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Ciprofol versus propofol for gastrointestinal endoscopy in hypertensive patients: a randomized double-blind controlled trial

Hongling Zhuang[1]
The Affiliated Hospital of Guangdong Medical University
Jing Zhang[1]
The Affiliated Hospital of Guangdong Medical University
Haorong Liu[1]
The Affiliated Hospital of Guangdong Medical University
Mingzhi Luo[1]
The Affiliated Hospital of Guangdong Medical University
Yanwen Zhu[1]
The Affiliated Hospital of Guangdong Medical University
Heng Li[1]
The Affiliated Hospital of Guangdong Medical University
Qixia He[1]
The Affiliated Hospital of Guangdong Medical University
Yan Lu[1]
249110951@qq.com

The Affiliated Hospital of Guangdong Medical University

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Abstract

Background

Hypotension during sedated gastrointestinal endoscopy is clinically relevant in patients with hypertension because long-standing hypertension may impair cardiovascular compensation. Propofol can cause dose-dependent cardiovascular and respiratory depression. We compared the incidence of hypotension with ciprofol and propofol in this population.

Methods

In this single-center, parallel-group, double-blind randomized controlled trial, patients aged 18–75 years with primary hypertension, American Society of Anesthesiologists physical status II–III, and body mass index 18–28 kg/m² who were scheduled for sedated gastrointestinal endoscopy were assigned 1:1, using a computer-generated sequence and sealed opaque envelopes, to ciprofol 0.5 mg/kg or propofol 2.0 mg/kg after sufentanil 0.1 μg/kg. Patients, endoscopists, anesthesiologists, outcome assessors, and statisticians were blinded. The primary outcome was hypotension during the procedure (systolic blood pressure < 90 mmHg or > 30% decrease in mean arterial pressure from baseline). Secondary outcomes included hemodynamic variables, time metrics, rescue vasoactive medication use, and adverse events.

Results

A total of 122 patients were randomized (61 per group), and all were analyzed. Hypotension occurred in 14 patients (23.0%) receiving ciprofol and 26 (42.6%) receiving propofol (relative risk, 0.54; 95% confidence interval [CI], 0.31 to 0.93; absolute risk reduction, 19.7%; 95% CI, 3.0% to 34.9%; P = 0.021). Norepinephrine was given to the same patients per protocol. In unadjusted secondary comparisons, injection pain (0% vs 19.7%; P < 0.001) and respiratory depression (3.3% vs 18.0%; P = 0.008) were less frequent with ciprofol. After adjustment for baseline, mean arterial pressure did not differ significantly between groups at any time point. Induction time, procedure duration, recovery time, and body movement did not differ significantly. All procedures were completed.

Conclusions

Ciprofol reduced the incidence of hypotension compared with propofol in hypertensive patients undergoing sedated gastrointestinal endoscopy. Lower rates of injection pain and respiratory depression are supportive but require confirmation. Larger multicenter trials are warranted.

Trial registration:

Chinese Clinical Trial Registry, ChiCTR2500110441. Registered on 14 October 2025 (prospectively registered).

Background

Gastrointestinal endoscopy is widely used for the diagnosis, screening, and treatment of digestive tract diseases [1]. Sedation or anesthesia can reduce anxiety and procedural discomfort, improve patient tolerance, facilitate complete examination, and enhance procedural efficiency. Sedation practices vary across countries and healthcare systems, but propofol-based deep sedation is commonly used because of its rapid onset, predictable sedative effect, and short recovery profile. Nevertheless, the increasing use of deep sedation has raised concerns regarding cardiopulmonary safety, particularly in patients with comorbidities [2].

Cardiopulmonary adverse events, including hypotension, bradycardia, hypoxemia, apnea, and respiratory depression, remain among the most clinically important sedation-related complications. Although many of these events are transient, they may have serious consequences in vulnerable patients. A marked reduction in arterial pressure may compromise perfusion of the myocardium, brain, and kidneys, and intraoperative hypotension has been associated with adverse postoperative outcomes [3, 4]. Reducing sedation-related hypotension is therefore an important goal of endoscopic anesthesia, especially in patients with cardiovascular risk factors.

Propofol has a narrow therapeutic window and may produce dose-dependent cardiovascular and respiratory depression. Propofol-related hypotension is mainly attributed to reduced sympathetic vasomotor tone, vasodilation, and myocardial depression [5–7]. These effects may be acceptable in low-risk individuals but can be problematic in patients with impaired cardiovascular reserve.

Long-term primary hypertension can lead to vascular remodeling, reduced arterial compliance, impaired baroreflex sensitivity, and autonomic dysfunction [8, 9]. Consequently, hypertensive patients may be less able to compensate for anesthetic-induced vasodilation or myocardial depression. Given the prevalence of hypertension among patients undergoing endoscopy, identifying a sedative regimen with a lower risk of hypotension is clinically important.

