Annals of Medicine and Surgery 79 (2022) 104102

Contents lists available at ScienceDirect

Annals of Medicine and Surgery

journal homepage: www.elsevier.com/locate/amsu

Cohort Study

One anastomosis gastric bypass surgery in Type2 diabetes patients with body mass index < 35 kg/m^2: A multi-center retrospective cohort study

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ARTICLE INFO

Keywords:
One anastomosis gastric bypass surgery
Obesity
Diabetes
Glycemic control

ABSTRACT

Introduction: Bariatric surgeries have shown efficacy in weight reduction, glycemic control and improvement of type-2 diabetes (T2DM) in patients with obesity. We aimed to assess the efficacy of one anastomosis gastric bypass surgery (OAGB) in T2DM patients with body mass index (BMI) < 35 kg/m^2 within a year after surgery.
Methods: In this multicenter retrospective cohort study, 14 T2DM patients with BMI <35 kg/m^2 (females, %: 71.4% (10 of 14), and age, mean (standard deviation): 51.2 (12.3) years) who had underwent OAGB surgery by the same surgeon, were followed at intervals of one, three, six, and 12 months after surgery. The remission rates of T2DM were calculated and the metabolic indices were compared using paired *t*-test and Wilcoxon rank test.
Results: No adverse outcomes were detected 12 months after surgery. Within six months, seven (50%) patients underwent remission (one (7.1%) within one, three (21.4%) within three, and three (21.4%) within six months). Post-operative weight ($p < 0.001$) and fasting blood glucose ($p < 0.01$) in all time periods were significantly lower compared to pre-operative values. Hemoglobin A1C (HbA1C) was significantly lower at three- and six-month intervals ($p < 0.05$) but not at twelve months ($p = 0.2$). Thyroid-stimulating hormone and triglyceride levels were lower at six months compared to pre-surgical levels ($p < 0.05$) but cholesterol levels were not different in any of time points ($p > 0.05$).
Conclusion: OAGB surgery is associated with weight reduction, glycemic control and a 50% remission rate within six months in patients with diabetes and BMI <35 kg/m^2.

1. Introduction

Type 2 Diabetes Mellitus (T2DM) is one of the most common chronic metabolic diseases characterized by high blood sugar and insulin resistance, which leads to short-term and long-term complications and an increasing burden on global health including over 1 million attributable deaths per year globally [1]. This increasingly large prevalence of T2DM is attributable to the unhealthy diet, sedentary life-style, and the resultant increased Body Mass Index (BMI) and high blood sugar, along with aging of the population. According to the report by World Health Organization (WHO), among the multiple risk factors for T2DM, obesity, which is defined as a BMI greater than or equal to 30 kg/m^2, is the most important one [2–4]. In addition to the increased risk for T2DM, obesity confers an increased risk for conditions such as hypertension, hypercholesterolemia, and cardiovascular diseases resulting in a large burden [5,6]. Therefore, several measures including calorie restriction, physical exercise, pharmacotherapy, and bariatric surgery methods are extensively used for treatment of obesity [4,7]. Due to the low efficacy of non-surgical methods for weight loss, especially in the long run, bariatric surgery is known as the most effective way to achieve weight loss in patients with severe obesity [7,8]. Significant and lasting weight loss, treatment of some underlying diseases such as diabetes, improvement of

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https://doi.org/10.1016/j.amsu.2022.104102
Received 29 April 2022; Received in revised form 25 June 2022; Accepted 25 June 2022
Available online 27 June 2022

cardiovascular diseases and reduction of all-cause mortality are among the reasons for the popularity of bariatric surgeries, especially in patients with morbid obesity (i.e., BMI greater than 35 kg/m^2) [8,9]. Today, laparoscopic gastric bypass surgery (LRYGB), as well as other bariatric surgeries, including laparascopic sleeve gastrectomy (LSG), laparoscopic gastric banding (LAGB), biliopancreatic diversion with duodenal switch (BPD/DS), and one anastomosis gastric bypass (OAGB) surgeries are the most popular and effective methods of bariatric surgery.

