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ORIGINAL RESEARCH

# Clinical Application of Bilateral Nasopharyngeal Airway in Painless Colonoscopy for Obese Patients

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**Objective:** This study aims to evaluate the safety and efficacy of using bilateral nasopharyngeal airways (NPA) during colonoscopic polypectomy performed under sedation anesthesia in obese patients.

**Methods:** Ninety obese patients undergoing colonoscopic polypectomy under elective sedation anesthesia at Shanghai Shuguang Hospital were randomly allocated to two groups. Patients in group B had a nasopharyngeal airway inserted bilaterally after induction of anesthesia, whereas patients in group U had a nasopharyngeal airway inserted in only one nostril. Spontaneous breathing was maintained in both groups. The primary observation parameter was the incidence of oxygen saturation (SpO2) ≤ 92% during anesthesia, while secondary observation parameters included preoperative, intraoperative, and post-operative SpO2 levels, mean arterial pressure (MAP), heart rate (HR), dosage of propofol, duration of the operation, time to anesthesia recovery, need for emergency airway intervention, and occurrence of other adverse events.

**Results:** Hypoxia occurred in 5 out of 45 patients (11.1%) in group B, whereas it was observed in 14 out of 45 patients (31.1%) in group U ($P < 0.05$). Patients in group B exhibited higher SpO2 levels during and after surgery compared to those in group U ($P < 0.05$). Furthermore, the decrease in intraoperative and post-operative SpO2 levels from baseline was significantly lower in group B compared to group U ($P < 0.05$). The number of emergency airway interventions, operation time, propofol dosage, and anesthesia recovery time were significantly lower in group B compared to group U ($P < 0.05$). However, there were no significant differences in MAP, HR, or the incidence of adverse events between the two groups ($P > 0.05$).

**Conclusion:** The utilization of bilateral nasopharyngeal airway placement proves to be an effective strategy in decreasing the occurrence of hypoxia among obese patients undergoing colonoscopy under sedation anesthesia, thereby improving procedural safety.

**Keywords:** bilateral, colonoscopy, colorectal polypectomy, nasopharyngeal airway, obese patients, sedation anesthesia

## Introduction

Colorectal polyps represent precancerous lesions associated with colorectal cancer, emphasizing the importance of early detection and treatment.[1,2] Colonoscopic polypectomy is the preferred treatment.[3] However, conventional colonoscopy may induce unbearable abdominal distension and abdominal pain in patients, potentially resulting in procedural failure due to lack of cooperation. Sedation anesthesia has been shown to enhance patient comfort during colonoscopic polypectomy and improve surgery success rates.[4,5]

Propofol, a short-acting intravenous anesthetic, is the predominant sedative anesthetic used in painless colonoscopy procedures. However, it exerts a strong inhibitory effect on respiration and circulation,[6] particularly notable in obese individuals. Alterations in airway physiology in this patient population increase the likelihood of displacement of the base of the tongue post-anesthesia, potentially obstructing the airway and diminishing chest wall compliance, thereby leading to respiratory depression and even fatal hypoxemia.[7] Hence, ensuring airway patency is paramount in such cases.

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The nasopharyngeal airway is frequently employed in cases of glossoptosis-induced airway obstruction, effectively reducing the occurrence of hypoxemia and improving the safety of sedation anesthesia.[8] Studies have indicated that the use of nasopharyngeal airways reduces the risk of hypoxemia during gastroscopy procedures in obese patients under sedation anesthesia with propofol.[9] However, there remains a paucity of research concerning the safety and efficacy of nasopharyngeal airway utilization during colonoscopic polypectomy procedures in obese patients, particularly in scenarios involving extended anesthesia durations.

The primary challenges associated with glossoptosis-induced airway obstruction in obese patients following anesthesia are attributed to soft tissue hyperplasia within the oropharynx and the constrained upper airway space, predisposing it to obstruction by a falling tongue. Clinical observations have indicated that unilateral nasopharyngeal airway placement may not consistently achieve desired outcomes, with episodes of hypoxemia occurring intermittently. In the present study, we hypothesize that bilateral nasopharyngeal airway insertion could offer improved resolution of glossoptosis-induced airway obstruction in obese patients. Therefore, the study aimed to assess the safety and efficacy of bilateral nasopharyngeal airway placement in obese patients undergoing colonoscopic polypectomy under sedation anesthesia with propofol.

