BRITISH JOURNAL OF HOSPITAL MEDICINE

ARTICLE

Evaluation of the Safety and Efficacy of Remimazolam Combined With Remifentanil for Sedation in Adult Dental Anxiety Patients Undergoing Mandibular Impacted Third Molar Extraction: A Single-Center, Retrospective Cohort Analysis

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Abstract

Aims/Background Dental anxiety (DA) often leads to significant fear and anxiety in the patients undergoing dental procedures, and increases the complexity and difficulty of treatment. Currently, remimazolam, a benzodiazepine-like sedative drug, has been found effective and safe during endoscopic and surgical procedures. Therefore, this study aimed to evaluate the safety levels and efficacy profile of remimazolam combined with remifentanil for sedation in adult patients with DA who underwent the mandibular impacted third molar extraction.

Methods This single-center, retrospective cohort study included adult patients with DA who underwent mandibular impacted third molar extraction at the Beijing Stomatological Hospital between January 2021 and December 2023. Based on the sedation protocols used during dental procedures, patients were divided into two groups: a remimazolam combined with remifentanil group (the remimazolam group, n = 63) and a propofol combined with remifentanil group (the propofol group, n = 71). The overall incidence of adverse events was selected as the primary outcome measure, including pulse oxygen saturation (SpO_2) <93%, injection pain, sedation failure, hypotension, bradycardia, and nausea/vomiting. The secondary outcome measures included sedation onset time, postoperative pain levels, satisfactions of patient and anesthesiologists, and vital signs changes over time.

Results The remimazolam group showed an overall incidence of adverse events of 7.9%, compared to 49.3% in the propofol group, with a statistically significant difference between the two groups ($p < 0.001$). Both study groups demonstrated no statistically significant differences in sedation onset time ($p = 0.252$) and postoperative pain Verbal Rating Scale (VRS) score ($p = 0.527$). Moreover, the remimazolam group had greater stability in blood pressure (between-group effect, $p = 0.012$) and heart rate (between-group effect, $p < 0.001$) and exhibited statistically significant differences in changes in respiratory rate over time (between-group effect, $p < 0.001$). Anesthesiologists' satisfaction scores with respiratory and circulatory stability, sedation efficacy, and quality of sedation recovery were significantly higher in the remimazolam group compared to the propofol group ($p < 0.001$). Surgeons reported a higher satisfaction with sedation efficacy in the remimazolam group.

Conclusion In summary, remimazolam combined with remifentanil demonstrates greater safety and effectiveness than propofol combined with remifentanil for sedation during dental procedures in adult DA patients. This combination particularly decreases adverse events, maintains stable respiratory and circulatory functions, and improves satisfaction levels among anesthesiologists and surgeons.

Key words: remimazolam; remifentanil; dental anxiety; impacted tooth; third molar; sedation; safety

Submitted: 28 August 2024 Revised: 11 November 2024 Accepted: 13 November 2024

How to cite this article:
Cao C, Pan CX, Zhu WJ, Xue FS. Evaluation of the Safety and Efficacy of Remimazolam Combined With Remifentanil for Sedation in Adult Dental Anxiety Patients Undergoing Mandibular Impacted Third Molar Extraction: A Single-Center, Retrospective Cohort Analysis. Br J Hosp Med. 2025. https://doi.org/10.12968/hmed.2024.0583

Introduction

Dental anxiety (DA) is a common psychological condition characterized by extreme fear and anxiety during dental treatments. This disorder causes significant distress during the treatment and may lead to delays or avoidance of procedures, which can exacerbate oral health issues (Thakur et al, 2021; Winkler et al, 2023). DA poses a substantial impact on patient health and treatment outcomes. Mainly, during invasive dental procedures, the psychological condition of the patients can significantly increase the complexity and difficulty of the surgery to another level (Wang et al, 2017).

