Original Article

Analgesic efficacy of surgeon placed paravertebral catheters compared with thoracic epidural analgesia after Ivor Lewis esophagectomy: a retrospective non-inferiority study

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Background: The Ivor Lewis esophagectomy is an operation that involves a laparotomy and a right thoracotomy, both of which are associated with severe postoperative pain and subsequent impairment of respiratory function. Currently, the accepted "gold standard" for postoperative analgesia for laparotomies and thoracotomies is the thoracic epidural. A systematic review has shown paravertebral blocks to be equivalent to epidural analgesia for post-thoracotomy pain control and have decreased incidence of nausea and vomiting, hypotension and respiratory depression. To our knowledge, the use of the paravertebral catheter (PVC) in open Ivor Lewis esophagectomy has not been formally studied. The primary outcome is the area under the curve (AUC) pain scores in the first 48 hours after surgery.

Methods: We performed a retrospective chart review of the open Ivor Lewis esophagectomy patients at our local institution, with local research ethics board (REB) approval.

Results: A total of 92 patients were included in this study: 43 patients had a PVC and 49 had a thoracic epidural for postoperative pan control. Overall, the PVC group was non-inferior and statistically equivalent to the epidural group. Time to ambulation in the PVC group was non-inferior compared to epidurals. The PVC group was superior when comparing total opioid consumption.

Conclusions: Our retrospective study continues to challenge the role of epidurals as the gold standard of pain control post thoracotomy and laparotomy. Further prospective studies with a larger population are needed to better compare the two modalities.

Keywords: Esophagectomy; thoracotomy; pain management; paravertebral

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Introduction

The Ivor Lewis esophagectomy is used to treat both benign and malignant diseases of the distal esophagus and the gastroesophageal junction (1). This procedure involves two stages: first, a laparotomy and mobilization of the stomach, and second, a right thoracotomy, resection of the esophagus and esophagogastric anastomosis (1,2). Both the laparotomy and thoracotomy on their own can be associated with severe postoperative pain, and subsequent impairment of respiratory function (3).

Historically the thoracic epidural has been considered the "gold standard" for postoperative analgesia after upper abdominal incisions and thoracotomies (4,5). Epidurals have been shown to reduce intraoperative surgical stress and provide effective post-operative analgesia (3,4,6). However, they are not without risks and side effects. The most serious risk is an epidural hematoma or an abscess with consequent spinal cord injury (7,8). Common side effects include hypotension, nausea and vomiting, and pruritus. These risks are amplified in the early postoperative period after esophagectomy where significant hypotension can lead to ischemia of the gastric conduit and vomiting can disrupt the gastroesophageal anastomosis. Epidurals are also contraindicated in the presence of coagulopathy or sepsis (3).

A paravertebral block is a technique that involves administration of local anesthetic into the paravertebral space. This can be done by ultrasound guidance or by the surgeon under direct visualization. First performed in 1905, it has recently emerged as a possible alternative to the thoracic epidural (9). In 2007, The Procedure-Specific Postoperative Pain Management (PROSPECT) working group listed both the paravertebral block and thoracic epidural analgesia as top recommendations for thoracotomy, both based on Grade A evidence (10). Several systematic reviews and meta-analyses have shown continuous paravertebral blocks to be equivalent to epidural analgesia for pain control (11,12). They have also been found to be associated with less nausea and vomiting and a decreased incidence of adverse events such as hypotension and respiratory depression (3,13-15).

The paravertebral space can be used for a single injection or a continuous infusion of local anesthetic through a catheter. Currently no studies have reported the effectiveness of a paravertebral catheter (PVC) for pain relief in a combined thoracotomy and upper abdominal midline incision procedure such as the Ivor Lewis esophagectomy.

Our institution has been using surgeon placed PVCs since 2005. In this study, we performed a retrospective review of all our Ivor Lewis esophagectomy patients from 2012 to 2018. We hypothesized that paravertebral analgesia would be non-inferior to epidural analgesia with respect to pain scores over the first 48 hours. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-689/rc).