# Methods

## Study Design

This is a single-center, open-label, evaluator-blinded randomized controlled trial conducted at the Digestive Endoscopy Center of Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine. Ninety obese patients undergoing colonoscopic polypectomy under sedation anesthesia between October 2022 and October 2023 were enrolled in this trial. Approval for the study was obtained from the Ethics Committee of Shuguang Hospital, Shanghai University of Traditional Chinese Medicine (2021–989-64-01), and the trial was registered in the China Clinical Trial Registry (ChiCTR2100048241). The trial was conducted following the principles outlined in the Declaration of Helsinki. Informed consent was obtained from all patients or their family members before enrollment in the study. When patients were unable to sign the anesthesia informed consent form due to limitations in their educational level, a family member may sign on their behalf.

## Patient Recruitment

Inclusion criteria: (1) Age between 18 and 75 years; (2) Body mass index (BMI) ranging from 28 to 35 kg/m2; (3) American Society of Anesthesiologists (ASA) grade I–III; (4) Estimated operation duration not exceeding 30 minutes.

Exclusion criteria: (1) BMI < 28 kg/$m^2$ or > 35 kg/$m^2$; (2) Preoperative oxygen saturation (SPO2) < 90% without supplemental oxygen; (3) Obstructive sleep apnea syndrome; (4) Respiratory tract infection; (5) Nasopharyngeal conditions such as nasal polyps, bleeding, trauma, deformity or inflammation; (6) Severe cardiovascular or pulmonary disorders; (7) Allergy to propofol or silica gel.

## Randomization and Blinding

Following the acquisition of written informed consent, patients were randomly allocated in a 1:1 ratio into either the experimental group (group B) or the control group (group U) using the SPSS random number table While patients, anesthesiologists, and endoscopists were not blinded to the group assignments, the grouping of participants, outcome assessment, and statistical analysis were conducted in a blinded manner.

## Trial Protocol

All patients were instructed to abstain from both food and liquids before anesthesia. Forearm venous access was established for intravenous administration of medications. Non-invasive blood pressure (NBP), heart rate (HR), and oxygen saturation (SpO2) were monitored. All patients were positioned in the left lateral position. Mask oxygen inhalation was provided for 3 minutes before anesthesia with an oxygen flow rate of 5 L/min. Anesthesia induction was initiated by intravenous injection of 0.1 μg/kg sufentanil (Yichang Renfu) and 2 mg/kg propofol (FRESENIUS

KABI), administered based on actual body weight. The level of sedation was assessed using the modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale, with deep sedation maintained at a score of 1 to 2 throughout the procedure. After the patients' eyelash reflex dissipated, the nasopharyngeal airway (MEDIS) of appropriate size was selected and inserted into each nostril of patients in group B. Lubrication of the nasopharyngeal airway surface with paraffin oil was performed before insertion. Proper insertion depth of the airway was ensured, with the curved end facing towards the hard palate, positioned from the earlobe to the nasal alar. One side of the nasopharyngeal airway was connected to the ventilator for spontaneous breathing. The anesthesia machine was set to an inspired oxygen concentration (FiO2) of 50% with an oxygen flow rate of 5 L/min. The patient maintained spontaneous breathing and no additional respiratory support was used. Patients in group U had the nasopharyngeal airway inserted into either nostril, and the procedures were consistent with those in group B. The intraoperative maintenance dose of propofol was administered at 0.1–0.2 mg/kg/min, with adjustments based on surgical stimulation and the patient's movement. Total propofol dosage was recorded. Hypoxemia was defined as SpO2 ≤ 92%, and the following steps were taken when SpO2 ≤ 92%: (1) Discontinuation of anesthesia drugs. (2) Increase in oxygen flow rate from 5 L/min to 8 L/min. (3) Elevation of the lower jaw to open the airway. (4) Use of oropharyngeal airway. (5) Mask oxygen inhalation for assisted ventilation. (6) Laryngeal mask insertion. (7) Endotracheal intubation if all interventions fail. Electronic colonoscopic polypectomy was performed by an experienced endoscopist for all patients. During postoperative management, hemostasis of the surgical wound was performed, propofol infusion was discontinued before scope withdrawal, and the nasopharyngeal airway was removed once the patient regained consciousness. The MOAA/S scale was used to assess the patient's level of consciousness. When the MOAA/S score reached 5, the patient was considered to have regained consciousness. After the nasopharyngeal airway was removed, if hypoxemia occurred (SpO2 ≤ 92%), the patient was provided with a face mask delivering pure oxygen and instructed to take deep breaths.

