Project Name: The Influence of Ciprofol on Left Ventricular Outflow Tract Velocity-Time Integral (VTI) in Elderly Patients Undergoing Painless Colonoscopy

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Project Name	Influence of Ciprofol on Left Ventricular Outflow Tract Velocity-Time Integral (VTI) in Elderly Patients Undergoing Painless Colonoscopy
Research Objective	This study intends to randomly assign elderly patients scheduled for painless colonoscopy to the propofol group and ciprofol group, and compare the left ventricular outflow tract VTI at 2 minutes after drug administration between the two groups to evaluate the effects of the two anesthetics on cardiac systolic function in elderly patients undergoing painless colonoscopy, so as to provide guidance for anesthetic selection in painless colonoscopy.
Research Design	Single-center, randomized, double-blind, controlled study
Total Number of Cases	120 cases
Case Selection	Inclusion Criteria: (1) ASA physical status classification I-III; (2) Age ≥ 65 years and ≤ 80 years; (3) BMI between 18-30 kg/m² (including critical values); (4) Patients scheduled for elective painless colonoscopy; (5) Subjects voluntarily participate in this study and sign the informed consent form.
	Exclusion Criteria: (1) Patients with respiratory depression or high risk of respiratory depression (e.g., sleep apnea syndrome, bronchial asthma, etc.); (2) Patients with severe hepatic/renal insufficiency, neurological and psychiatric diseases, or other major illnesses; (3) Patients with severe aortic regurgitation, atrial fibrillation, tachycardia (heart rate > 120 beats/minute), grade II or higher atrioventricular block, or other severe arrhythmias; history of

	myocardial infarction or unstable angina within 6 months before the examination; NYHA classification II or higher; (4) Allergy or abuse of any drug used in the study; (5) Participation in other clinical trials within the recent 3 months.
Treatment Plan	Experimental Group (Group C): Intravenous injection of ciprofol at 0.2-0.5 mg/kg during anesthesia induction (injection rate > 30 seconds) Control Group (Group P): Intravenous injection of propofol at 1-2 mg/kg during anesthesia induction (injection rate > 30 seconds)
Efficacy Evaluation	1. Primary Outcome Measure: Left ventricular outflow tract VTI measured by transthoracic echocardiography at 2 minutes after drug administration (T1). 2. Secondary Outcome Measures: (1) Adverse events: incidence of hypotension, injection pain, nausea, vomiting, hypoxemia (oxygen saturation ≤ 90%), bradycardia (heart rate < 50 beats/minute), body movement (unconscious limb movement of patients), intraoperative awareness. (2) Sedation success rate: completion of colonoscopy without the need for rescue sedatives, with a maximum of 5 supplementary doses within 15 minutes after the initial dose. (3) Induction time: time from the start of drug administration to Modified Observer's Assessment of Alertness/Sedation (MOAA/S) score ≤ 1. (4) Recovery time: time from the end of the last drug administration to MOAA/S score = 5. (5) Operation time: time from colonoscope insertion to withdrawal. (6) Induction drug dose (mg), additional dose (mg), total dose (mg), and dosage of vasoactive drugs (mg). (7) Patient satisfaction: patients' satisfaction with anesthesia, divided into 5 options: very satisfied, satisfied, average, dissatisfied, very dissatisfied. (8) Left ventricular ejection fraction (LVEF) measured by transthoracic echocardiography before drug administration (T0), at 2 minutes after drug administration (T1), and at the time of leaving the room (T2).

