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Comparison of the efficacy and safety of remimazolam and propofol for fiberoptic bronchoscopy in older patients: a prospective, randomized controlled study

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Abstract

Objective The aim of this study was to compare the efficacy and safety of remimazolam with those of propofol in older patients undergoing fiberoptic bronchoscopy with preserved spontaneous breathing.

Methods Sixty older patients were randomly and equally divided into a remimazolam group (group R) and a propofol group (group P). Both groups received 0.15 μg/kg of sufentanil for analgesia. Group R received an initial dose of 0.2 mg/kg remimazolam and was injected with a maintenance dose of 1 mg/kg/h. Group P received an initial dose of 2 mg/kg propofol and was injected with a maintenance dose of 4 mg/kg/h. The primary evaluation indicators were the success rate of sedation and the incidence of hypotension. The secondary evaluation indicators were respiratory depression, hypertension, tachycardia, bradycardia, awakening time, quality of recovery-15 (QOR-15) score, patient satisfaction, physician satisfaction, and adverse events.

Results Success rates of sedation were similar between group R (96.7%) and group P (100%). The incidence of hypotension in group R was lower than that in group P (2/30 vs. 10/30, $p=0.01$). Respiratory depression was lower in group R than in group P (3/30 vs. 10/30, $p=0.03$). Fewer patients reported injection pain in group R (0/30 vs. 7/30, $p=0.01$). There were no significant differences in hypertension, tachycardia, bradycardia, awakening time, QoR-15 score, patient satisfaction, physician satisfaction, or adverse events between the two groups.

Conclusions Remimazolam has a high sedation success rate for painless fiberoptic bronchoscopy in older patients, and the incidence of hypotension and respiratory depression is lower than that of propofol. Remimazolam may be a better choice for sedation during painless fiberoptic bronchoscopy in older patients with preserved spontaneous breathing.

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Background

Fiberoptic bronchoscopy is the most direct technique for the diagnosis and treatment of respiratory diseases [1]. However, fiberoptic bronchoscopy is an invasive procedure that can elicit a strong stress response in patients. Thus, a painless fiberoptic bronchoscopy procedure would ensure a more comfortable medical experience for the patient and a safe and convenient diagnosis and treatment environment for the surgeon. In clinical practice, painless fiberoptic bronchoscopy is the most common and safe method because of its simple operative procedure and short operative time and the use of moderate-to-deep sedation that allows patients to maintain spontaneous respiration. As the population has aged, the incidence of respiratory diseases has risen, and the number of older patients undergoing bronchoscopy has increased significantly in recent years [2]. Advanced age is a risk factor for complications of fiberoptic bronchoscopy that cannot be ignored [2]. Older individuals who are more sensitive to drugs have lower cardiovascular and respiratory compensatory capacity, and their risk of hypotension, hypoxemia, arrhythmia and other adverse events during clinical procedures is significantly increased. The identification of sedatives with good sedation effects and relatively few adverse effects has become a pressing issue for the implementation of fiberoptic bronchoscopy in older patients.

Anesthesia management is a great challenge for painless fiberoptic bronchoscopy that preserves spontaneous breathing. Propofol is the most common sedative used in painless bronchoscopy [3, 4]; however, its severe inhibitory effects on respiration and circulation increase the incidence of hypotension, hypoxemia and arrhythmia, which is particularly prominent in bronchoscopy. Notably, the inhibitory effects of propofol are more significant in older patients, limiting its application in this population to a certain extent [5]. Remimazolam is a new ultrashort-acting benzodiazepine that has an almost immediate effect, is rapidly metabolized, has little impact on respiratory circulation, does not accumulate, and has other advantages; thus, it has been used for sedation and the induction and maintenance of general anesthesia for diagnosis and treatment [6]. Previous studies have reported that remimazolam is safe and effective for painless fiberoptic bronchoscopy [7, 8].

To date, studies of remimazolam in older patients undergoing painless fiberoptic bronchoscopy have been relatively rare. Therefore, we conducted a prospective, randomized, single-blind trial to compare the efficacy and safety of remimazolam with those of propofol in older patients undergoing fiberoptic bronchoscopy with preserved spontaneous breathing.