Ciprofol is an intravenous anesthetic structurally similar to propofol. Previous studies have shown that it provides effective sedation for gastrointestinal endoscopy, with potential advantages in injection pain, respiratory depression, and hemodynamic stability [10–13]. However, most studies have enrolled general endoscopy populations or other surgical and procedural settings [14, 15]. A recent randomized trial in hypertensive women undergoing gynecological day surgery reported less hypotension with ciprofol during induction of general anesthesia [16], but direct evidence in hypertensive patients undergoing sedated gastrointestinal endoscopy remains limited. We therefore compared the incidence of hypotension between ciprofol and propofol in this setting, hypothesizing that ciprofol would reduce procedure-related hypotension.

Methods

Study design and ethics

This was a single-center, prospective, randomized, parallel-group, double-blind controlled trial conducted at The Affiliated Hospital of Guangdong Medical University, Zhanjiang, Guangdong, China. The protocol was approved by the hospital Ethics Committee (protocol code: PJKT2025-213; approval date: 23 September 2025). The trial was prospectively registered in the Chinese Clinical Trial Registry (ChiCTR2500110441) on 14 October 2025, before enrollment of the first participant. It was conducted in accordance with the Declaration of Helsinki and reported according to the CONSORT 2025 statement [17] (Additional file 1). Written informed consent was obtained from all participants before enrollment.

Participants

Patients scheduled for painless gastrointestinal endoscopy (anesthesiologist-administered sedation for combined gastroscopy and colonoscopy) between November 2025 and January 2026 were assessed for eligibility. Eligible patients were aged 18–75 years and had primary hypertension, American Society of Anesthesiologists (ASA) physical status II–III, and a body mass index (BMI) of 18–28 kg/m².

Exclusion criteria were severe cardiopulmonary dysfunction, including heart failure or chronic obstructive pulmonary disease grade III or above; poorly controlled blood pressure, defined as systolic blood pressure (SBP) > 180 mmHg or diastolic blood pressure > 110 mmHg after routine pre-procedural assessment; severe hepatic or renal dysfunction; known allergy to sedatives or anesthetic agents; psychiatric disorders; or inability to cooperate with study procedures.

Hypertension grade was determined from previous medical records, history of hypertension, or documented outpatient blood pressure before treatment. Patients with a history of grade 3 hypertension were therefore not necessarily uncontrolled immediately before the procedure, and all enrolled patients had pre-procedural blood pressure below the exclusion threshold.

Sample size

The sample size was estimated using PASS 15.0 software. A pilot study of 20 patients per group was conducted to obtain preliminary event rates and assess feasibility; it was not powered for hypothesis testing. The observed incidence of hypotension was 20% with ciprofol and 45% with propofol. For a comparison of two independent proportions with a two-sided alpha of 0.05 and 80% power, approximately 55 patients per group were required. Allowing for a 10% dropout rate, we planned to enroll 61 patients per group (122 in total).

Randomization and blinding

Patients were randomly assigned 1:1 to the ciprofol or propofol group using a computer-generated sequence. Allocation was concealed in sequentially numbered, opaque, sealed envelopes. Randomization and drug preparation were performed by an independent anesthesia nurse who was not involved in patient management, outcome assessment, data collection, or statistical analysis.

Study drugs were prepared according to a prespecified volume-matched and appearance-masked protocol in identical 50-mL syringes, each covered with opaque material and labeled only with the patient study number. The concentrations were adjusted so that the administered volumes for both induction and supplemental boluses were identical between groups. Patients, endoscopists, attending anesthesiologists, outcome assessors, data collectors, and statisticians were blinded to group assignment throughout the study.

Anesthesia protocol and monitoring

Patients fasted for 8 h from solids and 2 h from clear liquids. Chronic antihypertensive medications, including calcium channel blockers and beta-blockers, were continued on the morning of the procedure with a small sip of water. Angiotensin-converting enzyme inhibitors and angiotensin receptor blockers were withheld that morning to minimize the risk of refractory hypotension.

In the procedure room, patients were placed in the left lateral decubitus position and monitored with non-invasive blood pressure, electrocardiography, and pulse oximetry. Oxygen was administered through a nasal cannula at 4 L/min. The cuff was placed on the dependent left arm and kept at heart level to minimize hydrostatic error. Blood pressure was measured automatically at 3-min intervals, with additional measurements when clinically necessary. Baseline mean arterial pressure (MAP), SBP, heart rate, and peripheral oxygen saturation (SpO_2) were calculated as the average of three measurements before induction.

All patients received sufentanil 0.1 μg/kg (Sufentanil Citrate Injection, Yichang Humanwell Pharmaceutical Co., Ltd.), followed by ciprofol 0.5 mg/kg (Ciprofol Injection, Shenyang Haisco Pharmaceutical Co., Ltd.) or propofol 2.0 mg/kg (Propofol Injectable Emulsion, Sichuan Guorui Pharmaceutical Co., Ltd.), administered over 30 s. Sedation depth was assessed using the Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale, and the procedure began at a MOAA/S score ≤ 1. If the score increased above 1 or clinically significant body movement occurred, a supplemental bolus of ciprofol 0.1 mg/kg or propofol 0.5 mg/kg was administered. Study drug administration stopped after endoscope withdrawal. Patients were transferred to the post-anesthesia care unit and discharged once fully awake and without discomfort.