	(9) Left ventricular outflow tract VTI measured by transthoracic echocardiography before drug administration (T0) and at the time of leaving the room (T2). (10) Inferior vena cava collapse index measured by transthoracic echocardiography before drug administration (T0). 3. Safety Evaluation Indicators: Vital signs: pulse, blood pressure, SpO2
Statistical Methods	Statistical analysis was performed using SPSS 26.0 software. The significance level was set at $\alpha = 0.05$, with $P < 0.05$ indicating a statistically significant difference. Continuous data with normal distribution were expressed as mean ± standard deviation ($x \pm s$), and comparisons between groups were made using two independent samples t-test. Repeated measurement indicators at different time points were analyzed by repeated measures analysis of variance. Continuous data with non-normal distribution were expressed as median (M) and interquartile range (IQR), and comparisons between groups were made using Mann-Whitney U test. Count data were expressed as case numbers or rates, and comparisons between groups were made using chi-square test or Fisher's exact test. Rank sum test was used for comparison of ranked data. The normality of data distribution was determined using Kolmogorov-Smirnov test for continuous data.

I. Research Background

Currently, colonoscopy is the most common and reliable method for the diagnosis and treatment of intestinal diseases [1], which is significantly associated with reduced cancer incidence and mortality. Although the duration of colonoscopy is relatively short, it can easily cause patient discomfort such as vomiting, frequent body movements, and low satisfaction among both surgeons and patients [2][3]. With the development of comfortable medical care, the number of patients choosing painless colonoscopy is gradually increasing [4], and propofol is the preferred anesthetic. However, in elderly patients undergoing painless colonoscopy, propofol may cause cardiovascular events such as hypotension and arrhythmias [6]. The occurrence of these side effects is closely related to the following factors: first, volume depletion due to bowel preparation; second, elderly patients have reduced tolerance to anesthetics due to declining organ function, and their coronary flow reserve is reduced, making them more sensitive to perioperative ischemia and hypoxia [7]; in addition, anesthetics may increase these risks by inhibiting myocardial function and dilating peripheral blood vessels.

The decline in cardiac systolic function in elderly patients may be due to changes in cardiac structure, such as aging and reduction in the number of cardiomyocytes [8][9]. When the body encounters stress such as infection or surgery, this pathological state can increase the risk of acute decompensated heart failure [10]. Heart failure is the main cause of death in various cardiovascular diseases [11].

With technological advancements, various monitoring devices such as Swan-Ganz floating catheters can be used to evaluate cardiac function and hemodynamic status, but they still have limitations, such as invasiveness, many complications, and high cost. Transthoracic echocardiography can qualitatively and quantitatively evaluate the global and local systolic function of the left ventricle [11], and as a monitoring method for cardiac assessment in non-intubated patients, it has the advantages of non-invasiveness and simplicity [12]. Transthoracic Doppler echocardiography measures parameters in the apical view, including left ventricular outflow tract VTI and left ventricular ejection fraction (LVEF). Left ventricular systolic function is a key indicator reflecting hemodynamic changes in the left ventricle [13]. Studies have shown that changes in LVEF cannot fully describe systolic function changes in the aging heart [8]. Left ventricular outflow tract VTI is an indicator for evaluating cardiac systolic function and cardiac output [11]. Low cardiac output is a precursor to cardiogenic shock and multiple organ dysfunction [14]; even if cardiac contractility decreases (e.g., in heart failure patients with low ejection fraction), cardiac output may sometimes remain normal. In patients with tachycardia due to cardiogenic shock and left ventricular dysfunction, the increased heart rate can partially offset the decline in left ventricular function to maintain cardiac output, but the left ventricular outflow tract VTI will still decrease [15]. Cardiac output = stroke volume (SV) × heart rate, and SV = $\pi \times r^2 \times VTI$. Here, r is the radius of the left ventricular outflow tract measured in the parasternal long-axis view of the left ventricle, and VTI is the velocity-time integral calculated from the left ventricular outflow tract blood flow spectrum obtained by pulsed Doppler in the apical five-chamber view. Since the left ventricular outflow tract is elliptical, the calculation of its area using the radius is a major source of error in deriving cardiac output [16]; therefore, left ventricular outflow tract VTI can be directly used to replace Doppler-derived cardiac output.

