Effectiveness of Postoperative Epidural Analgesia for Thoracic and Abdominal Surgery in Siriraj Hospital

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Background: *Epidural analgesia is the recommended analgesic technique in patients having surgery with moderate to severe postoperative pain. Inadequate pain control in patients receiving epidural analgesia frequently occurred in clinical practice but the number of the success rate or the failure rate have not been reported in our university hospital.*
Objective: *The aim of the prospective descriptive study is to examine various data related to and evaluate the effectiveness of the postoperative epidural analgesia in Siriraj Hospital, a university hospital in Thailand.*
Material and Method: *Patients scheduled to have elective thoracic or abdominal surgery under general anesthesia combined with epidural analgesia from December 2014 to October 2015 were enrolled in this study. Three hundred and sixty-four patients were finally analyzed. All data about demographics, surgery, epidural techniques, postoperative pain scores at rest and on movement, and postoperative complications were collected.*
Results: *The number of patients having acceptable postoperative pain score at rest at all time period was 51.4%, (95% CI 46.3-56.5). Fifty patients (13.7%) in this group needed intravenous rescue medication for breakthrough pain. The incidence of severe postoperative pain at rest during running of epidural medication was 24.5% (95% CI 20.3-29.1). One hundred patients (27.5%) experienced postoperative nausea and vomiting; and 28 patients (7.7%) had episodes of hypotension. The incidences of accidental dural puncture and post-dural puncture headache were 1.36% and 0.8%, respectively.*
Conclusion: *Inadequate postoperative analgesia with epidural technique occurred in up to 50% of patients in this study in which the rescue pain medication was necessary. In-depth analysis to identify associated factors to improve the effectiveness of postoperative epidural analgesia should be further investigated.*

Keyword: *Epidural analgesia, Postoperative pain, Pain management*

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Epidural analgesia is the recommended postoperative analgesia in patients having major surgery in order to significantly reduce pain score, minimize patient distress and accelerate postoperative recovery[1-7]. Compared with patients receiving general anesthesia only, this technique has been reported to provide better outcomes[4,5,8,9]. Additionally, it is recommended in patients having major surgery to allow them to mobilize quickly and effectively[3,9]. This technique has been shown to be highly effective at preventing postoperative ileus and various complications[1-3,7,10,11]. Moreover, epidural analgesic technique is demonstrated to be safer and have fewer side effects than using intravenous opioids alone[6,12,13].

However, the epidural technique is not universally successful and the number of patients experiencing inadequate analgesia with this technique is approximately 12-32%[14-16]. The failure of epidural analgesia is still a frequent clinical problem and needs active management including a new block or other analgesic medication in order to rescue postoperative pain[14,17]. Previous study showed that the incidence of patients having epidural analgesia with postoperative moderate pain was 20.9% and these with severe pain was 7.8%[17]. In Siriraj Hospital, a recent study showed that 19.6% of patients having elective upper abdominal surgery under general anesthesia combined with epidural analgesia reported severe first pain score in post anesthetic care unit[18]. As a result, patients needed a number of interventions and management from acute pain service, and spent longer time in post anesthetic care unit[17,18].

Inadequate pain control in patients receiving epidural analgesia frequently occurred in clinical practice but the number of the success rate or the failure rate have not been reported in our hospital. This study

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aims to evaluate the effectiveness of the epidural analgesia during postoperative 48 hours in patients having elective thoracic and abdominal surgery under general anesthesia combined with epidural analgesia at Siriraj Hospital.

Material and Method

Study design and population

The research protocol was approved by the Siriraj Institution Review Board (SI529/2557) and registered with ClinicalTrials.gov (NCT02315261). The prospective study was conducted from December 2014 to October 2015 at Siriraj Hospital, Mahidol University, Bangkok, Thailand. All patients aged more than 18 years old scheduled to have thoracic or abdominal surgery under general anesthesia combined with epidural analgesia were approached and explained about the objective of this study. Then the patients were asked to sign informed consent by one of the authors before having an operation. Exclusion criteria were patients having: inability to communicate or inform pain score, cesarean section or labor analgesia, additional other analgesic techniques (spinal analgesia, paravertebral nerve block, intercostal block, transversus abdominis plane block, rectus sheath block, ilioinguinal block, iliohypogastric block), emergency surgery and duration of catheter placement less than 6 hours postoperatively.

