

Original Research Article

A comparison of high thoracic epidural anaesthesia versus conventional intravenous opioids in pediatric patients undergoing corrective open heart surgery for ventricular septal defect

Kshetrimayum Sandeep Kumar Singh¹, Vipul K. Sharma², Sachin Shouche³,
Shibu Sasidharan^{4*}, Gurpreet Kaur Dhillon⁵

¹Department of Anaesthesiology, Critical Care Medicine, CMC Vellore, Tamil Nadu, India

²Consultant Cardiothoracic Anaesthesiologist, Ex- Indian Army, India

³Consultant Cardiothoracic Anaesthesiologist, Indian Air Force, India

⁴Department of Anaesthesia and Critical Care, CHAF, Level III IFH Hospital, Goma, DRC

⁵Department of Pediatrics, 166 Military Hospital, Jammu, India

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*Correspondence:

Dr. Shibu Sasidharan,

E-mail: shibusasi@gmail.com

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ABSTRACT

Background: We compared high thoracic epidural anaesthesia with a combination of morphine and bupivacaine versus IV fentanyl as an alternative for perioperative pain management.

Methods: Group-E: Injection Morphine 75-100 mcg/kg and Injection 0.25 % Bupivacaine 0.5 ml/kg was given via epidural catheter at insertion, Injection 0.25% Bupivacaine 0.5 ml/kg just before skin incision, and continuous infusion of Injection 0.125% Bupivacaine at 0.2 ml/kg/hr intra-operatively. Post-operative 0.1 ml/kg/hr infusion. Group F- intravenous fentanyl 2-3 mcg/Kg IV bolus given just before skin incision, followed by 1-2 mcg/Kg/hr IV fentanyl started after weaning from cardiopulmonary bypass.

Results: The mean ScvO₂ was comparable between the two groups during induction period but became higher in group E during bypass and post bypass period intraoperatively, and the difference in rise in ScvO₂ is statistically significant with a p<0.05. The mean rSo₂- C was comparable between the two groups in the first postoperative hour but group F shows higher rSo₂-C postoperatively which was statistically significant. The postoperative pain was significantly lower in group E in the postoperative period (except for 4,5,6 and 40 and 48th hour).

Conclusions: HTEA to paediatric patients prior to sternotomy for cardiac surgeries resulted in a much better control of haemodynamic parameters. Produces better central venous and regional tissue oxygenation during bypass and post bypass intraoperatively as compared to the patients that received only intravenous fentanyl. There was lower amount of postoperative bleeding in the HTEA group with significant reduction in requirement of post-operative ventilation and time to extubation after surgery, better post-operative pain control and overall outcome.

Keywords: HTEA, Epidural anaesthesia, ScvO₂, Bupivacaine, CPB

INTRODUCTION

Ventricular septal defects are the most common congenital cardiac abnormality seen in paediatric age group.¹

Depending on their location in the interventricular septum, ventricular septal defects are described as perimembranous, muscular, sub-arterial, and in-flow. VSD are usually associated with pulmonary hypertension, failure to thrive and congestive heart failure. Ideal management

requires early primary surgical repair, within 3 months to 1 year of age.

Surgical closure of a VSD is performed on cardiopulmonary bypass with cardioplegic arrest. Intraoperatively patients are usually cooled to 32 to 34 degrees. Intravenous opioid analgesia is the conventional methods generally practiced to manage the perioperative pain for VSD patients undergoing corrective surgery. Nevertheless, intravenous opioids administration is associated with a range of side effects including respiratory depression requiring reintubation, sedation and lethargy, nausea and vomiting, constipation, urinary retention, pruritis and ileus requiring multimodal pain management techniques.

Control over postoperative pain in Cardiac surgical patients is a challenging aspect. Pain due to sternotomy is often severe and difficult to control. Poor control of pain in post op period often leads to poor respiratory effort and further complications related to it especially in the paediatric age group. High thoracic epidural analgesia (HTEA) has many beneficial effects in the paediatric patient population. It is commonly used to augment general anaesthesia and to manage perioperative pain. Effective pain relief from epidural analgesia has numerous benefits including earlier ambulation, rapid weaning from ventilator, stable hemodynamics, lowered circulating stress hormone level.

Insufficient peri-operative pain control can lead to an uncontrolled surgical stress response, could initiate pathophysiological alterations in all major organs that may cause considerable postoperative morbidity.^{2,4} Postoperative pain scores were at any point significantly lower with Thoracic epidural analgesia.² Studies have proven immediate extubation after cardiac surgery is feasible. TEA provides better pain relief after cardiac surgery.

In this study, we compared high thoracic epidural anaesthesia with a combination of morphine and bupivacaine versus IV fentanyl as an alternative for perioperative pain management.³ It is hypothesized that High thoracic epidural anaesthesia has the advantage of superior quality analgesia, un-paralleled obtundation of stress response, superior left ventricular function, improved cardiac output and tissue perfusion, improved platelet function and reduced peri-Op bleeding leading to earlier extubation and reduced length of stay in the post-operative ICU.^{2,3}

The most dreaded side effect of neuroaxial opioids is respiratory depression which may require treatment in 1%, similar as that after routine doses of IM or IV opioids.² Risk factors of respiratory depression consist of high or repeated doses of narcotics, old age, and simultaneous use of IV sedatives.

The objective of this study was to compare the various intraoperative and post-operative vital parameters and events including the time to extubation, duration of post-operative ventilation required between patients on high thoracic epidural analgesia and patients receiving conventional IV opioid analgesia.

METHODS

This was a prospective randomised control study done on 40 patients with VSD undergoing corrective open heart surgery under cardiopulmonary bypass in a tertiary care centre (Cardiothoracic centre, Pune) from May 2015 to January 2017. The study was approved by the Ethical committee of the hospital and written informed consent was obtained from the parents/guardian. The Patients with VSD for corrective surgery between 03 months to 5 years of age were included in the study. Patients with any contraindications to central neuraxial blocks namely deranged coagulation (INR>1.5), spinal deformity and any other associated congenital cardiac defects were excluded from the study.

The randomisation was done by computer generated randomisation method into two groups, Group E – epidural anaesthesia and Group F- intravenous opioids. Children in both groups received Oral Chloral hydrate (trichlorophos) 50 mg/kg in the ward, 45 mins prior to shifting to the operation theatre. In the Pre-operative room, all the patients were administered Intranasal ketamine – 7 mg/Kg and nasal midazolam 0.4 mg/Kg 15 mins prior to induction.

