

FREQUENCY OF COMPLICATIONS AND EFFICACY OF SINGLE ANASTOMOSIS GASTRIC BYPASS FOR THE TREATMENT OF MORBID OBESITY: A CROSS SECTIONAL STUDY

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ABSTRACT

Objectives: To assess the outcomes of Single anastomosis Gastric Bypass in the management of Morbid Obesity.

Materials and Methods: This study was conducted at Lady Reading Hospital, Peshawar between 1st June, 2017 and 28th February 2021 and included 88 patients that underwent Mini-gastric Bypass/ One anastomosis gastric bypass. Following DVT prophylaxis with subcutaneous enoxaparin, a 15-18 cm long gastric pouch was formed over a bougie 36-40Fr and a variable length of biliopancreatic limb was decided between 150-200cm, which was anastomosed to the terminal part of the gastric pouch. All anastomoses were Antecolic fashioned and a minimum 3cm anastomosis preferably to the anterior wall was performed. In all cases Covidien ENDO GIA Tristaple™ technology reloads were used and enterotomies were closed using Barbed V-lockR 2/0 sutures. During follow-up relevant investigations based of emerging complaints and monitoring of weight was performed and documented on an approved proforma.

Results: Out of totla 88 patients, the mean age of patients was 38.7 years (+12.3) with predominantly male patients (53.4%). Mean Body Mass Index was 55.1(+7.8) with a mean operative time of 127.6(+37.1) min. Remission of diabetes, hypertension and improvement in patients with obstructive sleep apnea at end of 6 months was observed in 37 patients (66%), 41 patients (80.3%) and 25 patients (89.2%) respectively. Excess body weight loss at one month was 26.5% and at six months was 58.1%. There were no leaks observed in this study and two cases had bleeds (2.2%). One mortality (1.1%) was observed due to pulmonary embolism.

Conclusion: One Anastomosis Gastric Bypass is a safe and effective procedure which can be modified and tailored to the individual needs of most bariatric patients including Super Obese patients. It has good results in maintaining remission of Diabetes and Hypertension.

Key words: Single Anastomosis, Mini gastric Bypass, Morbid Obesity

INTRODUCTION

The estimated population of obese patients in a Report by UN is approaching 2 billion people which suggests a surge of Bariatric procedures in the near

future¹. The Lap BandR was a favorite for most surgeons for the treatment of obesity in patients from the mid-90s, but as all treatment evolves around an endemic disease there has been demand for more physiologically acceptable procedures to combat the morbid conditions related to obesity². Due to technical feasibility of the Laparoscopic sleeve gastrectomy (LSG) even stronger proponents have reasons to incline towards this restrictive option³, technically because of the ease with which it is per-

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formed as compared as the time-tested Laparoscopic Roux en-Y Gastric Bypass (LRYGB)⁴.

When comparing the skill and learning curve to master the LRYGB, results are deceiving from the outcomes with a higher leak rate reported following LSG suggesting that the issue of a longer staple line (Frequently in the vicinity of the Gastro-esophageal junction) is the cause for such dreadful complications⁵. After the introduction of the Mini-gastric Bypass (MGB) by Ruthledge⁵ and other variants of the Single Anastomoses Gastric Bypass (SAGB) described by authors such as Miguel and Carbajo⁶, many surgeons around the world are now inclined to accept the mentioned as primary procedures for treatment of all patients with morbid Obesity.

Apart from the technical feasibility of these procedures and the benefits of adding restrictive/malabsorptive elements to a primary procedure, the lower rates of complications have widely been reported with a sustained weight loss over longer periods⁷. Moreover, the metabolic benefits such as resolution of Diabetes, hypertension and obstructive sleep apnea suggests the a limited 150-200cm by pass, had adequate potential to fashion a tailor-made common alimentary channel to meet individual needs of most patients⁸.

Despite having quoted the benefits many opponents have reported added rates of Nutritional complications and exaggerated/de-novo Gastro-esophageal reflux (GERD) and bile reflux following such procedures. Hence, suggesting higher incidence of junctional ulcers over a longer period of time⁹. With a large population of patients that have had inadequate weight-loss following LSG/Lap BandR revisional procedures for such patients have allowed SAGB and MGB as feasible options to be performed instead of a more technical LRYGB¹⁰. The leak rates reported by various authors range from 0.1%-2.1% depicted from a meta-analytic review conducted by Quan et al¹¹.

