

Weight Loss, Type 2 Diabetes, and Nutrition in 355 Patients with Obesity Undergoing Sleeve Gastrectomy with Transit Bipartition: Two-Year Outcomes

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Keywords

Obesity · Diabetes · Sleeve gastrectomy with transit bipartition · SG with transit bipartition · Type 2 diabetes · A1C

Abstract

Introduction: This study examined whether 355 obese patients with type 2 diabetes (T2D) of varying duration and severity experienced equivalent weight loss and T2D remission following a newer sleeve gastrectomy (SG) procedure – SG with transit bipartition (SG-TB). **Methods:** Primary outcomes were changes in body mass index (BMI), total weight loss (TWL), excess BMI loss (EBMIL), A1C, and diabetes medication use through 24 months. **Results:** Between December 2015 and December 2019, 399 patients who underwent SG-TB reached the 2-year time point. Follow-up was possible in 355 patients (89.0%): 206 females (58.0%), mean age 51.5 years (24.0–73.0), BMI 34.0 kg/m² (28.0–50.5), and T2D duration 12.0 years (4.0–37.0). At 2 years, total sample respective mean TWL and EBMIL were 20.2 ± 6.1% (95% CI: 19.5, 20.8) and 87.7 ± 35.2% (84.1, 91.4) corresponding to mean BMI change of 7.0 ± 2.7 kg/m² (6.7, 7.3) ($p < 0.001$). T2D duration and severity subgroups experienced comparable BMI and A1C change from baseline ($p < 0.001$); 281 (79.2%) maintained complete remission. ANOVA

showed significant mean increases in vitamin D, calcium, and albumin: overall complication rate, 10.2%; no mortality. **Discussion/Conclusion:** In 355 patients with obesity who underwent SG-TB, excellent weight loss, T2D, and nutritional outcomes were seen at 2-year follow-up regardless of preoperative T2D duration and severity.

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Introduction

Metabolic/bariatric surgery produces the most sustained weight loss and resolution of type 2 diabetes mellitus (T2D) of any available therapeutic modality [1, 2]. The still-novel sleeve gastrectomy with transit bipartition (SG-TB) procedure, introduced in 2006 by Santoro et al. [3] for patients with severe obesity, was designed to have the metabolic efficacy of the biliopancreatic diversion (BPD) with duodenal switch without its technical complexity or long-term nutritional instability. Several short-term investigations of SG-TB [4–9] have shown it to be safe and effective in facilitating weight loss and resolution of diseases comorbid with all stages of obesity.

Whether the effectiveness of SG-TB is maintained over several years is unknown. We also questioned wheth-

er patients with long-term and severe preoperative T2D and lower BMI experience post SG-TB resolution of T2D similar to patients who had short-term and less-severe T2D. The extent of postoperative body mass index (BMI) reduction and T2D remission in relation to preoperative T2D duration and severity has been examined in primary metabolic/bariatric procedures (e.g., BPD, Roux-en-Y gastric bypass [RYGB], SG) [10, 11] but not explored in patients undergoing SG-TB.

The current study examined the relationship between duration and severity of T2D to weight loss, change in A1C, and T2D remission. We also examined nutritional status through 2-year follow-up. We aimed to identify if differences in preoperative T2D duration and severity might be useful in predicting which patients were best suited for SG-TB.

Materials and Methods

Design and Inclusion

The study design was a retrospective, single-center analysis of an SG-TB surgical series. The study was approved for our bariatric surgery center of excellence by the University Institutional Review Board (#261020-04). The surgical technique was approved by the Medical Center Faculty Ethics Committee in required compliance with the 1964 Helsinki declaration and amendments. Written informed consent was obtained from all study participants after receiving a highly detailed description of the still-experimental SG-TB procedure. The surgeon discussed the potential effectiveness and safety of SG-TB relative to that of established metabolic/bariatric operations with every patient.

Patients ≥ 18 years with a baseline BMI ≥ 30.0 kg/m² who requested a metabolic/bariatric procedure for obesity and T2D were included. Patients were required to be of Caucasian or Asian descent per Diabetes Surgery Summit (DSS-II) guidelines [12] and American Diabetes Association 2017 Standards of Diabetes Care [13]. These guidelines specify that, due to the lower BMI at which Asian populations develop comorbidities of obesity, patients with a baseline BMI ≥ 27.5 kg/m² could also be considered for metabolic/bariatric surgery. In light of the experimental nature of the procedure, participants were required to be able to pay privately for their care independent of insurance. Patients were not included if they had a C-peptide value < 1.5 ng/dL or had sustained T2D for > 10 years with end-stage renal disease, or who, upon discussion, were determined not to be able to comply with the protocol for follow-up. Fasting c-peptide levels were checked, and a mixed meal test was also given to patients prior to surgery to assess postprandial c-peptide levels. This test serves to observe the late response of the pancreas in order to more accurately evaluate insulin reserves before SG-TB. Patients with fasting c-peptide levels < 1.5 ng/dL and 2-h postprandial values < 2.5 ng/dL were excluded from the study [14].

Enoxaparin (low-molecular-weight heparin [LMWH]) was initiated 1 day prior to surgery. Patients who smoked were required to quit smoking for at least 21 days prior to the procedure.

Surgery and Postoperative Management

Gastroscopy and the test for *H. pylori* were performed preoperatively. The SG-TB was performed in the manner of Santoro et al. [15]. First, a sleeve gastrectomy was established 8 cm from the pylorus. A 39 F orogastric bougie was used in patients with BMI ≥ 30.0 kg/m², and a 45 F bougie was used in patients with BMI < 30.0 kg/m² to establish a calibrated sleeve pouch. After that, the gastro-ileal anastomosis was made at a distance 260 cm from the ileocecal valve. A common channel of 150–200 cm was established in patients with a BMI < 30.0 kg/m². In those with a BMI ≥ 30.0 kg/m², a 100–150-cm common channel was established. A 45-mm Tri-Staple™ (Medtronic, Minneapolis, MN) was used to create the 35-mm gastro-ileal anastomosis at the antrum, 2 cm away from the pylorus. The ileo-jejuno-stomy to establish the common channel was made with a 60-mm white cartridge (Medtronic, Minneapolis, MN, USA). In all patients, the SG stapler line was imbricated with sero-serosal 3/0 nonabsorbable sutures. A methylene blue leak test was performed intraoperatively.

Postoperatively, as preoperatively, our multidisciplinary team was involved in patient follow-up. Low-molecular-weight heparin was maintained for 14 days or longer if thrombosis was an indication in the patient's history. Patients were followed at 1, 3, 6, 9, 12, 18, and 24 months by both the surgeon and the nutritionist. At 6 months, and yearly thereafter, patients underwent routine abdominal sonography and gastroscopy.

Weight Loss

Absolute weight and BMI reduction were calculated. Percentage of total weight loss (TWL) was calculated by the formula: %TWL = $([\text{baseline weight} - \text{follow-up weight}] / [\text{baseline weight}]) \times 100$. Percentage of excess BMI loss (EBMIL) was calculated by the formula: %EBMIL = $([\text{baseline BMI} - \text{follow-up BMI}] / [\text{baseline BMI} - 25.0 \text{ kg/m}^2]) \times 100$.

