Exploration and Application of Intelligent Difficult Airway Assessment Scheme

Protocol

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Project Name: Exploration and Application of Intelligent Difficult Airway Assessment Scheme
Sponsor: Min Su
Principal Investigators: Min Su, Cheng Wenjie

Protocol Summary

Trial Name	Exploration and Application of Intelligent Difficult Airway Assessment Scheme
Applicant	Min Su
Principal Investigators	Min Su, Cheng Wenjie
Objective of the Trial	To investigate the correlation between the intelligent airway assessment system with Articulation and tongue position adjustment and the improved Mallampati grading and Cormack-Lehane grading, and to establish a model and plan for predicting difficult airways.
Trial Design	A prospective, self-controlled design is adopted.
Sample Size	A total of 430 subjects are planned to be enrolled.
Case Selection	Inclusion Criteria: 1.Age ≥ 18 years, gender unrestricted; 2.Subjects planned to undergo general anesthesia and require endotracheal intubation; 3.Subjects classified as ASA-PS (American Society of Anesthesiologists Physical Status) Class I, II, and III; 4.Volunteers who participate in this clinical trial and sign the informed consent form.
	Exclusion Criteria: 1.Subjects with known airway deformities, tumors, or other structural abnormalities that may affect airway assessment; 2.Subjects with mental abnormalities who cannot cooperate; Pregnant or lactating women; 3.Subjects who have participated in other interventional clinical trials within 1 month before the start of this trial; 4.Subjects deemed unsuitable for this clinical trial by the investigators.
Validity Indicators	Primary Evaluation Indicator: The correlation between the intelligent airway assessment system with Articulation and tongue position adjustment and the improved Mallampati grading and Cormack-Lehane grading. Secondary Evaluation Indicators: 1.The consistency between different methods of the intelligent airway assessment system with Articulation and tongue position

	adjustment; 2.The accuracy of the intelligent airway assessment system with Articulation and tongue position adjustment in predicting difficult airways; 3.The duration of endotracheal intubation, the need for assistance, and the number of intubation attempts.
Safety Indicators	Complications related to endotracheal intubation.
Statistical Analysis	Analysis will be conducted using R 4.3.2 software.
Presentation of Research Findings	Publication of 1-2 research papers.

Clinical Trial Schedule

Item	Screening Period (Day 3 to -1)	Trial Period		Follow-up Period	
	(Day 3 to -1)	Day 1 Pre-op Visit	Day 2 Intubation	10 minutes Post-Extubation	1 Day Post-Extubation
Baseline Data					
Informed Consent	√				
Medical History	√				
Inclusion/Exclusion Criteria	√				
Demographic Data	√				
Vital Signs	√				
Physical Examination	√				
Laboratory Tests					
Complete Blood Count (WBC, Gra)	√				
Coagulation Function (APTT, PT, TT, D-dimer)	√				
Electrocardiogram	√				
Research Methods					
M Grade		√			
N Grade		√			
A Grade		√			
C-L Grade			√		
Research Evaluation Indicators					
Endotracheal Intubation Time			√		
Number of Endotracheal Intubation Attempts			√		
Need for Assistance			√		
Safety Indicators					

Complications of Endotracheal Intubation				√	√

Note: WBC: White Blood Cell count; Gra: Neutrophil percentage; APTT: Activated Partial Thromboplastin Time; PT: Prothrombin Time; TT: Thrombin Time. M Grade: Modified Mallampati Grade; A Grade: Articulation and Tongue Position Adjustment Software Assessment; N Grade: Articulation and Tongue Position Adjustment Physician Assessment; C-L Grade: Cormack-Lehane Grade.

Abbreviation

AE	Adverse Event
BMI	Body Mass Index
ASA	American Society of Anesthesiologists
SAE	Serious Adverse Event
CRF	Case Report Form
ICF	Informed Consent Form
CRO	Contract Research Organization
FAS	Full Analysis Set
PPS	Per-Protocol Set
SS	Safety Set
GCP	Good Clinical Practice
CRA	Clinical Research Associate

I. Research Background

1. Definition and Classification of Difficult Airway

The American Society of Anesthesiologists (ASA) defines a difficult airway as a situation where "an anesthesiologist with routine training experiences difficulty with mask ventilation of the upper airway, difficulty with tracheal intubation, or both." It encompasses clinical situations that anesthesiologists may anticipate or not anticipate, including but not limited to the following one or more scenarios: mask ventilation, laryngoscopy, use of supraglottic airway devices, tracheal intubation, extubation, or invasive airway management[1].A large-scale retrospective study including 50,000 general subjects undergoing general anesthesia showed that the incidence of difficult mask ventilation and impossible mask ventilation were 2.2% and 0.15%, respectively[2].Another study analyzing 861,533 general anesthesia events found the incidence of difficult or failed intubation to be between 0.43% and 0.52% [3].

