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Efficacy and safety of ciprofol for gastroscopy in patients with obesity: a randomised clinical controlled trial using different weight-based dosing scales

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Abstract

Background This study aimed to compare the efficacy and safety of ciprofol-induced doses based on three indices: total body weight (TBW), ideal body weight (IBW), and lean body weight (LBW) in patients with obesity undergoing gastroscopy.

Methods In a single-centre, prospective, randomised study conducted at an endoscopy centre, a total of 108 patients aged 18–65 years who underwent painless gastroscopy and had a body mass index (BMI) of 28–39.9 kg/m^2 were included. Patients with obesity from the intended study population were randomised to receive a ciprofol infusion (0.4 mg/kg) for the induction of anaesthesia based on TBW (Group T), IBW (Group I), or LBW (Group L). A Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale score of < 1 was considered a marker of loss of consciousness, prompting gastroscopy. The primary outcomes were the success rate of anaesthesia for the procedures, and that of general anaesthesia achieved using the initial dose. Secondary outcomes included the frequency of remedial sedation, total ciprofol dose, and adverse events

Results The procedure success rate was 100% in all three groups. Compared to Group L, the general anaesthesia success rate achieved with the initial dose was higher and the frequency of remedial sedation was lower in Groups T and I. Compared to Group L, fewer patients in Group T required additional medication. Compared to Group T, the occurrence of hypoxaemia was lower in the remaining two groups, and Group L had a lower incidence of posterior tongue drops and hypotension.

Conclusions Induction doses of ciprofol based on TBW or IBW provided better anaesthesia than doses based on LBW for gastroscopy in patients with obesity. LBW-based induction doses of ciprofol improved cardiovascular stability and respiratory safety, whereas IBW-based induction doses of ciprofol reduced respiratory depression.

Trial registration This study was registered in the Chinese Clinical Trial Registry (ChiCTR2300073539 first registration date 13/07/2023).

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Keywords Ciprofol, Weight-based scalars, Gastroscopy, Obesity

Background

The incidence of obesity is increasing at an alarming rate worldwide [1]. Numerous epidemiological studies have demonstrated a link between obesity and the risk of developing upper gastrointestinal tumours [2]. Gastroenteroscopy is considered to be the most reliable and accurate method for the diagnosis and detection of gastrointestinal diseases. Consequently, the proportion of patients with obesity undergoing gastroscopy has increased [3]. As the concept of comfort continues to evolve, there is an increasing need for secure and comfortable anaesthesia for individuals requiring unpleasant and painful treatments [4]. During procedural anaesthesia, obesity is more likely to lead to hypoxaemia [5] because of changes in airway morphology and respiratory insufficiency [6]. For patients undergoing non-operating room treatments requiring sedation, intravenous propofol is a good sedation option with a fast-acting sedative effect [7]. However, it can worsen hypoxaemia [8] by obstructing the airways and causing cardiopulmonary depression [9], particularly in patients with obesity [10, 11]. Therefore, when a sedative is chosen for patients with obesity undergoing painless gastroscopy, optimising the sedation strategy is crucial.

Ciprofol is a newly developed short-acting gamma-aminobutyric acid-A receptor agonist with a chemical structure similar to that of propofol [12]. Compared with propofol, ciprofol is less likely to cause injection-related pain and has fewer effects on respiration and circulation [13]. According to the manufacturer's instructions, ciprofol is indicated for sedation and anaesthesia, particularly for non-tracheal intubation. However, it has some drawbacks, such as an increased risk of side effects, including hypotension, respiratory depression, and injection pain, when administered at higher doses [14]. Therefore, several factors regarding the dosage and the patient undergoing the procedure should be considered to eliminate potentially negative clinical outcomes.

In addition, the current dosing recommendations for ciprofol are usually based on strategies used for patients with normal body weight and lack recommendations for patients with obesity. The concepts typically included in clinical drug dosage calculation methods include total body weight (TBW), ideal body weight (IBW), and lean body weight (LBW) [15]. Previous studies have shown that individuals with obesity received propofol based on TBW to provide a shorter induction time in a rapid infusion model [16]. Compared to normal-weight individuals, individuals with obesity administered propofol based on LBW for the induction of anaesthesia demonstrated a similar onset of loss of consciousness [17]. This effect may be explained by the unchanged initial volume of the distribution based on the LBW. In practice, many metrics, such as perioperative medication doses, intraoperative ventilation, and rehydration, are calculated based on IBW. As patients with obesity have different drug distributions and body compositions [18], this study aimed to compare different weight-based scalars to determine the optimal dosage for a single bolus induction of ciprofol for gastroscopic diagnosis and treatment of patients with obesity.

Methods

Trial design

This study was conducted in accordance with the principles of the Declaration of Helsinki and Chinese Clinical Trial Specifications. This trial was registered on 13 July 2023 in the Chinese Clinical Trial Registry (www.chictrorg.cn, registration number: ChiCTR2300073539). This study was approved by the Medical Ethics Committee of the Shunde Hospital of Southern Medical University (approval no. KYLS20230624). All participants, whether patients or their families, provided informed consent after signing an informed consent form.

