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Retrospective Cohort Study

New results on the safety of laparoscopic sleeve gastrectomy bariatric procedure for type 2 diabetes patients

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Abstract

BACKGROUND

It has been established that bariatric surgery, including laparoscopic sleeve gastrectomy (LSG), has a positive impact on type 2 diabetes mellitus (T2DM). However, less frequently T2DM is reported as a risk factor for complications with this type of surgery.

AIM

To evaluate the safety of LSG in T2DM.

METHODS

A retrospective cohort study was conducted over patients admitted for LSG from January 2008 to May 2015. Data was collected through digitized records. Any deviation from normal postoperative care within the first 60 d was defined as an early complication, and further categorized into mild or severe.

RESULTS

Nine hundred eighty-four patients underwent LSG, among these 143 (14.5%) were diagnosed with T2DM. There were 19 complications in the T2DM group (13.3%) compared to 59 cases in the non-T2DM (7.0%). Out of 19 complications in the T2DM group, 12 were mild (8.4%) and 7 were severe (4.9%). Compared to the non-T2DM group, patients had a higher risk for mild complications (Odds-ratio 2.316, CI: 1.163-4.611, $P = 0.017$), but not for severe ones ($P = 0.615$). An increase of 1% in hemoglobin A1c levels was associated with a 40.7% increased risk for severe complications ($P = 0.013$, CI: 1.074-1.843) but not for mild ones.

CONCLUSION

Our data suggest that LSG is relatively safe for patients with T2DM. Whether pre-operative control of hemoglobin A1c level will lower the complications rate has to be prospectively studied.

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Core tip: Laparoscopic sleeve gastrectomy is the most popular bariatric procedure worldwide today. Its impact among diabetic patients has been beneficial regarding diabetes control. This study is the first to examine the safety of the procedure in this subgroup of the population. We found that the diagnosis of diabetes mellitus is associated with an increased rate of mild postoperative complications but not with severe ones. Elevated hemoglobin A1c is a good predictor for the risk of severe complications.

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INTRODUCTION

Bariatric surgery is the standard of care for obesity and related morbidity. In the past few years, the most popular procedure worldwide has become laparoscopic sleeve gastrectomy (LSG) and accounting for more than 50% of bariatric procedures in the United States since 2014^[1,2]. In addition, bariatric surgery has proved to be the only modality that has the potential to achieve complete remission of type 2 diabetes mellitus (T2DM), and its advantage over conservative therapy is significant^[3-6]. The Diabetes Surgery Summit of experts in Rome in 2007, the American Diabetes Association in 2009, and the International Diabetes Federation in 2011 published guidelines to consider laparoscopic bariatric surgery as a treatment for T2DM^[4,7].

T2DM is a proven risk factor for postoperative complications in other fields of surgery^[8-12]. There is likely no single mechanism to explain this increased risk but wound healing, re-epithelization, angiogenesis, inflammatory response, pain, and coagulopathy are all negatively affected by T2DM. In addition, the risk for renal, cardiovascular, and respiratory failure is increased in T2DM patients undergoing surgery^[13-22]. In bariatric procedures involving stapling of the gastrointestinal tract, specifically gastric bypass, T2DM is a significant risk factor for re-admission and early complications in some reports but not in others^[23-31].

Nevertheless, reports of the contributing effects of T2DM in post-LSG complications are far and few between. As a result, the quoted risk in LSG for the general population was adopted for the T2DM subgroup and described in diabetes literature and guidelines as up to 15% for mild complications, 2%-6% for severe complications, and 0.1%-0.5% for mortality^[32]. Our hypothesis is that postoperative morbidity of LSG in T2DM patients is higher than that of patients without T2DM^[33]. The aim of this study is to examine the prevalence of complications after LSG in T2DM patients in comparison to control non-T2DM patients.

MATERIALS AND METHODS

Settings

A retrospective cohort study including all patients admitted for LSG from January 2008 to May 2015 at the Soroka University Medical Center (SUMC) was conducted. SUMC is a regional academic tertiary 1044-bed medical center in southern Israel, providing healthcare to a diverse population of one million.

Data sources

SUMC has been using digitized records, including in-hospital reports and outpatient follow-up (diagnoses, chronic diseases, surgical reports, BMI measurements, laboratory, and imaging tests) since 2000. After approval from the local ethics committee, data regarding patients in our study were gathered using this database.

