Original Article

Incidence of and modifiable risk factors for inadequate epidural analgesia in pediatric patients aged up to 8 years

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Abstract

Background and Aims: Postoperative pain in pediatric patients is one of most inadequately treated conditions. This study aimed to investigate the incidence of and modifiable risk factors for inadequate epidural analgesia in pediatric patients aged up to 8 years at Siriraj Hospital—Thailand's largest national tertiary referral center.

Material and Methods: This retrospective study included pediatric patients aged 0–8 years who underwent surgery with epidural catheter during January 2015 to January 2020. Patients with missing data were excluded. Records from both the ward staff and the acute pain service were reviewed. All relevant data were extracted until the epidural catheters were removed.

Results: One hundred and fifty pediatric patients were included. The median age was 29 months and the range varied from 12 days to 98 months on the day of surgery, and 86 (57.3%) were male. The incidence of inadequate epidural analgesia was 32%. Most patients (95.8%) had an unacceptably high pain score within 4 hours after arriving at the ward. Univariate analysis revealed direct epidural placement, the length in epidural space less than 5 cm, and postoperative leakage to be substantially higher in the inadequate pain epidural analgesia group. When those factors were included in multivariate analysis, only length in epidural space less than 5 cm was identified as an independent risk factor.

Conclusion: The incidence of inadequate epidural analgesia in this pediatric study was 32%. Multivariate analysis showed length of catheter in epidural space less than 5 cm to be the only factor independently associated with inadequate epidural analgesia.

Keywords: Inadequate epidural analgesia, incidence, modifiable risk factors, pediatric

Introduction

Postoperative pain in pediatric patients is one of the most misdiagnosed, under-recognized, and inadequately treated conditions.[1] Moreover, despite a decline in pediatric epidural use over time,[2] epidural analgesia remains an effective method of managing postoperative pain in children, especially in severely painful procedures, such as thoracic[3] and major abdominal surgery.[4,5] Compared with the volume of studies in adults, studies in pediatric epidural analgesia remain scarce. Previous study at our center in adults found an incidence of inadequate epidural analgesia that required rescue pain medication of 48.6%.[6] Another study reported inadequate epidural analgesia in 35% of children after laparotomy surgery.[7] The fact that the margin of safety in pediatric patients is narrower than in adults, it is worth investigating the efficacy of pediatric epidural analgesia. Moreover, if we can identify modifiable factors that are significantly associated with inadequate pediatric epidural analgesia, we may be able to achieve a level of efficacy of

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pain control that outweighs the risk of pediatric epidural insertion.

Younger age was reported to be the only factor that predicts successful epidural analgesia in pediatric patients.[7] Overweight status[8] and type of operation[9] were both reported to be associated with severe pain in adults. However, the present study focused on the five following modifiable risk factors that were reported to be associated with inadequate epidural analgesia in adults and children: 1) direct or indirect placement of epidural catheters from the segmental level required for surgery[10], 2) level of epidural insertion[7], 3) length in epidural space more than 5 cm[11], 4) epidural medication, including local anesthetics and opioids[12], and 5) leakage at the puncture site.[13]

The definition of adequate epidural analgesia in this study was mild pain at any time after surgery until the epidural catheter was removed when age-appropriate pain measurement tools were used. Inadequate epidural analgesia was defined as moderate to severe pain at any time after surgery until the epidural catheter was removed. Using the acute pain service database and patient medical records, the aim of this study was to investigate the incidence of and modifiable risk factors for inadequate epidural analgesia in pediatric patients aged up to 8 years. The results of this study will lead to improved optimization of pediatric postoperative pain management in the future.

Material and Methods

This retrospective study included pediatric patients aged 0–8 years who underwent surgery with epidural catheter at a single, large, tertiary referral center in Thailand during January 2015–January 2020. Patients with missing pain score data or analgesic administration data were excluded. The study protocol was approved by the Siriraj Institutional Review Board (SIRB) of the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand (approval no. 137/2020). Records from both the ward staff and the acute pain service were reviewed. All relevant postoperative data were collected until the epidural catheters were removed. These data included patient demographics (gender, weight, height, and age, which was categorized as newborn (0–1 month), infant (1 month–1 year), and children (1–8 years). Surgical incision and operative time were also retrieved and recorded. Concerning the epidural, epidural insertion technique (direct *vs.* indirect placement from incision level), level of epidural insertion (thoracic, lumbar, or caudal), intraoperative and postoperative epidural medication including local anesthetics and opioids, and postoperative epidural leakage at the puncture site were recorded.

