ABSTRACT:

Background: Morbid obesity has become a serious health problem due to its multiple complications and co-morbidities. Bariatric surgery proved to be an effective way for management of morbid obesity and its co-morbidities.

Aim of work: to prospectively assess the post-operative weight loss and the evidence of a Gastro-esophageal reflux (GERD) after mini-gastric by-pass.

Patient and method: Our study was conducted in El-Demerdash hospital, Ain- Shams University and other private hospitals. Thirty patients were operated upon from May 2013 to January 2016 with minimal follow up of 15 months. Thirty (30) morbidly obese patients with BMI >40 or >35 were undergone mini gastric bypass from Jan 2014 to July 2016 at the department of surgery Ain-Shams University Hospitals.

The procedure is obtained from Elinton Adami et al.

Results: A statistically significant weight reduction had been occurred at 3,6,9,12,15 months after laparoscopic mini-gastric bypass (LMGBP). There was also a significantly diminished esophageal acid exposure postoperatively, in addition to, improvement in pre-operative obesity co-morbidities.

Conclusion: Laparoscopic mini-gastric by-pass (LMGBP) is a technically simple and safe procedure showing excellent results for weight loss in obese patients with a significantly low complication rate, in addition to low incidence of postoperative Gastro-esophageal reflux (GERD).

Key words: Bariatric surgery – Gastric – Laparoscopy– Morbid obesity – Mini-gastric – bypass – Weight loss.

INTRODUCTION:

Obesity, today's one of the major health problems, is a condition in which fat is accumulated to exceed normal verities, and body weight and fat percentage are increased. Moreover, associated with increased risk of several diseases (e.g. type 2 diabetes, certain cancers, and cardiovascular diseases), and with a worse prognosis once disease happens, it is relevant to target fat accumulation and prevent life time weight gain (2).

Nearly all epidemiologic studies have found an association between increasing BMI and symptoms of gastroesophageal reflux disease (GERD). Changes in gastroesophageal anatomy and physiology caused by obesity may explain the association. Central adiposity may be the
most important risk for the development of reflux and related complications (3).

The relation between Mini-gastric bypass and GERD not highly studied. The mechanism of action through this surgery is successful at improving GERD may be independent of weight loss and needs further examination (4).

**AIM OF THE WORK:**

This study aims to prospectively assess the evidence of a Gastro-esophageal reflux and weight loss post mini-gastric by-pass operation.

**PATIENTS AND METHODS:**

I. **Patients:**

Thirty (30) morbidly obese patients with BMI >40 or >35 were undergone mini gastric bypass from Jan 2014 to July 2016 at the department of surgery Ain-Shams University Hospitals.

Ethical approval was taken from Ain Shams University ethical committee and written consent was taken from every patient after explanation of all details of the operations.

**Inclusion criteria:**

1) Male or female patient, age (18 - 50 year).
2) Body mass index (BMI) > 40 kg/m² or (BMI) >35 kg/m² with co-morbidities such as cardio-pulmonary problems (e.g., severe sleep apnea), diabetes type II or dyslipidemia.
3) History of obesity >5 years, with failure of conservative treatment for >2 years.

**Exclusion criteria:**

1) Patients who were unfit for General Anesthesia (ASA IV or V).
2) History of previous gastric resection or upper abdominal surgery.
3) Alcohol abuse and/or drug dependency.
4) None stabilized psychotic disorders, severe depression and personality disorders.
5) Patients who have reflux esophagitis, gastritis, peptic ulcer and duodenitis.
6) Patients who had shown non-compliance for post-operative and nutritional follow up.

II. **Methods:**

**All patients in our study had Preoperative medical assessment:**

- Full clinical history:
  i. **Personal history:** Age, sex, occupation, address and any habits of medical importance.
  ii. **Present history:** Duration and effect of obesity on daily activities and different trials of losing weight.
  iii. **Past history:** Medical disease and any surgical history.

- Full clinical examination: i.e. body weight, height, BMI and detailed body examination:
  - **Full laboratory investigations:**
    Complete blood cell count, lipid profile, random blood sugar (HbA1c in diabetics) and liver enzymes.
  - **Radiology:** Pelvi-abdominal ultrasound
  - **Instrumental:**
    - Upper endoscopy: To exclude asymptomatic gastro-esophageal reflux and biopsy from any suspicious lesion.
    - ECG: was performed in all patients with a history of cardiovascular disease.
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- Pulmonary function test: in obstructive Sleep Apnea Syndrome (OSAS).

Operative procedure: Laparoscopic Mini Gastric-By-pass (5)

Postoperative assessment:

Early ambulation was highly advised 4-6 hours post-operative. Prophylactic dose of low molecular weight heparin was used 12-hours post-operative. LV fluids, broad spectrum antibiotics and pain killers.