Methods

Experimental design

This was a prospective, single-center, randomized, single-blind clinical trial that compared the efficacy and safety of remimazolam with those of propofol in older patients undergoing fiberoptic bronchoscopy with preserved spontaneous breathing. This study was approved by the Ethics Committee of Tongxiang First People's Hospital (No. 2023-001-01) and registered at the Chinese Clinical Trial Center (ChiCTR2300069041) on 6 March 2023. All patients or their families signed informed consent forms.

Participants

Older patients who underwent painless fiberoptic bronchoscopy at the Endoscopy Center of Tongxiang First People's Hospital between March 2023 and April 2024 were eligible to enter the study. (Fig. 1). The inclusion criteria were: age 65–80 years, American Society of Anesthesiologists (ASA) grade I or II, body mass index (BMI) of 18.5–28 kg/m2, and oxygen saturation (SPO_2) of ≥ 93%. The exclusion criteria were: unsatisfactorily controlled hypertension, an ECG recording indicating a heart rate (HR) of < 50 beats/min or a HR of > 100 beats/min, apnea syndrome, coronary heart disease, a difficult airway, allergy to the investigational drug, intermittent or long-term use of benzodiazepines or opioids within 2 months before admission, and inability to communicate effectively. The interruption criteria were: serious adverse reactions, including severe hypoxemia during surgery requiring emergency intubation, intraoperative puncture or treatment procedures, or critical conditions such as massive bleeding during surgery.

Randomization

Each patient received a visit from the physician 1 day before surgery, and admission and exclusion criteria were used to determine whether the patient was suitable for enrollment in the trial. Patients were entered randomly into the P or R groups sequentially (1:1, $n = 30$) according to the order of enrollment and group randomization numbers generated by SPSS, without skipping numbers or choosing anesthetics independently. The allocation concealment was conducted with sequentially numbered opaque sealed envelopes. Owing to differences in the color, properties and dosage of the two groups of drugs, a single-blind design was used in this study.

