



# Randomized Controlled Trial of One Anastomosis Gastric Bypass Versus Roux-En-Y Gastric Bypass for Obesity: Comparison of the YOMEGA and Taiwan Studies

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## Abstract

**Background** The YOMEGA study (Y-study) was a randomized trial comparing one anastomosis gastric bypass (OAGB) and Roux-en-Y gastric bypass (RYGB). Here, we aim to compare the Y-study and our pioneer trial from Taiwan (T-study).

**Methods** Data from the Y-study and the T-study were collected and compared.

**Results** The Y-study recruited 234 patients with a mean body mass index (BMI) of 43.9 and age of 43.5 years. The T-study recruited 80 patients with a similar mean BMI of 44.3 and mean age of 31.4 years. The studies had similar findings including (1) *OAGB is easier and possibly safer procedure than RYGB*. Both studies showed that OAGB had a shorter operation time than RYGB, but a lower surgical complication rate was only demonstrated in T-study. (2) *Both procedures have similar weight loss but OAGB features better glycemic control than RYGB*. Weight loss at 2 years after surgery was similar between two procedures, but OAGB reduced HbA1c to a greater degree than RYGB at 2 years in Y-study (−2.3% vs. −1.3%;  $p = 0.025$ ). The resolution of the metabolic syndrome was 100% for both groups in the T-study. (3) *OAGB carried a higher risk of malnutrition*. OAGB had more malabsorptive problems with a lower hemoglobin level than RYGB at 2 years after surgery. Adverse malnutrition events occurred in nine (7.8%) OAGB patients in the Y-study. Four (3.4%) patients of OAGB received revision surgery in Y-study but none in T-study. (4) *Bile reflux was noted in OAGB patients but did not influence quality of life or revision rate*. Y-study found that bile in the gastric pouch was present in 16% of patients in the OAGB group versus none in the RYGB, but no inter-group difference in quality of life was detected. There was a trend for RYGB patients to experience more abdominal pain than OAGB.

**Conclusions** Both studies showed that OAGB is a technically easier procedure and features better glycemic control than RYGB, but has a mal-absorptive effect. However, the bile reflux and abdominal pain controversies persisted.

**Keywords** OAGB · RYGB · Type 2 diabetes · Gastric bypass

## Introduction/Purpose

Bariatric/metabolic surgery is the most effective treatment for clinically severe obesity and has been proven successful in treating obesity-related type 2 diabetes (T2D) [1–3]. The

volume of bariatric/metabolic surgery, according to the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) survey, grew exponentially in the past decade [4–7]. However, bariatric/metabolic surgery types along with their variations are still evolving. The most commonly performed procedure is sleeve gastrectomy (SG) followed by Roux-en-Y gastric bypass (RYGB). Another procedure being increasingly used is one anastomosis gastric bypass (OAGB), constituting approximately 4.8% of bariatric/metabolic surgeries worldwide in 2017 [7].

OAGB, first introduced in 2001, was confirmed in other studies to be equivalent to but simplified versus RYGB [8–11]. This procedure has the technical advantages of using tension-free gastro-jejunal anastomosis, avoiding Roux-en-Y limb construction and its potential complications [12]. Because of the controversy surrounding this procedure, single

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anastomosis gastric bypass (SAGB) was proposed by IFSO and later changed to OAGB to avoid confusion. However, controversy persisted around this procedure but very little evidence-based data are available. A recently published high-quality randomized control trial (RCT) comparing OAGB and RYGB provided much needed level 1 evidence [13]. This study was completed 14 years after we published the first RCT comparing OAGB and RYGB (“Taiwan study”) [9]. However, the interpretation of the findings of this study was criticized quickly [14]. Therefore, this study aimed to examine the YOMEGA study (Y-study) and the Taiwan study (T-study) to compare the findings of these two studies and discuss the possible improvement of OAGB in the future.

## Materials and Methods

Data from the two studies on baseline characteristics and primary and secondary outcomes. The primary outcomes for this review were safety and weight loss, while the secondary outcomes were long-term complications, quality of life, and glycemic control.

