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ORIGINAL CONTRIBUTIONS

Impact of Intragastric Balloon Before Laparoscopic Gastric Bypass on Patients with Super Obesity: a Randomized Multicenter Study

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Abstract

Background Super obese patients are recommended to lose weight before bariatric surgery. The effect of intragastric balloon (IGB)-induced weight loss before laparoscopic gastric bypass (LGBP) has not been reported. The aim of this prospective randomized multicenter study was to compare the impact of preoperative 6-month IGB with standard medical care (SMC) in LGBP patients.

Methods Patients with BMI >45 kg/m^2 selected for LGBP were included and randomized to receive either SMC or IGB. After 6 months (M6), the IGB was removed and LGBP was performed in both groups. Postoperative follow-up period was 6 months (M12). The primary endpoint was the proportion of patients requiring ICU stay >24 h; secondary criteria were weight changes, operative time, hospitalization stay, and perioperative complications.

Results Only 115 patients were included (BMI 54.3 ± 8.7 kg/m^2), of which 55 underwent IGB insertion. The proportion of patients who stayed in ICU >24 h was similar in both groups ($P = 0.87$). At M6, weight loss was significantly greater in the IGB group than in the SMC group ($P < 0.0001$). Three severe complications occurred during IGB removal. Mean operative time for LGBP was similar in both groups ($P = 0.49$). Five patients had 1 or more surgical complications, all in the IGB group ($P = 0.02$). Both groups had similar hospitalization stay ($P = 0.59$) and weight loss at M12 ($P = 0.31$).

Conclusion IGB insertion before LGBP induced weight loss but did not improve the perioperative outcomes or affect postoperative weight loss.

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Keywords Gastric balloon · Gastric bypass · Morbid obesity · Bridge therapy · Complications

Abbreviations

BMI	Body mass index
ICU	Intensive care unit
IGB	Intragastric balloon
IW-QOL	Impact of Weight on Quality of Life Questionnaire
IU	Intensive unit
LGBP	Laparoscopic gastric bypass
SF-12	Short form 12 questionnaire
SMC	Standard medical care

Introduction

Bariatric surgery is the only treatment for severe obesity to demonstrate long-term effective weight loss, improving health-related quality of life alongside reduction on comorbidities such as hypertension and type 2 diabetes [1]. In patients with super obesity, i.e., a body mass index (BMI) greater than 45 kg/m^2, weight loss induced by lifestyle intervention before bariatric surgery is recommended in order to improve associated comorbidities, decrease the surgical risk during the perioperative period, and facilitate surgery mainly by decreasing liver volume and fat adiposity [2–7]. It has also been suggested that preoperative weight loss could be a predictive factor of postoperative weight loss [8, 9]. However, these data are mainly supported by prospective cohort studies or retrospective studies and only two prospective randomized controlled studies have been reported to date [10, 11]. They demonstrated that preoperative weight loss induced by dietary restrictions was associated with significant decreases in operative time and the risk of perioperative complications but had no effect on postoperative weight loss.

Intragastric balloon (IGB) is a temporary (6-month) restrictive technique which has been proposed in obese patients. Several retrospective or observational studies have demonstrated that IGB insertion induced weight loss and also improved associated comorbidities such as type 2 diabetes, hypertension, sleep apnea syndrome, and respiratory failure [12, 13]. IGB also induces a decrease in liver volume and may thus facilitate surgery [14]. The effect of IGB has been reported in different prospective, randomized studies [15–21]; however, no study has investigated the use of IGB as a bridge therapy with the objective to obtain preoperative weight loss in patients selected for gastric bypass [15, 22]. Bussetto et al. demonstrated that in a case-controlled study on super-obese patients scheduled for laparoscopic adjustable gastric banding, preoperative IGB treatment reduced the risk of conversion to open surgery and the risk of intraoperative complications [23].