Participants

The study included 110 patients with obesity who underwent painless gastroscopy between 1 September 2023 and 30 October 2023.

The inclusion criteria were as follows.

1) Patients undergoing diagnostic gastroscopy and simple treatment under gastroscopy for various reasons.
2) Aged 18–65 years.
3) American Society of Anaesthesiologists (ASA) grade I–II.
4) Body mass index (BMI) between 28 and 39.9 kg/m2.
5) Both patients and their families were fully aware of the study objectives and provided signed informed consent.

The exclusion criteria were as follows:

1) Endoscopic diagnostic and therapeutic techniques involving longer operating times and more complex procedures include endoscopic retrograde cholangiography, endoscopic ultrasonography, endoscopic mucosal resection, endoscopic submucosal dissection, peroral endoscopic myotomy, and small enteroscopy.
2) Patients undergoing emergency procedures;

3) History of a negative response to anaesthesia, such as an allergic reaction to the anaesthetic or familial predisposition to malignant hyperthermia.
4) Bradycardia or other severe cardiovascular conditions.
5) Severe injuries or diseases affect critical organs such as the lungs, brain, liver, or kidneys.
6) Severe mental disorders.
7) History of substance addiction or drug abuse.

The grounds for rejection were as follows:

1) Patients with serious complications during intervention.

2) Failure to meet the inclusion criteria or adhere to the exclusion criteria.

3) Blindness in blind tests.

Randomization and blinding

The enrolled patients were randomly divided into three groups based on the intended operation. Randomisation was performed by an independent investigator, and the results were sealed in an opaque envelope and delivered to the anaesthetist responsible for sedation. Non-blinded anaesthetists were trained before the trial to improve their understanding and knowledge of the intervention protocol. During the procedure, a skilled, non-blinded anaesthetist was responsible for administering the patients' medications based on their body weight, movement, and vocal reaction. This anaesthetist was aware of the group allocation but was not involved in any other research procedures or evaluations. Another blinded anaesthesia resident was responsible for assessing the research endpoints and collecting data. All patients, analysts, and endoscopists involved in the study were blinded to the treatment allocation. The investigators were blinded to the randomisation results except for the occurrence of unforeseen serious adverse events during the procedure.

Intervention and sedation/anaesthesia protocol

A standardised preparation for gastroscopy was performed for all patients. Upon entering the endoscopy centre, an intravenous catheter was placed in the patient's right forearm to administer the drugs. Once in the clinic, blood pressure (BP), heart rate (HR), respiratory rate (RR), and pulse oxygen saturation (SpO_2) are routinely monitored. Before diagnosis and treatment, the patients were administered 5 L/min of oxygen via a nasal catheter, which was continued until they fully recovered after surgery. First, 0.05 mg/kg dezocine was injected intravenously according to the actual body weight. After 3 min, the group received a slow injection of ciprofol at a dose of 0.4 mg/kg according to different weight-based scalars. The injection time was not less than 30 s. IBW and LBW were calculated as follows:

$$\text{IBW (for } men) = \text{H-100} \tag{1}$$

$$\text{IBW (for } women) = \text{H-105} \tag{2}$$

$$\text{LBW (for } men) = \frac{9270 \times \text{TBW}}{6680 + 216 \times \text{BMI}} \tag{3}$$

$$\text{LBW (for } women) = \frac{9270 \times \text{TBW}}{8780 + 244 \times \text{BMI}} \tag{4}$$

Where *H* is height (cm), *TBW* is in (kg), and *BMI* is in kg/m^2.

The depth of sedation was evaluated 2 min after administration of the initial dose using the Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale, which provides a detailed description of sedation levels, with scores ranging from 5 to 0 [19] (Supplemental Table 1). The procedure was initiated when the eyelash reflex disappeared, and the MOAA/S scale score was <1. The supplementary dose in the corresponding group was equivalent to 50% of the initial ciprofol dosage.

If the desired level of sedation (MOAA/S scale ≤ 1) was not attained after 2 min of administering the initial dosage, it was maintained to provide 50% of the original dose of ciprofol until the desired level of sedation was achieved. However, the administration of sedation was considered unsuccessful if more than three rescue sedations were required in a 5-minute period. In cases where ciprofol dosages were inadequate to induce sufficient sedation, propofol was administered to achieve the desired level of sedation. Under such circumstances, approximately 0.2–0.5 mg/kg propofol was administered once or several times as rescue sedation. If the patient displayed any body movements that were considered insufficient for sedation, such as lifting the head, choking, coughing, or limb movement, 50% of the original dose was rapidly delivered throughout the procedure. SpO2 was maintained at > 90% during surgery. An anaesthesiologist determined whether the situation was due to respiratory depression or airway blockage if the SpO2 dropped to < 90% during surgery. Examining of the respiratory airflow, chest expansion, and belly fluctuations helped identify the cause. If this occurred, it was managed by supporting the lower jaw, placing an oropharyngeal tube, and pressurising the mask with oxygen. Mechanical ventilation via endotracheal intubation was performed if necessary. After surgery, all patients were transferred to the post-anaesthesia care unit (PACU) for resuscitation. The modified Aldrete scale was used to evaluate recovery quality across five parameters: respiration, BP, SpO_2, activity, and level of consciousness [20]. Patients could

not exit the PACU when their Aldrete score reached ≥ 9 or matched their pre-procedure level.