Outcomes

The primary outcome was the incidence of hypotension from anesthesia induction to the end of the procedure, assessed using all non-invasive blood pressure measurements. Hypotension was defined as

SBP < 90 mmHg or a > 30% decrease in MAP from baseline [3]. Any patient meeting either criterion at any time was recorded as having hypotension. Hypotension status was determined from the anesthesia records, which included all automated measurements during the procedure; values at the seven predefined time points were analyzed separately as secondary outcomes.

Secondary outcomes were changes in MAP, SBP, heart rate, and SpO_2 at seven prespecified time points; anesthesia-related time metrics; body movement; procedure success; rescue vasoactive medication use; and adverse events. The time points were T0, baseline; T1, immediately after loss of consciousness; T2, gastroscope insertion; T3, gastroscope withdrawal; T4, colonoscope insertion; T5, colonoscope withdrawal; and T6, discharge from the post-anesthesia care unit.

Injection pain was assessed using a 4-point verbal rating scale and defined as a score ≥ 1 [18]. Bradycardia was defined as heart rate < 50 beats/min [19]. Respiratory depression was defined as SpO_2 <90% for > 10 s, or the need for airway assistance [20]. Hiccups were defined as spontaneous spasmodic diaphragm contractions [21]. Nausea and vomiting were assessed according to international consensus guidelines [22]. Induction time was the time from the start of study drug injection to loss of consciousness. Procedure duration was the time from gastroscope insertion to final colonoscope withdrawal. Recovery time was the time from the end of the procedure to full awakening.

If hypotension occurred, norepinephrine 4–12 μg was administered intravenously. If heart rate fell below 50 beats/min, atropine 0.5 mg was administered intravenously. If SpO_2 fell below 92% and did not improve with increased nasal oxygen flow or a jaw-thrust maneuver, positive-pressure ventilation was applied by face mask, followed by endotracheal intubation if hypoxemia persisted.

Statistical analysis

Analyses were performed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). All randomized patients were analyzed according to their assigned groups. Continuous variables are presented as mean ± standard deviation and compared using the independent-samples t test. SpO_2, which showed a marked ceiling effect, and rescue medication counts and doses are presented as median (Q1, Q3) and compared using the Mann–Whitney U test. Categorical variables are presented as n (%) and compared using the Pearson chi-square test, or Fisher's exact test when any expected count was < 5.

The primary treatment effect was expressed as relative risk, absolute risk reduction, and number needed to treat with 95% confidence intervals (CIs). CIs for risk differences were calculated using the Newcombe hybrid score method. MAP and heart rate were analyzed using repeated-measures analysis of variance with group, time, and group-by-time interaction effects, with Greenhouse–Geisser correction. Because baseline MAP was numerically higher in the ciprofol group, MAP at each post-baseline time point was also compared using analysis of covariance adjusted for baseline MAP (post hoc analysis). Intergroup comparisons at individual time points were performed without adjustment for multiplicity and were considered exploratory. Norepinephrine boluses and cumulative dose were analyzed only among patients who received norepinephrine. A two-sided P value < 0.05 was considered statistically significant.

Results

Patient flow and baseline characteristics

A total of 138 patients were assessed for eligibility. Sixteen were excluded before randomization: eight did not meet the inclusion criteria, four declined participation, and four underwent unsedated endoscopy. The remaining 122 patients were randomized (61 per group); all completed the protocol and were included in the analysis (Fig. 1).

Baseline characteristics are shown in Table 1. Patients were aged 37–75 years, and BMI ranged from 16.6 to 33.8 kg/m². Baseline MAP was numerically higher in the ciprofol group (110.45 ± 14.07 vs 106.42 ± 13.93 mmHg; P = 0.114) (Table 3).

Table 1
Baseline demographic and clinical characteristics

Characteristic	Ciprofol (n = 61)	Propofol (n = 61)	P value
Age, years	59.92 ± 8.51	61.79 ± 8.07	0.216
Sex, n (%)			0.717
Male	28 (45.9)	30 (49.2)	
Female	33 (54.1)	31 (50.8)	
Height, m	1.62 ± 0.08	1.61 ± 0.08	0.191
Weight, kg	63.15 ± 10.31	60.23 ± 10.40	0.122
BMI, kg/m²	23.90 ± 3.34	23.25 ± 2.91	0.252
ASA physical status, n (%)			0.817
II	50 (82.0)	49 (80.3)	
III	11 (18.0)	12 (19.7)	
Duration of hypertension, years, n (%)			0.530
<5	22 (36.1)	17 (27.9)	
5–10	28 (45.9)	34 (55.7)	
>10	11 (18.0)	10 (16.4)	
Historical hypertension grade, n (%)			0.971
Grade 1	12 (19.7)	11 (18.0)	
Grade 2	33 (54.1)	34 (55.7)	
Grade 3	16 (26.2)	16 (26.2)	
Antihypertensive medication, n (%)			0.520
Calcium channel blocker alone	30 (49.2)	35 (57.4)	
ACEI/ARB alone	24 (39.3)	18 (29.5)	
Combination therapy	7 (11.5)	8 (13.1)	