During induction, peripheral venous access was secured and the patients were induced with inj. Midazolam-0.1 mg/kg IV, injection Ketamine 2 mg/kg IV and injection Fentanyl- 2 mcg/kg IV. During Intubation, all the patients were administered injection Rocuronium 1 mg/kg IV and orotracheal intubation carried out with endotracheal tube of appropriate size. Patients were then put on mechanical ventilator and ventilated with 50% FiO₂ (air and Oxygen mixture) and 0.2 to 1.5% Isoflurane and Methyl prednisolone 30 mg/kg IV was given to all patients.

In group-E, Injection Morphine 75-100 mcg/kg and Injection 0.25% Bupivacaine 0.5 ml/kg were given in the epidural space at placement of epidural catheter. Injection 0.25% Bupivacaine 0.5 ml/kg was given just before skin incision, followed by continuous infusion of Injection 0.125% Bupivacaine at 0.2 ml/kg/hr intra-operatively followed by 0.1 ml/kg/hr post-operatively.

In group F, intravenous fentanyl 2-3mcg/Kg IV bolus was given just before skin incision, followed by 1-2 mcg/Kg/hr IV fentanyl was started after weaning from cardiopulmonary bypass.

All the patients received Injection Dexmedetomidine 0.25 mcg/kg/hr after induction which was continued throughout the peri-operative period. The ScvO₂ catheter attached to

the CVC was connected to the optical module (reflection spectrophotometry) and monitoring platform (Vigileo TM Monitor, Edwards Lifesciences LLC IRVINE, CA 92614-5686 USA). In vivo calibration performed by adjusting for hemoglobin (Hb), hematocrit (Hct), and oxygen saturation values (SvO₂-blood as measured by venous blood gas samples from central line). The right subclavian vein was cannulated with 22-gauge single lumen catheter placed in right atrium and intraoperatively surgically placed in left atrium across the inter-atrial septum to monitor the Left atrial pressure. The NIRS sensor on temporal region and over the flanks was placed to monitor cerebral and somatic oximetry respectively. The readings from the monitor were taken as continuous central venous oxygen saturation measurements- ScvO₂. After surgery, the patients were assessed for fitness to extubate on table with the following criteria:

Hemodynamic stability with minimal inotropic support, no ongoing inappropriate bleeding, adequately rewarmed, adequate spontaneous respiratory effort after reversal with standard doses of neostigmine and glycopyrrolate, appropriate LVEF on epicardial echo, any of the following present- gag reflex on suctioning, child opening eyes and looking around, appropriate limb movements.

If the patient did not meet the extubation criteria, they were shifted to cardiac surgical Intensive Care Unit and mechanically ventilated with inotropes support (dopamine and milrinone) till the extubation criteria were met. During post-operative stay in ICU, rescue sedation of propofol-25-50 mcg/Kg/min IV were started as per requirement.

Parameters measured were HR, IBP, ScVO₂, LAP, NIRS, LVEF(ECHO), blood sugar, urine output, pain scores, time to extubation, length of stay in the ICU and post-operative bleeding(drainage). 2D Echo was done on the table after the surgery and 12 hrs post-op in the ICU. All these values measured once at the preoperative period, at the time of induction, every 10 mins intraoperatively, and post op reading at 1-hour intervals for initial 6 hrs followed by 4 hourly reading till the stay in the ICU. Universal protocol for fasting status in paediatric age group was adhered to.

Statistical analysis

Data analysis done by using Statistical package for social sciences (SPSS). Qualitative data expressed by using frequency and percentage. Quantitative data expressed by using, mean SD, median and range. 2 independent sample T test / Mann-Whitney U test used to find the significant difference between group E & F. P<0.05 considered as significant

RESULTS

The patients were divided into 2 groups: Group E (HTEA) and Group F (IV opioids). The demographic profile was comparable between the two groups. The mean age group in the two groups were comparable with no statistical difference, p>0.05 (2 independent sample t-test used). The mean weight in the two groups were comparable with no statistical difference, p>0.05 (2 independent sample t-test used).

Table 1: Preoperative and intraoperative heart rate at different time intervals.

| Heart rate at | Group E | | | Group F | | | P value |
|----------------------|---------|------------|-------|---------|-----------|-------|---------|
| | N | Mean (±SD) | SD | N | Mean(±SD) | SD | |
| Pre-operative | 20 | 128.65 | 8.25 | 20 | 129.65 | 12.65 | 0.768 |
| At induction | 20 | 129.75 | 7.53 | 20 | 131.30 | 12.73 | 0.642 |
| 10 min | 20 | 130.60 | 8.37 | 20 | 131.55 | 13.29 | 0.788 |
| 20 min | 20 | 129.80 | 8.75 | 20 | 132.25 | 13.31 | 0.495 |
| 30 min | 20 | 130.45 | 7.19 | 20 | 132.80 | 13.61 | 0.498 |
| 40 min | 20 | 130.95 | 6.90 | 20 | 133.10 | 14.26 | 0.547 |
| 50 min | 20 | 131.45 | 7.50 | 20 | 135.15 | 12.63 | 0.269 |
| 60 min | 20 | 130.25 | 7.10 | 20 | 135.30 | 12.38 | 0.124 |
| 70 min | 20 | 129.75 | 7.33 | 20 | 137.00 | 12.83 | 0.036* |
| 80 min | 20 | 129.45 | 7.55 | 17 | 136.82 | 12.80 | 0.047* |
| 90 min | 20 | 128.80 | 7.50 | 7 | 139.71 | 13.50 | 0.080 |
| 100 min | 13 | 129.08 | 7.52 | 1 | 140.00 | 0.00 | - |
| 110 min | 6 | 126.17 | 4.83 | 0 | - | - | - |
| 120 min | 1 | 126.00 | 0.00 | 0 | - | - | - |
| 130 min | 0 | - | - | 0 | - | - | - |
| 140 min | 0 | - | - | 0 | - | - | - |
| 150 min | 0 | - | - | 5 | 136.20 | 13.97 | - |
| 160 min | 6 | 134.67 | 10.21 | 15 | 136.00 | 11.99 | 0.802 |
| 170 min | 12 | 132.58 | 7.83 | 20 | 137.35 | 12.94 | 0.204 |
| 180 min | 16 | 131.81 | 8.04 | 20 | 137.35 | 12.58 | 0.119 |