Methods

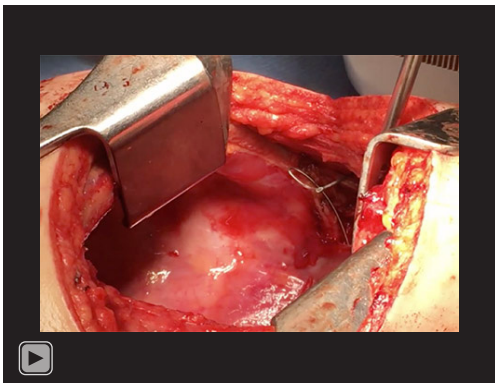
The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Research Ethics Board (REB) approval (No.1023762) was obtained from the Nova Scotia Health Authority for this retrospective chart analysis. Request for waiver of consent was granted by our local ethics board.

Patients

All patients who underwent an open Ivor Lewis esophagectomy between 2012 and 2018 at tertiary care thoracic surgery centre were included. A list of operations booked as an open Ivor Lewis was obtained by the surgical operations database manager. Exclusion criteria consisted of high-grade opioid tolerant patients [defined as an oral morphine equivalent (OME) of 72 mg/day] (16), patients with previous or current neurologic disease affecting the hemithorax or below, and significant missing data. Demographic data such as age, sex, significant comorbidities, and American Society of Anesthesiologists Physical Status Class (ASA) were obtained.

Description of surgical placement of PVC

PVCs were inserted by the surgical team prior to closing the thoracotomy incision. Please see *Video 1* for a demonstration of the procedure. An extrapleural pocket extending to the sympathetic chain was created using a blunt instrument in the same interspace as the thoracotomy. Next, a Tuohy needle was used to transcutaneously guide the catheter into the pocket and under direct vision the tip was placed near the sympathetic chain. Care was taken to ensure the pleura was not disrupted. Typically, the pocket creation and catheter placement were completed in less than 5 minutes. The pocket was tested with 20 mL of bupivacaine 0.5% delivered in 3–5 mL aliquots



Video 1 Step by step instructions for inserting a paravertebral catheter intraoperatively for postoperative pain control.

given roughly every 5 minutes as the incision was closed. The catheter was secured to the skin with steri-strips and covered with a transparent dressing prior to breaking the sterile field.

Management of paravertebral and epidural catheters

All patients with a paravertebral or epidural catheter at our institution are managed by the acute pain service. We routinely use 0.375% ropivacaine for our PVCs and 0.125% bupivacaine with 30 µg/mL of Hydromorphone for our epidural solution.

Outcomes

The primary outcome was the area under the curve (AUC) pain score in the first 48 hours after surgery. Patients' pain scores were assessed based on a numeric/visual pain scale [0–10]. Patients with PVCs were assessed every 3 hours and patients with epidurals were checked every hour for the first 24 hours, then every 4 hours thereafter. Using the pain scores from the nursing chart, an AUC for pain was calculated using the trapezoid method as described by Aloia *et al.* (17). Missing data points were not entered. Using the trapezoid method, each data point was connected to the next one. Time 0 was the first recorded pain score.

Secondary outcomes include total opioid consumption over 48 hours, time to ambulation and highest pain score, among others. To calculate total opioid use, all opioid medications were converted to OMEs using previously reported conversions (18-21). For our study, we referred to the equianalgesic tables from Essentials of Pain Management, by Hickey *et al.* (19), which suggested a conversion ratio of 5:1 for intravenous to epidural hydromorphone.

The incidence of side effects such as nausea, vomiting, pruritus and hypotension were reported. Medication records for pharmaceutical interventions such as dimenhydrinate, diphenhydramine or ondansetron administration, and the nursing progress notes were reviewed. Hypotension was defined as a recorded systolic blood pressure of less than 90 mmHg (22), as this has been associated with adverse outcomes postoperatively.

