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Emergence profiles of remimazolam-flumazenil versus propofol in pediatric general anesthesia for strabismus correction: a randomized clinical trial

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Abstract

Background Remimazolam (Rm) is a novel ultra-short-acting benzodiazepine used in general anesthesia. However, its application in pediatric general anesthesia remains limited. This study aims to compare the efficacy, safety, and postoperative emergence profiles of remimazolam and propofol (Pf) in pediatric surgical anesthesia.

Methods Children (aged 3–12 years) undergoing strabismus correction surgery were randomly assigned to the Group Rm or the Group Pf. The Group Rm and Group Pf received an induction dose of 0.3 mg/kg and 2 mg/kg, respectively. For emergence, the Group Rm was administered flumazenil 0.2–0.3 mg. The primary outcome was the time from the discontinuation of anesthetic agents to the first eye opening. Secondary outcomes included the time from the end of surgery to laryngeal mask airway (LMA) removal, the time to achieve a Modified Observer's Assessment of Alertness/Sedation (MOAA/S) score of 5 after LMA removal, and Aldrete scores during the postanesthetic care unit (PACU) stay. Additionally, the changes of vital signs before and after anesthesia were compared between the two groups.

Results In all patients, both remimazolam and propofol induced anesthesia successfully. Regarding emergence profiles, the Group Rm had significantly shorter times to first eye opening, LMA removal, and achieving an MOAA/S score of 5 post-LMA removal compared to the Group Pf ($p < 0.001$). Upon arrival at the PACU, the number of patients with Aldrete scores ≥ 9 was significantly higher in the Group Rm ($p < 0.001$). Following injection, the reduction in DBP was significantly greater in the Group Pf compared to the Group Rm ($p < 0.001$). The Group Rm maintained a more stable HR compared to the Group Pf.

Conclusion Remimazolam provides more stable hemodynamic characteristics and significantly shorter postoperative emergence time in pediatric patients compared to propofol. This suggests that remimazolam may be more suitable than propofol for pediatric general anesthesia, though larger scale clinical trials are needed for further validation.

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Keywords Remimazolam, Propofol, Pediatric anesthesia, Emergence profiles, Hemodynamics

Introduction

Propofol, the most commonly used intravenous anesthetic, is known for its rapid onset, fast recovery, and low incidence of postoperative nausea and vomiting [1]. However, it has notable side effects, including respiratory and circulatory depression, which may lead to hypotension and insufficient cerebral oxygen supply [2–4]. These limitations have prompted the search for alternative anesthetic agents.

Remimazolam, a novel ultra-short-acting benzodiazepine, has been approved for general anesthesia and procedural sedation in several countries [5]. It acts on γ-aminobutyric acid type A ($GABA_A$) receptors, inducing central nervous system depression [6, 7]. Unlike propofol, remimazolam is metabolized by nonspecific plasma cholinesterase rather than hepatic or renal pathways [8]. It offers advantages such as rapid onset, minimal respiratory and circulatory depression, stable hemodynamics, lower incidence of hypotension, rapid emergence, and reversibility with flumazenil [9, 10].

Randomized controlled trials have compared the safety and efficacy of remimazolam and propofol. For instance, Chen et al. reported similar anesthetic efficacy in elderly patients undergoing gastroscopy but found a lower incidence of injection pain and adverse effects with remimazolam [7]. Other studies highlight remimazolam's reduced hypotensive effects [11, 12], suggesting its potential as a safer alternative to propofol [13, 14].

While most studies focus on adults, data on pediatric patients remain limited despite their distinct physiological and metabolic characteristics [15]. This is particularly relevant for general anesthesia with laryngeal mask airway (LMA) insertion in children. Remimazolam's advantages may make it more suitable for pediatric use. Emergence profiles, key indicators of anesthetic efficacy, influence complications such as postoperative nausea, dizziness, disorientation, recovery time, and patient satisfaction [16, 17]. However, limited research has evaluated the effects of remimazolam versus propofol on emergence profiles in children undergoing general anesthesia with LMA insertion.

This prospective, randomized, double-blind clinical trial compares the effects of remimazolam combined with flumazenil versus propofol on emergence profiles in pediatric patients undergoing general anesthesia for strabismus correction surgery. By reflecting real-world clinical practices, where flumazenil is routinely used, this study aims to evaluate awakening speed, emergence comfort, and hemodynamic stability, contributing to the optimization of pediatric anesthesia management.