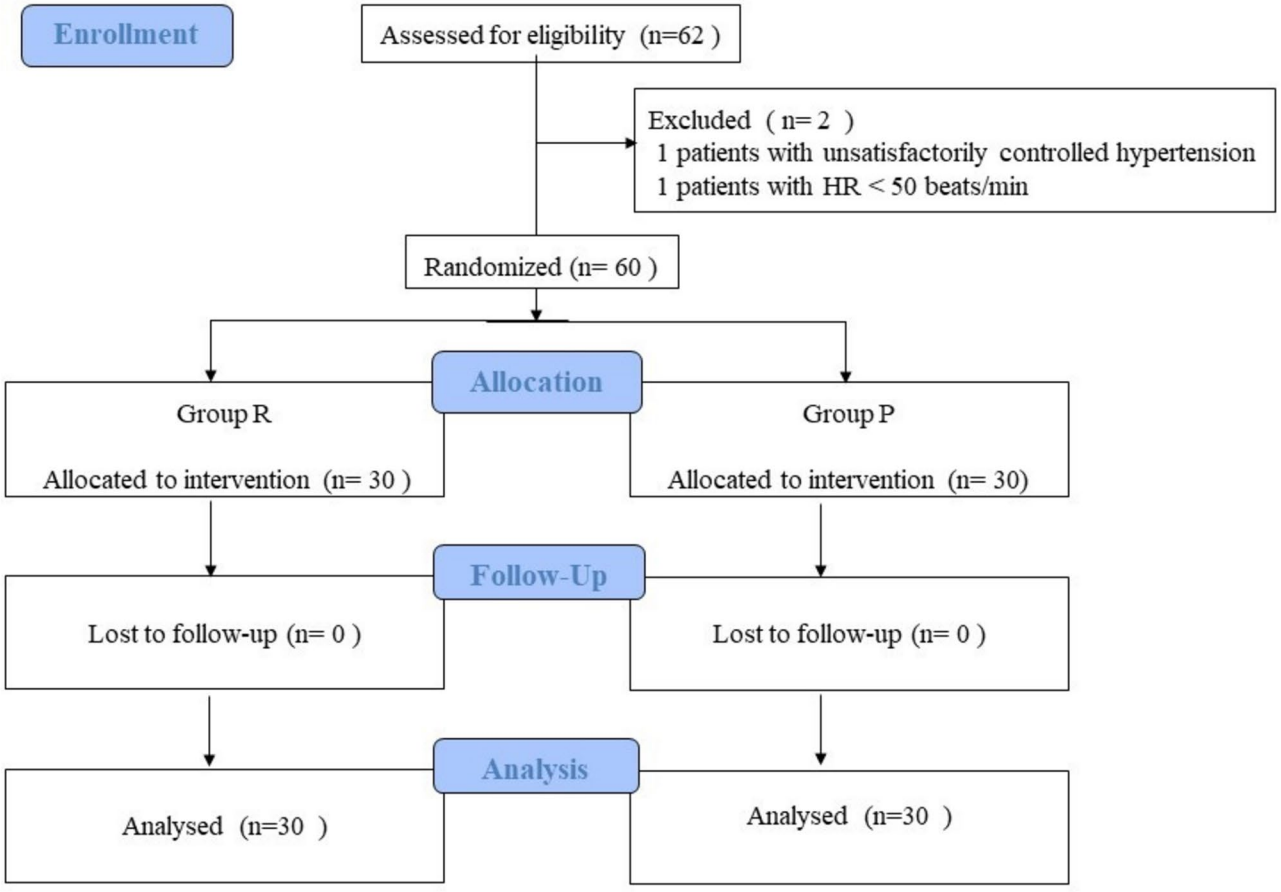

Fig. 1 Patient flowchart with CONSORT guidelines

Anesthesia method

A total of 10 ml of nebulized 2% lidocaine was administered in the waiting area (for not less than 15 min) with open venous access. After entering the endoscopy room, oxygen was administered via a nasal catheter (4 L/min), and the electrocardiogram (ECG), mean arterial pressure (MAP), SPO_2 and respiratory rate were routinely monitored. The HR and MAP were defined as the average HR and MAP, respectively, of the patients and were measured three times before the procedures. The patients in both groups were treated according to their actual body weights. Sedation in Group R was induced with 0.2 mg/kg remimazolam and 0.15 μg/kg sufentanil (slow intravenous injection over 30 s), followed by 1 mg/kg/h remimazolam. Sedation in Group P was induced with 2 mg/kg propofol [8] and 0.15 μg/kg sufentanil (slow intravenous injection over 30 s), followed by continuous pump injection of 4 mg/kg/h propofol. When the improved Modified Observer's Assessment of Alertness and Sedation (MOAA/S) score was less than or equal to 1 point [9], a nasopharyngeal endotracheal catheter was inserted, the anesthetic machine was connected to provide continuous oxygen (4 L/min), and the end-expiratory CO2 monitoring catheter was connected. When the fiberoptic bronchoscope was inserted through the glottis, 2% lidocaine was sprayed around the glottis to enhance local anesthesia. The sedation pump was stopped immediately upon the end of fiberoptic bronchoscopy. Patients who exhibited coughing or body movement in Group R were given 0.075 mg/kg remimazolam, and those in Group P were given 0.75 mg/kg propofol. If the supplementary dose was administered more than 3 times, the procedure was categorized as a sedation failure, and a rescue sedative (propofol) was given. MAP, HR, SPO_2, and MOAA/S scores were recorded at T0 (after the patient entered the room), T1 (1 min after anesthesia), T2 (bronchoscope reached the carina), T3 (after microscopy), and T4 (before exiting the resuscitation room).

