Informed Consent Form

Version Number: 1.0 Date of Issue: 2024.06.1

Introduction to the Study Background:

Dear Patient (Participant),

As you are a patient scheduled for elective tracheal intubation under general anesthesia, you are invited to participate in a study on the exploration and application of intelligent difficult airway assessment schemes conducted by Professor Min Su from the Department of Anesthesiology, The First Affiliated Hospital of Chongqing Medical University. This study aims to demonstrate the effectiveness of different methods for predicting the anatomical structure of the pharynx in patients undergoing elective tracheal intubation under general anesthesia and is expected to last up to 5 days.

This informed consent form provides you with some information to help you decide whether to participate in this clinical study. Your participation in this study is voluntary. This study has been reviewed and approved by the Institutional Review Board (IRB) of this research institution. If you agree to join this study, please read the following explanations:

Please read carefully, and if you have any questions, please raise them

with the researcher responsible for the study.

Purpose of the Study:

Difficult airway is an important challenge in the field of anesthesiology, referring to situations where doctors find it difficult to manage the airway smoothly during surgery or in emergencies. The American Society of Anesthesiologists has provided a detailed definition of difficult airways and proposed some commonly used assessment methods. Research has shown that the incidence of difficult airways varies globally, and China, as a large population country with high demand for healthcare resources, faces particularly prominent challenges with difficult airways.

To more accurately assess patients' airway conditions and improve the efficiency and safety of airway management, researchers have proposed an intelligent airway assessment system that combines changes in patient articulation and tongue position adjustments. This system uses advanced artificial intelligence technology to analyze patients' oral anatomical structures by uploading images and predicting the difficulty of airway management. Compared with traditional methods, this new method has higher accuracy and reliability, especially suitable for remote medical services and intelligent medical systems.

The significance of this study lies in exploring and comparing the correlation between the intelligent airway assessment system and the

modified Mallampati grading and Cormack-Lehane grading, with the aim of establishing a more accurate prediction model for difficult airways to provide more reliable decision support for clinical doctors. At the same time, this study also helps to promote the development of airway management towards a more intelligent and personalized direction, improving the overall quality and efficiency of anesthetic management.

Study Process and Methods:

If you agree to participate in this study, we will number each subject and establish a medical record file. The main content of this study is to assess the effectiveness of different methods in predicting the anatomical structure of the pharynx in patients undergoing elective tracheal intubation under general anesthesia, as well as their impact on the Cormack-Lehane laryngoscope exposure grading, intubation time, number of intubation attempts, and the need for assistance. This trial is a self-controlled study, with an expected number of participants of 430 cases, and the participation time is up to 5 days. The research process includes: pre-screening of subjects to ensure they meet the inclusion criteria (≥18 years old, requiring elective tracheal intubation under general anesthesia). Preoperative airway grading using different methods will be conducted three times on subjects. After induction of anesthesia, the pharyngeal anatomical structure will be exposed using a video laryngoscope, and the Cormack-Lehane grading, intubation time, number

of intubation attempts, and need for assistance will be recorded. The number of follow-ups with subjects will be based on the experimental design, and one or more follow-ups may be required after surgery to ensure complete recording and accuracy of evaluation indicators. For examination operations, operations such as modified mallampati grading, tongue position adjustment, software grading, and direct laryngoscopy will be conducted. If you agree to participate in this study, we will explain the purpose and process of the study to you before your participation and obtain your written consent. During the study, we will respect your privacy and rights and ensure the confidentiality of your medical information.

Possible Benefits of the Study:

Participants in this study will receive treatment and care from clinically experienced medical staff and will have an individualized subject file established. Through individualized preoperative airway assessment, anesthesiologists can more accurately predict and identify difficult airways, thus providing you with safer and more suitable 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, tracheal intubation failure, etc., which will directly improve surgical safety and reduce your postoperative

recovery time and medical costs. By participating in this study, you will receive medical services that pay more attention to individual differences, and anesthesiologists will be more meticulous and cautious when managing the airway, reducing your preoperative anxiety and intraoperative discomfort, thus improving your overall satisfaction and surgical experience. The results of this study will help to promote the development of medical services towards a more personalized and precise direction. Your participation will not only bring direct benefits to yourself but also provide more optimized and safer airway management strategies for future patients.