Propofol has a rapid onset time of approximately 30 seconds [19] and a peak time of approximately 90 seconds [20], with good pharmacokinetic properties and almost no residual effects. It is currently widely used for sedation in endoscopic procedures, but it still has many drawbacks, such as a narrow therapeutic window, injection pain, hypotension, and respiratory depression [21]. Studies have found that the incidence of hypoxemia and hypotension associated with propofol sedation is 6.9%-17% and 6%-15.6%, respectively [22].

Ciprofol is a 2,6-disubstituted phenol derivative. Based on the chemical structure of propofol, a cyclopropyl group is introduced, which increases its affinity for GABA receptors and stereoeffect, so its efficacy is 4-5 times that of propofol [23]. Studies have shown that intravenous injection of ciprofol at 0.4 mg/kg is the optimal dose for inducing deep sedation, equivalent to intravenous injection of propofol at 2 mg/kg, with higher safety [24][25]. Ciprofol gradually takes effect 1 minute after administration, reaches peak efficacy at approximately 2 minutes, and begins to recover within 10-18 minutes [26]. It is mainly metabolized in the liver and excreted by the kidneys, with an elimination half-life of 1.58-2.47 hours. Its main

metabolite is M4, a conjugate of ciprofol and glucuronic acid, which is neither active nor toxic, so ciprofol has a fast recovery time. In addition, ciprofol has fewer adverse effects. Studies have found that the incidence of hypotension, injection pain, and respiratory depression during ciprofol anesthesia is lower than that of propofol, possibly because the introduction of the cyclopropyl group increases the lipid solubility of the drug and reduces the concentration of free drugs [21].

Currently, there are many studies on the incidence of hypotension between ciprofol and propofol in elderly patients, but few further observe other hemodynamic indicators. This study aims to analyze the influence of ciprofol and propofol on left ventricular outflow tract VTI in elderly patients undergoing painless colonoscopy, further explore the reason why the incidence of hypotension with ciprofol is lower than that with propofol, in order to provide guidance for anesthetic selection in painless colonoscopy.

II. Research Objectives

1. Primary Objective: To investigate the influence of ciprofol on left ventricular outflow tract VTI in elderly patients undergoing painless colonoscopy.

2. Secondary Objectives: To explore the incidence of hypotension in elderly patients undergoing painless colonoscopy with ciprofol; whether ciprofol can reduce the incidence of injection pain, nausea, vomiting, hypoxemia (oxygen saturation ≤ 90%), and bradycardia (heart rate < 50 beats/minute); as well as the sedation success rate, induction time, recovery time, and operation time of ciprofol, and to observe patients' satisfaction with anesthesia.

III. Research Design

1. Research Type: Single-center, randomized, double-blind, controlled trial.

2. Randomization: A computer-generated random sequence will be used, with a 1:1 allocation ratio to Group C (ciprofol group) or Group P (propofol group). The random sequence will be concealed in sealed opaque brown envelopes. Before colonoscopy, an anesthetic nurse not involved in patient enrollment, perioperative care, or data collection will open the sealed envelopes and assign patients to receive ciprofol or propofol anesthesia according to the random results. Ciprofol and propofol will be uniformly prepared into injections of equal volume (20 ml) with consistent appearance. Anesthesia will be administered by a non-blinded physician, while all ultrasound data will be collected by the same blinded ultrasound researcher, and all other clinical data will be collected by the same blinded researcher. Patients will be blinded to the group assignment.

IV. Case Selection

1. Inclusion Criteria:

(1) ASA physical status classification I-III;

(2) Age ≥ 65 years and ≤ 80 years;

(3) BMI between 18-30 kg/m² (including critical values);

(4) Patients scheduled for elective painless colonoscopy;

(5) Subjects voluntarily participate in this study and sign the informed consent form.

