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## Sedative efficacy and safety of remimazolam tosylate in painless gastroscopy diagnosis and treatment

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**Abstract: Objective** To compare the differences in efficacy and safety between remimazolam tosylate and propofol for sedation during painless gastroscopy, and its effect on awakening time and discharge time. **Methods** A total of 80 patients scheduled for painless gastroscopy at Henan Provincial People's Hospital from August 2023 to October 2024 were selected as the study subjects. According to a random number table, the patients were divided into a remimazolam group (n=40) and a propofol group (n=40). The sedation success rates were compared between the two groups. Mean arterial pressure (MAP), heart rate and end-tidal carbon dioxide partial pressure ( $P_{ET}CO_2$ ) were compared between the two groups at the following time points: upon entering the procedure room, during gastroscopy insertion, during gastroscopy withdrawal, and at the end of anesthesia. The incidence of adverse events (including swallowing movements and body movements during gastroscopy insertion, as well as intraoperative respiratory depression, etc.) was recorded for both groups. The time from the end of the last drug administration to complete awakening and the time to discharge were recorded for both groups. **Results** There was no statistically significant difference in sedation success rate between the remimazolam group and the propofol group [92.5% (37/40) vs 87.5% (35/40),  $\chi^2=0.139$ ,  $P=0.709$ ]. In terms of MAP, heart rate and  $P_{ET}CO_2$  between the two groups, had statistically significant between-group effect, time effect, and between-group  $\times$  time interaction effect ( $P<0.01$ ). Moreover, the three indicators in the remimazolam group were better than those in the propofol group at gastroscopy insertion, gastroscopy withdrawal and the end of anesthesia ( $P<0.05$ ). The total incidence of adverse reactions in the remimazolam group was 15.00% (6/40), and the difference was not statistically significant compared with 27.50% (11/40) in the propofol group ( $\chi^2=1.867$ ,  $P=0.172$ ). There was no statistically significant difference in recovery time between the remimazolam group and the propofol group [(7.2 $\pm$ 3.6) min vs (8.5 $\pm$ 4.2) min,  $t=1.486$ ,  $P=0.141$ ]. The discharge time in the remimazolam group was earlier than that in the propofol group, and the difference was statistically significant [(23.6  $\pm$  5.7) min vs (27.4  $\pm$  7.8) min,  $t=2.488$ ,  $P=0.015$ ]. **Conclusion** Remimazolam tosylate provides effective sedation with good safety when used for painless gastroscopy.

**Keywords:** Remimazolam tosylate; Propofol; Painless gastroscopy; Endoscopy; Anesthesia

In recent years, an increasing number of patients have chosen to undergo gastrointestinal endoscopy under painless and comfortable conditions [1]. Propofol has the advantages of rapid onset, quick recovery, short context-sensitive half-life, and complete awakening, making it the most widely used drug in the field of anesthesia sedation in China. However, propofol has side effects such as respiratory depression and intravenous injection pain [2-4]. Remimazolam tosylate is a novel benzodiazepine drug that is rapidly hydrolyzed *in vivo* by tissue esterases in the blood. It has the characteristics of rapid onset, short maintenance and recovery times, no accumulation, metabolism independent of liver and kidney function, and no serious side effects. Even after prolonged infusion, patients can awaken within a few minutes after drug discontinuation, allowing for neurological assessment [5-7]. This study aims to compare the efficacy and safety of remimazolam tosylate and propofol in painless gastroscopic diagnosis and treatment.

### 1 Data and Methods

#### 1.1 General Data

This study was approved by the Ethics Committee of Henan Provincial People's Hospital [Ethics Number: (2021) Ethics Review No. (58)], and all patients signed informed

consent forms. A total of 80 patients undergoing painless gastrointestinal endoscopy diagnosis and treatment at Henan Provincial People's Hospital from August 2023 to October 2024 were selected. The patients were divided into a propofol group and a remimazolam group by a random number table method, with 40 patients in each group.

Inclusion criteria: age 18-60 years; body mass index (BMI) 18.5-29.9 kg/m<sup>2</sup>; American Society of Anesthesiologists (ASA) physical status classification I-III.

