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ORIGINAL CONTRIBUTIONS

Safety and Efficacy of Bariatric Surgery in Advanced Liver Fibrosis

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Abstract

Background There is limited data on the safety and efficacy of metabolic and bariatric (MBS) surgery in patients with advanced liver fibrosis.

Methods This is a retrospective analysis of data of patients with advanced liver fibrosis undergoing MBS at a tertiary care centre. Weight loss and complications were analysed. Transient elastography and liver biopsy findings 1 year after surgery were compared with baseline.

Results Twenty-two patients had cirrhosis and 16 had stage 3 fibrosis; all were Child Pugh A. Majority (76%) underwent sleeve gastrectomy. Mean excess BMI loss was 65.8 ± 18.9%. There were no leaks or 30-day mortality. One patient with cirrhosis had late mortality due to liver decompensation. Preoperative and postoperative median LSM were 15.5 kPa (interquartile range IQR = 24.4–11.6) and 10.9 kPa (IQR 19.3–7.6), respectively. Preoperative and postoperative median CAP were 352.5 dB/m (IQR = 372–315.5) and 303 dB/m (IQR 331–269.5), respectively. On follow-up biopsy, nine of twelve patients had improvement in fibrosis, while three had no change. Four out of five patients in the cirrhotic cohort had improvement in fibrosis stage and LSM improved in all of them. Five out of seven patients with stage 3 fibrosis had an improvement in fibrosis stage and none progressed to cirrhosis. LSM improved in three of these five patients.

Conclusion MBS has the potential to ameliorate advanced liver fibrosis, including cirrhosis. Transient elastography can be used as an effective tool for screening and follow-up of liver disease in patients undergoing MBS.

Keywords Bariatric surgery · NASH · Cirrhosis · Fibroscan · Liver biopsy

Background

The prevalence of non-alcoholic fatty liver disease (NAFLD) in the general population varies from 25 to 30%, increasing up to 90% in morbid obese patients [1]. It represents a spectrum, of which, a subset with more severe liver disease, namely non-alcoholic steatohepatitis (NASH), may progress to severe fibrosis, cirrhosis, and hepatocellular carcinoma [2]. Cirrhosis frequently coexists in patients seeking metabolic and bariatric surgery (MBS), with 1–4% of patients found to have incidental liver cirrhosis during surgery [3]. While up to 69.5% patients have shown complete resolution of NASH after MBS [4], traditionally, cirrhosis of liver has been considered an irreversible pathology. Although some recent evidence has challenged this concept [5], there is still a dearth of literature on the safety and efficacy of MBS in patients with advanced

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liver disease. This study aims to evaluate the safety and outcomes of MBS in severely obese patients with advanced liver fibrosis, i.e. stage 3 and 4 liver fibrosis.

Methods

This is a retrospective review of a prospectively collected database of patients undergoing MBS at a tertiary care centre from July 2014 to December 2018. All patients with evidence of cirrhosis or advanced liver fibrosis on intraoperative liver biopsy (IOLB), i.e. stage 3 or 4 fibrosis as per the NASH Clinical Research Network scoring system [6], were included. Patients who had grossly nodular liver on laparoscopy were also included.

Demographic and clinical details of all patients, including weight, body mass index (BMI), comorbidities, liver function test (LFT), and Child Turcotte Pugh (CTP) class, were noted. All patients had preoperative assessment of Liver Stiffness Measure (LSM) and Controlled Attenuation Parameter (CAP) by transient elastography (TE), performed using an XL probe, to estimate the degree of fibrosis and steatosis, respectively. The detailed technique of TE has been described in a previous publication [7]. Biopsy was done from the left lobe of the liver using 16G BARD® MAX-CORE® Disposable Core Biopsy Instrument.

These patients were then followed up for 6–12 months. The outcome measures included weight loss, perioperative complications, early and late mortality, LFT, LSM, CAP, and liver histology on follow-up biopsy, if done. Percutaneous biopsy of the right lobe of the liver was done under local anesthesia 1 year after surgery in patients who gave consent.