Diabetes Diagnosis, Resolution, and Medication Use

A1C provides a reliable biomarker of long-term glycemic control by averaging pre- and postprandial glycemic levels over the preceding 2–3 months. Diagnosis of active T2D was based on an A1C value $\geq 7.0\%$. Full T2D resolution was set at A1C $\leq 6.5\%$ with no medication use for ≥ 12 months. After SG-TB, for patients whose A1C was 6.5–7.0%, lifestyle modification including diet and exercise was used to achieve a nondiabetic status rather than return them to T2D medication. Three months after surgery, patients with an A1C of 7.0–8.0% received only a single oral antidiabetic (OAD) drug to achieve glycemic control.

Nutrition Profile

Ferritin, vitamin D, parathormone, calcium, albumin, and vitamin B₁₂ levels were checked pre- and postoperatively at all follow-up time points. Postoperatively, for vitamin-deficient patients, ordinary minerals and multivitamins were prescribed for 2 months, and only if needed thereafter. In patients with a vitamin deficiency before surgery, minerals and multivitamins were continued beyond 2 months until normalized. For example, we substituted 15,000 units of vitamin D3 for the first 2 weeks continuing with 5,000 units in 12 weeks' time. We substituted 1,000 mg calcium carbonate for all patients with a vitamin D deficiency for at least 3 months after the operation.

Table 1. Preoperative characteristics for total sample ($n = 355$) and by duration of T2D

	Total population	T2D duration, years			<i>p</i> value
		≤5	6–10	>10	
<i>N</i>	355	39	147	169	–
Age, years	51.5±9.1	47.3±8.2	48.2±8.2	55.3±8.5	<0.001 ^a
Height	1.67±0.09	1.67±0.09	1.67±0.10	1.66±0.09	0.461 ^a
Weight	94.2±14.5	93.5±13.5	94.0±14.8	94.6±14.6	0.875 ^a
BMI, kg/m ²	34.0±4.6	33.6±3.4	33.6±4.7	34.4±4.9	0.269 ^a
Excess BMI	9.0±4.6	8.6±3.4	8.6±4.7	9.4±4.9	0.269 ^a
Mean years diagnosed T2D	12.0±6.0	4.9±0.2	8.1±1.6	17.0±4.9	<0.001 ^a
A1C	9.8±1.4	9.9±1.8	9.7±1.4	9.8±1.4	0.688 ^a
Fasting C-peptide	2.77±1.0	2.83±0.8	2.75±0.9	2.78±1.1	0.921 ^a
Postprandial C-peptide	4.35±1.6	4.53±1.5	4.44±1.6	4.23±1.6	0.359 ^a
C-peptide ratio	1.61±0.4	1.63±0.4	1.66±0.4	1.58±0.4	0.168 ^a
Gender/female	206 (58.0)	25 (64.1)	86 (58.5)	95 (56.2)	0.659 ^b
Smoker/yes	82 (23.1)	10 (25.6)	43 (29.3)	29 (17.2)	0.084 ^b
Hypertension	127 (35.8)	6 (15.4)	45 (30.6)	76 (45.0)	<0.001 ^b
Hyperlipidemia	54 (15.2)	6 (15.4)	24 (16.3)	24 (14.2)	0.870 ^b
Hypertriglyceridemia	152 (42.8)	15 (38.5)	67 (45.6)	70 (41.4)	0.639 ^b
OAD medication use	316 (89.0)	33 (84.6)	133 (90.5)	150 (88.8)	0.576 ^b
Insulin use	308 (86.8)	30 (76.9)	123 (83.7)	155 (91.7)	<0.05 ^b

Values are mean ± SD or *n* (%). BMI, body mass index; T2D, type 2 diabetes mellitus; A1C, hemoglobin A1C; OAD, oral antidiabetic. ^a*p* value based on ANOVA results. ^b*p* value based on χ^2 results.

Statistical Analysis

The SPSS statistical package (version 27.0; IBM, Chicago, IL, USA) was used to perform analyses. Quantitative (demographic and outcome) variables were reported as means, standard deviations, and 95% confidence intervals, or as otherwise noted. Normality of data was assessed using recommendations by Kim [16] regarding kurtosis and skewness of data for large sample sizes; assessments were augmented by visual inspection of data histograms and Q-Q plots.

Qualitative variables were presented as frequency and percentage and evaluated using the χ^2 test or McNemar's test, as appropriate. Weight and A1C outcomes were provided at 24 months; between-group comparisons along continuous variables were carried out using independent samples *t* tests or one-way ANOVAs. Measures of change from baseline were analyzed with the paired-samples *t* test. Repeated measures ANOVA was used to assess mean trends in nutritional variables at 1, 3, 6, 9, 12, 18, and 24 months. Statistical significance was set at $p < 0.05$; all statistical tests were two tailed.

Results

Between December 2015 and 2019 at a single bariatric surgery center of excellence, 883 patients underwent SG-TB. Our study sample was comprised of Turkish Cauca-

sian individuals and patients who came to our center from abroad mainly from ex-Soviet Central-Asian Turkish republics, (Kazakhstan, Turkmenistan, Uzbekistan). Thus, we have taken in account the Interdisciplinary European Guidelines on Metabolic and Bariatric Surgery when selecting patients with relatively low BMI (BMI 30–35 kg/m²) where it is clearly stated that patients with class 1 obesity may be considered for bariatric surgery on an individual basis, as there are evidence-based data supporting bariatric surgery benefits with respect to T2DM remission or improvement [17]. As our database is prospectively maintained, there were few patients with BMI <30 kg/m² in our group, and detailed consent was obtained for all patients regarding the effect and experimental nature of the surgery in patients with BMI <35 kg/m². Of these patients, 399 had reached the 2-year time point; however, 44 patients (11.0% lost to follow-up) did not attend their 2-year visit and were excluded from the analysis, leaving 355 patients who were actually seen. There were no statistically significant differences in baseline characteristics between included patients and those lost to follow-up.

Table 2. Preoperative characteristics by severity of T2D

	T2D severity (medication usage; <i>n</i> = 355)			<i>p</i> value
	OAD	insulin	OAD + insulin	
<i>N</i>	47	39	269	–
Age, years	51.7±9.3	52.1±9.0	51.4±9.1	0.878 ^a
Height	1.66±0.09	1.69±0.10	1.66±0.09	0.161 ^a
Weight	95.1±14.8	96.1±14.4	93.8±14.6	0.615 ^a
BMI, kg/m ²	34.6±4.6	33.7±5.4	33.9±4.5	0.597 ^a
Excess BMI	9.6±4.6	8.7±5.4	8.9±4.5	0.597 ^a
Mean years diagnosed T2D	9.7±4.8	11.9±6.5	12.4±6.1	<0.05 ^a
A1C	8.5±0.3	10.1±1.5	10.0±1.4	<0.001 ^a
Fasting C-peptide	2.98±1.0	2.47±0.9	2.78±1.0	0.064 ^a
Postprandial C-peptide	5.21±1.6	3.87±1.3	4.27±1.6	<0.001 ^a
C-peptide ratio	1.79±0.4	1.64±0.4	1.58±0.4	<0.005 ^a
Gender/female	25 (53.2)	27 (69.2)	154 (57.2)	0.283 ^b
Smoker/yes	6 (12.8)	13 (33.3)	63 (23.4)	0.242 ^b
Hypertension	18 (38.3)	15 (38.5)	94 (34.9)	0.846 ^b
Hyperlipidemia	6 (12.8)	4 (10.3)	44 (16.4)	0.526 ^b
Hypertriglyceridemia	22 (46.8)	14 (35.9)	116 (43.1)	0.583 ^b
OAD medication use	47 (100.0)	0 (0.0)	269 (100.0)	<0.001 ^b
Insulin use	0 (0.0)	39 (100.0)	269 (100.0)	<0.001 ^b

Values are mean ± SD or *n* (%). BMI, body mass index; T2D, type 2 diabetes mellitus; A1C, hemoglobin A1C; OAD, oral antidiabetic. ^a*p* value based on ANOVA results. ^b*p* value based on χ^2 results.