Statistical analysis

Based on the available literature, we used a difference of two on the pain scale to establish non-inferiority (23). With respect to our primary outcome, a difference of less than 96 in the AUC would be required for non-inferiority, as pain scores will be analyzed over a 48-hour period. We used the confidence interval (CI) approach to simultaneously test for: (I) equivalence; (II) non-inferiority; (III) superiority of PVC; or (IV) inferiority of PVC. Non-inferiority is met when the 90% CI excludes the upper bound of the non-inferiority margin. Equivalence is a more stringent subset of non-inferiority that is met when the 90% CI is fully contained within the upper and lower bounds of the non-inferiority margin. Superiority or inferiority of PVC is met when the 95% CI does not include any values within the range of the non-inferiority margin. When using the P value method, non-inferiority tests are one-sided P values and equivalence tests use two one-sided tests (TOST), hence 90% CIs are used for alpha of 0.05. In contrast, the superiority/inferiority tests are two-sided, so a 95% CI is used. We prefer the CI approach, as we believe it minimizes confusion about what is being tested.

A power analysis was done using the difference of 96. Seventy-eight patients were required to be 95% sure that the lower limit of a one-sided 95% CI (or equivalently a 90% two-sided CI) was above the non-inferiority limit of −96. For an equivalence test, 92 patients were required to be 95% sure that the limits of a two-sided 90% CI excluded a difference in means of more than 96.

For secondary outcomes non-inferiority margins were also used. The highest pain score used a difference of two on the pain scale to establish non-inferiority. Time to ambulation was compared, with a pre-established clinical difference of 12 hours as the non-inferiority margin, based on local surgeon consensus. Total opioid use in 48 hours

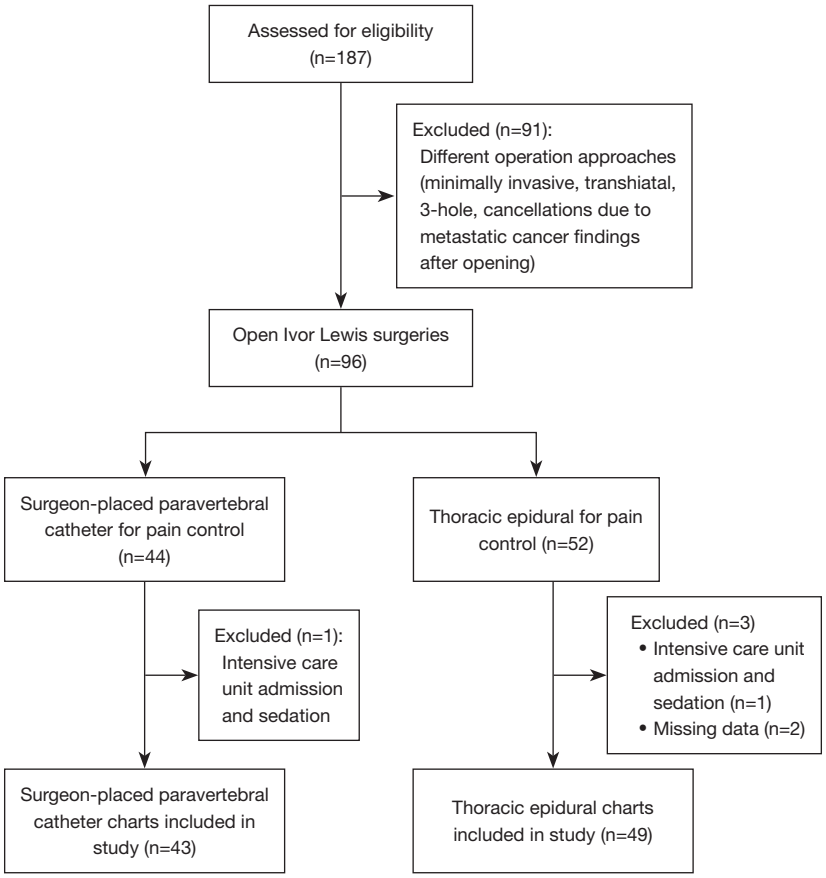


Figure 1 Inclusion and exclusion flow diagram.

was also compared. The non-inferiority margin in this study was based on one third of the mean opioid consumption of the epidural group (24).

