Research Protocol

(Version No. 2.3 Version Date: 2024.08.02)

Project Name ： Observation of the clinical effect of a new oropharyngeal airway in patients with obstructive sleep apnea hypopnea syndrome during painless gastroenteroscopy

Department： Anesthesia and perioperative Medicine

Main Investigator： Jianbo Wu

Investigator Statement and Protocol signature page

As the principal investigator of this research project,Will be guided by the ethical principles of the Guidelines on the Issuance of Ethical Review of Life Sciences and Medical Research Involving Humans (2023), the Ethical Review of Biomedical Research Involving Humans (2016), the WMA Declaration of Helsinki (2013) and the CIOMS International Ethical Guidelines on Biomedical Research on Humans (2002) and the GCP,The study shall be conducted in accordance with the requirements of the protocol approved by the Ethics Committee under the guidance of the quality Management Practice for drug clinical research, in order to ensure the scientific study and protect the health and rights of the study participants.

signature: _____

Date: _____

Scheme summary

Scheme title	Observation of clinical effect of new oropharyngeal airway in patients with obstructive sleep apnea hypopnea syndrome during painless gastroenteroscopy
Version number/version date	Version Number 2.3 Version Date: 2024.08.02
Main Investigator	Jianbo Wu
Nature of the study Prospective	andomized, controlled clinical intervention study
Objective To investigate	the incidence of hypoxia in patients with obstructive sleep apnea hypopnea syndrome who underwent painless gastroenteroscopy using a new type of oropharyngeal airway.
Sample size	130
Subjects Obstructive	sleep apnea hypopnea syndrome patients undergoing painless gastroenteroscopy
Inclusion criteria	(1) Age 18-65 years old (2) evidence of polysleep monitoring for diagnosis of OSAHS (3) written informed consent of patient or family member (4) painless stomach + colonoscopy (5) ASA grade I-II
Exclusion criteria	(1) There is a clotting disorder or a tendency to nose and mouth bleeding, mucosal damage or space occupation,Patients who cannot perform oropharyngeal ventilation (2) upper respiratory tract infections such as mouth, nose or throat (3) fever (core body temperature ≥37.5 ° C) (4) diagnosed pregnancy or breastfeeding (5) allergy to sedatives such as propofol or devices such as tape (6) emergency surgery (7) multiple trauma (8) Breathing air before surgerypO2 < 95% (9) History of drug and/or alcohol abuse (drinking more than three times standard alcoholic beverages per day, equivalent to approximately 10g of alcohol or equivalent to 50g of Chinese liquor) in the 2 years prior to initiation of the screening period (10) Patients with prior psychiatric and neurological conditions:Such as depression, severe central nervous depression, Parkinson's disease, basal ganglia disease, schizophrenia, epilepsy, Alzheimer's disease,

	myasthenia gravis (11) are currently participating in other clinical trials (13) Patients with a history of smoking should not participate in this trial
Research program	Heart rate, pulse oxygen saturation (SpO2), end-expiratory carbon dioxide, ECG monitoring, and noninvasive blood pressure (measured every 3 minutes) were routinely monitored before anesthesia induction.In this study, SAS was used to achieve simple randomization: 1. In the group using the new oropharyngeal airway (test group), oxygen was continuously supplied through a catheter connected to the endoscopic bites until the end of the gastroenteroscopy before induction of anesthesia.2. In the conventional endoscopic bite group (control group), oxygen was continuously supplied through a conventional nasal catheter before induction of anesthesia and until the end of gastroenteroscopy.Before anesthesia induction, patients in the experimental group received 5-6L/min of oxygen for about 1min through the endoscopic bite connecting oxygen supply device, and patients in the control group inhaled 5-6L/min of oxygen for about 1min through the nasal catheter.Propofol 3mg/kg and sufentanil 7μg were used to induce anesthesia in both groups.Sufentanil was given at the beginning of pre-oxygen inhalation, and propofol was given 1min later. When participants achieved sufficient sedation (about BIS40), the new oropharyngeal airway group was placed into the oropharyngeal airway through the endoscopic bite and then began gastroscopy.The ordinary endoscopic bite group began to perform endoscopic operation after sufficient sedation was achieved.In both groups, 5mg/kg·h propofol was injected continuously to maintain anesthesia until the examination was completed.If participants showed frowning or slight body movement during diagnosis and treatment, 40 to 50mg of propofol was added intravenously.If HR < 50 times/intravenous injection of atropine 0.5mg;MAP < 60mmHg intravenous hydroxyamine 1mg;When SpO2 < 92%, artificial airway intervention such as jaw support, assisted breathing or mask was given.After the examination is completed, the patient should not leave the examination room until the MOAA/S is 3-4 points.If the sedation/anaesthesia

