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Remimazolam tosilate in the general anesthesia induction for elderly patients undergoing arthroscopic shoulder surgery

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Abstract: Objective To explore the application effect of remimazolam tosilate in the induction of general anesthesia for arthroscopic shoulder surgery in elderly patients, and its influence on cognitive impairment and postoperative delirium. **Methods** A total of 110 elderly patients who underwent arthroscopic shoulder surgery at Neijiang Hospital of Traditional Chinese Medicine from May 2021 to June 2024 were prospectively enrolled. They were divided into the experimental group and the control group with 55 cases each using a random number table method. Both groups received conventional general anesthesia combined with ultrasound - guided nerve block. In the control group, anesthesia induction was performed using propofol 1.0-1.5 mg/kg, sufentanil 0.25 μg/kg, and rocuronium 0.6 mg/kg, while the experimental group replaced propofol with remimazolam tosilate 0.1 mg/kg. The intraoperative hemodynamic parameters [mean arterial pressure (MAP) and heart rate], anesthesia-related indicators [induction time, recovery time, extubation time, and post-Mini Mental State Examination (MMSE) score], postoperative delirium, and adverse events were compared between the two groups. **Results** Compared with pre-administration, MAP and heart rate in both groups decreased at 1 minute after drug administration and immediately after intubation (P<0.05), and the MAP and heart rate in the experimental group were significantly higher than those in the control group (P<0.05). The recovery time, extubation time, and PACU stay time in the experimental group were shorter than those in the control group (P<0.05). There was no statistically significant difference in VAS scores between the two groups at each time point (P>0.05). The MMSE scores of both groups at 1 day and 3 days after surgery were lower than those before surgery (P<0.05), while the score at 3 days after surgery was significantly higher than that at 1 day after surgery (P<0.05). The MMSE scores of the experimental group were higher than those of the control group on 1 day and 3 days after surgery (P<0.05). At 5 days after surgery, the incidence of postoperative delirium in the control group was significantly higher than that in the experimental group (21.82% vs 7.27%, χ^2=4.681, P=0.031). There was no statistically significant difference in the incidence of adverse events between the two groups (P>0.05). **Conclusion** Remimazolam tosilate used in the induction of general anesthesia for arthroscopic shoulder surgery in elderly patients can alleviate postoperative cognitive impairment, reduce the incidence of postoperative delirium, effectively improve recovery quality, and has good safety.

Keywords: Remimazolam tosilate; Propofol; Arthroscopic shoulder surgery; Anesthetic induction; Postoperative delirium; Cognitive function; Elderly

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Shoulder arthroscopic surgery is a minimally invasive procedure. Due to its characteristics of small trauma and rapid recovery, it has become the main treatment for clinical rotator cuff injury diseases [1]. Elderly patients, due to decreased physiological reserve and multiple comorbidities, are prone to developing complications such as postoperative cognitive dysfunction or circulatory system abnormalities during the perioperative period due to the effects of surgical trauma stress and anesthetic drugs [2]. The mainstream anesthesia methods for shoulder arthroscopic surgery are general anesthesia and/or ultrasound-guided nerve blocks [1]. Studies have shown that compared with regional anesthesia or combined anesthesia regimens, general anesthesia alone may increase the risk of postoperative delirium, especially in elderly patients [3]. Postoperative delirium usually occurs within one week after surgery, can lead to cognitive impairment, decreased physiological function, and also prolong hospital stay, seriously affecting patient prognosis [4]. Propofol and midazolam are both traditional anesthetic induction drugs for shoulder arthroscopic surgery [2,5]. Although propofol has rapid onset and quick recovery, it can exacerbate hemodynamic fluctuations in elderly patients, which may indirectly increase the risk of postoperative delirium [5]; midazolam is a commonly used benzodiazepine drug with a relatively short half-life, but it may prolong postoperative sedation time due to active metabolites or accumulation effects, and may also exacerbate neurotransmitter inhibition, increasing the incidence of postoperative delirium in elderly patients or high-risk groups [2].

Remimazolam tosylate is a novel ultrashort-acting benzodiazepine drug characterized by rapid metabolism, hemodynamic stability, and precise sedation [6]. Studies showed that remimazolam tosylate can stabilize blood pressure, reduce postoperative cognitive impairment in patients, promote rapid postoperative consciousness recovery, and reduce the occurrence of postoperative delirium [7-8]. Although previous studies have confirmed that the application of remimazolam tosylate in general

anesthesia has good sedative effects and more stable hemodynamics [6], there is still limited research evidence on its application in shoulder arthroscopic surgery in elderly patients. Therefore, this study aims to observe the application of remimazolam tosylate in elderly shoulder arthroscopic surgery and its effect on postoperative delirium.

1 Data and Methods

1.1 General Data

PASS software was used to calculate the sample size. Substituting into the sample size calculation formula and considering a dropout rate of 10% to 15%, 55 patients were needed in each group, with a total sample size of 110. A total of 110 patients undergoing shoulder arthroscopic surgery at Neijiang Traditional Chinese Medicine Hospital from May 2021 to June 2024 were prospectively enrolled. Subjects were evenly assigned to the experimental group and the control group using a random number table method, with 55 patients in each group. There were no statistically significant differences in baseline data between the two groups (P>0.05). See **Table 1**.

Inclusion criteria: (1) age ≥ 60 years; (2) scheduled for elective shoulder arthroscopic surgery; (3) American Society of Anesthesiologists (ASA) [9] physical status classification II to III; (4) patients informed and signed voluntary consent forms; (5) conscious and cognitively normal before surgery.

