



Effect of Preoperative Accurate Evaluation and Intervention on Prognosis and Outcome in Elderly Patients with Painless Gastroenteroscopy: Protocol for A Single-Centre Randomized Controlled Trial

Hongzhou Chen¹, Rurong Wang¹^{ID*}

¹Department of Anesthesiology, West China Hospital, Sichuan University, China

Corresponding Author: Rurong Wang ^{ORCID ID}

Address: Department of Anesthesiology, West China Hospital, Sichuan University, No.37 Guo Xue Xiang, Chengdu, Sichuan 610041, P.R China; Tel: +861 7780629096; Email: rurongwang@foxmail.com

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Abstract

Background: Factors such as abstinence from drinking, fasting, intestinal preparation, and stress responses can contribute to issues like inadequate blood volume, hypoglycemia, and electrolyte imbalances. The ASA classification presently serves as a primary assessment standard globally. In response to prevailing clinical challenges, we propose enhancing the preoperative assessment for elderly patients undergoing painless gastroenteroscopy. This enhancement involves incorporating the Frailty score, bedside ultrasound, and bedside laboratory results alongside the ASA classification, to establish a comprehensive assessment system. This holistic approach aims to monitor patients' fluid balance, electrolyte levels, and blood glucose changes, facilitating precise interventions and optimized anesthesia strategies. The ultimate goal is to diminish perioperative adverse events, especially those related to the cardiovascular system, thereby enhancing prognosis, outcomes, and patient satisfaction among the elderly.

Methods: This study is a randomized controlled trial conducted at a single center. It includes 204 patients scheduled for painless gastroenteroscopy. Eligible subjects will be randomly assigned to either Group A or Group B. Pre-anesthesia assessments will be conducted twice – during the preoperative visit and upon entry to the endoscopy center on the examination day. Evaluation parameters will encompass the Edmonton Frail Scale (EFS), bedside ultrasound measurements including inspiratory IVCDmax, expiratory IVCDmin, and calculation of the inferior vena cava collapse index (IVC-CI). Additionally, serum electrolyte (potassium) and blood glucose levels will be measured. Patients in Group A will receive specific interventions based on predetermined criteria. The primary endpoint is anesthesia-related adverse events. The measurements will be performed perioperatively, post-treatment, and at 1 day, 3 days, and 7 days after the end of treatment.

Keywords

Anesthesia-Related Adverse Events, Accurate Evaluation System, Painless Gastroenteroscopy

Background

Gastroenteroscopy stands as a potent technique enhancing the precision of clinical diagnosis and treatment for digestive system ailments. However,

bowel preparation can lead to noteworthy shifts in systemic electrolytes, fluids, or patient comfort. In our nation, the count of gastroenteroscopy recipients surpassed 20 million in 2016. Regrettably, the proportion of painless digestive endoscopy within our country stands at a mere 48.3%, a markedly lower figure compared to other nations [1].

As the global populace of individuals aged 65 years and above is projected to escalate from 10% in 2022 to 16% in 2050 [2], over 1 million patients yearly encounter major cardiac complications following non-cardiac surgeries. Notably, the majority of these cases involve elderly patients, with a cardiac event incidence of 1% to 5% (e.g., myocardial ischemia, infarction, cardiac death) during non-cardiac surgery [3,4]. Additionally, elderly patients often experience physical discomfort and electrolyte disturbance caused by bowel preparation [5,6]. Electrolyte imbalance disorders, such as hypokalaemia, hyponatremia, and hypermagnesaemia, may be life-threatening and increase postoperative complications, especially for elderly people [7,8]. The burgeoning aging demographic has ushered in complexities in endoscopic diagnosis and treatment, particularly given the surge in elderly patients with coexisting conditions in pivotal organs like the cardiovascular and respiratory systems. Consequently, ensuring anesthesia safety and quality presents formidable challenges.

While postoperative complications and mortality rates associated with painless digestive endoscopy are relatively low, a comprehensive preoperative assessment remains pivotal in optimizing patient condition, enhancing outcomes, and ensuring comfort. Presently, the ASA classification is a widely employed global assessment metric; however, its comprehensive nature renders individual evaluations challenging [9]. The utility of frailty scores and ultrasound measurements of the inferior vena cava diameter in preoperative assessments for elderly patients has been validated, yet their widespread adoption remains limited [10-12]. Drawing from current clinical predicaments and a review of prior literature, we contend that an advanced assessment paradigm should be established, building upon the ASA classification.