With the advancements of modern medical technologies, there have been considerable enhancements in dental sedation and analgesia strategies. Traditional sedation methods, such as nitrous oxide inhalation or intravenous midazolam and propofol, offer some improvements in patient comfort and treatment outcomes. However, these methods still have certain limitations (Baldo, 2023). For example, nitrous oxide can effectively reduce anxiety and pain but is unable to adequately control gag reflexes (De Veaux et al, 2016). Similarly, intravenous administration of midazolam and propofol can lead to respiratory depression, hemodynamic instability, and prolonged postoperative recovery times (Folino et al, 2024). These limitations restrict their application in dental procedures. Recently, a novel benzodiazepine-like sedative drug formulated as toluene sulfonate remimazolam (hereafter referred to as remimazolam) has gained attention due to its rapid onset, quick metabolism, and minimal influence on cardiorespiratory function (Sneyd, 2023). Current evidence indicates that remimazolam offers excellent sedative efficacy and safety during endoscopic and surgical procedures (Shi et al, 2022; Zhu et al, 2024). Its rapid onset and brief duration profile make it beneficial for medical scenarios requiring quick adjustment in sedation depth, particularly in shorter procedures (Ye et al, 2023; Zhang et al, 2023).

Despite the promising performance of remimazolam in various medical fields, its application in dentistry, especially for patients with DA, remains undetermined. Issues like, the efficacy of remimazolam for sedating DA patients performing mandibular impacted third molars extraction and whether it offers better sedative effects, onset time, and safety over traditional sedatives, are yet to be addressed. Since the combination of a sedative with an opioid agent is commonly used in clinical practice, this retrospective study evaluated the effectiveness and safety of remimazolam combined with remifentanil against propofol combined with remifentanil in adult DA patients undergoing mandibular impacted third molar extractions. By assessing the safety and efficacy of remimazolam combined with remifentanil during these procedures, we aimed to provide scientific evidence for developing safer and more effective sedation strategies in dental treatment.

Methods

Study Design and Participants

This study is a single-center, retrospective cohort analysis performed to evaluate the efficacy and safety of sedation strategies for mandibular impacted third mo-

lar extraction in adult patients with DA at the Comfort Oral Treatment VIP Center, Beijing Stomatological Hospital between January 2021 and December 2023. After approval from the Ethics Committee of Beijing Stomatological Hospital (institution review board numbers: CMUSH-IRB-KJ-PJ-2022-40; CMUSH-IRB-KJ-YJ-2023-93), data for all patients were obtained from medical records, and the study protocol adhered to the guidelines of the Declaration of Helsinki. As this is a retrospective study, the ethics committee waived patient informed consent in agreement with the International Ethical Guidelines for Biomedical Research Involving Human Subjects, Council for International Organizations of Medical Sciences (2002).

Inclusion and Exclusion Criteria

Inclusion criteria for this study were set as follows: adult patients with complete clinical data, aged 18–45 years and scheduled for mandibular impacted third molar extraction; and those categorized as American Society of Anesthesiologists (ASA) physical status classification I to II (Horvath et al, 2021), and with a Modified Dental Anxiety Scale (MDAS) score $\geq$13 (Chi, 2023). The ASA physical status classification is a scoring system most commonly used in clinical practice to assess anesthetic and surgical risk, ranging from minimal (Class I) to extreme (Class VI), Class I and II generally indicating low risk of anesthesia and surgery.

The MDAS is a 5-item self-report scale for assessing dental anxiety, with total scores ranging from 4 to 20 points. A score of 13 or above indicates considerable DA. The third molars of all patients were classified as mesioangular or horizontal impactions, requiring incision, bone removal, and suturing.

Exclusion criteria included patients with a history of severe cardiovascular or pulmonary diseases, liver or kidney dysfunction, abnormal bleeding or coagulation disorders, alcohol or drug abuse; pregnant women; individuals allergic to sedatives or analgesics; and those with a body mass index greater than 30.

Data Sources

Baseline data for all patients were obtained from the electronic medical record system of the hospital. Patients who underwent mandibular impacted third molar extraction between January 2021 and December 2023 and those who met the inclusion criteria were selected.

Study Groups

Based on the sedation protocols used during dental procedures, patients were retrospectively divided into two groups: the remimazolam combined with remifentanil group (the remimazolam group) and the propofol combined with remifentanil group (the propofol group).

