Research Square

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Remimazolam versus Propofol for General Anesthesia in Elderly Patients Undergoing TAVI: A Randomized Controlled Trial

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Abstract

Background

Remimazolam, a novel short-acting benzodiazepine, has emerged as a potential alternative to propofol for anesthesia. This study aimed to examine the effectiveness and safety of remimazolam compared to propofol for anesthesia in elderly patients undergoing transcatheter aortic valve implantation (TAVI) procedures.

Methods

We conducted a single-center, prospective, randomized controlled, non-inferiority trial in elderly patients undergoing TAVI under general anesthesia with a laryngeal mask airway (LMA). The eligibility criterion was age 65 to 80 years. Of 118 patients assessed for eligibility, 76 met the inclusion criteria and were randomized (39 remimazolam, 37 propofol). Patients were blinded to allocation; the treating anesthesiologist, who administered the agents and recorded the emergence times, was not blinded. The primary outcome was time to LMA removal, with a prespecified non-inferiority margin of 2 minutes.

Results

The remimazolam group demonstrated significantly faster recovery: LMA removal time was 9.7 ± 1.5 minutes versus 20.8 ± 2.0 minutes in the propofol group (mean difference − 11.1 minutes, 95% confidence interval (CI) − 11.9 to − 10.3; $p < 0.001$), indicating both non-inferiority and, as a post-hoc observation, superiority. Recovery of consciousness (6.7 ± 1.6 vs. 16.6 ± 2.2 minutes, $p < 0.001$) and time to spontaneous respiration (8.5 ± 1.5 vs. 19.4 ± 2.2 minutes, $p < 0.001$) were also significantly shorter with remimazolam. Total norepinephrine dose was lower in the remimazolam group (0.06 ± 0.03 vs. 0.17 ± 0.05 mg, $p < 0.001$), a descriptive finding not interpreted as evidence of hemodynamic superiority given the prophylactic-infusion protocol. Hospital length of stay did not differ significantly (10 [8–12] vs. 11 [10–13] days, $p = 0.06$).

Conclusions

In elderly patients undergoing TAVI under general anesthesia, remimazolam was associated with significantly faster recovery than propofol and met the prespecified non-inferiority margin for time to LMA removal; the large observed difference is a post-hoc, hypothesis-generating finding. Because the trial was single-center and retrospectively registered, these results should be interpreted with caution and require confirmation in protocolized, prospectively registered multicenter trials.

Trial registration:

Chinese Clinical Trial Registry (ChiCTR; https://www.chictr.org.cn/), ChiCTR2500109737. Registered on 24 September 2025; retrospectively registered.

Background

Transcatheter aortic valve implantation (TAVI) has revolutionized the treatment of severe aortic stenosis, particularly in elderly patients who are at high risk for traditional open-heart surgery [1]. As the global population ages, TAVI procedures are becoming increasingly common, with more than 300,000 performed worldwide each year [2]. The success of TAVI procedures depends not only on technical expertise but also on optimal anesthetic management that accommodates the unique physiological challenges of elderly patients [3].

Currently, propofol is the most commonly used anesthetic agent during TAVI procedures because of its rapid onset and short duration of action [4]. However, using propofol in elderly patients is a concern because propofol's efficacy is dependent on blood pressure and respiratory depression, which may highly fluctuate in elderly patients, considering their pre-existing health concerns and diseases [5]. These adverse events of using propofol may lead to increased demand for vasopressor support, airway interventions, and a prolonged recovery period [5]. Remimazolam is a short-acting benzodiazepine that has been considered as an alternative anesthetic agent because of its rapid onset of action, safe recovery, and metabolism that is largely, though not entirely, independent of organ function, relying on tissue esterases [6]. Additionally, remimazolam has an excellent hemodynamic profile compared to many other anesthetic agents [6].

Elderly patients undergoing TAVI present distinct anesthetic challenges due to age-related changes in pharmacokinetics and pharmacodynamics, increased comorbidity burden, and heightened sensitivity to anesthetic agents [7]. As people age, their physiology affects drug metabolism since hepatic and renal function do not work efficiently, resulting in altered protein binding and changes in volume of distribution. These issues require very careful selection of anesthetic agents among the elderly patients to ensure rapid recovery while maintaining hemodynamic stability throughout the procedure [8, 9]. Remimazolam has been evaluated against propofol in several anesthesia settings, with reports of comparable efficacy and more stable hemodynamics [10–12]. Theoretically, remimazolam could be an alternative anesthetic agent for elderly patients undergoing TAVI procedure. However, comparative evidence between remimazolam and propofol in the TAVI procedure among the elderly population is very rare. Therefore, this study aimed to conduct a non-inferiority randomized controlled trial to evaluate and compare the efficacy and perioperative outcomes between remimazolam and propofol.

