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STUDY PROTOCOL

Effects of Preoperative Stellate Ganglion Block on Postoperative Sore Throat and Hoarseness in Patients Undergoing Double-Lumen Endobronchial Intubation: Protocol for a Prospective Randomized Controlled Trial

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Background: Postoperative sore throat (POST) is a common complication after general anesthesia, especially following double-lumen endobronchial tube (DLT) intubation in thoracic surgery, adversely affecting recovery. Stellate ganglion block (SGB) modulates sympathetic tone and inflammation, potentially reducing airway complications, but its efficacy for POST and hoarseness after DLTs remains unclear.

Objective: To evaluate the impact of preoperative SGB on the incidence and severity of POST and hoarseness in patients undergoing DLT intubation, and to explore its effects on postoperative sleep, anxiety, depression, and hemodynamics.

Methods: In this single-center, prospective, randomized controlled trial, 124 patients scheduled for thoracic surgery with left DLT intubation are to be included. Patients will be randomly assigned in a 1:1 ratio to the SGB group or the control group. Patients in the SGB group will receive ultrasound-guided right SGB (5 mL of 0.5% ropivacaine) approximately 30 minutes before anesthesia induction. In the control group, ultrasound-guided scanning of the stellate ganglion will be conducted without performing SGB, and local lubrication with 1% tetracaine gel will be administered prior to intubation. The primary outcome is the incidence of POST at 6 hours after surgery.

Discussion: This trial will determine whether SGB can effectively reduce POST and hoarseness after DLT intubation, potentially offering a multimodal strategy to improve postoperative recovery in thoracic surgery patients.

Clinical Trial Registration: Chinese Clinical Trial Registry (ChiCTR2400092313).

Keywords: postoperative sore throat, double-lumen endobronchial tube, stellate ganglion block, postoperative sleep disturbance

Introduction

Postoperative sore throat (POST) is a frequently encountered complication following general anesthesia (GA), primarily manifesting as pharyngeal pain or discomfort.[1,2] Despite its typically self-limiting course, POST remains clinically significant due to its high prevalence and impact on patient recovery.[1] Previous studies report a wide variation in the

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incidence of POST after general anesthesia, ranging from 12.1% to 70%.[3,4] The risk is notably elevated in patients undergoing thoracic surgery who require double-lumen endobronchial tube (DLT) intubation.[5–7] In such procedures, one-lung ventilation (OLV) is an essential technique for maintaining surgical field clarity and preventing cross-contamination of the contralateral lung, with DLTs serving as the standard modality for achieving effective OLV across various thoracic operations.[8] However, despite their clinical necessity, DLTs exert substantial mechanical trauma on the pharyngeal mucosa, recurrent laryngeal nerve, and tracheobronchial smooth muscle, contributing to a high incidence of postoperative airway complications.[6] Previous studies report that 41.5% to 70% of patients experience POST within the first 6 hours after DLT intubation, with a notable subset enduring symptoms beyond 24 hours.[9–11] More than mere discomfort, POST and hoarseness can precipitate dysphagia, aggravate coughing, impede early mobilization and oral intake, and potentially prolong hospitalization—thereby increasing the healthcare burden and impairing the quality of recovery.[7,12] This high burden underscores POST as a critical yet inadequately addressed perioperative problem in thoracic anesthesia.[10]

Preventive strategies to mitigate POST after DLT intubation have included mechanical maneuvers (eg, two-handed jaw thrust, tube rotation), topical pharmacologic interventions (eg, licorice or esketamine gargle), and regional nerve blocks targeting upper airway innervation, such as ultrasound-guided internal branch of the superior laryngeal nerve block (US-guided iSLNB).[9,12–17] These approaches possess inherent limitations, largely due to mechanistic and anatomic constraints. For instance, while US-guided iSLNB may partially mitigate sensory irritation in the upper airway, its protective effect is limited in regions innervated by the recurrent laryngeal nerve, and a subset of patients continues to experience moderate to severe POST symptoms despite these measures.[9] Therefore, there is a compelling need for a more comprehensive intervention that modulates the broader pathophysiological response, including sympathetic tone and inflammation, to effectively reduce the burden of POST and hoarseness in this high-risk population.