## Results

### Baseline Characteristics

The Y-study was a multi-institutional study that included 9 centers and a total of 234 patients (mean, 26 patients for each center). The T-study was a single-center trial with 80 patients (Table 1). The mean BMI of the recruited patients was similar between studies ( $43.5 \pm 10.8$  and  $44.3 \pm 6.8$  kg/m<sup>2</sup>), but the

**Table 1** Comparison of clinical characteristics of patients in the Omega Loop Versus Roux-en-Y Gastric Bypass (YOMEGA) randomized controlled trial and Taiwan study

	YOMEG ( <i>n</i> = 234)	Taiwan ( <i>n</i> = 80)
Institutes included, <i>n</i>	9	1
Age (mean + SD)	43.5 (10.8)	31.4 (8.7)
Female sex, %	75%	69%
Mean weight (kg)	120.5 ( $\pm$ 21.7)	117.3 ( $\pm$ 17.3)
Mean BMI (kg/m <sup>2</sup> )	43.9 ( $\pm$ 5.6)	44.3 ( $\pm$ 6.8)
Type 2 diabetes, <i>n</i> (%)	58 (27%)	NA
Metabolic syndrome (%)	NA	44 (56%)
BP limb of OAGB	200 cm	200 cm
BP limb of RYGB	50 cm	50 cm
RY limb of RYGB	150 cm	100–150 cm
Mesentery closure	Yes	No

Data are mean (SD)

BMI body mass index, NA not available, BP bilio-pancreatic

\**p* < 0.05

mean age was lower in the T-study ( $31.4 \pm 8.7$  versus  $43.9 \pm 10.8$  years old). Both studies used a 50 cm biliopancreatic (BP) limb and 150 cm alimentary (RY) limb for RYGB and a 200 cm BP limb in the OAGB. The T-study used an antecolic, retrogastric-route RY limb and circular stapler for the anastomosis. The mesentery defect was closed in the Y-study but not in the T-study. The OAGB technique was similar between the two groups. T2D affected 25% of the patients in Y-study but was not reported in the T-study which stated that metabolic syndrome affected 56% of the patients.

### Operation Parameters and Safety

Both studies demonstrated a significantly shorter operation time for OAGB than RYGB (Table 2). The mean operation time in the Y-study was about half that of the T-study. The overall early surgical complication rate was higher for RYGB than OAGB in both studies but only significant in T-study (3.6% versus 6.8% [*p* = 0.24] in Y-study and 7.5% versus 20% [*p* < 0.05] in T-study). Both studies reported cases requiring intra-operative conversion to another procedure due to technical difficulties in RYGB (2 [2%] in the Y-study and 1 [2.5%] in the T-study) but not in OAGB.

### Weight Loss and Clinical Results After Surgery

Weight loss at 2 years after surgery was similar for the OAGB and RYGB groups in both studies, although greater weight loss after OAGB was found at 1 year in the T-study. Total weight loss was around 35% in both studies, but excess weight loss was greater in the Y-study than in the T-study (Table 3). This discrepancy is due to normal BMI being 25 in the Y-study versus 23 in the T-study (Asian cohort).

At follow-up, both studies demonstrated that RYGB and OAGB significantly decreased blood glucose, blood lipid, blood pressure, and liver enzymes without intergroup differences. The incidence of malnutrition was also not significantly different between groups in both studies. However, both studies detected a significant decrease in hemoglobin in the OAGB versus RYGB group (Table 3).

### Adverse Events and Revision Surgery

At 2 years of follow-up, there was no significant difference in the proportion of participants with severe adverse events between the OAGB and RYGB group in the Y-study (28 patients [22%] vs. 19 patients [15%]; *p* = 0.19) (Table 3). However, when counting the overall adverse events, Y-study reported a significantly higher overall number of adverse events in the OAGB group than in RYGB group (42 events [35.9%] vs. 24 events [20.5%]; *p* = 0.042]. The type of adverse events were different between OAGB and RYGB groups. The most common adverse event was malnutrition in nine (7.7%) patients in

