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Research Article

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Determinants of Propofol Dose Requirements in Morbidly Obese Patients Undergoing Gastroscopy

(*Running title*: Propofol in gastroscopy in morbid obesity)

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Abstract

Background: *Morbid obesity is associated with numerous problems during procedural sedation and propofol administration, including changes in physiology and pharmacokinetics. We analyzed the relationship between propofol demand during gastroscopy and body mass index, severity of hepatosteatosis, and gender in morbidly obese patients.*

Methods*: In a prospective observational cohort study, one hundred adult patients with morbid obesity who were scheduled to undergo an elective sleeve gastrectomy and thus were subjected to routine upper gastrointestinal endoscopy. Sedation was administered using propofol in a titrated manner to maintain a Modified Observer's Assessment of Alertness/Sedation (MOAA/S) score of 2-3. The total amount of propofol used was measured. Grading of hepatosteatosis was done preoperatively through the use of abdominal ultrasonography.*

Results: *The mean total propofol dose was 137.0 ± 28.4 mg. Males required a significantly greater dose compared to females (142.9 ± 32.7 mg vs. 131.4 ± 22.4 mg, p = 0.008). There was no significant correlation between propofol dose and body mass index, age, grade of hepatosteatosis, and liver enzyme concentrations. Multivariate linear regression indicated that male gender was only independent predictor for propofol demand (beta = 10.890, standard error = 6.064, p = 0.012).*

Conclusion: *In morbidly obese patients undergoing gastroscopy, male gender is associated with higher propofol requirements, while neither body mass index nor hepatosteatosis severity is. This is the first prospective study in morbidly obese patients undergoing gastroscopy specifically assessing male gender as a potential predictor.*

Keywords: morbid obesity; propofol; hepatosteatosis; body mass index.

Introduction

The global prevalence of obesity has now reached epidemic proportions, causing a formidable public health challenge. Morbid obesity (BMI ≥ 40 kg/m²) is associated with a complex constellation of comorbidities, including cardiovascular disease, type 2 diabetes, and obstructive sleep apnea [1,2]. As a result, this patient demographic is increasingly presenting for a wide range of diagnostic and therapeutic procedures. Of these, upper gastrointestinal endoscopy (gastroscopy) remains one of the most common. [3] The provision of safe and effective procedural sedation in this high-risk population is a critical aspect of peri-procedural care, [3] yet it is fraught with unique and significant challenges.

Physiologic changes associated with morbid obesity have a profound effect on anesthetic care. Impaired respiratory mechanisms, like a decrease in functional residual capacity, along with an increased incidence of airway obstruction, reduce physiological reserves, thereby making these patients prone to hypoxia and apnea [4,5]. Additionally, pharmacokinetic properties of anesthetic medications are greatly affected. Body composition changes, especially fat accumulation, translate into an affected volume of distribution for lipophilic medications [6]. This is further aggravated by differences in cardiac output, regional blood flow, or protein binding patterns, making physiological responses to medications quirky [7].

The pharmacological efficacy of propofol (2,6-diisopropylphenol), an iv anesthetic, has made it the preferred anesthetic for gastroscopic procedures, because it has multiple desirable pharmacokinetic properties: rapid onset and recovery, ease of titration, short duration of action, and rapid recovery and antiemetic prophylaxis [8]. Nevertheless, the lipophilic character of propofol is associated, paradoxically, with the clinical challenge of dosing it centrally, especially in morbidly obese subjects [9]. Dose adjustment for morbidly obese patients according to their total body weight (TBW) is likely to result in overdose and potentially may cause serious cardio-respiratory complications such as hypotension, bradycardia, and apnea [10]. Dose adjustment according to ideal body weight (IBW), which is comparable to LBW, is associated, conversely, with undertreatment and adverse outcomes because it may cause discomfort, patient movement, and suboptimal conditions for the endoscopist during the procedure, thereby increasing the risks of complications and unsuccessful diagnosis [11].

