## **ORIGINAL CONTRIBUTIONS**





# Bariatric Surgery Is Efficacious and Improves Access to Transplantation for Morbidly Obese Renal Transplant Candidates

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## Abstract

**Background** The surgical risk of morbidly obese patients is high and even higher for kidney transplant candidates. A BMI >  $35-40 \text{ kg/m}^2$  is often a contraindication for that surgery. The safety, feasibility, and outcome of bariatric surgery for those patients are inconclusive.

**Methods** We conducted a retrospective chart review of prospectively collected data on morbidly obese renal transplant candidates who underwent laparoscopic sleeve gastrectomy (LSG) or laparoscopic Roux-en-Y gastric bypass (LRYGB) in our institution between January 2009 and September 2017. The reported outcome included body weight and graft status after a mean follow-up of 47 months (range 0.5–5 years).

**Results** Twenty-four patients (8 females, 16 males, average age 54 years, average preoperative BMI 41 kg/m<sup>2</sup> [range 35–51]) underwent LSG (n = 17) or LRYGB (n = 7). Sixteen of them (67%) proceeded to kidney transplantation. Of the 8 pre-transplant and post-bariatric surgery patients, 5 are on the waitlist, and 2 patients died (one of staple line leakage, and one from sepsis unrelated to the bariatric surgery). The average time from bariatric surgery to transplantation was 1.5 years (range 1 month to 4.3 years). The average pre-transplantation BMI was 28 kg/m<sup>2</sup> (range 19–36). The mean percentage of excess weight loss was 66% (n = 21), and the total percentage of weight loss was 29% (n = 21). Comorbidities (type 2 diabetes, hypertension, and dyslipidemia) improved significantly following both surgical approaches.

**Conclusions** LSG and LRYGB appear to effectively address obesity issues before kidney transplantation and improve surgical access. Morbidly obese transplant candidates would benefit from prior bariatric surgery.

Keywords End-stage renal disease · Chronic renal disease · Dialysis · Morbid obesity · Bariatric surgery · LSG · LRYGB

Abbreviations		
BMI	Body mass index	
ESRD	End-stage renal disease	

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%EWL	Percent excess weight loss
LAGB	Laparoscopic adjustable gastric banding
LRYGB	Laparoscopic Roux-en-Y gastric bypass
LSG	Laparoscopic sleeve gastrectomy
T2DM	Type 2 diabetes mellitus
%TWL	Percent total weight loss

# Introduction

Kidney transplantation is the renal replacement therapy of choice for the majority of patients with end-stage renal disease (ESRD). Successful kidney transplantation is associated with improved survival, improved quality of life, and healthcare cost savings compared to dialysis [1]. Obesity has become a global pandemic, with more than one-third of the population meeting the criteria for obesity [2]. It is commonly associated with comorbidities, such as heart and renal disease and non-alcoholic steatohepatitis which, in turn, can lead to end-stage organ failure [3]. Bariatric surgery is the most effective solution for morbid obesity, and the number of patients undergoing it is constantly growing [4, 5]. Indeed, according to Hawn et al. [6], the only successful remedy for these patients, in the long run, is bariatric surgery.

Patients with end-stage organ failure comprise a subgroup of obese individuals. Almost 60% of patients undergoing renal transplantation have a body mass index (BMI)  $\geq$  30 kg/m<sup>2</sup>. The majority of those who are kidney and liver transplant recipients experience additional weight gain following the procedure [7]. Specifically, obesity (body mass index  $[BMI] > 30 \text{ kg/m}^2$ ) and morbid obesity (BMI > $35 \text{ kg/m}^2$ ) are more prevalent following transplantation. The reasons for this high prevalence are twofold: the first is the promotion of end-stage organ disease by obesity and its associated comorbidities, and the second is the increase in body weight often seen after transplantation due to maintenance immunosuppressive therapy with steroids, as well as improved general health and appetite following transplantation [8]. Hoogeveen et al. found that the prevalence of obesity increased from 5.6% before the transplantation to 11.5% 1 year after it and that obesity at 1-year post-transplantation increased the risk of mortality and graft failure by approximately 40% compared with normal weight [6].

Performing any major surgical procedure on obese patients is more difficult, takes longer, and is subject to a higher rate of operative and perioperative complications [9, 10]. In addition, the surgical outcomes are worse in obese patients compared with their non-obese counterparts [11, 12]. Large studies have shown that obesity among kidney transplant recipients is associated with a higher risk of allograft failure and death [11–14]. There are currently no universally accepted guidelines for BMI cutoffs for potential transplant patients.