The patients were categorized into two cohorts—'Cirrhosis' and 'Stage 3 Fibrosis'. The 'Cirrhosis' cohort included patients with obvious nodularity on laparoscopy and/or stage 4 fibrosis (for NAFLD-related cirrhosis) or features of cirrhosis (for other types of cirrhosis) on IOLB. The rest of the patients were categorized as 'Stage 3 Fibrosis'. The variables were analysed for all the patients as well as separately for Cirrhosis and Stage 3 Fibrosis cohorts.

Results

Whole Cohort

Overall, 38 patients with advanced fibrosis of the liver underwent MBS. Of these, 22 had cirrhosis of liver and 16 had stage 3 fibrosis. All patients were CTP class A; only one patient in the Cirrhosis cohort had portal hypertension and grade 3 esophageal varices. The etiology of liver disease was NAFLD in all but three patients of cirrhosis; two of these were reformed alcoholics, while one was on treatment for hepatitis B. Mean age was 41.2 ± 10.7 years and mean BMI was 47.7 ± 7 kg/m^2. Twenty-three (60.5%) patients were diabetic and 11 (28.9%) were hypertensive. The median LSM and CAP were 15.5 kPa (interquartile range IQR = 24.4–11.6) and 352.5 dB/m (IQR 372–315.5) respectively.

Majority (76%) of the patients underwent sleeve gastrectomy (SG), followed by RYGB (15.8%) and OAGB (7.9%). All patients with nodular liver underwent SG. Intraoperatively, two patients had staple line ooze that needed oversewing. Of these, one with portal hypertension and gastric varices was transfused one unit of packed red blood cells.

Follow-up

Thirty-one (81.6%) patients came for follow-up. The median follow-up was 34.5 months (range 6–56). The mean weight and BMI at 12 months were 86.4 ± 14.8 kg and 33.1 ± 5.5 kg/m^2. The mean excess BMI loss was 65.8 ± 18.9%. Of the 23 diabetic patients, 20 patients did not require or had a decrease in dosage of hypoglycemic agents.

All the patients had a follow-up TE, except one patient in the Cirrhosis group, who died at 7 months from liver decompensation. The median LSM and CAP at 12 months were 10.9 (IQR 19.3–7.6) kPa and 303 ± (331–269.5) dB/m, respectively. Seven patients (23.3%) showed worsening on TE, three in the Cirrhosis cohort and four in the Stage 3 Fibrosis cohort. Twelve patients consented for percutaneous liver biopsy at the end of 1 year, of which, nine had an improvement in fibrosis, while three had no change in the fibrosis (Tables 3 and 4). None of the patients with stage 3 fibrosis had progression to cirrhosis.

Complications

There were no leaks or 30-day mortality. One patient with portal hypertension developed transient postoperative liver decompensation, which was managed conservatively. Another cirrhotic patient developed postoperative flank ecchymoses, which settled with withholding of the anticoagulants. However, he was readmitted after 6 months with ascites and died after a month of hospital stay due to progressive hepatic decompensation. One patient with stage 3 fibrosis had transient hepatic decompensation at 21 months after surgery. While these serious complications were seen after SG, no major complications occurred in the patients who underwent bypass procedures. However, on comparison, the difference was not statistically significant. There were no leaks or mortality in the Stage 3 Fibrosis cohort. Two patients had postoperative fever, which was managed conservatively.

Cirrhosis Cohort

Out of 22 patients in this cohort, 18 had gross nodularity of the liver at laparoscopy, while 4 had a non-nodular but fatty and

enlarged liver. These four patients had a stage 4 fibrosis on liver biopsy. Twenty patients had a preoperative TE; the median LSM was 19.2 (IQR 14.2–26.7) kPa and the median CAP was 344 (323.7–362) dB/m. The baseline characteristics of both the cohorts are shown in Table 1.

