Ethics Application Form for Human Research, the Second Affiliated Hospital of Zhejiang University School of Medicine

Reference No.:

Project Information	Project Title: Development and Preliminary Validation of an AI-Assisted Intel ligent Video Laryngoscope for Tracheal Intubation in Critically Ill Adults
	English Title: Development and Preliminary Validation of an AI-Assisted Intelligent Video Laryngoscope System for Endotracheal Intubation in Critically Ill Adults
	Application Type Registered study: □ Drug clinical trial □ Device clinical trial □ Special medical food clinical trial Non-registered study: ☑ Clinical research □ Post-market product study
	Drug/Device Name: Drug/Device Category: Trial Phase/Category:
	Indication: Endotracheal intubation
	Number of cases at our hospital: 120 Total research funding: CNY 0
Sponsor	Sponsoring institution: The Second Affiliated Hospital of Zhejiang University School of Medicine
	Contact: Zhang Mao Tel: 13757119125
CRO	Name: Contact: Tel:
Study Site	Study site (Department): Department of Emergency Medicine, the Second Affiliated Hospital of Zhejiang University School of Medicine Lead site: Yes ☑ No □
	The principal of the specialty group or department head coordinates the PI and participating investigators (conflicts of interest identified in advance; listed by role and responsibility): Participating investigators: Zhang Mao, Wei Jintao, Xu Shanxiang, Li Qiang PI signature: Date: 2026.02.4
	Specialty group lead / department head signature: Date: February 04, 2026

Functional Department Opinion	**For post-market studies (non-registered), the Research Office fills in the opinion; not required for registered studies.** Date: ____

Note: Registered studies refer to studies for product registration or re-registration, typically drug/device clinical trials. Non-registered studies are not for product registration, typically post-market observational or investigator-initiated studies.

Research Protocol

Development and Preliminary Validation of an AI-Assisted Intelligent Video Laryngoscope for Tracheal Intubation in Critically Ill Adults

1. Background

(1) Rationale and Significance

Endotracheal intubation (ETI) is a core technique in modern emergency and critical care resuscitation and general anesthesia, widely used for in-hospital and out-of-hospital cardiac arrest, severe trauma, severe infection, and acute respiratory failure. Evidence shows that first-pass success (FPS) is closely associated with patient outcomes; failed intubation markedly increases the risk of severe hypoxemia, arrhythmia, and even cardiac arrest [1-2]. In the ICU and emergency department (ED), failed intubation is associated with multiple attempts, delayed ventilation, and airway injury, seriously threatening survival and prognosis [3]. Improving intubation success, especially in emergency and difficult-airway settings, remains a major global challenge in anesthesiology and critical care medicine.

Direct laryngoscopy (DL) relies on direct visual laryngeal exposure by the operator, but has a long learning curve and demands strong anatomical knowledge, hand-eye coordination, and emergency response [4]. Even in relatively standardized anesthesia settings, the FPS of inexperienced novices is below 50% [5]. In high-risk environments such as the ED, ICU, primary care, and pre-hospital emergency care, where airway conditions are complex and time is critical, junior physicians have higher

failure and complication rates [6], highlighting the capability gaps in airway management at primary institutions and among junior operators.

Video laryngoscopy (VL) has markedly improved the operability of endotracheal intubation. VL captures glottic images through a high-definition camera and displays them in real time on a screen, breaking the limitation of direct line of sight [7]. Multiple systematic reviews and meta-analyses show that, compared with DL, VL improves FPS and glottic exposure scores in most clinical scenarios, particularly in patients with difficult airways [8-9]. VL also supports image sharing, enabling real-time guidance by senior physicians, with notable educational value [10]. However, VL has limitations in complex clinical settings: (1) Image obstruction: ED patients often have vomitus, blood, or secretions that blur the lens and impair judgment [11]. (2) Experience dependence: even with a clear view, junior physicians may fail due to insufficient anatomical recognition and operational experience. (3) Complex airways: anatomical variations such as neck trauma, laryngeal edema, or micrognathia may still cause intubation failure.