Materials and methods

Materials

Remimazolam tosilate for Injection was provided by Jiangsu Hengrui Pharmaceuticals Co., Ltd (China). Propofol Injection was provided by Fresenius Kabi (Gemany). Remifentanil Hydrochloride and Flumazenil for Injection was provided by Jiangsu Nhwa Pharmaceutical Co., Ltd (China). Atropine Sulfate Injection was provided by Chengdu Brilliant Pharmaceutical Co., Ltd (China).

Patients (Participants)

We selected 60 children aged 3–12 years who underwent general anesthesia for strabismus correction surgery at Ningbo Aier Guangming Eye Hospital from June to August 2024. The patients were randomly divided into the remimazolam group (Group Rm) and the propofol group (Group Pf), with 30 patients in Group Rm and 30 patients in Group Pf, using a random number table method. Each patient was assigned a unique identification number. Patients were then allocated to the two groups based on the sequence of the randomized numbers. The group allocation was concealed within an envelope, which the anesthesiologist opened upon the patient's entry into the operating room. Consequently, the anesthesiologists were aware of the group assignments to properly administer the medication. However, this information was not disclosed to the follow-up investigators or the patients [18].

Inclusion Criteria: (1) Age 3–12 years; (2) BMI 14–25 kg/m^2; (3) American Society of Anesthesiologists (ASA) classification of I or II; (4) Suitable for laryngeal mask airway (LMA) insertion.

Exclusion Criteria: (1) History of neurological or psychiatric disorders; (2) Anticipated difficult airway or difficult mask ventilation; (3) Need for additional anesthesia methods other than the local infiltration of extraocular muscles specified in this study protocol (e.g., local anesthesia at other sites or regional nerve blocks); (4) Asthma, pneumonia, or active upper respiratory tract infection; (5) Known use of drugs that interact with benzodiazepines, such as sedative-hypnotics, proton pump inhibitors, or certain antibiotics; (6) History of long-term use of benzodiazepines; (7) Allergy to benzodiazepines, propofol, or opioids.

Withdrawal Criteria: (1) Patients who did not meet the inclusion criteria or whose guardians requested withdrawal from the trial were excluded; (2) Patients with incomplete clinical data records or missing measurements were also excluded.

Anesthesia induction

Upon arrival in the operating room, patients had an intravenous line opened, and standard monitors were used to measure non-invasive blood pressure, electrocardiogram, and pulse oximetry. Atropine (0.01 mg/kg) was administered intravenously before induction. Each patient received preoxygenation with 100% oxygen while breathing spontaneously before anesthesia induction.

Induction commenced with the Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scoring [19]. A single anesthesiologist slowly administered the induction drugs intravenously. Group Rm: During anesthesia induction, remifentanil (2 μg/kg) and remimazolam (0.3 mg/kg) were injected sequentially over 2 min. If consciousness was not lost, an additional 0.1 mg/kg (maximum dose 0.45 mg/kg) could be given once. Group Pf: During anesthesia induction, remifentanil (2 μg/kg) and propofol (2 mg/kg) was injected over 2 min, with a single additional dose of 1 mg/kg if required.

After the administration of remimazolam or propofol, the patients were observed for 150 s. Another anesthesiologist, who was blinded to the drug dosage, assessed the loss of consciousness (LOC) using the MOAA/S score. LMA was inserted upon successful induction (MOAA/S score of 0).

Additionally, local anesthesia was administered before the procedure. Specifically, sub-Tenon's local infiltration was performed near the origin of the target extraocular muscle, using 0.1–0.3 mL of 2% lidocaine solution. Postoperatively, if the face, legs, activity, cry, consolability (FLACC) score exceeded 3, oral diclofenac sodium was administered for analgesia.

Anesthesia maintenance

After the LMA was inserted, anesthesia was maintained using either remimazolam or propofol. Remimazolam was infused at a rate of 1–2 mg/kg/h, while propofol was infused at a rate of 4–12 mg/kg/h. Remifentanil was continuously infused at a rate of 0.2 μg/kg/min to maintain the depth of anesthesia.

Monitoring of vital signs and indicators

The administration of remimazolam or propofol, as well as remifentanil, was stopped 5 min before the end of the surgery. Vital signs were recorded at the following time points: baseline before anesthesia (T0), at the LOC (T1), immediately after LMA insertion (T2), 1 min after LMA insertion (T3), and 3 min after LMA insertion (T4). The monitored indicators included systolic blood pressure (SBP), diastolic blood pressure (DBP), saturation of peripheral oxygen (SpO_2), and heart rate (HR).

