Additional file 1

CONSORT 2025 checklist of information to include when reporting a randomised trial

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

Page numbers refer to the revised manuscript. Table and figure numbers are those used in the manuscript.

Section/topic	No.	CONSORT 2025 checklist item	Reported	Page	How addressed in this manuscript
Title and abstract	1a	Identification as a randomised trial in the title	Yes	1	Title ends ": a randomized double-blind controlled trial"; Abstract Methods: "single-center, parallel-group, double-blind randomized controlled trial".
	1b	Structured summary of the trial design, methods, results and conclusions	Yes	1-2	Structured abstract (Background, Methods, Results, Conclusions): single-centre parallel-group double-blind design, 122 patients (61 per group), hypotension 23.0% vs 42.6% (RR 0.54, 95% CI 0.31-0.93; P=0.021), and conclusion that ciprofol reduced hypotension with confirmation required.
Open science	2	Name of trial registry, identifying number (with URL) and date of registration	Partly	2, 4	Chinese Clinical Trial Registry, ChiCTR2500110441, registered 14 October 2025 (prospectively, before the first participant); the registry URL is not given in the manuscript.
	3	Where the trial protocol and statistical analysis plan can be accessed	Partly	4, 13	Protocol approval is described (PJKT2025-213, 23 September 2025), but accessibility of the protocol and of the statistical analysis plan is not stated.
	4	Where and how individual de-identified participant data (including data dictionary), statistical code and other materials can be accessed	Partly	13	"The datasets ... are available from the corresponding author on reasonable request"; data dictionary, statistical code and other materials are not specified.
Funding and conflicts of interest	5a	Sources of funding and other support, and role of funders in design, conduct, analysis and reporting	Yes	13	No funding or other support was received for this study, and no funder had any role in its design, conduct, analysis or reporting.
	5b	Financial and other conflicts of interest of the manuscript authors	Yes	13	"The authors declare that they have no competing interests."
Introduction	6	Scientific background and rationale	Yes	2-3	Background describes sedation-related hypotension, propofol pharmacology, arterial and autonomic consequences of long-standing hypertension, and the limited direct evidence for ciprofol in this population (refs 1-16).
	7	Specific objectives related to benefits and harms	Yes	3, 6-7	Objective: comparison of the incidence of hypotension between ciprofol and propofol, hypothesising lower hypotension with ciprofol; benefits and harms specified as primary outcome, adverse events and rescue medication use.
Methods	8	Details of patient or public involvement in the design, conduct and reporting of the trial	No	-	Not reported.
	9	Trial design including type of trial, allocation ratio and framework	Yes	4-5	Single-centre, prospective, randomized, parallel-group, double-blind controlled trial; allocation 1:1 to ciprofol or propofol; superiority hypothesis.
	10	Important changes to the trial after it commenced, including outcomes or analyses not prespecified, with reasons	No	-	Not reported; no statement on whether outcomes and analyses were prespecified or modified.
	11	Settings and locations where the trial was conducted	Yes	4	The Affiliated Hospital of Guangdong Medical University, Zhanjiang, Guangdong, China; endoscopy centre of a single tertiary (Grade A) hospital.

