



Safety and efficacy of laparoscopic sleeve gastrectomy in patients with portal hypertension with liver function of Childs A

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Abstract

Introduction Advanced liver disease and portal hypertension (PH) are seen as a relative contraindication for bariatric and metabolic surgery. Several studies have shown significant improvement in liver function and liver histology after bariatric surgery. There are very few studies describing bariatric surgery in patients with PH. The purpose of this retrospective study is to evaluate the feasibility and results of laparoscopic sleeve gastrectomy (SG) in patients with PH.

Material and methods We present our experience of performing laparoscopic SG in 15 patients with evidence of PH. All the patients were Childs Pugh Criteria A. PH was confirmed by the presence of dilated esophageal varices on endoscopy.

Results The mean operative time was 77.33 ± 15.22 min and mean blood loss was 80.67 ± 37.12 ml. The mean length of stay was 2.73 ± 0.59 days. There were no intraoperative or immediate postoperative complications. None of the patients required blood transfusion in the postoperative period. The weight, BMI, Excess body weight loss% (EBWL%), Total weight loss (TWL) and TWL% at 1 year were 86.05 ± 14.40 kg, 31.16 kg/m² ± 3.82 , $63.84\% \pm 15.24$, 31.49 ± 9.54 kg and $26.50 \pm 5.42\%$, respectively. Diabetes and hypertension resolution at 1 year was 80% and 72.72%, respectively. All the patients were followed up for mean 3 ± 1.5 years. There were no immediate or long-term morbidity and mortality noted.

Conclusion SG is a feasible and safe option for the treatment of obesity in carefully selected patients with PH with good weight loss and comorbidity resolution.

Keywords Laparoscopic Sleeve Gastrectomy (SG) · Roux-En-Y Gastric Bypass (RYGB) · Percentage Excess weight loss (%EWL) · Total weight loss (TWL) · Type 2 diabetes mellitus (T2DM) · Body mass index (BMI) · Portal Hypertension (PH) · Chronic Liver Disease (CLD)

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 India
² Institute of Liver Gastroenterology and Hepatobiliary Sciences, Sir Ganga Ram Hospital, Old Rajender Nagar, New Delhi 110060, India Bariatric and metabolic surgery (BMS) has proven to be one of the most robust solution for obesity and its related comorbidities [1]. But even today advanced liver disease and portal hypertension (PH) is seen as a relative contraindication for bariatric surgery [2].

Studies have shown that 84–96% of patients with obesity have Non-alcoholic fatty liver disease (NAFLD) [3]. Nonalcoholic steatohepatitis (NASH) is present in 25–55% of patients with NAFLD [4]. NAFLD includes a wide spectrum of diseases. This may progress as NASH which may in turn progress to cirrhosis. Several studies have shown significant improvement in liver function and liver histology after bariatric surgery as seen on liver biopsy [5–9]. The role of bariatric surgery in the resolution of hepatic fibrosis is controversial. Though some studies have shown worsening of hepatic fibrosis after surgery, in a study, it was seen that there was an improvement in stage 4 fibrosis in 2/3 of the patients [10], while in another review there was a resolution of hepatic fibrosis in 65.5% of the patients [6]. Apart from this, bariatric surgery improves graft function and reduces the chances of NASH in liver transplant recipients [11, 12]. But there is very limited data on outcomes of bariatric surgery in cirrhotic patients with PH. In a review, there were only 5.7% (n=7/122) patients with PH out of which six underwent SG [13].

The purpose of this retrospective observational study is to evaluate the safety and efficacy of Laparoscopic Sleeve Gastrectomy (SG) in patients with PH in terms of postoperative morbidity and mortality and also the weight loss and comorbidity resolution at 1 year follow-up.

Materials and methods

This is a retrospective analysis of patients suffering from obesity with PH and Child A cirrhosis SG between January 2012 and January 2019. Informed written consent was taken from all the patients involved in the study. Institutional Review Board approval was taken.

