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NEW CONCEPT

Efficacy and Safety of Intra-gastric Balloon Placement in Dialyzed Patients Awaiting Kidney Transplantation

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Abstract

Background The number of obese patients who are candidates for renal transplantation has considerably increased, but obesity can be a barrier to kidney transplantation. Weight loss is often difficult through diet alone. We studied the efficacy and tolerance of the intra-gastric balloon (IGB) procedure in obese patients who were undergoing dialysis and were candidates for a renal transplantation.

Patients and Methods Obese patients (BMI > 30 kg/m^2) who were candidates for renal transplantation were prospectively included in the study between 2010 and 2012. The balloon was inserted and removed during a gastric endoscopy under general anesthesia. The treatment lasted 6 months. The end point was a decrease in BMI after 6 months. Body impedance spectrometry (BIS) and nutritional statute were evaluated initially and then after IGB removal.

Results Seventeen patients (nine females and eight males) with a mean age of 53.4 years [19.4–69.4] were included. The decrease in body mass index (BMI) during the 6-month placement was 3 kg/m^2 (from 37.7 to 34.4 kg/m^2). The mean weight loss was 7 kg. The mean percentage of excess weight loss after 6 months was 20.2 (± 11.4). The tolerance was good without any complications. Eleven patients underwent kidney transplantation.

Conclusion IGB in obese dialyzed patients who are candidates for renal transplantation is safe and effective. However, the amount of weight loss can vary.

Keywords Obesity · Intra-gastric balloon · Awaiting kidney transplantation · Hemodialysis · Efficacy · Safety

Introduction

Kidney transplantation (KT) is the treatment of choice for patients with end stage renal disease (ESRD), since patients with a functional renal graft have better survival rates and a higher quality of life [1, 2]. Forty percent of transplant-waitlisted patients die [3]. Obesity, defined as a body mass index (BMI) of more than 30 kg/m^2, is associated with increased morbidity and mortality in the general population [4]. Obesity is a significant problem among patients with ESRD who are on dialysis. Average BMI among dialysis patients has increased steadily over the last 15 years. As a consequence, greater numbers of obese patients are candidates for kidney transplantation. However, maintenance hemodialysis patients have exhibited an "obesity paradox," where higher BMI is associated

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with greater survival, as seen in numerous observational studies [5–8]. Reliable guidelines concerning target BMI before kidney transplantation are not available. It is widely agreed that a BMI of more than 50 kg/m^2 is a contraindication for kidney transplantation, but there is less consensus regarding patients' suitability for kidney transplantation when their BMI is between 30 and 40 kg/m^2. However, most transplant centers do not waitlist obese patients with a BMI above 30 kg/m^2 or 35 kg/m^2 and refer them for weight reduction procedures—such as bariatric surgery—as a prerequisite for transplantation [9]. A BMI of more than 35 kg/m^2 is the third most common reason to deny patients active transplant waitlisting [10]. Some studies have confirmed the relationship between overweightness/obesity and comorbidities in kidney transplantation patients. Wound dehiscences and infections are more frequent in obese transplanted patients, by between 16 and 44% according to studies [11–13]. Anastomotic and perinephric complications are frequent. Lymphocele occurs at a median rate of 7.7% among obese recipients, with a mean of 9.9% and a range of 2.9 to 18.2% [14–18]. Two studies reported a higher rate of hematoma [14, 17], and one study reported a rate of renal artery stenosis among obese patients as high as 17.6%, accompanied by a rate of renal vein thrombosis of 2% [17]. Obesity can induce delayed graft function (DGF), as observed in some studies and particularly in an analysis of over 11,836 transplant patients, where BMI was an independent and significant predictor of DFG [19]. Obesity is associated with new onset diabetes after transplantation [20], the length of stay at the hospital, and a higher incidence of cardiac disease (atrial fibrillation and myocardial infarction) [21]. Given the association of technical difficulties and surgical site complications, transplant programs may impose a maximum BMI eligibility threshold for transplantation. Some data support the efficacy of transplant facilitation through effective pre-transplant weight reduction using bariatric surgery [22, 23]. The two most common bariatric surgeries used before kidney transplantation are laparoscopic sleeve gastrectomy (LSG) and Roux-en-Y gastric bypass (RYGB). These strategies support excellent weight loss, in the range of 50 to 60% of excess weight loss at 1 year, but they are irreversible and can have some complications. Moreover, patients with chronic kidney disease are 1.5 times more likely to have a complication following bariatric surgery than patients without chronic kidney disease [24]. Intra-gastric balloon (IGB) is another strategy. Contrary to the abovementioned strategies, IGB placement is a minimally invasive modality for weight loss. A meta-analysis of IGB placement showed weight loss of 14.7 kg or 12.2% of initial weight and 5.7 kg/m^2 or 32.1% of excess weight at 6 months [25]. Complications of IGB placement are uncommon, and the most common side effects are nausea and vomiting (8.6%) [25]. IGB has never been tested in obese patients awaiting kidney transplantation. We proposed to test the efficacy and safety of IGB placement for 6 months in obese patients awaiting kidney transplantation.