**Table 2** Comparison of perioperative parameters of OAGB and RYGB in YOMEGA and Taiwan studies

	YOMEGA			TAIWAN		
	OAGB ( <i>n</i> = 117)	RYGB ( <i>n</i> = 117)	<i>P</i> value	OAGB ( <i>n</i> = 40)	RYGBP ( <i>n</i> = 40)	<i>P</i> value
Mean operative time (min)	85 (35)	111 (42)	<0.001*	147.7 (46.7)	205 (60.5)	<0.001*
Mortality	0	0	NS	0	0	NS
Conversion rate	0	2 (2%)	NS	0	1 (2.5%)	NS
Postoperative hospital stay (day)	5	5	NS	5.5 (1.4)	6.9 (2.8)	<0.001*
Intra-operative complication <i>n</i> (%)	8 (7%)	4 (3%)	NS	NA	NA	
Early surgical complication	4 (3.8%)	8 (6.8%)	0.24	3 (7.5%)	8 (20.0%)	<0.05*
Major	1 (1%)	2 (2%)		0 (0.0%)	2 (5.0%)	
Minor	3 (3%)	6 (4.8%)		3 (7.5%)	6 (15.0%)	
Late complication	19 (16.2%)	15 (12.8%)	0.45	3 (7.5%)	3 (7.5%)	NS

Data are mean (SD)

NS not significant, NA not available

\**p* < 0.05

the OAGB group versus none in the RYGB group. The most common adverse event was abdominal pain in five (4.3%) patients in the RYGB group versus none in OAGB group. More patients in the RYGB group had marginal ulcer (3 versus 2) and bowel obstruction (3 versus 1) than in the OAGB group, but not statistically significant. The incidence of late

complication was similar in both studies (16.2% vs. 12.8%, *p* = 0.45, in Y study; 7.5% in both groups, in T-study).

At 2 years of follow-up, four (3.4%) patients in the OAGB group of the Y-study required revision surgery: one for leakage, one for severe nutrition problems, and two for bile reflux. In the T-study, no revision surgeries were required.

**Table 3** Comparison of weight loss, clinical data, and serious adverse events between OAGB and RYGB in YOMEGA and Taiwan study at 2 years after surgery

	YOMEGA			TAIWAN		
	OAGB ( <i>n</i> = 117)	RYGB ( <i>n</i> = 117)	<i>P</i> value	OAGB ( <i>n</i> = 40)	RYGBP ( <i>n</i> = 40)	<i>P</i> value
BMI (kg/m <sup>2</sup> )	NA	NA		28.3 (3.5)	30.0 (6.3)	NS
Total weight loss	−37.1 (10.3)%	−35.4 (8.1)%	NS	36.8	31.5	NS
Excess weight loss	−87.9 (23.6)%	−85.8 (23.1)%	NS	64.4 (8.8)%	59.2 (15.1)%	NS
Hemoglobin g/dL	NA	NA		12.0 (1.9)	12.9 (1.6)	0.02*
ΔHemoglobin g/L	−10.3 (20.6)	−3.0 (10.0)	0.036*	NA	NA	
Albumin, g/L	NA	NA		4.3 (0.3)	4.4 (0.2)	NS
ΔAlbumin, g/L	−0.5 (3.9)	−0.1 (3.5)	0.51	NA	NA	
Parathyroid hormone, pg/mL	NA	NA		NA	NA	
ΔParathyroid hormone, pg/mL	5.2 (34.5)	−8.2 (27.7)	0.1	NA	NA	
Patients with serious adverse events, <i>n</i> (%)	28 (22%)	19 (15%)	0.24	3 (7.5%)	3 (7.5%)	NS
Overall serious adverse events, <i>n</i>	42	24	0.042*	NA	NA	
Nutritional complications, <i>n</i>	9 (21%)	0	0.0034*	NA	NA	
Anastomotic ulcer, <i>n</i>	2 (5%)	3 (13%)				
Bowel obstruction	1 (2%)	3 (13%)				
Abdominal pain, <i>n</i>	0	5 (21%)	NS	NA	NA	
Diarrhea or anal fistula, <i>n</i>	6 (14%)	0				
Revision surgery, <i>n</i> (%)	4 (3.4%)	0	NS	0	0	NS