Thus, although VL is recommended by international guidelines as a difficult-airway tool, it cannot fully resolve the operational challenges faced by junior physicians in real-world emergency settings [12]. The 2022 ASA Practice Guidelines for Management of the Difficult Airway recommend VL as a first-line or important alternative tool in multiple scenarios [13]; the UK DAS guidelines also emphasize that VL should be readily available, especially for unpredictable difficult airways [14]. These guidelines confirm the clinical value of VL and provide a policy basis for its global dissemination. However, their application presupposes that operators can correctly identify airway anatomy and perform appropriately. For primary institutions, junior physicians, and pre-hospital emergency settings, hardware upgrades alone are insufficient; intelligent tools are urgently needed to assist recognition and decision-making.

Artificial intelligence (AI), especially deep learning (DL), has recently made breakthroughs in medical image recognition and surgical navigation. Based on convolutional neural networks (CNN), object detection (YOLO, Faster R-CNN), and semantic segmentation (UNet, DeepLab), AI can achieve real-time recognition and segmentation of key anatomical structures in medical images [15]. Preliminary studies have shown that: glottic recognition-AI can automatically annotate glottic position in VL video with >90% accuracy at near-real-time speed [16]; frame selection and information extraction-AI can automatically select the clearest key frames from laryngoscopy video to reduce interference and improve efficiency [17]; tumor and lesion recognition-in laryngopharyngeal cancer diagnosis, AI has

achieved accuracy approaching that of experts. These advances demonstrate the feasibility of AI for video laryngoscopy. AI empowerment can enable: 1) real-time anatomical cues-automatic recognition and annotation of the glottis, epiglottis, and vocal cords, reducing recognition difficulty for junior physicians; 2) procedural path guidance-on-screen prompts for tube advancement direction to improve success; 3) risk warning-real-time alerting of difficult airways based on Cormack-Lehane grade, prompting escalation to advanced airway strategies; 4) teaching and assessment-AI-based recording and analysis of procedures to establish a standardized skills evaluation system. AI model performance depends heavily on the diversity and quality of training data. A single department (e.g., anesthesiology) may provide large volumes of standardized intubation images but lacks emergency scenarios with blood, secretions, and difficult airways. Relying solely on anesthesia data would limit generalization in complex clinical settings.

References

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2. Significance

1. Improving emergency and primary care capability: In ED and primary-care settings, the AIA can lower the operational threshold, improve success rates, and promote balanced regional healthcare and critical-care outcomes.

2. Optimizing teaching models: The AIA enables anatomical recognition, path guidance, and risk warning, shortening the learning curve and improving junior physicians' success in complex airways, driving innovation in intubation training.

3. Advancing AI in medicine: Findings can be extended to emergency care and procedural teaching, promoting deep integration of AI with clinical practice and medical education and advancing digital and intelligent healthcare.

4. Social value: Improving intubation safety and success, reducing complications and rescue delays, and improving patient outcomes carries important public-health significance.

3. Objectives

This study aims to develop an integrated AI-assisted intelligent video laryngoscope system (AIA) and validate its efficacy for endotracheal intubation in critically ill adults in resource-limited settings.

4. Study Design

The study comprises two phases: system development of the AIA and external validation.

(1) System development of the AIA.

This phase has completed ethics review, Ethics No.: (2025) Clinical Research Ethics No. 1423.

(2) External validation.

This phase conducts clinical validation based on the AIA developed in Phase 1.

5. Clinical Feasibility Design

(1) Validation Centers and Sample Size

1. Clinical validation

This is a prospective, stratified, randomized, controlled study. We enroll 120 patients requiri ng endotracheal intubation in the ED of the Second Affiliated Hospital of Zhejiang University S chool of Medicine from January 2026 to December 2027. Subjects are randomized 1:1, stratifie d by operator clinical experience, to the AIA group (n=60) or the conventional VL group (n=60; VL brand: UE Medical, China), with strata of junior (1-5 years) and senior (>=6 years) operat ors. Written informed consent is obtained from all subjects or their legal representatives.

(1) Patient inclusion and exclusion criteria: Inclusion: critically ill adults (>=18 years) requiring laryngoscopic endotracheal intubation. Exclusion: pregnancy, imprisonment, recent airway surgery, oral or pharyngeal malformation, emergency intubation precluding rando mization, or operator judgment that AIA/VL/DL is mandatory or contraindicated at the fir st attempt.

(2) Operator inclusion and exclusion criteria: Inclusion: licensed physicians with indepe ndent endotracheal intubation qualifications, working in the ED, who voluntarily sign infor med consent and can participate throughout. Exclusion: personnel without independent pra ctice qualifications; physicians who have been away from front-line ED work for >6 month s; physicians who received specialized training related to this intervention within the past 3 months; physicians participating in other concurrent intubation studies; physicians who r efuse consent or cannot complete the study for personal reasons.