Exclusion criteria: any cerebrovascular accident (e.g., stroke, transient ischemic attack) within the past 3 months; unstable angina or myocardial infarction within the past 3 months; confirmed or suspected abuse or long-term use of narcotic sedatives and analgesics; contraindications or allergies to the study drugs or other anesthetics.

There was no statistically significant difference in general data between two groups ( $P>0.05$ ). See **Table 1**.

**Tab.1** Comparison of general data between two groups

(n=40, $\bar{x} \pm s$ )				
Group	Male/Female (case)	Age (years)	BMI (kg/m <sup>2</sup> )	Surgery time (min)
Propofol group	22/18	46 $\pm$ 13	22.3 $\pm$ 4.6	8.5 $\pm$ 3.2
Remimazolam group	19/21	42 $\pm$ 17	24.1 $\pm$ 3.9	9.1 $\pm$ 2.6
$\chi^2/t$ value	0.450	1.182	1.888	0.920
<i>P</i> value	0.502	0.241	0.063	0.360

1.2 Methods

After the patients entered the operating room, a peripheral intravenous line was established, and vital signs were monitored: (1) non-invasive blood pressure using a non-invasive cuff; (2) heart rate; (3) saturation of peripheral oxygen (SpO<sub>2</sub>); (4) end-tidal carbon dioxide partial pressure (P<sub>ET</sub>CO<sub>2</sub>) monitored using Capnostream™20P (Medtronic, USA). The remimazolam group received intravenous injection of remimazolam tosylate (Jiangsu Hengrui Medicine, National Drug Approval Number H20190034, 36 mg), with an initial dose of 0.2 mg/kg and a supplemental dose of 0.05 mg/kg each time. The propofol group received intravenous injection of propofol (Fresenius Kabi (China), National Drug Approval Number HJ20150661, 50 mL:0.5 g), with a loading dose of 1.5 mg/kg and a supplemental dose of 0.5 mg/kg each time. Both groups received sufentanil (Yichang Humanwell Pharmaceutical, National Drug Approval Number H20054171, 1 mL:50 μg) 5 μg before administration of the study drug. Blood pressure fluctuations were maintained within 20% of baseline blood pressure, with systolic blood pressure ≥90 mmHg; vasoactive drugs were used if necessary. If heart rate <50 beats/min during the procedure, atropine or ephedrine could be given as a small single intravenous dose, while the cause was identified and the treatment recorded; if heart rate >90 to 100 beats/min, the cause was identified and the treatment recorded, and 5-10 mg of esmolol was given intravenously if necessary. Ventilation was performed by Capnostream™20P dual-lumen nasal cannula. All the examinations were completed by the same group of physicians.

1.3 Observation Indicators

(1) The sedation success rate in both groups was recorded (criteria for successful sedation:

- ① completion of the gastroscopic diagnosis and treatment;
- ② no use of rescue sedative drugs;
- ③ number of drug administration's ≤5 times within a 15-minute period).

(2) Mean arterial pressure (MAP), heart rate, and P<sub>ET</sub>CO<sub>2</sub> were recorded in both groups at the time of entering the room (T<sub>0</sub>), when the gastroscope was inserted

(T<sub>1</sub>), when the gastroscope was withdrawn (T<sub>2</sub>), and at the end of anesthesia (T<sub>3</sub>).

(3) The incidence of adverse events such as swallowing movements and body movement responses during gastroscope insertion, as well as intraoperative respiratory depression, was recorded for both groups.

(4) The time from the last drug administration to full awakening and the discharge time from the hospital were recorded for both groups. Discharge criteria: The Post-Anesthesia Discharge Scoring System [3] was used; discharge was allowed only when the score was >9.

1.4 Statistical Methods

SPSS 25.0 software was used for data analysis. Measurement data conforming to normal distribution were expressed as  $\bar{x} \pm s$  and analyzed by *t*-tests; comparisons at multiple time points were performed using repeated measures analysis of variance. Count data were expressed as case (%), and intergroup comparisons were performed using the chi-square test. *P*<0.05 was considered statistically significant.

2 Results

2.1 Comparison of sedation success rates between the two groups

The sedation success rate of the propofol group was 87.5% (35/40), and that of the remimazolam group was 92.5% (37/40). There was no statistically significant difference in sedation success rates between the two groups ( $\chi^2=0.139, P=0.709$ ).

