

Original Article

METABOLIC EFFECTS OF THREE DIFFERENT BARIATRIC PROCEDURES-A RETROSPECTIVE STUDY

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ABSTRACT

Objective: In this study it is proposed to compare the effect of three different bariatric metabolic procedures such as Laparoscopic Roux-en-Y gastric bypass (RYGB) Laparoscopic Mini gastric bypass (MGB) and Laparoscopic sleeve gastrectomy (SG) on diabetes remission and reduction in co-morbidities.

Methods: A retrospective analysis of prospectively collected data base of three bariatric metabolic surgery groups were screened from the year 2010-2014 at the study centre for patients satisfying the inclusion criteria. Three follow up data at an interval of three months and a base line value for all the three groups were collected. Outcome measure the percentage of patients achieved diabetes remission according to American Diabetes Association Criteria (ADA)/International Diabetic Federation (IDF) criteria i.e. Glycosylated haemoglobin (HbA1c) <6 % or <6.5 % without active pharmacological therapy at least 1 year post surgically and percentage patients lost >60% excess body weight. Secondary outcome includes the percentage reduction in cardiovascular risk factors, changes in medication associated with diabetes and cardiovascular diseases and immediate and later complications of the three different procedures of surgery. All calculations were performed using SPSS Version 18 statistical software. Descriptive statistics included are calculation of mean and standard deviation. Chi-square test and two factor ANOVA for comparison of means between groups under study.

Results: All the three surgical groups were comparable in reducing the excess body weight, HbA1c and cardiovascular complications. Highest response to weight reduction at 9 to 12 mo was reported from MGB group which was statistically significant between groups. Percentage of patients achieved diabetes remission according to ADA/IDF criteria was not statistically significant between groups but within group it was highly significant. Hypercholesteremia reduction between MGB and GB was highly significant P value is **0.002. The lowest percentage of complications after surgery was reported by MGB group followed by SG.

Conclusion: MGB relatively a new surgical procedure seems to be a better option for treating, obesity, uncontrolled diabetes and related co-morbidities.

Keywords: Bariatric metabolic surgery, Glycosylated hemoglobin, Obesity, Type 2DM Laparoscopic Roux-en-Y gastric bypass, Laparoscopic mini gastric bypass, Laparoscopic sleeve gastrectomy, Essential weight loss % (EWL%).

INTRODUCTION

In 2013, an estimated 382 million people had type 2DM and this number predicted to rise to 592 million by 2035 according to international diabetic federation [1]. Majority of patients with Type 2DM are obese showing a close relationship between obesity and Type 2DM [2]. Obesity increases morbidity and associated complications and reduces life expectancy. The risk may be diminished if hyperglycaemia and overweight is optimized to a modest level. In the look AHEAD (Action for Health in Diabetes) trial, intensive life style intervention caused significant weight loss and improvement in glycosylated haemoglobin (HbA1c) level and was more effective than routine life style advice in achieving diabetes remission [3]. But the effect reduced from 12% at one year to 7% at four years. The weight loss associated with intensive life style modifications and oral medication are moderate and effects will not last for the long period of time. Bariatric surgery initially a weight loss surgery is becoming a most effective treatment method for the obese and diabetic patients [4]. Several factors make type 2DM challenging to treat in obese and diabetic Patients. Patients who lost weight via behavioural changes tends to regain the weight. Anti-diabetic drugs of newer classes are available but most patients fail to achieve the set goal. A variety of weight loss surgical procedures are available such as RYGB, MGB and SG but it is difficult to say which is the most effective surgical procedure based on the patient characteristics [5]. Weight loss induced by bariatric surgery is a major factor of diabetes improvement but in several studies, it is reported that improvement in diabetes status occurred even before significant weight loss was reported. Early post surgical

improvement suggests involvement of various intestinal gut hormones [6]. These observations suggest a difference in efficacies between surgical procedures depending up on the mode of surgery (restrictive, malabsorptive or combined) and patients with relatively different anthropometric characters as well as other coexisting illness. The aim of the present study was to evaluate the efficacy of these three procedures to induce weight reduction, remission or amelioration of diabetes and related co morbidities.