(2) Interventions

(1) AIA group: operators use the AIA during the first laryngoscopic intubatio n attempt. Operators receive instructional training beforehand, covering function keys, prompt tones, and image display. Whether to follow AIA prompts is at the operator's discretion.

(2) VL group: operators use the conventional VL without AI assistance durin

g the first attempt.

All operators complete standardized training and pass an assessment before participating. The operating procedure and contingency plan are defined (if the first attempt exceeds 120 s or severe hypoxemia occurs, immediately switch to the standard rescue protocol to ensure patient safety). To safeguard patients, all intubations performed by junior physicians are supervised bedside by a senior physician who intervenes when necessary.

All other aspects of the procedure are determined by the operator, including the type of laryngoscope used in subsequent attempts. A stylet is routinely used in the first attempt, and correct endotracheal tube position is confirmed by auscultation and CO2 waveform monitoring。

(3) Study Device

The VL used in this study (Model: UET-C; Brand: UE Medical; Origin: China) holds a medical device registration certificate and is routinely used in the ED and Department of Anesthesiology at our hospital. The AIA adds a software functionality—an AI algorithm deployed after model training—on top of the existing software, without altering the registered product's technical requirements or performance specifications, and without any changes to the wiring, hardware, structure, or appearance of the laryngoscope. Based on this design, the intervention introduces no additional potential harm to patients, and safety is reliably ensured. The core purpose of this study is to preliminarily validate the accuracy, sensitivity, and specificity of the AI algorithm through an observational study after model development, providing data support and a scientific basis for subsequent optimization of related medical devices.



Figure 1. AIA prototype. Panel A: front view; Panel B: back view.

1. Device operation instructions

(1) Power-on and anatomical structure recognition. Power-on: press the white button at the upper-right corner to start the system; an "AI" indicator appears at the upper-left of the screen (this can be manually disabled in system settings). The system automatically identifies anatomical structures including the glottis, epiglottis, esophagus, and arytenoid cartilage; upon successful recognition, the corresponding region is boxed with a green solid line and labeled with the structure name (e.g., "glottis," "epiglottis"). When glottic exposure reaches >=80% and intubation conditions are met, the green glottic box turns red and the screen displays "Ready to intubate" (Figure 2).

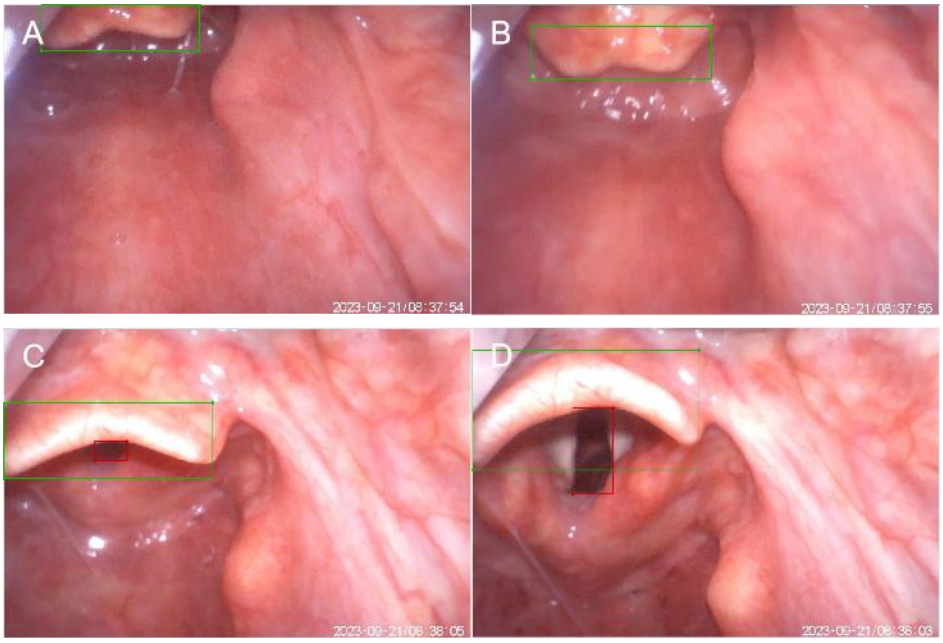


Figure 2. Annotated laryngeal images under different exposure degrees. Panel A: epiglottis just visible; Panel B: epiglottis exposed; Panel C: glottis just visible; Panel D: glottis fully exposed.

