



RESEARCH ARTICLE

OUTCOME FOLLOWING BANDED VS. NON-BANDED ROUX-EN-Y GASTRIC BYPASS, A
LONGITUDINAL STUDY

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ARTICLE INFO

Article History:

Received 13th April, 2018
Received in revised form
19th May, 2018
Accepted 28th June, 2018
Published online 31st July, 2018

Key words:

Roux en Y gastric bypass,
Banded RYGB,
Non-banded RYGB,
Resolution of comorbidities.

ABSTRACT

Background: Banded Roux-en-Y gastric bypass is a further modified standard RYGB which was designed in a view to achieve greater weight loss and avoid or diminish weight regain in the long term. There is conflicting evidence as whether the banded RYGB is better than standard non-banded type and lack of literature in this part of south India made us to conduct this study.

Objectives: To compare the outcomes in terms of mean weight loss, % excess weight loss, significant weight loss and resolution of comorbidities among banded and non-banded Roux-En-Y Gastric Bypass groups at 1 year of post-operative period.

Methodology: A longitudinal observational study was carried out at two tertiary care hospitals in the Department of Laparoscopic and Bariatric Surgery, Bangalore in 109 morbidly obese patients who underwent standard non-banded RYGB and banded RYGB during January 2012 to December 2015 and were followed up till 2016 for a period of 1 year. The 1-year total weight loss, excess weight loss (%) and significant excess weight loss were comparatively analyzed using independent t test, Mann Whitney, Fisher's exact test and Chi-square test wherever, required. A P value of <0.05 was taken as statistically significant

Results: Among 109 patients who underwent RYGB, 67.9% underwent non-banded RYGB and 32.1% banded RYGB. The mean age of study subjects was 43.91yrs with a standard deviation of 11.71yrs and females predominated the study and both the groups were comparable in all the socio-demographic characteristics except for age and presence of hypertension. Mean Total Weight loss, Median Excess Weight loss, >50.0% BMI loss, resolution of comorbidities were nearly similar and not significantly different in both the study groups. (P>0.05)

Conclusion: Both banded and non-banded RYGB were equally effective in reducing excess weight loss and resolution of comorbidities at the end of 1 year of post-operative period. On comparing with other literatures, highlights the requirement of long term follow up.

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Citation: Dr Piara Singh, Dr. Makam Ramesh, Dr. Tulip Chamany and Dr. Amarpreet Marwaha, 2018. "Outcome following banded vs. non-banded roux-en-y gastric bypass, A longitudinal study", *International Journal of Current Research*, 10, (7), 71830-71834.

INTRODUCTION

Obesity has reached epidemic proportions globally as a result of being overweight or obese with at least 2.8 million people dying each year. Once related with high-income countries, obesity is now also prevalent in low- and middle-income countries (WHO, 2018). It has been found that the results of traditional weight loss therapies, including diet, exercise, and medications, are relatively poor in long-term. Bariatric surgery has been the most effective treatment of morbidly obese patients to allow substantial, sustained weight loss, improve or resolve obesity-associated comorbidities, thereby resulting in reduced mortality (Kissler and Settmacher, 2013). To treat moderate and severe obesity especially when associated with

type 2 diabetes, Roux-en-Y gastric bypass (RYGB) is one of the most widely used bariatric surgeries in the world (SAGES Guidelines Committee, 2009). RYGB shows good and significant health improvement and sustained weight loss in the long-term. Nonetheless, some patients either do not achieve sufficient weight loss or regain weight over time. The technical causes for weight regain after RYGB are suggested mainly to be loss of restriction due to enlargement of the gastric pouch, dilation of the gastrojejunostomy, and enlargement of the jejunum directly after the gastroenterostomy. Thus to obtain an adequate restriction possibly again is by application of an adjustable gastric band over the gastric pouch or gastrojejunostomy (Vijgen et al., 2012). Banding the pouch in a gastric bypass operation forms a banded gastric bypass operation, that is an accepted and frequently used variant of the gastric bypass operation that is reported to enhance and stabilize the weight loss (Lemmens et al., 2014; O'Brien, 2009). Bhandari et al., 2014 reported in his study that banded