MATERIALS AND METHODS

The retrospective observational study was conducted at the bariatric and metabolic surgery department of Moulana hospital Perinthalmanna after receiving the institutional ethical committee approval. The study population who had undergone any of the three surgical procedures namely RYGB, SG or MGB with an age of 25-60 y, body mass index (BMI) >30 kg/m² with type 2DM for more than 2 y and HbA1c not less than 7.5%, at the base level with a minimum follow up of 18 mo, with co morbidities preferably, cardiovascular risk factors (hypertension systolic above 180 and diastolic above 85, total cholesterol above 180 mg/dl) were selected for the study. Initially there were 180 patients, 60 from each group, but lack of follow-up details only 176 patients included in the final analysis. The data were collected for a follow up period of 12 mo. The reduction in BMI and percentage of EWL, reduction in HbA1c, immediate (within 30 d reported) and late surgical complications were noted. The patient group was matched for age, gender, BMI and HbA1c, total cholesterol, and distribution of other co morbidities. Diagnosis of type 2 DM was made according to American Diabetes Association

guidelines and surgery followed fulfilment of the Consensus in Asia-Pacific 2005 criteria [7]. The initial data collected at baseline included height, weight, HbA1c, total cholesterol, cardiovascular medications, and all other baseline laboratory values. Similarly follow-up data were collected at three months interval which included changes in BMI, weight loss, HbA1c, lab values, medication use pattern, immediate and late complications of the three surgical procedures change in lab values from baseline were followed in the three groups. Weight loss is reported as the mean percentage of excess weight loss which is the standard procedure in the bariatric procedures.

Outcome measure

Primary outcome was the difference in the percentage of patients achieved complete remission <6%, or partial remission <6.5% without active pharmacological therapy at least one year post surgically according to ADA/IDF criteria. Secondary outcome includes, post surgical complication of the three procedures, percentage of patients lost more than 60% excess body weight from the baseline with percentage reduction in anti-diabetic and cardiovascular drugs and reduction in cardiovascular risk factors.

Statistics

Data collected for the study were tabulated, and the result was analyzed using SPSS (Version 18.0, SPSS Inc, Chicago, Ill). Descriptive statistics included the calculation of mean and standard deviation. Chi-square test and two factor ANOVA for comparison of parameters between groups under study. The effects were found to be significant to the least significant difference (LSD) at 5% level of significance to separate out significant parameters. If found significant in ANOVA, a Post Hoc test namely Bonferroni test was applied to separate out the independent difference between individual groups.

RESULTS AND DISCUSSION

A total of 176 patients, all diagnosed with type 2DM at base line, of which 47.7% males and 52.3% females were selected from three different surgical groups namely RYGB (N=60), MGB (N=57), and SG (N=59) screened from the electronic bariatric data base of the Moulana hospital who satisfies the inclusion criteria. The mean value of pre-surgical HbA1c, metformin dose, duration of diabetes in the entire group showed uniformity in distribution. Age, BMI insulin dose and total cholesterol had difference at base line mean values (Table 1). After surgical intervention (table 2) a significant and consistent reduction in BMI, HbA1C values was observed relative to the base line values in all the groups. In MGB the mean baseline value for BMI changed from 41.832±9.332 to 28.504±8.275, and in RYGB 47.4938±8.00 to 32.84±6.80 and in SG 40.474±4.87 to 31.28±3.758 and HbA1c there was change in MGB 8.405±1.441 to 5.993±0.88 and in RYGB 8.1681±0.366 to 5.898±0.717 and in SG 8.306±0.957 to 6.014±0.7740. In total cholesterol there was change in MGB from 192.313±7.360 to 176.221±37.718 and in RYGB 212.07±74.932 to 161.95±28.122 and in SG 207.926±5.399 to 164.140±32.643. The mean value of insulin dose shows difference at the baseline to post intervention at one year MGB 60.556±9.668 to 0 RYGB 48.17±24.67 to 0 and in SG 33.90±23.098 to 0. For all the three surgical groups at one year insulin was stopped. Oral hypoglycaemic agents were significantly reduced after one year in all groups in MGB 956.05±571.036 to 279.53±350 RYGB 1109.325±55.573 to 279.53±338 and in SG 1082.765±53.819 to 232.92±325. In all the groups' reduction of insulin dose and oral hypoglycaemic agents were highly significant between baseline values and post interventional values. Between groups reduction was uniform hence there is no statistical significance for insulin and oral hypoglycaemic agents (OHA) reduction in the three groups [8, 9].

