# Protocol

Ultrasound-guided thyroid cartilage plane block for patients with awake tracheal intubation: a randomized controlled trial

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## One: Background

Traditional surface anesthesia, administered via fiberoptic bronchoscope spray, is limited by the penetration of airway secretions and local anesthetics. Excessive airway secretions can significantly compromise the effectiveness of surface anesthesia. Moreover, the vicinity of the glottis is rich in neural fibers, making the airway highly sensitive. During fiberoptic bronchoscope spray, patients often experience coughing and even laryngospasm. In contrast, thyroid cartilage plane block circumvents these limitations and offers a more precise method of airway blockage.

In recent years, both international and domestic research has focused extensively on blocking the superior laryngeal nerve. Blocking the superior laryngeal nerve can significantly reduce stimulation to the tongue base and pharynx during laryngoscopy, diminish the irritation caused by the endotracheal tube to the trachea, mitigate stress responses, and minimize adverse cardiovascular effects. This technique provides a reliable airway management method for clinical anesthesia and ICU tracheal intubation [1]. Research by Mathur et al. demonstrated that ultrasound-guided superior laryngeal nerve block provides effective airway anesthesia during fiberoptic bronchoscopy and reduces the incidence of adverse reactions such as coughing [2]. Additionally, superior laryngeal nerve block is widely applied in managing challenging airways, such as in patients with severe acute pharyngitis, cervical spine injuries,

awake tracheal intubation, percutaneous tracheostomy, laryngoscopy examinations, treatment of chronic pharyngitis, and neurogenic cough.

However, the method of performing nerve blocks through surface anatomy localization has its drawbacks, including inaccurate positioning, low success rates, poor safety, and unsatisfactory outcomes. Some researchers argue that using the thyrohyoid membrane as a target for ultrasound-guided superior laryngeal nerve block can be challenging. Traditional ultrasound-guided superior laryngeal nerve block methods often rely on the thyrohyoid membrane and the superior thyroid artery as ultrasound landmarks, injecting local anesthetic solution beneath the thyrohyoid membrane and adjacent to the superior thyroid artery. However, locating the thyrohyoid membrane and the small superior thyroid artery can be extremely challenging, especially for beginners. Even experienced clinicians, despite their familiarity with anatomy and skill, can struggle to identify these structures under ultrasound. Therefore, there is a pressing need for simpler, more precise, and easier-to-locate methods of superior laryngeal nerve block in clinical practice.

In our preliminary research, while performing superior laryngeal nerve block, we observed that the injected solution could spread along the surface of the thyroid cartilage plate, extending towards the thyrohyoid membrane. Given that the solution could reach the superior laryngeal nerve from the surface of the thyroid cartilage, we propose that injecting

local anesthetic solution on the surface of the thyroid cartilage can effectively block the superior laryngeal nerve, a technique we refer to as "Thyroid Cartilage Plane Block." This method offers the advantage of easy identification of the thyroid cartilage under ultrasound, making it more convenient to perform than traditional methods. Therefore, this study aims to investigate the clinical effectiveness and safety of superior laryngeal nerve block through surface injection of local anesthetic solution on the thyroid cartilage in patients undergoing general anesthesia with endotracheal intubation.

**Two: Research Objectives**

1. Primary Objective: To evaluate the effectiveness of ultrasound-guided Thyroid Cartilage Plane Block for superior laryngeal nerve blockade.

2. Secondary Objectives: To assess the safety and ease of performance of ultrasound-guided Thyroid Cartilage Plane Block for superior laryngeal nerve blockade.

**Three: Research Design, Methods, and Study Steps**

1. Research Design

Select patients undergoing elective awake tracheal intubation surgery and randomly assign them to two groups using a random number table. The control group will receive surface anesthesia of the throat using local anesthetic sprayed via fiberoptic bronchoscope, while the experimental group will undergo ultrasound-guided Thyroid Cartilage Plane Block.

The sample size for the study is determined based on the results of a pilot study. The primary outcome measure is the success rate of superior laryngeal nerve blockade. With a statistical power of 1-β=0.9 and a significance level of α=0.05, a sample size of n=25 is calculated. Assuming a dropout rate of 10%, the final sample size for each group is determined to be 30 cases.

2. Research Methods

The study will clinically evaluate the effectiveness, safety, and ease of performing Thyroid Cartilage Plane Block.

3. Study Steps

Select 60 patients undergoing elective awake tracheal intubation surgery.

Instruct patients to fast (no food or drink) for 8 hours before the procedure.