Seventeen patients were available for follow-up at a median duration of 27 months (range 6–51). An excess BMI loss of 62.4 ± 15.83% was observed, with a mean weight and BMI progression as shown in Fig. 1. The impact on LFT is shown in Table 2. The median LSM and CAP decreased to 15.2 (IQR 24.1–8.7) kPa and 321.5 (IQR 339–282.5) dB/m respectively. Three patients showed worsening on follow-up TE evaluation. Five patients consented for a follow-up liver biopsy. The impact on the grade of fibrosis and LSM in these five patients is depicted in Table 3. The median hospital stay was 4.8 days.

Stage 3 Fibrosis Cohort

In this cohort, all the 16 patients were found to have gross fatty liver without any nodule on laparoscopy. All of them had stage 3 fibrosis on IOLB. None of the patients in this cohort had any history of significant alcohol intake or hepatitis B/C infection. The median LSM and CAP were 12.6 (8.5–19.4) kPa and 358.5 (299.5–382.5) dB/m respectively.

Fourteen patients were available for follow-up at a median duration of 43.5 months (range 19–56). The excess BMI loss was 69.64% ± 21.71. The mean weight and BMI progression are shown in Fig. 1 and the impact on LFT in Table 2. The median LSM and CAP decreased to 8.5 (IQR 14.825–6.35) kPa and 293 (IQR 311.5–252) dB/m, respectively. Four patients showed worsening on follow-up TE evaluation and the results of 7 patients, who consented for liver biopsy after 12 months of surgery, are shown in Table 4. Five patients showed improvement in fibrosis stage to F1 or F2. None of the patients showed progression to F4 stage. The median hospital stay was 4.12 days.

Discussion

The incidences of early and late hepatic decompensation in our study were 2.6% ($n = 1$) and 5.3% ($n = 2$), respectively. There was only one late mortality at 7 months from liver decompensation. These results reconfirm the safety of MBS in advanced liver disease. In the era of open surgery, risk of mortality after major abdominal surgery was around 10%, 30%, and 80% for Child's A, B, and C cirrhosis, respectively [8, 9]. With the advent of minimal access surgery, improved outcomes have been observed in a range of surgical procedures compared with open surgery [10–13]. In a systematic review of 122 patients of cirrhosis who underwent MBS, incidences of overall complication and early and late surgical mortality were 21.3%, 1.6%, and 2.45%, respectively. Mean age and BMI were 49.6 years and 50.4 kg/m^2, respectively. Majority were female (60.6%) and had CTP A cirrhosis (96.5%) and only 5.7% patients had portal hypertension [3]. In contrast, the cirrhotic patients in our study were younger and majority (70%) were males. Only one patient in our series had portal hypertension; he developed early postoperative liver decompensation, which could be managed conservatively. In a recent study of 13 patients with cirrhosis and portal hypertension, there were three early complications, including wound infection, subcutaneous hematoma, and intra-abdominal hematoma, without any mortality. Notably, none

Table 1 Baseline characteristics of the two cohorts

Parameter	Cirrhosis ($n = 22$)	Stage 3 Fibrosis ($n = 16$)	p value
Age (years) Mean ± SD	41.4 ± 10.9	40.9 ± 10.5	0.89
Weight (kg) Mean ± SD	129 ± 24.7	119.5 ± 23.8	0.23
BMI (kg/m^2) Mean ± SD	48.8 ± 7.5	45.7 ± 5.6	0.17
Male/female	14/8	6/10	0.82
T2DM, *n* (%)	15 (68.2)	8 (50)	0.26
HTN, *n* (%)	7 (31.8)	4 (25)	0.38
LSG/RYGB/MGB	20/2/0	9/4/3	-
LSM (kPa)	19.2	12.6	0.03
Median (interquartile range)	(14.2–26.7)	(8.5–19.4)	
CAP (dB/m)	344	358.5	0.47
Median (interquartile range)	(323.7–362)	(299.5–382.5)	

BMI body mass index, *T2DM* type 2 diabetes mellitus, *HTN* hypertension, *LSG* laparoscopic sleeve gastrectomy, *RYGB* Roux en Y gastric bypass, *MGB* mini gastric bypass, *LSM* liver stiffness measurement, *CAP* controlled attenuation parameter

