ORIGINAL CONTRIBUTIONS





Safety and Efficacy of One Anastomosis Gastric Bypass on Patients with Severe Obesity Aged 65 Years and Above

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Abstract

Purpose With the global increase in life expectancy and the subsequent impaired quality of life in older obese adults, modalities such as bariatric surgery become crucial to help lose excess weight. This study was conducted to evaluate the effectiveness and safety of one anastomosis gastric bypass (OAGB) in patients 65 years old and above.

Materials and Methods This retrospective cohort study was conducted on 61 patients with severe obesity aged \geq 65 years through Iran National Obesity Surgery Database. The patients had undergone OAGB and were followed up for 12 to 60 months. The required data was extracted through national database.

Results Mean age and BMI of the patients were 67.62 ± 2.03 years and 46.42 ± 5.46 kg/m², respectively. Regarding gender, 90.1% of the participants were female. Mean operative time and length of hospital stay were 41.37 ± 13.91 min and 1.16 ± 0.61 days, respectively. Five patients (8.19%) required ICU admission. The changes in %TWL after 3, 6, 12, 24, 36, 48, and 60 month follow-up was 18.62%, 25.51%, 32.84%, 35.86%, 38.49%, 31.41%, and 29.52%, respectively. The resolution of gastroesophageal reflux disease, diabetes mellitus, dyslipidemia, obstructive sleep apnea, and hypertension after 24 month was about 100%, 65%, 73.33%, 100%, and 76%, respectively. The postoperative early and late complications were 6.53% and 11.46%, respectively. We did not find significant difference in above results between two age groups of 65–70 and >70 years. **Conclusions** OAGB can be a good choice in older obese adults because of its shorter operative time, higher potency, and low complication rate.

Keywords One anastomosis gastric bypass · Severe obesity · Elderly · Efficacy · Safety

Key points

1. OAGB is safe and effective procedure in patients older than 65 years old.

2. OAGB has the same safety and efficacy between ages 65–70 and older than 70 years old.

3. Nutritional support and regular follow up in older patients should be done more carefully.

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Introduction

Obesity is not only associated with medical consequences but can also impair the quality of life [1]. With the global increase in life expectancy and the subsequent impaired quality of life in older obese adults, modalities such as bariatric surgery become crucial to help lose excess weight [2]. Older adults have many medical concerns compared with younger age groups. The development of diseases becomes

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more widespread with age, such as hypertension (HTN), ischemic heart disease, diabetes, cancer, and musculoskeletal diseases [2]. In addition to its underlying medical conditions, such as type-2 diabetes mellitus (T2DM) and obstructive sleep apnea (OSA), obesity has many other associated medical problems [3].

Bariatric surgery in older patients is a challenging procedure because the bariatric surgeon has to tackle medical concerns related to advanced age and obesity [4]. The postoperative period is usually difficult for older adults because of their musculoskeletal problems and underlying diseases. While advanced age used to be a contraindication for bariatric surgery [5], with the advances in surgical and anesthetic equipment, which contribute to safe operation even at older ages, bariatric operations are routinely performed nowadays with great safety [6]. Meanwhile, some studies have demonstrated the lower efficacy of bariatric surgery in older adults compared to younger age groups [6]. Given these issues, the choice of the best type of bariatric surgery for these patients is a subject of debate, as it has to be safer than normal and have a shorter operative time and less post-operative complications and dietary problems due to the older patients' age-related limitations.

One anastomosis gastric bypass (OAGB) is an IFSOapproved procedure with established safety and efficacy in weight loss outcomes and resolution of associated medical problems [7]. OAGB is a hypoabsorptive surgery with more persistent weight loss than laparoscopic sleeve gastrectomy (LSG) and is more simple to perform compared to laparoscopic Roux-en-Y gastric bypass (LRYGB) and biliopancreatic diversion with duodenal switch (BPD-DS) [7]. In addition, the simplicity of its reversal is another advantage of OAGB [8]. Because of these characteristics, this operation may be an ideal choice for older patients, although it is an ongoing debate among experts. Despite the recent consensus on the safety of OAGB for older adults [9, 10], some bariatric surgeons refuse to perform OAGB in patients over 65 years old [3]. This study was conducted to evaluate the effectiveness and safety of OAGB in patients 65 years old and above.