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DOI: <https://doi.org/10.24941/ijcr.30850.07.2018>

gastric bypass had significantly better results in terms of weight loss, weight stability at 2 years follow-up (Bhandari *et al.*, 2016). Bessler *et al.*, 2010 in his study noted that addition of an Adjustable gastric banding (ASGB) causes significant weight loss in patients with poor weight loss outcome after RYGBP (Bessler *et al.*, 2010). Vijgen *et al.*, 2012 has observed that in case of insufficient weight loss or technical pouch failure after RYGB, all reports suggest that salvage banding is a safe and feasible revisional procedure (Vijgen *et al.*, 2012). A systematic review by Buchwald H *et al.*, who has evaluated the outcomes of 8,707 B-RYGB procedures in 15 reports of the literature published during a 23-year period, from January 1990 to November 2013 has concluded that the Banded RYGB is an effective and safe procedure, with acceptable rates of early (10.9 %) and late (20.0 %) complications. Banded gastric bypass appears to result in sustained weight loss, perhaps greater than that achieved by standard RYGB (Buchwald *et al.*, 2014). Lemmens L in his study found that there was no difference in the banded and non-banded treatment group outcomes in terms of weight loss following the first year after surgery whereas 5 years following surgery, patients who received banded surgery maintained better weight loss and had less weight regain compared to the non-banded group (Lemmens, 2017). Moon *et al.*, 2018 in his comparative study observed that Banded laparoscopic RYGB with a pericardial patch may not demonstrate a significant additional weight loss or prevent future weight regain (Moon *et al.*, 2018). Although most of the literature shows banded RYGB is better than non-banded RYGB, with the above literatures, there is conflicting evidence that exist as to whether banded RYGB can demonstrate a better long term weight loss compared to non-banded RYGB which needs further research to prove the same. Hence the current study was undertaken with the following objective.

Objectives

1. To compare the outcomes in terms of mean weight loss, % excess weight loss, significant weight loss among banded and non-banded Roux-En-Y Gastric Bypass groups at 1 year of post-operative period.
2. To compare the resolution of comorbidities (Diabetes, Hypertension and Dyslipidemia) among banded and non-banded Roux-En-Y Gastric Bypass groups at 1 year of post-operative period.

MATERIALS AND METHODS

This was a longitudinal study conducted at two tertiary care hospitals in the Department of Laparoscopic and Bariatric Surgery, Bangalore among the patients undergoing gastric bypass surgery between January 2012 to December 2015 and were followed up till 2016 for a period of 1 year. A total of 109 obese study subjects who underwent gastric bypass surgeries in the two tertiary care hospitals during the study period were selected by convenient sampling and included in the study. Based on whether a band (the GaBP Ring™, Bariatric Corporation, Carson, CA, USA) was implanted or not, the patients were categorized into a banded or a nonbanded group. Out of the 109 study subjects, 35 underwent banded RYGB and 74 underwent non banded RYGB. Ethical approval was obtained from the Institutional Ethics committee. After obtaining the written informed consent, detailed clinical history was taken from the study subjects using a pre-tested semi-structured questionnaire. Preoperative data collected

included age, gender, weight, height, body mass index (BMI) and presence comorbidities like hypertension, diabetes, hypothyroidism, IHD. Comorbidities were only defined after physician evaluation as per departmental protocol. Operative data included operative procedure, band implantation or not. Postoperative data included weight loss (reduction in weight, BMI, excess weight loss), comorbidity resolution and complications if any. Follow up was done every 6 months for a period of 1 year after surgery. Patients not adhering to the protocol and those without a complete 1-year follow-up were excluded from this study and analysis. Statistical analysis was done using chi square test for qualitative data and t test for quantitative data. A *P* value of <0.05 was considered significant.

Surgical techniques: All the subjects underwent Roux-en-Y Gastric Bypass (RYGB). For banded RYGB along with the standard technique for RYGB, including creating 150-cm antecolic antegastric Roux limb and using a linear-stapler technique to create a < 2-cm gastrojejunostomy(GJ) and an approximately 15–20-mL gastric pouch. After the GJ anastomosis was formed, a 10 cm long 8F silicone ring was placed around the pouch, at a distance 1–2 cm below the esophago-gastric junction through an opening in the lesser omentum. A 2-0 silk suture was used to secure both end and close the ring to create a 6.5-cm circumference ring. Interrupted plication sutures were inserted to fix the silicone ring to the gastric pouch.

Outcome: After the surgery all the subjects were followed up for a period of 12 months to study the weight loss pattern and resolution of comorbidities (Diabetes Mellitus, Hypertension, Dyslipidemia) among banded versus non banded gastric bypass surgeries.

Weight loss: Body weights were measured at baseline i.e., 1 week pre-surgery and 6 and 12 months post-surgery. Our primary endpoint was comparison of percentage of mean change in weight, BMI, excess weight loss 12 months after surgery between groups.

Operational Definitions: Excess body weight was defined as measured body weight minus the body weight that would result in a BMI of 25 kg/m², which in simple terms would mean measured body weight minus ideal body weight (IBW) (Praveenraj *et al.*, 2016).

Significant excess body weight loss: % Excess body weight loss ≥ 50 % 12 months after surgery was considered as significant excess weight loss.