In recent years, stellate ganglion block (SGB), a regional anesthetic technique, has gained prominence as an intervention for pain management, anxiety reduction, and perioperative stress modulation, owing to its ability to modulate sympathetic tone and suppress inflammatory responses.[18–24] Evidence has demonstrated that SGB can reduce the incidence of visceral pain in elderly patients undergoing thoracoscopic lung cancer surgery, while also improving postoperative sleep quality and emotional well-being.[19,23,25] Furthermore, SGB holds potential utility in airway management. For patients undergoing right-sided thoracic surgery with left-sided DLT intubation, a right-sided SGB was chosen to target the sympathetic innervation of the central airway and to enhance procedural safety; this approach also helps standardize the intervention. Preclinical studies suggest SGB can reduce neurogenic inflammation and airway hyperreactivity, likely via modulating the IKK/NF-κB/IL-4/IL-5/IL-13 pathway and decreasing inflammatory cell infiltration in respiratory mucosa.[26] Clinically, SGB has been associated with improved airway symptoms in conditions like dysphagia, and has shown promise in reducing post-intubation complications.[27,28] Prior research has further shown that preoperative SGB may alleviate POST following tracheal intubation in patients undergoing lumbar spine surgery.[29]

Nevertheless, to date, no randomized controlled trial (RCT) has specifically evaluated the efficacy of SGB for preventing POST and hoarseness after DLT intubation. This study aims to assess the effectiveness of SGB in reducing the incidence of POST and hoarseness following DLTs and to explore its potential as a therapeutic strategy to improve postoperative sleep disturbances, anxiety-depression status and hemodynamic stability. The incidence of POST at 6 hours postoperatively is designated as the primary outcome, as this time point captures the crucial period of symptom burden during early recovery and is commonly used to evaluate interventions aimed at mitigating intubation-related POST.

Methods

Study Design

This single-center, randomized controlled superiority trial will enroll 124 patients undergoing thoracic surgery under GA at The Second Qilu Hospital of Shandong University, Jinan, China, from December 2024 to December 2025. The protocol follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2025 statement (Supplementary Table 1).[30] The trial flow diagram is shown in Figure 1.

