Clinical Investigation

Comparative study of ultrasound-guided paravertebral block with ropivacaine versus bupivacaine for post-operative pain relief in children undergoing thoracotomy for patent ductus arteriosus ligation surgery

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ABSTRACT

Background and Aims: Thoracotomy incision following patent ductus arteriosus (PDA) ligation surgery is often associated with severe post-operative pain that has deleterious effects on respiratory function. We aimed to assess pain relief with thoracic paravertebral block using either bupivacaine or ropivacaine in these surgeries. **Methods:** One hundred paediatric patients of age group between 2 and 10 years undergoing PDA ligation surgery were randomised either to bupivacaine or ropivacaine group in this prospective double-blinded study. After induction of general anaesthesia, the ultrasound-guided paravertebral block was carried out using 0.25% bupivacaine 0.4 ml/kg in Group B patients and 0.2% ropivacaine 0.4 ml/kg in Group R patients. Monitoring included minimum mandatory monitoring with pulse rate, pulseoximetry (SpO_2), electrocardiogram, blood pressure, temperature during surgery and also in Intensive Care Unit (ICU). Additionally, modified objective pain score (MOPS) was used in ICU for assessment of pain for 12 h after surgery. Incidence of complications was noted. **Results:** Mean values of MOPSs were comparable in both the groups. The time to rescue analgesic was 8 to 10 h in over 80% of patients in both the groups. More patients had hypotension and bradycardia in bupivacaine group compared to ropivacaine group. **Conclusion:** Paravertebral injection of 0.4 ml/kg of either 0.2% ropivacaine or 0.25% bupivacaine provided equipotent analgesia, but ropivacaine had a better side effect profile. Ultrasound-guided paravertebral block is a safe and effective mode of analgesia in paediatric patients undergoing thoracotomy.

Key words: Bupivacaine, post-thoracotomy pain, ropivacaine, ultrasound-guided paravertebral block

INTRODUCTION

Thoracotomy is one of the most painful surgical procedures. Post-thoracotomy pain can adversely affect coughing and deep breathing, resulting in respiratory complications such as hypoxia, atelectasis, chest infection and respiratory failure that may delay recovery and if severe, could be life-threatening. It may also contribute to the development of chronic pain syndrome.[1]

Surgical approach to patent ductus arteriosus (PDA) ligation surgery is carried through left posterolateral thoracotomy. This incision has often been reported to be associated with severe post-operative pain that may have deleterious effects on pulmonary function.[2,3] A thoracic paravertebral block (TPVB) by local anaesthetic provides effective pain relief

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with few side effects. This technique also reduces the occurrence of chronic post-thoracotomy neuralgia, stress responses and preserves pulmonary function.[4] Efficacy of TPVB depends on properneedle placement, potency, concentration and volume of the local anaesthetic.[5] Ultrasonographic visualisation of in-plane needle advancement reduces the risk of pleural puncture as well as entry of the needle into the intervertebral foramen.[6] Bupivacaine has been the most frequently used local anaesthetic according to published studies. It is a potent drug; however toxicity is reported when higher dosages are injected.[7] Ropivacaine is a newer local anaesthetic that could be a useful alternative to bupivacaine for TPVB.[8] There is paucity of literature comparing the efficacy of the two local anaesthetics in PDA ligation surgeries, and hence this study was undertaken to compare the efficacy of bupivacaine with that of ropivacaine.

METHODS

After obtaining Institutional Ethics Committee and Scientific Committee approval, we studied hundred consecutive patients aged between 2 and 10 years, of American Society of Anaesthesiologists (ASA) physical status I and II, undergoing PDA ligation surgery. The duration of study was 1-year. Patients with cutaneous infection at the site of needle puncture, pathology in the paravertebral space, allergy to local anaesthetic drugs, coagulopathy, kyphoscoliosis and previous thoracotomy were excluded from the study.

Written informed consent from the parents of the patients was taken. Patients were randomly distributed into two groups using computer-generated random table. Fifty patients received a pre-incisional single thoracic paravertebral injection of 0.2% ropivacaine (Group R), and another 50 patients received pre-incisional single thoracic paravertebral injection of 0.25% bupivacaine (Group B).

