# Comparison of Ultrasound-Assisted and Classic Approaches to Continuous Paravertebral Block for Video-Assisted Thoracoscopic Surgery: a Prospective Randomized Trial

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**Abstract:** *Background:* Continuous paravertebral blocks (PVBs) are an established means of providing postoperative analgesia in thoracic surgery. While PVBs can be administered using multiple methods, no randomized clinical trial comparing the relative advantages of the ultrasound-assisted approach to the traditional landmark approach, the two most commonly-used approaches in our hospital, has been conducted to date. Our study thus sought to compare the efficacy of these two methods of PVB placement.

*Methods:* From July 1, 2013 to June 5, 2014, 45 patients scheduled for thoracic surgery consented to participate in the study. Each patient was randomized into a group receiving PVB placed with either the classic landmark-based (CL) or ultrasound-assisted (US) approach. Each group received 20 ml of ropivacaine 0.5% as the local anesthetic (LA). Onset time and spread of the block were then assessed by a blind observer. The main outcome was hydromorphone consumption 24 hours after initiation of patient-controlled analgesia (PCA). Secondary outcomes were the following: Pain Numeric Rating Scale (NRS) score after 24 hours at rest and during deep inspiration; requested PCA boluses in 24 hours; total LA consumption and number of boluses through the catheter; and changes between pre-and post-operative (24 hours after surgery) tidal volume, forced vital capacity, forced expiatory volume in 1 sec, and peak expiatory flow.

*Results:* Mean opiate consumption during the 24 hours after PCA initiation was 5.75 mg (4.23-7.26) for the CL group and 6.38 mg (4.51-8.25) for the US group (p= 0.643). None of the secondary outcomes statistically differed between the two groups.

*Conclusions:* Our data supports the concept that choice of continuous PVB approach does not affect the outcome. The expertise of the anesthesiologist performing the block remains a key factor in choosing which approach to use.

**Keywords:** Surgery-thoracic, Anesthetic techniques-regional-paravertebral.

## 1. INTRODUCTION

Video-assisted thoracoscopic surgeries (VATS) and thoracotomies are characterized by pulmonary impairment and severe pain in the post-surgical period. Because it can exacerbate pulmonary dysfunction by compromising breathing pattern, lung volume, and secretion clearance, intense postoperative pain can lead to atelectasis and pneumonia and ultimately intensive care unit (ICU) admission [1-3]. Hence, effective pain management for patients undergoing VATS and thoracotomies is critical, as it can improve their respiratory effort and sequentially, their recovery [4-6].

First described in the early twentieth century, paravertebral block (PVB) is an established method of administering postoperative analgesia for thoracic procedures PVB blocks the somatic and sympathetic nervous systems and is placed by injecting a local anesthetic (LA) into the paravertebral space where the nerve and its branches are located after exiting the intervertebral foramen. A safe side-effect profile and low complication rate make PVBs popular in clinical settings. Indeed, PVB reduces opiate consumption and opiate-related side effects, as well as incidence of chronic pain after surgery [6-8] a recent meta-analysis reported that while PVBs and epidural thoracic analgesia provide equivalent pain relief, only PVB reduces the incidence of pulmonary complications following thoracotomies [9-11]. given its dual ability to mitigate pulmonary morbidity and alleviate postoperative pain, PVB is an effective technique for analgesia after thoracic surgery.

PVB can be placed using multiple methods, including loss of resistance, neuro-stimulation, and

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lateral/intercostal and ultrasound-assisted approaches. At our institution, the two most common approaches are the classic landmark-based approach (CL) and the ultrasound-assisted approach (US). To date, no randomized clinical study has compared these most commonly-used PVB placement approaches. Choice of technique is left to the preference and expertise of the anesthesiologist performing the procedure. The purpose of this prospective, randomized, clinical trial was to compare the relative values of the US vs. CL approaches for the placement of a paravertebral catheter.

