

Non Inferiority Clinical Trial Comparative Between Laparoscopic Roux-En-Y Gastric Bypass Versus Laparoscopic One Anastomosis Gastric Bypass in Morbid Obesity Patients

Willberto Medina Aguirre¹, Edgard Efrén Lozada Hernández^{1*}, Norberto Muñoz Montes², Judith Rodríguez García³ and Alberto Aguilar Garcia⁴

¹General Surgery, Hospital de Alta Especialidad del Bajío (HRAEB), UNAM, Mexico

²Bariatric Surgery, Hospital de Alta Especialidad del Bajío (HRAEB), UNAM, Mexico

³Department of Nutrition, Hospital Regional de Alta Especialidad del Bajío (HRAEB), UNAM México

⁴Department of Endocrinology, Hospital Regional de Alta Especialidad del Bajío (HRAEB), UNAM México

***Corresponding Author:** Edgard Efrén Lozada Hernández, General Surgery, Hospital de Alta Especialidad del Bajío (HRAEB), UNAM, Mexico.

Received: July 11, 2019; **Published:** August 08, 2019

Abstract

Bariatric surgery has proven to be the most effective option on severe obesity treatment and almost the only one that achieves enough long-term results unless for 60% of the patients in comparative with conservative methods; improve the quality-life and resolves comorbidity related to obesity. Reduce the mortality and morbidity in morbid obesity patients.

The preferential techniques of bariatric surgery includes the gastric band, gastric sleeve, the laparoscopic Roux-en-Y gastric bypass (RYGB) and the laparoscopic One-anastomosis gastric bypass (OAGB) or Mini-bypass. The RYGB is the gold standard bariatric procedure, but nevertheless the OAGB has proven to be a safe procedure with less complications and similar or better results than the RYGB. We report a non inferiority clinical trial, comparative, prospective, longitudinal, double blind between the RYGB and the OAGB.

Were realized 52 bariatric surgery procedures. The group A was confirmed by 25 patients, which they were operated by OAGB, 17 women and 8 men, three patients from this group were lost of the six months follow-up. The group B includes 30 patients: 21 women and 9 men, which they were treated by RYGB. Clinical data were collected for both groups following 6 months after surgery. The loss of weight excess on the OAGB group was 61.4%, meanwhile for the RYGB group was 57.3% without significance statistical difference, were not identified severe complications related to surgical procedures on basis the Clavien-Dindo classification.

The OAGB is a safe procedure, feasible technically, shows a minor learning /training curve and obtains the same clinical results in weight loss compared with the RYGB.

Keywords: Bariatric Surgery; One Anastomosis Gastric Bypass; Mini-Bypass; Morbid Obesity; Laparoscopic Gastric Bypass; Roux-En-Y Gastric Bypass

Abbreviations

OAGB: One-anastomosis Gastric Bypass; RYGB: Roux-en-Y Gastric Bypass; WHO: World Health Organization; BMI: Body Mass Index; WL: Weight Loss; %EWL: Percentage of Excess Weight Lost; %EBMIL: Percentage of Body Mass Index Lost; LGS: Laparoscopic Gastric Sleeve

Citation: Edgard Efrén Lozada Hernández, *et al.* "Non Inferiority Clinical Trial Comparative Between Laparoscopic Roux-En-Y Gastric Bypass Versus Laparoscopic One Anastomosis Gastric Bypass in Morbid Obesity Patients". *EC Gastroenterology and Digestive System* 6.9 (2019): 766-771.

Introduction

The obesity has been converted in a main health problem and increases quickly globally. The severe obesity increases progressively, mainly in children and young people. The morbid obesity and super-obesity represents a severe chronic and disabling disease that reduces quality and expectation of life, as well as causes incalculable economical and social losses.

World Health Organization (WHO) data mentions since 1980 the obesity has been increasing more than the double of cases on worldwide. On 2008, 1500 millions of people had weight excess, by the way, the WHO declares obesity and overweight as a global epidemic problem [1].

In Mexico, the National Health and Nutrition Survey (ENSANUT) 2016 evaluated the prevalence of overweight and obesity in children, adolescents and young adults, reporting increases in comparison with 2012 data on the three age-population groups [2,3]. On the adult population, the overweight and the obesity increases from 6.1% at 2012 to 69.9% for 2016. Nowadays 7 from each 10 adults (72.5%) continue to suffer overweight and obesity [3].

The body mass index (BMI) is used to classify the overweight and the obesity in adulthood. The WHO define the overweight as BMI > 25 kg/m² and the obesity as BMI > 30 kg/m², this categorized by grade I (30.0 - 34.9 kg/m²), grade II (35.0 - 39.9 kg/m²), grade III as morbid obesity more than 40.0 kg/m² [1].

