

Comparative Study between Single Stage (Mini-bypass) Versus 2 Staged Operations (Sleeve Gastrectomy Followed by Mini-bypass) for Management of Super-obese Patients with BMI Over 60

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ABSTRACT

Background: Single stage bariatric procedures showed some sort of failure in many cases with very high BMI in the aspect of weight regain or initial failure to achieve proper weight loss. So we decided to adopt the concept of 2 staged operations (Sleeve gastrectomy followed by Omega loop or mini gastric bypass) comparing it with single stage (Omega loop gastric bypass) mainly regarding weight loss after 2 years as a primary end point and improvement of different co-morbidities as a secondary end point, in super-super obese patients with BMI >60 kg/m². **Patients and methods:** This prospective randomized study was held in Ain-Shams university hospitals between August 2013 and August 2016 over 28 patients with BMI>60kg/m², divided into 2 equal groups; (A) underwent mini-bypass only and group (B) underwent sleeve gastrectomy followed 12 months later by mini-bypass, BMI and co-morbidities were assessed before and 2 years after the bypass procedures. **Results:** In this study, 28 patients were randomly divided into 2 equal groups; group (A) 14 patients who were subjected to MGBP as a solo procedure and group (B) 14 patients who were subjected to SG as a primary stage followed 12 to 15 months by a second stage MGBP. The mean age of group (A) was 37.2±9.95 versus 36.1±8.5 years in group (B), group (A) had 36% (n=5) males and 64% (n=9) females, while group (B) had 57% males (n=8) and 43% (n=6) females. The mean BMI of group (A) was 66.2±3.8 versus 67.07±3.9 in group (B). The BMI decreased from 66.2 to 41.4 in group A, while in group B the mean BMI decreased from 67.07 after sleeve gastrectomy to 48.1 at 12 months, then to 34.4 two years after the second stage. The mean operative time was 118.4±17.9 in group A versus 79.4 ±25.1 in the first stage group B and 100.2±21.6 in the second stage group B. The mean post-operative hospital stay was 4.2±3.07 days in group A, 3.6±2.43 in first stage group B and 4.04±2.5 in second stage group B. Regarding the complications; in group A: we had one case of intra-operative bleeding, another case of post-operative bleeding. Regarding complications in Group B: We had one case of intra-operative bleeding, another case of staple line leak in the first stage, we had one case of port site hernia after the second stage. **Conclusion:** We found that the two stages concept demonstrated superior results when compared to single stage LMGBP regarding the aspects of weight loss, improvement of co-morbidities along with the complication rates.

Key words: Bariatric, Sleeve gastrectomy, Mini gastric bypass, BMI.

INTRODUCTION

Patients with extreme obesity, known as super-obese, represent a formidable challenge for both surgeons and anesthesiologists. Intraoperative complications are much higher in super-obese than in morbidly obese patients¹. Intra-abdominal huge fat deposition leads to an increase in technical problems during laparoscopic surgery. Large fatty omental tissue is often an obstacle in visualizing the stomach. Huge ponderous fatty livers are always not well retracted by laparoscopic retractors, resulting in poor exposure. Laparoscopic instruments usually

lose their mechanical advantage when passed through thick abdominal walls, and the distance from skin to esophageal hiatus markedly increases.^{1,2}

Laparoscopic sleeve gastrectomy (LSG) was introduced by Gagner and colleagues as a first-step procedure to minimize surgical risk for super-super-obese or high-risk patients, followed later by either laparoscopic biliopancreatic diversion with duodenal switch (BPD-DS) or laparoscopic Roux-en-Y gastric bypass (LRYGBP).^{3,4}

According to the review of Brethauer *et al.*, LSG is an effective weight loss procedure that can be performed safely as a first stage procedure

with low postoperative major complication rates and mortality rates.⁵

So we decided to adopt the concept of 2 staged operations (Sleeve gastrectomy followed by mini-gastric bypass) comparing it with single stage (mini-gastric bypass) mainly regarding weight loss as a primary end point and improvement of different co-morbidities as a secondary end point, in super-super obese patients with BMI >60 kg/m².

PATIENTS AND METHODS

This is a prospective randomized control study that was held in Ain-Shams university hospitals (El-Demerdash and Ain shams university specialized hospital) in the period from August 2013 to August 2016 over 28 morbid obese patients with BMI over 60kg/m² who were randomly divided into two equal groups (14 patients each) via computer based randomization, where group A were subjected to Omega loop mini-gastric bypass as a single stage, while group B were subjected to sleeve gastrectomy (SG) as a primary stage followed 12 months later by a second stage omega loop mini gastric bypass (MGBP).