## 2. METHODS

The University of Pittsburgh Medical Center (UPMC) Institutional Review Board (IRB) reviewed and approved this study protocol (n. PRO09090367), and the trial was registered on www.clincaltrials.gov (NCT01949480). This research was planned and conducted in accordance with the Declaration of Helsinki. Patients scheduled to undergo lung resection with VATS at UPMC Shadyside and UPMC Passavant hospitals were screened for study participation. Patients were asked to provide written informed consent prior to taking part in the study. Inclusion and exclusion criteria are listed in Table **1**.

Each patient's general information was recorded and a pre-operative pulmonary function test was performed before nerve block placement on the day of admission to surgery. The following baseline respiratory parameters were measured during a bedside spirometry exam using a ventilometer (Viasys Healthcare Inc. Microloop. Rochester, Kent, England); SpO2 on room air, respiratory rate (RR), tidal volume (TV), functional vital capacity (FVC), forced expiratory volume in 1 sec (FEV1), and peak expiratory flow (PEF).

Nerve block and catheter placement were performed by a member of the Acute Interventional Perioperative Pain Service (AIPPS). Each patient was randomized to one of two groups: Group 1 had continuous PVB performed using the CL approach and Group 2 had continuous PVB performed using the US approach. A random, computer-generated list was used to randomize subjects at a 1:1 ratio. Aside from the physician performing the block and the research associate responsible for the randomization sequence, all other study personnel involved in the remainder of the study procedures were blinded to the group assignments.

### 2.1. General Procedure

After standard monitors (NIBP cuff and pulse oximetry) and supplemental oxygen were applied, midazolam and fentanyl were titrated for light sedation during the procedure. Patients were placed in a sitting position for the procedure.

**Table 1: Inclusion and Exclusion Criteria**

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| Scheduled for elective thoracic surgery | Inability to provide adequate informed consent |
| ASA status I-III | Any contraindication to the placement of thoracic paravertebral catheters |
| 18-75 years old | Unstable vertebral and transverse process fractures |
| BMI less than or equal to 40 | Any chronic painful conditions or preoperative opioid use Any chronic painful conditions or preoperative opioid use |
| | Coagulation abnormalities or expectation to be on therapeutic anticoagulants postoperatively |
| | Allergy to any of the drugs/agents used in study protocol |
| | History of malignant hyperthermia |
| | Serum creatinine greater than 1.4 mg/dl |
| | Altered mental status or emergency surgery |
| | Comorbid conditions such as sepsis, unstable angina, congestive heart failure |
| | Non-English speaking patient |

### 2.2. Classic Landmark (CL) Paravertebral Block Approach

The block was placed in one intervertebral space (range T3 to T5) corresponding to the incision as preoperatively determined by the surgeon. The needle entry site was 2.5 cm lateral to the midpoint of the spinous process of the corresponding thoracic vertebrae. The area was prepped with 1% chlorhexidine and draped in a sterile fashion, and 1% lidocaine was infiltrated subcutaneously at the point of anticipated needle entry. For the catheter placement, a sterile 18 gauge Tuohy needle (B. Braun Medical, Inc., Perifix Continuous Epidural Anesthesia Set, Product Code CE18T) was introduced perpendicularly to the skin until the transverse process was encountered and the depth to the skin was noted. The needle was then readjusted in a caudal direction and inserted inferior to the corresponding transverse process to a depth 1 cm deep to the transverse process. After final needle placement, a hanging drop technique was used to rule out intrapleural placement while the patient took a deep breath.

### 2.3. Ultrasound-assisted (US) Paravertebral Nerve Block

The thoracic spine level was at the anatomic level corresponding to the midpoint of the incision as preoperatively determined by the surgeon (range T3 to T5). The needle entry site was 2.5 cm lateral to the midpoint of the spinous process of the corresponding thoracic vertebrae. The transverse process was identified with a portable ultrasound (SonoSite Inc., Bothell, WA, USA). The area was prepped with 1% chlorhexidine and draped in a sterile fashion, and 1% lidocaine was infiltrated. The low frequency 2-5 MHz curved array transducer was placed longitudinally 2.5 cm from midline between two transverse processes at the level of the future puncture site. The orientation of the probe was adjusted to visualize the transverse processes, costotransverse ligament, and pleura. The puncture site was anesthetized with 1% lidocaine. An 18-gauge Tuohy needle (B. Braun Medical, Inc., Perifix Continuous Epidural Anesthesia Set, Product Code CE18T) was placed under direct ultrasound guidance between two transverse processes, puncturing the costotransverse ligament.

