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ORIGINAL CONTRIBUTIONS

Applying Enhanced Recovery After Bariatric Surgery (ERABS) Protocol for Morbidly Obese Patients With End-Stage Renal Failure

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Abstract

Background In 2015 our hospital implemented the ERABS protocol. From that moment also morbidly obese patients with end-stage renal disease (ESRD) were enrolled. The objective of this study was to evaluate the potential benefits and safety of the ERABS protocol for ESRD morbidly obese patients compared with patients who are morbidly obese patients undergoing bariatric surgery.

Methods A retrospective review of a prospectively collected database was conducted for ESRD patients who underwent bariatric surgery according to the ERABS protocol. The primary endpoint was the length of hospital stay in days. Secondary endpoints were the number of re-admissions, re-operations, length of renal replacement therapy, and complications during admission and within 30 days after surgery. Propensity score matching was used to compare groups.

Results From 2015 onward 1199 non-ESRD patients and 21 with ESRD were operated. Propensity score matching resulted in two groups of 19 patients. In terms of comorbidities, both groups presented typical components of metabolic syndrome. In the ESRD group, one patient had serious complications (rated as Clavien-Dindo IIIb and IVb) at the first postoperative day after OAGB. The overall complication rate was comparable and not significantly different compared with the non-ESRD group.

Conclusion Our study shows that ERAS in this population has overall minimal adverse events and lack of any ERAS-related complications.

Keywords Bariatric surgery · Obesity · End-stage renal disease · ERABS · Enhanced recovery after surgery · Perioperative complications

Introduction

Organ transplantation surgery is still challenging nowadays because there are too many patients on the waiting list and not enough donors. In the Eurotransplant region (consisting of Austria, Belgium, Croatia, Germany, Hungary, the Netherlands, Luxembourg, and Slovenia), there were 6636 transplantations done with organs from deceased donors in 2017, and in January 2018, there were still 14,733 active patients on the waiting list [1] . According to Poltransplant data of 2017 around 1000 cases of kidney transplantation (KTx) procedures are provided annually in Poland [1]. Only 5% are from alive donors. Every year there are more than 1500 patients on the waiting list [2] . Obesity is an independent risk factor of chronic kidney disease (CKD) development, which in patients with obesity 85% higher. Obesity-associated conditions such as diabetes type 2 (DMt2), hypertension, cardiovascular disease, and dyslipidemia significantly increase the risk of CKD occurrence [3–5]. Chronic renal failure is an additional risk factor in the group of patients with obesity, already burdened with other metabolic diseases. It makes these patients particularly vulnerable to postoperative complications.

Obesity in a group of patients with ESRD may preclude access to kidney transplantation or at least delays it [6]. Bariatric surgery is becoming more recognized as a treatment option either to help diminish progression of CKD on early stage or to prepare for KTx if the weight loss is needed to

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qualify for transplantation. Obesity has been associated with poor graft and patient survival after kidney grafting requiring a significant increase in anti-rejection drugs [6]. A conservative treatment for obesity is doubtful. It unnecessary prolongs the moment of transplantation. The only effective solution brings bariatric surgery which can be a bridge treatment to KTx which additionally brings the resolution or at least improvement of comorbidities [6, 7].

Several studies already show the efficacy of bariatric surgery for patients with renal failure. In general, it seems that bariatric surgery is safe and feasible, complication rates might be slightly higher compared to the non-transplant population, whereas weight loss and improvement of comorbidities were comparable [8–11].

Enhanced Recovery After Bariatric Surgery (ERABS) has been implemented in many bariatric centers to optimize the patient pathway care and its safety and efficacy are well known [12–15]. The ERABS protocol is associated with improved quality of the surgical treatment. This includes a best practice of preoperative preparation and standardization of perioperative and postoperative care, which would ensure early recovery and improves the outcome [12–15]. In 2015, the ERABS protocol was implemented and also morbidly obese patients with ESRD were enrolled in it. To our knowledge, there is no study showing the benefits of ERABS for the population of patients with ESRD, especially in a population that needs an organ transplantation. The objective of this study was to evaluate the potential benefits and safety of the ERABS protocol for patients who are morbidly obese with ESRD and compare outcomes with the non-ESRD population undergoing bariatric surgery.

Materials and Methods

In our hospital, the first kidney transplantation was performed in 1980. From 2015, the surgical department started bariatric operations for morbidly obese patients with end-stage renal disease (ESRD) as a bridge to kidney transplant. So far, 21 patients were operated, and 9 of them already received a new organ. In our study we present a retrospective review of a prospectively collected database which was conducted for ESRD patients who underwent bariatric surgery according to the ERABS protocol. The fundamentals of the protocol used in our hospital were described earlier [16].