Many studies have shown the effectiveness of these surgical procedures in the alleviation or remission of T2DM [10–12]. Also a myriad of studies have shown that bariatric surgeries are not only effective in T2DM remission compared to control group [11,12], but also the rate of development and incidence T2DM was significantly lower over the follow-up years [9]. Among these methods, OAGB has shown promise in both weight reduction and improvement of glycemic indices especially in patients with extreme obesity but the evidence on its efficacy in patients with BMI less than 35 kg/m^2 is scarce [10,13,14]. In OAGB surgery, a very small part of the stomach is cut from the rest of the stomach with the help of a stapler, and then the small intestine is anastomosed about 180 cm after the Tritz ligament. This method requires a lower number of patients for learning curve completion and has a shorter operation time. In addition, it is associated with less complications and more favorable outcomes [10].

The aim of this multi-center retrospective cohort study was to evaluate the effectiveness of one anastomosis gastric bypass method in improving type 2 diabetes in T2DM patients with BMI <35 kg/m^2 undergoing surgery in Sina Hospital, Tehran, Iran and Shahid Bahonar Hospital, Kerman, Iran.

2. Methods

2.1. Study participants

In this multi-center retrospective cohort study, from November 2019 to December 2021, all patients with T2DM according to American Diabetes Association (ADA) criteria [15], as diagnosed by an endocrinologist, a body mass index of less than 35 kg/m^2 and indications for bariatric surgery in Sina Hospital, Tehran, Iran and Shahid Bahonar Hospital, Kerman, Iran, were included. The objectives of the study were clearly explained to the patients and if they gave informed written consent, were finally included in the study. This study was approved by the ethics committee of Kerman University of Medical Sciences, Kerman, Iran (ethics code: IR.KMU.AH.REC.1400.155) and reported in line with the STROCSS criteria [16].

Before surgery, 14 patients who were referred for bariatric surgery, filled in a data collection form for demographic information (including age and sex), as well as family history, other underlying diseases (as confirmed by their physician), the time from diagnosis of T2DM and the treatments they receive for T2DM. Before the surgery, weight and height were measured, BMI was calculated and recorded in the data collection form. The levels of hemoglobin A1C (HbA1C), fasting blood sugar, cholesterol, triglyceride, and thyroid stimulating hormone (TSH) were also measured before surgery.

2.2. Procedures and measurements

The 14 recruited patients underwent OAGB surgery using similar protocols in each hospital by the same surgeon with twenty years of experience. Thereafter, the patients were followed and visited for assessment of post-operative complications.

After the surgery, data including the type of surgery, time and duration of the operation, surgery procedure, and postoperative complaints were recorded. Outcome measures were weight, BMI, HbA1c, fasting blood sugar, cholesterol, triglyceride, and TSH levels at follow-up visits (one, three, six, and 12 months after surgery). The remission of diabetes was defined and measured by fasting blood glucose levels less than 110 mg/dL or hemoglobin HbA1C levels less than 6.5% without the use of blood glucose control drugs.

2.3. Statistical analysis

The descriptive statistics of the demographic and clinical characteristics of the patients were calculated and reported using mean and standard deviation (SD) for quantitative variables and proportions (in percentages) for qualitative variables. The values for each of the outcome variables including weight, FBS, HbA1C, triglyceride, cholesterol, and TSH levels were compared between baseline and one month, three months, six months, and 12 months after surgery. To assess the normality of the data, Shapiro Wilk test was used. Paired *t*-test for or Wilcoxon test were used for analysis depending on the presence of parametric conditions (details in Table 2). Statistical Analysis was performed using IBM SPSS Statistics 20.0 and significance threshold was considered less than 0.05.

3. Results

3.1. Study participants

Of the patients included in this study, 71.4% (10 of 14) were female and 28.6% (4 of 14) were male. The age of patients, mean (SD), was 51.2 (12.3) years in total population, with 48 (11.84) years in female and 59.2 (11.84) years in male patients. The BMI, mean (SD), was 33.1 (4.0) Among the 14 patients, there were 9 patients (64.3%) with a positive history of hypertension, 9 patients (64.3%) with hyperlipidemia, 1 patient (7.1%) with hypothyroidism, and 2 patients (14.3%) with other underlying chronic diseases including steatohepatitis, and hyperuricemia. Also, 8 patients (61.5%) had a positive family history for diabetes and neither of the patients had complications after surgery (Table 1).