2. Exclusion Criteria:

(1) Patients with respiratory depression or high risk of respiratory depression (e.g., sleep apnea syndrome, bronchial asthma, etc.);

(2) Patients with severe hepatic/renal insufficiency, neurological and psychiatric diseases, or other major illnesses;

(3) Patients with severe aortic regurgitation, atrial fibrillation, tachycardia (heart rate > 120 beats/minute), grade II or higher atrioventricular block, or other severe arrhythmias; history of myocardial infarction or unstable angina within 6 months before the examination; NYHA classification II or higher;

(4) Allergy or abuse of any drug used in the study;

(5) Participation in other clinical trials within the recent 3 months.

3. Exclusion Criteria

(1) Change in anesthesia plan;

(2) Dropout during the study;

(3) Inadequate bowel preparation;

(4) Occurrence of severe postoperative complications or unplanned ICU admission;

(5) Inability to monitor data via transthoracic ultrasound;

(6) Operation time exceeding 20 minutes;

(7) Patients with inferior vena cava collapse index (IVC-CI) > 50% and end-inspiratory inferior vena cava width (IVCMAX) ≤ 2.1 cm (hypovolemia) or IVC-CI < 50% and IVCMAX > 2.1 cm (hypervolemia) before induction.

V. Research Methods and Technical Route

1. Names and Specifications of Research Drugs

(1) Generic name: Propofol Injectable Emulsion

Specification: 20 ml: 0.2 g

Approval number: National Medical Products Administration (NMPA) Approval HJ20150655

Manufacturer: Beijing Fresenius Kabi Pharmaceutical Co., Ltd.

(2) Generic name: Ciprofol Injection

Specification: 20 ml: 50 mg, 5 vials/box

Approval number: NMPA Approval H20200013

Manufacturer: Shenyang Haishi Pharmaceutical Co., Ltd.

2. Treatment Plan

(1) Examination Room:

All patients will fast for 8 hours and abstain from water for 4 hours before the procedure, and receive oral compound polyethylene glycol electrolyte powder for bowel preparation. An intravenous access with an indwelling needle will be established, and lactated Ringer's solution will be infused at 8-10 ml/kg. Upon arrival at the examination room, patients will be placed in the left lateral position, and a monitor (Mindray Bio-Medical Electronics Co., Ltd., NMPA Approval 20153210922) will be connected for routine monitoring of heart rate (HR), pulse oxygen saturation (SpO2). An appropriately sized electronic sphygmomanometer cuff will be fixed on the patient's right upper limb, and the average of two consecutive systolic blood pressure measurements will be taken as the baseline systolic blood pressure, followed by blood pressure measurements every 2 minutes using the electronic sphygmomanometer. HR, SpO2, and mean arterial pressure (MAP) before drug administration will be recorded. Meanwhile, the same ultrasound device (General Electric Medical Systems, Product No.: 6194065WX0) will be used with standardized parameters (gain, depth, frequency). At the end of expiration, left ventricular outflow tract VTI and LVEF will be measured by transthoracic Doppler echocardiography, and the inferior vena cava collapse index will be measured.

After nasal cannula oxygen inhalation at 4 L/min, anesthesiologists will start intravenous injection of ciprofol at 0.2-0.5 mg/kg or propofol at 1-2 mg/kg at a constant rate (injection rate > 30 seconds). Colonoscopy can be started when the patient's MOAA/S score ≤ 1 and there is no corneal reflex, and the induction time will be recorded. MOAA/S assessments will be performed every 30 seconds during anesthesia induction and every 2 minutes during maintenance. If the patient shows signs of body movement, verbal response, or painful expressions during the examination, additional sedatives will be administered (0.1 mg/kg for the ciprofol group, 0.5 mg/kg for the propofol group). If the ideal sedation level cannot be achieved after 5 additional doses in the ciprofol group, rescue propofol (20-50 mg) will be administered as needed. HR, SpO2, and MAP will be recorded at 2 minutes after drug administration. Meanwhile, left ventricular outflow tract VTI and LVEF will be measured by transthoracic Doppler echocardiography at the end of expiration. Intravenous injection of ciprofol or propofol will be stopped when the colonoscope reaches the ileocecal valve.