This is a prospective observational study, reviewing the implementation of a standard care practice and requiring de-identified data collection only. All collected data were routinely part of normal clinical practice. The research team systematically collected data on each patient. The information was obtained from the medical record, intra-operative anesthetic record and acute pain service record whereas other information was obtained from direct observation at the bedside.

Data collection and outcomes

Perioperative data including patients' demographics, ASA physical status classification, surgical site, surgical unit, duration of surgery, epidural insertion technique, status of level of epidural analgesia, intra-operative and postoperative epidural medication including local anesthetics and opioids were recorded.

Pain scores of all patients were evaluated at rest at the postoperative 0, 2, 6, 12, 24 and 48 hours, and on movement at postoperative 6, 12, 24 and 48 hours. Pain score was measured with the verbal rating scale (VRS) from '0' (no pain) to '10' (maximal pain) and categorized into three groups: acceptable pain or mild pain (VRS 0-3), moderate pain (VRS 4-6) and severe pain (VRS 7-10). The effectiveness of epidural analgesia was analyzed according to the proportion of patients having mild pain and severe pain, and postoperative rescue analgesic requirement within 48 hours postoperatively. The data about postoperative recue analgesic medication including oral and intravenous routes, all adverse effects and postoperative epidural complications, were collected.

Statistical analysis and sample size calculation

A sample size was calculated using historic data in Siriraj Hospital to estimate the proportion of patients having the postoperative pain score after epidural insertion between 0-3 with 95% confidence interval (CI) of 30$\pm$5%. This formulation, $n = Z_{\alpha/2}^{2} P (1-P)/d^2$, was used to calculate the sample size when 1-α was a confidence interval of 0.95, α is 0.05 (2-sided), $Z_{0.025}$ was 1.96, P was the proportion of patients with acceptable pain score and d was 0.05. Finally, 323 patients were required for this study and the number was increased to 420 to compensate for 30% drop out.

All data were collected in a private computer database. Categorical variables were described as number and percentage. Continuous variables were presented as mean and standard deviation (SD) or median and interquartile range as appropriated. All statistical analyses were performed using SPSS version 18 for Windows (SPSS Inc., Chicago, IL).

Results

Patients

Six hundred and ten patients were recruited in this study and 364 patients were finally analyzed as shown in a flow chart presenting participants through each stage (Fig. 1). The patient characteristics and clinical data were presented in Table 1.

Epidural technique

Epidural catheters were placed in 359 patients (98.6%) in the lateral position whereas in the other five in the sitting position due to anesthesiologists' preference. Identification of epidural space was done with air in 347 patients (95.3%) and with 0.9% normal saline in 17 patients (4.7%). The length of catheter in epidural space between 3 to 5 cm in 298 patients (81.9%), 5 to 7 cm in 62 patients (17.0%), 8 cm in two patients and 10 cm in one patient.

Data including a number of attempts required,

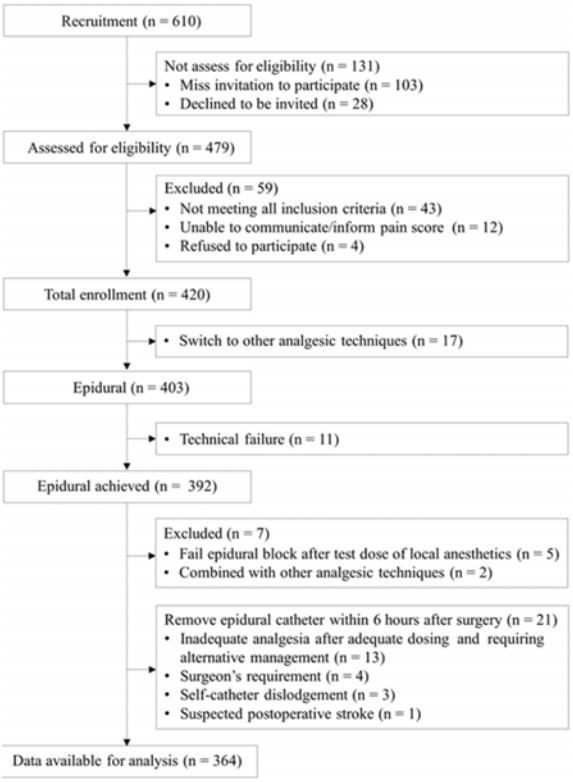

Fig. 1 Flow chart presenting study selection process.

