Evaluation of the Effects of Bariatric Surgery in Terms of Weight Loss and Diabetes Remission in the Indian Population

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Keywords
Excess weight loss · Laparoscopic sleeve gastrectomy · Mini-gastric bypass · Roux-en-Y gastric bypass · Type 2 diabetes mellitus

Abstract
Objectives: The growing prevalence of obesity rates worldwide is associated with an upsurge in its comorbidities, particularly type 2 diabetes mellitus (T2DM). Bariatric surgery is a proven treatment modality for producing sustained weight loss and resolution of associated T2DM providing marked improvement in quality of life with rapid recovery. This study aims to investigate the effects of laparoscopic sleeve gastrectomy (LSG), Roux-en-Y gastric bypass (RYGB), and mini-gastric bypass (MGB) on obese patients suffering from T2DM in the Indian population and their long-term association with regard to diabetes remission, resolution of comorbidities, and percentage EWL. Methods: Retrospective data of obese patients with T2DM (preoperative BMI 45.37 ± 8.1) who underwent bariatric surgery (RYGB, LSG, and MGB) were analyzed in this study over a period of 9 years. The mean follow-up period was 2.2 years. Following surgery, the clinical outcome on BMI, resolution of percentage weight loss, and T2DM were studied. The predictive factors of diabetic remission after surgery were determined. Student's t test and ANOVA and McNemar's test were applied. Results: Out of a total of 274 patients, complete remission of T2DM was achieved in 52.9% (n = 145) with mean fasting blood glucose and glycated hemoglobin values being 6.1 ± 0.769 (p = 0.00) at 1 year after surgery. The independent predictive factors of remission were age, gender, BMI, preoperative comorbidities, and % EWL. Gender had no correlation with the chance of achieving disease remission. Conclusion: Based on our results, bariatric surgery proves to be a successful treatment option resulting in sustained weight loss in obese patients suffering from T2DM. It is found to be beneficial for the long-term resolution of T2DM and improving comorbidities such as hypertension and dyslipidemia. The outcome of the different surgical methods is found to be similar for all patients irrespective of the independent predictors of complete remission. © 2021 The Author(s).

Introduction
The upsurge in the prevalence of obesity is a reason behind the development or worsening of several complications. Type 2 diabetes mellitus (T2DM) is one of the major conditions affected by obesity [1, 2]. It is affecting >171 million people globally while yearly around 3 mil-
lion patients are succumbing to it. Currently, one-fifth of the world’s population is overweight [1]. Bariatric surgery has demonstrated to be a viable therapeutic option in patients suffering from severe obesity. It is advocated in patients with BMI >40 kg/m² or 35 kg/m² or above accompanied with at least 2 comorbidities including T2DM and different components of metabolic syndrome [3]. Weight loss induced via bariatric surgery is associated with reducing cardiovascular risk factors significantly [4].

There is mounting evidence that established the superiority of bariatric surgery over conventional medical treatment for improving outcomes related to T2DM [5]. Data from observational studies suggest that bariatric surgery has caused around 45–95% rate of diabetes remission. The rate of diabetes remission depends upon the procedure used in bariatric surgery [6]. A meta-analysis comprising 3,188 patients with T2DM who had undergone bariatric surgery demonstrated that 78% of patients reported resolution in T2DM while 87% of patients showed resolution or improvement [7]. An improvement or remission of diabetes is evident after bariatric surgery in obese patients with type 2 diabetes, and also there is a significant reduction in the mortality associated with diabetes [8]. Diabetes improvement was seen due to weight loss associated with bariatric surgery [9]. On the contrary, few studies reported the resolution of diabetes before achieving significant weight loss [10].

Several restrictive, malabsorptive, or combined bariatric procedures are currently available as a promising treatment for T2DM [11]. The Roux-en-Y gastric bypass (RYGB) reported a significant improvement or total resolution in patients with T2DM. The RYGB was able to attain better outcomes in terms of weight loss and T2DM resolution and long-term maintenance of these results than other restrictive procedures [12]. The RYGB is superior owing to potential mechanisms which alter gut hormones, ghrelin, and GLP-1 [13]. On the contrary, recent evidence recommends laparoscopic sleeve gastrectomy (LSG) as an absolute treatment for morbid obesity; the excess weight loss (EWL) was in the range of 50–83.3% [14]. However, the contention is to demonstrate the long-term efficacy of different bariatric surgical procedures in a cohort of Indian patients at both 1 year and over a mean last follow-up of 2.2 years. The objective of this study was to retrospectively evaluate the effects of LSG, mini-gastric bypass (MGB), and RYGB on obese patients with T2DM and their long-term association with regard to diabetes remission, resolution of comorbidities, and percentage EWL.

