



# Comparison of the Bile Reflux Frequency in One Anastomosis Gastric Bypass and Roux-en-Y Gastric Bypass: a Cohort Study

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## Abstract

**Introduction** One of the most acceptable procedures in bariatric surgery is laparoscopic gastric bypass. Laparoscopic Roux-en-Y gastric bypass (RYGB) is a common technique used in bariatric surgery. Recently, one anastomosis gastric bypass (OAGB) has been suggested as a simple, fast, and effective technique for obesity treatment. This study aims to compare the frequency of histologically proven bile reflux in OAGB and RYGB among patients with morbid obesity.

**Methods** This prospective cohort study was performed from 2015 to 2017 in the Department of Bariatric Surgery of Isfahan University of Medical Sciences, Isfahan, Iran. Patients who had undergone RYGB or OAGB surgery were enrolled. Patients who had undergone revisional surgery were excluded. Data on demographics, symptoms, fasting blood sugar, lipid profile, endoscopic, and histologic findings (based on the Sydney bile reflux index) of bile reflux and postoperative complications were collected and compared for the two techniques.

**Results** A total of 122 obese patients (22 males) who had undergone RYGB or OAGB surgery were included. The Sydney bile reflux index showed no statistically significant difference between RYGB and OAGB groups. Similarly, no statistically significant difference was found in the self-reported history of bile reflux–related symptoms, bile reflux markers in esophagogastroduodenoscopy, and postoperative complications between groups.

**Conclusions** OAGB and RYGB appear to be equal with respect to postoperative complications, bile reflux frequency, bile reflux index, and the Sydney system score.

**Keywords** Roux-en-Y gastric bypass · Omega gastric bypass · One anastomosis gastric bypass · Bile reflux · Morbid obesity

## Introduction

Morbidity and mortality are hazardous inclining risks of obesity, especially in developed societies and in younger age

groups [1–3]. Surgical procedures are the most effective treatments for obesity when other treatments are not efficacious [4]. Although the benefit of bariatric surgery is evident from the results of several clinical trials and meta-analyses [1, 5],

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these procedures require advanced technology and can result in unwanted complications [2–6].

Laparoscopic Roux-en-Y gastric bypass (RYGB) was first described by Lonroth et al. in 1996 [7]. It is the first choice and gold standard for treating metabolic disorders in the majority of international bariatric surgical centers and has been consistently used for the past 20 years [5, 8, 9]. The success rate associated with this procedure is high. Some studies have reported loss of 60 to 70% of excess body weight by patients undergoing this procedure [10].

One anastomosis gastric bypass (OAGB) was developed by Robert Rutledge in 1997 as a simple, fast, and effective procedure for obesity treatment and an alternative to RYGB [10–13]. In this procedure, after creating a gastric pouch, an anastomosis is made between the gastric tube and jejunal omega shape loop, usually by linear stapler [11–15]. Despite the promising outcomes of this procedure, concerns exist regarding its safety and associated complications, particularly in comparison with RYGB. Bile reflux is a controversial complication of this method [16]. A recently published meta-analysis suggested that bile reflux is an occasional complication of OAGB [17]. Patients may experience heartburn and gastroesophageal reflux disease (GERD) after bariatric surgery [13], but it is unclear whether or not these symptoms are associated with bile reflux. Clinical signs and symptoms are not sufficiently sensitive and reliable; thus, esophagogastroduodenoscopy (EGD) and biopsy should be performed to confirm the presence of bile reflux [15].

Previous studies on both techniques solely assessed the outcome and safety of the procedure. A small number of studies have compared the outcomes of these techniques, but they all failed to compare the frequency of bile reflux between OAGB and RYGB in obese patients. The current study used EGD to take a gastric pouch biopsy and compare biopsy findings regarding bile reflux between the two methods.