The obesity treatment includes bariatric surgery and non-surgical treatment. These non-surgical treatment seems a multidisciplinary way that includes life style changes and pharmacological therapy [4].

Bariatric surgery has proven to be the most effective treatment for the severe obesity and almost the only one that shows long term results in more than 60% of the patients in comparison to conservative methods; improve life quality and resolves comorbidity obesity-related. Reduces the mortality and morbidity in morbid obese patients [4].

The guidelines recommend bariatric surgery for BMI > 40 kg/m² and > 35 kg/m² patients whose suffer severe comorbidity related to obesity [5].

The loss of weight results can be expressed in different ways: 1. Absolute amount lost kg, 2. Percentage of weight lost (%WL), 3. Percentage of excess weight lost (%EWL), 4. Percentage of excess BMI lost (%EBMIL).

Nowadays we do not have any consensus about which one is the measure of weight loss for the evaluation in bariatric patients, nevertheless in the studies describing weight loss, shows an excellent correlation between %EWL and %EBMIL meanwhile, for this study the measure of weight loss were expressed by %EWL. The weight loss success is valued by the Reinhold modified criteria. A great result is considering %EWL > 65%, a good/enough result 50 - 60% and failure for < 50%. In proportion, the maximal variation can be observed 6 months after surgery.

Into the main bariatric surgery techniques we can found the gastric band, gastric sleeve (LGS), RYGB and OAGB or Mini-bypass.

The BGYR is the bariatric surgical procedure more frequently realized and represents 45% into all the bariatric procedures. The surgical intervention consist in perform a gastric reservoir between 20 to 30 ml and after that requires gastrojejunostomy of 1.5 to 2.0 cm and yeyuno-yeyuno latero-lateral Roux-en-Y anastomosis with a 60 cm loop bilio-pancreatic and a 120cm alimentary loop [6].

The OAGB consists of making a large and narrow gastric reservoir between 13 to 15 cm large, with capacity 25 - 30 ml since gastroesophageal junction to the minor gastric curvature. after that, the reservoir has latero-lateral anastomosis directed to an intestinal loop between 200 to 350 cm after the Treitz angle [7].

The Mini-bypass was described on 2001 by Rutledge with an initial experience of 1,274 patients followed-up 2 years proving a weight loss from 51% at 6th month, 68% at 12 months and 77% after 24 months, furthermore less surgical timing and less surgical-related complications than RYGB, considered as gold standard of surgical bariatric procedures [8].

Chakhtoura on 2008 reported weight loss $51 \pm 13\%$ at 6th month after surgery in a retrospective study realized in 100 patients whose perform OAGB [12].

Another study, reported by Carbajo in 2017, which describes MBP in 100 patients with 24 months follow-up, proving weight loss until 87% for 6 months after surgery considered an excellent result respect weight loss [11]. AT the same way, another study realized by Lessing, *et al.* in 2017, in 407 patients performed OAGB achieving an excess weight loss $69.8 \pm 18.7\text{kg}$ [16].

Exist controversial reports about the efficacy and the adverse events related to this procedure. Nevertheless diverse retrospective published studies comparing RYGB and OAGB have shown the safety and efficacy of MBP [9].

In spite of both surgical techniques can be safe performed by expert surgeons, the OAGB is a safer procedure. Systematical reviews proved that OAGB has unless, same efficacy than RYGB about weight loss and comorbidity resolution. Shows a smaller learning curve and is associated to less major complications [10].

In another retrospective comparative study between RYGB and OAGB with 10 years follow-up reported by Lee, describes that after 5 years, the OAGB patients had less IMC (27.7 vs 29.2) and greater weight loss (72.9% vs 60.1%) without significative difference respect comorbidity [6].

Carbajo in 2016 published results of OAGB in 1200 patients 12 years followed up concluding safety and effectivity of this procedure. With a 12-year follow-up concluding that the safety and effectiveness of this procedure. Proving less complexity for the surgical technique, reduction for the surgical timing and lower surgical complication incidence at short and long term. (internal hernia, anastomosis leakage, marginal ulcer, biliary reflux) [7].

Some of the concerns about MBP were the after-surgery esophagitis and gastritis caused by alkaline biliary reflux, but in this procedure the alkaline reflux is not a real problem because the anastomosis is performed in the low gastric area far from the esophagus. Exist published information in the last 16 years proving low alkaline reflux incidence in patients treated with OAGB [10].

The internal hernia continues been the main complication after RYGB and one of the causes for surgical re-intervention with estimate incidence 4 to 14% [6-10] meanwhile for the OAGB this risk do not exist.

Both types of gastric bypass shown a similar effect for the morbid obesity treatment. This procedures can resolve obesity related complications and improve life quality without difference [8].