Our primary endpoint was to assess the changes in the BMI following the MGBP operation in groups, while the secondary endpoints were to assess improvement of co-morbidities, operative and post-operative complications and the quality of life in both groups.

All patients were admitted at least one day before the procedure, full history and thorough examination was done, assessment of comorbidities, full labs along with any special labs needed were done, Pelvi-abdominal ultrasonography, Echo-cardiography and pulmonary function tests were done routinely for all patients, ICU beds were routinely booked for all patients pre-operatively.

Statistical analysis

Data were collected and analyzed using computer program IBM SPSS (Version 4.11; Abacus Concepts Inc, Berkeley, CA, USA); Continuous data are presented as mean \pm standard deviation (SD). Categorical data are presented as percentages. Analysis of variance (ANOVA) and the rank-sum test were used to analyze continuous data. The results were significant (S) with $P < 0.05$

& highly significant (HS) with $P < 0.01$, $P \geq 0.05$ were regarded non-significant (NS). χ^2 test (with

Yates correction and Fisher's exact test) and the Student t or Mann Whitney U tests according to the characteristics of the study variables and the conditions of applicability. Randomization was done using Excel random sample software (version 7.0).

Operative technique:

Sleeve gastrectomy:

Insertion of 6 ports after Verres insufflation (10mm midway between the umbilicus and Xiphisternum in the midline for camera, 5mm sub-xiphoid for liver retractor, 15mm right midclavicular, 5mm right subcostal, 12mm left midclavicular and 5mm left subcostal), Ligasure[®] (Valleylab, Covedian, Medtronic, USA) is used for dissection of the greater omentum, then short gastric vessels, then the posterior fundal attachments to the diaphragm, then downwards dissection till 5 cm from the pylorus, introduction of 30fr bougie is done followed by application of 60 mm green cartridge using Endo GIA[®] (Covedian, Medtronic, USA) followed by 60 mm blue cartridges towards the angle of Hiss. Test with Methylene blue is done after closure of the sleeve with a fired cartridge, application of 20 fr Nelaton's drain is done followed by extraction of the removed stomach via the 15 mm port site.

Mini-Bypass (as a primary procedure):

Insufflation and ports insertion are the same as sleeve except for the 15 mm port is replaced by a 12 mm one, dissection is started at the lesser curve of the stomach at the incisura level till entering the retro-gastric space, first staple applied as a 45mm blue cartridge, then a 38 fr bougie is introduced along the lesser curve and stapling alongside the bougie is done using 60 mm blue cartridges towards the angle of Hiss till complete separation of the pouch, raising of the greater omentum and the colon followed by identification of the DJ flexure, counting 2 meter of the jejunum is done followed by ante-colic isoperistaltic side to side Gastro-jejunal anastomosis using linear Endo-GIA stapler with a blue 45 mm cartridge, only 2-2.5 cm of the cartridge are used, closure of the anastomotic rent with continuous 3/0 Vicryl sutures is done followed by methylene blue test, then application of tube drain is done.

Mini-bypass (as a secondary procedure):

Insufflation is done via left subcostal Verres insertion, port sites are the same as above, we

start dissecting adhesions around the sleeve that is identified by the introduced bougie, complete dissection of the left side is done first then we start dissection on the lesser curve at the incisura till entering the retro-gastric space, the same procedure is followed as above with the need of longitudinal stapling in many cases to decrease the size of enlarged sleeves. The same steps are followed as the primary procedure.

All patients are put on the same regimen of post-operative antibiotics (3rd generation Cephalosporin), proton pumps, analgesia on demand and low molecular weight heparin, patients are all kept NPO for one day followed by routine gastro-graffin meal in the second post-operative day, followed by introduction of oral fluids.

Patients are assessed for: Operative time, operative complications, post-operative complications, weight loss and improvement of co-morbidities, patients are scheduled on regular visits after discharge at 1 week, 1,3,6,12,15,18 and 24months after each procedure.

Patients who didn't show on the regular visits or their contacts were lost were excluded from our study (only two cases).