Materials and Methods

Design and Setting

This retrospective cohort study was conducted on 61 patients with severe aged \geq 65 years. The inclusion criteria were BMI above 35 kg/m² with obesity associated medical problems or BMI over 40 kg/m² with or without associated medical problems. The patients had undergone OAGB and were followed up for 12 to 60 months at Rasoul-e-Akram Hospital, a Bariatric Center of Excellence endorsed by the European Branch of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO).

Perioperative Measures and Surgical Technique

In these patients because of higher age and more age-related medical problems, bariatric surgery may harbor more dangers in these patients, so that we discussed these patients in our multidisciplinary team including bariatric surgeon, cardiologist, anesthesiologist, nutritionist, and psychologist in order to find best approach of preparing these patients for operation and postoperative managements. Also, we seek other specialists' consultations such as nephrologist or pulmonologist or endocrinologist based on patients' associated medical problems.

Operational technique and postoperative follow-ups differ in older patients than younger ages. The operation was performed in a modified lithotomy position using five trocars. A narrow 16 to 18 cm length pouch was created over 36 F orogastric tube. Then, a 40-mm side to side gastrojejunostomy was created between the posterior wall of the pouch and the small intestine, 150 to 170 cm from the ligament of Treitz. The enterostomy site was closed using 00 PDS with running stitches.

All the patients were prescribed ursodeoxycholic acid 300 mg every 12 h and proton pump inhibitors (PPIs) 40 mg every 12 h for 6 months and multivitamins with minerals lifelong.

Data Collection

The required data was extracted through the Iran National Obesity Surgery Database (INOSD), and access provided by the minimally invasive surgery research center. The extracted data included demographic information such as age and gender and associated medical problems such as T2DM, HTN, OSA, dyslipidemia (DLP), hypoalbuminemia, and gastroesophageal reflux disease (GERD), which were recorded 3, 6, 12, 24, 36, 48, and 60 months after surgery.

Outcome Definitions

We defined efficacy as improvement/remission of associated medical problems and assessed weight loss outcomes by measuring the total weight loss (TWL) and excess weight loss (EWL).

Associated medical problems resolution or improvement was defined based on Standardized Outcomes Reporting In Metabolic And Bariatric Surgery [11] as follows:

DLP (improvement: decrease in dose of lipid-lowering agents with equivalent control of dyslipidemia or improved control of lipids on an equivalent medication; complete remission: normal lipid panel off medication). GERD (complete resolution: absence of symptoms and no medication use; improvement: improved symptom severity or frequency or decreased or as needed medication use).

HTN (improvement: decrease in the dosage or number of antihypertensive medications or decrease in systolic or diastolic blood pressure on the same medication; complete remission: being normotensive off antihypertensive medication).

T2DM (complete remission: HbA1c < 6%, FBG < 100 mg/ dl in the absence anti-diabetic medications; improvement: reduction in HbA1c and FBG (not meeting the criteria for remission) or decrease in anti-diabetic medication requirement.

OSA (complete remission: in those patients with preoperative polysomnography (PSG) with a diagnosis of OSA, complete remission would be defined as AHI/RDI of o5 off CPAP/BIPAP on repeat objective testing with PSG; improvement: self-discontinued use of sleep apnea treatment CPAP/BIPAP due to improved symptoms) [11].

The procedure's safety was checked by assessing early and late complications such as hypoalbuminemia (Alb < 3.5 g/dl), intolerance to bariatric surgery (frequent biliary vomiting or poor feeding because of severe bile gastritis or extreme changes in taste) and excessive weight loss (BMI < 18.5 kg/m^2).

Ethical Issues

The research adhered to the principles of the Declaration of Helsinki. The Ethics Committee of Iran University of Medical Sciences approved the protocol for the study. For this type of study formal consent is not required.