The aims of this prospective, randomized, multicenter study were to investigate preoperative weight loss induced by IGB insertion as a bridge therapy in super-obese patients with super obesity (BMI >45 kg/m^2) and selected for laparoscopic gastric bypass (LGBP) and to determine whether IGB insertion, used as a bridge therapy, decreased the risks during the perioperative period in comparison with standard medical care (SMC).

Patients and Methods

This was a prospective multicenter study conducted from January 2008 to June 2012. Each of 21 centers was asked to enrol patients aged 18–65 years with super obesity (BMI >45 kg/m^2) selected for LGBP. The duration of the study was 12 months. At inclusion (time point M0), patients were randomly assigned in a 1:1 ratio either in the IGB group or the SMC group. In the IGB group, a second randomization was performed in order to compare the efficacy of a 600-mL water-filled balloon (BIB®, Allergan®, France) versus a 650-mL air-filled balloon (Heliopshere®, Helioscopie®; France); patients were randomly assigned in a 1:1 ratio to receive 1 of the 2 balloons (BIB® or Heliosphere®). The randomization lists were generated using of a computer-generated sequence with blocks of variable and undisclosed size stratified by center. Strategy and balloon were assigned by voice server.

In the IGB group, upper gastrointestinal endoscopy was performed to eliminate any contraindication before IGB insertion under sedation or general anesthesia according to local endoscopic practice. After 6 months (M6), the IGB was removed under sedation or general anesthesia under endoscopic control.

In the SMC group, patients were instructed to follow a low-calorie diet regimen as per the protocol followed in each center with dietician evaluations at least every 2 months, in accordance with French recommendations.

In both groups, a systematic clinical evaluation was performed after 3 months (M3) and again before LGBP was performed at M6. In the IGB group, LGBP was performed as soon as possible after IGB removal but no exact time interval was specified. A clinical evaluation by the surgeon was systematically performed at 1 month postoperatively and a final clinical evaluation was performed 6 months after LGBP (M12).

Quality of life was measured at baseline (M0), M6, and M12 by using the Short form 12 (SF-12) and the Impact of Weight on Quality of Life (IW-QOL) questionnaire.

The study protocol was approved by the Comité de Protection des Personnes Ile de France 1 and the NTC registration number was 00504036. Informed consent was

obtained from all individual participants included in the study. This study was funded by the French Ministry of Health as a Soutien aux Techniques Innovantes et Couteuses (STIC) program or support to innovative and costly techniques. No commercial entity had any role in the study, and the funding source had no role in study design, data collection, analysis, or interpretation.

Endpoints

The primary endpoint was the decrease in complications during the perioperative period. As there was no specific score or index of severity of patients commonly accepted at the time of the study design, we used as an objective marker the duration of stay in intensive units (IUs) or intensive care units (ICUs) or reanimation for at least 24 h after the end of surgery. The secondary endpoints were the safety of the procedure in the IGB group (insertion and removal), weight loss expressed as change in BMI during 3 periods (M0–M6, M6–M12, and M0–M12), operative time, the perioperative complications, duration of hospitalization stay, and quality of life in both groups.

Statistical Analysis

Based on previous findings reporting that the prevalence of postoperative complications during the first 30 postoperative days, defined as a stay in ICU >24 h, was 24 % [24] and the hypothesis that the IGB would decrease these complications by 50 %, we calculated that randomization of 314 patients (157 in each group) would provide a power of 80 % to detect this difference with a type I error of 5 %.

We performed our analyses on a modified intention-to-treat basis. Not all patients underwent LGBP, and thus, for 3 patients, the primary endpoint was missing. For the primary analysis, missing data were not imputed. In a secondary analysis, missing data were imputed in a sensibility analysis using the best case and the worst case imputation methods. The characteristics of patients at baseline were described using frequency and percentage for categorical variables, and mean and standard deviation or median [IQR] for continuous variables. We compared the proportion of patients with a stay in IU, ICU, or reanimation >24 h within the first 30 days after surgery between the SMC and the IGB group using the chi-squared test. We compared operative time, weight loss (from M0 to M6, from M6 to M12, and from M0 to M12), perioperative complications, duration of hospitalization stay, and quality of life between M0 and M12 (assessed via the SF-12 and the IWQOL) using the Student *t* test or Wilcoxon *t* test. In the IGB group, we compared the weight loss from M0 to M6 between the 2 types of balloons (air-filled versus water-filled) using the Student *t* test or Wilcoxon *t* test. Pearson's correlation coefficient was used to evaluate the relationship between initial weight loss (from M0 to M6) and postoperative weight loss (from M6 to M12). All the analyses were performed using SAS software, version 9.2.

