



## RESEARCH ARTICLE

### EFFICACY OF NON ADJUSTABLE GASTRIC BAND IN EXCESS WEIGHT LOSS OUTCOMES AND DIABETES RESOLUTION IN BARIATRIC SURGERY

\*Sharath Chandra Kaushik, Tulip Chamany and Ramesh Makam

Department of Minimal Invasive, Metabolic and Bariatric Surgery, Vikram Hospital,  
Miller's Road, Opp. St. Anne's College, Bangalore

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#### ABSTRACT

**Background:** Bariatric surgery is the most effective treatment for resolution of co-morbidities of obesity as well as weight loss. The concept of banding the neo-stomach in sleeve gastrectomy (LSG) and roux-en-y gastric bypass (LRYGB) was proposed to combat insufficient weight loss or weight regain due to pouch dilation. The aim of the study is to know the efficacy of non adjustable gastric band in weight loss outcomes of banded sleeve gastrectomy (BLSG) and banded roux-en-y gastric bypass (BLRYGB) and comparing them to the outcomes of LSG and LRYGB respectively.

**Materials and methods:** This is retrospective analysis of all the patients who underwent bariatric surgery from January 2013 to December 2014 with 1 year follow-up. Data included age, height, weight, body mass index(BMI), gender, presence of type 2 diabetes mellitus(DM), fasting blood sugar (FBS), glycosylated hemoglobin(HbA1c), lipid profile, percentage excess body weight loss (%EBWL) and resolution of DM.

**Results:** A total 230 patients (117females, 53males) were retrospectively analyzed. At one year follow up of LSG, BLSG, LRYGB and BLRYGB groups, %EBWL were 73.43±19.66, 82.41±26.33, 82.72±25.09 and 86.30±19.06 respectively. The BLSG group attained statistical significance ( $p=0.026$ ) in bariatric success and %EBWL ( $p=0.021$ ) on comparison to LSG group, but not BLRYGB to LRYGB. There was no statistical significance in DM resolution between banded and non banded procedures.

**Conclusions:** Placement of non adjustable gastric band has significant weight loss outcomes after LSG, but not after LRYGB at 1 year follow up. In DM resolution there is no significance after band placement.

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## INTRODUCTION

The prevalence of obesity is increased in the last decades. More than 80% of type 2 diabetes mellitus (DM) is related to excess weight (Vetter *et al.*, 2009, Buchwald *et al.*, 2009). Bariatric surgery is the most effective treatment for resolution of co-morbidities of obesity as well as weight loss (Dixon *et al.*, 2011, Adams *et al.*, 2007). The most commonly performed bariatric operations in India are laparoscopic sleeve gastrectomy (LSG) and Roux-en-Y gastric bypass (LRYGB) (Sandeep Aggarwal 2013). The weight regain and insufficient weight loss are attributed to sleeve dilatation and dilated pouch in LSG and LRYGB respectively (Deguines *et al.*, 2013, Madan *et al.*, 2007, Baumann *et al.*, 2011). The concept of banding the neo-stomach in LSG and LRYGB was proposed to combat insufficient weight loss or weight regain (Agrawal *et al.*, 2010, Alexander *et al.*, 2011, Heneghan *et al.*, 2014, Moon *et al.*, 2014).

Many surgeons fashioned bands or rings from materials like marlex mesh, silastic tubing, porcine graft, bovine graft, fascialata and linea alba (Alexander *et al.*, 2009). GaBP Ring™ system (Bariatec Corporation, Palos Verdes Peninsula, CA, USA) is a pre-manufactured non-absorbable, standard ring than the others (Fobi *et al.*, 2005). The data regarding these new techniques is sparse. The aim of the study is to know the efficacy of non adjustable gastric band in weight loss outcomes of banded sleeve gastrectomy (BLSG) and banded roux-en-y gastric bypass (BLRYGB) and comparing them to the outcomes of LSG and LRYGB respectively.

## MATERIALS AND METHODS

This is retrospective analysis of all the patients who underwent bariatric surgery from January 2013 to December 2014 with 1 year follow-up in a tertiary hospital with a dedicated department for bariatric surgery. Data is collected from prospectively maintained database. This is a retrospective study, so approval from hospital Ethics Committee was not required.

\*Corresponding author Sharath Chandra Kaushik,  
Department of Minimal Invasive, Metabolic and Bariatric Surgery,  
Vikram Hospital, Miller's Road, Opp. St. Anne's College, Bengal.

Informed consent was taken from all the patients to include them in the study. Patients included in the study met National Institutes of Health (NIH) guidelines for eligibility. The presence of type 2 diabetes mellitus (DM), gastro-esophageal reflux disease and patient preference determined the choice of bariatric surgery (LRYGB or LSG). The GaBP™ ring was placed on patient's preference after counseling regarding the ring. The preoperative data included age, height, weight, body mass index (BMI), gender, presence of DM, fasting blood sugar (FBS), glycosylated hemoglobin (HbA1c) and lipid profile.

### Laparoscopic banded sleeve gastrectomy

The gastro-colic and gastro-splenic omentum was divided from greater curvature close to the stomach. The sleeve is created over 36-Fr bougie, starting from 5 cm to the pylorus using linear staplers using green load near the pylorus and rest with the blue load. Intra-operative methylene blue leak test was performed. The GaBP™ ring composed of radio-opaque silicon coat was placed 3cm distal to oesophago-gastric junction through retro-gastric tunnel. The diameter of ring was 7cm.