The planned analyses for numerical variables were non-inferiority tests conducted in Jamovi (The Jamovi Project, 2020) using independent samples Welch's *t*-tests. The PVC group was set as the reference group (i.e., the mean difference was calculated as PVC – epidural). Non-inferiority is demonstrated if the 90% CI of the mean difference does not cross over the upper equivalence bound.

Demographics, other than age and body mass index (BMI), were analyzed using the Fisher exact test. The ASA scores from both groups were compared using Chi-squared test for trend. Side effects were presumed to be rare, and thus were analyzed using descriptive statistics only (i.e., frequencies, percentages).

Results

A total of 187 charts were obtained from the surgical operations database manager (*Figure 1*). Ninety-one patients were excluded as different surgical techniques were used. Ninety-six patients underwent completely open Ivor Lewis esophagectomies between 2012 and 2018. Two patients were excluded due to missing data, and two patients were excluded due to prolonged sedation in the intensive care unit (ICU). Ninety-two patients were included in this study: 43 patients had PVCs and 49 had thoracic epidurals.

Demographic characteristics by group are described in *Table 1*. The mean age of the PVC group was 63.7±7.9 versus 61.9±8.7 years in the epidural group (P=0.3042). The mean BMI in the PVC group was 26.5±4.5 versus 27.6±4.8 kg/m^2 in the epidural group (P=0.2618).

Some differences in the demographics were noted in the paravertebral group including a higher prevalence of ischemic heart disease (P=0.413) and ASA class 3 (P=0.373). In the epidural group, there was a higher prevalence of smokers (P=0.215) and patients with chronic obstructive pulmonary disease (COPD) (P=0.327). Analysis of the demographics did not demonstrate any statistical

Table 1 Demographic characteristics

Patient characteristics	PVC, n (%)	Epidural, n (%)	P value
Male	34 (79.1)	42 (85.7)	0.424
Pre-operative opioid use	3 (7.0)	7 (14.3)	0.327
Ischemic heart disease	4 (9.3)	2 (4.1)	0.413
Heart failure	1 (2.3)	0	0.462
Hypertension	16 (37.2)	21 (42.9)	0.672
Valvular heart disease	1 (2.3)	0	0.467
Peripheral vascular disease	2 (4.7)	1 (2.0)	0.597
Smoker	7 (16.3)	14 (28.6)	0.215
COPD	3 (7.0)	7 (14.3)	0.327
Asthma	4 (9.3)	2 (4.1)	0.413
Obstructive sleep apnea	4 (9.3)	6 (12.2)	0.745
Anemia	33 (76.7)	38 (77.6)	>0.99
Diabetes	3 (7.0)	8 (16.3)	0.209
Cerebral vascular disease	2 (4.7)	2 (4.1)	>0.99
ASA			0.373
1	1 (2.3)	0	
2	30 (69.8)	39 (79.6)	
3	12 (27.9)	10 (20.4)	

PVC, paravertebral catheter; COPD, chronic obstructive pulmonary disease; ASA, American Society of Anaesthesiologists Physical Status Class.

Table 2 Primary and secondary outcomes

Outcomes	PVC (n=43), mean ± SD	Epidural (n=49), mean ± SD
AUC	126±68.7	90.8±60.8
Max pain score	5.74±2.1	5.03±2.38
Time to ambulation (hours)	25.6±17.5	29.8±52.4
Duration of catheter (hours)	102±22	69.34±14.87
Length of stay (days)	14.02±8.70	13.86±7.54
Total OME (mg)	178±118	579±196

PVC, paravertebral catheter; SD, standard deviation; AUC, area under the curve; OME, oral morphine equivalent.

significance. None of the patients were considered highly opioid tolerant.

