Research Article
Liver Transplantation

JOURNAL OF HEPATOLOGY

Simultaneous liver transplant and sleeve gastrectomy provides durable weight loss, improves metabolic syndrome and reduces allograft steatosis

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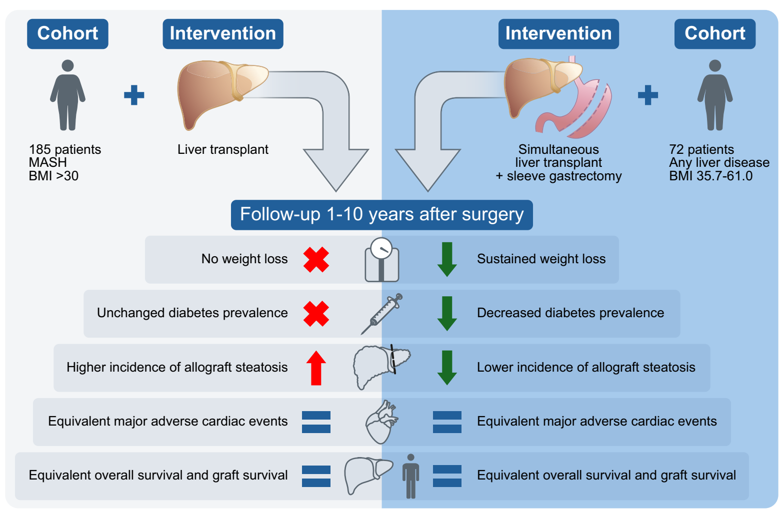
Graphical abstract



Highlights

- Simultaneous LT and sleeve gastrectomy (LTSG) leads to significant, sustained weight loss compared to LT alone.
- LTSG is associated with decreased incidence of allograft steatosis compared to LT alone.
- LTSG is associated with decreased prevalence of post-operative diabetes compared to LT alone.
- LTSG is associated with equivalent mortality, graft loss, and major cardiovascular events compared to LT alone.

Impact and implications

The optimal approach to liver transplant for patients with obesity and end-stage liver disease remains uncertain, especially given the risk for recurrent metabolic dysfunction-associated steatotic liver disease. The current study provides the first multicenter analysis of outcomes for patients treated with combined liver transplant and sleeve gastrectomy and includes an assessment of key outcomes of interest such as weight loss efficacy, recurrent steatosis and fibrosis, and diabetes, as well as reflux (a known complication of sleeve gastrectomy) in addition to assessing for sarcopenia prior to transplant. The results demonstrate that combined liver transplant and sleeve gastrectomy can be successfully adopted at multiple centers and provides long-term efficacy in managing both end-stage liver disease and obesity, which may be of interest not only for clinicians and researchers, but also for patients and policy makers.

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Simultaneous liver transplant and sleeve gastrectomy provides durable weight loss, improves metabolic syndrome and reduces allograft steatosis

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Background and Aims: The prevalence of obesity and metabolic syndrome is rising among liver transplant (LT) candidates, many of whom have metabolic dysfunction-associated steatotic liver disease (MASLD). We aimed to determine the long-term impact of simultaneous LT and sleeve gastrectomy (LTSG) in patients with obesity transplanted for MASLD.

Methods: We analyzed patients undergoing LTSG using a single clinical protocol (n = 72), and patients with BMI >30 who underwent LT alone for MASLD (n = 185) in a multicenter retrospective cohort study. Follow-up duration was 4-153 (median 41) months for LTSG and 12-161 (median 75) months for LT. Outcomes included mortality, graft loss, BMI, metabolic syndrome components, allograft steatosis and fibrosis.

Results: Mortality and graft loss were not significantly different between the LT and LTSG groups. The prevalence of diabetes was significantly lower in patients undergoing LTSG *vs.* LT alone after 8 years of follow-up (p <0.05), while hypertension decreased from 61.1% to 35.8% in the LTSG group (p <0.01). Patients undergoing LTSG (average starting BMI of 45.5) experienced significant weight loss compared to baseline for >9 years (p <0.001), while no significant change was seen for the LT-alone group (average starting BMI 34.0). The incidence of allograft steatosis was significantly lower in the LTSG *vs.* LT group (p = 0.004). The prevalence of fibrosis was reduced in the LTSG *vs.* LT group 3-10 years postoperatively (relative risk ratio 0.46; p = 0.09). One patient in the LTSG group had a gastric sleeve leak and one required hiatal hernia repair. Severe gastroesophageal reflux disease occurred in 11.1% of the LTSG group; risk factors included pre-existing diabetes and gastroesophageal reflux disease.

Conclusions: LTSG results in sustained weight loss, resolution of diabetes and hypertension, and reduced recurrence of steatosis and possibly fibrosis compared to LT alone. It confers no increase in mortality or graft loss.

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Introduction

The percentage of liver transplant (LT) candidates in the US with obesity is steadily increasing. In 2022, 41.3% of waitlisted candidates had a BMI >30 and 17.3% had a BMI >35.[1] The impact of obesity on long-term LT outcomes is complex. Early studies found obesity to be associated with decreased 5-year overall and graft survival,[2] and increased postoperative infectious complications.[3,4] However, more contemporary studies have demonstrated similar patient and graft survival in obese and non-obese LT recipients.[5–7] Instead, they have identified comorbid conditions including metabolic syndrome (MetS),[8] diabetes,[7,9–11] hypertension,[12] sarcopenia,[13] or cardiovascular disease as more important predictors of patient and graft survival. However, obesity is a major component of the pathophysiology of metabolic dysfunction-associated steatotic liver disease (MASLD) and a risk factor for progression of fibrosis, which in the setting of MASLD is associated with hepatic decompensation and mortality.[14,15] Patients transplanted for MASLD are at high risk of recurrent steatosis and fibrosis in the allograft, possibly because of persistent metabolic disease.[16]

