

SURGERY FOR OBESITY AND RELATED DISEASES

Surgery for Obesity and Related Diseases 🔳 (2022) 1–8

Original article

Validation of the individualized metabolic surgery score for bariatric procedure selection in the merged data of two randomized clinical trials (SLEEVEPASS and SM-BOSS)

Ilmari Saarinen, M.D.^{a,b,c,*}, Sofia Grönroos, M.D.^{a,b,c,*}, Saija Hurme, M.Sc.^d, Ralph Peterli, M.D.^{e,f}, Mika Helmiö, M.D., Ph.D.^{a,b}, Marco Bueter, M.D., Ph.D.^g, Marjatta Strandberg, M.D., Ph.D.^{b,h}, Bettina K. Wölnerhanssen, M.D.^{e,i}, Paulina Salminen, M.D., Ph.D.^{a,b,*}

^aDivision of Digestive Surgery and Urology, Department of Digestive Surgery, Turku University Hospital, Turku, Finland

^bDepartment of Surgery, University of Turku, Turku, Finland ^cDepartment of Surgery, Satasairaala Central Hospital, Pori, Finland

^dDepartment of Biostatistics, University of Turku, Turku, Finland

^eDepartment of Surgery, University of Basel, Basel, Switzerland

^fClarunis, Department of Visceral Surgery, University Centre for Gastrointestinal and Liver Diseases, St Clara Hospital and University Hospital Basel,

Basel, Switzerland

^gDepartment of Visceral and Transplantation Surgery, University Hospital, Zürich, Switzerland

^hEmergency Care, Turku University Hospital, Turku, Finland

ⁱSt Clara Research Ltd, St Clara Hospital, Basel, Switzerland

Received 26 June 2022; accepted 27 October 2022

Abstract

Background: LSG and LRYGB are globally the most common bariatric procedures. IMS score categorizes T2D severity (mild, moderate, and severe) based on 4 independent preoperative predictors of long-term remission as follows: T2D duration, number of diabetes medications, insulin use, and glycemic control. IMS score has not been validated in a randomized patient cohort. **Objectives:** To assess the feasibility of individualized metabolic surgery (IMS) score in facilitating procedure selection between laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB) for patients with severe obesity and type 2 diabetes (T2D). Setting: Merged individual patient-level 5-year data of 2 large randomized clinical trials (SLEEVE-PASS and SM-BOSS [Swiss Multicenter Bypass or Sleeve Study]). **Methods:** IMS score was calculated for study patients and its performance was analyzed. Results: One hundred thirty-nine out of 155 patients with T2D had available preoperative data to calculate IMS score as follows: mild stage (n = 41/139), moderate stage (n = 77/139), severe stage (n = 21/139). At 5 years, 135 (87.1%, 67 LSG/68 LRYGB) were available for follow-up and 121 patients had both pre- and postoperative data. Diabetes remission rates according to preoperative IMS score were as follows: mild stage 87.5% (n = 14/16) after LSG and 85.7% (n = 18/21) after LRYGB (P = .999), moderate stage 42.9% (n = 15/35) and 45.2% (n = 14/31) (P = .999), and severe stage

Funding: The SLEEVEPASS trial was supported by the Mary and Georg C. Ehrnrooth Foundation (Dr. Salminen), by a government research grant from the EVO Foundation awarded to Turku University Hospital (Dr. Salminen, Dr. Helmiö), by the Gastroenterological Research Foundation (Dr. Grönroos), and by The Finnish Medical Foundation (Dr. Grönroos). The SM-BOSS trial was funded by the Swiss National Science Foundation, and Ethicon Endo Surgery USA.

Equal contribution.

* Correspondence: Paulina Salminen, M.D., Ph.D., University of Turku, Department of Surgery, Turku University Hospital, Division of Digestive Surgery and Urology, P.O. Box 52, Turku 20521, Finland. E-mail address: paulina.salminen@tyks.fi (P. Salminen).

https://doi.org/10.1016/j.soard.2022.10.036

1550-7289/© 2022 American Society for Metabolic and Bariatric Surgery. Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

ARTICLE IN PRESS

Ilmari Saarinen et al. / Surgery for Obesity and Related Diseases 🔳 (2022) 1–8

18.2% (n = 2/11) and 0% (n = 0/7) (P = .497), respectively. The T2D remission rate varied significantly between the stages as follows: mild versus moderate odds ratio (OR) 8.3 (95% CI, 2.8–24.0; P < .001), mild versus severe OR 52.2 (95% CI 9.0–302.3; P < .001), and moderate versus severe OR 6.3 (95% CI, 1.3–29.8; P = .020).

