

# A cross-sectional observation study to evaluate the efficacy and complications of epidural analgesia in paediatric population

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## Abstract

**Background and Aims:** With advances in pediatric surgery, pediatric epidurals are increasingly being used for analgesia. As there is scarcity of data in India about the pediatric epidurals, we sought to determine the efficacy and complications of epidural analgesia. The aim of this study was to determine the efficacy of pediatric epidural analgesia and the incidence of complications aimed at improving the quality of care.

**Material and Methods:** It was a prospective observational study in tertiary care hospital in the Southern part of India. Newborns to children aged 18 years in whom continuous epidural analgesia was planned were recruited. They were followed up postoperatively at specified intervals wherein pain scores were used to determine analgesic efficacy. Complications were noted in a specified format and the level of satisfaction of patient and surgeon was noted objectively. All the statistical analyses were performed using SPSS 25.0.

**Results:** 100 children were recruited of which 63 received thoracic epidurals and 37 lumbar epidurals. Overall efficacy of epidural in pain management was 90.96% with the highest efficacy for lower abdominal epidurals (94.9%). Kinking of a catheter was the most common complication encountered (11%), followed by migration of catheter, occlusion of pump, and motor block.

**Conclusion:** Continuous epidural analgesia has proven to be a safe and effective method to provide analgesia to the children in a protected environment and experienced hands.

**Keywords:** Complications, epidural analgesia, pediatric population

**Key Message:** Epidurals are safe and effective modality of postoperative pain relief in protocolized setup.

## Introduction

Regional analgesia is an established analgesia model for children, caudal being the most common due to ease of technique and safety. However, the downside of caudal and single-shot epidurals is their limited duration of postoperative analgesia. The continuous infusion techniques with epidural catheters gain importance. Continuous epidural analgesia for children is considered challenging because of its imprecise pain

assessment among the different age groups, technical difficulty, safety concerns on drug dosing, patient acceptability, lack of expertise, and supervision.<sup>[1]</sup>

There is a paucity of data on epidural analgesia in children.<sup>[2]</sup> Very few studies looked into the efficacy and complications of epidural analgesia, and the existing published ones are retrospective<sup>[3,4]</sup> in nature. Hence, we attempted a prospective observational study to assess the efficacy of epidural blocks

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with specific mention to the complications involved among children.

The primary aim of our study was to assess the efficacy of epidural analgesia in children in the postoperative period. The secondary aim was to find the incidence of complications and the factors involved thereof. The study also intended to find the satisfaction scores with epidural analgesia among parents and surgeons as its secondary outcome.

## Material and Methods

In order to find the efficacy of epidural analgesia in children in the postoperative period and complications, we have done a prospective observational study in a tertiary care teaching hospital in South India after obtaining approval from the Institutional Review Board (IRB Min. No. 10462, Dated 05.01.2017).

Based on the current literature, the estimated rate of complications is 30% for continuous epidural anesthesia. Considering our complication rate of 30% with a 9% precision margin and 95% confidence limit, the sample size for the study was calculated as 100.

One hundred children requiring consecutive continuous epidural analgesia during the period from July 1, 2017 to August 31, 2018, were recruited after parent's consent and assent from children as appropriate. We divided patients into three groups: thoracic and upper abdominal surgeries (above T10), infraumbilical surgeries (below T10), and limb surgeries (below L1) for ease of evaluation.

The following protocol was used for their anesthesia. After induction of anesthesia under standard monitoring, all children were positioned in a lateral position with torso-in-fetal position; an epidural catheter was sited using a midline approach, under sterile condition. All epidurals were inserted using landmark technique, and needle insertion level was based on the desired sensory cover required. 4–5 cm of the catheter was placed in the epidural space after identifying epidural space with loss of resistance to saline. The selection of Tuohy needle size was based on the weight of infant as departmental policy, i.e., 20G Tuohy needle which comes with 24G catheter for children weighing <5 kg, 19G needle with 23G catheter for children weighing 5–25 kg, and 18G needle with 20G catheter for children weighing >25 kg. Only experienced anesthesiologists performed epidurals in children less than 10 kg, whereas epidurals in children weighing more than 20 kg were done under an experienced anesthesiologist's supervision. For the purpose of this study, we defined an experienced anesthesiologist as the one who has been placing epidurals for children for more than 3 years.<sup>[3]</sup>

A bolus (0.4–0.6 mg/kg of 0.2% ropivacaine or 0.2% bupivacaine) followed by continuous epidural infusion (0.1–0.4 mg/kg/h of 0.1% ropivacaine or 0.1% bupivacaine with 1 mcg/ml of fentanyl) of local anesthetics was started intraoperatively as per anesthesiologist's discretion based onsite and nature of surgery. We follow a strict policy of maintaining a close circuit at the Luer lock connector level and additional boluses should be given with the connected 50 cc syringe.