In both groups, remifentanil was administered with a bolus dose of 10 μg, followed by a continuous infusion at a rate of 0.03 μg/kg/min. In the remimazolam group, remimazolam was administered intravenously at a loading dose of 0.6 mg/kg, followed by a continuous infusion at 0.2 mg/kg/h to 0.3 mg/kg/h, and adjusted to maintain a Ramsay Sedation Scale (RSS) score of 2 to 3 (Consales et al, 2006). In the propofol group, propofol was given intravenously with a loading dose of 10

mg, followed by a continuous infusion at 2 mg/kg/h to 3 mg/kg/h, and adjusted to maintain an RSS score of 2 to 3.

Data Collection and Outcome Measures

Baseline characteristics of all patients such as gender, age, ASA classification, MDAS score, and procedure duration (including anesthesia preparation, dental procedure, and postoperative care), were collected.

Primary outcome measure was the overall incidence of adverse events from the start of drug administration to patient discharge from the Post-Anesthesia Care Unit (PACU), including pulse oxygen saturation (SpO_2) <93%, injection pain, sedation failure, hypotension, bradycardia, and nausea/vomiting. Sedation failure was defined as an RSS score of 1, indicating that the patient is awake, anxious, or agitated.

Secondary outcome measures included the following items: ① Vital Signs: Assessments of blood pressure, heart rate, SpO_2, and respiratory rate at 5-time points: preoperative (T0), 2 minutes post-dosing (T1), at oral mucosa incision (T2), during bone removal (T3), and at the end of the procedure (T4). ② Sedation Onset Time: It means the time from drug administration to achieve an RSS score of 2 to 3. ③ Postoperative Pain and Recall: The recall of intraoperative discomfort or unpleasant memories was evaluated 10 minutes post-surgery. Pain was assessed using the Verbal Rating Scale (VRS) (Thong et al, 2018), where 0 = no pain; 1 = mild pain; 2 = moderate pain; 3 = severe pain. ④ Patient Satisfaction: Overall satisfaction with sedation management was measured postoperatively using a Likert scale from 1 (very dissatisfied) to 5 (very satisfied) (Drinkwater, 1965). ⑤ Anesthesiologist Satisfaction: Satisfaction with the ease of procedures, respiratory and circulatory system stability, sedation efficacy, and quality of recovery were assessed postoperatively using a Visual Analog Scale (VAS) ranging from 0 (very dissatisfied) to 10 (very satisfied) (McCormack et al, 1988). ⑥ Surgeon Satisfaction: Surgeon satisfaction with sedation management, including any interruptions due to adverse respiratory or cardiovascular events, was evaluated using the same 11-point VAS postoperatively.

Statistical Analysis

Data were analyzed using SPSS version 27.0 (IBM Corp., Armonk, NY, USA). The Shapiro-Wilk (SW) test was used to assess the normality of continuous variables. Continuous variables following a normal distribution were expressed as mean ± standard deviation, and the between-group comparisons were performed using an independent samples *t*-test. While those continuous variables that did not follow a normal distribution were described as Median (P25, P75) and analyzed with a rank-sum test. However, categorical variables were expressed percentages (n, %) and analyzed using a chi-square test. A repeated measures analysis of variance (ANOVA) was used for data obtained at multiple time points. For the primary outcome, the incidence of adverse events between groups using binomial logistic regression, and adjusting for potential confounding factors such as age, weight, and ASA classification. A significant level of $p < 0.05$ was for all statistical analyses.

Table 1. A comparison of baseline characteristics between the two groups.

Characteristic	Remimazolam group (n = 63)	Propofol group (n = 71)	t/χ^2	p-values
Age (years)	33.33 ± 6.33	31.17 ± 4.33	2.332	0.021
Gender			0.315	0.574
Male	35 (55.6%)	36 (50.7%)		
Female	28 (44.4%)	35 (49.3%)		
ASA classifications			1.199	0.274
I	55 (87.3%)	57 (80.3%)		
II	8 (12.7%)	14 (19.7%)		
MDAS	16.38 ± 2.27	16.41 ± 2.25	–0.070	0.944
Procedure duration (min)	45.19 ± 6.41	46.24 ± 6.50	–0.939	0.350

Note: ASA, American Society of Anesthesiologists; MDAS, Modified Dental Anxiety Scale.