As more centers assess transplant candidates with class III obesity, bariatric surgery is one strategy to optimize care and manage the burden of both obesity and other MetS components.[17] In selected patients with compensated cirrhosis, it has been shown to reduce the risk of major adverse cardiac events (MACE).[18] Weight loss has been associated with regression of hepatic fibrosis, a reduction in rates of hepatocellular

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carcinoma,[18] and reduced need for transplant in patients with MASLD.[19,20]

Bariatric surgery can be performed before,[21–25] during,[26–29] or after the liver transplant, though the optimal approach is not yet established.[30–37] To date, the published data on bariatric surgery before or after transplantation consists of case series, often with short follow-up. These early results demonstrate effective weight loss, improvement in diabetes, and stable immunosuppressive regimens. However, performing bariatric surgery before or after transplant presents challenges. When performed before transplantation, patient selection is generally limited to those with compensated cirrhosis, as elective surgery in patients with decompensated cirrhosis is correlated with unacceptable rates of perioperative mortality.[38] Patients undergoing bariatric surgery who had compensated cirrhosis had a mortality odds ratio of 2.17, while those with decompensated cirrhosis had a mortality odds ratio of 21.2 compared to patients without liver disease undergoing bariatric surgery.[39,40] Additionally, a recent intention-to-treat analysis showed that transplant wait-list patients with a history of bariatric surgery have higher rates of death and delisting prior to transplant, and lower overall survival.[41] Bariatric surgery after transplantation can be technically challenging because of adhesions and altered anatomy, as well as the risks of long-term immunosuppression. In a meta-analysis, 16% of patients undergoing bariatric surgery following LT experienced major complications or mortality.[42] Bariatric surgery at the time of transplant has been proposed to address these concerns, while also providing effective treatment for obesity. Case-reports and single-center series have demonstrated both safety and efficacy for weight loss.[26,28]

Sleeve gastrectomy (SG) is the preferred bariatric surgical option, as it preserves endoscopic access to the biliary tree, access to the stomach and gastroesophageal junction for treatment of varices, and limits nutrient and drug malabsorption. We present the first multicenter cohort study of patients with long-term follow-up who underwent simultaneous LT and sleeve gastrectomy (LTSG), with a focus on metabolic endpoints, allograft steatosis and fibrosis, and post-transplant gastroesophageal reflux disease (GERD).

Patients and methods

The study design was approved by the institutional review board. Retrospective analysis was performed on all patients who underwent LTSG at three large transplant centers in the US, using an identical clinical protocol. All patients who underwent LT and SG during the same operative procedure (LTSG) were included in the analysis, including seven who received concurrent kidney transplant. Patients with BMI >35 were identified and offered non-invasive obesity management: physical activity recommendations, dietary counseling, weight loss goals, with ongoing follow-up and monitoring. Patients who were unsuccessful with non-invasive weight loss or had a BMI >40 at the time of LT were offered SG. Patients with prior bariatric surgery were not offered SG. There was no upper BMI or model for end-stage liver disease (MELD) cut-off. Patients (n = 2) who planned to undergo both procedures at the time of incision but underwent LT alone were excluded. One exclusion was due to an intraoperative finding that raised suspicion of diaphragmatic hepatocellular carcinoma invasion, and one was due to a grade 3 laceration in the liver allograft due to a traumatic injury in the donor which caused post-recirculation hemorrhage.

A comparison cohort was constructed using the following criteria: patients who underwent LT at the highest volume site in the study after August 2000, had BMI >30, and had a diagnosis of MASLD. MASLD was defined according to consensus criteria: hepatic steatosis in the presence of one or more cardiometabolic comorbidities, in the absence of excessive alcohol consumption.[43] Control patients from the largest study site were selected to reduce bias, since 71% of the patients undergoing LTSG were transplanted there, including all patients prior to 2018.

Both groups were assessed for transplant using the 6-minute walk test. Both cohorts were treated using the same immunosuppression protocol and were followed annually after the first post-transplant year. Demographic data, including age, sex, and self-reported race were collected. Primary outcomes assessed included BMI, mortality and graft loss. Secondary outcomes included evolution of MetS, including diabetes, development of allograft steatosis and fibrosis, and MACE. MACE was defined as non-fatal myocardial infarctions, non-fatal strokes, or death from cardiovascular causes as reported to UNOS (United Network for Organ Sharing). For LTSG, outcomes data also included cause of death, data regarding GERD, and CT imaging data.

Diagnostic methods

Diabetes was defined as HbA1c >6.5% in the absence of treatment, or current treatment with insulin or anti-diabetic agents. Hypertension was defined as the use of antihypertensive agents and a documented clinical diagnosis of hypertension. Hyperlipidemia was defined as the elevation of fasting total cholesterol levels in the absence of treatment, or current treatment with lipid- or cholesterol-lowering agents. Gastrointestinal reflux was defined as nausea, vomiting, heartburn, and anorexia, or endoscopic evaluation due to patient-reported reflux symptoms. All patients undergoing LT and LTSG were prescribed a proton pump inhibitor (PPI) for at least 1 year postoperatively per transplant center protocol, so only cases with breakthrough reflux symptoms were noted.

Magnetic resonance elastography (MRE) is a non-invasive imaging technique to assess the development of hepatic fibrosis. Our institutional protocol correlates stiffness and fibrosis according to the following scale: normal: <2.5 kPa; normal or inflammation: 2.5–3.0 kPa; Stage 1-2 fibrosis: 3.0–3.5 kPa; Stage 2-3 fibrosis: 3.5-4.0 kPa; Stage 3-4 fibrosis: 4.0-5.0 kPa; Stage 4 fibrosis or cirrhosis: >5 kPa. MRE also allows for quantification of hepatic steatosis via proton density fat fractionation (PDFF); however, due to the low availability of this measurement in our cohort, PDFF was not used in this study. MRE was recommended every other year for patients undergoing LT and LTSG. Radiologist assessment of parenchyma texture on protocolized annual ultrasonography was used to assess the development of steatosis. Although some patients also had biopsy or Fibroscan data, these were inconsistently available and were not used.