Diabetes control: Glycosylated haemoglobin (HbA1c), fasting blood glucose (FBS) and post prandial blood glucose (PPBS) were also recorded at 1 week pre-surgery and 6 and 12 months post-surgery. Diabetes was considered resolved in patients who had a normal HbA1c, and who required no diabetic medications after surgery. Patients were considered improved if there was significant improvement in FBG (by >25 mg/dL) or if there was a significant reduction of HbA1c (by >1%), or if there was a significant reduction in diabetes medication or dose (by discontinuing one agent or 1/2 reduction in dose) (Praveenraj *et al.*, 2016; Sarmah, 2012).

Dyslipidemia: Dyslipidemia was defined according to NCEP ATP-III guidelines: Total cholesterol > 200 mg/dl TG >150 mg/dl, HDL cholesterol <40mg/dL (Singhal *et al.*, 2016).

Table 1. Clinical characteristics of the patients with age groups of <45 years and ≥45 years

Variables	Non-banded RYGB n=74	Banded RYGB n=35	P- Value
Age (Mean±SD)	46.30±11.48	38.86±10.65	0.002*
Gender (%)			
Males	33 (44.6)	10 (28.6)	0.11
Females	41 (55.4)	25 (71.4)	
Pre-op BMI	41.04±8.59	41.93±7.77	0.60
Pre-op Weight	108.18±22.08	108.94±23.77	0.87
HTN (%)	29 (39.2)	08 (17.1)	0.02*
DM (%)	36 (48.6)	12 (34.3)	0.16
DL (%)	59 (79.7)	31 (88.6)	0.26

*significant at P <0.05. For continuous variables: mean±standard deviation, categorical variables in absolute numbers and proportions (%) showing the greatest frequency

Table 2. Comparison of descriptives of weight loss after bariatric surgery

Variables	Non-banded RYGB n=74 (Mean±SD)	Banded RYGB n=35(Mean±SD)	P- Value
Mean Total Weight loss (%)§	45.75±14.54	46.97±19.75	0.11
Median Excess Weight loss (%)¥	114.23 (92.69 – 145.15)	109.19 (95.52 – 120.58)	0.38
>50.0% BMI loss (%)²	74 (100.0)	34 (97.1)	0.32
Control of Diabetes (HbA1c<6.5%) (%)*	54 (73.0)	28 (80.0)	0.43
Control of Hypertension (%)	74 (100.0)	34 (100.0)	-
Control of Dyslipidemia (%)	74 (100.0)	34 (100.0)	-

§-Independent t-test applied; ¥-Median (IQR) and Mann Whitney U test applied; ²-Fisher's exact test applied; * -Ch-square test applied
BMI-Body Mass Index; SD - Standard Deviation; %TWL - % Total Weight Loss, calculated as 100 x (Weight Reduction/ Initial weight); %EWL - % Excess Weight Loss, calculated as 100 x [BMI Reduction/ (Initial BMI – 25)].

Control of Dyslipidemia: If total cholesterol levels reach ≤ 200mg/dL and LDL ≤ 100mg/dL it was considered as control of dyslipidemia (National Institutes of Health, 2001).

Hypertension Remission: Remission of hypertension was defined among those who were on antihypertensives and now has completely ceased taking antihypertensive medications.

Statistical Analysis: The collected data were entered into an excel sheet. The data were expressed in means and proportions and presented in the form of tables and graphs where ever necessary. The outcomes of bariatric surgery for means and standard deviations of the parameters viz., weight and BMI at 1 year, excess weight loss were compared. Mean total weight loss was compared using independent t- test, Median Excess Weight loss were compared using Mann Whitney U test, >50.0% BMI loss using Fisher's exact test. The resolution of co-morbidities was tested for significance using Chi-square test. The analysis was done using standard statistical package. A P value of <0.05 was taken as statistically significant.

RESULTS

Among 109 patients who underwent RYGB, 67.9% underwent non-banded RYGB and 32.1% banded RYGB. The mean age of study subjects was 43.91yrs with a standard deviation of 11.71yrs and the age group ranged from a minimum of 20yrs and a maximum of 66yrs. The mean age of the participants were significantly higher in non-banded RYGB compared to banded ones ($P<0.05$). Females predominated in both non-banded (55.4%) and banded (71.4%) RYGB. However the difference was not statistically significant ($P>0.05$). The pre-operative weight and BMI were not significantly different in non-banded and banded RYGB ($P>0.05$). The proportion of those with hypertension and diabetes were higher in non-banded type of RYGB and dyslipidemia in banded type. However the difference in proportions was not statistically different ($P>0.05$) among both the groups except for hypertension ($P<0.05$). The mean total weight loss and diabetes remission was more and better in banded RYGB

(46.97kgs and 80.0%) compared to non-banded RYGB (45.75kgs and 73.0%). The median excess weight loss was slightly higher in non-banded RYGB (114.23kgs) compared to RYGB (109.19kgs), however it was not significantly different. The proportion of those with significant weight loss, control of hypertension and dyslipidemia was similar and 100.0% in both non-banded and banded RYGB except for significant weight loss which is nearly same as non-banded. However mean total weight loss, median excess weight loss, significant weight loss, control of hypertension and dyslipidemia, diabetes remission was not statistically significantly associated with type of surgery ($P>0.05$).

