

SLEEVEPASS RCT: SLEEVE vs. byPASS 5-year results

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Swiss Society for the Study of



morbid Obesity
and metabolic disorders



LIHAVUUS-JA
METABOLIAKIRURGIAN YHDISTYS

Disclosures

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 - Government research grant foundation (EVO)
 - Turku University Research Grant

Research

Key Points

Question Is weight loss at 5 years equivalent with laparoscopic sleeve gastrectomy and laparoscopic Roux-en-Y gastric bypass in patients with morbid obesity?

JAMA | **Original Investigation**

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

Paulina Salminen, MD, PhD; Mika Helmiö, MD; Jari Ovaska, MD, PhD; Anne Juuti, MD, PhD; Marja Leivonen, MD, PhD; Pipsa Peromaa-Haavisto, MD, PhD; Saija Hurme, MSc; Minna Soinio, MD, PhD; Pirjo Nuutila, MD, PhD; Mikael Victorzon, MD, PhD

Patient enrollment 3/2008 – 6/2010

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Yves Borbély, MD; Bernd Schultes, MD; Christoph Beglinger, MD; Jürgen Drewe, MD, MSc; Marc Schiesser, MD;
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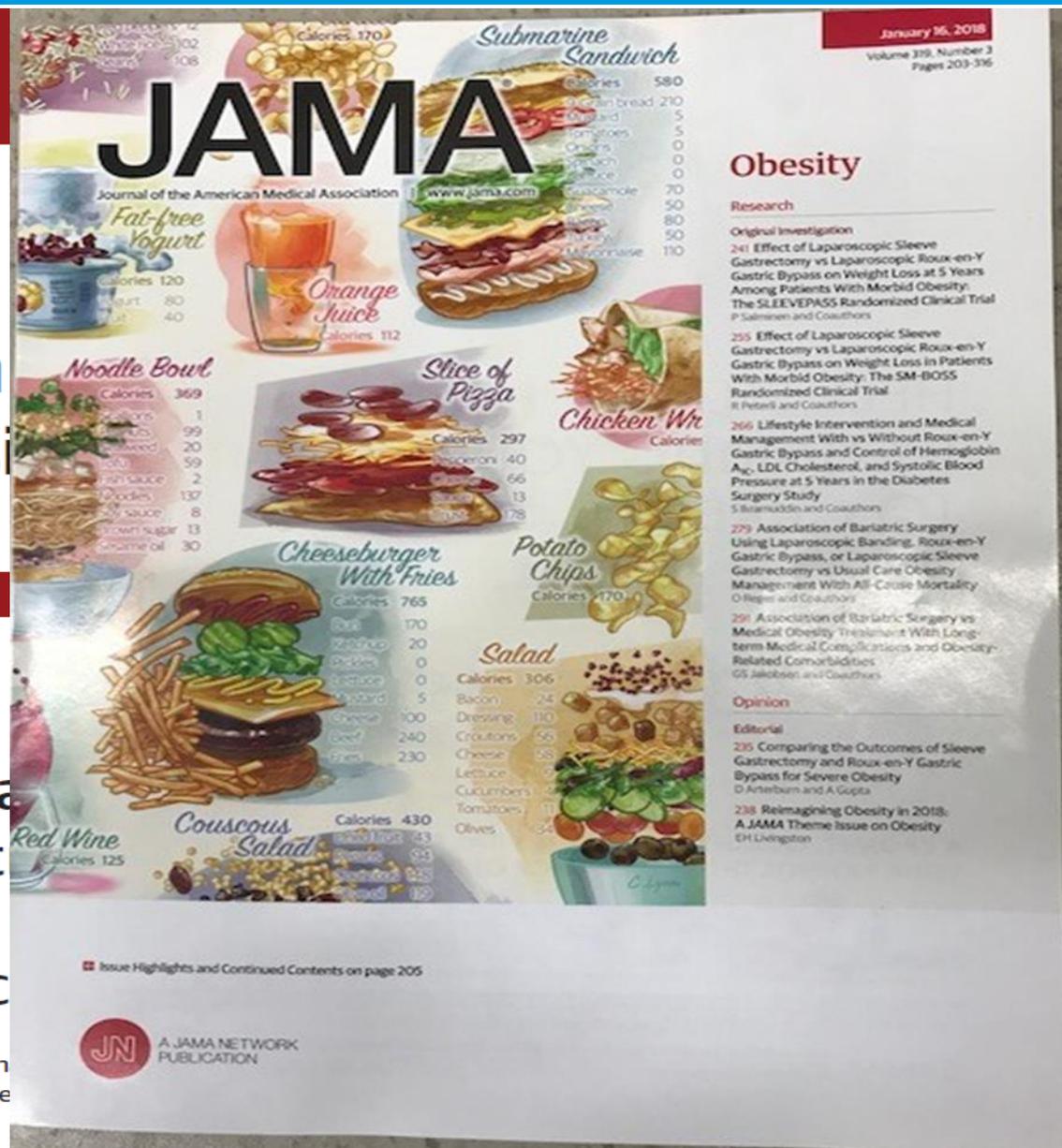
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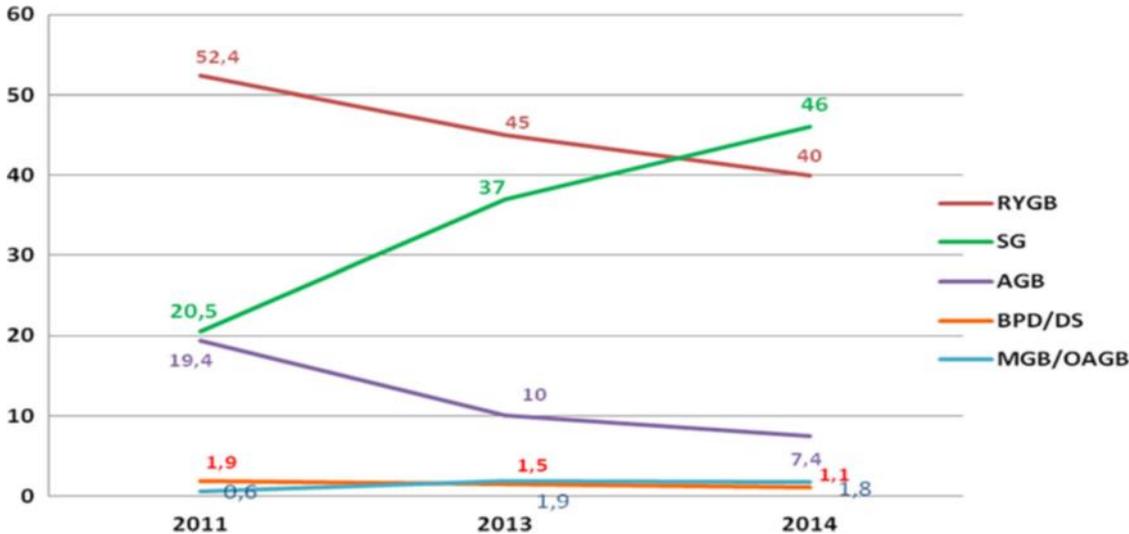
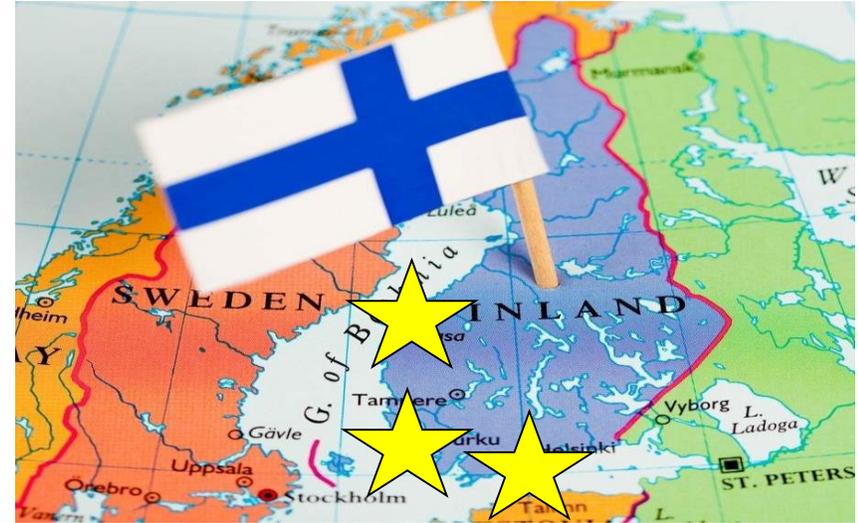