(2) Recovery Room:

After the examination, patients will be transferred to the recovery room, given nasal cannula oxygen inhalation at 4 L/min in the left lateral position, and vital signs will continue to be monitored. Patients can leave the recovery room when the Steward score ≥ 4 after awakening. HR, SpO2, and MAP at the time of leaving the room will be recorded, and left ventricular outflow tract VTI and LVEF will be measured by transthoracic Doppler echocardiography at the end of expiration. Adverse events during the operation such as hypotension, sinus bradycardia, hypoxemia, nausea, vomiting, body movement, injection pain, and intraoperative awareness will be recorded. Operation time, recovery time, and patient satisfaction will be recorded after the operation. After unblinding at the end of the

study, the induction dose, additional dose, total dose of anesthetics, and dosage of vasoactive drugs will be additionally recorded.

(3) Regulation Plan

① In case of hypoxemia (oxygen saturation ≤ 90%) during the examination, first increase the oxygen flow rate and perform jaw thrust; if not relieved, 暂停内镜检查，perform mask-assisted ventilation, and if necessary, insert a nasopharyngeal airway or laryngeal mask airway for assisted ventilation.

② In case of bradycardia (heart rate < 50 beats/minute), intravenous injection of atropine 0.5 mg will be administered.

③ In case of hypotension (systolic blood pressure decrease by more than 20% from the baseline), intravenous injection of norepinephrine bitartrate 8 μg or ephedrine 5 mg will be administered.

VI. Observation Items and Detection Time Points

1. Primary Outcome Measure:

Left ventricular outflow tract VTI measured by transthoracic echocardiography at 2 minutes after drug administration (T1).

2. Secondary Outcome Measures:

(1) Adverse events: incidence of hypotension, injection pain, nausea, vomiting, hypoxemia (oxygen saturation ≤ 90%), bradycardia (heart rate < 50 beats/minute), body movement (unconscious limb movement of patients), intraoperative awareness.

(2) Sedation success rate: completion of colonoscopy without the need for rescue sedatives, with a maximum of 5 supplementary doses within 15 minutes after the initial dose.

(3) Induction time: time from the start of drug administration to MOAA/S score ≤ 1.

(4) Recovery time: time from the end of the last drug administration to MOAA/S score = 5.

(5) Operation time: time from colonoscope insertion to withdrawal.

(6) Induction drug dose (mg), additional dose (mg), total dose (mg), and dosage of vasoactive drugs (mg).

(7) Patient satisfaction: patients' satisfaction with anesthesia, divided into 5 options: very satisfied, satisfied, average, dissatisfied, very dissatisfied.

(8) LVEF measured by transthoracic echocardiography before drug administration (T0), at 2 minutes after drug administration (T1), and at the time of leaving the room (T2).

(9) Left ventricular outflow tract VTI measured by transthoracic echocardiography before drug administration (T0) and at the time of leaving the room (T2).

(10) Inferior vena cava collapse index measured by transthoracic echocardiography before drug administration (T0).

3. Safety Evaluation Indicators: pulse, blood pressure, SpO2.

VII. Efficacy Evaluation Criteria

(1) Modified Observer's Assessment of Alertness/Sedation (MOAA/S) Scale

Level	Description
5	Fully awake, normal response to name called in normal tone
4	Dull response to name called in normal tone
3	Response to repeated loud calling of name
2	Response to mild stimulation or shaking
1	Response to trapezius squeeze (including active and reflex withdrawal)
0	No response to painful stimulation (trapezius squeeze)

(2) Steward Recovery Scale: Evaluated from three aspects: level of consciousness, patency of airway, and degree of limb movement

Level of Consciousness	Fully awake	2 points
	Responsive to stimulation	1 point
	Unresponsive to stimulation	0 point
Airway Patency	Able to cough on command	2 points
	Able to maintain airway patency without support	1 point
	Airway requires support	0 point
Limb Movement	Purposeful limb movement	2 points

	Unconscious limb movement	1 point
	No limb movement	0 point

VIII. Observation of Adverse Events

(1) In case of hypoxemia (oxygen saturation ≤ 90%) during the examination that cannot be improved by jaw thrust, ventilation via mask or endotracheal intubation will be required.