Measurements and data collection

The primary outcomes of this study were the success rate of anaesthesia for the procedures and the success rate of induction of general anaesthesia produced by the initial bolus dose. Successful sedation or anaesthesia for the surgeries encompassed successful execution of the procedures, absence of the necessity for alternative sedatives, and requirement for no more than three instances of rescue sedation within a 5-min timeframe. Successful general anaesthesia was defined as patients who achieved successful induction after the initial bolus dose without requiring a top-up dose.

The secondary outcomes of this study included the proportion of patients requiring additional intraoperative medication, frequency of remedial sedation, or total doses of ciprofol and dezocine administered during surgery. Additionally, variables such as gastroscopy duration, recovery time (defined as the period from the conclusion of gastroscopy to full patient awakening), time to regain orientation (from the end of the examination to the patient's ability to provide personal details), and PACU residence time were recorded for each group.

Other secondary outcomes included the occurrence of diverse adverse events during and after surgery, such as posterior tongue drop, decreased respiratory rate, hypoxaemia, hypertension, hypotension, bradycardia, cough, body movement, injection pain, dizziness, nausea, and vomiting. Intraoperative hypotension was defined as a > 20% decrease in baseline BP or mean arterial blood pressure (MAP) during induction. Marked hypotension was defined as a > 30% decrease in baseline BP or MAP during induction. Intraoperative hypertension was defined as BP or MAP > 20% of the baseline. In addition, a respiratory rate of < 12 breaths/min indicated decreased respiration. A SpO_2 of < 90% for > 10 s was considered hypoxaemia. Intraoperative bradycardia was defined as a HR ≤ 60 beats/min. Dopamine (1–2 mg) was intravenously injected if marked hypotension was observed, and atropine (0.5 mg) was injected intravenously when the HR was < 50 beats/min.

The anaesthetic effect was evaluated based on the success rates of sedation, anaesthesia, and remedial sedation. Safety assessments involve many factors, including the frequency of adverse events, alterations in vital signs, occurrence of coughing and body movements throughout the process, and experience of pain upon injection. Additionally, haemodynamic factors (including MAP and HR), RR, and SpO_2 were measured at five different time points: T_0 (upon entry into the room), T_1 (following anaesthesia induction), T_2 (upon insertion of the endoscope), T_3 (upon endoscope exit from the pharyngeal cavity), T_4 (during full patient awakening), and T_5 (at discharge from the hospital).

Sample size estimation and statistical analysis

The sample size was determined on the basis of an initial study. Sixty patients were recruited for the study. Participants were randomly allocated to three groups: Group T ($n = 20$), Group I ($n = 20$), and Group L ($n = 20$). The outcomes of our preliminary experiment, which was conducted with a limited number of participants, revealed a statistically significant disparity in the percentage of successful induction of general anaesthesia and sedation obtained by the first dose among the three groups (Group T, 80%; Group I, 70%; Group L, 35%). The overall sample size of the three groups ($n = 78$ cases) was calculated using the PASS 15 software, with a significance threshold of 0.05, $\alpha = 0.05$, and a power of 90% ($\beta = 0.10$). Considering a dropout rate of 10%, we required a minimum of 87 patients and evenly distributed them into three groups, each comprising 29 patients.

SPSS (version 26.0) was used for data processing and analysis. The Kolmogorov-Smirnov test was used to determine whether the data followed a normal distribution. Continuous variables that follow a normal distribution are presented as means and standard deviations. Data that passed this test were analysed using one-way analysis of variance (ANOVA) to compare multiple groups. Pairwise comparisons were performed using the Bonferroni test if a significant difference was observed between groups. If the data showed a non-normal distribution, the Kruskal-Wallis test was used. Repeated-measures analysis was used for within-group analysis of changes in intraoperative vital signs. Categorical variables are expressed as frequencies (percentages) and analysed using the chi-square or Fisher exact test, with the Bonferroni test used for pairwise comparisons between the groups. Statistical significance was set at $P < 0.05$. However, to address the issue of multiple comparisons, a Bonferroni post-hoc correction was performed, with a significance level of 0.016 considered as the threshold for statistical significance.

Results

Patients' baseline demographic and clinical characteristics

This study included a cohort of 110 participants, of whom 108 had completed the study. The 108 participants were assigned to receive ciprofol infusion to induce general anaesthesia, with the exception of one patient who declined to participate and one patient who did not successfully receive the allocated intervention because of a failed venous access opening. Figure 1 shows a flow diagram of the study. The patients were randomly divided into three groups: Group T ($n = 36$), Group I ($n = 38$), and Group L ($n = 34$).