3.2. Diabetes remission rates within a year

Within one year after OAGB surgery, 50% of patients (7 of 14) were free of diabetes mellitus, among which 7.1% (1 of 14) were diabetes-free within one month, 21.4% (3 of 14) within three months, and 21.4% (3 of 14) within six months. In addition, although the other patients did not undergo T2DM remission, they all required lower dosage of blood glucose control drugs and their FBS and HbA1C levels were significantly lower compared to pre-surgical levels.

3.3. Weight, BMI, and metabolic indices within a year

Post-operative weight ($p < 0.001$ at all follow-up visits) and FBS ($p < 0.01$ at one- and three-month intervals and $p < 0.001$ at six-month interval) were significantly lower compared to pre-operative values. The levels of HbA1C significantly decreased three and six months ($p <$

Table 1
Characteristics of participants.

		Patients with OAGB surgery
Age, years: mean (SD)		51.2 (12.3)
Sex, female: n (%)		10 (71.4%)
BMI before surgery, kg/m2: mean (SD)		33.1 (4.0)
Duration of T2DM, years: mean (SD)		7.0 (5.13)
Family history of T2DM: n (%)		8 (57.2%)
Comorbidities	Hypertension: n (%)	9 (64.3%)
	Hyperlipidemia: n (%)	9 (64.3%)
	Hypothyroidism: n (%)	1 (7.1%)
	Steatohepatitis: n (%)	1 (7.1%)
	Hyperuricemia: n (%)	1 (7.1%)

Abbreviations: BMI: Body mass index, T2DM: Type 2 diabetes mellitus, OAGB: one anastomosis gastric bypass, n: number, SD: standard deviation.

Table 2
Comparison between metabolic indices at follow-up visits.

Metabolic index	Weight (kg)		FBS (mg/dL)		HbA1C (%)		Triglyceride (mg/dL)		Cholesterol (mg/dL)		TSH (mIU/L)	
Statistics	Mean (SD)	t (p-value)	Mean (SD)	t (p-value)	Mean (SD)	t (p-value)	Mean (SD)	t (p-value)	Mean (SD)	t (p-value)	Mean (SD)	t (p-value)
Before surgery	86.7 (14.8)	–	200.1 (44.8)	–	8.6 (2.1)	–	242.7 (76.6)	–	195.9 (47.7)	–	2.7 (1.8)	–
One-month interval	78.0 (11.5)	12.2 (<0.001)	137.7 (17.8)	4.4 (<0.01)	–	–	–	–	–	–		–
three-month interval	74.1 (11.1)	8.4 (<0.001)	116.3 (38.02)	4.4 (<0.01)	6.7 (1.8)	−2.0[a] (<0.05)	193.5 (61.6)	1.3 0.3))	202.4 (22.9)	−0.4[a] 0.7))	1.9 (0.6)	1.2 (0.3)
Six-month interval	66.8 (10.8)	12.7 (<0.001)	105.9 (29.5)	5.7 (<0.001)	6.6 (1.5)	−2.4[a] (<0.05)	106.9 (23.1)	−2.5[a] (<0.05)	168.3 (58.6)	−1.1[a] (0.3)	1.9 (0.9)	3.1 (<0.05)
12-month interval	68.8 (9.3)	7.2 (<0.001)	–	–	6.8 (2.0)	−1.6[a] (0.2)	138.8 (11.9)	4.0 (<0.05)	170 (43.9)	−0.5[a] (0.6)	–	–

Abbreviations: FBS: Fasting blood sugar, HbA1C: hemoglobin A1C, SD: standard deviation, TSH: Thyroid stimulating hormone.
For triglyceride, cholesterol, and TSH, data for only one patient were recorded one month after surgery.
For TSH, one year after surgery, data for only two patients were recorded.
For the HbA1C variable, one month after surgery, data for only two patients were recorded.
[a] Wilcoxon rank test.