Patients and Methods

Patients

We performed a prospective non-randomized study for 3 years from January 1, 2009 to January 1, 2012 at the Paris-Sud University Hospital. We included adults awaiting kidney or pancreas–kidney transplantation with a BMI greater than 30 kg/m^2 and displaying a contraindication for kidney transplantation because of obesity. The obesity contraindication concerned patients with BMI of more than 40 kg/m^2 and patients with a BMI of between 30 and 40 kg/m^2 whose external iliac artery is difficult to access due to the distance between the area of skin and the external iliac artery and the presence and the locations of vascular calcifications. All cases were evaluated during a multidisciplinary meeting. Patients who were not candidates for kidney transplantation or who had IGB contraindications such as a history of gastric ulcers, hiatal hernia greater than 4 cm, or ulcerative esophagitis (C–D grade, Los Angeles classification) were excluded from the study, as patients who were planning to become pregnant or who refused a 15-month follow-up. Other exclusion criteria included: breastfeeding, alcoholism, drug addiction, severe liver disease, non-steroidal anti-inflammatory drugs without proton pump inhibitors, psychiatric disorders, bulimia nervosa, and secondary obesity (hypothyroidism, Cushing syndrome, Prader–Willi syndrome, and Laurence–Moon–Biedl syndrome).

All patients gave their informed consent. All patients underwent evaluation in a multidisciplinary weight loss clinic, including consultation with an endocrinologist, nutritionist, psychologist, gastroenterologist, and bariatric surgeon.

Methods

IGB Insertion and Removal

The intra-gastric balloon (IGB) (Heliosphere Bag®, Helioscopie, France, which was the only available device in our unit) was inserted and removed by endoscopy under general anesthesia. The patients were hospitalized for 24 h. The balloon was placed in the stomach for 6 months, as recommended. All patients were treated after IGB insertion with lansoprazole 30 mg/day.

Follow-Up

The primary end point was the measurement of BMI (W/S^2; W: weight in kilograms, S^2: size in meters squared). The secondary end points corresponded to (i) efficacy criteria: weight, waist, and hip measurements; the mean percentage of excess body weight loss at 6 months ([W before − W after] × 100 / [W before − ideal W]); cholesterolemia and triglyceridemia; fat and lean mass measurements with body impedance spectrometry (BSI) (medical Body Composition Analyzer (mBCA) 515 by seca gmbh, Hamburg, Germany) and resting metabolism with indirect calorimetry at IGB placement and at IGB removal; and (ii) safety criteria: abdominal pain (on a visual analogic scale from 0 to 10), vomiting, digestive bleeding, early IGB removal because of appearance of complications, albuminemia, prealbuminemia, KT/V (dose of dialysis with K clearance of urea, T time of dialysis, V distribution volume), and the number of dialysis sessions.

