Effect of Moderate Sedation Versus Deep Sedation on Recovery Following Outpatient Gastroscopy in Older Patients: A Randomized Controlled Trial

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Abstract

Background

Although gastrointestinal endoscopy with sedation is being increasingly performed in older patients, the appropriate level of sedation remains unclear. This study compared the effect of moderate sedation (MS) and deep sedation (DS) on recovery following outpatient gastroscopy in older patients.

Methods

In this randomized, partly blinded, controlled trial, 270 patients older than 60 years scheduled for elective outpatient gastroscopy were randomly divided into MS or DS group according to Modified Observer’s Assessment of Alertness/Sedation (MOAA/S). The primary outcome was the post-anesthesia care unit (PACU) stay time. Secondary outcomes include total hospital stay time, the incidence of retching, bucking, and body movements during the examination, the endoscopist and patient satisfaction, and sedation-associated adverse events during procedure.

Results

A total of 264 patients completed the study, of whom 131 received MS, and 133 received DS. MS was associated with a shorter PACU stay time [15.83 ± 8.69 min vs. 19.28 ± 9.70 min, \( P = 0.001 \)] and total hospital stay time [30.37 ± 8.99 min vs. 34.02 ± 12.16 min, \( P = 0.001 \)], lesser hypoxemia [2.3% (3/131) vs. 12.8% (17/133), \( P = 0.014 \)], use of fewer vasoactive drugs (\( P = 0.001 \)) and more retching (\( P = 0.001 \)). There was no difference in the incidence of bucking and body movements and endoscopist and patient satisfaction between two groups.

Conclusion

MS may be a better option for older patients undergoing outpatient gastroscopies, as demonstrated by shorter PACU stay time and total hospital stay time, lower sedation-associated adverse events, equal endoscopist and patient satisfaction.

Trial registration

Chinese Clinical Trial registration number ChiCTR2100049180. Registered 24/07/2021.

Background
Endoscopy is frequently used to diagnose and treat gastrointestinal (GI) disorders and is mostly performed with sedation. Although commonly used in gastrointestinal endoscopy, considerable variability in sedation practices has been reported. A systematic review including 19 guidelines and 7 position statements showed that the recommended sedation practices in routine gastrointestinal endoscopy differ across guidelines/position statements and often lack supporting evidence with potential implications for patient safety and procedural efficiency. There was no agreement on the class of drugs and sedation levels for sedating patients undergoing GI endoscopy.\(^1\)

Sedation level can be assessed according to the 2018 American Guidelines for Sedation and Anesthesia for gastrointestinal endoscopy\(^2\) or Modified Observer’s Assessment of Alertness/Sedation (MOAA/S)\(^3\). Moderate sedation (MS) refers to a level of sedation in which the patients remain responsive to verbal commands, with or without the need for tactile stimulation, and spontaneous ventilation is often adequate without airway intervention, and circulatory function can be maintained.\(^2\) The use of small incremental boluses of propofol with an opioid and benzodiazepine is referred to as balanced propofol sedation (BPS).\(^4\) BPS can be effective in achieving moderate sedation for endoscopic procedures.\(^5\) In contrast, deep sedation (DS) refers to a level of sedation in which the patient requires repeated or painful stimulation to elicit a response, spontaneous ventilation may be insufficient, and airway intervention may be required, while circulatory function can be maintained.\(^2\) Propofol administration by anesthesia professionals to induce DS is one of the most common sedation methods for GI procedures in North America and Europe.\(^6\) A meta-analysis\(^7\) suggested that DS resulted in improved patient satisfaction compared to minimal sedation or MS, but no significant difference in oxygen saturation, systolic blood pressure, heart rate, and procedure times. A randomized controlled trial showed that MS was associated with shorter recovery, lower incidence of sedation-related adverse events, and higher recall rates compared to DS for colonoscopy, but the choice of sedation level was not recommended.\(^8\) Therefore, current evidence regarding proper sedation for GI endoscopy remains controversial.