During the study, if a patient's SBP decreased by more than 30% from baseline, 2 μg of norepinephrine was administered intravenously. If the HR dropped below 60 bpm, 0.01 mg/kg of atropine was injected.

Emergence profiles assessment

In the Group Rm, flumazenil (0.2–0.3 mg) was administered post-surgery to antagonize remimazolam; the time and dosage of flumazenil were recorded. The time to the first eye opening and the time to LMA removal were also documented. The primary outcome was the time from the discontinuation of anesthetic agents to the first eye opening. The secondary outcomes included the time from the end of surgery to LMA removal, time to the first MOAA/S score of 5 after LMA removal, and Aldrete score during the postanesthetic care unit (PACU) stay. PACU nurses, who were blinded to the group assignments, measured the Aldrete score every 5 min and assessed the level of consciousness to determine whether re-sedation had occurred. Patients with an Aldrete score of ≥ 9 were allowed to return to their ward [20, 21].

Statistical analysis

The clinical sample size for this study was calculated based on the primary outcome (emergence time). Preliminary pilot data from our pre-experiment indicated a mean emergence time of 156.7 ± 68.1 s ($n = 6$) for Group Rm, while 291.5 ± 188.4 s for Group Pf ($n = 6$). Using PASS 15.0 software (NCSS, Kaysville, UT, USA), we determined the required sample size with a significance level (α) set at 0.05 (two-tailed) and a statistical power of 0.90. Considering a potential dropout rate of 20% and assuming an equal allocation ratio (1:1) between the Group Rm and Group Pf, the final calculated sample size was 60 participants, who would be randomly assigned to either Group Rm or Group Pf.

Statistical analysis was performed using GraphPad Prism 8.0 (GraphPad Software Inc., San Diego, CA, USA). Normally distributed continuous data were expressed as mean ± standard deviation (SD) and compared between groups using an independent samples t-test. Categorical data were expressed as counts (percentage) and compared between groups using the chi-square test or One-way ANOVA. A p-value of less than 0.05 was considered statistically significant.

Results

Patient information

A total of 60 patients were included in this study, with 30 patients assigned to the Group Rm and 30 patients assigned to the Group Pf (Fig. 1). The baseline demographic and clinical characteristics of the two groups were comparable. There were no significant differences between the groups in terms of gender, age, height, weight, BMI, and ASA Physical Status Classification (Table 1). The surgery durations were also similar

