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ORIGINAL RESEARCH

Effect of remimazolam versus propofol on inferior vena cava collapse index during general anesthesia induction: a randomized controlled trial

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Abstract

Background: This study was aimed to evaluate the effect of remimazolam compared to propofol on the inferior vena cava collapse index (IVC-CI) during general anesthesia induction. **Methods**: A total of 60 patients were randomly assigned to receive remimazolam (0.3 mg/kg; n = 30) or propofol (2–2.5 mg/kg; n = 30). IVC-CI was the primary outcome after induction. The recorded secondary outcomes included maximum and minimum diameters of inferior vena cava (dIVCmax and dIVCmin, respectively), mean arterial pressure (MAP), heart rate (HR), bispectral index (BIS), and adverse events. **Results**: Among 60 patients, 59 were evaluable for the outcomes (1 canceled surgery). After administering the anesthesia, mean IVC-CI was 25.5% in remimazolam group *vs.* 26.1% in propofol group (adjusted mean difference, −0.6% (95% confidence interval (CI), −4.5 to 3.3), $p = 0.755$); mean dIVCmin was 1.26 mm *vs.* 1.30 mm (adjusted mean difference, 0 (95% CI, −0.12 to 0.13), $p = 0.960$); mean dIVCmax was 1.71 mm *vs.* 1.77 mm (adjusted mean difference, −0.04 (95% CI, −0.21 to 0.14), $p = 0.693$); mean MAP was 81.4 mmHg *vs.* 75.5 mmHg (adjusted mean difference, 5.6 mmHg (95% CI, 1.8 to 9.3), $p = 0.005$); mean HR was 77.7 bpm *vs.* 69.3 bpm (adjusted mean difference, 7.9 bpm (95% CI, 5.2 to 10.6), $p < 0.001$); and mean BIS was 55.6 *vs.* 54.0, respectively (adjusted mean difference, 1.7 (95% CI, −1.0 to 4.4), $p = 0.215$). Hypotension was recorded in 2 (6.7%) *vs.* 9 (31.0%) ($p = 0.016$), while injection pain in 0 *vs.* 11 (37.9%) ($p < 0.001$). There was no agitation, bradycardia, reflux aspiration or bronchospasm. **Conclusions**: The remimazolam usage for anesthesia induction did not significantly reduce the IVC-CI compared to propofol. **Clinical Trial Registration**: The study was registered on www.chictr.org.cn (ChiCTR2300070911).

Keywords

Remimazolam; Propofol; Hypotension; Inferior vena cava ultrasound

1. Introduction

Hypotension during surgery may lead to postoperative myocardial injury, acute kidney injury and other adversities [1–3]. Recent studies show that more than half of intraoperative hypotensive events happen postinduction [4]. Propofol is the most employed intravenous anesthetic which causes postinduction hypotension [4, 5]. Remimazolam is a novel benzodiazepine that acts on ester-based gamma-aminobutyric acid type A receptor and shows rapid induction and recovery [6]. It may offer favorable pharmacological profile for cardiovascular stability, and thus exhibit reduced hypotension risk in the induction and maintenance phases of anesthesia compared to propofol [7, 8]. However, the reasons for greater remimazolam hemodynamic stability remain unclear. Hypotension can be caused by decrease in sympathetic tone, in preload and afterload, or by direct myocardial depression [9]. Preload related blood volume status can be assessed by ultrasonographic measurements of the diameter of inferior vena cava (IVC) and associated collapsibility indices, which provide accurate and rapid information of postinduction hypotension risk [10]. Current guidelines in America and Europe suggest that IVC diameter $\leq$2.1 cm and collapsibility >50% indicate right atrial pressure (RAP) of 0–5 mmHg, while diameter >2.1 cm with <50% collapse demonstrates RAP of 10–20 mmHg. A mean pressure value of 8 mmHg is used if the clinical picture does not fit these criteria [11]. Limited studies describe whether these two anesthetics affect preload. This study was thus designed to test the hypothesis in randomized clinical trial if the remimazolam usage for anesthesia induction compared to propofol would reduce the inferior vena cava collapse index (IVC-CI).

2. Materials and methods

2.1 Trial design

This trial was a prospective, single-center, parallel-group, double-blind, and randomized controlled trial. The trial adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

2.2 Trial participants

The trial included eligible participants of 18–65 years' age, who had American Society of Anesthesiologists (ASA) physical status of I or II (I (healthy), II (mild systemic disease)). They were scheduled for surgical procedures with laryngeal mask general anesthesia. Exclusion criteria were body mass index (BMI) $\geq$30 kg/m^2, systolic blood pressure $\geq$180 mmHg or $<$90 mmHg, severe heart valve disease, heart failure, severe arrhythmia, pregnancy or contraindications for laryngeal masks.

2.3 Randomization and blinding

Participants were randomly assigned in 1:1 ratio to remimazolam or propofol group via computer-generated randomization numbers. The allocation process involved the usage of opaque envelopes sealed by medical statistician. The participants and evaluator were unaware of group allocation. An opaque film was applied to syringe and infusion pipelines because of the distinct colors of remimazolam and propofol.

2.4 Ultrasonographic measurements

Participants underwent ultrasound before and after the anesthesia induction in supine position. The IVC ultrasound images were taken by curvilinear probe (SonoSite X-Porte, FUJIFILM SonoSite Inc., Bothell, WA, USA) using subcostal approach for capturing the longitudinal view of IVC with M-mode [12]. IVC diameters were measured at a location ~1 cm distal to the hepatic vein inlet of IVC to record the maximum and minimum diameters of IVC (dIVCmax and dIVCmin, respectively) during inspiration and expiration. IVC-CI was used in patients with spontaneous respiration and calculated by the following formula: IVC-CI = (dIVCmax $-$ dIVCmin)/dIVCmax $\times$ 100%. The IVC distensibility index (IVC-DI) was used in patients on mechanical ventilation and calculated by the formula: IVC-DI = (dIVCmax $-$ dIVCmin)/dIVCmin $\times$ 100%. As to facilitate comparison, the IVC-DI will be converted to: IVC-CI = IVC-DI/(1 + IVC-DI) [12]. IVC measurements were made by a highly skilled anesthesiologist.

2.5 Anesthesia

Electrocardiogram, blood pressure, pulse oxygen saturation, end-tidal carbon dioxide ($EtCO_2$), and bispectral index (BIS) were monitored in the entire process. All patients received 0.01 mg/kg penehyclidine hydrochloride 30 mins prior to surgery. The anesthesia was induced after ultrasound examination of IVC. Remimazolam 0.3 mg/kg [13, 14] or propofol 2–2.5 mg/kg was administered in 1 min followed by fentanyl 2–4 μg/kg and rocuronium 0.6–0.8 mg/kg once the consciousness loss was confirmed. A laryngeal mask airway of appropriate size was inserted. Mechanical ventilation was maintained with the tidal volume of 6–8 mL/kg based on predicted body weight and inspiratory pressure of $<$20 cmH_2O. The respiratory rate was adjusted to maintain $EtCO_2$ of 30–35 mmHg. If the systolic arterial pressure (SAP) was $<$70% of baseline value or mean arterial pressure (MAP) $<$65 mmHg during induction, 8 μg norepinephrine was administered until Systolic Blood Pressure (SBP) was increased to minimum 70% of baseline value or MAP $\geq$65 mmHg. Atropine 0.5 mg was administered if the heart rate (HR) dropped below 50 beats per min.

2.6 Measurements of outcomes

The baseline measurements were made before anesthesia followed by the post-anesthesia after two min. IVC-CI (converted from IVC-DI) was the primary outcome after anesthesia induction. Secondary outcomes were the dIVCmax, dIVCmin, MAP, HR and BIS. Adverse events after the anesthesia induction were hypotension (SAP $<$70% of baseline value or MAP $<$65 mmHg), injection pain, agitation, bradycardia (HR $<$50 beats per min), reflux aspiration, and bronchospasm.

2.7 Sample size calculation

Sample sizes were calculated using PASS 15.0 software (NCSS Inc, Kaysville, UT, USA). In the preliminary study of 10 cases (n = 5 in each group), mean (standard deviations, SD) IVC-CI after induction was 20.3% (5.8) in the remimazolam group and 26.1% (8.1) in propofol group. Total of 25 patients per group had 80% power at 2-sided α of 5%. The resulting sample size was 60 patients assuming 20% dropout rate.

2.8 Statistical methods

Patients were analyzed according to their randomization group in modified intention-to-treat analysis set (patients randomly assigned for either anesthetic were included). Continuous variables if normally distributed were presented as mean (SD) and as median (interquartile range, IQR) if not. Analyses of covariance were made for the primary and secondary outcomes to determine mean differences between the groups at post-induction period, and to adjust for the baseline values of outcome. Mean differences were presented with 95% CIs. Categorical data were shown as numbers (percentage) and analyzed by 2-tailed χ^2 tests or Fisher exact test. The secondary outcomes were interpreted as exploratory because of the type I error caused by multiple comparisons. Multiple imputations (5 in number) were used to impute missing data. All the statistical tests were 2-sided. p value $<$ 0.05 was considered statistically significant. Statistical analyses were conducted using SPSS for mac, version 25.0 (IBM Corp, Chicago, IL, USA).

3. Results

Patients were enrolled between 01 June 2023 and 30 November 2023 at Wenzhou People's Hospital. A total of 60 patients consented among the 67 patients screened for eligibility. They were randomly assigned to receive remimazolam (n = 30) or propofol (n = 30). One patient in the propofol group was excluded because of the surgery cancellation. Six patients had poor IVC visualization wherein 2 cases were in remimazolam

group and 4 in propofol group. Finally, the data of 59 patients in modified intention-to-treat analysis set were analyzed (Fig. 1). The baseline characteristics of patients were similar for the two groups and provided in Table 1.

Primary and secondary outcomes are given in Table 2 and Fig. 2. The primary outcome of IVC-CI after anesthesia induction did not differ when accounting for missing data using multiple imputations between the two groups, *i.e.*, 25.5% (5.3) in remimazolam group and 26.1% (5.5) in propofol group (adjusted mean difference, −0.6% (95% CI, −4.5 to 3.3), p = 0.755) (Table 2). The dIVCmin (adjusted mean difference, 0 mm (95% CI, −0.12 to 0.13); p = 0.960) and dIVCmax (adjusted mean difference, −0.04 mm (95% CI, −0.21 to 0.14), p = 0.693) after the anesthesia induction were not different for remimazolam and propofol groups. MAP (adjusted mean difference, 5.6 mmHg (95% CI, 1.8 to 9.3), p = 0.005) and HR (adjusted mean difference, 7.9 bpm (95% CI, 5.2 to 10.6), p < 0.001) after anesthesia induction were higher in the remimazolam group compared to propofol. There was no significant difference in BIS values for the two groups after anesthesia induction (adjusted mean difference, 1.7 (95% CI, −1.0 to 4.4), p = 0.215).

Adverse events are provided in Table 3. After the anesthesia induction, 2 (6.7%) and 9 (31.0%) patients in remimazolam and propofol groups, respectively, experienced hypotension (p = 0.016). Injection pain happened in 0 patients of remimazolam group and 11 (37.9%) of propofol group (p < 0.001). No cases of agitation, bradycardia, reflux aspiration, or bronchospasm were observed.

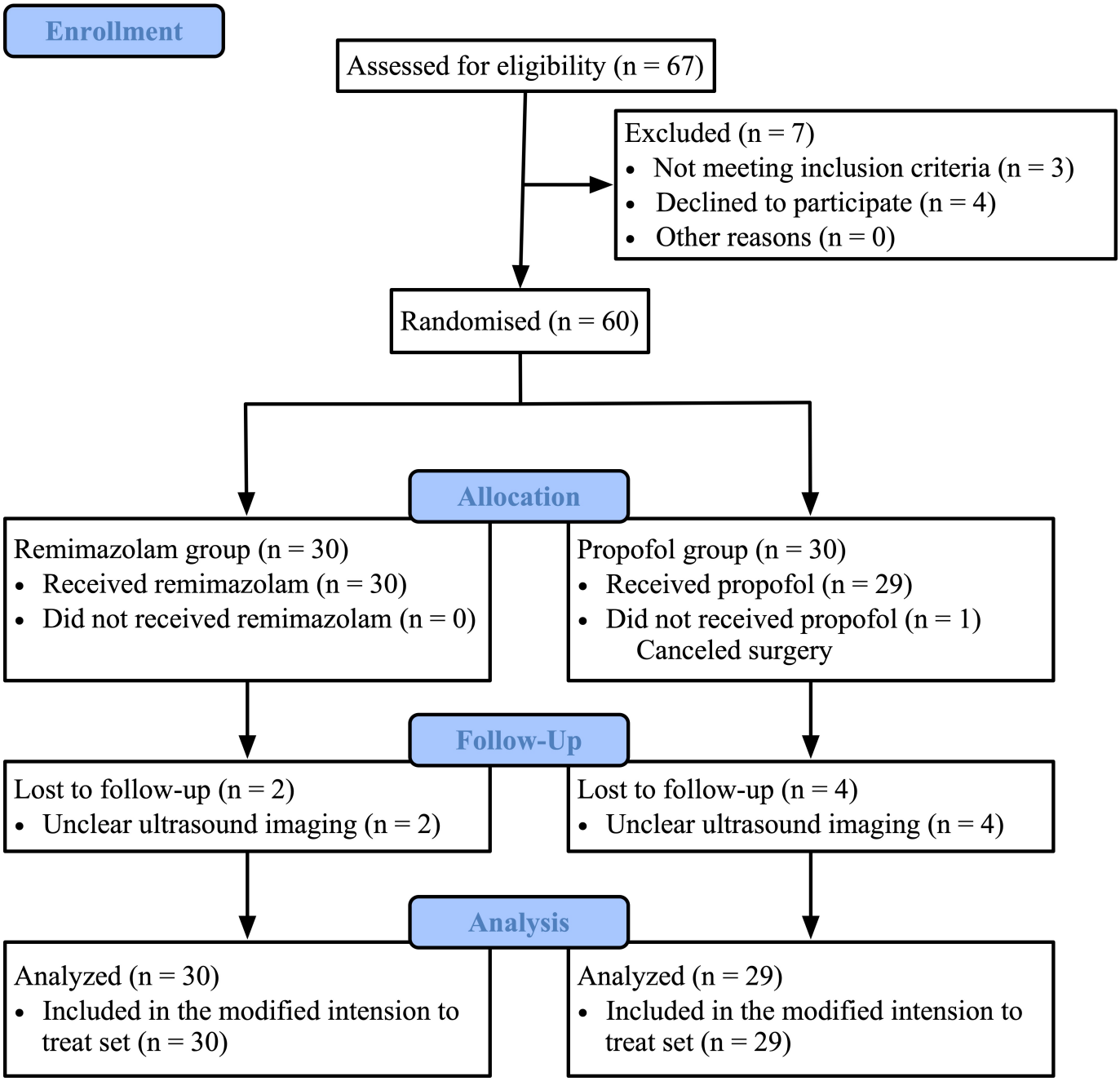

FIGURE 1. The study flow diagram.

TABLE 1. Baseline characteristics of the participants.

Characteristic	Remimazolam (n = 30)	Propofol (n = 29)
Age (yr), mean (SD)	41 (10)	42 (11)
Sex, n (%)		
Women	17 (56.7)	18 (62.1)
Men	13 (43.3)	11 (37.9)
Weight (kg), median (IQR)	62 (51–74)	57 (54–66)
Height (cm), median (IQR)	164 (157–170)	162 (158–167)
BMI (kg/m^2), median (IQR)	22.7 (20.9–26.1)	22.2 (20.4–25.7)
Hypertension, n (%)	5 (16.7)	5 (17.2)
ASA, n (%)		
I, Healthy	12 (40.0)	14 (48.3)
II, Mild systemic disease	18 (60.0)	15 (51.7)
Surgery type, n (%)		
Urology	13 (43.3)	8 (27.6)
Orthopedic	5 (16.7)	4 (13.8)
Gynecology	8 (26.7)	13 (44.8)
General	4 (13.3)	4 (13.8)
Fasting time (h), median (IQR)		
Clear liquids	8 (6–12)	8 (6–12)
Foods	16 (14–18)	14 (14–16)

ASA: American Society of Anesthesiologists; BMI: body mass index; SD: standard deviation; IQR: interquartile range.

TABLE 2. Primary and secondary outcomes.

	Remimazolam (n = 30)		Propofol (n = 29)		Adjusted between-group difference, mean (95% CI)	*p* value
	At baseline, mean (SD)	At post-induction, mean (SD)	At baseline, mean (SD)	At post-induction, mean (SD)		
Primary outcome						
IVC-CI (%)	35.5 (10.1)	25.5 (5.3)*	33.4 (9.5)	26.1 (5.5)*	−0.6 (−4.5 to 3.3)	0.755
Secondary outcomes						
dIVCmin (cm)	1.00 (0.28)	1.26 (0.26)	1.01 (0.24)	1.30 (0.18)	0 (−0.12 to 0.13)	0.960
dIVCmax (cm)	1.55 (0.31)	1.71 (0.36)	1.51 (0.25)	1.77 (0.29)	−0.04 (−0.21 to 0.14)	0.693
MAP (mmHg)	97.7 (11.2)	81.4 (7.2)	97.1 (11.1)	75.5 (11.2)	5.6 (1.8 to 9.3)	0.005
HR (bpm)	78.4 (10.3)	77.7 (8.1)	77.2 (10.5)	69.3 (5.4)	7.9 (5.2 to 10.6)	<0.001
BIS	97.7 (1.0)	55.6 (4.5)	97.2 (1.8)	54.0 (5.6)	1.7 (−1.0 to 4.4)	0.215

*The between-group difference was adjusted for the baseline values of outcome. IVC-CI: Inferior vena cava collapse index; dIVCmin: minimum diameters of inferior vena cava; dIVCmax: maximum diameters of inferior vena cava; MAP: mean arterial pressure; HR: heart rate; BIS: bispectral index; SD: standard deviation; CI: confidence interval. *: converted from IVC-DI.*

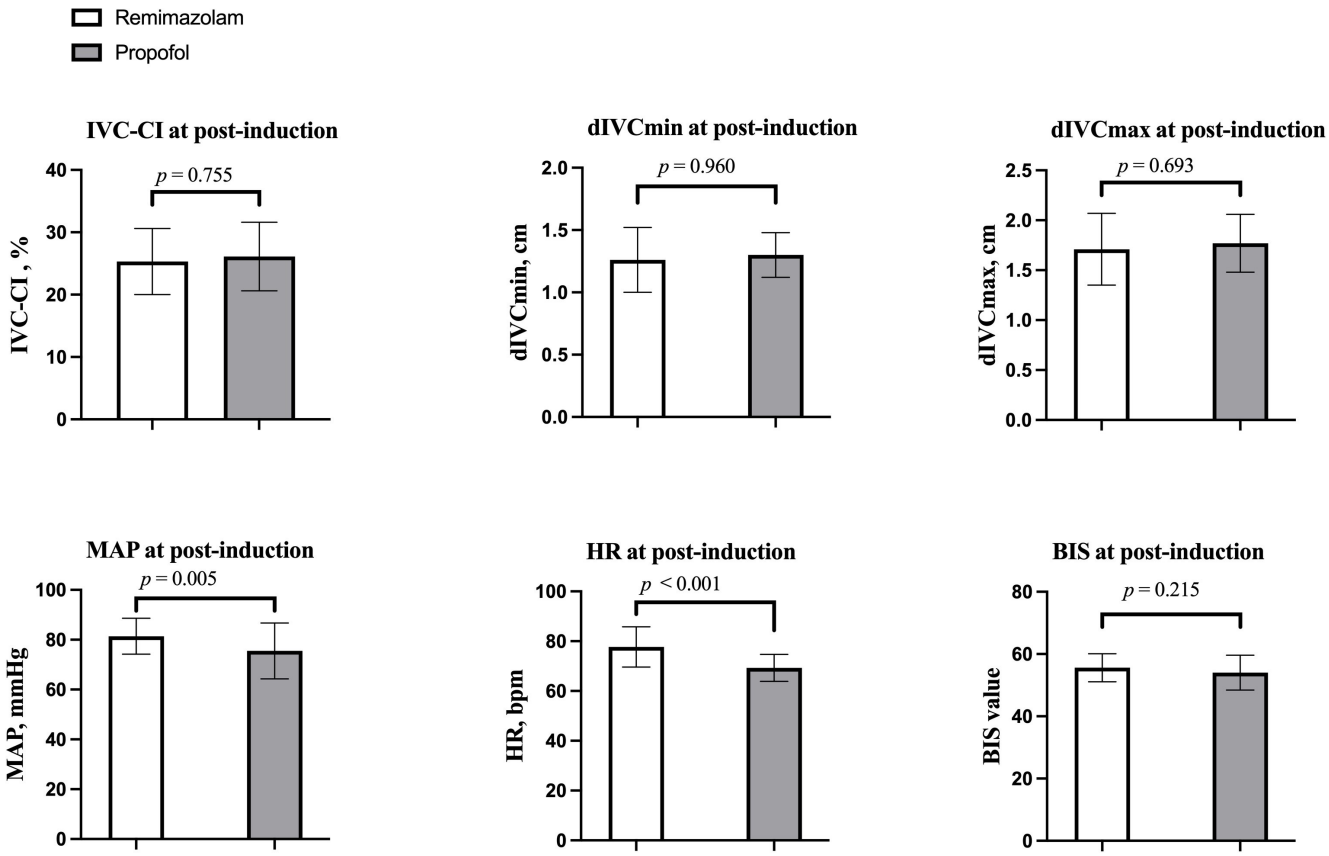

FIGURE 2. Primary and secondary outcomes. IVC-CI: Inferior vena cava collapse index; dIVCmin: the minimum diameters of inferior vena cava; dIVCmax: the maximum diameters of inferior vena cava; MAP: mean arterial pressure; HR: heart rate; BIS: bispectral index.

TABLE 3. Adverse events.

Adverse event	Remimazolam (n = 30)	Propofol (n = 29)	*p* value
Hypotension after anesthesia induction, n (%)	2 (6.7)	9 (31.0)	0.016
Injection pain, n (%)	0 (0)	11 (37.9)	<0.001
Agitation, n (%)	0	0	-
Bradycardia, n (%)	0	0	-
Reflux aspiration, n (%)	0	0	-
Bronchospasm, n (%)	0	0	-

4. Discussion

In this randomized clinical trial, the remimazolam usage for anesthesia induction compared to propofol did not reduce IVC-CI. The dIVCmax, dIVCmin and BIS values had no significant difference. Remimazolam resulted in higher HR and MAP compared to propofol after the anesthesia induction, with lower incidence of postinduction hypotension.

Ultrasonographic evaluation of IVC had been used as the non-invasive technique for central venous pressure (CVP) assessment because of wide availability, low cost and easier use [15]. Volume status estimation was made by measuring the dynamic respiratory fluctuations in various clinical settings. Dynamic parameters indicated heart-lung interactions which varied according to the cardiac and respiratory cycles. In this study, patients were spontaneously breathing before the anesthesia induction. In this state, negative intrathoracic pressure increased the venous flow to heart and reduced the IVC diameter. At the end expiration, intrathoracic pressure was increased to zero which decreased the venous return and maximized IVC diameter. This had been defined as IVC-CI. IVC-CI was calculated by the following formula: IVC-CI = (dIVCmax − dIVCmin)/dIVCmax × 100% [12]. The mechanical ventilation reversed the cycle. The positive intrathoracic pressure decreased venous flow to the heart and increased IVC diameter during inspiration. End-expiration intrathoracic pressure was decreased to zero which increased the venous flow and reduced IVC diameter. This was defined as distensibility index (IVC-DI). IVC-DI = (dIVCmax − dIVCmin)/dIVCmin × 100% [12]. Positive pressure ventilation increased the

intrathoracic pressure, decreased systemic venous return, and increased venous blood volume in the IVC. This effect resulted in IVC-CI reduction following the induction of both drugs as compared to baseline measurements. The convention to normalize by end-expiratory diameter, IVC-CI for spontaneous breathing and IVC-DI for ventilated breathing used in some studies did not allow the data comparison between ventilated and spontaneously breathing encounters. IVC-CI and IVC-DI could be interconverted: IVC-CI = IVC-DI/(1 + IVC-DI) [12]. IVC-CI was calculated for all the patients if ventilated or not, to ensure consistency and convenience.

This was the pioneering study to utilize IVC-CI for examining hemodynamic mechanism of propofol and remimazolam. Several mechanisms led to the hypotension including decreased myocardial contractility, venous return, and vascular resistance in systemic circulation [9]. A previous study suggested that remimazolam prevented hypotension because of better preservation of cardiac output as well as the product of cardiac output and systemic vascular resistance [14]. However, it did not explore the impact of cardiac preload. A patient with large IVC-CI might be a small CVP, and small IVC-CI might be a large CVP [11]. IVC-CI could assess the relative intravascular volume and explain the hypotension cause [12]. It was shown that the volume responsiveness was predicted with similar accuracy during spontaneous breathing (pooled sensitivity 71%, specificity 81%) and mechanical ventilation (pooled sensitivity 75%, specificity 82%) [12]. The results herein exhibited that there was no difference in IVC-CI between the two anesthetics. The reasons could be that both drugs did not dilate the venous and caused the same degree of venous dilatation. Venous dilation had been a cause of propofol-induced hypotension [16]. Zucker *et al.* [17] demonstrated that propofol anesthesia reduced mean systemic filling pressure which led to the conclusion that propofol-induced hypotension was mitigated by preload reduction as the result of decreased venous vasomotor tone. It was thus concluded herein that remimazolam caused the same venous dilatation as that of propofol. In this study, the insertion of laryngeal mask airway and intravenous administration of penehyclidine hydrochloride were used to mitigate the HR impact. Remimazolam led to higher HR and MAP than propofol. Patients could compensate for the reduced preload or significant vasodilation by increasing the heart rate to increase the cardiac output and perfusion [9]. The blood pressure stability after remimazolam induction could be attributed to less pronounced inhibition of the sympathetic nervous system. It was anticipated that patients receiving rehydration therapy before anesthesia induction would have more benefit.

A previous study compared remimazolam and propofol for total intravenous anaesthesia in urological surgery patients. Remimazolam had non-inferior efficacy as of propofol with lower incidence of hypotension during anaesthesia [18]. Another study evaluating the quality of recovery in urological surgery patients showed that MAP and HR were higher in remimazolam group compared to propofol group after the anesthesia induction [19]. Zhang *et al.* [20] compared the efficacy and safety of remimazolam besylate versus propofol. A total of 82 patients undergoing hysteroscopy were included in this study. Remimazolam had low incidence of hypotension. Liu *et al.* [21] evaluated the impact of remimazolam anesthesia induction on hemodynamics in the patients of valve replacement surgery. It was found that the hypotension and cumulative norepinephrine doses used per patient were lower in the remimazolam group than in propofol. A recent European multicenter trial in large population of patients with major comorbidities (ASA physical status of 3 or 4) depicted same results [22]. Consistent with the literature, this study also found that the participants receiving remimazolam for anesthesia induction also had stable hemodynamics. This outcome was contrary to that of Sekiguchi *et al.* [23], who found that hemodynamics were not different for remimazolam and target-controlled propofol groups during anesthesia induction. They concluded that the choice and dosage of anesthetics were important for hemodynamic stability. Propofol often caused injection pain which negatively impacted the patient experience. This study found that remimazolam did not induce injection pain. It might thus be more feasible for clinical applications.

This study had certain limitations. First, the impact of anesthetics on vascular volume was exclusively assessed by IVC ultrasound. Future studies should consider the addition of echocardiography to evaluate anesthetics effects on cardiac function [24]. Second, patients in this study were young, and relatively thin with ASA physical status of 1 or 2. Results could be different in obese individuals, elderly or those with major comorbidities. Replication studies should thus be conducted for these groups. Finally, 6 patients obtained poor IVC visualization in this study. There were several other factors which could reduce visualization including obesity, abdominal distention, gas in the bowel, and subcutaneous emphysema. Expanding ultrasound window and technique repertoires might overcome the visual limitations [25].

5. Conclusions

The remimazolam usage for anesthesia induction as compared to propofol did not significantly reduce IVC-CI. Remimazolam caused same venous dilatation as that of propofol.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

HBC and QZ—designed the research study. HBC, QZ, YYZ and JCX—performed the research. JJC—analyzed the data. HBC and ZYJ—wrote the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The research protocol was approved by the Clinical Research Ethics Committee of Wenzhou People's Hospital (No. 2023-031) and was prospectively registered on www.chictr.org.cn/

(ChiCTR2300070911). Enrolled participants provided written informed consent.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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