After correct needle placement using either approach and because the paravertebral space is small, [12] in order to prepare the space for the catheter insertion, 10 mL of 0.5% ropivacaine was slowly injected through the needle after negative aspiration. Next, the nerve block catheter was inserted to a depth 5 cm beyond the tip of the needle. An additional 10 mL of 0.5% ropivacaine was injected in 5 mL increments through the catheter with negative aspiration in between, yielding a total activation dose of 20 ml of 0.5% ropivacaine. The catheter was secured with Steri-strips and a transparent occlusive dressing.

Following the block procedure, a blind observer recorded the patient's level of sensory (pinprick test) and temperature (ice test) blockade every five minutes for 30 minutes (six assessments). Vital signs were monitored by the acute pain nurse at regular intervals until the patient was taken to the operating room.

### 2.4. Anesthesiology Care and Post-surgery Pain Protocol

For induction of Anesthesia, standard doses of propofol, fentanyl, and succinylcholine were used. Sevoflurane, fentanyl, and a medium acting neuromuscular blocking agent were administered as needed during surgery. Before the end of surgery, a multimodal analgesic regimen of magnesium 2g, acetaminophen 1g, and ketamine 0.2 mg/kg (up to 25 mg) was administered intravenously to each study patient. Following surgery, patients were assisted in the Post-Anesthesia Care Unit (PACU) in accordance with standard guidelines. Upon arrival to the PACU, patients received a bolus of lidocaine 1% 10 ml through the catheter, as well as a continuous infusion of bupivacaine 0.0625% starting at 7 ml/h. For pain relief, nurses were permitted to administer boluses of 7 ml bupivacaine 0.0625% (no more than one per hour). Hydromorphone 0.3 mg IV boluses were available as necessary every 30 minutes in the PACU. After patients reported a score of 4 or less on the Pain Numeric Rating Scale (NRS), Patient Control Analgesia (PCA) pumps were started (bolus 0.2 mg of hydromorphone IV, lock-out eight minutes, no basal infusion, no one hour limit). Nerve block infusion and PCA were continued for study purposes for at least 24 hours. All patients were assessed daily by members of the AIPPS.

The primary outcome was opiate consumption over the first 24 hours after the initiation of surgery. Secondary outcomes included LA volume infused, including the number of LA boluses received for the first 24 hours, NRS score at rest and during deep inspiration, and pain Likert scale score 24 hours after initiation of surgery. Spirometry outcomes in the

recovery room included SpO2, respiratory rate, FVC, TV, FEV1, and PEF 24 hours after the initiation of the PCA. Opiate consumption in the 24-hour period after the surgery and PCA initiation was obtained from the PCA pump record. The PCA log file was reviewed for the number of requested and denied boluses. LA consumption and boluses were obtained from medical records and pump infusion records.

The research coordinators responsible for the pre and post-operative recording were blinded to the patient assignment.

### 2.5. Statistical Analysis

Results were analyzed using R version 3.0.3.12. Continuous data are shown as mean (CI 95%) or median (1st-3rd interquartile) as appropriate. Percentages were used for qualitative variables. For continuous variables, the Shapiro-Wilk test was used to assess data normality. Non-paired t-test was used for normally distributed data and Mann-Whitney test for non-normally distributed data. The alpha level was 0.05 for all tests used. FVC, TV, FEV1, and PEF values were analyzed as percentages of change from pre-surgery measurement (post-surgery/pre-surgery) with t-test or Mann-Whitney test as appropriate. The results from the pinprick and cold tests were compared with Fischer exact test between groups. Chi-square or Fischer exact test were used to compare the incidence of side effects. To detect an effect size of 0.92 SD units with a power of 81% and alpha level of 0.05, a total sample size of 40 patients (20 patients/group) was calculated. After enrolling the expected number of patients, we conducted an interim analysis to establish if we needed to file a request with the IRB to enroll additional patients to replace those excluded.