Data are mean (SD)

NS not significant, NA not available, Δ difference between pre-operative and follow-up data

\**p* < 0.05

**Table 4** Comparison of T2D and metabolic syndrome remission after OAGB and RYGB in the YOMEGA and Taiwan studies [9, 13]

	YOMEGA			TAIWAN		
	OAGB ( <i>n</i> = 117)	RYGB ( <i>n</i> = 117)	<i>P</i> value	OAGB ( <i>n</i> = 40)	RYGBP ( <i>n</i> = 40)	<i>P</i> value
Fasting glucose, mmol/L	5.6 (1.5)	6.1 (2.9)	0.801	87.8 (7.8)	88.3 (8.3)	NS
<sup>Δ</sup> glucose, mmol/L	−3.8 (3.8)	−2.6 (4.8)	0.505	NA	NA	
A1C %	5.6 (0.8)%	6.1 (0.9)%	0.055	5.5 (0.8)	6.2 (1.1)	< 0.001*
<sup>Δ</sup> A1C %	−2.3 (1.6)	−1.3 (1.0)	0.025*	−2.9 (1.9)	−2.7 (1.7)	0.149
T2D remission rate	60% (12/20)	38% (6/16)	0.28	81.9%#	55.45%	< 0.001*
Metabolic syndrome	NA	NA		55.0%	57.5%	NS
Resolution of MS	NA	NA		100%	100%	NS

Data are mean (SD)

A1C hemoglobin A1c, MS metabolic syndrome, NA not available

### Glycemic Control and Metabolic Syndrome Remission

In the Y-study, 58 of the 253 (27%) had type 2 diabetes (T2D). The mean decrease in HbA1c at 2 years was significantly greater in the OAGB versus RYGB group (−2.3% vs. −1.3%; *p* = 0.025) (Table 4). In Y-study, the T2D remission rate after OAGB was 60% (12 of 20), higher than the 38% after RYGB (six of 16), but did not achieve statistical significance (*p* = 0.28). This is probably due to the small case numbers (20 and 16).

In the T-study, the resolution of the metabolic syndrome was 100% in both groups with no difference in blood-glucose. There was no data of HbA1c in the T-study because the focus at that time was metabolic syndrome and not T2D [15].

### Bile Reflux and Quality of Life

The T-study used the Gastrointestinal Quality-of-Life Index (GQLI) to investigate postoperative quality of life. The Y-study used the Bariatric Analysis and Reporting Outcome System (BAROS), the Impact of Weight on Quality of Life (IWQOL), and GQLI assessment tools to evaluate postoperative quality of life surgery. Both studies found that OAGB and RYGB significantly improved the quality of life of obese patients in both overall and different domains except gastro-intestinal symptoms without intergroup difference (Table 5). T-study detected an increase of gastro-intestinal symptoms in both groups but without inter-group difference.

Using routine endoscopy screening, the Y-study found that bile in the gastric pouch was present in 16% of patients in the OAGB group versus none in the RYGB. Gastritis and esophagitis were also non-significantly more common in the OAGB versus RYGB group. However, none of these findings caused any symptoms in the quality of life study.

### Discussion

YOMEGA is a high-quality RCT that provided important information in the field of bariatric/metabolic surgery, in which sufficient amounts of evidence-based medicine are lacking. Our analysis revealed that the Y-study results were similar to those of the T-study, the first pioneer RCT reported by Lee et al. from Taiwan [9]. Although the methodology and quality of T-study are not high according to today's standards, the findings are now confirmed by the Y-study, including OAGB is simpler and possibly safer than RYGB; OAGB boasts non-inferior or superior weight loss than RYGB; OAGB resulted in better glycemic control than RYGB at the cost of a higher incidence of malnutrition. The incidence of bile reflux was low in OAGB and did not influence the quality of life comparing to RYGB. These findings are in accordance with recent studies of meta-analysis [16, 17] and retrospective matched comparison [18–20].