The rationale of this study was to observe the complications of Lap MGB/SAGB indicated for morbid obesity in our population that does not gain access to good nutritional support, hence assessing the efficacy and safety of such procedures. Despite the argument that no one procedure can be labelled as a primary procedure for all obese patients undergoing Bariatric surgery, tailoring appropriate sized Gastric

pouch and modification of the Bilio-pancreatic limb (BP-limb) could be a viable solution.

MATERIALS AND METHODS

This cross-sectional study was conducted at Lady Reading Hospital in which consecutive patients presenting in the Out-patient Department with complaints related to Morbid obesity were included. Prior to data collection a detailed consent form and relevant documents for Ethical Approval from the Ethical Board was submitted. Following approval from the ethical board, appropriate endocrine, metabolic and nutritional work-up was performed by relevant team members of multi-disciplinary team for management of obesity. All patients with BMI ≥ 40 was subjected to appropriate counselling to progress to bariatric surgery.

All patients were informed of the procedure they were to undergo and relevant complications of the procedure from literature was explained. Those patients consenting without evidence of major co-morbidities, grade $\frac{3}{4}$ NYHA status or previous history of abdominal surgery were included in the study. Baseline ABGs and sleep studies by the pulmonology team was performed to document obstructive sleep apnea. Diabetes, and Hypertension were diagnosed by relevant members of the team and relevant medications to achieve adequate control before surgery was performed. Patients with prominent symptoms of gastro-esophageal reflux and epigastric symptoms were subjected to Upper Gastrointestinal endoscopy by the Gastroenterologist. Anesthetist opinion regarding work-up was performed prior to admission and all patients were advised pre-operative and post-operative DVT prophylaxis with subcutaneous enoxaparin. In selected cases where enoxaparin was not recommended per-operative pneumatic stockings were advised. Surgically a 15-18 cm long gastric pouch was formed over a bougie 36-40Fr and a variable length of biliopancreatic limb was decided between 150-200cm, which was anastomosed to the terminal part of the gastric pouch. All anastomoses were Antecolic fashioned and a minimum 3cm anastomosis preferably to the anterior wall was performed. In all cases Covidien ENDO GIA Tristaple™ technology reloads were used to form the Gastric pouch and the gastrojejunal anastomoses whereas all Gastrotomies and enterotomies were closed using Barbed V-lock^R 2/0 sutures. Intraoperative Leak tests

with Methylene Blue was performed in all patients after which bougie was withdrawn and multi-porous drains were connected to a closed collection bag.

Following recovery all patients were shifted to a High dependency unit for appropriate monitoring and allowed oral fluid intake 6 hours later. Discharge from the hospital was decided following 24 hours by the operating surgeon with relevant details of diet and follow-up plan. Nutritionist was asked to counsel all patients before discharge to explain weekly course of action along with relevant supplements. Follow-up of all patients in the out-patient department was performed at day 4, one week, two weeks, one month, three months and six months after surgery. During follow-up relevant investigations based of emerging complaints and monitoring of weight was performed and documented on an approved proforma. Early (peri-operative) complications included anastomotic/staple line leak, Bleeding, atelectasis (pulmonary complications). Late complications included Dumping, marginal ulcers, nutritional deficiencies, inadequate weight loss, persistent vomiting due to anastomotic stricture and Gastroesophageal reflux disease (De novo). Body Mass index and excess body weight loss (%) was calculated for each case. Data from proformas was converted to SPSSR version 11.0. Demographic data, preoperative data such metabolic co-morbidities and postoperative complications were presented in tabulated format. Qualitative data was presented along with percentage whereas quantitative data was presented as mean and

standard deviation.

RESULT

Out of total of 88 single anastomosis gastric bypass procedures were performed which included One anastomosis gastric bypass and Mini-Gastric bypass. In the initial part of the series majority patients were women but after 2019 mostly males presented for weight loss procedures. Only two patients that were operated were above the age of 50yrs (range 23-56yrs). The average BMI of all cases was considerably a case mix of quite a few super obese patients with the highest weight of 232kg (range: 112-232kg). Major co-morbidities included diabetes, hypertension and Obstructive sleep apnea.

Most of the procedures were performed with 4 ports and a modest operative time in most cases except one case that had an intraluminal post-operative bleed along the gastric staple line that was not amenable to clipping with the therapeutic endoscope, for which the patient was re-explored the same day. This was the only patient that required ventilatory support and was routinely on BiPAP support at home. All patients in the study were subjected to prolonged pharmacologic prophylaxis for Deep venous thrombosis. Post-operative Hospital stay was limited to less than 24hrs in most cases with oral allowance after 6 hours. Nasogastric decompression was not performed in any case. No conversions were recorded in our study.