Methods

Study Design and Setting

This single-center, prospective, randomized controlled trial was conducted at the Fuwai Central China Cardiovascular Hospital between January 2024 and September 2025 (Fig. 1). The study was designed as a non-inferiority trial for the primary outcome; comparisons of secondary outcomes were exploratory and any superiority interpretation is post-hoc. The protocol was approved by the hospital's Institutional Review Board and registered with the Chinese Clinical Trial Registry (ChiCTR2500109737). Registration occurred on 24 September 2025, at the end of the enrollment period (January 2024 to September 2025) and after data collection was substantially complete; the trial was therefore retrospectively registered, and the prespecification of outcomes and analyses cannot be independently verified (see Limitations). The reporting of this randomized controlled trial followed the CONSORT 2025 guidelines. A completed CONSORT 2025 checklist is provided as an additional file.

Participants

The protocol specified an eligibility criterion of age 65 to 80 years. Of 118 patients assessed for eligibility, 76 met the inclusion criteria and were randomized (39 remimazolam, 37 propofol); the remaining 42 were excluded before randomization (30 outside the 65 to 80 year age range, 6 for other inclusion criteria, and 6 who declined to participate) (Fig. 1). Eligible patients had severe aortic stenosis scheduled for elective TAVI and were aged 65 to 80 years per the protocol eligibility criterion. Patients were excluded if they had a known allergy to the study drugs, severe hepatic dysfunction (excluded because impaired hepatic function alters the metabolism of anesthetic agents and would confound recovery-time comparisons; a specific laboratory threshold was not prespecified in the protocol, and standard clinical criteria were applied), or an inability to provide informed consent. Written informed consent was obtained from all participants before enrollment. All TAVI procedures were performed via transfemoral access, and all participants were hospitalized (inpatient) for the procedure.

Randomization and Blinding

Participants were randomly assigned in a 1:1 ratio using a computer-generated sequence, with allocation concealment via sealed opaque envelopes. Patients were blinded to group allocation. The study drugs were prepared and reconstituted by the hospital pharmacy, with the syringes covered by an opaque black bag, and were delivered through opaque, light-protective infusion tubing with pumps displaying only the infusion rate (mL/h); flumazenil, a benzodiazepine-specific antagonist effective only against remimazolam, was administered in only one remimazolam-group patient (see Interventions) and therefore did not materially compromise blinding. Because the treating anesthesiologist administered the agents and recorded the emergence times, the primary and recovery (time-based) outcomes were, of necessity, recorded by an unblinded assessor; the trial was therefore patient-blinded but not assessor-blinded for these endpoints, which is acknowledged as a limitation.

Interventions

Anesthesia was induced and maintained with either remimazolam or propofol according to standardized institutional protocols, and all procedures were performed under general anesthesia with a laryngeal mask airway (LMA). In both groups, general anesthesia was induced with sufentanil and the neuromuscular blocking agent rocuronium, the LMA was coated with lidocaine cream before insertion, and remifentanil was used for intraoperative analgesia during maintenance. In the remimazolam group, anesthesia was induced with remimazolam 0.1 mg/kg and maintained with a continuous infusion of 0.3–0.7 mg/kg/h. In the propofol group, anesthesia was induced with propofol 1–1.5 mg/kg and maintained with a continuous infusion of 4–10 mg/kg/h. In both groups, the maintenance infusion was titrated to a target depth of anesthesia defined by a Bispectral Index (BIS) of 40–60 together with the Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale. All patients received a prophylactic norepinephrine infusion (0.02–0.05 μg/kg/min) per institutional protocol; norepinephrine was the sole vasopressor used, and additional (rescue) norepinephrine was administered when systolic blood pressure fell more than 20% below baseline. At the end of the procedure, neuromuscular block was reversed with neostigmine in both groups; flumazenil was available for remimazolam antagonism but was administered in only one remimazolam-group patient (0.2 mg), for prolonged laryngeal-mask tolerance. Analgesia and neuromuscular blockade were therefore identical in both groups, so that only the hypnotic agent differed between them.

Outcomes

The primary outcome was time to LMA removal (minutes), used as a surrogate for emergence from general anesthesia and measured from discontinuation of the anesthetic agent. LMA removal was performed by the attending anesthesiologist once the patient had fully awakened with recovered spontaneous respiration, on the basis of a formal post-anesthesia recovery assessment encompassing level of consciousness, muscle strength, and respiratory status. Secondary outcomes included time to recovery of consciousness (minutes), assessed using the MOAA/S scale supplemented by the Glasgow Coma Scale (GCS) and responsiveness to verbal command; time to spontaneous respiration (minutes), defined as resumption of adequate unassisted breathing following discontinuation of the anesthetic agent; hospital length of stay (days); and GCS at 30 minutes. Hemodynamic and pharmacological outcomes included total norepinephrine dose (mg). Intraoperative mean arterial pressure and heart rate were recorded at predefined perioperative time points.