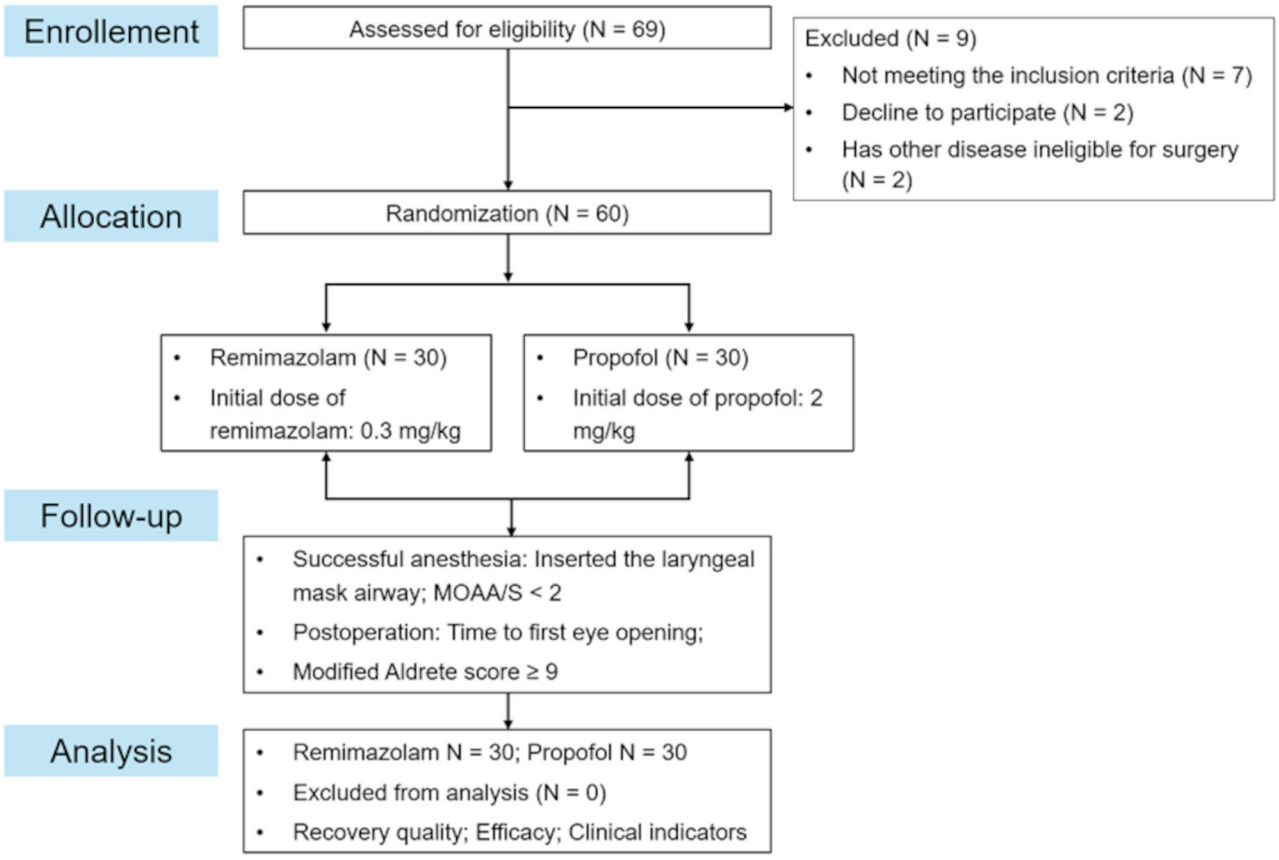

Fig. 1 Flow diagram of the study

Table 1 Basic patient demographics

	Group Rm (*N* = 30)	Group Pf (*N* = 30)	p_value
Sex (Male/Female)	16/14	13/17	$p = 0.438$
Age (Year)	8.5 ± 2.8	8.1 ± 2.8	$p = 0.582$
Weight (kg)	34.6 ± 14.3	33.1 ± 15.3	$p = 0.696$
Height (cm)	137.0 ± 19.2	134.6 ± 19.4	$p = 0.632$
BMI (kg/m^2)	17.6 ± 3.1	17.4 ± 3.4	$p = 0.813$
ASA Physical Status Classification			
ASA-I	30 (100%)	30 (100%)	/
Surgical time (s)	2354 ± 1135	2022 ± 1302	$p = 0.297$

between the two groups. All 60 patients completed the study.

Differences in emergence profiles

To compare the effects of remimazolam and propofol on postoperative emergence profiles, four key indicators were introduced: time to first eye opening, time to LMA removal, time to achieve a MOAA/S score of 5, and the number and timing of patients reaching an Aldrete score of 9 in the PACU (Table 2). Due to the use of flumazenil to antagonize remimazolam post-surgery, the times to first eye opening, LMA removal, and achieving a MOAA/S score of 5 were significantly shorter in the Group Rm compared to the Group Pf. The time to first eye opening was 74.3 ± 46.5 s in the Rm group and 392.1 ± 174.3 s in the Pf group, showing a significant difference ($p < 0.0001$). The time to LMA removal was 76.8 ± 16.3 s in the Rm group and 395.7 ± 174.6 s in the Pf group, also significantly different ($p < 0.0001$). The time to achieve a MOAA/S score of 5 was 80.2 ± 46.4 s in the Rm group and 401.3 ± 174.4 s in the Pf group, with a statistically significant difference ($p < 0.0001$).

In the PACU, the proportion of patients achieving an Aldrete score of ≥ 9 on the first assessment was 83.3% in the Group Rm and 36.7% in the Group Pf, with a significant difference ($p < 0.0001$). After 10 min in the PACU,

Table 2 Comparison of anesthesia effects and postoperative emergence profiles between remimazolam and Propofol

	Group Rm ($N=30$)	Group Pf ($N=30$)	p_value
Anesthesia induction, time to LOC	53.1 ± 13.5	49.6 ± 11.2	$p=0.279$
Success rate of anesthesia	100%	100%	/
Time to the first eye opening (s)	74.3 ± 46.5	392.1 ± 174.3	$p<0.0001$
Time to LMA removal (s)	76.8 ± 16.3	395.7 ± 174.6	$p<0.0001$
Postoperation, time to the first MOAA/S score = 5 (s)	80.2 ± 46.4	401.3 ± 174.4	$p<0.0001$
Patients satisfying PACU discharge criteria (modified Aldrete score ≥ 9)			
Upon arrival, N (%)	25 (83.3)	11 (36.7)	$p<0.0001$
After 10 min, N (%)	30 (100)	21 (70.0)	$p=0.0011$
After 20 min, N (%)	30 (100)	30 (100)	/