	Discharge rating scale scores more than 9 points, patients can be accompanied by relatives and friends.The incidence of hypoxia (75%≤SpO2 < 90%, ≤60s) and severe hypoxia (SpO2 < 75% or 75%≤SpO2 < 90%, ≥60s) during anesthesia were recorded.The incidence of choking, reflux aspiration and laryngeal spasm were recorded.The time of intervention was half or disappearance of end-expiratory carbon dioxide and/or disappearance of thoracic fluctuation and/or SpO2 < 95%, that is, open airway manipulation was taken successively until SpO2≥95%, and the last means of opening the airway was recorded.The means of opening the airway of the two groups were the same, including: 1) adjusting the oxygen flow;2) Lift the lower jaw; 3) Mask ventilation (pull out the gastroscope if necessary);4) Tracheal intubation or laryngeal mask for ventilator assisted ventilation.
Shedding/culling criteria	After postoperative recovery, patients were assessed for adverse reactions. The score of discharge scale after sedation/anesthesia was more than 9 points. Patients could be accompanied by relatives and friends to leave the hospital.
Shedding/culling criteria	Patients who were lost to follow-up, had adverse events, or voluntarily withdrew from the trial
Early exit criteria	Patients with severe airway spasm, obstruction of ventilation, inability to effectively improve airway, and need emergency tracheal intubation or cricothyroid puncture.
Primary outcome measure	Incidence of hypoxia (75%≤SpO2 < 90%, ≤60s) during anesthesia and sedation.
Secondary outcome measure	1, severe hypoxia (SpO2 < 75% or 75%≤SpO2 < 90%, ≥60s) 2, the incidence of airway intervention 3, intraoperative dose of additional drugs 4, endoscopist satisfaction 5, recorded adverse events: choking, laryngeal spasm and reflux aspiration incidence;Apnea or slow breathing episodes (defined as respiratory rate ≤6 beats/min);Bradycardia is defined as a heart rate ≤50 beats/min.Serious adverse events such as tracheal intubation, non-invasive ventilation, use of vasopressors, and hospitalization are required.

Safety index	1. Primary outcome measures: incidence of hypoxia 2. Secondary outcome measures: (1) incidence of airway intervention (2) monitoring of vital signs at different time points 3. Adverse events: (1) Intraoperative laryngeal spasm, reflux aspiration, hypotension, hypoxia saturation, respiratory depression, bradycardia/tachycardia etc. (2) postoperative:Pharyngeal pain, oropharyngeal hemorrhage, wake score, etc. 4. Satisfaction: patient, endoscopist
Statistical analysis method	SPSS22.0 statistical software package was used for statistical analysis, and the measurement data were expressed in the form of mean ± standard deviation (x±S). Independent sample t test was used for statistical analysis of the data with normal distribution or transformed data conforming to normal distribution.For non-normal data, wilcoxon rank sum test was used to compare inter-group analyses.Counting data were represented by frequency (%), and Chi-square test was used for statistical analysis.$P < 0.05$ was considered to be statistically significant.
Research progress plan	1. From July 2024 to August 2024, improve the study design, formulate relevant CRF tables, pass ethics and register online; 2. From August 2024 to May 2025, complete case enrollment; 3. From June 2025 to September 2024, summarize data, make statistical analysis, and write the paper
Form of publication of research results	The results of the study will be published in the form of a paper, and 1-2 articles included in SCI will be published.

一、 Objective

1.Primary outcome measures

To investigate the incidence of novel oropharyngeal airway hypoxia (75%≤ SpO2 < 90%, ≤60s) during anesthesia in patients with obstructive sleep apnea hypopnea syndrome undergoing painless gastroenteroscopy.

2. Secondary outcome measure

(1) Incidence of severe hypoxia (SpO2 < 75% or 75%≤SpO2 < 90%, ≥60s)

(2) The incidence of airway intervention required

(3) the dosage of additional drugs during the operation was recorded

(4) the satisfaction of endoscopists was recorded

(5) Adverse events were recorded: the incidence of choking, laryngeal spasm and reflux aspiration were observed;Apnea or slow breathing episodes (defined as respiratory rate ≤6 beats/min);Bradycardia is defined as a heart rate ≤50 beats/min.Serious adverse events such as tracheal intubation, non-invasive ventilation, use of vasopressors, and hospitalization are required.