The primary and secondary outcomes are reported in *Table 2*. The 90% CI and 95% CI are presented in *Figure 2*. For AUC, the 90% CI around the mean difference ranged from 12.9 to 58.2, which is within the ±96 bounds of the non-inferiority margin. Thus, the two treatments were equivalent. Max pain similarly met the criteria for equivalence (between ±2), with the 90% CI ranging from –0.1 to 1.5. In contrast, time to ambulation met the criteria for non-inferiority because the upper bound of the 90% CI (–17.4 to .9.1) excluded 12; however, it failed to meet the more stringent criteria for equivalence, because the lower bound of the interval included –12. Finally, total OME was non-inferior because the 90% CI (–457 to –346) excluded 193; moreover, it also indicated that PVC was superior to the epidural group, because the 95% CI (–467 to –335) excluded –193.

The incidence of side effects is reported in *Table 3*. Between the two groups, the incidence for somnolence and nausea or vomiting were similar. Epidurals had a much higher incidence of pruritus. Interestingly, more patients met the definition of hypotension in the PVC group.

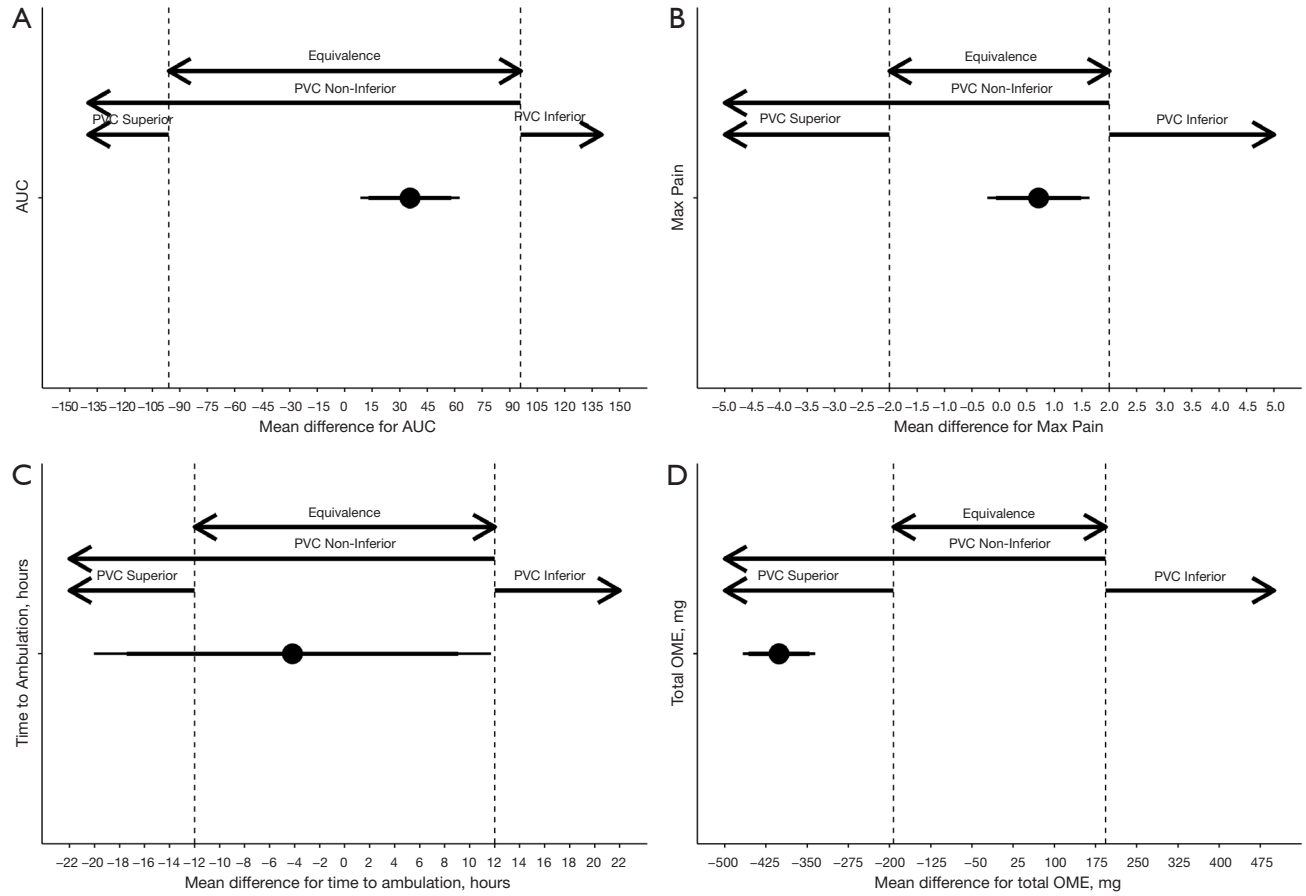


Figure 2 Inferiority and equivalence testing of primary and secondary outcomes. The dot indicates the mean difference, the thicker error bars around the dot represent the 90% CI and the thinner bars indicate the 95% CI. The dotted lines indicate the non-inferiority margins. Mean difference is calculated by PVC – epidural. PVC superior: if the 95% CI for the mean difference does not include the lower bounds of the equivalency margin, and the CI contains only negative numbers. PVC inferior: if the 95% CI for the mean difference does not include the upper bounds of the noninferiority margin, and the CI contains only positive numbers. Equivalence: if the 90% CI does not overlap either of the non-inferiority regions. Non-inferiority: if the 90% CI does not include the upper bounds of the non-inferiority margin. AUC, area under the curve; PVC, paravertebral catheter; OME, oral morphine equivalent; CI, confidence interval.

Table 3 Incidence of side effects

Side effect	PVC (n=43), n (%)	Epidural (n=49), n (%)
Nausea or vomiting	13 (30.2)	14 (28.6)
Pruritis	4 (9.3)	15 (30.6)
Somnolence	1 (2.3)	1 (2.0)
Hypotension	14 (32.6)	11 (22.4)

PVC, paravertebral catheter.

Discussion