Definitions

Complication: Any deviation from normal postoperative course in the first 60 d was defined as an early complication. An admission longer than 5 d and readmissions or reoperations within 60 d after surgery were considered a complication and were reviewed. In such cases, the record was expeditiously inspected in order to classify the exact type (leak, bleeding, stricture, dysphagia, renal and respiratory failure, or other) and the grade of the complication. The complications were graded using the conventional Clavien-Dindo (CD) classification system for postoperative complications^[34]. In this study, severe complications are defined as CD 3b or higher (requiring intervention under general anesthesia, ICU hospitalization, multiorgan failure, or death). Complications graded as CD 3a or below (any deviation from the normal postoperative course requiring any drug therapy, parenteral nutrition, blood transfusion, or intervention not under general anesthesia) are defined as mild.

Type 2 diabetes: Patients are said to have T2DM if one of the following conditions is fulfilled: (1) diagnosis made by the general practitioner or taken from the admission note; (2) a diagnosis of complication of T2DM (ICD-9 code 2504 for diabetes with nephrotic manifestations, 2505 for diabetes with ophthalmic manifestations, 2506 for diabetes with neurological manifestations, 2507 for diabetes with peripheral circulatory disorders) was previously performed; and (3) hemoglobin A1c (HbA1c) level above 6.5% (48 mmol/mol) drawn 2 years prior to the operation.

Preoperative evaluation

In the bariatric practice, every patient with a BMI > 40 kg/m² is eligible for bariatric surgery. Additionally, patients with T2DM are considered for bariatric surgery with a BMI as low as 35 kg/m² or above. In Israel, a patient who is planned for a bariatric procedure needs approval of an institutional multidisciplinary committee that is composed by a bariatric surgeon, anesthesiologist, internist, nutritionist, and social worker. The patient was admitted the day before operation for final evaluation and preparation, which includes blood tests, preoperative anticoagulation therapy, fasting, and IV fluid administration.

Surgical technique

LSG was performed in a standardized fashion. At induction of anesthesia, a first-generation cephalosporin was given for prophylaxis. After peritoneal CO₂ insufflation unto 15 mmHg, 4 to 5 trocars were inserted through the abdominal wall. The greater omentum was dissected away from the gastric greater curvature. A bougie was then introduced by the anesthesiologist and positioned along the lesser curvature of stomach, as a template for gastric resection that starts about 5 cm above the pylorus, up proximally to the gastro-esophageal junction. Resection was performed with laparoscopic staplers fired along the greater curvature close to the bougie. Upon surgeon decision, staple line reinforcement technique was performed (with suture, bio-material, or none). A closed suction drain was positioned along the stomach stump. The bougie that was inserted to the stomach by the anesthesiologist was withdrawn at the end of the operation.

Postoperative care and follow-up

In the first postoperative day the patient was encouraged to drink 300 mL of clear liquid, followed by unlimited drink in the second postoperative day. In the third postoperative day, the patient was instructed to ingest a liquid diet. On the third postoperative day, if vital signs were within normal limits, the patient was in well condition, did not complain of abdominal pain, maintained an acceptable liquid intake, and the suction drain was of serous content under 100 mL a day, he or she was discharged. All patients were advised by a dietitian about the recommended diet for the next month. Every patient was discharged with prophylaxis anticoagulation therapy for the first 30 postoperative days. Follow-up visits at the bariatric clinic for encounter with the surgeon were held at 1 wk, 4 mo, 8 mo, and 1 year post-op.

T2DM patients were routinely followed in the pre-, intra-, and post-operative periods for plasma glucose levels. Insulin therapy was administered if needed in order to control levels below 180 mg/dL.

Statistical analysis

All analyses were performed using IBM SPSS Statistics, version 24.0 (Armonk, NY, United States, IBM Corp). All tests were two-tailed and were considered significant at $P \leq 0.05$. Baseline clinical and demographic variables were compared between study groups by Chi-square for categorical variables or *t*-test for continuous variables. We used chi-square or binomial logistic regression to examine the association between total, mild, and severe early complications as dependent variables and the following

independent variables: diabetes type 2, fasting glucose level, and HbA1c. In addition, the following independent variables were examined as well: age, gender, BMI, previous bariatric surgery, concomitant removal of gastric banding, length of operation, surgeon identity, cumulative surgeon experience for each case, and comorbidities including hypertension, chronic ischemic heart disease, dyslipidemia, smoking status, asthma, sleep apnea, and fatty liver. In the next stage we used multivariate binomial logistic regression with stepwise method to assess the variables presenting statistical significance in the univariate study ($P < 0.05$), and the possible interactions were considered.

RESULTS

In a seven-year study period, 984 patients underwent LSG (66.2% were women). Mean age and BMI were 39.2 ± 12.2 years and 41.7 ± 5.9 kg/m², respectively. There were 143 patients (14.4%) with T2DM. Only one mortality (0.1%) was reported from the whole cohort and occurred at postoperative day 56 in the non-T2DM group. Unfortunately, we could not find any information about any illnesses before the death of the patient, and that raises the suspicion that it was not caused by a medical condition.