3. Exploratory index

To observe whether the use of a new oropharyngeal airway during anesthesia can effectively reduce the incidence of adverse events other than hypoxia in patients with obstructive sleep apnea hypopnea syndrome undergoing painless gastroenteroscopy, and its safety and efficacy.

Research background

In recent years, gastroscopy has been applied more and more in clinical practice. It is a new endoscopic examination technology that finds all possible small lesions in the upper digestive tract (esophagus, stomach, duodenum) of patients through white light gastroscopy, and performs chemical staining, electron staining, optical/electronic amplification, targeted biopsy, etc., for suspicious lesions with indistinguable properties, so as to clarify the nature of the lesions.This technology can improve the diagnostic rate of early gastric cancer and is a major breakthrough in the early diagnosis of gastric cancer [1].Compared with ordinary gastroscopy, gastroscopy takes a longer time (it may take longer if suspicious lesions are found) and intraoperative airway management is more difficult.

Obstructive sleep apnea hypopnea syndrom (obstructive sleep apnea hypoapnea syndrome OSAHS) is a kind of to sleep appear periodically in the process of syndrome characterized by partial or complete obstruction of upper respiratory tract.Patients with obstruction during the attack, faced with percutaneous arterial blood oxygen saturation (percutaneousarterialoxygensaturation, SpO2) to reduce the risk of can also trigger hypercapnia and cardiovascular dysfunction.The global incidence of OSAS is 4.0% in males and 2.0% in females [2].Sedative drugs inhibit the response of OSAS patients to external stimuli and may cause pharyngeal muscle collapse, leading to an increased risk of respiratory adverse events during painless gastroscopy in this population [3].In fact, OSAS has been identified as an independent risk factor for endoscopic hypoxia [4].Currently, there is no special oropharyngeal ventilation device used during gastroenteroscopy. Recently, a new type of oropharyngeal ventilation channel has been developed and applied in clinic.Compared with the conventional nasal catheter, the new oropharyngeal airway nasal mask can better fit the patient's face, ensure the air tightness inside the nose mask and maximize the oxygen supply efficiency. The carbon dioxide outlet connected to the oropharyngeal airway body can not only collect the patient's exhaled gas, but also reduce the backflow of carbon dioxide gas.It can also access carbon dioxide detection equipment to monitor the patient's PCO2 at the end of breath in real time [5-6].In order to evaluate whether the new oropharyngeal airway can reduce the incidence of

hypoxia during painless gastroenteroscopy in general patients, the study was designed to investigate the safety and efficacy of the new oropharyngeal airway.The new oropharyngeal airway is composed of nasal plug, biting mouth, oropharyngeal passage, oxygen supply tube, lanyard and optional accessories carbon dioxide gas catheter and carbon dioxide collection tube.It is used to prevent airway obstruction due to retrolingual fall in patients undergoing endoscopic surgery/examination, and to establish an oropharyngeal airway for study participants while providing nasal oxygen.

【reference】

[1] MUTO M, YAO K, KAISE M, et al. Magnifying endoscopy simple diagnostic algorithm for early gastric cancer (MESDA-G) [J]. Dig Endosc, 2016, 28(4): 379-393.

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Test basis

1. Preliminary literature and experimental basis of this study:

Obstructive sleep apnea hypopnea syndrom (obstructive sleep apnea hypoapnea syndrome OSAHS) is a common sleep-related breathing disorder, as caused by pharyngeal cavity stenosis during the period of sleep apnea and low ventilation.During the time-consuming gastroscopy, patients have certain difficulties in airway management due to the narrow anatomical position of the upper respiratory tract, enhanced local soft tissue collapse, and occupation of the oropharyngeal airway by endoscopist [1-2], and the risk of adverse respiratory events is also higher.At present, the commonly used airway management method is nasal catheter oxygen inhalation.It