(2) In case of bradycardia (heart rate < 50 beats/minute), intravenous injection of atropine 0.5 mg will be administered.

(3) In case of hypotension (systolic blood pressure decrease by more than 20% from the baseline), intravenous injection of norepinephrine bitartrate 8 μg or ephedrine 5 mg will be administered.

IX. Quality Control and Quality Assurance (Determined based on the specific circumstances of the project)

(1) The trial protocol must be strictly followed throughout the trial period;

(2) All results must be accurately recorded to ensure the reliability of the data;

(3) Monitors and other instruments used during the study will be regularly inspected and calibrated to ensure their normal operation;

(4) Statisticians and investigators will conduct rigorous data analysis.

X. Data Safety Monitoring

A corresponding data safety monitoring plan will be formulated based on the risk level of the clinical study. All adverse events will be recorded in detail, properly managed, and followed up until they are properly resolved or the condition stabilizes. Serious adverse events and unexpected events will be reported to the Ethics Committee, competent authorities, sponsors, and drug regulatory authorities in a timely manner in accordance with regulations; the principal investigator will regularly review all adverse events cumulatively, and if necessary, hold an investigator meeting to evaluate the risks and benefits of the study; emergency unblinding may be performed in double-blind trials to ensure the safety and rights of subjects; studies with more than minimal risk will arrange for an independent data monitor to monitor the study data, and high-risk studies will establish an independent data safety monitoring committee to monitor the accumulated safety and efficacy data and make recommendations on whether to continue the study.

XI. Statistical Analysis

Statistical analysis was performed using SPSS 26.0 software. The significance level was set at $\alpha = 0.05$, with $P < 0.05$ indicating a statistically significant difference. Continuous data with normal distribution were expressed as mean ± standard deviation ($x \pm s$), and comparisons between groups were made using two independent samples t-test. Repeated measurement indicators at different time points were analyzed by repeated measures analysis of variance. Continuous data with non-normal distribution were expressed as median (M) and interquartile range (IQR), and comparisons between groups were made using Mann-Whitney U test. Count data were expressed as case numbers or rates, and comparisons between groups were made using chi-square test or Fisher's exact test. Rank sum test was used for comparison of ranked data. The normality of data distribution was determined using Kolmogorov-Smirnov test for continuous data.

XII. Ethics of Clinical Research

Clinical research will comply with relevant regulations such as the World Medical Association Declaration of Helsinki. Before the start of the study, clinical research will be implemented only after the trial protocol is approved by the Ethics Committee. Before each subject is enrolled in the study, the investigator is responsible for fully and comprehensively introducing the purpose, procedures, and possible risks of the study to the subject or their agent, and obtaining a signed informed consent form. Subjects should be informed that they have the right to withdraw from the study at any time, and the informed consent form should be retained as a clinical research document for future reference. The privacy and data confidentiality of subjects will be protected during the study.

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Informed Consent Form

Protocol Name: Influence of Ciprofol on Left Ventricular Outflow Tract Velocity-Time Integral in Elderly Patients Undergoing Painless Colonoscopy

Protocol Version: V1.3, Version Date: May 15, 2025

Informed Consent Form Version: V1.3, Version Date: May 15, 2025

Research Institution: Lianyungang First People's Hospital

Principal Investigator (Responsible Research Physician): Zhao Zhibin

You are invited to participate in a clinical study. This notice provides you with information to help you decide whether to join this clinical study. Please read it carefully and feel free to ask the investigator in charge of the study any questions.

Your participation in this study is voluntary. This study has been reviewed and approved by the Ethics Committee of our institution.