Continued.

| Heart rate at | Group E | | | Group F | | | P value |
|---------------|---------|------------------|------|---------|-----------------|-------|---------|
| | N | Mean (\pm SD) | SD | N | Mean(\pm SD) | SD | |
| 190 min | 19 | 132.53 | 7.29 | 20 | 137.30 | 12.65 | 0.156 |
| 200 min | 20 | 132.30 | 7.66 | 19 | 138.05 | 12.76 | 0.101 |
| 210 min | 17 | 132.24 | 7.68 | 11 | 135.27 | 11.68 | 0.457 |
| 220 min | 10 | 130.00 | 6.94 | 6 | 131.67 | 14.09 | 0.795 |
| 230 min | 6 | 131.17 | 9.58 | 2 | 136.00 | 0.00 | - |
| 240 min | 1 | 134.00 | - | 0 | - | - | - |

*Significant (p<0.05) 2 independent sample t-test used

Table 2: Postoperative heart rate at different time intervals.

| Heart rate at | Group E | | | Group F | | | P value |
|---------------|---------|--------|------|---------|--------|-------|---------|
| | N | Mean | SD | N | Mean | SD | |
| 1 hr | 20 | 131.30 | 7.06 | 20 | 131.65 | 12.73 | 0.031* |
| 2 hr | 20 | 130.90 | 6.62 | 20 | 138.55 | 12.59 | 0.023* |
| 3 hr | 20 | 131.00 | 6.49 | 20 | 138.30 | 12.90 | 0.032* |
| 4 hr | 20 | 131.20 | 8.43 | 20 | 137.30 | 12.47 | 0.079 |
| 5 hr | 20 | 130.95 | 7.49 | 20 | 137.80 | 12.73 | 0.047* |
| 6 hr | 20 | 130.80 | 7.41 | 20 | 137.95 | 13.28 | 0.044* |
| 10 hr | 20 | 130.90 | 7.27 | 20 | 139.35 | 13.98 | 0.019* |
| 14 hr | 20 | 130.10 | 6.82 | 20 | 138.75 | 12.93 | 0.013* |
| 16 hr | 20 | 130.15 | 6.95 | 20 | 139.95 | 13.17 | 0.006* |
| 20 hr | 20 | 130.90 | 7.50 | 20 | 141.50 | 13.37 | 0.004* |
| 24 hr | 20 | 130.15 | 7.10 | 20 | 138.90 | 11.13 | 0.009* |
| 28 hr | 20 | 130.60 | 6.77 | 20 | 138.05 | 11.22 | 0.016* |
| 32 hr | 20 | 130.00 | 5.63 | 20 | 138.15 | 11.75 | 0.009* |
| 36 hr | 20 | 130.40 | 6.85 | 20 | 138.00 | 11.85 | 0.019* |
| 40 hr | 20 | 130.15 | 6.02 | 20 | 137.95 | 11.79 | 0.013* |
| 44 hr | 20 | 130.75 | 6.86 | 20 | 138.00 | 11.23 | 0.019* |
| 48 hr | 20 | 129.50 | 6.48 | 20 | 136.65 | 11.56 | 0.022* |
| 52 hr | 0 | - | - | 20 | 136.40 | 10.95 | - |
| 56 hr | 0 | - | - | 20 | 136.05 | 10.95 | - |
| 60 hr | 0 | - | - | 20 | 136.40 | 10.56 | - |
| 64 hr | 0 | - | - | 20 | 136.10 | 11.10 | - |
| 68 hr | 0 | - | - | 16 | 136.06 | 11.58 | - |
| 72 hr | 0 | - | - | 6 | 138.17 | 11.41 | - |

*Significant (p<0.05) 2 independent sample t-test used

Table 3: Preoperative and intraoperative systolic blood pressure at different time intervals.

| Systolic blood pressure at | Group E | | | Group F | | | P value |
|----------------------------|---------|-------|------|---------|-------|------|---------|
| | N | Mean | SD | N | Mean | SD | |
| Pre operative | 20 | 84.50 | 6.90 | 20 | 87.05 | 7.98 | 0.287 |
| At induction | 20 | 84.45 | 6.30 | 20 | 88.80 | 8.77 | 0.080* |
| 10 min | 20 | 84.20 | 6.10 | 20 | 90.15 | 7.73 | 0.010* |
| 20 min | 20 | 83.55 | 6.66 | 20 | 89.50 | 7.47 | 0.011* |
| 30 min | 20 | 83.50 | 6.42 | 18 | 88.89 | 7.58 | 0.025* |
| 40 min | 20 | 83.70 | 6.22 | 7 | 89.43 | 4.12 | 0.014* |
| 50 min | 13 | 85.15 | 7.08 | 1 | 92.00 | - | - |
| 60 min | 6 | 88.50 | 8.07 | 0 | - | - | - |
| 70 min | 1 | 88.00 | - | 0 | - | - | - |
| 80 min | 0 | - | - | 0 | - | - | - |
| 90 min | 0 | - | - | 0 | - | - | - |
| 100 min | 0 | - | - | 5 | 89.80 | 8.32 | - |
| 110 min | 6 | 81.33 | 3.44 | 15 | 85.87 | 9.19 | 0.117 |
| 120 min | 12 | 81.50 | 4.19 | 20 | 87.55 | 6.54 | 0.003* |
| 130 min | 16 | 80.94 | 4.99 | 20 | 87.85 | 7.69 | 0.003* |

Continued.

| Systolic blood pressure at | Group E | | | Group F | | | P value |
|----------------------------|---------|-------|------|---------|-------|------|---------|
| | N | Mean | SD | N | Mean | SD | |
| 140 min | 19 | 82.95 | 5.39 | 20 | 88.75 | 7.66 | 0.010* |
| 150 min | 20 | 83.20 | 6.01 | 19 | 89.37 | 8.13 | 0.011* |
| 160 min | 17 | 84.24 | 6.51 | 13 | 90.46 | 8.35 | 0.037* |
| 170 min | 10 | 84.80 | 6.89 | 5 | 88.60 | 4.34 | 0.217 |
| 180 min | 5 | 87.40 | 8.20 | 1 | 88.00 | - | - |
| 190 min | 1 | 89.00 | - | 0 | - | - | - |
| 200 min | 20 | 84.50 | 6.90 | 20 | 87.05 | 7.98 | 0.287 |
| 210 min | 20 | 84.45 | 6.30 | 20 | 88.80 | 8.77 | 0.080 |
| 220 min | 20 | 84.20 | 6.10 | 20 | 90.15 | 7.73 | 0.010* |
| 230 min | 20 | 83.55 | 6.66 | 20 | 89.50 | 7.47 | 0.011* |
| 240 min | 20 | 83.50 | 6.42 | 18 | 88.89 | 7.58 | 0.025* |