On discharge, the patients were advised to take broad spectrum antibiotic and proton pump inhibitor for 1st 2 weeks post-operative. After 2 weeks, the patients were advised to take (Pantoprazole 40mg/day). After 1-month, multi-vitamins and supplemental minerals for long life.

Follow-up Measures: The follow up period of 15 months was carried out on an outpatient clinic:

- Weekly visit for one month after discharge from the hospital.
- Monthly visit till the end of the third month.
- Visit every three months till the end of the follow up period.

In each visit patient had full clinical assessment including assessment of reflux symptoms.

Post-operative assessment of esophageal reflux:

1. Upper GIT endoscopy.
2. Esophageal PH monitoring.

Esophageal pH monitoring:

Patients were asked to fast for at least 4 hours prior to placing the PH probe. The sensor is placed 5 cm above upper border of the lower esophageal sphincter. To measure proximal esophageal acid exposure the second sensor is placed 15 above the lower esophageal sphincter.

PH monitoring duration

A reflux episode is defined as esophageal PH drop below 4.0. Esophageal pH monitoring is performed for 24 or 48 hours and at the end of recording, patients tracing is analyzed, and the results are expressed using six standard components. Of these 6 parameters a pH score called DeMeester Score has been calculated, which is a global measure of esophageal acid exposure. A DeMeester score > 14.72 indicates reflux.

Statistical Analysis:

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 20. Qualitative data were presented as number and percentages while quantitative data with parametric distribution were presented as mean, standard deviations and ranges.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:

RESULTS

Demographic Data:

Out of 30 patients included in the current study, Male participants were 10 (33.0 %), while female participants were 20 (67.0%). Mean age of the participants was 35.5 years, while median age was 35years and (rang: from 19 years to 50 years).

Pre-operative Data:

Mean preoperative weight was 147.6 kg, the maximum weight was for a female with 181kg, 25 years old and the minimum weight was also for a female with 101 kg, 35years old. The mean height was 167 cm (range from 150 to 183 cm). Mean preoperative BMI was 46.1 kg/m^2 (range: from 40 to 60 kg/m^2).
Patients classified according to BMI into the following:

- Twelve (40.0%) patients had (BMI>50 kg/m²), 5 (17.0%) females and 7 (23.0%) males.
- Ten (33.0%) patients had (BMI >45-50 kg/m²), 8 (27.0%) females and 2 (7%) males.
- Eight (27.0%) patients had (BMI 40-45 kg/m²), 7 (23.0%) females and 1 (4.0%) males.

Clinical history:

All patients had history of obesity for more than five years, with a history of failure of conservative treatment for weight loss using dieting and/or exercise system for more than two years. About 9 (30%) patients had a positive family history of obesity and 13 (43.0%) patients had one or more co-morbidities.

Obesity co-morbidities

- **Diabetes mellitus** in 6 (20.0%) patients, about 4 patients were known diabetics (DM II) on oral hypoglycemic drugs and controlled on treatment and 2 (7.0%) patients were newly diagnosed by RBS during pre-operative assessment.
- **Hypertension** in 8 (27.0%) patients, all patients were on antihypertensive drugs and controlled on treatment.
- **Dyslipidemia** in 9 (30%) patients diagnosed by lipid profile during pre-operative assessment.
- **Coronary artery disease**: in 4 (13.0%) patients, with 2 (7.0%) patients were on treatment.
- **Obstructive sleep apnea** in 3 (10%) patients and osteoarthritis in 5 (17.0%) patients.

Operative Data

**Operative time**: The mean operative time was 90 ± 12.6 min (range, 80–120).

Length of hospital stay (LOS): Mean value of hospital stay period of patients was 5.83± 3.93 days, (range: from 2 to 10 days). 3 patients (10.0%) required an overnight ICU admission due to obstructive sleep apnea.

Mortality: There was no surgical or procedure related mortality during follow up period.

Intra-operative and Post-operative complications:

*Intra-operative complications*: intra-abdominal uncontrolled bleeding in 1 patient due to splenic injury during last stapling at gastro-esophageal junction and splenectomy was done.

*Post-operative complications*: early and late post-operative complications that occurred after.

Two patients (7.0%) had post-operative leak; One of them is 23 years old male patient, non-diabetic, non-hypertensive with BMI=45.5, was discharged 4 days post-operatively after negative contrast study and smooth post-operative course. However, the patient was re-admitted after 10 days. The patient was managed conservatively for 7 days.

The second, is 38 years old male diabetic, with BMI= 51.6, was discharged 4 days post-operatively and then re-admitted after 8 days with abdominal pain. Exploration was done, and leak was found at the site of anastomosis and decision of conversion to simple loop to Roux-en-Y gastro-jejunostomy was taken with insertion of feeding jejunostomy.