The following figures demonstrate some of the steps of the second stage procedure:



Fig. (1): Dissecting adhesions

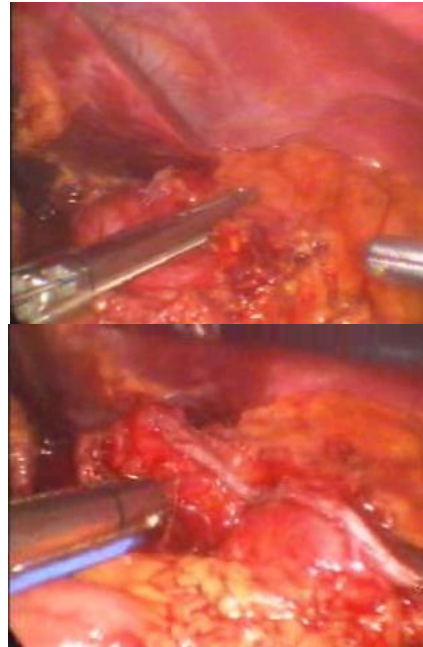


Fig. (2): Creation of the pouch from the previous sleeve



Fig. (3): Minimization of the pouch



Fig. (4): Gastro-jejunosomy formation

RESULTS

In this study we had 28 patients that were randomly divided into 2 equal groups; group (A) 14 patients who were subjected to MGBP as a single procedure and group (B) 14 patients who were subjected to SG as a primary stage followed 12 months later by a second stage MGBP.

Patients' demographics:

The mean age of group (A) was 37.2 ± 9.95 versus 36.1 ± 8.5 years in group (B), group (A) had 36% (n=5) males and 64% (n=9) females, while group (B) had 57% males (n=8) and 43% (n=6) females. The mean BMI of group (A) was 66.2 ± 3.8 versus 67.07 ± 3.9 in group (B).

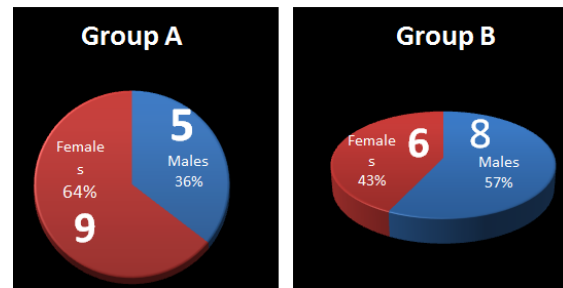


Chart (1): Sex distribution in both groups

Associated co-morbidities are demonstrated in table 1 for both groups.

Table 1: Pre-operative Patients' demographics

Item	Group A	Group B
Males	n=5 (36%)	n=8 (57%)
Females	n=9 (64%)	n=6 (43%)
Mean age (years)	37.2 ± 9.95	36.1 ± 8.5
Mean BMI (Kg/m ²)	66.2 ± 3.8	67.07 ± 3.9
Comorbidities	n (%)	n (%)
Diabetes	7 (50%)	8 (57%)
Hypertension	9 (64%)	7 (50%)
Sleep Apnoea	8 (57%)	9 (64%)
Ischemic heart	2 (14%)	1 (7%)
Dyslipidaemia	2 (14%)	4 (28%)
GERD	5 (35%)	8 (57%)
Degenerative arthritis	3 (21%)	5 (35%)
Steatohepatosis	14 (100%)	14 (100%)

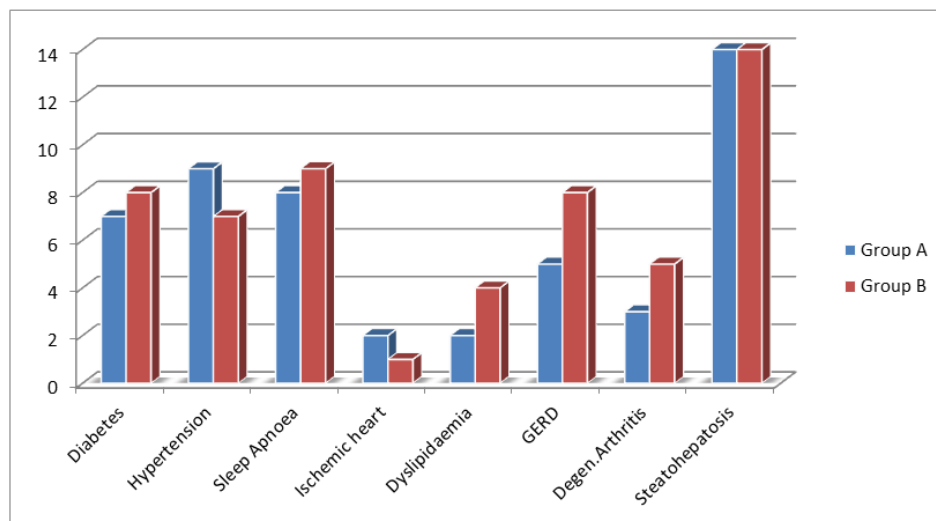


Chart (2): Pre-operative co-morbidities.