This study has been approved by the Institutional Review Board and has been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki.

Patients

All the patients were initially qualified for the bariatric treatment based on International Federation for the Surgery of Obesity (IFSO) criteria. Table 1 shows the elements of the ERABS protocol. A multidisciplinary team screened all patients preoperatively, consisting of a physician assistant, a psychologist, a nutritionist, and a surgeon. Patients were eligible for surgery if they had a BMI of 40 kg/m^2 or higher, or a BMI between 35 and 40 kg/m^2 with significant comorbidities, with serious attempts to lose weight in the past. Comorbidities were considered significant when medication had to be used, or if continuous positive airway pressure (CPAP) had to be used in case of obstructive sleep apnea (OSAS). The indication for a bariatric procedure was made in a multidisciplinary consultation, taking into account the patients' preference, age, polypharmacy, reflux complaints, body composition in relation to BMI, and bowel diseases. A nephrologist prior to surgery consulted all patients with ESRD. Due to the need of dialysis prior to surgery patients were admitted to the hospital 1 day before surgery. The anesthetics used during surgery were the same in both groups. As a standard, all of them had hemodialysis at the first postoperative day at our hospital. After the first postoperative day, they resumed with their own hemodialysis schedule.

Outcomes

Patients were followed at the bariatric outpatient clinic. To assess the safety of fast track care in bariatric surgery in ESRD patients, the primary endpoint was the length of hospital stay in days, i.e., the day the patient was admitted until discharge. Secondary endpoints were the number of re-admissions, re-operations, length of renal replacement therapy, and complications during admission and within 30 days. Included postoperative complications were bleeding, anastomotic

Table 1 Elements of ERABS protocol

Preoperative counseling
Reduce fasting times
Optimize operating scheduling times
Optimize anesthesia protocols
Multimodal analgesia
Avoidance of nasogastric tubes and intraabdominal drains
Avoidance of high intraabdominal pressure during leak tests
Early mobilization
Analgesia
Antiemetic
IPP/H2 antagonist
Early enteral feeding
Rigorous blood sugar control
Discharge planning
Follow-up telephone call the day after discharge
Postoperative appointment 2 weeks after discharge

leakage, gastrointestinal perforation, various infectious complications (e.g., abscess, pneumonia, wound infection), any major cardiovascular event, and venous thromboembolism. Additionally, all postoperative complications were categorized according to the Clavien-Dindo scale [17, 18].

Statistical Analysis

Data management and analysis were performed using SPSS version 22 for Windows (IBM Corporation, Armonk, NY, USA). Continuous variables were presented as mean ± standard deviation (SD). Complications and rate of re-admissions are presented as a percentage. Dependent on the distribution and type of variable, either Student's *t* test, Mann Whitney *U* test, chi-squared test, or Fisher's exact test was used to determine any statistical significance between the observed differences among groups.

A propensity score-matched analysis was performed to create comparable risk groups in the ESRD and non-ESRD group with respect to demographics, comorbidities, complications, and type of surgery. Standardized differences were calculated to compare before and after matching with imbalance being defined as an absolute value greater than 0.10 (small effect size). Matching was performed using the nearest neighbor algorithm with a caliper distance of 0.0001. R software was used for propensity score matching [19]. Differences were considered significant in case of a p value less than 0.05.

Results

From 2015 onward, 1199 non-ESRD patients were operated and 21 with ESRD. Propensity matching resulted in two groups of 19 patients. Overall, ERABS protocol compliance was 100% for all elements of the protocol, except preoperative counseling scored 98% for non-ESRD patients. In terms of other comorbidities, both groups presented typical components of metabolic syndrome. The gastric bypass operation was considered for patients with ESRD as being highly effective in terms of weight reduction and resolution of comorbidities. In only one case, a sleeve gastrectomy was performed. Table 2 gives an overview of the included patients' baseline and demographic data. We present the date before and after matching of the two groups. Table 3 presents after matching the complications, re-admissions, and re-operations within 30 days after discharge.

We observe in the ESRD group no smokers, while in the non-ESRD group, this amount is 30.9%.

