



RESEARCH ARTICLE

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

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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.

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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/m² 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 ²)	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

Table 3. Details of bariatric success and DM resolution

	Group LSG	Group BLSG	P value	Group LRYBG	Group BLRYGB	P value
Bariatric success (>50%EBWL)	72(84.7%)	56(96.6%)	0.026*	47(94%)	37(100%)	0.258
%EBWL	73.43±19.66	82.41±26.33	0.021*	82.72±25.09	86.30±19.06	0.467
DM resolution	7(46.7%)	2(28.6%)	0.412	24(48%)	18(48.6%)	0.952
complication	1	1		0	0	

* significant

Table 4. Comparison of bio-chemical variables @ 12 months assessment in four groups of patients studied

Variables at 12 months	Group LSG	Group BLSG	P value	Group LRYBG	Group BLRYGB	P value
Fasting blood sugar	109.93±19.24	122.47±18.75	0.023*	109.4±15.54	106.57±15.72	0.213
Hba1c	6.01±0.41	6.29±0.50	0.725	6.26±1.32	6.05±0.75	0.721
Cholesterol	173.31±43.78	147.62±43.33	<0.001*	152.86±37.08	136.05±29.19	0.035*
HDL	40.97±7.21	42.52±16.09	0.021*	38.89±7.98	35.78±5.58	0.019*
LDL	113.99±41.20	95.08±24.93	<0.001*	93.08±34.25	88.74±31.97	0.001*
TGL	111.69±36.40	113.33±30.00	0.813	125.32±34.88	107.78±24.95	0.046*

* significant

procedures. We registered 2 postoperative complications, one each in LSG and BLSG groups (Table 3). Bleeding which occurred in LSG group was controlled by re-laparoscopy on first postoperative day. Other complication was excessive vomiting at 9 months in BLSG group. On barium study there was no extrinsic compression of band on to the sleeve. On conservative management patient did not respond well, but after band retrieval patient was symptom free. In banded procedures on comparing with non-banded, there was statistical significance in cholesterol, LDL and HDL. Whereas TGL are significantly reduced in BLRYGB and not in BLSG group (Table 4).

DISCUSSION

Bariatric surgery is effective in treatment of morbid obesity, with significant reduction in co-morbidities. Insufficient weight loss and weight regain pose a great challenge in bariatric surgery. Weight regain is related to gastric pouch enlargement (Heneghan *et al.*, 2012). White *et al* reported regain of weight, following removal of band (White S *et al.*, 2005). Burton and Brown concluded that weight loss is due to early satiety rather than restriction (P R Burton *et al.*, 2011). Different band materials were used. Bessler used synthetic mesh material which had disadvantage of incorporation into the scar tissue and was difficult in removing whenever there were complications (Bessler *et al.*, 2007). In our study we used GaBP™ ring system which was originally used by Fobi. There were no ring related complications in the initial study of fifty patients compared to the other banding materials in the study conducted by Fobi (Fobi *et al.*, 2005).

The ring is available in different sizes. In 2014 Karcz *et al* published retrospective analysis of 25 obese patients who underwent banded sleeve gastrectomy. There was no statistical significance ($p=0.787$) in %EBWL at 12 month (BLSG vs LSG: 58.02 vs 58.36) between both the groups (WK Karcz *et al.*, 2014). Lemmens *et al* had a mean %EBWL of 75.2 at 1 year follow up following banded gastric bypass (Lemmens *et al.*, 2014). In the study conducted on 13 patients by Daigle *et al.*, there was mean %EBWL of 54.8 and only 58.3% patients achieved EBWL of >50% following banded sleeve gastrectomy (Daigle *et al.*, 2015). In our study there was 96.6% of bariatric success and 82.41 of %EBWL in BLSG. The retrospective study by Awad *et al* showed that weight loss benefits from banded bypass are significant only after 3 years.

Whereas in our study, there was statistical significance in %EBWL between LSG and BLSG groups in 1 year follow up, but not in the LRYGB and BLRYGB groups. This finding raises a question, whether neo-stomach created by LSG dilates more rapidly than the one created by LRYGB, for which further volumetric studies have to be done to know the rates of dilation in sleeve and gastric bypass. Lee *et al* had up to 50% DM resolution in 20 patients with mean BMI of 31 ± 2.9 kg/m² who underwent LSG (Lee *et al.*, 2010). In our study results are almost similar but the mean BMI was 43.30 ± 7.31 kg/m². But the placement of band did not have significance in terms of DM resolution. The major criticism for band application is erosion. The reported incidence of erosion of non adjustable band through gastric wall is 1%-6% (Fobi M *et al.*, 2001). In our study, for one patient band ex-plantation was done due to recurrent vomiting, probably due to mal-compliance with pouch enlargement as explained by Mason *et al* (Mason *et al.*, 2003). To the best of our knowledge ours is the first study showing statistical significance in lipid profile after application of GaBP™ ring compared to non banded LSG and LRYGB. There are many questions to be answered in regard to non-adjustable gastric band. Most important is standardization of size of band for different procedures. Others questions are the best position of the ring on the neo-stomach and the best material to secure it. There are obvious limitations of the study as it is a retrospective study. Other limitations are small case number and only 1 year follow up. So randomized control multicenter trials, with longer follow up and large studies are needed to know the efficacies of non adjustable gastric band.

Conclusion

In conclusion, the application of nonadjustable gastric band following LSG has significant effect on weight loss outcomes than non-banded LSG. Though %EBWL was more in banded LRYGB, it was not statistically significant. In DM resolution, there was no significant difference whether band was placed or not. Placement of band helps in better control of lipid parameters. Further studies are necessary for standardization of ring reinforcement and explore the safety and efficacy of the non adjustable gastric band.

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