Statistical Analysis

To analyze the data, number and percentage indices were utilized for the qualitative variables and mean and standard deviation or mean and minimum–maximum for the quantitative variables. Given the normal distribution of the data, parametric tests such as repeated-measures ANOVA were used. All the descriptive tables and statistical tests were developed in SPSS software, version 21, and the statistical significance level was taken as 0.05.

Results

Sixty-one patients were included in the study. The mean age of the participants was 67.62 ± 2.03 years and their mean BMI was 46.42 ± 5.46 kg/m²; also, 90.1% (n = 55) of the participants were female. Table 1 presents the variables of T2DM, OSA, GERD, HTN, and DLP at baseline. The mean operative time (skin to skin) and length of hospital stay were

Variable	Value
Age, mean \pm SD (range), year	67.62±2.03 (65–72)
Female sex, no. (%)	55 (90)
BMI, mean \pm SD (range), kg/m ²	$46.42 \pm 5.46 (37 - 58)$
T2DM, no. (%)	37 (60.65)
OSA, no. (%)	11 (18.03)
GERD, no. (%)	12 (19.67)
HTN, no. (%)	44 (72.13)
DLP, no. (%)	28 (45.90)

BMI body mass index, *BS* before surgery, *SD* standard deviation, *T2DM* type 2 diabetes mellitus, *OSA* obstructive sleep apnea, *GERD* gastroesophageal reflux disease, *HTN* hypertension, *DLP* dyslipidemia

41.37 \pm 13.91 min and 1.16 \pm 0.61 days, respectively. Five patients (8.19%) required ICU admission (Table 2). The changes in TWL% and EWL% are shown in Table 3 and Fig. 1. Associated medical problems improvement/remission (OSA, HTN, DLP, GERD, and T2DM) and changes in diabetic markers and function and renal function tests are presented in Tables 4 and 5.

Post-operative complications were checked during the 60-month follow-up to assess the surgery's safety. There was no Denovo GERD, intolerance to bariatric surgery, pulmonary thromboembolism/deep vein thrombosis (PTE/DVT), excessive weight loss (BMI < 18.5 kg/m²), and mortality in the participants. Regarding early post-operative complications, there were four cases overall (6.53%), including leakage (n = 1, 1.63%), bleeding (n = 2, 3.27%), and wound infection (n = 1, 1.63%). Regarding late post-operative complications, there were seven cases in total (11.46%), including hypoalbuminemia (Alb < 3.5 g/dl; n = 3, 4.91%) and marginal ulcer (n = 4, 6.55%).

Discussion

Bariatric surgery is currently an established modality for reducing obesity-related mortalities and increasing life expectancy in patients with severe obesity [12]. Bariatric surgery in older patients with severe obesity should be performed with more caution and greater sensitivity toward its type due to this age group's different tolerance of rapid changes in ingestion habits and physical adaptability compared to younger people.

Although a few studies have evaluated the efficacy and safety of some bariatric surgical procedures in older adults, mainly Roux-en-Y gastric bypass and sleeve gastrectomy [4, 6, 13–17], there is a limited number of studies on OAGB in this group of patients [18, 19].

Table 2 Operative data and complications after OAGB in patients older than 60 years old

Operative time (min)		41.37 ± 13.91			
Intraoperative complication		0 (0)%			
ICU admission		5 (8.19)%			
Length of stay (day)		1.16 ± 0.61			
Postoperative complication	early (<30 days)	Clavien-Dindo classification (33)			
		Overall	4 (6.55%)		
		Grade II	1 (1.63%) (1 bleeding)		
		Grade IIIa	1 (1.63%) (1 wound infection)		
		Grade IIIb	2 (3.27%) (1 leak, 1 bleeding)		
late (> 30 days)		Clavien-Dindo classification			
		Overall	7 (11.47%)		
		Grade II	5 (8.19%) (3 hypoalbuminemia, 2 marginal ulcer)		
		Grade IIIb	2 (3.27%) (2 perforated marginal ulcer)		
Readmission		4 (6.55%)			
Mortality		0 (0)%			