*Significant (p<0.05) 2 independent sample t-test used

Table 4: Postoperative systolic blood pressure at different time intervals.

| Post-operative Systolic blood pressure at | Group E | | | Group F | | | P value |
|---|---------|-------|------|---------|-------|------|---------|
| | N | Mean | SD | N | Mean | SD | |
| 1 hr | 20 | 85.00 | 5.53 | 20 | 88.90 | 6.43 | 0.047* |
| 2 hr | 20 | 84.30 | 6.11 | 20 | 90.15 | 6.06 | 0.004* |
| 3 hr | 20 | 84.10 | 4.97 | 20 | 89.90 | 6.61 | 0.003* |
| 4 hr | 20 | 84.45 | 4.98 | 20 | 90.20 | 6.62 | 0.004* |
| 5 hr | 20 | 84.60 | 7.09 | 20 | 91.55 | 6.86 | 0.003* |
| 6 hr | 20 | 83.80 | 5.52 | 20 | 91.65 | 8.00 | 0.001* |
| 10 hr | 20 | 85.55 | 4.93 | 20 | 93.00 | 8.35 | 0.014 |
| 14 hr | 20 | 84.30 | 4.37 | 20 | 92.55 | 7.22 | <0.001* |
| 16 hr | 20 | 84.65 | 5.45 | 20 | 90.75 | 6.72 | 0.003* |
| 20 hr | 20 | 84.30 | 5.16 | 20 | 90.15 | 7.43 | 0.007* |
| 24 hr | 20 | 85.90 | 5.32 | 20 | 92.10 | 7.08 | 0.033* |
| 28 hr | 20 | 84.65 | 4.39 | 20 | 90.75 | 6.03 | 0.001* |
| 32 hr | 20 | 84.70 | 4.50 | 20 | 91.20 | 5.93 | <0.001* |
| 36 hr | 20 | 85.25 | 4.44 | 20 | 89.50 | 6.95 | 0.028* |
| 40 hr | 20 | 85.70 | 5.77 | 20 | 90.60 | 6.04 | 0.012* |
| 44 hr | 20 | 85.30 | 5.28 | 20 | 89.85 | 6.48 | 0.020* |
| 48 hr | 20 | 84.85 | 5.48 | 20 | 90.60 | 5.97 | 0.003* |
| 52 hr | 0 | - | - | 20 | 91.65 | 5.91 | - |
| 56 hr | 0 | - | - | 20 | 91.85 | 7.45 | - |
| 60 hr | 0 | - | - | 20 | 92.10 | 7.05 | - |
| 64 hr | 0 | - | - | 20 | 90.05 | 5.53 | - |
| 68 hr | 0 | - | - | 13 | 91.08 | 6.66 | - |
| 72 hr | 0 | - | - | 6 | 85.33 | 5.79 | - |

*Significant (p<0.05) 2 independent sample t-test used

Table 5: Intraoperative ScvO₂ at different time intervals.

| ScvO ₂ at | Group E | | | Group F | | | P value |
|----------------------|---------|-------|------|---------|-------|------|---------|
| | N | Mean | SD | N | Mean | SD | |
| Pre operative | 0 | - | - | 0 | - | - | - |
| At induction | 0 | - | - | 0 | - | - | - |
| 10 min | 0 | - | - | 0 | - | - | - |
| 20 min | 0 | - | - | 0 | - | - | - |
| 30 min | 0 | - | - | 20 | 68.85 | 2.54 | - |
| 40 min | 18 | 71.39 | 3.11 | 20 | 69.80 | 2.86 | 0.111 |
| 50 min | 17 | 72.24 | 3.25 | 20 | 70.80 | 2.75 | 0.161 |
| 60 min | 20 | 72.30 | 3.79 | 20 | 71.60 | 2.37 | 0.488 |
| 70 min | 17 | 72.29 | 3.16 | 20 | 71.65 | 2.43 | 0.498 |

Continued.

| ScvO ₂ at | Group E | | | Group F | | | P value |
|----------------------|---------|-------|------|---------|-------|------|----------|
| | N | Mean | SD | N | Mean | SD | |
| 80 min | 17 | 72.76 | 3.95 | 20 | 71.55 | 2.54 | 0.285 |
| 90 min | 20 | 72.40 | 3.02 | 20 | 71.15 | 3.12 | 0.205 |
| 100 min | 17 | 72.65 | 3.24 | 20 | 71.00 | 2.34 | 0.092 |
| 110 min | 17 | 73.88 | 4.21 | 20 | 70.65 | 2.35 | 0.004* |
| 120 min | 17 | 73.59 | 3.28 | 20 | 70.70 | 2.60 | 0.003* |
| 130 min | 20 | 73.85 | 3.65 | 20 | 70.20 | 2.28 | < 0.001* |
| 140 min | 17 | 72.71 | 3.31 | 20 | 70.45 | 1.99 | 0.015* |
| 150 min | 17 | 72.06 | 3.36 | 20 | 70.85 | 1.90 | 0.178 |
| 160 min | 17 | 73.24 | 3.29 | 20 | 71.40 | 1.93 | 0.041* |
| 170 min | 20 | 73.85 | 3.22 | 20 | 71.55 | 2.06 | 0.015* |
| 180 min | 17 | 73.47 | 3.18 | 20 | 72.05 | 1.70 | 0.092 |
| 190 min | 17 | 74.65 | 3.86 | 20 | 71.05 | 1.73 | < 0.001* |
| 200 min | 17 | 74.76 | 3.01 | 19 | 71.37 | 1.86 | < 0.001* |
| 210 min | 15 | 74.07 | 2.69 | 11 | 71.73 | 2.05 | < 0.001* |
| 220 min | 10 | 74.50 | 2.84 | 6 | 72.17 | 2.14 | 0.106 |
| 230 min | 5 | 74.60 | 2.61 | 2 | 71.50 | 0.71 | 0.176 |
| 240 min | 0 | - | - | 0 | - | - | - |