If hypotension occurred (MAP decreased by 20% from baseline), fluid therapy (rapid intravenous infusion of 200 ml of normal saline) was given; if severe hypotension occurred (MAP decreased by 30% from baseline), 40 μg of deoxyadrenaline was administered intravenously. If bradycardia occurred, 5 μg/kg sedate atropine was given; if the SPO_2 concentration was <90% or the respiratory rate was <8 breaths/min, the jaw was supported, and

the oxygen flow was increased. If the SPO_2 was < 85% and persisted for 15 s without remission, the endoscopic procedure was suspended, the bronchoscope was withdrawn, oxygen was given via a mask, and bronchoscopy was continued after the oxygen saturation returned to normal. If severe hypoxemia could not be relieved, tracheal intubation was performed when necessary.

Data collection

The primary evaluation outcomes of the trial were the success rate of sedation and the incidence of hypotension. The success rate of sedation was defined as (i) completion of the whole endoscopy procedure; (ii) no requirement for an alternative and/or rescue sedative; and (iii) administration of a maximum of three supplemental doses after the initial dose. Hypotension was defined as a MAP of less than 60 mmHg or with more than a 20% reduction from baseline.

The secondary evaluation outcomes were respiratory depression (defined as an SPO_2 of < 90% or a respiratory rate of < 8 beats/min), hypertension (defined as an increase in the perioperative MAP of more than 20% from baseline), tachycardia (defined as a HR of > 100 beats/min), bradycardia (defined as a HR of < 50 beats/min), awakening time (defined as the starting point of timing based on the withdrawal of general anesthesia, with the endpoint determined when patients could correctly complete a nod as well as mouth and tongue extension), the QoR-15 score at 24 h postoperatively, patient satisfaction, physician satisfaction (full satisfaction scores for both assessments totaled 10 points, with 0–3 points defined as unsatisfactory, 4–7 points defined as relatively satisfactory, and 8–10 points defined as satisfactory), and adverse events: injection pain, hiccup, vertigo, postoperative nausea and vomiting (PONV).

Statistical analysis

In the preliminary tests, we found that the sedation success rates were 100% in both groups. Therefore, the incidence of hypotension was selected as a reference factor in the calculation of the sample size. The incidence of hypotension was 7% in the remimazolam group and 36% in the propofol group. The test level was set to 0.05, the efficacy was set to 0.8, and the software PASS 21.0 was used to estimate the sample size. The minimum sample size required for each group was 28. With expected dropout and loss to follow-up rates of approximately 10%, the final decision was made to include 60 patients.

SPSS 22.0 statistical software was used for data analysis. Normally distributed measurement data are expressed as the mean ± standard deviation; repeated-measures ANOVA was used for multiple-group comparisons, and independent sample t tests were used for between-group comparisons. Nonnormally distributed measurement data are presented as medians and quartiles. The Mann–Whitney U test was used for comparisons between groups, and the χ^2 test was used for comparisons of count data. A P value < 0.05 was considered to indicate statistical significance.

Table 1 Comparison of the general data of the patients

	Group R ($n=30$)	Group P ($n=30$)	P value
Age (years)	70.2 ± 4.1	69.7 ± 4.4	0.65
Sex (male/female)	17/13	18/12	0.79
ASA (I/II)	2/28	1/29	0.55
Weight (kg)	60.2 ± 10.0	61.8 ± 8.9	0.53
Height (cm)	163.7 ± 7.2	160.5 ± 8.2	0.55
BMI (kg/m^2)	22.4 ± 2.7	23.4 ± 2.7	0.17
Inspection time (min)	12.2 ± 2.8	12.6 ± 2.7	0.50

The data are presented as the mean ± standard deviation or as the number of patients

Abbreviations: ASA, American Society of Anesthesiologists;

BMI, body mass index

Table 2 Comparison of cardiovascular events and respiratory depression

	Group R ($n=30$)	Group P ($n=30$)	P value
Hypotension, n (%)	2(6.7%)	10(33.3%)	0.01*
Severe hypotension	0(0%)	4(13.3%)	0.04*
Hypertension	4(13.3%)	1(3.3%)	0.16
Tachycardia	4(13.3%)	1(3.3%)	0.16
Bradycardia	2(6.7%)	4(13.3%)	0.39
Respiratory depression	3(10%)	10(33.3%)	0.03*
Number of patients given mask support	0(0%)	1(3.3%)	0.31