Table 3 Within-subjects difference for TWL% and EWL% indices during 60-month follows up

Variable	Mean	SD	Sig
TWL% at 3 months	18.62	4.636	0.017
TWL% at 6 months	25.51	4.872	
TWL% at 12 months	32.84	5.621	
TWL% at 24 months	35.86	7.670	
TWL% at 36 months	38.49	19.19	
TWL% at 48 months	31.41	4.746	
TWL% at 60 months	29.52	0.54	
EWL% at 3 months	41.52	12.32	< 0.001
EWL% at 6 months	56.69	13.94	
EWL% at 12 months	73.03	15.48	
EWL% at 24 months	78.32	19.27	
EWL% at 36 months	82.72	38.30	
EWL% at 48 months	70.14	6.85	
EWL% at 60 months	70.53	11.87	

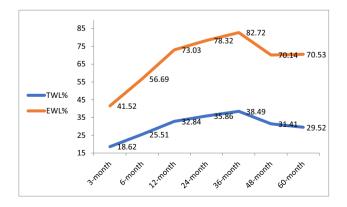


Fig. 1 Changes of EWL% and TWL% at seven time points (3, 6, 12, 24, 36, 48, and 60 months)

Although there is an expert consensus on performing OAGB in eligible older patients [9, 10], more evidence is required on the safety of this procedure.

In the present study, 61 patients aged 65 or above underwent OAGB with a 150 to 170-cm biliopancreatic limb (BPL). The mean operation time (skin to skin) was about 41 min, which suggests that this operation can be performed more rapidly than other types of bariatric surgeries, as reported in literature [2, 4, 13, 15]. Lower operating time and shorter general anesthesia are assumed to be important factors in the safety of this procedure and also in reducing postoperative complications in older patients. In this study, early complications were observed in 6.5% of the patients. About 8.2% of all operated patients required ICU admission after surgery. The rates of ICU admission rate in our patients are relatively high. This was due to our anesthesiologist's decision and planned preoperatively according to MDT suggestions. There was not any unplanned ICU admission due to intraoperative complications in these patients.

In the present study, the rate of development of early complications was comparable to the rate reported after LSG (2–7.2%) and LRYGB (5–7.5%) in other studies, which demonstrates the better efficacy of OAGB in older adults [4, 13–17, 20]. A recent systematic review and meta-analysis performed by Vallois [6] showed that the total rate of early complications after LSG and LRYGB was about 8.95% and 12.4% in patients older than 60 years [6]. The comparison of these results with the present findings on complication rates after OAGB suggests the safety of OAGB in older patients.

In current study, marginal ulcer (MU) was found in 4 patients (6.55%). Two patients were admitted because of perforated MU and others underwent medical treatment. All of these four patients used NSAIDs because of chronic knee and back pains. No one had history of smoking because

Associated medical problems	Comorbid- ity resolu- tion after 12-month	Comorbidity improve- ment after 12-month	Comorbid- ity resolu- tion after 24-month	Comorbidity improve- ment after 24-month	Comorbid- ity resolu- tion after 36-month	Comorbidity improve- ment after 36-month	Comorbid- ity resolu- tion after 60-month	Comorbidity improvement after 60-month
GERD	10/10 (100%)	0/10 (0%)	7/7 (100%)	0/7 (0%)	2/2 (100%)	0/2 (0%)	-	-
DM	21/30 (70%)	9/30 (30%)	13/20 (65%)	5/20 (25%)	5/7 (71.5%)	2/7 (28.5%)	2/2 (100%)	0/2 (0%)
DLP	14/25 (56%)	5/25 (20%)	11/15 (73.33%)	2/15 (13.33%)	8/8 (100%)	0/8 (100%)	2/2 (100%)	0/2 (0%)
OSA	10/10 (100%)	0/10 (0%)	4/4 (100%)	0/4 (0%)	2/2 (100%)	0/2 (0%)	-	-
HTN	26/41 (63.41%)	12/41 (29.26%)	19/25 (76%)	4/25 (16%)	8/10 (80%)	2/10 (20%)	1/1 (100%)	0/1 (0%)

