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Comparative efficacy of ciprofol and propofol in reducing respiratory depression during ERCP anesthesia: a randomized controlled trial

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Abstract

Background Propofol is one of the important drug causes of respiratory depression in endoscopic retrograde cholangiopancreatography (ERCP) anesthesia. This study aims to clarify whether Ciprofol in ERCP anesthesia reduces the respiratory depression rate.

Methods In this randomized controlled trial performed at the Surgical Endoscopy Center, the First Hospital of Lanzhou University between Jun 01, 2022 and Feb 20, 2024, patients undergoing ERCP anesthesia were randomly assigned into ciprofol (study group) or propofol (control group). Primary outcomes included respiratory depression rate during anesthesia, and secondary outcomes included body movement and hypoxemia, awakening time, mean arterial pressure and heart rate changes at key points during surgery.

Results 20 of the 306 patients had respiratory depression (6.5%). The frequency of respiratory depression was 3.3% in the group C and 9.8% in the group P, with a difference of 6.5% between the two groups ($P=0.035$). Ciprofol anesthesia decreased the hypoxemia, injection pain, and circulation and heart rate fluctuations. Multivariable logistic regression analyses showed that Propofol (OR 1.970; 95% CI, 1.121–3.461, $P=0.018$), mallampati classification>II (OR 1.594; 95% CI, 1.129–2.249, $P=0.008$), and fasting time>10.5 h (OR 3.184; 95% CI, 1.531–6.621, $P=0.002$) were independent risk factors for incidence of respiratory depression in ERCP anesthesia.

Conclusions For patients undergoing anesthesia for ERCP, Ciprofol, compared to Propofol, has been shown to effectively reduce the incidence of intraoperative respiratory depression, thereby enhancing the safety of the anesthesia process.

Trial registration This study was registered in the Chinese Clinical Trial Registry on 15/01/2022 (ChiCTR2200055629).

Keywords Endoscopic retrograde cholangiopancreatography (ERCP), Ciprofol, Respiratory depression, Propofol

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a minimally invasive diagnostic and therapeutic technique essential for managing various benign and malignant diseases of the biliary and pancreatic systems [1, 2]. Due to the significant stimulation induced by ERCP procedures, which can trigger stress responses, deep sedation or anesthesia is commonly employed [3, 4].

Propofol, a rapid ultra-short-acting intravenous anesthetic, is frequently used for ERCP anesthesia [5]. Although propofol demonstrates good sedative effects, it has several notable limitations, including a narrow therapeutic window, a high incidence of hypotension, respiratory depression, and injection pain [6, 7]. Consequently, it is crucial to develop alternative anesthetics that meet clinical needs, offering greater efficacy and fewer side effects. Ciprofol, a novel 2,6-disubstituted phenol derivative, is a new intravenous agent used for inducing pain-free and general anesthesia [8]. Research indicates that a dose of 0.6 mg/kg of ciprofol is equivalent in efficacy to 2.5 mg/kg of propofol, with rapid onset and quick recovery, and only minimal residual effects after a single dose, demonstrating good efficacy and safety profiles [8]. Given the drawbacks of propofol in causing hemodynamic changes and respiratory depression, exploring alternative drugs for intravenous anesthesia during ERCP procedures is of significant importance.

We designed a randomized controlled trial to compare rates of respiratory depression in ERCP anesthesia between the ciprofol and propofol.

Methods

Study design and participants

Patient studies were conducted according to the guiding principles of the Helsinki Declaration and were registered with Chinese Clinical Trial Registry (ChiCTR2200055629). This study was approved by the Ethics Committee of the First Hospital of Lanzhou University (LDYYLL-2021-078). All patients or their legal representatives provided written informed consent. This trial followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.

A prospective, single-blinded randomized controlled trial was conducted between Jun 01, 2022 and Feb 20, 2024 at surgical ERCP training center at the First Hospital of Lanzhou University. Patients who planned to undergo endoscopic retrograde cholangiopancreatography without induction under general anesthesia. The exclusion criteria included: age < 18 or > 90 years; pregnant or breastfeeding; morbid obesity, body mass index (BMI) ≥ 30 kg/m²; uncontrolled diabetes with or without complications; Severe heart, lung and brain disease, including intracranial hypertension, stroke, unstable angina pectoris, myocardial infarction, pulmonary

embolism and so on; long term history of taking psychotropic drugs and cognitive dysfunction; American Association of Anesthesiologists (ASA) > III; the modified Malampati classification was Grade IV; allergies to any drug involved in the study.