China, being the most populous country in the world, leads to a significant demand for healthcare resources, especially in the fields of surgery and anesthesia. The large number of general anesthesia procedures provides a wealth of clinical data but also poses a challenge to the healthcare system in terms of providing efficient and high-quality services. Additionally, the diverse regional, ethnic, and genetic backgrounds of the Chinese population may affect airway structure differences, thereby influencing airway management strategies and increasing the challenge of difficult airways for anesthesiologists.

2. Preoperative Airway Assessment

Airway management is a core area in anesthesiology and emergency medicine, crucial for ensuring the safety of surgical patients. Predicting difficult airways and taking appropriate management measures can significantly reduce anesthesia-related complications [4].The modified Mallampati grade and the Cormack-Lehane grade are two commonly used clinical methods for predicting difficult airway assessment. The Mallampati grade assesses airway difficulty by observing the visibility of oral structures. It was first proposed by Dr. Seshagiri Mallampati in 1985, classifying

patients' airways into three levels based on the visibility of the soft palate, uvula, tonsils, and posterior pharyngeal wall, playing a significant role in guiding airway management decisions and helping anesthesiologists predict potential intubation difficulties. However, over time, its application has shown limitations and variability. Factors such as patient positioning and tongue size can affect the Mallampati grade, leading to inconsistent predictions of intubation difficulties. To address these limitations, Samsoon and Young introduced the modified Mallampati grade in 1987, which added a fourth level for when only the hard palate is visible, which is now the most commonly used modified Mallampati four-grade assessment system.

The Cormack-Lehane grading system is another key tool used in anesthesia and airway management to assess the visibility of laryngeal structures during direct laryngoscopy. It was first proposed by Drs. Robert J. Cormack and William C. Lehane in 1984, classifying laryngeal views into four grades based on the visualization of the glottic structures. These methods are widely used in clinical practice, and literature has pointed out their correlation[5].The modified Mallampati grade does not require subjects to articulate, and literature has proven that articulation exposes more than non-articulation[6].

Previous methods relied on clinicians' intuitive observations of subjects' oral anatomical structures to judge the ease of intubation. However, these methods suffer from strong subjectivity, poor repeatability, and limited accuracy, especially in non-standardized assessment environments, where their predictive power is challenged. With the advancement of medical technology, especially the rapid development of Artificial Intelligence (AI) and telemedicine, new opportunities have emerged to improve the assessment methods for difficult airways. Using intelligent devices and algorithms, more precise measurements and analyses of subjects' airway anatomical structures can be made, thereby improving the accuracy and reliability of assessments. This new method not only reduces the interference of subjectivity but also enhances repeatability through standardized image capture and analysis processes. Additionally, the application of intelligent airway assessment methods also supports telemedicine and intelligent healthcare. In areas with limited resources or remote

locations, doctors can use intelligent devices to assess subjects' airways through remote connections, achieving high-quality medical services. At the same time, the development of this method aligns with the current trend of digital transformation in the healthcare industry, helping to improve overall medical efficiency and subject safety.

In our extensive clinical practice, we have found that introducing slight articulation of "ha" and adjusting tongue position during the modified Mallampati grade may affect the position of the base of the tongue and the view of the oropharynx, potentially improving the accuracy and reliability of the grading. However, there is currently little research on this assessment method, and its correlation with the Cormack-Lehane grade and its actual application value in predicting difficult airways have not been fully verified. Accordingly, we propose to use a combination of changing patients' articulation and adjusting tongue position with an intelligent airway assessment system, and to explore and compare the correlation of this new method with the modified Mallampati grade for the Cormack-Lehane grade, with the aim of establishing a prediction model and corresponding plan for difficult airways.

3. Introduction to the Intelligent Airway Assessment Software

Our intelligent airway assessment software (the "zhyayolo" mobile app) is developed based on the modified Mallampati grading system. It includes a reading module and a deep learning module for the airway grading system. The airway grading system is a cloud-based image data listening program deployed on the server side. After taking a photo, the uploaded images are stored in the cloud via Alibaba Cloud OSS. The airway grading system predicts the images uploaded in real-time to the cloud and writes the prediction data into the database. The airway grading system retrieves data from the cloud, predicts data that has not been predicted on the cloud, and returns it to the cloud. The prediction is carried out using a deep learning four-class model for airway grading, trained with a large dataset of airway grading samples. The YOLO object recognition network, trained under the Darknet architecture, is used as a pre-trained network for determining the presence of specific targets and the exact levels, as well as for bounding them. The test units include a

photo-taking interface unit, an image uploading unit, and an intelligent shooting prompt unit. By clicking on the mouth opening test unit, one enters the main interface, which features operational instructions, a start test button, and an image upload button. Clicking the start test button leads to the photo-taking interface unit. The top left corner of this interface has a template image that can be clicked to enlarge for viewing. The hollowed-out area in the middle of the interface is the core sampling area, where one should aim the center of the target for shooting.