## Methods and Materials

This prospective cohort study was performed between November 2015 and June 2017 in the Department Of Bariatric Surgery. Obese patients who had undergone RYGB (length of gastric pouch was 7–10 cm, length of biliopancreatic limb was 120–150 cm, length of alimentary limb was 50–70 cm, antecolic/antegastric, gastrojejunal anastomosis was performed with a 45-mm stapler) or OAGB (length of gastric pouch was 18–22 cm, antecolic/antegastric, length of bypass was 150–200 cm from treitz ligament, gastrojejunal anastomosis was performed with a 45-mm stapler) [18] were enrolled initially. They all were visited postoperatively according to local hospital protocol and were followed for 1 year after surgery. Patients who had undergone revisional surgery were excluded. In the follow-up visit, the height, weight, body mass index (BMI), postoperative

complications, and blood tests, including fasting blood sugar (FBS) and lipid profile, were measured, and all patients underwent EGD and gastric pouch biopsy with intravenous sedation [19]. EGD was performed within 12 to 13 months after the surgery by a single gastroenterologist in all cases.

The data was compared between patients who had undergone RYGB and OAGB. Bile reflux was evaluated by history (heart burn, bile regurgitation, and bile emesis), endoscopic findings (gastritis, presence of bile in gastric pouch, mucosal abnormality), and histologic criteria of bile reflux. Specimens were fixed in formalin, sectioned, and stained with hematoxylin and eosin.

The Sydney system is a method for diagnosis and classification of gastritis and was introduced in the World Congress of Gastroenterology held in Sydney. In 1994, the updated Sydney system was introduced to resolve the faults of the first Sydney system [20, 21]. The bile reflux index was calculated using the Sydney scoring system after grading intestinal metaplasia, edema, chronic inflammation, and *Helicobacter pylori* status on a 0–3 scale using the formula:  $(7 \times \text{lamina propria edema}) + (3 \times \text{intestinal metaplasia}) + (4 \times \text{chronic inflammation}) - (6 \times H. pylori)$  [22]. Scores that were greater than 14 were considered to be bile reflux with the highest combined sensitivity and specificity. The specimens were all evaluated by a single expert gastrointestinal pathologist who was blinded to the study groups. This study was approved by the ethical research committee of Isfahan University of Medical Sciences, Isfahan, Iran and all participants provided written voluntary informed consent. SPSS version 23 (SPSS; USA) and the independent *t* test, paired *t* test, and chi-squared test were used for statistical analysis.

## Results

The 122 patients enrolled in the study included 58 subjects in the RYGB group and 64 cases in the OAGB group. Baseline demographic characteristics and clinical features of RYGB and OAGB groups are presented in Table 1. Although BMI decreased significantly in both groups after surgery ( $p < 0.001$ ), this reduction was more in RYGB group ( $p = 0.007$ ). No statistically significant difference was found in the BMI between groups at the 12-month follow-up ( $p = 0.15$ ). The mean FBS and lipid profile in each group decreased significantly at the 12-month follow-up ( $p < 0.01$ ) (Table 2).

Bile reflux history, endoscopic findings attributed to bile reflux, and postoperative complications in both groups were not significantly different (Table 3). The bile reflux index was positively correlated to bile reflux history (2 patients out of 5 with a bile reflux history developed bile reflux; Pearson correlation = 0.35;  $p = 0.005$ ) and positive findings in EGD (all patients with positive findings in EGD developed bile reflux; Pearson correlation = 0.76;  $p < 0.001$ ) in patients who had undergone OAGB, but no correlations were observed in patients in the RYGB group ( $p > 0.05$ ). It was not correlated to age, BMI, history of diabetes

**Table 1** Baseline characteristic of study participants

	RYGB	OAGB	<i>p</i> value
Age	33.72 ± 7.94 <sup>a</sup>	34.11 ± 11.32 <sup>a</sup>	0.83
Sex	47/11	53/11	0.79
Diabetes mellitus	5	7	0.66
Preoperative EGD: <sup>2</sup>			
• Normal	43	51	0.08
• GERD	9	7	
• Gastritis	0	4	
• Hiatal hernia	6	2	

<sup>a</sup> Mean ± SD

*p* values resulted from independent sample *t* test for continuous and chi-square test for categorical variables

mellitus, preoperative EGD findings, or postoperative complications in either group at the 12-month follow-up.