Baseline Characteristics Relative to T2D Duration and Severity

Preoperative patient characteristics for the total study population and subgroups according to T2D duration and severity are presented in Tables 1 and 2. This cohort (*n* = 355) was comprised predominantly of individuals with class 1 obesity (BMI 30.0–34.9 kg/m²) with a mean BMI of 34.0 ± 4.6 kg/m²: 233 (65.6%) had a BMI between 28.0 and 35.0 kg/m² and 122 patients (34.4%) had severe obesity (BMI ≥35.0 kg/m²). Mean duration of diabetes among patients prior to SG-TB was 12.0 ± 6.0 years (range 4–37), and mean A1C was 9.8 ± 1.4% (7.9–15.0). Just under half of the study population (*n* = 169, 47.6%) had been diagnosed with T2D for more than 10 years before surgery; 39 patients (10.9%) carried a T2D diagnosis for ≤5 years. The vast majority of patients were on T2D medication(s) at the time of surgery: 316 (89.0%) reported OAD medication usage (with insulin, 269 [75.8%], and without, 47 [13.2%]); and 308 (86.8%) reported insulin use (insulin only, 39 [11.0%] or in combination with OAD medications). Hypertension was significantly more prevalent in patients with diabetes of >10 years (*p* < 0.001). Although baseline A1C levels did not vary signifi-

cantly between T2D duration subgroups, it was significantly higher in patients with severe disease as indicated by insulin use (*p* < 0.001).

Mean SG-TB operative time was 124 ± 25.4 min. The mean length of hospital stay was 4.0 ± 2.5 days. No significant differences in hospital stay were noted when patients were stratified by T2D duration and severity.

Weight Loss

At 2 years, mean TWL and EBMI for the total population were 20.2 ± 6.1% (95% confidence intervals: 19.5, 20.8) and 87.7 ± 35.2% (84.1, 91.4), respectively, which corresponded to a mean BMI change of 7.0 ± 2.7 kg/m² (6.7, 7.3) (*p* < 0.001) (Table 3). These results were similar to results at 1 year (TWL 19.8 ± 6.0%; EBMI 85.8 ± 33.7%). There were no significant between-group differences in BMI at 2 years relative to T2D duration (*p* = 0.552) or severity (*p* = 0.756). As depicted in Figure 1a, b, all subgroups experienced comparable amounts of significant BMI change from baseline levels (*p* < 0.001). Frequency distributions in relation to the ranges of TWL for T2D duration (<10 years vs. ≥ 10 years) and severity (insulin use: no vs. yes) subgroups are presented in Figure 2a, b. Mean TWL for duration subgroup ≥10

Table 3. 24-month weight and A1C outcomes in T2D patients ($n = 355$)

	Preoperative, mean \pm SD	24-month follow-up			<i>p</i> value ^a
		mean \pm SD	mean change \pm SD	95% CI	
Absolute weight, kg ($n = 355$)	94.2 \pm 14.6	74.9 \pm 11.2	19.3 \pm 7.7	18.5, 20.1	<0.001
BMI, kg/m ²	34.0 \pm 4.6	27.0 \pm 3.4	7.0 \pm 2.7	6.7, 7.3	<0.001
TWL, %	–	20.2 \pm 6.1	–	19.5, 20.8	
EBMIL, %	–	87.7 \pm 35.2	–	84.1, 91.4	
BMI change by T2D duration					
≤ 5 years ($n = 39$)	33.6 \pm 3.4	26.6 \pm 2.8	7.0 \pm 2.8	6.1, 7.9	<0.001
6–10 years ($n = 147$)	33.6 \pm 4.7	26.9 \pm 3.6	6.7 \pm 2.5	6.3, 7.1	<0.001
>10 years ($n = 169$)	34.4 \pm 4.9	27.2 \pm 3.5	7.2 \pm 2.9	6.8, 7.7	<0.001
<i>p</i> value ^b	0.269	0.552	–	–	–
BMI change by T2D severity					
OAD ($n = 47$)	34.6 \pm 4.6	27.3 \pm 3.6	7.4 \pm 3.0	6.5, 8.2	<0.001
Insulin ($n = 39$)	33.7 \pm 5.4	26.7 \pm 3.3	7.0 \pm 3.5	5.9, 8.2	<0.001
OAD + insulin ($n = 269$)	33.9 \pm 4.5	27.0 \pm 3.5	6.9 \pm 2.5	6.6, 7.2	<0.001
<i>p</i> value ^b	0.597	0.756	–	–	–
A1C ($n = 355$)	9.8 \pm 1.4	6.2 \pm 0.7	3.5 \pm 1.5	3.3, 3.7	<0.001
A1C, % change	–	35.1 \pm 10.2	–	34.0, 36.2	
A1C change by T2D duration					
≤ 5 years ($n = 39$)	9.9 \pm 1.7	6.0 \pm 0.7	3.9 \pm 1.8	3.3, 4.5	<0.001
6–10 years ($n = 147$)	9.8 \pm 1.4	6.1 \pm 0.7	3.6 \pm 1.6	3.3, 3.9	<0.001
>10 years ($n = 169$)	9.8 \pm 1.4	6.4 \pm 0.6	3.4 \pm 1.4	3.2, 3.6	<0.001
<i>p</i> value ^b	0.688	<0.005	–	–	–
A1C change by T2D severity					
OAD ($n = 47$)	8.5 \pm 0.3	5.8 \pm 0.5	2.7 \pm 0.6	2.5, 2.9	<0.001
Insulin ($n = 39$)	10.1 \pm 1.5	6.4 \pm 0.7	3.8 \pm 1.5	3.3, 4.3	<0.001
OAD + insulin ($n = 269$)	9.9 \pm 1.4	6.3 \pm 0.7	3.7 \pm 1.6	3.5, 3.9	<0.001
<i>p</i> value ^b	<0.001	<0.001	–	–	–

Results are based on patients with complete weight and A1C data at baseline and 24-month follow-up. BMI, body mass index; TWL, total weight loss; yrs, years; OAD, oral antidiabetic. ^aPaired-samples *t* test. ^bOne-way ANOVA for independent samples.

years was slightly, not significantly, greater than that of patients with duration <10 years (20.6 \pm 6.1% vs. 19.7 \pm 6.1%; $p = 0.220$). Mean TWL for severity subgroups was also virtually equivalent (no; 20.9 \pm 7.0% vs. yes; 20.1 \pm 6.0%; $p = 0.371$). Overall, weight loss did not correlate with T2D duration or severity.

