Submitted: 15 November, 2023 Accepted: 05 January, 2024 Published: 15 April, 2024 DOI:10.22514/ejgo.2024.035

ORIGINAL RESEARCH

European Journal of Gynaecological Oncology

Clinical comparative study of remimazolam tosilate and propofol on anesthesia effect in patients undergoing radical mastectomy

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Abstract

This study aims to compare the anesthetic effects of remimazolam tosilate and propofol in patients undergoing radical mastectomy. The study group received remimazolam tosilate in combination with sufentanil and cisatracurium besilate for anesthesia induction, while the control group received propofol with sufentanil and cisatracurium besilate. In the study group, the eyelash reflex disappearance time was longer and the recovery time was shorter compared to the control group ($p < 0.05$). No significant differences were observed in Post-Anesthesia Care Unit (PACU) retention time and Visual Analogue Scale (VAS) scores at 24 hours post-operation between the groups ($p > 0.05$). Furthermore, the study group exhibited a lower decrease in Mean Arterial Pressure (MAP) at 1, 3 and 5 minutes after anesthesia induction ($p < 0.05$). After losing consciousness, there was no statistically significant difference in HR decrease between both groups ($p > 0.05$). The study group also had higher respiratory rate (RR) and Tidal volume (VT) levels, with a lower incidence of apnea compared to the control group ($p < 0.05$). Thirty minutes before anesthesia, no significant differences were found in the five indicators between the groups ($p > 0.05$). At 24 hours post-operation, the study group showed higher Cluster of Differentiation 3^+ ($CD3^+$), $CD4^+$, natural killer (NK) cell levels and $CD4^+/CD8^+$ ratios compared to the control group ($p < 0.05$). However, at 72 hours post-operation, no statistically significant differences were observed in these five indicators between the groups ($p > 0.05$). Compared with propofol, remimazolam tosilate achieves rapid sedation, maintains adequate sedation, and reduces suppression of the respiratory and circulatory systems.

Keywords

Remimazolam tosilate; Propofol; Radical mastectomy; Anesthetic effect

1. Introduction

In recent years, there has been a consistent year-on-year increase in the incidence of breast cancer, which is now the most prevalent among female malignancies, with a notable trend towards younger patients and significantly impacting the physical and mental well-being of affected individuals [1]. Currently, its primary treatment approach is surgical intervention; however, both anesthesia and surgery can adversely affect the immune function of patients, subsequently influencing the postoperative recovery process and the quality of life of patients to varying extents.

Hence, when considering patients undergoing radical mastectomy, the selection of anesthetic agents with minimal impact on immune function is crucial [2, 3]. Propofol is a commonly employed anesthetic agent known for its clinical advantages, including rapid induction of anesthesia and swift postoperative recovery. However, it is associated with disadvantages such as respiratory and circulatory system inhibition, particularly when administered at high doses or rapid injection rates, potentially resulting in adverse reactions such as respiratory weakening, reduced heart rate, blood pressure fluctuations and prolonged patient recovery [2, 3].

In contrast, remimazolam tosilate is a novel anesthetic drug primarily metabolized by plasma esterases, independent of liver and kidney functions. It offers a rapid onset of anesthesia, effective sedation, and rapid metabolism with no accumulation in the patient's body. Notably, even at higher doses and faster injection rates, remimazolam tosilate has a limited impact on the respiratory and circulatory systems of patients, resulting in shortened recovery times, reduced incidence of respiratory depression, and more stable blood pressure. It also demonstrates a higher level of safety with minimal occurrence of serious adverse reactions [4, 5].

To compare the anesthetic effects of remimazolam tosilate and propofol in patients undergoing radical mastectomy, 120 patients who underwent radical mastectomy at our hospital from January 2020 to January 2021 were assessed, and the

findings reported below provide new insights for anesthetic drug selection in such patients.

2. Materials and methods

2.1 General information

We enrolled a total of 120 patients who underwent radical mastectomy at our hospital between January 2020 and January 2021, who were then randomly assigned to either the control group or the study group, with 60 patients in each group. In the study group, the mean age was (42.52 ± 5.16) years, mean Body Mass Index (BMI) was (22.18 ± 1.96) kg/m^2, operation time was (88.35 ± 17.12) minutes, blood loss was (48.45 ± 4.92) mL, and infusion volume was (992.25 ± 99.52) mL. In the control group, the mean age was (42.57 ± 5.12) years, mean BMI was (22.13 ± 1.94) kg/m^2, operation time was (88.32 ± 17.16) minutes, blood loss was (48.40 ± 4.96) mL, and infusion volume was (992.22 ± 99.56) mL. There were no significant differences in age, BMI, operation time or blood loss between the two groups, indicating that their baseline characteristics were well-balanced.