### Materials and Methods

#### Study Design and Participants

This is a retrospective observational study carried out with the objective of assessing the effect of bariatric surgery in terms of weight loss and on the evolution of metabolic parameters (T2DM, dyslipidemia, hypertension, and others). The study group included 274 obese patients who underwent RYGB, MGB, or LSG – between 2010 and 2018 in our center. The decision of which procedure to pursue was made between the surgeon and the patient based on needs and expectations. Data were collected from preoperative visits as well as postoperative visits each year during the 9-year period.

#### Clinical Parameters Evaluated

Preoperatively, all patients were evaluated for medical history, and patient demographics were recorded. A clinical examination was carried out, and information on associated risk factors and comorbidities such as arterial hypertension, dyslipidemia, and others was collected. The serum levels of glycosylated hemoglobin were measured. Afterward, surgical procedures such as LSG, MGB, and RYGB were used. After surgery, patients were evaluated in terms of postoperative clinical outcomes, including percent EWL (% EWL), complications, and improvement or resolution of preoperative comorbidities (T2DM, hypertension, obstructive sleep apnea, and hyperlipidemia) over a mean period of 2.2 years. A patient is regarded to be in diabetes remission if they meet no criteria of ADA guidelines 2019, that is, HbA1c ≥6.5% and under the absence of antidiabetic medication and treatment during the defined observation period.

#### Statistical Analysis

The qualitative data were presented as number and percentages, while quantitative data were presented as mean ± standard deviation and ranges. Continuous variables were evaluated for normality using the Shapiro-Wilk test. The comparison of normally distributed variables was assessed by paired t-test and ANOVA. McNemar’s test was carried out to find out the differences in a dichotomous dependent variable between 2 related groups. Multivariate logistic regression analyses were conducted to evaluate the related risk factors like age, gender, BMI, preoperative comorbidities, surgical methods, and % EWL. All the “p” values <0.05 were deliberated as statistically significant. IBM SPSS statistics software version 20 was used for performing statistical analyses.

### Results

#### Participant Characteristics

In all, 274 obese patients with T2DM underwent bariatric surgery between 2010 and 2018. Among the patients included in the study, 16.1% submitted to LSG, 3.6% to MGB, and 80.3% to RYGB. There were 168 females (61.3%) and 106 males (38.7%) with a mean ± SD age of 44.75 (± 11.8) (range 20–75) years. The mean ± SD weight of patients was 118.93 ± 24.7 with a range of 68–250 kg. For height, it was 161.98 ± 9.9 with a range of 120–250 cm.
136–189 cm. All patients had the mean initial BMI of 45.37 ± 8.1 with a range (29.4–87.5 kg/m²). The mean ± SD HbA1c before operation was 8.2 ± 1.5 with a range of 6–13%. With regard to preoperative comorbidities, 49.6% of the patients had hypertension, 19.7% had dyslipidemia, 5.1% had obstructive sleep apnea, and 21.9% had other comorbidities (Table 1). The mean period of follow-up was 2.2 ± 1.4 (range 1–6.8) years, and the median length of follow-up was 1.7 years (IQR 1.1–2.6 years).

Postoperative Results
The changes in body weight, resolution of comorbidities, and HbA1c values following LSG, MGB, and RYGB are reported in Table 2. One year after the surgery, patients achieved a mean weight of 83.5 ± 22.6 kg from 118.93 ± 24.7 kg of initial weight reported at baseline. A significant change in the patient’s weight was obtained at the last follow-up, reaching 80.8 ± 21 kg. The mean ± SD weight loss was found to be 64.4 ± 46.4 and 73.4 ± 42.6 after 1 year and at last follow-up, respectively. The long-term follow-up made us understand the durability of the improvement or resolution of obesity-associated comorbidities. The improvement in all comorbidities was striking, that is, 61% of patients had remission of hypertension, 31.5% had remission of dyslipidemia, and 66.7% had remission of other comorbidities at the end of 1 year. A remarkable improvement has been found at the end of the last follow-up where hypertension was resolved in 97.1% of patients, dyslipidemia in 79.6%, and other comorbidities in 18.3% of patients. For all the patients with obesity suffering from diabetes, the serum HbA1c level was reduced significantly from 8.2 ± 1.5 to 6.1 ± 0.769 1 year following surgery. However, different surgical procedures did not differ significantly in terms of decrease in HbA1c levels (p = 0.792).

The diabetes improvement was significant (p = 0.00) after bariatric surgery irrespective of the overall surgical approach. In total, 145 (52.9%) patients achieved diabetes remission at 1 year postoperatively (p = 0.00). Thirty-four patients were lost to follow-up, and 145 patients (60.4%) out of 240 achieved remission at the end of the last follow-up. However, it is intriguing to see that 13 patients (9%) had diabetes recurrence after initial diabetes remission (Table 3).