Sample Size and Non-Inferiority Margin

The non-inferiority margin for the primary analysis was 2 minutes, chosen on clinical grounds, reflecting the importance of prompt emergence in elderly patients, in whom prolonged recovery may delay post-anesthesia care unit discharge and increase the risk of respiratory and cognitive complications. At the design stage, for patients aged 65 to 80 years with an American Society of Anesthesiologists (ASA) physical status of IV, the sample size was determined for a non-inferiority margin of 2.55 minutes, half the a-priori planning standard deviation for emergence time (based on a prior unpublished study in which

emergence after propofol-based anesthesia was 10.3 ± 5.1 minutes), with a one-sided alpha of 0.025, 80% power, and an assumed true between-group difference of zero minutes under the alternative hypothesis; PASS 15 indicated 128 patients, and allowance for 10% attrition gave a target of 142 (71 per group). In the event, 76 eligible patients aged 65 to 80 years were randomized (39 remimazolam, 37 propofol). The analyzed sample was below the planned size, which is acknowledged as a limitation. The 2-minute clinical margin applied in the primary analysis is more conservative than the 2.55-minute design margin, so non-inferiority is concluded under both.

Statistical Analysis

The analysis included all 76 randomized participants aged 65 to 80 years (39 remimazolam, 37 propofol). Non-inferiority for the primary outcome was concluded if the upper limit of the two-sided 95% confidence interval (CI) for the between-group difference in time to LMA removal lay below the prespecified 2-minute margin. Comparisons of secondary outcomes were exploratory. Continuous variables were analyzed using Student's t-test [13] or the Mann–Whitney U test [14], and categorical variables using the chi-square or Fisher's exact test [15]. Results were reported as mean ± standard deviation or median (interquartile range, IQR), with 95% confidence intervals. A two-sided p-value < 0.05 was considered statistically significant. Because multiple secondary outcomes were tested without formal adjustment for multiple comparisons, secondary findings are exploratory, at increased risk of type I error, and should be interpreted as hypothesis-generating [16].

Results

A total of 118 patients were assessed for eligibility, of whom 76 met the age criterion of 65 to 80 years and the other inclusion criteria and were randomized to receive either remimazolam (n = 39) or propofol (n = 37); the remaining 42 were excluded before randomization (Fig. 1). All randomized participants received the allocated intervention and completed follow-up, with no losses to follow-up.

Baseline Characteristics of the Study Participants

In Table 1, baseline characteristics were well balanced between the remimazolam (n = 39) and propofol (n = 37) groups. There were no statistically significant differences in age, weight, height, or body mass index (BMI).

Table 1
Baseline characteristics of the study participants.

Characteristic	Remimazolam (n = 39)	Propofol (n = 37)	SMD	P-value
Age, years	73.1 ± 4.0	71.6 ± 4.2	0.36	0.12
Male sex, n (%)	24 (61.5)	29 (78.4)	0.37	0.14
Height, cm	161.8 ± 8.7	163.9 ± 6.8	0.26	0.27
Weight, kg	61.9 ± 10.2	64.1 ± 9.3	0.23	0.31
BMI, kg/m²	23.6 ± 3.3	23.8 ± 2.8	0.08	0.73
Hypertension, n (%)	11 (28.2)	8 (21.6)	0.15	0.60
Diabetes mellitus, n (%)	6 (15.4)	8 (21.6)	0.16	0.56
Coronary artery disease, n (%)	35 (89.7)	32 (86.5)	0.10	0.73
NYHA class IV, n (%)	29 (74.4)	25 (67.6)	0.15	0.62
Left ventricular ejection fraction, %	50.3 ± 10.4	52.5 ± 10.1	0.22	0.35

SMD, standardized mean difference; BMI, body mass index; NYHA, New York Heart Association. Continuous variables are presented as mean ± standard deviation; categorical variables as n (%). Comorbidity coding (hypertension, coronary artery disease) follows the per-patient source data provided by the study authors.

The mean age was similar between groups (73.1 ± 4.0 vs. 71.6 ± 4.2 years; p = 0.12). The sex distribution did not differ significantly between groups (male 61.5% vs. 78.4%; p = 0.14), and there were no significant differences in weight, height, or BMI. Comorbid conditions, including hypertension, diabetes mellitus, and coronary artery disease, were evenly distributed, with no statistically significant differences observed.

All patients were in New York Heart Association (NYHA) class III or IV, and the proportion in NYHA class IV was comparable between groups (74.4% vs. 67.6%; p = 0.62). Left ventricular ejection fraction was also similar (50.3 ± 10.4% vs. 52.5 ± 10.1%; p = 0.35). Standardized mean differences (SMD) for all variables were small (≤ 0.37), indicating good balance between groups at baseline (Table 1).