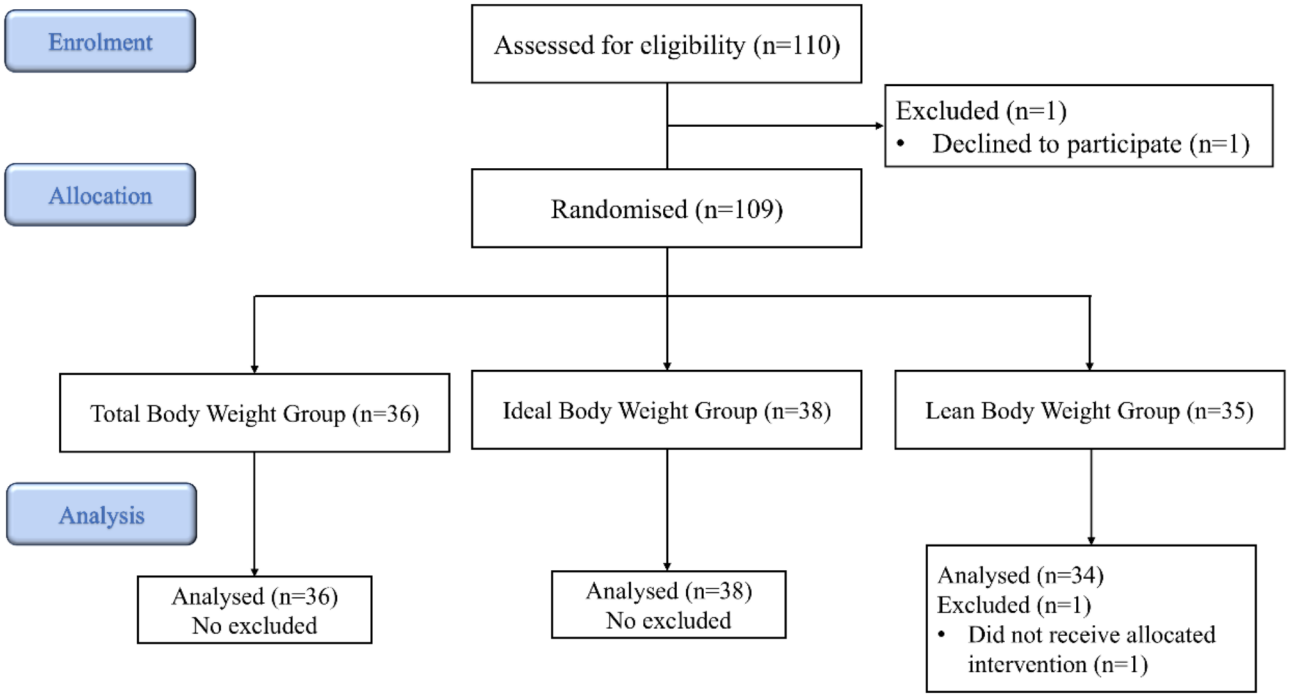

Fig. 1 Flow diagram of patient enrolment, allocation, and analysis

The demographic and surgical characteristics of the patients are shown in Table 1. There were no statistically significant differences in the general condition of the patients in terms of age, sex ratio, height, weight, body mass index, BMI, ASA status, comorbidities, dezocine dose, or gastroscopy time among the three groups. (all $p > 0.05$)

Primary outcomes

The success rate of surgery in all three groups was 100%. Sedation was successfully achieved by the initial dose induction in 30 patients (83.33%) in Group T, 28 patients (73.68%) in Group I, and 13 patients (38.24%) in Group L. Compared to Group L, the success rate of general anaesthesia induction achieved by the initial dose was significantly higher in Groups T and I ($P < 0.05$). Nonetheless, no statistically significant difference was observed between Groups T and I ($P > 0.05$). (Table 2)

Secondary outcomes

Remedial sedation

The number of patients who did not require additional intraoperative medication in Group T (24 patients, 66.67%) was greater than that in Group L (7 patients, 20.59%). There was no statistically significant difference in the number of patients in Group I who did not require additional intraoperative medication (18 patients, 47.37%) compared to those in Groups T and L ($P < 0.05$). The frequency of remedial sedation was lower in Groups T and I than in Group L ($P < 0.05$) (Table 3).

Total dose of ciprofol

The total dose of ciprofol in Groups I and L was significantly lower than that in Group T. ($P < 0.05$) (Table 3).

Time spent in each time slot

There were no differences between the three groups in terms of time of recovery, time of restoration of directional force, or time of stay in the PACU. (all $P > 0.05$) (Table 3).

Adverse events

Adverse events included both intra-and postoperative adverse events. Potential intraoperative adverse events included posterior tongue drop, decreased respiratory rate, hypoxaemia, hypertension, hypotension, bradycardia, cough, body movements, and injection pain. Potential postoperative adverse events include dizziness, nausea, or vomiting.

