

Up-Down Determination of the 50% and 95% Effective Dose of Ciprofol for Sedation in Gastrointestinal Endoscopy of Obese Patients

Zhongxue Su*

Department of Anesthesiology, Zhongshan Hospital, Fudan University, Shanghai, China

***Corresponding author:** Zhongxue Su, Department of Anesthesiology, Zhongshan Hospital, Fudan University, Shanghai, China

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ABSTRACT

Keywords: Ciprofol; ED50; ED95; Gastrointestinal Endoscopy; Obese; Sedation

Abbreviation's: GABAa: γ -Aminobutyric Acid; GI: Gastrointestinal; TBW: Total Body Weight; ASA: American Society of Anesthesiologists; BMI: Body Mass Index; CI: Confidence Interval; MOAA/S: Modified Observer's Assessment of Alertness and Sedation

To the Editor

Propofol is sedative that is currently widely used for gastrointestinal (GI) endoscopy [1]. However, it can lead to adverse events such as respiratory depression, especially in obese patients. Therefore, there is a need to develop a new medicine that has the beneficial features of propofol but with reduced or no side effects. A new anesthetic called ciprofol has recently been approved by the State Food and Drug Administration (China). Ciprofol is a novel anesthetic agent that binds to γ -aminobutyric acid (GABAa) receptors [2]. Ciprofol has a stronger affinity for GABAa receptors, and the potency of ciprofol is four to five times higher than that of propofol [3]. Ciprofol has the characteristics of rapid onset and smooth and rapid recovery [4]. Phase III clinical results have shown that the incidence of injection pain and respiratory and circulatory depression with ciprofol was lower than that with propofol [5]. Therefore, the prospects for ciprofol application in sedation/anesthesia in GI endoscopy are good, especially for special populations (such as obese patients).

Currently, in the general population for GI endoscopic sedation, the recommended initial dose of ciprofol is 0.4 or 0.5 mg/kg total body weight (TBW) [6]. However, obesity affects the pharmacokinetics and pharmacodynamics of medicines. Therefore, to ensure the accurate use of ciprofol in clinical practice, exploring the initial dose of the ED50 and ED95 of ciprofol in obese patients is of great significance, with the aim of avoiding insufficient and excessive sedation and ensuring the comfort and safety of patients. Therefore, we conducted a single-center clinical trial between September and November 2022 at Renji Hospital to explore the initial dose of the ED50 and ED95 of ciprofol given to obese patients undergoing sedation for GI endoscopy. This study was approved by the Ethics Committee of Renji Hospital (approval No. KY2022-154-B) and registered at ClinicalTrials.gov (NCT05517408).

For this study, we enrolled adult outpatients undergoing GI endoscopy. All patients provided written informed consent.

The inclusion criteria were as follows:

- 1) Patients aged ≥ 18 and ≤ 60 years.
- 2) Those undergoing routine GI endoscopic procedures for diagnosis and treatment.
- 3) Those with an American Society of Anesthesiologists (ASA) classification I–II.
- 4) Those with a body mass index (BMI) >28 kg/m², and
- 5) Those who clearly understood and voluntarily participated in the study and provided signed informed consent.

The exclusion criteria were as follows:

- 1) Binge drinking, defined as consuming an average of more than 2 units of alcohol per day (1 unit = 360 mL of beer, 45 mL of 40% liquor, or 150 mL of wine) in the 3 months before the screening period.
- 2) History of drug abuse within the 3 months before the screening period.
- 3) Known allergy to eggs, soy products, opioids and their rescue drugs, propofol, and so forth; and
- 4) Those deemed unsuitable by the investigator.