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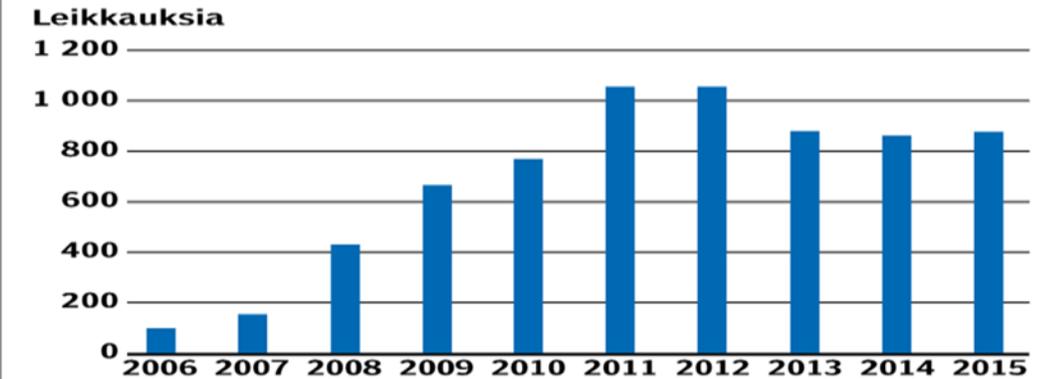
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- Multicenter RCT: Turku, Vaasa and Helsinki



Lihavuusleikkausten määrät Suomessa 2006–2015.