Final diagnoses, including of MASLD, were determined based on explant pathology reports, clinical syndromes, hepatitis status, alcohol consumption, and genetic analysis.

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For patients undergoing LTSG, sarcopenia was determined by assessing the total abdominal musculature area (TAMA) in cm^2 in an abdominal CT section at the L3 vertebral level according to our previously published institutional protocol.[44] TAMA was normalized by height in meters squared. Men with TAMA index <53 and women with TAMA index <41 were classified as sarcopenic.[45] The majority of patients underwent an abdominal CT scan in the pre-operative period as part of the standard assessment. The contrast phase and methodology for obtaining scans were heterogenous. The scan immediately preceding the LTSG was selected for the analysis. If no pre-operative CT was available, scans taken up to 2 weeks post-operatively were used. Data was available for 51 patients undergoing LTSG. All muscle area selections were reviewed by the manuscript authors (ELL or SDE) and manually corrected to accurately capture the skeletal muscle.

Statistical methods

All analyses were performed using R 4.2.1 (supplementary CTAT table). *P* values for comparison tests were calculated using t-tests for continuous data, Mann-Whitney tests for continuous non-normally distributed data, and χ^2 or Fisher's exact tests for categorical data. Kaplan-Meier survival curves were compared using the Cox proportional hazards (PH) method. Pre-operative age, BMI, and diabetes status were significantly different between LT and LTSG populations and were subject to multivariate survival analysis. Midpoint imputation was used in Kaplan-Meier analysis for steatosis, and sensitivity testing was performed as described in the results. Statistical significance was set at p <0.05.

Results

Demographics

There were 72 patients in the LTSG cohort and 185 patients in the LT-alone cohort. In the LTSG group, the median follow-up duration was 40 months (range 4 to 153 months), while one patient died before their 4-month follow-up visit. In the LT-alone group, the median follow-up duration was 72 months (range 12 to 161 months); 10 patients died or were lost to follow-up prior to their first annual exam. The LT-alone cohort was significantly older and had a significantly lower BMI at the time of transplant (Table 1). There was a significantly lower proportion of Hispanic patients in the LT-alone cohort. In the LT-alone cohort, among patients with MASLD and BMI >30, there was no clinically significant difference in gender distribution, age, or BMI at the non-primary sites compared to the primary site; there were significantly more Hispanic or Latino patients (data not shown).

In the LT-alone cohort, MASLD contributed to liver failure in 100% of patients. In the LTSG cohort, metabolic dysfunction-associated steatohepatitis (MASH)/MASLD was present in 60 (83.3%) cases (Table 2); steatosis was present in 50 (69.4%) explanted livers.

Metabolic endpoints

Patients undergoing LTSG had mean total body weight loss of 30.2% at 1 year, 18.6% at 5 years, and 17.3% at 10 years. This decrease in BMI was significant for at least 9 years after surgery (p <0.001); there was too little data for years 10-12 to determine statistical difference, although the trend favored sustained weight loss (Fig. 1A). In contrast, patients in the LT-alone cohort had no significant decrease in BMI. The average weight change for the LT-alone cohort ranged from -1.5% to +7.9% over the course of monitoring.

At the time of transplant, 31 (43.1%) patients in the LTSG group had diabetes compared to 58.4% of patients in the LT-alone cohort; this difference was not statistically significant (p = 0.23). At 1 year after surgery, the prevalence of diabetes was significantly decreased to 20.3% (13 cases) in the LTSG cohort (p <0.001), while remaining steady at 58.9% in the LT-alone group (p = 0.997) (Fig. 1B). In both LT and LTSG populations, some patients experienced remission of their diabetes while others developed new-onset disease. The significant difference between diabetes prevalence in patients undergoing LT and LTSG persisted for at least 8 years postoperatively; there was too little data after 9 years to determine statistical significance.

Following LTSG, the prevalence of hypertension significantly decreased. Of the patients with at least 1 year of follow-up after LTSG, 44 (58.5%) had hypertension at transplant and 24 (36.9%) had hypertension at their last follow-up visit (p = 0.02) (Fig. 1C). Last follow-up was an average of 48 months after surgery. Hyperlipidemia prevalence decreased throughout the

Table 1. Demographics of the LTSG and LT cohorts.

Parameter	LTSG cohort	LT-alone cohort	*P* value
Mean age at transplant, years [range]	53 [29, 68]	61 [29, 72]	<0.001
Gender			
Male	44 (61.1%)	117 (63.2%)	0.86
Female	28 (38.9%)	68 (36.8%)	
Race and ethnicity			
Asian/Pacific Islander	1 (1.4%)	3 (1.6%)	0.03
American Indian/Alaska Native	1 (1.4%)	6 (3.2%)	
Black/African American	1 (1.4%)	0	
Caucasian	62 (87.3%)	169 (91.3%)	
Hispanic/Latino	6 (8.3%)	2 (1.1%)	
Middle East/North African	1 (1.4%)	5 (2.7%)	
Median BMI at transplant in kg/m^2 [range]	44.6 [35.7, 61.0]	34.0 [30.0, 44.1]	<0.001
T2DM at transplant	31 (43.1%)	108 (58.4%)	0.01
Median duration of follow-up, months [Q1, Q3]	41 [23, 82]	75 [36, 123]	<0.001

Categorical data analyzed using χ^2-tests. Continuous data analyzed using t-tests (age) and Mann-Whitney *U* tests (BMI, follow-up).
LT, liver transplant; LTSG, liver transplant plus simultaneous sleeve gastrectomy; T2DM, type 2 diabetes mellitus.

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Table 2. Additional cohort features.