Impact on Diabetes – A1C Biomarker

The percentage change in A1C for the total sample at 2 years was 35.1 \pm 10.2% (34.0, 36.2), corresponding to a mean A1C change of 3.5 \pm 1.5% (3.3, 3.7) ($p < 0.001$) (Table 1). There were significant between-group differences in A1C levels relative to T2D duration ($p < 0.005$). Patients with ≤ 5 years of T2D duration experienced the largest mean change in A1C (3.9%); those with >10 years' duration experienced the least change (3.4%). However,

all duration subgroups demonstrated a significant A1C mean change from baseline ($p < 0.001$) and maintained normal levels ($\leq 6.5\%$) at 2 years (Table 3; Fig. 1c). Significant differences in A1C were also observed between disease severity subgroups at baseline and follow-up ($p < 0.001$), with insulin-identified subgroups entering the study with significantly higher A1C ($p < 0.001$). Although the OAD subgroup had the lowest A1C at follow-up (5.8%), all severity groups achieved a significant change from baseline ($p < 0.001$) and maintained normal levels at 2 years (Table 3; Fig. 1d). Frequency distributions in relation to ranges of percentage A1C change for T2D duration (<10 years vs. ≥ 10 years) and severity (insulin use: no vs. yes) subgroups are presented in Figure 2. Mean percentage A1C change for the <10-year duration subgroup was significantly greater than for the ≥ 10 -year sub-

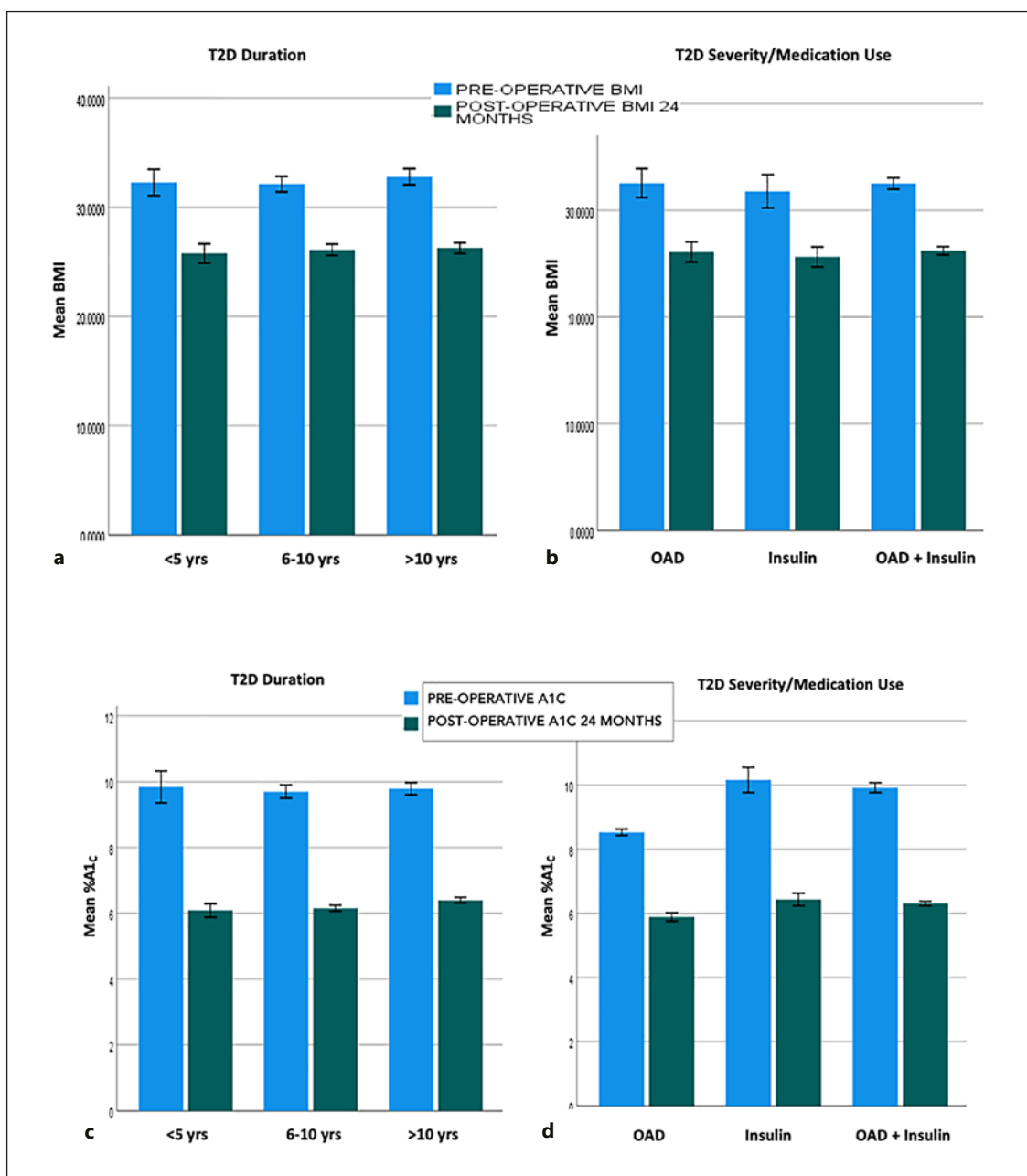


Fig. 1. a, b BMI outcomes at 24 months based on preoperative T2D duration and severity. BMI, body mass index; T2D, type 2 diabetes mellitus; A1C, hemoglobin A1C; OAD, oral antidiabetic. **c, d.** A1C outcomes at 24 months based on preoperative T2D duration and severity. T2D, type 2 diabetes mellitus; A1C, hemoglobin A1C; OAD, oral antidiabetic.

group ($36.2 \pm 10.7\%$ vs. $33.9 \pm 9.5\%$; $p < 0.05$) (Fig. 2c). Interestingly, as shown in Figure 2d, the mean summarizing the frequency distribution of percentage A1C change for the insulin subgroup was significantly higher than for the no-insulin subgroup ($35.6 \pm 10.6\%$ vs. $31.5 \pm 6.2\%$; $p < 0.01$).