For more focused doses, it is crucial to explore particular patient-related factors, which might later prove to modify the doses needed for propofol administration. BMI has already become the widely accepted criteria for measuring the severity of obesity, although it is not sufficient as the only predictive criteria for dose administration, as it does not document the differences in the composition of the patient's body [12]. To better address the issue, it is essential to explore the pathopharmacology of morbid obesity. Hepatosteatosis, which is known as non-alcoholic fatty liver disease (NAFLD), has already become exceptionally prevalent among the morbid population, as it has been reported as present in more than 90% of those suffering from morbid obesity [13]. It is crucial since the main pathopharmacology for propofol is extensive liver metabolism, and possibly serious fatty infiltration may later interfere with the blood flow and enzyme activity within the liver [14].

Moreover, the existence of gender differences in pharmacology is becoming increasingly obvious in the area of anesthesia. Known gaps in body composition ratios (fat/muscle ratio) and the levels of drug metabolizing enzymes of the liver (cytochrome p450) have already provided evidence of gender differences in pharmacology, leading to potential pharmacokinetic or pharmacodynamic differences in the response to propofol anesthesia [15]. Nonetheless, the impact of gender in the dosing of propofol in patients with morbid obesity has not yet been explored.

These complexities, together with the existing gap within the current literature, prompted the design of this study to enhance the assessment of propofol administration beyond the simplistic paradigms of weight-based administration. The main aim of our study is to try to explore the correlation between the total dose of propofol needed to maintain satisfactory sedation to proceed to gastroscopy and the separate variables of BMI, the presence and severity of hepatosteatosis, and gender in morbidly obese patients. We hypothesized that higher BMI, the presence of severe hepatosteatosis, and male gender independently correlate to higher propofol doses. These findings will be crucial to inform the future development of more personalized paradigms to improve the safety and efficacy of the process of procedural sedation among this ever-growing and high-risk patient group.

Patients and Methods

Study Design and Ethical Approval

This prospective observational cohort study was carried out in Istanbul Okan University during the period extending from 2022 to 2024. This study protocol complied strictly with the rules and guidelines constituting the ethical guidelines related with medical studies involving human subjects, according to the tenets embodied in the Declaration of Helsinki. This study obtained full ethical approval from the Institutional Review Board/Independent Review Board for Okan University (Approval Number: 2023/09, Protocol Number: 23/195, the date of prospective registration: 2023/09/22, the date of first patient enrollment: 2023/11/05). Before any study-related procedure, the purpose and intent of this study were explained to all potential participants, who provided their written consent.

Patient Selection

The research population was the hundred (n=100) consecutive consenting adult patients posted for elective sleeve gastrectomy, for the treatment of morbid obesity, and they all underwent routine upper gastrointestinal endoscopy (gastroscopy), as part of comprehensive surgical assessment, where the data for the research was collected.

Inclusion criteria for the research included patients between the age of 18 and 65 years, morbid obesity, as defined by the presence of BMI >=40 kg/m^2, and the ASA-physical status classification of I, II, and III, scheduled for elective sleeve gastrectomy, and the willingness and ability to give written, informed consent, while the exclusion criteria included patients known to have an allergy/hypersensitivity reaction to propofol, soy, and/or egg products, and those suffering from severe and unstable cardio-respiratory diseases (such as severe congestive heart failure, recent myocardial infarction, and severe chronic obstructive pulmonary disease), as well as those known to have severe hepatic or renal impairment (such as those with cirrhosis and end stage renal disease), and those taking chronic opioids, benzodiazepines, and/or sedative-hypnotic medications, which might have altered anesthetic plans and treatment, pregnant and lactating women, and any patient already asked not to participate in the research.

Anesthetic and Procedural Protocol

All patients were placed under instructions to fast for at least eight hours prior to solids as well as two hours prior to clear fluids before undergoing gastroscopy. Upon arrival at the endoscopy unit, routine ASA monitoring was activated, which consisted of continuous electrocardiography (ECG), intermittent non-invasive blood pressure (NIBP) every 3 minutes, as well as peripheral oxygen saturation (SpO2). All patients received supplemental oxygen at a rate of 3 L/min from a nasal cannula during the entire test. All sedation was handled by a certified anesthesiologist distinct from the endoscopic portion of care. A standardized sedation protocol was used for all subjects. An initial bolus of propofol (1% solution) was given, followed by intermittent boluses as needed for target-controlled administration of a desired sedation level with a correspondingly defined Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale of 2-3, which means responding to loud verbal or tactile stimulation. The dosage of propofol was titrated according to the anesthesiologist's clinical assessment of the response of the patient, vital signs, and the requirements for immobility during procedure. The actual cumulative dose of propofol in milligrams delivered from the onset of sedation until withdrawal of the endoscope was accurately obtained from the anesthetic record. The duration of procedure was likewise documented.