2.2 Comparison of MAP, heart rate, and P<sub>ET</sub>CO<sub>2</sub> between the two groups

The differences in MAP, heart rate, and P<sub>ET</sub>CO<sub>2</sub> at each time point between the two groups were statistically significant (*P*<0.05). See Table 2.

2.3 Comparison of the incidence of adverse reactions between the two groups

There was no statistically significant difference in the total incidence of adverse reactions between the two groups (*P*>0.05). See Table 3.

Tab.2 Comparison of MAP, heart rate, and P<sub>ET</sub>CO<sub>2</sub> between two groups (n=40,  $\bar{x} \pm s$ )

Group	MAP (mmHg)				heart rate (beats/min)				P <sub>ET</sub> CO <sub>2</sub> (mmHg)			
	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>3</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>3</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>3</sub>
Propofol group	83±9	76±6	70±5	71±6	72±8	62±6	64±2	59±5	39±3	39±5	48±4	47±5
Remimazolam group	81±11	79±9	77±8	78±9	78±4	91±7	86±4	84±7	38±5	39±3	41±4	41±3
<i>F/P</i> <sub>between-group value</sub>	29.163/<0.001				969.350/<0.001				60.277/<0.001			
<i>F/P</i> <sub>time value</sub>	14.695/<0.001				10.261/<0.001				38.291/<0.001			
<i>F/P</i> <sub>interaction value</sub>	5.473/0.002				61.340/<0.001				11.345/<0.001			

Tab.3 Comparison of adverse reaction rates between two groups (n=40, case)

Group	Swallowing	Somatic reaction	Intraoperative respiratory depression	Total incidence rate (%)
Propofol group	3	2	6	27.50
Remimazolam group	2	1	3	15.00
$\chi^2$ value				1.867
<i>P</i> value				0.172

2.4 Comparison of awakening time and discharge time between the two groups

There was no statistically significant difference in the time from the end of the last drug administration to complete awakening between the two groups (*P*>0.05). The discharge time of the remimazolam group was earlier than that of the propofol group (*P*<0.05). See Table 4.

**Tab.4** Comparison of awakening time and discharge time between two groups ( $n=40$ ,  $\bar{x} \pm s$ )

Group	Awaking time (min)	Discharge time (min)
Propofol group	8.5±4.2	27.4±7.8
Remimazolam group	7.2±3.6	23.6±5.7
<i>t</i> value	1.486	2.488
<i>P</i> value	0.141	0.015

### 3 Discussion

Gastroscopy is the most direct and effective method widely used in the diagnosis and treatment of digestive system diseases at present. However, the examination process can bring a certain degree of pain to patients [6]. Therefore, the implementation of painless gastroscopy has become very important. Currently, intravenous anesthesia with propofol combined with opioid analgesics is mostly used in clinical practice [1, 8], which has good sedative and analgesic effects. However, besides injection pain, propofol also has significant inhibitory effects on the respiratory and circulatory systems [2, 4, 9]. Remimazolam, when used for painless gastroscopy, ensures successful sedation while significantly reducing the incidence of respiratory and circulatory depression [10-12]. The results of this study show that the sedation success rate was similar between the propofol group and the remimazolam group, but the  $P_{ETCO_2}$  was lower in the remimazolam group. The respiratory depression effect of propofol is mainly related to its influence on the sensitivity of central chemoreceptors, reducing the body's responsiveness to hypercapnia and hypoxia, and causing a decrease in respiratory rate and tidal volume [2, 4]; at the same time, propofol causes a decrease in blood pressure through the dual effects of directly inhibiting myocardial contraction and dilating peripheral blood vessels, and the degree of respiratory and circulatory depression caused by propofol is dose-dependent [13-16].

The results of this study show that compared with the propofol group, the remimazolam group had a lower incidence of respiratory depression and lower  $P_{ETCO_2}$ , with statistically significant differences. Although the heart rate increased after drug administration in the remimazolam group, vital signs remained stable throughout, with no occurrence of hypotension or hypertension, and no carbon dioxide accumulation. The pharmacokinetics of remimazolam are linear, and its clearance is independent of body weight [7, 17]. Studies have shown that the remimazolam group has rapid onset and dose-dependent sedative effects [7, 12]. Remimazolam is a novel short-acting water-soluble benzodiazepine derivative. Its sedative effect has rapid onset and short duration; it can be rapidly hydrolyzed by tissue esterases into inactive metabolites, has little effect on the cardiovascular and respiratory systems, and patients recover cognitive ability quickly and completely [18-20]. The results of this study show that compared with the propofol group, patients in the remimazolam group recovered neuropsychiatric function faster, had earlier discharge times from the hospital, and returned to normal faster. Moreover, no serious adverse events requiring emergency treatment occurred in the remimazolam group.