Exclusion criteria: (1) preoperative cognitive dysfunction, Mini Mental State Examination (MMSE) [10] score < 24; (2) severe liver or kidney dysfunction; (3) long-term use of sedatives or antipsychotics; (4) emergency surgery or combined with severe cardiopulmonary disease; (5) combined with malignant tumors, immune system diseases, or hematological diseases; (6) combined with uncontrolled diabetes or hypertension.

This study was approved by the Ethics Committee of Neijiang Traditional Chinese Medicine Hospital (Approval Number: 2021023).

Tab.1 Comparison of baseline data between the two groups of patients (n=55)

Group	Gender (Male/Female, case)	Age (years, $\bar{x}\pm s$)	BMI (kg/m^2, $\bar{x}\pm s$)	ASA grade (case)		Affected side (case)	
				II	III	Left	Right
Experimental group	38/17	70.26±4.58	24.01±2.63	43	12	20	35
Control group	32/23	69.85±4.06	24.32±2.59	37	18	29	26
χ^2/t value	1.141	0.497	0.623	1.650		2.981	
P value	0.234	0.620	0.535	0.199		0.084	

1.2 Methods

1.2.1 Anesthesia regimen for control group

Patients fasted and abstained from fluids routinely before surgery. After entering the operating room, basic vital signs were routinely monitored, oxygen was administered via face mask, and a peripheral intravenous line was established. Ultrasound-guided superior trunk of brachial plexus nerve block was performed, and 15 mL of 0.375% ropivacaine (Ruiyang Pharmaceutical, National Drug Approval Number: H20183152, 10 mL:100 mg) was injected. Dexmedetomidine (Yangtze River Pharmaceutical Group, National Drug Approval Number: H20183219, 2 mL:0.2 mg) loading dose of 0.5 μg/kg was given for sedation over 20 minutes. After successful block, general anesthesia was induced with intravenous injection of propofol (Sichuan Guorui Pharmaceutical, National Drug Approval Number: H20030114, 50 mL:0.5 g) 1.0-1.5 mg/kg, sufentanil (Yichang Humanwell Pharmaceutical, National Drug Approval Number: H20054171, 1 mL:50 μg) 0.25 μg/kg, and rocuronium bromide (Zhejiang Huahai Pharmaceutical, National Drug Approval Number: H20183264, 5 mL:50 mg) 0.6 mg/kg. After induction, tracheal intubation was performed and connected to an anesthesia machine for mechanical ventilation. Parameter settings: tidal volume 6-8 mL/kg, respiratory rate 12 breaths/min, maintaining end-tidal carbon dioxide partial pressure ($P_{ET}CO_2$) at 35-45 mmHg. During surgery, sevoflurane 0.5-1.0 minimum alveolar concentration (MAC) was inhaled, and propofol 2 mg/(kg·h), remifentanil (Yichang Humanwell Pharmaceutical, National Drug Approval Number: H20030197, 1 mg) 0.1 μg/(kg·min), and dexmedetomidine 0.2 μg/(kg·h) were infused intravenously. The bispectral index (BIS) was controlled between 40 and 60. Muscle relaxants were administered intermittently or continuously as needed to maintain monitoring values within the ideal range. Postoperatively, a patient-controlled intravenous analgesia (PCIA) pump was used for analgesia, with sufentanil 0.5 μg/kg + butorphanol (Fu'an Pharmaceutical Group Qingyutang Pharmaceutical, National Drug Approval Number: H20233095, 1 mL:2 mg) 0.05 mg/kg + flurbiprofen axetil (Shanghai Zhongxi Sunve Pharmaceutical, National Drug Approval Number: H20153041, 50 mg) 50 mg. The analgesia pump was based on sufentanil, with a continuous infusion rate set at 0.02 μg/(kg·h), and a single self-controlled dose of 0.02 μg/kg with a lockout interval of 30 minutes. Postoperatively, when the patient's Visual Analogue Scale (VAS) [12] score was >4 after pressing the PCIA pump twice, sufentanil 0.015 μg/kg was given intravenously as a bolus. Postoperative intravenous injection of ondansetron (Fu'an Pharmaceutical Group Ningbo Tianheng Pharmaceutical, National Drug Approval Number: H10960148, 4 mL:8 mg) 4 mg or dexamethasone 5 mg was given for prophylactic antiemesis.

1.2.2 Anesthesia regimen for experimental group

Propofol in the anesthetic induction drugs was replaced with remimazolam tosylate (Yichang Humanwell Pharmaceutical, National Drug Approval Number: H20200006, 25 mg) 0.1 mg/kg, and anesthesia maintenance remained unchanged. The remaining anesthetic drugs and dosages were the same as those in the control group.

1.3 Observation Indicators

(1) Hemodynamic stability: Intraoperatively, hemodynamic changes of patients were closely monitored. Mean arterial pressure (MAP) and heart rate were recorded before administration of propofol or remimazolam tosylate, 1 minute after administration, and immediately after intubation.

(2) Anesthesia-related indicators: Induction time (time to loss of consciousness), awakening time (time from drug discontinuation to eye opening), extubation time, and duration of stay in the post-anesthesia care unit (PACU) were recorded.

(3) Pain level: Patient pain levels were assessed using VAS scores at 2, 4, 8, and 24 hours postoperatively.

(4) Cognitive impairment and occurrence of postoperative delirium: MMSE was used as a tool to assess cognitive impairment before surgery, at 1 day postoperatively, and at 3 days postoperatively. The occurrence of postoperative delirium each day within 5 days postoperatively was recorded, with screening twice daily. The Confusion Assessment Method (CAM) [11] evaluation criteria are as follows: ① acute onset and fluctuating course; ② inattention; ③ disorganized thinking; ④ altered level of consciousness. If a patient meets criteria ① and ②, and also meets one of ③ or ④, a diagnosis of postoperative delirium is made.