The occurrence of hypoxaemia was notably lower in Groups I and L than in Group T ($P < 0.05$). The incidence of posterior tongue drop and hypotension was lower in Group L than in Group T ($P < 0.05$). There were no significant differences in the occurrence of decreased respiratory rate, hypertension, bradycardia, cough, body movement, dizziness, nausea, or vomiting among the three groups ($P > 0.05$). Injection pain was not reported in any of the three groups. (Table 4)

Table 1 Demographic characteristics of the three groups

	Group T (*n* = 36)	Group I (*n* = 38)	Group L (*n* = 34)	*P* value
Age (years)	46.69 ± 12.45	46.84 ± 11.82	43.88 ± 11.89	0.514
Sex:				0.711
Men, n (%)	30 (83.33)	29 (76.32)	28 (82.35)	
Women, n (%)	6 (16.67)	9 (23.68)	6 (17.65)	
Height (cm)	169.67 ± 7.32	167.68 ± 7.56	168.38 ± 7.07	0.503
Total body weight (kg)	87.11 ± 8.86	83.32 ± 7.29	84.18 ± 7.87	0.111
Ideal body weight (kg)	69.53 ± 7.46	67.05 ± 8.55	67.65 ± 7.31	0.372
Lean body weight (kg)	60.79 ± 5.97	57.77 ± 7.02	58.00 ± 6.24	0.089
BMI (kg/m^2)	30.22 ± 1.84	29.61 ± 1.59	29.64 ± 1.48	0.211
ASA status:				0.254
I, n (%)	1 (2.78)	5 (13.16)	4 (11.76)	
II, n (%)	35 (97.22)	33 (86.84)	30 (88.24)	
Hypertension, n (%)	6 (16.67)	9 (23.68)	7 (20.59)	0.755
Diabetes, n (%)	5 (13.89)	2 (5.26)	1 (2.94)	0.178
Smoker, n (%)	27 (75.00)	25 (65.79)	25 (73.53)	0.642
Asthma, n (%)	0 (0.00)	0 (0.00)	1 (2.94)	0.333
Drinker:				0.420
Seldom, n (%)	28 (77.78)	33 (86.84)	30 (88.24)	
Occasional, n (%)	8 (22.22)	5 (13.16)	4 (11.76)	
SBQ:				0.406
≥3, n (%)	10 (27.78)	9 (23.68)	5 (14.71)	
< 3, n (%)	26 (72.22)	29 (76.32)	29 (85.29)	
Dose of dezocine (mg)	4.26 ± 0.54	4.04 ± 0.43	4.12 ± 0.44	0.152
Gastroscopy time (min)	8.00 ± 2.15	7.39 ± 1.59	6.91 ± 1.91	0.059

Note: Data are presented as mean ± standard deviation or n. Data on frequency (percentage) were analysed using Pearson chi-squared test. The remaining data were analysed using the analysis of variance for group comparisons, and pairwise comparisons were conducted using the least significant difference test

ASA, American Society of Anesthesiologists; BMI, body mass index; SBQ, STOP-BANG questionnaire

Changes in hemodynamic

There were no statistically significant differences in preoperative MAP or HR among the three groups. Moreover, intraoperative haemodynamic changes were not significantly different among the three groups ($P > 0.05$). The MAP of the three groups showed a downward trend after anaesthesia induction ($P < 0.05$). In Group I, the MAP was lower at T_3 than at T_1 and T_2. In Group L, the MAP was lower at T_3 than at T_1 ($P < 0.05$). These findings indicate sometime an excessive depth of anaesthesia in Groups I and L. The HR fluctuations were small in all three groups. ($P > 0.05$) (Table 5; Figs. 2 and 3).

Discussion

The prevalence of obesity in China [21] is a significant obstacle for anaesthesiologists in drug dosing management for patients with challenging healthcare needs [22].

Table 2 Comparison of the success rate of sedation or anaesthesia and general anaesthesia success rate achieved by the initial dose

	Group T (*n* = 36)	Group I (*n* = 38)	Group L (*n* = 34)	*P* value
Success rate of induction of general anaesthesia, n (%)	36 (100)	38 (100)	34 (100)	-
General anaesthesia success rate achieved by the initial dose				< 0.001*
Yes, n (%)	30 (83.33)	28 (73.68)	13 (38.24)[ab]	
No, n (%)	6 (16.67)	10 (26.32)	21 (61.76)[ab]	

Note: Values are presented as numbers (%). Data were analysed using Pearson chi-squared test. For multiple comparisons, Bonferroni correction was performed to determine the *p* value significance threshold

*$P < 0.05$

[a]$P < 0.016$ compared to Group T

[b]$P < 0.016$ compared to Group I

Table 3 Remedial sedation conditions, drug dosage, recovery time, time to restore directional force, and PACU residence time

	Group T (*n* = 36)	Group I (*n* = 38)	Group L (*n* = 34)	*P* value
Remedial sedation, n (%)				0.010*
Yes, n (%)	12 (33.33)	20 (52.63)	27 (79.41)[a]	
No, n (%)	24 (66.67)	18 (47.37)	7 (20.59)[a]	
Frequency of remedial sedation (times)	0.42 ± 0.65	0.53 ± 0.51	0.94 ± 0.60[ab]	< 0.001*
Total dose of ciprofol (mg)	40.32 ± 11.36	33.07 ± 7.57[a]	34.89 ± 7.93[a]	0.003*
Recovery time (min)	5.47 ± 3.86	5.47 ± 3.33	5.79 ± 3.50	0.910
Time to restore directional force (min)	4.64 ± 2.55	3.50 ± 1.35	3.97 ± 1.55	0.054
PACU residence time (min)	20.67 ± 4.13	19.95 ± 3.00	19.26 ± 2.34	0.202