During the 3 months before IGB insertion, the patients received nutritional care. The IGB was then placed in the stomachs of the patients with a BMI of more than 30 kg/m^2 for 6 months. After 6 months, the IGB was removed and the patients were monitored for 6 months. The patients attended monthly follow-up appointments, and clinical and biological evaluations were performed (Fig. 1).

Statistical Analysis

Data are represented as the mean, standard deviation, and range. The normal distribution of variables was assessed with the d'Agostino Pearson test. For variables with normal distribution, Student's t test was used for paired samples and the z test for independent samples. For variables without normal distribution, the Mann–Whitney test was used to compare the means of two independent samples and the Wilcoxon test to compare the means of paired samples.

Results

Demographic Data and Parameters of Dialysis

Seventeen patients were included in the study. The mean age at IGB insertion was 53.4 years [19.4–69.4]. All patients were dialyzed (15 by hemodialysis [3 sessions of 4 h per week] and 2 by automatized peritoneal dialysis) (Table 1). The main nephropathy was secondary to diabetes mellitus. During the study, no patient required supplementary dialysis sessions because of cardiac insufficiency, hyperkalemia, or insufficient KT/V. The KT/V for the hemodialyzed patients was greater than 1.3 and for the peritoneal dialyzed patients greater than 1.7.

Efficacy of IGB

Anthropometric Parameters

The patients' weight and BMI decreased significantly during the 6 months after IGB insertion, from 100.8 kg [78–128] to 93.4 kg [67–118] ($p < 0.005$) and from 37.7 kg/m^2 [29.7–44.5] to 34.4 kg/m^2 [29–42] ($p < 0.005$), respectively. The mean percentage of excess body weight loss at 6 months was 20.2 (± 11.4). Waist and hip measurements were significantly reduced during the 6 months after IGB insertion, from 121.1 cm [109–136] to 114 cm [99–124] ($p < 0.005$) and 110.6 cm [100–122] to 107 cm [97–125] ($p < 0.005$),

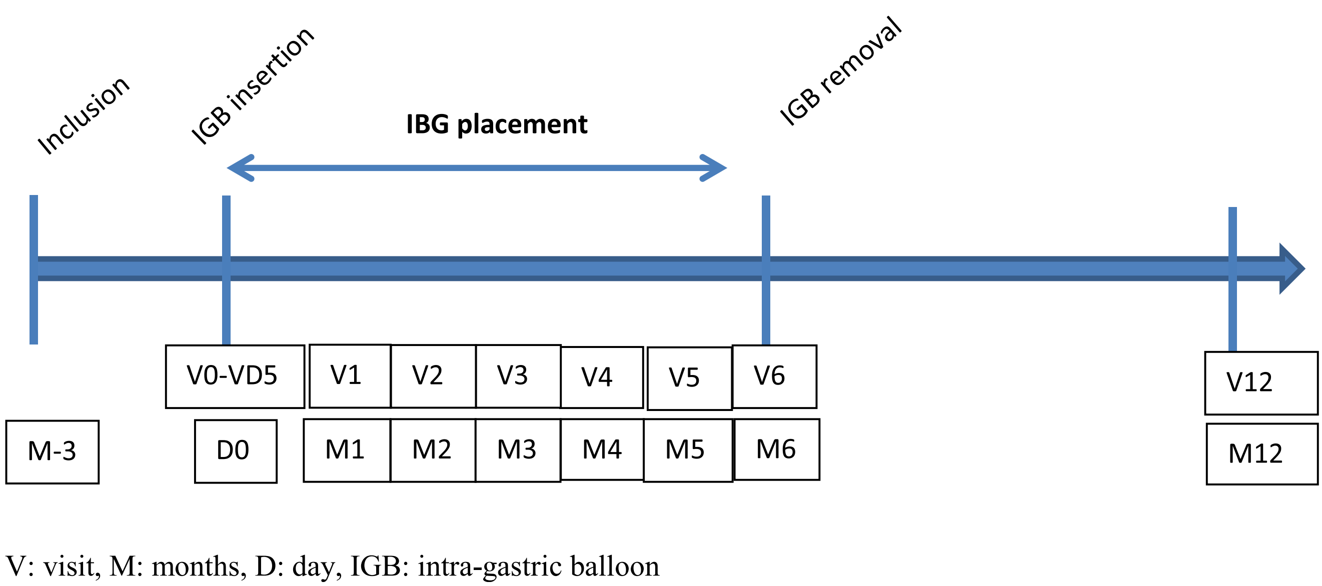

Fig. 1 Schema of the study. V visit, M months, D day, IGB intra-gastric balloon

Table 1 Demographic data of obese dialyzed patients awaiting kidney transplantation