The pain scores and details relating to all rescue analgesic drugs administered during the postoperative period were collected during the course of epidural infusion. Pain was assessed using the following pain measurement tools: the validated NIPS (Neonatal Infant Pain Scale), CHEOPS (Children's Hospital of Eastern Ontario Pain Scale), or NRS (Numerical Rating Scale) depending on the patients's age. The NIPS scale was validated to assess postoperative pain in children aged 0–1 year. NIPS 1–3 indicates mild pain, 4–5 moderate pain, and 6–7 severe pain.[14] The CHEOPS scale is used in children aged 1–6 years. CHEOPS 0–4 indicates no pain, 5–7 mild pain, 8–10 moderate pain, and 11–13 severe pain.[15] The NRS scale was applied in children older than 6 years who could self-report their level of pain.[7] NRS 1–3 indicates mild pain, 4–6 moderate pain, and 7–10 severe pain.

The primary outcome of this study was the incidence of inadequate postoperative pain control when using an epidural catheter. The definition of inadequate epidural analgesia was moderate to severe pain at any time during the postoperative period until the epidural catheter was removed when using an age-appropriate measurement tool. In this study, patient pain scores recorded by nursing ward staff were used because pain assessment was made every 4 hours, which is more frequent than that of the acute pain service, which recorded the pain score both at rest and during movement once a day or during a follow-up after adjusting the analgesic regimen.

Regarding secondary outcomes, there were five possible modifiable factors associated with inadequate epidural analgesia obtained from literature review in both pediatric and adult patients. First, direct or indirect placement of epidural catheter at the segmental level required for surgery. We defined the direct placement site as being not below the T10–11 levels for the upper abdominal incision, T12–L1 levels for both the lower abdominal incision and extended incision to middle and lower abdomen, and T8–9 for thoracotomy operation. Second, the level of epidural insertion, was categorized as thoracic, lumbar, and caudal. Third, the length of catheter in epidural space was categorized as less or more than 5 cm. Fourth, epidural medication including local anesthetics and opioids were categorized as intraoperative and postoperative. Local anesthetics were categorized as low concentration when bupivacaine was less than 0.1% and high concentration when bupivacaine was equal to or greater than 0.1%. Epidural opioids were categorized as none, morphine (hydrophilic), and fentanyl (lipophilic). Fifth and last, whether epidural catheter had a leak at the puncture site or not.

Abstractor is a nurse anesthetist in the department who was not involved with the study protocol and collected all interesting variables as mentioned above in the excel file. One of the investigators (K. S.) checked for the accuracy in each of the 10 patients for the first 50 patients in order to discuss or clarify any conflicting issues. After that, the record was checked in each of the 25 patients. The principal investigator (P. P.) randomly examined the 50 patients.

Sample size calculation

Sample size calculation for the primary objective was based on an expected incidence of inadequate epidural analgesia of 35%, which was obtained from a previous study.[7] To obtain a 95% confidence interval and an allowable error of 0.1, the calculated sample size was 88 patients. Sample size was also calculated for the secondary objective, which was based on the current recommendation of statisticians for multiple logistic regression analysis. The recommendation was that the number of patients with inadequate pain control should be ten times the number of risk factors. Therefore, approximately 50 cases were needed. With a 35% expected incidence of inadequate epidural analgesia for the primary objective, a sample size of at least 143 subjects was required. The sample size was inflated by 5% to compensate for incomplete information; so 150 subjects were enrolled in this study.

Statistical analysis

All statistical analyses were performed using PASW Statistics for Windows, version 18.0 (SPSS, Inc., Chicago, IL, USA). Continuous data were presented as the mean ± standard deviation or median (min–max), whereas categorical data were shown as number and percentage. Data were tested for normal distribution using Kolmogorov–Smirnov test. For univariate analysis, association between categorical variables and inadequate pain control was assessed by Chi-square test, whereas association between continuous variables and inadequate pain control was assessed by Student's *t*-test. Variables with a *P* value <0.20 in univariate analysis were included in multivariate analysis. The results of multivariate analysis are shown as adjusted odds ratio and 95% confidence interval. A *P* value < 0.05 was regarded as statistically significant.