Table 2 Liver function tests of the two cohorts

Parameter	Cirrhosis ($n = 22$)			Stage 3 Fibrosis ($n = 16$)		
	Preoperative	Follow-up ($n = 17$)	p value	Preoperative	Follow-up ($n = 14$)	p value
Serum bilirubin (mg/dl)	0.7 ± 0.3	0.5 ± 0.2	0.13	0.5 ± 0.1	0.6 ± 0.2	0.12
AST (IU/ml)	43.4 ± 23.5	34.6 ± 22.7	0.24	42.1 ± 19.4	34.1 ± 19.4	0.26
APT (IU/ml)	47.5 ± 29.4	33.2 ± 20.2	0.09	37.1 ± 16.4	22.3 ± 16.4	0.02
ALP (IU/ml)	151 ± 128.7	95.4 ± 46.9	0.09	135 ± 71.8	120 ± 71.9	0.57
Albumin (g/dl)	3.9 ± 0.3	3.8 ± 0.4	0.35	3.9 ± 0.4	3.6 ± 0.4	0.06

Values reported as mean ± SD

AST aspartate aminotransferase, *ALT* alanine aminotransferase, *ALP* alkaline phosphatase

of the patients had early postoperative hepatic decompensation. However, four patients developed late ascites and were enrolled for liver transplantation. Interestingly, six patients had TIPS procedure either prior to ($n = 4$) or after ($n = 2$) MBS [14]. In another study of 71 patients with cirrhosis, there were nine major and two minor complications; however, there was no reoperation or mortality [5]. From these data and also from the review by Jan et al., it appears that late mortality is a greater concern than early surgical mortality. Most early complications are manageable with conservative treatment. Whether the delayed mortality is due to MBS or a result of the natural course of cirrhosis is difficult to determine, as there has been no randomized trial comparing MBS with conservative management in obese patients with cirrhosis. In contrast, in a study involving 26 patients with cirrhosis, there were no long-term cirrhosis-related complications or mortality but the incidence of 30-day complications was quite high (38.5%). Interestingly, majority of the complications in this series were noted in patients who had undergone RYGB [15].

Regarding the choice of operative procedure in patients with cirrhosis, although there is no comparative study, SG and RYGB are the two most reported in the literature. Over the last 10 years, more literature on SG has been published [15–18], suggesting that more surgeons are favouring SG over RYGB in patients with cirrhosis. This preference arises from a potential risk of hepatic decompensation after malabsorptive procedures as well as difficult access to the bypassed stomach and bile duct, for endoscopic surveillance of varices and extraction of bile duct stones, respectively. A third reason for preferring SG is that the altered anatomy with RYGB may make future liver transplantation more difficult [19]. As observed by Jan et al. in their review, none of the patients, who had sleeve gastrectomy, died, despite a higher rate of liver decompensation, which the authors reckoned was due to sicker patients being offered SG. On the other hand, 20% and 3.9% of patients having biliopancreatic diversion and RYGB, respectively, died [3]. Brolin reported one perioperative and two late deaths in seven patients with cirrhosis who underwent RYGB [20]. In contrast, Dallal et al., in their series of RYGB on 27 patients with cirrhosis, observed acceptable complication rate and only a single late unrelated death [21]. In our study, although there was a greater incidence of hepatic decompensation after SG, this is probably due to selection of higher risk patients (e.g. nodular liver, portal hypertension) for SG. The patient who had liver decompensation at 21 months post SG had actually been consuming alcohol throughout but