4. Significance of the Study

The results of this study will help clinical doctors more accurately assess the risk of difficult airways, optimize airway management strategies, reduce complications during anesthesia and surgery, thereby enhancing the safety and satisfaction of subjects. Additionally, the research outcomes may also provide new theoretical foundations and practical guidelines for the field of airway assessment, promoting the development and innovation of related technologies and methods. By thoroughly exploring the effectiveness and feasibility of changing articulation and tongue position assessment methods, this study not only fills the gaps in existing research but may also propel the field of airway management towards more precision, personalization, and applicability to intelligent assessment.

II. Research Objectives

To explore and compare the correlation between the intelligent airway assessment system combined with altered patient articulation and tongue position adjustment, the modified Mallampati grading, and the Cormack-Lehane grading. The aim is to establish a prediction model and corresponding grading measures for difficult airways, promote innovative iterative development of the airway management field towards remote intelligent assessment, and enhance the quality of anesthetic management.

III. Trial Design

1.Overall Design

A prospective, self-controlled clinical trial design will be employed.

2.Research Methods

Subjects undergoing elective tracheal intubation under general anesthesia in the operating room of the trial unit (aged ≥18 years, both genders) will be selected and divided into three groups based on a self-controlled design:

Group 1:

Method A: The anesthesiologist uses the modified Mallampati grading method to observe the subject's oropharyngeal anatomical structure and assigns a grade.

Group 2:

Method B: The subject opens their mouth wide, relaxes the base of the tongue, extends the tongue outward as much as possible, and lightly articulates the "ha" sound. The anesthesiologist observes and then assigns a grade.

Group 3:

Method C: The subject opens their mouth wide, relaxes the base of the tongue, extends the tongue outward as much as possible, and lightly articulates the "ha" sound. After the anesthesiologist takes a photo of the subject, the software assigns a grade.

Preoperatively, the subject's thyromental distance, mouth opening, and degree of neck mobility will be measured. After anesthesia induction, the oropharyngeal anatomical structure will be exposed using a video laryngoscope, and the anesthesiologist will assign a Cormack-Lehane laryngoscope exposure grade and record the endotracheal intubation time, the number of intubation attempts, and whether intubation assistance was needed.

Assessment criteria: The modified Mallampati airway grade refers to the literature [7], defined as: Grade I allows visibility of the hard palate, soft palate, palatoglossus arch, and uvula; Grade II allows visibility of the hard palate, soft palate, and uvula; Grade III allows visibility of the hard palate and soft palate; Grade IV allows visibility of only the hard palate. The Cormack-Lehane laryngoscope exposure grade refers to the literature [8], defined as: Grade I allows full visibility of the glottis, Grade II allows

partial visibility of the glottis and the posterior commissure, Grade III allows visibility of only the epiglottis, and Grade IV allows no visibility of the epiglottis or glottis. Endotracheal intubation time is defined as the period from the video laryngoscope blade reaching the lips until the endotracheal tube is confirmed to be in place (three consecutive normal end-tidal carbon dioxide waveforms appear on the monitor). Intubation assistance is defined as including, but not limited to, the need for pressure on the cricoid cartilage or assistance from other physicians.

3.Sample Size Estimation

It is anticipated that 430 subjects will be enrolled.

4.Inclusion/Exclusion Criteria

4.1 Inclusion Criteria

1.Age ≥ 18 years, gender unrestricted;

2.Subjects planned to undergo general anesthesia and require endotracheal intubation;

3.Subjects classified as ASA-PS (American Society of Anesthesiologists Physical Status) Class I, II, and III;

4.Volunteers who participate in this clinical trial and sign the informed consent form.

4.2 Exclusion Criteria

1.Subjects with known airway deformities, tumors, or other structural abnormalities that may affect airway assessment;

2.Subjects with mental abnormalities who cannot cooperate;

Pregnant or lactating women;

3.Subjects who have participated in other interventional clinical trials within 1 month before the start of this trial;

4.Subjects deemed unsuitable for this clinical trial by the investigators.

5. Subject Withdrawal Criteria and Procedures

5.1 Dropout Criteria

Any subject who has signed the informed consent form and qualified for the trial, regardless of when or for what reason they withdraw from the trial, will be considered

a dropout case. This includes: the subject themselves requesting to withdraw from the clinical trial; the investigator considering it medically necessary for the subject to discontinue the trial.

5.2 Criteria and Procedures for Terminating the Trial/Trial Treatment

(1) If significant errors are found in the clinical trial protocol or significant deviations occur during the trial, making it difficult to evaluate the safety and effectiveness of the trial product;

(2) The sponsor (for reasons such as funding, management, etc.) requests the termination of the trial;

(3) The administrative authority revokes the trial.

