine (0.25%, 1 ml/kg) with respect to the quality and duration of analgesia, motor, and sensory effects.[15]

Da Conceicao et al. studied pediatric patients undergoing elective unilateral herniorrhaphy and concluded that a single bolus injection of 1 ml/kg of 0.2–0.375% ropivacaine in the caudal epidural space provides similar postoperative analgesia as with 0.25% bupivacaine. The time to onset of analgesia, time to first rescue analgesic requirement, and duration as well as quality of pain relief were comparable between the groups. However, postoperative motor blockade was significantly less in the ropivacaine group compared to the bupivacaine group.[16] Another study by Chipde et al. among patients undergoing urogenital procedures under general anesthesia found that efficacy in terms of onset and duration of analgesia were almost similar in patients receiving both caudal ropivacaine and bupivacaine.[17] However, there was a significant difference in the motor block score at 2, 3, and 4 h postoperatively that was same 1 h postoperatively.

In a study comparing caudal-epidural bupivacaine-fentanyl (BF Group) and ropivacaine-fentanyl (RF Group) in pediatric infraumbilical surgeries, the RF Group was found to have significantly longer duration of postoperative analgesia and significantly shorter duration of motor blockade compared to the BF Group.[18] The author concluded that caudal 0.2% ropivacaine is equally effective as caudal 0.2% bupivacaine in terms of postoperative analgesia, but with faster motor recovery in pediatric patients.[19]
Thus, ropivacaine is associated with faster recovery from motor block than bupivacaine. It is essential in lumbosacral spine surgeries that neurological evaluation of the patient should be done as early as possible after the patient recovers from anesthesia to recognize potential complications such as epidural hematoma or compressive injury of the cord and nerve roots. Thus, ropivacaine is an ideal local anesthetic agent owing to its dominant sensory blocking properties and lower propensity to cause any residual motor block, which could come in the way of neurological assessment of these patients.

**Conclusion**

We concluded that pre-emptive analgesia using a single injection of ropivacaine in caudal epidural space is a simple, safe, and effective technique for decreasing perioperative opioid requirement as well as providing postoperative analgesia for up to 24 h that facilitate early mobilization of these patients postoperatively.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.

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