Table 1: Demographic data, pre-operative data and co-morbidity. (n=88)

Mean Age (years)(+s.d)	38.7(+12.3)
Gender	
Male (%)	47(53.4%)
Female (%)	41(46.5%)
Pre-operative Weight(kg) (+s.d)	158kg (+28.9)
Pre-operative Body Mass Index (g/m2)	55.1(+7.8)
Smoker (%)	06(6.8%)
Hypertensive (%)	51(57.9%)
Obstructive sleep Apnea (%)	28(31.8%)
Alcoholic (%)	02(2.2%)
Diabetic (%)	56(63.3%)
Osteoarthritis (%)	14(15.9%)
Gastroesophageal Reflux disease (%)	18(20.4%)
Coronary Artery Disease (%)	03(3.4%)

Table 2: Per-operative data and hospital stay. (n=88)

Mean Operative time (min) (+s.d)	127.6(+37.1)
Mean Hospital stay (days) (+s.d)	2.9(+1.8)
Mean Duration of Pharmacological DVT prophylaxis (Days)	6.7
Per-operative Blood Loss (ml) (+s.d)	58.5(+24.7)
ICU stay for ventilatory support(days)	2.3days

Table 3: Outcomes after single anastomosis gastric Bypass. (n=88)

Remission of diabetes (%)	37(66%)
Remission of Hypertension (%)	41(80.3%)
Improvement of sleep apnea (%)	25(89.2%)
Excess Body Weight Loss (%) at 1st month	26.5%
Excess Body Weight Loss (%) at 6 months	58.1%
Mean Post-operative BMI at 6 months (kg/m2)	37.6

Over a period of 6 months all patients were subjected to relevant investigations to detect improvement or worsening of their co-morbidities. Three patients (3.4%) in our study were candidates that were diagnosed cases of Obstructive sleep apnea and were on regular devices/BiPAP during sleeping hours. At three months all were relieved of their requirement for any devices, although there were no sleep studies documented after surgery. The benefit of the procedure can be demonstrated by the 26.5% excess body weight loss after the first month and a drastic drop of BMI by the 6th month. Metabolic benefits were mainly observed after the first month with sustained benefit despite variable outcomes.

One mortality (1.1%) was observed in the entire study of a patient that was well mobilized and still receiving pharmacological prophylaxis for DVT on the 3rd post-operative day. CT scan confirmed a thrombus in the pulmonary veins but the patient did not respond to therapy and no added treatment was advised by the cardiovascular team. Re-enforcement with sutures for staple-line was not performed in any of the cases. A second case where bleed was documented through the port-site, settled with stopping Injection enoxaparin and transfusion of Fresh Frozen Plasma.

The frequency of nutritional complications was

Table 4: Post-Operative complications after Single anastomosis gastric Bypass. (n=88)

Exacerbation of GERD (%)	06(6.8%)
Pulmonary complications (%)	21(23.8%)
Deep vein thrombosis/pulmonary embolism (%)	01(1.1%)
Prolonged vomiting (%)	03(3.4%)
Post-operative bleed (%)	02(2.2%)
Anastomotic/staple-line leak (%)	00
Inadequate weight loss/weight gain (%)	14(15.9%)
Stomal Ulcer (%)	02(2.2%)
Dumping (%)	24(27.2%)
Internal Herniation (%)	01(1.1%)
Port-site infection (%)	16(18.1%)
Post-operative Pyrexia (%)	19(21.5%)
Iron Deficiency anemia (%)	12(13.6%)
Neurological signs (%)	02(2.2%)
Hypocalcemia (%)	04(4.5%)
Hair loss/skin problems (%)	09(10.2%)
Mortality (%)	01(1.1%)

28% in our series with majority of cases presenting with anemia despite being advised Oral Iron therapy for prolonged duration. Following anemia, skin problems and hair loss was frequent adding to the few rare neurological symptoms seen in 2 patients. Both were advised heavy doses of injection Thiamine, yet one patient developed more advanced neurological impairments and required repeated admissions due to her non-compliant nature. Over her 6-month period she achieved improvement but still required physiotherapy for the restricted movements in her upper limbs. Deficiency of Vitamin D3 was frequent with little or no Hypocalcemia and were advised replacement.

Three patients had complaints of vomiting after small meals not responding to gastric prokinetics. Following Upper Gastro-intestinal Endoscopy two patients had evidence of Marginal ulcers (2.2%). Patients were advised high doses of proton Pump Inhibitors with surveillance. Dumping was observed in most patients with Biliopancreatic lengths approaching 200cm as compared to 150cm where inadequate weight loss.

