



# Propofol Sedation for Intra-gastric Balloon Removal: Looking for the Optimal Body Weight Descriptor

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## Abstract

**Aim** Sedation is considered as a prerequisite for the safe and effective conclusion of Bioenterics Intra-gastric Balloon (BIB) removal (our aim was to ascertain the most appropriate body size scalars for propofol dosing and assess the efficacy and safety of a sedative approach involving the infusion of propofol for BIB removal).

**Method** Retrospective analysis of prospectively collected data of 414 adults scheduled to undergo BIB removal. Our primary end-point was to delineate the relationship between propofol dosing and body size descriptors namely body mass index, total body weight, ideal body weight, lean body weight (LBW) and normalized LBW. Sedative efficacy of this practice, anesthesia or procedural-related adverse events and patients' satisfaction level served as secondary outcome parameters.

**Results** Propofol dose (mg/kg/min) was positively related to all body weight descriptors in an important manner ( $p < 0.001$ ). Among them, LBW was singled out as the body size descriptor to best capture the appropriate needs of propofol ( $R^2 = 0.432$ ;  $p = 0.000$ ). Hypoxemia, hemodynamic compromise, gastroesophageal reflux or moderate movement occurred rarely; all of them were readily reversed. The majority of participants had no recollection of the noxious phase of the procedure or declared at least adequately satisfied from the experience (84% and 95%, respectively).

**Conclusion** LBW could serve as relatively more accurate dosing scalar compared to actual or ideal body weight descriptors, in obese individuals undergoing BIB removal under propofol sedation. The conscious/deep sedation based on propofol infusion emerges as a feasible and efficacious sedative approach for this procedure.

**Keywords** Obesity · Intra-gastric balloon · Propofol · Body weight scalar

## Introduction

Sedation is considered as a prerequisite for the safe and effective conclusion of almost any endoscopic procedure and for Bioenterics Intra-gastric Balloon (BIB) removal, as well [1–3]. Selection of the sedation technique is mainly determined by

both the endoscopist's experience and personal preferences and the availability of an anesthesia provider throughout the procedure.

Taking into account the complexity of BIB removal process, provision of anesthesia is rather challenging in this population due to the augmented risk of aspiration, compromised

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cardio-respiratory reserves and altered drug pharmacokinetics, considering that upon BIB removal, a substantial number of patients still remains overweighted—if not obese [4, 5].

Albeit several sedative regimens have been applied for BIB removal, clear anesthetic guidance for this group of patients is lacking, yet [1]. Propofol seems to be an appealing alternative for the induction and maintenance of sedation due to its unique pharmacokinetic and pharmacodynamic properties. Continuous intravenous infusion of propofol is assumed to be more advantageous over its intermittent administration as boluses, in terms of ease of use and stability of effect, while ensuring early and full recovery of consciousness and protective reflexes, which are of paramount importance in obese patients [6, 7].

Nevertheless, the appropriate dosing strategy of propofol for obese subjects has not been delineated, yet. Total body weight (TBW) is the most popular body size descriptor for dosing anesthetics, based on the assumption that volume of distribution, clearance and elimination of most drugs increase proportionally to body weight in a linear manner [1, 7, 8]. Nonetheless, TBW seems to become invalid for morbid obese subjects in whom drug clearance and elimination of most drugs increase in a nonlinear manner with weight, as obesity is characterized by a disproportionate increase in fat mass with a concomitant moderate increase in lean body mass and basal metabolic rate [9–11]. Both ideal body weight (IBW) and lean body mass weight (LBW) have also been proposed as suitable scalars in terms of dose adjustments of intravenous anesthetics, but no consensus exists, as to the optimal weight-based dosing model to be used in obese patients [12]. Moreover, the existing evidence on propofol-based sedation protocols for BIB removal is extremely limited.

The aims of the present study were to validate the most appropriate size descriptors for propofol dosing adjustments among TBW, IBW and LBW and assess the applicability of sedation provided by continuous intravenous infusion of propofol in terms of efficacy and safety in patients undergoing BIB removal.