Patients were followed up on regular visits as mentioned above; patients who didn't show up were excluded from the study.

Regarding the BMI results, in group A the mean BMI decreased from 66.2 pre-operatively to 55.03 at 6 months, then to 49.36 at one year and 45.4 at 18 months and finally to 41.4 at 2 years.

While in group B the mean BMI decreased from an initial of 67.07 after sleeve gastrectomy to 53.9 at 6 months, then 48.1 at 12 months, then after the second stage it started to decrease again to 43.11 at 6 months, then 39.7 at 12 months then 35.2 at 18 months and finally 34.4 at two years.

In terms of excess weight loss (EWL): Mean pre-operative body weight was 191.3±9.2 Kg in group A versus 198.4±11.6 Kg in group B. Regarding group A; The mean EWL at 6 months

was 46.3 Kg, then at 12 months 54.6 Kg, then 62 kg at 18 months and finally 66kg at 2 years. While in group B the mean EWL after the first stage was 48.1 kg after 6 months, then 55.6 kg after 12 months, after the second stage mean EWL advanced to 68.5 Kg at 18 months, then 73.4 kg at 24 months, then 77.3kg at 30 months and finally 81.2 kg at 3 years.

The mean operative time was 118.4±17.9 in group A versus 79.4 ±25.1 in the first stage group B and 100.2±21.6 in the second stage group B, diversity in operative time in the second stage was due to diversity in intra-abdominal adhesions in between patients after the first stage mainly regardless their BMI.

Comorbidities improvement in the 2 groups is illustrated in table 2 and chart 3.

Table 2: improvement of comorbidities

Comorbidity	Group A	Postop.Gr. A n(%)	Group B	Gr B after stage 1	Postop.Gr. B n(%)	P Value	Sig.
Diabetes	7	2 (71%)	8	4(50%)	2(75%)	<0.05	S
Hypertension	9	3 (66%)	7	3(57%)	1(85%)	<0.05	S
Sleep Apnoea	8	1 (87.5%)	9	5(44%)	0(100%)	<0.05	S
Ischemic heart	2	1 (50%)	1	0(100%)	0(100%)	>0.05	NS
Dyslipidaemia	2	0 (100%)	4	2(50%)	1(75%)	>0.05	NS
GERD	5	1 (80%)	8	1(87%)	1(87%)	>0.05	NS
Degen.Arthritis	3	1 (66%)	5	3(40%)	1 (80%)	<0.05	S
Steatohepatosis	14	5 (64%)	14	7(50%)	2 (85%)	<0.01	HS