Both studies demonstrated that OAGB is a simpler and easier procedure than RYGB by showing a significantly shorter operation time for OAGB than RYGB. However, the operation time was much shorter in the Y-study than in the T-study. This reduction in operation time reflected the improved technique and shortened learning curve of both procedure, especially for laparoscopic RYGB. Concerning the safety, there was only a weak support that OAGB is safer than RYGB. The support for this is based on significantly increased complication rate in the T-study. However, although the complication rate was higher in RYGB than in OAGB, there is no significant difference between groups in the Y-study. There is also no significant difference in conversion rate. Although both studies demonstrated a lower surgical complication rate for OAGB, the major complication rate of RYGB decreased from 5% in the T-study to 2% in the Y-study. The improved safety of RYGB over the past 15 years may be attributed to the improved technique, especially mesentery defect closure [21, 22]. Other factors included a shortened learning curve, center of excellence certification, and the surgical quality

**Table 5** Comparison of quality of life and bile reflux after OAGB and RYGB in the YOMEGA and Taiwan studies [9, 14]

	YOMEGA			TAIWAN		
	OAGB (n = 117)	RYGB (n = 117)	P value	OAGB (n = 249)	RYGBP (n = 157)	P value
Bile in gastric pouch	16% (9/58)	0% (0/63)	NS	NA	NA	
Gastritis	19% (11/58)	6% (4/63)	NS	NA	NA	
Esophagitis	10% (6/58)	3% (2/63)	NS	NA	NA	
BAROS $\geq$ good	93% (54/63)	86% (63/67)	0.15	NA	NA	
IWQOL						
Physical	+ 20.4 (11.9)	+ 21.5 (8.4)	0.51	NA	NA	
Self-esteem	+ 11.2 (9.3)	+ 12.1 (6.8)	0.52	NA	NA	
Public stress	+ 5.5 (6.2)	+ 6.1 (3.8)	0.52	NA	NA	
Work conditions	+ 4.0 (3.2)	+ 3.0 (8.0)	0	NA	NA	
GQLI overall	NA	NA		113.9 (17.0)	113.3 (16.1)	NS
GI symptoms	NA	NA		58.9 (10.3)	60.1 (9.0)	NS
Physical	NA	NA		21.3 (4.2)	20.9 (4.8)	NS
Emotional	NA	NA		15.8 (4.8)	15.0 (3.7)	NS
Social	NA	NA		17.9 (6.1)	17.3 (2.8)	NS
Trouble with diarrhea#	19.7% (14/71)	7% (5/71)	0.04*	3.0@	2.9	NS
Abdominal bloating#	NA	NA		2.8@	2.8	NS
Eating with pleasure#	NA	NA		2.6@	2.7	NS
GERD	5.6% (4/71)	1.4% (1/71)	0.15	3.6@	3.8	NS

Data are mean (SD)

BAROS Bariatric Analysis and Reporting Outcome System, IWQOL Impact of Weight on Quality of Life, GQLI Gastrointestinal Quality of life Index, GI gastro-intestinal, NS not significant, NA not available, @, score of GIQL, higher is better (maximum 4 for each item), GERD gastro-esophageal reflux disease

improvement program [23–26]. However, RYGB remains a technically challenging procedure; there were some patients (two in Y-study, one in T-study) in the RYGB group versus none in the OAGB of the Y-study required conversion to another procedure because of technical difficulties.

The most important benefit of OAGB is that it resulted in better glycemic control and a possible higher T2D remission rate than RYGB. Although the support of this is weak based on the Y-study, 1% difference in HbA1c decrease ( $p = 0.025$ ) and 60% T2D remission rate of OAGB versus the 38% in RYGB ( $p = 0.28$ ), the reason might be due to the small case number (36 T2D patients). We did not analyze the T2D remission rate in T-study, but we had a similar finding in our following report with 406 T2D patients (249 OAGB, 157 RYGB) [27]. The difference in HbA1c reduction was also around 1% between the OAGB and RYGB groups at 1 year after surgery but resulted in a significantly higher T2D complete remission rate in the OAGB versus RYGB group (81.9% vs. 55.4%, respectively;  $p < 0.001$ ). At 5 years after surgery, OAGB still had a better T2D remission rate than RYGB (70.5% vs. 39.4%;  $p = 0.002$ ). Other studies also had the similar findings [16–20].