## Methods

### Study Participants

After institutional review board approval of the study protocol and written informed consent obtained from each participant, the prospectively collected data of all adults scheduled to undergo BIB removal as outpatients—according to a standardized protocol [4]—in our endoscopic unit from May 2012 to November 2018, were retrospectively reviewed. Patients with a history of cardiopulmonary and/or hepatic disease, renal dysfunction or

evidence of difficult airway management, who received a more individualized approach—were excluded.

### Study Design

On the day of BIB removal, per protocol-fasted individuals underwent a detailed preoperative clinical evaluation, involving registration of demographic and anthropometric characteristics and quality of health status assessment. Body mass index (BMI) and other body size descriptors such as LBW and IBW were calculated using the Janmahasatian equation: [LBW male (kg) =  $(9.27 \times 10^3 \times \text{TBW}) / (6.68 \times 10^3 + 216 \times \text{BMI})$ ] [13] and LBW female (kg) =  $(9.27 \times 10^3 \times \text{TBW}) / (8.78 \times 10^3 + 244 \times \text{BMI})$ ] and the following formula: IBW male (kg) =  $50 + 0.9 \times (\text{height [cm]} - 152)$  and IBW female (kg) =  $45.5 + 0.9 \times (\text{height [cm]} - 152)$  [14]. Normalized LBW was calculated from the estimated LBW which was multiplied with the normalization factors 1.23 for males and 1.53 for females [15], while the formula  $\text{IBW} + 0.25 \times (\text{TBW} - \text{IBW})$  was used for adjusted BW estimation [16].

Each individual was conveyed to the operating suite without premedication. While in the operating theater, routine monitoring was employed, including continuous electrocardiography, non-invasive blood pressure measurement, pulse oximetry and capnography. An 18-G peripheral venous line was instituted under local anesthesia for the purpose of fluid and drug administration. Patients were placed in the left lateral decubitus position and oxygen insufflation was applied via a nasopharyngeal catheter, viewing to maintain oxygenation at acceptable levels.

Propofol, given as a continuous intravenous infusion, was the anesthetic regimen of choice to achieve the desired sedation level throughout the procedure. Sedation level was evaluated clinically with the Modified Assessment of Alertness/Sedation (MOAA/S) Scale. In detail, MOAA/S score ranges from 0 to 5, with 0 to 1 defining loss of consciousness, 2 to 4 moderate to deep sedation and 5 alertness. In order to achieve the desired level of sedation during the different stages of the procedure, the infusion rate of propofol was titrated, accordingly. As appropriate level of sedation was considered to be an MOAA/S score of 3–4 during endoscope insertion, suction of the gastric contents and BIB puncture and deflation and a MOAA/S score of 0–1 after grasping the balloon by the forceps and throughout the removal procedure, which is regarded as the most intense stimulus of the procedure [17]. After the conclusion of the procedure, all patients were transferred to the Post-Anesthesia Care Unit (PACU) until being fully awake.

### Data Collection

During the procedure and immediate follow-up period until PACU discharge, vital signs were recorded at 5-min intervals.

Adverse events were considered the occurrence of respiratory suppression, hemodynamics derangement or gastric reflux/vomiting. Respiratory suppression was defined as any incident of airway obstruction, apnea or oxygen desaturation ( $\text{SpO}_2$  value  $\leq 90\%$  for at least 1 min) necessitating rescue maneuvers, whilst as hemodynamic impairment was defined as any alteration of more than 20% in heart rate and/or arterial blood pressure recordings compared to baseline [18, 19].

Over and above, any episode of patient movement during the procedure was reported as an adverse event and was classified into five categories as none (no movement), mild (minor movement not requiring any restraint), moderate (requiring restraint but without discontinuation of the procedure) and severe (imposing discontinuation of the procedure).