(2) Path guidance. When the blade is far from the glottis, the screen displays "Advance" with an upward arrow (↑); when inserted too deeply, "Retreat" with a downward arrow (↓); when offset to the right, "Move left" with a leftward arrow (←); when offset to the left, "Move right" with a rightward arrow (→); when secretions, blood, or other obstructions are detected, the screen displays "Suction." The on-screen guidance arrows and text are optimized not to obstruct the operator's view (Figure 3).

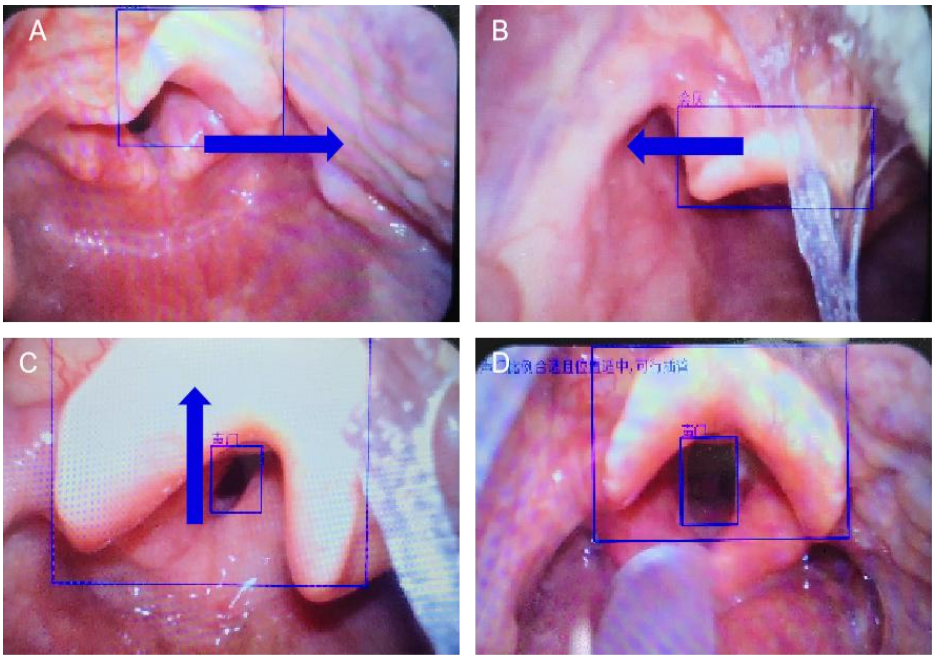


Figure 3. AIA internal test images. Panel A: prompt to move right; Panel B: prompt to move left; Panel C: prompt to advance the laryngoscope; Panel D: prompt to lift up / move forward / move left-right.

(4) Clinical Outcomes

1. Primary outcome: First-pass intubation success rate. Successful placement of an endotracheal tube during the first laryngoscopic intubation attempt, confirmed by end-tidal carbon dioxide monitoring. Time frame: from enrollment to completion of intubation, usually within 10 minutes.

2. Secondary outcomes:

(1) Intubation time: duration from insertion of the laryngoscope into the oral cavity until the endotracheal tube passes through the glottis. Unit: seconds. Time frame: during the intubation procedure, usually within 10 minutes after enrollment.

(2) Severe peri-intubation complications: proportion of participants experiencing at least one of the following: severe hypoxemia (SpO2 <80%), severe hypotension (systolic blood pressure <65 mmHg), initiation of vasoactive agents, cardiac arrest, or death. Each participant is counted once for this composite outcome regardless of the number of events. Time frame: from enrollment through 2 minutes after intubation.

(3) AI recall: true-positive anatomical detections divided by the sum of true-positive and false-negative detections, evaluated against reference annotations. Time frame: video acquired during intubation, usually within 10 minutes after enrollment.

(4) AI precision: true-positive anatomical detections divided by the sum of true-positive and false-positiv

e detections, evaluated against reference annotations. Time frame: video acquired during intubation, usually wi thin 10 minutes after enrollment.

(5) AI specificity: true-negative assessments divided by the sum of true-negative and false-positive assess ments, evaluated against reference annotations. Time frame: video acquired during intubation, usually within 1 0 minutes after enrollment.