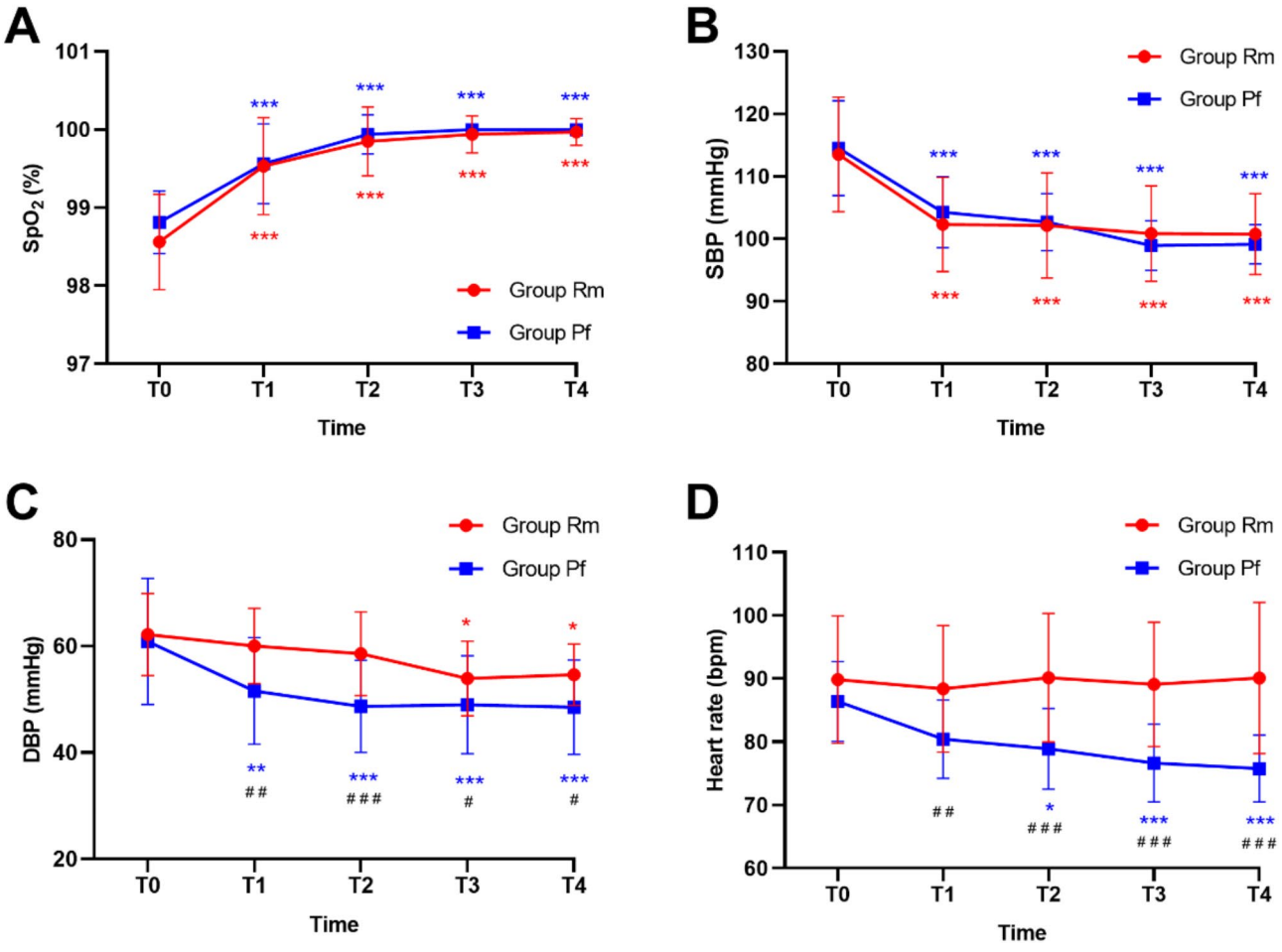

Fig. 2 Effects of remimazolam and propofol on SBP, DBP, HR, and SpO_2. $^{*}p<0.05$, $^{**}p<0.01$, $^{***}p<0.001$ for T0 versus T1, T2, T3, and T4 in Group Rm or Pf. $^{\#}p<0.05$, $^{\#\#}p<0.01$, $^{\#\#\#}p<0.001$ for the Group Pf versus Group Rm

100% of patients in the Group Rm achieved an Aldrete score of ≥ 9, compared to 70.0% in the Group Pf. After 20 min in the PACU, 100% of Group Pf patients reached an Aldrete score of ≥ 9.