Sample size determination

Sample size was calculated based on the incidence of respiratory depression in a recent study [9]. We assumed a respiratory depression rate of 15% in the control group (group P) and 10% in the group C. Under the power of 80% and the level of 0.05, 133 patients were needed in each group, and the loss to follow-up rate was expected to be 15%. Finally, 153 patients were needed in each group, and a total of 306 patients were enrolled.

Randomization and masking

The patients were randomly divided into to assign them to the P group and C group at a ratio of 1:1. Randomization was completed by an independent statistician using a computer-generated random number with a block size of ten. We blinded only the investigators who undertook follow-up and statistical analyses.

Procedures

All patients were prohibited from drinking water for 2 h and fasted for 8 h before the operation. Prior to the procedure, peripheral venous access was established, a dental pad was inserted, and oxygen was administered via a nasal cannula at a rate of 2 to 4 L/min. The patient was positioned in the left lateral decubitus position, and Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP), Heart rate (HR), and Oxygen saturation (SpO₂) were continuously monitored using a multifunctional monitor (Model: uMEC6, Shenzhen Mindray Biomedical Electronics Co., Ltd.) and connected to the bispectral index (BIS) of the Electroencephalogram (EEG).

Anesthesia induction: no preoperative medication was used in all patients. After positioning, dexmedetomidine 0.15 µg/kg was given (intravenous pumping was completed within 5 min), sufentanil 0.2 µg/kg was given in two intravenous injections. Ciprofol was induced by 0.2 mg/kg and supplemented by 0.1 mg/kg in group C, and propofol was induced by 1 mg/kg and supplemented by 0.5 mg/kg in group P. The dosage and times of addition were recorded. When the MOAA/S score (Table S1) was ≤ 1 or BIS of EEG drops to 60, the surgery will be started and the induced dose of ciprofol will be changed to the maintenance dose [10].

Anesthesia maintenance: group C and P were treated with 0.6–0.8 mg/kg/h and 4–6 mg/kg/h for continuous infusion (maintain BIS value between 50 and 60 according to BIS value adjustment). Blood pressure, ECG, SpO₂

and BIS were monitored during operation. When the nasobiliary duct is placed at the end of the operation, drug infusion is stopped. All operations were performed by the same group of doctors. If the patient has body movements during the operation, 0.1 mg/kg of ciprofol and 0.5 mg/kg of propofol are given for treatment. If $SpO_2 < 93\%$, immediately raise the jaw, and if necessary, place the nasopharynx airway to help ventilate.

Outcomes

The primary endpoint was respiratory depression. Respiratory depression was defined as thoracic motion disappeared for > 30 s.

The secondary outcomes included the MAP, HR before anesthesia induction (T0), complete induction of anesthesia (T1), after the duodenum enters the mouth (T2), at successful cannulation (T3), at the end of the operation (T4), post-anesthesia (T5), and leave the operating room (T6). The adverse events of during anesthesia operation were recorded, including body movement reaction, hypoxemia ($SPO_2 < 90\%$ and duration > 30 s), injection pain, and recovery time (from induction to full recovery). Besides, we collected satisfaction scores from surgeons and patients after surgery (from 0 to 10, with 10 being very satisfied, Table S2) [11]. All patients were followed up within 48 h after ERCP surgery.

Statistical analysis

Basic characteristics and clinical information were presented as the means and standard deviations for normal quantitative variables (assessed by histogram), and for skewed continuous variables, medians and inter quartile ranges (IQR) were used, and counts and percentages were used for dichotomous variables. Tests between two groups were conducted using the t test, Wilcoxon test, chi-square test, and Fisher's exact test, as appropriate. Factors associated with respiratory depression were analyzed using a Logistic regression model. Variables with a value of $p < 0.10$ in univariate analysis were considered for adjustments in the multivariable model. All tests were two-sided, and a p value of < 0.05 was considered statistically significant. All analysis were conducted using Python (Version 3.9.0).