Cohort	LTSG	LT
Median ascites volume at transplant, ml [range]	300 [0, 8,200]	500 [0, 9,800]
Mean MELD (standard deviation)	29.2 (8.9)	NA
Donor type		
DCD	4	9
DBD	66	165
Living	1	11
Directed donor	1	NA
Diagnosis (>1 diagnosis per patient is allowed)		
A1AT	12	12
AIH	4	1
Allograft failure	2	0
ALD	10	16
CCA	0	1
Fulminant/toxic	1	0
HBV or HCV	6	3
HCC	16	59
Hemochromatosis	0	2
HHT	1	0
HPS	3	5
MASH	60	185
Oxalosis	1	0
PBC	1	0
Steatosis in explanted liver		
No	19	NA
5% or less, "mild"	13	
Yes	37	
No comment on steatosis	3	

A1AT, alpha-1-antitrypsin deficiency; AIH, autoimmune hepatitis; ALD, alcohol-associated liver disease; CCA, cholangiocarcinoma; DBD, donor brain death; DCD, donor cardiac death; HBV/HCV, hepatitis B/C virus; HHT, hereditary hemorrhagic telangiectasia; HPS, hepatopulmonary syndrome; MASH, metabolic dysfunction-associated steatohepatitis; NA, not available; PBC, primary biliary cholangitis; PHTN, portopulmonary hypertension; PSC, primary sclerosing cholangitis.

first year postoperatively, then increased slightly at the last follow-up: from 25 persons (37.7%) to 24 (39.3%) (p = 0.99).

Patients received yearly allograft ultrasounds which assessed steatosis. Patients undergoing LTSG missed 68 (22.8%) of their annual ultrasounds, while those undergoing LT alone missed 172 (16.3%). This was partially due to travel restrictions during the COVID pandemic. Using Cox PH testing, the incidence of post-transplant steatosis as measured by ultrasonography was significantly higher in the LT group compared to the LTSG group (p = 0.003) (Fig. 1D). Midpoint imputation was used for this calculation; however, the overall result is robust to the assumption of steatosis development at the beginning or end of the interval between ultrasounds (Cox PH p = 0.002 and p = 0.004, respectively). Multivariate hazard analysis determined the proportional effects of LT *vs.* LTSG, BMI, age, and diabetes on the development of steatosis. While LTSG was significantly associated with steatosis (hazard ratio 0.202, 95% CI 0.095–0.431, p <0.0001), age and diabetes did not have a significant effect on the development of steatosis (Fig. 1E). BMI was statistically associated with steatosis development, but this association was not clinically significant (hazard ratio 1.08, 95% CI 1.03–1.13, p = 0.0014).

Patients were less frequently able to obtain MREs than ultrasounds. MRE was rarely administered prior to 2010; even after 2010, they were administered sporadically, possibly due to a combination of patient preference, clinical circumstance, and travel restrictions. MREs were performed at 81 (23.3%) annual LT follow-up visits and 243 (27.2%) annual LTSG visits. As fibrosis is anticipated to progress over months to years, MRE results were grouped as early (1-2 years postoperatively) and long-term (3-10 years postoperatively). Only the latest MRE in each period was analyzed. The incidence of post-transplant fibrosis at years 3-10 was higher in the LT cohort, 28 (33.3%) having resistance indices indicating fibrosis > grade 1, *vs*. 4 (15.4%) in the LTSG cohort (Fig. 1F), though the difference was not statistically significant (Fisher's exact, p = 0.09) due to low case numbers.

Univariate Kaplan-Meier analysis demonstrated a significantly lower incidence of MACE in the LTSG group (p = 0.037) (Fig. 1G). Multivariate Cox PH analysis showed that type of surgery (LT *vs*. LTSG) was not statistically significantly associated with MACE (p = 0.25); instead, underlying differences in age (p = 0.02) and diabetes (p = 0.01) were significantly associated with differences in MACE between cohorts (Fig. 1H).

Survival

Kaplan-Meier curves of overall survival and graft survival demonstrated no significant survival differences between patients who underwent LT alone *vs*. LTSG (Fig. 2A,B), and no significant effects due to diabetes, age, or BMI in multivariate analysis (Fig. 2D,E). Eleven patients died after LTSG. The median time from LTSG to death was 22 months, range 3.7 to 141 months. Causes of death included motor vehicle collision, malignancy, septic shock due to COVID, voluntary cessation of dialysis, and two deaths at home with unknown etiology and no recent hospitalizations. Two deaths were direct sequelae of transplant, including idiopathic refractory cholestasis and persistent encephalopathy. No consistent pre-operative risk factors were identified for mortality. Ascites, MELD, donor type, pre-existing diabetes, hypertension, and hyperlipidemia were not independent significant predictors of any adverse post-operative outcome in the LTSG group. The overall conclusions regarding development of steatosis, graft loss, and MACE were unchanged by the introduction of all-cause mortality as a competing risk (supplement 1).

Reflux and other complications

In the LTSG group, 46 patients had GERD prior to transplantation (Fig. 3). Postoperatively, 17 patients in the LTSG group experienced GERD symptoms despite PPI administration; 15 of those had pre-operative reflux, 12 were male, and 12 had pre-operative diabetes. Seven patients experienced severe post-LTSG reflux requiring endoscopy for further assessment; all seven had pre-operative reflux, six were male, and six had pre-operative diabetes. Pre-operative reflux was a significant predictor of both PPI-refractory and severe reflux (p = 0.02 and 0.04). Diabetes was also a significant predictor of both PPI-refractory and severe reflux (p = 0.01 and 0.04). Male sex is associated with both PPI-refractory and severe reflux, with odds ratios of 1.71 and 4.19, respectively, though these associations were not statistically significant (p = 0.41 and 0.24, respectively).