The patients were followed up postoperatively at 2, 8, 16, 24, 48, and 72 h for pain scores and complications related to epidural catheters. The postoperative premixed syringes contained 0.1% ropivacaine alone (< 10 kg), 0.1% ropivacaine with fentanyl 1 mcg/ml (< 30 kg), and 0.1% bupivacaine with fentanyl 2 mcg/ml for children weighing >30 kg. Motor block, if found, was managed with a reduction in the concentration of ropivacaine to 0.08%.

As we follow the multimodal analgesia protocol, all children received injection paracetamol (15 mg/kg) 6<sup>th</sup> hour. All patients were followed up and managed by the acute pain service (APS) team as per department policy and by the principal investigator. Plans, problems, and troubleshooting were documented by APS and principle investigators.

We followed validated pain scores—crying, oxygenation, vital signs, facial expression, and sleepiness (CRIES) for neonates; face, leg, activity, cry, consolability (FLACC) for children less than 7 years and numeral rating scale (NRS) for more than 7 year old. The infusion, boluses, and pain scores were noted at specific time intervals. An effective epidural was taken as one that provides a pain score of less than five.<sup>[4]</sup>

Various factors that were thought to affect efficacy were analyzed, like age and weight of the patient, type of surgery, technical difficulties like multiple punctures intraoperatively, the experience of the anesthesiologists, and the level of placement of epidural (thoracic or lumbar).

We divided intraoperative and postoperative complications into major and minor. A major complication was defined as that which caused or had the potential to cause significant morbidity or mortality.<sup>[3]</sup> Major complications included failure to achieve analgesia, respiratory depression, intravascular or intrathecal administration of the drug, peripheral nerve injury, meningitis, seizures, and cardiac arrest. Local inflammation, oozing, leaking, and kinking of catheters, faulty pump, migration of catheter, and transient motor block were regarded as minor complications.

The satisfaction score by the patient and the surgeon to each epidural that was placed was also recorded.

All categorical variables were reported using frequencies and percentages and continuous variables expressed in terms of mean ± standard deviation or median/interquartile range. Differences were considered significant at  $P < 0.05$ . All the statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) 25.0 (IBM, Chicago, IL, USA).

## Results

The study population includes 34 females and 66 males. The median age of the patients was 7 years (2 months to 18 years), and the median weight of the patients was 20 kg (2.8–61 kg). Among 100 patients, 48% underwent thoracic and upper abdominal surgeries, 33% laparotomies, and 19% limb surgeries.

The average efficacy of continuous epidural was 90.96% in our study. The maximum efficacy was noted for lower limb surgeries (94.9%), followed by infraumbilical laparotomies (91.7%) and thoracotomies (86.3%), as described in Figure 1. Children experienced maximum pain at 16 h postoperatively with only 78% were comfortable at rest. 98% of children were comfortable at rest on postoperative day (POD)-3 against 95% at movement [Figure 2]. Our mean pain scores were as follows: 0.66 (0–7) for the first 2 h, 2.04 (0–9) for 8 h, 3.0 (0–8) for 16 h, 2.04 (0–7) for 24 h, and 0.88 (0–5) for 48 h. Among the various factors analyzed for association with high pain scores, a positive correlation was seen only between upper abdominal surgeries and thoracic surgeries. We found no correlation between the experience of the anesthesiologist and the effectiveness of epidural analgesia.

We did not observe any major complications. We had a total of 48 minor complications [Figure 3]. Kinking of the catheter was the most noted complication (11%), followed by failure to palpate the space and ultimately resulting in senior anesthetist attempting the procedure (6%), followed by motor block (5%) and epidural leak (5%). The above-mentioned complications were followed by occlusion and catheter migration (4%).