Recently, the number of older patients undergoing gastroscopy has increased. A previous study found that older age (70–99 years) and sedation were independent risk factors for cardiocerebrovascular adverse events in individuals who underwent GI endoscopy.\(^9\) However, only a limited number of studies have compared different sedation level during GI endoscopy in older patients. Therefore, we conducted this prospective randomized controlled study to compare the effect of MS and DS on recovery in older patients who underwent outpatient gastroscopy.

**Materials And Methods**

**Study population and design**

A single-center, prospective, randomized, partly blinded study was conducted with 270 consecutive patients referred for gastroscopy between August 2021 and September 2021. The study was approved by the Institutional Ethics Committee of Beijing Hospital (2021BJYYEC-150-02) and registered in the Chinese...
Clinical Trial Registry (www.chictr.org.cn; ChiCTR2100049180; Date of registration:24/07/2021). The inclusion criteria were as follows: (1) patients aged ≥ 60 years, (2) American Society of Anesthesiologists (ASA) I–II patients, (3) scheduled to undergo a sedative gastroscopy, (4) patient consented to participate in the trial, signed the informed consent form, and was willing to comply with study requirements. The exclusion criteria were as follows: patients (1) who were allergic to used drugs or had a history of anesthesia-associated adverse events, (2) with mental illness, alcohol or drug abuse, (3) with difficult airway or severe respiratory diseases (obstructive sleep apnea syndrome, mouth opening < 3 cm, limited movement of the neck or jaw, morbid obesity, acute respiratory infections, acute onset of chronic obstructive pulmonary disease, and uncontrolled asthma), (4) who had acute heart failure, unstable angina pectoris, myocardial infarction occurred within 6 months, resting electrocardiograph (ECG) heart rate < 50 beats/min, grade III atrioventricular block, severe arrhythmia, moderate to severe heart valve disease, (5) with liver dysfunction (aspartate aminotransferase and/or alanine aminotransferase ≥ 2.5 upper limit of normal (ULN), total bilirubin ≥ 1.5 ULN), or renal dysfunction (urea or urea nitrogen ≥ 1.5 ULN, serum creatinine > ULN), (6) with uncontrolled blood pressure (sitting systolic blood pressure ≥ 160 mmHg or ≤ 90 mmHg, and/or diastolic blood pressure ≥ 100 mmHg), (7) who required an examination time exceeding 30 min, (8) who had participated in other studies within the previous 30 days, and (9) with an unwillingness or inability to cooperate.

Data Collection And Blinding

Written informed consent was obtained from all the eligible patients. The patients’ basic information (age, sex, height, weight, comorbid diseases, smoking and drinking history, and concomitant medication history) was collected by the outpatient doctor during the anesthesia assessment 3–7 days before the examination. On the day of examination, patients with inclusion criteria were randomly assigned to the MS group (2 ≤ MOAA/S ≤ 4) or the DS group (MOAA/S ≤ 1) using computer-generated random sequences. Randomization was not blinded to the anesthesiologists, data record anesthesia nurses, or endoscopists but blinded to patients and nurses in PACU. Vital signs and adverse events during the examination were recorded by the anesthesia nurse. Evaluation in PACU and satisfaction of endoscopists and patients were recorded by the PACU nurse after the examination.

Study Procedures And Drug Administration

Eight hours of fasting for food and 2 hours of fasting for water was performed before the examination. All patients received basic anesthetic monitoring using a five-lead-electrocardiogram, pulse oximetry, and blood pressure cuff and the end-expiratory carbon dioxide. Supplemental oxygen was delivered to all patients during the procedure via nasal cannula (2 L/min). Before entering the examination room, a peripheral intravenous line was set up.