The better glycemic control of OAGB might be derived from the anti-diabetic effect of a long BP limb. The Y-study

and T-study used a 50-cm BP limb in RYGB and 200-cm BP limb in the OAGB. Randomized trials showed better weight loss and glycemic control with a longer versus shorter BP limb [28–30]. Animal studies also demonstrated the importance of BP limb length and that the effect of metabolic disorder control might be related to the serum bile acid levels [31–34]. The longer the BP limb, the higher the serum bile acid level [34, 35].

The most important disadvantage of OAGB was the associated malabsorptive effect with higher risk of malnutritional problems. Both studies demonstrated a significantly lower hemoglobin level in the OAGB versus RYGB group at 2 years after surgery. Serious adverse nutritional complications were detected in nine (7.7%) patients of the OAGB group versus none in the RYGB group of the Y-study. These results corroborated our findings in OAGB at long-term follow-up, but are lower than the 20% incidence of malnutrition of true malabsorptive procedures [20, 36, 37]. The reason for the high malnutrition incidence rate after OAGB is use of the 200-cm BP limb which may be too long for low BMI patients. We had recommended to use 150-cm BP limb for those with patients with a lower BMI (35–40 kg/m<sup>2</sup>) [38]. In the Y-study, the pre-operative BMI was 43 kg/m<sup>2</sup>, and about half of the patients had BMI < 40 kg/m<sup>2</sup>. Another reason for the high incidence of malnutrition

after OAGB problems is probably due to the wide variety of small bowel lengths. We had found that patients with intractable protein deficiency usually had a shorter bowel length that resulted in an inadequate common channel length [39]. By measuring the entire small bowel length and maintaining a common channel longer than 400 cm, we could avoid most malnutritional problems after OAGB.

There were some controversies about bile reflux and marginal ulcer about OAGB before, but none of them was supported by both Y-study and T-study. Although routine endoscopy revealed that 16% of OAGB patients versus none of the RYGB patients had bile in the gastric pouch in Y-study, the clinical significance of this finding is unclear. There was no difference in the frequency of gastro-esophageal reflux disease or quality of life evaluation at follow-up between OAGB and RYGB. In the long-term follow-up study, the revision rate was both around 5% for OAGB and RYGB, a finding that corroborated with that of the Y-study [40–43]. The reasons for OAGB revision were malnutrition, marginal ulcer, and bile reflux. By measuring the entire small bowel length, we may reduce the incidence of malnutrition after OAGB in the future.

Although RYGB is now a safe and effective bariatric procedure, chronic abdominal pain remained to be the major disadvantage of RYGB. There were five cases with severe adverse events of abdominal pain after RYGB and none in OAGB in Y-study. A recent large cohort study disclosed that severe self-reported abdominal pain occurred in 21% of patients undergoing RYGB, and chronic abdominal pain occurred in 11% [44].

The limitations of this study included having one small and one mid-size RCT to base conclusions on. Although there was another RCT including sleeve gastrectomy, RYGB and OAGB, this study was not recruited for comparison because of difference in design, lack of data of intraoperative parameters, and quality of life evaluation [20]. Another limitation was the rather huge difference in age (12 years) at surgery might influence the results on diabetes remission and weight loss. The last limitation was lack of long-term follow-up. However, existing long-term non-RCT studies have provided enough data for comparison [18–20, 42, 43, 45–49].

In conclusion, the YOMEGA was an important clinical study for continually improving bariatric/metabolic surgery. OAGB is a technically easier and safer procedure than RYGB. OAGB had a greater mal-absorptive effect than RYGB but features better glycemic control than RYGB. Thus, OAGB may be considered in high-risk patients and those with super obesity, T2D, or habitual constipation. However, measuring the entire bowel length was recommended for tailoring the BP limb in OAGB. More RCTs are needed to evaluate the issue about limb length in both OAGB and RYGB. The controversy of bile reflux requires elucidation after longer follow-up.

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## Compliance with Ethical Standards

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

**Informed Consent Statement** For this type of study, formal consent is not required.

**Ethical Approval Statement** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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