2.1.1 Inclusion criteria

(1) Met the diagnostic criteria of breast cancer, and the diagnosis was confirmed by pathological examination; (2) had an American Society of Anesthesiologists (ASA) grade I–II; (3) BMI ranged 18–28 kg/m^2; (4) provided signed informed consent for study participation.

2.1.2 Exclusion criteria

(1) Patients with immune system diseases; (2) suffering from severe heart, liver and kidney dysfunction; (3) had long-term use of sedative drugs; (4) presence of cognitive impairment.

2.2 Method

Before surgery, patients in both groups observed an 8-hour fasting period and refrained from drinking for 4 hours. Upon entering the operating room, their standard vital signs, such as blood pressure, heart rate, oxygen saturation and electrocardiogram, were continuously monitored, and peripheral venous access was established.

2.2.1 Study group

(1) Induction of anesthesia: an intravenous bolus injection of remimazolam tosilate (manufacturer: Jiangsu Hengrui Medicine Co., Ltd., Lianyungang, China, approval number: State medical permit no. H20190034), sufentanil (manufacturer: Yichang Humanwell Pharmaceutical Co., Ltd., Yichang, China, approval number: State medical permit no. H20150126), and cisatracurium besilate (manufacturer: Jiangsu Hengrui Medicine Co., Ltd., Lianyungang, China, approval number: State medical permit no. H20183042) was administered, with dosage determined based on drug strength and patient weight.

(2) During surgery, endotracheal intubation and mechanical ventilation were performed. Tidal volume (VT) was set at 8 to 10 mL/kg, respiratory rate (RR) was maintained at 10–12 breaths/min, inspiratory and expiratory ratio was set at 1:2, end-tidal carbon dioxide ($PETCO_2$) was maintained between 35 to 45 mmHg (1 mmHg = 0.133 kPa), and intraoperative bispectral index (BIS) values were targeted within the range of 40–60. A blood pressure fluctuation within 20% of the baseline value during surgery indicated an appropriate depth of anesthesia.

(3) Preoperative endotracheal intubation was performed.

(4) Maintenance of anesthesia was achieved through intravenous pump administration of remimazolam tosilate (manufacturer: Jiangsu Hengrui Medicine Co., Ltd., approval number: State medical permit no. H20190034) and remifentanil hydrochloride (manufacturer: Yichang Humanwell Pharmaceutical Co., Ltd., Yichang, China, approval number: State medical permit no. H20030198).

2.2.2 Control group

(1) Anesthesia induction: intravenous bolus injections of propofol (manufacturer: Xi'an Libang Pharmaceutical Co., Ltd., Xi'an, China, approval number: State medical permit no. H19990282), sufentanil (manufacturer: Yichang Humanwell Pharmaceutical Co., Ltd., approval number: State medical permit no. H20150126), and cisatracurium besilate (manufacturer: Jiangsu Hengrui Pharmaceutical Co., Ltd., approval number: State medical permit no. H20183042) were administered, with dosage calculations based on drug potency and patient weight.

(2) During the surgical procedure, endotracheal intubation and mechanical ventilation were employed. Tidal volume (VT) was set at 8 to 10 mL/kg, respiratory rate (RR) was maintained at 10–12 breaths/min, inspiratory and expiratory ratio was adjusted to 1:2, end-tidal carbon dioxide ($PETCO_2$) was maintained within the range of 35 to 45 mmHg (1 mmHg = 0.133 kPa), and intraoperative bispectral index (BIS) values were targeted between 40–60. An intraoperative blood pressure fluctuation within 20% of the baseline value indicated an appropriate depth of anesthesia.

(3) Maintenance of anesthesia was achieved through intravenous pump administration of propofol (manufacturer: Xi'an Libang Pharmaceutical Co., Ltd., approval number: State medical permitment number H19990282) and remifentanil hydrochloride (manufacturer: Yichang Humanwell Pharmaceutical Co., Ltd., approval number: State medical permitment number H20030198).

2.3 Outcome measures

(1) We assessed various outcome measures to compare the effects of anesthesia between the two groups. First, we examined the anesthetic effect by evaluating the time it took for the eyelash reflex to disappear, the duration of recovery, the retention time in the Post-Anesthesia Care Unit (PACU), and the Visual Analogue Scale (VAS) scores at 24-hour postoperation. Higher VAS scores indicated a greater degree of pain in patients.

