Comparison of analgesic efficacy and safety of continuous epidural infusion versus local infiltration and systemic opioids in video-assisted thoracoscopic surgery decortication in pediatric empyema patients

ABSTRACT

Introduction: The stripping of the densely innervated and inflamed parietal pleura in empyema during video-assisted thoracoscopic surgery (VATS) decortication can lead to significant pain and major postoperative respiratory compromise. Hence, we compared the analgesic efficacy of continuous epidural infusion versus local infiltration and systemic opioids in children undergoing VATS decortications.

Methodology: Following ethics approval and informed consent, forty patients from 1 to 12 years of age were randomized into two groups, Group E (epidural) and Group L (local infiltration) after induction of anesthesia. In Group E, a thoracic epidural catheter was inserted between T4 and T8. A bolus dose of 0.5 ml/kg of 0.25% injection bupivacaine was given epidurally before incision. Postoperatively, the patients received epidural infusion with bupivacaine and fentanyl up to 48 h using an elastomeric balloon pump. In Group L, patients received local infiltration of bupivacaine (2 mg/kg) and lignocaine (5 mg/kg) at the port sites before incision and at the end of surgery. They also received injection tramadol 1 mg/kg intravenously TDS with thrice daily postoperatively. The pain scores (Face, Legs, Activity, Cry, Consolability/ Wong-Baker FACES scale) were assessed every 4 h on the 1st day and 6 h on the 2nd day. Injection diclofenac 1 mg/kg intravenous was used as a rescue analgesic for pain scores more than 4. Side effects such as nausea, vomiting, constipation, and motor blockade were noted. Quantitative and categorical data were assessed using t-test and Chi-square test, respectively.

Results: The pain scores were lower in the epidural group than in the local infiltration group at 0, 4, and 20 h postoperatively (P = 0.001, 0.01, and 0.038, respectively). Seventeen out of nineteen patients required rescue analgesia in the local infiltration group in the postoperative period as compared to five patients in the epidural group with a P value of 0.000081.

Conclusion: Epidural analgesia can be considered as an effective modality of reducing pain in patients undergoing VATS decortication for empyema in pediatric patients.

Key words: Children; decortications; empyema; epidural anesthesia; video-assisted thoracoscopic surgery

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**Introduction**

Empyema thoracis, an accumulation of infected fluid within the thoracic cavity, is common secondary to postinfectious pneumonia or can be posttraumatic, after thoracic surgeries or esophageal leaks. The incidence of thoracic empyema in children has increased dramatically over the past years.[1,2] Video-assisted thoracoscopic surgery (VATS) and decortication are the treatments of choice nowadays in Stage 2, i.e., the fibrinopurulent stage. This approach is supposed to have the advantages of a smaller incision, less postoperative pain, and a faster recovery as compared with thoracotomy.[3] Hence, the standard practice at our institute is local infiltration at the port and intercostal drain sites and systemic opioids such as tramadol postoperatively. However, the stripping of the densely innervated and inflamed parietal pleura along with the visceral pleura in cases of empyema as well as irritation due to the intercostals drain can lead to significant pain.[4] If managed suboptimally in patients with severely limited respiratory reserve, it can have major respiratory consequences.[5] There is a paucity of studies regarding various modalities of pain relief in children undergoing VATS decortications for empyema. This randomized study was designed to compare continuous epidural infusion versus local infiltration and systemic opioids for pain relief after VATS decortication in pediatric patients having empyema.

**Methodology**

This was a randomized prospective controlled study. The trial has been registered with the CTRI with registration no. 2017/06/008729. Patients in the age group of 1–12 years posted for VATS decortication for empyema thoracis were included in this study. Patients with contraindications for regional anesthesia, i.e., local sepsis at the site of insertion, coagulopathy, severe valvular heart disease, patient/parental refusal, and known allergy to local anesthetic agents were excluded from the study. The withdrawal criteria were cases converted to open decortications and inadvertent epidural catheter removal or displacement. The primary objective of the study was to compare the analgesic efficacy of continuous epidural infusion versus local infiltration and systemic opioids in pediatric patients undergoing VATS decortication for empyema thoracis. The secondary objective was to compare the safety of continuous epidural infusion versus local infiltration and systemic opioids in these patients. We hypothesize that epidural infusion provides better analgesia than local infiltration and intravenous (IV) opioids in pediatric patients undergoing VATS decortications for empyema.