Conclusions: In our study, remission rates of T2D were not statistically different after LSG and LRYGB among all patients and among patients with mild, moderate, and severe diabetes stratified by the IMS score. However, the study may be underpowered to detect differences due to small number of patients in each subgroup. IMS score seemed to be useful in predicting long-term T2D remission after bariatric surgery. (Surg Obes Relat Dis 2022; \blacksquare :1–8.) © 2022 American Society for Metabolic and Bariatric Surgery. Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

Keywords: Bariatric surgery; Sleeve gastrectomy; Roux-en-y gastric bypass; Type 2 diabetes; IMS score

The global obesity epidemic is ever increasing, resulting in concurrent increase of obesity associated diseases with type 2 diabetes (T2D) as one of the most important comorbidities driving towards an increased rate of cardiovascular morbidity and mortality [1–3]. To date, bariatric surgery is the most effective treatment of severe obesity with good and sustainable weight loss and remission or alleviation of associated diseases at long-term follow-up [4–9]. Currently, the annual number of bariatric procedures worldwide is around 750,000 and since 2014, laparoscopic sleeve gastrectomy (LSG) has been the most frequently performed bariatric procedure, while laparoscopic Rouxen-Y gastric bypass (LRYGB) represents the second most common procedure [10].

Tailoring the surgical treatment of severe obesity for all bariatric surgery patients aiming to optimize outcomes is under active research and the optimal treatment choice is naturally a multifactorial issue. The severity of T2D and its predicted remission play an important role in this decision. Recent meta-analyses have shown no difference in either weight loss or T2D remission between LSG and LRYGB [11,12], but as stated by Lee et al. [12], longterm data from randomized controlled trials (RCTs) are lacking and firm conclusions cannot be drawn. In addition, even the most recent meta-analysis [12] still includes the RCT by Ruiz-Tovar et al., which was retracted in March 2021 for scientific inconsistencies further reducing the number of available RCT patients. In a large retrospective cohort study, LRYGB was associated with greater weight loss, a slightly higher T2D remission rate, less T2D relapses, and better long-term glycemic control compared to LSG [13].

In order to increase statistical precision, the 5-year individual patient data of 2 large RCTs (SLEEVEPASS and SM-BOSS) were merged and additional patient-level data for T2D were retrieved. In this merged data, although LRYGB induced greater weight loss and better amelioration of hypertension than LSG, there was no difference in T2D remission and there were more complications after LRYGB [14].

While the probability of T2D relapse increases with follow-up, it should not be considered a failure as the

trajectory of the disease and the associated cardiometabolic risk factors change favorably after bariatric surgery [7,15]. Longer preoperative duration of T2D, patient age, preoperative insulin use, poor glycemic control, and the number of T2D medications at baseline are all associated with greater likelihood of T2D relapse [14,16–19].

Several scoring systems have been assessed as tools to facilitate optimal metabolic procedure choice for patients with severe obesity and T2D, and many of these scores have been validated and compared within a variety of patient cohorts [20–27]. The individualized metabolic surgery (IMS) score [23] categorizes patients into 3 stages of T2D severity (mild, moderate, and severe) based on the following 4 independent preoperative predictors of long-term remission: T2D duration, number of diabetes medications, insulin use, and glycemic control. The IMS score suggested LSG as the procedure of choice for patients with severe T2D based on the better risk-benefit ratio and LRYGB for patients with moderate stage T2D [23]. To our knowledge, the IMS score has only been validated in retrospective cohorts and at short- or mid-term follow-up [28,29].

Using the unique merged individual patient data of the so far 2 largest RCTs (SLEEVEPASS [30] and SM-BOSS [31]) comparing LSG and LRYGB with 5-year follow-up data [14], the aim of this study is to validate the IMS score in a large prospective cohort assessing the feasibility of the IMS score in both tailoring the metabolic surgery procedure choice for patients with T2D and predicting the sustainability of T2D remission.

Methods

The study design, rationale, and methods of both RCTs have been previously reported [30,31]. The study protocols were approved by the local ethics committees of each participating hospital, the trials were conducted in accordance with the principles of the Declaration of Helsinki and registered at the clinical trials registry of the National Institutes of Health (ClinicalTrials.gov NCT00356213, NCT00793143). All patients gave written informed consent.

The methods and analyses of the merged individual patient data have been previously described in detail [14]. Briefly, both trials were randomized, controlled, multicenter, and multisurgeon trials comparing LSG and LRYGB involving a total of 240 patients with severe obesity from Finland and 225 patients from Switzerland, and similar inclusion and exclusion criteria and similar operative techniques [30,31]. For LSG, a 33-Fr to 35-Fr calibration bougie was used, and the resection was initiated from 3-6 cm proximal to the pylorus. For LRYGB, in both trials the standardized surgical technique for LRYGB entailed creating a small gastric pouch and constructing an antecolic end-to-side gastrojejunostomy, as either a circular or a linear anastomosis according to the preference of the surgeon. The alimentary limb was measured to 150 cm and the biliopancreatic limb was 50-80 cm in the SLEEVEPASS trial and 50 cm in the SM-BOSS trial.

Raw patient level data from the 2 original RCTs were combined, and outcomes were standardized. Additional 5-year data were retrieved on T2D (preoperative T2D duration and number of T2D medications). Out of the 398 patients (398/465, 85.6%) available for follow-up in this merged data, 155 patients had T2D at baseline and were included in this study.