6. Medical Ethical Requirements

(1) The principal investigator is responsible for the trial and must submit the clinical research protocol and written informed consent form to the Ethics Committee of The First Affiliated Hospital of Chongqing Medical University for approval before the trial can commence.

(2) Before participating in the trial, the subject must provide written informed consent. The investigator must explain the nature, purpose, and risks of the clinical trial to the subject, and ensure that the subject is convinced that they have the right to withdraw from the trial at any time after giving their consent. After due consideration, the subject voluntarily participates in the clinical trial, and both the subject and the investigator sign the informed consent form, noting the date.

IV. Evaluation Methods

1. Effectiveness Evaluation

1.1 Primary Evaluation Indicator:The correlation between the intelligent airway assessment with Articulation and tongue position adjustment, the modified Mallampati grading, and the Cormack-Lehane grading.

1.2 Secondary Evaluation Indicators:

(1) The consistency between different methods of the intelligent airway

assessment system with Articulation and tongue position adjustment;

(2) The accuracy of the intelligent airway assessment with Articulation and tongue position adjustment in predicting difficult airways;

(3) Endotracheal intubation time, the need for assistance, and the number of intubation attempts.

1.3 Methods and Timing for Evaluating, Recording, and Analyzing Effectiveness Parameters

1.3.1 Primary Evaluation Indicator:The correlation between the intelligent airway assessment with Articulation and tongue position adjustment, and the modified Mallampati grading and Cormack-Lehane grading.

Evaluation Criteria:The correlation coefficient will be calculated using the Spearman rank correlation coefficient based on the different assessment results of the same anesthesiologist and their video laryngoscopic Cormack-Lehane grading assessment results. The correlation coefficients will be transformed using Fisher's z transformation and subjected to a z-test.

1.3.2 Secondary Evaluation Indicators

(1) Construct a confusion matrix for the different assessment methods of the new method and calculate the Kappa coefficient: The Kappa coefficient will be calculated based on the data from the confusion matrix. The closer the Kappa coefficient is to 1, the more consistent the observations are. Calculate the positive agreement rate and the negative agreement rate: The positive and negative agreement rates will be calculated based on the confusion matrix to understand the degree of consistency for positive and negative cases.

Table 1 Confusion Matrix

Confusion Matrix		N				
		Grade Ⅰ	Grade Ⅱ	Grade Ⅲ	Grade Ⅳ	Total
A	Grade Ⅰ					

	Grade II					
	Grade III					
	Grade IV					
	Total					

*A: Articulation and Tongue Position Adjustment Software Assessment; N: Physician Assessment of Articulation and Tongue Position Adjustment.

Calculation Formula:

$$Kappa=(1-P_e)/(P_o-P_e)$$

Where, P_o is the observed agreement, i.e., the probability that two observers agree on the classification; P_e is the expected agreement, i.e., the probability of agreement by chance.

Recorded Time Point: During the trial period.

(2) Accuracy in Predicting Difficult Airways: Sensitivity, specificity, positive predictive value, and negative predictive value under each method.

Table 2 Different Method Assessment Results

		Cormack-Lehane Assessment*		Total
		Positive (+)	Negative (−)	
Different Method Assessment**	Positive (+)	a	b	a+b
	Negative (−)	c	d	c+d
Total		a+c	b+d	N

*Cormack-Lehane assessment > Grade 2 is recorded as an anticipated difficult airway; **Different method assessment includes M, N, and A > Grade 2 is recorded as a questionable difficult airway.

Calculation Formulas:

Positive agreement rate = True positive cases / (True positive cases + False negative cases) * 100%

That is, Positive agreement rate = a / (a+c) * 100%

Negative agreement rate = True negative cases / (True negative cases + False positive cases) * 100%

That is, Negative agreement rate = d / (b+d) * 100%

(3) Endotracheal intubation time, need for assistance, number of intubation attempts: Calculate the mean, standard deviation, median, and maximum and minimum values under each method.