Objectives

A precise assessment system for painless gastroenteroscopy in elderly patients was established by combining bedside assessment scales, point-of-care ultrasound (POCUS), point-of-care testing (POCT), and targeted interventions. The study aimed to investigate the impact of accurate assessment and intervention on the prognosis and outcomes of elderly patients.

Methods and Analysis

Study Design:

The experiment has been approved by the Biomedical Ethics Committee of West China Hospital of Sichuan and registered at the Chinese Clinical Trial Registry (ChiCTR) (registration number: ChiCTR2300067729). The study employs a parallel, single-blind, randomized controlled clinical trial (RCT) design. Patients who fulfill the eligibility criteria and sign the informed consent will be randomly assigned to either the combination intervention group (Group A) or the control group (Group B). Periodic evaluations will be conducted daily within 1 day, the third day, and 1 week after the procedure. The overall study design is shown in **Fig-1**.

Eligibility Criteria:

We will recruit and include 204 hospitalized participants scheduled for painless gastroenteroscopy. Participants will be eligible if they meet the following inclusion criteria: Over 65 years old, with American Society of Anesthesiologists (ASA) Physical Statuses I–III.

Exclusion criteria are as follows: Patients with poor compliance and inability to follow up, allergic to narcotic drugs, long-term use of diuretics, inflammatory bowel disease, combined with inferior vena cava disease (including Booga syndrome, congenital dysplasia, inferior vena cava obstruction); Fasting for more than 2 days due to illness, and participation in other clinical trials within the last 3 months.

Patient Screening and Baseline Assessment:

The research assistants will screen patients who are scheduled for elective painless gastroenteroscopy at each site for eligibility to participate in the study.