The IMS score [23] was calculated based on 4 different independent preoperative variables predicting long-term remission of T2D as follows: duration of T2D in years, the number of diabetes medications, insulin use, and glycemic control (glycated hemoglobin level, A1c <7%). Based on the calculated scores, patients were categorized into the following 3 different groups according to IMS score T2D severity stage: mild (IMS score <25), moderate (IMS score >25 to \leq 95), and severe (IMS score >95), and the T2D remission rates were assessed according to these groups. Long-term T2D remission was defined according to ADA consensus statement as A1c<6.5%, fasting blood glucose 126 mg/dl, and off T2D medications at 5 years or more after surgery [32]. Furthermore, the changes in BMI were calculated according to T2D severity. Weight loss was defined as percentage total weight loss (%TWL [preoperative weight postoperative weight/preoperative weight \times 100]), as it is the recommended metric of choice when reporting weight loss.

Statistical analyses

Continuous variables were described using as means with standard deviations (SD) or, if the data were skewed, as medians with 25^{th} (Q₁) and 75^{th} (Q₃) percentiles. Nonparametric Kruskal-Wallis test was used to test differences in continuous baseline variables between the IMS T2D severity stages. Categorical variables were characterized using frequencies and percentages and tested using Pearson's Chi Squared test or Fisher's exact test when appropriate. In order to be able to compare the results to the original publication, Pearson's Chi Squared test was used to compare the remission rates of T2D between the operations separately in 3 severity stages, and one-way analysis of variance (ANOVA) was used to evaluate the differences in body mass index (BMI) between the severity stages separately in 2 operations. In addition, logistic regression analysis was used to evaluate the effect of T2D severity stage, operation, and percentage total weight loss (%TWL) on T2D remission. In contrast to the original article, we used %TWL in the model to represent the weight loss instead of change in BMI used in the original article. In the severe T2D stage, there was no remission after LRYGB operation and thus, we combined the severe stage with the moderate stage and this modified variable was used in the first reported model. First model included T2D severity stage (severe and moderate stages combined), operation, %TWL, and interaction of severity stage and operation. The final model included only the main effects of T2D severity stage (original variable with 3 categories) and operation because using this simple model enabled the use of severity stage with original categories. The results of logistic regression models were quantified using odds ratios (OR) with 95% confidence intervals (95% CIs).

Two-sided tests were used and P values <.05 were considered statistically significant. Missing observations were excluded from the analyses. Statistical analyses were performed using SAS System for Windows (Version 9.4, SAS Institute Inc., Cary, NC, USA).

Results

The patient flow is presented in Figure 1 and the patient baseline characteristics are displayed in Table 1. Out of the 155 patients with T2D at baseline, 139 (89.7%) had the preoperative data for IMS calculations, and 135 (87.1%) were available for follow-up at 5 years. The T2D remission rate 5 years after LSG was 49.3% (n = 33/67) and 55.8% (n = 38/68) after LRYGB (*P* = .418). Baseline characteristics of the patients according to T2D severity stage and operation are shown in Table 2.

There were altogether 121 patients with available data for both IMS score calculation and T2D remission analysis at 5 years. In total, 52.6% (n = 63/121) of these patients had complete remission of T2D at 5 years. Within the severity stages, the rates in achieving long-term remission at 5year follow-up were 86.5% (n = 32/37) in the mild stage, 43.9% (n = 29/66) in the moderate stage, and 11.1% (n = 2/18) in the severe stage (P < .001). The remission rates after LSG and LRYGB according to T2D severity are presented in Table 3. The remission rates did not differ statistically and significantly between the operations in any of the severity stages.

The change in BMI at 5 years after LSG or LRYGB according to T2D severity is shown in Table 4. The change in BMI differed significantly (P = .043) between the



Figure 1. Flow diagram. LSG = laparoscopic sleeve gastrectomy; LRYGB = laparoscopic Roux-en-Y gastric bypass; T2D = type 2 diabetes; IMS = individualized metabolic surgery.

severity stages in patients who underwent LRYGB with the highest BMI loss associated with T2D mild stage. In patients who underwent LSG, there were no significant differences (P = .454) in BMI change between the T2D severity stages.

In the logistic regression analyses for T2D remission, interaction of IMS severity (severe and moderate stages combined) and operation was not statistically significant (P = .524) and thus no further analyses were needed to test the difference between the operations separately in IMS severity stages. The effect of %TWL on T2D remission was statistically significant (P = .001) and the odds for remission increased with greater %TWL (OR, 1.1; 95% CI, 1.0–1.2). In the final model there was no statistically significant difference in T2D remission between LSG and LRYGB (OR, 1.1; 95% CI, 0.5–2.6; P = .812). Difference

in T2D remission between the IMS score T2D severity stages was statistically significant (P < .001). The odds for T2D remission were the highest in the mild stage (mild versus moderate OR, 8.3; 95% CI, 2.8–24.0; P < .001 and mild versus severe OR, 52.2; 95% CI, 9.0–302.3; P < .001). There was also a statistically significant difference between the moderate and the severe stages in the odds for T2D remission (OR, 6.3, 95% CI, 1.3–29.8; P = .020).