A study published on 2017 including 1520 patients of whom 683 suffer type 2 Diabetes were treated by OAGB between 2009 and 2015 and prove diabetes remission on 84.1% of these patients, defined by glyated hemoglobin value less than 6.0% without pharmacological treatment after 1 year. In the same way, the MBP shows a glyceimic better control than RYGB [13]. At 2017, Carbajo proves diabetes remission in 94% of his group, and for 2018, Abu-Abeid reports diabetes remission in 91.1% [15].

In the last systematical review published on 2017 describes better dyslipidemia, arterial systemic hypertension, and type 2 diabetes remissions, 1 year after OAGB surgery compared LGS [17].

Other advantages observed in the OAGB in comparison RYGB are surgical materials reduction and in consequent less costs and surgical timing [6-10].

Actually, do not exists any justification to restrict the performing of OAGB as one of the main bariatric surgical techniques, for this reason, we realized a prospective study comparing both surgical techniques and our results.

Materials and Methods

We realized a non inferiority clinical trial study, comparative, prospective and longitudinal. The universe was confirmed by all the patients in the period since 2016 January to 2018 August, between 18 and 60 years old with BMI more or equal to 35 kg/m² and had comorbidity related, BMI more or equal to 40 kg/m² that accept to participate in this study and sign the informed application. The blindness of the study was double blind as well the patient and who realized statistical analyses unknown the surgical technique performed. Data analyses records 6 months after surgery.

We calculate the sample size in basis of in our hospital realize 60 gastric bypass per year, achieving 50% weight loss at 6th month after surgery considering this goal as effective/successful non-inferiority treatment 10%, 80% statistical power and alpha 0.05% for one tail, resulting a total 25 patients per group. Calculate an estimated of follow-up loss 10% resulting 22 patients per group.

Using SPSS 21-Windows software, we realized descriptive statistics for describe the variable’s distribution. The quantitative normal distribution variables were reported as media and standard deviation and the comparison between groups was performed by T student test for independent groups, in case of do not have normality criteria the variables were reported as mean and inter-quartile range 25 - 75% and the comparison between groups was calculated by U Mann Whitney. The qualitative variables were reported as frequency and percentage and the comparison between groups was realized by X² test or Fisher exact test depends of case. Non inferiority result was evaluated by confidence intervals 95% comparing proportion of effective/successful treatments in patients for both surgical methods. The *p* values less than 0.05% was considered as statistical significance.

Results and Discussion

Were realized 53 bariatric procedures in the study period. The A group conformed by 25 patients treated by OAGB technique: 17 women and 8 men of whom 3 patients were lost of 6 months follow up. The B group patients were treated by RYGB conformed by 30 patients: 21 women and 9 men, everyone continues at follow up analysis.

Variable	OAGB	RYGB	p value
Cases	22	30	NA
Gender	Women 15 (68.1%) Men 7 (31.9%)	Women 21 (70%) Men 9 (30%)	NS
Age	40.9 ± 9.8	42.1 ± 10.9	0.69
Size (m)	1.62 ± 0.08	1.62 ± 0.008	0.97
Inicial weight (kg)	143.95 ± 32.4	128.57 ± 21.03	0.043
Initial BMI (kg/m ²)	54.2 ± 10.53	48.8 ± 7.81	0.037
Comorbidity			
Type 2 Diabetes	7 (31.9%)	6 (20%)	0.51
Arterial Hypertension	11 (50%)	10 (33.3%)	0.263

Table 1: Demographical characteristics of patients before surgery. OAGB: One-anastomosis Gastric Bypass; RYGB Roux-en-Y Gastric Bypass; BMI: Body Mass Index.

We realized T-Student test for independent samples, showing homogeneous and comparable groups.

Data were collected from both groups at 6th month after surgery procedure, described in table 2.

Variable	OAGB (22)	RYGB (30)	p value
6 Months weight (kg)	97.39 ± 22.03	92.87 ± 16.36	0.399
6 Months BMI	36.68 ± 6.91	35.23 ± 6.08	0.427
% Excess of weight loss	61.42 ± 15.2	57.30 ± 14.25	0.322

Table 2: Six months after surgery results.

In our study we do not found any difference respect the excess of weight loss at 6 months after surgery OAGB or RYGB evaluation.

The initial weight in the group treated by OAGB was higher at moment study starts because that is possible to inference weight loss were quicker in the first 6 months after OAGB surgery than RYGB, nevertheless, applying statistical tests do not result any statistical significance difference (Table 2).

We confirm the study hypotheses proving OAGB is equivalent respect weight loss in comparison than RYGB considered by literature, the election bariatric procedure nowadays.

In accordance with Lee, *et al.* [6] and Parmar, *et al.* [14] OAGB shows been superior than RYGB in the weight loss at first 6 months after surgery.