In MS group, patients received an initial intravenous bolus of 1 µg/kg of fentanyl and 1mg of midazolam. Propofol (0.25–0.5 mg/kg) was administered 2 minutes later to achieve moderate sedation (2 ≤
MOAA/S ≤ 4). Subsequent incremental boluses of 10 to 20mg of propofol were given to perform moderate sedation. If the patient seemed agitated or unable to cooperate under MS, propofol was used to deepen sedation level based on clinical experience. In DS group, patients also received an initial intravenous bolus of 1 µg/kg of fentanyl and 1mg of midazolam. Propofol (1–2 mg/kg) was administered 2 minutes later to achieve deep sedation (MOAA/S ≤ 1). Propofol (0.5 mg/kg) was repeated given to maintain DS. MOAA/S was shown in Appendix 1. After examination, all patients were intravenously injected with flumazenil 0.2 mg for antagonism and transferred to PACU. If the fast-track criteria score\textsuperscript{10} reached 14 points, patients could be discharged. If not reach 14 points 1h after examination, patients cannot be discharged and should be transferred to the emergency observation room for observation and treatment.

**Outcome Measurements And Definitions**

The primary outcome assessed was the PACU stay time, defined as the time from the end of the examination to scoring 14 points using the fast-track criteria (assessments were performed every 2 min in PACU). Recorded the time of scoring 2 points in each of the following areas: level of consciousness, physical activity, hemodynamic stability, respiratory stability, oxygen saturation status, postoperative pain assessment, and postoperative emetic symptoms, shown in Appendix 2.

The secondary outcomes were the (1) total hospital stay time (from hospital admission to discharge home), induction time (from administration to gastroscope insertion), operation time (from gastroscope insertion to withdrawal), (2) retching during procedure (the act of vomiting, without vomit), bucking during procedure (an irritating dry cough during examination), and body movement during procedure (the activity of the trunk and extremities, scored according to the following: 0: no movement; 1: general body movements where hand or foot movements do not affect the examination; 2: severe physical movements where leg or hip movements affect the examination), (3) the satisfaction of the endoscopist and patient (using an 11-point numerical rating scale (NRS), where 0 equals totally unsatisfied, 10 equals completely satisfied), (4) the mean blood pressure, heart rate and blood oxygen saturation (SpO\textsubscript{2}) (basal values (T1), immediately before gastroscope insertion (T2), 2 min after insertion (T3), 5 min after insertion (T4), at the time of withdrawal (T5), and at the time of discharge (T6)), and (5) sedation-associated adverse events during procedure.\textsuperscript{11} Severe sedation-associated adverse events were defined as the need for intensive-care unit admission, intubation, resuscitation and/or death; while minor sedation-associated adverse events included respiratory depression which could be corrected rapidly and hemodynamic fluctuations requiring vasoactive drugs. Respiratory depression was defined as hypoxemia (85%<SpO\textsubscript{2} < 90% which could be corrected by mask oxygen inhalation and thrusting the jaw), severe hypoxemia (SpO\textsubscript{2} ≤ 85% could be corrected by assisted ventilation). Hypotension was the largest decrease in mean arterial pressure at least 20% from the baseline value. Bradycardia was described as heart rates < 50 beats/min. Tachycardia was described as heart rates > 100 beats/min.
Patients with the following criteria had to be withdrawn: unanticipated examination changes, insufficient MS or DS, requiring deepening of anesthesia, and termination of the procedure by the anesthesiologists and endoscopists because of safety concerns.

**Sample Size Estimation**

The PACU discharge has been reported to be approximately 20 min with DS for elective outpatient colonoscopies. [8] Meanwhile, our pilot study showed that the PACU stay time in DS group was approximately 20 ± 9 min, and the PACU stay time was shorter in MS group. An equivalence margin of 20% in the recovery times between MS and DS groups was selected by investigator consensus, owing to the lack of literature to inform this decision. Therefore, to attain a significance level of 0.05 and a power of 0.9, each group needed 108 participants (total = 236) to show the equivalence using PASS (version 15.0.5, Kaysville, Utah, USA). A recruitment target of 270 patients was set to account for 15% dropouts and allow sufficient power to analyze secondary outcomes.

**Statistical Analysis**

All the analyses were performed using SPSS Statistics for Windows (version 24.0, IBM Corp., Armonk, New York, USA). Continuous data were tested using the student’s t-test and summarized as the mean (standard deviation) if the data were normally distributed, or tested with a Wilcoxon Rank sum test and summarized as the median (interquartile ranges) if the data were non-normally distributed. A χ² test or Fisher’s exact test was used to analyze the categorical data. The analysis of repeated measurement data, such as the heart rate and mean blood pressure, was performed using the analysis of variance for multi-factor repeated measurements. All tests were two-tailed, and a value of $P<0.05$ was accepted as significant.