(2) We also investigated the degree of Mean Arterial Pressure (MAP) decrease by measuring MAP values at specific time points (1st minute, 3rd minute and 5th minute) after anesthesia induction in both groups.

(3) Additionally, we compared various physiological pa-

rameters following the loss of consciousness, including heart rate (HR), respiratory rate (RR), tidal volume (VT), and the incidence of apnea.

(4) Furthermore, the study analyzed immune function by collecting peripheral venous blood samples from patients 30 minutes before anesthesia as well as at 24 hours and 72 hours after surgery. In these samples, we monitored levels of $CD3^+$, $CD4^+$, $CD8^+$ and NK cells in the blood and calculated the $CD4^+/CD8^+$ value for comparative analysis.

(5) Finally, we assessed the incidence of adverse reactions, such as nausea, vomiting, emergence agitation, and respiratory depression, in both study groups.

2.4 Statistical methods

Data analysis was performed using SPSS 27.0 (International Business Machines Corporation, Armonk, NY, USA). Measurement data were analyzed using a *t*-test and presented as mean $\pm$ standard deviation ($\bar{x} \pm s$), while enumeration data were analyzed with the χ^2 test and expressed as (n (%)). A significance level of $p < 0.05$ indicated statistical significance for observed differences.

3. Results

3.1 Comparison of anesthetic effect between the two groups

In the study group, the eyelash reflex disappearance time was longer compared to the control group, and the recovery time was shorter ($p < 0.05$) (Table 1). However, there were no significant differences in PACU retention time and VAS scores at 24 hours post-operation between the two groups ($p > 0.05$).

3.2 Analysis of mean arterial pressure reduction in both groups

The degree of MAP decrease in the study group was significantly lower than that in the control group at 1 minute, 3 minutes and 5 minutes after anesthesia induction ($p < 0.05$) (Table 2).

3.3 Comparison of relevant indicators after loss of consciousness between the two groups

After loss of consciousness, there was no significant difference in the reduction of HR between the two groups ($p > 0.05$) (Table 3). However, the study group showed higher levels of RR and VT and a lower incidence of apnea compared to the control group ($p < 0.05$).

3.4 Comparison of immune function indicators between the two groups

Thirty minutes before anesthesia, there was no significant difference in $CD3^+$, $CD4^+$, $CD8^+$, NK cells and $CD4^+/CD8^+$ between the two groups ($p > 0.05$) (Table 4). However, at 24 hours after surgery, the values of $CD3^+$, $CD4^+$, NK cells and $CD4^+/CD8^+$ in the study group were higher than that in the control group ($p < 0.05$). Conversely, at 72 hours after surgery, there was no significant difference in the values of $CD3^+$, $CD4^+$, $CD8^+$, NK cells and $CD4^+/CD8^+$ between the two groups ($p > 0.05$). The results were shown in Tables 4,4-1,4-2.

3.5 Comparison of incidence of adverse reactions between the two groups

The study group exhibited a lower incidence of adverse reactions, including nausea, vomiting, emergence agitation, and respiratory depression, compared to the control group ($p < 0.05$) (Table 5).

4. Discussion

Breast cancer, the most prevalent malignant tumor among women, is characterized by multifactorial causes and has shown a consistent increase in incidence in recent years, often detected through routine physical examinations. The primary treatment for this disease often involves radical mastectomy, a surgical procedure aimed at eliminating the lesion as thoroughly as possible [4]. However, due to the extensive surgical trauma involved, the use of anesthetic drugs is necessary to manage patient pain during surgery. Nonetheless, these drugs can induce immunosuppression, leading to adverse effects such as respiratory depression. Moreover, immunosuppression is a significant risk factor for the potential metastasis of residual cancer cells, heightening the risk of cancer recurrence. Research has demonstrated that different anesthetic agents can have varying impacts on the postoperative prognosis of breast cancer patients. Consequently, the judicious selection of appropriate anesthetic drugs plays a critical role in improving patient quality of life and extending overall survival rates [5].

In patients undergoing radical mastectomy, optimizing the preservation of immune function can minimize the risk of

TABLE 1. Comparison of anesthetic effect between the two groups ($\bar{x} \pm s$).