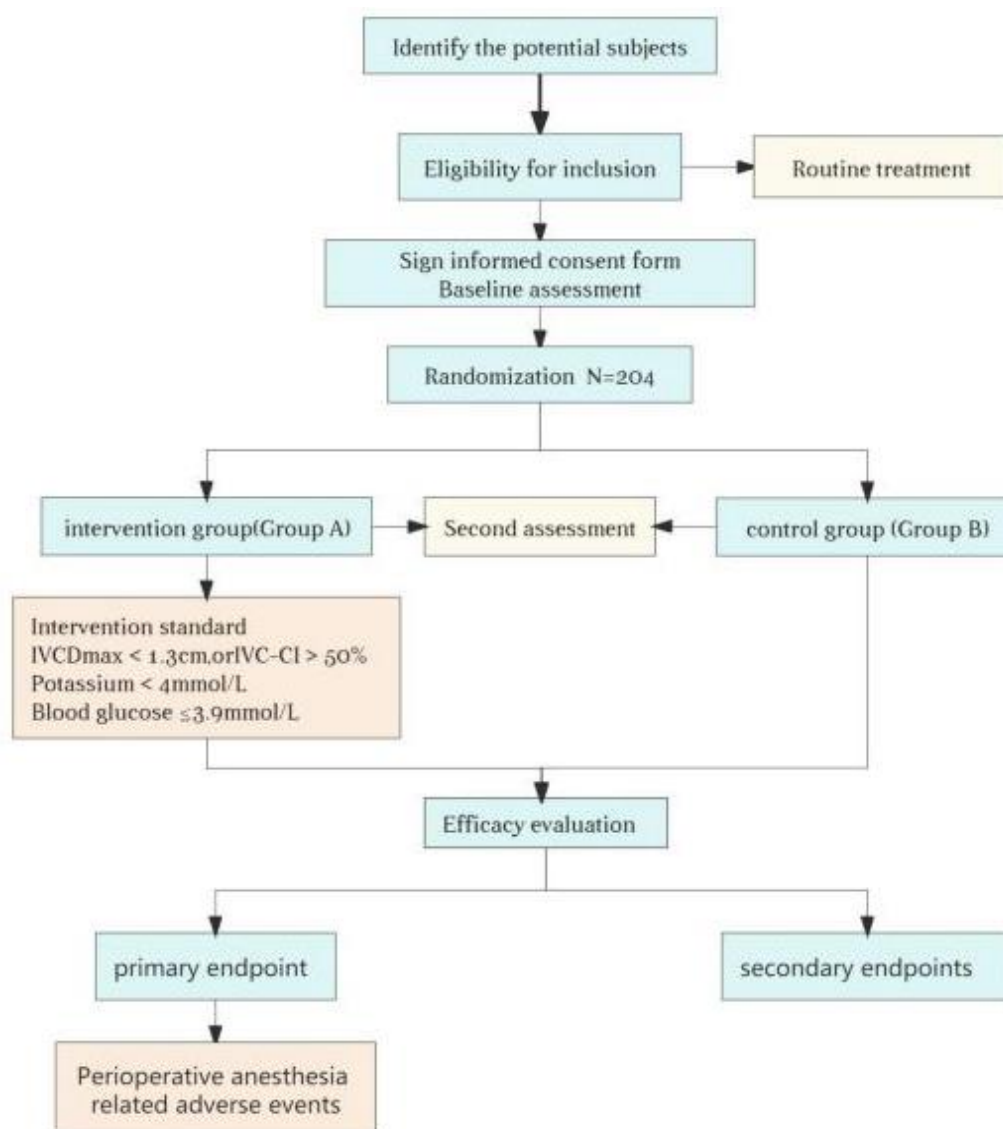


Fig-1: Flowchart of the Study

There will be no financial or non-financial incentives provided to participants for enrollment. Those interested in participating in the study will be given written information about the objectives and procedures. Research assistants will ask patients to provide written informed consent prior to collecting the baseline assessment. Simultaneously, the first bedside Edmonton Frail Scale (EFS) will be performed, and the diameter of the inferior vena cava will be collected by bedside ultrasound (IVCDmax, IVCDmin), along with laboratory examinations (potassium, blood glucose), electrocardiogram, and cardiac ultrasound [13-16].

Standard Procedure:

To avoid interfering with the trial intervention, deep

sedation based on propofol is conducted by a fairly fixed team of anesthesiologists following clinical routine. The following strategies are recommended (see Fig-2):

1. All patients scheduled for painless gastroscopy and colonoscopy will be evaluated and screened by an anesthesiologist the day before surgery to assess their risk of sedation according to ASA guidelines.
2. Participants will be filtered in accordance with the inclusion and exclusion criteria before the procedure. Corresponding interventions will be made according to random groups.
3. Upon admission to the endoscopic room, the

following parameters will be continuously monitored: electrocardiogram, noninvasive blood pressure of the right upper limb, peripheral oxygen saturation, and respiratory rate, in accordance with clinical routine.

4. Patients will be placed in a left lateral position, and 5 L/min of oxygen via a nasal cannula will be supplied.
5. Intravenous anesthesia regimen: Intravenous sufentanil 3-5ug. An initial bolus of propofol 1-2 mg/kg is administered. Then, the Modified Observer's Assessment of Alertness (MOAA/S) will be evaluated. A repeated dose of 0.2-0.5mg/kg propofol is injected if MOAA/S >2 or involuntary body movements are observed, until the patient's MOAA/S score is ≤ 2 [17]. The gastroscope will then be inserted by a skilled endoscopist.
6. Upon completion of painless gastroscopy and colonoscopy, all patients will be transferred to the post-anesthesia care unit (PACU).

7. After diagnosis and treatment, the patient will be monitored in the PACU for non-invasive blood pressure, pulse oxygen saturation, five-lead ECG monitoring of the right upper limb, nasal catheter oxygen inhalation with an oxygen inhalation flow of 5L/min, and resuscitation. The Aldrete score should be ≥ 9 points [18], indicating that the patient can leave the PACU.

Interventions:

A computer-generated randomization list for each participating site will be created by a research analyst who is not involved in the study. The patient assignments will be placed in serially numbered order.