Data collection and variable definitions

A special form for data collection was employed per patient. The variables collected included: 1) Demographic variables: age (years) and gender (male/female), 2) Anthropometric variables: height (cm), weight (kg), and BMI which was calculated according to the formula weight divided by height squared, and 3) Primary study variables: Total propofol dose (mg), and grade of hepatosteatosis. Also, the presence and degree of hepatosteatosis were evaluated by a preoperative abdominal ultrasonography performed by a skilled radiologist who didn't know any information about sedation status. The severity of hepatosteatosis was evaluated based on a standardized semi-quantitative scale as follows: Grade 0 (None): Normal liver echopattern; Grade 1 (Mild): A slight increase in liver echogenicity with normal visualization of diaphragm and borders of intrahepatic vessels; Grade 2 (Moderate): A moderate increase in liver echogenicity with slightly decreased

visualization of the diaphragm and intrahepatic vessels; and Grade 3 (Severe): A high increase in liver echogenicity with poor or nonexistent visualization of diaphragm, intrahepatic vessels, and posterior aspect of the right hepatic lobe [16].

Statistical Analysis

The collected data was all computerized and was processed using the SPSS Statistics for Windows software, version 26.0 (IBM Corp., Armonk, NY). The descriptive analysis was utilized to evaluate the patients' population for their characteristics. Continuous data was reported utilizing the mean ± SD or median [interquartile range (IQR)] depending on the normality of the data, which was determined using the Shapiro-Wilk normality test. The categorical data was, on the other hand, reported using the frequency and the corresponding percentages (n, %). The study utilized the Independent Sample T Test (or the Mann Whitney-U Test for non-normal distributions) to analyze the difference in the mean dose of Propofol for male patients compared to the dose for the female patients. Also, the study utilized the one-way analysis of variance (or the Kruskal Wallis Test for non-normal distributions) to analyze the mean dose of Propofol among the different levels of Hepatosteatosis Grades (Grade 0 to Grade 3). Also, the Pearson's correlation coefficient- or Spearman's rank correlation in cases of nonlinear or non-normally distributed data-was calculated in order to assess the strength and direction of the linear relationship between continuous variables: namely, BMI and total propofol dosage. A multiple linear regression analysis was performed in order to identify independent predictors of total propofol dosage. The total propofol dose was entered as the dependent variable, with age, gender, BMI, and hepatosteatosis grade entered as independent predictor variables. All statistical tests used a two-tailed p-value less than 0.05 for significance.

Results

In total, 100 patients were included into the study. The average age of the participants was 34.04±9.74 years (ranged 18 to 59 years) with a mean BMI of 48.16±4.81 kg/m^2 that 49.0% were male (Table 1).

Table 1: Baseline characteristics and studied parameters (n = 100).

Male gender, %	49 (49.0)
Mean age, year	34.04±9.74
Mean body mass index, kg/m^2	48.16±4.81
Hepatosteatosis grade	
0	11 (11.0)
1	16 (16.0)
2	31 (31.0)
3	42 (42.0)
Median serum AST level, mg/dL	19.0 (15.0, 25.0)
Median serum ALT level, mg/dL	26.5 (18.0, 37.7)
Mean dose of propofol, mg	137.0±28.37

Regarding hepatosteatosis grade, 73.0% of the subjects had grade 3 to 4. The mean dose of propofol used was 137.0±28.37 mg ranged 100 to 240 mg. The mean value of propofol was 142.86±32.72 mg in men and 131.37±22.36 mg in women indicating a significant difference (p = 0.008). Regarding the association of propofol with hepatosteatosis grade, the mean value of propofol in grade 0 was 128.18±17.21 mg, in grade 1 was 148.75±37.03 mg, in grade 2 was 136.45±22.59 mg and in grade 3 was 135.24±30.30 mg showing no difference across the different grade of hepatosteatosis (p = 0.266). However, adjusting gender variable, the dose of propofol was significantly higher in men than in women in hepatosteatosis grades of 1 to 3 (Figure 1).