Discussion

In this large merged randomized patient cohort, T2D remission rates between LSG and LRYGB were similar in all 3 IMS score T2D severity groups. However, the T2D severity stage was strongly associated with T2D remission with patients in the mild stage group being more likely to

Table 1 Baseline patient characteristics

	SM-BOSS (N = 54)	SLEEVEPASS ($N = 101$)	LSG (N = 78)	LRYGB $(N = 77)$
Age (yr), mean (SD)	47.9 (10.3)	51.6 (8.1)	50.4 (8.9)	50.2 (9.2)
Sex: female/male, frequency (%)	30/24 (55.6%)	62/39 (61.4%)	43/35 (55.1%)	49/28 (63.6%)
Body Mass Index, BMI (kg/m ²), mean (SD)	44.7 (10.3)	46.9 (6.2)	46.1 (6.2)	46.1 (6.0)
Preoperative duration of T2D (yr), median	1.0 (0.5-7.0)	5.0 (2.0-8.0)	5.0 (1.1-7.5)	4.0 (1.0-7.0)
$(Q_1 - Q_3)$				
No T2D medication, frequency (%)	17/44 (38.6%)	0/100 (0.0%)	9/75 (12.0%)	8/69 (11.6%)
1 T2D medication, frequency (%)	22/44 (50.0%)	51/100 (51.0%)	32/75 (42.7%)	41/69 (59.4%)
2 T2D medications, frequency (%)	5/44 (11.1%)	40/100 (40.0%)	31/75 (41.3%)	14/69 (20.3%)
3 T2D medications, frequency (%)	0/44 (0.0%)	8/100 (8.0%)	3/75 (4.0%)	5/69 (6.8%)
4 T2D medications, frequency (%)	0/44 (0.0%)	1/100 (1.0%)	0/75 (0.0%)	1/69 (1.5%)
Insulin use, frequency (%)	10/54 (18.5%)	32/101 (31.7%)	24/78 (30.7%)	18/77 (23.4%)
Glycated hemoglobin, A1c (%), median (Q_1-Q_3)	6.8 (6.1–7.9)	6.6 (6.3–7.2)	6.7 (6.3–7.5)	6.6 (6.1–7.7)
Glycemic control, frequency (%)*	31/51 (60.8%)	67/101 (66.3%)	51/77 (66.2%)	47/75 (62.7%)

LSG = Laparoscopic sleeve gastrectomy; LRYGB = Laparoscopic Roux-en-Y gastric bypass; T2D = Type 2 Diabetes mellitus; A1c = Glycated hemoglobin level; SD = Standard deviation.

* Glycated hemoglobin level (A1c) < 7%.

achieve remission compared to patients in the moderate or severe stage groups. Our results, therefore, suggest that IMS score does not facilitate the procedure selection between LSG and LRYGB, but IMS could be used as a general predictive model for T2D remission in patients with severe obesity.

Our findings are in contrast to the original IMS score article [23] by Aminian et al., who suggested LRYGB for patients with moderate stage T2D due to their retrospective results of LRYGB resulting in superior T2D remission rates in this group, but are in line with Chen et al., [28] who also found no difference in 5-year remission rates between LSG and LRYGB in the moderate stage. However, the latter study may have been influenced by the Asian ethnicity and lower preoperative BMI of the study population, while in our merged data set, both these factors are likely more similar to the dataset of the original IMS score article.

A recent study by Ohta et al. [29] found LSG superior to LRYGB regarding T2D remission in patients with moderate T2D, although patients undergoing LSG had higher BMI compared to LRYGB in their study population. Their results showed sleeve gastrectomy with duodenojejunal bypass to be the most effective procedure in treatment of T2D in the moderate stage [29] in line with results showing that biliopancreatic diversion with duodenal switch is superior for T2D remission [9].

To our knowledge, this is the first validation of the IMS score using randomized data comparing LSG and LRYGB

Table 2

Baseline patient characteristics by type 2 diabetes severity according to calculated individualized metabolic surgery score

	Mild stage $(N = 41)$		Moderate stage ($N = 77$)		Severe stage $(N = 21)$	
	LSG (N = 19)	LRYGB (N = 22)	LSG $(N = 41)$	LRYGB (N = 36)	LSG (N = 12)	LRYGB $(N = 9)$
Age (yr), mean (SD) Sex: female/male, frequency (%) Body Mass Index, BMI (kg/m ²), mean (SD)	46.4 (9.2) 12/7 (63.2%) 47.6 (6.4)	50.6 (11.0) 15/7 (68.2%) 47.8 (5.7)	52.2 (8.0) 24/17 (58.5%) 46.1 (6.4)	49.2 (8.0) 22/14 (61.1%) 46.8 (6.4)	51.8 (8.0) 5/7 (41.7%) 42.9 (6.0)	52.5 (9.7) 7/2 (77.8%) 43.8 (6.2)
Glycated hemoglobin, A1c (%), median (Q ₁ -Q ₃)	6.2 (5.8–6.7)	6.1 (5.7–6.5)	6.7 (6.4–7.0)	6.8 (6.2–7.7)	8.6 (7.4–9.7)	8.7 (8.2–9.7)
Preoperative duration of T2D (yr), median (Q_1-Q_3)	1.0 (0.5–1.5)	1.0 (0.5–1.0)	5.0 (4.0-7.0)	5.0 (4.0–7.0)	11.0 (8.0–20.5)	15.0 (13.0–26.0)
No T2D medication, frequency (%)	7/19 (36.8%)	8/22 (36.4%)	1/41 (2.4%)	0/36 (0.0%)	0/12 (0.0%)	0/9 (0.0%)
1 T2D medication, frequency (%)	12/19 (63.2%)	14/22 (63.6%)	19/41 (46.3%)	22/36 (61.1%)	0/12 (0.0%)	4/9 (44.4%)
2 T2D medications, frequency (%)	0/19 (0.0%)	0/22 (0.0%)	20/41 (48.8%)	10/36 (27.8%)	10/12 (83.3%)	3/9 (33.3%)
3 T2D medications, frequency (%)	0/19 (0.0%)	0/22 (0.0%)	1/41 (2.4%)	4/36 (11.1%)	2/12 (16.67%)	1/9 (11.1%)
4 T2D medications, frequency (%)	0/19 (0.0%)	0/22 (0.0%)	0/41 (0.0%)	0/36 (0.0%)	0/12 (0.0%)	1/9 (11.1%)
Insulin use, frequency (%)	0/19 (0.0%)	0/22 (0.0%)	10/41 (24.4%)	7/36 (19.4%)	12/12 (100.0%)	9/9 (100.0%)
Glycemic control, frequency (%)*	18/19 (94.7%)	22/22 (100.0%)	28/41 (68.3%)	19/36 (52.8%)	1/12 (8.3%)	1/9 (11.1%)