(5) Occurrence of adverse events: The occurrence of adverse events such as intraoperative hypotension, headache and dizziness, respiratory depression, nausea, and vomiting was recorded.

1.4 Statistical Methods

SPSS 24.0 was used for data analysis. Measurement data conforming to normal distribution were described as $\bar{x}\pm s$, and intergroup comparisons were performed using independent sample *t*-test. Measurement data at multiple time points were analyzed using repeated measures analysis of variance, and pairwise comparisons were performed using the LSD-*t* test. Count data were described as case (%), and the chi-square test was used. $P<0.05$ was considered statistically significant.

2 Results

2.1 Comparison of Hemodynamic Stability Between Two Groups

The between-time and between-group effects, as well as the interaction effects, were statistically significant in both groups ($P<0.05$). At 1-minute post-administration and immediately after intubation, both groups showed lower MAP and heart rate compared to pre-administration ($P<0.05$), with the test group exhibiting higher MAP and heart rate than the control group ($P<0.05$). See **Table 2.**

2.2 Comparison of Anesthesia-Related Indicators Between Two Groups

Compared with control group, experimental group had a lower awaking time, extubation time and PACU staying time ($P<0.05$). See **Table 3.**

2.3 Comparison of Pain Level Between Two Groups

There were time effect and interaction effect between the two groups of VAS scores ($P<0.05$). At 4, 8, and 24 hours postoperatively, the VAS scores of both groups increased compared to 2 hours postoperatively ($P<0.05$), but there was no statistically significant difference in VAS scores between the two groups at each time point ($P>0.05$). See **Table 4.**

Tab.2 Comparison of hemodynamic stability between two groups (n=55,$\bar{x}\pm s$)

Group	MAP(mmHg)			Heart rate (beats/min)		
	Pre-administration	1-minute post-administration	Immediately after intubation	Pre-administration	1-minute post-administration	Immediately after intubation
Control Group	87.61±4.30	83.17±4.93[a]	81.44±4.02[a]	77.47±3.36	74.35±4.22[a]	72.77±3.52[a]
Experimental Group	88.28±4.00	85.55±5.56[ab]	83.52±4.75[ab]	77.99±4.11	76.48±3.40[ab]	75.00±3.64[ab]
$F_{time}/F_{between\text{-}group}/F_{interaction}$ **value**	23.069/30.257/25.246			19.862/29.604/35.115		
$P_{time}/P_{between\text{-}group}/P_{interaction}$ **value**	0.007/<0.001/0.004			0.013/<0.001/<0.001		

Note: Compared with same group at pre-administration, [a]$P<0.05$; Compared with Control group at the same time-point, [b]$P<0.05$.

Tab.3 Comparison of anesthesia-related indicators between two groups (n=55,$\bar{x}\pm s$)

Group	Induction time (s)	Awaking time (min)	extubation time (min)	PACU stay (h)
Control Group	90.29±38.15	18.70±4.55	20.84±4.47	2.10±0.38
Experimental Group	99.03±33.82	16.12±3.99	18.41±4.83	1.86±0.52
***t* value**	1.271	3.162	2.738	2.764
***P* value**	0.206	0.002	0.007	0.007

Tab.4 Comparison of VAS Scores between two groups (n=55, point, $\bar{x}\pm s$)

Group	2-hours	4-hours	8-hours	24-hours
Control Group	1.40±0.64	1.65±0.61[a]	2.52±1.04[a]	3.33±1.13[a]
Experimental Group	1.38±0.59	1.75±0.92[a]	2.48±1.01[a]	3.09±1.20[a]
$F_{time}/F_{between\text{-}group}/F_{interaction}$ **value**	31.138/3.269/27.234			
$P_{time}/P_{between\text{-}group}/P_{interaction}$ **value**	<0.001/0.435/0.001			

Note: Compared with 2-hours after surgery in the same group, [a]$P<0.05$.

2.4 Comparison of Cognitive Impairment and Postoperative Delirium Between Two Groups

The time, between-roup, and interaction effects of the MMSE scores between the two groups were statistically significant (P<0.05). Compared with preoperative levels, MMSE scores decreased at 1 day and 3 days postoperatively in both groups. However, compared with 1 day postoperatively, the scores at 3 days postoperatively were significantly higher (P<0.05). See **Table 5**. Postoperative delirium mainly occurred within the first 3 days after surgery. Within 5 days postoperatively, 12 cases of postoperative delirium occurred in the control group, compared with 4 cases in the experimental group. The difference in the incidence of postoperative delirium between the control group and the experimental group was statistically significant (21.82% *vs* 7.27%, χ^2=4.681, P=0.031).

2.5 Comparison of Adverse Events between Two Groups of patients

There was no statistically significant difference in the incidence of adverse events between the two groups (P>0.05). See **Table 6**.

Tab.5 Comparison of MMSE Scores between two groups (n=55, point,$\bar{x}$±s)

Group	Before surgery	1 day after surgery	3 days after surgery
Control Group	27.13±2.39	23.71±2.02[a]	25.35±2.14[ab]
Experimental Group	27.85±2.17	25.00±2.23[ac]	26.50±1.85[abc]
$F_{time}/F_{between-group}/F_{interaction}$ **value**	30.572/42.508/34.129		
$P_{time}/P_{between-group}/P_{interaction}$ **value**	<0.001/<0.001/<0.001		

Note: Compared with before surgery, [a]P<0.05; Compared with 1 day after surgery, [b]P<0.05; Compared with control group at the same time-point, [c]P<0.05.