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	12a	Eligibility criteria for participants	Yes	4-5	Inclusion: age 18-75 years, primary hypertension, ASA physical status II-III, BMI 18-28 kg/m2, scheduled painless gastroscopy plus colonoscopy; exclusions: severe cardiopulmonary disease, poorly controlled blood pressure (SBP >180 mmHg or DBP >110 mmHg), severe hepatic or renal dysfunction, allergy, psychiatric disorders, inability to cooperate.
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions	Partly	4	Single tertiary centre is named; no stated eligibility criteria for the site or for the anesthesiologists and endoscopists delivering the interventions.
	13	Intervention and comparator with sufficient detail to allow replication	Yes	5-6	Sufentanil 0.1 ug/kg followed by ciprofol 0.5 mg/kg or propofol 2.0 mg/kg over 30 s; manufacturers named; volume-matched, appearance-masked preparation in identical 50-mL syringes; supplemental boluses ciprofol 0.1 mg/kg or propofol 0.5 mg/kg at MOAA/S >1 or body movement; fasting and antihypertensive management described.
	14	Prespecified primary and secondary outcomes, with measurement variable, analysis metric, aggregation method and time point	Yes	6-7	Primary: incidence of hypotension from induction to end of procedure, defined as SBP <90 mmHg or >30% decrease in MAP from baseline, assessed from all non-invasive measurements, aggregated as proportion of patients meeting either criterion at any time. Secondary: MAP, SBP, HR and SpO2 at seven prespecified time points (T0-T6), time metrics, body movement, procedure success, rescue medication, adverse events.
	15	How harms were defined and assessed	Yes	7	Prospectively defined: injection pain (4-point verbal rating scale, score >=1), bradycardia (<50 beats/min), respiratory depression (SpO2 <90% for >10 s or need for airway assistance), hiccups, nausea and vomiting; recorded from anesthesia records and reported per group (Table 5).
	16a	How sample size was determined, including all assumptions	Yes	5	PASS 15.0; pilot of 20 patients per group gave event rates of 20% (ciprofol) and 45% (propofol); two independent proportions, two-sided alpha 0.05, 80% power required about 55 per group; allowing 10% dropout, 61 per group (122 total) were planned.
	16b	Explanation of any interim analyses and stopping guidelines	No	-	Not reported.
	17a	Who generated the random allocation sequence and the method used	Yes	5	Computer-generated sequence; randomization and drug preparation performed by an independent anesthesia nurse not involved in patient management, outcome assessment, data collection or analysis.
	17b	Type of randomisation and details of any restriction (e.g. stratification, blocking)	Partly	5	1:1 allocation to two groups; stratification, blocking and block size are not described.
	18	Mechanism used to implement the sequence, describing steps to conceal it until assignment	Yes	5	Allocation concealed in sequentially numbered, opaque, sealed envelopes; study drugs supplied in identical syringes labelled only with the study number.
	19	Whether the personnel who enrolled and those who assigned participants had access to the sequence	Partly	5	Sequence and drug preparation were handled by an independent nurse; whether the enrolling anesthesiologists had access to the allocation sequence is not stated.
	20a	Who was blinded after assignment to interventions	Yes	1, 5	Patients, endoscopists, attending anesthesiologists, outcome assessors, data collectors and statisticians were blinded.
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	Yes	5	Volume-matched and appearance-masked protocol: identical 50-mL syringes covered with opaque material and labelled only with the study number; concentrations adjusted so that induction and supplemental volumes were identical between groups.