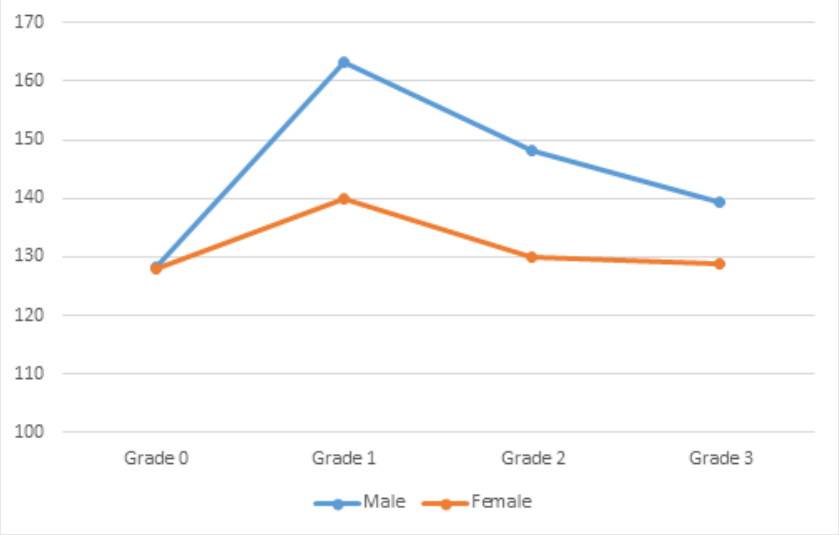

Figure 1: Trend of the changes in the dose of propofol based on hepatosteatosis grade in men and women.

As indicated in Table 2, no association was revealed between the dose of propofol and other quantitative parameters including age, BMI, and serum values of AST and ALT liver enzymes in both men and women. Using a multivariable linear regression model, male gender was only independent predictor for propofol demand (Table 3).

Table 2: The correlation of propofol dose and baseline parameters.

Item	Male		Female	
	r coefficient	P-value	r coefficient	P-value
Age	-0.191	0.190	-0.133	0.352
BMI	-0.052	0.723	-0.085	0.685
ALT	0.033	0.820	-0.059	0.689
AST	-0.027	0.855	-0.047	0.745

Table 3: Multivariate linear regression model to determine the main predictors of the dose of propofol adjusting baseline variables.

Item	Unstandardized Coefficients		P-value	95% Confidence Interval for Beta	
	Beta	SE		Lower Bound	Upper Bound
Gender	10.890	6.064	0.012	-22.934	1.154
Age	-0.512	0.323	0.117	-1.154	0.131
HS	0.196	3.413	0.954	-6.582	6.974
BMI	-0.562	0.662	0.397	-1.876	0.752
ALT	-0.026	0.233	0.911	-0.489	0.437
AST	0.065	0.448	0.884	-0.824	0.955

Discussion

The purpose of this prospective observational cohort study was to examine the association between total propofol requirements for the performance of gastroscopy, as well as certain individual variables related to the patients: namely, BMI, hepatosteatosis, and gender, in a group of morbidly obese patients. On the basis of the main result of this study, the following can be stated: Firstly, there was a significant difference between the cumulative requirements of propofol among men and women, where men had a greater requirement of propofol. Secondly, there was no significant association between the cumulative propofol requirements and variables of BMI or the severity of hepatosteatosis. Thirdly, none of the variables included in the regression analysis were significant.

One of the most interesting findings of the current study is that the dosage requirement of propofol is significantly higher in male patients than females. This finding is in agreement with the increasing evidence that gender affects the pharmacokinetics and pharmacodynamics of anesthetics. Several factors might explain the current finding. Male patients have more lean body mass and less body fat percentage compared with females; as a result, the rapid redistribution and clearance of lipophilic drugs such as propofol might occur [17]. On the other hand, gender differences and the activities of the hepatic P450 isoenzymes responsible for the metabolism of propofol might result in increased dosage requirements of the anesthetic agent in male patients [17].