Group	n	Eyelash reflex disappearance time (s)	Emergence time (min)	PACU retention time (min)	VAS score at 24 hours after operation (point)
Study group	60	75.24 ± 15.23	6.85 ± 2.12	39.25 ± 7.76	2.68 ± 0.54
Control group	60	57.18 ± 11.21	9.06 ± 2.06	38.81 ± 8.05	2.65 ± 0.55
t		7.398	5.791	0.305	0.302
p		<0.001	<0.001	0.761	0.764

PACU: Post-Anesthesia Care Unit; VAS: Visual Analogue Scale.

TABLE 2. Comparison of mean arterial pressure reduction between the two groups ($\bar{x} \pm s$).

Group	n	Degree of MAP decrease		
		1 min after anesthesia	3 min after anesthesia	5 min after anesthesia
Study group	60	8.22 ± 2.12	12.67 ± 2.52	15.65 ± 1.16
Control group	60	12.08 ± 4.12	20.17 ± 2.84	22.95 ± 1.91
t		6.453	15.301	25.304
p		<0.001	<0.001	<0.001

MAP: Mean Arterial Pressure.

TABLE 3. Comparison of relevant indicators after loss of consciousness between the two groups ($\bar{x} \pm s$, n (%)).

Group	n	Related indicators after the loss of consciousness			
		The degree of HR decrease (%)	RR (beats/min)	VT (mL)	Apnea condition
Study group	60	7.68 ± 2.75	13.27 ± 2.14	193.57 ± 43.51	9 (15%)
Control group	60	7.65 ± 2.72	9.92 ± 2.02	125.38 ± 48.86	18 (30%)
t/χ^2		0.060	8.818	8.073	3.871
p		0.952	<0.001	<0.001	0.049

HR: heart rate; RR: respiratory rate; VT: tidal volume.

TABLE 4. Comparison of immune function indicators between the two groups ($\bar{x} \pm s$).

Group	n	$CD3^+$ (%)			$CD4^+$ (%)		
		30 min before anesthesia	24 hours after operation	72 hours after operation	30 min before anesthesia	24 hours after operation	72 hours after operation
Study group	60	76.14 ± 6.25	69.87 ± 5.14	75.87 ± 6.51	45.63 ± 5.56	38.26 ± 5.16	43.83 ± 6.16
Control group	60	76.16 ± 6.27	57.92 ± 6.12	75.56 ± 6.53	45.66 ± 5.53	27.24 ± 5.02	44.87 ± 6.15
t		0.018	11.582	0.260	0.030	11.857	0.926
p		0.986	<0.001	0.795	0.976	<0.001	0.357

CD: Cluster of Differentiation.

TABLE 4-1. Comparison of immune function indicators between the two groups-1.

Group	n	$CD8^+$ (%)			NK cell		
		30 min before anesthesia	24 hours after operation	72 hours after operation	30 min before anesthesia	24 hours after operation	72 hours after operation
Study group	60	33.18 ± 7.45	31.57 ± 5.74	33.67 ± 7.51	19.82 ± 3.25	14.42 ± 2.26	19.07 ± 2.14
Control group	60	33.15 ± 7.48	31.52 ± 5.76	33.64 ± 7.53	19.85 ± 3.58	11.37 ± 2.24	18.78 ± 2.16
t		0.022	0.048	0.022	0.048	7.425	0.739
p		0.983	0.962	0.983	0.962	<0.001	0.462

CD: Cluster of Differentiation; NK: natural killer.

TABLE 4-2. Comparison of immune function indicators between the two groups-2.

Group	n	$CD4^+/CD8^+$		
		30 min before anesthesia	24 hours after operation	72 hours after operation
Study group	60	1.43 ± 0.57	1.28 ± 0.46	1.32 ± 0.36
Control group	60	1.32 ± 0.52	0.88 ± 0.14	1.39 ± 0.35
t		1.104	6.444	1.080
p		0.272	<0.001	0.282

CD: Cluster of Differentiation.

TABLE 5. Comparison of incidence of adverse reactions between the two groups (n (%)).

Group	n	Nausea and vomiting	Emergence agitation	Respiratory depression
Study group	60	1 (1.67)	0 (0)	2 (3.33)
Control group	60	7 (11.67)	4 (6.67)	8 (13.33)
χ^2		4.821	4.138	3.927
p		0.028	0.042	0.048

metastasis and serve as a preventive measure against cancer recurrence [6].

During radical mastectomy surgery, it is necessary to administer certain medications to alleviate intraoperative pain for patients. However, the use of some drugs can lead to immunosuppression, impacting immune function and potentially causing adverse reactions such as respiratory depression.