Diabetes Medication Use and Remission Rate

At 2 years, all 308 patients (100.0%) on insulin prior to surgery no longer required insulin. Similarly, OAD percentage use fell markedly from 89.0% (316/355) preoperatively to 15.2% (54/355) postoperatively ($p < 0.001$). The marked change in diabetes medication use was re-

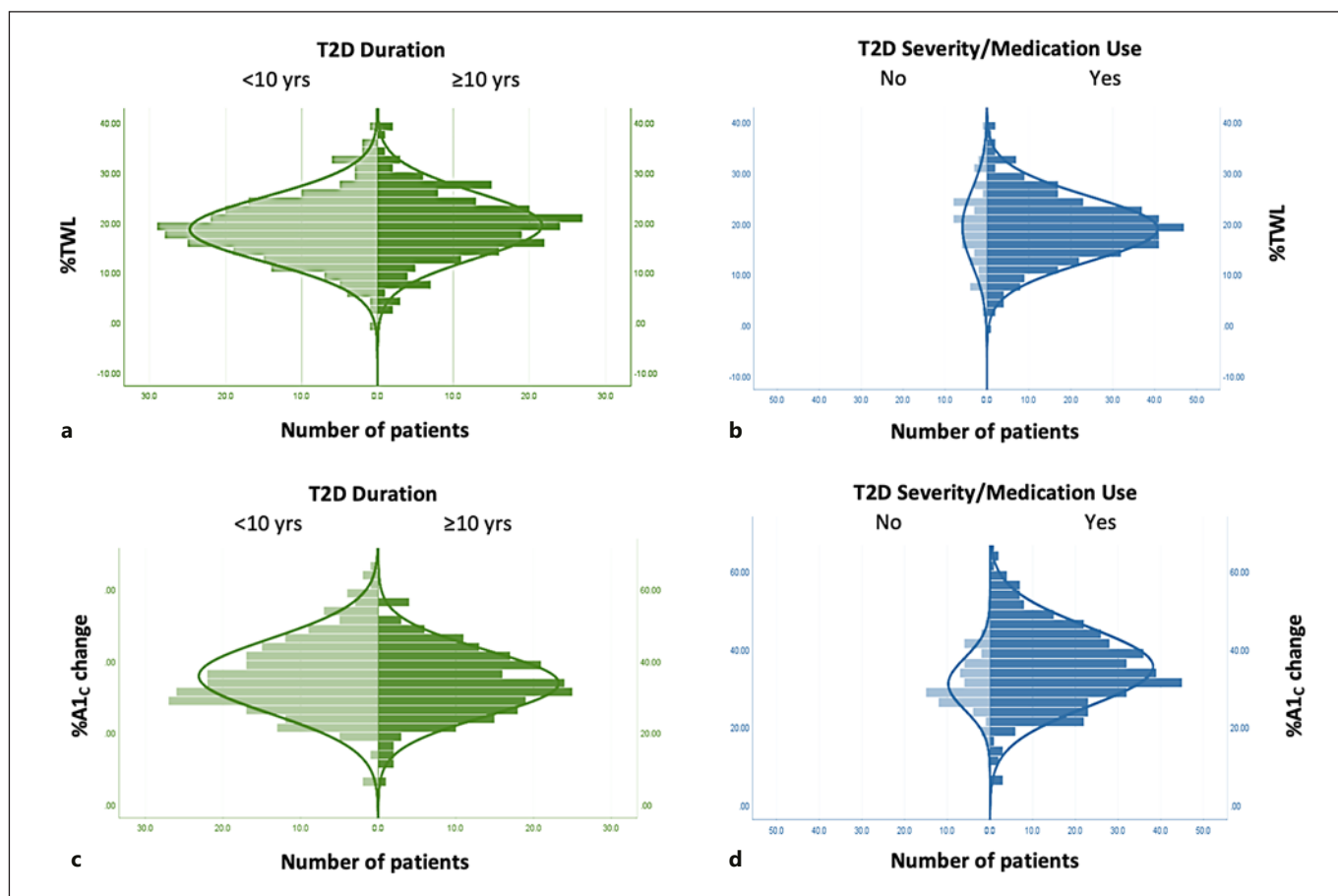


Fig. 2. a–d TWL and A1C frequency distributions by T2D duration and severity (insulin use). TWL, total weight loss; A1C, hemoglobin A_{1c}; T2D, type 2 diabetes mellitus.

flected in overall remission rate: 281 patients (79.2%) achieved and maintained complete remission (i.e., A1C \leq 6.5% and off all diabetes medications for 1 year). Another 31 patients (8.7%) experienced T2D improvement (i.e., A1C \leq 6.5 with medication use, or A1C between 6.5% and 7.0% with or without medication).

Remission rates stratified by T2D duration and severity subgroups are instructive. Complete T2D remission was achieved in 33/39 patients (84.6%) with duration of \leq 5 years, comparable to the complete remission rate of 87.1% (128/147) in those with duration of 6–10 years. However, the complete remission rate for patients with duration $>$ 10 years (71.0%, 120/169) was significantly lower than both other duration subgroups ($p < 0.05$). Statistically significant differences were also evident between T2D severity subgroups. Complete T2D remission was achieved in 46/47 patients (97.9%) only using OAD medications. In contrast, remission rates were significantly

lower ($p < 0.05$) in those taking both insulin and OAD medications preoperatively (205/269, 76.2%), as well as in those taking insulin only at baseline (30/39, 76.9%).

Comparing Weight Loss, A1C, Remission Outcomes, and Common Channel Lengths Stratified by BMI

As anticipated, patients with BMI \geq 35.0 kg/m² experienced a greater BMI reduction and an accompanying higher TWL at 2 years post SG-TB (Table 4). However, there was no significant correlation ($p = 0.81$) between %TWL and %A1C change. Indeed, the BMI $<$ 35.0 kg/m² group experienced a greater percentage change in A1C, although the difference was not statistically significant ($p = 0.289$). In addition, the BMI groups were fairly well matched in terms of T2D duration and severity stratification. Notably, both BMI groups experienced excellent remission rates at 2 years after SG-TB with no statistical difference between them ($p = 0.770$).

Table 4. Mean trends in nutritional variables through 24-month follow-up

	BMI <35.0 (<i>n</i> = 233)	BMI ≥35.0 (<i>n</i> = 122)	<i>p</i> value
Preop BMI, kg/m ² (mean±SD)	31.3±1.9	39.3±3.7	<0.001 ^a
Postop BMI, kg/m ² (mean±SD)	25.4±2.0	30.2±3.4	<0.001 ^a
BMI change, kg/m ² (mean±SD)	5.9±1.8	9.1±2.9	<0.001 ^a
%TWL (mean±SD)	18.7±5.5	23.0±6.4	<0.001 ^a
Preop A1C (mean±SD)	9.9±1.5	9.6±1.4	0.073 ^a
Postop A1C (mean±SD)	6.3±0.7	6.2±0.6	0.585 ^a
A1C change (mean±SD)	3.6±1.6	3.4±1.4	0.144 ^a
% A1C change (mean±SD)	35.5±10.6	34.3±9.2	0.289 ^a
T2DM duration, years (mean±SD)	11.4±5.3	13.3±7.1	<0.005 ^a
T2DM severity, <i>n</i> (%)			
OAD	30 (12.8)	17 (13.9)	0.900 ^b
Insulin	26 (11.2)	13 (10.7)	
OAD + Insulin	177 (76.0)	92 (75.4)	
T2DM remission, <i>n</i> (%)	182 (78.1)	99 (81.1)	0.77 ^b

Preop, preoperative; postop, postoperative; BMI, body mass index; TWL, total weight loss; A1C, hemoglobin A1C; T2DM, type 2 diabetes mellitus; OAD, oral antidiabetic. Severity was determined by medication usage. ^aIndependent samples *t* test. ^b χ^2 test.