Results

Between Jun 01, 2022, and Feb 20, 2024, 418 consecutive patients scheduled for ERCP were assessed for eligibility. After screening, 112 patients were excluded. Finally, a total of 306 patients were randomly assigned to the P group ($n = 153$) and C group ($n = 153$), as shown in Fig. 1. The baseline characteristics of the enrolled patients are shown in Table 1.

The incidence of respiratory depression was detected in 5 of 153 patients (3.3%) and 15 of 153 patients (9.8%) in the group C and the control group P, respectively, with

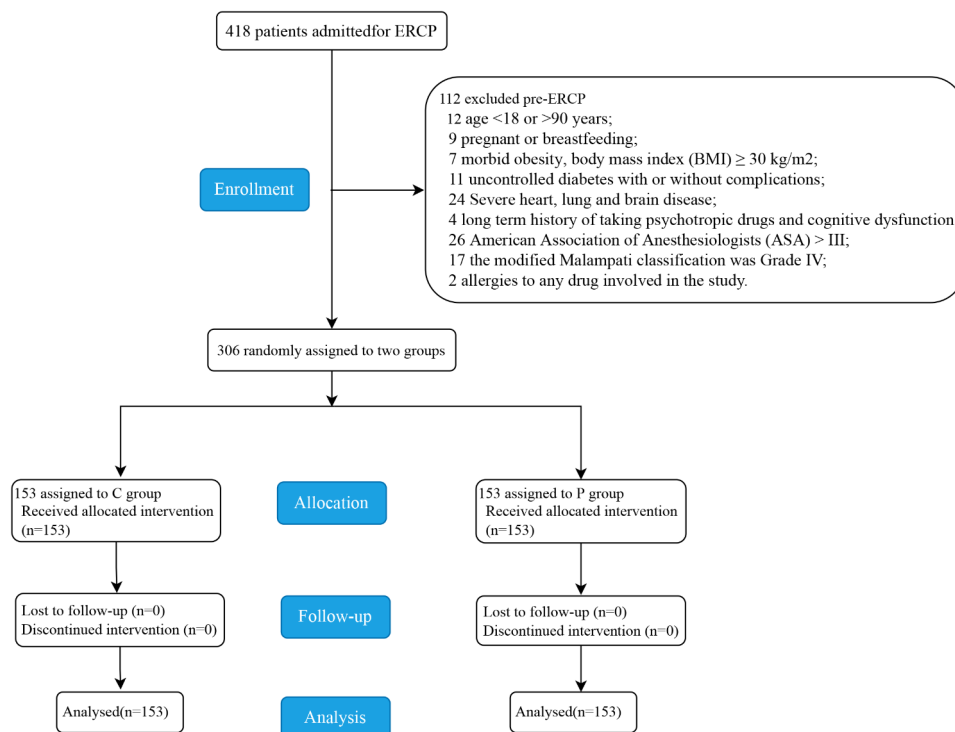


Fig. 1 Flow diagram of the study

Table 1 Comparison of basic characteristic about the patients in two groups

Characteristic	C group(n= 153)	P group(n= 153)
Sex		
Male	77 (50.3%)	86 (56.28%)
Female	76 (19.7%)	67 (43.8%)
Age(years)	55.03 (13.04)	54.81 (13.621)
BMI(kg/m ²)	22.90 (3.52)	23.366 (2.86)
Hypertension		
No	127 (83.0%)	122 (79.7%)
Yes	26 (17.0%)	31 (20.3%)
ASA classification	1.35 (0.48)	1.53 (0.50)
I-II	103 (67.3%)	92 (30.1%)
III	50 (32.7%)	61 (39.9%)
Mallampati classification		
I-II	148 (96.7%)	147 (96.1%)
III	5 (3.3%)	6 (3.9%)
Fasting time(hours)	11 (9, 12)	10 (10, 11)
MAP(mmHg)	94.45 (10.34)	96.74 (10.96)
HR(times/min)	80.05 (12.39)	81.87 (8.52)