In the ESRD group, there was one patient with a serious complication (rated as Clavien-Dindo IIIb and IVb) at the first postoperative day after OAGB. Due to the symptoms of a leak the patient underwent revisional surgery. The place of the leak at the gastrojejunal anastomosis was identified and sutured. This patient has been on peritoneal dialysis for more than 3 years. However, this was changed postoperatively to the hemodialysis. During several sessions of hemodialysis, there were multiple episodes of hypotension, which resulted in a poor tolerance of hemodialysis in this particular patient. Therefore, the patient was referred to the intensive care unit where the Continuous Renal Replacement Therapy (CRRT) was provided. In this particular case, the length of hospital stay reached 26 days. After re-operation, there were no other surgical complications. In case of ESRD patients, the hospitalization time was 3.8 ± 0.5 day (excluded one case where the LOS reached 26 days) comparing with non-ESRD patients undergoing bariatric surgery where the average hospital stay was 2.1 ± 0.5 day.

Discussion

Considering an increasing trend in the prevalence of obesity and its complications like diabetes type 2 and hypertension, obesity seems to be one of the leading causes of ESRD. The more components of metabolic syndrome are present, the higher the risk of ESRD development is observed [20].

KTx significantly improves survival rate and the comfort of life and is economically justified. Most surgical centers consider transplantation if body mass index (BMI) does not exceed 35 kg/m^2 [5, 21]. Patients with BMI > 35 kg/m^2 are at great risk of perioperative and postoperative complications and are usually disqualified. Morbidly obese patients have higher complication risk and worse long-term outcome after kidney transplantation than non-obese transplanted individuals [6]. The risk of other medical complications (pulmonary, cardiac, and gastrointestinal), the mean length of hospitalization, and risk of admission to intensive care units are increased among obese compared to non-obese renal recipients [6]. For this reason, bariatric treatment seems to be an effective solution as a bridge therapy to KTx.

As mentioned earlier, most of the surgical centers consider transplantation if BMI does not exceed 35 kg/m^2. Even moderately patients with obesity have prolonged waiting time and are sometimes bypassed if the organ is available. Obese graft recipients have an increased complication rate, worse outcome, and higher risk of graft loss [21]. Only bariatric surgery allows for effective weight loss and improvement of the patient's metabolic status. Bariatric treatment being a bridge therapy for kidney transplantation must be safe for the patient [5]. Patients with ESRD are perceived as a higher risk one and greater complexity of the preoperative period; hence, not all the

Table 2 Baseline demographic, comorbidity, and type of operation data of the included patients

	Unmatched comparisons			Matched comparison		
	ESRD	Non-ESRD	*P* value	ESRD	Non-ESRD	*P* value
N	21	1199		19	19	
Age (in years)	45 ± 11	43 ± 13	0.351	45 ± 11	42 ± 11	0.406
Male/female (%)	5 (22%)/16 (78%)	492 (41%)/707 (59%)	0.479	5 (26%)/14 (74%)	9 (47%)/10 (53%)	0.179
Length of hospital stay (days)	3.8 ± 0.5	2.1 ± 0.5	< 0.001	3.8 ± 0.6	2.0 ± 0.4	< 0.001
Body mass index (kg/m^2)	43.1 ± 7.5	42.7 ± 3.2	0.174	43.0 ± 7.4	44.2 ± 4.2	0.543
Hypertension	21 (100%)	837 (69.8%)	0.378	19 (100%)	16 (84.2%)	0.230
T2DM	16 (76.2%)	511 (42.6%)	0.064	15 (79.0%)	9 (47.4%)	0.091
Obstructive sleep apnea	5 (52.4%)	302 (25.2%)	0.773	4 (21.1%)	6 (31.6)	0.714
Current smoker	0 (0%)	370 (30.9%)	0.826	0 (0%)	5 (26.3%)	0.046
COPD	11 (52.4%)	343 (28.6%)	0.678	10 (52.6%)	4 (21.1%)	0.091
GERD	13 (61.9%)	823 (68.6%)	0.346	13 (68.4%)	13 (68.4%)	1.000
Dyslipidemia	17 (81.0%)	780 (65.1%)	0.089	15 (79.0%)	11 (57.9%)	0.295
Length of dialysis (in years)	2 ± 1.7	–	–	2 ± 1.7	–	–
RYGBP	8 (38.1%)	118 (9.8%)	0.937	6 (31.6%)	4 (21.1%)	0.714
OAGB	12 (57.1%)	411 (34.4%)	0.789	11 (58.9%)	7 (36.8%)	0.330
SG	1 (4.76%)	670 (55.9%)	0.729	1 (5.3%)	10 (52.6%)	0.003