Changes in vital signs and clinical indicators

After the administration of remimazolam or propofol, we continuously monitored the patients' vital signs and hemodynamic profiles (Table 2; Fig. 2). The degree of LOC was assessed using the MOAA/S score. The time from the start of anesthesia to LOC showed no significant difference between the Group Rm and Group Pf ($p=0.279$). In both groups, anesthesia was successfully induced in all patients.

Compared to baseline values (T0), the SpO_2 significantly increased from T1 to T4 after the injection of remimazolam or propofol ($p<0.001$), with no significant difference between the two groups. Both remimazolam

Table 3 Adverse events

Adverse events	Group Rm ($N=30$)	Group Pf ($N=30$)
Hypoxaemia	0/30	0/30
Bradycardia	0/30	0/30
Nausea	1/30	0/30
Vomiting	0/30	0/30
Choking and coughing	0/30	0/30
Dysphoria	0/30	0/30
Dizziness	1/30	0/30
Re-sedation	0/30	0/30
Laryngospasm	0/30	0/30

and propofol caused a significant decrease in SBP ($p<0.001$), but the reduction remained within a safe range of less than 20%. During T1-T4, both remimazolam and propofol led to a decrease in DBP, but the reduction in DBP was significantly greater in the Group Pf compared to the Group Rm ($p<0.05$). Regarding HR, remimazolam did not cause significant fluctuations during T1-T4, while propofol significantly reduced HR ($p<0.001$); the reduction in HR was significantly greater in the Group Pf compared to the Group Rm ($p<0.001$).

Adverse events

During anesthesia and emergence, one patient in the Group Rm experienced nausea without vomiting, and another patient experienced dizziness (Table 3). These symptoms were mild and resolved spontaneously without any medical intervention. No other adverse reactions were observed. In the Group Pf, no patients experienced nausea, vomiting, agitation, dizziness, coughing, or bradycardia. Notably, our findings demonstrated that no re-sedation occurred in either Group Rm or Group Pf, regardless of whether patients were in PACU or had already been discharged. Additionally, no cases of laryngospasm were observed in either Group Rm or Group Pf.

Discussion

In recent years, several studies have been published comparing the effects of remimazolam and propofol on the emergence profiles after anesthesia. These studies have shown differences in emergence between the two drugs, providing valuable insights into their comparative efficacy [22]. However, these studies have primarily focused on adult populations. Given remimazolam's potential advantages, it may be more suitable for pediatric general anesthesia.

This study, conducted as a Randomized Controlled Study, investigated the safety and efficacy of remimazolam and propofol in pediatric patients undergoing strabismus correction surgery, with a particular focus on the differences in emergence profiles between the two anesthetics. We focused on evaluating the differences in emergence profiles between remimazolam and propofol postoperatively. Our results showed that remimazolam combined with flumazenil significantly outperformed propofol in terms of emergence quality. The times to first eye-opening, LMA removal, and achieving a MOAA/S score of 5 were all significantly shorter in the Group Rm compared to the Group Pf. Upon arrival at the PACU, the number of patients with an Aldrete score ≥ 9 was significantly higher in the Group Rm compared to the Group Pf. The shorter emergence time is associated with the antagonistic effect of flumazenil. The use of flumazenil is advantageous as it can be used clinically as a specific antagonist of benzodiazepines in cases of delayed recovery, further shortening emergence time and significantly reducing adverse events [23]. Oh et al. reported that among patients who arrived at the PACU, 88% of those in the remimazolam plus flumazenil group achieved an Aldrete score ≥ 9, compared to 68% in the Group Pf, with a significant difference ($p=0.028$) [17]. A comparative study on patients undergoing general anesthesia for endotracheal tumor resection or stent implantation showed that the emergence time after general anesthesia with remimazolam-flumazenil was shorter than with propofol, with no significant hemodynamic fluctuations or adverse events between the two drugs [23]. In a study on cirrhotic patients undergoing general anesthesia, remimazolam combined with flumazenil resulted in shorter recovery times and shorter PACU stays compared to the Group Pf [24]. A meta-analysis indicated that compared to propofol, remimazolam combined with flumazenil resulted in faster extubation, shorter PACU stays, and a lower risk of respiratory depression [22].