Patients in both groups will be evaluated twice during the pre-anesthesia visit and upon entering the endoscopy center on the examination day. The evaluation contents will include the score of the Edmonton Asthenia Scale and ultrasound volume assessment, which includes inspiratory IVCDmax,

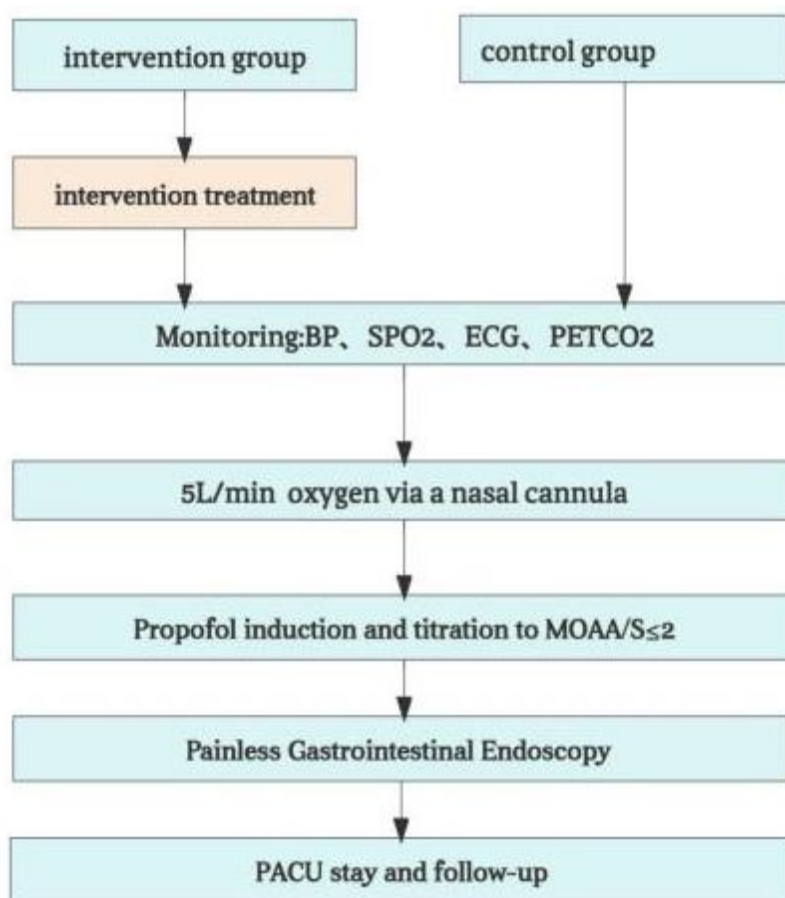


Fig-2: Perioperative Protocol

Table-1: Means of intervention

Intervention group (Group A)
<p>After the second evaluation of the trial group, patients are treated using the following criteria [10-12]:</p> <ol style="list-style-type: none"> 1) IVCDmax < 1.3cm or IVC-CI > 50%, Intravenous infusion of crystal solution, according to weight and fasting time, according to the 4-2-1 principle to calculate the physiological loss, 30 minutes to quickly supplement half of the physiological fluid loss, and then according to the physiological needs.; 2) Venous blood potassium < 4.0mmol/L, penangin amount (ml) = (target value - measured value) × body weight kg × 0.2/0.265; 3) Blood glucose ≤ 3.9mmol/L, give 100ml of 10% glucose intravenously.
control group (Group B)
<p>All control groups received endoscopic diagnosis and treatment directly after evaluation without intervention.</p>

expiratory IVCDmin, and calculation of the inferior vena cava collapse index (IVC-CI) ((expiratory IVCDmax - inspiratory IVCDmin) / IVCDmax * 100%), as well as serum electrolyte (potassium) and blood glucose measurements. Interventions should be carried out according to the above test results (see **Table-1**). There will be no change to the type of bowel preparation before the colonoscopy, anesthesia, or postoperative pain management for patients in both groups at the participating centers [19-23].

Study Endpoints:

The primary endpoint of the study is the incidence of perioperative anesthesia-related adverse events, including: 1) Respiratory adverse events: hypoxemia, apnea, aspiration, and aspiration pneumonia. 2) Circulatory adverse events: hypotension, arrhythmia, myocardial ischemia, infarction, cardiac arrest, and death. 3) Postoperative nausea and vomiting, lethargy, fatigue, and dizziness.