Primary and Recovery Outcomes

The primary outcome, time to LMA removal, was significantly shorter in the remimazolam group than in the propofol group (9.7 ± 1.5 vs. 20.8 ± 2.0 minutes; mean difference − 11.1 minutes, 95% CI − 11.9 to − 10.3; p < 0.001), meeting the prespecified non-inferiority margin; the magnitude of the difference is reported as a post-hoc, exploratory superiority observation (Table 2).

Table 2
Recovery, hemodynamic, and clinical outcomes.

Outcome	Remimazolam (n = 39)	Propofol (n = 37)	Difference (95% CI)	P-value
Time to LMA removal (minute)	9.7 ± 1.5	20.8 ± 2.0	−11.1 (− 11.9, − 10.3)	< 0.001
Recovery of consciousness (minute)	6.7 ± 1.6	16.6 ± 2.2	−9.9 (− 10.8, − 9.1)	< 0.001
Spontaneous respiration (minute)	8.5 ± 1.5	19.4 ± 2.2	−10.8 (− 11.7, − 9.9)	< 0.001
Hospital length of stay (days)	10 [8–12]	11 [10–13]	−1 (− 2, 0)	0.06
Glasgow Coma Scale at 30 min	15 [14–15]	15 [14–15]	0 (0, 0)	0.89
Total norepinephrine dose (mg)	0.06 ± 0.03	0.17 ± 0.05	−0.11 (− 0.13, − 0.10)	< 0.001

LMA, laryngeal mask airway; CI, confidence interval. Normally distributed variables are presented as mean ± standard deviation; non-normally distributed variables as median [interquartile range]. Mean differences were computed from unrounded values; subtraction of the rounded group means shown may differ by up to 0.1 minute.

As illustrated in Fig. 2, recovery times were consistently shorter in the remimazolam group compared to the propofol group across all measured endpoints. Time to LMA removal, recovery of consciousness, and time to spontaneous respiration all favored the remimazolam group, with minimal overlap in variability between groups. All comparisons were statistically significant ($p < 0.001$ for all outcomes).

Consistent with these findings, quantitative analysis showed significantly shorter recovery of consciousness (6.7 ± 1.6 vs. 16.6 ± 2.2 minutes; mean difference − 9.9 minutes, 95% CI − 10.8 to − 9.1; $p < 0.001$) and time to spontaneous respiration (8.5 ± 1.5 vs. 19.4 ± 2.2 minutes; mean difference − 10.8 minutes, 95% CI − 11.7 to − 9.9; $p < 0.001$) in the remimazolam group (Table 2).

Secondary recovery and hemodynamic outcomes are summarized in Table 2. Hospital length of stay did not differ significantly between groups (10 [IQR 8–12] vs. 11 [10–13] days; $p = 0.06$). The Glasgow Coma Scale at 30 minutes did not differ between groups (both median 15 [IQR 14–15]; $p = 0.89$). Total norepinephrine dose was lower in the remimazolam group (0.06 ± 0.03 vs. 0.17 ± 0.05 mg; mean difference − 0.11 mg, 95% CI − 0.13 to − 0.10; $p < 0.001$). Intraoperative mean arterial pressure and heart rate over time are shown in Fig. 3: mean arterial pressure decreased more after induction in the propofol group, whereas it remained relatively stable with remimazolam, while heart-rate trends were similar between groups. These hemodynamic comparisons should be interpreted in light of the limitations noted below. No failures of the assigned anesthetic (the registered outcome termed "sedation failures") occurred in either group; all patients achieved and maintained adequate general anesthesia with the assigned hypnotic agent, and none required conversion to an alternative agent. Transient intraoperative

BIS values below 40 were manually noted in a minority of patients in both groups, were promptly managed by adjusting the infusion rate without adverse sequelae; continuous BIS values were not archived (see Limitations).

Discussion

In this single-center, randomized controlled trial involving elderly patients undergoing TAVI, remimazolam was associated with significantly faster recovery than propofol. Patients receiving remimazolam achieved quicker recovery from anesthesia, as reflected by shorter time to LMA removal, earlier recovery of consciousness, and more rapid return of spontaneous respiration. Remimazolam use was also associated with a lower intraoperative norepinephrine requirement and a more stable mean arterial pressure trajectory, while hospital length of stay remained comparable between groups.

Although the study was designed to demonstrate non-inferiority within a 2-minute margin, the observed between-group difference was approximately 11.1 minutes. An effect of this magnitude is substantially larger than the prespecified margin and larger than typically reported in anesthesia recovery studies. Anesthetic depth was titrated to a common target (BIS 40–60 with MOAA/S) in both groups, so the difference is unlikely to be explained by unequal depth alone; and flumazenil was administered to only one remimazolam patient (0.2 mg, for prolonged laryngeal-mask tolerance), so pharmacological reversal does not account for the group-level recovery difference. Any superiority interpretation nonetheless remains post-hoc, because the trial was designed for non-inferiority, and should be treated with caution. Beyond agent pharmacology, remimazolam's rapid, largely organ-independent metabolism, together with the slower propofol clearance expected in elderly patients with reduced cardiac output and hepatic reserve, may contribute to the difference in emergence times.