Results

Of the 21 centers asked to enroll patients, only 9 enrolled at least 1 patient. Due to insufficient enrollments, the last inclusion was performed on June 30, 2012 before the study was stopped on the advice of an independent board. A final total of 181 patients were screened, of which 115 provided written informed consent and were randomized into the SMC group ($n = 60$) or the IGB group ($n = 55$). Figure 1 is the flow chart of the study design. Demographic data, weight, BMI, age at the onset of obesity, and comorbidities were similar in both groups (Table 1). In the IGB group, 26 patients (53.1 %) were randomized into the air-filled balloon group and 23 (46.9 %) into the water-filled balloon group.

Balloon Procedure

IGB insertion was always performed under general anesthesia. The mean duration of the insertion procedure was 17.0 ± 6.7 min. Balloon removal was performed at M6 in all patients, except for 5 cases in which the IGB was removed earlier due to complications related to the IGB ($n = 3$) or at the patient's request ($n = 2$). Removal was also performed under general anesthesia, with tracheal intubation in 79.2 % of cases. The mean duration of the removal procedure was 27.2 ± 24.0 min (range 10–161 min). Technical difficulties during IGB removal were noted in 17 patients (35.4 %). These were not considered clinically significant complications and mainly involved either difficulties in emptying or grasping the balloon, or cardial or esophageal erosions. There was no significant difference in complication rate between the air-filled group and the water-filled group. Two significant complications, 1 esophageal tear and 1 hemorrhage, occurred in the water-filled balloon group; both were treated endoscopically. In the air-filled balloon group, IGB removal of the balloon was unsuccessful in 1 patient and a surgical gastrotomy was required.

Weight Loss in the Period from M0 to M6

In the IGB group, subgroup analysis demonstrated a similar M0–M6 weight loss using both types of IGB (air-filled versus water-filled balloon $P = 0.65$); thus, the results of both IGB subgroups were combined and reported together. As shown in Fig. 2, the median M0–M6 weight loss between the SMC group was −0.4 kg/m^2 (range −2.2 to −0.3 kg/m^2), while in