Although retrospective, with the inherent limitations, this study suggests PVCs are non-inferior to epidurals with respect to pain control, as suggested by the AUC and highest pain score over the first 48 hours. At our local institution, PVCs and epidurals are evaluated at different intervals. Given this difference and the retrospective nature

of this study, the AUC was used to compare and reconcile the different intervals between the two groups as well as to compare the two modalities over a 48-hour period, rather than at arbitrary time points postoperatively. Although pain scores tend to be higher in the PVC group, the two groups are statistically equal using a non-inferiority margin of two on the pain scale. The results of our study continue to support previously reported literature that compared the two modalities (11,12) but also suggests the effectiveness of the PVC in addressing pain for both the laparotomy and the thoracotomy, simultaneously.

When looking at opioid consumption as another surrogate of pain control, the PVC group had significantly less opioid consumption, as compared to the epidural group: 579 versus 178 OMEs. However, evidence-based guidelines for converting neuraxial opioids to intravenous or OMEs are lacking. Conversion ratios for intravenous to epidural vary significantly from 5:1 to 10:1. We used the 5:1 conversion ratio in this study as it was more conservative and would minimize overestimating OME. The 10:1 ratio, would have resulted in an even greater difference in total opioid consumption. Using OME as an outcome has many limitations, and the neuraxial opioid conversion simply adds to the confusion (25). Using an epidural solution containing opioids is problematic when opioid consumption is an outcome of interest because of the wide range of conversion ratios, but also because patients with epidurals will continue to get opioids regardless of their function or pain scores.

In the 1990s, the American Pain Society started the "pain is the fifth vital sign" campaign and added pain assessment as a measure of patient wellbeing. But in recent years pain scores have been implicated in the opioid epidemic as well as with over-sedation of patients (26). Function is perhaps the more important measure and is one of the key aspects to postoperative recovery. In this retrospective study, we used time to ambulation as a surrogate for function. The PVC group was found to be non-inferior and equivalent to the thoracic epidural.