Faster emergence is generally considered desirable in elderly patients. We note, as a hypothesis only, that shorter recovery times might be associated with reduced risk of postoperative delirium, aspiration, or prolonged immobilization; however, none of these outcomes were measured in the present study, so this remains speculative and cannot be supported by our data.

The improved recovery profile of remimazolam is consistent with its pharmacological properties [17, 18]. As a short-acting benzodiazepine, remimazolam offers rapid recovery; its clearance depends on tissue esterases rather than the plasma esterases that metabolize remifentanil, and is therefore largely organ-independent [6, 17–21]. Propofol, by contrast, can cause dose-dependent cardiovascular depression [22, 23]. In the present trial, total norepinephrine dose was lower in the remimazolam group; however, because the prophylactic background infusion was given to all patients and neither procedure duration nor a breakdown of background versus rescue dosing was recorded, this difference cannot be interpreted as established evidence of hemodynamic superiority (see Limitations) [24–26].

Length of hospital stay was not significantly different between groups ($p = 0.06$); however, with only 76 of a planned 142 participants, the trial was underpowered to detect a difference in this outcome, so this result should be interpreted as an absence of evidence rather than evidence of no effect.

Several limitations should be considered. First, although the induction and maintenance regimens and the depth-of-anesthesia target (BIS 40–60 with MOAA/S) were defined, the total administered dose of each agent and the procedure and anesthesia durations were not recorded; consequently, drug exposure cannot be normalized to body weight or duration. Second, flumazenil, a benzodiazepine antagonist active only against remimazolam, was administered to only one remimazolam-group patient (0.2 mg, for prolonged laryngeal-mask tolerance) and to no propofol-group patient; pharmacological reversal therefore does not account for the observed group-level difference in recovery, and the recovery comparison reflects the agents themselves. Third, the emergence endpoints (time to LMA removal, recovery of consciousness, and spontaneous respiration) were timed by the treating anesthesiologist, who was not blinded to allocation, so detection bias cannot be excluded and may have contributed to the magnitude of the observed differences. In addition, although recovery endpoints were defined (recovery of consciousness assessed by MOAA/S, with all times measured from discontinuation of the anesthetic agent), the observation that recovery of consciousness sometimes preceded the return of spontaneous respiration is physiologically unexpected, is not fully explained by the recorded data, and warrants confirmation with prospectively defined, blinded endpoint assessment. Fourth, the hemodynamic comparison is limited: because a prophylactic norepinephrine infusion was given to all patients and procedure/anesthesia durations and a background-versus-rescue breakdown were not recorded, total norepinephrine dose cannot be interpreted as definitive evidence of hemodynamic superiority. Fifth, the trial was retrospectively registered, so prespecification of outcomes and analyses cannot be independently verified and outcome switching cannot be excluded. Sixth, multiple secondary outcomes were tested without correction for multiplicity, increasing the risk of type I error, and the design was non-inferiority while the observed effect was large, so any superiority claim is post-hoc. Seventh, TAVI-specific safety endpoints (e.g., new pacemaker implantation, conduction disturbances, paravalvular leak, and 30-day mortality), validated procedural risk scores (e.g., EuroSCORE II, STS), and between-group postoperative complications were not recorded outcomes, limiting clinical interpretation. Eighth, the single-center design and institution-specific protocols, including routine prophylactic norepinephrine, may limit generalizability. Finally, no formal cost-effectiveness analysis was performed. Several of these constraints reflect data that were not collected during the study and cannot be supplied retrospectively; they should be addressed in a future, fully protocolized, prospectively registered multicenter trial. Lastly, continuous bispectral index (BIS) values were not archived and only manual out-of-range observations were available, so depth of anesthesia could not be quantified continuously.

The trial adhered to CONSORT statements [27], with complete follow-up of all randomized participants and no losses to follow-up. Baseline characteristics were well balanced between groups, supporting the internal validity of the comparisons.

From a clinical perspective, these findings suggest that remimazolam may be a preferable anesthetic agent for elderly patients undergoing TAVI, particularly when rapid recovery is desired. However, given the single-center nature of the study and the post-hoc interpretation of superiority, multicenter randomized trials are needed to confirm these results and assess broader applicability across different clinical settings.

These findings can be placed in the context of prior work. In a retrospective analysis of patients with severe aortic stenosis undergoing transcatheter aortic valve replacement, remimazolam required less vasopressor support than propofol during both induction and maintenance of general anesthesia (for example, lower maintenance norepinephrine requirements, 0.019 vs. 0.042 μg/kg/min) [24]. Randomized and observational studies in structural-heart and aortic-valve procedures have similarly reported greater hemodynamic stability and lower vasopressor requirements with remimazolam [28–30], and meta-analyses across broader surgical populations report comparable efficacy with more stable hemodynamics relative to propofol [10–12]. Our observation of lower total norepinephrine use in the remimazolam group is directionally consistent with these reports; however, for the reasons set out in the Limitations, it cannot be regarded as definitive evidence of hemodynamic superiority in this cohort.