Total propofol consumption (mg) for each participant was registered. Based on this parameter, the dose of propofol (mg/TBWkg/min) was further calculated. Duration of anesthesia, defined as the time that elapsed from propofol commencement to discontinuation, and time to fully awakening were also determined. As delayed discharge was defined as a PACU stay for more than 60 min.

Before PACU discharge, the Brice interview [20] and Likert scale [21] were applied to each participant for awareness detection and satisfaction appraisal, respectively.

The relationship between body size scalars such as BMI, TBW, IBW, LBW or normalized LBW and propofol dose (mg/kg/min) served as primary outcome end-point, while the sedative efficacy of this practice and the occurrence of anesthesia or procedural-related adverse events and patients' satisfaction level served as secondary outcome parameters.

## Statistical Analysis

Normality of data was assessed by the Shapiro-Wilk test. One-way analysis of variance (ANOVA) was undertaken for comparison of means of continuous variables and normally distributed data, while a nonparametric rank test, the Kruskal-Wallis test, was used to compare means in the case of non-normally and non-continuously distributed data. Categorical variables were assessed by Chi-square (with Yates correction when applicable) or Fisher's exact test when the expected value of a cell was less than 5. Pearson correlation coefficient ( $r$ ) or Spearman rank correlation ( $\rho$ ) was calculated to investigate the correlation between continuous variables. To determine independent explanatory body size descriptors affecting propofol consumption in a multiple linear stepwise regression analysis was performed through the use of five clinically significant body size descriptors. For all statistical procedures, a  $P$  value of less than 0.05 was considered significant. Statistical Package for Social Sciences [SPSS 25.0; Chicago, IL, USA] and MedCalc (version 18.11.6; Ostend, Belgium) were used for all calculations.

## Results

Of the 438 cases meeting the eligibility criteria, 16 patients were excluded from the study as endoscopy revealed solid food remnants in their stomach and were rescheduled for BIB removal but beyond the study period, while 8 refused to consent to their study participation. Consequently, a total of 414 obese individuals treated with a BIB for weight loss and admitted as outpatients for BIB removal were enrolled.

The baseline characteristics of the study population and anesthesia-related parameters classified according to BMI sub-categories are presented in Table 1. Half of the participants belonged to the BMI group defining obesity status of class I–II. No differences were recorded among the BMI groups in terms of age, height and co-morbidities, with the exception of the female sex that predominated in the study population (71%) and ASA-PS class of 3–4 encountered in a higher percentage in obese patients (14% for class I–II and 30% for class III). The mean duration of anesthesia for BIB removal was 18.7 (SD 7, range 5–55) minutes and mean awakening time was 4.6 (SD 1.7, range 2–14) minutes.

Propofol dosing (mg/kg/min) was significantly higher in male individuals compared to female ones (median, 0.29; IQR, 0.21–0.38 and median, 0.17; IQR, 0.14–0.44 mg/kg/min;  $p < 0.001$ , respectively) (Fig. 1). Furthermore, it was proportional to all body weight descriptors being assessed in this study, with the strongest relationship being recorded between dose and LBW ( $r = 0.548$ ) followed by normalized LBW ( $r = 0.523$ ). As expected, a profoundly weak correlation was recorded between propofol dose calculated in mg/kg/min and duration of anesthesia ( $r = -0.169$ ), but no relation to awakening time could be documented (Table 2).

By entering the body weight scalars that presented a statistically significant relationship in univariate analysis into a multivariate linear regression model, all of them—with the single exception of BMI—were significantly related to the administered amount of propofol (Table 3). Figure 2 demonstrates the regression lines and coefficients of determination ( $R^2$ ) of the scalars with the higher relationship with propofol dose. Stepwise linear regression analysis identified LBW ( $R^2 = 0.432$ ;  $p = 0.000$ ) as the most powerful independent explanatory body size descriptor affecting propofol dosing in mg/kg/min.