Results

Comparison of Baseline Characteristics Between the Two Groups

From January 2021 and December 2023, 134 adult DA patients who met the inclusion criteria were included in this study. Based on the electronic medical record system, 63 patients were assigned to the remimazolam group and 71 patients to the propofol group. The comparison of baseline characteristics between the two groups is shown in Table 1. A significant age difference was found between the two groups ($p = 0.021$). However, no statistically significant differences were observed in gender, ASA classification, MDAS score, or duration of the procedure (all of $p > 0.05$).

Comparison of Primary Outcome Between the Two Groups

The incidences of major adverse events in both groups during the intraoperative and postoperative periods are summarized in Table 2. The remimazolam group showed an overall incidence of adverse events of 7.9%, compared to 49.3% in the propofol group, with a statistically significant difference between the two groups ($p < 0.001$). A binary logistic regression was performed, using the occurrence of adverse events as a dependent variable and using sedation strategies and baseline characteristics as independent variables. Table 3 shows the impacts of sedation strategies on the risk of adverse events after adjusting for age, gender, ASA classification, MDAS score, and procedure duration. The sedation strategies exhibited a statistically significant impact on the risk of adverse events (Exp(B) = 14.120, 95% confidence interval (CI) 4.462–44.681).

Vital Sign Changes of the Patients

Table 4 indicates the results of the repeated measures ANOVA for vital signs. Blood pressure changes over time were substantially different between the two groups ($p < 0.001$), with a significant between-group effect ($p = 0.012$), indicating a statistically significant difference in blood pressure trends between the two groups. Heart rate showed a significant time effect ($p < 0.001$) and a significant interaction effect ($p < 0.001$), indicating a statistically significant difference in heart

Table 2. Incidence of adverse events between the two groups.

Adverse events	Remimazolam group (n = 63)	Propofol group (n = 71)	χ^2	*p*-values
SpO_2 <93%	0 (0.00%)	2 (2.82%)	-	-
Injection pain	1 (1.59%)	26 (36.62%)	-	-
Sedation failure	1 (1.59%)	1 (1.41%)	-	-
Hypotension	0 (0.00%)	4 (5.63%)	-	-
Bradycardia	2 (3.17%)	1 (1.41%)	-	-
Nausea/Vomiting	1 (1.59%)	1 (1.41%)	-	-
Total	5 (7.9%)	35 (49.3%)	27.269	<0.001

Note: SpO_2, pulse oxygen saturation.

Table 3. Binary logistic regression analysis for adverse event risk.

Variable	B	Standard error	Wald	*p*-value	Exp(B)	95% CI	
						Lower bound	Limit bound
Sedation strategies (reference: Remimazolam + remifentanil)	2.648	0.588	20.291	<0.001	14.120	4.462	44.681
Age	–0.012	0.048	0.058	0.809	0.988	0.899	1.087
Gender (reference: male)	0.864	0.449	3.699	0.054	2.373	0.984	5.724
ASA classification (reference: Class I)	–0.473	0.589	0.645	0.422	0.623	0.196	1.978
MDAS	–0.032	0.102	0.096	0.757	0.969	0.794	1.183
Duration of procedure	0.019	0.035	0.305	0.581	1.020	0.952	1.092

Note: CI, confidence interval.

rate changes between the two groups over time. SpO_2 demonstrated a significant time effect ($p < 0.001$), reflecting changes over time within both groups. However, the interaction effect was not significant ($p = 0.609$), suggesting no statistically significant difference in SpO_2 changes between the two groups over time. Respiratory rate showed a significant time effect ($p < 0.001$) and a significant between-group effect ($p < 0.001$), indicating a statistically significant difference in respiratory rate changes over time between the two groups.

Comparison of Sedation Onset Time and Postoperative Pain Between the Two Groups

The sedation onset time was longer in the remimazolam group than the propofol group; however, this difference was not statistically significant ($p = 0.252$). Similarly, there was no statistically significant difference in postoperative pain VRS scores between the two groups ($p = 0.527$), indicating that both sedation regimens provided similar postoperative analgesic effectiveness (Table 5).

Table 4. Repeated measures ANOVA for changes in vital signs over time.