Patient characteristics differed among the study and control group in a few variables. The majority of the T2DM patients were male, older, and had a higher prevalence of essential hypertension, dyslipidemia, chronic ischemic heart disease, and sleep apnea.

Fasting plasma glucose (FPG) levels were available for 560 patients (56.9%) of the total study population, of which 112 were T2DM patients (78.3%). Mean FPG levels were 152 ± 51 mg/dL and 96 ± 13 mg/dL in the T2DM group and non-T2DM group, respectively ($P = 0.001$).

HbA1c levels were available for 286 patients (29.1%) of the total study population, of which 115 were T2DM patients (80.4%). Mean HbA1c levels were $7.6\% \pm 1.8\%$ (60 ± 15 mmol/mol) and $5.6\% \pm 0.5\%$ (38 ± 5 mmol/mol) in the T2DM group and non-T2DM group, respectively ($P = 0.001$).

Demographic, biometric, and morbidity characteristics are shown in Table 1. To note, chronic diseases such as anemia, smoking status, dyslipidemia, and chronic ischemic heart disease were reported by the general practitioner and collected from the patient's record.

Table 2 shows the complications by CD Classification. There were 78 early complications in this study (7.9%) with 44 (4.5%) of them categorized as mild and 34 (3.5%) of them categorized as severe. T2DM patients had significantly higher early complications compared to the non-T2DM patients (13.3% *vs* 7.0%, $P = 0.01$). When analyzing the subgroups of mild and severe complications, T2DM patients had significantly more mild complications (8.4% *vs* 3.8%, $P = 0.01$) but not severe complications (4.9% *vs* 3.2%, $P = 0.31$). In a multivariate binomial logistic regression for total early complications, we included T2DM, gender, age, dyslipidemia, hypertension, chronic ischemic heart disease, sleep apnea, and previous bariatric history. After a stepwise procedure, only T2DM was observed to be a significant factor for early complications (Odds ratio 2.031, CI: 1.171-3.522, $P = 0.012$). A similar result was observed for mild complications (Odds ratio 2.316, CI: 1.163-4.611, $P = 0.017$) but not for severe complications ($P = 0.615$).

When analyzing FPG level as an independent variable, it was not found to be significant for early complications ($P = 0.557$), mild complications ($P = 0.668$), or severe complications ($P = 0.701$). When setting a cut point of FPG level below 126 or equal and above 126, we did not find any significant differences in early complications ($P = 0.260$), mild complications ($P = 0.708$), or severe complications ($P = 0.230$).

When analyzing HbA1c as an independent variable, we found that for every elevation of 1% in HbA1c, there was an elevation of 1.314 in the risk for early complications ($P = 0.008$, CI: 1.074-1.609). A similar result of an elevation of 1.407 in risk was observed for severe complications ($P = 0.013$, CI: 1.074-1.843) but not for mild complications. Data on complication subtypes across study population are detailed in Table 3. Due to low event rates in these subgroups, only descriptive statistics are detailed.

DISCUSSION

Reports of early complications after bariatric surgery are abundant, specifically in

Table 1 Patient characteristics

	Non-type 2 diabetes group, n = 841, n (%) or mean (\pm SD)	Type 2 diabetes group, n = 143, n (%) or mean (\pm SD)	P-value
Female	573 (68.1)	78 (54.5)	0.02
Age, yr	38 (\pm 12.0)	48 (\pm 11.0)	< 0.01
BMI, kg/m ²	41.8 (\pm 5.9)	41.4 (\pm 6.1)	0.48
Operative time, min	55 (20.8)	57 (24.6)	0.57
Dyslipidemia	110 (13.1)	75 (52.4)	< 0.01
Essential hypertension	106 (12.6)	63 (44.1)	< 0.01
Chronic ischemic heart disease	10 (1.2)	10 (7.0)	< 0.01
Smoking status	89 (10.6)	22 (15.4)	0.09
Asthma	34 (4.0)	9 (6.3)	0.22
Sleep apnea	36 (4.3)	13 (9.1)	0.01
Anemia	15 (1.8)	4 (2.8)	0.41
Previous bariatric surgery	237 (29.0)	29 (20.3)	0.03
Hemoglobin A1c level % (\pm SD), mmol/mol (\pm SD)	5.6 (\pm 0.5), 38 (\pm 5.0)	7.6 (\pm 1.8), 60 (\pm 15.0)	< 0.01
Fasting plasma glucose mg/dL (\pm SD)	96 (\pm 13.0)	152 (\pm 51.0)	< 0.01