**Results**

From August 2021 to September 2021, 270 patients scheduled for outpatient gastroscopy were included, 131 in MS group and 133 in DS group completed the trial according to the study protocol. Four patients in MS group withdrew from this study, two changed examinations, and two received deeper anesthesia due to intolerance. Two patients in DS group withdrew from this study due to low basic blood pressure and frequent premature ventricular bigeminy before induction. A flowchart summarizing the patients enrolled in the study is shown in Fig. 1. The incidence of deepening anesthesia had no significant difference (1.5% in MS group vs. 0 in DS group, $P=0.498$). We provide an overview of the baseline characteristics of the enrolled participants in Table 1. Overall, the patient and clinical data were well balanced between the two groups. The average dosage of propofol in DS group was higher than MS group (76.56 ± 26.33mg vs. 36.06 ± 15.23mg, $P<0.001$) and the average dosage of fentanyl in two groups was comparable (DS group 61.60 ± 9.79mg vs. MS group 62.76 ± 10.48mg, $P=0.362$). Significant differences in PACU stay time (16.15 ± 9.01 min vs. 20.02 ± 11.13 min, respectively; $P=0.003$) and hospital stay time (27.32 ± 9.86
min vs. 30.82 ± 12.37 min, respectively; \( P = 0.007 \) between MS and DS groups were observed. The recovery of consciousness, physical activity, and hemodynamic stability was faster in MS group \( (P<0.05) \). MS group had longer induction time than DS group (3.44 ± 0.69 min vs. 3.26 ± 0.54 min, \( P = 0.025 \)), as shown in Table 2.
<table>
<thead>
<tr>
<th>Variables</th>
<th>Moderate sedation (n = 131)</th>
<th>Deep sedation (n = 133)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age(years)</td>
<td>66.76 ± 5.03</td>
<td>67.75 ± 5.04</td>
<td>0.109</td>
</tr>
<tr>
<td>Sex(male)</td>
<td>47(35.9%)</td>
<td>40(30.1%)</td>
<td>0.360</td>
</tr>
<tr>
<td>BMI(Kg·m$^{-2}$) a</td>
<td>24.86 ± 14.00</td>
<td>23.43 ± 3.21</td>
<td>0.252</td>
</tr>
<tr>
<td>Hypertension</td>
<td>52(39.7%)</td>
<td>49(36.8%)</td>
<td>0.704</td>
</tr>
<tr>
<td>Cardiovascular diseases b</td>
<td>11(8.4%)</td>
<td>12(9.0%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28(21.4%)</td>
<td>20(15.0%)</td>
<td>0.204</td>
</tr>
<tr>
<td>Cranial vascular disease</td>
<td>4(3.1%)</td>
<td>4(3.0%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Respiratory disease c</td>
<td>10(7.6%)</td>
<td>10(7.5%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Other diseases d</td>
<td>9(6.9%)</td>
<td>12(9.0%)</td>
<td>0.650</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>38(29.0%)</td>
<td>44(33.1%)</td>
<td>0.508</td>
</tr>
<tr>
<td>Reflux</td>
<td>45(34.4%)</td>
<td>44(33.1%)</td>
<td>0.897</td>
</tr>
<tr>
<td>Smoking history</td>
<td>16(12.2%)</td>
<td>9(6.8%)</td>
<td>0.146</td>
</tr>
<tr>
<td>Alcohol history</td>
<td>10(7.6%)</td>
<td>9(6.8%)</td>
<td>0.816</td>
</tr>
<tr>
<td>Use of sedative drugs</td>
<td>31(23.7%)</td>
<td>34(25.6%)</td>
<td>0.565</td>
</tr>
<tr>
<td>History of endoscopy under sedation</td>
<td>67(87.0%)</td>
<td>65(79.3%)</td>
<td>0.212</td>
</tr>
<tr>
<td>Total propofol dose(mg)</td>
<td>35.92 ± 15.23</td>
<td>77.29 ± 27.64</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Total fentanyl dose (µg)</td>
<td>62.82 ± 10.34</td>
<td>61.65 ± 9.75</td>
<td>0.345</td>
</tr>
</tbody>
</table>