Forty patients were enrolled in the study. Randomization was done using the website www.randomisation.com using a plan which divided forty patients into two groups and assigned either epidural or local infiltration with systemic therapy to each patient randomly. Allocation concealment was done using sequentially numbered opaque-sealed envelopes technique. The study was carried out in pediatric surgery operation theater, and the postoperative data were collected in the surgical intensive care unit in a tertiary care referral hospital.

Following institutional ethics committee’ approval, obtaining informed consent from parents, and obtaining assent from children more than 7 years of age, patients were randomized into two groups, Group E (epidural) and Group L (local infiltration) after induction of anesthesia and endotracheal intubation. In Group E patients, a thoracic epidural catheter was inserted between T4 and T8 using a paramedian approach. The epidural set used for patients <20 kg had a 20G epidural needle and 24G catheter. The epidural set used for patients more than 20 kg had an 18G needle with 20G catheter. Test dose of 1% adrenalized lignocaine 0.1 ml/kg was given to rule out intravascular or intrathecal injection. A bolus dose of 0.5 ml/kg of 0.25% injection bupivacaine was given epidurally before incision. Postoperatively, the patients received epidural infusion with bupivacaine and fentanyl up to 48 h. The volume of drug required for 48 h calculated was filled in a multidose elastomeric balloon pump (Baxter® Multirate infusor IV) which delivered the drug at the set rate continuously. The concentration and amount of drug for continuous infusion was 0.25 mg/kg/h (0.4 mL/kg/h of a 0.0625% solution) in the age group of 12–18 months and 0.3125–0.375 mg/kg/h (0.25–0.3 mL/kg/h of a 0.125% solution). The fentanyl concentration used in the infusion was 2 mcg/ml.

The Group L patients received local infiltration of injection bupivacaine and injection lignocaine not exceeding their toxic doses (total 2 mg/kg and 5 mg/kg, respectively, divided into two doses) at the port sites before incision and at the end of surgery. They also received injection tramadol 1 mg/kg intravenously TDS thrice daily postoperatively. Both groups received 2 mcg/kg fentanyl at induction and 1 mcg/kg fentanyl intraoperatively. The analgesic efficacy in the postoperative period was assessed using the Face, Legs, Activity, Cry, Consolability scale for preverbal children, i.e., 1–3 years and the Wong-Baker FACES scale for more than 3 years of age. The pain scores were assessed at an interval of 4 h on the first day and at an interval of 6 h on the second day. Injection diclofenac 1 mg/kg IV was used as a rescue analgesic in both the groups in case pain scores were more than 4. Safety was assessed by looking for adverse events such as
motor blockade, nausea and vomiting, constipation, urinary retention, respiratory depression, toxicity of local anesthetics, pruritus, and infection at catheter site. We did not measure blood levels of local anesthetic. The clinical parameters used to assess toxicity were arrhythmias or cardiovascular collapse intraoperatively and perioral tingling, numbness, excitation, convulsions, and drowsiness postoperatively.

According to a previous study,[6] the mean difference in the VAS scores among the two groups was 0.87. The standard deviation for nonepidural group was 1.01, and for epidural group, it was 0.88. Using these values, with 95% confidence interval and power of study 90%, the sample size came to 19 in each group. The results were analyzed using SPSS version 16.0 (SPSS Inc., Chicago, USA.) version 16. Unpaired t-test was used to analyze the quantitative data, and Chi-square test was used to analyze the categorical data. P < 0.05 was considered statistically significant.

Results

The study was conducted over a period of one and a half year from October 2015 to March 2017. The data from thirty-eight patients out of the forty enrolled were statistically analyzed [Figure 1]. One patient in Group L had video-assisted surgery converted to open decortication while one patient in Group E had accidental catheter removal on day one. They were withdrawn from the study. Both the groups were comparable with respect to the demographic characteristics, i.e., age, gender, weight, and duration of surgery [Table 1]. The number of children below 18 months and above 18 months were 5 and 14, respectively, in Group E and 6 and 13 patients, respectively, in Group L with P = 0.720. Thus, the difference was not statistically significant. Differences in the pain scores were statistically significant with P values of 0.001, 0.01, and 0.038 at 0, 4, and 20 h, respectively [Table 2]. Seventeen out of nineteen patients required rescue analgesia in the local infiltration group in the postoperative period as compared to five patients in the epidural group [Graph 1] with P = 0.000081. Urinary retention was seen in two patients in the epidural group. Nausea was experienced by one patient in the epidural group while nausea and vomiting was seen in five out of nineteen patients in the local infiltration group. No other side effects were seen. There was no failure of block in the epidural group.