As far as adverse events are concerned, hypoxemia was encountered in 22 patients (5.3%), being successfully managed with the release of upper airway obstruction maneuvers. No patient necessitated bag-mask ventilation or endotracheal intubation and assisted ventilation. Hypotension developed in 11 (2.65%), but it was easily reversed by crystalloid infusion and/or small boluses of intravenous ephedrine. No bradycardia event was recorded. Gastroesophageal reflux occurred in 18 patients (4.34%) but no incidence of vomiting or aspiration occurred. As to the patient's movement during the procedure,

**Table 1** Participants’ characteristics and anesthesia-related parameters according to BMI categories

Characteristics	All patients	Body mass index			p value
		< 29.9 mg/m <sup>2</sup>	30–39.9 mg/m <sup>2</sup>	≥ 40 kg/m <sup>2</sup>	
<i>N</i> (%)	414	77 (19)	216 (52)	121 (29)	
<b>Demographics</b>					
Age (years)	40 (32–46)	41 (35–58)	38 (30–46)	40 (31–46)	0.190
Female sex	294 (71)	67 (87)	162 (75)	65 (54)	0.000
ASA-PS class 3–4	70 (17)	3 (4)	31 (14)	36 (30)	0.000
BMI (kg/m <sup>2</sup> )	36 (31–41)	27 (22–29)	35 (33–37)*	45 (42–50)*	0.000
Height (cm)	168 (163–175)	166 (162–174)	168 (163–174)	170 (165–178)	0.053
TBW (kg)	104 (87–123)	75 (68–80)	99 (91–108)*	133 (120–148)*	0.000
IBW (kg)	63 (58–67)	61 (58–67)	63 (58–67)	64 (60–69)	0.063
LBW (kg)	55 (49–68)	45 (42–48)	54 (49–65)*	65 (57–80)*	0.000
Normalized LBW (kg)	83 (74–91)	68 (64–74)	81 (76–86)*	94 (86–100)*	0.000
<b>Comorbidities</b>					
Hypertension	97 (23)	12 (16)	42 (19)	43 (28)	0.071
Diabetes mellitus	30 (7)	5 (6)	16 (7)	9 (7)	0.961
CAD	16 (4)	2 (3)	8 (4)	6 (5)	0.692
Smoking history	224 (54)	45 (58)	112 (52)	67 (55)	0.576
<b>Anesthesia-related</b>					
Anesthesia time (min)	17 (14–22)	16 (14–22)	16 (14–22)	18 (15–23)	0.078
Awakening time (min)	5 (3.7–6)	5 (4–6)	4 (3–6)	5 (4–6)	0.441
<b>Propofol dose</b>					
Mg	356 (233–520)	210 (161–320)	310 (234–450)*	540 (380–807)*	0.000
mg/kg/min	0.19 (0.15–0.25)	0.17 (0.13–0.21)	0.19 (0.15–0.23)	0.22 (0.18–0.32)*	0.000

Notes: Data are expressed as median (25–75% IQR) and number (%)

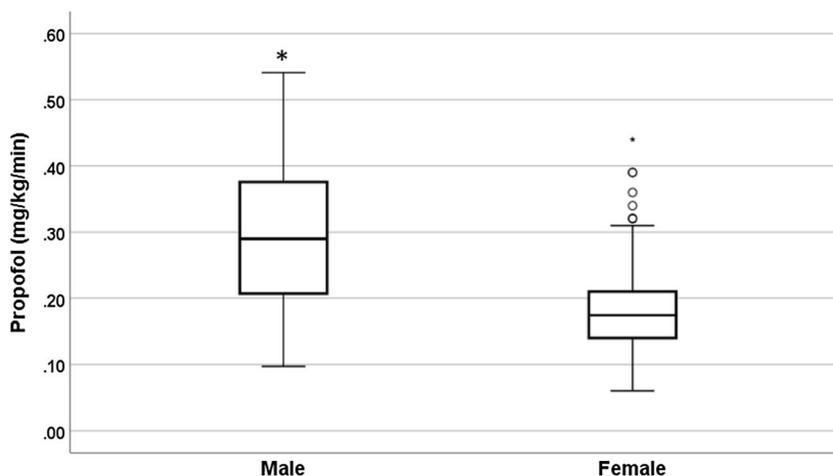
\**p* < 0.05; \**p* < 0.001

ASA-PS ASA-physical status, BMI body mass index, TBW total body weight, LBW lean body weight, CAD coronary artery disease