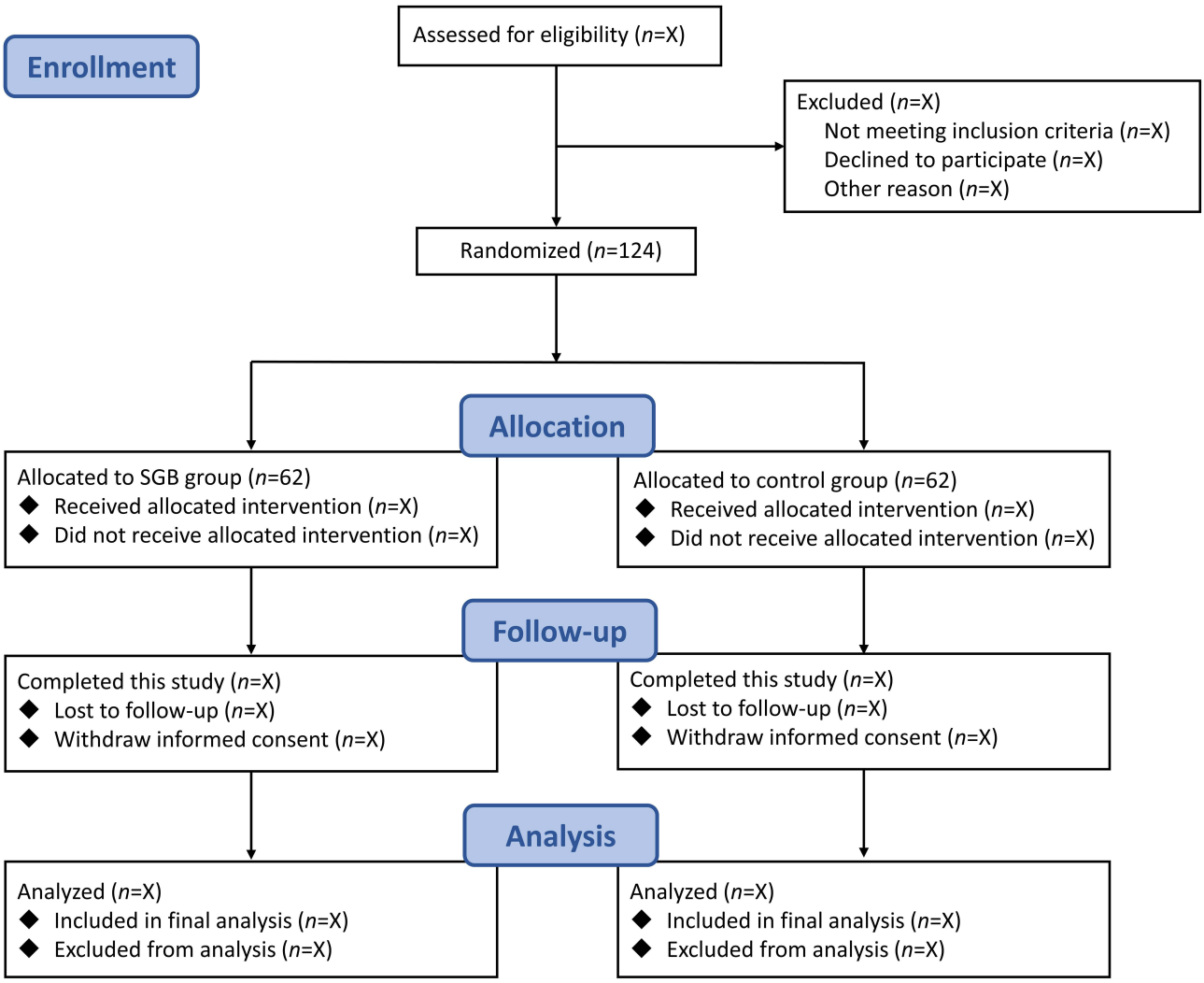

Figure 1 Flow diagram of this trial. SGB, Stellate ganglion block.

Ethics and Registration

The protocol was approved by the Institutional Ethics Committee of the Second Qilu Hospital of Shandong University (No: KYLL-2024-880) on October 31, 2024. The trial was registered prior to patient enrollment at the Chinese Clinical Trial Registry (Registration no: ChiCTR2400092313; Principal investigator: Yanwu Jin; Date of registration: November 14, 2024). This study will comply with the Declaration of Helsinki. Written informed consent will be obtained from all patients. The implementation and reporting of this trial will conform to the Consolidated Standards of Reporting Trials guidelines.

Eligibility Criteria

To be included in this study, patients should meet the following criteria: (1) age ≥18 years, no limitation to gender; (2) American Society of Anesthesiologists (ASA) physical classifications I~III; and (3) scheduled for thoracic surgery under GA with right-sided one-lung ventilation (OLV), requiring intubation with a left-sided double-lumen tube DLT.

Exclusion criteria include (1) patient refusal; (2) contraindications to GA or SGB, including coagulopathy, local or systemic infection. Coagulopathy was defined as prothrombin time or activated partial thromboplastin time exceeding normal reference values, international normalized ratio (INR) ≥ 1.4, or platelet count < 80×10^9/L;[9,13,23] (3) predicted difficult airway (Mallampati classifications III or IV, facial dysmorphism, or mouth opening < 3 finger breadths); (4)

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history of POST and cough; (5) upper respiratory tract infection within the past 2 weeks; (6) history of oral or pharyngeal surgery; (7) diagnosis of asthma or chronic obstructive pulmonary disease (COPD); (8) History of hypertension or coronary heart disease (CAD) with long-term use of medications affecting hemodynamics (eg, blood pressure or heart rate); (9) metabolic disorders associated with abnormal cortisol levels; (10) severe hepatic dysfunction (Child-Pugh class C) or severe renal impairment (creatinine > 442 μmol/L or requirement for renal replacement therapy); (11) poor glycemic control or known diabetes mellitus; (12) sick sinus syndrome (SSS), severe bradycardia (HR < 50 beats/min), or second-degree or higher atrioventricular block (AVB) and (13) severe cognitive or language impairment.