Other complications included one gastric staple-line leak; this patient underwent multiple surgical procedures, endoscopic procedures, drain placement, and long-term antibiotic therapy but fully recovered. One patient developed hiatal hernia

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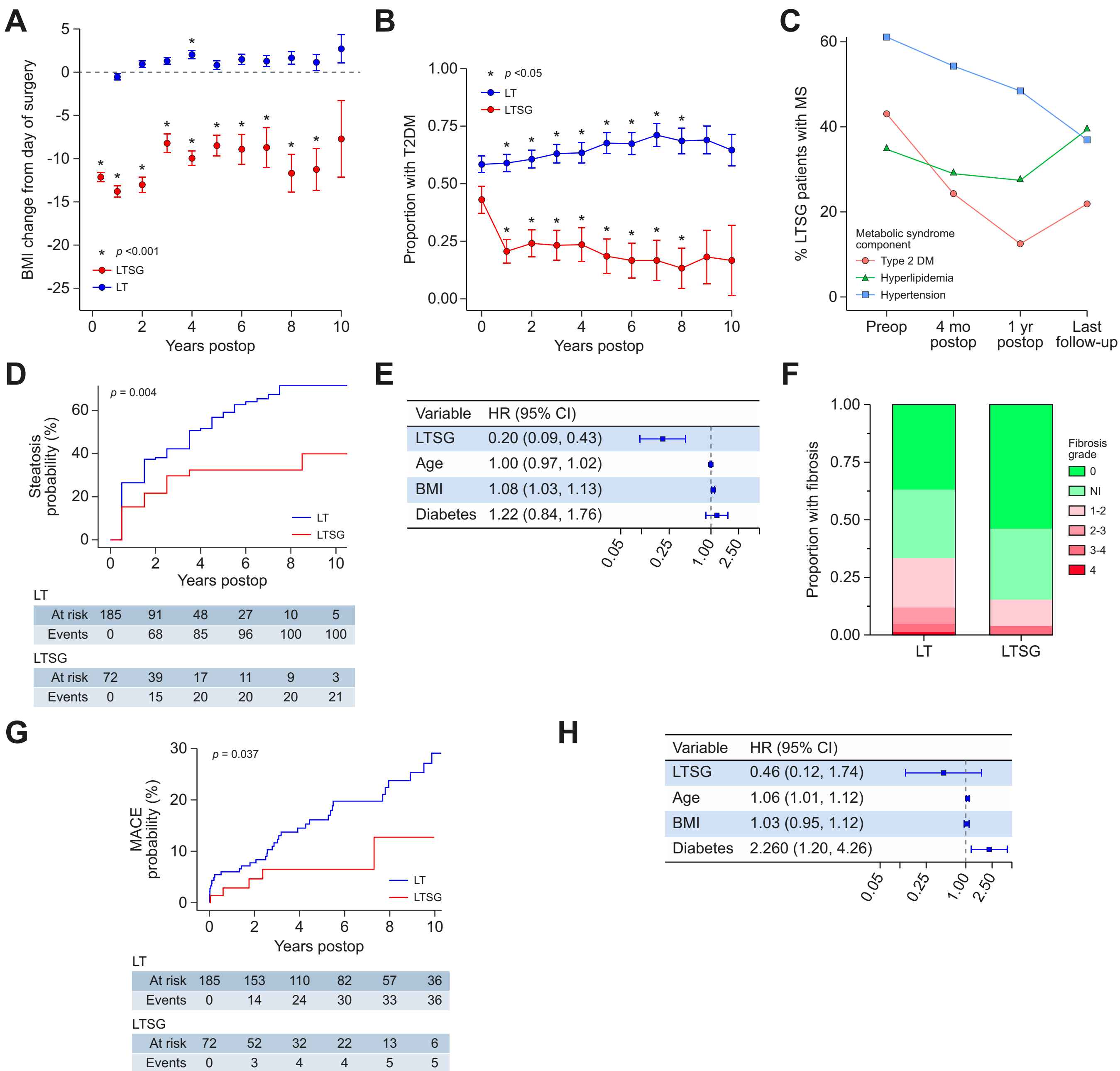

Fig. 1. Evolution of metabolic syndrome, fibrosis, and steatosis in patients undergoing LT and LTSG. (A) The LTSG group had a decrease in BMI which was significant for at least 9 years postop (all p <0.001, one-sample t-tests; p values not adjusted for multiple comparisons). The LT-alone group had no significant decrease in BMI, although one significant increase in BMI was observed during year 4 (p <0.001, one-sample t-test). Mean BMI changes with standard error bars are shown. (B) The LTSG group had a significant remission of T2DM in the first postoperative year and maintained a significantly lower prevalence compared to the LT-alone group for at least 8 years (all p <0.05, χ^2-tests; p values not adjusted for multiple comparisons). Bars represent standard errors. (C) Metabolic syndrome evolution over time in the LTSG group. Diabetes prevalence decreases significantly (p <0.001, χ^2-test), as does hypertension (p = 0.02, χ^2-test). Hyperlipidemia prevalence decreases transiently but is ultimately unchanged (p = 0.99, χ^2-test). (D) Inverse Kaplan-Meier curves show that patients undergoing LTSG are less likely to develop allograft steatosis than those undergoing LT alone (p = 0.004, Cox PH). (E) Surgery type (LTSG *vs.* LT) remains significantly associated with steatosis development in multivariate analysis (p <0.0001, multivariate Cox PH). Pre-operative age and diabetes are not significantly associated with steatosis development (p = 0.83 and 0.29), while BMI is statistically but not clinically (HR 1.08, 95% CI 1.03–1.13, p = 0.0014). Bars represent 95% CI. (F) The LTSG group had a lower prevalence of fibrosis measured by MRE stiffness score at an aggregated endpoint of the most recent scan 3-10 years after transplant. LT prevalence is 33.3%, LTSG prevalence is 15.4% (p = 0.09, χ^2-test). (G) Inverse Kaplan-Meier curves show that patients undergoing LTSG had significantly lower incidence of MACE (p = 0.037, univariate Cox PH). (H) Surgery type (LTSG *vs.* LT) was no longer significantly associated with MACE once underlying demographic differences in the LTSG and LT populations were considered (p = 0.25, multivariate Cox PH). Pre-operative diabetes and age were significantly associated with MACE (p = 0.01 and 0.02, multivariate Cox PH). Bars represent 95% CI. LT, liver transplant; LTSG, liver transplant plus simultaneous sleeve gastrectomy; MACE, major adverse cardiac events; PH, proportional hazards; MRE, magnetic resonance elastography; T2DM, type 2 diabetes mellitus.