Tab.6 Comparison of adverse events between two groups [case(%)]

Group	Intraoperative hypotension	Headache and dizziness	Nausea and vomiting	Respiratory depression
Control Group	5(9.09)	11(20.00)	9(16.36)	1(1.82)
Experimental Group	1(1.82)	5(9.09)	3(5.45)	1(1.82)
χ^2 **value**	1.587	2.633	3.367	0.509
P **value**	0.208	0.105	0.067	0.475

3 Discussion

Shoulder arthroscopic surgery compensates for the shortcomings of traditional open surgery. It has small incisions, low risk of infection, mild postoperative pain, and less systemic stress response, which is particularly advantageous for elderly patients with poor tolerance [1]. The beach chair position is commonly used in shoulder arthroscopic surgery, but patients have difficulty tolerating this position for long periods. General anesthesia can ensure surgical safety and patient comfort [3]. However, general anesthesia requires large doses and prolonged anesthesia time, and some patients may develop postoperative delirium due to advanced age or poor physical condition [13]. Studies have shown that the incidence of postoperative delirium after general anesthesia ranges from 15.6% to 53%, with higher risk in elderly and critically ill patients [14-15]. Therefore, there is an urgent clinical need to explore new anesthetic drugs. Recent studies have shown that remimazolam, as a novel ultrashort-acting gamma-aminobutyric acid subtype A ($GABA_A$) receptor agonist, not only exhibits better hemodynamic stability during general anesthesia induction [16] but some studies have also observed that it can reduce the incidence of postoperative delirium. Additionally, the metabolism of this drug is not significantly affected by liver function [6], providing a new option for optimizing anesthesia regimens.

Remimazolam causes less circulatory depression. It selectively binds to the α1 subunit (associated with sedation) of the $GABA_A$ receptor and does not directly act on cardiovascular receptors (such as α2-adrenergic receptors or calcium channels), thus having minimal impact on myocardial contractility and peripheral vascular resistance, with good hemodynamic stability [16]. A study by Zhang *et al.* [17] also showed that compared with propofol, remimazolam has less impact on hemodynamics, with milder fluctuations in MAP and heart rate, reducing brain injury caused by circulatory instability. The results of this study show that compared with before administration, MAP and heart rate decreased in both groups at 1 minute after administration and immediately after intubation, but remained at safe levels, indicating that remimazolam can maintain hemodynamic stability, consistent with the findings of Zhang *et al.* [17]. Furthermore, the results of this study show that compared with propofol, remimazolam also has good anesthetic effects, but remimazolam exhibited earlier awakening and extubation, and shorter PACU stay. Its mechanism of action may stem from the unique esterase metabolism pathway and low circulatory depressant effect of remimazolam [6]. Propofol relies on hepatic metabolism and renal clearance, and when metabolic capacity declines in elderly patients, it can easily lead to drug accumulation. Remimazolam tosylate is metabolized by hydrolysis via tissue esterases, does not depend on liver or kidney function, and its metabolites are inactive, so its metabolic rate is stable and it is not prone to accumulation, making it particularly suitable for elderly patients with decreased liver and kidney function, reducing the occurrence of delayed awakening [18].

This study further explored the potential mechanism of remimazolam on postoperative delirium. The results showed that MMSE scores at 1 day and 3 days postoperatively decreased compared with preoperative scores in both groups, but scores at 3 days postoperatively improved compared with 1 day postoperatively, and scores in the experimental group were consistently better than those in the control group. Within 5 days postoperatively, the incidence of postoperative delirium in the experimental group was lower than that in the control group, suggesting that remimazolam can reduce the occurrence of

postoperative delirium. This may be related to the rapid metabolism of remimazolam, low accumulation in the body, and hemodynamic stability. The specific mechanisms of action are: (1) Remimazolam is hydrolyzed by tissue esterases into an inactive metabolite (CNS7054); prolonged or higher doses do not lead to accumulation or prolonged drug effect, avoiding drug accumulation and reducing the risk of long-term postoperative cognitive function inhibition [19-20]; (2) Elderly patients are sensitive to blood pressure fluctuations. The mild hemodynamic depressant property of remimazolam can avoid intraoperative hypotension or cerebral hypoperfusion, reducing cognitive impairment related to cerebral ischemia [6,15]. Therefore, remimazolam, by virtue of its multiple mechanisms including unique rapid metabolic properties, stable hemodynamic maintenance, mild respiratory depressant effects, and significant anti-inflammatory effects, can effectively reduce the risk of adverse events. A randomized controlled trial showed that elderly patients with mild hypertension undergoing lower limb orthopedic surgery who received remimazolam combined with sufentanil for general anesthesia induction exhibited stable hemodynamics and a low incidence of adverse events such as hypotension, bradycardia, hiccups, nausea, and vomiting [21]. A study by Deng et al. [22] also showed that surgical patients receiving remimazolam intervention had a significantly lower rate of adverse reactions. In this study, there was no statistically significant difference in the overall incidence of adverse events between the two groups, further confirming the good safety of remimazolam in clinical application.

In summary, the application of remimazolam in anesthesia induction for elderly arthroscopic surgery reduces the occurrence of postoperative delirium, reduces postoperative cognitive impairment, maintains hemodynamic stability, improves postoperative awakening quality, and does not increase the occurrence of adverse events. This study has certain limitations. Long-term follow-up was not conducted, so the long-term cognitive protective effect cannot be determined. Subsequent long-term follow-up studies will be added.