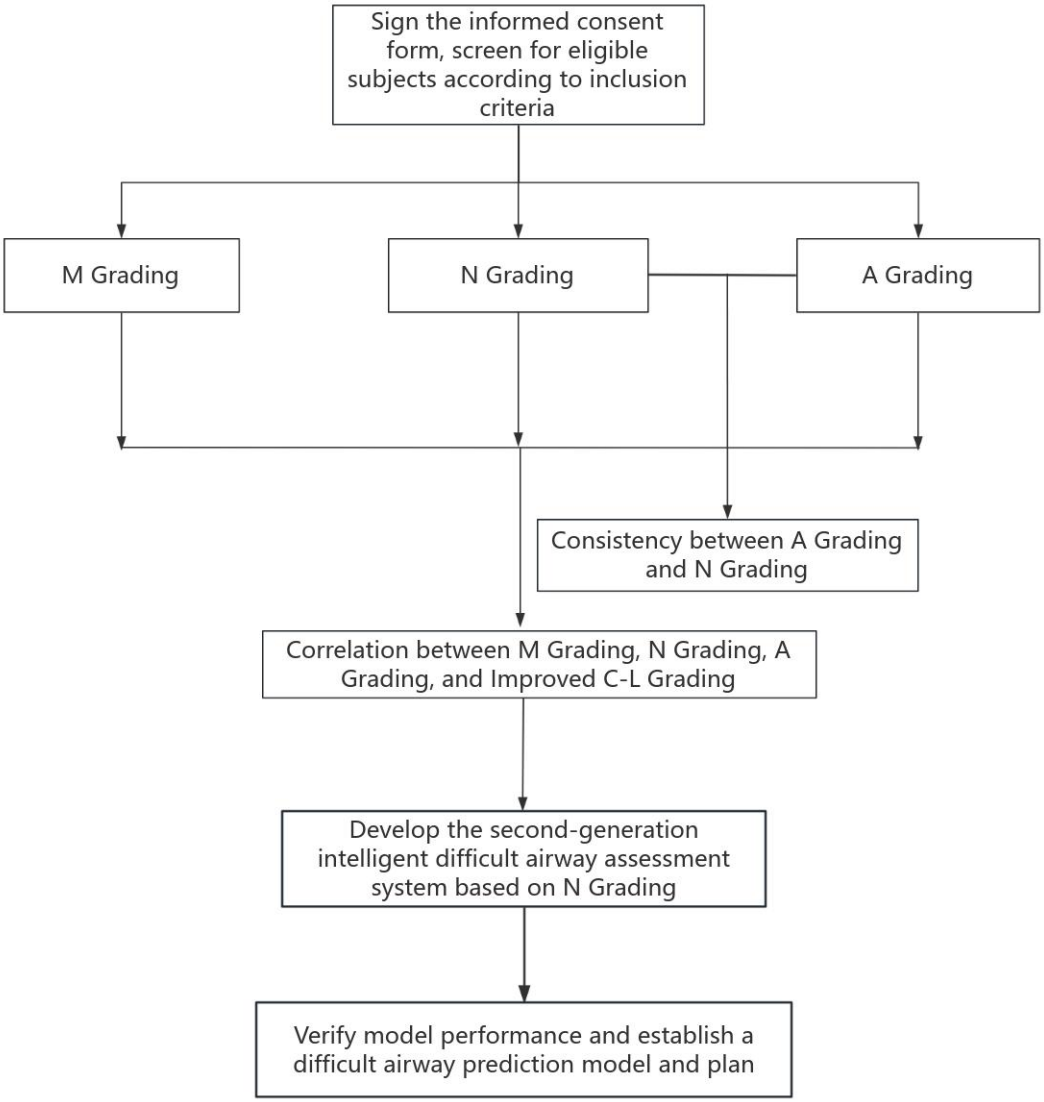
Recorded time point: During the trial period.

2.Safety Evaluation

Complications of endotracheal intubation.

V. Trial Process

1. Research Process



Note：Method M (Standard Modified Mallampati Grading Assessment): The patient sat upright, looked straight ahead, and opened their mouth as wide as possible. The researcher observed the anatomical structures of the patient's pharynx and larynx using the modified Mallampati grading method and assigned a grade.Method N (New Method with Pronunciation and Tongue Extension): The patient sat upright with a slight head extension (10-20°), opened their mouth as wide as possible, relaxed the base of the tongue, extended the tongue outward as much as possible, exhaled, and gently pronounced "ha". The researcher observed the anatomical structures of the patient's pharynx and larynx and assigned a grade.Method A (New Method Combined with Artificial Intelligence Software Assessment): The same as Method N, but the intelligent assessment software graded based on images captured by a camera. The camera was positioned approximately 15 cm from the patient's face and perpendicular to the oral axis.

2. Implementation of the Trial (Methods, Content, Steps, etc.)

Before any trial-related procedures, an informed consent form must be signed, and a unique identification number must be assigned to each subject, which remains unchanged throughout the trial.

2.1 Screening Period (Days -3 to -1)

(1) Sign the informed consent form;

(2) Medical history;

(3) Inclusion/exclusion criteria;

(4) Demographic data (gender, age, height, weight);

(5) Vital signs: temperature, pulse, respiration, blood pressure;

(6) Physical examination.

After obtaining the data from the screening period, the investigator must review it to ensure that the subject is eligible to continue participating in the trial. If the subject does not meet the inclusion criteria or meets the exclusion criteria, the subject is screened out.