MAP, mean arterial pressure; HR, heart rate; BMI, body mass index.

a difference of 6.5% between the two groups ($P=0.035$). The MAP of the patients in the two groups at T0, T2 and T6 showed no statistical difference ($P>0.05$). From T1,T3-T5, compared with group C, MAP of the patients in the group P showed a tendency to go down and then high (Fig. 2A), the difference was statistically significant ($P<0.05$). The comparison of HR of the patients in the two groups at T0 showed no statistical difference ($P>0.05$). From T1-T6, the HR in group C was relatively stable, group P was still a trend of first rising and then falling (Fig. 2B), the difference is obvious($P<0.05$).

The number of intraoperative body movements in group C and P were 27(17.6%), 32(20.9%), respectively. The incidence of hypoxemia (14 [9.2%] vs. 3 [2.0%], $P=0.010$) and injection pain (34 [22.2%] vs. 13 [8.5%], $P=0.001$) in group P was significantly higher than group C. Compared with the group P, the recovery time was approximately 2 min longer in the group C ($P<0.001$), but eyelash response time(31.25 ± 15.62) vs. 54.11 ± 15.67 ; $P<0.001$) and induction time(54.95 ± 13.66 vs. 67.75 ± 22.29 ; $P<0.001$) of group C better than group P. Postoperatively, the satisfaction scores reported by surgeons (9.92 ± 0.30 vs. 9.91 ± 0.30 ; $P=0.710$) and patients (9.84 ± 0.44 vs. 9.79 ± 0.48 ; $P=0.270$) were no significant difference between groups, as shown in Table 2. Fasting time was transformed into a binary variable based on the optimal cutoff value of 10.5 h, determined through Receiver Operating Characteristic (ROC) analysis. The ROC curve exhibited an area under the curve (AUC) of 0.756 (95% CI, 0.646–0.866), with a sensitivity of 85.0% and specificity of 54.0%, as shown in Fig. 3.

Univariate logistic analyses showed that age, hypertension, fasting time>10 h, Propofol, and Mallampati

classification were associated with significantly increased incidence of respiratory depression. Multivariate analyses showed that Propofol (OR 1.970; 95% CI, 1.121–3.461, $P=0.018$), Mallampati classification>II (OR 1.594; 95% CI, 1.129–2.249, $P=0.008$), and fasting time>10 h (OR 3.184; 95% CI, 1.531–6.621, $P=0.002$) were independent risk factors for incidence of respiratory depression (Table 3).

Discussion

This randomized controlled study investigated the benefits and safety of propofol versus ciprofol in improving respiratory depression during anesthesia for elective ERCP procedures. The results indicated that, compared to propofol, ciprofol significantly reduced the incidence of respiratory depression during ERCP, shortened induction time, and even alleviated intraoperative blood pressure and heart rate fluctuations. Furthermore, multivariate logistic regression analysis showed that fasting time, propofol, and Mallampati classification were independent risk factors for the occurrence of respiratory depression.

Intravenous anesthesia serves as a routine anesthetic method for ERCP procedures, effectively mitigating the stress response associated with the manipulation through the oropharynx, cardia, and into the duodenum to reach the ampulla of Vater [12, 13]. Compared with general anesthesia, intravenous anesthesia improves surgical safety and patient comfort [14]. Although propofol is widely used for sedation during endoscopic examinations, it presents notable limitations, including inter-individual variability in pharmacokinetics and pharmacodynamics, respiratory depression, hypotension, and the lack of an effective antagonist [15]. Ciprofol, a novel intravenous anesthetic agent, shares similar characteristics with propofol, such as rapid onset, no accumulation, and quick recovery [5]. During ERCP, the BIS, which reflects the depth of anesthesia, is utilized for guidance. By maintaining the BIS value between 50 and 60, the infusion rate of ciprofol can be effectively controlled, preventing excessive drug concentration and overly deep anesthesia that could interfere with the assessment of potential perioperative adverse events [16, 17].