has been reported that although nasal high-flow oxygen therapy can reduce the incidence of hypoxia in ordinary patients during painless gastroscopy, its effect on improving ventilation in OSAHS patients is relatively limited [3-4].Painless gastroenteroscopy has been widely used in the diagnosis and treatment of digestive tract diseases, during which the occurrence of intraoperative hypoxia is also concerned.At present, nasal catheter oxygen delivery is widely used clinically to prevent the occurrence of intraoperative hypoxia [5]. In addition, studies have shown that carbon dioxide monitoring can reduce the incidence of hypoxemia, but cannot avoid the occurrence of severe hypoxia [6].However, hypoxia still occurred during the operation (8%) after the application of low flow nasal catheter [7].Previous studies have shown that although new devices such as high-flow nasal catheter oxygen inhalation and supragtal airway injection technology can reduce the incidence of hypoxia, they are difficult to be widely used in clinical practice due to high cost and inconvenience [8,9].Supraglotic jet ventilation devices can reduce the incidence of hypoxia from 9% to 3% [10], but they are costly, prone to adverse events such as nosebleedings, and troublesome to use.High oxygen flow can increase FiO2 to 1.00 and maintain slight PEEP, and produce the effect of dead cavity flushing [11], which further reduces the incidence of hypoxia and increases the minimum oxygen saturation [12], but it is expensive and prone to adverse reactions such as airway dryness, pharyngeal pain and barotrauma [9].The oropharyngeal airway is an important airway auxiliary device for short-term airway management during the perianesthetic period, which can provide patients with an unobtrusived airway during autonomous ventilation [12].The oropharyngeal vent has been proven to be successfully used in infants, the elderly and MRI examinations, and can be used in short outpatient surgery instead of laryngeal mask [13].The oropharyngeal airway has a low incidence of pharyngeal trauma and laryngeal pain immediately after surgery, requiring a shorter exposure time of inhaled anesthetic and a lower concentration of propofol to successfully place it [14].During the operation to preserve spontaneous breathing, the oropharyngeal airway is introduced as a ventilation device [15].The new oropharyngeal airway can accept the implantation of gastroscopy and provide oxygen to patients without affecting the operation at the same time. In order to explore whether the new oropharyngeal airway can provide better oxygen to patients undergoing painless gastroenteroscopy and reduce the incidence of hypoxia during the operation, we have drafted this study and explored the safety of the new oropharyngeal airway in painless gastroenteroscopy.

【reference】

[1] MUTO M, YAO K, KAISE M, et al. Magnifying endoscopy simple diagnostic algorithm for early gastric cancer (MESDA-G) [J]. Dig Endosc, 2016, 28(4): 379-393.
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2. Study participant selection basis

By combining precision medicine with comfortable diagnosis and treatment, painless gastroscopy has become the first choice for the diagnosis and treatment of upper gastrointestinal diseases.Propofol is widely used in painless gastroscopy because of its rapid onset and rapid elimination, but the incidence of hypoxemia is high, which is related to the easy cause of apnea and abnormal ventilation of patients with propofol.Obstructive sleep apnea hypopnea syndrome is a potentially dangerous disease, and is one of the common causes of sudden cardiac death and stroke in clinical practice [1].OSAHS patients, especially those with severe (AHI > 40), have repeated apnea at night, resulting in a long-term state of low blood oxygen at night and serious lack of sleep, and their tolerance to surgery and anesthesia drugs has decreased significantly, especially when accompanied by hypertension, asymptomatic cerebral embolism and other complications, the risk of surgery is greater.Death after operation has been reported at home and abroad [2].However, most severe OSAHS patients not only have palatopharyngeal plane obstruction, but also have multiple plane obstruction at the same time.In order to improve the surgical success rate of OSAHS patients with multiplane obstruction of upper airway, it is necessary to implement comprehensive treatment based on simultaneous combined multiplane surgery for severe OSAHS patients with multiplane obstruction to improve the curative effect, which has been a consensus at present.However, this may cause higher level of postoperative upper airway asphyxia, which puts forward higher requirements for postoperative upper airway management.In order to improve the surgical success rate of OSAHS patients with multi-plane obstruction of upper airway, reduce postoperative respiratory complications, and alleviate patients' pain, nasopharyngeal airway airway and oropharyngeal airway airway are generally recognized as the best methods for postoperative respiratory management.Due to a large amount of fat accumulation in the chest and abdomen of the patient, the total compliance of the chest and lungs is reduced. The lower position of the intubation head under general anesthesia and abdominal surgery will lead to further upward movement of the diaphragm, resulting in decreased thoracic volume, reduced total compliance of the chest and lung, decreased functional residual chest volume, premature closure of small airways, and reduced number of ventilation alveoli.At the same time, the abdominal venous blood is squeezed into the thoracic vein during abdominal surgery, resulting in the accumulation of blood in the chest and the increase of physiologically ineffective cavities, resulting in a decrease in the ventilation/blood flow ratio [3].Airway management in OSA patients is difficult due to excessive fat accumulation in the front neck, lower neck and chest, which leads to limited movement of the neck. In addition, there may be excess tissue in the throat, which leads to airway stenosis.Especially for patients with OSA, induced intubation