The present study aimed to retrospectively investigate our experience with bariatric surgery in patients with coexisting morbid obesity and ESRD who had not been eligible for transplantation due to their weight.

## Methods

## **Patient Selection**

The study population consisted of patients who were evaluated by the Transplant Surgery Division but were found to be ineligible for kidney transplantation because their BMIs exceeded the recommended BMI for transplantation at our institution which was set at 35 kg/m<sup>2</sup>. They had failed to lose the required weight by means of conservative measures. The institutional review board approved the prospective data collection. All kidney transplant candidate patients who underwent bariatric surgery and were evaluated for transplantation in our institute were studied prospectively between January 2009 and September 2017. We excluded 3 patients who underwent laparoscopic adjustable gastric banding (LAGB) before kidney transplant due to insufficient followup information, and 2 patients with missing essential data. The patients were referred by their nephrologist to the Bariatric Surgery Clinic for management of morbid obesity after conservative approaches had failed. They underwent a multidisciplinary evaluation by a dietitian, psychologist, anesthesiologist, and bariatric surgeon, as well as other specialist consultants as needed. They all fulfilled the criteria for bariatric surgery established by the National Institutes of Health consensus conference [15].

The retrieved data included baseline and change in BMI, % excess weight loss (%EWL), % total weight loss (%TWL), change in comorbidities, acceptance or rejection of candidacy to undergo a kidney transplant, and kidney transplant outcomes. The bariatric procedure was chosen according to the individual characteristics of the patient, BMI, health-related conditions, previous operations, medications, eating habits, and patient preference.

## **Operative Management**

The surgical techniques of laparoscopic sleeve gastrectomy (LSG) or laparoscopic Roux-en-Y gastric bypass (LRYGB) were the same as those widely described and discussed in the literature. Kidney transplantation was performed through an extraperitoneal approach in the iliac fossa. The renal vessels were anastomosed to the external iliac vessels, and the ureter was implanted into the bladder by an extravesical ureterocystostomy by means of the anti-reflux technique. A double-J stent was routinely placed in the ureter and removed 3 to 6 weeks after transplantation.

## **Post-Bariatric Surgery Management**

The patients were started on clear liquids on postoperative day 1 and discharged on postoperative days 3–4 with instructions to gradually increase diet volume and intake of solids. They were followed routinely at the Bariatric Surgery Clinic at 2 weeks, and 3, 6, and 12 months, and annually thereafter. The bariatric program includes routine follow-up visits (including consultation with a nutritionist), nutrition classes, and support groups. Hemodialysis was continued for patients with ESRD according to their usual schedules. We conducted a close follow-up for all the post-BS patients including a blood test for vitamins and other essentials supplements they were instructed to consume daily (vitamin D, vitamin B12, folic

acid, iron, Ca + 2). Patients who underwent a transplant continued a separate follow-up at the designated transplant clinic and underwent appropriate function tests.

## **Statistical Analysis**

Mean values, standard deviations, and absolute and relative frequencies were calculated for descriptive statistical analysis. Statistical analyses were performed using IBM SPSS Statistics, software version 22.0 (IBM Corp., Armonk, NY).

## Results

## **Patient Characteristics**

Twenty-four ESRD patients (8 females and 16 males) with a mean age of  $54 \pm 3.11$  and a median age of 56 years (range 28–68 years), a mean weight of  $115 \pm 2.96$  kg (range 91– 131 kg) and a mean BMI of  $41.5 \pm 0.79$  kg/m<sup>2</sup> (range 35–51 5 kg/m<sup>2</sup>), were considered as being medically appropriate candidates for kidney transplantation and underwent bariatric surgery as part of the pre-transplant preparation process. Either an LSG (n = 17) or an LRYGB (n = 7) procedure was performed for the treatment of morbid obesity to with the aim of fulfilling the requirements for candidacy for kidney transplantation. Among the patients were 17 dialysis-dependent renal failures (hemodialysis n = 16, peritoneal dialysis n = 1) and 7 with stage 4 renal disease. Three of the dialysis-treated patients were on the waitlist for re-transplant. The etiology of renal failure was T2DM in 15 patients, focal segmental glomerulosclerosis in 2, polycystic kidneys disease in 3, hemolytic uremic syndrome in 1, and unknown in 3. Comorbidities included T2DM in 16 (67%) patients, hypertension in 22 (92%), dyslipidemia in 18 (75%), and ischemic heart disease in 5 (21%). The mean HbA1c of the patients with T2DM was 7.7% (range 6-10.5%). The patients' demographics are presented in Table 1.