0.05) after surgery but the changes were not significant after twelve months ($p = 0.2$). While triglyceride levels were not significantly lower three months after surgery ($p = 0.3$), they showed a decline in in six and twelve months postoperatively ($p < 0.05$). Also, TSH levels decreased six months after surgery ($p < 0.05$), despite no significant difference in three months ($p = 0.3$). However, cholesterol levels did not change significantly after surgery at any time point ($p < 0.05$) (Table 2, Fig. 1).

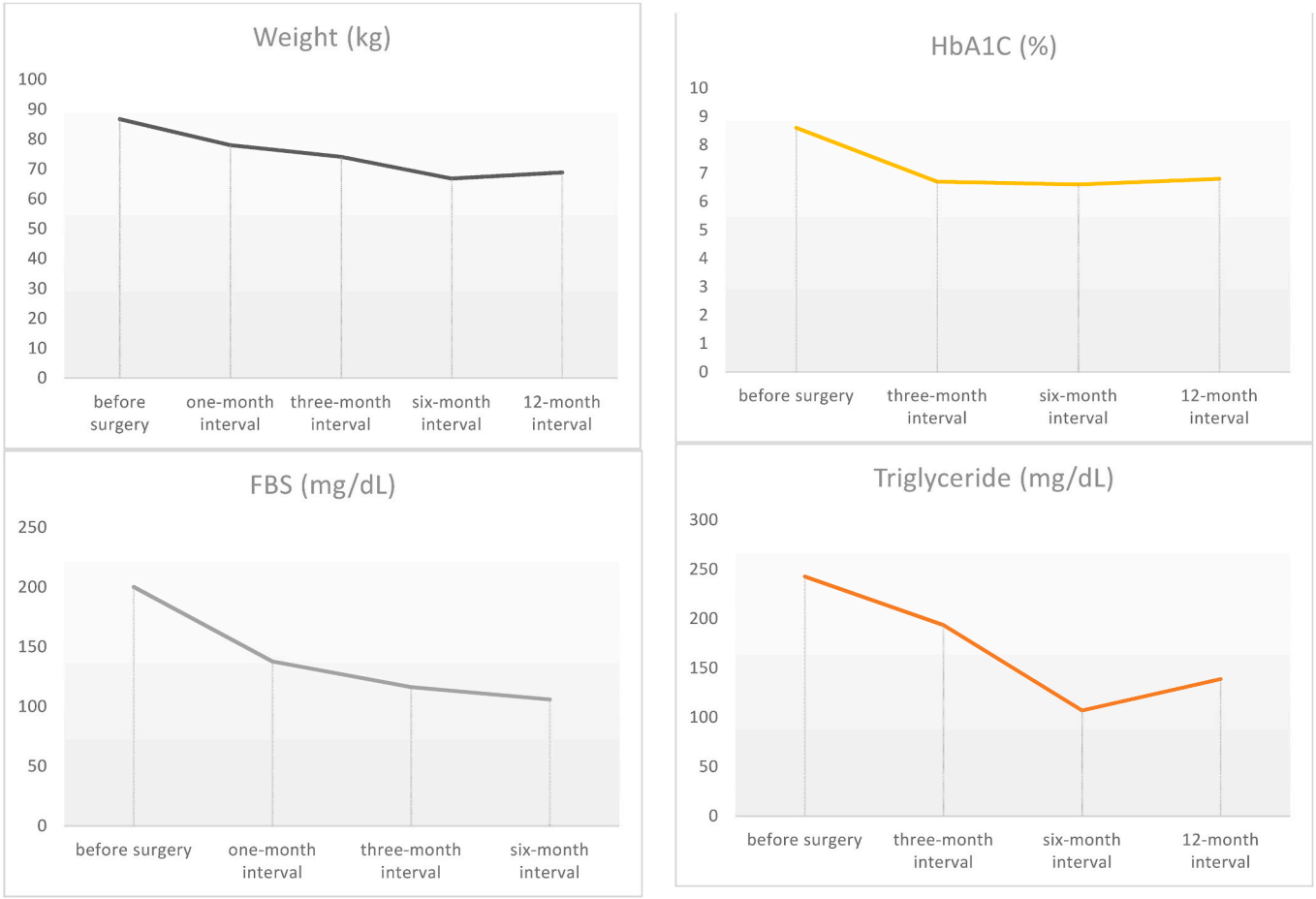

Fig. 1. Alterations of weight, fasting blood glucose, hemoglobin A1C, triglyceride, total cholesterol, and thyroid stimulating hormone during a one-year follow-up period.
Abbreviations: FBS: Fasting blood sugar, HbA1C: hemoglobin A1C, SD: standard deviation, TSH: Thyroid stimulating hormone.
For triglyceride, cholesterol, and TSH, data for only one patient were recorded one month after surgery.
For TSH, one year after surgery, data for only two patients were recorded.
For the HbA1C variable, one month after surgery, data for only two patients were recorded.

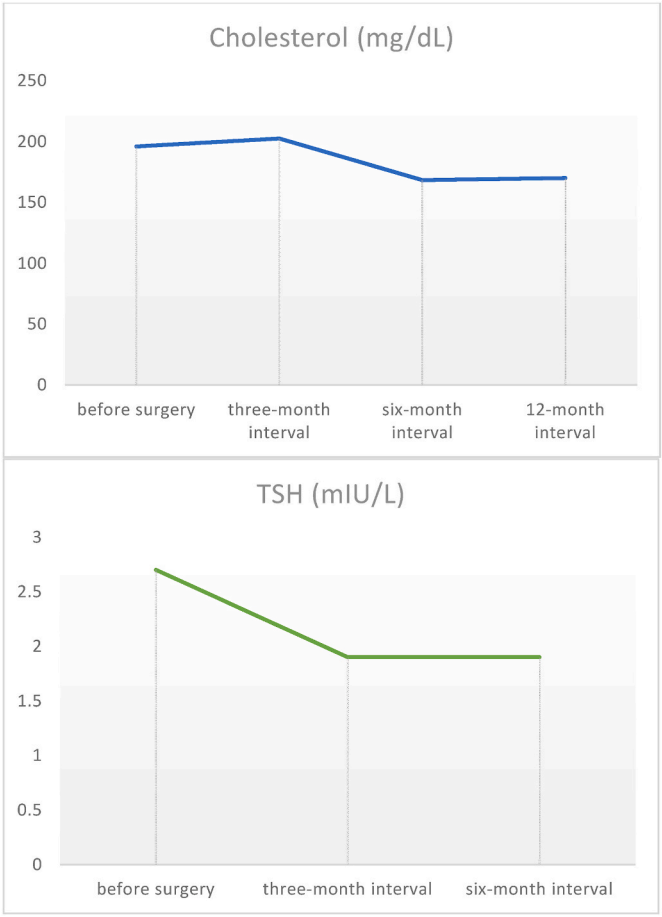

Fig. 1. (*continued*).

4. Discussion

In this multi-center retrospective study, we aimed to assess the effectiveness of one anastomosis gastric bypass surgery in the improvement of anthropometric, glycemic, and metabolic indices in patients with obesity (BMI <35 kg/m^2) and type 2 diabetes (T2DM). Within six months, 50% of T2DM patients included in this