Table 1. Patient characteristics and perioperative data

	n = 364
Age (years)	59±13
Gender, n (%)	
Male	122 (33.5)
Female	242 (66.5)
Body mass index (kg m^{-2})	23.9±5.1
ASA physical status classification; n (%)	
ASA I	53 (14.6)
ASA II	215 (59.1)
ASA III	94 (25.8)
ASA IV	2 (0.5)
Surgical site, n (%)	
Thoracic	36 (9.9)
Upper abdomen	131 (36.0)
Lower abdomen	192 (52.7)
Whole abdomen	5 (1.4)
Duration of surgery (minutes)	192±85

The data was presented as mean ± standard deviation or number (percentage).
ASA = American society of anesthesiologists

successful epidural performance and epidural approach technique categorized with epidural insertion site are demonstrated in Table 2. A test dose for detecting intrathecal or intravascular epidural catheter placement was performed in all patients, but only 42 patients (11.5%) were checked for the levels of dermatome blocked before starting the operation.

Pharmacological management of epidural anesthesia

Most common intra-operative epidural medication was bupivacaine which was used in 209 patients (58%). Ninety-nine patients (27%) received a loading of lidocaine and followed by bupivacaine; 40 patients (11%) received only lidocaine intra-operatively; and 16 patients (4%) did not receive any intra-operative local anesthetics. The concentration of intra-operative bupivacaine ranged from 0.0625% to 0.25% and the average volume of epidural bupivacaine administration was 5 ml/hour. About a delivery modality of intra-operative epidural analgesia, 80% of patients received a continuous infusion and 16 patients (20%) had intermittent epidural bolus. A combination of bupivacaine with low dose of fentanyl was used in 180 patients (49.5%), with morphine in 91 patients (25%) and 37 patients (10.2%) received local anesthetics without opioid.

A total of 323 patients (89%) received a bolus of opioids loading via epidural catheter before finishing the operation; 297 patients (92%) with morphine, 9 patients (3%) with fentanyl and 17 patients (5%) with both morphine and fentanyl. The median doses of morphine and fentanyl loading were 2 mg and 50 mcg, respectively; and the median duration of opioids loading before finishing the operation was 75 minutes.

The most common postoperative epidural medication was a combination of 0.0625% bupivacaine and morphine 0.02 mg/ml which was used in 345 patients (97%). There were 278 patients (76.3%) infused with an postoperative epidural medication in the rate of 4-6 ml/hour. Thirty-five patients (9.6%) needed to increase an epidural infusion rate and 13 patients (3.6%) needed to decrease. Duration of epidural catheter in place was 55.8 hours (95% CI 53.9-57.6).

Postoperative pain and rescue analgesic medication

Percentage of patients having postoperative pain score at rest and on movement at each time periods (0, 2, 6, 12, 24 and 48 hours postoperatively) are shown in Fig. 2 and 3. The proportion of patients having mild pain at rest at all time periods (postoperative 0, 2,

Table 2. Data about epidural techniques categorized by epidural insertion site

	Mid-thoracic (T5-T8) (n = 130)	Low-thoracic (T9-T12) (n = 126)	Lumbar (L1-L3) (n = 108)
Surgical site			
Thoracic surgery	35 (26.9)	1 (0.8)	0 (0)
Upper abdomen	81 (62.3)	46 (36.5)	4 (3.7)
Lower abdomen	14 (10.8)	75 (59.5)	103 (95.4)
Whole abdomen	0 (0)	4 (3.2)	1 (0.9)
Surgical unit			
General surgery	90 (69.2)	77 (61.1)	17 (15.7)
Gynecology	0 (0)	29 (23.0)	82 (75.9)
Thoracic surgery	33 (25.4)	1 (0.8)	0 (0)
Urology	7 (5.4)	16 (12.7)	9 (8.3)
Vascular surgery	0 (0)	3 (2.4)	0 (0)
Epidural approach			
Midline	6 (4.6)	18 (14.3)	85 (78.7)
Paramedian	123 (95.4)	108 (85.7)	23 (21.3)
Attempts to successful placement			
1	45 (34.6)	39 (31.0)	34 (31.5)
2	46 (35.49)	48 (38.1)	50 (46.3)
3	33 (25.4)	24 (19.0)	22 (20.4)
>3	6 (4.6)	15 (11.9)	2 (1.8)
Successful placement by			
Resident 1	13 (10.0)	25 (19.8)	24 (22.2)
Resident 2	33 (25.4)	16 (12.7)	32 (29.6)
Resident 3	48 (36.8)	39 (31.0)	24 (22.2)
Staff	36 (27.7)	46 (35.5)	28 (25.9)