#### **Outcomes of Bariatric Surgery**

There were no intraoperative complications, one patient died of sleeve staple line leakage on postoperative day 21, and one patient died from sepsis unrelated to the bariatric surgery 18 months after the surgery. The mean follow-up was  $47 \pm$ 6.5 months, and a follow-up longer than 12 months was available for 22 patients. Specifically, 22, 16, 14, 8, and 5 patients were followed up for > 1, 2, 3, 4, and 5 years, respectively. None of the patients were lost to follow-up; the results of the bariatric procedure met the criteria for successful weight loss (> 50% percentage excess weight loss [%EWL]) in 21 of the 22 patients (95%) at the time of transplant or last follow-up (for listed patients). The mean weight decreased from 115 to

Table 1 Demographic and bariatric characteristics of the study patients

No. patients	24
Mean age at bariatric surgery, y	54 (range 28-68)
Gender	
Male	16
Female	8
Type of surgery	
LSG	17
LRYGB	7
Status	
Preemptive	7
Hemodialysis	16
Peritoneal dialysis	1
Chronic kidney disease etiology	
T2DM	15
Other	9
Focal segmental glomerosclerosis	2
Polycystic kidney disease	3
Hemolytic uremic syndrome	1
Unknown	3
Comorbidities	
T2DM	16
Hypertension	22
Dyslipidemia	18
IHD	5
Follow-up (mean $\pm$ SD), months	$47 \pm 6.5$

*LSG*, laparoscopic sleeve gastrectomy; *RYGB*, Roux-en-Y gastric bypass; *T2DM*, type 2 diabetes mellitus; *IHD*, ischemic heart disease; *SD*, standard deviation

84 kg, and the mean BMI decreased from 41.5 to 29 kg/m<sup>2</sup>. The mean EW decreased from 55 to 17 kg, with a mean %EBWL of 66 and a mean %TWL of 29. The bariatric surgery results are presented in Table 2. Of the 8 pre-transplant and post-BS patients, 5 are on the waitlist, and 2 patients died (one of sleeve staple line leakage on a postoperative day 21, and the other from sepsis 18 months after the bariatric surgery and unrelated to it). The patient who died after staple line leakage had undergone an LSG that also included the suture repair of a medium-sized diaphragmatic hernia. The leakage was found to have caused a severe mediastinitis which deteriorated to severe sepsis and it was the cause of death. One patient was removed from the transplant list due to a newly diagnosed malignancy.

## Improvement in Comorbidities

Most of the obesity-related comorbidities underwent remission (defined as a complete withdrawal of medical treatment with normal lab results) or improvement (defined as a decrease of medication dosage or improvement in lab

Table 2Bariatric surgeryoutcomes

No. patients	23
Mean weight before bariatric surgery, kg	
All	$115 \pm 2.9$ (range 91–131)
RYGB	121 (range 96–131)
LSG	110 (range 91–125)
BMI, kg/m <sup>2</sup>	
All	$41 \pm 0.9$ (range 35–51)
RYGB	42 (range 35–51)
LSG	41 (range 35–49)
Excess weight before surgery, kg	$55 \pm 3.0$
Total weight loss, kg	$35\pm2.9$
%EWL	$66 \pm 6.3$
%TWL	$29\pm2.3$
Weight before transplant/last follow-up (for waitlist), kg	$87 \pm 4.3$
BMI before transplant/last follow-up (for waitlist), kg	$29 \pm 1.3$