Data are mean ± standard deviation or n (%). Hypertension grade was classified from previous medical records, documented outpatient blood pressure before treatment, or established history of hypertension. ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ASA, American Society of Anesthesiologists; BMI, body mass index.

Table 3
Hemodynamic and oxygen saturation variables at each time point

Parameter	Group	T0	T1	T2	T3	T4	T5	T6
MAP, mmHg	Ciprofol	110.45 ± 14.07	90.08 ± 11.97	87.49 ± 13.00	85.13 ± 11.94	83.26 ± 9.77	86.41 ± 10.61	87.14 ± 9.80
	Propofol	106.42 ± 13.93	88.13 ± 14.45	82.16 ± 14.50	82.60 ± 12.12	81.16 ± 11.51	82.46 ± 9.97	84.21 ± 9.18
	P value	0.114	0.418	0.034*	0.249	0.280	0.036*	0.092
	Adjusted difference (95% CI)‡	—	−0.35 (− 4.20 to 3.51)	2.68 (− 1.04 to 6.41)	0.54 (− 3.05 to 4.13)	0.73 (− 2.75 to 4.21)	2.83 (− 0.63 to 6.30)	1.77 (− 1.36 to 4.91)
	Adjusted P value‡	—	0.859	0.157	0.767	0.678	0.108	0.265
SBP, mmHg	Ciprofol	152.85 ± 13.06	119.95 ± 15.94	118.07 ± 15.77	114.67 ± 11.85	113.10 ± 12.67	114.93 ± 10.44	117.00 ± 9.48
	Propofol	151.07 ± 15.24	116.43 ± 15.92	112.43 ± 14.02	110.98 ± 13.51	109.00 ± 11.02	112.54 ± 8.98	114.02 ± 7.51
	P value	0.488	0.224	0.039*	0.112	0.059	0.177	0.056
HR, beats/min	Ciprofol	76.84 ± 11.51	73.18 ± 10.74	70.07 ± 10.06	67.70 ± 9.34	66.74 ± 9.70	67.49 ± 9.45	67.98 ± 9.02
	Propofol	75.13 ± 10.71	72.90 ± 10.23	69.87 ± 9.75	68.46 ± 9.85	68.25 ± 9.61	67.74 ± 9.36	68.57 ± 9.36
	P value	0.399	0.884	0.913	0.665	0.390	0.885	0.724
SpO_2, %‡	Ciprofol	100 (100, 100)	100 (100, 100)	100 (99, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)
	Propofol	100 (100, 100)	100 (99, 100)	100 (99, 100)	100 (99, 100)	100 (99, 100)	100 (99, 100)	100 (99, 100)
	P value	0.954	0.140	0.753	0.540	0.159	0.602	0.199

Data are mean ± standard deviation unless otherwise indicated. P values are unadjusted between-group comparisons at each time point (independent-samples t test). ‡Ciprofol minus propofol, from analysis of covariance adjusted for baseline MAP. ‡Median (Q1, Q3), compared using the Mann–Whitney U test. T0, baseline after entering the room; T1, immediately after loss of consciousness (MOAA/S ≤ 1); T2, gastroscope insertion; T3, gastroscope withdrawal; T4, colonoscope insertion; T5, colonoscope withdrawal; T6, discharge from the post-anesthesia care unit. HR, heart rate; MAP, mean arterial pressure; MOAA/S, Modified Observer's Assessment of Alertness/Sedation; SBP, systolic blood pressure; SpO_2, peripheral oxygen saturation. *P < 0.05.

Primary outcome

Hypotension occurred in 14 of 61 patients (23.0%) in the ciprofol group and 26 of 61 (42.6%) in the propofol group (relative risk, 0.54; 95% CI, 0.31 to 0.93; absolute risk reduction, 19.7%; 95% CI, 3.0% to 34.9%; P = 0.021) (Table 2). The number needed to treat to prevent one patient from experiencing hypotension was approximately five (95% CI, 3 to 33).

Table 2
Primary outcome: incidence of hypotension

Outcome	Ciprofol (n = 61)	Propofol (n = 61)	Relative risk (95% CI)	Absolute risk reduction, % (95% CI)	P value
Hypotension, n (%)	14 (23.0)	26 (42.6)	0.54 (0.31 to 0.93)	19.7 (3.0 to 34.9)	0.021*

CI, confidence interval. *P < 0.05.