In summary, when remimazolam tosylate is used for painless gastroscopy diagnosis and treatment in the endoscopy center, it can provide effective sedation and has the characteristics of rapid onset, short maintenance and recovery times, no accumulation, and no intravenous injection pain. It can be safely and effectively used for painless gastroscopy diagnosis and treatment.

### Conflict of Interest None

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· 临床麻醉专题·论著·

# 甲苯磺酸瑞马唑仑在无痛胃镜诊疗中的镇静有效性和安全性

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**摘要:** **目的** 比较甲苯磺酸瑞马唑仑和丙泊酚用于无痛胃镜诊疗镇静有效性和安全性的差异, 及对苏醒时间和离院时间的影响。**方法** 选择于河南省人民医院2023年8月至2024年10月行无痛胃肠镜检查的患者80例为研究对象。按照随机数字表法将患者分为瑞马唑仑组( $n=40$ )和丙泊酚组( $n=40$ )。比较两组患者的镇静成功率。比较两组患者入室时、进胃镜时、退出胃镜时、麻醉结束时的平均动脉压(MAP)、心率和呼气末二氧化碳分压( $P_{ET}CO_2$ )。记录两组患者不良事件(包括进胃镜时有吞咽动作、体动反应以及术中呼吸抑制等)发生情况。记录两组患者最后一次给药结束至完全苏醒的时间、离院时间。**结果** 瑞马唑仑组与丙泊酚组镇静成功率比较差异无统计学意义[92.5%(37/40) vs 87.5%(35/40),  $\chi^2=0.139$ ,  $P=0.709$ ]。两组在MAP、心率及 $P_{ET}CO_2$ 三项指标中的组间效应、时间效应、组间 $\times$ 时间的交互效应均有统计学意义( $P<0.01$ ), 且瑞马唑仑组进胃镜时、退出胃镜时及麻醉结束时的三项指标均优于丙泊酚组( $P<0.05$ )。瑞马唑仑组不良反应总发生率为15.00%(6/40), 与丙泊酚组的27.50%(11/40)相比差异无统计学意义( $\chi^2=1.867$ ,  $P=0.172$ )。瑞马唑仑组和丙泊酚组的苏醒时间比较差异无统计学意义[(7.2 $\pm$ 3.6)min vs (8.5 $\pm$ 4.2)min,  $t=1.486$ ,  $P=0.141$ ]。瑞马唑仑组离院时间早于丙泊酚组, 差异有统计学意义[(23.6 $\pm$ 5.7)min vs (27.4 $\pm$ 7.8)min,  $t=2.488$ ,  $P=0.015$ ]。**结论** 甲苯磺酸瑞马唑仑用于无痛胃镜的诊疗时, 可以提供有效的镇静, 且安全性较好。

**关键词:** 甲苯磺酸瑞马唑仑; 丙泊酚; 无痛胃镜; 内镜; 麻醉

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## Sedative efficacy and safety of remimazolam tosylate in painless gastroscopy diagnosis and treatment

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**Abstract: Objective** To compare the differences in efficacy and safety between remimazolam tosylate and propofol for sedation during painless gastroscopy, and its effect on awakening time and discharge time. **Methods** A total of 80 patients scheduled for painless gastroscopy at Henan Provincial People's Hospital from August 2023 to October 2024 were selected as the study subjects. According to a random number table, the patients were divided into a remimazolam group ( $n=40$ ) and a propofol group ( $n=40$ ). The sedation success rates were compared between the two groups. Mean arterial pressure (MAP), heart rate and end-tidal carbon dioxide partial pressure ( $P_{ET}CO_2$ ) were compared between the two groups at the following time points: upon entering the procedure room, during gastroscopy insertion, during gastroscopy withdrawal, and at the end of anesthesia. The incidence of adverse events (including swallowing movements and body movements during gastroscopy insertion, as well as intraoperative respiratory depression, etc.) was recorded for both