Respiratory depression is one of the common adverse events associated with sedation. Our study demonstrated that the incidence of respiratory depression (3.3% vs. 9.8%, $p=0.035$) and hypoxemia (2.0% vs. 9.0%, $P=0.010$) was significantly lower in the ciprofol group compared to patients sedated with propofol. These findings suggest that, relative to propofol, ciprofol may exert a lesser impact on respiratory center depression and airway compromise, thereby maintaining a more stable respiratory state in patients. Additionally, the incidence of injection pain was notably lower in the ciprofol group (8.5%

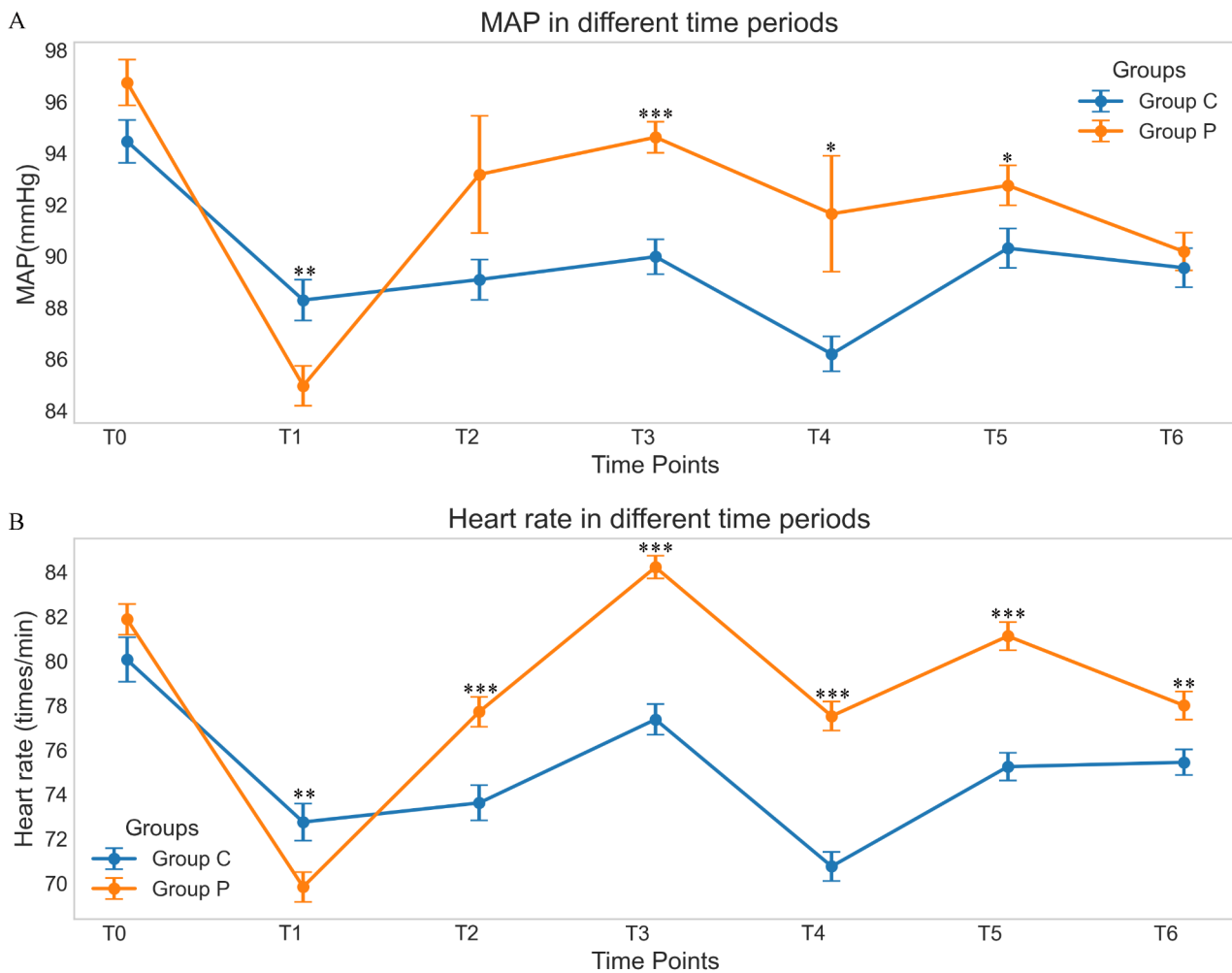


Fig. 2 Comparison of the MAP and HR change at different time points in the two groups of patients. MAP, mean arterial pressure; HR, heart rate. T0, induction; T1, complete induction of anesthesia; T2, after the duodenum enters the mouth; T3, at successful cannulation; T4, at the end of the operation; T5, post-anesthesia; T6, leave the operating room. Notes Compared with Group P. * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$