Beyond structural-heart procedures, remimazolam has been evaluated across a widening range of surgical and non-operating-room settings. A recent narrative synthesis of cardiac and non-cardiac surgery concluded that, across diverse patient populations, remimazolam offers greater hemodynamic stability, rapid emergence, and minimal respiratory depression relative to propofol, while cautioning that heterogeneity among existing studies limits generalizability [31]. Its pharmacokinetic profile, and in particular the context-sensitive decrement time that underlies its short duration of action, has been highlighted as a key determinant of the faster recovery observed with the agent [32]. This favorable profile also extends beyond the operating room: in a prospective non-inferiority study of high-risk patients undergoing electrical cardioversion for atrial arrhythmia, remimazolam achieved sedation adequacy comparable to propofol with more favorable blood-pressure indices and fewer episodes requiring rescue ventilation [33]. Spanning cardiac and non-cardiac surgery, pharmacokinetic modeling, and non-operating-room sedation, these reports place the present findings in elderly TAVI patients within a broader and consistent body of evidence supporting remimazolam as a short-acting benzodiazepine with a favorable recovery and hemodynamic profile.

Conclusions

This randomized controlled trial found that, in elderly patients undergoing TAVI under general anesthesia, remimazolam was associated with faster recovery than propofol and met the prespecified non-inferiority margin for time to LMA removal. Because the trial was single-center and retrospectively registered, and because it was designed for non-inferiority while the observed effect was large, the larger superiority interpretation is post-hoc and these findings should be regarded as hypothesis-generating. Protocolized, prospectively registered multicenter trials are needed to confirm them.

Declarations

Conflicts of Interest

The authors declare no conflicts of interest.

Ethics approval and consent to participate

The protocol of this study was approved by the Ethics Review Committee (ERC) of Zhengzhou University Central China Fuwai Hospital, affiliated with Henan Provincial People's hospital, on 27 June 2024 ((2024) Ethical Approval No. 37). Written informed consent was obtained from all participants prior to enrollment. The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Author Contribution

This study was designed by P.Q. and H.L. Experiments and data collection were performed by P.Q., H.J., and H.Z. The data were managed and analyzed by X.S. and H.Z., with data visualization prepared by P.Q. and S.S. The initial draft of the manuscript was written by P.Q., and the manuscript was critically reviewed and edited by H.L. The final version of the manuscript was prepared and finalized by P.Q. All authors have approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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Data Availability

The datasets generated and/or analyzed during the current study are not publicly available due to hospital data confidentiality policies but are available from the corresponding author on reasonable request. Requests for access to anonymized data should be directed to the corresponding author.