Mean age at IGB insertion (years)	53.39 [19.4–69.34]
Sex ratio M/F (*n*)	8/9
Type of dialysis HD/DP (*n*)	15/2
Duration of dialysis before IGB insertion (months)	31.3 (± 28.1)
Time on waiting list (months)	12.5 (± 12.4)
Underlying nephropathy (*n*):	
Glomerular	2
Hereditary	1
Uropathy	1
Vascular	5
Diabetes	7
Unknown	1
Diabetes mellitus (*n*)	11

HD hemodialysis, *DP* peritoneal dialysis, *IBG* intra-gastric balloon

respectively (Table 2). The anthropometric parameters continued to decline until 1 year after IGB placement. The difference was significant when we compared the data before IGB placement and at 1 year, but it was not significant when we compared the data at IGB removal and 6 months later (Table 2). During IGB insertion, the rate of weight loss was significantly higher during the first 3 months ([Weight at M0 − Weight at M3/Weight at M3]) compared to the last 3 months ([Weight at M3 − Weight at M6)/Weight at M6]), respectively 0.069 (± 0.03) and 0.009 (± 0.025), $p < 0.05$.

Impedance Spectrometry and Theoretical Resting Metabolic Rate Measured by Indirect Calorimetry

Between M0 and M6, we observed a significant decrease in fat mass, from 41.74 kg [39.48–47.76] to 38.56 kg [35.5–44.5] ($p < 0.05$), but lean mass decreased only very slightly, from 55.38 kg [48.49–73.62] to 54.94 kg [48.21–60.13] (p = ns) (Table 3). In fact, three patients' lean mass increased.

Resting metabolic rate was measured in 13 patients. Theoretical resting metabolic rate was calculated in the same 13 patients. The two parameters were not statistically different before and after IGB insertion (Table 4).

Table 3 Results of body impedance spectrometry (BIS) before and 6 months after IGB insertion

	M0	M6	*p*
Fat mass (kg) median	41.74	38.56	< 0.005
[IQR]	[39.48–47.76]	[35.351–44.49]	
Lean mass (kg) median	55.38	54.94	ns
[IQR]	[48.49–73.62]	[48.21–60.13]	
Fat mass/lean mass	0.81	0.76	ns
Median [IQR]	[0.68–0.88]	[0.65–0.80]	

M0 0 months before IGB, *M6* 6 months after IGB, *ns* non-significant

Biological Parameters

Albuminemia and prealbuminemia levels were similar throughout the study, unlike triglyceridemia levels which decreased significantly ($p = 0.02$) during the 6 months after IGB insertion. Cholesterolemia levels were constant throughout the study in the same way as glycated hemoglobin, HDL level, and hemoglobin level (Table 5).

Safety of IGB

The IGB was placed for 6 months in every patient. No complications such as ulcers, digestive hemorrhages, obstruction or displacement were observed.

The mean range of abdominal pain was measured at 2 [0–7] on the EVA scale during the first 5 days after IGB insertion and then at 0 for the rest of the study. The abdominal pain was successfully treated with paracetamol and phloroglucinol/thrimethylphloro. No patient had nausea or vomiting.