(6) AI F1 score: harmonic mean of precision and recall, calculated as 2 x precision x recall / (precisio n + recall). Time frame: video acquired during intubation, usually within 10 minutes after enrollment.

(7) Mean average precision (mAP): mean of average precision across the evaluated anatomical classes a gainst reference annotations. Time frame: video acquired during intubation, usually within 10 minutes after en rollment.

(8) Duration of mechanical ventilation. Unit: days. Time frame: from enrollment through the end of trea tment, up to 8 weeks.

(9) ICU length of stay. Unit: days. Time frame: from enrollment through the end of treatment, up to 8 weeks.

(10) Total hospital length of stay. Unit: days. Time frame: from enrollment through the end of treatment, up to 8 weeks.

(11) All-cause 28-day mortality: proportion of participants who die from any cause within 28 days after enrollment. Time frame: enrollment through day 28.

(5) Study Procedure

1. Screen and preliminarily enroll eligible patients (meeting intubation criteria).
2. Confirm the enrolled population.
3. Discuss with the patient's family; after confirmation, obtain written informed consent.
4. Stratify and randomize 1:1 into the AIA and VL groups.
5. Collect patient data.

(6) Data Collection

An independent observer collects primary-outcome data (number of passes of the laryngoscope blade, stylet, and endotracheal tube through the mouth), intubation durati on, and the lowest oxygen saturation and lowest systolic blood pressure during the in terval from anesthetic induction to 2 minutes after intubation.

Operators rate anticipated intubation difficulty (easy, moderate, or difficult) before randomization, and immediately after intubation report the Cormack-Lehane grade (1-

4), reason for first-attempt failure, procedure-related complications (esophageal intubation, dental injury, or aspiration), and number of intubation attempts.

6. Sample Size

This study is designed as a preliminary exploratory investigation, with the primary goal of obtaining proof-of-concept evidence and the direction of effect. Accordingly, a power analysis was not used for sample size estimation; 120 patients are enrolled.

7. Statistical Analysis

Statistical analysis is performed using SPSS 26.0 and R 4.2.0. Categorical data are expressed as frequency (%) and compared between groups using the chi-square test; Fisher's exact test is used when expected cell counts are <5. Continuous data are expressed as mean +/- standard deviation; normality is tested first, and normally distributed data are compared using the independent-samples t test, while non-normally distributed data are compared using the Mann-Whitney U test. Multi-group comparisons use ANOVA or the Kruskal-Wallis H test. Receiver operating characteristic curves are plotted and the area under the curve (AUC) is calculated. All tests are two-sided, and $P<0.05$ is considered statistically significant.

8. Data Management and Confidentiality

(1) Data management: Data are managed and stored in both Excel and paper form. A designated person collects paper records, enters them into Excel, and both electronic and paper versions are consolidated for statistical analysis and storage.

(2) Confidentiality: All records identifying subjects are kept confidential and are not disclosed beyond what is permitted by applicable laws and regulations.

9. Informed Consent

Written informed consent must be obtained before any study procedure is performed. Patients, legal representatives, or guardians are informed of the study details; see the informed consent form for details.

The consent process: after confirming eligibility, the written consent form is printed. The attending physician and study investigator jointly discuss the study with the patient or authorized family member, explain the study details, and the patient or authorized family member signs before enrollment. (In principle, the patient signs the consent form personally. If literacy or other factors prevent self-signing, a patient-designated authorized person signs while the patient is present. If the patient is unconscious or otherwise unable to sign on admission, the legal represent

ative or guardian signs. For patients with psychiatric/cognitive impairment, consent follows three tiers based on capacity: 1) full capacity—the patient signs; 2) partial capacity—the patient and legal guardian co-sign; 3) no capacity—the legal guardian signs.)

10. Adverse Event Reporting

All adverse events are promptly managed and recorded in the case report form.

Serious adverse events (SAEs) are promptly managed and recorded in the CRF. The investigator decides on study cessation or dose reduction, and the SAE is immediately reported to the ethics committee, the clinical trial institution, and the sponsor, and reported to the national and provincial drug administrations within 24 hours. SAEs must be submitted via the hospital intranet "No-blame Adverse Event and Near-Miss Reporting System." See the figure below for the reporting workflow.

iang University School of Medicine

Dear Patient,

We invite you to participate in a clinical study titled "Development and Preliminary Validat ion of an AI-Assisted Intelligent Video Laryngoscope for Tracheal Intubation in Critically Ill Ad ults." Before deciding whether to participate, please read the following carefully; it will help yo u understand the study, its rationale, procedures and duration, and the potential benefits, risks, a nd inconveniences.