*Significant (p<0.05) 2 independent sample t-test used

Table 6: Postoperative ScvO₂ at different time intervals.

| Post op ScvO ₂ at | Group E | | | Group F | | | P value |
|------------------------------|---------|-------|------|---------|-------|------|---------|
| | N | Mean | SD | N | Mean | SD | |
| 1 hr | 20 | 71.50 | 2.93 | 20 | 71.95 | 1.43 | 0.542 |
| 2 hr | 17 | 71.53 | 4.21 | 20 | 73.35 | 1.95 | 0.468 |
| 3 hr | 17 | 71.76 | 3.47 | 20 | 72.90 | 1.94 | 0.243 |
| 4 hr | 17 | 71.35 | 3.71 | 20 | 73.40 | 1.73 | 0.033* |
| 5 hr | 20 | 71.20 | 3.43 | 20 | 73.24 | 2.59 | 0.040* |
| 6 hr | 17 | 70.65 | 4.21 | 20 | 73.95 | 3.22 | 0.807 |
| 10 hr | 17 | 70.06 | 3.42 | 20 | 73.55 | 3.20 | 0.003* |
| 14 hr | 17 | 70.76 | 3.51 | 20 | 73.45 | 3.09 | 0.018* |
| 16 hr | 20 | 69.95 | 3.50 | 20 | 73.20 | 2.46 | 0.002* |
| 20 hr | 17 | 69.35 | 4.30 | 20 | 73.90 | 4.01 | 0.002* |
| 24 hr | 17 | 67.24 | 4.67 | 20 | 70.75 | 4.19 | 0.021* |
| 28 hr | 17 | 67.88 | 4.47 | 20 | 70.05 | 3.89 | 0.123 |
| 32 hr | 20 | 68.15 | 3.82 | 20 | 69.05 | 3.72 | 0.455 |
| 36 hr | 17 | 68.59 | 3.18 | 20 | 69.05 | 3.36 | 0.671 |
| 40 hr | 17 | 68.71 | 3.48 | 20 | 68.05 | 3.35 | 0.565 |
| 44 hr | 17 | 67.35 | 3.71 | 20 | 67.20 | 3.74 | 0.902 |
| 48 hr | 20 | 67.95 | 1.50 | 20 | 67.10 | 2.88 | 0.249* |
| 52 hr | 0 | - | - | 20 | 65.15 | 2.78 | - |
| 56 hr | 0 | - | - | 20 | 65.20 | 2.71 | - |
| 60 hr | 0 | - | - | 20 | 65.15 | 2.56 | - |
| 64 hr | 0 | - | - | 20 | 64.45 | 2.63 | - |
| 68 hr | 0 | - | - | 13 | 63.69 | 2.29 | - |
| 72 hr | 0 | - | - | 6 | 63.33 | 2.94 | - |

*Significant (p<0.05) 2 independent sample t-test used

Table 7: Preoperative and intraoperative rSO₂- cerebral at different time intervals.

| RSO ₂ C at | Group E | | | Group F | | | P value |
|-----------------------|---------|-------|------|---------|-------|------|---------|
| | N | Mean | SD | N | Mean | SD | |
| Pre operative | 0 | - | - | 0 | - | - | - |
| At induction | 20 | 71.35 | 3.65 | 20 | 69.45 | 3.19 | 0.088 |
| 10 min | 20 | 76.55 | 5.51 | 20 | 79.75 | 4.70 | 0.056 |

Continued.

| RSO ₂ C at | Group E | | | Group F | | | P value |
|-----------------------|---------|-------|------|---------|-------|------|----------|
| | N | Mean | SD | N | Mean | SD | |
| 20 min | 20 | 80.10 | 5.18 | 20 | 82.65 | 4.67 | 0.110 |
| 30 min | 20 | 82.40 | 5.23 | 20 | 84.30 | 4.70 | 0.234 |
| 40 min | 20 | 84.00 | 4.98 | 20 | 85.25 | 4.54 | 0.412 |
| 50 min | 20 | 86.25 | 4.38 | 20 | 86.15 | 4.27 | 0.942 |
| 60 min | 20 | 86.75 | 4.01 | 20 | 87.10 | 4.15 | 0.788 |
| 70 min | 20 | 87.70 | 3.97 | 20 | 88.20 | 3.41 | 0.672 |
| 80 min | 20 | 88.60 | 4.07 | 20 | 88.00 | 3.29 | 0.611 |
| 90 min | 20 | 89.15 | 4.06 | 20 | 88.70 | 2.41 | 0.673 |
| 100 min | 20 | 90.65 | 3.65 | 20 | 88.15 | 3.27 | 0.028* |
| 110 min | 20 | 91.70 | 3.56 | 20 | 87.30 | 3.39 | < 0.001* |
| 120 min | 20 | 90.95 | 4.03 | 20 | 87.35 | 3.13 | 0.003* |
| 130 min | 20 | 89.10 | 3.64 | 20 | 87.40 | 3.33 | 0.131 |
| 140 min | 20 | 90.75 | 3.57 | 20 | 87.90 | 2.47 | 0.006* |
| 150 min | 20 | 89.75 | 4.06 | 20 | 87.35 | 3.31 | 0.047* |
| 160 min | 20 | 89.30 | 3.51 | 20 | 87.00 | 3.29 | 0.070 |
| 170 min | 20 | 90.70 | 4.17 | 20 | 87.30 | 3.18 | 0.006* |
| 180 min | 20 | 89.70 | 3.73 | 19 | 87.42 | 3.49 | 0.056 |
| 190 min | 20 | 89.65 | 4.46 | 11 | 88.00 | 2.61 | 0.271 |
| 200 min | 20 | 89.50 | 4.16 | 6 | 86.33 | 1.86 | 0.085 |
| 210 min | 18 | 89.22 | 4.53 | 2 | 84.00 | 0.00 | - |
| 220 min | 11 | 89.45 | 4.48 | 0 | - | - | - |
| 230 min | 6 | 88.67 | 4.76 | 0 | - | - | - |
| 240 min | 1 | 88.00 | - | 0 | - | - | - |