Values are given in mean  $\pm$  standard deviation

*BMI*, body mass index; *LSG*, laparoscopic sleeve gastrectomy; *RYGB*, Roux-en-Y gastric bypass; *%EWL*, percentage excess weight loss; *%TWL*, percentage total weight loss; *kg*, kilograms

results). Sixteen patients (67%) had T2DM before they underwent bariatric surgery: 7 of them (44%) underwent complete remission, 7 (44%) underwent partial remission, and only 2 (12%) remained unchanged. Following bariatric surgery, the mean HbA1c of the T2DM patients decreased from 7.7 to 6.2% (normal = 4–5.6%). Dyslipidemia was diagnosed in 18 (75%) patients before bariatric surgery: following the surgery, the mean total cholesterol and triglycerides levels of 4 (22%) were within normal limits (total cholesterol < 200 mg/dL, triglycerides < 150 mg/ dL, high-density lipoprotein > 40 mg/dL), 9 (50%) showed improvement, and 5 (28%) remained unchanged. One year following bariatric surgery, the mean total cholesterol and triglycerides levels of the 24 bariatric-operated patients decreased from 175 to 159 mg/dL and from 260 to 146 mg/ dL, respectively. Twenty-two (92%) patients had hypertension: the levels of 10 (45%) were within normal limits (systolic/diastolic pressure  $\leq 120/80$ ), 2 (10%) showed improvement, and 10 (45%) remained unchanged. Figure 1 presents the obesity-related comorbidities for the LSG and LRYGB groups.

#### **Transplantation Following Bariatric Surgery**

Sixteen (67%) of the 24 operated patients successfully proceeded to kidney transplantation, of which 11 were living and 5 were cadaveric transplants. The mean dialysis treatment duration before transplantation was 35 months. Fourteen patients underwent a first-time transplant and 2 patients underwent a second transplantation (1 living and 1 cadaveric). The average time from bariatric surgery to transplantation was 1.5 years (range 1 month–4.3 years). The 16 patients' mean weight before the

transplant was 84 kg, and their mean pre-transplant BMI was 29 kg/m<sup>2</sup>. Analysis of the records of the post-transplant followup revealed that the mean weight did not increase following transplantation; mean follow-up of  $24 \pm 5.2$  months after KT shows a mean change in weight of  $-1.7 \pm 1.9$  kg (LSG, n =13; LRYGB, n = 3). The mean hospital stay was  $11 \pm 2.1$  days. Eight of the 16 patients were readmitted to the hospital during the first post-transplant year (mean 3 admissions, range 1-6). Two patients sustained acute tubular necrosis with delayed graft function and required dialysis during hospitalization, and one patient sustained acute rejection that was successfully treated with highdose steroids. The mean serum creatinine level (mg/dL) on posttransplant days 7, 30, 180, and 1 year were  $2.3 \pm 0.6$ ,  $1.7 \pm 0.2$ ,  $1.4 \pm 0.1$ , and  $1.4 \pm 0.1$ , respectively. The tacrolimus blood trough levels (ng/mL) on post-transplant days 7, 30, and 90 and at 1 year were  $9.9 \pm 2.5$ ,  $11.2 \pm 3.3$ ,  $12.0 \pm 4.0$ , and  $7.0 \pm$ 2.5, respectively. The kidney transplant outcomes are presented in Table 3.

# Discussion

The findings of this study augment the sparse data on the outcomes of LSG and LRYGB among morbidly obese patients who are candidates for kidney transplantation. We are not aware of any publications on large groups of such patients or relevant randomized controlled trials. Our study results demonstrated that bariatric surgery can effectively and safely enable otherwise unsuitable patients to undergo kidney transplant, with 16 of our 24 study subjects (67%) having proceeded to kidney transplantation following successful postoperative weight reduction. Fig. 1 Obesity-related comorbidities with subdistribution into separate and combined laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB) groups. HTN, hypertension; T2DM, type 2 diabetes mellitus



 Table 3
 Transplanted patient characteristics

No. patients	16
Mean age at bariatric surgery, years	57 (range 29–70)
Gender	
Male	13
Female	3
LSG	13
RYGB	3
Status	
Preemptive	3
Hemodialysis	13
Dialysis duration, months	35 (3–92)
Chronic kidney disease etiology	
T2DM	11
Hypertension	2
Other	3
Average time from BS to KT	1.5 (range 1 month-4.3 years)
Before KT	
Weight before transplant, kg	$84\pm4.6$
BMI before transplant, kg/m <sup>2</sup>	$29\pm1.3$
Post-BS follow-up, months	$46\pm7.1$
After KT	
Weight at last follow-up, kg	$79 \pm 4.1$
BMI at last follow-up, kg/m <sup>2</sup>	$27 \pm 1.0$
Post-KT follow-up, months	$24\pm5.2$