Outcomes of Transplanted Patients

Eleven patients were transplanted. The mean time between IGB removal and kidney transplantation was 28.46 months (± 11.5). The mean period between inscription on the waiting list and kidney transplantation was 44 months (± 19). The mean weight and the mean percentage of weight loss on the day of kidney transplantation were respectively 87.3 kg (± 15) and 12.6 (± 12). The mean BMI on the day of transplantation

Table 2 Follow-up of anthropometric criteria before and 6 months after IGB insertion

	M0	M6	M12
Weight (kg)	100.82 [78–128]	93.44 [67–118]**	96 [66–114.5]**
BMI (kg/m^2)	37.7 [29.7–44.5]	34.38 [29–42]**	35.37 [26.9–42]**
Waist measurement (cm)	121.15 [109–136]	114 [99–124]**	116.85 [108–126]**
Hip measurement (cm)	110.62 [100–122]	107 [97–125]*	107.92 [93–115]*
Waist/hip ratio	1.1 [1–1.18]	1.07 [1–1.13]*	1.09 [1.01–1.16]

M0 0 months, *M6* 6 months, *M12* 12 months, *BMI* body mass index

*$p = 0.05$; **$p < 0.05$

Table 4 Measured and theoretical resting metabolic rate by indirect calorimetry before and 6 months after IGB insertion

	M0	M6	*p*
Measured RMR (Weiss equation)	1.816.4 [1.616–2.054]	1.863 [1.574–2.020]	ns
Estimated RMR Harris and Benedict	1.857 [1.621–2.041]	1.735 [1.471–1.997)	ns
Black formula	1.819 [1.556–1.928]	1.735 [1.460–1.893]	ns

M0 0 months before IGB, *M6* 6 months after IGB, *ns* non-significant, *RMR* resting metabolic rate

was 31 kg/m^2 (± 4.3). The change in weight from IGB placement to IGB removal to kidney transplantation is reported on Fig. 2. The mean creatinemia level at 1 year after kidney transplantation was 109 μmol/l (± 43). There were no delays as a result of wound healing. One patient had urinoma treated successfully and one a delayed graft function because of acute tubular necrosis.

Discussion

This is the first study which has tested the efficacy and safety of IGB placement in obese dialyzed patients awaiting kidney transplantation. Even though the aim recommended by the ASGE and FDA was not achieved, we found a significant decrease in BMI, weight, and waist and hip measurements.

IGB is a minimally invasive modality for weight loss. A meta-analysis of 15 articles examining IGB placement in the general population (3608 patients) demonstrated a mean weight loss of 14.7 kg or 12.2% of initial weight and 5.7 kg/m^2 or 32.1% of excess weight at 6 months [25]. Complications of IGB are uncommon and the most common side effects are nausea and vomiting (8.6%). In our study, the IGBs were well tolerated and none were removed because of discomfort or complication. A few of the patients experienced pain but without nausea or vomiting in the first few days after insertion and symptomatic treatment was successful. This was surprising because nausea and vomiting are frequent in the two first weeks after a device is implanted. This could be explained because each patient was carefully monitored with regular clinical evaluation during hemodialysis in the first 2 weeks after IGB insertion and because we used air-filled rather than fluid-filled IGBs. No patients had to increase their number of dialysis sessions. The weight loss was maximal during the first 3 months of IGB placement, as has been observed in most of the studies testing the effects of IGBs in obese patients.

Generally, other side effects include intolerance to the balloon (resulting in early removal), gastric ulcers or erosions, esophagitis, spontaneous deflation, persistent vomiting, gastro esophageal reflux, and abdominal pain. However, severe complications are rare. A large Italian series of 2525 cases showed the following complications: acute gastric dilatation in 0.08%, gastric outlet perforation in 0.19% (corresponding to five cases, four which had already had gastric surgery), gastric obstruction in 0.76%, balloon rupture in 0.36%, esophagitis in 1.27%, and gastric ulcers in 0.2% [26]. Acute renal failure is reported as a complication of IGB placement in a few studies, at a rate of 1.1 to 4.5%. In all cases, vomiting with dehydration is the cause of acute kidney failure, which is reversible after adapted hydration [27, 28]. None of our patients had vomiting.