study were in remission (7.1% within a month, 21.4% within three months, 21.4% within six months). We observed that weight, body mass index, and fasting blood glucose reduced significantly in all of follow-up time points within a year after bariatric surgery. Also, triglyceride and TSH levels decreased after six months but not after three months. While HbA1C levels decreased three and six months after surgery, the changes were nonsignificant after 12 months. Cholesterol levels showed no change in either of the time points within a year. Overall, these results point to the effectiveness of these bariatric surgery methods in the remission/improvement of T2DM, as well as reducing weight and BMI.

A meta-analysis by Wiggins et al. showed efficacy of bariatric surgery in reducing all-cause mortality, and incidence of diabetes, hypertension, hyperlipidemia, and cardiovascular disease at a population level [9]. A review by Gibbons et al. showed that bariatric surgery in patients with a BMI between 30 and 35 kg/m^2 was associated with a more significant weight reduction as well as better blood sugar control in these patients, within 1–2 years [11]. In a prospective matched cohort study in Sweden, it was shown by Sjostrom et al. that two years after bariatric surgery, 72.3% of 343 type 2 diabetic patients were in remission, compared to 16.4% remission rate in the control group. Also, after 15 years of follow-up, 30.4% of patients treated by surgery were in remission compared to only 6.5% of controls [12].