Values are given in mean ± standard deviation

*BMI*, body mass index; *LSG*, laparoscopic sleeve gastrectomy; *RYGB*, Roux-en-Y gastric bypass; *HTN*, hypertension; *T2DM*, type 2 diabetes mellitus; *SD*, standard deviation; *kg*, kilograms; *BS*, bariatric surgery; *KT*, kidney transplant

Obesity has reached epidemic proportions in the general population [16], and the epidemic and its health consequences have not spared people with ESRD [17]. Obesity comorbidities are reported as the leading cause of ESRD, with reports of diabetes mellitus in 44% and hypertension in 29% of them [17]. Moreover, obesity is known as an independent predictor for ESRD [18]. Bariatric surgery has been relatively uncommon among kidney transplant candidates and recipients despite their fulfilling the qualifications for undergoing it. Furthermore, a gastric leak could be more difficult to manage in a patient on immunosuppressive medication than in one with chronic renal failure. If sepsis were to develop, it is likely that lowering the level of immunosuppression would be necessary, thereby increasing the risk for graft rejection. Nevertheless, a number of epidemiologic studies with large samples of ESRD patients have indicated paradoxically inverse associations between classic risk factors for cardiovascular disease and mortality [19]. The findings of those studies showed worse survival with a lower BMI and also indicated that higher BMI values reflecting overweight or obesity seemed to be associated with better survival. This phenomenon has been referred to as the "obesity paradox" and has not been confirmed in interventional studies that are needed to establish causality [19, 20]. Furthermore, when considering the balance of benefit and risk, the transplant specialist needs to weigh the operative risks of bariatric surgery in a morbidly obese patient with chronic renal failure, taking into consideration the potentially improved likelihood of the success of kidney transplantation in a less obese recipient versus the combined risks of kidney transplantation in an obese candidate and the risks of bariatric surgery in an immunosuppressed patient [21].

The results of meta-analyses support the superior efficacy of bariatric surgery compared with non-surgical therapy in achieving sustained weight loss in morbidly obese patients in the general population [22, 23]. The lack of prospective interventional trials, however, precludes the possibility of generalizing those encouraging outcomes to determine the management of morbidly obese transplant candidates. In 1996, Marterre et al. [24] first described an open gastric bypass performed on 3 morbidly obese kidney transplant recipients 6-8 years following transplantation and reported significant reduction in weight, hypertension, post-transplant diabetes mellitus, and hyperlipidemia. Dziodzio et al. [25] recently published an overview on bariatric surgery in pre-transplant ESRD and kidney waitlist patients and found only 8 retrospective studies involving 154 patients. Those authors recorded weight loss in all the reported series (EWL range 21-68%) and noted that RYGB was the most effective procedure (EWL 64.3 vs. 48.9% after SG), with LAGB showing the least weight loss (EWL  $35.3 \pm 3.5\%$ ). The overall mortality was 4.2% for the RYGB patients and 3.9% for the LSG patients. Improvement of comorbid conditions, such as diabetes, hypertension, and renal function, was reported in 3 studies [26-28].

Kim et al. [29] recently published a large series of 100 morbidly obese patients with ESRD who underwent LSG as part of their transplant program, which had adopted an aggressive approach toward pre-transplant weight loss. Only 19 (19%) of those patients eventually underwent renal transplantation. Thomas et al. [30] described another series of 31 morbidly obese and ESRD patients who underwent LRYGB, of whom 14 were subsequently transplanted.

Gill et al. [31] published a retrospective analysis of 702,456 incident ESRD patients aged 18–70 years (captured in the US Renal Data System between 1995 and 2007). Those authors found that obesity impacted many inter-related considerations for transplant practice, including candidate selection, outcome prediction before and after transplant, and waitlist management. Consistent with the findings of a recent work by Segev et al. [32], obese patients were less likely to receive a deceased donor transplant after being listed and had a higher frequency of being placed on hold [32].