Preoperative

Table 1 Classification and

Preoperative evaluation included measurements of height in cm, weight in kg and BMI in kg/m² comorbidity evaluation (HbA1c, ECG, echocardiography, thyroid profile), upper gastrointestinal endoscopy (UGIE), ultrasound abdomen, chest X-ray and nutritional status evaluation (total protein, serum albumin, serum globulin, serum ferritin, serum iron,

vitamin B12, vitamin D3). All the patients in this study had evidence of esophageal varices on UGIE. The varices were graded according to Conn's classification(Table 1). These patients were then appropriately evaluated by the gastroenterologist and were investigated accordingly with Hepatitis B and C blood viral markers, transient elastography (TE) and CTA. TE (Fibroscan) was performed for all the patients and the Fibrosis stage was designated to each patient (Table 1). CTA was also done for all the patients to note the condition of the liver, to rule out the presence of any mass lesion in the liver, Portal vein thrombosis and ascites. CTA also helped to visualise collateral portosystemic vessels specially around Gastro esophageal junction involving splenic and left gastric vessels and to plan the surgery. Patients with esophageal varices size of more than 7 mm and gastric adventitial varices and splenic vein of more than 10 mm size on CT angiography underwent measurement of Hepatic Venous pressure gradient [14]. Patients were selected for the surgery by a multidisciplinary team including gastroenterologists after evaluating the risk vs benefit for each patient. Informed consent after explaining the pros and cons of the surgery was taken for all the patients.

The surgery was offered to patients who had evidence of PH diagnosed by the presence of dilated esophageal varices on preoperative upper gastrointestinal endoscopy (UGIE). The surgery was not offered to patients who on preoperative work up had Childs Pugh B & C liver disease and ascites. These patients were not offered surgery keeping in mind higher risk of morbidity in these patients.

Out of 400 bariatric procedures performed from January 2012 to 2019, 18 patients who were selected for SG

gradings used on UGIE, TE and	Conn's classification for esophageal varices		
liver biopsy	Ι	Visible only during one phase of respiration/performance of Valsalva Manoeuvre	
1.0	II	Visible during both phase of respiration	
	III	3–6 mm in diameter	
	IV	>6 mm in diameter	
	Fibrosis score on TE		
	F1 (2–7 kPa)	Mild fibrosis	
	F2 (7-10 kPa)	Moderate fibrosis	
	F3 (10–14 kPa)	Severe fibrosis	
	F4 (14 or higher kPa)	Cirrhosis or advanced fibrosis	
	Fibrosis score		
	0	No fibrosis	
	1	Fibrosis expansion of some portal areas, with or without short fibrous septa	
	2	Fibrosis expansion of most portal areas, with or without short fibrous septa	
	3	Fibrosis expansion of most portal areas with occasional portal to portal bridging	
	4	Fibrosis expansion of most portal areas with marked portal to portal bridging as well portal to central bridging	
	5	Marked portal to portal bridging as well portal to central bridging with occa- sional nodules (incomplete cirrhosis)	
	6	Cirrhosis (probable or definite)	

had evidence of PH in the form of esophageal varices on UGIE. Out of these two patients were excluded as there was a presence of large collateral portosystemic vessels around the gastroesophageal junction on CTA involving the splenic and short gastric vessels. Hepatic Venous Pressure Gradient (HPVG) was measured for these two patients which were high (HPVG > 10) and thus they were not offered bariatric surgery. In one patient the procedure was abandoned due to the presence of ascites intraoperatively (Fig. 1).