Discussion

The incidence of empyema thoracis has declined in the west due to effective use of broad-spectrum antibiotics, but it continues to be a health burden in developing countries due to malnutrition, prevalence of tuberculous infection, delayed diagnosis of pneumonia, and delayed referral to higher center.[7] The treatment modality for empyema depends on the clinical stage with VATS being increasingly used in the fibrinopurulent stage. Suboptimal pain management of these patients with limited respiratory reserve can lead to splinting of diaphragm,

### Table 1: Demographic data

| Parameter                        | Group E | Group L | P     |
|----------------------------------|---------|---------|-------|
| Age (years), mean±SD             | 6.39±4.06 | 6.21±3.91 | 0.902 |
| Gender (male/female), number of patients | 12/7 | 13/6 | 0.709 |
| Weight (kg), mean±SD             | 17.34±7.08 | 16.43±6.3 | 0.732 |
| Duration of surgery (min), mean±SD | 149±21 | 139±21 | 0.212 |

SD: Standard deviation

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**Figure 1: CONSORT 2010 flow diagram**
Epidural analgesia has shown many advantages over IV opioids in patients undergoing thoracotomy for decortication of empyema. However, there is still a debate regarding the need for epidural analgesia after thoracotomy. In general, regional anesthesia techniques described for pediatric thoracotomy include thoracic epidural, thoracic paravertebral blockade, multiple intercostals blocks by the surgeon under direct vision or by anesthesiologist, or intrapleural analgesia. Patient-controlled analgesia using morphine or fentanyl has also been described in children. The problem with paravertebral catheter is that it would lie directly in the infected cavity in cases of empyema and be colonized right from insertion. Our literature search did not reveal any study addressing need and modalities for analgesia specifically for pediatric patients undergoing thoracoscopic decortications for empyema. A study conducted by Kamiyoshihara compared continuous epidural analgesia with continuous subcutaneous morphine infusion after VATS lobectomy in 30 adult patients and concluded that epidural analgesia is not necessary in such cases and may add to discomfort and cost. However, the study cohort was small and the surgery was VATS lobectomy and not decortication where there is removal of the pleural peel. They too believe that rigid adhesions of the pleura may require epidural analgesia. Furthermore, using a continuous morphine infusion may not be feasible in children due to the risk of respiratory depression.

A randomized study comparing postoperative epidural analgesia with nonsteroidal anti-inflammatory drugs in 46 adult patients undergoing VATS lobectomy or partial lung resection showed that patients in the epidural group experienced less postoperative pain and needed less additional analgesics than those in the nonepidural group. However, the incidence of nausea and vomiting was considerably higher in the epidural group. The reason for this could be the high concentration of fentanyl used in the continuous epidural infusion (1 mg in 80 ml). In our study, the pain scores in the local infiltration group were considerably higher than in the epidural group in the first 24 h after surgery. Hence, the need for rescue analgesia was much higher in that group. There was no hypotension or bradycardia in the epidural group. Only one patient experienced nausea in the epidural group while two patients had urinary retention. Nausea and vomiting was seen in five out of nineteen patients in the local infiltration group. The increased nausea and vomiting in the local infiltration group was probably due to the tramadol used for pain relief.

A major concern for the use of epidural analgesia in empyema patients is spread of infection and formation of epidural abscesses. The majority of local infections and catheter colonizations in critically ill patients are caused by skin flora. The most important controllable factor in the prevention of catheter-related epidural abscesses is the sterility of the site and equipment. An audit of epidural analgesia in empyema patients states that epidural analgesia cannot be contraindicated solely by the presence of thoracic sepsis. A limitation of our study could be the low patient numbers enrolled in the study. A larger or multicenter trial may be required to conclusively prove the benefit of epidural anesthesia in thoracoscopic decortication in pediatric patients.

### Conclusion

Epidural analgesia can be considered as an effective, safe, and necessary modality of pain relief in VATS decortication for pediatric thoracic empyema patients.
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Conflicts of interest
There are no conflicts of interest.

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