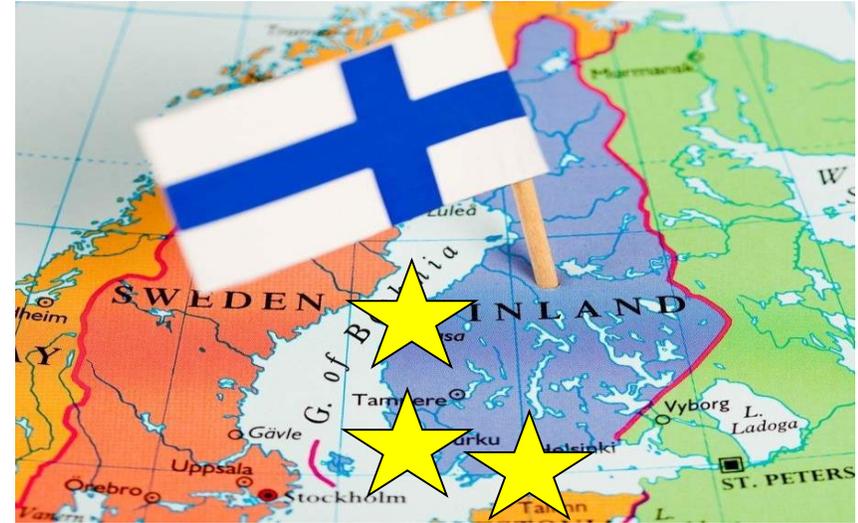


Lähde: Suomen lihavuus- ja metabolisen kirurgian yhdistys

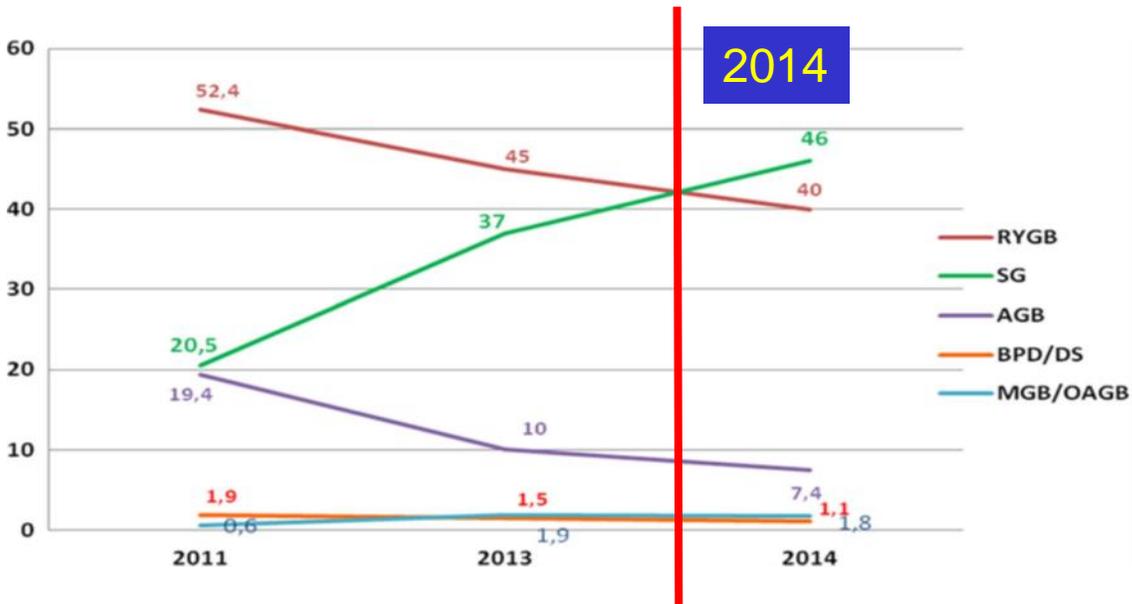
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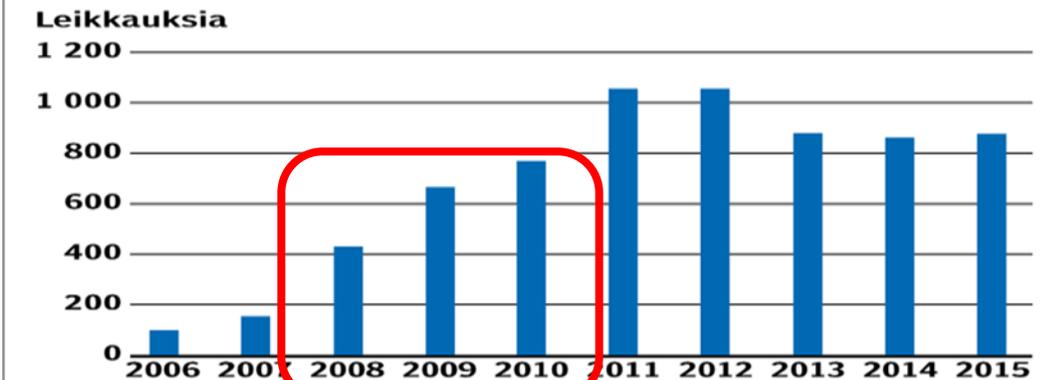
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SLEEVEPASS patient enrollment 2008-2010



Lihavuusleikkausten määrät Suomessa 2006–2015.



Lähde: Suomen lihavuus- ja metabolisen kirurgian yhdistys

SLEEVEPASS RCT: Primary endpoint

- Primary endpoint: weight loss = %excess weight loss, %EWL
 - Equivalence trial: prespecified equivalence margins for minimal clinically important weight loss difference LSG vs. LRYGB from -9% to 9 % in %EWL
 - At the time of study initiation, no available long-term data on LSG
 - Originally at 1-year follow-up ➤ revised during the study to 5 years (no effect on the sample size calculation)

%EWL: $(\text{initial weight} - \text{follow-up weight}) / (\text{initial weight} - \text{ideal weight for BMI 25}) \times 100\%$



ASMBS, SOARD, outcome reporting standards

Standardized outcomes reporting in metabolic and bariatric surgery

Stacy A. Brethauer, MD^{a,*}, Julie Kim, MD^b, Maher el Chaar, MD^c, Pavlos Papasavas, MD^d,
Dan Eisenberg, MD^e, Ann Rogers, MD^f, Naveen Ballem, MD^g, Mark Kligman, MD^h,
Shanu Kothari, MDⁱ for the ASMBS Clinical Issues Committee

1. Mean initial BMI of the cohort
2. Change in BMI (Δ BMI):
$$\Delta\text{BMI} = (\text{Initial BMI}) - (\text{Postop BMI})$$
3. Percent of total weight loss (%TWL):
$$\% \text{TWL} = [(\text{Initial Weight}) - (\text{Postop Weight})] / [(\text{Initial Weight})] \times 100$$
4. Percent excess BMI loss (%EBMIL):
$$\% \text{EBMIL} = [\Delta\text{BMI} / (\text{Initial BMI} - 25)] \times 100$$

and/or

Percent excess weight loss (%EWL)
$$\% \text{EWL} = [(\text{Initial Weight}) - (\text{Postop Weight})] / [(\text{Initial Weight}) - (\text{Ideal Weight})]$$