## Outcomes

The primary outcome measure was the incidence of SpO2 ≤ 92% during anesthesia. While hypoxia is typically defined as SpO2 ≤ 90%, we chose 92% as the threshold for hypoxia in line with previous studies, considering a patient's FiO2 of 0.5.[10] The peripheral oxygen saturation (SpO2) was measured using a pulse oximeter. SpO2 was continuously monitored throughout the sedation process. If SpO2 dropped to ≤92%, it was recorded as hypoxemia, and the hypoxemia management protocol was initiated.

Secondary outcome measures included SpO2, MAP, and HR at three-time points: before anesthesia induction (preoperative), after colonoscopy insertion (intra-operative), and after anesthesia recovery (post-operative), which was defined as a MOAA/S score of 5. Other secondary outcomes comprised operation time, which was defined as the time from the insertion of the endoscope to its complete removal, propofol dosage, anesthesia recovery time, which was defined as the time from discontinuation of medication to achieving a MOAA/S score of 5, and the occurrence of emergency airway interventions. Additional adverse events recorded were body movement, choking, bradycardia (HR < 50 beats/min), hypotension (blood pressure lower than 30% of the baseline value), and epistaxis.

The three time points were defined as follow:

- Pre-anesthesia induction (preoperative): Baseline SpO2, MAP, and HR values with the patient breathing air.
- Post-Endoscope Insertion (intra-operative): SpO2, MAP, and HR values when deep sedation levels are achieved (1≤MOAA/S≤2) after the endoscope is inserted.
- Post-Anesthesia Wake-Up (post-operative): SpO2, MAP, and HR values when the patient is fully awake with a MOAA/S score of 5.

## Statistical Analyses

In the pre-trial involving 15 patients, the observed incidence of hypoxia (SpO2 ≤ 92%) was 6.7% with bilateral nasopharyngeal airway and 30.0% with unilateral nasopharyngeal airway. Based on these estimates, a 1:1 randomization, two-tailed alpha of 0.05, and (1-beta) of 0.8, each group required 40 patients according to the formula. Considering the

potential loss to follow-up, we decided to include 45 patients in each group. SPSS 25.0 software was used for statistical analyses. Measurement data are presented as mean ± standard deviation (Equation), and comparisons of respiratory and circulatory indexes at different time points were conducted using repeated measures ANOVA. Other continuous variables were compared between the two groups using the *t*-test. The categorical variables were expressed as percentages and compared using the chi-squared test ($\chi 2$ test) or Fisher's exact probability test. A p-value $< 0.05$ was considered statistically significant.

# Results

## Subject Characteristics

Between October 2022 and October 2023, a total of 895 patients underwent colonoscopic polypectomy, out of which 90 patients were included in the analysis. Among them, 45 patients were assigned to the bilateral nasopharyngeal airway group (group B), and 45 patients were assigned to the unilateral nasopharyngeal airway group (group U). Comparison of baseline data showed no significant differences in age, sex, BMI, or ASA grade between the two groups ($p > 0.05$), indicating comparability (Table 1).

## Primary Outcome

The incidence of SpO2 ≤ 92% in group B was 11.1% (5/45), which was significantly lower than that in group U (31.1%, 14/45) (Table 2).

## Secondary Outcomes

There were no significant differences in preoperative MAP, HR, and SpO2 between the two groups ($p > 0.05$). Intra-operative and post-operative MAP and HR also showed no significant differences between the two groups ($p > 0.05$). However, intra-operative and post-operative SpO2 were significantly higher in group B compared to group U ($p < 0.05$). In group B, SpO2 decreased from 98.33% before surgery to 96.69% during surgery and 97.73% after surgery. The decrease in intra-operative SpO2 was statistically significant compared to the preoperative value ($p < 0.05$). In group U, SpO2 decreased from 98.22% before surgery to 91.42% during surgery and 97.69% after surgery. The decrease in intra-operative and post-operative SpO2 was statistically significant compared to the preoperative value ($p < 0.05$). The decrease in intra-operative and post-operative SpO2 in group B (1.64%; 0.6%) was significantly less than that in group U (6.8%; 3.18%) compared to the baseline value ($p < 0.05$) (Table 3).