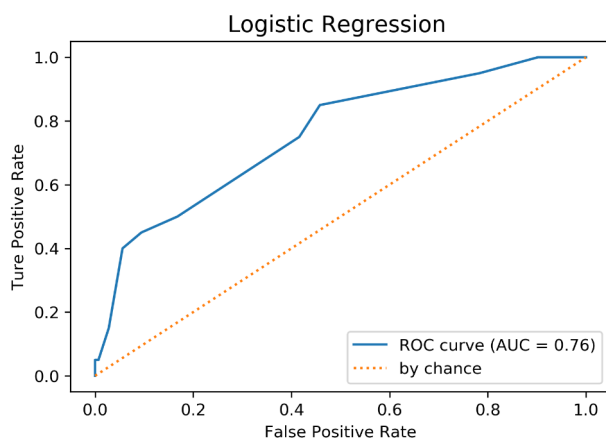
vs. 22.2%, $p = 0.001$), a finding consistent with previous research [18, 19]. During the operation, both groups exhibited a higher incidence of body movement (17.6% vs. 20.9%, $p = 0.56$), particularly during periods of intense stimulation, such as when the duodenum or bile duct was stretched. However, this difference was not statistically significant. Postoperative follow-up revealed that none of the patients experienced intraoperative awareness. Injection pain is a common side effect of propofol, and its mechanism may be related to increased vascular permeability, differences in drug pH, and local inflammatory responses [20]. In this study, 34 patients (22.2%) in the propofol group experienced injection pain, while only 13 patients (8.5%) in the ciprofol group reported the same, a significantly lower incidence. This finding is consistent with previous studies [9, 21].

This study observed changes in MAP and HR at different time points in two groups of patients. At T0 and T6,

there were no significant difference in MAP between the groups. However, during anesthesia (T1-T5), patients in the P group who received propofol exhibited a pattern of MAP decreasing followed by an increase, with HR showing similar fluctuations. This suggests that propofol anesthesia may lead to significant intraoperative variations in blood pressure and heart rate. Previous study indicates that propofol, being a highly lipophilic agent, rapidly binds to postsynaptic γ -GABA receptors, enhancing GABA's effect to inhibit the central nervous system, leading to deep sedation [22]. During the procedure, the P group's MAP and HR experienced a decrease followed by a recovery, which may be attributed to initial vasodilation and myocardial depression caused by propofol, followed by the waning of the drug's effects and the activation of homeostatic mechanisms. Therefore, ciprofol has a smaller impact on the circulatory system compared to propofol, leading to more stable hemodynamics during

Table 2 Comparison of adverse events in three groups of patients

Characteristic	C group(n=153)	P group(n=153)	P
Sufentanil(ug)	12.35 (2.29)	12.54 (2.16)	0.450
Dexmedetomidine(ug)	9.75 (1.75)	9.95 (1.92)	0.360
Ciprofol/Propofol			
Induction(ml)	5.30 (1.25)	7.07 (1.77)	<0.001
Venous pumping(ml)	16.33 (8.14)	17.03 (7.70)	0.290
Induction time(s)	54.95 (13.66)	67.75 (22.29)	<0.001
Eyelash response time(s)	31.25 (15.62)	54.11 (15.67)	<0.001
Recovery time(min)	8.03 (3.04)	6.35 (2.54)	<0.001
Body movements			0.560
No	126 (82.4%)	121 (79.1%)	
Yes	27 (17.6%)	32 (20.9%)	
Respiratory depression			0.035
No	148 (96.7%)	138 (90.2%)	
Yes	5 (3.3%)	15 (9.8%)	
Hypoxemia			0.010
No	150 (98.0%)	139 (90.8%)	
Yes	3 (2.0%)	14 (9.2%)	
Injection pain			0.001
No	140 (91.5%)	119 (77.8%)	
Yes	13 (8.5%)	34 (22.2%)	
Physician satisfaction	9.92 (0.30)	9.91 (0.30)	0.710
Patient satisfaction	9.84 (0.44)	9.79 (0.48)	0.270