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Figures

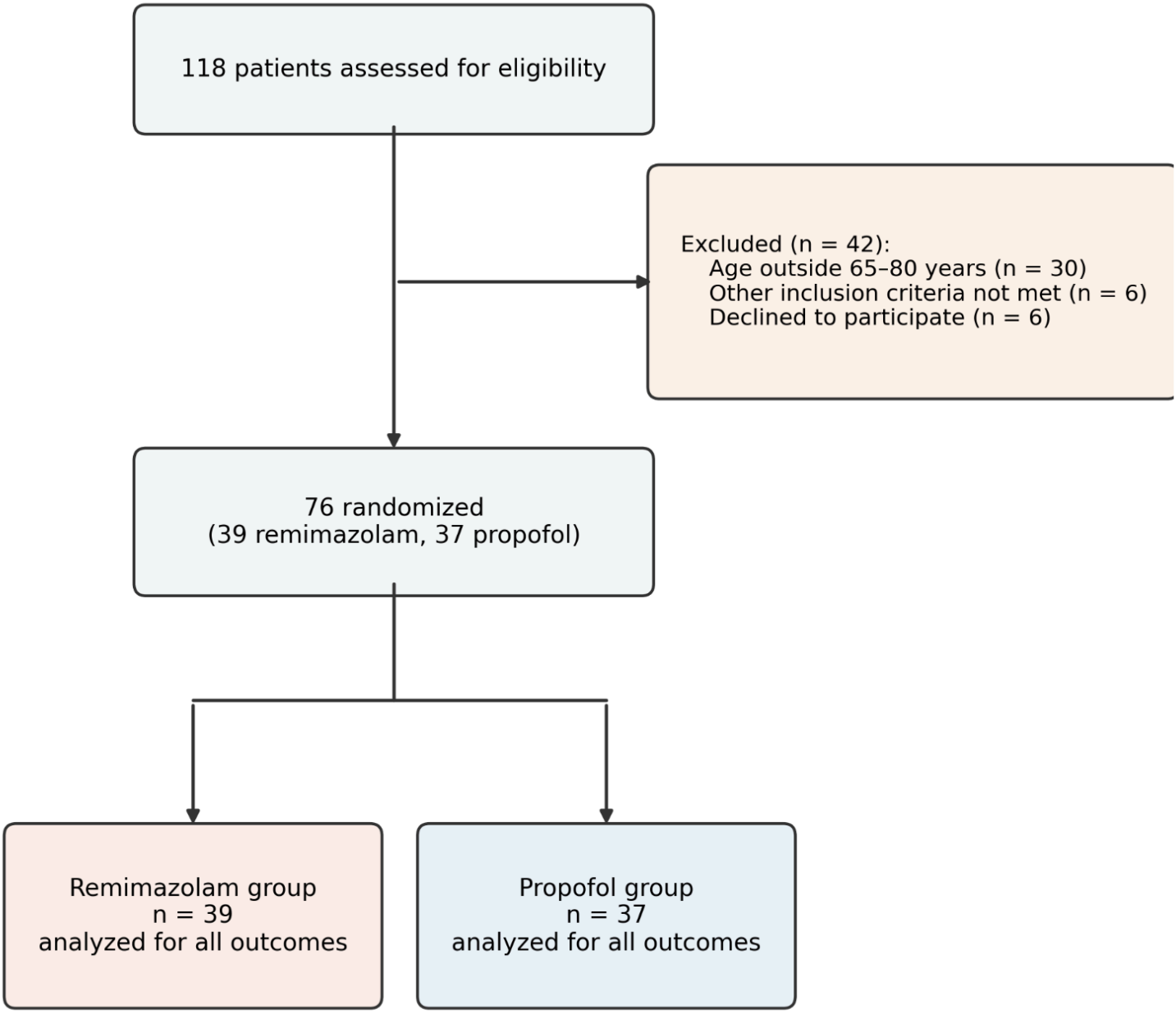


Figure 1

CONSORT Flow Diagram. Flow diagram showing patient enrollment, randomization, and analysis according to CONSORT guidelines.

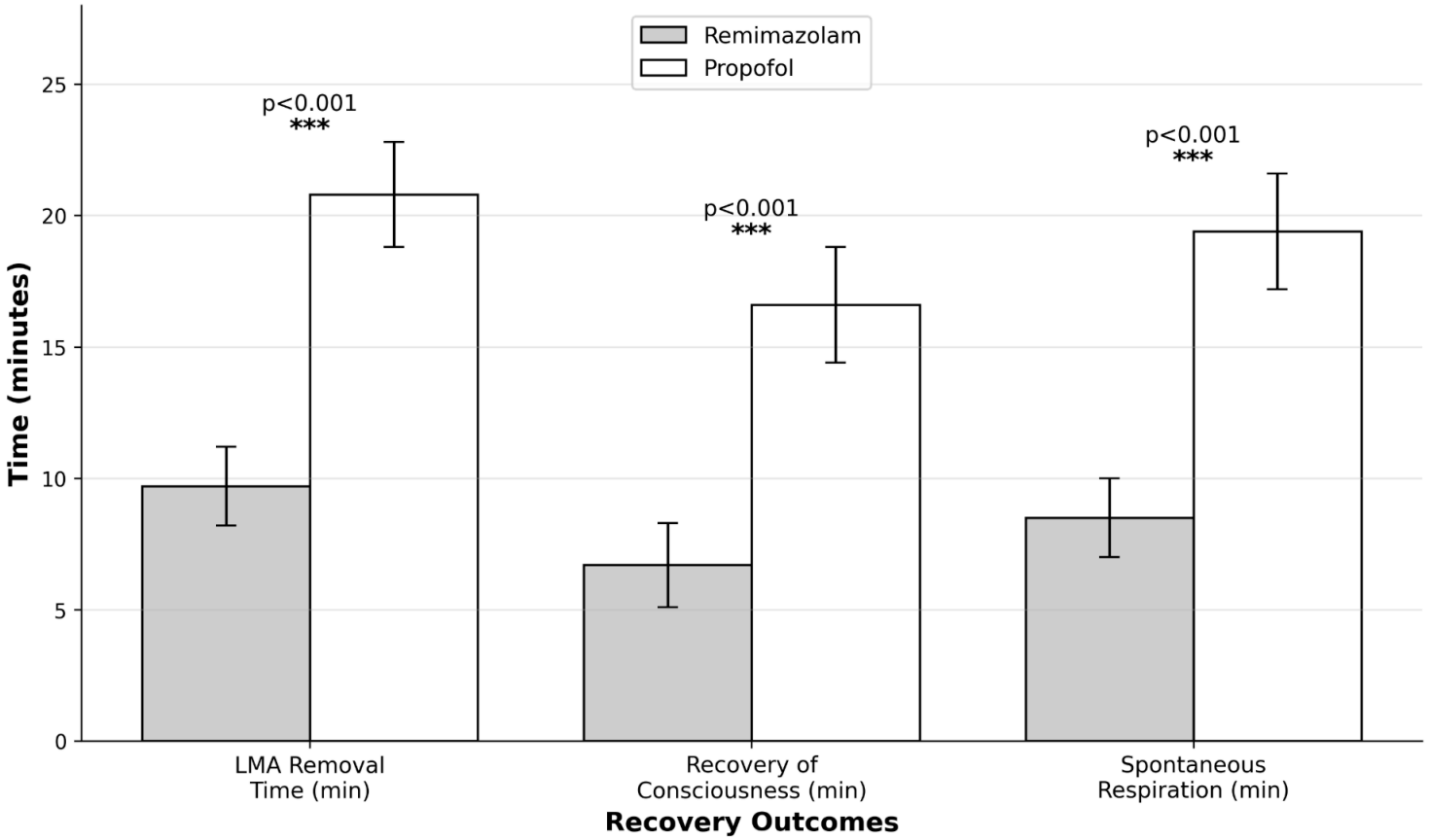


Figure 2

Recovery Time Comparison Between Remimazolam and Propofol Groups. Comparison of time to laryngeal mask airway (LMA) removal, recovery of consciousness, and spontaneous respiration between the remimazolam and propofol groups. Data are presented as mean values with standard deviation. ***p < 0.001.

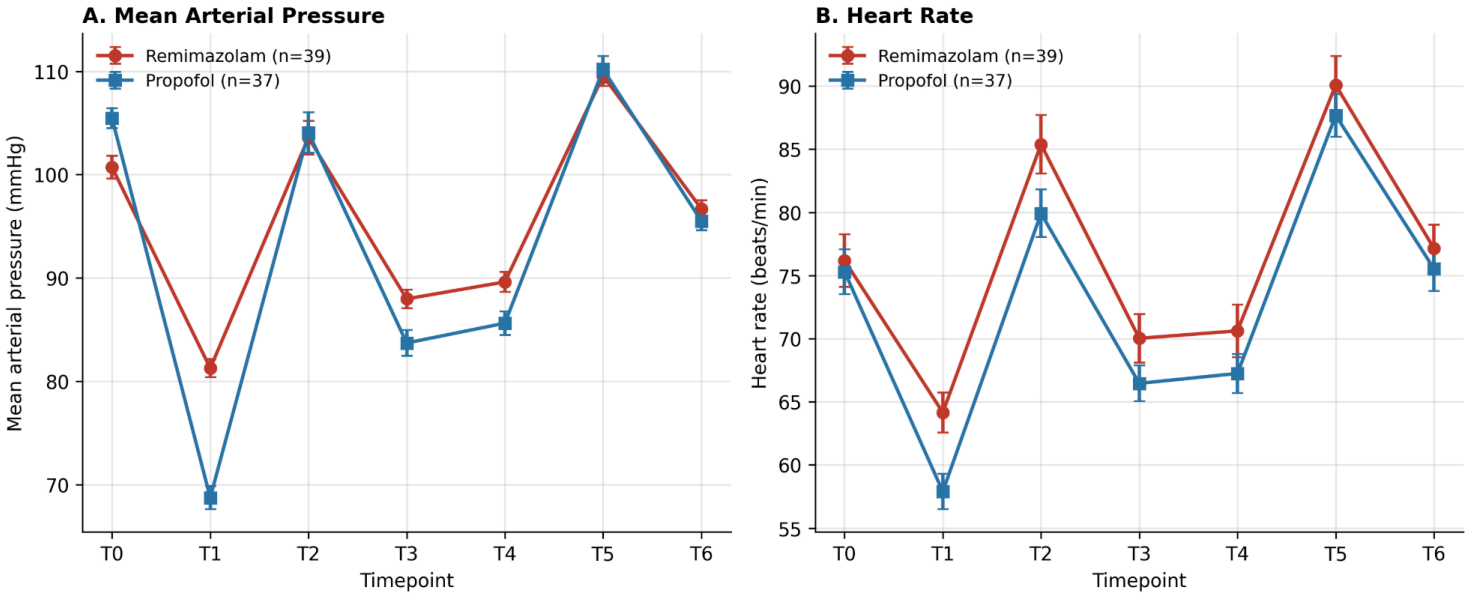


Figure 3

Hemodynamic Parameters Over Time. Mean arterial pressure (MAP) and heart rate (HR) trends during the transcatheter aortic valve implantation (TAVI) procedure. Data are presented as mean values with standard error of the mean. Mean arterial pressure decreased less after induction in the remimazolam group than in the propofol group. Heart rate trends were similar across groups.