Another patient (3.0%) had post-operative chest infection (Pneumonia) treated with IV antibiotics, nebulizers and chest physiotherapy.

Access port infection had occurred in one (3.0%) patient and managed in outpatient clinic.

Incidence of post-operative GERD:
Four (13.0%) patients had with heartburn, dyspepsia, regurgitation and gastritis which 2 patients were discovered by routine endoscopy done at the 6th and 12th months post-operative, while the other 2 patients were diagnosed in the 4th and 8th months post-operatively.

1. Routine upper GIT endoscopy findings

Two patients showed lower esophagitis (Grade A), peri-anastomotic and diffuse gastritis by upper GIT endoscopy done at the 6th and 12th months post-operatively. Also, multiple biopsies were taken which were sent to histopathological examination. The results showed non-specific esophagitis and mild peri-anastomotic gastritis with no evidence of dysplasia or metaplasia.

2. Upper GIT endoscopy (symptomatic postoperative)

Two (13.3%) patients complaining with heartburn and regurgitation at 4th and 8th months post-operatively. Endoscopy was done out of regular scheduled routine endoscopy where patients showed evidence of esophagitis (Grade B and C), peri-anastomotic and diffuse gastritis.

Esophageal PH monitoring results:

Four patients had done an esophageal pH metry (2 symptomatic and 2 asymptomatic); Three (10.0%) patients showed acidic-reflux while 1 (3.0%) patient showed non-acidic reflux.

For any patient in our study complaining from GERD symptoms; pH metry was done in parallel with upper GI endoscopy. It was very helpful in the detection of one case of acid reflux (Diagram 1) with De Meester score: 33.5.

However, there is a limitation using esophageal PH metry to identify only reflux episodes during which the pH drops below 4.0, therefore providing limited information on reflux episodes during which the pH doesn't drop below 4.0 (i.e., nonacid reflux).

All of them got proton pump inhibitor (PPI) 40mg/12hrs for 4weeks then reduced to 40mg/24hr. Patients who had acidic reflux improved on medical treatment while patient with non-acidic reflux re-admitted, after failure of medical trials for 3 months, for Roux-en-Y gastro-jejunostomy bypass.

Main Outcome Measures:

Body Weight: Tables (1)

The preoperative weight with mean ± SD: 147.6 ± 12.0 kg (range: from 101 to 181 kg).

The post-operative weight at 3 months with mean ± SD value of 128.8 ± 13.5 kg (range: from 91 kg to 150 kg) and this difference show a statistical significance (P value=0.001).
The post-operative weight at 6 months with mean ± SD value of 113.8 ± 14.11 kg (range: from 80 to 134 kg) and this difference show a statistical significance (P value=0.001).

Similarly, the post-operative weight at 9 months with mean ± SD value of 98.4 ± 12.6 kg (range: from 72 to 120 kg) and this difference show a statistical significance (P value<0.001).

Finally, the post-operative weight at 12 months with mean ± SD value of 84.4 ± 8.95 kg (range: from 63 to 99.9 kg) also this difference shows a high statistical significance (P value<0.0001).

In addition, the post-operative weight at 15 months with mean ± SD value of 77.1 ± 7.9 kg (range: from 60 to 89 kg).

Table (1): Comparison between pre and post-operative Weight at 3, 6, 9, 12 and 15 months:

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<tr>
<th>Weight pre-operative</th>
<th>P value</th>
<th>Significance</th>
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<tr>
<td>Weight at 3 months</td>
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<tr>
<td>Weight at 6 months</td>
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Excess body weight loss (%EBWL):

Percentage of excess weight loss (%EBWL) evaluated at 3, 6, 9, 12 and 15 months post-operatively was 25%, 38%, 51%, 65% and 70.1% respectively.

Poor weight loss:

Weight loss at 12 months defined as poor if (<40% excess weight loss) or good if (>40% excess weight loss). In the current study we had 2 (7.0%) patients who lost less than 40% of excess weight after 12 months, which was attributed to their bad diet habits as they are much sweet eaters and didn't commit to instructions of the dietician while other patients 28 (93.0) had achieved accepted weight loss.

Body mass index (BMI) (Tables 2):

The preoperative BMI with mean ± SD: 46.1± 2.12 kg/m² (range: from 40 kg/m² to 60 kg/m²). Post-operative BMI at 3 months with mean ± SD value of 41.9 ± 6.6 kg/m² (range: from 38 kg/m² to 54 kg/m²). Post-operative BMI at 6 months with mean ± SD value of 38.03 ± 5.7 kg/m² (range: from 34 kg/m² to 50 kg/m²), post-operative BMI at 9 months with mean ± SD value of 34.6 ± 5.3 kg/m² (range: from 30 kg/m² to 46 kg/m²), post-operative BMI at 12 months with mean ± SD value of 31 ± 4.2 kg/m² (range: from 28 kg/m² to 35 kg/m²). Post-operative BMI at 15 months post-operatively with mean ± SD value of 27.9 ± 2.8 kg/m² (range: from 23 kg/m² to 35 kg/m²).