Multivariable Analysis
Logistic regression was carried out to establish the effects of age, gender, BMI, preoperative comorbidities, surgical methods, and % EWL on remission of diabetes

| Descriptive statistics                  | Sample | Mean ± SD or n (%) | Range   |
|-----------------------------------------|--------|--------------------|---------|
| Age, years                              | 274    | 44.75±11.8         | 20–75   |
| Gender, n (%)                           | 274    | -                  |         |
| Male                                    | 106 (38.7) |                |         |
| Female                                  | 168 (61.3) |                |         |
| Preop weight, kg                        | 274    | 118.93±24.7        | 68–250  |
| Height, cm                              | 274    | 161.98±9.9         | 136–189 |
| BMI, kg/m²                              | 274    | 45.37±8.1          | 29.4–87.5 |
| Preop HbA1c                             | 274    | 8.2±1.5            | 6–13    |
| Time of last follow-up, years           | 274    | 2.2±1.4            | 1–6.8   |
| Median time of follow-up, years         | 274    | 1.7                | 1.1–2.6** |
| Preoperative comorbidity, n (%)         | 274    |                    |         |
| Hypertension                            | 136 (49.6) |                |         |
| Dyslipidemia                            | 54 (19.7) |                |         |
| OSA                                     | 14 (5.1) |                |         |
| Others#                                 | 60 (21.9) |                |         |
| Surgical method, n (%)                  | 274    |                    |         |
| LSG                                     | 44 (16.1) |                |         |
| MGB                                     | 10 (3.6)  |                |         |
| RYGB                                    | 220 (80.3) |               |         |

OSA, obstructive sleep apnea; LSG, laparoscopic sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass; MGB, mini-gastric bypass; IQR, interquartile range. ** IQR (1st quartile–3rd quartile). # Others include epilepsy, GERD, kidney/liver diseases, psychiatric, thyroid issues, and pains.

Table 1. Patients’ baseline characteristics at the time of surgery
after bariatric surgery. The model explained 23.8% (Nagelkerke $R^2$) of the variance in the remission and correctly classified 91.0% of cases. Patients with age ≥50 years are 16% less likely to reach complete remission of T2DM compared with patients with age <50 years (OR $= 0.84$, 95% CI: 0.5–1.42, $p = 0.51$). Patients with no preoperative dyslipidemia were 57% (OR $= 0.43$, 95% CI: 0.22–0.84) less likely to exhibit diabetes remission as compared to those who had preoperative dyslipidemia ($p = 0.01$). Increasing % EWL was positively associated with diabetes remission. Of the selected preoperative factors, irrespective of gender, BMI, preoperative hypertension, and other comorbidities, surgical methods did not remain statistically significant with diabetes remission in the multivariable analyses (Table 4).

Discussion/Conclusion

Bariatric surgery is able to reduce weight, decrease morbidity and mortality, and improve quality of life. The outcome measures of bariatric surgery have been well documented in the literature [15–18]. This study reinforces the observation that bariatric surgery (LSG, MGB, and RYGB) is an effective procedure causing a substantial weight loss during the first year after surgery and favorable effect on diabetes remission. In our study, weight was reduced by $35.43 ± 2.1$ and $38.13 ± 3.7$ kg in patients at 1 year and at last follow-up, respectively. With regard to the resolution of T2DM, 52.9% of diabetes remission occurred at 1-year follow-up. This is in line with previous findings where 1-year remission rates varied between 50% and 80% [19–23].

| Table 2. Excess weight loss, resolution of comorbidities, and HbA1c status from baseline |
|--------------------------------------|------------------|------------------|
| **Descriptive statistics** | **Mean ± SD or n (%)** | **Remission from baseline** |
| HbA1c at 1 year* ($n = 274$) | 6.1±0.769 | 4.9–8.5% |
| **LSG** | 6.1±0.742 | **MGB** | 6.2±0.772 |
| **RYGB** | 6.1±0.769 | |
| Comorbidity status at 1 year, n (%) | | |
| Hypertension | 53 (19.3) | 66.7 |
| Dyslipidemia | 37 (13.5) | 31.5 |
| Others | 20 (7.2) | 66.7 |
| Comorbidity status at the last follow-up, n (%) | | |
| Hypertension | 4 (1.5) | 79.6 |
| Dyslipidemia | 11 (4) | 79.6 |
| Others | 49 (17.8) | 18.3 |
| Weight, kg | | |
| At 1 year | 83.5±22.6 | 49–185 |
| At last follow-up | 80.8±21 | 42–186 |
| % excess weight loss at BMI = 25 | | |
| At 1 year | 64.4±46.4 | −213.9 to 161% |
| At last follow-up | 73.4±42.6 | −214 to 290% |