All patients in this study were pre-medicated with syrup promethazine 0.3 mg/kg per orally, 90 min before induction of anaesthesia. The standard anaesthesia technique, as described below was used in all patients. Patients were monitored using electrocardiogram (ECG), invasive blood pressure, heart rate and pulse oximeter in the perioperative period. Intravenous (IV) cannula was inserted with inhalational induction using oxygen, nitrous oxide and halothane and IV fluid (Ringer lactate or normal saline) was administered. Tracheal intubation was carried out with fentanyl 2 μg/kg, midazolam 0.1 mg/kg, muscle relaxation with pancuronium 0.1 mg/kg body weight.

After tracheal intubation, patients were ventilated with intermittent positive pressure ventilation with O_2 and N_2O in 50:50 ratio and later, anaesthesia maintained along with isoflurane (minimum alveolar concentration 1). Tidal volume of 8–10 ml/kg and ventilatory frequency of 16–24 breaths/min were adjusted to maintain normal end tidal CO_2 levels.

Paravertebral block was administered under ultrasound guidance by in-plane approach with patients in right lateral decubitus position to expose their upper thoracic region. After skin disinfection, phased array transducer of S8 frequency (Philips ultrasound machine HD 11 XE) kept in sterile sleeve, was placed in an axial (transverse) plane on the rib at the selected thoracic level, just lateral to the spinous process. Machine was optimised for imaging capability by selecting the appropriate depth of field (within 2–3 cm), focus range and gain. The transverse process and rib were visualised as a hyperechoic line with acoustic shadowing below it. Thoracic paravertebral space (TPVS) localisation was done by moving the transducer caudally into the intercostal space between adjacent ribs. The transverse process was visualised on the medial side as a hyperechoic convex line with acoustic shadowing beneath. The TPVS and the adjoining intercostal space could be visualised as a wedge-shaped hypoechoic layer demarcated by the hyperechoic lines of the pleura below and the internal intercostal membrane above.

After ultrasound-guided identification of paravertebral space (in plane approach), 0.25% bupivacaine 0.4 ml/kg was injected in Group B patients and 0.2% ropivacaine 0.4 ml/kg was injected in Group R patient using 21-gauge hypodermic needle, which was attached to 20 cm pressure monitoring line for convenience of administration of medication. The operator was blinded to the drug administered. Local anaesthetic deposition translated as an anterior displacement of the parietal pleura on the ultrasound image. Vascular puncture was ruled out by aspiration before administration of the drug. Pneumothorax was ruled out using ultrasound after administration of the block.

The haemodynamic parameters - heart rate and blood pressure (systolic, diastolic and mean) were measured. Baseline parameters were recorded after

induction of anaesthesia and just before administering paravertebral block. Intra-operatively, monitoring was continued and incidence of bradycardia and hypotension noted.

Bradycardia was defined as <80 bpm (below 1-year), <70 bpm (1–3 years) and <65 bpm (3–6 years) and <60 (6–12 years).[9] Hypotension was defined as fall in blood pressure more than 20% below baseline.[10] Hypotension and bradycardia were treated with titrated doses of injection ephedrine. However, intra-operatively, hypotension was induced momentarily during ligation of PDA using infusion and bolus of injection nitroglycerine. After ligation, hypotension was corrected. After surgery, the patients were transferred to the post-operative Intensive Care Unit (ICU) with endotracheal tube *in situ*. Patients were extubated within 30 min, after stabilisation of acid-base status and surgical drainage and confirmation of normal chest X-ray. Monitoring of pulse rate, blood pressure, SpO_2, ECG, respiratory rate and modified objective pain score (MOPS) was carried out in ICU for 12 h after surgery.

Assessment of post-operative pain based on MOPS [Table 1] score (0 = no pain and 10 = worst pain imaginable) was assessed hourly for the first 4 h, 2nd hourly till 12 h after the surgery.[11] Post-operative analgesic (injection ketorolac 0.5 mg/kg IV) was given as a rescue analgesic only if the pain score on MOPS was more than 5.

