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Original Contribution

Thoracic paravertebral block versus thoracic epidural analgesia for post-operative pain control in open pancreatic surgery: A randomized controlled trial

Jacob L. Hutchins, MD, MHA[a,*], Anthony J. Grandelis, MD[a], Alexander M. Kaizer, PhD[b], Eric H. Jensen, MD[c]

[a] Department of Anesthesiology, University of Minnesota, Minneapolis, MN, USA
[b] Department of Biostatistics and Informatics, Colorado School of Public Health, University of Colorado, Aurora, CO, USA
[c] Department of Surgery, University of Minnesota, Minneapolis, MN, USA

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ABSTRACT

Study objective: The purpose of this study was to compare the efficacy of bilateral ultrasound guided thoracic paravertebral catheters to a thoracic epidural after open pancreatic surgery.
Design: This was a prospective non-blinded randomized controlled trial.
Setting: Academic hospital operating room, postoperative recovery area, and ward.
Patients: 53 patients aged 18 and above who had open pancreatic surgery.
Interventions: Patients received either bilateral thoracic paravertebral block at T8 with an infusion of 0.2% ropivacaine or thoracic epidural analgesia at T7/8 with an infusion of 0.125% bupivacaine with hydromorphone 6 μg/mL.
Measurements: Pain scores, opioid use, length of recovery room and hospital stay, adverse events, and incidence of nausea and vomiting.
Main results: There was no difference in baseline demographics between the two groups. There were no significant differences in pain scores between the two groups in each of the first five days after surgery. There was no difference in length of stay nor nausea and vomiting. There was significantly less modality related adverse events in the paravertebral group compared to the epidural group ($p = 0.02$).
Conclusions: The use of thoracic paravertebral catheters provided comparable analgesia and less modality related adverse events when compared to a thoracic epidural in patients undergoing open pancreaticoduodenectomy.

1. Introduction

Thoracic epidurals are commonly used for the management of acute postoperative pain after abdominal surgery. Proper pain control has been shown to lead to improved postoperative outcomes [1]. Several studies have shown that thoracic epidural analgesia provides superior pain control when compared to standard intravenous opioids in major abdominal surgery [2,3]. Pancreaticoduodenectomy is commonly performed through an upper midline abdominal incision and thus these studies are often applied to this patient population. In comparison to intravenous analgesia, epidurals generally result in lower rates of complications such as respiratory failure, earlier bowel recovery, shorter intensive care unit (ICU) and shorter hospital stays in both pancreaticoduodenectomy and other abdominal procedures [4–8]. However, when evaluating just epidurals themselves, they have been shown to be associated with significant side effects or complications. These include hypotension, pruritus, and oliguria [9,10]. Epidurals in PD surgery have been shown to increase the risk of ICU admission and require more adjustments in pain control [11]. Furthermore, epidurals have been associated with early discontinuance due to inadequate pain control or hemodynamic compromise, both of which contribute to longer hospital stays [12,13].

An emerging alternative to epidural analgesia in abdominal surgery is the use of ultrasound guided bilateral paravertebral catheters [14]. Recent studies have shown paravertebral catheters to provide less side effects when compared to epidurals [15,16]. Additionally, studies also showed that paravertebral blocks had less hypotension than epidurals [17,18]. Along with a low side-effect profile and fewer

* Corresponding author at: University of Minnesota, Department of Anesthesiology, MMC 294 Mayo, B515 Mayo Building, 420 Delaware Street SE, Minneapolis, MN 55455, USA.
E-mail addresses: hutc0079@umn.edu (J.L. Hutchins), alex.kaizer@ucdenver.edu (A.M. Kaizer), jense893@umn.edu (E.H. Jensen).

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contraindications, paravertebral catheters can be performed under real time ultrasound guidance, which may increase the success rate of placement. However, only two studies, one in pediatrics, [19] and one in adults [20] have compared epidural analgesia to bilateral continuous paravertebral infusions in major abdominal surgery such as the pancreaticoduodenectomy.

The primary objective of this study was to determine the effect of epidural analgesia and continuous paravertebral infusions on post-operative maximal pain scores after open pancreatic surgery. Secondary objectives were to evaluate the effect of the modalities on the number of adverse events related to either the epidural analgesia or paravertebrals, incidence of post-operative nausea and vomiting, duration of stay in post anesthesia care unit (PACU) and length of hospital stay.

2. Materials and methods

This prospective randomized controlled trial was approved by the University of Minnesota Institutional Review Board and was registered at clinicaltrials.gov (NCT02363777). Eligible patients who provided consent were randomized to receive either bilateral thoracic 8 (T8) paravertebral catheters or a T 7-8 epidural catheter. Inclusion criteria included patients aged 18 and older who were undergoing open pancreatic resection surgery. Exclusion criteria were those patients who were non-English speaking, patients on anticoagulation, patients taking opioids for greater than three weeks prior to surgery, patients with a contraindication to regional anesthesia, and those with a history of chronic pain. Randomization was performed using a random number generator on the day of surgery. Due to the nature of the treatment modalities none were blinded to the treatment group. The opiates in the epidural infusion were not included in the total opiate calculations.