Hemodynamic and respiratory variables

MAP and heart rate decreased after induction in both groups (time effect, both P < 0.001). For MAP, neither the group effect ($F_{1,120}$=3.34; P = 0.070) nor the group-by-time interaction (P = 0.51) was significant; for heart rate, the corresponding P values were 0.94 and 0.23 (Table 3; Figs. 2 and 3). In unadjusted comparisons, MAP was higher in the ciprofol group at gastroscope insertion (T2; P = 0.034) and colonoscope withdrawal (T5; P = 0.036), and SBP was higher at T2 (P = 0.039). After adjustment for baseline MAP, these differences were 2.68 mmHg (95% CI, − 1.04 to 6.41; P = 0.157) and 2.83 mmHg (95% CI, − 0.63 to 6.30; P = 0.108), and no time point differed significantly. The lowest recorded MAP from T1 to T5 was 79.3 ± 9.8 vs 75.3 ± 10.1 mmHg (baseline-adjusted difference, 2.42 mmHg; 95% CI, − 0.55 to 5.40; P = 0.109), and the maximum decrease from baseline was 27.6% ± 8.7% vs 28.8% ± 8.0% (P = 0.416). Median SpO_2 was 100% at all time points in both groups, with no significant differences (Table 3).

Anesthesia-related outcomes and adverse events

Induction time, procedure duration, recovery time, and body movement did not differ significantly between groups, and all procedures were completed (Table 4). Injection pain was less frequent with ciprofol [0/61 (0.0%) vs 12/61 (19.7%); P < 0.001], as was respiratory depression [2/61 (3.3%) vs 11/61 (18.0%); P = 0.008]. The incidences of bradycardia, hiccups, and nausea and vomiting were low and similar between groups (Table 5).

Table 4
Anesthesia and procedure-related characteristics

Variable	Ciprofol (n = 61)	Propofol (n = 61)	Difference (95% CI)□	P value
Induction time, s	65.4 ± 12.3	62.8 ± 11.5	2.6 (− 1.7 to 6.9)	0.230
Procedure duration, min	15.32 ± 3.41	15.08 ± 3.27	0.24 (− 0.96 to 1.44)	0.692
Recovery time, min	5.40 ± 0.75	5.59 ± 0.69	−0.19 (− 0.45 to 0.07)	0.149
Body movement, n (%)	3 (4.9)	4 (6.6)	−1.6 (− 11.3 to 7.8)	1.000
Successful procedure, n (%)	61 (100.0)	61 (100.0)	—	—

Data are mean ± standard deviation or n (%). CI, confidence interval. □Ciprofol minus propofol: mean difference for continuous variables; risk difference in percentage points for categorical variables.

Table 5
Adverse events

Adverse event	Ciprofol (n = 61)	Propofol (n = 61)	Risk difference, % (95% CI)□	P value
Injection pain, n (%)	0 (0.0)	12 (19.7)	−19.7 (− 31.3 to − 9.7)	< 0.001*
Respiratory depression, n (%)	2 (3.3)	11 (18.0)	−14.8 (− 26.4 to − 3.7)	0.008*
Bradycardia, n (%)	0 (0.0)	1 (1.6)	−1.6 (− 8.7 to 4.4)	1.000
Hiccups, n (%)	2 (3.3)	2 (3.3)	0.0 (− 8.3 to 8.3)	1.000
Nausea and vomiting, n (%)	2 (3.3)	2 (3.3)	0.0 (− 8.3 to 8.3)	1.000

CI, confidence interval. □Ciprofol minus propofol. *P < 0.05; comparisons were not adjusted for multiplicity.

Rescue vasoactive medication use

In accordance with the protocol, all patients with hypotension received norepinephrine [14/61 (23.0%) vs 26/61 (42.6%); P = 0.021] (Table 6). Among these patients, the number of boluses was 1.0 (1.0, 2.0) vs 2.0 (1.0, 2.0) (P = 0.083), and the cumulative dose was 8.0 (6.0, 12.0) vs 12.0 (8.0, 16.0) μg (P = 0.061). One patient in the propofol group and none in the ciprofol group required atropine.

Table 6
Rescue vasoactive medication use

Variable	Ciprofol (n = 61)	Propofol (n = 61)	P value
Patients requiring norepinephrine, n (%)	14 (23.0)	26 (42.6)	0.021*
Norepinephrine boluses, number□	1.0 (1.0, 2.0)	2.0 (1.0, 2.0)	0.083
Cumulative norepinephrine dose, μg□	8.0 (6.0, 12.0)	12.0 (8.0, 16.0)	0.061
Patients requiring atropine, n (%)	0 (0.0)	1 (1.6)	1.000

Data are n (%) or median (Q1, Q3). □Analyzed only among patients who received norepinephrine (ciprofol, n = 14; propofol, n = 26); these comparisons are not protected by randomization. *P < 0.05.

Discussion

In this randomized double-blind trial, ciprofol reduced the incidence of hypotension compared with propofol in hypertensive patients undergoing sedated gastrointestinal endoscopy. Injection pain and respiratory depression were also less frequent, whereas induction time, recovery time, body movement, and procedural completion did not differ significantly. Our relative risk of 0.54 is in the same direction as the pooled estimate of 0.73 (95% CI, 0.58 to 0.92) from a meta-analysis of general endoscopy trials [23], and as a trial in hypertensive women undergoing induction of general anesthesia [16], although differences in population and hypotension definition limit direct comparison.

We focused on hypertensive patients because reduced arterial compliance, impaired baroreflex function, and altered autonomic regulation may limit compensation for anesthetic-induced vasodilation or myocardial depression [8, 9]. Our sample included patients up to 75 years of age and with BMI up to 33.8 kg/m², but patients with severe cardiopulmonary disease were excluded.

The incidence of hypotension and the mean hemodynamic trajectories should be interpreted together. MAP was higher with ciprofol at T2 and T5 in unadjusted comparisons, but baseline MAP was also 4.03 mmHg higher in that group. After adjustment for baseline, no time point differed significantly, the group-by-time interaction was not significant, and the maximum proportional decrease in MAP was similar between groups. These data therefore provide little evidence of better average hemodynamic stability with ciprofol. Because the primary outcome captured threshold events across all intraprocedural measurements rather than at the predefined time points, it may differ between groups even when mean trajectories are similar.

Differences in sedation depth could affect hemodynamic comparisons. The induction ratio of 0.5 mg/kg ciprofol to 2.0 mg/kg propofol was selected from previous potency and sedation evidence [12, 13] and has also been used in hypertensive patients [16]. Body movement, induction time, and recovery time did not differ significantly, which suggests broadly comparable clinical sedation. However, these non-significant results do not establish equivalence, and objective depth monitoring was not used.

Norepinephrine use was identical to the primary outcome because the protocol required treatment of every hypotensive event; it should not be regarded as independent confirmation. Bolus number and cumulative dose were analyzed only among treated patients, did not differ significantly, and are not protected by randomization.

Respiratory depression was less frequent with ciprofol even though median SpO_2 was 100% at all recorded time points in both groups, suggesting that intermittent time-point values may not capture individual events. This is consistent with evidence of less respiratory suppression with ciprofol [12, 24]. However, this secondary finding was not adjusted for multiplicity and requires confirmation.

Injection pain occurred in approximately one fifth of patients receiving propofol and in none receiving ciprofol, consistent with previous reports. This may reflect a formulation with less free drug in the aqueous phase and thereby less vascular irritation [25–28]. The propofol rate was lower than the 72.9% reported in a recent trial in hypertensive patients [16], which may reflect differences in injection site, pretreatment, and assessment. Recovery time also differed from that trial, in which recovery was longer with ciprofol [16]; differences in procedure type and anesthetic exposure may contribute.

This study has several limitations. First, it was a single-center trial with a modest sample, and the primary result was statistically fragile: one additional event in the ciprofol group would have rendered the Fisher's exact comparison non-significant. Second, the bispectral index was not used. Third, intermittent blood pressure measurement at 3-min intervals may have missed brief hypotension, and hypotension duration was not analyzed. Fourth, multiple secondary comparisons were unadjusted. Fifth, absence of injection pain could have compromised blinding, and blinding integrity was not formally assessed. Sixth, the results may not apply to patients with more severe cardiopulmonary disease, and the study was not powered for subgroup analyses by age or BMI. Finally, the study was not powered for rare adverse events or major cardiovascular outcomes.

Conclusions

In hypertensive patients undergoing sedated gastrointestinal endoscopy, ciprofol reduced the incidence of hypotension compared with propofol and was associated with less injection pain and fewer respiratory depressive events. These results suggest that ciprofol may be a useful alternative to propofol for endoscopic sedation in patients with hypertension. Larger multicenter randomized trials are warranted to confirm these findings and to evaluate their applicability to broader high-risk populations.

Abbreviations

ACEI, angiotensin-converting enzyme inhibitor;

ARB, angiotensin receptor blocker;

ASA, American Society of Anesthesiologists;

BMI, body mass index;

CI, confidence interval;

HR, heart rate;

MAP, mean arterial pressure;

MOAA/S, Modified Observer's Assessment of Alertness/Sedation;

SBP, systolic blood pressure;

SpO_2, peripheral oxygen saturation.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Ethics Committee of The Affiliated Hospital of Guangdong Medical University, Zhanjiang, Guangdong, China (protocol code: PJKT2025-213; approval date: 23 September 2025). Written informed consent was obtained from all participants before enrollment.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Author Contribution

HZ and JZ contributed equally to this work. HZ and HRL contributed to study conception and design. YL contributed to methodology. HZ and JZ contributed to investigation and data collection. HZ, JZ, QH, and HRL contributed to data analysis. ML, YZ, and HeL contributed to resources and study implementation. HZ and JZ drafted the manuscript. YL critically revised the manuscript and supervised the study. All authors read and approved the final manuscript.

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Availability of data and materials

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

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Figures

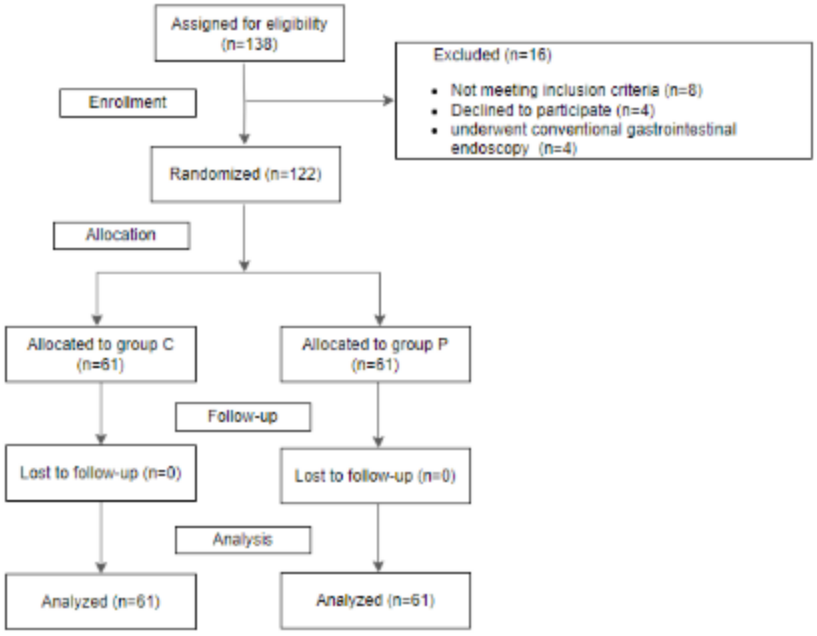

Figure 1

CONSORT flow diagram of the study.