The following introduces the study:

1. Background and Objectives

Endotracheal intubation (ETI) is a core technique in critical care and anesthesia managemen t. First-pass success (FPS) is directly associated with prognosis, and failed intubation significantl y increases risks of hypoxemia and cardiac arrest; improving FPS remains a major clinical chall enge. Direct laryngoscopy (DL) has a long learning curve, with junior operators achieving FPS below 50%, and higher failure rates in complex emergency airways. Video laryngoscopy (VL) o vercomes the limitations of direct vision through a camera, improving FPS and glottic exposure and offering educational value, but still suffers from image obstruction, experience dependence, and inadequate handling of complex anatomical variations. International guidelines confirm VL's clinical value, but primary-care and junior operators still face operational challenges. Artificial i ntelligence (AI), especially deep learning, has made breakthroughs in medical image recognition, achieving high-accuracy real-time glottic recognition and enabling VL empowerment through an atomical cues and path guidance. However, existing AI models rely mostly on standardized anes thesia data and lack complex emergency scenarios, limiting generalization.

Building on prior work, this project develops the AIA for product development and clinical translation of a new intubation technology for critically ill patients, aiming to improve in-hospi tal and out-of-hospital emergency care, primary care, and training. It carries important scientific, clinical, and social significance.

2. Procedures and Process

(1) Validation Centers and Sample Size

1. Clinical validation

This is a prospective, stratified, randomized, controlled study. We enroll 120 patients requiri ng endotracheal intubation in the ED from January 2026 to December 2027. Subjects are rando

mized 1:1, stratified by operator clinical experience, to the AIA group (n=60) or the convention al VL group (n=60; VL brand: UE Medical, China), with strata of junior (1-5 years) and senior (>=6 years) operators. Written informed consent is obtained from all subjects or their legal rep resentatives.

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(2) Interventions

(1) AIA group: operators use the AIA during the first laryngoscopic intubatio n attempt. Operators receive instructional training beforehand, covering function keys, prompt tones, and image display. Whether to follow AIA prompts is at the operator's discretion.

(2) VL group: operators use the conventional VL without AI assistance durin g the first attempt.

All operators complete standardized training and pass an assessment before participating. Th e operating procedure and contingency plan are defined (if the first attempt exceeds 120 s or s evere hypoxemia occurs, immediately switch to the standard rescue protocol to ensure patient sa fety). To safeguard patients, all intubations performed by junior physicians are supervised bedsid e by a senior physician who intervenes when necessary.

All other aspects of the procedure are determined by the operator, including the type of lar yngoscope used in subsequent attempts. A stylet is routinely used in the first attempt, and corre ct endotracheal tube position is confirmed by auscultation and CO2 waveform monitoring

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(2) Severe peri-intubation complications: proportion of participants experiencing at least one of the following: severe hypoxemia (SpO2 <80%), severe hypotension (systolic blood pressure <65 mmHg), initiation of vasoactive agents, cardiac arrest, or death. Each participant is counted once for this composite outcome regardless of the number of events. Time frame: from enrollment through 2 minutes after intubation.

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(11) All-cause 28-day mortality: proportion of participants who die from any cause within 28 days after enrollment. Time frame: enrollment through day 28.

(5) Study Procedure

1. Screen and preliminarily enroll eligible patients (meeting intubation criteria).
2. Confirm the enrolled population.
3. Discuss with the patient's family; after confirmation, obtain written informed consent.
4. Stratify and randomize 1:1 into the AIA and VL groups.
5. Collect patient data.

(6) Data Collection

An independent observer collects primary-outcome data (number of passes of the laryngoscope blade, stylet, and endotracheal tube through the mouth), intubation duration, and the lowest oxygen saturation and lowest systolic blood pressure during the interval from anesthetic induction to 2 minutes after intubation.

Operators rate anticipated intubation difficulty (easy, moderate, or difficult) before randomization, and immediately after intubation report the Cormack-Lehane grade (1-4), reason for first-attempt failure, procedure-related complications (esophageal intubation, dental injury, or aspiration), and number of intubation attempts.