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	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	Yes	7-8	Independent-samples t test; Mann-Whitney U test for SpO2 and rescue medication; Pearson chi-square or Fisher's exact test; relative risk, absolute risk reduction and number needed to treat with Newcombe hybrid score 95% CIs; repeated-measures ANOVA with Greenhouse-Geisser correction; ANCOVA adjusted for baseline MAP (post hoc).
	21b	Definition of who is included in each analysis and in which group	Yes	7-8	All randomized patients analysed according to their assigned groups (no exclusions after randomization).
	21c	How missing data were handled in the analysis	Partly	8	All 122 randomized patients completed the protocol and were analysed, indicating no missing outcome data; the handling of missing data is not explicitly described.
	21d	Methods for any additional analyses, distinguishing prespecified from post hoc	Yes	8-9	Baseline-adjusted ANCOVA of MAP at each post-baseline time point is identified as post hoc; comparisons at individual time points were unadjusted for multiplicity and are labelled exploratory; no subgroup analyses were performed.
Results	22a	For each group, numbers randomly assigned, receiving intended intervention and analysed for the primary outcome	Yes	8; Fig. 1 (p.17)	138 assessed; 16 excluded before randomization (8 ineligible, 4 declined, 4 unsedated); 122 randomized (61 ciprofol, 61 propofol); all received the allocated regimen and all 61 per group analysed for the primary outcome; CONSORT flow diagram (Fig. 1).
	22b	For each group, losses and exclusions after randomisation, with reasons	Yes	8	No losses or exclusions after randomization; all patients completed the protocol and were included in the analysis.
	23a	Dates defining recruitment and follow-up periods for benefits and harms	Yes	4, 6-7	Recruitment November 2025 to January 2026; follow-up from induction to discharge from the post-anesthesia care unit (T6).
	23b	If relevant, why the trial ended or was stopped	Partly	4	Recruitment window is given, but the reason for ending recruitment (planned sample size reached) is not stated.
	24a	Intervention and comparator as actually administered	Yes	5-6	Drugs administered by the attending anesthesiologist after sufentanil; procedure started at MOAA/S <=1; supplemental boluses given for MOAA/S >1 or body movement; study drug stopped after endoscope withdrawal; all patients followed the same protocol.
	24b	Concomitant care received during the trial for each group	Yes	5-7	Calcium channel blockers and beta-blockers continued on the morning of the procedure; ACE inhibitors and ARBs withheld; fasting 8 h for solids and 2 h for clear fluids; protocolised norepinephrine, atropine and airway rescue, applied identically to both groups.
	25	A table showing baseline demographic and clinical characteristics for each group	Yes	8; Table 1 (p.18)	Table 1 reports age 59.92 +/- 8.51 vs 61.79 +/- 8.07 years, sex, BMI and ASA distribution with P values; baseline MAP was numerically higher with ciprofol (110.45 +/- 14.07 vs 106.42 +/- 13.93 mmHg; P=0.114).
	26	For each outcome by group: numbers analysed, numbers with available data, result per group, effect size and precision, and absolute and relative effects for binary outcomes	Yes	9-10; Tables 2-6 (pp.18-19)	Primary outcome: 14/61 (23.0%) vs 26/61 (42.6%); RR 0.54 (95% CI 0.31-0.93); ARR 19.7% (95% CI 3.0-34.9); NNT 5 (95% CI 3-33); P=0.021. MAP, HR and SpO2 at seven time points, time metrics, body movement and rescue medication reported per group with estimates and CIs.
	27	All harms or unintended events in each group	Yes	9-10; Table 5 (p.19)	Injection pain 0/61 (0.0%) vs 12/61 (19.7%), P<0.001; respiratory depression 2/61 (3.3%) vs 11/61 (18.0%), P=0.008; bradycardia, hiccups and nausea/vomiting reported by group; one propofol patient required atropine; no other events reported.
	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing prespecified from post hoc	Yes	8-10	Post hoc baseline-adjusted ANCOVA of MAP, lowest recorded MAP and maximum proportional decrease in MAP; analyses restricted to norepinephrine-treated patients (bolus number and cumulative dose); no subgroup or sensitivity analyses.

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Discussion	29	Interpretation consistent with results, balancing benefits and harms and considering other relevant evidence	Yes	10-12	Interpretation limited to the incidence of hypotension; explicitly states that no evidence supports better average haemodynamic stability; compares RR 0.54 with a meta-analysis estimate of 0.73 (95% CI 0.58-0.92) and with a hypertensive induction trial; advises confirmation rather than a change in practice.
	30	Trial limitations addressing sources of potential bias, imprecision, generalisability and multiplicity	Yes	12	Single-centre design and modest sample with a statistically fragile primary result; no bispectral index; intermittent 3-min blood pressure measurement and no analysis of hypotension duration; multiple unadjusted secondary comparisons; possible compromised blinding due to absence of injection pain; limited generalisability; not powered for rare events or subgroups.

Reported: Yes, fully reported; Partly, reported but incomplete; No, not reported in the current manuscript. Checking was performed against the revised manuscript file (20 pages).

Abbreviations: ACE, angiotensin-converting enzyme; ANCOVA, analysis of covariance; ANOVA, analysis of variance; ARB, angiotensin receptor blocker; ARR, absolute risk reduction; ASA, American Society of Anesthesiologists; CI, confidence interval; MAP, mean arterial pressure; MOAA/S, Modified Observer's Assessment of Alertness/Sedation; NNT, number needed to treat; RR, relative risk; SBP, systolic blood pressure; SpO2, peripheral oxygen saturation.