We also compared %A1C change and T2D remission rates in patients with a BMI <30.0 kg/m² (*n* = 72) in whom a 150–200-cm common channel was established versus patients with a BMI ≥30.0 kg/m² (*n* = 283) in whom a 100–150-cm common channel was established. There were no significant differences in %A1C change (35.5 ± 11.5 vs. 34.9 ± 9.8, respectively; *p* = 0.671) or in T2D complete remission rates (75.0% vs. 80.2%, respectively; *p* = 0.333). Further, there were no significant differences in overall nutrition profiles between the two groups with different common channel lengths.

Nutrition Profile

Preoperative deficiencies in this study population manifested most often in below-normal levels of vitamin D (*n* = 95, 26.8%) and calcium (*n* = 63, 17.7%). Profile patterns of mean changes over time in vitamin concentrations following SG-TB surgery are presented in Figure 3. Repeated measures ANOVA with Bonferroni correction revealed consistent significant decreases in ferritin and B12 levels out to 3 months (*p* < 0.001), which held constant to 6 months. Ferritin remained significantly lower than baseline out to 24 months; however, B12 trended significantly upward through 18 and 24 months (*p* < 0.001). At no point were parathormone levels significantly different from baseline, or from one time point to another. At 2 years, due to relatively consistent upward trends, significant mean increases from baseline levels were observed in vitamin D, calcium, and albumin (*p* < 0.001) (Fig. 3; Ta-

ble 5). The most common vitamin-related complication at 2 years was iron deficiency (i.e., below normal ferritin level; 108 patients, 30.4%; up from 53, 14.9% at baseline), followed by B₁₂ deficiency (12, 3.4%). Preoperative vitamin deficiencies were eliminated: vitamin D deficiency fell from 26.8% to 0.3% (*p* < 0.001), and prevalence of calcium deficiency fell from 17.7% to 2.4% (*p* < 0.05).

Complications

There was no mortality in the study. Complications herein were evaluated using the total cohort: the overall complication rate was 10.2% (90/883). Incidence of intraoperative complications was 2.03%; all such complications were successfully addressed. Patients who developed diarrhea postoperatively (*n* = 8) were managed conservatively with diet modification and loperamide HCL 6 mg daily for 8–2 weeks. Two patients had persistent diarrhea for 6 months, which was managed by adding atropine sulfate (0.025 mg BID) diphenoxylate (2.5 mg BID) in adjunct to loperamide treatment. Patients' symptoms resolved after 6 months and no revisional surgery was required. Early complications occurred in 8.6% of patients and late complications in 1.60%. Late-developing complications included an upper gastrointestinal bleed and a stenosis at the gastro-ileal anastomosis at 6-month follow-up, as well as a late-onset marginal ulcer, each of which was resolved with conservative treatment. A detailed description of total complications can be found in our initial study of 1-year SG-TB outcomes [18].

Table 5. Mean trends in nutritional variables through 24-month follow-up

	Preoperative, mean (\pm SE) 95% CI	1 month, mean (\pm SE) 95% CI	3 month, mean (\pm SE) 95% CI	6 month, mean (\pm SE) 95% CI	9 month, mean (\pm SE) 95% CI	12 month, mean (\pm SE) 95% CI	18 month, mean (\pm SE) 95% CI	24 month, mean (\pm SE) 95% CI
Ferritin, ng/mL (<i>n</i> = 294)	57.9 (2.5) 52.9, 62.9	50.9 (2.3) 46.4, 55.5	50.2 (2.2) 45.7, 54.6	49.3 (2.2) 44.9, 53.7	49.2 (2.3) 44.7, 53.6	49.0 (2.3) 44.4, 53.6	48.8 (2.4) 44.0, 53.5	49.1 (2.3) 44.6, 53.7
Parathormone, pg/mL (<i>n</i> = 318)	50.1 (1.6) 46.8, 53.3	50.3 (1.3) 47.7, 52.9	49.4 (1.2) 47.1, 51.7	47.4 (1.3) 44.9, 50.0	49.0 (0.9) 47.2, 50.9	48.5 (0.9) 46.8, 50.2	48.7 (0.9) 46.9, 50.5	50.7 (1.1) 48.5, 52.9
Vitamin D, ng/mL (<i>n</i> = 252)	16.0 (0.6) 14.9, 17.2	20.2 (0.5) 19.2, 21.1	24.1 (0.5) 23.1, 25.1	25.7 (0.5) 24.8, 26.6	26.2 (0.4) 25.4, 27.0	25.8 (0.3) 25.1, 26.4	25.9 (0.3) 25.2, 26.5	25.2 (0.3) 24.5, 25.8
Vitamin B ₁₂ , ng/mL (<i>n</i> = 294)	420.9 (13.8) 393.7, 448.2	381.8 (12.0) 358.1, 405.4	345.7 (9.1) 327.7, 363.8	340.3 (8.3) 323.9, 356.6	346.0 (7.5) 331.3, 360.7	358.9 (8.2) 342.8, 375.0	376.1 (7.9) 360.5, 391.8	396.4 (7.6) 381.6, 411.3
Calcium, mmol/L (<i>n</i> = 200)	9.15 (0.04) 9.10, 9.24	9.37 (0.03) 9.30, 9.43	9.43 (0.03) 9.37, 9.49	9.45 (0.03) 9.39, 9.50	9.43 (0.03) 9.37, 9.48	9.45 (0.02) 9.40, 9.50	9.44 (0.03) 9.39, 9.48	9.42 (0.03) 9.37, 9.47
Albumin, g/L (<i>n</i> = 234)	4.22 (0.03) 4.16, 4.28	4.26 (0.03) 4.21, 4.32	4.29 (0.03) 4.23, 4.34	4.47 (0.15) 4.18, 4.76	4.36 (0.02) 4.32, 4.40	4.34 (0.02) 4.29, 4.38	4.35 (0.02) 4.31, 4.39	4.31 (0.02) 4.27, 4.35

Normal reference ranges: hemoglobin, 10.6–15.0 gm/dL; ferritin, 30.0–400 ng/mL; parathormone 15–65 pg/mL; vitamin D: 9.5–55.5 ng/mL; vitamin B₁₂, 191–663 pg/mL; calcium, 8.6–10.0 mg/dL; albumin: 3.5–5.2 g/dL. SE, standard error for estimated marginal means based upon repeated measures ANOVA; *n*, number of patients with complete data across all time points relative to nutrition parameter assessed.