Study termination criteria are as follows: (1) identification of early leakage of the blinding protocol; (2) detection of significant protocol violations during trial execution; and (3) unfeasibility of the trial due to severe delays in patient recruitment or a high frequency of protocol deviations.

Randomization and Masking

An independent study coordinator will generate a random sequence (1:1 allocation, with block sizes of 2 and 4) using the Sealed Envelope online randomization tool (https://www.sealedenvelope.com/simple-randomiser/v1/lists). Patients will be randomized to either the SGB group or the control group. The allocation codes will be concealed in sequentially numbered, opaque, sealed envelopes, which will be opened by a research anesthesiologist immediately before performing the SGB. This anesthesiologist will not be involved in any subsequent study procedures.

All SGB procedures will be performed by the same experienced regional anesthesiologist. The anesthesiologists responsible for tracheal intubation will be aware of the group allocation but will have no other involvement in the trial. All other personnel, including anesthesiologists managing intraoperative care, outcome assessors, clinicians, follow-up staff, and the patients themselves, will remain blinded to group allocation throughout the study.

Anesthetic Care

Standard monitoring includes invasive blood pressure (IBP), heart rate (HR), electrocardiogram (ECG), oxygen saturation (SpO_2), and bispectral index (BIS). GA will induce with intravenous sufentanil (0.3 $\mu g \cdot kg^{-1}$) and propofol (1.5–3.0 $mg \cdot kg^{-1}$), and the neuromuscular block was achieved using rocuronium bromide (0.7 $mg \cdot kg^{-1}$). During induction, all patients will receive 100% oxygen via assisted ventilation. DLT intubation will then be performed following denitrogenation, confirmation of adequate oxygenation, and achievement of complete muscle relaxation.

The insertion of DLT and establishment of the airway will follow our previously established protocols.[9,13] The size of the left-sided DLT will be selected by the attending anesthesiologist according to a standard institutional guideline based on the patient's sex and height, and the chosen size will be recorded. Only patients with successful intubation on the first attempt will be retained in the trial; any case requiring more than one attempt will be excluded per protocol. Accurate DLT positioning will be confirmed via fiberoptic bronchoscope (FB) examination to ensure proper alignment. OLV will be performed with a tidal volume (TV) of 5–7 $mL \cdot kg^{-1}$, respiratory rate of 14–16 $times \cdot min^{-1}$, and positive end-expiratory pressure of 3 to 10 cmH_2O.[9,13] During surgery, anesthesia will be maintained at a BIS value between 40 and 60, as determined by the attending anesthesiologist, using sevoflurane inhalation (1–2% in 50% oxygen, at a flow rate of 1–2 $L \cdot min^{-1}$), along with propofol, remifentanil, and rocuronium bromide as needed. Vasoactive agents will be administered as required to maintain hemodynamic stability (within ±20% of pre-induction baseline values).

At the end of surgery, residual neuromuscular blockade will be reversed with sugammadex. The DLT will be removed once spontaneous respiration is adequate, as evidenced by a TV > 6 $mL \cdot kg^{-1}$, SpO_2 > 95% on room air, a BIS value > 90, and recovery of muscle strength to at least grade IV.

All patients will receive a T5–T6 thoracic paravertebral block (0.5% ropivacaine, 10–15 mL) before induction. Postoperative pain will be treated with patient-controlled intravenous analgesia (PCIA), containing sufentanil (100 μg) and ondansetron (8 mg) diluted with 0.9% saline to 100 mL. For rescue analgesia, NSAIDs, oral analgesics or intravenous pethidine will be administered as needed. The target is to maintain the Visual Analog Scale (VAS) for pain intensity (an 11-point scale where 0 = no pain and 10 = the worst imaginable pain) at rest of <4.