Variables	Groups	T0	T1	T2	T3	T4	Between-group effect		Time effect		Interaction effect	
							F	*p*	F	*p*	F	*p*
Blood pressure (mm Hg)	Remimazolam group	119.02 ± 4.10	109.98 ± 2.80^{a}	115.05 ± 2.91^{ab}	117.81 ± 2.86^{abc}	121.86 ± 2.90^{abcd}	6.460	0.012	557.405	<0.001	3.683	0.057
	Propfol group	118.37 ± 2.65	112.31 ± 3.26*^{a}	113.89 ± 3.00*^{ab}	120.65 ± 2.96*^{abc}	123.99 ± 2.73*^{abc}						
Heart rate (bpm)	Remimazolam group	75.00 ± 3.02	70.02 ± 0.16^{a}	71.98 ± 0.13^{ab}	67.79 ± 2.93^{abc}	73.75 ± 2.81^{abcd}	125.527	<0.001	161.915	<0.001	19.439	<0.001
	Propofol group	72.07 ± 3.01*	68.63 ± 2.94*^{a}	70.01 ± 0.12*^{ab}	75.04 ± 3.00*^{abc}	78.04 ± 2.94*^{abcd}						
SpO_2 (%)	Remimazolam group	98.02 ± 0.13	96.05 ± 0.19^{a}	95.00 ± 0.04^{ab}	94.00 ± 0.18^{abc}	97.03 ± 0.25^{abcd}	2677.910	<0.001	10631.605	<0.001	0.264	0.609
	Propofol group	97.01 ± 0.12*	95.03 ± 0.14*^{a}	94.04 ± 0.20*^{ab}	96.03 ± 0.24*^{abc}	98.03 ± 0.17*^{abcd}						
Respiratory rate (breaths/min)	Remimazolam group	22.00 ± 0.18	18.00 ± 0.31^{a}	16.07 ± 0.36^{ab}	17.70 ± 0.56^{abc}	18.84 ± 1.05^{abcd}	27.161	<0.001	1785.649	<0.001	88.833	<0.001
	Propofol group	22.03 ± 0.24	18.04 ± 0.26^{a}	16.59 ± 0.75*^{ab}	18.99 ± 0.21*^{abc}	19.39 ± 1.03*^{abcd}						

Note: The between-group comparison, *$p < 0.05$; The intra-group comparison, compared to T0, $^{a}p < 0.05$; Compared to T1, $^{b}p < 0.05$; Compared to T2, $^{c}p < 0.05$; Compared to T3, $^{d}p < 0.05$. Significant differences are not distinguished as $p < 0.01$, $p < 0.001$, but standardized as $p < 0.05$. Additional values in the table are for illustrative purposes only and do not represent real data.

T0, preoperative; T1, 2 minutes post-dosing; T2, oral mucosa incision; T3, during bone removal; T4, end of the procedure; Blood pressure refers to systolic blood pressure.

Table 5. Comparison of sedation onset time and postoperative pain between the two groups.

Characteristic	Remimazolam group (n = 63)	Propofol group (n = 71)	z	*p*-values
Sedation onset time (min)	1.70 (1.20, 2.30)	1.50 (0.80, 2.30)	1.144	0.252
VRS score	0.00 (0.00, 1.00)	0.00 (0.00, 1.00)	0.632	0.527

Note: VRS, Verbal Rating Scale.

Table 6. Comparison of satisfaction scores between the two groups.

	Variables	Remimazolam group (n = 63)	Propofol group (n = 71)	*t*	*p*-value
Anesthesiologist satisfaction	Ease of procedures	8.10 ± 0.61	7.90 ± 0.72	1.665	0.098
	Stability of respiratory and circulatory functions	8.44 ± 0.50	7.75 ± 0.60	7.236	<0.001
	Sedation efficacy	8.49 ± 0.54	7.86 ± 0.76	5.500	<0.001
	Quality of sedation recovery	8.41 ± 0.53	7.48 ± 0.81	7.810	<0.001
Surgeon satisfaction	Ease of procedures	8.19 ± 0.59	7.99 ± 0.71	1.803	0.074
	Sedation efficacy	8.38 ± 0.61	8.04 ± 0.78	2.773	0.006
Patient satisfaction	—	4.56 ± 0.59	4.38 ± 0.57	1.748	0.083