However, it should be kept in mind that the gender differences found under the present study are retained irrespective of the hepatocellular steatosis grade, which is to say that gender differences might be given priority over the hepatocellular lipid infiltration in the propofol requirements. In contrast to our hypothesis, the total amount of propofol required is not significantly correlated to the BMI of the patient [18]. This observation highlights the drawbacks of the present methodology in utilizing the BMI as an index for proper anesthesia dosing in morbidly obese individuals. Despite the extensive utilization of the BMI in measuring the gravity of obesity, it is incapable of taking into account the differences in body composition and blood flows of various organs. Our observation is in line with the accumulating opinion that utilization of the BMI in anesthesia dosing is likely to be overly simplistic and misleading. Previous investigations have already illustrated that there is poor correlation between the dosages of sedative and anesthetic drugs, particularly propofol, and the BMI of the individual, especially in more complex pharmacokinetic profiles [19,20].

Another interesting and somewhat unexpected finding was the absence of association between hepatosteatosis grade and propofol dosing. Whereas propofol is known to be a drug that is predominantly metabolized in the liver, one would hypothesize that advanced grades of hepatosteatosis might potentially affect drug metabolism and dosing [21]. Notwithstanding a remarkably high incidence of moderate to severe grades of hepatosteatosis demonstrated in our study population, there were no differences in propofol dosing identified according to hepatosteatosis grades. There are several possible explanations for this finding. First, non-alcoholic hepatosteatosis in its benign form might maintain hepatic metabolic function in a relatively normal manner, particularly in younger patients who lack extensive fibrosis and cirrhosis [22]. Second, it is possible that extrareticular metabolism and uptake of propofol, including pulmonary uptake and metabolism, may significantly blunt direct hepatotoxic effects of steatosis on drug concentration [23]. Finally, ultrasonographic grading of hepatosteatosis, which is a widely used clinical methodology, might not yet be sensitive to small impairments in direct hepatic metabolism [24].

The lack of independent variables in the multivariate regression equation emphasizes the complex and personalized nature of propofol dosing in morbidly obese subjects. The need for sedation is determined not only by certain biological variables but also by certain unpredictables, including genetic variability, central sensitivity, levels of anxiety, and operative stimuli. These data remind us of the importance of a personalized approach to propofol administration.

Clinically, our findings have a few implications. First, male morbidly obese patients would need higher doses of propofol for equivalent sedation during gastroscopy. Second, routine escalation of propofol dose is not justified based on BMI or ultrasonographic evidence of hepatosteatosis alone, and such could not only increase the risk of oversedation but also that of cardiorespiratory complications. Lastly, our findings reinforce current best practice recommendations to carefully titrate propofol to effect and with vigilant monitoring in high-risk obese populations.

The present study has some limitations, which deserve mention. The sample size, although appropriately powered to explore the effect of moderate doses, may not be as proficient in picking up the subtle correlations, especially while using multivariable analysis. This study cannot establish a causation relationship. The hepatosteatosis in this study was evaluated by ultrasonography, and not by histopathological or advanced imaging studies. Moreover, pharmacokinetic data, like the levels of propofol in the bloodstream, was not collected. Studies with a larger sample, evaluation of body composition, genetic predisposition, and pharmacokinetic modeling are required to confirm the personalized approach in sedation regimens.

Conclusion

In morbidly obese patients undergoing gastroscopy, male gender is associated with significantly higher propofol requirements, while BMI and the presence or severity of hepatosteatosis are not. These findings question traditional weight-based paradigms for dosing and, furthermore, point out the low utility of both BMI and ultrasonographic grading in fatty liver as predictors of propofol dose. Sedation based on individualization and titration remains the safest and most effective approach in this high-risk population. Recognition of gender-related differences in anesthetic requirements may contribute to improved procedural safety and optimized sedation practices in morbidly obese patients.

Authors' contribution: OAS supervised the study protocol, OAS and MS performed the project and collected the data, and AS drafted the paper and analyzed the data Use or non-use of some form of AI: We did not use the AI to write the paper

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