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老年肩关节镜手术全身麻醉诱导中的应用

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摘要：目的　探讨甲苯磺酸瑞马唑仑在老年患者肩关节镜手术全身麻醉诱导中的应用效果，及对认知功能损伤和术后谵妄的影响。**方法**　前瞻性纳入内江市中医医院2021年5月至2024年6月接受肩关节镜手术的110例患者，采用随机数字表法分为试验组与对照组各55例。两组患者均接受常规全身麻醉+超声引导神经阻滞。其中对照组使用丙泊酚1.0~1.5 mg/kg、舒芬太尼0.25 μg/kg、罗库溴铵0.6 mg/kg进行麻醉诱导，试验组以甲苯磺酸瑞马唑仑0.1 mg/kg替换丙泊酚。比较两组术中血流动力学参数[平均动脉压(MAP)和心率]、麻醉相关指标[诱导时间、苏醒时间、拔管时间及麻醉恢复室(PACU)停留时间]、疼痛程度[视觉模拟评分表(VAS)评分]、认知功能损伤[简易精神状态检查量表(MMSE)评分]、术后谵妄及不良事件发生情况。**结果**　给药后1 min和插管后即刻两组MAP和心率均较给药前降低(P<0.05)，且试验组的MAP和心率均高于对照组(P<0.05)。试验组苏醒时间、拔管时间及PACU停留时间短于对照组(P<0.05)。两组各时间点VAS评分比较，差异无统计学意义(P>0.05)。两组术后1 d与术后3 d的MMSE评分较术前均降低(P<0.05)，而术后3 d的评分高于术后1 d(P<0.05)。术后1 d和3 d试验组的MMSE评分均高于对照组(P<0.05)。术后5 d，对照组术后谵妄发生率高于试验组，差异有统计学意义(21.82% *vs* 7.27%，χ^2=4.681，P=0.031)。两组各不良事件发生率比较差异无统计学意义(P>0.05)。**结论**　甲苯磺酸瑞马唑仑用于老年患者肩关节镜手术全身麻醉诱导中可减轻术后认知功能损伤，减少术后谵妄的发生，有效提高苏醒质量，安全性好。

关键词：甲苯磺酸瑞马唑仑；丙泊酚；肩关节镜手术；麻醉诱导；术后谵妄；认知功能；老年

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Remimazolam tosilate in the general anesthesia induction for elderly patients undergoing arthroscopic shoulder surgery

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Abstract: Objective　To explore the application effect of remimazolam tosilate in the induction of general anesthesia for arthroscopic shoulder surgery in elderly patients, and its influence on cognitive impairment and postoperative delirium. **Methods**　A total of 110 elderly patients who underwent arthroscopic shoulder surgery at Neijiang Hospital of Traditional Chinese Medicine from May 2021 to June 2024 were prospectively enrolled. They were divided into the experimental group and the control group with 55 cases each using a random number table method. Both groups received conventional general anesthesia combined with ultrasound-guided nerve block. In the control group, anesthesia induction was performed using propofol 1.0-1.5 mg/kg, sufentanil 0.25 μg/kg, and rocuronium 0.6 mg/kg, while the experimental group replaced propofol with remimazolam tosilate 0.1 mg/kg. The intraoperative hemodynamic parameters [mean arterial pressure (MAP) and heart rate], anesthesia-related indicators [induction time, recovery time, extubation time, and post-

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anesthesia care unit (PACU) stay time], pain intensity [Visual Analog Scale (VAS) score], cognitive impairment [Mini Mental State Examination (MMSE) score], postoperative delirium, and adverse events were compared between the two groups. **Results** Compared with pre-administration, MAP and heart rate in both groups decreased at 1 minute after drug administration and immediately after intubation (P<0.05), and the MAP and heart rate in the experimental group were significantly higher than those in the control group (P<0.05). The recovery time, extubation time, and PACU stay time in the experimental group were shorter than those in the control group (P<0.05). There was no statistically significant difference in VAS scores between the two groups at each time point (P>0.05). The MMSE scores of both groups at 1 day and 3 days after surgery were lower than those before surgery (P<0.05), while the score at 3 days after surgery was significantly higher than that at 1 day after surgery (P<0.05). The MMSE scores of the experimental group were higher than those of the control group on 1 day and 3 days after surgery (P<0.05). At 5 days after surgery, the incidence of postoperative delirium in the control group was significantly higher than that in the experimental group (21.82% *vs* 7.27%, χ^2=4.681, P=0.031). There was no statistically significant difference in the incidence of adverse events between the two groups (P>0.05). **Conclusion** Remimazolam tosilate used in the induction of general anesthesia for arthroscopic shoulder surgery in elderly patients can alleviate postoperative cognitive impairment, reduce the incidence of postoperative delirium, effectively improve recovery quality, and has good safety.

Keywords: Remimazolam tosilate; Propofol; Arthroscopic shoulder surgery; Anesthetic induction; Postoperative delirium; Cognitive function; Elderly

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肩关节镜手术属于微创手术，因其创伤小、恢复快的特点，已成为当下临床肩袖损伤疾病的主要治疗手段[1]。老年患者因生理储备下降、合并症多等特点，在围手术期容易因手术创伤应激和麻醉药物作用的影响，诱发术后认知功能障碍或循环系统异常等并发症[2]。肩关节镜手术主流麻醉方式为全身麻醉和(或)超声引导下神经阻滞[1]。现有研究表明，相较于区域麻醉或联合麻醉方案，单纯全身麻醉可能会增加术后谵妄的发生风险，尤其是在老年患者中[3]。术后谵妄通常发生于术后1周之内，可导致认知功能受损、生理机能下降，还会延长住院时间，严重影响患者预后[4]。丙泊酚和咪达唑仑均是肩关节镜手术传统麻醉诱导药物[2,5]。前者虽然起效快、苏醒迅速，但其会加剧老年患者血流动力学波动，可间接增加术后谵妄风险[5]；后者为临床常用苯二氮䓬类药物，半衰期较短，但可能因活性代谢产物或蓄积作用延长术后镇静时间，还可能加剧神经递质抑制，增加老年患者或高危人群的术后谵妄发生率[2]。