Table 1: Modified objective pain score (MOPS)

Parameters	Score
Crying	
None	0
Consolable	1
Not consolable	2
Movement	
None	0
Restless	1
Thrashing	2
Agitation	
Asleep	0
Calm	0
Mild	1
Hysterical	2
Posture	
Normal	0
Flexed	1
Holds injury site	2
Verbal	
Asleep	0
No complaint	0
Complaint but cannot localise	1
Complaint and can localise	2

Descriptive statistical analysis was carried out in the present study. Results on continuous measurements are presented on mean, SD (minimum-maximum) and results on categorical measurements are presented in number (%). Chi-square/Fisher exact test was used to find the significance of study parameters on a categorical scale between two groups. Paired samples *t*-test was used to find the significance of study parameters on the continuous scale within the group (intra-group analysis) on metric parameters. Student's *t*-test (two-tailed, independent samples) was used to find the significance of study parameters on continuous scale between two groups (inter-group analysis) on metric parameters.

The sample size of 50 patients in each group was based on previous study,[12] with pain score and time of first rescue analgesic as parameters, with 90% statistical power, 5% level of significance and 95% confidence interval.

The statistical software SPSS 16 (SPSS Version 16, SPSS, Inc., Chicago, IL, USA) was used for the analysis of the data and Microsoft word and excel used to generate graphs and tables.

RESULTS

Demographic data was comparable between the groups with respect to age (5.68 ± 2.59 vs. 5.78 ± 2.66 years), weight (16.16 ± 4.88 vs. 16.06 ± 4.88 kg), height (107.36 ± 15.54 vs. 107.88 ± 16.36 cm) and gender (28 male, 22 female vs. 26 male 24 female patients). The mean duration of anaesthesia in the ropivacaine group was 51.42 ± 4.89 min as compared to 51.48 ± 5.32 min in the bupivacaine group, and the difference was statistically not significant ($P = 0.372$).

Both the groups had a reduction in heart rate at 5 min and 10 min. Reduction in heart rate from baseline was comparable in both the groups at 5 min and 10 min, and the difference was not statistically significant. During post-extubation period both the groups had a reduction in heart rate, which was more in ropivacaine group, but the difference was not statistically significant. There was no statistically significant difference in heart rate between the two groups throughout the study [Figure 1].

There was a reduction in blood pressure at 5 min, 10 min and 15 min from baseline in both the groups. Fall in systolic blood pressure in Group B was statistically significant at 10 min and 15 min. Post-extubation, systolic blood pressure started rising after 6 h in both the groups. Difference in diastolic blood pressure was statistically significant ($P < 0.001$) between the two groups at 10 min.

Mean arterial pressure (MAP) was lower in bupivacaine group at 10 min and 15 min, which was statistically significant with $P < 0.001$ and 0.009, respectively. MA*P* values were comparable in both the groups intra-operatively and post-extubation [Figure 2].

Related to analgesia, other parameters assessed after extubation were the respiratory rate, SpO_2, MOPS and time of rescue analgesic administered. There was no statistically significant difference in respiratory rate and SpO_2 of the two groups. MOPS increased in both the groups as time interval increased from the administration of block. Difference between MOPS score was not statistically significant throughout the study [Figure 3].

In both the groups, 10% patients received rescue analgesic at 6 h. At 8 h, 44% patients received rescue analgesic in Group R and 42% patients received rescue analgesic in Group B. At 10 h, in both the groups 38% patients received rescue analgesic. At 12 h, 8% patients in Group R and 12% patients in Group B received rescue analgesic. This difference was not statistically significant [Table 2].

In Group R, hypotension was observed in four patients, while in Group B, 10 patients had hypotension. Bradycardia was seen in three patients in Group R and nine patients in Group B, which was found to be statistically significant. Two patients had vascular puncture in Group R and one patient in Group B. Pneumothorax and arrhythmias were not seen in any of the groups.