Upon admission to the operating room, monitor patients' ECG (electrocardiogram), BP (blood pressure), and $SpO_2$ (pulse oxygen saturation). Establish intravenous access in the upper extremities and administer normal saline solution. Administer a loading dose of dexmedetomidine at 0.5 μg/kg over 5 minutes, followed by an infusion at a rate of 0.3-0.6 μg/(kg·h) and intravenous injection of fentanyl at 0.1 μg/kg. Perform radial artery puncture and catheter placement for invasive arterial pressure monitoring. Use a computer-generated random number table to allocate patients into two groups in a 1:1 ratio. To ensure

objectivity, a nurse not involved in the study prepares sealed opaque envelopes containing the group assignments. All patients are divided into the Thyroid Cartilage Plane Block Group (T Group) and the Control Group (C Group). Patients in the C Group receive airway surface anesthesia using the fiberoptic bronchoscope-guided local anesthetic spray method throughout the procedure. In the experimental T Group, ultrasound-guided bilateral Thyroid Cartilage Plane Block is performed using the thyroid cartilage plate as an anatomical landmark. Local anesthetic is injected on the surface of the thyroid cartilage plate. The blocking procedure is as follows: Use a Sonosite high-frequency linear array transducer (5-13 MHz, Sonosite, USA). Place the transducer parallel to the spine on one side of the neck, ensuring clear visualization of the thyroid cartilage plate under ultrasound. Employ ultrasound-guided in-plane or out-of-plane techniques to display the needle insertion path and tip. Once the needle tip contacts the upper half of the thyroid cartilage plate, inject 3 ml of 2% lidocaine on the surface of the thyroid cartilage plate (the dosage is consistent with the commonly used local anesthetic volume for classic superior laryngeal nerve block methods in clinical practice). Subsequently, perform fiberoptic bronchoscope-guided oropharyngeal, subglottic, and tracheal surface anesthesia. After completing surface anesthesia, select an appropriate-sized tracheal tube and perform fiberoptic bronchoscope-guided tracheal intubation, securing

it properly.

4. The research flowchart is as follows:

**Four: Patient Selection**

Inclusion Criteria: We will select 60 patients who meet the following criteria for inclusion in the study:

- Patients scheduled for awake tracheal intubation surgery under general anesthesia.
- Patients with difficult airways (e.g., limited cervical spine mobility, full stomach, partial airway obstruction, craniofacial deformities or trauma, micrognathia, mouth opening <3cm, Mallampati III or IV classification) posing challenges for mask ventilation or intubation.
- Age between 18 and 65 years.
- Gender is not restricted.
- ASA classification of I or II.

Exclusion Criteria: Patients meeting any of the following criteria will be excluded from the study:

- Cardiovascular dysfunction or arterial aneurysms.
- Mental or neurological disorders or concomitant arterial aneurysms.
- Infection at the puncture site.
- Allergy to local anesthetics.
- Continuous use of antiplatelet or anticoagulant medications preoperatively.

- Hoarseness or coughing while drinking water.
- Bronchial asthma.
- Participation in other clinical trials within the previous 3 months before enrollment or current participation in other clinical trials.

3. Study Termination Criteria

The study may be terminated under the following circumstances:

1） Any medical condition or event occurs during the study that poses a potential risk to the continued participation of the research subjects.

2） Subjects receive anesthetic regimens other than the specified airway surface anesthesia rescue protocol, or if they are unable to complete the trial according to the study protocol for any reason.

3 ） The investigator determines that other circumstances warrant discontinuation from the trial.

4 ） Poor effectiveness of airway surface anesthesia, resulting in the patient's inability to tolerate awake tracheal intubation, or patient refusal to proceed.

**Five: Alternative Diagnostic and Therapeutic Methods**

In cases where the airway surface anesthesia is ineffective, and patients are unable to tolerate intubation, we will proceed with additional airway surface anesthesia using 2% lidocaine via a fiberoptic bronchoscope through an epidural catheter to enhance airway surface anesthesia.

**Six: Assessment Parameters and Timing**

Primary Outcome:

Record the comfort score immediately after intubation (5 points: resistance movement of the head or limbs; 4 points: verbal protest; 3 points: severe painful expression; 2 points: slight painful expression; 1 point: no response).

Secondary Outcomes:

1. Record the duration of the blocking procedure (from the start of ultrasound probe positioning to completion of drug administration).

2. Record the following parameters at specific time points (T0: upon entry to the operating room, T1: before insertion of the tracheal tube, T2: immediately after tracheal tube insertion, T3: 5 minutes after successful intubation):

- Mean Arterial Pressure (MAP)
- Heart Rate (HR)
- Ramsay Sedation Score (6 points: unarousable; 5 points: arousable but slow response to stimulation; 4 points: asleep but brisk response to stimulation; 3 points: asleep with a moderate response to command; 2 points: calm and cooperative with orientation; 1 point: anxious, restless, or agitated. Sedation satisfaction is defined as 2-4 points, while oversedation is defined as 5-6 points).

3. Record the number of cases with reduced voice tone before intubation.

4. Document patient coughing upon contact of the fiberoptic bronchoscope with the vocal cords before intubation (1 point: no response, 2 points: mild cough, 3 points: severe cough).

