A Prospective Clinical Validation Study of an End-to-End Difficult Airway Pathway Planning Algorithm (EAP-LC) in Patients with Laryngeal Cancer: A Spatial Consistency Assessment Based on Awake Flexible Bronchoscopic Intubation Videos

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Study Design, Randomization, and Blinding

Study design: Single-center, prospective, observational cohort study.
Randomization and blinding: None.
Control group: None.

Eligibility, Exclusion, Withdrawal, and Discontinuation Criteria

Subject source and enrollment: This single-center prospective observational study will enroll inpatients at Fudan University Eye, Ear, Nose, and Throat Hospital (Fenyang Campus) who are scheduled for laryngeal tumor surgery and, according to preoperative anesthesia assessment, require awake endoscopic flexible laryngoscopy (EAP-LC). From the date of ethical approval until the study completion, all patients meeting the inclusion and exclusion criteria will be consecutively enrolled.

Inclusion criteria:

- Patients scheduled for laryngeal cancer surgery under general anesthesia (including supraglottic, glottic, subglottic laryngeal cancer, and lesions at the pharyngo-laryngeal junction), with preoperative anesthesia assessment indicating a need for awake EAP-LC to secure the airway.
- Age ≥ 18 years, any gender.
- Diagnosed with laryngeal cancer or laryngeal tumor by preoperative imaging or pathology, and scheduled for laryngeal surgery.
- Completion of enhanced CT scan of the larynx/neck within 2 weeks before surgery, with image quality suitable for EAP-LC algorithm analysis.
- Conscious and able to understand the study procedures, and willing to provide written informed consent.

Note: This study does not alter the standard indications or procedures for awake laryngoscopy; it only adds standardized video acquisition and data analysis, representing minimal-risk observational research.

Exclusion criteria:

- Inability to cooperate with awake laryngoscopy (e.g., severe anxiety, cognitive impairment, psychiatric disorders).
- Prior total laryngectomy or loss of normal laryngeal anatomy, preventing oral/nasal flexible laryngoscopy.
- Severe coagulopathy or uncontrollable bleeding risk.
- Other conditions judged by the investigators as unsuitable for participation (e.g., refusal of video recording, special confidentiality requirements).

Discontinuation criteria:

- Subject withdraws voluntarily.
- Serious adverse events require termination of laryngoscopy or emergency airway management.
- Incomplete preoperative or intraoperative data, making key registration analysis impossible.

Definition of Awake EAP-LC Failure and Management Plan

General principle: Awake EAP-LC failure is defined, after excluding absolute contraindications (e.g., patient refusal, severe non-cooperation), as any stage in the planned awake laryngoscopy procedure where the patient cannot tolerate the procedure, physiological decompensation occurs, or technical completion is impossible, requiring abandonment of the technique and initiation of a backup airway plan.

Failure may occur in the following two independent stages:

1. Airway preparation stage failure:

- Definition: During local anesthesia and sedation preparation, the procedure cannot advance to the formal intubation attempt due to patient intolerance or physiological reasons.
- Criteria (any one sufficient):
    1. Intolerance: Patient exhibits uncontrolled coughing, vomiting, agitation, or clearly refuses to continue during topical anesthesia (spray, cotton swab application, or percutaneous nerve block), preventing completion of the planned anesthesia to the glottic and subglottic levels.
    2. Anesthesia failure: After completing all planned anesthesia steps, evaluation (e.g., light contact of bronchoscope with glottis) reveals persistent severe laryngospasm or intolerable cough, predicting inevitable failure of intubation.
    3. Physiological failure: Severe physiological disturbances arise during preparation and cannot be corrected with simple measures (e.g., SpO_2 < 90% or >20% decrease from baseline; severe hemodynamic instability requiring pharmacologic intervention such as systolic BP < 90 mmHg or > 200 mmHg, bradycardia < 40 bpm or tachycardia > 130 bpm).

2. Intubation attempt stage failure:

- Definition: After successful airway preparation, failure occurs if the endotracheal tube cannot be inserted into the trachea within the allowed number of attempts and time limits.
- Criteria (any one sufficient):

1. Number of attempts: Failure after a maximum of 3 complete insertion attempts.
2. Time limit: Active insertion exceeding 5 minutes from the first attempt (excluding prior airway preparation, sedation, topical anesthesia, and scope navigation) constitutes failure.
3. Technical/safety failure:
    - Loss of visual field due to bleeding or secretions despite active suction.
    - Obstruction preventing passage of the tube due to airway pathology or severe anatomical distortion.
    - Airway safety decompensation: severe laryngospasm or bronchospasm.
    - Physiological decompensation: $SpO_2 < 90\%$ or severe hemodynamic instability.

Management plan:

- Stop all airway stimulation, administer 100% high-flow oxygen (HFNO ≥ 60 L/min, or switch to closed mask + two-person ventilation if needed), and rapidly assess oxygenation and cooperation.
- Decisions by anesthesiology and ENT teams follow this priority:
    1. Keep the patient awake or lightly sedated (Ramsay 2, able to respond verbally, $SpO_2 \geq 90\%$, adequate spontaneous ventilation), and allow a single expert anesthesiologist to attempt awake re-intubation (with path, tube, or tool adjustments).
    2. If failed, ENT physician establishes anterior neck airway under local anesthesia (FONA).
    3. In cannot-intubate-cannot-ventilate (CICV) scenarios, ENT immediately performs emergency FONA.
    4. Only if anterior airway and FONA fail and patient is near death (persistent severe hypoxia or cardiac arrest) may anesthesiologist attempt rescue laryngoscopy, possibly with minimal muscle relaxant and concurrent chest compressions.
- ENT attending physician or above, full tracheostomy and cricothyrotomy equipment must be ready in the OR.
- Record all steps, SpO_2, decisions, and outcomes for safety analysis.

Sample Size Calculation

The primary outcome is the proportion of patients achieving an average deviation ≤ 5 mm between the EAP-LC predicted path and actual awake laryngoscopy trajectory. The 5 mm threshold is based on prior airway navigation literature: in electromagnetic navigation bronchoscopy (ENB), navigation errors < 5 mm increased diagnostic success from 71.4% to 78.5%, indicating clinical relevance and acceptable spatial accuracy [5]. Considering typical laryngeal airway diameters (10–15 mm) and scope

outer diameter (~4–5 mm), an average deviation ≤ 5 mm generally indicates the predicted path remains within the central lumen. Based on preliminary pilot data and multidisciplinary expert opinion, approximately 80% (P = 0.80) of patients are expected to achieve the target deviation ≤ 5 mm. Using PASS 11 software (NCSS, LLC, Kaysville, UT, USA), "Confidence Intervals for One Proportion" module, with a two-sided 95% confidence interval and desired total width of 0.20 (half-width 0.10, i.e., 0.70–0.90), the minimum required sample size is 60 patients (Wilson method). Accounting for ~10–15% of cases potentially excluded due to incomplete intraoperative recordings, poor image quality, or failed 3D registration, the planned enrollment is 70 patients.