Values are mean ± SD, median (interquartile range) or number (%)

a: BMI: body mass index

b: Cardiovascular diseases: include coronary heart disease, myocardial infarction, percutaneous coronary intervention, arrhythmia.

c: Respiratory diseases: include chronic bronchitis, chronic obstructive pulmonary disease, asthma.

d: Other diseases: include renal function impairment, hepatic function impairment, abnormal thyroid function, anemia, hematological disease, immune system diseases.
<table>
<thead>
<tr>
<th>Variables</th>
<th>Moderate sedation (n = 131)</th>
<th>Deep sedation (n = 133)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction time (min)</td>
<td>$3.44 \pm 0.69$</td>
<td>$3.26 \pm 0.54$</td>
<td>0.025</td>
</tr>
<tr>
<td>Operation time (min)</td>
<td>$7.74 \pm 4.19$</td>
<td>$7.54 \pm 4.09$</td>
<td>0.696</td>
</tr>
<tr>
<td>PACU stay time (min)</td>
<td>$16.15 \pm 9.01$</td>
<td>$20.02 \pm 11.13$</td>
<td>0.002</td>
</tr>
<tr>
<td>Consciousness recovery time (min)</td>
<td>$0.47 \pm 1.44$</td>
<td>$2.35 \pm 2.38$</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Physical activity recovery time (min)</td>
<td>$15.62 \pm 8.56$</td>
<td>$18.77 \pm 8.60$</td>
<td>0.003</td>
</tr>
<tr>
<td>Hemodynamic stability recovery time (min)</td>
<td>$2.34 \pm 4.77$</td>
<td>$5.76 \pm 8.51$</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Respiration recovery time (min)</td>
<td>$0.02 \pm 0.17$</td>
<td>$0.02 \pm 0.17$</td>
<td>0.991</td>
</tr>
<tr>
<td>Oxygen saturation recovery time (min)</td>
<td>$0.02 \pm 0.17$</td>
<td>$0.00 \pm 0.00$</td>
<td>0.319</td>
</tr>
<tr>
<td>Postoperative pain recovery time (min)</td>
<td>$0.02 \pm 0.17$</td>
<td>$0.02 \pm 0.17$</td>
<td>0.991</td>
</tr>
<tr>
<td>Postoperative emetic symptoms recovery time (min)</td>
<td>$0.46 \pm 5.24$</td>
<td>$0.36 \pm 3.99$</td>
<td>0.866</td>
</tr>
<tr>
<td>Total hospital stay time (min)</td>
<td>$27.32 \pm 9.86$</td>
<td>$30.82 \pm 12.37$</td>
<td>0.012</td>
</tr>
</tbody>
</table>

Values are mean $\pm$ SD

PACU: Post-anesthesia care unit

Retching during procedure was 16.8% in MS group and 3.8% in DS group ($P<0.001$). Bucking during procedure was 16.0% in MS group and 9.0% in DS group ($P=0.096$). General body movements occurred in 42 patients (32.1%) in MS group and 31 (23.3%) in DS group but did not affect the examinations. None of the patients of MS group and only two patients (1.5%) in DS group experienced severe physical movements that affected the examinations ($P=0.117$). The median patient satisfaction score for the procedure was 10 (10, 10) in both groups ($P=0.181$). The median satisfaction score of the endoscopists for the procedures was 10 (10, 10) in MS group and DS group ($P=0.061$). No severe sedation-associated adverse events occurred in either group. The incidence of hypoxemia occurred in 2.3% (n = 3) of MS group vs. 12.8% (n = 17) of DS group ($P=0.008$). Severe hypoxemia occurred in one patient (0.8%) in each group ($P=1.000$). The percentage of patients using vasoactive drugs was higher in DS group (33.0%, n = 63) than MS group (18.3%, n = 24) ($P<0.001$). The results are summarized in Table 3.
There was a significant difference in time course of mean blood pressure between the two groups, and the average decrease in mean blood pressure was larger in DS group \( (P < 0.001) \). Over time, the mean blood pressure gradually decreased, with the lowest T3 time point, and the basal level was restored upon departure. Meanwhile, there was a significant difference in time course of heart rate between the two groups, and the average decrease was larger in DS group \( (P = 0.043) \). The results are presented in Fig. 2.