Study Interventions

The SGB technique will be performed as previously described.[23] For the SGB group, a right-sided SGB will be performed approximately 30 minutes before surgery. The patient will be positioned supine with the head rotated slightly to the left (contralateral side), mouth slightly open, and the anterior neck muscles relaxed. Under standard monitoring (electrocardiogram, blood pressure, pulse oximetry), a high-frequency linear ultrasound transducer (6–13 MHz) will be placed in a transverse orientation over the cricoid cartilage. The transducer will then be moved laterally from the medial border of the sternocleidomastoid muscle to identify the transverse process of the C6 vertebra.[23] Subsequently, the probe will be shifted caudally toward the C7 level until the anterior tubercle of C6 disappears. Key anatomical structures, including the sternocleidomastoid muscle (SCM), carotid artery (CA), internal jugular vein (IJV), C6 nerve root, and the longus colli muscle (LCo), will be clearly identified. Color Doppler imaging will be employed to identify vascular structures along the intended needle trajectory. Under in-plane ultrasound guidance, the needle will be advanced into the space between the C6 nerve root and IJV, with careful avoidance of critical structures such as the internal CA and brachial plexus.[23] The needle tip will be positioned at the surface of the LCo beneath its anterior fascia. After confirming the absence of blood or cerebrospinal fluid via negative aspiration, 5 mL of 0.5% ropivacaine will be injected. Successful SGB will be indicated by the presence of Horner's syndrome, which is characterized by ptosis, miosis, anhidrosis, and facial flushing.[19]

In the control group, ultrasound-guided scanning of the stellate ganglion will be conducted without performing SGB, and local lubrication with 1% tetracaine gel will be administered prior to intubation. This approach represents a common clinical practice for POST prevention, ensuring the control arm receives an active, standard-of-care intervention.

Study Outcomes

The primary outcome of our study will be the incidence of POST at 6 h after surgery. This time point was selected as the primary endpoint because it represents a crucial period of symptom burden during early recovery and aligns with key assessment times used in comparable RCTs on POST after DLT intubation.[9,17] The severity of POST and hoarseness will be assessed using the 4-grade scale (Table 1).[9,10]

Secondary outcomes: (1) the incidence of POST at 2 and 24 h after surgery; (2) the severity of POST at 2, 6, and 24 h after surgery; (3) the incidence and severity of hoarseness at 2, 6 and 24 h after surgery; (4) sleep disturbance before surgery and at POD1. Sleep disturbance will be assessed on the morning (8–10 a.m.) at 24 h and is defined as an Numeric Rating Scale-sleep (NRS-sleep) scale of 6 or higher or an Athens Insomnia Scale (AIS) score of 6 points or higher, indicating that sleep was repeatedly interrupted throughout the night or even worse;[31–34] (5) Hospital Anxiety and Depression Scale (HADS) before surgery and at 24 h;[32,35] and (6) intraoperative hemodynamics.

Exploratory outcomes will include (1) duration of PACU time; and (2) length of postoperative hospital stay. Safely outcomes will include perioperative-related adverse events from the beginning of anesthesia until 24 h after surgery. Specific procedure-related complications of SGB to be recorded include local anesthetic systemic toxicity, hematoma, infection, pneumothorax, recurrent laryngeal or phrenic nerve block, and brachial plexus block.

Protocol Adherence and Concomitant Care

Protocol adherence will be defined as the successful performance of SGB. Success will be confirmed by the development of Horner's syndrome and documented accordingly. All participants will receive the standardized perioperative care detailed in

Table 1 Grading System for Severity of POST and Hoarseness

Grades	Severity of POST	Severity of Hoarseness
None	No sore throat	No hoarseness
Mild	Pain with deglutition	Noticed by patient
Moderate	Pain constantly present and increasing with deglutition	Obvious to observer
Severe	Pain interfering with eating and requiring analgesic medication	Aphonia

Abbreviation: POST, Postoperative sore throat.