In other studies where flumazenil was not used, remimazolam generally required a longer emergence time compared to propofol. In patients undergoing cerebral endovascular procedures, the mean time to emergence from anesthesia was 16.1 min in the remimazolam group vs. 19.0 min in the propofol group [25]. In our study, the combination of flumazenil with remimazolam led to a significantly shorter emergence time. These findings indicated that remimazolam combined with flumazenil offers potential advantages in postoperative emergence profiles compared to propofol.

Our clinical research also found that the induction times and success rates of anesthesia for remimazolam and propofol were similar, indicating that both remimazolam and propofol can be used for general anesthesia in children. Regarding hemodynamic profiles, propofol led to a significant decrease in DBP, whereas the DBP in the Group Rm was more stable compared to the Group Pf. The significant decrease in DBP caused by propofol may be due to its ability to directly relax vascular smooth muscle through direct or indirect vasodilator effects [26]. This is consistent with studies in adults. In a study on adult patients undergoing outpatient surgery

under general anesthesia, the decrease in SBP and DBP in the Group Pf was greater than that in the Group Rm [27]. In another study on adult patients undergoing hysteroscopic surgery, the mean arterial pressure (MAP) in the Group Pf was lower than that in the Group Rm at T1-T4 [28]. Regarding heart rate, the Group Rm showed minor fluctuations, while the Group Pf showed a significant decrease from T1 to T4 compared to T0. This is consistent with previous findings, which indicate that propofol leads to a greater reduction in heart rate compared to remimazolam [27, 28]. These results suggest that remimazolam provides more stable hemodynamic characteristics, demonstrating significant advantages.

From an alternative perspective, it remains to be elucidated whether the circulatory inhibition effects of remimazolam or propofol are attributed to pharmacological interactions between remifentanil and these anesthetic agents. Current evidence suggests that propofol combined with remifentanil produces a stronger inhibitory effect on the circulatory system [29] However, the effects of combining remimazolam with remifentanil on the circulatory system have not been fully investigated. Previous studies have demonstrated that the coadministration of remimazolam with higher concentrations of remifentanil resulted in a more pronounced incidence of cardiovascular depression compared to regimens utilizing lower remifentanil doses [30, 31]. In our study, remimazolam combined with flumazenil resulted in less circulatory depression. This outcome may be attributed to factors such as dosing regimens, surgical type, and patient age.

Currently, there is limited research on the use of remimazolam in children, but some exploratory clinical trials have demonstrated that remimazolam can provide safe and effective sedation and anesthesia for pediatric procedures [32]. In a clinical study involving 48 pediatric patients (mean age 7.0 years), remimazolam provided a safe and effective sedation pathway for pediatric populations [33]. Another clinical study, which included 418 children (mean age 4.6 years), who underwent general endotracheal anesthetic, demonstrated that they met the discharge criteria within an average of 13.8 min after arrival at the PACU. This suggests that remimazolam may offer the benefit of rapid emergence after general endotracheal anesthesia [34]. Another important consideration is that the correlation between remimazolam and the bispectral index (BIS) remains controversial, particularly in pediatric populations where this relationship has not been fully investigated [35]. Consequently, BIS monitoring was not incorporated into the assessment parameters of the present study.

Previous studies have shown that remimazolam causes fewer adverse reactions compared to propofol. Remimazolam appears to result in better emergence profiles due to fewer side effects, such as less nausea, vomiting, and hallucinations. In a study on patients undergoing hysteroscopy under general anesthesia, the total incidence of adverse events in the Group Rm was only 3.7%, whereas it reached 36.6% in the Group Pf [13]. In our study, two patients in the Group Rm experienced nausea, but no vomiting occurred; one patient experienced dizziness. These symptoms were mild and resolved spontaneously without medication. However, no adverse reactions were observed in the Group Pf. The adverse reactions in the Group Rm might be related to the type of surgery (strabismus correction surgery) rather than the drug itself.