Research Risks and Discomfort:

This study will not affect the actual treatment of patients. It only involves the assessment and documentation of airway structure, with no invasive interventions. The airway assessment will be conducted by qualified anesthesiologists from our hospital to ensure professionalism and safety. The assessment methods used in this study (Modified Mallampati Classification and Cormack-Lehane Classification) are commonly used tools for airway evaluation in clinical practice. For the photo-taking process, we will strictly implement patient privacy protection measures as follows:

1. Strict limitation of photo-taking scope: To minimize the risk of privacy leakage, the photos will be limited to the oral cavity and the

necessary surrounding areas. The upper boundary will not exceed the lower edge of the eye socket, and the lower boundary will not exceed the chin.

2.Photo processing and storage: All photos used for assessment will be automatically deleted from the computer after being uploaded to a dedicated computer for intelligent analysis, with no copies retained.

3.Data encryption and anonymization: During the entire process of uploading and assessment, advanced data encryption technology will be used to protect the security of the transmission. Photos will also be anonymized to ensure that they be cannot directly linked to any specific individual.

Since no additional drugs or invasive procedures are required during the operation, there will be no additional drug costs or medical risks for the participants. Moreover, no additional medical equipment is involved in this study. All assessments will be conducted in a routine clinical setting, ensuring the simplicity and feasibility of the operation.

Other Treatment Interventions:

Apart from participating in this study, there are no other interventions or treatments.

Privacy Issues:

If you decide to participate in this study, all information about your

participation and personal data will be kept confidential. For example, your examination and assessment information will be identified by a research number rather than your name. Identifiable personal information will not be disclosed to anyone outside the research team unless you give your permission. All research team members and sponsors are required to keep your identity confidential. Your records will be stored in the file cabinet at the First Affiliated Hospital of Chongqing Medical University, accessible only to researchers. To ensure the study is conducted according to regulations, government regulatory authorities or members of the ethics review committee may review your personal data at the research site as required by regulations. If the study results are published, the researchers will also commit to maintaining confidentiality.

Costs and Compensation:

This project is a clinical observational study that only collects disease-related information and clinical data without interfering with your routine treatment and medication. All medications and examinations are required for routine clinical care and must be covered by yourself. The study will not impose any additional financial burden or physical harm on you. If you suffer any damage related to this clinical study, you will be provided with free treatment and corresponding compensation, funded by the project team.

Freedom to Withdraw:

As a participant, you have right the to access information about the study and its progress at any time and can voluntarily decide whether to (continue) participate or not. After joining, you can choose to withdraw from the study at any time for any reason without providing an explanation to the researchers. Your data will not be included in the study results, and your medical treatment and rights will not be affected. If continuing participation in the study causes serious harm to you, the researchers will also the terminate study. However, during the study period, you are required to provide truthful information about your medical history and current health status; inform the study doctor of any discomfort you experience during the study; avoid taking restricted medications or foods; and inform the study doctor if you have recently participated in or are currently participating in other studies. If you fail to comply with the study plan, or if there is any study-related injury or other reasons, the study physician may terminate your participation in the study.

Contact Information:

If you have any questions related to this study, experience any discomfort or injury during the study, or have concerns about the rights of participants, you can contact Dr. Cheng Wenjie at phone number: 17815370965.

Post-Study Benefits:

After the study is completed, the results will be published in domestic and international journals. You can learn about the study results through the researchers.

Informed Consent Signature:

I have read this informed consent form, and my doctor has explained to me in detail the purpose, content, risks, and benefits of this clinical trial. All my questions have been answered. I understand this clinical study and voluntarily agree to participate.

Participant's Signature: _____ **Date:** _____ **Phone Number:** _____

Guardian's Signature: _____ **Date:** _____ **Phone Number:** _____

Relationship to the Participant: _____

Researcher's Signature: _____ **Date:** _____ **Phone Number:** _____