must be avoided and conscious intubation under surface anesthesia or guided intubation under fiberoptic bronchoscope should be adopted [4].To sum up, airway management in obese patients is a clinical focus and difficulty. In order to reduce the trauma of patients and promote ERAS, endotracheal intubation is often not possible during the operation of painless gastroenteroscopy. Therefore, it is a topic worthy of our exploration to not only meet the comfort requirements of patients, but also ensure the safety of patients during the whole perioperative period.Whether the birth of new oropharyngeal airway can solve the ventilation problem of obese patients during anesthesia is the significance of this research.

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Research content：

1. Study population

The principal investigator was responsible for recruitment under strict control, and 130 patients with obstructive sleep apnea hypopnea syndrome (diagnosed as OSAHS by polysomnography monitoring) who underwent painless gastrocolonoscopy from today were selected. They were informed and consented to this clinical trial.

2. Sample size calculation：

According to the pre-test results, the incidence of hypoxia in the test group and the control group were 0.2 and 0.5, respectively. The sample size was calculated using PASS software, and the bilateral test level $\alpha=0.05$ and the test efficacy power=0.9

were set. 52 cases were required in each group according to the incidence of hypoxia, and 65 cases in each group were calculated after considering 20% shedding rate, totaling 130 cases.

3. Specific research content：

Study participants entered the examination room to establish intravenous access, using 2% lidocaine gel 5ml containing mouth cavity and pharynx.Heart rate (HR), pulse oxygen saturation (SpO2), end-expiratory carbon dioxide, IPI (composite lung index), ECG monitoring, and non-invasive blood pressure (measured every 2.5 minutes) were routinely monitored before anesthesia induction.Ask patient to lie on left side.

In this study, the investigators planned to implement simple randomization using SAS:

(1) The group using the new oropharyngeal airway (test group) : Oxygen was continuously supplied through a catheter partially attached to the endoscopic mouth before induction of anesthesia until the end of gastroenteroscopy.

(2) In the conventional endoscopic bite group (control group), oxygen was continuously supplied through a common nasal catheter before induction of anesthesia until the end of gastroenteroscopy.

The entire trial operation process was completed by the investigators participating in the clinical trial.Before induction of anesthesia, study participants in the experimental group received 5-6L/min of oxygen for about 1 minute through an endoscopic biting oxygen supply device, and participants in the control group inhaled 5-6L/min of oxygen for about 1 minute through a nasal catheter.Propofol 3mg/kg and sufentanil 7μg were used to induce anesthesia in both groups.Sufentanil was given at the beginning of pre-oxygen inhalation, and propofol was given 1min later. When participants achieved sufficient sedation (about BIS40), the new oropharyngeal airway group was placed into the oropharyngeal airway through the endoscopic bite and then began gastroscopy.The ordinary endoscopic bite group began to perform endoscopic operation after sufficient sedation was achieved.In both groups, 5mg/kg·h propofol was injected continuously to maintain anesthesia until the examination was completed.If participants showed frowning or slight body movement during diagnosis and treatment, 40 to 50mg of propofol was added intravenously.If HR < 50 times/intravenous injection of atropine 0.5mg;MAP < 60mmHg intravenous hydroxyamine 1mg;When SpO2 < 92%, artificial airway intervention such as jaw support, assisted breathing or mask was given.After the examination, study participants were not allowed to leave the examination room until they had a

MOAA/S score of 3-4.If the sedation/anaesthesia Discharge rating scale scores more than 9 points, patients can be accompanied by relatives and friends.The incidence of hypoxia (75%≤SpO2 < 90%, ≤60s) and severe hypoxia (SpO2 < 75% or 75%≤SpO2 < 90%, ≥60s) during anesthesia were recorded.The incidence of choking, reflux aspiration and laryngeal spasm were recorded.The time of intervention was half or disappearance of end-expiratory carbon dioxide and/or disappearance of thoracic fluctuation and/or SpO2 < 95%, that is, opening the airway successively until SpO2≥95%, and recording the last means of opening the airway.