DISCUSSION

As part of the study design this cross-sectional study included patients with no previous history of abdominal surgery hence no revisional procedures were performed. In a meta-analytic review conducted by Kermansaravi et al⁸. One Anastomosis Gastric Bypass and Mini-gastric Bypass were concluded to be effective and safe procedures following failed restrictive procedures⁹. In the same study 7.4% of all patients developed de novo Gastroesophageal reflux symptoms that was comparable to our study where worsening of existing GERD was observed in 6.8%. No new cases of GERD were observed in our study.

Opponents of the one anastomosis techniques have over-emphasized the development of Gastroesophageal disease, considering that the anatomical mechanisms protecting reflux at the cardia are destroyed during mobilization of the and of His¹². But in literature, few cases have been observed possibly due to a very long pouch and the eventual shrinking of the fat pad around the crurae hence gaining added length of intra-abdominal esophagus. In a recent study by Sumer et al¹³ the authors focused on a new modification of the Mini-gastric Bypass technique where the Angle of His was preserved leaving a

substantial gastro-gastric fistula with longer lengths of Biliopancreatic limbs. Hence proposing the distalization of the BP limb beyond 200cm and the reduced risk of Bile reflux and decreased leak rates. In our study the biliopancreatic limb was modified from the original techniques described by Rutledge et al and Carbajo et al⁶ which had variations in technique from 150-300cm with varying results. In our study the length of the Biliopancreatic limb was limited to 200cm. Despite this reduction in the malabsorptive component there was a 28% observation of nutritional complications.

In another study conducted by study conducted Kermansaravi et al¹⁴ different length of BP limbs were observed with insignificantly increasing anemia and Hypoalbuminemia recorded. When comparing the nutritional markers such as hemoglobin levels and albumin levels with EBWL% showed no significant differences in outcomes ($p=0.344$). The Mean EBWL% in the study by Kermansaravi et al. was 66.89% vs 58.1% (our study) which could be due to much higher BMI and the reduced length of Biliopancreatic limbs. The duration of our study lacked prolonged follow-up being limited only to 6 months in each case, suggesting longer durations of weight loss and better patient outcomes. In a study by Kular et al¹⁵ very long durations of follow up had suggested that there was a 91% excess weight lost at 2 years and was maintained at 85% when data collected till 5 years. Ashour et al¹⁶ had conducted a study of 80 patients all undergoing Mini-gastric Bypass with lesser mean operative times when compared to our study with a mean time of 92(+11.3) min versus 127.6(+37.1)min. this could be explained by the mean BMI difference before surgery in both studies where our study included more obese patients {55.1(+7.8) vs 45(+8.35)}. On the contrary, their mean hospital stay was similar when compared to our study despite longer operative times recorded in our study (2.9days). Mortality rates observed in a study conducted by Carbajo et al. was 0.9% which included 209 patients whereas in our study only one mortality (1.1%) was observed. The number of patients in most studies were much higher than our study, hence suggesting a limited sample to claim inferences from. With the risk associated with patients with very high BMI, the complications rates hold strong association; on the contrary, much higher samples (2410 patients) from a study conducted by Ruthledge and Walsh¹⁷

showed a very low mortality of 0.08%.

In a study of 100 patients conducted by Chakhtoura et al¹⁸ there was a conversion rate of 3% which was not observed in our study and the rate of conversions varied between 0.2%-3% from other studies. There was no leakage reported in our study whereas, a study comprising of 423 patients by Wang et al¹⁹ documented leakage in 9 (2.1%) patients. There was only one case of re-operation due to bleeding (1.1%) whereas the rate of reoperation documented by Musella et al²⁰ was 2% where leak rate was 1% and bleeding was observed in 2.5%. Debates regarding the need to over suture and protect staple-lines have been exhausted in literature over the last two decades but no firm evidence has supported this cause^{21,22}. The limitations of this study were the number of patients and the duration of follow-up. Moreover, the study design and comparison of procedures mentioned in literature suggests different outcomes in different ethnic groups and individuals.

CONCLUSION

One Anastomosis Gastric Bypass is a safe and effective procedure which can be modified and tailored to the individual needs of most bariatric patients including Super Obese patients. It has good results in maintaining remission of Diabetes and Hypertension. There is need to stratify patients according to BMI and compare in Randomized controlled trials with other procedures such as Roux en-Y gastric bypass to draw inferences about the choice of procedure for every individual patient. Modifications of the procedure with larger sample frames and long-term follow-up is required to observe benefits and limitations of the procedure.

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