All patients were required to follow standard preparations prior to GI endoscopy (typically fasting for at least 6 hours and refraining from drinking water for at least 2 hours). Throughout the entire process, all patients received additional oxygen (6 L/min) and 10 g of lidocaine viscous oral liquid (0.2 g lidocaine). Approximately 1 minute after the administration of 5- μ g sufentanil, sedation was induced using ciprofol 0.3 mg/kg (TBW) at an injection rate of 1 mg/s. If the Modified Observer’s Assessment of Alertness and Sedation (MOAA/S) score was <2 at 2 minutes after administration, then this case was negative and the concentration gradient was dropped for the next patient (the previous patient’s dose per kilogram of body weight < 0.9). If the MOAA/S score was ≥ 2 at 2 minutes after administration, then this case was positive.

The dose and timing of propofol additional were administered at the investigator’s discretion, and the concentration was increased up a gradient in the following patient (i.e., the previous patient’s dose per kilogram of body weight/0.9). Patients were enrolled consecutively until the eighth crossover point (positive to negative or negative to positive), with a dose ceiling of 0.6 mg/kg. When the MOAA/S score was <2 , the endoscopist began GI endoscopic intubation. Additional doses of propofol were administered as needed to maintain a certain degree of sedation (MOAA/S score <2). Each additional bolus was given for 10 seconds, with an interval of at least 2 minutes. We enrolled 20 patients from September 2022 to November 2022. The age of the patients ranged from 27 to 58 years. Two patients received 0.3 mg/

kg of ciprofol, seven received 0.27 mg/kg, eight received 0.243 mg/kg, and three received 0.2187 mg/kg. The mean patient BMI was 30 kg/m², and five patients were classified as ASA grade I, with 15 patients as grade II. One patient underwent gastroscopy, four underwent colonoscopy, and 15 underwent gastroscopy and colonoscopy (Table 1).

Table 1: General characteristics of the patients.

General information	Value
Gender, n	
Male/female	15-May
ASA classification (I/II)	May-15
Age (years), mean $\pm$ SD	42.7 $\pm$ 8.4
BMI (kg/m ²), mean $\pm$ SD	30.0 $\pm$ 1.6
Height (cm), mean $\pm$ SD	170.0 $\pm$ 9.1
Weight (kg), mean $\pm$ SD	87.0 $\pm$ 10.7
Type of procedure, n (%)	
Gastroscopy	1 (5.0)
Colonoscopy	4 (20.0)
Gastroscopy and colonoscopy	15 (75.0)
Antecedent history, n (%)	
Hypertension	6 (30)
Diabetes mellitus	1 (5)
Dose group, n	
0.3 mg/kg	2
0.27 mg/kg	7
0.243 mg/kg	8
0.2187 mg/kg	3

Note: ASA = American Society of Anesthesiologists; BMI = body mass index.

The results of this study showed that the ED50 and ED95 of ciprofol for successful sedation in obese patients undergoing GI endoscopy is 0.250 mg/kg (95% confidence interval [CI] 0.229, 0.268) and 0.279 mg/kg (95% CI 0.263, 0.381), respectively. In this trial, we used the TBW of the patients for clinical convenience, and based on the TBW, we calculated the ideal, lean, and corrected weights of the patients, whose means were 68.8 $\pm$ 10.4 kg, 58.7 $\pm$ 9.8 kg, and 76.1 $\pm$ 10.2 kg, respectively. We calculated that, when based on lean body mass, the ED95 was closest to the recommended dose of 0.4 mg/kg of ciprofol. However, this trial also has some limitations.

- 1) The data in our study are for the Chinese population only.
- 2) We included patients with obesity defined as a BMI >28 kg/m² and ASA grade I–II, which means that the results might not necessarily apply to morbidly obese patients (i.e., BMI >40 kg/m²).

3) The subjects in this study were adults, and the results might not be applicable to adolescents with obesity.

In conclusion, this study proved that the ED50 and ED95 of ciprofol for successful sedation in obese patients undergoing GI endoscopy are 0.250 (95% CI 0.229, 0.268) and 0.279 (95% CI 0.263, 0.381), respectively.

Declaration of Competing Interest

No.

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