a mild or moderate movement was evidenced in 99 (23.9%) and 48 (11.6%) cases, respectively. No incidence of severe movement that imposed the discontinuation of the endoscopic procedure occurred.

All participants could recall the first phase of the endoscopy, involving the advancement of endoscope up to the point of gastric evacuation. As for the second phase of the procedure, the vast majority (84%, *n* = 348) of them had no recollection

**Fig. 1** Propofol dosing between male and female participants. Notes: \**p* < 0.001



**Table 2** Univariate co-relation analysis between propofol dose and participants' characteristics, body size descriptors and anesthesia-related parameters

Parameters	Propofol dose (mg/kg/min)		<i>p</i> value
	Spearman rank coefficient	95% CI	
Age (years)	− 0.077	− 0.172 to 0.019	0.116
ASA-PS	0.107	0.010 to 0.201	0.033
BMI (kg/m <sup>2</sup> )	0.319	0.230 to 0.403	0.000
TBW (kg)	0.479	0.402 to 0.550	0.000
IBW (kg)	0.452	0.372 to 0.525	0.000
LBW (kg)	0.548	0.477 to 0.612	0.000
Normalized LBW (kg)	0.523	0.449 to 0.589	0.000
Anesthesia time (min)	− 0.169	− 0.262 to − 0.074	0.018
Awakening time (min)	− 0.049	− 0.145 to 0.047	0.316

CI confidence interval, ASA-PS ASA-physical status, BMI body mass index, TBW total body weight, IBW ideal body weight, LBW lean body weight

of the intervention, while certain and uncertain awareness implicated 25 (6%) and 41 (10%) cases, respectively.

The mean level of satisfaction recorded in our study population was 4.5 (SD 0.5). In detail, 211 (51%) patients declared that they were completely satisfied, 185 (44%) very satisfied, 15 (4%) somewhat satisfied and 3 (1%) slightly satisfied. None of the participants experienced complete dissatisfaction.

All patients fulfilled discharge criteria from PACU within 60 min and then were transferred to the ward and after an uneventful 4-h course allowed to return home under instructions.

## Discussion

The findings of the present large-size study substantiate that LBW and normalized LBW can serve as relatively more accurate dosing scalars compared to actual or ideal body weight-based ones, in obese individuals subjected to BIB removal under a sedative practice based on the continuous infusion of propofol. Among them, LBW was singled out as the body size descriptor to best capture the appropriate propofol dosing, in this challenging from the viewpoint of titration of sedation endoscopic procedure. Over and above, the implementation of propofol as a continuous infusion achieved a satisfactory sedative effect with no serious adverse events.

Propofol has extensively been implemented into anesthesia practice in obese populations, presenting a very favorable drug profile. Nevertheless, sedation with propofol exhibits a relatively narrow margin of safety in terms of the respiratory and cardiovascular compromise, as it can commonly be implicated in the occurrence of apneic events, loss of airway protective reflexes or upper airway patency and hemodynamic deterioration. Apparently, the adaption of a more

individualized approach in propofol administration could aim towards the elimination of adverse events [12, 22–24].

## Determinants of Anesthetics' Pharmacokinetics in Obesity

The pharmacokinetic properties of most anesthetics could be affected by the increased body size via the consequent physiological alterations, mainly involving cardiac output, total blood volume, regional blood flow and distribution volumes and/or clearance of drugs [12, 25–27].