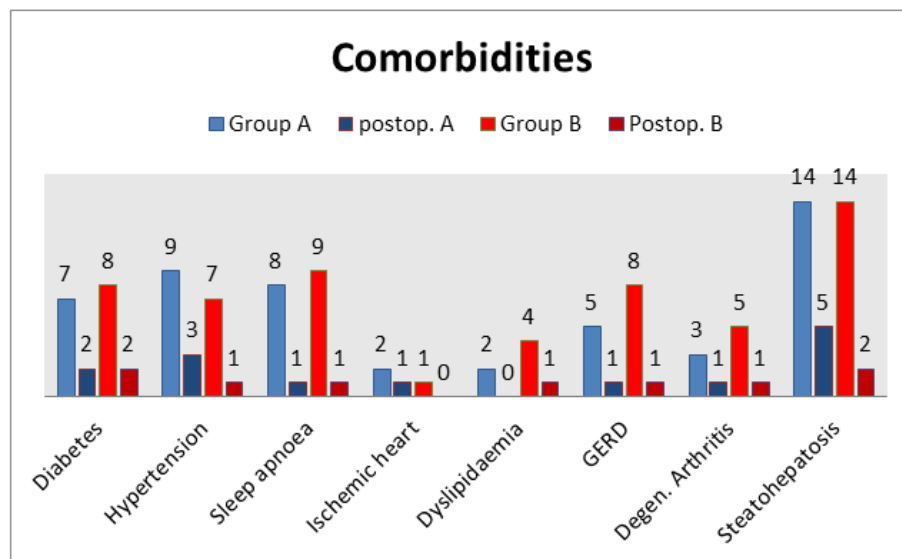


Chart 3: Improvement of co-morbidities

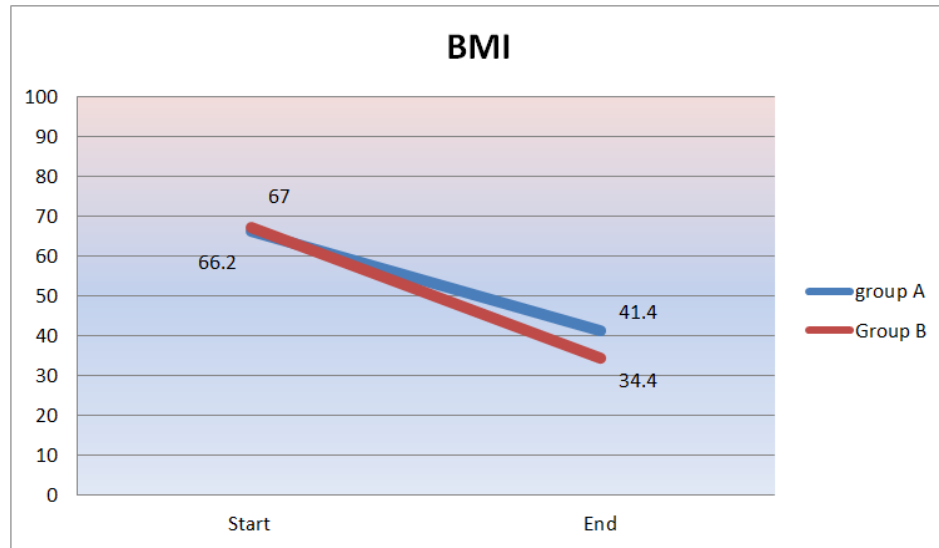


Chart 4: changes in the BMI from the start to the end of the study

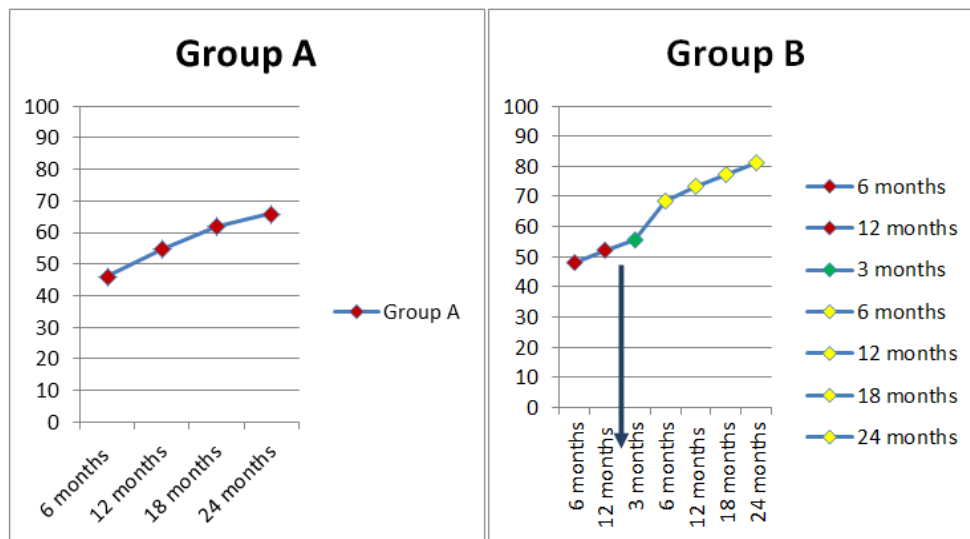


Chart 5: EWL in Group A& B (The arrow states the start of stage 2)

The mean post-operative hospital stay in days was 4.2 ± 3.07 days in group (A), 3.6 ± 2.43 in first stage group B and 4.04 ± 2.5 in second stage group B.

In our study we had no mortalities.

Regarding the complications; in group A: we had one case of intra-operative bleeding from a short gastric vessel during dissection at the angle of His that caused blood loss about 400cc before full control (by gauze pressure, followed by

clipping and application of Surgicel® hemostatic agent, another case of post-operative bleeding that required re-exploration 19 hours after the operation and was found to be from a branch of the left gastric artery that was under-run by a Vicryl 2/0 suture and the case went on without further complications.