甲苯磺酸瑞马唑仑是一种新型的超短效苯二氮䓬类药物，具有代谢快速、血流动力学稳定、精准镇静的特点[6]。研究结果显示，甲苯磺酸瑞马唑仑可稳定血压，减轻患者术后认知功能损伤，促进术后意识快速恢复，减少术后谵妄的发生[7-8]。尽管既往研究已证实，全身麻醉中应用甲苯磺酸瑞马唑仑镇静效果良好，血流动力学更稳定[6]，但其在老年患者肩关节镜手术应用的研究证据尚少。因此，本研究旨在观察甲苯磺酸瑞马唑仑在老年肩关节镜手术的应用，及对术后谵妄的影响。

1　资料与方法

1.1　一般资料　采用PASS软件计算样本量，代入样本量计算公式考虑到10%~15%的脱落率，每组应纳入55例，总样本量为110例。前瞻性纳入2021年5月至2024年6月在内江市中医医院进行肩关节镜手术的患者110例，通过随机数字表法将受试者均衡分配至试验组和对照组，各组纳入55例患者。两组基线资料差异无统计学意义(P>0.05)。见表1。

表1　两组患者基线资料比较　(n=55)

Tab.1　Comparison of baseline data between the two groups (n=55)

组别	性别(男/女，例)	年龄(岁，$\bar{x}\pm s$)	身体质量指数(kg/m^2，$\bar{x}\pm s$)	ASA分级(例)		患侧(例)	
				Ⅱ级	Ⅲ级	左肩	右肩
试验组	38/17	70.26±4.58	24.01±2.63	43	12	20	35
对照组	32/23	69.85±4.06	24.32±2.59	37	18	29	26
χ^2/t值	1.141	0.497	0.623	1.650		2.981	
P值	0.234	0.620	0.535	0.199		0.084	

纳入标准：(1) 年龄≥60岁；(2) 拟行择期肩关节镜手术；(3) 美国麻醉医师协会(American Society of Anesthesiologists，ASA)[9]分级Ⅱ~Ⅲ级；(4) 患者知情，且签署自愿同意书；(5) 术前意识清醒、认知正常。排除标准：(1) 术前存在认知功能障碍，简易精神状态检查量表(Mini Mental State Examination，MMSE)[10]评分<24分；(2) 严重肝肾功能不全；(3) 长期使用镇静药或抗精神病药；(4) 急诊手术或合并严重心肺疾

病。(5) 合并恶性肿瘤、免疫系统疾病或血液系统疾病;(6) 合并难以控制的糖尿病、高血压。本研究已通过内江市中医医院伦理委员会审批(批号:2021023)。

1.2 方法

1.2.1 对照组麻醉方案 患者术前常规禁食禁饮,入室后常规监测基本生命体征,面罩吸氧,开放外周静脉通路。在超声引导下行臂丛上干神经阻滞,并注射0.375%罗哌卡因(瑞阳制药,国药准字H20183152,10 mL∶100 mg)15 mL,右美托咪定(扬子江药业,国药准字H20183219,2 mL∶0.2 mg)负荷剂量0.5 μg/kg镇静,输注时间为20 min。阻滞成功后进行全身麻醉,麻醉诱导采用静脉注射丙泊酚(四川国瑞药业,国药准字H20030114,50 mL∶0.5 g)1.0~1.5 mg/kg,舒芬太尼(宜昌人福药业,国药准字H20054171,1 mL∶50 μg)0.25 μg/kg,罗库溴铵(浙江华海药业,国药准字H20183264,5 mL∶50 mg)0.6 mg/kg。诱导完成后,气管插管接麻醉机行机械通气,参数设置:潮气量6~8 mL/kg,呼吸频次12次/min,维持呼气末二氧化碳分压(partial pressure of end-tidal carbon dioxide, $P_{ET}CO_2$) 35~45 mmHg。术中维持七氟烷0.5~1.0最低肺泡有效浓度(minimum alveolar concentration, MAC)吸入,静脉输注丙泊酚2 mg/(kg·h)、瑞芬太尼(宜昌人福药业,国药准字H20030197,1 mg)0.1μg/(kg·min)及右美托咪定0.2 μg/(kg·h)。脑电双频指数(bispectral index, BIS)控制在40~60;肌肉松弛药按需间断或持续给药,维持监测值在理想范围。术后采用患者自控静脉镇痛(patient controlled intravenous analgesia, PCIA)泵进行镇痛,舒芬太尼0.5 μg/kg+布托啡诺(福安药业集团庆余堂制药,国药准字H20233095,1 mL∶2 mg)0.05 mg/kg+氟比洛芬酯(上海中西三维药业,国药准字H20153041,50 mg)50 mg。PCIA泵以舒芬太尼为基础,设置持续输注速率为0.02 μg/(kg·h),并配置单次自控剂量0.02 μg/kg,锁定间隔30 min。术后患者按压PCIA泵2次后视觉模拟评分表(Visual Analogue Scale, VAS)[12]评分>4分时,给予舒芬太尼0.015 μg/kg静脉推注。术后静脉注射昂丹司琼(福安药业集团宁波天衡制药,国药准字H10960148,4 mL∶8 mg)4 mg或地塞米松5 mg,预防性止吐。

1.2.2 试验组麻醉方案 将麻醉诱导药物中的丙泊酚换为0.1 mg/kg甲苯磺酸瑞马唑仑(宜昌人福药业,国药准字H20200006,25 mg),麻醉维持不变,其余麻醉药物和剂量同对照组一致。