LSG, Laparoscopic sleeve gastrectomy; LRYGB, Laparoscopic Roux-en-Y gastric bypass; T2D, Type 2 Diabetes mellitus; A1c = Glycated hemoglobin level; SD = Standard deviation.

* Glycated hemoglobin level (A1c) < 7%.

Table 3

Severity stage	Remission after surgery	Remission after LSG	Remission after LRYGB	P value
		Merged data		
Mild [frequency (%)]	32/37 (86.5%)	14/16 (87.5%)	18/21 (85.7%)	.999*
Moderate [frequency (%)]	29/66 (43.9%)	15/35 (42.9%)	14/31 (45.2%)	.999*
Severe [frequency (%)]	2/18 (11.1%)	2/11 (18.2%)	0/7 (0.0%)	.497*
		SLEEVEPASS		
Mild [frequency (%)]	15/18 (83.3%)	5/7 (71.4%)	10/11 (90.9%)	.528*
Moderate [frequency (%)]	18/48 (37.5%)	10/26 (38.5%)	8/22 (36.4%)	.999*
Severe [frequency (%)]	0/13 (0.0%)	0/7 (0.0%)	0/6 (0.0%)	NA
		SM-BOSS		
Mild [frequency (%)]	17/19 (89.5%)	9/9 (100.0%)	8/10 (80.0%)	.474*
Moderate [frequency (%)]	11/18 (61.1%)	5/9 (55.6%)	6/9 (66.7%)	.999*
Severe [frequency (%)]	2/5 (40.0%)	2/4 (50.0%)	0/1 (0.0%)	.999*

1401						
T2D	remission	rates by	severity	stage	and c	peration

LSG = Laparoscopic sleeve gastrectomy; LRYGB = Laparoscopic Roux-en-Y gastric bypass.

* Fisher's exact test.

with the randomization mitigating the selection bias. The IMS score is based on a large retrospective patient cohort (n = 900) with severe obesity and T2D with long-term glycemic follow-up after metabolic surgery (LSG or LRYGB). In the original IMS score training cohort only a quarter of the patients underwent LSG, which could potentially have led to a false-positive effect of LSG in the severe stage group [23].

The present study showed no significant difference in T2D remission rates between LSG and LRYGB. This result is in line with a recent meta-analysis by Lee et al. [12], which included 33 RCTs and 2475 patients comparing these 2 procedures. The Oseberg trial [33] comparing LRYGB and LSG in the treatment of patients with T2D, and severe obesity with 2 endpoints of 1-year T2D remission and β -cell function was not included to this meta-analysis showing superior T2D remission after LRYGB with no difference in β -cell function. However, to detect a 10-percentage point difference in T2D remission rate between the operations, about 700 patients with T2D would need to be enrolled underlining the need for international scientific collaboration for an individual patient data meta-analysis.

Previous studies have reported the ability of the IMS score in predicting overall T2D remission [34,35]. Plaeke et al. [34] compared the performance of 11 different

predictive scores and found the IMS score to be the most accurate. In patients undergoing LSG, IMS score was able to discriminate T2D remissions [35]. Many scoring systems have been developed to predict T2D remission after bariatric surgery such as DiaRem [22], advanced-DiaRem (ad-DiaRem) [24], DiaBetter [25] and ABCD scores [20]. Chen et al. [28] reported that the ABCD scores have better discriminative ability between the procedures compared with the IMS score. This was suggested to derive from the lack of C-peptide value in the IMS score as it has been shown to predict T2D remissions [36–38]. However, there are contradicting results of the role of C-peptide in predicting T2D remissions showing comparable prediction results of the IMS score to the ABCD score in an Asian population [29].