## 3. RESULTS

From July 1, 2013 to June 5, 2014, 42 patients scheduled for thoracic surgery consented to participate in the study and were randomized into either the US group (22) or the CL group (20). Thirteen patients were discontinued for the following reasons: intrapleural catheter repositioning by the surgeon (two patients), nerve block catheters stopped because of a malfunction (three patients), change in surgical procedure (three patients), ICU transfer accompanied by 24 hours of sedation without the possibility of collecting data (four patients), and nerve block infusion and PCA discontinuation before 24 hours (one patient). Additionally, one patient was excluded from the data analysis because of a shoulder dislocation during surgical positioning. Therefore, a total of 27 patients were included in the interim analysis, 13 in the US group and 15 in the CL group. Figure **1** shows the CONSORT flow diagram for patients enrolled in the

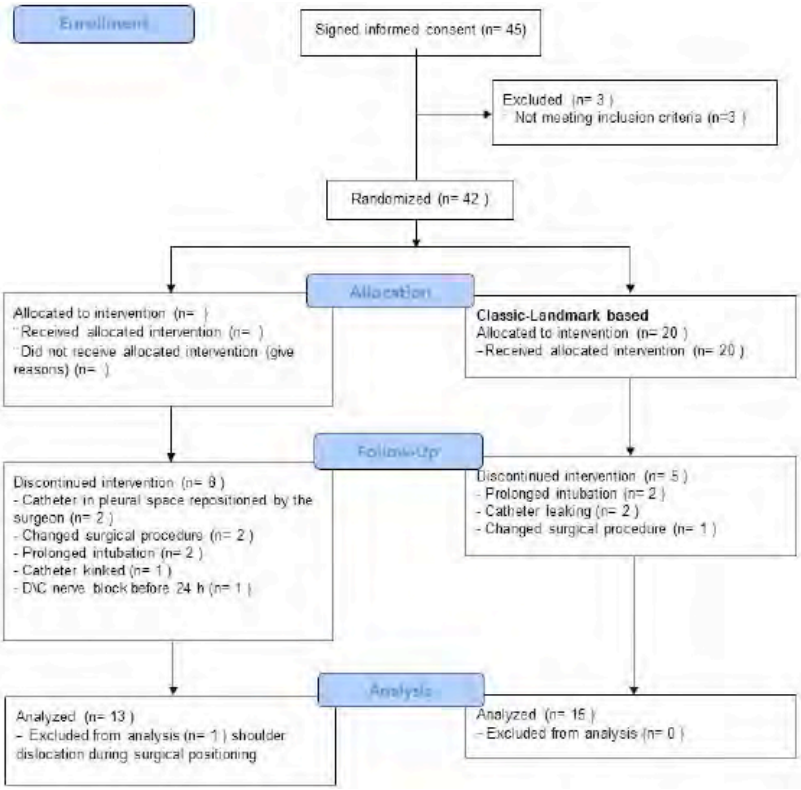


**Figure 1:** CONSORT flow diagram of patient distribution.

**Table 2: Patient Characteristics. Data Shown as Median (Interquartile Range)**

| | Ultrasound-Assisted | Classic Landmark |
|---|---|---|
| Patients (male) | 13(5) | 15 (6) |
| Age (years) | 64(57-70) | 68 (59.5-71.5) |
| Weight (kg) | 75 (57-86) | 78 (71.8-86) |
| Height (m) | 1.63 (1.60-1.73) | 1.63 (1.59-1.73) |
| BMI | 27.14 (21.5-30.86) | 28.40 (25.85-30.77) |

study. Table **2** summarizes the characteristics of the enrolled subjects before the randomization.