1.3 观察指标 (1) 血流动力学稳定性:术中密切监测患者血流动力学变化,记录丙泊酚或甲苯磺酸瑞马唑仑给药前、给药后1 min、插管后即刻的平均动脉压(mean arterial pressure, MAP)、心率。(2) 麻醉相关指标:记录诱导时间(意识消失时间)、苏醒时间(从停药到睁眼时间)、拔管时间、麻醉恢复室(postanesthesia care unit, PACU)停留时间。(3) 疼痛程度:分别于术后2、4、8、24 h以VAS评分评估患者疼痛程度。(4) 认知功能损伤及术后谵妄发生情况:以MMSE为工具评估患者术前、术后1 d及术后3 d认知功能损伤情况。记录术后5 d中每日术后谵妄的发生情况,每日筛查2次。谵妄评定法(Confusion Assessment Method, CAM)[11]评价标准如下。①急性起病,病情波动;②注意力不集中;③思维无序;④意识水平改变。若患者具备①和②,且符合③和④之一,即诊断为术后谵妄。(5) 不良事件发生情况:记录术中低血压、头痛头晕、呼吸抑制、恶心呕吐等不良事件的发生情况。

1.4 统计学方法 采用SPSS 24.0软件分析数据。符合正态分布的计量资料均以$\bar{x}\pm s$描述,组间比较采用独立样本t检验;多时点的计量资料采用重复测量方差分析,两两比较采用LSD-t检验。计数资料以例(%)描述,采用χ^2检验和校正χ^2检验。P<0.05为差异有统计学意义。

2 结 果

2.1 两组患者血流动力学稳定性比较 两组时间、组间、交互效应均有统计学意义(P<0.05)。给药后1 min和插管后即刻两组MAP和心率均较给药前降低(P<0.05),且试验组的MAP和心率均高于对照组(P<0.05)。见表2。

2.2 两组患者麻醉相关指标比较 与对照组相比,试验组苏醒时间、拔管时间及PACU停留时间较短(P<0.05)。见表3。

2.3 两组患者疼痛程度 两组VAS评分之间存在时间、交互效应(P<0.05)。术后4、8、24 h,两组VAS评分较术后2 h升高(P<0.05),各时间点两组间的VAS评分比较,差异无统计学意义(P>0.05)。见表4。

2.4 两组患者认知功能损伤及术后谵妄发生情况比较 两组MMSE评分时间、组间、交互效应有统计学意义(P<0.05)。两组术后1 d与术后3 d的MMSE评分较术前降低,与术后1 d相比,术后3 d的评分显著升高(P<0.05)。见表5。术后谵妄主要发生于术后3 d内。术后5 d对照组发生术后谵妄12例,试验组4

例，对照组和试验组术后谵妄发生率比较差异有统计学意义（21.82% *vs* 7.27%，χ^2=4.681，*P*=0.031）。

2.5　两组患者不良事件发生情况比较　两组间各不良事件发生率的差异均无统计学意义（*P*>0.05）。见表6。

表2　两组患者血流动力学稳定性比较　（*n*=55，$\bar{x}\pm s$）

Tab.2　Comparison of hemodynamic stability between two groups　（*n*=55，$\bar{x}\pm s$）

组别	MAP（mmHg）			心率（次/min）		
	给药前	给药后 1 min	插管后即刻	给药前	给药后 1 min	插管后即刻
对照组	87.61±4.30	83.17±4.93[a]	81.44±4.02[a]	77.47±3.36	74.35±4.22[a]	72.77±3.52[a]
试验组	88.28±4.00	85.55±5.56[ab]	83.52±4.75[ab]	77.99±4.11	76.48±3.40[ab]	75.00±3.64[ab]
$F_{时间}/F_{组间}/F_{交互}$值	23.069/30.257/25.246			19.862/29.604/35.115		
$P_{时间}/P_{组间}/P_{交互}$值	0.007/<0.001/0.004			0.013/<0.001/<0.001		

注：与同组给药前相比，[a]*P*<0.05；与对照组同时点比较，[b]*P*<0.05。

表3　两组患者麻醉相关指标比较　（*n*=55，$\bar{x}\pm s$）

Tab.3　Comparison of anesthesia-related indicators between two groups　（*n*=55，$\bar{x}\pm s$）

组别	诱导时间（s）	苏醒时间（min）	拔管时间（min）	PACU 停留时间（h）
对照组	90.29±38.15	18.70±4.55	20.84±4.47	2.10±0.38
试验组	99.03±33.82	16.12±3.99	18.41±4.83	1.86±0.52
t 值	1.271	3.162	2.738	2.764
P 值	0.206	0.002	0.007	0.007

表4　两组患者 VAS 评分比较　（*n*=55，分，$\bar{x}\pm s$）

Tab.4　Comparison of VAS scores between two groups　（*n*=55，point，$\bar{x}\pm s$）

组别	术后 2 h	术后 4 h	术后 8 h	术后 24 h
对照组	1.40±0.64	1.65±0.61[a]	2.52±1.04[a]	3.33±1.13[a]
试验组	1.38±0.59	1.75±0.92[a]	2.48±1.01[a]	3.09±1.20[a]
$F_{时间}/F_{组间}/F_{交互}$值	31.138/3.269/27.234			
$P_{时间}/P_{组间}/P_{交互}$值	<0.001/0.435/0.001			

注：与本组术后 2 h 相比，[a]*P*<0.05。

表5　两组患者 MMSE 评分比较　（*n*=55，分，$\bar{x}\pm s$）

Tab.5　Comparison of MMSE scores between two groups　（*n*=55，point，$\bar{x}\pm s$）

组别	术前	术后 1 d	术后 3 d
对照组	27.13±2.39	23.71±2.02[a]	25.35±2.14[ab]
试验组	27.85±2.17	25.00±2.23[ac]	26.50±1.85[abc]
$F_{时间}/F_{组间}/F_{交互}$值	30.572/42.508/34.129		
$P_{时间}/P_{组间}/P_{交互}$值	<0.001/<0.001/<0.001		