### Laparoscopic banded roux en y gastric bypass

A 30 ml gastric pouch is created. GaBP™ ring is placed 3 cm below oesophago-gastric junction. Biliopancreatic limb of 100cm and alimentary limb of 150 cm is made. Jejunojejunostomy was constructed with 60mm white load linear stapler and enterotomy was closed with intracorporeal suturing. The gastrojejunal anastomosis was done in 4 layered hand sewn technique. Leak test was done with air insufflation through endoscope.

resolution in BLSG and BLRYGB to LSG and LRYGB respectively at 12 months follow up. Secondary aims were comparison of lipid parameters in banded versus non banded procedures at 1 year follow up.

**Statistical Methods:** Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean  $\pm$  Standard Deviation (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Analysis of variance (ANOVA) has been used to find the significance of study parameters between three or more groups of patients, Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. The Statistical software namely SAS 9.2(SAS Institute Inc., Cary, NC, USA) was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs and tables.

## RESULTS

A total 230 patients (177 females, 53 males) were retrospectively analyzed, in which 85 underwent LSG, 58 BLSG, 50 LRYGB and 37 BLRYGB. The mean age and BMI of entire patients were 40.78 years and 43.30 kg/m<sup>2</sup> respectively. All the patients who received LRYGB and BLRYGB had DM, in LSG and BLSG groups only 15 and 7 had DM respectively (Table 1). The preoperative biochemical characteristics are not statistically significant in all the four groups except for HbA1c and FBS, which are significant in

**Table 1. Preoperative patient characteristics**

Variables	LSG	BLSG	LRYGB	BLRYGB	Total	P value
Female	70(82.4%)	48(82.8%)	30(60%)	29(78.4%)	177(77%)	
Male	15(17.6%)	10(17.2%)	20(40%)	8(21.6%)	53(23%)	
Age(years)	39.87 $\pm$ 12.40	35.72 $\pm$ 12.99	47.08 $\pm$ 11.12	42.30 $\pm$ 11.00	40.78 $\pm$ 12.64	<0.001*
Weight (kg)	105.89 $\pm$ 20.27	108.60 $\pm$ 20.37	111.56 $\pm$ 22.77	112.90 $\pm$ 18.35	108.93 $\pm$ 20.62	0.258
Height (cm)	157.99 $\pm$ 8.86	157.08 $\pm$ 9.49	160.91 $\pm$ 9.48	159.39 $\pm$ 6.72	158.62 $\pm$ 8.92	0.125
BMI (kg/m <sup>2</sup> )	42.41 $\pm$ 6.76	43.77 $\pm$ 7.37	43.30 $\pm$ 8.21	44.63 $\pm$ 7.15	43.30 $\pm$ 7.31	0.437
DM	15/85	7/58	50/50	37/37	109/230	<0.001*

\* significant

**Table 2. Comparison of preoperative blood parameters in four groups of patients**

Variables	Group SG	Group BSG	Group RYGB	Group BRYGB	Total	P value
HBA1C	6.19 $\pm$ 0.97	6.07 $\pm$ 0.86	7.71 $\pm$ 1.64	7.77 $\pm$ 1.79	6.78 $\pm$ 1.51	<0.001*
Fasting blood sugar	100.32 $\pm$ 28.69	100.39 $\pm$ 26.75	143.20 $\pm$ 62.63	132.89 $\pm$ 46.03	115.22 $\pm$ 45.11	<0.001*
Cholesterol	185.51 $\pm$ 33.62	175.34 $\pm$ 32.94	174.55 $\pm$ 35.31	176.69 $\pm$ 45.02	179.19 $\pm$ 36.23	0.289
HDL	37.73 $\pm$ 6.35	37.28 $\pm$ 6.90	38.50 $\pm$ 6.83	38.11 $\pm$ 4.28	37.95 $\pm$ 6.20	0.842
LDL	122.62 $\pm$ 33.02	108.91 $\pm$ 36.17	102.48 $\pm$ 44.68	106.46 $\pm$ 39.73	111.95 $\pm$ 38.49	0.017*
TG	138.12 $\pm$ 56.67	146.68 $\pm$ 69.89	141.71 $\pm$ 69.01	163.06 $\pm$ 42.86	145.24 $\pm$ 61.47	0.237

\* significant

The patients were advised follow up once in a week in the first postoperative month, then once in a month for a year and later once in every year. Twice daily multi-vitamin, calcium and protein supplementation were recommended. Patients were screened for nutritional deficiencies at 6 month and 1 year follow up and corrected. Percentage of excess body weight loss (%EBWL) was calculated by the formula: [(initial BMI- final BMI) / (initial BMI-25)] x 100. Bariatric success was defined as more than 50 %EBWL. DM resolution defined as less than 6.5 HbA1c and non requirement of medications. Primary aim of the study included comparison of bariatric success and DM

LRYGB and BLRYGB groups (Table 2), probably due to the presence of DM in all the patients. LDL is also significantly high in LSG group. At one follow up of LSG, BLSG, LRYGB and BLRYGB groups, %EBWL were 73.43 $\pm$ 19.66, 82.41 $\pm$ 26.33, 82.72 $\pm$ 25.09 and 86.30 $\pm$ 19.06 respectively. The BLSG group attained statistical significance ( $p=0.026$ ) in bariatric success and %EBWL ( $p=0.021$ ) on comparison to LSG group, but not BLRYGB to LRYGB. Though there is significant reduction in HbA1c from preoperative to 12 month follow up in all the four groups, there is no statistical significance in DM resolution between banded and non banded



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