The means of opening the airway of the two groups were the same, including: 1) adjusting the oxygen flow;2) Lift the lower jaw;3) Mask ventilation (pull out the gastroscope if necessary);4) Tracheal intubation or laryngeal mask for ventilator assisted ventilation.

Patient satisfaction scales usually use a 0-10 scale, where 0 is very dissatisfied and 10 is very satisfied.Patients are asked to select a number on the rating scale to indicate satisfaction with medical services or pain relief methods based on their actual experience;

The doctor satisfaction scale also uses a 0-10 scale, with 0 being very dissatisfied and 10 being very satisfied.Endoscopists need to select a corresponding number on the score sheet according to their actual experience to indicate whether the patient is satisfied with the cooperation and response of the operation process.

五、Research Methods

1. Inclusion criteria

130 patients with obstructive sleep apnea hypopnea syndrome who underwent painless gastroenteroscopy in our hospital from now on were selected.

1.1 Inclusion criteria:

1) Age 18-65 years old

2) evidence of OSAHS diagnosed by polysleep monitoring

3) written informed consent of patient or family member

4) painless stomach + colonoscopy

5)ASA grade I-II diagnostic criteria for OSAHS: 1) OSAHS diagnosed by polysleep monitoring (PSG).2. For patients who come to make an appointment for

gastroenteroscopy, the risk assessment results can be given through questionnaires combined with the major risk factors, physical examination, clinical symptoms, etc., which have been identified.For example, the STOP-BANG questionnaire evaluated the risk through eight items including snoring, fatigue, observed apnea, blood pressure, body mass index, age, neck circumference, and gender.For those at higher risk, a diagnosis can be made by providing free polysomnography monitoring (PM) with informed consent.

1.2 Exclusion criteria:

1) Patients with blood clotting disorders or a tendency to oropharyngeal bleeding, mucosal damage or space occupation, difficulty in placing oropharyngeal airway, etc., who cannot perform oropharyngeal airway ventilation;

2) Upper respiratory tract infections such as mouth, nose or throat;

3) Fever (core body temperature ≥37.5℃);

4) a confirmed diagnosis of pregnancy or breastfeeding;

5) Allergic to sedatives such as propofol or equipment such as tape;

6) Emergency surgery;

7) Multiple trauma;

8) SpO2 < 95% before operation;

9) A history of drug and/or alcohol abuse within 2 years prior to the start of the screening period;(Drinking more than three times standard alcoholic beverages per day, equivalent to about 10g of alcohol or equivalent to 50g of Chinese liquor);

10) Patients with previous psychiatric and neurological diseases, such as depression, severe central nervous depression, Parkinson's disease, basal ganglia disease, schizophrenia, epilepsy, Alzheimer's disease, myasthenia gravis;

11) Currently participating in other clinical trials;

12) Patients who are deemed unfit by the investigator to participate in the trial;

13) Patients with a history of smoking should not participate in this study.

1.3 Exclusion/removal criteria

1) The patient voluntarily withdrew the informed consent

2) the operation was cancelled

2. Grouping of study participants:

This study planned to implement simple randomization with SAS: Group 1 was the group using the new oropharyngeal airway (experimental group);The other group was the control group (control group).

3. Blinded/unblinded patients This study was an open trial, and no blinded method was used.

4. Remedial and supportive treatment (necessary treatment measures for the occurrence of SAE related to the study)

(1) Continue to inject propofol with a range of 5ml to achieve the appropriate depth of anesthesia again if coughing, limb struggle and other conditions occur during the procedure;

(2) If severe airway spasm, obstruction of ventilation occur during the operation, and the airway cannot be effectively improved, measures such as mask pressure oxygen, emergency tracheal intubation or cricothyroid puncture should be taken.In the event of intraoperative emergencies and accidents, patients should be treated primarily, and patients should be put in the first place in accordance with clinical routine rescue and treatment of study participants.

5. Study Participant Early withdrawal/Trial termination criteria: Unconditional termination of the trial at any time when a study participant proposes to withdraw from the trial, while still guaranteeing patient safety throughout the process.