In obese individuals in whom the increased body weight is associated with a high lean to adipose tissue ratio, cardiac output is expected to be elevated, as a smaller amount of blood flow is distributed to fat tissue compared to lean body mass [24]. Yet, the modulation of cardiac output by obesity seems not to be that predictable, considering that over time the presence of adiposity promotes vasoconstriction and deterioration of cardiac performance, which in turn warrants re-adjustment of drug dosing [28].

Typically, morbid obesity promotes the expansion of clearance and distribution volumes of drugs, as compared to lean individuals [7]. The magnitude of these effects, however, depends on the physical and pharmacokinetic properties of anesthetics [7].

The advanced age, as well as presence of co-morbidities, which constitute common underlying clinical features of obesity, act synergistically to body composition and distribution of blood flow alterations towards to modification of both distribution and elimination of various anesthetic drugs [29].

A valid approach for induction and maintenance of anesthesia in non-obese subjects is to use the actual body weight as appropriate size scalar for sedative drug dosing, on the basis that their plasma concentration depends on TBW [12, 26, 30]. Nonetheless, this approach might

**Table 3** Results of a multiple linear regression analysis for explaining propofol dose (mg/kg/min) and body size scalars

Body size descriptors	Coefficient (B)	95%CI for B	p value
(Constant)	-0.008	-0.170 to 0.155	0.928
BMI (kg/m <sup>2</sup> )	-0.002	-0.006 to 0.002	0.402
LBW (kg)	0.003	0.002 to 0.005	0.000
IBW (kg)	0.005	0.001 to 0.009	0.017
Normalized LBW (kg)	-0.007	-0.011 to -0.003	0.000
TBW (kg)	0.004	0.001 to 0.006	0.001

CI confidence interval, BMI body mass index, LBW lean body weight, TBW total body weight

be proven unreliable in obese subjects, in whom the excess of adipose tissue interferes with standard drug dose adjustment, an effect that becomes more pronounced in morbidly obese individuals. Even though the absolute value of LBW has been estimated to be 20–40% higher in obese to normal-weight individuals [12, 26, 31], its comparable change is not proportional to TBW, with the net effect being a relative decrease of the percentage of lean body tissue. In line with previous findings, we recorded an increase of LBW by 20% in cases of obesity class I–II and by 44% in those of class III compared to normal-weight subjects, whilst in the aforementioned obesity classes, TBW was increased by 32% and 77%, respectively.

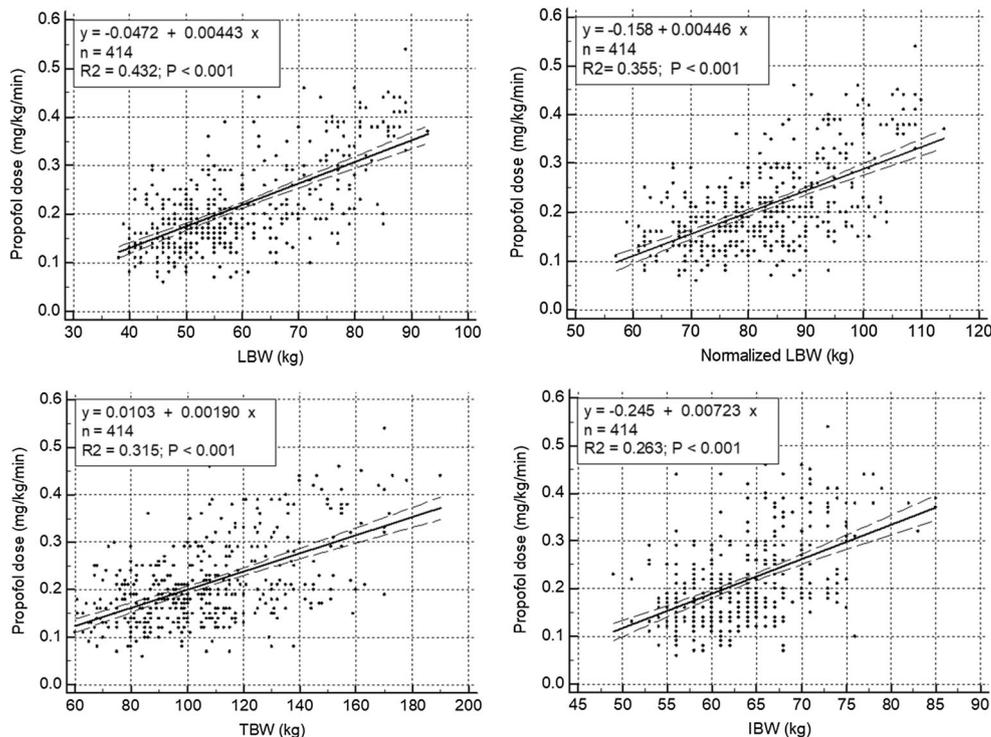
### Body Weight Scalars and Propofol Dosing in Obese Patients