**Fig. 3** The Receiver Operating Characteristic (ROC) analysis of Fasting time**Table 3** Logistic regression model for incidence of respiratory depression

Variables	Univariate analyses			Multivariate analyses		
	OR	95% CI	P	OR	95% CI	P
Group (Propofol)	1.793	1.067–3.014	0.027	1.970	1.121–3.461	0.018
Sex (Female)	1.425	0.573–3.546	0.445			
Age	1.735	1.070–2.814	0.025	1.481	0.794–2.763	0.216
BMI	1.079	0.939–1.241	0.281			
Hypertension(Yes)	1.724	1.199–2.481	0.003	1.335	0.824–2.162	0.239
Mallampati classification(III)	1.401	1.077–1.823	0.012	1.594	1.129–2.249	0.008
ASA classification(III)	1.484	0.956–2.303	0.078	0.902	0.489–1.665	0.743
Fasting time(>10 h)	2.588	1.386–4.831	0.003	3.184	1.531–6.621	0.002

anesthesia. This finding is consistent with previous studies [23, 24].

Previous studies have shown that prolonged fasting before surgery can lead to insulin resistance, increased breakdown of protein and glycogen, and a negative nitrogen balance in the body, so patients are more likely to experience symptoms of fatigue or weakness [25, 26]. A randomized controlled study by Meng et al. showed that fasting time before ERCP increased patients' fatigue level [27]. In our study, due to the elective ERCP surgery, the fasting time of patients was more than 8 h, and the fasting time was an independent risk factor for respiratory depression during ERCP surgery, and the fasting time increased the incidence of respiratory depression in patients during the operation. It is possible that fasting time increases the patient's symptoms of fatigue or weakness and increases the likelihood of intraoperative respiratory depression.

This study has several limitations. Firstly, this was a single-center study conducted at the Surgical Endoscopy Center of the First Hospital of Lanzhou University, which may limit the generalizability of our findings to other clinical settings or patient populations. Secondly, although we aimed to control for confounding variables through multivariable logistic regression analysis, residual confounding cannot be entirely ruled out due to the inherent limitations of studies. Lastly, the subjective assessment of outcomes such as body movement and hypoxemia could introduce bias if inter-rater reliability was not systematically evaluated. Future multi-center trials with larger sample sizes and more rigorous blinding protocols are warranted to confirm our findings and address these limitations.

Conclusions

For patients undergoing anesthesia for ERCP, Ciprofol, compared to Propofol, has been shown to effectively reduce the incidence of intraoperative respiratory depression, thereby enhancing the safety of the anesthesia process.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12871-024-02791-4>.

Supplementary Material 1

Supplementary Material 2

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Author contributions

JHW, RW, XFM, WJZ, BPZ, YHM and YTL performed the data analyses and wrote the manuscript; JHW, RW, XFM, YHM and YTL performed the experiment; JHW, RW, BPZ, YHM and YTL contributed significantly to analysis and manuscript preparation; JHW, RW, YHM and YTL helped perform the analysis with constructive discussions; JHW, YHM and YTL contributed to the conception of the study. All authors contributed to the article and approved the submitted version.

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Data availability

Corresponding authors have accessed and verified the data, and were responsible for the decision to submit the manuscript. All data and statistical analysis plan will be made available upon reasonable request via email to corresponding author (doctorliuyt@163.com).

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the First Hospital of Lanzhou University (LDYYLL-2021-078). All patients enrolled in this study were evaluated before anesthesia by anesthesiologists above the attending doctor and signed informed consent forms. If the patient refused to participate in the study or the surgical method was changed, the study was stopped.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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