Opiate consumption during the 24 hours after PCA initiation did not differ significantly between groups; mean opiate consumption was 5.75 mg (95% CI: 4.23-7.26) for the CL group and 6.38 mg (95% CI: 4.51-8.25) for the US group (p = 0.643). Patients in the CL group received a median of 28 (IQR: 13.5-57.2) doses of hydromorphone during the 24 hours and patients in the US group received a median of 48 (IQR: 17-63) doses. No significant difference was noted in the volume of LA infused in the 24 hours through the nerve block catheter; The CL group received a median of 173 ml (IQR: 168-184) and the US group received a median of 186 ml (IQR: 175-197). The number of LA boluses given by the nurses was one (IQR 0-1.5) for the CL group and two (IQR: 1-4) for the US group. Median pain NRS scores at rest 24 hours after PCA initiation were 2 (IQR: 0.5-2.5) and 2 (IQR: 2-5) for the CL and US groups, respectively (p = 0.100). During deep inspiration, pain NRS 24 hour scores were 4 (IQR: 2.5-5.5) for the CL group and 5 (IQR: 4-6) for the US group (p = 0.468).

The spirometry measurement results are shown in Table **3** and Figure **2**. No statistically significant difference was noticed between the two groups in FVC, TV, FEV1, and PEF. The onset time for the US group was five minutes (IQR: 0-5) and five minutes (IQR: 0-10) for the CL group. Of the 28 patients analyzed, four (14.2%) did not show any changes during the ice and pin prick tests, 3 (17%) were in the CL group and 1 (3.5%) was in the US group. The difference in failure between groups was not statistically significant (p = 0.60). The median number of dermatomes affected by the block were three (IQR: 3-4) in the CL group and five (IQR: 3-7) in the US group (p = 0.344).

**Table 3: Outcomes. Data are shown as Mean (95% CI) or Median (Interquartile Range). FVC (Forced Vital Capacity), TV (Tidal Volume), FEV1 (Forced Expiratory Volume in 1sec), PEF (Peak Expiratory Flow) are Expressed as Fractions of Pre-Operative Value**

| | Classic Landmark | Ultrasound-Assisted | p Value |
|---|---|---|---|
| Hydromorphone 24h (mg) | 5.75 (3.90-7.59) | 6.38 (4.09-8.66) | .643 |
| Requested PCA doses | 28 (14-57) | 48 (17-63) | .605 |
| Number of local anesthestic (LA) boluses in the fist 24h | 1 (0-1.5) | 2 (1-4) | .059 |
| LA volume in the first 24h (ml) | 173 (168-184) | 186 (175-197) | .104 |
| Pain NRS score at rest after 24h | 2 (0.5-2.5) | 2 (2-5) | .100 |
| Pain NRS score during deep inspiration at 24h | 4 (2.5-5.5) | 5 (4-6) | .468 |
| Pain Likert scale score | 5 (4-5) | 4 (4-5) | .764 |
| SpO2 after surgery (%) | 95 (94-96) | 94 (93-95) | .308 |
| Respiratory rate after surgery | 17 (15.8-18.2) | 17.7 (15.9-19.5) | .493 |
| FVC (fraction of pre-surgery value) | 0.551 (0.403-0.699) | 0.504 (0.395-0.613) | .574 |
| TV (fraction of pre-surgery value) | 0.658 (0.544-0.773) | 0.716 (0.575-0.857) | .487 |
| FEV1 (fraction of pre-surgery value) | 0.561 (0.4-0.722) | 0.571 (0.466-0.675) | .913 |
| PEF (fraction of pre-surgery value) | 0.568 (0.4-0.735) | 0.542 (0.42-0.664) | .783 |