Table 1: Baseline characteristics of patients in the three study group

Character	MGB (32.4%)	SG (33.5%)	RYGB (34.4%)
No of patients	N=57	N=59	N=60
Male%	28(49.1)	22(37.3)	34(56.7)
Female%	29(50.9)	37(62.7)	26(43.3)
Age in years	40.35±9.819	32.32±11.729	36.909±9.28
Duration DM	7.675±.12	6.1184±.18	7.625±.560
Excess Weight	45.859±25.576	44.144±13.6735	45.968±8
BMI kg/m ²	41.832±9.332	40.474±4.876	47.4938±8.00
HbA1c	8.405±1.441	8.036±0.9571	8.1681±0.366
Insulin I U	60.556±9.668	33.90±23.098	48.17±24.67
Metformin mg	956.05±571.036	1082.765±53.819	1109.325±55.573
chol-mg/dL	192.313±7.360	207.926±5.399	212.07±74.932

N=number of participants, MGB–mini gastric bypass SG–sleev gastrectomy, RYGB–Roux-en-y-gastric bypass. BMI–body mass index insulinIU dose/day, metformin milligram/day, chol–cholesterol.

Table 2: Anova for base line Pre-interventional

Characteristics	Df	F	P value
Age	2	8.787	**<0.001
Duration	2	8.345	>0.05
Bmi	2	18.448	**<0.001
Excess weight	2	8.326.	*<0.05
Hba1c	2	1.254	0.288
Insulin IU	2	5.268	**<0.006
Metformin	2	1.218	0.298
Total cholesterol	2	6.058	*0.003

*Pvalue<.05(significant), **<.01(more significant),***pvalue.001(highly significant).

The three surgical groups at one year showed >60% diabetes remission according to ADA criteria i.e. HbA1c ≤6 % without glucose lowering medications. More than 20% showed reduction in HbA1c <6.5% without glucose lowering medication and ≤15% showed HbA1c ≥ 6.5%. (fig. 1).

Fig. 1: X-axis showing different HbA1c level in three surgical group namely SG RYGB, MGB at 9-12 mo, Y axis showing % of population

achieving the different HbA1c level HbA1c <6%, between 6 to 6.5% (without pharmacological therapy) and HbA1c >6.5% with medications at one year. Remission of diabetes HbA1c <6% occurred 67% in MGB 66.7% in GB and 62% in SG group. HbA1c between 6-6.5% reported 25% in MGB, 21.0 % in RY GB and 22.7% in SG group, >6.5% HbA1c was reported 12% MGB, 11.4% RYGB and >15% in SG. The remission/reduction in diabetes occurred after surgery, in all three group was significant. Post hoc anova between groups

showed no statistical significance. In our study MGB and RYGB showed highest remission of diabetes. Several studies reports that no statistical significance between different surgical procedures in achieving diabetes remission [10, 11].

month and sixth weight loss reported in SG was more compared to the other two groups. During the next follow-ups MGB and RYGB showed better reduction compared to SG (fig. 2). Towards the end weight loss was more in MGB group and p value is **0.001