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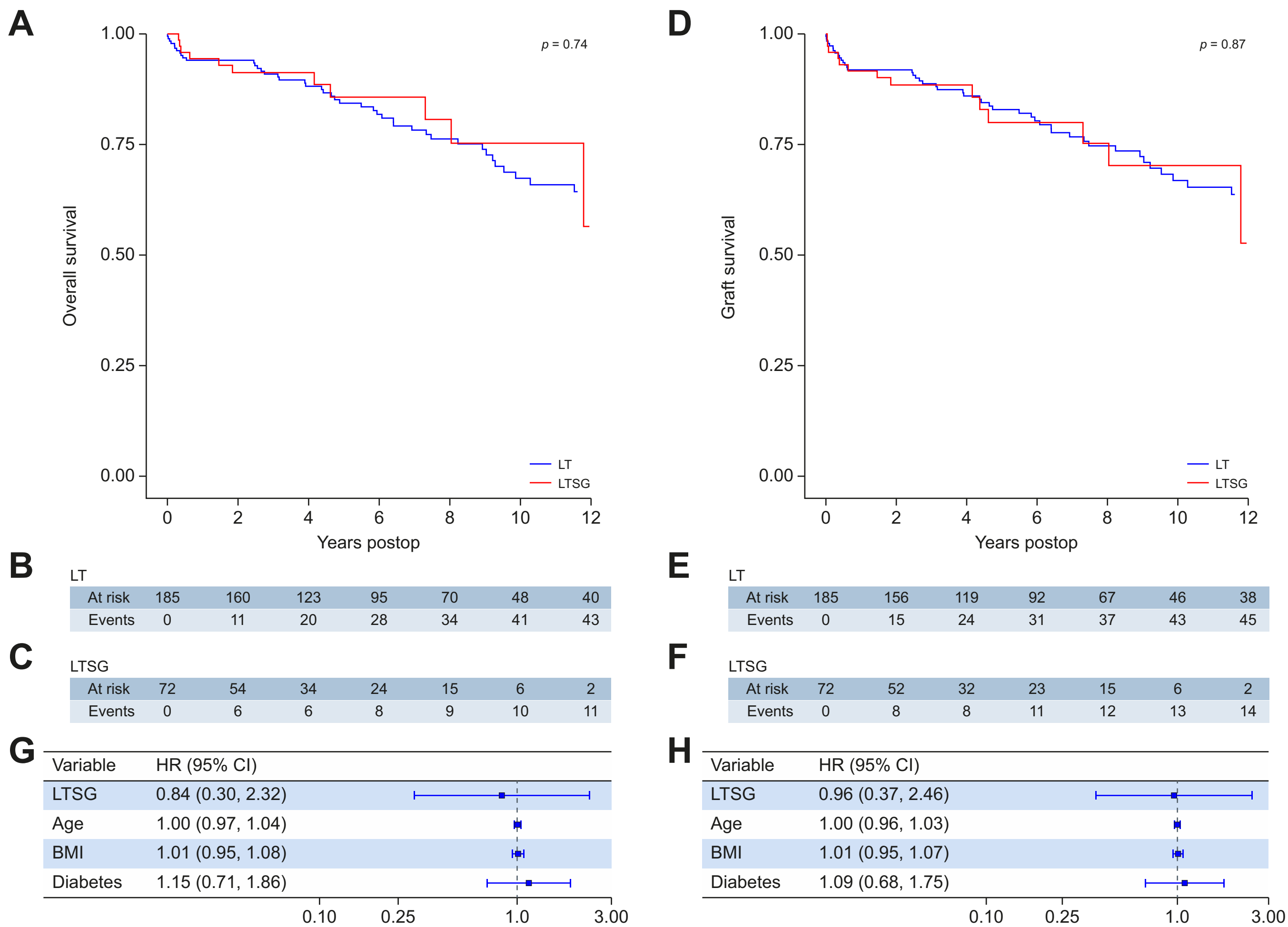

Fig. 2. Survival in patients undergoing LTSG and LT. (A–C). There is no significant difference in overall survival between LTSG and LT patients. (D–F). There is no significant difference in graft survival between LTSG and LT patients. G. A forest plot of multivariate Cox analysis shows that surgery type, age, BMI, and DM have no significant effect on the odds ratio (OR) of overall survival. H. Multivariate Cox analysis shows that surgery type, age, BMI, and DM have no significant effect on the odds ratio (OR) of graft survival. LT, liver transplant; LTSG, liver transplant plus simultaneous sleeve gastrectomy; PH, proportional hazards.

and underwent a technically challenging but otherwise uncomplicated transabdominal hiatal hernia repair.

Based on height-normalized TAMA at L3 (cm^2/m^2), only 3 (5.9%) patients in the LTSG group met pre-determined criteria for sarcopenia (Fig. 4). Sarcopenia was not associated with the presence of adverse postoperative outcomes.