Regarding complications in Group B: We had one case of intra-operative bleeding during the first stage sleeve operation from a tributary of the

splenic vein that required conversion via left subcostal incision and clipping was done, the patient received 1 unit of packed RBCs in the postoperative period, and was stabilized without any further events. Another case of staple line leak in the first stage, on the third post-operative day that was detected clinically, after failure of conservative management for 2 days, the patient had a Mega-stent inserted via upper GI endoscopy, leakage stopped and the stent was removed after 6 weeks with no more leakage. We had 1 case of port site hernia after the second stage from the right 15mm port site that developed 1 month after the second stage, it showed no grave complications and was repaired with mesh 6 months later as the patients refused to repair it immediately.

DISCUSSION

Laparoscopic gastric bypass in the super-obese patients is associated with higher morbidity and mortality as demonstrated by *Artuso et al*⁶. The major hazard when operating on the super-obese, is that when the patient has any complication, there may not be sufficient reserve (pulmonary, cardiovascular, renal, immunologic) to survive the difficulty, which is the rationale for the patient to lose enough weight preoperatively to perform the bariatric operation with less risk. The frequently used measures to achieve this are: 1) low carbohydrate diets, 2) intensive multidisciplinary medical regime, 3) in-hospital diet, 4) intragastric balloon and 5) sleeve gastrectomy.⁷

Laparoscopic sleeve gastrectomy (LSG) has been described as a possible first-stage operation before more complex procedures such as biliopancreatic diversion (BPD) with duodenal switch or Roux-en-Y gastric bypass (RYGBP).⁴

Regarding the decrease in BMI, in our study, it ranged from 66.2 to 41.4 at 2 years in group A, with mean EWL of 66 kg while in group B the mean BMI decreased from an initial of 67.07 to 48.1 twelve months after first stage then to 34.4 at two years after the second stage, with mean EWL of 81.2 kg, in the short term study by *Regan et al*⁴, mean BMI decreased from 63 to 50 after first stage, then to 44 at 2.5 months after second stage, and in the study of *Qureshi et al*.⁸, BMI decreased from 65.5 to 48.8 after first stage, then to 37.2 after the second stage with EWL of 62%, also in

the study of *Cottam et al*⁹, the mean BMI decreased from 65 to 49 after 12 months from the first stage SG then to 39 six months after the second stage RYGBP.

The mean operative time was 118.4±17.9 in group A versus 79.4 ±25.1 in the first stage group B and 100.2±21.6 in the second stage group B, compared to 124 and 158 minutes respectively in the study of *Regan et al*⁴, and 143 and 229 minutes respectively in the study of *Cottam et al*⁹. It is evident that Omega loop mini-gastric bypass yields a much less operative time when being used as a second stage procedure when compared to the more complicated Roux-en-Y procedure.

The mean post-operative hospital stay in days was 4.2±3.07 days in group A, 3.6±2.43 in first stage group B and 4.04±2.5 in second stage group B, it was 2.7 days in the study of *Regan et al*⁴ for all procedures, and was 3 days for both stages in the study of *Cottam et al*.⁹

Complication rate was 14% in group A versus 14% in first stage group B and 7% in second stage group B, the overall complication rate was 35.7% in the study of *Regan et al*⁴, and 14% in first stage and 17% in second stage in the study of *Cottam et al*.⁹

Resolution of co-morbidities was seen to be higher in those of group B after the second stage that was better than single stage regarding diabetes, hypertension and sleep apnea and highly significant regarding resolution of obesity associated steatohepatitis. *Qureshi et al*⁸. Stated that second stage patients had lower associated co-morbid conditions, making the two stage concept a viable option in treating super obese patients.

CONCLUSION

From our results we found that the two stage concept showed superior results when compared to single stage LMGBP in the aspects of weight loss, improvement of co-morbidities along with the complication rates, but the only concern we really met was that it was hard to convince most of the patients to have the staged procedure instead of a single definitive one, so routine justification to change sleeve to MGB as EWL% was good.

Recommendations:

Although it was a limited study group's number; we recommend the two staged

procedure; sleeve gastrectomy followed by mini gastric bypass in management of super-super obese patients with BMI more than 60 kg/m². for further studies and evaluation.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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