Practice guidelines issued by the American Society of Transplantation recommend a supervised weight loss regimen that includes a low-calorie diet, behavioral therapy, and a physical activity plan to achieve a target BMI of < 30 prior to kidney transplantation [33]. These guidelines also note that there are insufficient data to suggest which, if any, obese patients should be denied a transplant based on their obesity [33]. Morbidly obese patients with end-stage organ failure undergo more frustration and stress than non-obese patients before transplantation, which may be delayed by the need to lose weight while waiting for a suitable organ [21]. In addition, they face a higher risk of surgical complications during transplantation [34] and have higher rates of death and graft failure in the long term [13]. The patients described in this study had durable kidney transplant results with good graft function and a low complication rate, and only 2 patients sustained delayed graft function. The inevitable changes in the gastrointestinal anatomy and the possible effects on drug absorption, including immunosuppressive drug post-transplantation, are matters of some concern. It was recently reported by our group that the level of immunosuppressive drugs remained stable in transplanted patients who underwent bariatric surgery (LSG and LRYGB) without the need for any significant changes in drug dosage. In addition, there were no occurrences of graft loss or major graft complications, while weight reduction was maintained together with improvement in comorbidities [35].

We had for many years chosen not to perform LAGB which consistently yielded poorer results compared with LRYGB and LSG and high rates of long-term complications. Angrisani et al. [36, 37] reported long-term poor outcomes of LAGB compared with LRYGB, with 46% EWL and 69% EWL, respectively. In addition, Suter et al. [38] described insufficient weight loss (EWL < 25%) in 10.5% of their LAGB patients after 5 years and in 14% after 7 years. Looking at the overall results, Suter et al. [38] noted that the incidence of failure (EWL < 25% or band removal) constantly increased over time, going from 13.2% after 18 months (best mark) to 36.9% after 7 years. It should be noted that in the first several years, we chose LSG as the procedure of choice for transplanted patients due to its relatively shorter operative time, technical simplicity, lower overall morbidity, and the fact that it is a purely restrictive and non-malabsorptive procedure. We thought that these would pose critical advantages in patients at high risk for complications that are also dependent on immunosuppressive medications [39]. However, with time and experience, we realized that LSG is less effective in the long-term than previously thought [40] and is also problematic since leaks after LSG tend to have a chronic course as opposed to leaks after RYGB that generally heal better. In addition, other centers did not report a change in immunosuppressive drug dosage post-RYGB and since patients are under such rigorous follow-up of blood levels of immunosuppressive drugs, the benefit of LSG as a non-malabsorptive surgery becomes quite redundant. In this study, we report our results with both LSG and LRYGB in the pre-KT patients, and in the post-KT follow-up, which show good bariatric result continuing after the KT. We were limited by the small number of post-BS and post-KT patients (total n = 16, of them; LSG, n = 13; LRYGB, n = 3) to claim superiority of one procedure over another. Emphasized by our results, obesity continued to constitute a chronic and incurable disease which worsened in the post-transplant period. This was attributed mainly to the maintenance of immunosuppressive therapy with steroids, as well as improved general health and appetite following transplantation [8]. Hence, the surgical procedure to be used before transplantation is of great importance.

Our study has several limitations. First, it includes a relatively small number of patients and describes the experience of a single center. Second, it lacks a control group. Third, it has not taken into consideration ESRD patients who were not qualified to undergo BS. In addition, a larger prospective trial would be needed with a longer follow-up (5–10 years) to provide conclusive evidence of a benefit of bariatric surgery before kidney transplantation in terms of graft survival.

In summary, morbidly obese patients pose a multidisciplinary challenge and had been considered inoperable due to such limitations. Our study strongly supports previous experience by showing that bariatric surgical procedures appear to be effective for addressing the ramifications of morbid obesity before kidney transplantation and that they can improve access to the surgical field. Our results suggest that LSG and LRYGB ensure significant weight loss and improvement of conditions associated with morbid obesity, thus enhancing the likelihood of good transplant outcomes and immunosuppressive stability. While the surgical risk is probably higher than that of the regular bariatric surgery population, we believe that the net advantages of the resulting weight reduction before kidney transplantation provide a convincing argument in favor of bariatric surgery for morbidly obese patients who require kidney transplantation.

Author Contribution Renana Yemini participated in the research design, data analysis, writing of the paper and performance of the research.

Eviatar Nesher participated in the performance of the research.

Idan Carmeli participated in the research design and interpretation of data for the work.

Janos Winkler participated in writing of the paper.

Ruth Rahamimov participated in interpretation of data for the work. Eytan Mor participated in writing of the paper, data analysis, and

Eytan Mor participated in writing of the paper, data analysis, and interpretation of data for the work.

Andrei Keidar participated in the research design, writing of the paper, and interpretation of data for the work.

## **Compliance with Ethical Standards**

The institutional review board approved the prospective data collection.

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

Informed Consent For this type of study, formal consent is not required.

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