If you are successfully resuscitated and have decision-making capacity, we will fully explain the study purpose and process, answer your questions, and let you decide whether your data may be used in the final analysis. You may withdraw at any time without affecting your regular care. For subjects who are not resuscitated or who regain circulation but not full consciousness, the legal representative or guardian is fully informed, and withdrawal at any time likewise does not affect routine care.

3. What You Need to Do

Participation requires only your cooperation with the medical staff during data collection.

4. Potential Benefits

By participating, the existing VL hardware is unchanged; an added algorithm provides real-time anatomical labeling and guidance on a high-definition screen with a clear view, potentially shortening intubation time, improving success, reducing trauma and complications such as hypoxemia, lowering procedural burden and medical errors, and enabling process traceability. These technologies may improve rescue success, survival, and neurological outcomes. Patients also recei

ve closer monitoring and evaluation during the study, which may improve prognosis.

5. Potential Adverse Reactions, Risks, and Precautions

This study does not add extra procedures or examinations, and generally entails no additiona l adverse reactions or risks. Device-related potential risks and countermeasures are as follows:

(1) Potential risks: device failure (screen blackout), AI misjudgment; mucosal irritation, bleeding, or edema; cross-infection; data privacy breach (the same risks as with VL).

(2) Contingencies: AIVL performance is checked daily to ensure adequate power and normal operation; a backup direct laryngoscope is available; operators receive dual training and do not blindly rely on AI, with a senior physician bedside-supervised all junior intubations; strict disinfection and standardized privacy protection are enforced; upon intubation failure, an alternative plan is immediately initiated with monitoring and management. We will strengthen training to reduce these risks.

(3) Vulnerable populations and protections: because enrolled patients undergo emergenc y intubation and cannot provide consent themselves, informed consent is obtained from the patient's legal representative before the trial.

6. Costs

All study-related costs are borne by the research team; no additional fees are incurred by t he subject.

Endotracheal intubation is itself an invasive procedure that may cause oral mucosal injury, l oose or avulsed teeth, cardiovascular stress, or aggravation of cervical spine injury. These patien ts are already critically ill, and failure to restore spontaneous circulation or death may occur; n o compensation is provided for such events.

7. Compensation for Participation, Including Injury Compensation

This is a prospective, stratified, randomized study. The AIA prompt function focuses only o n anatomical recognition and procedural assistance and does not interfere with the physician's fi nal operational decisions (which remain at the physician's discretion), so it does not substantiall y affect procedural outcomes. No fees are charged to subjects, and no routine participation com pensation is provided. The hospital has purchased insurance for this ethics-approved, investigator -initiated research project; if a study-related serious adverse event occurs, the hospital will seek compensation for you in accordance with applicable laws and regulations.

8. Alternative Procedures

If you decline to participate, there is no required alternative; your routine clinical treatment will not be affected.

9. Confidentiality of Your Personal Information

Your medical records (including study records and laboratory reports) are stored at the hos pital as required. Except for authorized personnel (investigators, ethics committee, monitors, audi tors, and drug regulatory authorities), no unrelated party may access your records without permi ssion. Published reports of this study will not disclose your identity. We make every effort with in legal limits to protect the privacy of your medical information.

10. Withdrawal from the Study

Participation is entirely voluntary. You may decline or withdraw at any time without reason; this will not affect your relationship with your physician or your medical care or other entitle ments.

Because enrolled patients undergo emergency intubation and cannot provide consent themsel ves, informed consent is obtained from the patient's legal representative before the trial.

11. Ethics Committee

This study has been submitted to the Ethics Committee of Human Research at the Second Affiliated Hospital of Zhejiang University School of Medicine, which conducted a comprehensiv e review including risk assessment of subjects and granted approval. For ethics or rights-related matters, contact the Ethics Committee by phone (daytime: 0571-87783759; after-hours on-call: 13757118366) or email: HREC2013@126.com.**HREC2013@126.com**

I confirm that I have read and understood this informed consent form, voluntarily accept t he treatment in this study, and agree that my medical data may be used in the publication of t his study.

Subject signature: Contact: Date:

Representative signature: Relationship to subject Contact:

Date

(if applicable)

Witness (if applicable): Contact: Date:

I confirm that I have explained the details of this study to the patient, including their rights and potential benefits and risks, and have given them a signed copy of the informed consent form.

Investigator signature:

Contact: (mobile) Date: