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Anesthetic effects of remimazolam, ciprofol and propofol in total intravenous anesthesia for laparoscopic cholecystectomy

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Abstract: **Objective** To compare the anesthetic efficacy and effects on postoperative recovery of remimazolam, ciprofol and propofol, when applied separately for total intravenous anesthesia in laparoscopic cholecystectomy. **Methods** A total of 135 patients scheduled for elective laparoscopic cholecystectomy in Baoding No.1 Central Hospital between April 2023 and November 2024 were enrolled. The patients were divided into remimazolam group (Group R), ciprofol group (Group C) and propofol group(Group P)using the random number table method, 45 cases in each group. For anesthesia induction: Group R received intravenous injection of remimazolam 0.3 mg/kg; Group C received ciprofol 0.4 mg/kg; Group P received propofol 2 mg/kg. All groups were given intravenous injection of cisatracurium 0.15 mg/kg, followed by intravenous injection of remifentanil 2 μg/kg 3 minutes later for tracheal intubation. For anesthesia maintenance: all three groups were administered continuous intravenous infusion of remifentanil 0.2 μg/ (kg·min); Group R received remimazolam 1 mg/(kg·h), Group C received ciprofol 0.8 mg/(kg·h), and Group P received with propofol 4 mg/(kg·h) via continuous infusion. The observation indicators included mean arterial pressure (MAP), heart rate, saturation of peripheral oxygen (SpO2) and bispectral index (BIS) at the following time points: before anesthesia induction(T0), 3 minutes after administration of anesthetic sedatives(T1), immediately after intubation(T2), 1 minute after extubation(T3), and upon leaving the operating room(T4). Additionally, the incidence of adverse reactions such as hypotension, bradycardia, injection pain and postoperative nausea and vomiting (PONV) was recorded. Other outcome measures included the time taken for BIS to decrease to 60, extubation time, time to first postoperative flatus, duration of postoperative hospital stay and frequency of postoperative rescue analgesia. **Results** During the induction period, there were statistically significant differences in the incidence of hypotension among the Group P, Group R, and Group C [28.9%(13/45)*vs* 6.7%(3/45)*vs* 15.6%(7/45), χ^2 =7.966, *P*=0.019], with the Group P showing a higher incidence than that in the Group R(χ2=7.601, *P*=0.006). From intubation to before skin incision, the incidence of hypotension in the Group P was 68.9%(31/45), which was higher than that in the group C at 42.2%(19/45)and the Group R at 26.7%(12/45)(*P*<0.017). MAP in Group R at T1 and T2 was higher than those in Group P(*P*<0.05), and MAP at T2 in Group R was also higher than that in Group C (*P*<0.05). Heart rate in Group R at T1 and T2 was higher than that in Group C and Group P. Compared with Group C and Group P, Group R had longer time for BIS to decrease to 60 and longer extubation time(*P*<0.05). There was no statistically significant difference in time to first postoperative flatus, duration of postoperative hospital stays and frequency of postoperative rescue analgesia among the three groups(*P*>0.05). The incidence of PONV in Group R was higher than that in Group C and Group P(*P*<0.017). The incidence of injection pain in Group R and Group C was lower than that in Group P(*P*<0.017). **Conclusion** Remimazolam exhibits the most prominent advantage in hemodynamic stability among the three drugs, but shows sub prominent performance in terms of postoperative resuscitation and PONV. Ciprofol is superior to propofol but inferior to remimazolam in hemodynamic stability, while its performance in postoperative resuscitation, postoperative recovery and PONV is basically consistent with propofol.

Keywords: Remimazolam; Ciprofol; Propofol; Postoperative recovery quality; Total intravenous anesthesia

Laparoscopic cholecystectomy is a common surgical procedure for the clinical treatment of various gallbladder diseases. In laparoscopic surgery, the use of intravenous anesthetics for induction and maintenance shows better advantages than inhalational anesthesia [1]. Propofol is the most commonly used intravenous anesthetic at present, characterized by rapid onset, short duration of action, and rapid recovery; however, it can cause dose-dependent circulatory and respiratory depression, injection pain, and propofol infusion syndrome [2-3]. Remimazolam is an ultra-short-acting benzodiazepine that exerts central inhibitory effects by acting on gamma-aminobutyric acid (GABA) receptors. It has the advantages of rapid onset, rapid metabolism, stable hemodynamics, and rapid reversibility by flumazenil [4-5]. Ciprofol is an analogue of 2,6-diisopropylphenol and a novel intravenous anesthetic developed on the basis of propofol [6], with an efficacy 4 to 5 times that of propofol [6] and a low incidence of injection pain. It has been gradually used for induction and maintenance of general anesthesia [7]. This study aimed to compare the anesthetic efficacy and effects on postoperative recovery quality of total intravenous anesthesia (TIVA) with remimazolam, propofol, and ciprofol in laparoscopic cholecystectomy.

1 Materials and Methods

1.1 General Data

A total of 135 patients scheduled for laparoscopic cholecystectomy at Baoding First Central Hospital from April 2023 to November 2024 were enrolled.

Inclusion criteria: (1) aged 18–65 years; (2) body mass index (BMI) 18–30 kg/m²; (3) American Society of Anesthesiologists (ASA) physical status Grade I or II.

Exclusion criteria: (1) complicated with neuromuscular junction diseases; (2) history of allergy to study drugs or neurological diseases; (3) predicted difficult airway; (4) mental illness; (5) pregnant and lactating women; (6) preoperative medication; (7) unwillingness to participate in this study.

Withdraw or drop out criteria: (1) withdrawal from the trial midway; (2) occurrence of serious adverse events or accidents during the study.

This study was approved by the Medical Ethics Committee of Baoding First Central Hospital (Ethics Approval No.: [2023]150), and all patients and their families signed informed consent forms.

1.2 Grouping

Patients were randomly divided into remimazolam group (Group R), ciprofol group (Group C), and propofol group (Group P) using a random number table method, with 45 cases in each group. There was no statistically significant difference in general data among the three groups (P>0.05). See **Table 1**.

1.3 Anesthetic Methods

All patients fasted and abstained from water routinely before surgery. After entering the operating room, an upper extremity intravenous access was established, and lactated Ringer's solution was infused at 6–8 mL/kg. Oxygen was administered via face mask. A multifunctional monitor was used to continuously monitor electrocardiogram, non-invasive blood pressure, mean arterial pressure (MAP), heart rate, and peripheral oxygen saturation (SpO_2). Bispectral index (BIS) was used to monitor the depth of sedation. Anesthesia induction: Group R received slow intravenous injection of remimazolam tosylate (Jiangsu Hengrui Pharmaceutical, H20217078) 0.3 mg/kg; Group C received intravenous injection of ciprofol (Liaoning Haisco Pharmaceutical, H20200013) 0.4 mg/kg; Group P received intravenous injection of propofol (Sichuan Guorui Pharmaceutical, H20030113) 2 mg/kg. All three groups received intravenous cisatracurium 0.15 mg/kg, followed by intravenous remifentanil 2 μg/kg 3 minutes later, and tracheal intubation was performed 1 minute thereafter. Anesthesia maintenance: after tracheal intubation, all three groups received intravenous infusion of remifentanil at 0.2 μg/(kg·min) during surgery. Group R was infused with remimazolam at 1 mg/(kg·h), Group C with ciprofol at 0.8 mg/(kg·h), and Group P with propofol at 4 mg/(kg·h).

If BIS >70 or eyelash reflex persisted during anesthesia induction and maintenance, supplementary sedation was given with intravenous remimazolam 0.05 mg/kg in Group R, ciprofol 0.01 mg/kg in Group C, and propofol 0.5 mg/kg in Group P. When MAP < 60 mmHg, ephedrine 6 mg or norepinephrine 4 μg was administered intravenously. When heart rate < 45 beats/min, atropine injection 0.5 mg was given intravenously. Flurbiprofen axetil injection 50 mg was administered after gallbladder resection. All patients were transferred to the postanesthesia care unit (PACU) for further observation after extubation. If the Numerical Rating Scale (NRS) score was >3, nalbuphine 10 mg was administered. For postoperative nausea and vomiting (PONV), ondansetron 8 mg was given.

1.4 Observation Indexes

Primary outcome: incidence of hypotension during induction and from tracheal intubation to skin incision (MAP decrease exceeding 20% of baseline MAP).

Secondary outcomes: MAP, heart rate, SpO_2, and BIS at before anesthesia induction (T0), 3 min after administration of anesthetic sedatives (T1), immediately after tracheal intubation (T2), 1 min after extubation (T3), and upon leaving the operating room (T4); time taken for BIS to decrease to 60 during anesthesia induction and time from drug discontinuation to extubation; Richmond Agitation-Sedation Scale (RASS) and NRS scores immediately upon transfer to PACU; RASS score at 4 h after surgery; incidence of adverse events such as bradycardia and PONV. Time to first postoperative flatus, length of postoperative hospital stay, and number of postoperative analgesic administrations were recorded.

1.5 Statistical Methods

Sample size calculation was performed using PASS 15.0 software. A pilot study was conducted in 20 patients in each of the three groups. The incidence of hypotension during induction was 5% in Group R, 15% in Group C, and 35% in Group P. With α=0.05 and $1-\beta$=0.9, the calculated total sample size required was 122 cases. Considering 10% data loss, 135 patients were planned to be enrolled, with 45 cases in each group. Statistical analysis was performed using SPSS 23.0 software. Non-normally distributed measurement data were expressed as M (Q_1, Q_3), and intergroup comparisons were performed using Kruskal-Wallis H test. Enumeration data were expressed as cases (%) and analyzed using the χ^2 test or Fisher's exact test; pairwise comparisons were performed with Bonferroni correction (α'=0.017). A two-sided test was used, with α=0.05.

2 Results

2.1 General Conditions

All patients in the three groups completed the surgery successfully, with no dropouts or withdrawals. There was no statistically significant difference in operation duration among the three groups (P>0.05). See **Table 1.**

2.2 Incidence of Hypotension

During induction, hypotension occurred in 13 patients (28.9%) in Group P, 3 patients (6.7%) in Group R, and 7 patients (15.6%) in Group C. There was a statistically

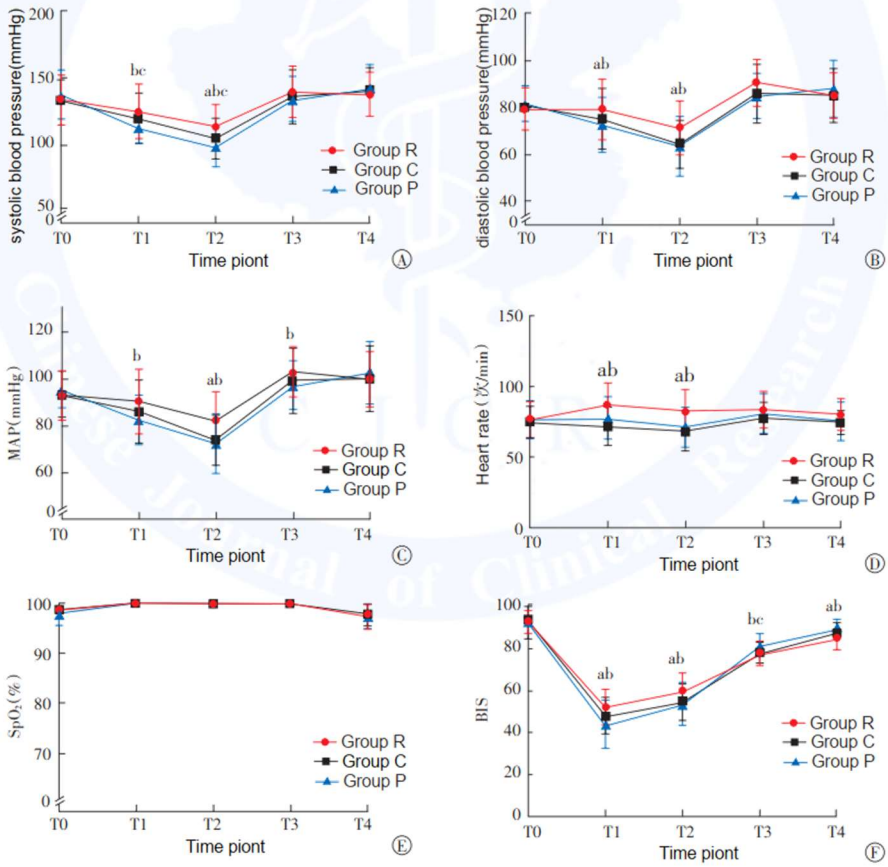
significant difference in the incidence of hypotension among the three groups (χ^2=7.966, P=0.019), and the incidence in Group P was higher than that in Group R (χ^2=7.601, P=0.006). From tracheal intubation to skin incision, hypotension occurred in 31 patients (68.9%) in Group P, 12 patients (26.7%) in Group R, and 19 patients (42.2%) in Group C. There was a statistically significant difference in the incidence of hypotension among the three groups (χ^2=16.525, P=0.005), and the incidence in Group P was higher than that in Group C and Group R, respectively (P<0.017). Compared with the induction period, the incidence of hypotension in all three groups was significantly increased from tracheal intubation to skin incision (P<0.05).

2.3 Hemodynamic Parameters

At T1, systolic blood pressure was higher in Group R and Group C than in Group P (P<0.05); at T2, systolic blood pressure was ranked Group R > Group C > Group P (P<0.05). Diastolic blood pressure was higher in Group R than in Group C and Group P at T2 and T3. MAP was higher in Group R than in Group P at T1, T2, and T3 (P<0.05), and higher in Group R than in Group C at T2 (P<0.05). Heart rate was higher in Group R than in Group C and Group P at T1 and T2. BIS was higher in Group R than in Group C and Group P at T1 and T2 (P<0.05), higher in Group P than in Group R and Group C at T3 (P<0.05), and higher in Group C and Group P than in Group R at T4 (P<0.05). There was no statistically significant difference in SpO_2 among the three groups at any time point (P>0.05). See **Figure 1.**

Tab.1 Comparison of general data among three groups [n=45, $M(Q_1, Q_3)$]

Group	BMI (kg/m²)	Gender [case(%)]		ASA Classification [case(%)]		Age (years)	Operation Time (min)
		Male	Female	Grade I	Grade II		
Group R	24.8(22.8,26.2)	20(44.4)	25(55.5)	18(40.0)	27(60.0)	52.0(34.0,58.0)	55.0(44.0,75.0)
Group C	24.0(22.7,26.5)	18(40.0)	27(60.0)	19(42.2)	26(57.8)	51.0(44.0,56.5)	60.0(40.5,79.5)
Group P	24.7(22.9,28.3)	17(37.8)	28(62.2)	14(31.1)	31(68.9)	54.0(45.0,58.0)	50.0(40.5,70.0)
***H* Value**	1.387	0.430		1.324		2.099	2.398
***P* Value**	0.563	0.861		0.611		0.350	0.302



Note: A: Systolic blood pressure; B: Diastolic blood pressure; C: Mean arterial pressure (MAP); D: Heart rate; E: Pulse oxygen saturation (SpO_2); F: Bispectral index (BIS). Compared with group C, [a]P<0.05 in group R; compared with group P, [b]P<0.05 in group R; compared with group P, [c]P<0.05 in group C.

Fig.1 Changes in perioperative hemodynamic parameters among three groups

2.4 RASS and NRS Scores

Compared with Group R, RASS scores were higher in Group C and Group P upon transfer to PACU, and higher in Group P at 4 h after surgery (P<0.05). There was no statistically significant difference in NRS scores among the three groups upon transfer to PACU (P>0.05). See **Table 2.**

2.5 Anesthesia Induction and Extubation Time

Compared with Group C and Group P, the time for BIS to decrease to 60 and extubation time were longer in Group R, the differences were statistically significant (P<0.05). See **Table 3.**

2.6 Postoperative Recovery

There was no statistically significant difference in time to postoperative flatus, length of postoperative hospital stay, or number of postoperative analgesic administrations among the three groups (P>0.05). See **Table 4.**

2.7 Adverse Reactions

There was no statistically significant difference in the incidence of bradycardia among the three groups (P>0.05). The incidence of PONV was higher in Group R than in Group C and Group P (P<0.017). The incidence of injection pain was lower in Group R and Group C than in Group P (P<0.017). See **Table 5.**

Tab.2 Comparison of RASS scores and NRS scores among three groups [n=45, $M(Q_1, Q_3)$]

Group	RASS Score (point)		NRS Score (point)
	Transfer to PACU	4 h Postoperatively	
Group R	−1.0(−1.0,−1.0)	0(0,0)	4(3,5)
Group C	0(−0.5,0)[a]	0(0,0)	3(3,5)
Group P	0(0,0)[a]	0(0,0)[a]	4(3,4)
H Value	51.279	7.202	0.973
P Value	<0.001	0.027	0.615

Note: Compared with Group R, [a]P<0.05.

Tab.3 Comparison of anesthesia induction and extubation time among three groups [n=45, $M(Q_1, Q_3)$]

Group	Time for BIS to decrease to 60 (s)	Extubation Time (min)
Group R	74.0(64.5,86.5)	11.0(9.0,12.5)
Group C	62.0(50.5,79.5)[a]	8.0(6.5,10.0)[a]
Group P	60.0(54.0,69.5)a	8.0(6.0,9.5)[a]
H Value	17.276	32.014
P Value	<0.001	<0.001

Note: Compared with Group R, [a]P<0.05.

Tab.4 Comparison of postoperative recovery among three groups [n=45, $M(Q_1, Q_3)$]

Group	Time to First Postoperative Flatus (d)	Postoperative Hospital Stay (d)	Postoperative Analgesia times
Group R	1.0(0.5,1.0)	3(3,3)	1.0(0.2,2.0)
Group C	1.0(0.5,1.0)	3(2,3)	1.0(0.2,2.0)
Group P	1.0(0.5,1.0)	3(2,3)	1.0(0.5,1.0)
H Value	0.74	5.013	3.01
P Value	0.691	0.082	0.222

Tab.5 Comparison of incidence of adverse reactions among three groups [n=45, $M(Q_1, Q_3)$]

Group	Injection Pain	PONV	Bradycardia
Group R	1(2.0)[a]	30(66.7)	0
Group C	3(6.7)[a]	18(40.0)[b]	3(6.7)
Group P	12(26.7)	18(40.0)[b]	5(11.1)
χ2 Value	14.606	8.538	5.049
P Value	0.001	0.018	0.097

Note: Compared with Group P, [a]P<0.017; Compared with Group R, [b]P<0.017.

3 Discussion

In this study, the incidence of hypotension during induction in the remimazolam group was significantly lower than that in the propofol group, which may be related to the differences in cardiovascular inhibitory effects between the two drugs [8-9]. A study by Soleimani *et al*. [9] suggested that the decrease in arterial blood pressure during propofol anesthesia induction is associated with reductions in cardiac output, stroke volume, and systemic vascular resistance. Propofol induction can cause severe vasodilation, whereas its effect on myocardial depression is not fully clear. The decrease in blood pressure after propofol administration may result from vasodilation and reduced sympathetic activity [10]. A study by Yoshikawa *et al*. [11] showed that remimazolam has no direct inhibitory effect on cardiac contractility, which may explain the relatively stable vital signs during general anesthesia induction with remimazolam. This study found that the incidence of hypotension in both the remimazolam and ciprofol groups was significantly lower than that in the propofol group from tracheal intubation to skin incision. Compared with the induction period, the incidence of hypotension in all three groups was significantly increased from tracheal intubation to skin incision. The presumed reason is that the dose of remifentanil used to suppress the intubation response exerted strong myocardial depression in patients. MAP decreased in all three groups during anesthesia induction, but the fluctuation of MAP in the remimazolam group was smaller than that in the ciprofol and propofol groups. MAP in the remimazolam group was significantly higher than that in the propofol group at T1, and significantly higher than that in the propofol and ciprofol groups at T2, with no statistically significant difference between the propofol and ciprofol groups. Systolic blood pressure in the propofol group was significantly lower than that in the remimazolam and ciprofol groups at T1, indicating that systolic blood pressure decreased rapidly and circulatory stability was poor during propofol induction. Systolic blood pressure decreased further at T2, with statistically significant differences among the three groups; the effect on systolic blood pressure was ranked propofol > ciprofol > remimazolam. There was no statistically significant difference in diastolic blood pressure among the three groups at T1; only at T2 was diastolic blood pressure significantly higher in the remimazolam group than in the propofol and ciprofol groups. Thus, the degree of influence of the three drugs on the patient's circulatory system was ranked propofol > ciprofol > remimazolam. Multiple studies have shown that the effect of remimazolam on blood pressure is significantly smaller than that of propofol [12-13]. No definitive conclusion has been reached regarding the effect of ciprofol on hemodynamics compared with propofol. Most studies have found that ciprofol is superior to propofol in circulatory effects [7,14], possibly because a lower dose of ciprofol is used to achieve the same anesthetic depth, with fewer components exerting circulatory depression. However, some studies have suggested that the advantage of ciprofol in circulatory

stability is not obvious [15]. This study found that remimazolam and ciprofol have certain advantages over propofol in circulatory effects, especially remimazolam. The circulatory advantage of ciprofol over propofol is mainly reflected in systolic blood pressure.

All three drugs have the effect of reducing PONV [16-18], and propofol has a more obvious antiemetic effect, mainly due to its action on dopaminergic and serotonergic systems [19]. Several retrospective surveys have also shown that remimazolam is inferior to propofol in terms of PONV [20-21]. Patients in the remimazolam group had low RASS scores upon admission to the PACU, often failing to follow commands or express clearly, which caused certain difficulties in the management of postoperative resuscitation patients. Compared with propofol, both remimazolam and ciprofol have a lower incidence of injection pain. Remimazolam is a water-soluble preparation with a low incidence of injection pain [22], and ciprofol also causes mild injection pain, which may be related to the low drug concentration in the aqueous phase of the emulsion [23]. In this study, BIS values and RASS sedation scores in the remimazolam group were lower than those in the propofol group during emergence at T3 and T4. A study by Yeon *et al*. [24] also showed significantly lower RASS scores in the remimazolam group than in the propofol group during PACU stay. At T3, BIS values in the ciprofol group were lower than those in the propofol group, with no statistically significant difference between the two groups at T4. This may be related to the fact that metabolic clearance of ciprofol mainly depends on the kidney [25], its potent sedative effect [26], or a higher plasma concentration at the end of prolonged infusion [27]. However, such changes recover rapidly and have no substantial clinical impact.

In conclusion, among the three drugs, remimazolam shows the most significant advantages in circulatory stability but is inferior in postoperative resuscitation and PONV. Ciprofol is superior to propofol but inferior to remimazolam in circulatory stability, and is generally comparable to propofol in postoperative resuscitation, postoperative recovery, and PONV.

Conflict of Interest: None

Author Contributions

Ren Fangyu: responsible for study design and protocol formulation, implementation of the study, data collection and analysis/interpretation, drafting the manuscript, reviewing and revising the intellectual content of the article, statistical analysis.
Han Yanan, Wang Shengyu: responsible for data collection and statistical analysis.
Chen Hua, Huang Jin: responsible for data collection, data analysis/interpretation, statistical analysis.
Zuo Qian, Liu Yuanzheng: responsible for data collection, statistical analysis, administrative, technical, or material support.
Wang Chunguang: responsible for critical review of the intellectual content of the article, supervision, and supportive contributions.

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·临床麻醉专题·论著·

瑞马唑仑、环泊酚及丙泊酚全凭静脉麻醉用于腹腔镜胆囊切除术的麻醉效果

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摘要：目的　比较瑞马唑仑、环泊酚及丙泊酚三种药物分别用于腹腔镜胆囊切除术全凭静脉麻醉的麻醉效果和对患者术后恢复的影响。**方法**　选取2023年4月至2024年11月于保定市第一中心医院择期行腹腔镜胆囊切除术患者135例，采用随机数字表法分为瑞马唑仑组（R组）、环泊酚组（C组）、丙泊酚组（P组），每组各45例。麻醉诱导：R组静脉注射瑞马唑仑0.3 mg/kg，C组环泊酚0.4 mg/kg，P组丙泊酚2 mg/kg，三组均静脉注射顺阿曲库铵注射液0.15 mg/kg，3 min后静脉注射瑞芬太尼2 μg/kg，行气管插管。麻醉维持：三组术中均静脉泵注瑞芬太尼0.2 μg/(kg·min)，R组泵注瑞马唑仑1 mg/(kg·h)，C组环泊酚0.8 mg/(kg·h)，P组丙泊酚4 mg/(kg·h)。观察指标：麻醉诱导前（T0）、给予麻醉镇静药物3 min后（T1）、插管后即刻（T2）、拔管后1 min（T3）、出手术室时（T4）的平均动脉压（MAP）、心率、外周血氧饱和度（SpO_2）、脑电双频指数（BIS）；低血压发生率及心动过缓、注射痛、术后恶心呕吐（PONV）等不良反应的发生情况；BIS降至60所用时间、拔管时间、术后首次排气时间、术后住院时间及术后镇痛次数。**结果**　诱导期P组、R组和C组低血压发生率差异有统计学意义[28.9%（13/45）*vs* 6.7%（3/45）*vs* 15.6%（7/45），χ^2=7.966，*P*=0.019]，且P组高于R组（χ^2=7.601，*P*=0.006）；插管后至切皮前低血压发生率P组为68.9%（31/45），分别高于C组的42.2%（19/45）和R组的26.7%（12/45）（*P*<0.017）。MAP在T1、T2、T3时R组高于P组（*P*<0.05），且T2时R组高于C组（*P*<0.05）；心率在T1、T2时R组高于C组、P组。与C组、P组相比，R组BIS降至60所用时间及拔管时间长（*P*<0.05）。三组术后首次排气时间、术后住院时间、术后镇痛次数比较差异无统计学意义（*P*>0.05）。R组PONV发生率高于C组和P组（*P*<0.017）；R组、C组注射痛发生率低于P组（*P*<0.017）。**结论**　与环泊酚和丙泊酚相比，瑞马唑仑循环稳定性方面的优势最明显，但在术后复苏及PONV方面表现欠佳；环泊酚在循环稳定方面优于丙泊酚但劣于瑞马唑仑，而在术后复苏表现、术后恢复方面及PONV方面与丙泊酚基本一致。

关键词：瑞马唑仑；环泊酚；丙泊酚；术后恢复质量；全凭静脉麻醉
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Anesthetic effects of remimazolam, ciprofol and propofol in total intravenous anesthesia for laparoscopic cholecystectomy

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Abstract: Objective　To compare the anesthetic efficacy and effects on postoperative recovery of remimazolam, ciprofol and propofol, when applied separately for total intravenous anesthesia in laparoscopic cholecystectomy. **Methods**　A total of 135 patients scheduled for elective laparoscopic cholecystectomy in Baoding No.1 Central Hospital between April 2023 and November 2024 were enrolled. The patients were divided into remimazolam group (Group R), ciprofol group (Group C) and propofol group (Group P) using the random number table method, 45 cases in each group. For anesthesia induction: Group R received intravenous injection of remimazolam 0.3 mg/kg; Group C received

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ciprofol 0.4 mg/kg; Group P received propofol 2 mg/kg. All groups were given intravenous injection of cisatracurium 0.15 mg/kg, followed by intravenous injection of remifentanil 2 μg/kg 3 minutes later for tracheal intubation. For anesthesia maintenance: all three groups were administered continuous intravenous infusion of remifentanil 0.2 μg/(kg·min); Group R received remimazolam 1 mg/(kg·h), Group C received ciprofol 0.8 mg/(kg·h), and Group P received with propofol 4 mg/(kg·h) via continuous infusion. The observation indicators included mean arterial pressure (MAP), heart rate, saturation of peripheral oxygen (SpO_2) and bispectral index (BIS) at the following time points: before anesthesia induction (T0), 3 minutes after administration of anesthetic sedatives (T1), immediately after intubation (T2), 1 minute after extubation (T3), and upon leaving the operating room (T4). Additionally, the incidence of adverse reactions such as hypotension, bradycardia, injection pain and postoperative nausea and vomiting (PONV) was recorded. Other outcome measures included the time taken for BIS to decrease to 60, extubation time, time to first postoperative flatus, duration of postoperative hospital stay and frequency of postoperative rescue analgesia. **Results** During the induction period, there were statistically significant differences in the incidence of hypotension among the Group P, Group R, and Group C [28.9%(13/45) *vs* 6.7%(3/45) *vs* 15.6%(7/45), χ^2=7.966, *P*=0.019], with the Group P showing a higher incidence than that in the Group R (χ^2=7.601, *P*=0.006). From intubation to before skin incision, the incidence of hypotension in the Group P was 68.9% (31/45), which was higher than that in the group C at 42.2% (19/45) and the Group R at 26.7% (12/45) (*P*<0.017). MAP in Group R at T1 and T2 was higher than those in Group P (*P*<0.05), and MAP at T2 in Group R was also higher than that in Group C (*P*<0.05). Heart rate in Group R at T1 and T2 was higher than that in Group C and Group P. Compared with Group C and Group P, Group R had longer time for BIS to decrease to 60 and longer extubation time (*P*<0.05). There was no statistically significant difference in time to first postoperative flatus, duration of postoperative hospital stay and frequency of postoperative rescue analgesia among the three groups (*P*>0.05). The incidence of PONV in Group R was higher than that in Group C and Group P (*P*<0.017). The incidence of injection pain in Group R and Group C was lower than that in Group P (*P*<0.017). **Conclusion** Remimazolam exhibits the most prominent advantage in hemodynamic stability among the three drugs, but shows subprominent performance in terms of postoperative resuscitation and PONV. Ciprofol is superior to propofol but inferior to remimazolam in hemodynamic stability, while its performance in postoperative resuscitation, postoperative recovery and PONV is basically consistent with propofol.

Keywords: Remimazolam; Ciprofol; Propofol; Postoperative recovery quality; Total intravenous anesthesia

腹腔镜胆囊切除术是临床治疗多种胆囊疾病的常见术式，在腹腔镜手术中，使用静脉麻醉药诱导和维持比吸入麻醉显示出更好的优势[1]。丙泊酚是目前最常用的静脉麻醉剂，具有起效快、作用时间短、恢复迅速的特点，但会引起剂量相关的循环呼吸抑制、注射痛和丙泊酚输注综合征[2-3]。瑞马唑仑是一种超短效苯二氮䓬类药物，其通过作用γ-氨基丁酸(gamma-aminobutyric acid，GABA)受体产生中枢抑制作用，具有起效快、代谢快、血流动力学稳定和可被氟马西尼迅速拮抗等优点[4-5]。环泊酚是一种2,6-二异丙基苯酚类似物，是由丙泊酚改良的新型静脉麻醉药[6]，效力是丙泊酚的4~5倍[6]，其注射痛发生率较低，已逐渐用于全身麻醉的诱导与维持[7]。本研究旨在比较瑞马唑仑、丙泊酚和环泊酚三种药物全凭静脉麻醉(total intravenous anaesthesia，TIVA)用于腹腔镜胆囊切除术的麻醉效果及对术后恢复质量的影响。

1 资料与方法

1.1 一般资料 选取2023年4月至2024年11月于保定市第一中心医院拟行腹腔镜胆囊切除术的患者135例。纳入标准：(1) 年龄18~65岁；(2) 身体质量指数(body mass index，BMI)18~30 kg/m^2；(3) 美国麻醉医师协会(American Society of Anesthesiologists，ASA)分级Ⅰ或Ⅱ级。排除标准：(1) 合并神经肌肉接头疾病；(2) 有试验药物过敏史、神经系统疾病史；(3) 预期气道困难；(4) 精神类疾病；(5) 孕产妇及哺乳期妇女；(6) 预用药；(7) 不愿参与本研究。剔除标准：(1) 中途退出试验；(2) 研究过程发生严重不良事件或意外事件。本研究经保定市第一中心医院医学伦理委员会批准(伦理批件号：〔2023〕150号)，患者及家属均签署知情同意书。

1.2 分组 采用随机数字表法将患者随机分为瑞马唑仑组(R组)、环泊酚组(C组)和丙泊酚组(P组)，每

组各 45 例。三组一般资料比较差异无统计学意义（P>0.05）。见表 1。

1.3　麻醉方法　患者术前常规禁食禁水，入室后建立上肢静脉通道，输注乳酸钠林格液 6～8 mL/kg，面罩吸氧，采用多功能监护仪连续监测心电图、无创血压、平均动脉压（mean arterial pressure，MAP）、心率和外周血氧饱和度（saturation of peripheral oxygen，SpO_2）；采用脑电双频指数（bispectral index，BIS）监测镇静深度。麻醉诱导：R 组缓慢静脉注射甲苯磺酸瑞马唑仑（江苏恒瑞医药，H20217078）0.3 mg/kg，C 组静脉注射环泊酚（辽宁海思科制药，H20200013）0.4 mg/kg，P 组静脉注射丙泊酚（四川国瑞药业，H20030113）2 mg/kg；三组均静脉注射顺阿曲库铵 0.15 mg/kg，3 min 后静脉注射瑞芬太尼 2 μg/kg，1 min 后行气管插管。麻醉维持：插管完成后，三组术中均静脉泵注瑞芬太尼 0.2 μg/（kg·min），R 组泵注瑞马唑仑 1 mg/（kg·h），C 组泵注环泊酚 0.8 mg/（kg·h），P 组泵注丙泊酚 4 mg/（kg·h）。麻醉诱导及维持过程中若 BIS>70 或睫毛反射依然存在，则 R 组静脉注射瑞马唑仑 0.05 mg/kg，C 组静脉注射环泊酚 0.01 mg/kg，P 组静脉注射丙泊酚 0.5 mg/kg 进行补救。当 MAP<60 mmHg 时静脉注射麻黄碱 6 mg 或去甲肾上腺素 4 μg；心率<45 次/min 时静脉注射阿托品注射液 0.5 mg。术中摘除胆囊后给予患者氟比洛芬酯注射液 50 mg。所有患者苏醒拔管后转入麻醉复苏室（postanesthesia care unit，PACU）进一步观察，若患者疼痛数字评分法（Numerical Rating Scale，NRS）评分>3 分，则予纳布啡 10 mg，发生术后恶心呕吐（postoperative nausea and vomiting，PONV）给予昂丹司琼 8 mg。

1.4　观察指标　主要结局：诱导期及插管后至切皮前低血压发生率（MAP 降幅超过基础 MAP 的 20%）。次要结局：麻醉诱导前（T0）、给予麻醉镇静药物 3 min（T1）、插管后即刻（T2）、拔管 1 min（T3）、出手术室时（T4）的 MAP、心率、SpO_2、BIS；麻醉诱导 BIS 降至 60 用时及患者停药到拔管所用时间；患者转至 PACU 时即刻的镇静躁动量表（Richmond Agitation-Sedation Scale，RASS）及 NRS 评分；手术后 4 h 的 RASS 评分；心动过缓及 PONV 等不良事件的发生情况。记录术后首次排气时间、术后住院时间及术后镇痛次数。

1.5　统计学方法　采用 PASS 15.0 软件进行样本量计算，三组各选取 20 例患者进行预试验，R 组诱导期低血压发生率为 5%，C 组发生率为 15%，P 组发生率为 35%，设置 α=0.05，1−β=0.9，计算所需总样本量为 122 例，考虑 10% 的数据缺失，拟纳入患者 135 例，每组 45 例。采用 SPSS 23.0 软件进行统计分析。非正态分布计量资料采用 $M(Q_1,Q_3)$ 表示，组间比较采用 Kruskal-Wallis H 检验；计数资料以例（%）表示，组间比较采用 χ^2 检验或 Fisher 确切概率法，两两比较采用 Bonferroni 校正后 α'=0.017。采用双侧检验，α=0.05。

2　结　果

2.1　一般情况　三组患者均顺利完成手术，无脱落或退出病例。三组手术时长差异无统计学意义（P>0.05）。见表 1。

2.2　低血压发生率　诱导期发生低血压的患者，P 组有 13 例（28.9%），R 组 3 例（6.7%），C 组 7 例（15.6%），三组间低血压发生率差异有统计学意义（χ^2=7.966，P=0.019），且 P 组发生率高于 R 组（χ^2=7.601，P=0.006）。插管后至切皮前发生低血压的患者，P 组有 31 例（68.9%），R 组 12 例（26.7%），C 组 19 例（42.2%），三组间低血压发生率差异有统计学意义（χ^2=16.525，P=0.005），且 P 组发生率分别高于 C 组和 R 组（P<0.017）。与诱导期相比，三组患者插管后至切皮前的低血压发生率均显著升高（P<0.05）。

2.3　血流动力学指标　收缩压在 T1 时 R 组和 C 组高于 P 组（P<0.05），T2 时 R 组>C 组>P 组（P<0.05）；舒张压在 T2、T3 时 R 组高于 C 组和 P 组；MAP 在 T1、T2、T3 时 R 组高于 P 组（P<0.05），且 T2 时 R 组高于 C 组（P<0.05）；心率在 T1、T2 时 R 组高于 C 组、P 组；BIS 在 T1、T2 时 R 组高于 C 组、P 组（P<0.05），T3 时 P 组高于 R、C 组（P<0.05），T4 时 C、P 组高于 R 组（P<0.05）；各时间点三组 SpO_2 比较差异无统计学意义（P>0.05）。见图 1。

表 1　三组一般资料比较　［n=45，$M(Q_1,Q_3)$］

Tab.1　Comparison of general data among three groups　［n=45，$M(Q_1,Q_3)$］

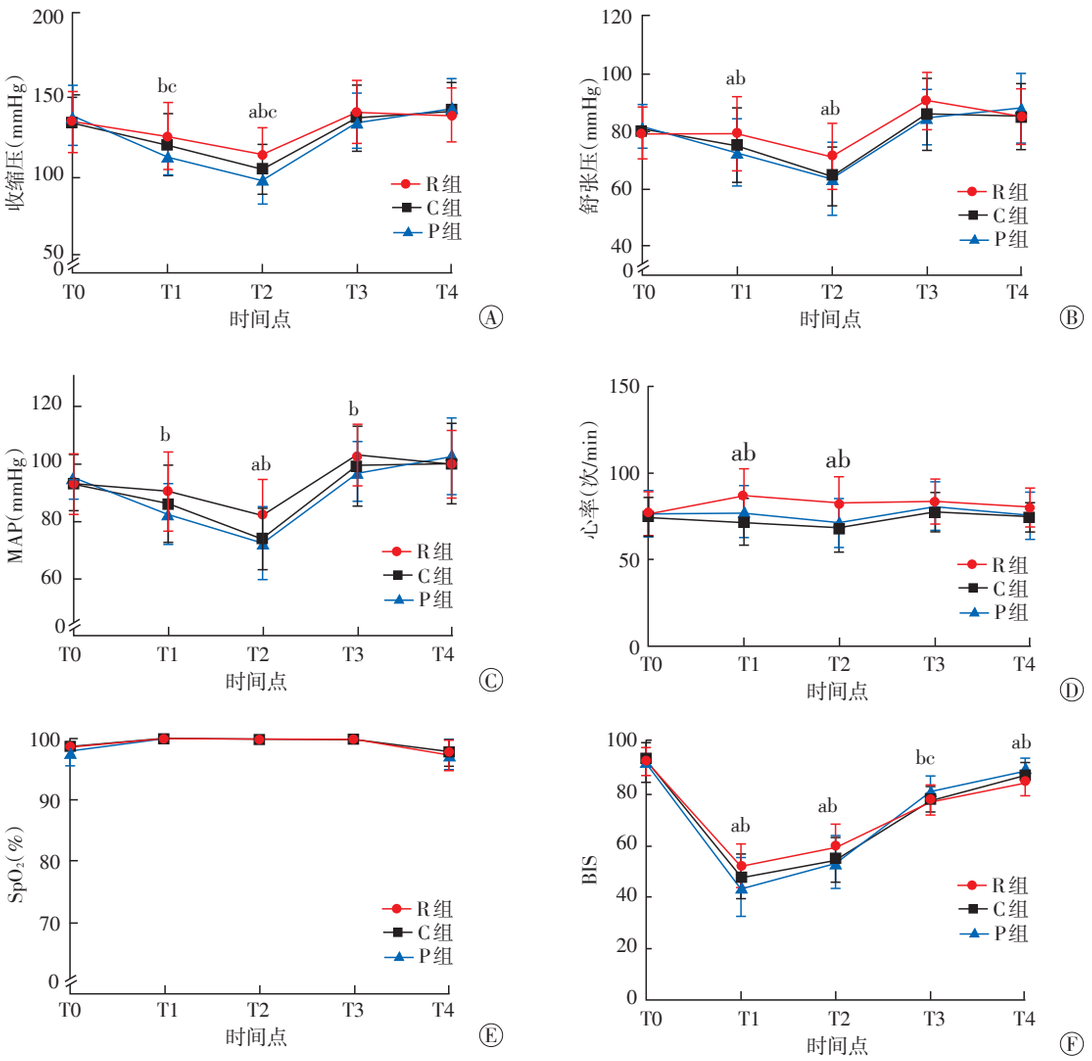
组别	BMI（kg/m²）	性别［例（%）］		ASA 分级［例（%）］		年龄（岁）	手术时长（min）
		男	女	Ⅰ级	Ⅱ级		
R 组	24.8（22.8，26.2）	20（44.4）	25（55.5）	18（40.0）	27（60.0）	52.0（34.0，58.0）	55.0（44.0，75.0）
C 组	24.0（22.7，26.5）	18（40.0）	27（60.0）	19（42.2）	26（57.8）	51.0（44.0，56.5）	60.0（40.5，79.5）
P 组	24.7（22.9，28.3）	17（37.8）	28（62.2）	14（31.1）	31（68.9）	54.0（45.0，58.0）	50.0（40.5，70.0）
H/χ^2 值	1.387	0.430		1.324		2.099	2.398
P 值	0.563	0.861		0.611		0.35	0.302

2.4　RASS评分及NRS评分　与R组相比，转至PACU时C组、P组RASS评分较高，术后4 h P组RASS评分较高（P<0.05）。三组转至PACU时NRS评分比较差异无统计学意义（P>0.05）。见表2。

2.5　麻醉诱导与拔管时间　与C组、P组相比，R组BIS降至60用时和拔管时间较长（P<0.05）。见表3。

2.6　术后恢复　三组术后排气时间、术后住院时间及术后镇痛次数比较差异无统计学意义（P>0.05）。见表4。

2.7　不良反应　三组心动过缓发生率比较差异无统计学意义（P>0.05）。R组PONV发生率高于C组和P组（P<0.017）。R组、C组注射痛发生率低于P组（P<0.017）。见表5。



注：A为收缩压；B为舒张压；C为MAP；D为心率；E为SpO_2；F为BIS。R组与C组比较，[a]P<0.05；R组与P组比较，[b]P<0.05；C组与P组比较，[c]P<0.05。

图1　三组围手术期血流动力学指标变化

Fig.1　Changes in perioperative hemodynamic parameters among three groups

表2　三组RASS评分及NRS评分比较　[n=45, $M(Q_1,Q_3)$]

Tab.2　Comparison of RASS scores and NRS scores among three groups　[n=45, $M(Q_1,Q_3)$]

组别	RASS评分(分)		NRS评分(分)
	转至PACU时	术后4 h	
R组	−1.0(−1.0,−1.0)	0(0,0)	4(3,5)
C组	0(−0.5,0)[a]	0(0,0)	3(3,5)
P组	0(0,0)[a]	0(0,0)[a]	4(3,4)
H值	51.279	7.202	0.973
P值	<0.001	0.027	0.615

注：与R组比较，[a]P<0.05。

表3　三组麻醉诱导及拔管时间比较　[n=45, $M(Q_1,Q_3)$]

Tab.3　Comparison of anesthesia induction and extubation time among three groups　[n=45, $M(Q_1,Q_3)$]

组别	BIS降至60用时(s)	拔管时间(min)
R组	74.0(64.5, 86.5)	11.0(9.0, 12.5)
C组	62.0(50.5, 79.5)[a]	8.0(6.5, 10.0)[a]
P组	60.0(54.0, 69.5)[a]	8.0(6.0, 9.5)[a]
H值	17.276	32.014
P值	<0.001	<0.001

注：与R组比较，[a]P<0.05。

表4　三组术后恢复情况比较　[n=45, $M(Q_1,Q_3)$]

Tab.4　Comparison of postoperative recovery among three groups　[n=45, $M(Q_1,Q_3)$]

组别	术后排气时间(d)	术后住院时间(d)	术后镇痛次数(次)
R组	1.0(0.5,1.0)	3(3,3)	1.0(0,2.0)
C组	1.0(0.5,1.0)	3(2,3)	1.0(0,2.0)
P组	1.0(0.5,1.0)	3(2,3)	1.0(0.5,1.0)
H值	0.740	5.013	3.010
P值	0.691	0.082	0.222

表5　三组不良反应发生率比较　[n=45,例(%)]

Tab.5　Comparison of incidence of adverse reactions among three groups　[n=45, case (%)]

组别	注射痛	PONV	心动过缓
R组	1(2.0)[a]	30(66.7)	0
C组	3(6.7)[a]	18(40.0)[b]	3(6.7)
P组	12(26.7)	18(40.0)[b]	5(11.1)
χ^2值	14.606	8.538	5.049
P值	0.001	0.018	0.097

注：与P组比较，[a]P<0.017；与R组比较，[b]P<0.017。

3　讨　论

在本研究中，瑞马唑仑组诱导期低血压发生率显著低于丙泊酚组，这可能与两种药物对心血管系统抑制作用的差异有关[8-9]。Soleimani等[9]研究认为丙泊酚麻醉诱导期间动脉血压的降低与心输出量、每搏输出量和全身血管阻力的降低有关。丙泊酚诱导可致严重的血管舒张，而对心肌抑制的影响尚不完全清楚，施用丙泊酚后血压下降可能是由于血管扩张的作用和交感神经活动减少[10]。Yoshikawa等[11]研究表明瑞马唑仑对心脏收缩力没有直接的抑制作用，这可能是瑞马唑仑全身麻醉诱导期生命体征较为平稳的原因。本研究发现，在插管后至切皮前，瑞马唑仑及环泊酚组患者低血压发生率均显著低于丙泊酚组；与诱导期相比，三组患者插管后至切皮前的低血压发生率均显著升高，推测原因可能是：为抑制插管反应所使用的瑞芬太尼剂量，对患者产生了较强的心肌抑制作用。三组患者在麻醉诱导阶段MAP均下降，但瑞马唑仑组在过程中相较于环泊酚组、丙泊酚组MAP波动更小，T1时瑞马唑仑组的MAP明显高于丙泊酚组，T2时瑞马唑仑组MAP明显高于丙泊酚组和环泊酚组，而丙泊酚组与环泊酚组差异无统计学意义。T1时丙泊酚组的收缩压明显低于瑞马唑仑组及环泊酚组，可见丙泊酚诱导时收缩压下降较快，循环稳定性较差；T2时收缩压进一步下降，此时三组收缩压差异均有统计学意义，对于收缩压的影响丙泊酚>环泊酚>瑞马唑仑。舒张压在T1时三组差异无统计学意义，仅在T2时呈现瑞马唑仑组明显高于丙泊酚组及环泊酚组。由此可见，三种药物对患者循环系统的影响程度为：丙泊酚>环泊酚>瑞马唑仑。多项研究表明瑞马唑仑对于血压的影响明显小于丙泊酚[12-13]。环泊酚对于血流动力学影响相对于丙泊酚似乎还没有形成确切的结论，多数研究发现环泊酚对于循环影响优于丙泊酚[7-14]，原因可能是达到相同麻醉深度使用环泊酚剂量较低，对循环起到抑制作用的成分更少。而一些研究认为环泊酚循环稳定性的优势并不明显[15]。本研究发现瑞马唑仑、丙泊酚对于循环的影响较丙泊酚相比有一定优势，特别是瑞马唑仑，环泊酚对丙泊酚的循环优势主要体现在收缩压方面。

三种药物都有降低PONV的作用[16-18]，丙泊酚止吐效果更加明显，主要由于其可通过影响多巴胺能和血清素能系统发挥作用[19]，在几项回顾性调查中，也发现瑞马唑仑在PONV方面表现不如丙泊酚[20-21]。瑞马唑仑组患者入复苏室时RASS评分低，患者常不能配合指令动作和清楚表达，对术后复苏患者管理造成一定困难。与丙泊酚相比，瑞马唑仑和环泊酚都有较低的注射痛发生率。瑞马唑仑是水溶性制剂，其发生注射痛情况较少[22]，环泊酚引起的注射疼痛也较小，这可能与乳液水相中的药物浓度较低有关[23]。在本研究T3和T4时，苏醒过程瑞马唑仑组的BIS值较丙泊酚低，RASS镇静评分偏低。Yeon等[24]研究中也显示瑞马唑仑组较丙泊酚组在PACU期间的RASS评分显著降低的情况。T3时环泊酚组BIS值较丙泊酚组低，T4两组比较差异无统计学意义，这可能与环泊酚的代谢清除主要依赖肾脏[25]、具有强效镇静作用[26]或其长时间输注结束时血浆浓度较高[27]有关，但这种变化恢复较快，对临床并无实质性的影响。

综上所述，三种药物中，瑞马唑仑在循环稳定性方面的优势最为显著，但在术后复苏及PONV方面表现较差；环泊酚在循环稳定方面优于丙泊酚但劣于瑞马唑仑，而在术后复苏表现、术后恢复方面及PONV方面与丙泊酚基本一致。

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