No statistically significant difference was found in bile reflux frequency between groups of RYGB and OAGB. Clinically, the experimental event rates (EERs) were 0.069 and 0.078 in RYGB and OAGB, respectively. This means that, of every 111 patients undergoing OAGB, one more patient showed bile reflux than for those undergoing RYGB (absolute risk reduction (ARR) = -0.009; number needed to harm (NNH) = 111).

## Discussion

The introduction of OAGB made it feasible and effective for weight reduction and obesity comorbidities, but concerns about direct contact of bile with gastric mucosa and its harmful effects in the long term remain. It is clear that, in this technique, bile enters the gastric pouch, but whether or not this can cause damage to mucosa was beyond the aim of this study. In fact, the presence of histopathological damage to mucosa is what was looked for.

**Table 3** Comparison of clinical and para-clinical bile reflux findings in RYGB and OAGB groups

	RYGB (58)	OAGB (64)	<i>p</i> value
Bile reflux history	2 (3.4%)	5 (7.8%)	0.27
Bile reflux EGD	1 (1.7%)	3 (4.7%)	0.35
Sydney system score	5.53 ± 5.66 <sup>a</sup>	4.33 ± 5.13 <sup>a</sup>	0.22
Sydney BRI	4 (6.9%)	5 (7.8%)	0.57
Postoperative complication			
• None	56	62	0.99
• Leak	1	1	
• Gastrointestinal bleeding	1	1	

Result from chi-square or Fisher’s exact test as appropriate and independent sample *t* test for continuous data

The EGD reports, histological findings, and the Sydney system scores showed no statistically significant differences in biliary reflux between groups. The results of the current study showed that OAGB is as safe as RYGB, especially with regard to postoperative biliary reflux.

The International Federation for Surgery of Obesity and Metabolic Disorders (IFSO) has recently published a meta-analysis about the safety and efficacy of OAGB which states that bile reflux is an ambiguous complication of this method [17]. In the current study, of the 64 OAGB patients, five developed biliary reflux (7.8%). These results were higher than the biliary reflux rate seen by Bruzzi et al. (2015) in which 2 out of 126 (1.6%) patients who had undergone OAGB developed biliary reflux [23]. A meta-analysis and systematic review by Wang et al. comparing OAGB and the gastric sleeve reported an incidence of bile reflux in OAGB patients to be 0 to 1.6% [24]. The difference between the results may be due to the different methods in which bile reflux was measured. Bruzzi et al. evaluated bile reflux using history, while in our study, bile reflux was measured by pathological methods. Wang et al. reported that bile may be neutralized by contact with gastric acid. This can cause an underdiagnosis in a symptomatic questionnaire-based bile reflux diagnostic tools.

**Table 2** Comparison of demographic and clinical features between patients in RYGB and OAGB groups before and after surgery

	RYGB		<i>p</i> value <sup>1</sup>	OAGB		<i>p</i> value <sup>1</sup>	<i>p</i> value <sup>2</sup>	Observed power
	Before	After		Before	After			
BMI	43.93 ± 5.17	25.62 ± 3.36	<0.001	41.73 ± 2.65	24.87 ± 2.16	<0.001		> 0.99
BMI changes	- 18.31 ± 3.52			- 16.86 ± 1.98			0.007	0.81
FBS	89.04 ± 11.82	84.57 ± 5.93	<0.001	89.38 ± 15.56	83.93 ± 6.40	<0.001		> 0.99
FBS changes	- 4.47 ± 9.16			- 5.46 ± 13.40			0.64	
Total cholesterol	215.68 ± 27.12	179.17 ± 12.79	<0.001	216.60 ± 28.41	180.5 ± 13.42	0.009		> 0.99
Total cholesterol changes	- 36.50 ± 23.93			- 36.10 ± 27.19			0.93	