*$P < 0.05$ vs. Group P

Results

Patient characteristics

After 62 participants were assessed and 2 patients were excluded, 60 patients were found to be eligible.These 60 patients were allocated into groups R and P (1:1, $n=30$). The patient demographics and baseline characteristics between the two groups were well balanced in terms of age, sex, weight, height, BMI, and ASA score, and there was no significant difference in the inspection time between the two groups ($P > 0.05$) (Table 1).

Primary outcomes

The sedation success rate was 96.7% in group R and 100% in group P. The difference in the sedation success rate between the two groups was not significant. One patient in the R group was determined to have failed sedation. The incidence of hypotension was lower in group R than in group P (2/30 vs. 10/30, $p=0.01$), and the incidence of severe hypotension was also lower in group R than in group P (0/30 vs. 4/30, $p=0.04$) (Table 2).

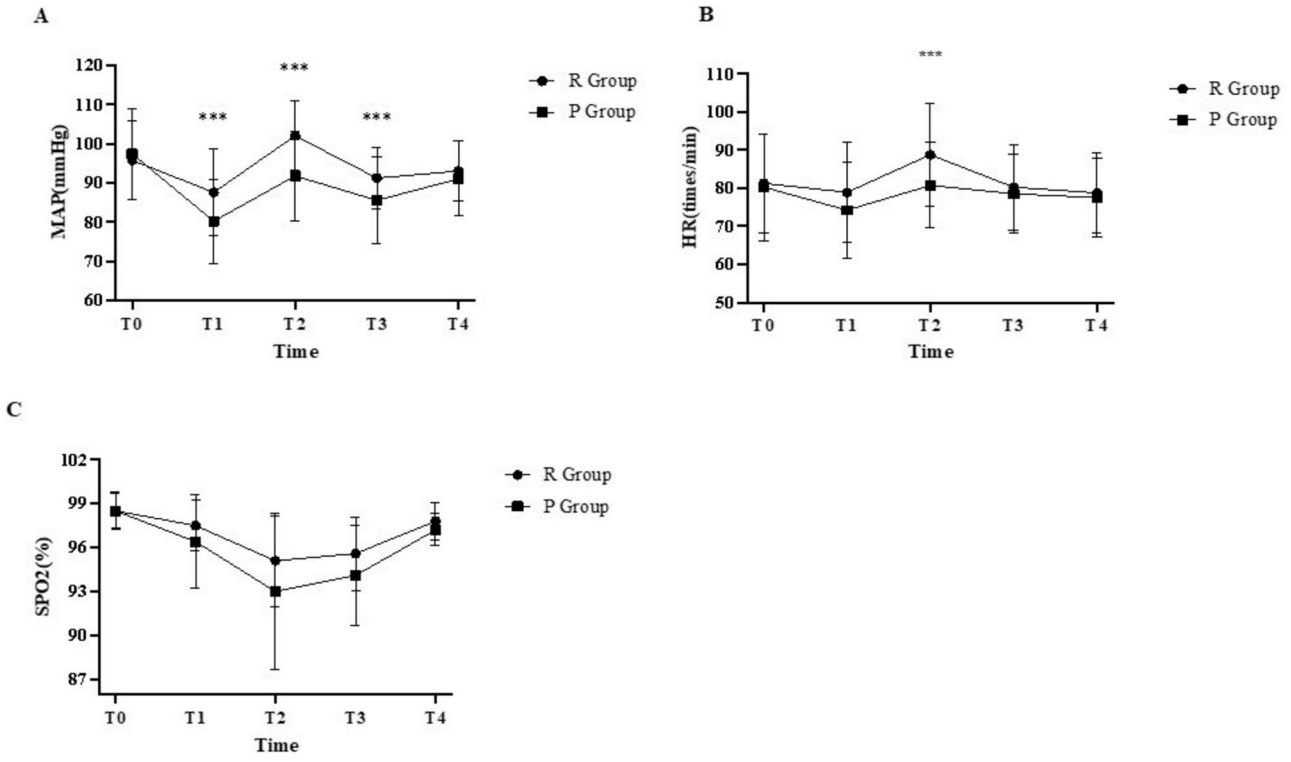

Fig. 2 Comparison of the (**A**) MAP, (**B**) HR and (**C**) SPO_2 between the two groups of patients at each time point. HR, heart rate; MAP, mean arterial pressure; SPO_2, oxygen saturation