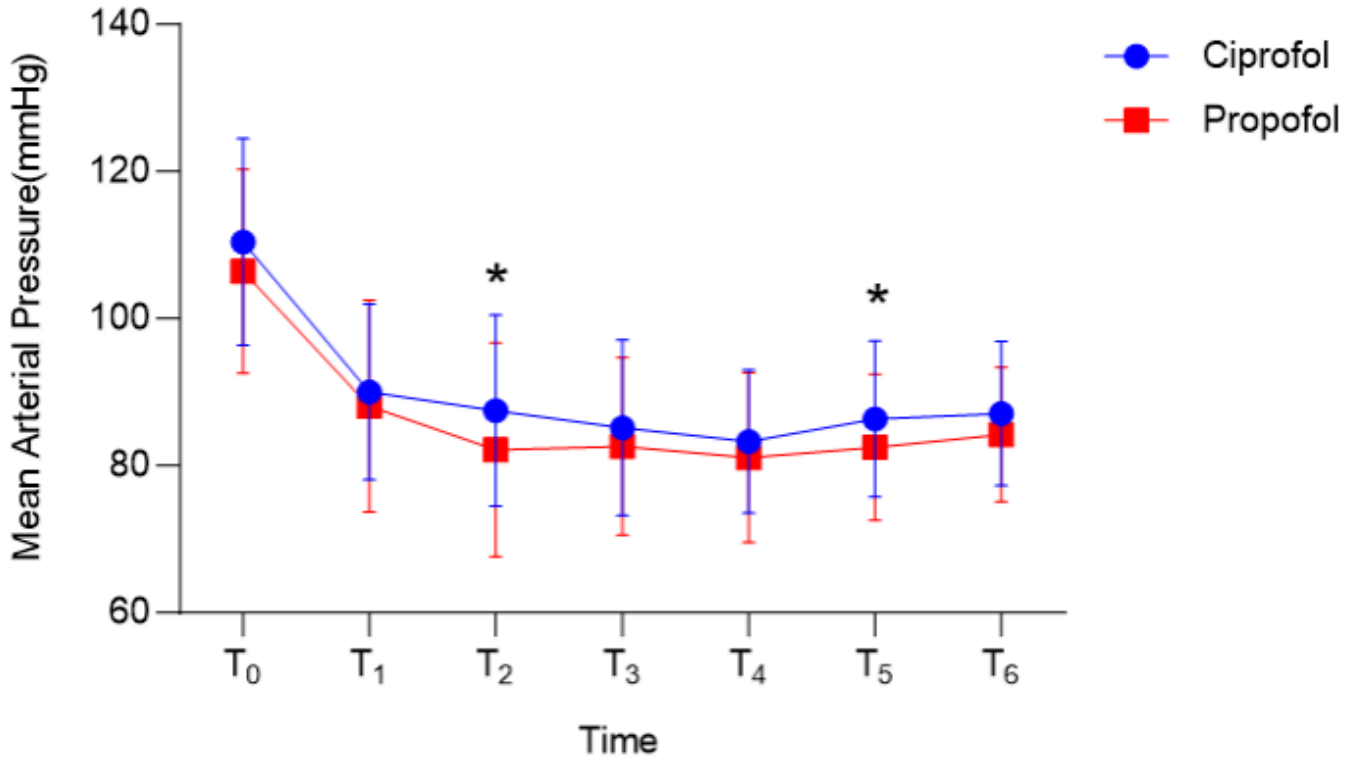

Figure 2

Mean arterial pressure over time. Data are mean ± standard deviation. *P<0.05, unadjusted. T0, baseline; T1, after loss of consciousness (MOAA/S ≤1); T2, gastroscope insertion; T3, gastroscope withdrawal; T4, colonoscope insertion; T5, colonoscope withdrawal; T6, discharge from the post-anesthesia care unit. MOAA/S, Modified Observer's Assessment of Alertness/Sedation.

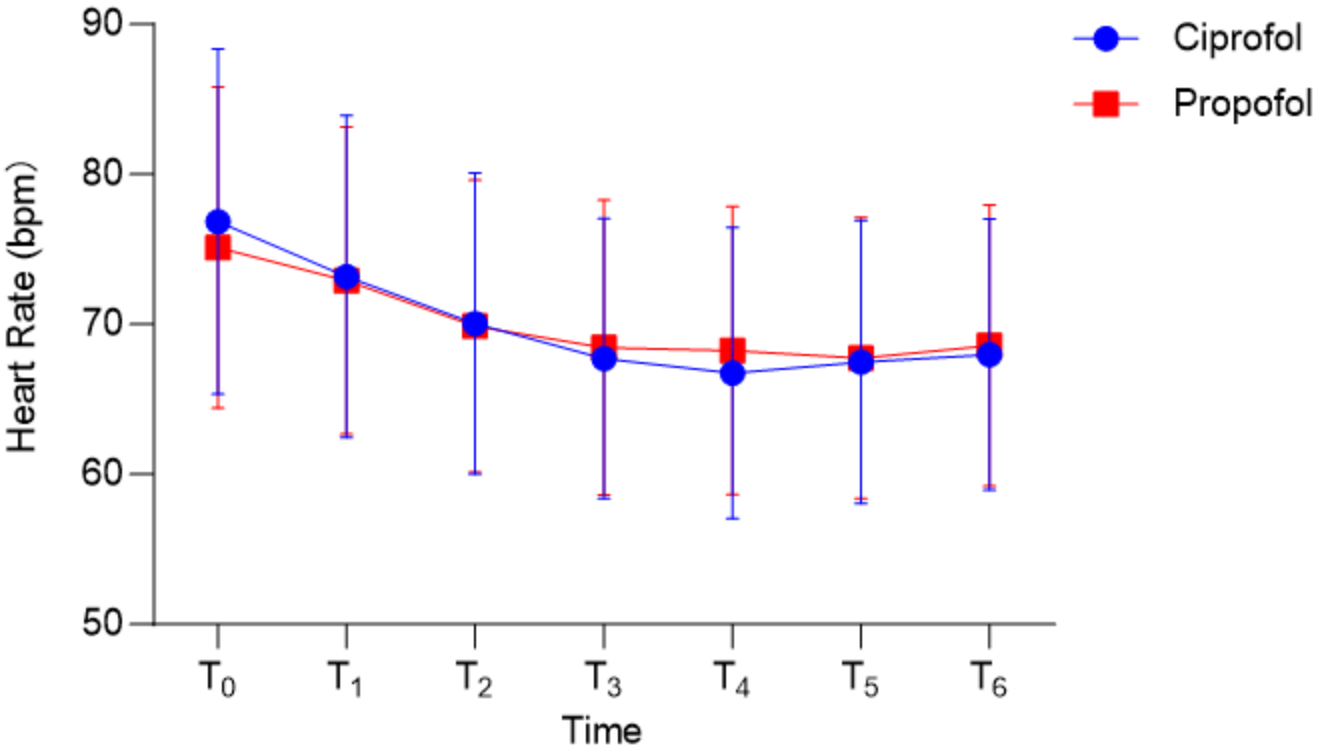

Figure 3

Heart rate over time. Data are mean ± standard deviation. There were no significant differences at any time point. T0, baseline; T1, after loss of consciousness (MOAA/S ≤1); T2, gastroscope insertion; T3, gastroscope withdrawal; T4, colonoscope insertion; T5, colonoscope withdrawal; T6, discharge from the post-anesthesia care unit. MOAA/S, Modified Observer's Assessment of Alertness/Sedation.

Supplementary Files

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- Additionalfile1CONSORT2025checklist.pdf