 Table 4
 Efficacy following bariatric surgery during 60-month follows up

Table 5 Liver, kidney, and diabetic profile changes		Variable	Mean	Std. deviation	t	P value
before surgery and 12 months follow-up	Diabetic markers	HbA1c before the operation	7.56	1.401	7.329	< 0.001
		HbA1c 12 month after operation	5.42	0.862		
		FBS before the operation	138.86	49.454	3.137	0.005
		FBS 12 month after operation	104.10	20.722		
		BS2hpp before the operation	208.83	57.091	3.169	0.025
		BS2hpp 12 month after operation	140.33	46.116		
		Insulin before the operation	12.80	11.597	1.085	0.474
		Insulin 12 month after operation	3.84	0.085		
		C peptide before the operation	3.43	0.742	5.000	0.126
		C peptide 12 month after operation	1.80	0.283		
	Liver markers	SGOT before the operation	17.19	5.713	-2.951	0.007
		SGOT 12 month after operation	22.15	7.672		
		SGPT before the operation	17.77	6.611	-2.020	0.054
		SGPT 12 month after operation	21.23	9.612		
		ALP before the operation	184.96	78.171	-3.115	0.005
		ALP 12 month after operation	251.67	100.704		
	Renal markers	BUN before the operation	15.81	4.204	0.445	0.672
		BUN 12 month after operation	14.53	7.302		
		Cr before the operation	1.01	0.210	1.342	0.222
		Cr 12 month after operation	0.94	0.074		

we generally do not perform OAGB in smokers [7]. In the study of Casillas et al. on patients older than 65 years, they reported marginal ulcer in 5 of 177 patients (2.8%) underwent LRYGB [17]. In our study, 52 (85%) of our patients used NSAIDs intermittently because of chronic knee and back pains. This higher rate of MU in our study may be due to high frequency NSAID use or the type of procedure. Some surgeons prefer SG in older patients to prevent MU.

The mean incidence of long-term complications after LRYGB is reported about 4.6%, with the wide range of 0.6 to 25% [21–23]. Some other studies reported the incidence of marginal ulcer after OAGB from 0.5 to 4% [19, 24]. The comparison of these results shows that the rates reported in the present study are similar to those after LRYGB but slightly higher than the rates for OAGB patients in all age

groups. This disparity may be due to the higher incidence of associated medical problems and lower medication tolerance in older patients. Because of these two issues, the postoperative management of older patients in our institutional protocol was to administer PPIs for at least 6 months after the surgery.

In the late post-operative period, 4.9% of the cases suffered from hypoalbuminemia, and all of the cases were treated with nutritional supports and there was no need for reversal. All the patients had BPL longer than 150 cm. There are very limited studies on nutritional deficiencies in older patients with severe obesity following bariatric surgery. The rate of hypoalbuminemia after RYGB and LSG has been reported as about 4.3 and 3.9 in all age ranges [25]. In other studies, the rate of hypoalbuminemia after OAGB in all age ranges was reported from 1.2 to 8.5% based on biliopancreatic limb length [19, 26]. These studies showed that the incidence of hypoalbuminemia reduced as biliopancreatic limb length was decreased [19]. The present study revealed that the risk of hypoalbuminemia in older patients is in the same range as that in younger patients, although it is in the upper limits of that range. Older patients may have more issues with diet compliance than younger adults; they may ignore or forget their medications and have some problems in adding sufficient protein to their daily food intake. According to these findings, we suggest the use of a lower BPL for OAGB in older patients, such as a 150-cm length.

