Original Article

Effects of the Roux-en-Y gastric bypass on DM and renal function in obese patients

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ABSTRACT

Obesity is one of the major issues in the health of the population worldwide. Roux-en-Y gastric bypass (RYGB) is considered a safe and effective treatment in obese patients. In addition RYGB has shown therapeutic potential in type 2 diabetic patients. This study represents a 6 months follow-up on 63 obese patients with BMI≥40 Kg/m^3, suffering from both DM2 and CKD, who underwent LRYGB. From 900 obese patients referred to Imam Reza, Sina, and Bentolhoda Hospitals of Mashhad University of Medical Sciences in 2019, 63 were selected for LRYGB. The patient's diabetic status evaluation 180 days post-surgery revealed that, from 30 patients who used insulin injection before RYGB, 20 (66.6%) achieved full remission, 9 (30%) showed improvement and 1 (3.3%) showed no change in their diabetic state. From 22 patients who received concomitant oral and insulin therapeutic regimens, 11 (50%) achieved full remission, while 9 (40.9%) showed improvement and 2 (9.1%) showed no change in their status. All the patients who received oral medications for DM treatment achieved full remission post-surgery. Duration of obesity was not correlated with either ΔHbA_{1c} or ΔGFR, however, duration of T2DM showed a significant correlation with ΔHbA_{1c} (*P*-value≤0.05). No correlation between T2DM duration and ΔGFR was observed. In conclusion, RYGB is considered a promising approach for T2DM treatment and CKD in obese patients with BMI≥40 Kg/m^3, and its therapeutic effects are due to metabolic alterations rather than weight reduction alone. However, technical considerations in AL and BL lengths for achieving optimal results are under debate.

Keywords: Bariatric surgery, Diabetes mellitus, Morbid obesity, Roux-en-Y gastric bypass

Introduction

Obesity is one of the major issues in the health of the population worldwide [1, 2]. Previous studies have shown that the prevalence of obesity/overweight has raised dramatically in the recent years [3, 4], resulting in approximately 3.4 million death, 3.9% life lost years, and 3.8% of DALYs globally [5]. It is believed that obesity predisposes individuals to serious diseases and comorbidities including hypertension (HTN), diabetes mellitus (DM), cancers, coronary artery disease, hyperlipidemia and it is a major risk factor for chronic kidney disease (CKD) as well [5-8]. Excess body weight is described by body mass index (kg/m^2), and BMI ≥ 25 kg/m^2 is considered overweight, and BMI ≥ 30 kg/m^2 as obese [9]. Although lifestyle modification and training are the primitive and obligatory steps in reducing weight, failure in sufficient weight loss or glycemic control, propose alternative methods and bariatric surgery provides a powerful approach [10]. Amid patients with BMI ≥ 35 kg/m^2, bariatric surgery can substantially reduce weight and improve obesity-related comorbidities such as DM2 and hypertension [11, 12]. There is an increasing proof that obesity can independently cause structural and functional glomerular kidney injury despite other obesity-related comorbidities such as HTN and DM2 [13]. Although the relationship between obesity and renal dysfunction is not clear yet, obesity can lead to glomerular hyperfiltration and elevation of albuminuria (a marker of glomerular dysfunction), these two factors are associated with renal failure progression [14]. The Roux-en-Y gastric bypass (RYGB) demonstrates a

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notable improvement in T2DM and CKD. In some meta-analysis studies, it has been shown that significant weight loss which is achieved in patients undergoing RYGB can cause complete remission or enhancement in diabetes, hyperlipidemia, HTN, and CKD [15]. There are several other benefits for diabetic patients after RYGB including decreased diabetes medication usage, increased insulin secretion, elevated insulin sensitivity, and significant reduction in diabetes-related comorbidities [16]. In some studies, obese individuals who undergo bariatric surgery are associated with improvement of glomerular filtration rate (GFR) and renal function, exclusively in patients with underlying kidney diseases regardless of weight loss alone [7, 17]. Amid highly obese individuals, bariatric surgery can result in a significant (92%) reduction in total morbidity and diabetes-related mortality [18, 19]. However, according to NIH, not every obese patient can go through this surgical method and there are some criteria for assessment of the risk-benefit ratio of this procedure [20]. In laparoscopic RYGB (LRYGB) the lengths of alimentary and biliopancreatic jejunal limbs can play a remarkable role in weight loss improvement and its comorbidities [21].