**Table 1** Comparison of the General Conditions of Patients in the Two Groups

| Items | Group B | Group U | *P* value |
|---|---|---|---|
| Age/years | 53.98±15.45 | 54.56±15.35 | 0.86 |
| Sex (male/female)/n | 27/18 | 28/17 | 0.83 |
| **BMI/ kg/m$^2$** | 31.65±1.95 | 31.19±2.20 | 0.30 |
| ASA grade/n (%) | | | 0.77 |
| Grade I | 17(37.8) | 20(44.4) | |
| **Grade II** | 25(55.6) | 23(51.1) | |
| **Grade III** | 3(6.7) | 2(4.4) | |

**Table 2** Comparison of the primary observation indicator

| Items | Group B | Group U | *P* value |
|---|---|---|---|
| Primary observation indicator SpO2≤92% | 5/45(11.1) | 14/45(31.1) | 0.020 |

**Table 3** Respiratory and Circulatory Indexes at Different Time Points in the Two Groups

| Groups | Time points | MAP | HR | $SPO_2$ |
|---|---|---|---|---|
| Group B | Pre-operative | 92.80±11.89 | 78.82±12.74 | 98.33±1.38 |
| | Intra-operative | 71.31±8.11[a] | 76.49±10.02[a] | 96.69±1.70[a] |
| | Post-operative | 82.98±9.20[ab] | 77.96±10.67 | 97.73±1.03[b] |
| Group U | Pre-operative | 91.38±11.06 | 80.13±11.31 | 98.22±1.36 |
| | Intra-operative | 71.40±9.43[a] | 76.84±10.38[a] | 91.42±2.14[ac] |
| | Post-operative | 83.53±9.56[ab] | 78.56±10.59 | 95.04±1.48[abc] |

**Notes**: Compared with the pre-operative value (baseline value), [a] $p < 0.05$; Compared with the intra-operative value [b] $p < 0.05$; Compared with the values of group B at each corresponding time point [c] $p<0.05$.

Compared to group U, the incidence of emergency airway interventions due to hypoxia in group B, which included maneuvers such as elevation of the lower jaw, increasing oxygen flow, inserting oropharyngeal airways, and providing mask-assisted ventilation, was significantly reduced ($p < 0.05$) (Table 4). Notably, no patients required laryngeal mask insertion or endotracheal intubation.

Furthermore, group B exhibited significantly shorter operation times, lower propofol dosages, and faster anesthesia recovery times compared to group U ($p < 0.05$) (Table 5).

All patients underwent successful nasopharyngeal airway insertion and removal without any complications such as nasal mucosal injury or bleeding during removal. After the patient has awakened, nurses routinely asked orally if there was any discomfort. There were no significant complaints of discomfort in the nasopharyngeal area. Importantly, there were no significant differences in other adverse events, including body movement, choking, bradycardia, and hypotension between the two groups ($p < 0.05$) (Table 6).

**Table 4** Patients in the Two Groups Requiring Emergency Airway Intervention Due to Hypoxia

| Items | Group B | Group U | *P* value |
|---|---|---|---|
| Elevation of the lower jaw /n (%) | 5(11.11) | 17(37.78) | 0.0032 |
| Increase of oxygen flow /n (%) | 6(13.33) | 15(33.33) | 0.0249 |
| Insertion of oropharyngeal airway /n (%) | 3(6.67) | 14(31.11) | 0.0031 |
| Mask-assisted ventilation /n (%) | 2(4.44) | 11(24.44) | 0.0070 |

**Table 5** Operation Time, Propofol Dosage, and Anesthesia Recovery Time of the Two Groups

| Items | Group B | Group U | *P* value |
|---|---|---|---|
| Operation time /min | 20.33±4.37 | 23.47±4.03 | 0.0007 |
| Propofol dosage /mg | 353.56±23.08 | 371.78±27.98 | 0.0011 |
| Anesthesia recovery time /min | 4.62±0.94 | 5.46±1.23 | 0.0005 |