Intraoperative

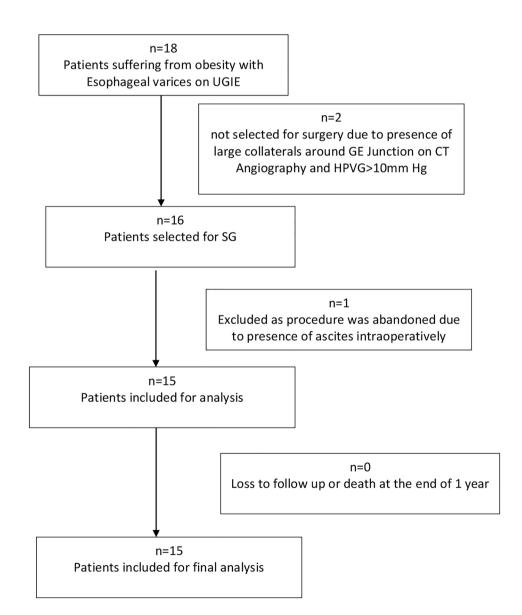
Fig. 1 Flow diagram of patients

included for the study

All the patients underwent SG by standard five-port technique over a 38F bougie. All the surgeries were performed by the same surgeon. Due diligence was followed while tackling the dilated vessels in the greater omentum especially near the gastroesophageal junction and short gastric vessels. Judicious use of vessel sealer and titanium ligating clips was done while taking down the omentum and the short gastric vessels. The staple line was reinforced with a bioabsorbable polymer membrane. Emphasis was given on maintaining absolute hemostasis after completion of SG. An intraoperative methylene blue dye test was done to see for any evidence of a leak. Liver biopsy was done intraoperatively for all the patients using a true-cut biopsy needle.

Postoperative

On the first postoperative day, patients underwent a gastrograffin study to check for any evidence of any leak or obstruction. Early ambulation was done and low molecular weight heparin (Inj Fragmin) was started after 24 h if no signs of haemorrhage were present. The drain was removed once the colour and output of the drain were satisfactory.



All patients were actively followed up regularly at tenth day, 1, 3, 6, 12 months and then annually. Patients were advised to take a high protein diet (minimum 1.5 g/kg body weight daily) and vitamin supplements regularly. During each follow-up, weight, BMI, HbA1c levels and blood investigations for nutritional status evaluation were done. Gastroenterology consultation was done at each follow-up.

Remission criteria for T2DM in this study included HbA1c < 6% without any medications for 1 year [15], while Hypertension remission was defined as a blood pressure less than 140/80 mmHg without medication [16].

Statistical analysis

Data were summarised as the mean and standard deviation using Microsoft Excel, Graphpad and QuickCalcs for continuous variables and as counts and/percentages for categorical variables.

Results

The results of 15 patients with PH who underwent SG and completed 1 year follow-up were analysed. The mean age, preoperative weight, preoperative BMI and Excess Body Weight (EBW) of the patients were 47.60 ± 6.56 years, 117.53 ± 19.97 kg, 43.70 ± 5.79 kg/m² and 52.60 ± 14.50 kg, respectively. There were nine males, four transgenders and two females. On UGIE, Conn's Grade II, III and IV esophageal varices were present in 3, 11 and 1 patients, respectively. TE showed severe fibrosis (F3) in 26.67% (4/15) patients, while cirrhosis (F4) was present in 73.34% (11/15) of the patients (Table 2). Eleven patients had a history of hypertension, while all the patients in our study were diabetic.

The mean operative time was 77.33 ± 15.22 min and mean blood loss was 80.67 ± 37.12 ml. The mean length of stay was 2.73 ± 0.59 days. There were no intraoperative or immediate postoperative complications. None of the patients

Table 2 Esophageal varices, TE and liver biopsy grading distribution

	n
Esophageal varices (Conn's classification)	
Grade II	3
Grade III	11
Grade IV	1
TE score	
F3	4
F4	11
Fibrosis score on liver biopsy	
Fibrosis score 6 (Cirrhosis)	15

required blood transfusion in the postoperative period. Drains were removed depending on the amount and colour of the contents. Liver biopsy showed features of cirrhosis with a Fibrosis score [17] of six in all the patients.

At 1 year follow-up, there was no major procedure-related morbidity or mortality. The weight, BMI, Excess body weight loss% (EBWL%), Total weight loss (TWL) and TWL% at 1 year and at mean follow-up of 3 ± 1.5 years(range 1–5 years) are mentioned in Tables 3 and 4.