This study represents a 6 months follow-up on 63 obese patients with BMI≥40 Kg/m2, suffering from both DM2 and CKD, who underwent LRYGB.

Materials and Methods

Patient selection

From 900 obese patients referred to imam Reza, Sina, and Bentolhoda Hospitals of Mashhad University of Medical Sciences in 2019, 63 were selected for LRYGB. All initial patients had nutrition consultation primarily, regardless of which, weight loss through lifestyle modification including nutrient regimens and exercise was not achieved. Of these 900 patients, 63 were chosen based on our inclusion criteria, which include BMI≥40 Kg/m^2, CKD, and DM2. Patients with DM1, DM2, or CKD alone, malignancy, pancreatitis, and alcohol or drug addiction were excluded from this study.

DM2 was defined as FBS≥126 mg/dL or diabetic symptoms accompanied by random glucose test≥200 mg/dL or glucose level ≥200 mg/dL, 2-hour following 75 g oral glucose intake [22]. GFR in CKD patients was calculated according to the CKD-EPI formula [23, 24].

Preoperative evaluation

LRYGB procedure along with its advantages and disadvantages, early and late post-operation complications, and alternatives were described for each patient, and all patients were provided a consent form. Nutrition consultation was provided for the post-operative state of each patient. Preoperative evaluation of each patient includes electrocardiogram and abdominal sonography (for the presence of gallstones), blood samples evaluation (CBC, lipid profile, FBS, HbA_{1c}, Bun, Cr, Fe), and GFR calculation. This study was conducted under the supervision of the Ethics Committee of Mashhad University of Medical Sciences.

Surgical technique

We used the standard laparoscopic technique with performing an antecolic antegastric RYGB and the effect of different long alimentary limb (AL) and biliopancreatic limb (BL) on the improvement of DM and GFR comorbidities were evaluated. We performed a stapled jejunojejunostomy 150/100/80 cm distal to gastrojejunostomy on the Roux limb, and the biliopancreatic limb is 100/80/50 cm from the ligament of Treitz to the jejunojejunostomy anastomosis. The standard gastric pouch was created by placing the first purple 45 mm linear stapler at 5 cm below the angle of his at the right angle to the minor curvature of the stomach. Finishing the gastric pouch was performed via placing two 60 mm staplers alongside a 36 French stomach tube. Gastrojejunostomy and jejunojejunostomy were performed using a linear stapler 30 mm and 45 mm, respectively, and completed anteriorly using proline suture 2-0. The staple line was evaluated for air leak, using methylene blue during the operation and mesenteric defects were sealed.

Post-operative management

Our team followed up patients 180 days post-operatively and weight measurement was performed and blood samples were taken. On each follow-up, visiting the pre-operatively advised nutrition regiment and supplementation was prescribed for each patient. None of the patients were lost during our post-operation follow-up.

Post-operative diabetic state classification

The patient's diabetic state was determined as follows; remission (cessation of oral medication or insulin injection with HbA_{1c}≤6.5%), improvement (change of insulin injection to oral medication or requiring lower doses of oral medication from baseline with HbA_{1c}≤ 7%), and no change.

Assessment of postoperative renal function

Serum creatinine is the main parameter used for indicating GFR and kidney function. The patient's renal function improvement was assessed using modification of diet in renal disease (MDRD) equation [25]. The patient's serum creatinine was assessed pre- and post-operatively.

Results and Discussion

Figure 1 represents the assessment of the patient's blood tests before surgery and 180 days post-surgery. Based on obtained results, pre-and post-surgical Hb, MCV, and serum iron levels did not show any significant changes. The patient's lipid profile shows a significant reduction in cholesterol, LDL, and TG levels, 6 months after surgery (P value<0.001). Mean HbA_{1c} reduced dramatically for all patients over the first 6 months following the

surgery, from 7.52 to 5.66%. Patient's mean FBS levels also decreased substantially from 148.24 to 95.86 mg/dL (*P* value<0.001). Renal function markers including blood urea nitrogen (BUN), Creatinine (Cr) and GFR have also improved significantly over 6 months from 17.9 to 12.54 mg/dL, 1.03 to 0.9 mg/dL and 73.09 to 84.54 ml/min, respectively (*P* value<0.001).