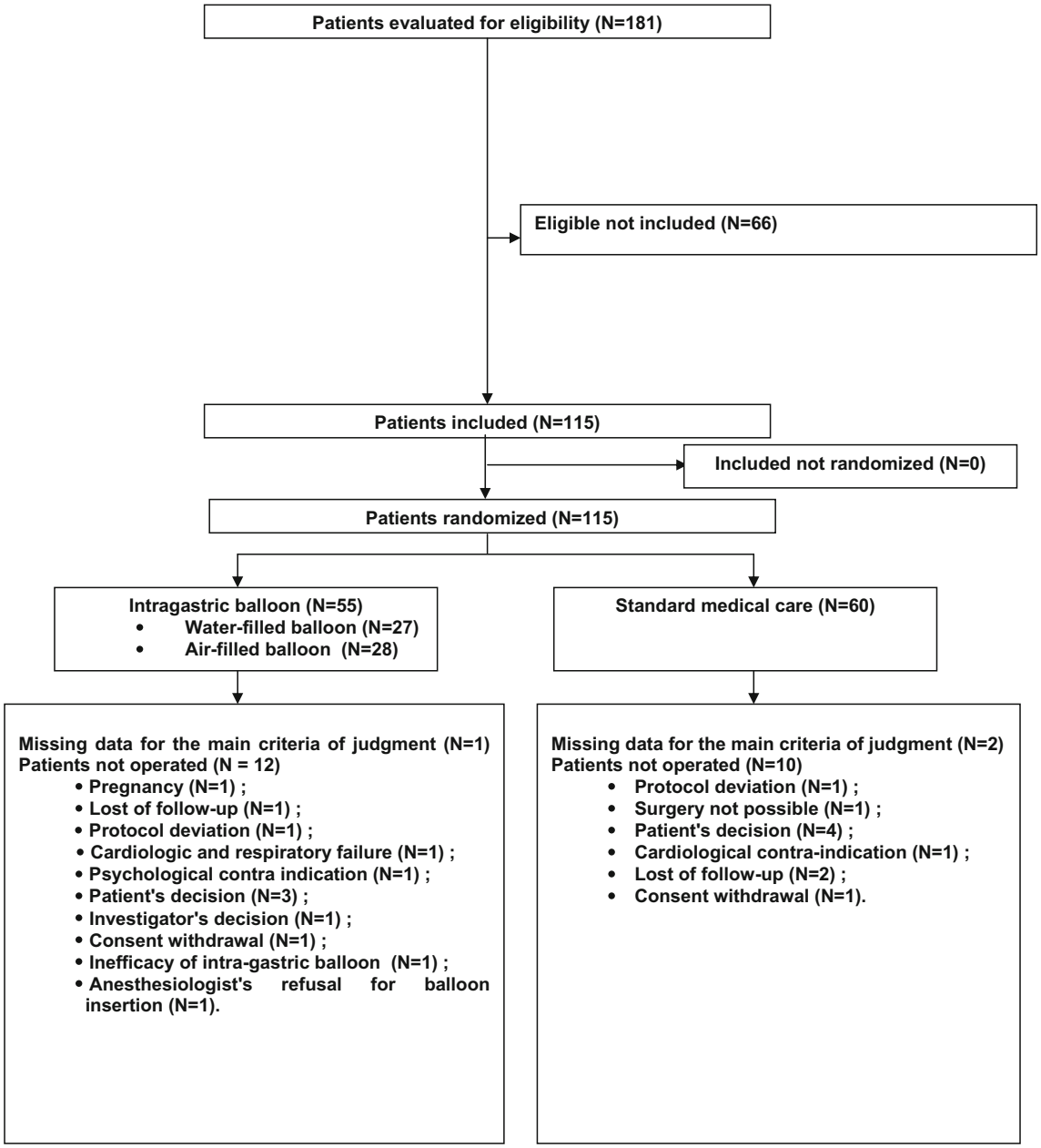


Fig. 1 Flow chart of the study

the IGB group, it was −2.8 kg/m^2 (range −6.2 to −1.7 kg/m^2) ($P < 0.0001$). It should be noted that in the IGB group, weight loss occurred during the first 3-month period (from M0 to M3), and the weight then remained stable during the last 3-month period (M3–M6).

Laparoscopic Gastric Bypass Surgery

LGBP was performed at time point M6. Both groups had similar median ASA score (SMC group 2.0 [2.0–3.0] versus IGB group 2.0 [2.0–3.0]; $P = 0.76$) and mean duration of surgery (SMC group 174.8 ± 83.1 min versus IGB group 188.1 ± 98.1 min, respectively; $P = 0.49$). In the IGB group, the median duration between IGB removal and LGBP was 9.5 days [range 7.0–29.0 days]. Laparotomy was required in 1 patient in the SMC group and in 2 in the IGB group ($P = 0.59$).

Primary Endpoint

The percentage of patients who stayed in IU, ICU, or reanimation for >24 h was 72.9 % in the SMC group and 71.4 % in the IGB group ($P = 0.87$). Results were similar in the sensibility analysis.