Furthermore, previous studies have indicated a certain probability of re-sedation after remimazolam administration. Oh et al. reported a re-sedation rate of 22% with remimazolam combined with flumazenil, whereas no re-sedation occurred in the Group Pf [17]. In our study, no re-sedation was observed in either the Group Rm or Group Pf. Remimazolam exhibits a high clearance rate and short half-life (67 min) in pediatric patients, enabling its rapid offset of action. Additionally, the metabolite CNS7054 of remimazolam is inactive, further reducing the risk of re-sedation. Moreover, flumazenil demonstrates a mean half-life of 40 min in children, which parallels the pharmacokinetic profile of remimazolam. This temporal congruence effectively prevents receptor reoccupation by remimazolam following flumazenil metabolism, thereby mitigating the risk of re-sedation [36]. Beyond these factors, this could be also related to the dose of anesthetic and flumazenil, the type of surgery, and the patients' gender and body mass index [37]. However, further research is needed to elucidate this phenomenon. In summary, both remimazolam and propofol have low adverse reaction rates and high safety profiles.

There are several limitations to this study. First, the study included relatively healthy pediatric patients, all classified as ASA I. The lack of diversity among patients limits the generalizability of our findings. Therefore, further research is needed to evaluate the feasibility of using remimazolam in pediatric patients with higher ASA classifications (e.g., ASA II or above), as its safety profile in these populations remains insufficiently studied. Second, all patients in this study underwent general anesthesia for strabismus correction surgery, resulting in a uniform surgery type. This limits our ability to generalize the findings across different types of surgeries. Third, the use of flumazenil as a specific antagonist for remimazolam may have influenced the emergence profiles observed in this study. While flumazenil is routinely used in clinical practice to reverse remimazolam's effects and ensure rapid recovery, its administration limits the ability to isolate the intrinsic recovery characteristics of remimazolam. This study reflects real-world clinical scenarios, but future research should explore the recovery profiles

of remimazolam without flumazenil to provide a more comprehensive understanding of its pharmacodynamic properties. Fourth, MOAA/S was used as the primary tool to assess emergence profiles. Although MOAA/S is widely used in clinical studies and has been shown to be effective in evaluating recovery, it may be influenced by external factors such as individual variability and environmental stimuli. Future research should consider incorporating additional objective monitoring tools, such as BIS or entropy, to validate recovery assessments. Finally, the sample size in this study was small. Larger-scale, multicenter comparative studies are needed to confirm the safety and efficacy of remimazolam in pediatric general anesthesia. Further research in other pediatric populations is necessary to better understand its potential advantages and limitations.

Conclusion

This study focused on pediatric patients undergoing strabismus correction surgery, aiming to fill the current research gap by directly comparing the effects and postoperative emergence profiles of remimazolam and propofol. Our study demonstrated that remimazolam and propofol have similar anesthesia induction times. Remimazolam offers more stable respiratory and hemodynamic characteristics. Additionally, remimazolam combined with flumazenil significantly outperformed propofol in terms of emergence outcomes, particularly in accelerated emergence. However, further clinical research and data are necessary to verify its safety and efficacy in pediatric populations. Moreover, future research should refine the dosing for different pediatric age groups, assess the long-term cognitive effects, and explore optimal drug combinations to enhance pediatric anesthesia management.

Abbreviations

Rm	Remimazolam
Pf	Propofol
LMA	Laryngeal mask airway
MOAA/S	Modified Observer's Assessment of Alertness/Sedation
PACU	Postanesthetic care unit
ASA	American Society of Anesthesiologists (ASA)
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
SpO_2	Saturation of peripheral oxygen
HR	Heart rate
LOC	Loss of consciousness

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12871-025-03050-w.

Supplementary Material 1

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Author contributions

All authors contributed to this paper. JLQ, WG, QL: Methodology, Investigation, Data collection, Writing—Original Draft. XLZ: Conceptualization, Formal analysis. XYL: Methodology, Data collection. BL, QS: Supervision, Writing—Reviewing. All authors read and approved the final manuscript.

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Data availability

The datasets used or analysed during the current study are available from the corresponding authors on reasonable request.

Declarations

Ethics approval

The present study followed the Declaration of Helsinki. This study was approved by the Medical Ethics Committee of Ningbo Aier Guangming Eye Hospital (SL-AIER-KY-2024-08).

Consent to participate

Informed consent was obtained from all subjects and/or their legal guardians.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Consort guidelines

This study followed the Consolidated Standards for Reporting Trials (CONSORT) guidelines, and the CONSORT checklist was submitted as an additional document.

Study registration

Chinese Clinical Trial Registry, ChiCTR2400083265. Registered 04/19/2024, http://www.chictr.org.cn.

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