*Significant (p<0.05) 2 independent sample t-test used

Table 8: Preoperative and intraoperative rSO₂- renal at different time intervals.

| RSO ₂ R at | Group E | | | Group F | | | P value |
|-----------------------|---------|-------|------|---------|-------|------|----------|
| | N | Mean | SD | N | Mean | SD | |
| Pre-operative | 0 | - | - | 0 | - | - | - |
| At induction | 20 | 68.85 | 3.66 | 20 | 67.15 | 3.22 | 0.127 |
| 10 min | 20 | 80.80 | 4.79 | 20 | 81.00 | 4.90 | 0.896 |
| 20 min | 20 | 80.10 | 4.73 | 20 | 82.45 | 4.68 | 0.123 |
| 30 min | 20 | 82.05 | 4.81 | 20 | 84.25 | 4.25 | 0.134 |
| 40 min | 20 | 83.45 | 4.47 | 20 | 84.85 | 3.80 | 0.293 |
| 50 min | 20 | 84.25 | 4.63 | 20 | 85.75 | 2.88 | 0.228 |
| 60 min | 20 | 84.85 | 3.75 | 20 | 86.05 | 4.21 | 0.347 |
| 70 min | 20 | 86.30 | 3.44 | 20 | 86.80 | 3.40 | 0.646 |
| 80 min | 20 | 85.90 | 3.54 | 20 | 87.15 | 4.07 | 0.307 |
| 90 min | 20 | 86.80 | 3.56 | 20 | 85.55 | 3.46 | 0.267 |
| 100 min | 20 | 88.70 | 3.44 | 20 | 85.65 | 2.78 | 0.003* |
| 110 min | 20 | 88.15 | 3.51 | 20 | 85.85 | 2.83 | 0.028* |
| 120 min | 20 | 88.75 | 3.29 | 20 | 85.85 | 2.78 | 0.004* |
| 130 min | 20 | 88.50 | 3.68 | 20 | 85.55 | 2.58 | 0.006* |
| 140 min | 20 | 88.45 | 3.90 | 20 | 85.25 | 2.83 | 0.005* |
| 150 min | 20 | 88.75 | 3.19 | 20 | 85.05 | 2.61 | < 0.001* |
| 160 min | 20 | 87.00 | 3.99 | 20 | 84.85 | 3.31 | 0.037* |
| 170 min | 20 | 88.70 | 3.34 | 20 | 85.40 | 3.03 | 0.002* |
| 180 min | 20 | 87.50 | 3.72 | 19 | 85.58 | 2.55 | 0.069 |
| 190 min | 20 | 86.25 | 3.73 | 11 | 86.36 | 2.20 | 0.929 |
| 200 min | 20 | 88.60 | 4.51 | 6 | 84.00 | 3.52 | 0.031* |
| 210 min | 18 | 87.33 | 5.17 | 2 | 84.00 | 5.66 | 0.401 |
| 220 min | 11 | 88.64 | 5.39 | 0 | - | - | - |
| 230 min | 6 | 88.33 | 4.27 | 0 | - | - | - |
| 240 min | 1 | 86.00 | - | 0 | - | - | - |

*Significant (p<0.05) 2 independent sample t-test used

Table 9: Postoperative rSO₂- renal at different time intervals.

| Post operative | Group E | | | Group F | | | P value |
|------------------------------|---------|-------|------|---------|-------|------|---------|
| | N | Mean | SD | N | Mean | SD | |
| R SO₂ R at | | | | | | | |
| 1 hr | 20 | 81.40 | 5.07 | 20 | 83.15 | 2.50 | 0.177 |
| 2 hr | 20 | 80.20 | 4.80 | 20 | 84.10 | 2.47 | 0.003* |
| 3 hr | 20 | 79.05 | 4.85 | 20 | 82.80 | 2.76 | 0.005* |
| 4 hr | 20 | 78.25 | 5.05 | 20 | 81.80 | 3.79 | 0.017* |
| 5 hr | 20 | 77.15 | 5.16 | 20 | 81.05 | 3.69 | 0.009* |
| 6 hr | 20 | 76.55 | 4.98 | 20 | 81.00 | 4.09 | 0.004* |
| 10 hr | 20 | 77.10 | 4.84 | 20 | 80.90 | 3.93 | 0.010* |
| 14 hr | 20 | 76.15 | 5.43 | 20 | 80.00 | 4.28 | 0.018* |
| 16 hr | 20 | 75.75 | 4.54 | 20 | 78.15 | 5.32 | 0.134 |
| 20 hr | 20 | 74.55 | 3.30 | 20 | 77.55 | 5.39 | 0.042* |
| 24 hr | 20 | 73.95 | 2.44 | 20 | 76.00 | 4.98 | 0.110 |
| 28 hr | 20 | 73.90 | 2.17 | 20 | 75.80 | 5.39 | 0.156 |
| 32 hr | 20 | 73.50 | 2.16 | 20 | 75.05 | 4.93 | 0.209 |
| 36 hr | 20 | 72.70 | 2.27 | 20 | 74.35 | 4.87 | 0.181 |
| 40 hr | 20 | 72.50 | 1.79 | 20 | 73.20 | 4.56 | 0.529 |
| 44 hr | 20 | 71.85 | 1.73 | 20 | 71.95 | 3.82 | 0.916 |
| 48 hr | 20 | 71.55 | 1.88 | 20 | 70.85 | 2.03 | 0.265 |
| 52 hr | 0 | - | - | 20 | 70.95 | 1.61 | - |
| 56 hr | 0 | - | - | 20 | 70.45 | 1.73 | - |
| 60 hr | 0 | - | - | 20 | 70.45 | 1.99 | - |
| 64 hr | 0 | - | - | 20 | 69.80 | 1.32 | - |
| 68 hr | 0 | - | - | 14 | 70.07 | 2.02 | - |
| 72 hr | 0 | - | - | 6 | 69.50 | 2.35 | - |

*Significant (p<0.05) 2 independent sample t-test used

Table 10: Post-operative pain scores.