2.2 Trial Period

2.2.1 Day 1

(1) The physician assesses the grade based on the modified Mallampati;

(2) The software assesses the grade based on voice modulation and tongue position adjustment;

(3) The physician assesses the grade based on the voice modulation and tongue position adjustment method.

2.2.2 Day 2

(1) Cormack-Lehane grading;

(2) Intubation time, number of attempts, and need for assistance.

2.3 Follow-up Period

(1) Complications related to endotracheal intubation.

VI. Bias Control Measures

Before the start of the clinical trial, the monitor, in conjunction with the principal investigator, should provide training to other researchers on the trial protocol and product use to ensure that researchers understand and master the trial software, protocol, and procedures.

VII. Enrollment Time

The time when the subject signs the informed consent form and meets all inclusion criteria and does not meet any exclusion criteria is the enrollment time.

The expected overall duration of the clinical trial and the reasons for its determination

This trial is an observational study, expected to be completed within 15 months.

The expected duration of each subject's participation

Based on the assessment and follow-up time, combined with the signing of the informed consent form, the maximum expected duration of participation in this clinical study for each subject is 5 days.

The number of subjects required for the clinical trial

This trial is expected to enroll 430 subjects for the trial.

VIII. Statistical Considerations

(I) Sample Size Estimation

The primary outcome measure for sample size estimation is the difference in correlation between the intelligent airway assessment technology with voice modulation and tongue position adjustment and the modified Mallampati grading with the Cormack-Lehane grading. Existing literature has shown that the correlation between the modified Mallampati grading and the Cormack-Lehane grading ranges from 0.5 to 0.9 [6,9]. For this trial, it is assumed that the correlation between the modified Mallampati grading and the Cormack-Lehane grading is 0.70, the

correlation between the software assessment of the intelligent airway assessment technology with voice modulation and tongue position adjustment and the Cormack-Lehane grading is 0.80, and the correlation between the physician assessment of the intelligent airway assessment technology with voice modulation and tongue position adjustment and the Cormack-Lehane grading is 0.90. Using Fisher's z transformation to calculate z-scores, with a predetermined significance level α of 0.05, a power of $1-\beta$ of 0.80, and Bonferroni correction for multiple comparisons, the minimum sample size required for the software assessment method of the intelligent airway assessment technology with voice modulation and tongue position adjustment and the modified Mallampati grading to achieve the target difference is approximately 390 cases, for the physician assessment method approximately 50 cases, and for the comparison between the software and physician assessment methods approximately 150 cases. Considering the research objectives and significance of this trial, the sample size is determined based on the target difference between the modified Mallampati grading and the software assessment method of the intelligent airway assessment technology with voice modulation and tongue position adjustment. With an expected 10% dropout rate, 430 subjects are planned to be included.

(II) Analysis Data Sets

Full Analysis Set (FAS): Refers to the ideal subject set that is as close as possible to the intention-to-treat principle. This data set is derived from all subjects with the least and most reasonable method of subject exclusion.

Per Protocol Set (PPS): Also known as the valid case, valid sample, or evaluable case sample. It is a data set produced by a subset of cases that fully comply with the trial protocol and is a subset of the FAS. Compliance includes considerations such as the treatment received, the feasibility of primary outcome measurements, and no major violations of the trial protocol.

Safety Analysis Set (SS): The set of subjects used for summarizing safety and tolerability assessments is called the safety analysis set.

(III) Subject Exclusion Criteria

1. Subjects who violate the inclusion or exclusion criteria and affect statistics after data review;

2. Subjects whose images cannot be recognized by the software after enrollment or whose tracheal intubation was not performed using a video laryngoscope.

(IV) Statistical Methods

1. Statistical Design

This trial uses a prospective, self-controlled clinical trial design.

2. General Principles

This trial mainly uses descriptive methods, and the main outcome measures calculate confidence intervals.

Quantitative indicators will calculate the mean, standard deviation, median, minimum, and maximum values.

Categorical indicators will describe the number and percentage of each category.

3. Data Analysis Methods

3.1 Subject Characteristics

Baseline demographic analysis: Mainly uses descriptive analysis methods, using quantitative and qualitative data description methods according to the type of data.

3.2 Effectiveness Evaluation Indicators

Primary Effectiveness Indicator:The correlation between the intelligent airway assessment system with voice modulation and tongue position adjustment and the modified Mallampati grading with the Cormack-Lehane grading is calculated according to the evaluation criteria, and the 95% confidence interval of the correlation is calculated.

Secondary Effectiveness Indicators:Accuracy in predicting difficult airways: The positive agreement rate under each method. Tracheal intubation time, need for assistance, number of intubation attempts: Calculate the mean, standard deviation, median, maximum, and minimum values under each method to show the distribution

of these indicators. Complication incidence rate: Calculate the complication incidence rate corresponding to each method and statistically describe it using the number of cases and percentage.

4. Acceptance Criteria for Clinical Trial Results

Not applicable for this trial.