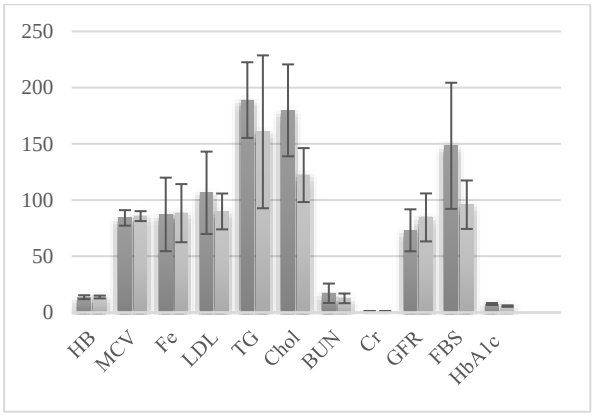

Figure 1. Patient's blood tests before surgery and 180 days post-surgery

In addition, we assessed the correlation of total weight loss (TWL) with ΔHbA_{1c} and ΔGFR. Our results showed a non-significant correlation between HbA_{1c} and GFR variations with TWL. As mentioned in the "surgical technique" section, different AL and BL lengths were used in patients during RYGB surgery. We studied the possible correlation between AL and BL lengths with ΔHbA_{1c} and ΔGFR in 180 days following surgery and found no significant correlation between them **(Table 1)**.

Table 1. correlation between TWL, AL, and BL length, duration of DM, and obesity with HbA1c and GFR variations following RYGB.

	Dependent (ΔHbA_{1c})		Dependent (ΔGFR)	
	Regression Coefficients	Sig	Regression Coefficients	Sig
TWL.10*	-0.019	0.35	-0.06	0.908
TWL.30**	-0.008	0.427	0.102	0.687
TWL.180***	0.001	0.8	0.025	0.554
AL length	0.007	0.296	0.186	0.348
BL length	0.012	0.135	0.277	0.185
Duration of obesity (year)	-0.005	0.78	-0.247	0.294
Duration of DM (year)	0.017	0.05	0.337	0.465

Duration of obesity was not correlated with either ΔHbA_{1c} or ΔGFR, however, duration of T2DM showed a significant correlation with ΔHbA_{1c} (*P*-value≤0.05). On the other hand, no correlation between the duration of T2DM and ΔGFR was observed **(Table 1)**.

Table 2. The relation of patient's gender with variations of HbA_{1c} and GFR

	Male	Female	*P* value
	Mean ± SD	Mean ± SD	
ΔHbA_{1c}	1.75 ± 1.01	1.91 ± 0.62	0.461
ΔGFR	-10.50 ± 22.04	-11.90 ± 18.30	0.792

According to our results, the patient's sex was not a determining factor in HbA_{1c} and GFR variations following RYGB surgery **(Table 2)**.

The patient's diabetic status evaluation 180 days post-surgery revealed that, from 30 patients who used insulin injection before RYGB, 20 (66.6%) achieved full remission, 9 (30%) showed improvement and 1 (3.3%) showed no change in their diabetic state. From 22 patients who received concomitant oral and insulin therapeutic regimens, 11 (50%) achieved full remission, while 9 (40.9%) showed improvement and 2 (9.1%) showed no change in their status. All the patients who received oral medications for DM treatment achieved full remission following the surgery **(Table 3)**.

Table 3. Patient's diabetic state and medication usage 180 days post-surgery; full remission state (discontinuation of medications with HbA_{1c}≤6.5%), improvement (decreased oral dose intake or changing from insulin injection to oral medication with HbA_{1c}≤7%), and no change in the diabetic state.

	Full remission	Improvement	No change	Total
Insulin Injection	20	9	1	30
Oral medication	9	0	0	9
Insulin injection + Oral medication	11	9	2	22
Total	40 (65.5%)	18 (29.5%)	3 (4.1%)	61 (100%)

Obesity is considered an important risk factor in the incidence of DM and CKD. However, CKD can be a morbidity of DM or a consequence of obesity alone. The RYGB surgery is an efficient therapeutic method for obese individuals who could not achieve substantial weight loss by lifestyle modifications and pharmaceutical therapies. In the present study, we aimed to determine the effect of weight reduction following RYGB surgery on the improvement of GFR and DM status in obese (BMI>40 Kg/m^3) and T2DM patients who had renal dysfunction.