The secondary endpoints are as follows: 1) The degree of electrolyte change and blood volume change in different types of intestinal washing fluids. 2) Other adverse events that lead to the suspension or termination of endoscopic procedures. 3) Digestive system adverse events: bleeding, perforation. 4) Postoperative subjective discomfort, thirst, and hunger (visual analog scale). 5) Postoperative recovery time, post-anesthesia care unit (PACU) residence time, postoperative recovery quality score. 6) Patient satisfaction. 7) Length of hospital stay. 8) Hospital expenses.

Definitions [24-25]:

Hypotension: Systolic blood pressure less than 90 mmHg or blood pressure less than 20% of the preoperative baseline value.

Hypoxemia: Oxygen saturation below 90%.

Apnea: Respiratory stop ≥ 10 seconds.

Aspiration pneumonia: Postoperative imaging reveals signs of pulmonary inflammation that did not appear before surgery.

Arrhythmia: An abnormal electrocardiogram pattern that was not present before surgery.

Endoscopic procedure suspension: Any action by the anesthesiologist to halt a procedure in order to address an adverse event related to sedation, including any measure taken to ensure airway safety.

Termination of endoscopic procedure: Abandonment or postponement of surgery due to sedation-related adverse events and/or residual gastric contents.

Bleeding: Hematemesis or black stool, or a drop in hemoglobin of more than 2 grams.

Perforation: Intraoperative or postoperative imaging findings indicative of perforation.

Time of recovery: The interval between admission to the post-anesthesia care unit (PACU) and the point of voluntary eye-opening.

PACU residence time: The duration from when the patient enters the PACU until they meet the discharge criteria and leave the PACU.

Criteria for Discontinuing or Modifying Allocated Interventions:

Participants can withdraw at any time during the trial. Study investigators can decide whether a

participant discontinues the trial due to safety concerns, including the following: 1) The occurrence of other diseases that affect the efficacy of this trial. 2) Investigators consider the subject unsuitable to continue the study intervention.

The reasons and circumstances for study discontinuation will be recorded in the Case Report Form (CRF). Any modifications to the protocol will be reported to the Ethics Committee and discussed by the study group prior to implementation [26].

Participant Timeline:

The participant timeline is summarized in **Table-2**. For a detailed description of each visit's procedures, please refer to the section Plans for assessment and collection of outcomes.

Sample Size:

In this study, the incidence of adverse reactions related to medium and deep sedation reported in previous literature was used as the main indicator to estimate the sample size. Previous literature reported that [24] 11.7% of patients had at least one adverse reaction. PASS 15.0 software was used to calculate the sample size. This study assumed that the preoperative

accurate evaluation and intervention system could reduce sedation-related complications to 1%, with β set to ≤ 0.2 , confidence (Power= $1 - \beta$) at 80%, and a significance level of $\alpha=0.05$. After accounting for a 20% dropout rate, a total of 204 subjects were required for the trial.

Blinding and Randomization

After ensuring the participant still meets all the eligibility criteria, group assignment will be determined by opening an opaque envelope (by a research assistant), revealing the participant's randomized assignment to one of the two groups. Randomization is based on a computer-generated random number sequence built by an independent investigator. In addition to the researchers, other personnel, including endoscopists, anesthesiologists, and follow-up staff, were unaware of patient randomization.

Strategies to Improve Adherence to Interventions

Both endoscopists and anesthesiologists have worked for more than 3 years, and all researchers are familiar with the trial procedures and can handle emergencies at any time.

Table-2: Participant timeline

	Period	Screening	Treatment			Follow-up		
	Time	Before fasting	Endoscopic center	Endoscopic chamber	PACU	First follow-up	Second follow-up	The third follow-up
	Schedule	-1 day	0 day	0 day	0 day	1 day	3±1 day	7±1 day
1	Signing informed consent form	√						
2 Clinical information	Basic information of the subject	√						
	clinical diagnosis	√						
	Past history	√						
	Special case	√						
3 Clinical examination	Electrocardiography	√	√					
	Echocardiography	√	√	√	√			
	Laboratory inspection	√	√	√	√			
4	Elected and excluded standards	√						
5	Questionnaire assessment	√	√	√	√	√	√	√
6	Accompanying medicine/implantation equipment	√						
7	Monitoring of adverse events		√	√	√	√	√	√
8	Scheme deviation record	√	√	√	√	√	√	√
9	Fill in CRF	√	√	√	√	√	√	√

Data and Statistical Analysis

The initial analysis will utilize descriptive statistics and data visualizations to both identify and address spurious values, as well as to characterize the study cohort. Characteristics will be described overall and grouped by study arm, without a plan to compare the study arms with statistical tests. Categorical variables will be described using frequencies and proportions, while continuous variables will be described using means and standard deviations, as well as medians. Missingness will be recorded for each variable.