| Post-operative | Group E | | | | Group F | | | | P value |
|----------------------|---------|-----|-----|--------|---------|-----|-----|--------|----------|
| | N | Min | Max | Median | N | Min | Max | Median | |
| Pain score at | | | | | | | | | |
| 1 hr | 20 | 1 | 4 | 2 | 20 | 2 | 5 | 3 | 0.007* |
| 2 hr | 20 | 2 | 4 | 2 | 20 | 3 | 5 | 3 | 0.03* |
| 3 hr | 20 | 2 | 4 | 3 | 20 | 3 | 4 | 4 | 0.017* |
| 4 hr | 20 | 3 | 4 | 3 | 20 | 3 | 4 | 3 | 0.495 |
| 55 hr | 20 | 2 | 5 | 3.5 | 20 | 3 | 4 | 3 | 0.478 |
| 6 hr | 20 | 2 | 5 | 3.5 | 20 | 3 | 5 | 3 | 0.841 |
| 10 hr | 20 | 3 | | 3 | 20 | 3 | 5 | 4 | 0.596 |
| 14 hr | 20 | 2 | 5 | 3.5 | 20 | 4 | 5 | 4 | < 0.001* |
| 16 hr | 20 | 3 | 4 | 3 | 20 | 4 | 6 | 5 | < 0.001* |
| 18 hr | 20 | 3 | 5 | 3 | 20 | 4 | 6 | 5 | < 0.001* |
| 20 hr | 20 | 3 | 5 | 4 | 20 | 3 | 6 | 5 | 0.001* |
| 24 hr | 20 | 2 | 4 | 3 | 20 | 3 | 6 | 5 | < 0.001* |
| 28 hr | 20 | 2 | 5 | 3 | 20 | 3 | 6 | 5 | < 0.001* |
| 32 hr | 20 | 2 | 4 | 3 | 20 | 3 | 6 | 4 | 0.003* |
| 36 hr | 20 | 2 | 4 | 3 | 20 | 3 | 6 | 4 | 0.002* |
| 40 hr | 20 | 3 | 5 | 4 | 20 | 3 | 5 | 4 | 0.414 |
| 44 hr | 20 | 3 | 4 | 3 | 20 | 2 | 5 | 4 | 0.035* |
| 48 hr | 20 | 3 | 4 | 3 | 20 | 3 | 5 | 3.5 | 0.108 |

*Significant (p<0.05) 2 independent sample t-test used

As seen in Table 1, the mean heart rate of patients in the two groups were almost comparable at the preoperative and induction period but the rise in heart rate was higher

in group F following skin incision and sternotomy, which is statistically significant with a p<0.05.

As shown in table 2, the mean heart rate of patients was higher in group F in the post-operative period which is statistically significant with a $p < 0.05$. (2 independent sample t-test used)

In the table 3, the mean systolic blood pressure of patients in the two groups were almost comparable at the preoperative and induction period but the rise in systolic blood pressure was higher in group F following skin incision and sternotomy and also intraoperatively which is statistically significant with a $p < 0.05$. (2 independent sample t-test used).

In the table 4, the mean systolic blood pressure of patients was higher in group F in the post-operative period which is statistically significant with a $p < 0.05$. (2 independent sample t-test used)

Preoperative and intraoperative diastolic blood pressure at different time intervals

The mean diastolic blood pressure of patients in the two groups were almost comparable at the preoperative and induction period. The diastolic blood pressure was slightly lower in group E following surgical insult. The difference was not statistically significant, $p > 0.05$. (2 independent sample t-test used)

Postoperative diastolic blood pressure at different time intervals

The mean diastolic blood pressure of patients was comparable between the two groups in the post-operative period. The difference between the groups was not statistically significant with a $p > 0.05$. (2 independent sample t-test used)

Intraoperative central venous pressure / left atrial pressure at different time intervals

The mean CVP/LAP was comparable between the two groups in the intra-operative period. The difference between the two groups is not statistically significant with a $p > 0.05$. (2 independent sample t-test used)

Post-operative central venous pressure / left atrial pressure at different time intervals

The mean CVP/LAP was comparable between the two groups in the postoperative period except for 20, 32, 44, 48th hr where CVP/LAP was lower in group F with a statistically significant $p < 0.05$. (2 independent sample t-test used).

In the table 5, the mean ScvO₂ was comparable between the two groups during induction period but became higher in group E during bypass and post bypass period intraoperatively, and the difference in rise in ScvO₂ is statistically significant with a $p < 0.05$. (2 independent sample t-test used)

In the table 6, the mean ScvO₂ was comparable between the two groups in the early postoperative period but group F shows higher ScvO₂ postoperatively which was statistically significant with a p value < 0.05 . (2 independent sample t-test used) at 4,5,10,14,16,20,24th hour.

In the table 7, the mean rSO₂-c was comparable between the two groups during induction period but became higher in group E during bypass and post bypass period intraoperatively, The difference in rSO₂-c rise is statistically significant with a $p < 0.05$. (2 independent sample t-test used)

Postoperative rSO₂- cerebral at different time intervals

The mean rSO₂- C was comparable between the two groups in the first postoperative hour but group F shows higher rSO₂-C postoperatively which was statistically significant with a $p < 0.05$. (2 independent sample t-test used) at 2nd to 14th hour, 20th hour post operatively.

In the table 8, the mean rSO₂-R was comparable between the two groups during induction period but became higher in group E during bypass and post bypass period intraoperatively, The difference in rSO₂-R rise is statistically significant with a $p < 0.05$. (2 independent sample t-test used).

In the table 9, the mean rSO₂-R was comparable between the two groups in the first postoperative hour but group F shows higher rSO₂-R postoperatively which was statistically significant with a $p < 0.05$. (2 independent sample t-test used) at 2nd to 14th hour, 20th hour post operatively.

Intraoperative urine output at different time intervals

The intraoperative urine output was comparable between the two groups. The statistical difference with a $p > 0.05$.

Post-operative urine output at different time intervals

The postoperative urine output was comparable between the two groups. The statistical difference was with a $p > 0.05$.

Intra-operative blood sugar levels at different time intervals

The blood sugar was significantly lower in group E during 60 th and 90th min intraoperative period. This difference is statistically different with a $p < 0.05$.

Post-operative blood sugar levels at different time intervals

The blood sugar was comparable between the two groups period. This difference is statistically not significant with a $p > 0.05$.

LVEF at immediate post op and 12 hours after surgery

Not significant ($p>0.05$) 2 independent sample t-test used.