Note: Data are presented as the mean ± standard deviation or n (%). Frequency data (percentages) were analysed using the Pearson chi-square test. For multiple comparisons, Bonferroni correction was performed to determine the *p* value significance threshold. Other data were analysed using analysis of variance for comparisons between groups, and the least significant difference test was used for pairwise comparisons. PACU, post anaesthesia care unit

*$P < 0.05$

[a]$P < 0.016$ compared to Group T

[b]$P < 0.016$ compared to Group I

In ambulatory endoscopy centres with high-volume and fast-paced operations, decreasing the frequency of airway interventions, enhancing the necessary levels of sedation, and expediting the recovery of walking ability are crucial. These factors are essential for promoting comfort-focused medical practices, particularly among high-risk individuals [23]. Clinical studies have shown that ciprofol is a safe sedative for gastrointestinal endoscopy [24].

Table 4 Comparison of adverse events among the three groups

	Group T (*n* = 36)	Group I (*n* = 38)	Group L (*n* = 34)	*P* value
Incidence of intraoperative adverse events				
Posterior tongue drop, n (%)	10 (27.78)	4 (10.53)	1 (2.94)[a]	0.007[*]
Hypoxemia, n (%)	11 (30.56)	3 (7.89)[a]	1 (2.94)[a]	0.005[*]
Decrease in respiratory rate, n (%)	4 (11.11)	2 (5.26)	1 (2.94)	0.362
Hypertension, n (%)	1 (2.78)	0 (0)	0 (0)	0.330
Hypotension, n (%)	19 (52.78)	10 (26.32)	8 (23.53)[a]	0.016[*]
Bradycardia, n (%)	1 (2.78)	1 (2.63)	2 (5.88)	0.735
Cough, n (%)	3 (8.33)	2 (5.26)	5 (14.71)	0.383
Body movement, n (%)	5 (13.89)	7 (18.42)	7 (20.59)	0.752
Injection pain, n (%)	0 (0)	0 (0)	0 (0)	-
Incidence of postoperative adverse events				
Dizziness, n (%)	0 (0)	2 (5.26)	3 (8.82)	0.104
Nausea/vomiting, n (%)	1 (2.78)	0 (0)	0 (0)	0.330

Note: Values are presented as numbers (%). Data were analysed using Pearson chi-squared test. For multiple comparisons, Bonferroni correction was performed to determine the *p* value significance threshold

[*] $P < 0.05$

[a] $P < 0.016$ compared to Group T

[b] $P < 0.016$ compared to Group I

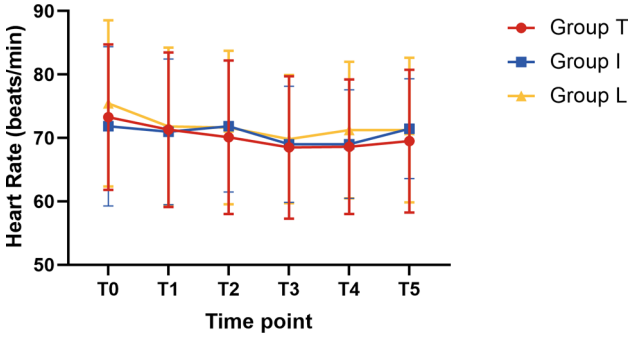

Fig. 2 Comparison of mean arterial pressure among the three groups. Note: T_0, upon entry into the room (basal); T_1, following anaesthesia induction; T_2, upon insertion of the endoscope; T_3, upon endoscope exit from the pharyngeal cavity; T_4, during full patient awakening; T_5, at discharge from the hospital

Additionally, these studies revealed a reduced occurrence of hypotension during induction and a decreased requirement for airway assistance [25]. Because of the structural similarity between ciprofol and propofol [26], it can be speculated that the appropriate dose of ciprofol in patients with obesity is similar to that of propofol; however, no study has yet verified this hypothesis.

This study aimed to assess the efficacy and safety of ciprofol, based on different body mass indices, to obtain procedural sedation for gastroscopy in patients with obesity. This study only targeted individuals with mild to moderate obesity who were appropriate candidates for the study design, as moderately deep sedation is often not recommended for patients with morbid obesity [27].