Previously, IGB was tested in nine obese patients in stage 3 or 4 chronic kidney disease (not in stage 5). The median weight and BMI loss were respectively 10.4 kg and 3.6 kg/m^2. Median waist circumference and total cholesterol decreased significantly. Glomerular filtration rate, blood pressure, triglycerides, adipokine, inflammation, and arterial stiffness did not decrease significantly. Five episodes of acute kidney injuries occurred in three patients because of

Table 5 Evaluation of biological parameters before and 6 months after IGB insertion

	M0	M6	*p*
FBG (mmol/l)	7.3 [4–13.7]	6.8 [4.6–11.8]	ns
HbA1c	6.93 [5.1–10]	6.49 [5.1–8.9]	ns
Cholesterol total (mmol/l)	4.16 [2.06–5.40]	4.16 [2.11–4.93]	ns
HDL cholesterol (mmol/l)	0.91 [0.57–1.29]	0.98 [0.68–1.26]	ns
LDL cholesterol (mmol/l)	2.35 [0.44–3.61]	2.27 [0.67–3.45]	ns
Triglycerides (mmol/l)	2.82 [1.4–5.13]	2.03 [0.87–3.67]	0.02
Albuminemia (gr/l)	36.76 [30.2–41.10]	36.47 [30.70–41.8]	ns
Prealbuminemia (gr/l)	0.39 [0.24–0.59]	0.38 [0.29–0.56]	ns
Hemoglobin level (gr/dl)	11.7 [10.2–13.4]	12.3 [10.9–13.8]	ns
CRP (mg/l)	11.85 [3–20]	10.08 [3–20]	ns

M0 0 months 0, *M6* 6 months 6, *ns* non-statistically significant, *FBG* fasting blood glucose, *HbA1c* glycated hemoglobin level

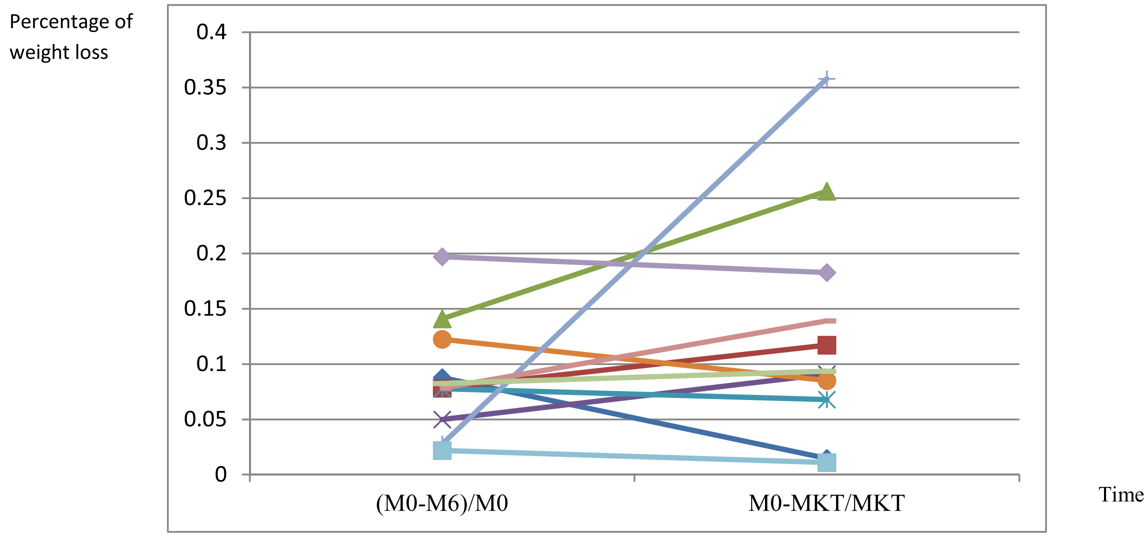

Fig. 2 Comparison of the percentage of weight loss for the period between IGB placement and IGB removal and the period between IGB placement and the day of kidney transplantation. M0 day of IGB placement, M6 day of IGB removal, KT day of kidney transplantation. Five patients lost weight between the day of IGB placement and the day of kidney transplantation; three patients saw no change and three gained weight (p = ns)

dehydration secondary to gastrointestinal symptoms [29]. If we compared the results of this study with the results of our study, weight loss was very similar, but tolerance was better in our study. We did not find any change in cholesterolemia or HbA1C level. On the other hand, we observed a significant decrease in triglyceridemia.