Table 3 Awakening time, QoR-15 score, patient satisfaction and physician satisfaction of the two groups

	Group R (*n* = 30)	Group P (*n* = 30)	*P* value
Awakening time (min)	12.5 ± 3.0	11.8 ± 2.4	0.27
QoR-15 score	144.0 ± 3.4	144.3 ± 3.0	0.72
Patient satisfaction	9.4 ± 0.8	9.2 ± 0.9	0.45
Physician satisfaction	9.6 ± 0.8	9.4 ± 1.0	0.33

The data are presented as the mean ± standard deviation or as the number of patients

Abbreviations: QoR-15 score, quality of recovery-15 score

Table 4 Comparison of the incidence of adverse events

	Group R (*n* = 30)	Group P (*n* = 30)	*P* value
Injection pain, n (%)	0(0%)	7(23.3%)	0.01*
Hiccup	1(3.3%)	0(0%)	0.31
Vertigo	3(10%)	2(6.7%)	0.64
PONV	2(6.7%)	1(3.3%)	0.55

Abbreviations: PONV, postoperative nausea and vomiting

*$P < 0.05$ vs. Group P

Secondary outcomes

The MAP in group R was significantly higher than that in group P at T1, T2 and T3, but there were no significant differences at the other time points. The HR in group R was significantly higher than that in group P only at T2, but there was no significant difference at the other time points. There was also no significant difference in SPO_2 between the two groups at any time points. There were significant differences in MOAA/S scores at T1 and T2 between the two groups, but there were no significant differences in the scores at the other time points. (Fig. 2).

For 1 patient in Group P, the procedure was interrupted due to a persistent SPO_2 below 85% for 15 s without relief. Except for this patient, neither group of patients needed the procedure interrupted for any other reason. After the administration of oxygen through a mask, the SPO_2 increased, and the bronchoscopy continued. Respiratory depression in group R was significantly lower than that in group P, and there were no significant differences in hypertension, tachycardia, bradycardia or number of patients given mask support between the two groups (Table 2).

There were no significant differences in terms of awakening time, QoR-15 score, patient satisfaction, or physician satisfaction between the two groups (Table 3).

Fewer patients reported injection pain in group R than in group P (0/30 vs. 7/30, $p = 0.01$). There were no significant differences in terms of the incidence of hiccups, vertigo, or PONV (Table 4).

Discussion

In this study, we observed that, compared with older patients who underwent bronchoscopy after propofol sedation, the older patients who maintained spontaneous breathing under painless fiberoptic bronchoscopy after

sedation with remimazolam had the following features: (1) The sedation success rate of remimazolam was similar to that of propofol and could supply the depth of anesthesia required for painless bronchoscopy; (2) Hemodynamic stability was better maintained with remimazolam, with a lower incidence of hypotension and a lower incidence of respiratory depression; and (3) The risks of hiccups, vertigo, nausea and vomiting were similar.