Research program

1. Study Participant Management

1) Study participant recruitment methods:The staff participating in this clinical trial was responsible for recruitment under the control of the principal investigator. 130 patients with obstructive sleep apnea hypopnea syndrome (diagnosed as OSAHS by polysomnography monitoring) who met the enrollment criteria and intended to undergo painless gastrocolonoscopy in our hospital were initially screened, and the recruitment materials were distributed to the study participants and their families.

2) Informed consent process: When enlisting study participants, inform study participants and their families of the detailed contents of the study, possible risks and benefits (see informed consent for details) in accordance with the content and requirements of informed consent, obtain consent from study participants and their families, and sign informed consent before anesthesia induction.

3) Check the admission criteria: Participants were selected strictly according to the admission and exclusion criteria, and should be checked before entering the operating room and before anesthesia induction.

2. Safety evaluation procedure: Study participants with oropharyngeal tumor, inflammation, infection, ulcer and other bleeding risk withdrew from the test, and ventilation should not be used.

3. Termination and withdrawal procedures: Study participants with severe airway spasm, obstruction of ventilation, or failure to effectively improve airway, requiring emergency tracheal intubation or cricothyroid puncture, should immediately take life-saving measures and automatically withdraw from the study.

4. This study was conducted in collaboration with the Department of Anesthesia and Perioperative Medicine, the Department of Digestive endoscopy, and the Sleep Disorder Diagnosis and Treatment Center of Neurology.In the stages of study participant recruitment and trial conduct, tasks are allocated according to the professional background and skills of each team member to ensure that everyone's responsibilities are clear and they can work together.

The beginning and end of the experiment

Start: Trial is expected to begin after ethical review in July-August 2024.

End: Clinical trial phase is expected to end in May-June 2025.

Clinical criteria for early termination of trials

Criteria for termination: The study should be terminated if participants had severe airway spasm, obstruction of ventilation, or inability to effectively improve airway, or if emergency tracheal intubation or cricothyroid puncture were required.Or withdrawal of informed consent by study participants requires termination of the trial.

Data security and monitoring Programme

1. Overview of data Management methods Original records refer to all kinds of data, text, charts, pictures and other original materials directly recorded or statistically formed by means of experiment, observation, investigation or data analysis in the process of clinical and scientific research.The original record is the direct record of the original data obtained in the process of scientific experiment, which can be used as the important basic data for in-depth research in different periods.The original test records should be able to reflect the most real and original conditions in the test, and

must be timely, true, accurate and complete, prevent omission and random alteration, and prohibit forgery and fabrication of data. The original test data and materials should be retained for at least 10 years after the complete end of the test.

2. Reporting and collection of adverse events and serious adverse events An adverse event is any adverse symptoms and abnormal signs that occur after the application of an intervention, whether or not the trial has a causal relationship.Any adverse events, including those voluntarily provided by study participants or queried by investigators or detected by monitoring, should be recorded on the CRF and actively managed and followed up closely until remission or stabilization.All adverse events must be tracked, and the case report form should be filled in by the investigator in time to ensure that the content is accurate and the summary is timely.CRF form should not be altered in general, if there are errors that need to be modified, you should sign the amendment and sign the amendment date.Adverse event reports should include: adverse event content (symptoms, signs, abnormal indicators), start and end dates, evaluation of adverse event severity (mild, moderate, alarming), action taken (no action, stop intervention, treatment), adverse event outcome (no adverse prognosis, hospitalization, permanent neurological deficits, death).Any serious adverse event occurring in the course of clinical research, in addition to timely active and effective treatment, the investigator should report the serious adverse event to the ethics committee of the research unit within 24 hours after learning about it.At the same time, the serious adverse event form must be filled in to record the occurrence time, severity, duration, measures taken and outcome of serious adverse events.

3. Medical safety measures If adverse events occur during the study, regardless of whether they are causally related to the intervention measures, the principal investigator should immediately give necessary and appropriate treatment and explain it to the study participants.At the same time, adverse events were followed up until they returned to normal or the principal investigator determined that no further follow-up was necessary.In addition, the principal investigator must record all adverse events in the case report form.

4. Communication with Ethics Committee and superior drug regulatory authorities Conduct clinical trials in accordance with the content of ethical approval, and timely communicate with ethics committee and superior drug regulatory authorities when there are problems encountered in the course of the trial or when the trial plan needs to be modified.Consent is required to change the test protocol.Communicate when there is a problem.