(V) Handling of Missing and Outlier Values

The clinical trial process should be strictly controlled, and there should be no missing values in principle. If a subject is normally included in the clinical trial, the effectiveness evaluation indicators should not be missing. Cases with missing effectiveness evaluation indicators due to subject dropout are not included in the PPS. If missing values occur during the clinical trial process, the missing values are not carried forward and are handled according to missing data procedures.

IX. Risk-Benefit Analysis

(I) Potential Benefits

Participants in this study will receive treatment and care from clinically experienced medical staff and will have individualized subject files established. Through personalized preoperative airway assessment, anesthesiologists can more accurately predict and identify difficult airways, providing subjects with safer and more appropriate anesthetic management strategies. With more accurate airway assessment, anesthesiologists can take appropriate preventive measures and response strategies in advance, reducing complications caused by improper airway management, such as hypoxemia, endotracheal intubation failure, etc. This will directly improve surgical safety, reduce the subject's postoperative recovery time, and medical costs. By participating in this study, subjects will receive medical services that pay more attention to individual differences. Anesthesiologists will be more meticulous and cautious when managing the airway, reducing the subject's preoperative anxiety and intraoperative discomfort, thereby improving overall

satisfaction and surgical experience. The results of this study will help promote the development of medical services towards a more personalized and precise direction. The participation of subjects will not only bring direct benefits to themselves but also provide optimized and safer airway management strategies for future subjects.

(II) Risk Analysis

This study aims to explore and compare the correlation between the intelligent airway assessment system combined with altered patient articulation and tongue position adjustment, the modified Mallampati grading, and the Cormack-Lehane grading, in order to provide more accurate airway management strategies for clinical use. This study will not affect the actual treatment measures of the subjects, only assessing and recording the airway structure of the participants, without involving any invasive interventions. Airway assessment will be conducted by qualified anesthesiologists in this hospital, ensuring the professionalism and safety of the assessment process. The assessment methods selected in this study (modified Mallampati grading and Cormack-Lehane grading) are commonly used airway assessment tools in clinical practice. For software photo shooting, we will strictly implement subject privacy protection measures, including: ① Strictly limit the shooting range: To minimize the risk of privacy leakage, the shooting is limited to the necessary oral and surrounding areas, ensuring that the upper boundary does not exceed the lower edge of the orbit, and the lower boundary does not exceed the chin; ②Photo processing and storage: All photos used for assessment will be automatically deleted from the computer after being uploaded to the dedicated computer for intelligent analysis, without retaining any copies; ③ Data encryption and anonymization processing: Advanced data encryption technology is used to protect the security of transmission throughout the upload and assessment process, and the photos are anonymized to ensure that they cannot be directly associated with specific individuals. Moreover, the operation process does not require the use of additional drugs or invasive operations, so it will not increase the subject's drug costs and medical risks. In addition, this study does not involve additional medical equipment,

and all assessment work is completed in a routine clinical environment, ensuring the simplicity and feasibility of the operation.

In summary, the risks and discomforts of this study are very low. We will take all necessary measures to ensure the safety and comfort of the subjects, and strictly follow ethical principles and standards to protect the privacy and rights of the subjects. Through this study, we hope to provide more accurate airway assessment methods for clinical use, thereby improving surgical safety and subject satisfaction. If any discomfort occurs during the study, we will intervene in time, and our hospital has corresponding operating procedures and measures to ensure the safety of the subjects throughout the process.

X. Quality Control of Clinical Trials

(I) Training of Investigators

Before the start of the clinical trial, the trial unit institution or sponsor should provide necessary training to investigators according to the investigator's manual, product instructions, and clinical protocol.

(II) Measures to Improve Subject Compliance

Investigators should earnestly implement informed consent to ensure that subjects fully understand the trial requirements and cooperate with the trial.

XI. Ethical Issues and Informed Consent of Clinical Trials

(I) Ethical Considerations

Clinical trials must be conducted in accordance with the Declaration of Helsinki and relevant clinical trial research regulations and laws in our country. Before the start of the trial, the trial protocol must be approved by the ethics committee of the responsible unit for the clinical trial before the clinical trial can be implemented.

Before each subject is included in this trial, the research physician has the responsibility to fully and comprehensively introduce the purpose, procedures, and possible risks of this trial in written form to them or their designated representative. Subjects should be informed that they have the right to withdraw from this trial at any time. A written informed consent form must be given to each subject before selection, and the research physician is responsible for ensuring that each subject obtains informed consent before entering the trial, and the informed consent form should be retained as part of the clinical trial documentation.

(II) Informed Consent Process

Before a subject participates in a clinical trial, the researcher should fully explain the details of the clinical trial to the subject or their guardian/legally authorized representative, including known and foreseeable risks and possible adverse events. After a full and detailed explanation, the subject or their legally authorized representative signs the name and date on the Informed Consent Form, and the researcher who performs the informed consent should also sign the name and date on the Informed Consent Form.