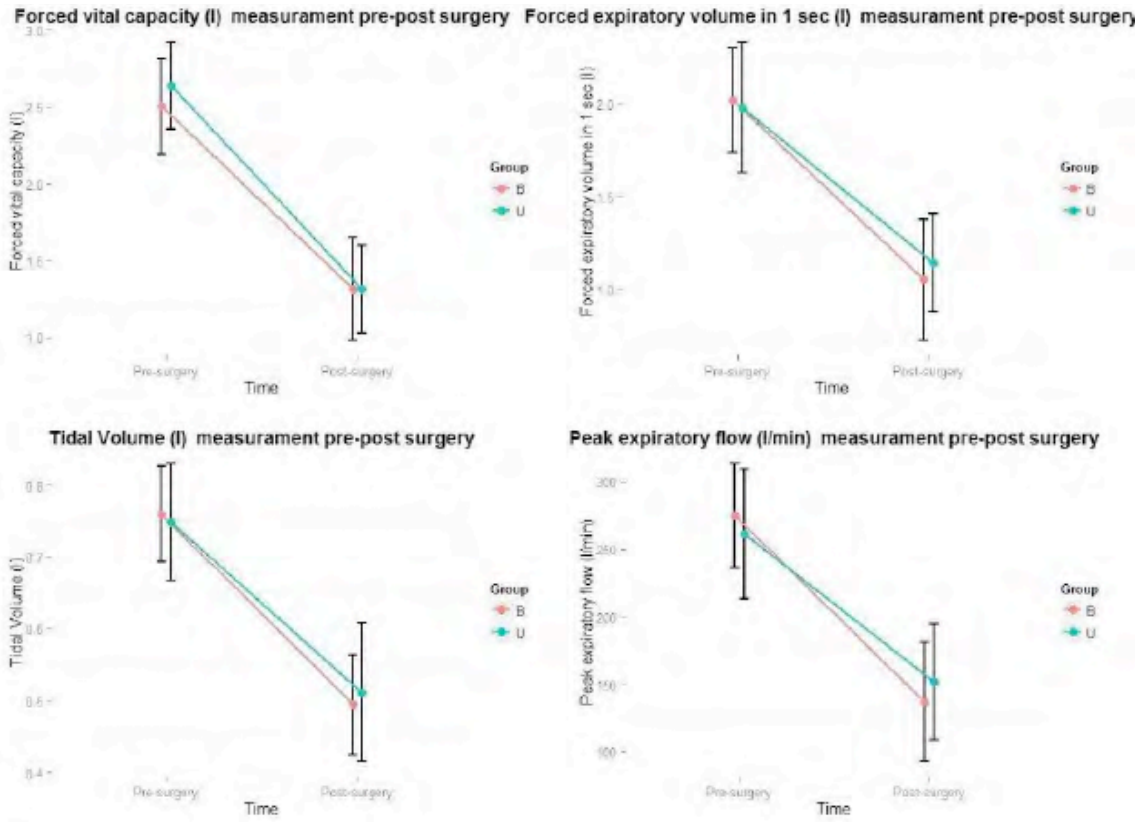


**Figure 2:** Spirometry results before and after surgery. Within-subject 95% C.I. RED: Classic landmark group. BLUE: Ultrasound-assisted group.

## 4. CONCLUSIONS

In our cohort, no differences in opiate consumption or pain NRS scores at rest and during deep inspiration and PFT were found between the US and CL groups. Given this set of conditions, a decision was made to end the trial and not enroll additional patients. Opiate consumption recorded in this trial was within the range observed in our historical data of thoracic surgery patients (personal communication). No difference in the amount of bupivacaine infused was found according to the technique.

There is no consensus regarding the relative efficacy of each PVB approach. Previous reports and prospective cohort studies have sought to evaluate the US technique specifically, focusing on different approaches for placing the transducer. [13-15] to date, this is the first randomized clinical trial comparing the US-assisted and the traditional CL approach described by Eason and Wyatt.

In the PACU, 4/28 patients did not exhibit any changes in the intensity of the sensory block, as measured using ice and pin prick tests. This represents a 14.2% overall PVB failure rate. Although three of these patients were in the CL group (10.7%) and one was in the US group (3.5%), this difference in failure rate was not statistically significant (p = 0.60). In addition, no evidence was found of a correlation between these tests and the analgesic properties of PVBs.