<sup>1</sup> Resulted from paired sample *t* test

<sup>2</sup> Resulted from independent sample *t* test

Tolone et al. studied 15 patients with OAGB and reported that no signs of bile reflux were seen in endoscopy or histology. However, 13 patients experienced mild perianastomotic inflammation. Similar to the present study, the histological assessment used the Sydney system. Their smaller sample size could be the reason for this difference [25].

We found that biliary reflux history and positive findings in EGD are positively correlated with the Sydney bile reflux index in OAGB patients. This fact can help surgeons to better evaluate the patient and assess possible postoperative complications using history and EGD. Based on our findings, OAGB had a similar outcome to RYGB for weight loss, FBS, and lipid profile changes. Lee et al. (2012) compared the outcomes of OAGB and RYGB over a 10-year period and suggested that OAGB is a simpler and safer alternative for RYGB with similar efficacy [26]. Chevallier et al. reported the results of their study on 1000 patients who had undergone OAGB surgery and found OAGB to be an effective, easy, and safe alternative for RYGB [9]. Similar findings were reported in IFSO meta-analysis as well [17].

In patients who underwent OAGB and experienced bile reflux that did not respond to medical treatment or those with marginal ulcers, revisional surgery and conversion to RYGB should be considered. In cases in which malnutrition is present concurrently, OAGB should be converted to the normal anatomy [27, 28]. While the major treatment of symptomatic bile reflux is surgical intervention, the necessity of these interventions among patients with subclinical bile reflux (those with pathologically approved bile reflux without clinical symptoms) is unknown [29]. Bile reflux is not limited to the gastric pouch, as has been shown in some studies that it can spread to the gastric remnant. Remnant gastrectomy and medical therapy have been successfully used to treat this condition [30, 31].

This study had some limitations. EGD as a common procedure at the first year follow-up is an invasive method and was not accepted by all patients. The short period of follow-up and the bile reflux evaluation as well as the small number of subjects were other limitations of the study. In addition, we were unable to blind the gastroenterologist performing the EGD because the two procedures were easily recognized during endoscopy; however, the gastropathologist was blinded to the group of specimens. The Sydney system index is not designed for evaluation of bile reflux in bariatric patients. Although it is not the first time the Sydney system has been used for evaluation of gastritis in bariatric patients [25], based on our knowledge, it is the first study in which the histological bile reflux index has been used for the evaluation of bile reflux in these patients. The ethical aspect of our study may be under question, but previous studies have shown that asymptomatic marginal ulcers can develop and may diagnosed only by endoscopy [32]. In previous studies, other methods (scintigraphy, GERD HRQL, etc.) were used for the evaluation of bile reflux in bariatric patients [33]. As noted, because it is known that bile

enters the gastric pouch so we were seeking an objective method of evaluating the effect of bile on the gastric mucosa.

This study was the first attempt to compare histologically evaluated bile reflux in morbidly obese patients who had undergone laparoscopic bariatric surgery by OAGB and RYGB. It enrolled a large number of patients and endoscopically evaluated both symptomatic and asymptomatic patients 1 year after surgery.

## Conclusion

In this study, weight loss, improvement of FBS and lipid profile, and postoperative complications were similar for the OAGB and RYGB groups, as well as bile reflux frequency, bile reflux index, and Sydney system score. We recommend OAGB as a safe and effective method of bariatric surgery with no increased chance of biliary reflux in affected patients. Studies with larger sample sizes and longer follow-up periods are recommended in the future.

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## Compliance with Ethical Standards

This study was approved by the Ethical research committee of Isfahan University of Medical Sciences, and all participants provided written voluntary informed consent

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

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