Table 2: Time of first rescue analgesic (h)

Time of rescue analgesic (h)	Group R *n* (%)	Group B *n* (%)
6	5 (10.0)	5 (10.0)
8	22 (44.0)	21 (42.0)
10	19 (38.0)	19 (38.0)
12	4 (8.0)	5 (10.0)
Total	50 (100.0)	50 (100.0)
Mean±SD	8.88±1.57	8.96±1.63

SD – Standard deviation

DISCUSSION

Pre-emptive analgesia is a treatment that is initiated before the surgical procedure in order to prevent central sensitisation to painful stimulus, thereby reducing hyperalgesia. The primary goals of preemptive analgesia are to decrease acute pain following tissue injury, to prevent pathological modulation of the central nervous system due to this pain and to prevent the development of chronic

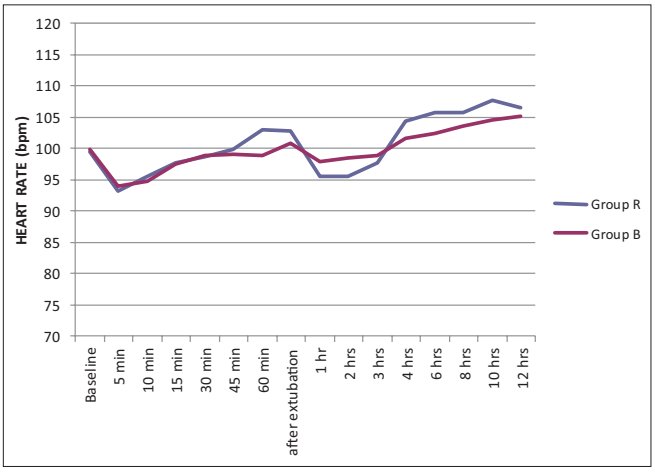

Figure 1: Comparison of heart rate in two groups studied

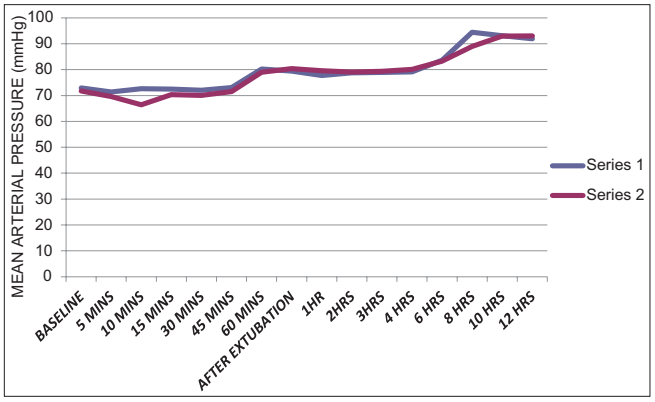

Figure 2: Comparison of mean arterial pressures

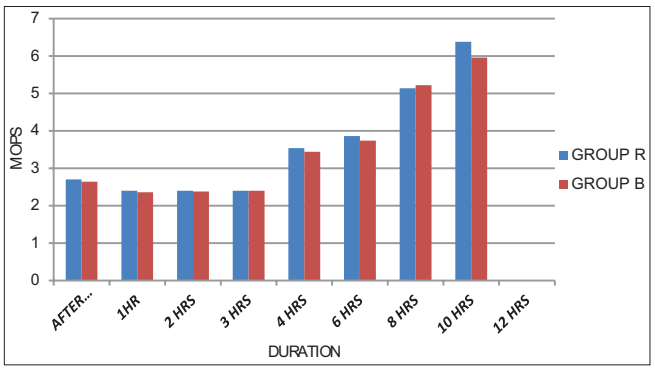

Figure 3: Comparison of mean objective pain scores

pain.[13] The various pharmacological options for preemptive analgesia include opioids, non-steroidal anti-inflammatory drugs, local anaesthetics, alpha agonists. The various routes of administration include local infiltration, IV route, neuraxial and peripheral blocks. IV opioids are not potent enough to control neurogenic pain without detrimental effects on respiratory outcome.[14] Thoracic epidural analgesia carries the risk of dural puncture, epidural haematoma, epidural abscess and side effects such as hypotension, bradycardia and urinary retention. Compared to epidural block, the paravertebral block is associated with less haemodynamic changes and is a suitable alternative in patients with severe comorbidities and contraindications to neuraxial blocks.[15,16] In cardiac surgery, where maintenance of stable haemodynamics is a prerequisite, TPVB has a vital role in pain management.