Values are expressed as mean ± standard deviation or absolute value (%)

COPD chronic obstructive pulmonary disease, GERD gastroesophageal reflux disease, RYGBP Roux-en-Y gastric bypass, OAGB one anastomosis gastric bypass, SG sleeve gastrectomy

Table 3 Postoperative complications graded by the Clavien-Dindo scale [17, 18]

	ESRD	Non-ESRD	*P* value[a]
Number of patients	19	19	
Minor	2 (10.5%)	4 (21.1%)	0.660
Grade I	2 (10.5%)	5 (26.3%)	0.410
Grade II	1 (0%)	5 (26.3%)	0.178
Major	1 (5.2%)	4 (21.1%)	0.340
Grade IIIa	0 (0%)	1 (5.2%)	1.000
Grade IIIb	1 (0%)	0 (0%)	1.000
Grade IVa	0 (0%)	0 (0%)	–
Grade IVb	1 (5.2%)	0 (0%)	1.000
Re-admissions	1 (5.2%)	6 (31.6%)	0.088
Re-operations	1 (5.2%)	7 (36.85%)	0.042
Mortality	0 (0%)	1 (5.2%)	1.000

Grade I: any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Grade II: requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included. Grade III: requiring surgical, endoscopic, or radiological intervention. Grade III-a: intervention not under general anesthesia. Grade III-b: intervention under general anesthesia. Grade IV: life-threatening complication requiring IC/ICU management. Grade IV-a: single-organ dysfunction (including dialysis). Grade IV-b: multi-organ dysfunction. Grade V: the death of a patient

[a] Using Fisher's exact test

bariatric centers would like to provide bariatric surgery for these cases. One of the arguments is that organs from deceased donors should preferably be allocated to recipients with a lower risk profile [22].

In terms of demographics, both groups of patients in our study did not differ in terms of BMI, age, or other comorbidities typical for metabolic syndrome. Preferably, metabolic surgery in this patient population should be performed as early as possible in the course of chronic kidney disease to improve cardiovascular morbidity and achieve the best possible outcome after transplantation [23].

There were no significant differences in both presented groups in terms of early minor postoperative (up to 30 days) complication—Clavien-Dindo scale I and II. Similarly noted complications in grade III and IV (major complications) were not statistically more frequent in the group of ESRD patients in relation to non-ESRD.

One patient in the ESRD group had a serious complication needing a re-operation. This patient at the first postoperative day presented tachycardia and severe abdominal pain resistant for opioids. Due to demonstrated symptoms the patient was qualified for revisional surgery. The place of the leak at the gastrojejunal anastomosis has been identified and sutured. Due to change of dialysis (from peritoneal dialysis to hemodialysis) and hemodynamic instability during hemodialysis, eventually CRRT was provided on the ICU. In comparison

with the group of 1199 patients without ESRD, 4 patients (0.33%) required ICU admittance.

In our study, we find that the length of stay (primary endpoint) of ESRD is on average 1.8 days longer than for non-ESRD patients. The average stay is longer due to the need of postoperative dialysis. Secondary endpoints were comparable for both groups. The results of our study show that patients with ESRD despite their complexity can be safety operated using ERABS protocol. For scheduling purposes in the ward, this is an important fact. There is no need for significant change in anesthesia protocol because ERABS protocol itself brings the intravenous liquid restriction no matter the kidney function.

To maintain the safety and effectiveness of bariatric surgery in this group, ESRD patients should be operated only in experienced, high-volume surgical centers. In order to minimize the risk, it seems advisable to apply the ERABS protocol. These protocols were designed to improve safety and the quality of perioperative and postoperative care. ERABS protocol has been implemented by many bariatric centers worldwide, and its safety and efficacy are already proven [15].

Limitations

There are some limitations to the current study design. Firstly, the retrospective approach is limiting since results are dependent on the accuracy with which the medical charts were managed. Second, our fast track anesthesia protocol is center-adjusted and there might a few differences with other bariatric centers. Despite these limitations and the fact that further research is needed to substantiate the current results, fast-track care appears to be safe and efficient for ESRD patients undergoing bariatric surgery.

Conclusion

Our study confirms that the use of the ERABS protocol in these morbidly obese patients with ESRD allows maintaining the quality as well as the efficiency of surgery while ensuring the highest safety standards.

Authors' Contributions *Initial idea and design of the study:* MP, PS.
Drafting and finalizing manuscript: MP, PS, SP, LK.
Final approval: MP, PS, SP, LK.

Compliance with Ethical Standards

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

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