Table 1 Patient characteristics and comorbidities at inclusion

	SMC (n = 60)	IGB (n = 55)
Age (years)	40.1 ± 11.6	40.5 ± 12.3
Sex M/F (%)	28.3/71.7	23.6/76.4
Weight (kg)	153.9 ± 36.2	148.3 ± 24.3
BMI (kg/m^2)	54.7 ± 10.3	53.9 ± 6.5
Age at onset of obesity (years)	17.4 ± 9.5	18.5 ± 9.3
Waist circumference (cm)	143.4 ± 19.8	138.0 ± 18.3
Hip circumference (cm)	155.8 ± 22.2	155.1 ± 17.7
Neck circumference (cm)	44.7 ± 6.2	42.9 ± 5.5
Hypertension (%)	41.7	38.9
Sleep apnea syndrome (%)	53.6	60.0
Diabetes (%)	25.0	38.9
Dyslipidemia (%)	35.0	22.2

Differences between the SMC group and the IGB group were non-significant

SMC standard medical care, *IGB* intragastric balloon, *BMI* body mass index

Complications

Complications within the first 30-day period postoperatively occurred in 5 patients, all of whom were in the IGB group and none in the SMC group (P = 0.02). No medical complications occurred. Postsurgical complications included digestive hemorrhage, intraperitoneal abscesses, fistula, peritonitis, occlusions, and re-interventions (in 1 or more per patient). The duration between IGB removal and LGBP in the 5 patients with complications (median 10.0 days, range 7.0–37.0 days) was similar to that in patients without complications (median 9.0 days, range 7.0–28.0 days; P = 0.57). No death occurred.

Duration of Hospitalization

The duration of hospitalization was similar in the SMC group (median 5.0, range 5.0–7.0 days) compared with the IGB group (median 6.0 days, range 4.0–7.0 days; P = 0.59).

Weight Loss in the Period from M6 to M12

The median weight at M12 tended to be greater in the IGB group (median 38.1 kg/m^2, range 34.2–43.7 kg/m^2) compared with the SMC group (median 37.6 kg/m^2; range 35.2–45.7 kg/m^2) but this difference was not significant (P = 0.56; Fig. 3).

Finally, we compared the impact of preoperative weight loss (from M0 to M6) on the postoperative weight loss (from M6 to M12); we found a significant and negative medium relationship (r = −0.29, P = 0.0065), which means that postoperative weight loss was significantly greater in patients with less preoperative weight loss.

Quality of Life

At baseline (M0), quality of life as measured by the SF-12 and the IWQOL was similar in both groups (results not shown). Between M0 and M12, quality of life improved in both groups; however, there was no significant difference between groups in improvement of quality of life as assessed with the SF-12 (P = 0.35) or the IWQOL (P = 0.71).

Discussion

This randomized, prospective, multicenter study in patients with super obesity (BMI >45 kg/m^2) demonstrated that IGB insertion induced significantly greater weight loss during the 6-month preoperative period compared with SMC. However, IGB insertion induced a specific morbidity, did not modify as expected some parameters of the perioperative period, increased the risks of complications during the perioperative period, and did not modify overall weight loss between M0 and M12.

In patients with severe obesity, weight loss before surgery is recommended in order to decrease the surgical risk during the perioperative period, mainly related to comorbidities, and

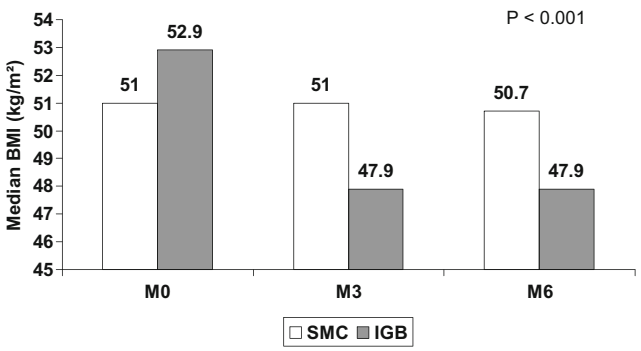


Fig. 2 Weight variations, expressed as median body mass index (BMI), from time point M0 to M6 in the standard medical care (SMC) and intragastric balloon (IGB) groups. As both types of balloon induced a similar weight loss, IGB results are reported together. Differences between the SMC group and the IGB group were significant at M3 and M6