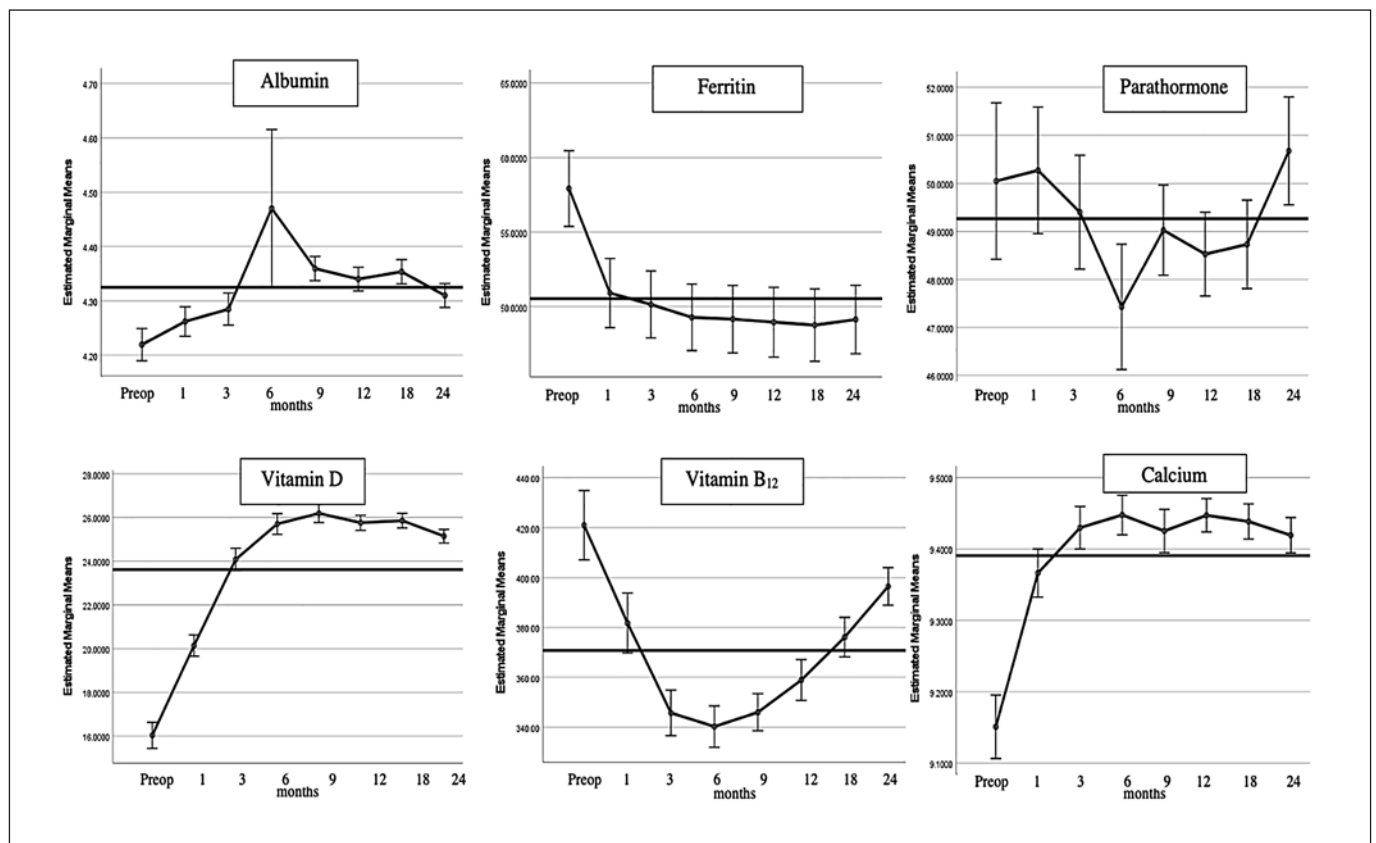


Fig. 3. Profile patterns of nutritional variable mean change.

Discussion

The Agency for Healthcare Research and Quality (AHRQ) assessed metabolic/bariatric surgery as safe in patients with a mean baseline BMI <35.0 kg/m² as in those with a BMI ≥ 35.0 kg/m² [19]. In terms of efficacy, an extremely large and robust meta-analysis (2018) comparing T2D after metabolic/bariatric surgery in 94,579 patients (60 studies, baseline BMI ≥ 35.0 kg/m² vs. 34 studies, BMI <35.0 kg/m²) found their rates of remission equivalent, 71.0% versus 72.0%, respectively [20]. While SG-TB is still an experimental procedure, the above evidence as well as the DSS-II guidelines [12] and American Diabetes Association 2017 Standards of Diabetes Care [13] (approving metabolic/bariatric surgery in Asian patients with BMI ≥ 27.5 kg/m²) support providing SG-TB to Asian patients with poorly controlled T2D in that weight range.

In the few SG-TB reports to date [3–9, 15, 21], this procedure appears to effect marked weight loss and reduction of comorbid disease, particularly T2D, with minimal complications and without causing malnutrition. Recently, we reported initial outcomes of our complete SG-TB series performed in patients with class 1 and 2 obesity ($n = 883$, mean preoperative BMI 34.1 ± 5.0 kg/m²) and diagnosed T2D ($n = 883$) [18]. At 1-year follow-up ($n = 646$), mean respective BMI and TWL were 27.2 ± 3.4 kg/m² ($p < 0.001$) and $19.8 \pm 6.0\%$, and comorbid conditions were significantly reduced. While T2D was not the focus of that study, A1C was normalized ($\leq 6.5\%$) in 83.3%. In the current study of lower-BMI patients with complete T2D data at the 2-year time point, we examined the relationship of the severity and duration of preoperative T2D to post-SG-TB outcomes.

In the current study, results showed that group with BMI <35.0 kg/m² experienced a greater percentage change in A1C, although the difference was not statistically significant ($p = 0.289$) and weight loss was greater, as expected in the group with BMI >35 kg/m². This demonstrates that metabolic surgery may be beneficial in patients with class 1 and class 2 obesity and does not cause excess weight loss and severe malnutrition in short- and mid-term follow-ups.

In the 355 patients who were seen at 2-year follow-up, weight loss did not correlate with T2D duration or severity: No significant between-group differences in BMI reduction were noted, and all groups lost significant weight relative to baseline ($p < 0.001$). There are only two prior SG-TB investigations (Santoro et al. [15] and Azevedo et al. [4]) that report weight and T2D data in lower BMI pa-

tients up to or beyond 2 years against which the current findings can be directly compared. Santoro et al. [15] present the longest-running (5-year follow-up) and largest SG-TB population ($n = 1,020$) to date in patients with BMIs ranging from 33.0 to 72.0 kg/m². Of their total cohort, 333 patients (32.6%) had T2D. Weight loss in Santoro et al. [15] (EBMIL = 94.0%) was comparable to that of the present study (EBMIL = 85.8%).

Complete remission at 2-year follow-up was achieved by 281 patients (79.2%), with all (100.0%) prior insulin users off insulin and another 8.7% improved. As anticipated, patients with the least severe T2D preoperatively (OAD use only) attained the highest remission rate of the subgroups (97.9%). Perhaps predictably, the current study found that resolution was greatest in patients with preoperative T2D duration ≤ 10 years (≤ 5 years, 84.6%; 6–10 years, 87.1%; >10 , 71.0%).

Of Santoro et al.'s [15] 333 SG-TB patients with T2D (281 with complete follow-up), 86.0% achieved T2D resolution (A1C $\leq 6.5\%$ without OAD medications or insulin). Their 2-year remission rate is higher than that of the current study (i.e., 79.2%) using the same assessment criteria. In Azevedo et al.'s [4] small RCT (10 patients had medical therapy, 10 underwent SG-TB), remission of T2D was achieved by all in the SG-TB group, with A1C reduced from 9.3 ± 2.1 at baseline to $5.5 \pm 1.1\%$ at 2 years ($p < 0.05$) with all patients off insulin.