The data was presented as number and percentage.
T = thoracic level; L = lumbar level

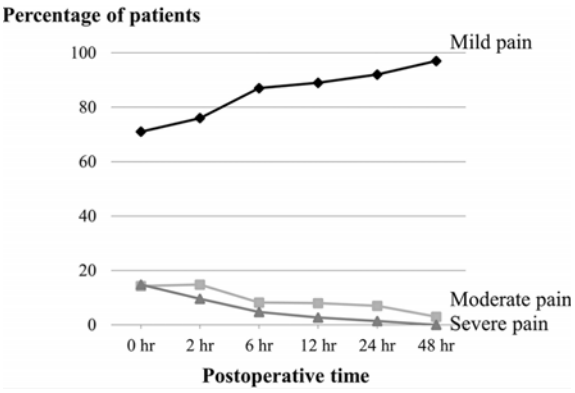

Fig. 2 Percentage of patients reporting mild, moderate and severe pain at rest at each time point.

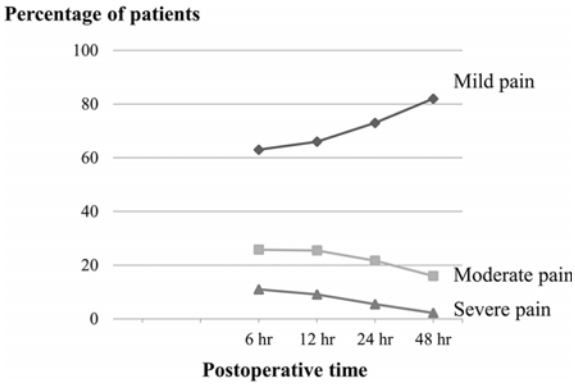

Fig. 3 Percentage of patients reporting mild, moderate and severe pain score on movement at each time point.

6, 12, 24 and 48 hours) within 48 hours was 51.4% (95% CI 46.3-56.5). Fifty patients (13.7%) in this group required intravenous rescue medication for breakthrough pain and 130 (35.7%) required extra doses of oral rescue medication. Pethidine was used as a rescue medication in 41 patients, tramadol in 6 patients, intravenous nonsteroidal anti-inflammatory drugs (NSAIDs) including parecoxib or ketorolac in 10

patients, oral NSAIDs in 43 patients and acetaminophen in 89 patients. Sixty-five patients (34.8%) needed more than one type of rescue drugs to relieve their postoperative pain in the period of 48 hours after surgery.

The proportion of patients experiencing at least one episode of severe postoperative pain at rest within 48 hours during running of epidural medication was 24.5% (95% CI 20.3-29.1) and 18 patients (4.9%) had severe postoperative pain more than one episode.

Adverse effects and complications

Hypotension

Twenty-eight patients (7.7%) had episodes of hypotension; 18 patients were resuscitated with additional intravenous boluses of crystalloid solution; two patients with colloid and one patient with blood transfusion. Two patients needed small doses of intravenous vasopressor, five patients needed to pause the epidural infusion. All patients were able to maintain postoperative blood pressure after that period of time.

Motor weakness

Nine patients had motor weakness and limited mobility of the lower limbs on the first postoperative day; four patients required discontinuing epidural medication for 4 hours and five patients needed to decrease an infusion rate of epidural medication. All patients had full recovery within 24 hours.

Postoperative nausea and vomiting

One hundred patients (27.5%) had an experience of postoperative nausea and vomiting in the first 24 hours postoperatively; 83 patients received a treatment with intravenous ondansetron, nine patients with metoclopramide, seven patients with dimenhydrinate and three patients needed no treatment postoperatively. Only three patients continued to nauseate and vomit after 24 hours postoperatively.