**Table 6** Comparison of Adverse Events Between the Two Groups

| Items | Group B | Group U | *P* value |
|---|---|---|---|
| Body movement/n (%) | 2(4.44) | 6(13.33) | 0.1384 |
| Choking /n (%) | 1(2.22) | 3(6.67) | 0.3063 |
| Bradycardia /n (%) | 2(4.44) | 7(15.56) | 0.0789 |
| Hypotension /n (%) | 3(6.67) | 9(20.00) | 0.0628 |

## Discussion

The results of this study substantiated that inserting a nasopharyngeal airway through bilateral nostrils in obese patients undergoing electronic colonoscopic polypectomy under propofol-based sedation anesthesia can effectively alleviate glossoptosis-induced airway obstruction, reduce the incidence of hypoxemia, and improve the safety of anesthesia during surgery.

Sedation anesthesia has been shown to enhance patient comfort and satisfaction during endoscopic examinations and treatments, including gastroscopy and colonoscopy, while also improving diagnostic and treatment efficacy of gastrointestinal diseases by minimizing patient movement.[11] However, during electronic colonoscopy, continuous perfusion of carbon dioxide aimed to provide a clear surgical field for endoscopists can lead to the gas and surgical procedures irritating the splanchnic nerves in the intestinal wall, causing discomfort and physiological responses such as slowed heartbeat and increased body movements. This may prolong the operation time and increase the risk of bleeding and perforation.[12] Sedation anesthesia, although beneficial, may also induce glossoptosis, airway obstruction, and hypoxemia, particularly in obese patients.

As per findings reported in the Lancet, approximately 10% of the global populace is classified as obese, with China registering an excess of 200 million obese individuals, making it the country with the highest number of obese citizens globally.[13–15] At the same time, there is a discernable uptrend in the proportion of obese patients encountered in clinical anesthesia practice. Anatomically, obese patients exhibit a narrowing of the pharyngeal cavity due to the accumulation of adipose tissue in the pharynx and hypertrophy of the tongue. Particularly under anesthesia, the structural integrity of the patient's respiratory tract is compromised, precipitating the collapse of pharyngeal muscles and subsequent airway obstruction alongside pulmonary ventilation dysfunction.[16] Furthermore, obese patients often present with diminished thoracic compliance, decreased functional residual volume, limited oxygen reserve capacity, and elevated oxygen consumption. Their hypoxia tolerance is notably abbreviated,[17,18] posing a significant challenge in the context of anesthesia management.

Presently, the primary approaches to mitigate glossoptosis-induced airway obstruction are elevation of the lower jaw, oropharyngeal airway insertion, nasopharyngeal airway placement, and utilization of laryngeal masks. However, obese patients frequently face challenges in elevating the lower jaw, ineffective resolution of obstruction via oropharyngeal or nasopharyngeal airway interventions, potential interference of laryngeal masks with oropharyngeal surgical operations, and the need for deeper anesthesia with laryngeal masks necessitating increased drug dosages and extended recovery periods. This scenario is particularly disadvantageous in the context of expeditious outpatient examinations and treatments. In recent years, high-flow oxygen has emerged as a modality for sedation anesthesia in obese patients. However, two concerns arise: firstly, the issue of airway obstruction remains unresolved, with research indicating that surgical procedures exceeding 18 minutes pose a risk of hypercapnia.[19] Secondly, a substantial volume of gas enters the stomach, increasing the likelihood of reflux aspiration.[20]

The utilization of bilateral nasopharyngeal airway in this study may enhance patient ventilation owing to the following rationales: (1) Bilateral placement of the airways may offer improved support; (2) The presence of lateral perforations at the anterior ends of both airways diminishes the risk of occlusion by soft tissues; (3) The total diameter of the airway apparatus has increased. In comparison to colonoscopy examinations, colonoscopic polypectomies entail prolonged operation times and impose greater demands on the airway. To date, there is no reported evidence of the safe and efficacious utilization of bilateral nasopharyngeal airways during colonoscopic polypectomies under sedation anesthesia in obese patients.