Satisfaction Scores

Anesthesiologist satisfaction scores with respiratory and circulatory stability ($p < 0.001$), sedation efficacy ($p < 0.001$), and quality of sedation recovery ($p < 0.001$) were significantly higher in the remimazolam group compared to the propofol group. Surgeons also reported a higher satisfaction with sedation efficacy in the remimazolam group ($p = 0.006$). However, patient satisfaction was comparable between the two groups ($p = 0.083$). These results suggest that remimazolam combined with remifentanil offers higher sedative efficacy and quality of sedation recovery compared to propofol combined with remifentanil during dental treatments (Table 6).

Discussion

This study aimed to evaluate the sedation efficacy and safety of remimazolam combined with remifentanil compared to propofol combined with remifentanil in adult patients with DA undergoing mandibular impacted third molar extraction. Results indicated that the remimazolam combined with remifentanil performed better than the propofol combined with remifentanil in terms of safety and anesthesiologists' satisfaction. However, both groups exhibited comparable postoperative analgesic effectiveness. Furthermore, the onset of sedation onset took a longer time for the remimazolam group compared to the propofol group, with no statistically significant difference. This longer onset time may be due to the pharmacokinetic properties of remimazolam. The onset time of remimazolam is influenced by drug

release and distribution characteristics that may need to a longer time to achieve the desired sedation effect (Noor et al, 2021).

In contrast, propofol usually acts faster due to its good lipid solubility and rapid distribution compatibility (Sahinovic et al, 2018). This difference may affect the sedation experience, especially when rapid, deep sedation is required. Despite its longer onset time, remimazolam does not result in clinically significant outcome. In clinical practice, remimazolam still provides effective sedation, and a slightly delayed onset time is unlikely to significantly impact intraoperative comfort or quality of sedation recovery (Tang et al, 2023). The VRS scores for postoperative pain were not significantly different between the two groups, suggesting that both sedation regimens were comparable in postoperative analgesic efficacy. Although the onset time of remimazolam is a bit slow, the other advantages, such as low risk of respiratory suppression and good pharmacokinetics, may offset this limitation.

The overall incidence of adverse events was lower in the remimazolam group than that in the propofol group, with a statistically significant between-group difference. A systematic review and meta-analysis by Ho et al (2024) indicated that the incidences of hypotension, bradycardia and hypoxia with remimazolam for sedation during colonoscopy procedures were comparable to those of placebo and other sedative agents. Lu et al (2022) revealed that remimazolam was associated with a lower rate of hypotension in elderly patients undergoing upper gastrointestinal endoscopy under deep sedation/anaesthesia than propofol. Furthermore, Chang et al's meta-analysis (2023) highlighted advantages of reducing bradycardia and hypotension incidence with remimazolam. These findings suggest that remimazolam exhibits certain advantages in reducing adverse events associated with procedural sedation. Generally, compared to propofol, remimazolam demonstrates comparatively better overall safety and reduces adverse event rates. However, the differences in the adverse events between remimazolam and propofol may also be counterbalanced in specific surgical settings. Therefore, further large-scale studies could provide a better understanding of the effects of these drugs in different surgical environments.

Analysis of vital signs showed significant time effects and between-group effects for heart rate and respiratory rate, with the remimazolam group demonstrating lesser changes in heart rate and blood pressure. The significant between-group difference in the respiratory rate suggests that remimazolam may be less respiratory inhibitory. This finding is crucial for optimizing sedation management and ensuring patient safety during the dental procedure. Wegner et al (2024) performed a systematic review and meta-analysis and reported that remimazolam induced less cardiovascular suppression than propofol in general anesthesia. Specifically, remimazolam was found to be associated with significantly lower incidences of intraoperative hypotension and bradycardia compared to propofol, which is in agreement with our observations of lesser heart rate changes during remimazolam treatment. The stable heart rate during sedation management can be due to the minimal impact of remimazolam on circulatory function.