Others

Pruritus occurred in 109 patients (29.9%) and intravenous chlorpheniramine was effective in 96 patients. Urinary retention occurred in four patients which required an intermittent urinary catheter.

Five patients (1.4%) had an accidental dural puncture with a Tuohy needle during epidural placement; two patients developed post-dural puncture headache (PDPH) requiring epidural blood patch. One patient developed PDPH without a previous history of an accidental dural puncture, and had a conservative treatment. None of the patients in this study had respiratory depression, local anaesthetic toxicity, epidural catheter migration into subarachnoid space or blood vessel, infection at epidural site, epidural hematoma or epidural abscess.

Discussion

The results demonstrate that 50% of patients in this study had acceptable pain score at rest (pain score less than or equal to 3) at all time within 48 hours postoperatively and the incidence of severe postoperative pain during postoperative 48 hours was one-fourth of the total patients. The severe pain reported in this study is more than the incidence of severe pain (19.6%) reported in post-anesthesia care unit in 2013[18]. The higher incidence in this study could be explained with the longer period of 48 hours to collect the postoperative pain whereas the previous study had the severe pain reported for a short period in post-anesthesia care unit only. Moreover, the incidence of severe pain of this study is much higher than 7.8-11% of the previous literature review and meta-analysis focusing on thoracotomy, laparotomy and major abdominal surgery; and the recommendation from the audit commission in the UK indicates that the number of patients who experience severe postoperative pain should be less than 5%[4,17,19]. However, the study of Dolin et al did not include an observation of pain score and pain management in the recovery room which may result the lower incidence than this study[17].

The evaluation of postoperative pain is complex and effective epidural analgesia should focus on various aspects of the pain experience. In addition, multimodal analgesia including around the-clock regimen of NSAIDs and acetaminophen is recommended for the acute postoperative pain management. Therefore, this study reported not only postoperative pain intensity but also about additional rescue analgesic medication for break through pain. The data also indicated the high percentage of patients requiring rescue pain medication although they reported only mild postoperative pain. It is probable that the reported pain score at each time point was an actual pain at that time, which may be an effect from a rescue pain medication and does not reflect an overall pain.

In the setting of university hospital, epidural block is usually performed by the residents and staff anesthesiologists. Therefore residents obtain a great deal of epidural training and are under the supervision of staff. However, performing epidural anesthesia needs manual skills and proficiency to succeed.

Previous study demonstrated that residents required at least 25 epidural anesthetics in order to significantly improve their skill over the baseline and 60 attempts were needed to reach 90% success rate[20]. Unfortunately, residents in our institute have an experience to perform epidural anesthesia approximately 10 attempts each year[21]. This may be one of many obstacles to improve an effectiveness of epidural analgesia in our institute.

About adverse effects, the incidence of nausea or vomiting (27.5%) in patients receiving epidural opioid in this study was similar to 5-60% reported in previous studies and meta-analysis[22-24]. Pruritus is one of the common adverse effects from epidural opioids. Our study had an incidence of approximately 30% compared to 7-38% in many observational studies[22,25]. The incidence of hypotension with a local anesthetic-based epidural regimen ranged from 3.0% to 30%; this study reported the incidence of approximately 8%[3,4,25]. Moreover, the incidence of motor block (2.5%) was not different from 2-3% reported from these two studies[4,26].

There are some limitations associated with this study. First, this study was an observational study which was designed to collect the data of normal clinical practice. Missing data, especially about postoperative pain score, was a common problem which needed to contact patients directly to assess their pain; and authors had to collect some necessary information about intra-operative epidural technique and medication retrospectively in some cases. Second, complications may be under-reported due to the compliance of medical recording. Third, authors collected only postoperative 48-hour complications; long-term complications may have been missed. Finally, our institution is a training hospital; so the effectiveness of epidural analgesia discovered in this study may not reflect the case in other hospitals.

Conclusion

In summary, inadequate pain control in patients receiving epidural analgesia has still been a problem. Half of patients in this study had an acceptable pain score; however the multimodal and rescue analgesia were still necessary for patients receiving epidural medication. The incidence of adverse effects from epidural analgesic medication was not different from other studies. In-depth analysis to identify associated factors to improve the effectiveness of postoperative epidural analgesia should be further investigated.