Results

One hundred and fifty pediatric patients were included. Postoperative pain scores, which was the primary outcome, were available for all patients. The median (min, max) age was 29 months (12 days, 98 months) on the day of surgery, and 86 (57.3%) patients were male. Demographic and surgical data between patients with adequate and inadequate epidural analgesia are shown in Table 1. One hundred and twenty (80%) children were transferred to the intensive care unit (ICU). The incidence of inadequate epidural analgesia based on the data extracted from medical records was 32% (48 out of 150). The vast majority of patients (46 out of 48) had an unacceptably high pain score within 4 hours after arriving at ward, which was the second time that pain was assessed. Only two patients had subsequent breakthrough pain, and epidural dislodgement was the cause in both cases.

All epidural catheters (PERIFIX® ONE Pediatric Continuous Epidural Set 20 Ga. x 2 in. [50 mm] Tuohy Needle Set with 24 Ga. Closed Tip Pediatric Catheter; B. Braun Melsungen AG, Hessen, Germany) were inserted immediately after the induction of anesthesia, but before the start of surgery. All epidural catheters were placed in the lateral position. Identification of the epidural space was performed using the loss of resistance technique using either air or 0.9% normal saline. The median (min, max) length of catheter in epidural space was 5 (2–24) cm. A test dose to detect intrathecal or intravascular misplacement using 1% xylocaine with adrenaline 1:200,000 0.1 ml/kg was performed in 140 (93.3%) patients. The epidural medications used intraoperatively varied according to the discretion of the attending anesthesiologist. All patients received continuous epidural infusion intraoperatively and continued into the postoperative period. The concentrations of intraoperative and postoperative bupivacaine were similar (range: 0.05–0.125%). Combination bupivacaine

Table 1: Demographic and surgical data between patients with adequate and inadequate epidural analgesia

Data	Adequate epidural analgesia (*n*=102)	Inadequate epidural analgesia (*n*=48)	*P*
Demographic data			
Age group			0.783
Newborn (0-1 month)	4 (3.9%)	2 (4.2%)	
Infant (1 month-1 year)	22 (21.6%)	8 (16.7%)	
Children (1-8 years)	76 (74.5%)	38 (79.2%)	
Gender			0.591
Male	60 (58.8%)	26 (54.2%)	
Female	42 (41.2%)	22 (45.8%)	
Body weight (kg)	11.86±5.30	11.92±5.74	0.948
Height (cm)	84.84±21.34	83.94±20.68	0.808
Surgical data			
Incision			0.105
Upper abdomen	63 (61.8%)	24 (50%)	
Lower abdomen	26 (25.5%)	13 (27.1%)	
Whole abdomen	5 (4.9%)	8 (16.7%)	
Thorax	8 (7.8%)	3 (6.3%)	
Operative time (min)	317.50 (60-745)	372.50 (75-720)	0.164

Data presented as number and percentage, mean±standard deviation, or median (min, max). A P<0.05 indicates statistical significance

and fentanyl was used in 65 (43.3%) patients, combination bupivacaine and morphine was given in 67 (44.7%) patients, and 18 (12%) patients received local anesthetics without opioid intraoperatively. Postoperatively, combination bupivacaine and fentanyl was used in 76 (50.7%) patients, combination bupivacaine and morphine in 70 (46.7%) patients, and 4 (2.7%) patients received local anesthetics without opioid.

Univariate analysis for modifiable risk factors significantly associated with inadequate epidural analgesia is shown in Table 2. The analysis revealed substantial ($p < 0.20$) difference between groups for catheter placement, length in epidural space, and leakage at the puncture site. When those factors were included in multivariate analysis, only length in epidural space less than 5 cm was identified as an independent risk factor for postoperative inadequate epidural analgesia [Table 3].

All 48 patients with inadequate epidural analgesia received intravenous fentanyl for pain rescue. Three of those patients received fentanyl plus ketorolac, and five patients received fentanyl plus paracetamol. Three patients also received additional local anesthetics to test whether the epidural catheter was working or not, but only one pediatric patient aged 6.5 years understood the test. The median (min, max) duration of epidural catheter in place was 45 (8, 121) hours.