1. Research Objectives

Gastrointestinal endoscopy is an important method for the diagnosis and treatment of gastrointestinal diseases, but patients may experience discomfort during traditional examinations. With the development of comfortable medical care, painless gastrointestinal endoscopy has gradually become a trend. This study aims to compare the application effects of ciprofol and propofol in painless gastrointestinal endoscopy to provide guidance for clinical anesthetic medication.

2. Research Process

You will be randomly assigned to either the ciprofol group or the propofol group. During anesthesia induction, you will receive an intravenous injection of ciprofol or propofol. During the study, we will assess your cardiac function and hemodynamic indicators through monitoring methods such as transthoracic echocardiography. We will carefully record your vital signs, adverse events, and medication use throughout the process.

3. Possible Risks and Inconveniences

All information about you will be kept confidential. You may experience pain or discomfort during drug injection, cardiovascular events such as blood pressure fluctuations and arrhythmias, respiratory problems such as respiratory depression and hypoxemia, as well as other unknown risks. Although we will take all necessary measures to ensure your safety, we cannot completely eliminate the occurrence of the above risks.

4. Expected Benefits

Echocardiographic monitoring of your heart will provide necessary suggestions for your treatment or useful information for disease research.

5. Privacy Protection

If you decide to participate in this study, your participation and personal data in the study will be kept confidential. The responsible research physician and other research personnel will use your medical information for research purposes. Information that can identify your identity will not be disclosed to members outside the research team unless you provide permission. All research members and the sponsor are required to keep your identity confidential. Your files will be stored in a locked cabinet for access by research personnel only. To ensure the study is conducted as specified, members of government regulatory agencies or the Ethics Committee may, as required, review your personal data at the research site. When the study results are published, no personal information about you will be disclosed.

6. Compensation

In the event of injury related to your participation in this study: If damage occurs due to the clinical study, you may receive free treatment and/or corresponding compensation.

7. Rights of Subjects and Researchers

You have the right to choose not to participate in this study or to withdraw at any time by notifying the investigator. Your data will not be included in the study results, and your medical treatment and rights will not be affected in any way.

The research physician may terminate your participation in the study if you require other treatments, fail to comply with the study plan, suffer study-related injuries, or for any other reason.

You can stay informed about the information and progress of this study at any time. If new safety information related to the study emerges, we will notify you promptly. If you have questions about this study, experience any discomfort or injury during the study, or have concerns regarding the rights of study participants, you can contact Wang Yunyan at 13477980772.

8. Obligations of Subjects

As a study subject, you have the following responsibilities: Provide truthful information about your medical history and current physical condition. Inform the research physician of any discomfort you experience during the study. Refrain from taking restricted medications, foods, etc. Disclose to the research physician whether you have participated in or are currently participating in other studies recently.

If you have any questions or complaints regarding your rights and health as a study participant, you can contact the Ethics Committee of our institution at:

Tel: 0518-85767557

Contact Person: Gao Shan

Signature Page of Informed Consent Form

I have read this Informed Consent Form.

I have had the opportunity to ask questions, and all my questions have been answered.

I understand that my participation in this study is voluntary.

I can choose not to participate in this study or withdraw at any time by notifying the investigator, without facing discrimination or retaliation, and my medical treatment and rights will not be affected.

The research physician may terminate my participation in the study if I require other treatments, fail to comply with the study plan, suffer study-related injuries, or for any other reason.

I will receive a signed copy of this "Informed Consent Form."

Subject's Name: _____

Subject's Signature: _____

Date: _____ Year _____ Month _____ Day

I have accurately informed the subject of this document. He/She has read this Informed Consent Form carefully and had the opportunity to ask questions.

Researcher's Name: _____

Researcher's Signature: _____

Date: _____ Year _____ Month _____ Day

(Note: If the subject is illiterate, a witness should sign. If the subject is incompetent, a legal representative should sign.)