DISCUSSION

Though Roux-en-Y gastric bypass (RYGB) procedure has been reported to have extremely high success rates up to 65–77% excess weight loss at 3 years in the treatment of morbidly obese individuals, evidence suggests that patients overtime have 10% failure rate of at 5 years which can be higher in certain groups such as the super-obese and also greater tendency to gain weight due to gradual increased pouch and stoma size (Christou *et al.*, 2006; Magro *et al.*, 2008; Heneghan *et al.*, 2012; Suppiah *et al.*, 2013). However, there is a 10%. Thus in order to revise failed RYGB procedures, bariatric surgeons have attempted to revise with placement of a nonadjustable or adjustable band around the gastric pouch with reasonable success rates (Vijgen *et al.*, 2012; Dapri *et al.*, 2009). Regardless of some evidence suggesting superior and durable weight loss after a banded gastric bypass, it has not become widely practiced, because of lack of comparative data between banded and the standard non-banded RYGB. With the evolving problem of super-morbid obesity in recent years, new interest has arisen in the banded gastric bypass as a promising variation of the RYGB. With an aim to compare the newer procedure, banded RYGB (32.1%) v/s non-banded RYGB (67.9%) among 109 patients the current study was taken up.²² Similarly in a study by Lemmens L has the proportion of those who underwent banded (41.2%) were lesser compared to non-banded gastric bypass (58.8%) (Lemmens *et al.*, 2014). Bessler

MA *et al.*, has noted lesser mean age (40.6yrs) among the banded group compared to non-banded group (42.6yrs) similar to the current study findings except for the significant difference in the two groups which may be due to the different study settings (Bessler *et al.*, 2010). Initial BMI among the two groups were similar in the current study and the finding is in line with the findings by Bessler *et al.* Heneghan *et al.*, have noted females as a predominant group similar to the current study. Pre-operative BMI, Comorbidities in both groups were comparable in both the groups except for dyslipidemia similar to the current study except for comparability in terms of hypertension. This slight difference might be due to different study settings (Heneghan *et al.*, 2012). The total post-op weight loss and percentage excess weight loss was slightly higher in banded group compared to non-banded in 1 yr post-operative period by Lemens LC similar to the findings in our study except for percentage excess body weight loss. No statistically significant differences were observed in weight loss and %EWL between banded and non-banded patients during the 3–12 months following surgery, indicating that both treatments were equally effective in reducing weight which is similar to our findings.⁵ Even significant excess weight loss (more than 50.0% excess weight loss) was similar in both groups which shows that both the procedures were equally good in reducing weight in the initial first year of post-operative period. Moon RC *et al.*, in their study in their mean follow up of 12 months, they concluded that they were not able to demonstrate a clear advantage of banded RYGB over non-banded RYGB in terms of weight loss which is consistent with the current study (Moon *et al.*, 2018). Bessler M *et al.*, and Arceo-Olaiz *et al.*, have not noted any significant differences in the percentage of excess weight loss at 6, 12, and 24 months postoperatively, however the banded patients in a study by Bessler *et al.*, had achieved a significantly greater percentage of excess weight loss at 36 months (Bessler *et al.*, 2010; Arceo-Olaiz *et al.*, 2008). The weight loss pattern and BMI demonstrated by Bhandari *et al.*, was significant at the end of 2 years (Bhandari *et al.*, 2016). Thus indicating the need for further follow up in the current study which was actually limited to 1 year. Bessler *et al.*, and Bhandari M *et al.*, found no differences in the resolution of co-morbidities between both banded v/s non-banded RYGB and are in line with our findings (Bhandari *et al.*, 2016; Bessler *et al.*, 2010). The sampling being convenient type, the study lacks generalizability and suggests the similar type of studies in a larger setting and involving larger samples. The limited follow up of 1 year and in addition the lesser number of subjects in banded type relative to non-banded type might act as limiting factors in demonstrating the actual effectiveness of banded RYGB over the other in the current study.

Conclusion

Both banded and non-banded RYGB were equally good and effective in reducing excess weight loss and resolution of comorbidities (Diabetes, Hypertension, Dyslipidemia) at the end of 1 year of follow up period. On comparing the results with other literatures, this study indicates the requirement of long term follow up to highlight the actual effectiveness of the banded RYGB compared to non-banded type.

Acknowledgements: I like to thank my teachers Dr Makam Ramesh and Dr Tulip Chamany and My wife Dr Amarpreet Marwaha who helped me day night to finish my study successfully.

Conflict of interest: Corresponding author and Contributing authors have nothing to disclose.

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