Interestingly; these differences show a statistical significance at 3, 6 months and a high statistical significance at 9, 12, 15 months post-operatively (p value: 0.003, 0.002, < 0.0001, < 0.0001 and < 0.0001 respectively).
Table (2): Comparison between pre and post-operative BMI at 3, 6, 9, 12, 15 months (n=30).

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P value < 0.005 is statistically significant*; H.S: highly statistical significant; S: significant; BMI: body mass index.

Follow up of obesity related comorbidities:
A significant improvement of obesity-related clinical symptoms and co-morbidities was significantly observed. Resolution of almost dyslipidemic patients (8 out of 9 patients) had been occurred. Remission of (4 out of 6 patients) of DM II with (fasting glucose <126 mg/dL and HbA1c <6.5% without glycemic therapy) was observed. Hypertension was controlled in (3 out of 8 patients) on diet and regular physical activity. Marked improvement in osteoarthritis (5 patients) and sleep apnea (3 patients) was also noted during follow up.

DISCUSSION:
Obesity has nowadays become a major medical and social problem of most countries (6). Morbid obesity is expanding worldwide (7), and increasing levels of obesity are associated with increasing risk of comorbidities and of death (8).

GERD is a common co-morbid condition in bariatric patients. The exposure of the esophagus to stomach content, leading to esophageal mucosal damage (6).

Mini-gastric bypass surgery is easy, simple, less expensive, and less time-consuming however mini-gastric bypass as any loop anastomosis carries the risks of bile reflux gastritis and reflux esophagitis which is not evident in the studies, so we need more studies to detect the possible complication specific to the mini-gastric bypass mainly biliary reflux gastritis (9).

In the current study, there was statistically significant difference between the preoperative weight and postoperative weight at 3, 6, 9, 12, 15 months following LMGB operation and remarkable improvement in obesity comorbidities had been occurred which more evident with dyslipidaemia, osteoarthritis, obstructive sleep apnea, diabetes type 2 and lastly hypertension. These findings were in agreement with a prospective, randomized controlled clinical trial of Lee et al. (10) who found that LMGB was effective for the treatment of morbid obesity, with results that were comparable to those obtained after RYGB for the resolution of obesity comorbidities and for the improvement of quality of life. These authors also regarded LMGB as a simpler and better tolerated procedure that has no disadvantage compared with RYGB after a follow-up of at least 2 years (11).

In the current study, the %EBWL evaluated at 3, 6, 9, 12 and 15 months post-operatively was 25%, 38%, 51%, 65% and 70.1% respectively Which was in agreement with Patel et al. (12) who showed a 72% excess weight loss at one-year follow-up in 108 patients undergoing LMGB and with Kular and Manchanda (13) findings about maximal % EBWL of 72.5% occurred at 18 months.

Interestingly, we found that there was significant decrease in the incidence of GERD in patients post-operatively; as it appeared only in (4/30) patients, this finding is concomitant with Tolone et al. (14) who found
that LMGB induced no modifications in terms of EGJ function and motility patterns in obese patients without preoperative GERD 12 months after surgery.

**Tolone et al.** (14) study was the first study, to our knowledge, in which the effects of LMGB on GERD are studied using pH monitoring for their assessment. The most prominent finding of the study was that a significant reduction both in esophageal acid exposure and in reflux episodes was observed in all patients after LMGB.

**Conclusion:**

LMGBP can be considered as an effective single stage procedure in obese patients showing excellent and reliable results for weight loss in obese patients with a significantly low complication rate. LMGB induced no modifications in terms of EGJ function and motility patterns in obese patients without preoperative GERD after 12 months from surgery. This procedure can significantly resolve obesity-related metabolic complications and increase quality of life for morbidly obese patients. LMGBP was shown to be a simple and safe procedure in bariatric surgery.

Further studies are required to confirm the impact of LMGB on obese patients with preoperative documented GERD or hiatal hernia to study their anti-reflux effects.

A more accurate method for oesophageal biliary reflux after LMGB should be planned via impedencemetry (HRiM), which is for assessing biliary reflux than the conventional pH metry. It was not included in our study due to financial unavailability.

Finally, LMGBP can be considered as an effective procedure in obese patients showing excellent and reliable results for weight loss in obese patients with a significantly low complication rate and low incidence of postoperative GERD.

**REFERENCES:**

Post-Operative Weight Loss And Evidence Of Gastro-Esophageal Reflux After Mini-Gastric Bypass