The Shapiro–Wilk test will be employed to test whether continuous variables are normally distributed. Normal distribution will be expressed as mean \pm standard deviation, and the independent samples t-test will be utilized to compare between groups. Non-normally distributed continuous variables will be expressed as the median (or interquartile range) using the Mann–Whitney U test for comparison. Enumeration data will be presented as the number of cases and percentages, and comparisons between groups will be conducted using the chi-squared test.

Survival time will be analyzed using Kaplan–Meier survival analysis, and comparisons between groups will be conducted using the log-rank test. SPSS version 25.0 will be employed for data analysis.

Discussion

From the diagnosis and treatment of digestive diseases to the development of surgical treatment and protocols, painless digestive endoscopy has seen an expansion in indications and examination scope. It now involves patients of all ages, encompassing those with various comorbidities, including critically ill patients, pregnant women, young children, and individuals in the ICU. There is a growing demand among endoscopists and the general public for accredited and comfortable pain-free endoscopic diagnosis and treatment. Factors such as abstinence from drinking, fasting, intestinal preparation, and stress response may lead to blood volume insufficiency, hypoglycemia, or even stress hyperglycemia, electrolyte changes, and disorders in patients undergoing painless gastroenteroscopy.

Building upon the ASA score and systematic evaluation, we aim to assess elderly patients undergoing painless gastroenteroscopy before and after receiving intestinal wash. This assessment will involve using a fissile score scale, ultrasound volume assessment, and bedside laboratory measurement of blood potassium, calcium, and blood glucose. Subsequently, targeted intervention plans will be constructed, and clinical pathways optimized according to the degree of change.

This study focuses on ensuring the safety and quality of anesthesia in painless diagnosis and treatment technology, particularly in elderly patients, aiming to improve prognosis and outcomes. It represents a positive exploratory attempt towards developing comfortable medical treatment and expanding indications. The application of bedside ultrasound technology and the establishment of a bedside laboratory to construct an accurate evaluation system for elderly patients, alongside targeted intervention and optimization of anesthesia strategy, contribute significantly to improving prognosis and outcomes. This approach holds scientific and clinical application value, playing a demonstrative and leading role in outdoor anesthesia construction.

The utilization of bedside ultrasound visualization technology in the preoperative evaluation system of elderly patients objectively guides perioperative anesthesia management and enhances the safety and quality of anesthesia.

Trial Registration

The trial was registered on 19 Jan 2023 with the Chinese Clinical Trial Registry (ChiCTR) under the registration number ChiCTR2300067729.

Ethics and Dissemination

The study has been approved by the Ethics Committee of West China Hospital of Sichuan University. The trial results will be published in peer-reviewed journals and presented at conferences.

Strengths and Limitations of this Study

Strengths:

This is the first randomized controlled trial designed

to assess ultrasound technology and bedside laboratory to build an accurate evaluation system for elderly patients, with targeted interventions, optimized anesthesia strategies, and improved prognosis and outcomes. Additionally, this study focused on improving the prognosis and outcomes of elderly patients to enhance perioperative comfort experience.

Limitations:

The study's single-center nature and relatively small sample size may limit the generalizability of our findings.

Competing Interests

We declare that there was no support from any organization for the submitted work; no financial relationships with any organization that might have an interest in the submitted work in the previous three years; and no other relationships or activities that could appear to have influenced the submitted work.

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Contributors

Hongzhou Chen designed the study. Rurong Wang contributed to the critical revision of the manuscript for important intellectual content and approved the final version of the manuscript. All authors have read and approved the final manuscript.

Conflict of Interest

The authors have read and approved the final version of the manuscript. The authors have no conflicts of interest to declare.

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