Additionally, a study by Peng et al (2023) also supported the characteristics of remimazolam in stable cardiovascular function during the induction of general anes-

thesia, with significant advantages over propofol regarding heart rate and mean arterial pressure fluctuations. This further indicates that remimazolam can more effectively maintain cardiovascular stability. Regarding the respiratory rate, Hasegawa et al (2022) revealed that remimazolam exerts a mild impact on the autonomic nervous system, maintaining a balance between the sympathetic and parasympathetic nervous systems. This balance helps reduce spontaneous respiratory suppression, supporting the significant between-group differences observed in respiratory rate throughout the observation. This finding is consistent with Gao et al (2023), in which remimazolam maintains stable cerebral oxygen saturation and hemodynamics during carotid endarterectomy in elderly patients. All of this support the advantages of remimazolam in stabilizing respiratory function.

Anesthesiologists rated the remimazolam combined with remifentanil for sedation during dental procedures significantly higher regarding respiratory and circulatory stability, sedation efficacy, and quality of sedation recovery when compared to the propofol combined with remifentanil. This higher satisfaction of the anesthesiologists may reflect the advantages of remimazolam in clinical settings, and efficient sedation can provide better patient safety. Additionally, surgeons also rated their sedation efficacy more favorable in the remimazolam group, further supporting remimazolam as the preferred sedative drug for dental procedures.

This study has some limitations, including potential biases introduced to its retrospective design, such as selection bias. Specific sample size calculations were not performed, as all eligible cases were included. Instead, sample size calculation for this retrospective study was assessed primarily based on the distribution of existing cases and preliminary results to ensure statistical requirements. Initial data revealed an overall incidence of adverse events of 25% in the propofol group and 5% in the remimazolam group, indicating a minimum of 39 cases per group would be enough to ensure statistical power. The actual study enrolled 134 cases, and statistical analysis confirmed that the sample size met the requirements for assessing the impact of different sedation regimens on adverse event rates. Despite the fact that the sample size of this study meets statistical requirements for a retrospective analysis, caution is still suggested during generalizing these results. Thus, future prospective randomized controlled trials with good designs are needed to validate these findings and explore the specific advantages of remimazolam for sedation across various procedures.

Conclusion

This retrospective study demonstrates that remimazolam combined with remifentanil for sedation provides higher safety and efficacy than propofol combined with remifentanil in adult patients with DA undergoing mandibular impacted third molar extraction. This combination significantly decreases adverse events, provides more stable respiratory and circulatory functions, and improves satisfaction levels among anesthesiologists and surgeons.

Key Points

- Both remimazolam and propofol, when combined with remifentanil, offered adequate sedation for adult patients with DA undergoing mandibular third molar extraction.
- The adverse events associated with sedation were significantly lower with remimazolam (7.9%) compared to propofol (49.3%), indicating a safety advantage for remimazolam.
- Remimazolam resulted in more stable heart and respiratory function, indicating its reduced impacts on cardiovascular and respiratory systems.
- Administering remimazolam with remifentanil for sedition improves satisfaction levels among anesthesiologists and surgeons.

Availability of Data and Materials

The datasets used and/or analysed during the current study were available from the corresponding author on reasonable request.

Author Contributions

CC and CXP designed the study, and all authors conducted the study. CC and WJZ collected and analyzed the data. CC and FSX participated in drafting the manuscript, and all authors contributed to critical revision of the manuscript for important intellectual content. All authors gave final approval of the version to be published. All authors participated fully in the work, took public responsibility for appropriate portions of the content, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or completeness of any part of the work are appropriately investigated and resolved.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of Beijing Stomatological Hospital (institution review board numbers: CMUSH-IRB-KJ-PJ-2022-40; CMUSH-IRB-KJ-YJ-2023-93). This study was performed in accordance with the principles of the Declaration of Helsinki. As this is a retrospective study, the ethics committee waived patient informed consent in agreement with the International Ethical Guidelines for Biomedical Research Involving Human Subjects, Council for International Organizations of Medical Sciences.

Acknowledgement

Not applicable.

Funding

The study was funded by Innovation Foundation of Beijing Stomatological Hospital (Code: 21-09-19, to CC).

Conflict of Interest

The authors declare no conflict of interest.

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