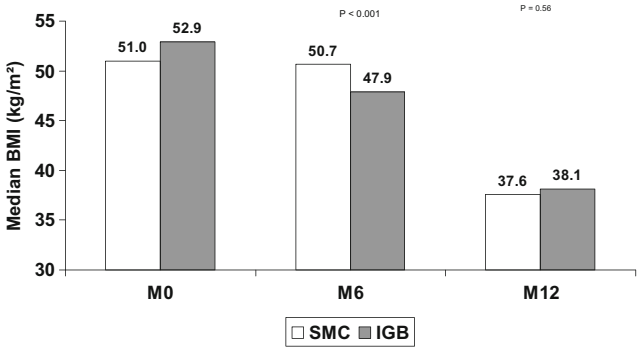


Fig. 3 Weight variations, expressed as median body mass index (BMI), from time point M0 to M12 in the standard medical care (SMC) and intragastric balloon (IGB) groups. As both types of balloon induced a similar weight loss, IGB results are reported together. At M0 and M12, differences between the SMC group and the IGB group were not significant

also to facilitate surgery. However, these assumptions are mainly supported by retrospective studies or by observational, non-randomized, prospective cohort studies [9]. A prospective, randomized study demonstrated that weight loss induced by a low-calorie regimen during a 5-month period induced a decrease in the operating room time and also improved the percentage of excess weight loss in the 6-month follow-up period [10]. Van Nieuwenhove et al. [11] reported that a short, 14-day, very low caloric diet had no or minor effects on surgery, except a significant decrease in the number of complications within the first 30 postoperative days.

IGB is a temporary restrictive technique that induces weight loss; its efficacy has been reported in randomized, prospective studies [15–21]. This device could potentially be used preoperatively as a bridge therapy to induce weight loss in patients with severe morbid obesity before bariatric surgery, including LGBP [22]. In this situation, the weight loss must be significant enough to improve comorbidities and the morbidity related to the device must be low. In the present study, we confirmed that IGB induced significantly greater weight loss in comparison with SMC, mainly during the first 3-month period. In comparison with previous data [15–21], the weight loss induced by IGB in the present study tended to be lower. There is no clear explanation for these results; the balloons were filled with water or air as recommended by the manufacturers and patients received adapted dietary recommendations. At study commencement, there were 2 available IGB devices (air- or water-filled), but no comparison of these devices has been reported. In the present study, similarly to other findings [19], we did not find evidence of any significant difference between the 2 devices, and thus, the IGB subgroup results have been reported together.

The use of the IGB induced a specific morbidity. Insertion of the IGB was safe in all cases; however, it had to be removed earlier in 3 patients due to complications (severe abdominal pain and vomiting) and in 2 cases due to the patient's request. Complications occurred in 35 % of patients during IGB removal, with 3 major complications, including 1 gastrotomy for extraction. Complications related to the IGB have been reported previously in large cohorts [25] and are usually minor complications when IGB insertion is conducted in cases without contraindications (mainly a past history of gastric surgery). Difficulties in IGB extraction are frequent, but usually only induce a moderate increase in extraction time when the procedure is performed by a trained physician as recommended [26]. In the present study, every center selected had extensive experience in IGB-related procedures and the 3 severe complications that occurred during IGB removal occurred in the centers that had the most experience. In the present study, IGB insertion and removal were always performed under general anesthesia with tracheal intubation. This is a reflection of French clinical practice with facilities to perform endoscopy under anesthesia. However, considering the duration of the procedure and the fact that severely obese patients have several comorbidities, general anesthesia is probably safer than sedation.