**Discussion**

Our study showed that both MS and DS could be safely and effectively used in elective outpatient gastroscopies in geriatric patients. MS provides quicker discharge than DS, with fewer sedation-associated adverse events during procedure and sustained satisfaction of the endoscopists and patients.
Some studies have reported that MS is safe and effective for endoscopic retrograde cholangiopancreatography surgery in older patients, and all patients can complete the procedure\cite{9}. In our study, anesthesia was deepened in only two patients in MS group, and the satisfaction level of the endoscopists and patients was high, demonstrating that MS was effective.

The mean PACU stay time for MS was 3.87 min shorter than that for DS, consistent with a recent meta-analysis,\cite{7} which was also clinically acceptable. We routinely used flumazenil, which may also have resulted in a shorter recovery time. A randomized controlled study showed that the time of recovery after flumazenil administration was significantly shortened, and the use of the drug did not increase the risk of adverse events or uncomfortable symptoms.\cite{12} Our center performs approximately 20,000 sedated gastroscopies annually, where a 4 min decrease in recovery time would cumulatively be significant. Using MS will save time and labor costs, given the increasing number of patients. Further research is needed to determine the factors affecting the quality of recovery in older patients undergoing gastroscopies.

Despite the increased incidence of retching in MS group, none of the patients experienced regurgitation and aspiration, and there was no consequent decrease in examination success rates, increase in examination time, or decrease in endoscopist and patient satisfaction. This could be due to (1) the patients were fasting and could be aspirated at any time during the examination. (2) endoscopists were full of experience, and retching had little effect on examination. (3) the patients could not recall after the examination. (4) the patients recovered faster, enabling quicker communication with their endoscopists.

Although rapid discharge can save time and labor costs, sedation safety is more important for older patients. In our study, MS group had fewer minor sedation-associated adverse events than DS group. The incidence of hypoxemia (85%<SpO$_2$<90%) was higher than published study, in which, the incidence of minor sedation-associated adverse events was 0.3% and respiratory depression (SpO$_2$ < 90% > 10 s) was most common.\cite{11} There may be three reasons: (1) Our study population was older adults, who were more prone to respiratory depression. (2) We recorded and corrected respiratory depression or hypoxemia as soon as it developed, rather than over a period of time. The SPO$_2$ of 3 patients with hypoxemia in MS group and 12 patients in DS group decreased to 89%, and all recovered quickly. Unfortunately, we did not record the duration. If we ignored these patients, the incidence would be very low. (3) Shared upper airway with endoscopists is more likely to induce desaturation.\cite{13}

Hemodynamic stability in MS group was more stable during the procedure (from insertion to withdrawal), which is beneficial for the long-term prognosis of older patients. A retrospective meta-analysis showed that hypotension is common during propofol sedation for colonoscopy and of a magnitude and duration associated with harm in surgical patients.\cite{14} A systematic review of 42 articles concluded that organ injuries might occur when the mean arterial pressure decreased to < 80 mmHg for ≥ 10 min, and this risk increased as the blood pressure progressively decreased.\cite{15} Unfortunately, we did not conduct long-term follow-ups.
DS must be performed by an anesthesiologist, while MS can be performed simultaneously by multiple nurses under the guidance of one anesthesiologist. Medications targeting MS can generally be administered incrementally by an appropriately trained registered nurse under the supervision of an endoscopist. In the case of a shortage of anesthesiologists, MS undoubtedly saves the burden of personnel. Some studies have reported that older patients sedated with propofol are more likely to develop hypoxemia during complex upper gastrointestinal endoscopy. Tracheal intubations should be implemented promptly when necessary by anesthesiologist.