(in which *ideal weight* is defined by the weight corresponding to a BMI of 25 kg/m²; see Appendix A)

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- Secondary endpoints

- Resolution of comorbidities
 - T2DM
 - Dyslipidemia
 - Hypertension
- Improvement of quality of life (QOL)
- All adverse events (overall morbidity)
- Mortality (intervention related mortality 0%)

SM-BOSS (Peterli et al. JAMA 2018)

- n = 217, 1/2007 – 11/2011
- T2DM: sleeve 24 %, bypass 26 %

SLEEVEPASS (Salminen et al. JAMA 2018)

- n = 240, 3/2008 – 6/2010
- T2DM: sleeve 43 %, bypass 41 %

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- Secondary endpoints

Patients with T2DM

- Resolution of comorbidities
 - T2DM
 - Dyslipidemia
 - Hypertension
- Improvement of quality of life (QOL)
- All adverse events (overall morbidity)
- Mortality (intervention related mortality 0%)

2. SM-BOSS (Peterli et al. JAMA 2018)

- n = 217, 1/2007 – 11/2011
- T2DM: sleeve 24 %, bypass 26 %

25 %

3. SLEEVEPASS (Salminen et al. JAMA 2018)

- n = 240, 3/2008 – 6/2010
- T2DM: sleeve 43 %, bypass 41 %

42 %

Operation techniques

LSG

- 33 or 35 Fr bougie
- Resection initiated 4-6 cm proximal to the pylorus
- **Difficult / severe GERD = exclusion criterion (large hiatal hernia)**
 - Upper gastrointestinal endoscopy
 - No pH-monitoring / manometry / symptom questionnaire

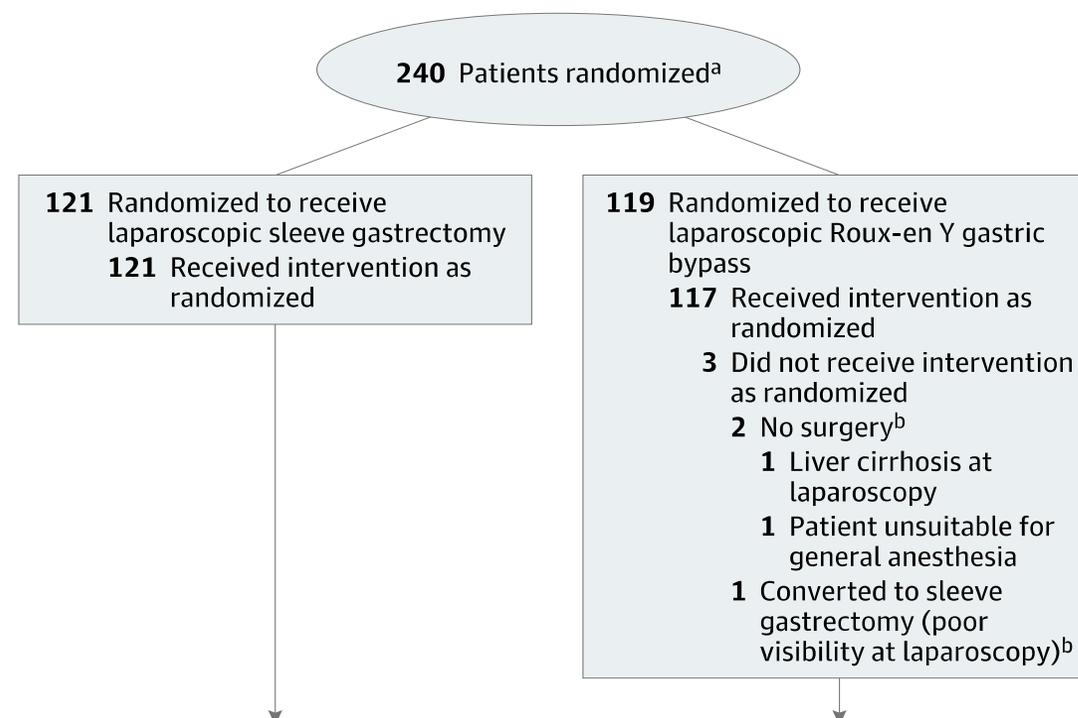
LRYGB

- 150 cm antecolic alimentary limb
- 50 -80 cm biliopancreatic limb
- Circular or linear gastrojejunostomy (surgeon preference)
- **No closure of mesenteric defects at the time of the trial**