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groups. The time from the end of the last drug administration to complete awakening and the time to discharge were recorded for both groups. **Results** There was no statistically significant difference in sedation success rate between the remimazolam group and the propofol group [92.5% (37/40) vs 87.5% (35/40),  $\chi^2=0.139$ ,  $P=0.709$ ]. In terms of MAP, heart rate and  $P_{ET}CO_2$  between the two groups, had statistically significant between-group effect, between-time effect, and group  $\times$  time interaction effect ( $P<0.01$ ). Moreover, the three indicators in the remimazolam group were better than those in the propofol group at gastroscope insertion, gastroscope withdrawal and the end of anesthesia ( $P<0.05$ ). The total incidence of adverse reactions in the remimazolam group was 15.00% (6/40), and the difference was not statistically significant compared with 27.50% (11/40) in the propofol group ( $\chi^2=1.867$ ,  $P=0.172$ ). There was no statistically significant difference in recovery time between the remimazolam group and the propofol group [(7.2 $\pm$ 3.6)min vs (8.5 $\pm$ 4.2)min,  $t=1.486$ ,  $P=0.141$ ]. The discharge time in the remimazolam group was earlier than that in the propofol group, and the difference was statistically significant [(23.6 $\pm$ 5.7)min vs (27.4 $\pm$ 7.8)min,  $t=2.488$ ,  $P=0.015$ ]. **Conclusion** Remimazolam tosylate provides effective sedation with good safety when used for painless gastroscopy.

**Keywords:** Remimazolam tosylate; Propofol; Painless gastroscopy; Endoscopy; Anesthesia

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近年来选择无痛舒适下行胃肠镜检查的患者越来越多<sup>[1]</sup>。丙泊酚具有起效快、恢复快、持续输注半衰期短、苏醒完全等优点,是目前国内麻醉镇静领域应用最广的药物,然而丙泊酚有呼吸抑制和静脉注射痛等副作用<sup>[2-4]</sup>。甲苯磺酸瑞马唑仑是一种新型苯二氮草类药物,通过血液中的组织酯酶在体内快速水解,具有起效快、维持和恢复时间短、无蓄积、代谢不依赖肝肾功能、无严重副作用等特点,即使长时间输注后也会在停药数分钟后苏醒,配合完成神经学评估<sup>[5-7]</sup>。本研究拟比较甲苯磺酸瑞马唑仑和丙泊酚在无痛胃镜诊疗中的有效性和安全性。

## 1 资料与方法

**1.1 一般资料** 本研究已获河南省人民医院伦理委员会批准[伦理号:[2021]伦审第(58)号],患者均签署知情同意书。选择2023年8月至2024年10月在河南省人民医院行无痛胃肠镜诊疗的患者80例,采用随机数字表法分为丙泊酚组和瑞马唑仑组,各40例。纳入标准:年龄18~60岁;身体质量指数(body mass index, BMI)为18.5~29.9 kg/m<sup>2</sup>;美国麻醉医师协会(American Society of Anesthesiologists, ASA)分级I~III级。排除标准:3个月内发生过任何脑血管意外,如脑卒中、短暂性脑缺血发作等;3个月内发生过不稳定心绞痛、心肌梗死;确定/怀疑有滥用或长期应用麻醉性镇静镇痛药;存在对试验药物及其他麻醉药物的禁忌证或者过敏。两组患者一般资料比较差异无统计学意义( $P>0.05$ )。见表1。

表1 两组患者一般资料比较 (n=40)

Tab.1 Comparison of general data between two groups (n=40)

组别	性别 (男/女,例)	年龄 (岁, $\bar{x}\pm s$ )	BMI (kg/m <sup>2</sup> , $\bar{x}\pm s$ )	手术时间 (min, $\bar{x}\pm s$ )
丙泊酚组	22/18	46 $\pm$ 13	22.3 $\pm$ 4.6	8.5 $\pm$ 3.2
瑞马唑仑组	19/21	42 $\pm$ 17	24.1 $\pm$ 3.9	9.1 $\pm$ 2.6
$\chi^2/t$ 值	0.450	1.182	1.888	0.920
$P$ 值	0.502	0.241	0.063	0.360