Duration of ICU stay during postoperative period

The mean duration of stay in ICU for Group E was 48.45 and Group F was 56.80. Significant $p=0.013$ ($p<0.05$)

Amount of post-operative bleeding

The postoperative bleeding was found to be comparable within the first 48 hours but was lower in group E in 72 hour. The difference was statistically significant with $p<0.05$ (2 independent sample t-test used)

As shown in table 10, the postoperative pain was significantly lower in group E in the postoperative period (except for 4,5,6 and 40 and 48th hour). The difference was statistically significant with a $p<0.05$.

DISCUSSION

The management of perioperative pain in cardiac surgical patients is a challenge to every anaesthesiologist especially in paediatric age groups. Pain due to sternotomy is severe and difficult to control. Poor control of pain in post op period often leads to poor respiratory effort and further complications related to it. High thoracic epidural analgesia has many beneficial effects in the paediatric patient population and is used to augment general anesthesia and to manage perioperative pain. Effective pain relief from epidural analgesia has numerous benefits including stable hemodynamics, lowered circulating stress hormone level, rapid weaning from ventilation and earlier ambulation.⁵

The present study was conducted to compare the various intraoperative and post operative vital parameters and events including the time to extubation and reintubation if any, duration of post-operative ventilation, length of stay in ICU in post operative period, amount of post-operative bleeding, urine output, blood glucose and pain score between patients receiving High thoracic epidural analgesia and patients receiving conventional IV opioid analgesia in paediatric patients undergoing VSD corrective surgery under cardiopulmonary bypass. Moreover this study was also conducted due to the paucity of previous studies using a similar technique in this patient population.⁶ Previous studies have shown potential benefit of regional anaesthesia in paediatric cardiac surgery.⁷⁻⁹

In our study, we employed the placement of high thoracic epidural at the level of T3-4.¹⁰ The high thoracic approach was favoured for several reasons. Firstly, among the epidural sites used, the site with the lowest complication rate was the thoracic site. Second, additional theoretical advantages of the thoracic approach include selective segmental anaesthesia at the level of the incision, short catheter threading distance, reducing the risk of vein

disruption, observed decreased incidence of paraesthesia, and no lower extremity motor blockade, permitting early postoperative assessment of motor function.¹¹ The catheter technique may be superior to the single shot technique in cardiac surgical children because it allows for smoother control of analgesia and anaesthesia. It is well known that the single shot dose effect can be variable and may wear off during a period of critical haemodynamic recovery.

ScvO₂ remains the gold standard surrogate for tissue extraction in paediatric cardiac surgery.¹² In our study both means of ScvO₂ and rSO₂ (cerebral and renal) was found to be within the normal limits but higher in group E during the bypass and the post bypass period when compared to group F. However both the parameters were on contrast lower in the post operative period in group E, which is possibly influenced by the large number of patients who were mechanically ventilated with 50% FiO₂ in group F whereas those of group E were mostly extubated on table and spontaneously breathing on room air during the period of comparisons postoperatively. Urine output was also measured intraoperatively and postoperatively between the two groups and was found to be lying within normal limits and comparable between the two groups with statistical significance of $p>0.05$. Regional tissue and venous oxygenation is also an indicator of cardiac output. In our study we estimated LVEF by echocardiography in the immediate post operative period just after extubation and 12 hours postoperatively in ICU. The mean LVEF was found to be 49.5% in group E and 49.75% in group F in the immediate post-operative period and 54.5% and 54% 12 hours later in ICU respectively, which was comparable in both groups with a $p>0.05$.

In our study the mean blood sugar levels were measured and found to be comparable between the two groups, with higher blood sugar levels in group F both intra-operatively and post-operatively which is statistically not significant ($p>0.05$). The post-operative bleeding was also estimated between the two groups. The mean chest drainage in group E was found to be 58.95 ml versus 64.40 ml in group F in the first postoperative day, whereas 20.90 ml in group E versus 21.50 ml in group F in 2nd postoperative day, both findings were comparable with a $p>0.05$, whereas bleeding was found to be higher on 3rd postoperative day in group F with mean of 6.30 ml against 4.25 ml in group E, which is statistically significant with a $p<0.05$.

There is an increasing trend to fast track these children undergoing paediatric cardiac surgery under cardiopulmonary bypass.¹³⁻¹⁷ Central neuraxial blockade facilitates the fast track protocols by sparing the use of intravenous opioids. In our study the mean time to extubation and requirement of post operative ventilation is significantly lower in group E with a mean of 3.7 hours only, whereas it is 23.55 hours in group F with a $p<0.001$. The duration of ICU stay was also compared, with lower mean duration of ICU stay in group E, which was 48.45

hours and in group F 56.8 hours, which is statistically significant with $p < 0.013$.

Perioperative pain management in cardiac surgery is vital in the outcome of surgery. In our study Wong baker face scale was used to analyse the post operative pain.¹⁶ Mann-whitney U test was used to compare the median scores in both the groups and it was found that group E have lower postoperative pain score which is statistically significant with a $p < 0.05$.

In our study to minimize the complications associated with infections, strict and meticulous sterile technique was employed as well as the catheter was tunnelled through the subcutaneous space. A small subcutaneous placement of the proximal portion of the catheter not only decreases the length of tubing exposed to contamination, but it also helps in a more secure catheter placement. Both of these features become especially advantageous in prolonged epidural catheter use. This study was undertaken after judging the potential advantages with the potential risk involved. We found that with better appreciation of the paediatric thoracic epidural anatomy and experience, the technical difficulties in performing the procedure can be overcome. However we encountered two accidental dural punctures, the catheter was subsequently removed and then placed one level above and followed up with no complications afterwards.

The limitations of the study were a relatively smaller number of subjects. Further research with a larger population would be required in future to confirm the findings.

CONCLUSION

To conclude we found that HTEA to paediatric patients prior to sternotomy for cardiac surgeries resulted in a much better control of haemodynamic parameters. Produces better central venous and regional tissue oxygenation during bypass and post bypass intraoperatively as compared to the patients that received only intravenous fentanyl. The results of the study also revealed lower amount of postoperative bleeding in the HTEA group. There was significant reduction in requirement of post operative ventilation and time to extubation after surgery in HTEA group. And better post operative pain control and overall outcome thereby reducing the total length of ICU stay. There was no evidence of any major complication to the epidural catheter placement in the form of epidural haematoma or systemic cardiotoxicity.

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