Study Protocol

Perioperative Paravertebral Block Reduces Postoperative Complications in Thoracic Surgery: An Observational Study

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Background

Minimally invasive thoracic surgery, including Video-Assisted Thoracoscopic Surgery (VATS) and Robotic-Assisted Thoracoscopic Surgery (RATS), has become the standard approach for early-stage lung cancer and is widely adopted in clinical practice. These techniques reduce rib injury and nerve traction, thereby alleviating postoperative pain, shortening hospital stay, and facilitating enhanced recovery after surgery (ERAS). Compared with conventional open thoracotomy, VATS and RATS significantly decrease postoperative complications, inflammatory responses, and drainage duration. However, despite their minimally invasive advantages, patients may still experience varying degrees and types of postoperative pulmonary complications (PPCs). Pulmonary complications, particularly infections, remain a leading cause of prolonged hospitalization and postoperative mortality.

Postoperative pulmonary complications are among the most common adverse events following thoracic surgery, typically occurring within 30 days after the procedure, and encompass a range of new-onset respiratory disorders that may negatively affect patient outcomes. Major PPCs include **pulmonary infection, respiratory failure, pleural effusion, atelectasis, bronchospasm, pneumothorax, aspiration-induced lung injury, pulmonary embolism, bronchopleural fistula, and acute respiratory distress syndrome (ARDS)**. Globally, over 300 million patients undergo surgeries requiring general anesthesia with endotracheal intubation each year, and the reported incidence of PPCs ranges from 8% to 40% due to variable definitions.

With advances in ultrasound technology, regional nerve block techniques have become increasingly applied in thoracic surgery. **Paravertebral block (PVB)** has emerged as a safe and effective analgesic method and is gradually becoming a key anesthetic option for thoracoscopic procedures. Ultrasound-guided PVB improves targeting accuracy, reduces complication rates, and enhances postoperative analgesia quality. Beyond pain control, thoracic PVB contributes to hemodynamic stability, attenuates stress responses, and reduces the incidence of postoperative complications. By avoiding contralateral sympathetic blockade, PVB minimizes hypotension and helps maintain stable intraoperative and postoperative hemodynamics, lowering the risk of adverse events caused by blood pressure fluctuations.

Surgical trauma typically induces a stress response, leading to hormonal changes and inflammatory reactions. PVB effectively reduces nociceptive stimulation, thereby attenuating stress hormone secretion, maintaining internal homeostasis, and promoting postoperative recovery. Adequate analgesia and stable hemodynamics also help decrease complications such as postoperative nausea, vomiting, and urinary retention. Furthermore, pain reduction encourages patients to perform deep breathing, coughing, and early mobilization, which supports lung expansion, facilitates sputum clearance, and lowers the risk of pulmonary infection and atelectasis, ultimately promoting rehabilitation.

Therefore, implementing intraoperative paravertebral block in patients undergoing thoracic surgery is of significant clinical importance for reducing postoperative pain and improving outcomes. Investigating the mechanisms by which PVB prevents postoperative pulmonary complications underscores its value, contributes to safer and more efficient thoracic surgery, mitigates adverse events, and enhances postoperative recovery quality.

Objective

To evaluate the clinical association between intraoperative paravertebral block (PVB) and the reduction of postoperative complications in patients undergoing thoracic surgery.

Study Design

This study is an **observational investigation combining both retrospective and prospective components**, targeting patients undergoing thoracic surgery, primarily pulmonary and mediastinal procedures.

Retrospective component: Data will be collected from patients across multiple campuses of Tongji Hospital who previously underwent thoracic surgery with intraoperative paravertebral block (PVB). These cases will be retrospectively analyzed to examine the association between PVB and postoperative complication reduction.

Prospective component: For patients enrolled prospectively, perioperative biochemical parameters—including **MMP3, neutrophils, leukocytes, procalcitonin (PCT), C-reactive protein**

(CRP), and other relevant regulatory factors—will be measured preoperatively and postoperatively. Postoperative outcomes will be assessed by recording **cough and pain scores**, as well as **time to first flatus and defecation** at 24 and 48 hours after surgery. Additionally, the incidence of postoperative complications will be followed up for **30 days postoperatively**.

Clinical correlation: The association between the measured biomarkers and patient outcomes will be systematically evaluated to determine their clinical relevance in predicting prognosis and postoperative recovery.

Participant Selection

Inclusion Criteria

- Male or female participants aged **18 years or older**;
- Scheduled to undergo **thoracic surgery via Video-Assisted Thoracoscopic Surgery (VATS) or Robotic-Assisted Thoracoscopic Surgery (RATS)**, including **wedge resection, segmentectomy, lobectomy, or mediastinal surgery**;
- **Provision of signed informed consent** prior to study participation.