DiaRem, ad-DiaRem, DiaBetter, and IMS score all include similar parameters; preoperative A1c along with the use of diabetes medications and insulin use all associated with T2D remission prediction [22,24,25,38–40]. Ad-Diarem, DiaBetter, and IMS score all include preoperative duration of T2D, which is strongly associated with remission rate [7,24,36,39], and these 3 scores performed best in the comparison of the 11 predictive scores by Plaeke et al. [34]. With the progressing nature of T2D

Table	e 4
-------	-----

Change of body mass index by severity stage and operation

Body Mass Index, BMI (kg/m ²), mean (SD)	LRYGB			LSG				
	Mild	Moderate	Severe	P value*	Mild	Moderate	Severe	P value*
Baseline	47.8 (5.7)	46.8 (6.4)	43.8 (6.2)	.275	47.6 (6.4)	46.1 (6.4)	42.9 (6.0)	.137
5 yr	33.25 (5.5)	34.8 (6.1)	35.1 (5.0)	.586	36.6 (6.4)	37.6 (5.9)	33.3 (6.7)	.172
Change from baseline	-14.6 (6.1)	-11.6 (4.2)	-10.0 (3.5)	.043	-11.0 (5.6)	-9.3 (4.1)	-10.4 (4.5)	.454

LSG = Laparoscopic sleeve gastrectomy; LRYGB = Laparoscopic Roux-en-Y gastric bypass.

* One-way analysis of variance.

pathophysiology, worse A1c, number of diabetes medications, and insulin use are basically by-products of T2D duration and signs of progression of disease severity [41,42].

In our study, we used both change in BMI and %TWL as weight loss variables, and change in BMI was used to facilitate the comparison with the original IMS score [23]. Currently %TWL is considered to be the variable of choice in reporting weight loss outcomes after bariatric surgery [43], and therefore, we used %TWL in our advanced model. The effect of preoperative BMI on T2D remission remains somewhat controversial [24,36,39]. A meta-analysis of 4944 patients showed preoperative BMI not to be a significant predictor of T2D remission [44].

This study has limitations. First, the present study is limited by the number of patients and underpowered to detect differences in T2D remission between LSG and LRYGB. However, to our knowledge, this is so far the largest randomized cohort with the longest follow-up and high follow-up rate comparing LSG and LRYGB of patients with severe obesity and T2D. Second, the patients in our study population had somewhat better glycemic control (hemoglobin [Hb] A1C<7%) and shorter T2D duration (5 years in SLEEVEPASS but 1 year in SM-BOSS) at baseline compared to the training and validating cohort of the original IMS score study (HbA1C, 7.3%-7.4% and T2D duration, 5-6 years), which may partly contribute to the differences in our results. Third, the LRYGB surgical technique used in the original IMS training and validating cohorts was not reported limiting the assessment on the potential differences of the procedure details (e.g., limb lengths). Fourth, the study population consisted mostly of patients with Caucasian ethnic background limiting the generalizability of the results in patients of other ethnicities.

Conclusions

In our study, remission rates of T2D were not statistically different after LSG, and LRYGB among all patients and among patients with mild, moderate, and severe diabetes were stratified by the IMS score. However, the study may be underpowered to detect differences due to small number of patients in each subgroup. IMS score seemed to be useful in predicting long-term T2D remission after bariatric surgery.

Acknowledgments

The authors give their thanks to all trial patients. We thank all the collaborators in original trials: A. Juuti, A.C. Meyer-Gerspach, M. Slawik, P. Peromaa-Haavisto, T. Peters, D. Vetter, D. Kröll, Y. Borbely, B. Schultes, C. Beglinger, J. Drewe, M. Schiesser, P. Nett, J. Ovaska, M. Leivonen and M. Soinio. They also express thanks to M. Victorzon (Department of Surgery, University of Turku, and Vaasa Central Hospital, Vaasa, Finland) who was involved in this trial, but passed away before this work was submitted.

Disclosures

All authors have completed and submitted the ICMJE (International Committee of Medical Journal Editors) form for disclosure of potential conflicts of interest. No other authors reported disclosures.

Author Contributions

Drs Saarinen, Grönroos and Salminen had full access to all the data in the study and take full responsibility for the integrity of the data and the accuracy of the data analyses. Dr. Salminen had the final responsibility for the decision to submit the manuscript for publication. Concept and design: Saarinen, Grönroos, Hurme, Strandberg, Peterli, Bueter, Wölnerhanssen, and Salminen. Acquisition, analysis, or interpretation of data: Saarinen, Grönroos, Hurme, Helmiö, Peterli, Bueter, Strandberg, Wölnerhanssen, and Salminen. Drafting of the manuscript: Saarinen, Grönroos, Hurme, Strandberg, and Salminen. Critical revision of the manuscript: Helmiö, Peterli, Wölnerhanssen, Bueter, Saarinen, Grönroos, Hurme, Strandberg, and Salminen. Statistical analyses: Saarinen, Grönroos, Hurme, and Salminen. Administrative, technical, or material support: Saarinen, Grönroos, Hurme, Helmiö, Peterli, Bueter, Strandberg, Wölnerhanssen and Salminen. Supervision: Salminen.