Discussion

The results of this study revealed that 32% of pediatric patients had inadequate epidural analgesia, which means that they had moderate to severe pain at any time during the postoperative period until the removal of epidural catheter. This rate is similar to those reported from other studies (range: 30–35%).[3,7,16] Interestingly, an unacceptably high pain score in this study showed early within 4 hours in all patients except two. The first pain score recorded upon arrival at the ward or ICU could be influenced by intraoperative anesthetic agents that just wore off. This may suggest the role of intraoperative risk factors as opposed to postoperative factors.

Level of epidural insertion (thoracic, lumbar, or caudal) did not show a statistically significant difference between the adequate and inadequate analgesia groups. This is in contrast to the result of a study in adults that showed thoracic level to have a higher failure rate than lumbar level.[9] However, our result was similar to that reported from a previous study in pediatric patients.[7] The difference between adult and pediatric patients can be explained by anatomy. As people age, the ligaments of the spine can thicken and harden. This calcification makes epidural insertion more difficult, especially at the narrow thoracic and caudal spaces in adults. The concentration of bupivacaine was also not significantly different between groups. This result is also similar to a previous study. Many studies have investigated the influence of different

Table 2: Univariate analysis for modifiable risk factors significantly associated with inadequate epidural analgesia

Factors	Adequate epidural analgesia (n=102)	Inadequate epidural analgesia (n=48)	OR (95% CI)	P
Catheter placement at incision level				0.122
Direct placement	22 (21.6%)	16 (33.3%)	1.82 (0.85-3.90)	
Indirect placement	80 (78.4%)	32 (66.7%)	1	
Level of epidural insertion				0.331
Thoracic	19 (18.6%)	14 (29.2%)	1	
Lumbar	74 (72.5%)	31 (64.6%)	0.57 (0.25-1.28)	
Caudal	9 (8.8%)	3 (6.3%)	0.45 (0.10-1.96)	
Length in epidural space >5 cm (yes)	53 (52.0%)	13 (27.1%)	2.91 (1.38-6.14)	0.004
Type of intraoperative local anesthetic				0.253
Low concentration	23 (22.5%)	15 (31.3%)	1	
High concentration	79 (77.5%)	33 (68.8%)	0.64 (0.30-1.38)	
Type of intraoperative opioid				0.526
None	14 (13.7%)	4 (8.3%)	1	
Morphine	43 (42.2%)	24 (50%)	1.95 (0.58-6.61)	
Fentanyl	45 (44.1%)	20 (41.7%)	1.56 (0.46-5.32)	
Type of postoperative local anesthetic				0.911
Low concentration	50 (49.0%)	24 (50%)	1	
High concentration	52 (51.0%)	24 (50%)	0.96 (0.48-1.91)	
Type of postoperative opioid				0.775
None	3 (2.4%)	1 (2.1%)	1	
Morphine	47 (46.1%)	25 (52.1%)	1.60 (0.16-16.15)	
Fentanyl	52 (51%)	22 (45.8%)	1.27 (0.13-12.88)	
Leakage at the puncture site (yes)	36 (35.3%)	27 (56.3%)	2.35 (1.17-4.75)	0.015

Data presented as number and percentage. Factors with a P<0.2 were included in multivariate analysis. Abbreviations: OR, odds ratio; CI, confidence interval

Table 3: Multivariate analysis for modifiable factors independently associated with inadequate epidural analgesia

Factors	Adjusted OR (95% CI)	*P*
Direct epidural placement (yes)	1.22 (0.53-2.81)	0.643
Length in epidural space <5 cm (yes)	2.46 (1.10-5.50)	0.029
Leakage at the puncture site (yes)	2.05 (0.99-4.21)	0.052

A P<0.05 indicates statistical significance. Abbreviations: OR, odds ratio; CI, confidence interval

volumes and concentrations of agents for epidural analgesia. However, the quality of epidural analgesia depends on total local anesthetic dose rather than volume or concentration.[12] The type of epidural opioids' use was also not found to be significant between groups. The hydrophilic property of epidural morphine, which has a greater rostral spread in the spinal canal,[17] could not demonstrate a better postoperative analgesia.