Our evaluation revealed a significant decrease in serum HDL, TG, and Cholesterol levels, 6 months following RYGB surgery. This finding is following previous reports [26, 27]. Metabolic surgeries, including RYGB, are considered an effective therapeutic approach for the treatment of hypercholesterolemia [28]. Positive alterations in all markers of lipid profile were observed in our study, however, cholesterol showed the most significant improvement.

In addition to hypercholesterolemia, RYGB is also considered an effective therapeutic approach for the treatment of T2DM in obese patients [10]. Besides weight reduction, the therapeutic effects of RYGB surgery are also related to alterations in metabolic and hormonal mechanisms [29-31]. HbA_{1c} and FBS are common markers of DM status in diabetic patients. The comparison between pre-and post-operative values of FBS and HbA_{1c} indicates DM amelioration in 6 months.

To further determine diabetes status during the follow-up program, we have divided patients into three groups based on individualized metabolic surgery (IMS) score [26] including A)

patients with complete remission defined as HbA_{1c}≤6.5% and discontinuation of oral medication therapy or insulin injection, B) improvement in diabetic status without remission, defined as HbA_{1c}≤7% with decreased oral dose intake of diabetes medications or changing from insulin injection to oral medication and C) patients with no change in their diabetic state. Group c patients who showed no change in their status are those who had HbA_{1c}≥8%, diabetes for more than 10 years, or used multiple anti-diabetic drugs. Our 6 month evaluation showed full remission in the majority of patients (65.5%) and improvement in 29.5% of cases while only 4.1% showed no change. The diabetes duration of the majority of patients who responded well to this method of treatment was <10 years and they did not use multiple anti-diabetic medications.

Of our total 61 patients, 9 had mild diabetes and used oral anti-diabetic medications alone, 30 used insulin injection alone and 22 used a combination of oral medication and insulin injection. During 6 months follow-up, all of the mild diabetic patients achieved full remission. Among the patients who used insulin injection alone, 66.6% achieved full remission, 33.3% achieved improvement and 3.3% showed no change in their status. In patients who received oral agents and insulin concomitantly (which are defined as multi-drug users), 50% showed full remission, 40.9% achieved improvement and 9.1% had no change. Patients who demonstrated no change in their diabetic status are those who received multi-drug regiments before surgery and/or had DM for more than 10 years. According to literature, insulin injection and duration of diabetes are two strong determining predictors for remaining diabetes untreated after RYGB surgery [32, 33].

Based on our results, we did not find any correlation between weight loss and duration of obesity with HbA_{1c} variations during 6 months following RYGB surgery, which indicates that RYGB-induced diabetes improvement is due to mechanisms other than weight reduction [29, 31]. Although no correlation has been observed between variable AL and BL lengths and HbA_{1c} in 6 months following RYGB, some previous researches have shown that longer BL lengths were associated with DM improvement following RYGB surgery in short term (<5 years) [34-36]. It is necessary to further investigate the implication of different AL and BL lengths on diabetes remission in obese patients undergoing RYGB surgery in longer follow-up periods.

Since our group of patients included diabetic obese patients with chronic kidney disease, BUN, Cr, and GFR were studied as markers of renal function. Lower BUN, Cr as well as improved GFR indicate therapeutic effects of RYGB on ameliorating CKD. Based on our obtained results, these beneficial effects are independent of TWL, duration of obesity and diabetes as well as AL and BL lengths, and may be related to improvement in diabetic status and alterations in its metabolic pathways following RYGB.

We also investigated whether a patient's gender plays a role in GFR and HbA_{1c} variations and found that improvement in kidney function and DM status is not dependent on the patient's sex.

There were no mortality, malnutrition, and excessive weight loss following RYGB surgery, which proves the safety of this surgical method for treatment of obese patients. Weight reduction and its consequent DM and dyslipidemia remission as well as hypertension reduction can prevent further chronic heart diseases and stroke events in these groups of patients.

Conclusion

The Roux-en-Y gastric bypass (RYGB) is considered a promising approach for treatment of DM and CKD in obese patients with BMI≥40 Kg/m^3, and its therapeutic effects are the consequence of metabolic alterations rather than weight reduction alone. However, technical considerations in AL and BL lengths for achieving optimal results are under debate.

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