Discussion

The rising prevalence of obesity in those awaiting LT has led to an increased need for safe and effective ways to manage not only obesity but also comorbid MetS, and to slow the onset of recurrent or *de novo* MASLD in the allograft. Similar to SG in other contexts, the benefits of LTSG include sustained weight loss and significant reduction in the prevalence of diabetes; no significant long-term changes in weight or diabetes were observed in our LT-alone cohort. Decrease in hypertension and no change in hyperlipidemia occurred in the LTSG population; although hypertension and hyperlipidemia data is not available for the LT cohort, other studies demonstrate an increase in the prevalence of hypertension and hyperlipidemia following

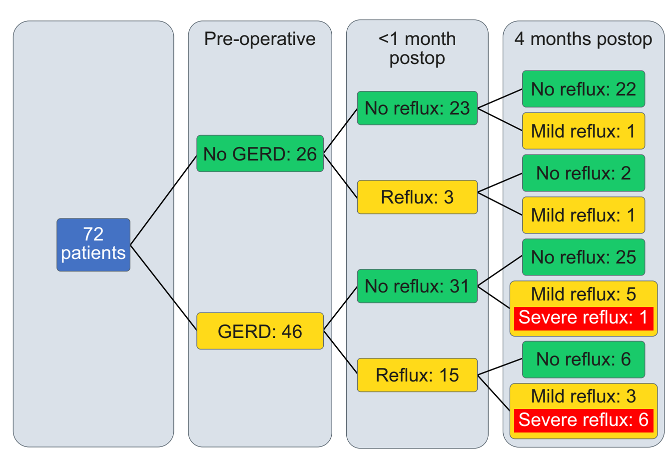

Fig. 3. The development of reflux over time in patients undergoing LTSG. Patients with pre-operative diagnosis of GERD were more likely to develop postoperative mild, medication-responsive reflux or severe reflux requiring interventions by 4 months postop (p = 0.02 or 0.04 respectively, Fisher's exact test). GERD, gastroesophageal reflux disease; LTSG, liver transplant plus simultaneous sleeve gastrectomy.

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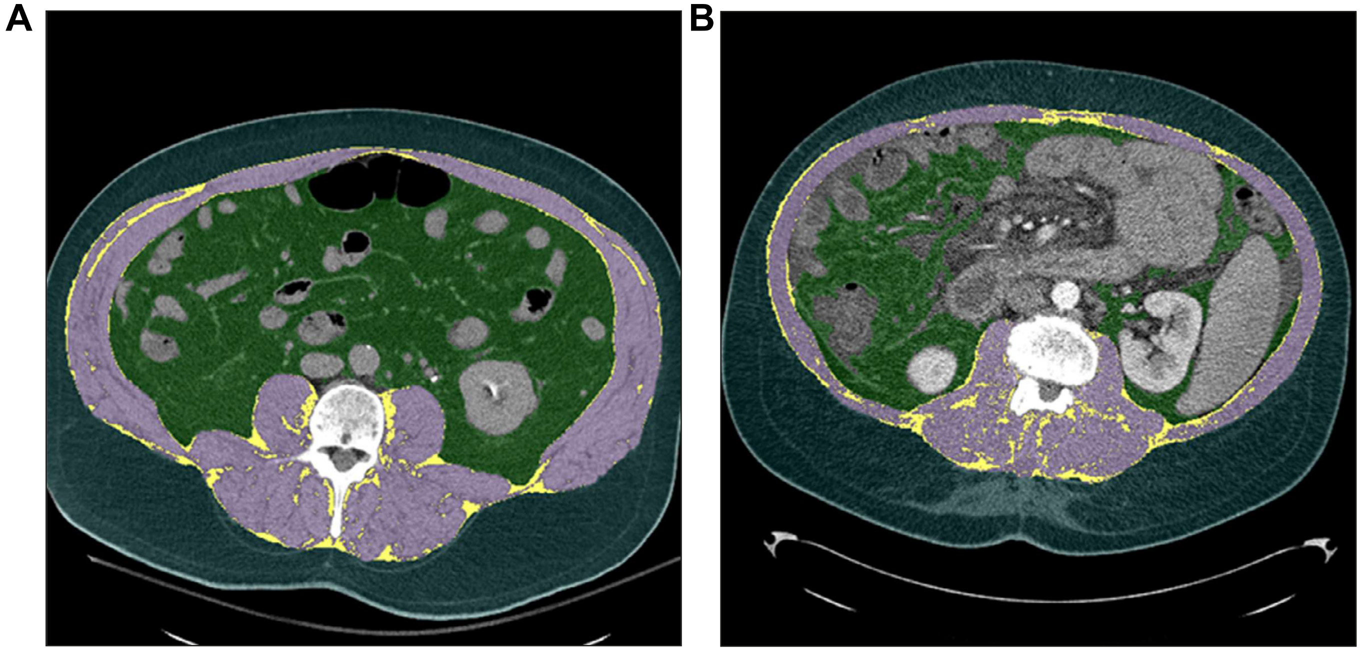

Fig. 4. Sarcopenia. CT cross-sections at the L3 level for patients (A) without and (B) with sarcopenia.

standard LT.[46] Our data support the importance of offering LTSG as a method to reduce metabolic comorbidities post-transplant in patients with obesity.

SG was overwhelmingly preferred by the patients in this study; nearly all patients at the primary study site with BMI >40 opted to undergo LTSG instead of LT alone. Anecdotally, some had sought bariatric surgery elsewhere prior to transplant but were denied due to liver disease.

The pathophysiology of MASH is marked by the progression from steatosis to steatohepatitis, fibrosis, and cirrhosis. Following LT, MASLD and MASH frequently reoccur. Meta-analysis demonstrates an 82% rate of recurrent MASLD 5 years after transplant, and 38% for recurrent MASH. Even in patients with no MASLD prior to transplant, 78% developed it by 5 years after transplantation.[47] In this study, we attempted to assess both steatosis and fibrosis non-invasively, as biopsy data is not routinely collected in our patients. One weakness of our study is that these are imperfect surrogate measures, although any measurement bias would affect both groups equally. In a meta-analysis of studies comparing MRE results to liver biopsy results, MRE had sensitivity of 83% and specificity of 89% for detecting stage 3 or greater fibrosis.[48] In a meta-analysis,[49] ultrasound had sensitivity of 85% and specificity of 94% for the detection of moderate or severe hepatic steatosis. PDFF data was not recorded consistently and was thus not used in this study.

This study shows a significantly lower incidence of allograft steatosis and a non-significantly lower allograft stiffness score in patients undergoing LTSG. Importantly, this suggests that the addition of SG may alter progression of recurrent MASLD. Reports of repeat LT for allograft MASH are rare,[50] although whether this is due to lower risk of decompensation, poor candidacy for repeat transplantation or altered pathophysiology also remains unclear. None of the patients in this study received repeat transplantation for recurrence of their original disease.