Some studies have shown high efficacy of LSG in improvement of T2DM and weight reduction, especially in patients with a BMI less than 35 [17–19]. Specifically, in a study by DePaula et al. in which 60 T2DM patients with BMI of less than 35 underwent sleeve gastrectomy or diverted sleeve gastrectomy, 52 patients achieved glycemic control during a mean post-operative period of 7.4 months [17]. In another study by Wu et al., it was shown that remission rates in 51 patients treated by LSG were significantly higher in patients with BMI of 30–35 (88.5%) compared to patients with BMI of 25–30 (44%) during a one-year follow-up period. Moreover, patients with longer disease duration and diabetes severity (ABCD score) had lower remission rates after surgery [18]. Alamo et al. observed that during an 18-month follow-up period after sleeve gastrectomy with jejunal bypass, 40 of 49 T2DM patients with BMI of less than 35 showed complete remission and the other nine patients showed partial remission [19]. A systematic review and meta-analysis has shown that laparascopic OAGB surgery, compared to LAGB, LSG, and LRYGB, was associated with a significantly higher amount of weight loss and T2DM remission, as well as requiring fewer cases for learning curve to be completed, less operation time compared to the other methods, less recovery time, and complication rate [10]. OAGB surgery has shown promise in reducing weight and glycemic control in patients with extreme obesity with stable remission in long-term [13]. However, Kular et al., in a study including 128 T2DM patients with BMI less than 35 kg/m^2 have shown the efficacy of OAGB in in inducing 64, 66, and 53 remission rates during 1, 2, and 7 years [14], which is in line with our results, showing a 50% remission rate during a year, and significant improvement of glycemic indices in patients treated by OAGB.

This study suffers from some limitation. First, we had a small sample size, which was due to low number of patients with indications and consent for OAGB surgery. Second, due to specific conditions for

inclusion, we could not recruit a control group with similar BMI. Instead, patients were compared longitudinally. Third, the missing data on laboratory data, which made some of the analyses impossible, may have restricted the interpretations of the results.

5. Conclusion

One anastomosis gastric bypass surgery in patients with diabetes and body mass index less than 35 in two centers in Iran was associated with 50% remission rates within a year after surgery. The patients showed significant weight reduction, glycemic control, and improvement of hyperlipidemia.

Acknowledgements & author contributions

A.A., F.A. M.T., and A.S. contributed to conception of the study, A.A., M.T., F.E., H.Z.M., and K.N. contributed to performing the procedures and data gathering, A.A., and F.A. contributed to data analysis, A.A., and F.A. contributed to writing the primary draft, M.T., A.S., and F.E. supervised the study, all the authors reviewed and revised the final draft.

Ethical approval

The patients were given informed written consent for inclusion in this study. This study was approved by the ethics committee of Kerman University of Medical Sciences, Kerman, Iran (ethics code: IR.KMU.AH.REC.1400.155).

Sources of funding

No particular funding was received for this research.

Author contribution

A.A., F.A. M.T., and A.S. contributed to conception of the study, A.A., M.T., F.E., H.Z.M., and K.N. contributed to performing the procedures and data gathering, A.A., and F.A. contributed to data analysis, A.A., and F.A. contributed to writing the primary draft, M.T., A.S., and F.E. supervised the study, all the authors reviewed and revised the final draft.

Registration of research studies

The study is not registered in the research registry. It is a retrospective study in form of a series of cases operated and was not accepted for registry in the mentioned websites. We have applied for registration in IRCT but it is pending for approval.

Guarantor

Alireza Amirbeigi.

Consent

Written informed consent was obtained from the patients for publication of this study. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

Provenance and peer review

Not commissioned, externally peer reviewed.

Declaration of competing interest

The authors declare no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amsu.2022.104102.

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