Although the failure rate of PVBs placed with the CL technique has been established to range from 6.1% to 10.7% [15, 16] the relative failure rate of an US-assisted PVB is unknown. In our study, the failure rate of the US-assisted approach was 3.5%. However, the sample size was small and additional data are required to validate this finding.

Some researchers have investigated the final location of the catheter tip in continuous PVB, suggesting that migration or displacement of the catheter happens in the majority of cases, influencing block efficacy. [18,19] While our protocol did not include a sensory function assessment after 24 hours from the placement of the catheter to check the effective functioning of the catheters, none of our patients needed rescue medication for uncontrolled pain and no sign of central spread was noted.

Spirometry test results did not differ between the two groups. The overall decrease of post-operative FVC, FEV1, and PEF observed in both groups was in accordance with what has previously been found for these measurements following thoracic surgery [4, 20].

Notably, there was a high rate of early termination in our study, primarily because in several cases VATS was performed after an open thoracotomy requiring prolonged postoperative intubation. Furthermore, one patient was excluded because of a shoulder dislocation during surgical positioning.

In this cohort of patients, we reported two cases of intrapleural positioning of the catheter, both of which occurred in the US-assisted group. Also, two catheters in the CL approach group were discontinued early by the nurse because of a significant leak at the insertion site.

No statistical difference in the incidence of adverse events was noted between groups, but the study was not powered to highlight such a difference. None of the adverse events led to increased duration of hospitalization or serious illness.

This is the first randomized controlled trial comparing two techniques for placing continuous paravertebral catheters. Although data from prospective studies without control groups suggest that the US technique might be advantageous when performing other peripheral nerve blocks, we did not find any evidence of such benefits when performing continuous PVBs.

Our study had several limitations. First, its small sample size; however, in the absence of a clear trend, it is apparent from our findings that enrolling additional patients would not have changed outcomes. Still, additional data are required to assess possible safety difference between the two approaches. Second, all patients included in the final analysis of our study underwent VATS, so caution should be used when generalizing our findings to patients undergoing other thoracic procedures (e.g. thoracotomy). In this regard, it is important to recognize that thoracic surgery is trending towards using a thoracoscopic approach. A thoracoscopic approach has been established to be less painful than an open approach. Therefore, whether differences between the two approaches would not exist in an open thoracotomy case is unknown. Third, no radiological films were taken to assess the spread of LA. Finally, the primary and secondary end points were assessed 24 hours after the initiation of PCA. Further studies are required to establish possible longer term differences between the techniques.

In summary, our data suggests that both the classic and ultrasound-assisted paravertebral approaches are safe and effective techniques for pain management after VATS, which represents the most frequently-used surgical approach. Therefore, the relative expertise of the anesthesiologist vis-à-vis with these approaches represents a key factor in choosing which approach to use.

## 5. DECLARATION OF INTERESTS

Anna Uskova reported no conflicts of interest.

Luca LaColla reported no conflicts of interest.

Filipo Albani reported no conflicts of interest.

Anne-Sophie M. Auroux reported no conflicts of interest.

Jacques E. Chelly reported no conflicts of interest.

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## AUTHOR CONTRIBUTIONS

**AU:** helped design the study, conduct the study and analyze the data. Has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

**LLC:** helped conduct the study, has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

**FA:** helped conduct the study, has seen the original study data, approved the final manuscript, and is the author responsible for archiving the study files.

**ASMA:** helped design and conduct the study, has seen the original study data, and approved the final manuscript.

**JEC:** helped design the study, conduct the study, analyze the data, and write the manuscript.

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None

## DISCLOSURE

Trial Registry Number: Registry URL: www.clinicaltrials.gov Identifier: NCT01949480

IRB Contact Information: University of Pittsburgh Institutional Review Board, 3500 Fifth Avenue, Hieber Building, Main Office, Suite 106, Pittsburgh, PA 15213, Phone: (412) 383-1480.

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