Table 5 Comparison of MAP and HR at each time point among the three groups

		T_0	T_1	T_2	T_3	T_4	T_5
MAP (mmHg)	Group T (*n* = 36)	104.69 ± 11.66	92.47 ± 11.95[a]	90.22 ± 14.43[a]	87.91 ± 15.45[a]	92.21 ± 13.47[a]	93.79 ± 11.95[a]
	Group I (*n* = 38)	108.97 ± 9.16	95.19 ± 10.94[ab]	94.90 ± 13.22[ab]	89.39 ± 9.11[a]	91.45 ± 7.64[a]	92.52 ± 7.46[a]
	Group L (*n* = 34)	106.11 ± 14.17	94.17 ± 12.22[ab]	92.65 ± 10.48[a]	88.10 ± 10.80[a]	91.10 ± 12.57[a]	92.55 ± 9.92[a]
	P value	0.283	0.598	0.356	0.336	0.905	0.825
HR (beats/min)	Group T (*n* = 36)	73.28 ± 11.46	71.31 ± 12.18	70.11 ± 12.11	68.50 ± 11.21	68.61 ± 10.59	69.50 ± 11.25
	Group I (*n* = 38)	71.84 ± 12.55	70.97 ± 11.48	71.84 ± 10.35	69.00 ± 9.15	69.03 ± 8.56	71.45 ± 7.88
	Group L (*n* = 34)	75.44 ± 13.10	71.82 ± 12.43	71.65 ± 12.10	69.82 ± 10.11	71.26 ± 10.77	71.26 ± 11.40
	P value	0.468	0.956	0.783	0.988	0.788	0.683

Note: Data are presented as mean ± standard deviation (mmHg or beats/min). Data were analysed using analysis of variance for comparisons between groups, and the least significant difference test was used for pairwise comparisons. If the assumption of homogeneity of variance was not satisfied, Welch analysis of variance was used for pairwise comparisons between the groups. Data within the groups were compared using repeated-measures analysis of variance. Each time point was defined as follows: T_0, upon entry into the room (basal); T_1, following anaesthesia induction; T_2, upon insertion of the endoscope; T_3, upon endoscope exit from the pharyngeal cavity; T_4, during full patient awakening; and T_5, at discharge from the hospital

Abbreviations: MAP, mean arterial pressure; HR, heart rate

[*] $P < 0.05$

[a] $P < 0.05$, compared to T_0

[b] $P < 0.05$, compared to T_3

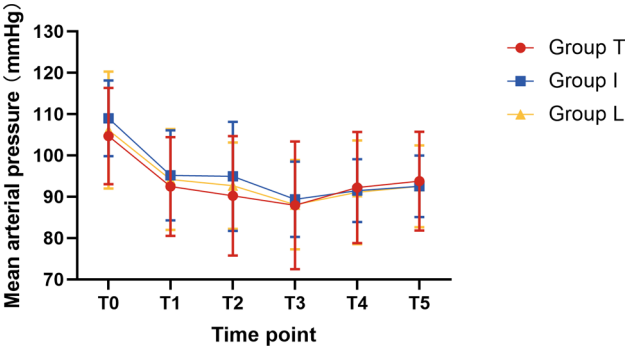

Fig. 3 Comparison of heart rates among the three groups. Note: T_0: upon entry to the room (basal); T_1: following anaesthesia induction; T_2: upon insertion of the endoscope; T_3: upon endoscope exit from the pharyngeal cavity; T_4: during full patient awakening; and T_5: at discharge from the hospital

Obesity is associated with a high adipose tissue-to-muscle-mass ratio. Similar to propofol, ciprofol is a lipophilic agent with a greater volume of distribution [28] in individuals with adipose tissue. TBW, IBW, and LBW have been suggested as suitable scalars for determining the induction dose of propofol in individuals with obesity [29]. Based on previous research, we aimed to establish an optimal dosage scale for ciprofol in patients with obesity. After considering TBW, LBW, and IBW, 0.4 mg/kg of ciprofol was selected as the induction dose based on the dose used in the phase III trial [12], with half of the initial dose used as a supplemental dose.

To provide safe and effective anaesthesia, anaesthetists must adjust the drug dose according to patient characteristics, thereby completely preventing surgical injury and minimising the risk of side effects [22]. In this study, the ideal level of sedation following induction was evaluated by comparing the success rate of anaesthesia for the procedures, the success rate of initial dose induction of general anaesthesia, and the remedial sedation conditions in the three groups. The findings indicated that all three groups achieved 100% surgical success rates. However, the success rate of anaesthesia achieved with the initial dosage was substantially greater in Groups T and I than in Group L. Dong et al. [30] showed an improved anaesthetic response and central nervous system sensitivity in patients receiving TBW-based administration. This result demonstrated that in the obese population drug concentration model, TBW-based administration resulted in increased plasma concentrations in larger body groups compared to LBW [31]. Additionally, an initial dose induction based on IBW generated the same anaesthetic effect as a dosing regimen based on TBW [29].

Most patients in the LBW group required extra ciprofol to reach a MOAA/S scale of 1, suggesting that the depth of sedation in the LBW dosing regimen was relatively shallow and that additional doses were needed. Subramani et al. [32] reported a propofol-induced obesity pharmacokinetic model that may explain this phenomenon. The model replaced TBW with LBW, and the simulated concentrations were lower for LBW-based dosing. Ingrande et al. [17] and van Kralingen et al. [33] found that LBW was the optimum dosing scale for propofol for anaesthesia induction in patients with obesity. The apparent discrepancy in the dosage recommendations for these patients was due to the significantly different levels of anaesthesia being targeted [34]. Compared with the other two studies that used a lower level of anaesthesia, the level of anaesthesia used in this study was closer to that used by Subramani et al.