Paravertebral catheters were placed in the preoperative holding area by an anesthesiologist on the regional anesthesia service or by a senior resident supervised by one of these anesthesiologists. The patients were consented and sedated using 1–2 mg of intravenous midazolam and 50–100 mcg of Fentanyl. The site was disinfected with chlorhexidine gluconate and isopropyl alcohol prep stick (CareFusion, Leawood, Kansas USA). The patient was either in prone position or lateral decubitus. The catheters were placed according to the description from Renes et al. [21] The T8 level was identified using the inferior border of the scapula as a landmark for T7. A 38 mm 13–6 or 10–5 MHz probe was used and the probe was placed in a transverse orientation on the patient's back at the T8 level. A skin wheal was placed using 1 mL of 1% lidocaine. A 17 gauge Tuohy needle was advanced in a lateral to medial direction until the tip rested beneath the transverse process. This was an open tip catheter. Then 1–3 mL of 1.5% lidocaine with epinephrine 1: 200,000 was injected to confirm placement and ensure no vascular injection and to visualize depression of the pleura to confirm correct placement. Then the catheter was advanced 1–2 cm past the tip of the Tuohy needle and the needle was removed. After needle removal, 1–3 mL of 1.5% lidocaine with epinephrine 1: 200,000 was injected to confirm the catheter tip was in the correct position. The catheter was then secured with skin glue (Dermabond®, Ethicon, Inc.: Somerville New Jersey USA) and a chlorhexidine impregnated patch (BIOPATCH®, Johnson & Johnson Wound Management, a division of Ethicon, Inc.: Somerville New Jersey USA). An occlusive clear dressing was placed over the site. The paravertebral kit was a CONTIPLEX ™ FX nerve block tray (BBraun Melsungen AG, 34209 Melsungen, Germany). This procedure was repeated on the contralateral side.

For the epidural catheters the procedure was also performed in the preoperative holding area. The patient was seated on the edge of the bed and the site was disinfected with chlorhexidine gluconate and isopropyl alcohol prep stick (CareFusion, Leawood, Kansas USA). The T8 level was identified using the inferior border of the scapula as a landmark for T7. A skin wheal of 0.5 mL of 1% lidocaine was made and then the 17 gauge Tuohy was advanced using loss of resistance technique with normal saline. When the epidural space was encountered the catheter was advanced 4–5 cm into the epidural space and secured at the skin using a Lockit Plus® device (Smiths Medical ASD Inc., Keene, New Hampshire USA) and a clear occlusive dressing was placed over the site. A test dose of 1–3 mL of 1.5% lidocaine with epinephrine 1: 200,000 was injected to ensure the catheter was in the correct space. This was an open tip catheter. The epidural kit was a PERIFIX® FX continuous epidural anesthesia tray (BBraun Melsungen AG, 34209 Melsungen, Germany).

The patient was then taken to the operative room and general anesthesia was induced. Induction and maintenance anesthesia were not standardized and left to the discretion of the attending anesthesiologist. However, all patients received 4 mg of intravenous ondansetron near the end of the surgery. At the end of the procedure when the surgeon began closure the epidural or paravertebral catheter infusion was started. No infusate bolus was given to either group. The epidural infusion consisted of bupivacaine 0.125% with hydromorphone 6 mcg/mL and was administered via a pump (CADD®-Solis Ambulatory Infusion Pump, Smiths Medical ASD Inc., Keene, New Hampshire USA) starting at 10 mL/h. The paravertebral catheters were connected to an elastomeric pump (On-Q®, Halyard Health, Alpharetta, Georgia USA) and an infusion of 7 mL per/h per side was started of 0.2% ropivacaine. If the patient was under 60 kg the infusion was decreased to 6 mL/h per side of 0.2% ropivacaine.

Once in the PACU, patients were assessed for pain every hour and treated with either intravenous hydromorphone or fentanyl based on nursing discretion. Pain intensity was assessed and recorded by the PACU nurse. When the patient met PACU discharge criteria (Aldrete score of 8) the patient was then transferred to the surgical ward [22]. The duration of PACU stay was stopped when the patient met the discharge criteria. Nurses in the PACU performed sensory tests with ice on the patient to ensure proper placement of the epidural or paravertebral catheters.

Once on the surgical ward, the pain was initially managed using intravenous opioids via patient controlled analgesia pump in addition to the epidural or paravertebral infusion. When patients were able to tolerate oral medications oral oxycodone was given. Oral acetaminophen was available for pain as an as needed medication. Pain was assessed using the Numerical Rating Scale and pain scores were obtained by the floor nurses as well as once per day by the acute pain team. The scores were recorded for the first 5 days post-operatively. The presence of nausea or vomiting each day was noted in the chart and all opioids the patient received were converted to intravenous morphine equivalents using an online calculator [23]. If incomplete epidural blocks were found, it was ensured that the catheter had not been removed and when confirmed the catheters were pulled back 1 cm and the infusion restarted. If they continued to have difficulty with incomplete blocks, the infusates were changed to local anesthetic only and the opioid PCA was continued. If incomplete paravertebral blocks were found a bolus of 5 mL of 0.25% bupivacaine was given and then the patient was tested with ice to ensure proper dermatomal spread. If the patient still had poor dermatomal spread we would pull the catheter back one centimeter and reinject and test.

The primary hypothesis was that paravertebral catheters will result in improved pain control relative to thoracic epidural analgesia for post-operative pain from open pancreatic surgery. This study was powered using prior institutional unpublished data using maximal pain scores in patients undergoing open pancreatic surgery Our previous data from patients with paravertebral catheters showed a mean maximum pain score of 4 with standard deviation of 3.3. We hypothesized that the patients who had paravertebrals would have improved pain compared to epidurals and chose a difference of 2 to be significant. Using this data, we determined we would need 22 patients to achieve 80% power with 5% alpha. We assumed 10% would be lost to follow up. Most continuous outcomes were not normally distributed ($p < 0.05$ for Shapiro-Wilk test for normality), therefore comparisons between the randomized groups used the robust, non-parametric