Propofol is a commonly utilized anesthetic agent in radical mastectomy procedures, appreciated for its rapid induction of anesthesia, quick recovery, and thorough anesthetic effects. Nevertheless, it may also give rise to adverse reactions, including respiratory depression, fluctuations in blood pressure and injection-related discomfort. Propofol's impact on patients includes effects on the respiratory and circulatory systems, leading to reduced myocardial contractility and vascular resistance, consequently lowering patients' blood pressure. This hypotension can result in immune system inhibition [7]. In contrast, remimazolam tosilate, a benzodiazepine derivative, offers a more effective inhibition of neurotransmitters, reducing neuronal excitation and providing sedative effects with fewer consequences on patients' respiratory and circulatory systems. It has also been associated with rapid anesthesia, quick recovery and rapid metabolism rate in the body, maintaining stable hemodynamics without the occurrence of adverse reactions such as injection-related discomfort, which ultimately contribute to the improved postoperative rehabilitation of patients [8, 9].

This study revealed several key findings. First, the study group exhibited a prolonged eyelash reflex disappearance time and a shorter recovery time compared to the control group. Second, during the initial 1–5 minutes after anesthesia induction, the study group displayed a significantly lower degree of reduction in MAP than the control group. Third, after the loss of consciousness, the study group demonstrated significantly higher RR and VT levels as well as a significantly lower incidence of apnea compared to the control group. These results collectively suggest that remimazolam tosilate was superior to propofol in terms of achieving deeper anesthesia, accelerating the recovery process and maintaining stable MAP levels in patients, reflecting superior anesthetic efficacy and enhanced safety [10–12].

T lymphocyte subsets, including $CD3^+$, $CD4^+$ and $CD8^+$, are important indicators for assessing cellular immune function. Elevated levels of T lymphocytes stimulate the body's immune response, helping in eliminating harmful substances. On the other hand, NK cells promote the apoptosis of target cells to effectively inhibit cancer cell metastasis, and increased NK cell levels have been shown to play a pivotal role in enhancing patient prognosis. Patients undergoing radical mastectomy often experience suppressed cellular immunity during anesthesia and surgery. Remimazolam tosilate's action on the sympathetic nervous system results in the release of substances such as prostaglandin E2 and catecholamines, which can reduce the inhibitory effects of anesthesia on immune cells in patients. Herein, we found that the fluctuations in $CD3^+$, $CD4^+$, NK cells and $CD4^+/CD8^+$ values between 24 to 72 hours after the operation were significantly smaller in the study group compared to the control group. Furthermore, the study group exhibited significantly higher levels of these four indicators at 24 hours post-operation, suggesting that remimazolam tosilate exerts a lesser inhibitory effect on immune function and holds potential benefits for patient prognosis [13–18].

Additionally, we observed a lower incidence of adverse reactions, such as nausea, vomiting, emergence agitation and respiratory depression, in the study group compared to the control group, implying that remimazolam tosilate may have a more favorable clinical effect than propofol.

5. Research limitations and future perspectives

This study has several limitations. First, the sample size was relatively small, and the study was conducted at a single center, which may limit the generalizability of the findings. Future investigations should consider larger, multicenter, randomized controlled trials to strengthen the validity of the results. Second, we did not perform cost analysis and comparison, which could provide valuable insights into the economic aspects of using remimazolam tosilate. Lastly, patient follow-up duration might not be long enough, and future research could benefit from retrospective analyses to explore the extended postoperative effects of remimazolam tosilate on patient recovery and provide a more comprehensive understanding of the drug's efficacy and safety profile in clinical practice.

6. Conclusions

In conclusion, remimazolam tosilate offers distinct advantages when compared to propofol. It facilitates rapid attainment and maintenance of sedation while minimizing suppression of the respiratory and circulatory systems. Additionally, its enhanced controllability reduces the risk of cardiovascular and cerebrovascular complications, making it a valuable candidate for clinical application.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be

obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

WW, ML—designed the study and carried them out; prepared the manuscript for publication and reviewed the draft of the manuscript. WW, ML, HFD and SSD—supervised the data collection, analyzed the data, interpreted the data. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of Affiliated Hospital of North Sichuan Medical College (Approval no. 2023ER286-1). Written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

ACKNOWLEDGMENT

Not applicable.

FUNDING

This research received no external funding.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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How to cite this article: Wen Wen, Mao Li, Shanshan Deng, Huifei Deng. Clinical comparative study of remimazolam tosilate and propofol on anesthesia effect in patients undergoing radical mastectomy. European Journal of Gynaecological Oncology. 2024; 45(2): 135-140. doi: 10.22514/ejgo.2024.035.