注：与术前相比，[a]*P*<0.05；与术后 1 d 相比，[b]*P*<0.05；与对照组同时点比较，[c]*P*<0.05。

表6　两组患者不良事件发生情况比较　［*n*=55，例（%）］

Tab.6　Comparison of incidence of adverse events between two groups　［*n*=55，case（%）］

组别	术中低血压	头痛头晕	恶心呕吐	呼吸抑制
对照组	5（9.09）	11（20.00）	9（16.36）	1（1.82）
试验组	1（1.82）	5（9.09）	3（5.45）	1（1.82）
χ^2值	1.587	2.633	3.367	0.509
P 值	0.208	0.105	0.067	0.475

3　讨　论

肩关节镜手术弥补了传统开放手术的不足，其伤口小，感染风险低，术后疼痛轻，对全身应激反应更小，尤其是对耐受能力差的老年患者优势明显[1]。肩关节镜手术常用沙滩椅体位，长时间保持该体位患者难以耐受，而全身麻醉状态可保障手术安全性与患者舒适性[3]。但全身麻醉用量大、麻醉时间较长，部分患者因高龄、机体基础差可能诱发术后谵妄[13]。有研究显示，全身麻醉术后谵妄的发生率在15.6%~53%，在老年及危重患者中发生风险更高[14-15]。因此，临床亟需探索新型麻醉药物，近年研究表明，甲苯磺酸瑞马唑仑作为新型超短效γ-氨基丁酸 A 型（gamma-aminobutyric acid subtype A，$GABA_A$）受体激动剂，不仅在全身麻醉诱导阶段表现出更优的血流动力学稳定性[16]，部分研究还观察到其还能降低术后谵妄发生率，同时该药代谢受肝功能影响不显[6]，为优化麻醉方案提供了新选择。

甲苯磺酸瑞马唑仑对循环抑制更轻，其通过选择性结合 $GABA_A$ 受体的α1 亚基（与镇静相关），不直接作用于心血管受体（如α2-肾上腺素受体或钙通道），因此对心肌收缩力、外周血管阻力影响极小，血流动力学稳定性好[16]。Zhang 等[17]研究也表明，与丙泊酚相比，瑞马唑仑对血流动力学影响更小，MAP 和心率波动更轻微，减少因循环不稳定引发的脑损伤。本研究结果显示，与给药前相比，给药后 1 min 和插管后即刻两组 MAP 和心率降低，并维持在安全水平，说明甲苯磺酸瑞马唑仑可维持血流动力学稳定，与 Zhang 等[17]研究结果一致。此外，本研究结果表明与丙泊酚相比，甲苯磺酸瑞马唑仑也具有良好的麻醉效果，但甲苯磺酸瑞马唑仑表现出更早的苏醒和拔管、更短的 PACU 停留时间，其作用机制可能来源于甲苯磺酸瑞马唑仑独特的酯酶代谢途径和低循环抑制效应[6]。丙泊酚依赖肝代谢和肾脏清除，老年患者代谢能力下降时易导致药物蓄积，而甲苯磺酸瑞马唑仑通过组织酯酶水解代谢，不依赖肝肾功能，代谢产物无活性，因此代谢速度稳定且不易蓄积，尤其适合肝肾功能减退的老年患者，可减少苏醒延迟的发生[18]。

本研究进一步探讨甲苯磺酸瑞马唑仑对术后谵妄的潜在作用机制，结果显示，两组术后 1 d 和 3 d 的 MMSE 评分较术前下降，但术后 3 d 较 1 d 有所改善，且试验组评分始终优于对照组。术后 5 d，试验组术后谵妄发生率低于对照组，提示甲苯磺酸瑞马唑仑可减术后谵妄的发生，这可能与苯磺酸瑞马唑仓快速代谢，体内蓄积少及血流动力学稳定有关。具体作用机制为：(1) 甲苯磺酸瑞马唑仑通过组织酯酶水解为无活性代谢物(CNS7054)，长时间或更高剂量不会导致蓄积和药效延长，避免了药物蓄积，降低术后长时间抑制认知功能的风险[19-20]；(2) 老年患者对血压波动敏感，甲苯磺酸瑞马唑仑的轻微血流动力学抑制特性可避免术中低血压或脑灌注不足，减少脑缺血相关认知损伤[6,15]。因此，甲苯磺酸瑞马唑仑凭借其独特的快速代谢特性、稳定的血流动力学维持作用、轻微的呼吸抑制效应以及显著的抗炎作用等多重机制，可有效降低不良事件的发生风险。一项随机对照试验显示，下肢骨科手术的老年轻度高血压患者采用甲苯磺酸瑞马唑仑联合舒芬太尼进行全身麻醉诱导，表现出稳定的血流动力学，且低血压、心动过缓、呃逆、恶心呕吐等不良事件的发生率低[21]。Deng 等[22]研究也显示，接受甲苯磺酸瑞马唑仑干预的手术患者，不良反应率显著较低。本研究中，两组患者不良事件总体发生率差异无统计学意义，进一步证实了甲苯磺酸瑞马唑仑在临床应用中的良好安全性。

综上所述，老年关节镜手术麻醉诱导中应用甲苯磺酸瑞马唑仑减少术后谵妄的发生，减轻术后认知功能损伤，维持血流动力学稳定，提高术后苏醒质量，且不增加不良事件的发生。本研究存在一定的局限性，未进行远期随访，无法判断长期认知保护效应，后续将增加远期随访研究。

利益冲突　无

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