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the anesthetic care section, which includes a standardized anesthetic regimen, thoracic paravertebral block, and patient-controlled intravenous analgesia (PCIA). No other restrictions on routine clinical care are imposed by the trial protocol.

Data Collection and Management

Table 2 outlines the planned schedule for patient enrollment, study interventions, and outcome assessments, structured in accordance with the SPIRIT guidelines. Upon admission, all patients will undergo relevant laboratory and imaging examinations. One day prior to the surgical procedure, preoperative education and consultations will be conducted for each participant. This process will involve a comprehensive review of the patient's condition, including the present illness, past medical history, laboratory findings, and mental status. Intraoperative and surgical data will be extracted from the electronic medical records and the anesthesia information management system. Postoperative follow-up

Table 2 Schedule of Patient Enrollment, Study Interventions, and Outcome Assessment According to SPIRIT Statement

	Study Period							
	Enrollment	**Allocation**	**Post-Allocation**					**Close-Out**
Timepoint	Preoperative	Before surgery	During surgery	PACU	2h	6h	24h	Hospital discharge
Enrollment								
Inclusion criteria	×							
Exclusion criteria	×							
Written informed consent	×							
Baseline data	×							
Randomization		×						
Allocation		×						
Study interventions								
SGB		×						
Control		×						
Outcomes								
Intraoperative hemodynamics			×					
Incidence of POST					×	×	×	
Severity of POST					×	×	×	
Incidence of hoarseness					×	×	×	
Severity of hoarseness					×	×	×	
Sleep disturbance	×						×	
Anxiety (HADS-A)	×						×	
Depression (HADS-D)	×						×	
Duration of PACU time				×				
Length of postoperative hospital stay								×
Perioperative related adverse events			×	×	×	×	×	

Note: × indicates the time points at which the event occurred or the assessment was performed.
Abbreviations: SGB, Stellate ganglion block; POST, Postoperative sore throat; HADS, Hospital Anxiety and Depression Scale; PACU, Post anesthesia care unit.

assessments will be conducted by two registered nurses and an anesthesiologist, all of whom will be blinded to group allocation. All data will be entered into designated case report forms (CRFs) and uploaded to a secure electronic database. Two statisticians, blinded to treatment allocation, will perform the analyses. The principal investigator will oversee the process to ensure data integrity. An independent data monitoring committee—composed of an attending thoracic surgeon, an attending anesthesiologist, a pharmacist, and a statistician—will monitor study conduct.

Sample Size Calculation

According to two previously published studies, the incidence of POST at 6 h after surgery for DLTs ranges from 41.5% to 59%, with a mean incidence of 50.25%.[9,17] Assuming that SGB reduces the incidence of POST by 30% (to 20.25%), with a significance level $\alpha = 0.05$ and statistical power $1 - \beta = 0.9$, a sample size of 49 patients per group is required. To account for a 20% dropout rate, 62 patients will be enrolled in each group, resulting in a total sample size of 124 participants. Sample size calculation was conducted using PASS (*version* 15.0. NCSS, LLC., Kaysville, UT, United States) with a two-sided χ^2-test.

Statistical Analysis

The balance of baseline data between groups will be assessed using the absolute standardized difference (ASD). A baseline variable with an ASD of 0.352 or greater (ie, $1.96 \times \sqrt{[n_1 + n_2]/[n_1 \times n_2]}$ will be considered imbalanced, where n_1 and n_2 represent the number of patients in each randomized group.[36]

The normality of continuous variables will be evaluated using the Kolmogorov–Smirnov test. Normally distributed continuous variables will be expressed as mean ± standard deviation and compared using independent-sample *t* tests; non-normally distributed variables as median (interquartile range) and compared using Mann–Whitney *U*-tests. Treatment effects will be reported as risk differences or mean/median differences with the 95% confidence intervals (CIs) using the Hodges–Lehmann estimator. Categorical variables were expressed as counts (percentages) and compared using the Chi-square test or Fisher's exact test, as appropriate. Between-group differences were reported as relative risks (RR) and 95% CI. Time-to-event result (length of postoperative hospital stay) was analyzed with the Kaplan–Meier survival analysis and Log Rank test; a univariable Cox proportional hazards model was used to calculate hazard ratio and 95% CI.