LSG. In large cohorts, the rate of early complications ranges from 5.4% to 7.3% and readmission rate within 30 d is 2.8%^[35-38]. The rate of severe complication in LSG is reported to be 1.2% to 2.2%. Our results show a higher rate of complications (7.9%) when compared to other studies and not only in T2DM patients. This discrepancy could be explained by the difference in definition of complication in each study. In this study we focused on the impact of the complication on general patient health and on the healthcare system rather than on the type of complication. For example, a leak is considered a formidable surgical complication, although in some cases it only moderately affects the patient, whereas a simple postoperative non-surgical complication such as pneumonia can lead to respiratory failure and death. We believe that this holistic approach is more instrumental for a non-surgeon professional, such as a general practitioner, endocrinologist, internist, or dietitian, when considering a bariatric surgery with the patient. In addition, because SUMC is the only medical center in southern Israel, every complicated case and readmission after surgery are seen at SUMC. Therefore, almost every complication is reported in this study. In other studies, it may be difficult to track complications after discharge of the patient due to the patient seeking treatment at a different facility.

For T2DM patients who undergo LSG, we found a significant increased risk for early complications, but this is significant only in the mild group and not in the severe group. This result is aligned with a retrospective Spanish-Portuguese multicenter study by Sánchez-Santos *et al*^[39]. Of 2882 patients, 29.2% of them were T2DM patients, and they found a significantly higher risk for early complications (Odds-ratio 1.48, CI: 1.12-1.95) in the T2DM group compared to the non-T2DM group. Mortality in the group of T2DM was increased as well in this study, but not in our study. In another study based on the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) database of 2012-2013, T2DM was associated with increased risk for re-admission during the first 30 postoperative days^[40].

In a study by Creange *et al*^[41] based on the American College of Surgeons-National Surgical Quality Improvement Program database of 2012, 941 out of 6062 LSG patients had T2DM (15.5%). As in our study, the T2DM patient group was more likely to be male and older. In contrast to our results, T2DM was not found to be associated with increased 30 d complication rate.

Aminian *et al*^[42] published an LSG risk calculator based on the same American College of Surgeons-National Surgical Quality Improvement Program 2012 database. In this analysis, type 1 and type 2 diabetes was found as a significant risk factor for 30 d complications. Creange *et al*^[41] state that this difference in results stems from the contribution of type 1 diabetes patients in the Aminian *et al*^[42] report. In our population, all patients with diabetes were diagnosed with T2DM.

This study is the first to assess the effect of FPG levels and HbA1c levels on 30 d complications after LSG. FPG was not found to affect 30 d complication rate, but it was found that any increase of 1% in HbA1c is associated with a significant increase of 31% in the risk for early postoperative complications. This result was maintained

Table 2 Mild and severe early complications (by Clavien-Dindo classification)¹, *n* (%)

Grade	Non-type-2-diabetes group, <i>n</i> = 841	Type 2 diabetes group, <i>n</i> = 143	<i>P</i> -value
1	14 (1.7)	6 (4.2)	0.01
2	15 (1.8)	6 (4.2)	
3a	3 (0.4)	0 (0.0)	
Mild (CD ≤ 3a)	32 (3.8)	12 (8.4)	
3b	15 (1.8)	4 (2.8)	
4a	7 (0.8)	1 (0.7)	0.31
4b	4 (0.5)	2 (1.4)	
5	1 (0.1)	0 (0.0)	
Severe (CD ≥ 3b)	27 (3.2)	7 (4.9)	
Total	59 (7.0)	19 (13.3)	0.01

¹This is a univariate analysis. CD: Clavien-Dindo.

when analyzing the subgroup of severe complications, but not for mild ones. The effect of elevated HbA1c upon early complications after surgery was reported in general surgery as a protective factor in some reports (probably due to heightened postoperative vigilance and lower threshold to treat hyperglycemia), or as risk factor in trauma surgery and several orthopedic procedures in other reports^[43-46]. In our study, the discrepancy between the result that elevated HbA1c is associated with higher risk for early postoperative complications (mild and severe) and the fact the T2DM as a disease by itself is not a risk factor for early complications (mild and severe) could be explained by the fact that many of the T2DM patients have balanced glucose levels, and the more important parameter when evaluating a patient is HbA1c level.