5. Assess the tolerance of the tracheal tube after successful intubation (3 points: strong resistance requiring immediate general anesthesia; 2 points: restlessness and mild resistance; 1 point: cooperative).

6. Record adverse reactions such as coughing and nausea/vomiting during intubation.

7. Document post-extubation throat pain, voice tone reduction, and voice tone reduction at 24 hours post-operation.

8. Assessment of superior laryngeal nerve blockade effectiveness based on clinical diagnostic criteria:

- Inability to produce high-pitched sounds, monotone voice.
- Morphological changes in the vocal cords observed during laryngoscopy (e.g., irregular vocal cord surface, wrinkles, malposition, reduced mobility).
- Absence of neural reflex upon touching the mucosa above the vocal cords.
- Meeting two of the above diagnostic criteria indicates successful superior laryngeal nerve blockade.

9. Record adverse reactions such as local anesthetic toxicity, local hematoma at the puncture site, and infections.

10. Record patient satisfaction.

**Seven: Efficacy Assessment Criteria**

- Record the duration of the blocking procedure (from the start of ultrasound probe positioning to completion of drug administration).
- Ramsay Sedation Score (6 points: unarousable; 5 points: arousable but slow response to stimulation; 4 points: asleep but brisk response to stimulation; 3 points: asleep with a moderate response to command; 2 points: calm and cooperative with orientation; 1 point: anxious, restless, or agitated. Sedation satisfaction is defined as 2-4 points, while oversedation is defined as 5-6 points).
- Patient coughing upon contact of the fiberoptic bronchoscope with the vocal cords before intubation (1 point: no response, 2 points: mild cough, 3 points: severe cough).
- Comfort score immediately after intubation (5 points: resistance movement of the head or limbs; 4 points: verbal protest; 3 points: severe painful expression; 2 points: slight painful expression; 1 point: no response).
- Tracheal tube tolerance after successful intubation (3 points: strong resistance requiring immediate general anesthesia; 2 points: restlessness and mild resistance; 1 point: cooperative).
- Assessment of superior laryngeal nerve blockade effectiveness based on clinical diagnostic criteria: nability to produce high-pitched sounds,

monotone voice.

- Morphological changes in the vocal cords observed during laryngoscopy (e.g., irregular vocal cord surface, wrinkles, malposition, reduced mobility).
- Absence of neural reflex upon touching the mucosa above the vocal cords.
- Meeting two of the above diagnostic criteria indicates excellent superior laryngeal nerve blockade effectiveness.

**Eight: Observation, Recording, and Management of Adverse Events**

In the event of oxygen saturation dropping below 90% during the experiment, the procedure will be halted. Patients will be instructed to take deep breaths or receive oxygen supplementation via a mask with increased pressure.

**Nine: Quality Control and Quality Assurance of the Study**

No specific quality control or quality assurance measures are outlined for this study.

**Ten: Data Security Monitoring**

Clinical research will establish an appropriate data security monitoring plan based on the level of risk. All adverse events will be meticulously documented, appropriately addressed, and tracked until resolution or stabilization. Serious adverse events and unexpected events will be reported to the ethics committee, regulatory authorities, sponsors, and

drug regulatory authorities in accordance with regulations and guidelines. The principal investigator will periodically conduct cumulative reviews of all adverse events, and if necessary, convene investigator meetings to assess the risks and benefits of the study. In double-blind trials, emergency unblinding may be performed if necessary to ensure subject safety and rights.

**Eleven: Statistical Analysis**

Statistical analysis will be conducted using SPSS 22.0 software. Normally distributed continuous data will be presented as mean ± standard deviation (x±s), and group comparisons will be made using analysis of variance (ANOVA). Categorical data will be presented as counts or percentages, and group comparisons will be made using the $X^2$ test. A significance level of $P<0.05$ will be considered statistically significant.

**Twelve: Ethical Principles and Requirements for Clinical Research**

This clinical research will adhere to ethical principles and requirements outlined in the World Medical Association's "Declaration of Helsinki" and the regulations set forth by the National Health and Family Planning Commission of the People's Republic of China, including the "Ethical Review Measures for Biomedical Research Involving Human Subjects." Specific measures will include informed consent, privacy protection, free participation in research, risk control, protection of special subjects, and

compensation for research-related harm. Prior to commencing the study, the research protocol must receive approval from the ethics committee. Before enrollment, every subject will be provided with comprehensive information about the study's purpose, procedures, and potential risks. They will sign a written informed consent form. Subjects will be informed that participation in the clinical research is entirely voluntary, and they have the right to refuse or withdraw from the study at any stage without discrimination or retaliation. Their medical treatment and rights will not be affected. Informed consent forms will be retained as part of the clinical research documents, ensuring the protection of subjects' personal privacy and data confidentiality.

**References**

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