Our primary outcome, the incidence of POST at 6 h after surgery, will be evaluated by a generalized estimating equation (GEE).[37–39] We will model the changes in the incidence of POST and hoarseness at 2, 6, and 24 h after surgery between the groups over time using the GEE method. The independent variables in these models were treatment group status (SGB versus standard; fixed effect in models) and time.

Post-hoc subgroup analyses will be examined treatment effects by age, ASA physical status, sex, smoking history, Cormack and Lehane grade, DLTs size and duration of surgery. Treatment-by-covariate interactions will be assessed separately for each subgroup factor using logistic regression. For the treatment-by covariate interaction in predefined subgroup analyses, $P < 0.10$ will be considered statistically significant.[40] For the secondary outcomes and exploratory outcomes, multiple comparisons were not corrected; thus, these results should be interpreted as exploratory.

This analysis will be performed by two statistical experts (ZPC and YLJ), who will be blinded to the group assignments. All reported *P* values will be two-sided, with $P < 0.05$ considered statistically significant. Statistical analyses will be conducted using SPSS for Windows (*version* 17.0; SPSS Inc., IBM, Chicago, IL, USA) and R Studio (*version* 4.1.0; RStudio, Boston, MA, USA).

Patient and Public Involvement

Patients or the public are not involved in the design, or conduct, or reporting, or dissemination plans of our study.

Discussion

This single-center, randomized controlled trial will enroll 124 eligible patients to assess the efficacy of preoperative SGB on POST and hoarseness. Secondary outcomes will include postoperative pain, postoperative sleep disturbance, anxiety and depression, and intraoperative hemodynamics. The primary hypothesis is that SGB reduces both the incidence and

severity of POST. The study will be conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

POST remains a common and distressing complication following tracheal intubation, especially in patients undergoing OLV with DLTs. Severe sore throat and hoarseness substantially impair postoperative recovery, as they often delay the resumption of oral intake and hydration.[10] Furthermore, pain-impaired cough compromises airway clearance and increases pulmonary risks.[3,41] Therefore, in patients undergoing thoracic surgery, POST constitutes a critical clinical problem that adversely affects recovery and justifies targeted intervention.

POST is primarily attributed to injury of the supraglottic structures, potentially induced by laryngoscope insertion, and damage to the subglottic structures, likely resulting from endotracheal intubation or tracheal cuff overinflation.[10] Although the precise etiology of POST remains incompletely understood, its pathophysiological mechanisms are thought to involve mucosal irritation, mechanical trauma, and subsequent inflammatory responses mediated by endotracheal tube placement and cuff pressure.[10] Despite the availability of various preventive strategies, a substantial proportion of patients still experience moderate to severe POST.[9,12]

SGB, a well-established regional anesthetic technique, has demonstrated potential in modulating sympathetic tone and attenuating inflammatory responses, mechanisms that may underlie its analgesic and anti-inflammatory effects in the upper airway.[19,42–44] Emerging evidence suggests that SGB may reduce the incidence and severity of POST in patients undergoing lumbar spine surgery;[29] however, its efficacy in preventing POST and related complications in the setting of DLT intubation has not been systematically evaluated.