In the current literature, no consensus exists regarding the appropriate weight scalar for propofol dosing in obese patients, as to achieve the optimal level of sedation with minimal side effects [7, 24].

TBW is the weight-based scalar more extensively used in clinical practice for calculating the dose of propofol in both non-obese and obese individuals, whilst the use of a corrected formula based on IBW is an attractive alternative for patients with a BMI less than 40 kg/m<sup>2</sup>[1, 24, 32–34]. The use of the previous dosing scalars is considered valid on the basis that alterations of distribution, clearance and elimination of drugs follow a proportional linear pattern compared to body weight [26, 35, 36]. Taking into account that obesity affects the pharmacokinetics of most anesthetics in a complex manner, the use of weight-based models enhances the risk of improper dosing [1]. In particular, dose calculation based on TBW incurs the risk of propofol overdosing, being further implicated by hemodynamic compromise and delayed recovery from anesthesia [8, 12, 37, 38]. On the other hand, the use of IBW might lead to under-dosing of some of our patients, as the height is the single parameter taking into account for dosage estimation, irrespectively of the coexistence of excess weight [1].

Considering that lean body mass plays a key role in most of the metabolic processes involved in drug kinetics or dynamics, its use constitutes a more rational choice for determining

**Fig. 2** Coefficients of determination ( $R^2$ ) and regression lines of linear regression analysis for explaining propofol dose (mg/kg/min) in relation to body size scalars. Abbreviations: LBW, lean body weight; IBW, ideal body weight; TBW, total body weight



both the loading and maintenance dose of propofol in obese patients [14, 24, 27, 31]. Our findings come to reinforce the relevance of LBW and normalized LBW as relatively more accurate dosing scalars compared to actual or ideal body weight-based ones, in obese subjects subjected to BIB removal, while multivariate analysis singled out LBW as the single body size descriptor defining propofol dosing in an important manner. By no means, this superiority of propofol adjustment on the basis of lean body mass over to body weight can be regarded as a profound one. In a group of morbidly obese patients, Ingrande J et al. showed that LBW was strongly related to the dose of propofol when used for anesthesia induction [24]. It has been speculated that the validity of LBM is higher for the determination of the bolus dose of propofol, while an adjusted scalar more closely related to TBW maybe is more suitable for the titration of continuous infusion rate of propofol [1, 24, 27]. Of note, previous findings support both TBW and LBW as predictive covariates for volumes of distribution and clearance of propofol when propofol is administered as a continuous infusion to obese subjects [24, 26, 29].

## Clinical Outcomes

Importantly, based on the fact that the vast majority of our patients had no recollection of the second phase of the procedure—involving the most intense stimulus—and no case was implicated by severe movement imposing the discontinuation of the endoscopic procedure, we can assume that the achieved level sedation was a satisfactory one. On top of this, the documented hemodynamic compromise due to the sedative technique can be regarded as negligible. Therefore, LBW scalar can be regarded as an accurate choice for the dose adjustment of propofol, viewing to avoid the hemodynamic sequelae of potential overdosing.