Laparoscopic sleeve gastrectomy (LSG) and Roux-en-Y gastric bypass (RYGB) are the two most common bariatric surgeries in obese patients awaiting kidney transplantation. In the largest of these series, 27 pre-transplant patients with a mean age of 57 years and a mean BMI before kidney transplantation of 48.3 kg/m^2 (38–60.4) underwent an LSG with subsequent mean percentage excess weight loss at 1, 3, and 12 months of 17%, 26%, and 50% respectively [23]. While overall mortality rates for LSG and RYGB are similar, LSG is less invasive with lower morbidity rates (20.5% for RYGB versus 6.5% for LSG). The procedures result in comparable weight loss at 6, 12, and 18 months, while RYGB appears to be more effective in terms of achieving diabetes remission [30, 31]. In comparison to these data, our patients had a lower BMI. Weight loss induced by IGB insertion would probably not be sufficient in patients with a higher BMI to allow kidney transplantation.

Other strategies not involving invasive treatment could be proposed to obese patients awaiting kidney transplantation. A multidisciplinary 1-year program combining exercise, dietary intervention, and orlistat could have an impact on weight loss of up to 7.1% and on functional ability in patients with chronic kidney disease. In this previous study, we can observe a significant reduction in weight (BMI of 35.7 kg/m^2 at the baseline versus BMI of 33.2 kg/m^2 at 12 months) and waist circumference (112.9 cm at the baseline versus 100 cm at 12 months), along with significant improvements in exercise capacity and functional ability at 12 months [32].

With regard to transplant-related outcomes associated with weight loss, there are few data specifically addressing intentional weight loss. The benefits of weight loss in dialyzed obese patients awaiting kidney transplantation are inconclusive. A higher risk of wound complications is associated with obesity. However, Kuo et al. observed that a history of weight loss was associated with a higher risk of complications, even in obese patients [33]. They also noted that weight loss may have created a subpopulation of patients who are at a higher risk of wound complications because of malnutrition [33]. In our population, the levels of albuminemia and prealbuminemia were constant, suggesting that the weight loss was not associated with malnutrition. In addition, BSI at 6 months showed a significant decrease in fat mass without a significant decrease in lean mass. Moreover, three patients increased their lean mass, suggesting that weight loss improves their capability to increase activity.

Molnar et al. examined the association between weight changes and patient survival among dialysis patients waitlisted for kidney transplantation and found an inverse association between weight change and hazard of death, such that the more weight patients lost the higher their risk of death [34]. The higher mortality associated with weight loss persists when the analysis is restricted to obese patients. However, the possibility that weight loss was an indicator of intercurrent illness cannot be excluded. In a large cohort of US transplant recipients, the authors reported that one third had a change in World Health Organization BMI category while on the transplant waiting list [35]. However, the weight loss was not associated with an improvement in graft survival among obese patients (and was associated with worse outcomes among normal and underweight patients). Furthermore, there was a graded and inverse association between weight changes before and after transplantation, such that those who lost weight beforehand generally gained weight afterwards [35].

Because of the efficacy and safety of IGB in our study, it could be interesting to test IGB in obese dialyzed patients with other medical or surgical indications. Furthermore, it could be interesting to confirm our results in a large cohort and to evaluate the efficacy, safety, and cost of the three main treatments—LSG, IGB, and a multidisciplinary program combining exercise and dietary intervention—in three groups of randomized patients.

To conclude, IGB can be used effectively and safely in dialyzed patients awaiting kidney transplantation. With air-filled IGBs, we observed few complications such as abdominal pain and no nausea or vomiting. IGB could therefore constitute an interesting strategy to test for weight loss in dialyzed patients with other medical or surgical indications.

Compliance with Ethical Standards

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

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

Statement of Human Rights The study was conducted in accordance with human rights.

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