Exclusion Criteria

- Patients who refuse to provide informed consent.
- Anesthesiologists who have not received training in ultrasound-guided paravertebral block (PVB-US).
- History of ipsilateral thoracic surgery.
- Conversion to open thoracotomy during the procedure.
- Patients who did not complete the scheduled surgery due to disease progression or medical reasons.

- Patients who are lost to follow-up or refuse postoperative follow-up.

Sample Size Estimation

As this study is an observational investigation, the final sample size will depend on the number of patients ultimately enrolled.

Retrospective component: Data will be collected from patients who underwent thoracoscopic surgery at the Department of Thoracic Surgery, Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, between January 2024 and December 2024, with a total of 2,000 cases included.

Prospective component: Based on previous similar studies, the anticipated sample size is approximately 50–100 patients. Sample size calculation will be performed using MedCalc software.

Statistical parameters for sample size calculation:Significance level (Type I error, α) = 0.01; Power (1 – Type II error, 1–β) = 0.90; Area under the ROC curve (AUC, AZ) = 0.85; Ratio of negative to positive groups = 0.176.

The calculation results are summarized as follows:

		Significance level(Type I error, α)			
		0.20	0.10	0.05	**0.01**
Power（**1-β**）	0.20	14 + 3	20+4	27+5	42+8
	0.10	18+4	25+5	32+6	**48+9**
	0.05	21+4	29+6	37+7	54+10
	0.01	29+6	38+7	46+9	66+12

Based on calculations performed using MedCalc software, the required total sample size for this study is 57 patients. To account for potential attrition during the study, such as loss to follow-up or incomplete data, an additional 10% of participants will be included. Consequently, for each type of thoracic surgery, 63 patients will be enrolled, resulting in a total of 63 × 4 = 252 patients for the study.

Study Procedures

Retrospective Analysis (January 1, 2024 – December 30, 2024)

Collect baseline and clinical data from patients who underwent thoracic surgery at Tongji Hospital and its affiliated campuses, including sex, age, occupation, past medical history, symptoms and onset time, complete blood count, liver and kidney function, blood gas analysis, coagulation profile, and postoperative inflammatory markers.

Analyze the association between intraoperative paravertebral block (PVB) and postoperative thoracic complications.

Prospective Analysis (Mar 2025 – May 2028)

Screen patients meeting the inclusion criteria and immediately collect baseline data, including sex, age, occupation, past medical history, symptoms and onset time, vital signs, MMP3 levels, complete blood count, liver and kidney function, blood gas analysis, coagulation profile, and postoperative inflammatory markers.

Record postoperative outcomes at 24 and 48 hours, including cough and pain scores, time to first flatus and defecation, length of hospital stay, and the incidence of 30-day postoperative complications, including pulmonary infection, respiratory failure, pleural effusion, atelectasis, bronchospasm, pneumothorax, aspiration-induced lung injury, pulmonary embolism, bronchopleural fistula, and acute respiratory distress syndrome (ARDS).

Evaluate the association between PVB and MMP3 levels with postoperative thoracic complications and validate these findings against the results of the retrospective analysis.

Potential Risks and Risk Mitigation

This study is an observational investigation combining retrospective and prospective components and is associated with minimal to no adverse reactions or direct risks to participants. The collection of clinical data and postoperative laboratory results is solely for statistical analysis and does not alter standard clinical care, ensuring no significant risk to patients.

The study strictly adheres to applicable laws and regulations, with all patient medical information treated as confidential. Necessary measures are implemented to ensure data security, and patient information will never be disclosed, sold, or used unlawfully, thereby protecting patient privacy and rights.

Data Collection and Statistical Analysis

Data will be collected and verified by three study personnel to ensure accuracy and reliability. The variables to be recorded are as previously described. Statistical analyses will be performed using R software version 4.4.

Within-group comparisons: Quantitative variables will be analyzed using paired t-tests or Wilcoxon one-sample tests.

Between-group comparisons:

Quantitative variables: analyzed using repeated measures ANOVA or Mann-Whitney U tests.

Qualitative variables: analyzed using Pearson's χ^2 test.

Ordinal variables: analyzed using Wilcoxon rank-sum tests.

Descriptive statistics:

Continuous variables: presented as mean ± standard deviation (SD) and confidence intervals (CI); when necessary, minimum, maximum, 25th percentile, median, and 75th percentile will be reported.

Paired continuous variables: differences reported as mean ± SD.

Non-parametric data: reported as median and mean ranks.

Categorical variables: presented as frequency distributions and percentages.

Ordinal variables: presented as frequency distributions, percentages, median, and mean ranks.

Binary/qualitative variables: reported as positivity rate, number of positive cases, and total sample size.

Diagnostic evaluation: When appropriate, the area under the receiver operating characteristic curve (AUC) will be calculated to assess the predictive value of ultrasound parameters.

Effect analysis: Associations and predictive effects will be evaluated using correlation analysis, multivariable linear regression, logistic regression, Cox proportional hazards models, and Kaplan-Meier survival analysis.

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