In terms of side effects, the epidural group had a higher incidence of pruritus, which can perhaps be attributed to the higher OME. Interestingly, the PVC group had a higher incidence of hypotension contradicting findings in the literature (3,13,14). Ultimately, the reason for this finding in our data is unclear, as the opposite would be expected. Both groups of patients underwent similar post-operative monitoring. It is possible that with the advent of more judicious use of fluid intraoperatively that hypotension was a consequence of this practice change rather than the mode of regional anesthesia. That said, the consistency of this adverse events would be best analyzed as in a randomized controlled trial.

A clear limitation of this study is its retrospective nature and the small sample size making propensity score matching difficult. Although the two groups look relatively similar, we did not have adequate numbers to do multivariate analysis. In addition, we reported complications such as pruritus and nausea and vomiting as these are incredibly relevant for patients, however we were unable to do any meaningful statistical analysis due to the small numbers. Thankfully previous studies have clearly shown the benefits of PVC over epidurals.

Outside of pain scores and function, it is also worthwhile to compare the two techniques and their perioperative management. A thoracic epidural is placed pre-induction, with or without the assistance of an ultrasound, and is usually a "blind" technique whereby the space is found based on anatomy and "loss of resistance". The PVC, on the other hand, is placed under direct vision intraoperatively while the patient is still asleep and may ultimately be more efficient in terms of placement and achieving postoperative analgesia. In addition, because they are surgeon-placed under direct vision, the removal of the catheter is not dependent on timing of postoperative venous thromboembolism prophylaxis. Although not reported in this study, our experience has been that epidural placement takes longer than surgical PVC insertion.

At our local institution, we routinely run ropivacaine 0.375% at 8 to 12 mL/hour for our unilateral paravertebral. Although this is a higher dose of local anesthetic than other institutions (15), we have not had any issues or concerns with local anesthetic toxicity. Meyer *et al.* studied ropivacaine plasma concentrations running at similar rates and concentrations to ours and found it to be below the toxic threshold in all of their patients (27). Marret *et al.* also supported this finding in their study, with a higher ropivacaine concentration but a similar hourly dose (28).

Due to the retrospective nature of this study, there were no specific patient selection criteria for choosing between the epidural and the PVC for pain control. The pain modality was at the discretion of the attending anesthesiologist and surgeon the day of the surgery, based on patient and surgical factors. From our demographics, the two populations appeared to be comparable. Four of the patients in the PVC group were conversions from minimally invasive esophagectomy (MIE) to an open esophagectomy. Advances in minimally invasive surgery

have made MIE more feasible. That said, the MIE is a technically challenging operation and like any minimally invasive operation, the likelihood of converting to an open technique needs to be considered preoperatively. We feel our data should give the surgeon and anesthesia team confidence that in the event of conversion, the PVC will provide adequate postoperative analgesia, thus avoiding an epidural at the start of the operation,

Conclusions

Our retrospective study is the first study that reviewed the use of PVC in an open Ivor Lewis esophagectomy. It challenges the role of epidurals as the gold standard for pain control after a midline laparotomy and thoracotomy. The PVC is a quick and straightforward technique that can be done by surgeons under direct vision, compared to the thoracic epidural which are usually done by identification of landmarks. For the reasons listed above, as well as the findings in our study including fewer overall opioids used and less pruritus, we believe PVCs should be strongly considered as a modality for pain control.

The retrospective nature and small sample size are clear limitations of this study. Prospective studies are needed to better compare the two modalities. A randomized controlled trial has recently been registered for PVC versus epidural analgesia in minimally invasive esophageal resection (29) and a similar study would be helpful for open Ivor Lewis esophagectomy.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-689/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-689/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-689/coif). D.F. reports consulting fees from AstraZeneca. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Research Ethics Board (REB) approval (No. 1023762) was obtained from the Nova Scotia Health Authority for this retrospective chart analysis. Request for waiver of consent was granted by our local ethics board.

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