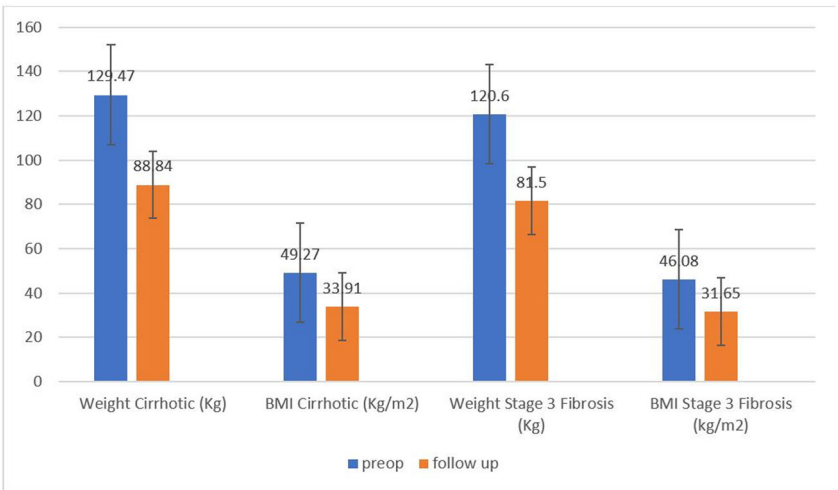

Fig. 1 Weight and BMI progression of both the cohorts

Table 3 Liver biopsies at follow-up (Cirrhosis cohort)

Patient number	Preop fibrosis	Postop fibrosis	Preop LSM (kPa)	Postop LSM (kPa)	Preop CAP (dB/m)	Postop CAP (dB/m)
1	Stage 4	Stage 0	23.2	20.9	373	334
2	Stage 4	Stage 3	11.4	8.4	280	286
3	Stage 4	Stage 3	9.2	5.7	338	261
4	Stage 4	Stage 4	24.6	17.1	324	226
5	Stage 3 (nodular liver)	Stage 0	21.1	9.7	400	268

LSM liver stiffness measurement, *CAP* controlled attenuation parameter

did not reveal until the time of liver decompensation. Moreover, the numbers were too small for any meaningful comparison and SG remains to be our preferred operation in patients with nodular liver. In fact, two patients, who were planned for RYGB and OAGB, were converted to SG on table due to nodularity of the liver; both had an uneventful recovery. In our opinion, RYGB should not be considered an absolute contraindication in cirrhosis; it should be reserved for situations when SG is contraindicated, as in Barrett's esophagus or severe gastro-esophageal reflux disease.

Notwithstanding the surge of evidence of safety and feasibility of MBS in patients with cirrhosis, the overall incidence of postoperative complications is still high compared with patients without cirrhosis. This, along with the risk of late mortality, should be explained to patients who opt for surgery. The biggest hindrance to preoperative counselling of patients is that majority of cases of cirrhosis are diagnosed incidentally during surgery, by visual inspection of a nodular liver. The incidence of unexpected finding of cirrhosis during MBS is 1–4% [16, 20–22]. This is because LFT and ultrasonography are not very sensitive for diagnosis of cirrhosis. The gold standard of diagnosis is liver biopsy, which is an invasive procedure. Transient elastography is a novel, non-invasive technique to assess hepatic fibrosis and steatosis, which has been validated in chronic hepatitis B, chronic hepatitis C, and NAFLD [23]. LSM and CAP correlate well with hepatic fibrosis and steatosis, respectively. Inaccuracies associated with the use of Fibroscan® due to subcutaneous fat in severely obese patients have been successfully surmounted by the use of XL-probes [24].

Considering gross nodularity of the liver and/or histopathology to be the gold standard for cirrhosis, LSM cut off of 11.8 kPa can reliably predict the presence of advanced fibrosis preoperatively with a sensitivity of 80% and specificity of 85.5% [25]. This is evident in the current study by the median LSM values of 19.2 kPa and 12.6 kPa in Cirrhosis and Stage 3 Fibrosis cohorts, respectively. In a similar study, the best LSM cut off for advanced fibrosis was 12.65 kPa, with a sensitivity of 63.6% and a specificity of 87.7% [26].

In our study, the median LSM decreased from 15.5 to 10.9 kPa and the CAP decreased from 352.5 to 303 dB/m at 12 months of follow-up. Four out of the five patients in the cirrhotic cohort, who consented for follow-up liver biopsy at 1 year, had an improvement in fibrosis stage. All these patients had an improvement in the LSM values. Similarly, five out of the seven patients in the Stage 3 Fibrosis group had an improvement in the stage of fibrosis. Three of these five patients showed a decrease in the LSM values. Thus, TE may be used as an indirect method to determine the impact of MBS on the condition of the liver. However, larger studies of follow-up liver biopsy and TE are required to establish the exact role of the latter as a follow-up tool.