**1.2 方法** 患者入手术室后,开放外周静脉通路,监测生命体征:(1)无创袖带检测无创血压;(2)心率;(3)外周血氧饱和度(saturation of peripheral oxygen, SpO<sub>2</sub>);(4)Capnostream™20P(美国美敦力公司)监测呼气末二氧化碳分压(partial pressure of end-tidal carbon dioxide,  $P_{ET}CO_2$ )。瑞马唑仑组给予静脉注射甲苯磺酸瑞马唑仑(江苏恒瑞医药,国药准字H20190034, 36 mg),初始给药剂量为0.2 mg/kg,追加给药剂量为每次0.05 mg/kg;丙泊酚组给予静脉注射丙泊酚[德国费森尤斯比卡(中国),国药准字HJ20150661, 50 mL:0.5 g],负荷剂量为1.5 mg/kg,追加给药剂量为每次0.5 mg/kg。两组受试者均在给予试验药物前给予舒芬太尼(宜昌人福药业,国药准字H20054171, 1 mL:50  $\mu$ g)5  $\mu$ g。维持血压波动在基础血压的20%以内,且收缩压 $\geq$ 90 mmHg,必要时使用血管活性药物。术中若心率 $<$ 50次/min,可予阿托品或麻黄碱小剂量单次静脉注射,同时查找原因并记录处理;心率 $>$ 90~100次/min,查找原因并记录处理,必要时给予5~10 mg艾司洛尔静脉注射。使用Capnostream™20P专用双腔鼻导管进行通气。全部检查

由同一组医师完成。

1.3 观察指标 (1) 记录两组患者的镇静成功率(镇静成功标准:①完成胃镜诊疗;②未使用补救镇静药物;③在15 min时间段内给药次数≤5次)。(2) 记录两组患者入室时( $T_0$ ),进胃镜时( $T_1$ )、退出胃镜时( $T_2$ )、麻醉结束时( $T_3$ )的平均动脉压(mean arterial pressure, MAP)、心率和 $P_{ET}CO_2$ 。(3) 记录两组患者进胃肠镜时有吞咽动作和体动反应以及术中呼吸抑制等不良事件的发生率。(4) 记录两组患者最后一次给药结束至完全苏醒的时间、离院时间。离院标准:采用镇静/麻醉后离院评分量表<sup>[3]</sup>,评分>9分方可离院。

1.4 统计学方法 采用SPSS 25.0软件进行数据分析。符合正态分布的计量资料采用 $\bar{x}\pm s$ 表示,采用 $t$ 检验,多时点的比较使用重复测量的方差分析;计数资料用例表示,组间比较采用 $\chi^2$ 检验。 $P<0.05$ 为差异

有统计学意义。

## 2 结果

2.1 两组患者镇静成功率比较 丙泊酚组镇静成功率为87.5%(35/40),瑞马唑仑组成功率为92.5%(37/40),两组患者镇静成功率比较差异无统计学意义( $\chi^2=0.139, P=0.709$ )。

2.2 两组MAP、心率、 $P_{ET}CO_2$ 比较 两组患者各时间点MAP、心率和 $P_{ET}CO_2$ 的比较差异有统计学意义( $P<0.05$ )。见表2。

2.3 两组患者不良反应发生率比较 两组患者不良反应的总发生率差异无统计学意义( $P>0.05$ )。见表3。

2.4 两组患者苏醒时间和离院时间比较 两组患者最后一次给药结束至完全苏醒的时间比较差异无统计学意义( $P>0.05$ ),瑞马唑仑组离院时间早于丙泊酚组,差异有统计学意义( $P<0.05$ )。见表4。

表2 两组各时间点MAP、心率及 $P_{ET}CO_2$ 比较 ( $\bar{x}\pm s$ )

Tab.2 Comparison of MAP, heart rate, and  $P_{ET}CO_2$  between two groups at each time point ( $\bar{x}\pm s$ )