Intraoperative stimulation and inadequate depth of anaesthesia as the procedure progresses lead to patient movement, which in turn requires additional sedation. Our results showed that the proportion and frequency of patients requiring remedial sedation were higher in Group L than in Group T. This may be because both the clearance and volume of the peripheral compartment were greater in patients with obesity receiving propofol for anaesthesia induction using LBW-based dosing than in those receiving TBW-based dosing [30].

Sedatives increase the probability of hypoxaemia [11] and hypotension [35], particularly in patients with obesity [36]. In Group T, we observed an increase in the total cumulative dose requirements compared to those in the other two groups. Although dosing based on LBW may result in inadequate anaesthesia [37], dosing based on TBW may result in a more frequent occurrence of drug-related adverse events [38]. Individuals who received ciprofol did not experience injection discomfort. Group T had a considerably higher incidence of posterior tongue drops than Group L. Hypoxemia was more common in Group T. Similarly, Duan et al. [39] verified that even though the incidence of ciprofol hypoxaemia was low, a dose-related negative respiratory depressant response to ciprofol hypoxaemia was also observed in specific patients. Sedatives can increase the likelihood of respiratory depression and worsen hypoxaemia during procedural sedation due to airway blockage [40].

In this study, we found significant fluctuations in BP after ciprofol administration in all three groups, and Group T had a considerably higher occurrence of hypotension than Group L. Similar to the findings of Shearin et al. [41], our results indicate that a TBW dosing scale could lead to an excessive amount of ciprofol. An overdose would lead to a higher concentration of ciprofol in the bloodstream, perhaps causing a more severely low BP than that in patients administered a ciprofol dose based on their lean body weight. No serious adverse circulatory events were observed intraoperatively, as the intraoperative hypotension was transient. In addition, we observed a significant decrease in BP at the conclusion

of the procedure in Group I compared to that observed intraoperatively, probably due to the short duration of the procedure and the effect of intraoperative remedial sedation.

This study has several limitations. This study is limited in scope owing to its small sample size and single-centre design. Therefore, to establish more reliable conclusions, replicating this study with a larger sample size and more rigorous experimental techniques is warranted. Second, this study included only patients who underwent gastroscopy, which was completed in approximately 15 min. Finally, for the sake of medical ethics and safety, we specifically selected surgical patients with ASA grades I–II and eliminated those with ASA grades > III. In addition, our study did not include individuals with significant comorbidities or fragility, such as older individuals.

Single-bolus induction remains a popular induction method in outpatient surgical procedures. The reported clinical data indicate that ciprofol is a powerful sedative characterised by a sufficiently high speed of emergence from the state of anaesthesia, which is necessary for outpatient conditions. The dosage requirement of ciprofol is an important factor for maintaining its efficacy and safety because different doses of ciprofol can have different effects. Therefore, when considering specific populations and clinical situations, it is important to apply an appropriate dosing regimen for each patient. There are a few concerns regarding ciprofol single-bolus induction among the obese population, and the optimal weight-based dosing scalar for single-bolus induction has not been validated, which is important for anaesthesiologists. Despite these limitations, our study is one of the few to examine the application of ciprofol for anaesthetic induction in patients with obesity and offers preliminary data for further research.

Conclusions

Anaesthesia is better induced when TBW or IBW is used to calculate the induction dose of ciprofol than when the LBW dosing regimen is used for gastroscopy in patients with obesity. In terms of safety, TBW-based induction doses tended to cause respiratory depression and hypotension. The LBW-based induction dose has better cardiovascular stability and respiratory safety, whereas the IBW-based induction dose reduces respiratory depression during anaesthesia induction. Clinicians should use smaller doses when developing dosing regimens for these patients, and these doses should be repeated incrementally and adjusted at the time of administration based on clinical outcomes. We are committed to continuously collecting data on different surgical or treatment procedures to develop a more personalised anaesthesia plan and ensure the quality and safety of anaesthesia in patients with obesity.

Abbreviations

ASA	American Society of Anesthesiologists
BMI	Body mass index
BP	Blood pressure
HR	Heart rate
IBW	Ideal body weight
LBW	Lean body weight
MAP	Mean arterial blood pressure
MOAA/S	Modified Observer's Assessment of Alertness/Sedation
PACU	Post-anaesthesia care unit
RR	Respiratory rate
SpO_2	Pulse oxygen saturation
TBW	Total body weight

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

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Not applicable.

Author contributions

DX: Writing—original draft, investigation, data curation, and conceptualisation. YJZ: Writing the original draft, data curation, conceptualisation, and supervision. FL: Writing of the original draft and data curation. YY: Writing the original draft and investigation. MC: Writing the original draft and data curation. GL: Writing – original draft and investigation. YWZ: Writing – review and editing, data curation, conceptualisation, project administration.

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Data availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Medical Ethics Committee of Shunde Hospital of Southern Medical University (approval no. KYLS20230624). This study was conducted in accordance with the 1964 Declaration of Helsinki and its amendments. Written informed consent was obtained from all the participants or their families before initiating any study-related activities.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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