Kinking resulted in the early removal of catheter in two (2%) children, whereas analgesia was maintained by the withdrawal of catheter by 0.5–1 cm in nine children. 87% of the kinking was noticed with 20G epidural needle (24G catheter). The site of kinking was noted to be under the skin in most of the cases. Difficulty in removing catheter was seen in two patients whose catheter were removed safely without breaking by applying some pressure.

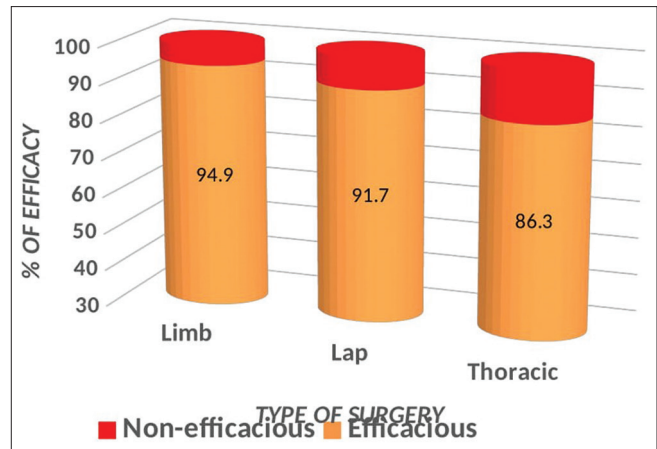


Figure 1: Types of surgeries and efficacy

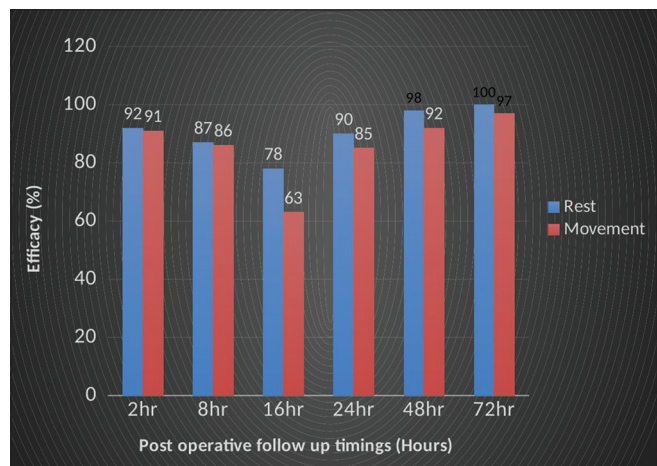


Figure 2: Efficacy of epidural at different time intervals

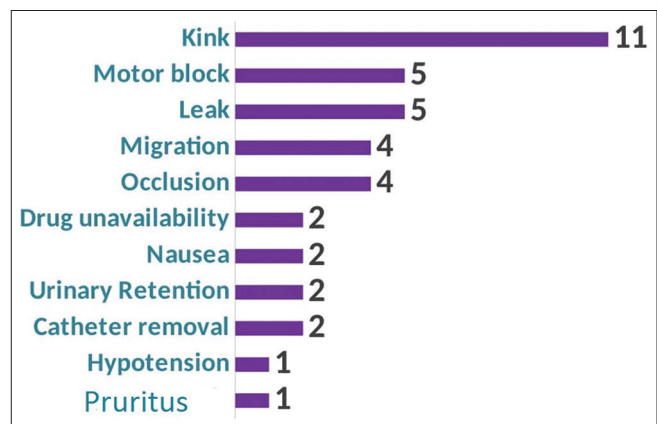


Figure 3: Postoperative complications

We observed 5% catheter leak, which was managed with redressing, but the analgesia could be maintained with an epidural infusion. The most common reason for catheter leak was found to be the size disparity between the needle and catheter.

Motor block was seen in five children and was managed with a reduction in the concentration of ropivacaine to 0.08%. Other

minor complications noted in our study were nausea (2%), urinary retention, accidental premature catheter removal, hypotension which required single fluid bolus (1%), and pruritus (1%).