References

- Collaborators GBDO, Afshin A, Forouzanfar MH, et al. Health effects of overweight and obesity in 195 Countries over 25 years. N Engl J Med 2017;377(1):13–27.
- [2] Flegal KM, Kruszon-Moran D, Carroll MD, Fryar CD, Ogden CL. Trends in obesity among Adults in the United States, 2005 to 2014. JAMA 2016;315(21):2284–91.
- [3] La Sala L, Pontiroli AE. Prevention of diabetes and cardiovascular disease in obesity. Int J Mol Sci 2020;21(21):8178.
- [4] Courcoulas AP, Belle SH, Neiberg RH, et al. Three-year outcomes of bariatric surgery vs lifestyle intervention for type 2 diabetes mellitus treatment: a randomized clinical trial. JAMA Surg 2015;150(10): 931–40.
- [5] Ikramuddin S, Korner J, Lee WJ, et al. Lifestyle intervention and medical management with vs without Roux-en-Y gastric bypass and control of hemoglobin A1c, LDL cholesterol, and systolic blood pressure at 5 years in the diabetes surgery study. JAMA 2018;319(3):266–78.
- [6] Rubino F, Nathan DM, Eckel RH, et al. Metabolic surgery in the treatment Algorithm for type 2 diabetes: a joint statement by international diabetes organizations. Diabetes Care 2016;39(6):861–77.
- [7] Schauer PR, Bhatt DL, Kirwan JP, et al. Bariatric surgery versus intensive medical therapy for diabetes - 5-year outcomes. N Engl J Med 2017;376(7):641–51.
- [8] Adams TD, Davidson LE, Litwin SE, et al. Weight and metabolic outcomes 12 Years after gastric bypass. N Engl J Med 2017;377(12): 1143–55.
- [9] Mingrone G, Panunzi S, De Gaetano A, et al. Metabolic surgery versus conventional medical therapy in patients with type 2 diabetes: 10-year follow-up of an open-label, single-centre, randomised controlled trial. Lancet 2021;397(10271):293–304.

- [10] Angrisani L, Santonicola A, Iovino P, et al. IFSO worldwide survey 2016: primary, endoluminal, and revisional procedures. Obes Surg 2018;28(12):3783–94.
- [11] Han Y, Jia Y, Wang H, Cao L, Zhao Y. Comparative analysis of weight loss and resolution of comorbidities between laparoscopic sleeve gastrectomy and Roux-en-Y gastric bypass: a systematic review and meta-analysis based on 18 studies. Int J Surg 2020;76:101–10.
- [12] Lee Y, Doumouras AG, Yu J, et al. Laparoscopic sleeve gastrectomy versus laparoscopic Roux-en-Y gastric bypass: a systematic review and meta-analysis of weight loss, comorbidities, and biochemical outcomes from randomized controlled trials. Ann Surg 2021;273(1): 66–74.
- [13] McTigue KM, Wellman R, Nauman E, et al. Comparing the 5-year diabetes outcomes of sleeve gastrectomy and gastric bypass: the national patient-centered clinical research network (PCORNet) bariatric study. JAMA Surg 2020;155:e200087.
- [14] Wölnerhanssen BK, Peterli R, Hurme S, et al. Laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy: 5-year outcomes of merged data from two randomized clinical trials (SLEE-VEPASS and SM-BOSS). Br J Surg 2021;108(1):49–57.
- [15] Aminian A, Vidal J, Salminen P, et al. Late relapse of diabetes after bariatric surgery: not rare, but not a failure. Diabetes Care 2020;43(3):534–40.
- [16] Jiménez A, Casamitjana R, Flores L, et al. Long-term effects of sleeve gastrectomy and Roux-en-Y gastric bypass surgery on type 2 diabetes mellitus in morbidly obese subjects. Ann Surg 2012;256(6):1023–9.
- [17] Brethauer SA, Aminian A, Romero-Talamás H, et al. Can diabetes be surgically cured? Long-term metabolic effects of bariatric surgery in obese patients with type 2 diabetes mellitus. Ann Surg 2013;258(4):628–36;discussion 636-7.
- [18] Aminian A, Brethauer SA, Andalib A, et al. Can sleeve gastrectomy "cure" diabetes? Long-term metabolic effects of sleeve gastrectomy in patients with type 2 diabetes. Ann Surg 2016;264(4):674–81.
- [19] Sjöström L, Peltonen M, Jacobson P, et al. Association of bariatric surgery with long-term remission of type 2 diabetes and with microvascular and macrovascular complications. JAMA 2014;311(22): 2297–304.
- [20] Lee WJ, Hur KY, Lakadawala M, et al. Predicting success of metabolic surgery: age, body mass index, C-peptide, and duration score. Surg Obes Relat Dis 2013;9(3):379–84.
- [21] Lee WJ, Almulaifi A, Tsou JJ, Ser KH, Lee YC, Chen SC. Laparoscopic sleeve gastrectomy for type 2 diabetes mellitus: predicting the success by ABCD score. Surg Obes Relat Dis 2015;11(5):991–6.
- [22] Still CD, Wood GC, Benotti P, et al. Preoperative prediction of type 2 diabetes remission after Roux-en-Y gastric bypass surgery: a retrospective cohort study. Lancet Diabetes Endocrinol 2014;2(1):38–45.
- [23] Aminian A, Brethauer SA, Andalib A, et al. Individualized metabolic surgery score: procedure selection based on diabetes severity. Ann Surg 2017;266(4):650–7.
- [24] Aron-Wisnewsky J, Sokolovska N, Liu Y, et al. The advanced-DiaRem score improves prediction of diabetes remission 1 year post-Roux-en-Y gastric bypass. Diabetologia 2017;60(10):1892–902.
- [25] Pucci A, Tymoszuk U, Cheung WH, et al. Type 2 diabetes remission 2 years post Roux-en-Y gastric bypass and sleeve gastrectomy: the role of the weight loss and comparison of DiaRem and DiaBetter scores. Diabet Med 2018;35(3):360–7.
- [26] Fatima F, Hjelmesæth J, Hertel JK, et al. Validation of ad-DiaRem and ABCD diabetes remission prediction scores at 1-year after Roux-en-Y gastric bypass and sleeve gastrectomy in the randomized controlled Oseberg trial. Obes Surg 2022;32(3):801–9.