What is already known on this topic?

Epidural analgesia is effective perioperative analgesic technique in patients having major operation. However, epidural technique is not universally successful and failure of epidural analgesia is a frequent clinical problem which needs active management in order to rescue postoperative pain. The evidence from many reviews indicates that the number of patients experiencing inadequate analgesia with this technique is approximately 12-32%.

What this study adds?

The incidence of patients having acceptable pain score at rest at all postoperative periods was 51.4%; whereas 13.7% needed some intravenous rescue medication for breakthrough pain. The incidence of postoperative severe pain at rest during the running of epidural medication was 24.5%.

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Register

Clinical Trials.gov as NCT02315261

Potential conflicts of interest

None.

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ประสิทธิผลของการระงับปวดหลังผ่าตัดโดยการบริหารยาเข้าช่องเหนือไขสันหลังสำหรับการผ่าตัดทรวงอกและช่องท้องในโรงพยาบาลศิริราช

มิ่งขวัญ วงษ์ยิ่งสิน, อันนิสา อนุวงศ์เจริญ

วัตถุประสงค์: เพื่อศึกษาข้อมูลและประเมินประสิทธิผลของการระงับปวดหลังผ่าตัดโดยการบริหารยาเข้าช่องเหนือไขสันหลังในโรงพยาบาลศิริราช

วัสดุและวิธีการ: ผู้ป่วยที่ได้รับการนัดหมายให้เข้ารับการผ่าตัดทรวงอกหรือช่องท้องภายใต้การดมยาสลบร่วมกับการบริหารยาเข้าช่องเหนือไขสันหลังเพื่อระงับปวดหลังผ่าตัดในโรงพยาบาลศิริราชระหว่างเดือนธันวาคม พ.ศ. 2557 ถึงตุลาคม พ.ศ. 2558 ได้รับการคัดเลือกให้เข้าร่วมในการศึกษาครั้งนี้ และผู้ป่วยจำนวน 364 คนได้ถูกนำมาวิเคราะห์ในท้ายที่สุด จากข้อมูลพื้นฐานของผู้ป่วย ชนิดของการผ่าตัด เทคนิคการใส่สายและการบริหารยาเข้าช่องเหนือไขสันหลัง คะแนนความปวดหลังการผ่าตัด และข้อมูลเกี่ยวกับภาวะแทรกซ้อนหลังผ่าตัดที่ได้รวบรวม

ผลการศึกษา: สัดส่วนของผู้ป่วยที่มีคะแนนความปวดขณะพักอยู่ในระดับที่ยอมรับได้ตลอดระยะเวลาหลังการผ่าตัด คือ 51.4% (95% CI 46.3-56.5) ในจำนวนนี้มีผู้ป่วย 50 คน (13.7%) ที่ขอยาแก้ปวดฉีดเข้าทางหลอดเลือดดำเพิ่มเติม สัดส่วนของผู้ป่วยที่มีอาการปวดรุนแรงหลังการผ่าตัด คือ 24.5% (95% CI 20.3-29.1) ผู้ป่วย 100 ราย (27.5%) มีอาการคลื่นไส้อาเจียน 28 ราย (7.7%) มีความดันเลือดต่ำ นอกจากนั้นยังพบอุบัติการณ์ของการแทงทะลุ dura โดยไม่ตั้งใจ 1.36% และอุบัติเหตุของอาการปวดศีรษะหลังการแทงหลัง 0.8%

สรุป: จากการศึกษาพบว่ามีผู้ป่วยประมาณ 50% ที่ไม่สามารถระงับปวดหลังผ่าตัดโดยการบริหารยาเข้าช่องเหนือไขสันหลังได้ การให้ยาเป็นครั้งคราวเมื่อผู้ป่วย เริ่มมีอาการปวดนั้นยังมีความจำเป็นในผู้ป่วยกลุ่มนี้ การวิเคราะห์ในเชิงลึกเพื่อระบุปัจจัยที่เกี่ยวข้องและปรับปรุงประสิทธิผลของการระงับปวดหลังผ่าตัด โดยการบริหารยาเข้าช่องเหนือไขสันหลังควรได้รับการศึกษาเพิ่มเติมต่อไป