According to the guidelines put forward by the American College of Chest Physicians, topical anesthesia, sedation, and analgesia are recommended for all patients who undergo fiberoptic bronchoscopy in the absence of contraindications. The combination of benzodiazepines and opioids is recommended because they have a synergistic effect on patient tolerance enhancement, and opioids have additional antitussive effects [10]. The ED95 of remimazolam used for bronchoscopy in Chinese patients was reported to be 0.219 mg/kg [11], and the maintenance dose of remimazolam used for bronchoscopy was 1 mg/kg/h in Pan et al.'s study [12]. Since there are no recommendations for drug dosing in older patients, the initial dose of remifentanil in our study was set at 0.2 mg/kg, followed by a 1-mg/kg/h remimazolam pump. According to previous studies and literature reports [8, 13], the initial dose of propofol was set at 2 mg/kg. In this study, the success rate of sedation in group R was close to 100%, indicating that 0.2 mg/kg remimazolam met the sedation requirements for painless bronchoscopy. One patient in group R still showed somatic movements after receiving three supplemental doses, and we did not administer further additional doses, considering the safety of the medication; this patient may have needed more remimazolam to achieve an adequate depth of anesthesia, which reflects certain individual differences in medication use among older patients. The optimal dosage of remimazolam, a new sedative for painless bronchoscopy in older patients who maintain spontaneous breathing, needs to be further explored.

Hypotension is a common complication of painless fiberoptic bronchoscopy with propofol, and in our study, the incidence of hypotension in group P was 33.3%. This rate was much higher than that in group R, and the incidence of severe hypotension in group P was higher than that in group R. A study by Zhou et al. showed that the incidence of hypotension in adult patients who underwent painless fiberoptic bronchoscopy with propofol was 31.6% [13], which was close to our findings. Advanced age is a risk factor for hypotension [14]. As chronic hypertension and end-organ autoregulation disorders become more common with age [15], older patients may be vulnerable to hemodynamic fluctuations [16] and have a higher incidence of postoperative myocardial injury, acute kidney injury, and other adverse outcomes that can be fatal in older individuals [17]; consequently, propofol should be used more cautiously for painless bronchoscopy in these patients. Older patients with hypertension and a rightward shift in the cerebral blood flow autoregulation curve require increased MAP to maintain cerebral perfusion. One retrospective study revealed that the risk of stroke in older patients was proportional to the degree of hypotension [18]. Multiple studies have shown that remimazolam has better hemodynamic stability in older patients [19, 20] and improves perioperative safety in these individuals, which may be related to its capacity to better maintain systemic vascular resistance levels and its weaker effect on cardiac systolic function [21].

In painless fiberoptic bronchoscopy with spontaneous respiration, respiratory complications are the most important indicator. The surgeon and the anesthesiologist are working in the same space (the airway), which poses a significant challenge to the anesthetic management of fiberoptic bronchoscopy [22], and respiratory depression is a particularly important risk in bronchoscopy. The incidence of hypoxemia is much higher for fiberoptic bronchoscopy than for other types of endoscopy (e.g., gastroscopy, colonoscopy, retrograde cholangiopancreatography). Our results showed that the incidence of respiratory depression was 10% in group R and 33% in group P, suggesting that remimazolam provided better respiratory safety during painless bronchoscopy, which is in line with earlier findings [23].

The respiratory dynamics during painless fiberoptic bronchoscopy are similar to those of sleep apnea and can be attributed to reduced central respiratory drive or upper airway obstruction [24]. Zha et al. reported that the incidence of hypoxemia in adult patients who underwent bronchoscopy under sedation with propofol was 37% [25]. Propofol-induced respiratory depression and hypoxemia are usually transient but may cause serious complications in older patients with a low cardiopulmonary reserve. Older patients are more prone to hypoxemia during the perioperative period, which may be related to the following factors. First, the lungs become less elastic with age, and older patients have a higher risk of airway collapse [26]. Second, propofol acts mainly by enhancing GABA receptors, reducing central respiratory drive and weakening pharyngeal muscle tension [27], and more obviously inhibits the respiratory center in older patients. In addition, the imbalance of ventilated blood flow and insufficient oxygen reserve in older patients also increases the risk of hypoxia in older patients undergoing medical procedures.