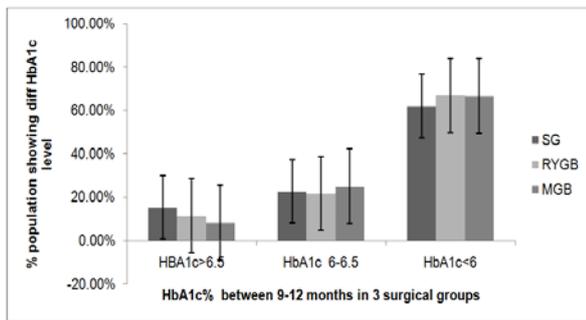


Fig. 1: HbA1c % in the three groups at one year

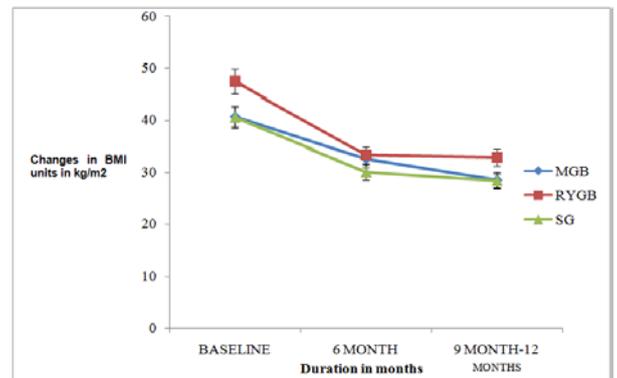


Fig. 3 BMI reduction during follow-ups

Excess weight loss at three different intervals

At base line following are the excess weight in the 3 interventional surgical groups RYGB (45.4938±21.29), SG (40.474±4.876), and MGB (40.7329±9.332) (Table1). Anova at base line for the entire group was significant the p value showed was * < 0.05 (table 2).

Fig. 3 showing changes in body mass index during the follow-ups. SG and RYGB showing sharp reduction whereas MGB showing more sustained and gradual reduction

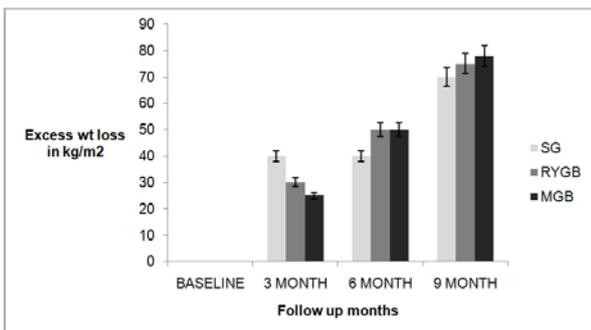


Fig. 2: Excess weight loss at three different intervals.

Fig. 2 shows excess weight loss at three different intervals during the follow up period. All the three groups showed weight reduction after surgery which was comparable among groups. Initially at third

Table 4 Shows post hoc-anova for significance. From the table it is found that, BMI and total cholesterol, having high statistical significance P value < **0.001 and < **0.002 respectively. The significance between groups were analyzed using Bonferroni test and it is found that there was a statistical significance between MGB versus SG in BMI and P value is *.035 and RYGB versus SG p **0.002 and in total cholesterol there was significance between MGB versus GB P value is **0.002.

Table 5 shows the reduction in number of cardiovascular risk factors. There is significant reduction between pre and post conditions p value is *0.05 Highest reduction in hypertension and hypercholesteremia were shown by RYGB group between group there was significance for hypercholesteremia and P value is **0.002. Ikramuddin et. al randomized 120 patients to receive RYGB of 12 mo of follow-up. The primary treatment goal was a composite of HbA1c < 7%, LDL cholesterol < 100 mg/dl, and systolic blood pressure < 130 mm Hg, and was reached by 49% of those receiving surgery.

In the entire group there was reduction in cardiovascular risk factors from base line to post intervention MGB 78 % reduction reported SG 73% reduction and RYGB 83.4% reported

Table 3: Post-Interventional value with mean and standard deviation

Characteristics	Group	N	Mean	Sd
Bmi post	MGB	57	28.504±	8.275
Bmi post	SG	59	31.28±	3.758
Bmi post	RYGB	60	32.84±	6.800
Hba1c % post	MGB	57	5.99 3±	0.880
Hba1c % post	SG	59	6.014±	0.774
Hba1c % post	RYGB	60	5.898±	0.717
Metformin post	MGB	55	279.53±	350
Metformin post	SG	59	232.92±	325
Metformin post	RYGB	60	258.33±	338
Excess weight loss	MGB	57	29.45±	7.380
Excess weight loss	SG	59	23.15±	6.413
Excess weight loss	RYGB	60	40.93±	14.601
Total cholesterol post	MGB	51	176.221±	37.718
Total cholesterol post	SG	56	164.14±	32.643
Total cholesterol post	RYGB	60	161.95±	28.122

Table 3 shows post interventional values with mean and standard deviations for the follow up criteria. Since Insulin was stopped in all the groups at 9-12 mo, post interventional value for insulin is not included.