Our study reports an excess of weight loss by OAGB 61.4% and 57.3% by RYGB without statistical significance difference.

On the follow up period, the patients treated by OAGB no developed any major complication surgery-related, so is possible inference that is a safe procedure and reduce the risk of present major complications surgery related as internal hernia example.

OAGB results to be a surgical procedure, less technically complex, less supplies and materials, and in consequence less surgical timing and hospital costs, by this way have advantages in comparison than RYGB.

Study Limitations

One of the limitations in the present study is the follow up period, in basis exists better results in weight loss achieved at 12 and 24 months after surgery. Another one could be no describes complete observations about differences in comorbidity resolutions, patients satisfaction, return of them to work and social activities, these results can be long term evaluated. For now, do not have any differences en all these items between both procedures at 6th month after bariatric surgery.

Conclusion

The OAGB is a safe surgical procedure with technically feasibility, showing smaller learning curve and obtained the same or equivalent weight loss results than RYGB that is considered the election treatment on bariatric surgery.

The OAGB is superior respect weight loss between the first 6 months after surgery.

In conclusion, in our study, as reported literature, we do not found technical, medical or another contraindications for not perform the OAGB as main procedure for the morbid obesity treatment.

Conflict of Interest

The authors declares any interest conflict.

Bibliography

1. Ulijaszek S. "Obesity: Preventing and Managing the Global Epidemic. Report of a WHO Consultation". *WHO Technical Report Series* 894 (2000): 252.
2. Juan Pablo G., *et al.* "Encuesta Nacional de Salud y Nutrición 2012. Estado de nutrición, anemia, seguridad alimentaria en la población Mexicana". *ENSANUT* (2012): 33.
3. Hernández M., *et al.* "Encuesta Nacional de Salud y Nutrición de Medio Camino 2016 ENSANUT MC. Informe final de resultados. Instituto Nacional de Salud Pública". *ENSANUT* (2016): 6-12.
4. Colquitt J., *et al.* "Surgery for weight loss in adults". *Cochrane Database of Systematic Reviews* 8 (2014): CD003641.
5. Gloy VL., *et al.* "Bariatric surgery versus non-surgical treatment for obesity: a systematic review and meta-analysis of randomised controlled trials". *BMJ* 347 (2013): f5934.
6. Lee W., *et al.* "Laparoscopic Roux-en-Y Vs. Mini-gastric Bypass for the Treatment of Morbid Obesity: a 10-Year Experience". *Obesity Surgery* 22.12 (2012): 1827-1834.
7. Carbajo M., *et al.* "Laparoscopic One-Anastomosis Gastric Bypass: Technique, Results, and Long-Term Follow-Up in 1200 Patients". *Obesity Surgery* 27.5 (2016): 1153-1167.
8. Rutledge R. "The Mini-Gastric Bypass: Experience with the First 1,274 Cases". *Obesity Surgery* 11.3 (2001): 276-280.
9. Mahawar K., *et al.* "Current status of mini-gastric bypass". *Journal of Minimal Access Surgery* 12.4 (2016): 305-310.
10. Mahawar K., *et al.* "Mini Gastric Bypass: Systematic Review of a Controversial Procedure". *Obesity Surgery* 23.11 (2013): 1890-1898.
11. Carbajo M., *et al.* "Evaluation of Weight Loss Indicators and Laparoscopic One-Anastomosis Gastric Bypass Outcomes". *Scientific Reports* 8.1 (2018): 1961.
12. Chakhtoura G., *et al.* "Primary Results of Laparoscopic Mini-Gastric Bypass in a French Obesity-Surgery Specialized University Hospital". *Obesity Surgery* 18.9 (2008): 1130-1133.
13. Taha O., *et al.* "Outcomes of One Anastomosis Gastric Bypass in 472 Diabetic Patients". *Obesity Surgery* 27.11 (2017): 2802-2810.
14. Parmar C., *et al.* "Management of super-super obese patients: comparison between one anastomosis (mini) gastric bypass and Roux-en-Y gastric bypass". *Surgical Endoscopy* 31.9 (2016): 3504-3509.
15. Abu-Abeid A., *et al.* "Diabetes resolution after one anastomosis gastric bypass". *Surgery for Obesity and Related Diseases* 14.2 (2018): 181-185.
16. Lessing Y., *et al.* "One-Anastomosis Gastric Bypass: First 407 Patients in 1 year". *Obesity Surgery* 27.10 (2017): 2583-2589.
17. Magouliotis D., *et al.* "One-Anastomosis Gastric Bypass Versus Sleeve Gastrectomy for Morbid Obesity: a Systematic Review and Meta-analysis". *Obesity Surgery* 27.9 (2017): 2479-2487.

Volume 6 Issue 9 September 2019

©All rights reserved by Edgard Efrén Lozada Hernández., et al.