Pulse oxygen saturation measurements are routinely used to monitor respiratory function during bronchoscopy but have several limitations. In this study, an SPO_2 of $<90\%$ or a respiratory rate of <8 breaths/min was used as a comprehensive indicator of respiratory depression because the median time to a 4% decrease in pulse

oxygen saturation from baseline after apnea was 32 s [28], and pulse oxygen saturation may not adequately reflect low ventilation [29]. The incidence of respiratory depression in group R was lower than that previously reported, which may be related to the following factors. First, we monitored the partial pressure of end-tidal carbon dioxide (PETCO2), which serves as an early warning of hypoventilation, allowing for earlier detection of respiratory depression and appropriate corrective measures [30]. Second, this lower incidence of respiratory depression may be related to the fact that the nasopharyngeal tracheal catheter provides a more efficient supraglottic oxygen delivery mode. However, Ibrahim et al. concluded that unclosed nasal cannulae dilute expired gas and thus falsely show low tidal volume PETCO2 levels [31]. Due to the use of open airways for nasal intubation, we used only PETCO2 monitoring as a reference in the assessment of respiratory depression. The effectiveness of PETCO2 monitoring in fiberoptic bronchoscopy remains a topic of discussion.

In our study, there was no significant difference in awakening time between the two groups, but it is worth noting that the sedation effect of remimazolam can be quickly reversed by the benzodiazepine receptor antagonist flumazenil [32]. Another study revealed that the awakening time of patients who received remimazolam and flumazenil and underwent bronchoscopy was only 140 s [12]. Thus, remimazolam may have an advantage in terms of rapid recovery. The awakening times in both groups were longer than those reported in previous studies [33]. This finding might be related to the test population; the drug metabolism of older patients is relatively slow, so their awakening time is relatively long. Remimazolam can be hydrolyzed and metabolized by nonspecific esterases, does not depend on hepatic or renal function, and may be more adaptable to older patients with hepatic or renal dysfunction [34]. The physician satisfaction in Group R was slightly higher than that in Group P because one procedure in Group P was interrupted due to severe hypoxemia. The QoR-15 is a patient-reported outcome questionnaire that measures the quality of recovery after surgery and anesthesia, and our results showed no statistically significant difference in scores between the two groups [35]. There was no significant difference in patient satisfaction scores or physician satisfaction scores between the two groups.

Fewer patients in group R than in group P reported injection pain, which is consistent with the findings of another study [36]. The degree of tissue irritation caused by remimazolam was low, and no injection pain was found in group R. Injection pain caused by propofol may not be a serious complication, but it is an unpleasant memory for the patient. The risk of pain caused by the injection of propofol is 60% [37], which may occur due to skin, mucosa, and blood vessel involvement [38], reducing patient satisfaction to some extent. There was no significant difference in the incidence of hiccups, vertigo, or PONV between the two groups.

There are several limitations to our study. First, this was a single-center cohort study with a small sample of patients. Second, we did not objectively monitor the depth of sedation (such as by the BIS or the Narcotrend index), which may have led to differences in the depth of sedation and therefore affected the results of this trial. Third, the protocol was single-blinded, which may have produced some bias in the study. Fourth, this study addressed only a shorter application of remimazolam in bronchoscopy. Whether the drug can be safely and effectively used in relatively time-consuming procedures, such as bronchoscopic puncture and treatment, needs to be analyzed and explored in future investigations.

Conclusions

Remimazolam has a high sedation success rate for painless fiberoptic bronchoscopy in older patients, and the incidence of hypotension and respiratory depression is lower than that of propofol. Remimazolam may be a better choice for sedation during painless fiberoptic bronchoscopy in older patients with preserved spontaneous breathing.

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None.

Author contributions

Binggao Chai and Xianhui Kang designed the study.Binggao Chai, Jiaxi Guo, Zhiwei Xu, Tao Chen, Hongquan Wang, Zhenqiang Zhu, Jian Zhong, Jianlong Du, Kanzheng Chen, and Jianlong Du interpreted the data and wrote the manuscript. All the authors contributed to the editing, review, and approval of the manuscript.

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Data availability

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Tongxiang First People's Hospital (No. 2023-001-01, February 24, 2023). Written informed consent was obtained from all the subjects. All methods were performed in accordance with the CONSORT guidelines and regulations.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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