Table 4: Post hoc-anova for significance of the follow ups

Parameters	Df	F	Significance
BMI-post	2	6.891	**0.001
Insulin dose	2	0.357	0.598
Metformin dose	2	0.111	0.740
HbA1c%	2	1.254	0.288
Total cholesterol	2	6.058	**0.002
Excess weight loss	2	6.321	>0.05

Df-degrees of freedom, F statistics factor

Table 5: Pre and Post cardio vascular risk factors (Secondary end points)

Parameters	MGB(N=57)	(SG) N=59	RYGB (N=60)	Significance
Hypertension	Pre N=13(22.8%)	Pre=18(30.5%)	Pre=29(48%)	*<0.05
	Post N=3(6.26%)	Post N=9 (15%)	Post N=5(8%)	0.111
Hypercholestermia	Pre N=16(27.6%)	Pre=17(28.5%)	Pre=30(50%)	<0.05
	Post N=2(6.26%)	Post=4(7%)	Post=10(16%)	*<0.05
Cardiac medicine	Pre N=20(35%)	Pre N=17(28%)	Pre N=25 (41%)	*<0.05
	Post N=5(9%)	Post N=5(9%)	Post N=6 (10%)	NS

HTN=Systolic BP>140 mmHg Diastolic= BP>95 mmHg Hypercholestermia= Total cholesterol>180 mg/dL, CAD=Coronary artery diseases, cardiovascular medicine=Anti hypertensives+Antilipidemic+Anticoagulants

Table 6: Immediate post surgical complications

Parameter	MGB	SG	RYGB
Leak	2(2.86)	0(0%)	6(9.3%)
Pneumonitis	3(5.3%)	14(24%)	8(13.6)
Pulmonary embolism	0(0%)	1(1.6)	1(1.5)

Table 7: Chi-square test for significance of complications after surgery

Parameter	SS	Df	P value 2 sided
Bleeding	5.901	2	0.52
Leak	4.887	2	0.087
Pneumonitis	6.372	2	0.041
Pulmonary embolism	2.100	2	0.350

ss-sum squares, df-degrees of freedom, ms-mean square*p value<.05 (significant) The chi square test shows no statistical significance between groups.

Table 6 shows immediate post surgical complications. RYGB group showing highest surgical complications after surgery followed by SG group. Lowest number of complications reported in MGB group.

DISCUSSION

Metabolic surgery not only brings about weight loss but has effects on gut hormones and beneficial in the management of diabetes and related co-morbidities. Weight loss obtained after surgery is associated with highly significant reduction in cardiovascular risk factors [12]. The three procedures were successful and weight reduction was impressive in all groups, patients showed remarkable improvement in their diabetic status ie more than 60% of patients showed complete remission of type2 DM while more than 90% showed a significant decrease in their insulin or OHA demand. The highest response to the treatment with the lowest number of complications was shown by MGB group. Similar result was shown by Milone M *et al.*[13]. A systematic review of bariatric literature showed that SG and MGB are safe alternative to RYGB. A report from Lee *et al.* Suggest that duodenal exclusion may play the role in diabetes remission other than weight loss [14, 15]. The new therapeutic algorithms of type 2DM suggest an earlier intervention for the remission of type 2DM. However, the choice of surgical procedure to be used remains an unresolved question. The choice of surgical procedure remains open according to IDF/ADA recommendations.

CONCLUSION

Type 2 Diabetes is no longer an uncontrollable disease. A return to normal level of glucose is possible with metabolic surgery. The three

surgical procedures were comparable in reducing the excess body weight, HbA1c and cardio vascular complications in accordance with ADA/IDF criteria. Highest response to weight reduction was shown by MGB which was statistically significant between groups. Reduction in comorbidities, less surgical complication was reported in MGB compared to RYGB and SG. These findings can potentially influence the physicians to choose the right type of bariatric and metabolic surgery.

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CONFLICT OF INTERESTS

Declared None

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