The current SG-TB findings should also be put into context with established metabolic/bariatric procedures. Nearly 80.0% of obese patients who underwent SG-TB in our study experienced complete resolution of long-standing uncontrolled T2D at 2 years. This outcome is comparable to that of T2D resolution in patients with severe obesity following RYGB at 2-year follow-up (70.9%); this was assessed as early as 2009 in a systematic review and meta-analysis by Buchwald et al. [22]. In 2012, a randomized controlled trial (RCT) by Mingrone et al. [23] compared T2D resolution after medical therapy, BPD, or RYGB ($n = 20$ per group). All patients had a ≥ 5 -year history of T2D. They observed T2D remission only in the two surgical groups with respective mean A1C levels of $4.95 \pm 0.49\%$, and $6.35 \pm 1.42\%$ in the BPD and RYGB groups. In the long-running Swedish Obese Subjects trial comparing the efficacy of surgery versus medical therapy, the prevalence of diabetes remission 2 years after RYGB was 72.3% ($n = 219/303$) [24]. This outcome was slightly less effective than that found in the current SG-TB study.

Interestingly, contrary to some observational study results in non-SG-TB procedures [25], patients being treated with insulin before surgery had a more rapid decrease

of their A1C levels than patients who used only OAD. They also reached their reduced A1C levels faster than the noninsulin using group. Moreover, the %TBWL was better in patients who were preoperative insulin users. This fact might be due to the anabolic effect of the insulin, in that, as a patient reduces insulin use after the operation, there may be a gradual change in their leptin to insulin ratio due to the rapid GLP-1 response caused by the nature of the SG-TB surgery.

Guraya and Strate's [26] systematic review and meta-analysis (9 accepted studies) found that RYGB appeared to resolve T2D equivalently to SG in patients with obesity during 1–5 years of follow-up. Their meta-analysis found a nonsignificant difference at 2 years between an 82.3% T2D resolution rate with RYGB ($n = 685$), and 80.7% rate with SG ($n = 698$). A 2021 systematic review and meta-analysis of RCTs by Lee et al. [27] (33 studies, total $n = 2,475$) compared outcomes of RYGB and SG, finding no difference in their rates of T2D up to 5-year follow-up. The findings of both Guraya and Strate [26] and Lee et al. [27] for T2D resolution in RYGB and SG (which are two of the five currently accepted metabolic/bariatric procedures) are consonant with those of this study of SG-TB. Weight loss and T2D resolution outcomes for lower-BMI patients after SG-TB appear to be quite similar to the best outcomes for proven metabolic/bariatric operations in both patients with BMI greater than, and less than, 35.0 kg/m^2 .

Some of the most common deficiencies following metabolic/bariatric surgery are vitamin D and B_{12} , calcium, and iron. These deficiencies can lead to secondary problems such as osteoporosis, peripheral neuropathy, and anemia. Vitamin status after surgery is also related to changes in eating patterns and nutrient intake, but it is also highly dependent on the type of surgical procedure [28]. In fact, nutritional deficiencies after RYGB can be extreme and often cannot be prevented by standard multivitamin supplementation [29]. Although few SG-TB studies have been reported, results suggest that no serious vitamin deficiencies occur after this surgery. For example, Karaca [9] observed no change in albumin and B_{12} levels at 1 year and speculated that the absence of the complete exclusion of the proximal small intestine in SG + TB reduces the likelihood of malnutrition and/or vitamin deficiency relative to other procedures. Corroboratively, in a retrospective evaluation of 109 patients with severe obesity who underwent SG-TB (mean follow-up: 16.6 ± 5.1 months) or distal RYGB (D-RYGB) (17.1 ± 6.2 months), Ece et al. [28] found SG-TB to be associated with significantly less deficiency in folic acid and iron, vitamin D, and B_{12} .

The current results add to the literature in support of the positive nutrition profile of SG-TB. At 2-year follow-up, relative increases from baseline values in vitamin D, calcium, and albumin ($p < 0.001$) were observed. Indeed, preoperative vitamin deficiencies were essentially eliminated: prevalence of vitamin D deficiency fell from 26.8% to 0.3% ($p < 0.001$), and prevalence of calcium deficiency fell from 17.7% to 2.4% ($p < 0.05$). Although the mean concentration of B_{12} declined initially out to 9 months after surgery, B_{12} levels increased significantly from 1 to 2 years ($p < 0.001$). At 2 years, only 3.4% of SG-TB patients were deficient in B_{12} . Iron deficiency at 2-year follow-up was 30.4% as determined by a below-normal ferritin level. Ferritin levels can be misleading in patients with chronic inflammation and liver disease. However, none of the patients in our group developed chronic liver disease after the operation. In our study, the increase of ferritin and B_{12} levels was mainly due to patient supplementation and their change toward healthy dietary habits. In addition, our findings may be in line with Ece et al. [28] because the prevalence of iron deficiency can range as high as 53.0% after RYGB and 54.0% after SG [30]. Although this study did not specifically assess cost effectiveness of the procedure, the limited use of multivitamins in response to the lower likelihood of malnutrition with SG-TB may produce cost savings.

Although the sample size of the series in this study was large, a limitation of our study was that there was no direct comparison group. Ongoing reporting of this cohort through the planned 5-year follow-up may provide evidence that strengthens these single-series findings.

Conclusion

We believe that this series presents the largest ($n = 355$) study of T2D resolution following SG-TB in relation to preoperative T2D duration and severity. Our results suggest that SG-TB is a good option for patients with obesity. Most patients in the current study, regardless of T2D duration and severity, experienced marked weight loss, excellent T2D resolution, and favorable nutritional outcomes with few complications at 2 years following SG-TB. Ongoing reporting of the current and other SG-TB cohorts is needed to evaluate the durability of diabetes resolution facilitated by the procedure.

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Statement of Ethics

The study protocol and all procedures of the study were approved as compliant with the ethical standards of the Near East University Committee of the Faculty of Medicine, Department of Surgery, Nicosia, Cyprus Institutional Review Board (IRB#261020-04). Written informed Consent was obtained from all study participants. Human and Animal Rights: The study was performed in accord with the ethical standards of the 1964 Declaration of Helsinki and subsequent amendments.

Conflict of Interest Statement

The authors have no conflict of interest to declare. Dr. Halit Eren Taskin, MD and Dr. Muzaffer Al, MD have no conflicts of interest or financial ties to disclose. The manuscript has been read and approved by all the authors; the requirements for authorship have been met; and both authors believe that the manuscript represents honest work.

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Author Contributions

Muzaffer Al and Halit Eren Taskin worked on design, intellectual content, clinical research, version review, and editing. Muzaffer Al performed the surgery. Halit Eren Taskin contributed to statistical editing and manuscript preparation and is guarantor.

Data Availability Statement

The raw data pertaining to this study are not publicly available outside of the university database for ethical reasons with the exception of its presentation in this current analyzed format, as a peer-reviewed journal article for publication in the medical literature. The data that support the findings of this study are openly available by the reasonable request to the first author.

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