When applying dosing techniques based on LBM, covariates such as patient's sex and height need also to be appraised [1]. Presumably, the significant difference in propofol dosing between males and females recorded in our study could be explained under the light of the impact of sex on lean body mass.

Early and full recovery of consciousness and protective reflexes is considered as the cornerstone of a sedative protocol, in terms of efficacy and safety [1]. For individuals subjected to BIB removal, this issue becomes more complex, as in the majority of them obesity constitutes still an underlying clinical entity, further implicating the pharmacokinetics of sedatives and incurring a heightened risk for regurgitation and aspiration.

It is an established knowledge that fat solubility of anesthetics can affect the awakening time in an important manner. Albeit, propofol—as a highly lipophilic drug—is expected to prolong the emergence from anesthesia in morbidly obese patients, relevant studies failed to demonstrate such an

important influence of either intravenous or inhaled anesthetics on recovery from anesthesia in this subset of patients [39]. Our results further reinforce these findings, as awakening time was similar in obese individuals compared to normal weight ones and irrelevant to the infusion rate of propofol. Apparently, the emergence time seems to depend more on blood gas compared to fat solubility of the anesthetic agent in question, whilst the pharmacodynamics of propofol seems to remain unaffected by the applied infusion rate [24, 39]. BIB removal itself is associated with an additional aspiration risk, mainly because the device impedes gastric evacuation and patients scheduled for BIB removal are commonly in compliant with recommendations for pre-procedural fasting. Even so, gastroesophageal reflux was encountered only in a limited number of our participants, while no incidence of vomiting or aspiration was recorded.

Our findings come to highlight previous reports showing that the main advantages of properly titrated infusion of propofol over its bolus administration are the stability of effect, ease of use, rapid recovery and minimization of periprocedural adverse events [40, 41]. All of the above in conjunction with the high level of satisfaction recorded in our study participants denote that this sedative approach is an attractive choice for BIB removal. In any case, sedation for BIB removal is an intriguing practice since it should be tailored not only to manage the different levels of procedure-related stimulus, but to the clinical particularities of the involved individuals. Moreover, both the high level of expertise and effective co-operation of the involved personnel seem to be of utmost importance for concluding the procedure uneventfully.

## Study Limitations

The authors acknowledge several limitations of the present study. Firstly—although it is a meticulously designed trial, based on prospectively, by a standardized protocol, carefully collected data involving a large group of participants—its retrospective character has the inherited and fundamental pitfall, of all retrospective studies. Our study group is heterogeneous in terms of population demographics and body size metrics, as well as, the course of the endoscopic procedure itself. Secondly, our single-center practice limits the generalizability of our finding, which clearly applies to all well-organized endoscopic departments performing advanced endoscopic procedures with the cooperation of a dedicated and experienced personnel. Thirdly, the use of LBW, IBW and normalized TBW as weight scalars is not readily available under normal clinical circumstances. Nowadays, all the aforementioned body size scalars can be readily calculated with the aim of an on-line available calculator, which has also been optimized for mobile devices.

## Conclusions

The current trial indicates that LBW-based body size descriptors confer relative superior accuracy over to TBW-based ones, in defining the actual propofol requirements in obese individuals subjected to sedation for BIB removal. On the basis of our single-center experience, the conscious/deep sedation achieved by the implementation of continuous infusion propofol emerges as a feasible and efficacious sedative approach, as it ensures adequate operative conditions, with a minimum of adverse event rate and high patient satisfaction. Our results accentuate the need for more intense research on the identification of the most appropriate dosing scalar for sedation based on propofol continuous infusion and to document the applicability of this sedative practice in divergent clinical settings incorporating obese subjects.

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## Compliance with Ethical Standards

**Conflict of Interest** The authors declare that they have no conflict of interest.

### Ethical Approval

- All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.
- For this type of study, formal consent is not required.

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