At 1 year follow-up, diabetes and hypertension resolutions were 80% (12/15) and 72.72% (8/11), respectively. A strict follow-up of all the patients was done with active phone calls and consultation visits. At the longer follow-up, the diabetes resolution was seen in 66.67% (10/15) of the patients, while hypertension resolution was seen in 75% of the patients.

Three patients on follow-up complained of Gastroesophageal Reflux Disease (GERD) symptoms and endoscopy was done. No varices were seen on the follow-up endoscopy for these three patients.

Discussion

At present approximately 50% of the patients undergoing bariatric surgery are diagnosed with NAFLD and around 1–4% suffer from incidental cirrhosis [4, 8, 9, 18–20]. Several studies have suggested that weight reduction can lead to significant improvement in NAFLD in terms of histology, a reversal of non-alcoholic steatohepatitis, and in some cases

Table 3 Follow-up data at 1 year

86.05 ± 14.40
31.16 ± 3.82
62.84 ± 15.24
31.49 ± 9.54
26.50 ± 5.42
80% (12/15)
72.72% (8/11)

Table 4 Follow-up data at mean 3 ± 1.5 years

Mean weight (kg)	79.87±10.9
Mean BMI (kg/m2)	29.09 ± 5.23
Mean EBWL (%)	$73.28 \pm 27.05\%$
Mean TWL (kg)	37.67 ± 17.62
Mean TWL%	30.90 ± 10.83
DM resolution	80% (12/15)
HTN resolution	72.72% (8/11)

reversal of fibrosis [5, 6]. A significant improvement in steatosis and steatohepatitis in 74.6% and 60.6% of the patients, respectively, were reported after SG [10], while in another study it was seen that hepatic fibrosis was reduced by 54.3% on liver biopsy after gastric bypass [21].

Patients with cirrhosis undergoing surgery have been reported to have a longer hospital stay, higher overall hospitalisation cost as well as an increased risk of adverse outcome [22, 23]. Similarly, bariatric surgery in patients without cirrhosis have lower mortality rates than those with compensated and decompensated cirrhosis (0.3 vs. 0.9% and 16.3%, respectively, P=0.0002). In the same study, the overall early mortality of 1.2% was noted in cirrhotic patients [24]. Similarly in a review, an early and late overall mortality of 1.6% and 2.45%, respectively, were seen. The late mortality occurred in the patients who underwent RYGB and BPD due to liver decompensation and fulminant hepatic failure [13].

It is important to note that postoperative mortality in patients with Childs A cirrhosis is around 10% which rises to 30% and 80% in patients with Childs B and C, respectively [25, 26]. Metabolic surgery can be performed safely in well-selected patients who have a compensated cirrhosis with Childs A disease with minimal risk of surgical and liver-related complications. The reluctance of bariatric surgeons to perform bariatric surgery on patients with Childs B and C disease is obvious in many studies [13]. Only 1/11 patients developed liver decompensation and encephalopathy at 2 years [27]. In another study that included 23 patients with cirrhosis who underwent RYGB and SG, no 30-day mortality was noted. Out of 23 patients, only one has Childs B cirrhosis while three patients had PH. They did not note any liver decompensation after surgery [19]. In our study, all the patients had Childs A cirrhosis of the liver with evidence of PH on endoscopy in form of varices. There were no surgery-related complications requiring re-surgery or readmissions in the immediate postoperative period or during the 1 year follow-up. The patients were discharged at mean 2.7 ± 0.59 days. There was no early or late mortality noted in our series both at the end of 1 year and on longer follow-up.