The Informed Consent Form should indicate the date it was established or the date of the revised version. If the Informed Consent Form is revised during the trial, the revised version must be reviewed and approved by the ethics committee before it is implemented. After the revised Informed Consent Form is approved and filed with the clinical trial institution, all subjects who have not completed the trial process must sign the newly revised Informed Consent Form.

XII. Provisions for Adverse Events

(I) Definition and Reporting Regulations of Adverse Events

1. Definition of Adverse Events

An adverse event refers to any unfavorable medical occurrence during the clinical trial process, regardless of whether it is related to the trial or not. In this trial, adverse events are recorded starting from the airway assessment.

2. Assessment of the Severity of Adverse Events

Observe the process, degree, treatment, and outcome of adverse events in detail, and fill them out in the adverse event report form. According to the following standards, the severity of adverse events can be divided into five levels:

- Level 1: Mild; asymptomatic or minor; only seen clinically or diagnostically; no treatment needed.

- Level 2: Moderate; requires minor, local, or non-invasive treatment; limitations in instrumentally activities of daily living appropriate for age.

- Level 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospital stay; disability; limitations in self-care activities of daily living.

- Level 4: Life-threatening; requires urgent intervention.

- Level 5: Death related to the adverse event.

3. Evaluation of Adverse Events

Adverse events are evaluated according to four levels of association with the assessment: definitely related, possibly related, possibly unrelated, and definitely unrelated.

- Related to the assessment: (1) There is a reasonable temporal relationship between the two; (2) The known risks of the assessment method or can be explained by the mechanism of the assessment method; (3) The injury is reduced or disappears after stopping the assessment; (4) The injury reappears after reassessing; (5) It cannot be explained by other influencing factors. If all five are met, it is judged as "definitely related"; if two are met, it is judged as "possibly related".

- Unrelated to the assessment: (1) There is no reasonable temporal relationship between the two; (2) The adverse event is a type of event that the assessment could not possibly cause; (3) The adverse event can be explained by concomitant medication/devices, progression of the subject's condition, or other treatments. If all three are met, it is judged as "definitely unrelated"; if one is met, it is judged as "possibly unrelated".

4. Expected Adverse Events and Handling Measures

This trial will not have adverse events directly caused by the assessment. The assessment results generated in this trial need to be confirmed as valid by a physician and are for reference only.

(II) Definition of Serious Adverse Events

1. Definition of Serious Adverse Events

Serious adverse events refer to events that occur during the study process, leading to death or a significant deterioration in health status, including fatal diseases or injuries, permanent defects in body structure or function, hospitalization or prolongation of hospital stay, medical measures needed to avoid permanent defects in body structure or function; events leading to fetal distress, fetal death, or congenital abnormalities, birth defects, etc.

2. Management and Recording of Serious Adverse Events

- Management and recording

1. Any serious adverse event should be handled immediately according to routine.

2. Any serious adverse event must be followed up until it is completely resolved or the treatment is finished.

3. Any serious adverse event should be recorded, including the time of occurrence, diagnosis, diagnosis time, treatment, duration, and sequelae.

4. If a serious adverse event occurs, in addition to the active treatment and recording mentioned above, it should be reported in writing to the principal investigator and the ethics committee within 24 hours.

5. If the death of a subject is related to the study medication, the clinical trial should be immediately stopped, and the incident should be reported to the ethics committee as soon as possible, with detailed records and careful preservation of relevant documents. The ethics committee will decide when the study can resume.

XIII. Provisions for Deviations from and Amendments to the Clinical Trial Protocol

Deviations from the protocol are generally reported regularly to the ethics committee, with the sponsor and/or investigator explaining the cause, impact, and handling measures of the event. After each deviation from the protocol, there should be handling or improvement measures to remedy the mistake or prevent similar deviations from occurring repeatedly.

After this protocol is approved by the ethics committee, any modifications must be documented in a "Protocol Amendment Explanation," signed by the principal investigator, and approved again by the ethics committee before implementation.

XIV. Direct Access to Source Data and Documents

Investigators should allow inspection by the clinical trial institution management department, ethics committee, drug regulatory authority, health administration department, or monitors, auditors, and provide direct access to source data/documents.

XV. Confidentiality Principle

This trial protocol is confidential and is intended for medical experts, researchers, and other trial-related staff involved in this trial, as well as medical institutions, ethics committees, and contract research organizations entrusted with this trial. Except for explaining the situation to the subjects, no content of this trial protocol shall be disclosed or leaked to a third party without the prior written consent of the sponsor. In addition, any part or all of the results of this clinical trial shall not be published externally to societies, magazines, etc., without the written consent of the sponsor.

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