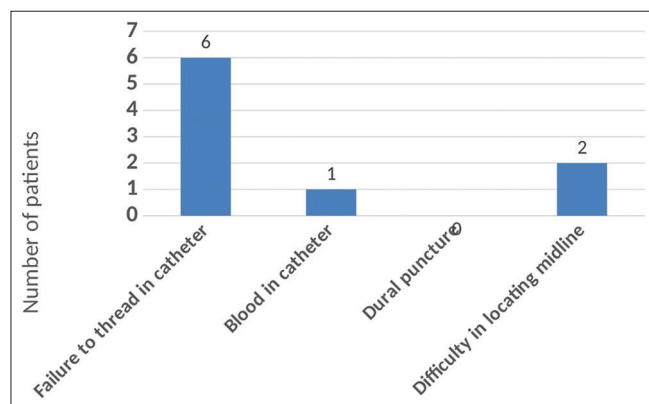
We had one child who received intraoperative epidural bolus of morphine developed both nausea, vomiting, and pruritus postoperatively, whereas another child developed pruritus after receiving 6 h of continuous epidural infusion of local anesthetics and fentanyl. Postoperative nausea and vomiting (PONV) was treated with IV ondansetron, whereas pruritus was managed conservatively.

Urinary retention was seen in 2 out of 19 children (10.52%) who underwent orthopedic surgery, and both had to be catheterized. The overall incidence of urinary retention cannot be estimated from our study as the pediatric surgery department, by default, catheterize all children with epidural.

We noticed two incidences of APS failure during our study period due to exhaustion of the available premixed syringes in the ward resulting in higher pain score for the adolescents, which was sorted out with intramuscular morphine.

The intraoperative complications [shown in Figure 4] included failure to thread in catheter requiring reattempting the epidural by an experienced anesthesiologist, blood in catheter demanding the withdrawal of catheter by few millimeters followed which it worked, and difficulty in locating midline which led to an experienced anesthesiologist attempting the block. No dural puncture and local site infection was observed during the study period.

One child had significant intraoperative blood loss and hypovolemia resulting in fluctuating hemodynamic in intra- and postoperative period. The epidural was stopped during the resuscitation and was initiated once the vitals



**Figure 4:** Intraoperative complications

got stabilized in postanesthesia care unit. One incidence of compartment syndrome occurred after orthopedic procedure in our study, which was timely diagnosed 6 h postoperatively with continuous epidural premixed infusion running.

We found a positive correlation between the experience of the anesthesiologist and the number of attempts at catheter insertion with the more experienced anesthesiologists reporting lesser incidence of multiple attempts at catheter insertion. However, this correlation was not statistically significant in our study.

The average satisfaction scores by patient and surgeon on the Likert scale of 10 were 8.5 and 8.2, respectively, and the interclass correlation was 0.868 (95% CI: 0.785–0.919).

## Discussion

Children undergoing major surgeries benefit from good pain relief and quick recovery with epidural analgesia. Inadequate pain relief has not only acute consequences but also long term. Long-term consequences could be anxiety during future procedures, lower pain threshold and sensitization to pain in the future, reduced analgesics effects, and increased analgesic requirement.<sup>[5]</sup> Postoperative pain control in the pediatric population frequently uses intraoperative epidural catheters and postoperative continuous drug administration through the catheter.

We present single-center prospective study demonstrating the overall efficacy of catheters with respect to pain management was noted to be 90.96% in contrast to 96.3% success of epidural as noticed by Thong *et al.*<sup>[1]</sup> in their retrospective study. Since management of thoracic and upper abdominal pain is of utmost importance for comfort of child and adequate gas exchange as well. Our absolute pain scores were very low, and that was due to alertness of the APS team and their interventions like bolus local anesthetics administration, increment of the infusion rate, and the usage of additional opioids that prevented the pain scores from going high. All the epidural catheters in our study required active management like top-ups, changing the infusion rate to optimize pain scores, but this was not considered to be an epidural failure as pain scores were less than five and systemic analgesia was not needed to control pain. Overall, the lower abdominal and limb surgeries have better pain scores than thoracic and upper abdominal.

A positive correlation was seen only between upper abdominal surgeries and thoracic surgeries with higher pain scores. The probable cause might be the maneuvers like ambulation, deep



breathing, coughing, crying, etc., which causes movement at the incision site.