At present, there is no consensus on the ideal bariatric procedure for patients with cirrhosis. In a review, it was seen that the overall complication rate with LAGB, RYGB, BPD and SG were 20%, 31.3%, 13.3% and 14.6%, respectively, while the liver decompensation rate were 0%, 3.92%, 13.3% and 12.5%, respectively. There were no mortalities noted in the LAGB and SG groups as compared to BPD and RYGB [13]. It was also noted that though a higher liver decompensation was noted with SG, it was self-limiting and none led to mortality [13]. A malabsorptive procedure like BPD and occasionally RYGB leads to malnutrition in the long term which leads to further decompensation of the cirrhotic liver [13]. SG does not involve any bowel anastomosis and

is relatively easier to perform, has shorter operative time and lesser postoperative complications as compared to other more complex bariatric procedures [28–30]. Also unlike RYGB, the remnant stomach tube remains accessible for diagnostic and therapeutic endoscopy if required in the future. Apart from this other advantage of SG is removal of fundal varices along with the fundus of the stomach. Because of these reasons SG has been the surgery of choice in such patients in several studies more so for patients with PH [19, 20, 27]. In our study, all the patients had PH and the mean operative time and intraoperative blood loss were 77.33 ± 15.22 min and 80.67 ± 37.12 ml, respectively, that was comparable to the literature [11, 31].

In cirrhotic patients who underwent bariatric surgery, complications were seen in 34.8% (8/23) of the patients including gastrojejunal stricture, gastrojejunal anastomotic leak and infected hematoma in the RYGB group and stricture, staple line leak and pneumonia in SG group [19]. Other complications during SG included uncontrolled intraoperative bleeding and postoperative hematoma managed with blood transfusion [31]. In a recently published large series of 71 patients with Child A NASH related cirrhosis without PH who underwent SG reported two intraoperative injuries and major complications in 9 patients which included four postoperative bleeding, two postoperative leakages, ascites, encephalopathy and chest infections which were all managed conservatively [10]. Hanipah et al. noted out of 13 patients who had PH and underwent bariatric surgery (SG in 10 and RYGB in 3 patients) noted 30-day complication in three patients which included wound infection treated by debridement, subcutaneous hematoma managed by drainage and one intra-abdominal haemorrhage managed conservatively. There was no 30-day mortality, while one patient died at 8 months due to infective colitis leading to septicaemia [32]. In our study, none of the patients had any intraoperative or postoperative procedure-related complications including haemorrhage or long-term liver decompensation.

While performing SG in these patients it is imperative to take care of haemostasis. The presence of dilated vessels especially near the fundus can lead to profuse intraoperative bleed if injured. It is a good idea to secure these vessels with clips before dividing them and to achieve adequate staple line hemostasis. Some authors have described reinforcement of the staple line by oversewing it with continuous sutures [10]. In our study, the staple line was reinforced with a bioabsorbable polymer membrane.

Bariatric procedures lead to significant weight loss and comorbidity resolution as has been seen in different studies. In our study EWL% was $62.84 \pm 15.20\%$ at 1 year with a significant reduction in weight from 117.53 ± 19.97 kg to 86.05 ± 14.40 kg which is comparable to the results of SG in the literature [10, 11, 31]. Patients suffering from obesity and cirrhosis are 3.5 more likely to have diabetes and hypertension [2]. Clinical remission of diabetes and improvement in hypertension following SG in these patients approach 66.7% and 68.7%, respectively [19]. Diabetes and hypertension remission rate was 80% and 72.72%, respectively, at 1 year follow-up in our study.

There are a few limitations to this study. Firstly, it is a retrospective study with a very limited number of patients from a single referral centre with a short follow-up 1 year. Secondly, the diagnosis of PH was made based on endoscopy and CT Angiography and HPVG was not measured for all the patients. Thirdly, we did not perform the follow-up TE or liver biopsy in our patients to avoid additional cost to the patient.

Conclusion

In patients suffering from obesity, the prevalence of NAFLD is quite common and this may progress to cirrhosis and PH. Bariatric surgery is an excellent modality to stop the progression of this disease and even reverse the disease process. SG due to its simplicity can be safely and effectively performed in patients with PH in carefully selected patients with minimal morbidity and good results in terms of weight loss and comorbidity resolution.

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Declarations

Disclosures Tarun Mittal, Anmol Ahuja, Ashish Dey, Vinod K Malik, Mohammed Taha Mustafa Sheikh, Naresh Kumar Bansal and Harish Kanuri declare that they have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

Research involving human and animal rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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