Gastroesophageal reflux is a well-documented long-term complication of SG. This study identified pre-operative diabetes, GERD, and potentially male sex as risk factors for both medication-responsive and refractory postoperative GERD. Increasing PPI frequency to twice daily, decreased dosage or complete elimination of mycophenolate mofetil, and administration of sucralfate slurry were effective treatments for GERD in most patients, and in all cases, severe GERD improved over time, potentially related to successful weight loss. GERD does have the potential to markedly impact quality-of-life. Patients with refractory reflux often underwent multiple invasive procedures, such as endoscopy and feeding tube placement; its risk factors should be carefully considered and anticipatory guidance provided as part of the risk-benefit discussion. While the current study did not perform a quality-of-life assessment, our prior single-center study on LTSG demonstrated no quality-of-life difference between LTSG and LT with weight loss by lifestyle modification.[28]

While performing LT and SG during the same procedure theoretically increases the risk of complications, these risks did not translate into increased mortality in this study. Compared to patients undergoing LT alone, LTSG did not increase the incidence of all-cause mortality or graft failure over a period of 12 years, which supports the low risk of life-limiting adverse events caused by simultaneous SG. Important technical considerations include ensuring adequate exposure, which is generally easier in an obese patient with advanced liver disease, due to muscle wasting and/or ascites. Ensuring adequate retractor instrumentation for increased patient size is essential. A second challenge is mobilization of the stomach due to gastric varices and splenomegaly; this component of the procedure is performed with the assistance of a transplant

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surgeon. SG is performed with the assistance of a surgeon with bariatric experience.

Despite the documented high prevalence of sarcopenia and sarcopenic obesity among LT candidates,[51] surprisingly only 3 (5.9%) patients assessed in this cohort met imaging criteria for sarcopenia. The 6-minute walk test is employed as part of the LT/LTSG pre-surgical assessment. We hypothesize that screening using this surrogate measure for debility excluded patients with sarcopenia. Sarcopenic obesity has been associated with mortality after LT;[13] however, this study was not adequately powered to determine the impact of sarcopenic obesity on outcomes. Further study of patient selection criteria in an increasingly obese and highly comorbid population is needed. In the LTSG population, pre-operative MELD, ascites, and metabolic comorbidities were not associated with decreased postoperative survival, reoperation, or re-transplantation.

The methodological limitations of this study must be acknowledged. This is not a randomized trial. Patients strongly preferred LTSG when it was offered, resulting in no BMI-matched comparison cohort of patients undergoing LT alone. Instead, a cohort of patients with obesity and with significantly lower BMI (30-35) was included. The comparison cohort was also limited to patients with MASLD, even though 16.7% of patients in the LTSG cohort did not carry a MASLD diagnosis. The LT-only population was older and more racially diverse than the LTSG population. In addition, though the study population of both cohorts reflects the study site demographics, it does not reflect the racial diversity present within the US. Statistical analysis shows the benefits of LTSG are robust even when differences in age, BMI, and diabetes are accounted for; however, as with any non-randomized study, the potential for significant, unmeasured covariate differences between groups persists.

Discerning which patients have true post-transplant hyperlipidemia, *vs*. those prescribed statin medications for risk reduction, is difficult. The diagnosis of hyperlipidemia was often made outside of the transplant program; therefore, the criteria and methods for diagnosis were unknown. Similarly, accurately pinpointing the resolution of hypertension is difficult. The diagnosis often persists in documentation even after the patient is no longer taking medication; blood pressure recordings are sporadic and may be obtained under suboptimal conditions. Endocrinology consults and HbA1c measurements were part of the transplant program, which makes this a more reliable, though still imperfect, outcome measure. Since documentation issues are present in both the LTSG and LT groups, the comparison between groups remains useful, but the potential for bias based on documentation persists.

The current analysis provides a comprehensive, multicenter assessment of the long-term impact of simultaneous LTSG on perioperative and long-term post-transplant outcomes. This strategy provides durable weight loss, resolution of diabetes and hypertension, reduction in allograft steatosis and potentially fibrosis, and can be successfully adopted across multiple institutions. This may provide important guidance to other centers currently managing patients with advanced liver disease and severe obesity. Given the rising obesity epidemic worldwide, it is essential to find solutions that provide increased transplant access and improved metabolic outcomes for this complex patient population.

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Abbreviations

GERD, gastroesophageal reflux disease; LT, liver transplant; LTSG, liver transplant plus simultaneous sleeve gastrectomy; MACE, major adverse cardiac events; MASLD, metabolic dysfunction-associated steatotic liver disease; MASH, metabolic dysfunction-associated steatohepatitis; MELD, model for end-stage liver disease; MetS, metabolic syndrome; MRE, magnetic resonance elastography; PDFF, proton density fat fraction; PH, proportional hazards; PPI, proton pump inhibitor; SG, sleeve gastrectomy; TAMA, total abdominal musculature area.

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Conflict of interest

The authors of this study declare that they do not have any conflict of interest.

Please refer to the accompanying ICMJE disclosure forms for further details.

Authors' contributions

Concept and design: JKH, ELL. Experiments and procedures: JKH, TAK, CCJ, JAM, EFE, CR, TT, TSD, KDW, MDL, SAM, DKP, LY, NFZ, HB. Data collection: ELL, SDE, JKH. Data analysis: ELL, JKH, DJB, JK, RPH. Writing manuscript: ELL, JKH. Reviewing manuscript: ELL, JKH, SDE, TAK, CCJ, JAM, EFE, CR, TT, TSD, KDW, MDL, SAM, DKP, LY, NFZ, IRN, DB.

Data availability statement

The data for this manuscript contains personal health information and is protected by HIPPA. It is not available for access.

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Supplementary data

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