The experience of the anesthesiologist did not have any correlation with the effectiveness of epidural analgesia in our protected environment. This might be because of our department protocols on experience of the anesthesiologist doing the procedure, guidance on level of insertion of needle, and drug boluses and the selection of epidural needle.

We found complication rate of 48% ( $n = 48$ ) with no major complication in our study. Also, we faced technical, drug-related, system failure, and epidural-related complications.

Majority of complications were technical like kinking of catheter—the overall most common complication observed in our study (11%), unlike oozing from catheter in Kasanavesi *et al.*<sup>[3]</sup> The kinking of 24G catheter (20G needle) was probably due to the small size of the catheter resulting in higher flexibility and lower tensile strength, which was in contrast to 22G and 23G catheters (19G needle) used in Western studies.<sup>[3]</sup> The incidence of the above complications are comparable to those reported in Western studies.<sup>[4,5]</sup> We had very less of premature catheter removal due to kinking (2%) compared to Thong *et al.*<sup>[1]</sup> whose early removal rate was 26% in their study on infants. In 82% of kinking and occlusion, analgesia was maintained by withdrawal of catheter. Sethi and Chaturvedi<sup>[6]</sup> suggested the use of 23G catheters, cephalad angulation of epidural needle, extending or flexing of the spine, using “blue” introducer, and injecting saline to open up the epidural space.

We did not see any catheter disconnection in our study even though the majority of reported studies<sup>[1]</sup> noticed catheter disconnections as the most common complication. This probably could be due to our strict protocol on Luer lock connectors, close circuit, and bolus with the connected 50 cc syringe.

All our catheter leak (5%) were managed with redressing with successful continuation of the analgesia. Tissue glue and tunneling<sup>[7]</sup> are among the various ways to reduce the leak but in our study, none were used. We did not notice local site infection or systemic infection due to catheter in our study which could be due to small sample size, strict protocols on assessment of local site, dressing protocols in ward and dedicated APS nurse whereas Wong *et al.*<sup>[4]</sup> recorded 13 infections in 10,653 epidurals, which presented between 3 and 11 days postoperative.

Difficulty in removing catheter was seen in two patients where removal was delayed for physiotherapy. After 90 h of postoperative period when catheter removal was attempted,

it was found difficult to remove. This could be attributed to fibrosis around the catheter. This needs further evaluation, and it points to the need to define a time frame for safe removal of catheter. In cases with difficulty in catheter removal, there is the danger of the tip incarceration after breaking inside the tract, leading to problems arising from retained catheter like infection and tip migration. Probably it is safe to have protocols for long duration catheters management.

Although transient motor block is not major yet is a significant complication making children anxious about inability to move and parents worried as well. In our study, changing the concentration improved the motor power, as in the multicentric observational study by Wranicz *et al.*<sup>[8]</sup> The incidence of urinary retention in general pediatric surgery could not be reported as all the children under pediatric surgery were catheterized postoperatively.

We had two children who presented with nausea and one with pruritus. Wong *et al.*<sup>[4]</sup> found that the most common complication seen was nausea and vomiting. In our study, only one child received morphine epidurally as intraoperative bolus followed by premixed syringe of ropivacaine and fentanyl and developed nausea and pruritis. PONV probably was related to the epidural opioid.

The development of acute compartment syndrome was timely diagnosed as our postoperative ward staff are instructed to look for compartment syndrome actively in orthopedics wards and also epidural analgesia did not mask the compartment pain like that found by Moriarty *et al.*,<sup>[2]</sup> which proves its safety in orthopedic procedures. Wong *et al.*<sup>[4]</sup> observed compartment syndrome in a child who underwent perineal surgery in lithotomy position which required fasciotomy, so the vigilance for early identification of compartment syndrome should not be restricted to orthopedic procedures but all high-risk groups as it happened in Wong *et al.*'s study.

The limitations of our study is its short duration of data collection and single centric in nature may not be sufficient to detect some rare complications and factors associated with these complications. The subjective nature of pain assessment scales is a well-known limitation and to overcome this factor, we used validated scores. This is an observational study so the results are reflective of our practice which has been clearly stated in our methodology.

In conclusion, with the high rate of efficacy and with no major complications, continuous epidural analgesia has proven to be a safe and effective method to provide analgesia to the children in a protected environment, and in experienced hands.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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