In this study, nasopharyngeal airways of suitable size and length were selected based on the distance from the nasal tip to the external auditory canal,[21] with routine preoperative assessment of the permeability of both nasal cavities. All airways were successfully inserted without notable bleeding or mucosal tissue damage. Comparative analysis revealed that patients in the bilateral nasopharyngeal airway group experienced a lesser decline in intra-operative SpO2 during colonoscopic polypectomy compared to their preoperative levels, with SpO2 essentially returning to baseline post-surgery. Conversely, SpO2 levels in the unilateral nasopharyngeal airway group remained lower post-surgery and failed to fully recover to baseline, indicating the efficacy of bilateral nasopharyngeal airways in mitigating upper respiratory tract obstruction, increasing pulmonary ventilation, and reducing the occurrence of hypoxemia in obese patients

undergoing colonoscopic polypectomy under sedation anesthesia with propofol. Additionally, the incidence of emergency airway interventions, such as elevation of the lower jaw, increased oxygen flow, oropharyngeal airway insertion, and mask-assisted ventilation, was significantly lower in the bilateral nasopharyngeal airway group thereby reducing surgical interruptions due to airway interventions and improving procedural efficiency. There were no significant differences in adverse events, including patient movement, choking, bradycardia, and hypotension between the two groups, underscoring the safety and efficacy of bilateral nasopharyngeal airways as supraglottic ventilation devices.

An interesting observation of our study was the shorter operation time noted in patients assigned to the bilateral nasopharyngeal airway group. We hypothesized that this may be attributed to reduced surgical interruptions stemming from emergency airway interventions and higher surgical efficiency in this group. Additionally, patients in the bilateral nasopharyngeal airway group exhibited lower propofol dosages and faster recovery from anesthesia, which could contribute to the observed phenomenon. Furthermore, there were no significant discrepancies in intra-operative and post-operative MAP and HR between the two groups undergoing colonoscopic polypectomy, suggesting that the use of bilateral nasopharyngeal airways did not cause notable fluctuations in blood pressure or HR.

The limitations of this trial warrant acknowledgment: (1) Patients undergoing colorectal polypectomy in this center were all positioned laterally, the results solely reflect the safety and efficacy of bilateral nasopharyngeal airways in patients in the lateral position. Further research is warranted to ascertain the safety and efficacy of this approach in other positions, particularly the supine position; (2) The trial could only be single-blinded, precluding blinding of surgeons and anesthesiologists; (3) The applicability of this intervention may be limited in patients with higher BMI (morbid obesity); (4) This may not be applicable to patients with obstructive sleep apnea syndrome; (5) The intervention may not be suitable for elderly and pediatric obese patients; (6) Due to supply limitations, carbon dioxide monitoring through end-tidal $CO_2$ or other methods was not performed during propofol sedation to assess ventilation adequacy, which may affect the interpretation of the results; (7) The intervention may not be suitable for obese patients with higher ASA grades; (8) The sample size was relatively small, suggesting the necessity for future large scale multi-center studies; (9) The study exclusively employed propofol in combination with a small dose of sufentanil, which may not be suitable for patients who underwent sedation anesthesia with alternative medications.

## Conclusion

In summary, bilateral nasopharyngeal airways effectively reduce the incidence of hypoxia in obese patients undergoing colonoscopic polypectomy under propofol sedation and anesthesia. They also decrease the frequency of emergency airway interventions, reduce the amount of propofol required, and lead to quicker recovery from anesthesia, thus improving surgical efficiency. Furthermore, patient tolerance is good, with no significant increase in discomfort. Compared to laryngeal masks and high-flow oxygen, bilateral nasopharyngeal airways not only effectively address upper airway obstruction but also are more cost-effective. They represent a safe, effective, and low-cost method for supraglottic ventilation.

## Abbreviations

$SpO_2$, oxygen saturation; MAP, mean arterial pressure; HR, heart rate; RCT, randomized controlled trial; $FiO_2$, fraction of inspired oxygen; BMI body mass index; ASA, American Society of Anesthesiologists; NBP, noninvasive blood pressure.

## Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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## Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine (No. 2021-989-64-01, Date: 9th, June 2021) and registered on the Chinese Clinical Trial Register website (https://www.chictr.org.cn/showproj.html?proj=129124, No. ChiCTR2100048241, Date: 5th, July 2021). Written consent was obtained from each patient and/or their family members.

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## Disclosure

The authors declare that they have no competing interests in this work.

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