The effect of preoperative weight loss on the operative period was not as expected. In the present study, the primary endpoint was the duration of stay in IU or ICU, or reanimation for longer than 24 h after the end of surgery; this was considered as an objective marker of the severity of the condition of the patient, as no specific marker of severity of polypathologic patients, like severely obese patients, had been developed at the time of study conception. Stay in intensive units may vary among the different centers, but is a marker of the severity of patient condition. To determine the number of included patients required to demonstrate a significant effect on ICU stay, we used previously reported findings that 24 % of American patients stayed for longer than 24 h in IU or ICU [3]. In our study, more than 70 % of the patients had a stay in IU or ICU of longer than 24 h, and this was similar in both groups. These discrepancies between French and American practice are difficult to explain, but probably reflect easier access to IUs and differences in the manner in which patients are managed. Indeed, we stopped the study earlier than planned, after the inclusion of 115 patients, when 314 included patients were necessary to demonstrate a significant effect. This low rate of recruitment occurred because most patients did not want to wait for 6 months if they were included in the SMC group, even though this was recommended. However, it is likely that the differences would not have been significant and the main endpoint, a decrease of 50 % in ICU stay, would not have been changed. Surprisingly, operative time was similar in both groups. In the present study, every operative team performed routinely LGBP and no center effect could be demonstrated. It has been suggested that the decrease in operative time after weight loss was mainly related to a decrease in liver volume. It has been demonstrated that IGB induced a decrease in liver volume [14], but we did not evaluate this parameter in our study.

In the present study, no death or medical complications occurred; one or more postoperative complications occurred in 5 patients, all in the IGB group. These complications might have been related to the preoperative weight loss. However, previous randomized studies found that postoperative complications were not increased due to weight loss before bariatric surgery [9–11]. Another potential explanation is that the complications could be the consequences of the 6-month gastric distension induced by the IGB. Consequences of a long duration of gastric distension on the gastric wall, gastric blood distribution, or innervation are unknown. The IGB induces a decrease in gastric emptying suggesting an effect on gastric motor activity and smooth muscle cells, i.e., an increase in gastric compliance [27], but this effect occurred mainly during the first 3-month period, and after IGB removal, at 6 months, gastric emptying returned to basal value [28, 29]. In our study,

the duration between IGB removal and LGBP was not standardized; surgery was planned to be performed as soon as possible, but the interval between IGB removal and LGBP surgery was not significantly different in the 5 patients who experienced complications compared with those without complications.

Finally, in patients with morbid obesity requiring bariatric surgery, the impact of preoperative weight loss on the postoperative weight loss is still controversial [8, 9]. In the present study, we demonstrated a significant negative relationship between pre- and postoperative weight loss at M6, which means that postoperative weight loss was significantly greater in cases with less preoperative weight loss. Similarly to our study, observational studies into IGB used before gastric lapband demonstrated that the importance of preoperative weight loss before surgery induced by an IGB was not predictive of the postoperative weight loss after 6 months [30]; however, a significant effect was reported later on, after a 1-, 3-, and 5-year follow-up [31].

In conclusion, in patients with super obesity, in comparison with SMC, IGB as a bridge therapy before LGBP induced specific morbidities and increased the risk of early postoperative complications without modifying surgical time, hospitalization stay, or postoperative weight loss at 6 months. These results were the opposite to our working hypothesis. Considering the limitations of our study, such as the poor recruitment rate, a higher than expected use of ICU facilities, and the poor weight loss in the IGB group in comparison with the literature, further randomized studies are required to determine whether IGB should be recommended as a bridge therapy before LGBP or other bariatric surgeries. The usefulness of IGB in morbidly obese patients requiring scheduled non-bariatric surgery also warrants further investigation.

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Authors' Contributions Study concept and design: BC and SM
Acquisition of data: all authors
Analysis and interpretation of data: BC, TA, DH, and SM
Drafting of the manuscript: BC and SM
Statistical analysis: TA and DH

Compliance with Ethical Standards

Conflict of Interest Authors 1 and 20 received an unrestricted grant from the French Ministry of Health during the STIC program to support this study.

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Author 4 received personal fees for educational activities from Abbvie, ARARD, MSD, Ferring, Janssens, Takeda, Fresenius Kabi, Nutrcia, and Baxter laboratories.

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 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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