This study has several limitations. First, it is composed of retrospective data. This fact may be tempered by the large number of patients and the wide range of background variables that were collected. Second, despite comprehensive data collection, most patient records were not reviewed individually. Moreover, some data, such as reoperations or readmissions in other medical centers (even if they are part of the same medical insurance organization as our center) were not retrieved. Third, the definition of T2DM is mostly based on patient and primary physician report and not on detailed biochemical evaluation of every patient. This may lead to distortion in the distribution between the two groups. Fourth, only 56.9% of patients had FPG levels drawn and even less had reported HbA1c levels drawn (29.1% of total study population and 80.4% of T2DM group). In addition, this study does not analyze long-term complications in LSG in T2DM patients. The strengths are large sample size and the meticulous assessment of complications. Both of which enabled us to carefully inform the patient of the spectrum of complications that they may face.

Our data show an increased risk only for mild complications of LSG in T2DM patients. Together with extensive data on the chance of T2DM remission^[6], we believe there is good evidence that LSG is a relatively safe and effective option for these patients. In addition, increased HbA1c should be noted as a risk factor for severe complications and further studies are required in order to assess whether strict diabetic control prior to operation may lead to reduced postoperative complications.

Table 3 Early complications (by type), *n* (%)

Early complication by type	Non-type 2 diabetes group, <i>n</i> = 841	Type 2 diabetes group, <i>n</i> = 143
Staple line dehiscence and leak	16 (1.9)	2 (1.4)
Stricture and dysphagia	20 (2.4)	8 (5.6)
Bleeding	7 (0.8)	3 (2.1)
Acute renal failure	0 (0.0)	3 (2.1)
Respiratory failure	4 (0.5)	0 (0.0)
Other	11 (1.3)	3 (2.1)
Total	59 (6.9)	19 (13.2)

ARTICLE HIGHLIGHTS

Research background

Bariatric surgery has been advocated as an effective therapy for type 2 diabetes mellitus (T2DM) in an abundance of studies. Nevertheless, when considering a modality of treatment, its benefits should be weighed against its risks.

Research motivation

The risks that lie in bariatric surgery in the subgroup of T2DM have not been thoroughly investigated. Complications after other types of surgery within this subgroup of patients has led us to believe that post-bariatric surgery complication rates may be elevated in T2DM patients.

Research objectives

The main objectives of the study were to evaluate any kind of postoperative complications in the T2DM group *vs* non-T2DM patients within 60 d of surgery. Any deviation from the normal postoperative course was considered a complication. Further categorization into mild and severe complications was performed. This categorization was based upon Clavien-Dindo classification which is a common postoperative complications grading system.

Research methods

All patients who underwent laparoscopic sleeve gastrectomy performed by three surgeons in a single institute were included. Data was extracted from a digitized database through specific queries regarding length of stay, imaging, reoperations, and readmissions in the first 60 d after the operation. Mortality was extracted from that system as well. Any case of deviation from the average length of stay (more than 3 d after operation), further imaging (no imaging is routinely performed after operation), reoperation, or readmission was studied carefully in order to define the exact type of complication and categorize as mild or severe.

Research results

Nine hundred and eighty-four patients underwent laparoscopic sleeve gastrectomy, among these 143 (14.5%) were diagnosed with T2DM. There were 19 complications in the T2DM group (13.3%) compared to 59 cases in the non-T2DM (7.0%). Out of 19 complications in the T2DM group, 12 were mild (8.4%) and 7 were severe (4.9%). Compared to the non-T2DM group, patients had a higher risk for mild complications (Odds-ratio 2.316, CI: 1.163-4.611, $P = 0.017$), but not for severe ones ($P = 0.615$). Any increase of 1% in hemoglobin A1c levels was associated with a 40.7% increased risk for severe complications ($P = 0.013$, CI: 1.074-1.843).

Research conclusions

In this study, we find that the rate of mild complications is increased in T2DM patients. It means that these patients will suffer more from problems such as dysphagia, surgical site infection, dehydration, pneumonia, and bleeding. But these complications can be treated easily and conservatively without the need for interventions under general anesthesia, reoperations, or prolonged ICU admissions. Together with our knowledge of significant weight loss and reduction in glycemic burden after bariatric surgery, we believe that these complications should be well tolerated in face of the potential long-term benefit of this therapy in this subgroup of patients.

Research perspectives

Another result of our study, that any elevation of 1% in HbA1c levels is associated with a 40.7% increased risk for severe complications should commence a process of evaluating preoperative diabetes control. We believe that in a future study, patients with relatively high HbA1c level (above 9%) should have a short course of pre-operative tight glycemic control tested against patients who do not receive this preoperative intervention. This will also help us understand the pathophysiology of diabetes in surgical patients, and whether complications are driven purely from glycemic control or from chronic micro- and macro-vascular damage associated with diabetes.

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