In this study, BPS regimen was used. BPS, which was originally described by Cohen et al, combines small incremental doses of propofol with single induction doses of benzodiazepines and opioids. BPS is effective in achieving MS during endoscopic procedures. Compared with conventional sedation, BPS provides higher satisfaction and compliance for the patients undergoing therapeutic endoscopic surgeries with comparable adverse event rates. Studies have confirmed that BPS has a good safety index for both cirrhotic and non-cirrhotic patients and is equally acceptable for both patients and endoscopists. A retrospective study showed that BPS could be used in patients with ASA III. Further research is needed to determine which MS regimens are more suitable for older gastroscopy patients.

**Limitations**

This study had several limitations. First, it was a single-center study, and the number of patients was too small to assess for rare adverse events accurately. We did not assess the patients for long-term adverse events after discharge. Second, the endoscopists in this study were skilled physicians and not blinded to the sedation level, and the findings may not apply to beginners. Third, our findings may only apply to gastroscopies in ASA I–II older patients. Whether they can be extended to the general population or to colonoscopies requires further research. In addition, our study did not set an upper age limit because we believe that age is not a contraindication to sedation and can be performed as long as the anesthesia clinic evaluates tolerability. Fourth, the depth of sedation was based on the MOAA/S without monitoring the bispectral Index (BIS). Gastroscopies are typically quick, making the BIS relatively delayed and costly. However, no guidelines mention that the BIS needs to be monitored in implementing gastroscopies.

**Conclusions**

This study confirmed that both MS and DS were safe and effective in geriatric endoscopy. MS resulted in faster discharge, fewer sedation-associated adverse events, and satisfied endoscopists and patients. Therefore, we suggest moderate sedation may be a better option for older patients undergoing outpatient gastroscopies.

**List Of Abbreviations**

moderate sedation (MS)
deep sedation (DS)

Modified Observer’s Assessment of Alertness/Sedation (MOAA/S)

post-anesthesia care unit (PACU)

gastrointestinal (GI)

balanced propofol sedation (BPS)

American Society of Anesthesiologists (ASA)

electrocardiograph (ECG)

upper limit of normal (ULN)

numerical rating scale (NRS)

blood oxygen saturation (SpO₂)

Declarations

Acknowledgments

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Author's contributions

Bing Chen: conception and design; analysis and interpretation of the data; drafting of the article; critical revision of the article for important intellectual content; final approval of the article.

Lin Lu: conception and design; analysis and interpretation of the data; drafting of the article; final approval of the article.

Jie Zhai: conception and design; final approval of the article.

Zhen Hua: conception and design; critical revision of the article for important intellectual content; final approval of the article.

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Availability of data and materials
The datasets generated and/or analysed during the current study are not publicly available due to laws about patients but are available from the corresponding author on reasonable request.

**Ethics approval and consent to participate**

This is a prospective randomized controlled study approved by the Beijing Hospital Clinical Research Ethics Committee (2021BJYYEC-150-02) and registered with the Chinese Trials Registry (ChiCTR2100049180; Date of registration: 24/07/2021). Written informed consent was obtained from all subjects. All methods were carried out in accordance with Declaration of Helsinki.

**Consent for publication**

Not Applicable.

**Competing interests**

The authors declare that they have no competing interests.

**References**


Figures
Figure 1

CONSORT diagram of patient flow through the study.

CONSORT, Consolidated Standards of Reporting Trials; MS, moderate sedation; DS, deep sedation.
Figure 2

Mean blood pressure and heart rate during examination. A: Comparison of mean blood pressure at different time points between two groups ($P<0.001$); B: Comparison of heart rate at different time points between two groups ($P=0.043$)

T1: basal values, T2: immediately before gastroscope insertion, T3: 2 min after gastroscope insertion, T4: 5 min after gastroscope insertion, T5: at the time of gastroscope withdrawal, T6: the time of discharge

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix.docx
- CONSORT2010Checklist.doc