In the present study, %TWL was 32%, 35%, 38%, 31%, and 29% and %EWL 73%, 78%, 82%, 70%, and 70% after 12, 24, 36, 48, and 60 months, respectively. The review of literature on LSG in older patients showed that %TWL was about 22%, 18%, 17%, and 16% and %EWL 55%, 46%, 43%, and 42% after 12, 24, 36, and 48 months [15, 17, 27]. The review of literature on LRYGB in older patients revealed a %TWL of approximately 30%, 28%, 26%, and 25% after 12, 24, 36, and 48 months and %EWL of 67%, 72%, 67%, and 66% [4, 13, 14, 17, 20]. The weight loss data obtained in the present study are similar to the results reported by Peraglie on OAGB in patients over 60 years old [28]. The comparison of the present findings with the results of other studies shows the higher efficacy of OAGB in older adults compared to LSG and LRYGB. Studies comparing weight loss after bariatric surgery between old and young patients have shown that %EWL was significantly lower in patients over 60 years old than in younger patients [6, 29], which could be due to the lower basal metabolic rate (BMR) and total energy expenditure [30] in older ages [6, 29, 31, 32]. The present study showed that OAGB with 150-170 cm of biliopancreatic limb length is more potent than LRYGB and LSG in older patients. Consequently, OAGB can be considered a good choice for bariatric surgery in older patients with a lower BMR who need a more potent bariatric surgery to achieve the desired outcome.

The present study also examined the rate of associated medical problems resolution one, two, three, and 5 years after OAGB and showed that the rate of complete resolution of T2DM, HTN, OSA, DLP, and GERD after 1 year of OAGB was about 70%, 63%, 100%, 56%, and 100%. In a recent systematic review of associated medical problems resolution after LSG and LRYGB, the complete resolution of T2DM, HTN, OSA, and DLP after LSG were 34%, 44.9, 26%, and 21% respectively [6]. The complete resolution of T2DM, HTN, and OSA after LRYGB were 45.9%, 35.6, and 56.3% respectively. [6] The comparison of these results shows that OAGB is as effective as LSG and LRYGB in associated medical problems resolution. A similar study on OAGB in older patients reported the resolution of T2DM and HTN as 84% and 76% [28], which reveal a better associated medical problems resolution after

Table 6 Comparison of safety and efficacy of OAGB between ages 65-70 and above 70

Variable		Age 65–70	Age > 70	P value
Operative time (min)		61.20 ± 14.76	62.50 ± 7.07	0.809
ICU admission		2/5	3/5	> 0.999
Length of stay (day)		1.17 ± 0.64	1.11 ± 0.33	0.781
Postoperative compli-	Early	2/4	2/4	-
cation	Late	4/7	3/7	> 0.999
TWL% at 12 months		33.01 ± 5.922	31.82 ± 3.51	0.610
TWL% at 24 months		35.94 ± 8.35	35.46 ± 2.89	0.913
TWL% at 36 months		38.89 ± 20.82	36.08 ± 1.86	0.857
TWL% at 48 months		30.22 ± 4.53	36.19 ± 0	0.323
TWL% at 60 months		29.52 ± 0.54	-	-
EWL% at 12 months		73.86 ± 16.24	68.15 ± 9.32	0.372
EWL% at 24 months		79.69 ± 20.52	71.47 ± 10.32	0.449
EWL% at 36 months		85.21 ± 41.07	67.78 ± 1.30	0.572
EWL% at 48 months		70.27 ± 7.90	69.61 ± 0	0.945
EWL% at 60 months		70.53 ± 11.87	-	-

OAGB than our study. This disparity may be the result of the longer BPL in that study compared to the present one, although nutritional status and albumin levels were not evaluated in their study [28]. The long-term safety of OAGB with 180-cm BPL is therefore a subject of debate. In a sub-group analysis of patients aged 65–70 and over 70, (Table 6) there were no statistically significant differences between the two groups in weight loss outcomes and complications, suggesting that OAGB is also safe and effective in patients over the age of 70 years.

Conclusion

This study demonstrates the safety and efficacy of OAGB in older patients ≥ 65 years. After careful patient selection, OAGB can be a good choice in this group of patients because of its shorter operative time, higher potency, and low complication rates. Nonetheless, nutritional support and regular follow-ups in older patients should be performed more carefully after OAGB.

Declarations

Conflict of Interest The authors declare no competing interests.

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