Very few studies have investigated and reported factors that are significantly associated with inadequate epidural analgesia in pediatric patients. Younger age results in both adequate analgesia[18,19] and inadequate analgesia.[7] However, the present study found no significant difference between analgesia groups for age. Direct epidural placement, insertion less than 5 cm, and leakage at the puncture site were found to be factors significantly associated with inadequate epidural analgesia in univariate analysis in this study. Of those three factors, only length in epidural space less than 5 cm was found to be independently associated with inadequate postoperative epidural analgesia. Previous study reported insertion of epidural catheters at the segmental level required for surgery to be more reliable in children, and this procedure was shown to be safe in experienced hands with appropriately sized equipment.[10] However, loosely packed epidural fat in pediatric patients may facilitate the spread of local anesthetic and help to achieve quicker block onset. It may also allow the unimpeded advancement of epidural catheters from the caudal epidural space to the lumbar and thoracic levels. In infants, the techniques of direct thoracic epidural placement and caudal placement with cephalad threading, each have distinct advantages and disadvantages. Moreover, the current data cannot support the safety of one technique over the other, and the site of epidural insertion remains largely a matter of the anesthetist's discretion.[20]

Various techniques have been suggested to improve correct placement of an epidural catheter, including fluoroscope, ultrasound, nerve stimulation, epidural waveform, and ECG guidance.[21] All of these techniques aim to position catheters at a level that innervates the surgical site to achieve optimal postoperative epidural analgesia. In pediatric studies, the failure rate was reduced to 15.1–20%.[16,22] However, other studies described significant migration of the tip of the epidural catheter later in the postoperative period.[23-25] During the postoperative period in this study, there was only one pediatric patient who could understand and was able to test the epidural catheter. It is very hard to evaluate the analgesic efficacy of postoperative epidural analgesia in children using a test dose. This is also a problem in infants and non-verbal children postoperatively. Children must have sufficient cognitive and communicative skills to be able to adequately report their pain.[26] Moreover, postoperative replacement of a suboptimal pediatric epidural catheter is difficult without providing additional sedation, which may be inconvenient outside of the operating room. Thus, it will be helpful to have a strategy to indicate whether the epidural catheter is in the correct space without the need for confirming the exact location of the tip.

The position of the epidural catheter and the distribution of the local anesthetic drugs in the epidural space are two of the most important determining factors for successful epidural analgesia.[11] A longer length of epidural catheter left in the epidural space may increase the likelihood of a unilateral block or intravenous cannulation.[11] This opposes the result in this study, where multivariate analysis showed length in epidural space less than 5 cm to be the only independent risk factor for inadequate epidural analgesia. Moreover, leakage at the puncture site was very close to achieving independent predictor status with a *P* value of 0.052. Leak at the catheter site has been identified as a risk factor for premature discontinuation of epidural catheters. However, 46 out of 48 (95.8%) patients with inadequate epidural analgesia in this study had an early high unacceptable pain score within 4 hours after arrival at the ward or ICU. By taking into account the factors, namely the amount of cerebrospinal fluid (CSF) per body weight is higher in neonates and infants (4 mL/kg) compared to that of adults (2 mL/kg), and the CSF is localized primarily in the spinal canal, if the epidural catheter was inserted too shallow, the epidural infusion may leak out and not reach the target pain receptors. These eventually lead to inadequate postoperative epidural analgesia. Future research to investigate this hypothesis is needed.

Limitations

This study has some limitations. First, this was a retrospective study that analyzed data from a single center. Therefore, the effectiveness of epidural analgesia found in this study may not be generalizable to other settings and centers. Second, the retrospective nature of our study rendered it vulnerable to missing or incomplete data. For example, it is possible that leakage occurred, but that it

was not documented, which would mean that the incidence of leakage was underreported. In this study, if leakage was not documented, it was assumed that no leakage had been detected.

Conclusions

The incidence of inadequate epidural analgesia in this pediatric study was 32%. Direct epidural placement, the depth of epidural insertion less than 5 cm, and leakage were higher in the inadequate pain epidural analgesia group. Multivariate analysis showed length of catheter in epidural space less than 5 cm to be the only factor independently associated with inadequate epidural analgesia.

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Conflicts of interest

There are no conflicts of interest.

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