5. The entry and management of the internal data analysis plan shall be the responsibility of the designated data manager.In order to ensure the accuracy of the data, two data managers should independently make two copies of the input and proofread.For problems in the case report, the data manager will produce an answer sheet and send an inquiry to the investigator through the Clinical Ombudsman, who should answer and return as soon as possible.The data manager will modify, confirm and enter the data according to the researcher's answers.

Compliance with ethical principles and related regulations

This trial will be conducted in accordance with the research protocol, the Guidelines for the Ethical Review of Life Sciences and Medical Research Involving Humans (2023), the Guidelines for the Ethical Review of Biomedical Research Involving Humans (2016), the WMA Declaration of Helsinki (2013), and the CIOMS International Ethical Guidelines for Biomedical Research on Humans (2002)Health institutions conducting investigator-initiated Clinical Research Management Measures (Trial) and Ethical Principles of GCP research implement all applicable laws and regulations of the country.Conduct the study only after obtaining written approval from the Ethics Committee (IRB/IEC) on the protocol, informed consent, and study participant recruitment materials/processes.The proposed amendments also require IRB/IEC approval.

Statistical analysis plan

1.Analysis Set

(1) Full analysis Set (FAS) : All randomized study participants who were evaluated for efficacy at least once were deleted from the analysis set for data that were not evaluated for efficacy at least once.

(2) Meeting protocol set (PP) : Study participants in FAS who met the inclusion criteria and did not meet the exclusion criteria, completed the CRF form as planned, and did not use drugs that might affect the efficacy evaluation during the trial.Safety Dataset (SS) : Study participants who received at least one treatment after randomization.

2. Statistical Analysis

(1) The statistical analysis plan will be developed before the end of the trial and determined before the database is locked.Including statistical description and analysis methods, all statistical tests were carried out by bilateral test and SPSS22 was used for

statistics.For patient information, if it is a continuous variable and follows normal distribution, it is described by mean ± standard deviation, and the difference between groups is compared by T-test.Those who did not follow the normal distribution were expressed as the median (upper and lower quartile), and the difference between groups was compared using the non-parametric rank sum test (Mann-WhitneyU test).For categorical variables such as the incidence of hypoxia, the frequency and rate (or composition ratio) were expressed, and the difference between groups was compared by Chi-square test or Fisher exact probability method.

(2) Main indicators:

1) Intraoperative hypoxia was described by frequency (incidence) and Chi-square test or Fisher analysis was intended to determine whether there was a difference in the incidence of hypoxia between the two groups. Test $P < 0.05$ was considered statistically significant, and confidence interval was 95%.

2) Processing of missing data: Missing data or illogical data delete cases with missing values or use missing value filling methods (mean interpolation, maximum likelihood estimation, or multiple interpolation, etc.).

3) It is planned to collect clinical data and CRF tables of all subjects for examination, data entry and statistical analysis before May 2025.

Description of the new oropharyngeal airway used in the test

This product is produced and sold by Shanghai Elifu Medical Technology Co., LTD., and has been officially put into clinical use in March 2023.The product is named oropharyngeal airway for disposable endoscope, which is composed of nasal plug, bite, oropharyngeal channel, oxygen supply tube, lanyard and optional accessories carbon dioxide gas catheter and carbon dioxide collection tube.The model used in this study is JK (Oropharyngeal airway for endoscope with end-expiratory carbon dioxide Collection) with L/M/S three specifications, which is used to prevent airway obstruction caused by backward tongue fall during endoscopic surgery/examination, establish oropharyngeal airway for patients, and provide nasal oxygen at the same time.Usage: 1) Put the bite into the patient's mouth and fix it behind the patient's head with an elastic lashing rope;2) One end of the oxygen supply tube is connected to the oxygen delivery interface at the bite of the inlet pharynx vent, and the other end is connected to the center for oxygen supply and pre-oxygen delivery;3) According to routine clinical procedures, the

patient was implanted into the oropharyngeal channel after anesthesia;4) When the JK/JK1 type is used, connect the carbon dioxide gas pipe with the carbon dioxide collection pipe, and connect the carbon dioxide collection pipe connection port to the carbon dioxide monitoring device;5) Endoscopic operation can be started;6) Patients were monitored with oxygen inhalation and end-expiratory carbon dioxide collection during endoscopic surgery or examination.This product should be operated by professional personnel, and the medical personnel using this product should be trained in the corresponding technology.

How research results are published

The results of the study will be published in the form of a paper, and 1-2 articles included in SCI will be published.