Beyond its analgesic properties, SGB has demonstrated beneficial effects across diverse surgical populations, including reduced postoperative pain, accelerated recovery, and attenuated perioperative stress responses.[45,46] Preclinical and clinical evidence has established that SGB exerts systemic anti-inflammatory and central neuromodulatory effects, which may contribute to the mitigation of postoperative hyperalgesia and the overall surgical stress response.[21,26,43,47,48] These mechanisms suggest a potential for broader improvements in postoperative well-being. Notably, SGB has also been linked to better sleep quality and improved emotional health in surgical patients.[25,49] This is particularly relevant because POST and hoarseness frequently disrupt sleep—through pain-related awakenings and swallowing discomfort that impedes sleep onset. Such sleep disturbances can, in turn, exacerbate anxiety and depression, creating a self-perpetuating cycle of pain, poor sleep, and emotional distress. Consequently, this study is designed to comprehensively evaluate the multimodal therapeutic potential of SGB by assessing its effects not only on POST and hoarseness but also on postoperative sleep quality and psychological state.

For right-sided OLV, a left-sided DLT is standard, as its bronchial cuff is designed to seal the left main bronchus. However, the presence of a left DLT occupies anatomical space in the left cervical and upper thoracic region. Performing a left-sided SGB in this setting carries two principal risks: (1) ultrasound-guided needle access to the left stellate ganglion may be impeded by the adjacent tracheal portion of the DLT, and (2) inadvertent displacement of the DLT during needle manipulation could compromise lung isolation or cause additional airway trauma—both of which could confound the assessment of postoperative sore throat and hoarseness. In contrast, a right-sided SGB avoids direct anatomical interference with the left DLT. The right stellate ganglion lies medial to the trachea and away from the left-sided tube, allowing clearer sonographic visualization and safer needle placement, thereby minimizing procedure-related airway complications.

Several study limitations should be acknowledged. First, the control group receives topical 1% tetracaine gel, which is an active intervention. Therefore, the trial evaluates the incremental value of SGB over a common clinical standard rather than against a placebo. Second, although the anesthesiologist performing the SGB assesses Horner's syndrome to confirm procedural success, all postoperative outcome assessors remain fully blinded to group allocation, which minimizes detection bias. Third, the sample size was calculated based on effect estimates from prior studies; consequently, a more modest treatment effect than hypothesized might not be detected. Fourth, due to the implementation of the Enhanced Recovery After Surgery (ERAS) protocol at our institution, the majority of patients recovered well and were discharged shortly after surgery; therefore, longer-term assessment of POST was not conducted. Finally, while the strict eligibility criteria strengthen internal validity, they may limit the generalizability of the findings to patients with significant comorbidities.

Conclusion

In conclusion, this trial is designed to generate high-quality evidence to test the hypothesis that preoperative SGB reduces POST and hoarseness following DLTs. Should the intervention demonstrate a significant and clinically meaningful benefit, the findings would support the incorporation of SGB into standardized perioperative care pathways for thoracic surgery patients, potentially providing a promising, non-opioid strategy to improve postoperative comfort and accelerate recovery.

Abbreviations

AIS, Athens Insomnia Scale; ASA, American Society of Anesthesiologists; AVB, Atrioventricular block; BIS, Bispectral index; CAD, Coronary artery disease; CONSORT, Consolidated Standards of Reporting Trials; COPD, Chronic obstructive pulmonary disease; CRF, Case report form; DLT, Double-lumen endobronchial tube; ERAS, Enhanced Recovery After Surgery; FB, Fiberoptic bronchoscope; GA, General anesthesia; HADS, Hospital Anxiety and Depression Scale; INR, International normalized ratio; NRS, Numeric Rating Scale; OLV, One-lung ventilation; PACU, Post-anesthesia care unit; PCIA, Patient-controlled intravenous analgesia; POD, Postoperative day; POST, Postoperative sore throat; SGB, Stellate ganglion block; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; SSS, Sick sinus syndrome; US-guided iSLNB, Ultrasound-guided internal branch of the superior laryngeal nerve block; VAS, Visual Analog Scale.

Data Sharing Statement

The datasets and trial protocol used or analyzed during the current study will be available from the two corresponding authors on reasonable request.

Ethics Approval and Consent to Participate

The study will be conducted with Institutional Review Board approval from The Second Qilu Hospital of Shandong University in China (No: KYLL-2024-880), and the guidelines outlined in the Declaration of Helsinki will be followed. Written informed consent will be obtained from all study participants.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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