All said and done, in spite of the commonly performed preoperative investigations, cirrhosis may still be missed and the surgeon may face a dilemma in deciding further management on incidental finding of a nodular liver on laparoscopy.

Table 4 Liver biopsies at follow-up (Stage 3 Fibrosis cohort)

Patient number	Preop fibrosis	Postop fibrosis	Preop LSM (kPa)	Postop LSM (kPa)	Preop CAP (dB/m)	Postop CAP (dB/m)
1	Stage 3	Stage 3	58	75	320	319
2	Stage 3	Stage 1	12.2	17.6	374	362
3	Stage 3	Stage 3	12.8	14.7	294	304
4	Stage 3	Stage 1	6.3	8.9	222	204
5	Stage 3	Stage 2	8.2	6.4	290	168
6	Stage 3	Stage 1	12.7	9.3	300	270
7	Stage 3	Stage 0	7.6	4.6	298	268

LSM liver stiffness measurement, *CAP* controlled attenuation parameter

Our policy is to counsel all patients of this possibility and take consent for change of procedure to sleeve gastrectomy, when other procedures are planned.

Another question that arises around this discussion is, if routine IOLB should be offered to all patients undergoing MBS, which is further substantiated by the findings from this study, where 4 out of 22 patients had evidence of stage 4 fibrosis on histopathology without having grossly nodular liver. While visual inspection can largely identify liver nodularity and resultant cirrhosis, it cannot be used as a standalone criterion to guide liver biopsy. Findings from USG, LFT, preoperative TE, and visual inspection at surgery may be used concurrently to guide the decision for liver biopsy. A policy of routine, or at least, liberal IOLB, would help surgeons to better prognosticate patients in the postoperative period. Various scoring systems have been formulated to determine the risk of severity of liver disease like AST Platelet Ratio Index (APRI), NAFLD Fibrosis Score, Fib-4 score, BARD score, and Fibroscan-based score [27]. These may be used if a policy of selective liver biopsy is undertaken. In a recent study, Ooi et al. have found a combination of wedge biopsy from left lobe and core biopsies from both lobes to be most sensitive for diagnosis of fibrosis [28]. Percutaneous liver biopsy done as a follow-up procedure, subject to patient consent, may help generate more data on the impact of MBS on cirrhosis.

Majority (75%) of patients in our study had improvement in liver fibrosis on follow-up liver biopsy, with 25% having complete resolution of fibrosis and none having any worsening. In a recent study on 71 biopsy-proven patients with cirrhosis, the authors reported improvement in steatosis, steatohepatitis, and fibrosis in over two-thirds of patients, 30 months after MBS. While 12.8% patients had complete resolution of steatosis and 36.8% had resolution of steatohepatitis, none of the patients had complete resolution of fibrosis [5]. Only a few patients in our study consented to follow-up biopsy, which, along with its retrospective nature, is a limitation of this study. However, all liver biopsies were examined by a liver histopathologist. To the best of our knowledge, this is the largest study on patients with advanced liver disease, showing the utility of TE as a follow-up investigation to assess impact of MBS on advanced liver fibrosis. A single surgeon performed all the procedures, ensuring a standard surgical technique and perioperative management protocol. The outcomes in terms of weight loss, remission of comorbidities, and complications confirm the safety and efficacy of MBS in patients with compensated cirrhosis and advanced fibrosis of the liver.

Conclusion

MBS may be safely performed in well optimized, CTP A patients with advanced fibrosis or cirrhosis. It results in good excess BMI loss, remission of comorbidities like diabetes and hypertension and has the potential to ameliorate NAFLD-related cirrhosis in a subset of patients. TE is an effective tool for screening patients for liver disease before surgery and also for subsequent follow-up.

Compliance with Ethical Standards The study was undertaken after clearance from Institutional Ethics Committee. There was no commission or omission of intervention for the study purpose and all the interventions were done in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

A written informed consent was taken from each patient for the surgical procedure.

Conflict of Interest The authors declare that they have no conflict of interest.

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