- [27] Debédat J, Sokolovska N, Coupaye M, et al. Long-term relapse of type 2 diabetes after Roux-en-Y gastric bypass: prediction and clinical relevance. Diabetes Care 2018;41(10):2086–95.
- [28] Chen JC, Hsu NY, Lee WJ, Chen SC, Ser KH, Lee YC. Prediction of type 2 diabetes remission after metabolic surgery: a comparison of the individualized metabolic surgery score and the ABCD score. Surg Obes Relat Dis 2018;14(5):640–5.
- [29] Ohta M, Seki Y, Ohyama T, et al. Prediction of long-term diabetes remission after metabolic surgery in obese East Asian patients: a comparison between ABCD and IMS scores. Obes Surg 2021;31:1485–95.
- [30] Salminen P, Helmio M, Ovaska J, et al. Effect of laparoscopic sleeve gastrectomy vs laparoscopic Roux-en-Y gastric bypass on weight loss at 5 years among patients with morbid obesity: the SLEEVEPASS randomized clinical trial. JAMA 2018;319(3):241–54.
- [31] Peterli R, Wolnerhanssen BK, Peters T, et al. Effect of laparoscopic sleeve gastrectomy vs laparoscopic Roux-en-Y gastric bypass on weight loss in patients with morbid obesity: the SM-BOSS randomized clinical trial. JAMA 2018;319(3):255–65.
- [32] Buse JB, Caprio S, Cefalu WT, et al. How do we define cure of diabetes? Diabetes Care 2009;32(11):2133–5.
- [33] Hofsø D, Fatima F, Borgeraas H, et al. Gastric bypass versus sleeve gastrectomy in patients with type 2 diabetes (Oseberg): a single-centre, triple-blind, randomised controlled trial. Lancet Diabetes Endocrinol 2019;7(12):912–24.
- [34] Plaeke P, Beunis A, Ruppert M, De Man JG, De Winter BY, Hubens G. Review, performance comparison, and validation of models predicting type 2 diabetes remission after bariatric surgery in a Western European population. Obes Surg 2021;31:1549–60.
- [35] Shen SC, Wang W, Tam KW, et al. Validating risk prediction models of diabetes remission after sleeve gastrectomy. Obes Surg Jan 2019;29(1):221–9.
- [36] Dixon JB, Chuang LM, Chong K, et al. Predicting the glycemic response to gastric bypass surgery in patients with type 2 diabetes. Diabetes Care 2013;36(1):20–6.
- [37] Lee WJ, Chong K, Ser KH, et al. C-peptide predicts the remission of type 2 diabetes after bariatric surgery. Obes Surg 2012;22(2):293–8.
- [38] Park JY, Kim YJ. Prediction of diabetes remission in morbidly obese patients after Roux-en-Y gastric bypass. Obes Surg 2016;26(4):749–56.
- [39] Schauer PR, Burguera B, Ikramuddin S, et al. Effect of laparoscopic Roux-en Y gastric bypass on type 2 diabetes mellitus. Ann Surg 2003;238(4):467–84;discussion 84-5.
- [40] Panunzi S, Carlsson L, De Gaetano A, et al. Determinants of diabetes remission and glycemic control after bariatric surgery. Diabetes Care Jan 2016;39(1):166–74.
- [41] Turner R, Cull C, Holman R. United Kingdom Prospective Diabetes Study 17: a 9-year update of a randomized, controlled trial on the effect of improved metabolic control on complications in non-insulindependent diabetes mellitus. Ann Intern Med 1996;124(1 Pt 2):136–45.
- [42] Turner RC, Cull CA, Frighi V, Holman RR. Glycemic control with diet, sulfonylurea, metformin, or insulin in patients with type 2 diabetes mellitus: progressive requirement for multiple therapies (UKPDS 49). UK Prospective Diabetes Study (UKPDS) Group. JAMA 1999;281(21):2005–12.
- [43] Corcelles R, Boules M, Froylich D, et al. Total weight loss as the outcome measure of choice after Roux-en-Y gastric bypass. Obes Surg 2016;26(8):1794–8.
- [44] Panunzi S, De Gaetano A, Carnicelli A, Mingrone G. Predictors of remission of diabetes mellitus in severely obese individuals undergoing bariatric surgery: do BMI or procedure choice matter? A metaanalysis. Ann Surg 2015;261(3):459–67.