组别	MAP(mmHg)				心率(次/min)				$P_{ET}CO_2$ (mmHg)			
	$T_0$	$T_1$	$T_2$	$T_3$	$T_0$	$T_1$	$T_2$	$T_3$	$T_0$	$T_1$	$T_2$	$T_3$
丙泊酚组	83±9	76±6	70±5	71±6	72±8	62±6	64±2	59±5	39±3	39±5	48±4	47±5
瑞马唑仑组	81±11	79±9	77±8	78±9	78±4	91±7	86±4	84±7	38±5	39±3	41±4	41±3
$F_{组间}/P_{组间}$ 值	29.163/<0.001				969.350/<0.001				60.277/<0.001			
$F_{时间}/P_{时间}$ 值	14.695/<0.001				10.261/<0.001				38.291/<0.001			
$F_{交互}/P_{交互}$ 值	5.473/0.002				61.340/<0.001				11.345/<0.001			

表3 两组患者不良反应发生率比较 ( $n=40$ , 例)

Tab.3 Comparison of incidence of adverse reactions between two groups ( $n=40$ , case)

组别	发生吞咽	体动反应	术中呼吸抑制	总发生率(%)
丙泊酚组	3	2	6	27.50
瑞马唑仑组	2	1	3	15.00
$\chi^2$ 值				1.867
$P$ 值				0.172

表4 两组患者苏醒时间和离院时间比较 ( $\bar{x}\pm s$ )

Tab.4 Comparison of awakening time and discharge time between two groups ( $\bar{x}\pm s$ )

组别	例数	苏醒时间(min)	离院时间(min)
丙泊酚组	40	8.5±4.2	27.4±7.8
瑞马唑仑组	40	7.2±3.6	23.6±5.7
$t$ 值		1.486	2.488
$P$ 值		0.141	0.015

## 3 讨论

胃镜检查是目前消化系统疾病诊断和治疗中普遍应用的最直接有效的方法,然而检查过程中会给患者带来一定程度的痛苦<sup>[6]</sup>,因此无痛胃镜检查的开

展变得十分重要。目前临床上大多采用丙泊酚复合阿片类镇痛药静脉麻醉<sup>[1,8]</sup>,其具有良好的镇静、镇痛效果,然而丙泊酚除了静脉注射痛之外,对呼吸和循环系统也有着明显的抑制作用<sup>[2,4,9]</sup>。瑞马唑仑用于无痛胃镜检查,在保证镇静成功的同时可明显降低呼吸、循环抑制的发生率<sup>[10-12]</sup>。本研究结果显示,丙泊酚组与瑞马唑仑组镇静成功率相近,但瑞马唑仑组 $P_{ET}CO_2$ 较低。丙泊酚对呼吸的抑制作用主要与其影响中枢化学感受器的敏感性、降低机体对高碳酸血症和缺氧的反应性、引起呼吸频率下降和潮气量减少有关<sup>[2,4]</sup>;同时丙泊酚通过直接抑制心肌收缩和扩张外周血管的双重作用引起血压下降,且丙泊酚对呼吸和循环的抑制程度呈剂量依赖性<sup>[13-16]</sup>。

本研究结果显示,与丙泊酚组相比,瑞马唑仑组呼吸抑制发生率和 $P_{ET}CO_2$ 更低,差异有统计学意义。尽管瑞马唑仑组在用药后心率有所升高,但生命体征始终保持稳定,没有低血压或高血压的发生,也无二氧化碳蓄积的发生。瑞马唑仑的药代动力学呈线

性,其清除与体质量无关<sup>[7,17]</sup>。研究表明,瑞马唑仑组起效迅速,并且具有剂量依赖性镇静作用<sup>[7,12]</sup>。瑞马唑仑是一种新型短效水溶性苯二氮草类衍生物,其镇静作用起效迅速、持续时间短,能迅速被组织酯酶水解为无活性的代谢产物,对心血管和呼吸系统影响小,患者认知能力恢复快且完全<sup>[18-20]</sup>。本研究结果显示,与丙泊酚组相比,瑞马唑仑组的患者神经精神功能恢复更快,离院时间更早,恢复正常的时间更快,且瑞马唑仑组未出现需紧急治疗的严重不良事件。

综上,甲苯磺酸瑞马唑仑用于内镜中心无痛胃镜的诊疗时,可以提供有效的镇静,并且具有起效快、维持和恢复时间短、无蓄积、无静脉注射痛等特点,可以安全有效地用于无痛胃镜的诊疗。

利益冲突 无

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