In our study, the changes in heart rate, MAP and respiratory rate were comparable in both the groups except for a significant fall in MAP in bupivacaine group at 10 and 15 min which responded promptly to drug therapy. We did not find statistically significant difference in mean respiratory rate and SpO_2 between the two groups after extubation. Similarly, Bariskaner *et al*. found that neither drug had a significant effect on respiratory rate or blood gas values ($P > 0.05$) in their study.[17]

Bupivacaine has been classically used for paravertebral blocks. Ropivacaine has emerged as a suitable alternative with comparable quality and duration of analgesia, but with lesser degrees of motor block.[18] In our study, mean values of MOPSs were comparable in both the groups throughout the study, and the difference in them was not statistically significant. Comparable results were found by Navlet *et al*. and Hura *et al*.[19,20]

The time observed for the demand of rescue analgesic was 8 to 10 h in over 80% of patients in both the groups indicating an adequate duration of analgesia post-operatively. But, lesser duration of analgesia was noted by Ivani *et al*. who conducted a double-blind, multicentre trial in 245 children, aged 1–10 years undergoing elective minor surgery receiving a single caudal extradural injection of 1 ml/kg of either 0.25% bupivacaine or 0.2% ropivacaine after induction of general anaesthesia. The mean time duration to administer first analgesia was 233 min (3.8 h) in the bupivacaine group and 271 min (4.5 h) in ropivacaine group.[21]

Bariskaner *et al*., described that ropivacaine was less cardio depressant and arrhythmogenic than bupivacaine.[17] Bupivacaine has more negative inotropic effect and increases AV conduction time more than ropivacaine.[22] In our series, significantly more patients had hypotension and bradycardia in bupivacaine group compared to ropivacaine group. Kerkkamp *et al*. compared 0.75% ropivacaine with epinephrine and 0.75% bupivacaine with epinephrine in lumbar epidural anaesthesia.[23] They reported that out of 43 patients, hypotension and bradycardia requiring treatment were experienced by seven and three patients, respectively, in the bupivacaine group, and by two and one patient, respectively, in the ropivacaine group.

We found that overall, both the study drugs, bupivacaine and ropivacaine produced satisfactory analgesia, without any technical failure and with minimal side effects, but ropivacaine group was associated with lesser adverse effects.

Paravertebral block has been established to be a superior analgesic technique offering superior pain relief compared to GA alone.[24] It has a better safety profile compared to IV and thoracic epidural analgesia and better preserves post-operative pulmonary function.[25] Ultrasound has been used to enhance efficacy and safety of the block by determining the location and depth of transverse process and parietal pleura.[26] In our study, success rate of the block was 100%. Incidence of vascular puncture was same in both the groups. Pneumothorax was not seen in any of our patients. Renes *et al*. also reported block success rate of 100% using in-plane ultrasound-guided TPVB.[27] Likelihood of vascular puncture and pneumothorax had been reported to be higher in bilateral compared to unilateral block by nerve stimulator technique.[28] Safety profile of the chosen analgesic technique is of paramount importance in cardiac surgery as heparin may be administered in elective or emergent setting, exposing the patient to the risk of dreadful complications such as epidural haematoma.[29] Ultrasound-guided block minimises the risk of such complications, and is thus, a safe and effective modality.

Nevertheless, the present study had limitations. First, we chose only ASA physical status I and II patients, so efficacy and side effects of the two drugs in high-risk patients could not be assessed. Also, in

our study surgical procedure performed for PDA cases was posterolateral thoracotomy, so the efficacy of paravertebral block in anterolateral thoracotomy and sternotomy could not be assessed.

CONCLUSION

Single pre-incisional ultrasound-guided paravertebral injection of 0.4 ml/kg of either 0.2% ropivacaine or 0.25% bupivacaine provided equipotent analgesia. Ultrasound-guided paravertebral block appears to be a safe and effective mode of analgesia in paediatric patients undergoing PDA ligation surgery.

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Conflicts of interest

There are no conflicts of interest.

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