LSG, laparoscopic sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass; MGB, mini-gastric bypass. * Used paired $t$ test to compare from baseline; significant decrease with $p$ value <0.001. # Range. ** $p$ value from the ANOVA test.

| Table 3. Status of remission of diabetes mellitus |
|-----------------------------------------------|------------------|------------------|
| **Time** | **Diabetic** | **Remission, %** | **Recurrence, %** | **p value*** |
| Preoperative (A), $N = 274$ | | | | |
| Postoperative 1 year (B), n (%) | 129 (47.1) | 145 (52.9) | 0.00 (B vs. A) |
| Last follow-up (C)*, n (%) | 95 (36.9) | 145 (60.4) | 13 (9) | 0.00 (C vs. A) |

* McNemar’s test, significant if $p$ value <0.05; otherwise not significant. # Thirty-four lost to follow-up.
A meta-analysis including 15 studies (n = 1,753) reported the predictive factors older age, long duration of diabetes, current insulin use, and poor glycemic control for poor diabetes remission after bariatric surgery [24]. The predictive factors we found in our analysis are consistent with other studies which include age, gender, BMI, EWL, preoperative comorbidity, and different surgical methods used [25–29].

Age was negatively correlated with the possibility of diabetes remission [30]. In our study, we found that patients >50 years of age are 16% less prone to reach remission of T2DM compared with patients <50 years old. It has been reported that aging is associated with increased fat mass, and younger patients are inclined to lose excess BMI compared to patients >45 years of age. As a result, the metabolic capacity was hampered in older patients and an elongated duration of comorbidities, a factor which could have guided the reduced chance of achieving complete remission [31, 32].

Furthermore, female T2DM patients showed a better remission rate at 1 year (p = 0.86) and at the last follow-up (p = 0.49) and correlated well compared to the male patients. According to a recent study [33], a decrease in % EWL was found more predominant in women than in men during the initial 3 years or perhaps due to the fact that the female sample size in our study was greater than the male one, which may have influenced the results.

Markers of preoperative comorbidities in our study cohort exhibited a negative effect on diabetes remission. Our findings suggest that patients with no preoperative dyslipidemia were 57% less likely to exhibit diabetes remission as compared to those who had preoperative dyslipidemia (p = 0.01) at 1 year.

In this study, a positive association between increasing % EWL and the chance of diabetes remission after bariatric surgery was seen. EWL was in direct association with diabetes remission (p = 0.59) at 1 year. The association between increasing percentage weight loss and improved
remission rates was reported by several randomized controlled trials and cohort studies which collectively supported the perception that greater weight loss brings higher possibilities of T2DM remission [34–36].

Several studies comparing RYGB and LSG have shown that RYGB improves diabetes remission rate compared with LSG [37–39]. On the contrary, some studies indicated similar results between both techniques [40]. In our study, irrespective of gender, BMI, and preoperative comorbidities, no statistically significant differences were found between different surgical methods with regard to diabetes remission.

However, this study had some limitations. First, it was a single-center retrospective study. Second, there is an inequality of the 3 groups – RYGB, MGB, and LSG, that is, the number of patients who had undergone RYGB is higher compared to the patients who had undergone MGB. Also, there was no mention of antidiabetic medications before and after surgery.

The important asset of this study is that patients were successively selected at 1 center and had undergone 3 different surgical techniques, that is, LSG, RYGB, and MGB. Furthermore, to our knowledge, our study had a relatively larger sample size compared with other series available in the Indian population which can balance the other mentioned limitations.

To conclude, bariatric surgery is an evidence-based approach supporting significant and sustainable weight loss in obese people. The presence of strong evidence suggests that T2DM is either improved or resolved after bariatric surgery that was durable in the long term. Our study provides further evidence that diabetes remission occurred in 68.1% of patients by 1 year after bariatric surgery indicating that bariatric surgery is a safe, efficient procedure to improve type 2 diabetes and associated comorbidities.

Statement of Ethics

The study was approved by the Institutional Ethics Committee of KD Hospital (Ref No. 01/kd/IEC/2020; Dated 06 August 2020) and conducted in accordance with the ethical standards of the ICH-GCP and Declaration of Helsinki guidelines. Written consent was obtained from the study participants after explaining the details of the surgery, its pros and cons, and all intraoperative, early, and late postoperative complications that could occur. Furthermore, all participants were informed of the research and that the data would be used for research purposes, giving patients the right to decline participation.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

All authors named in this manuscript contributed to the conception, conduct, and data analysis of the study and were involved in drafting, further development, and revision of the manuscript and approval of its final version.

Data Availability Statement

The data that support the findings of this study are not publicly available due to the confidentiality of the participants, for example, they contain information that could compromise the privacy of research participants, but are available from the corresponding author on reasonable request.

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