SLEEVEPASS: A randomized prospective multicenter study comparing laparoscopic sleeve gastrectomy and gastric bypass in the treatment of morbid obesity: preliminary results

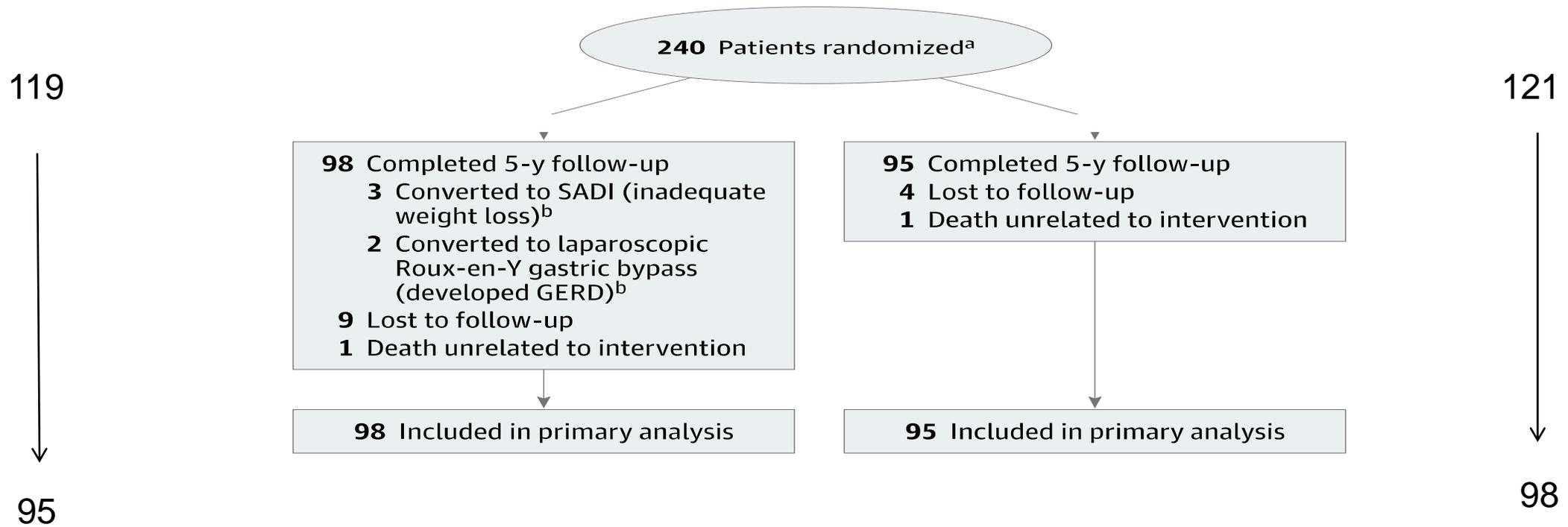
Mika Helmiö · Mikael Victorzon · Jari Ovaska ·
Marja Leivonen · Anne Juuti · Nabil Jaser · Pipsa Peromaa ·
Pekka Tolonen · Saija Hurme · Paulina Salminen

Characteristic	Laparoscopic Sleeve Gastrectomy (n = 121)	Laparoscopic Roux-en-Y Gastric Bypass (n = 119)
Sex, No. (%)		
Women	87 (71.9)	80 (67.2)
Men	34 (28.1)	39 (32.8)
Age, mean (SD), y	48.5 (9.6)	48.4 (9.3)
Weight, mean (SD), kg	130.1 (21.5)	134.9 (22.5)
BMI, mean (SD) ^a	45.5 (6.2)	46.4 (5.9)
Type 2 diabetes, No. (%)	52 (43.0)	49 (41.2)
Hypertension, No. (%)	83 (68.6)	87 (73.1)
Dyslipidemia, No. (%)	39 (32.2)	45 (37.8)
Moorehead-Ardelt QOL total score, mean (SD) ^b	0.10 (0.94)	0.12 (1.12)
Hospitals participating in the study, No.		
Turku	40	40
Vaasa	40	40
Helsinki	41	39



Trial flow chart at five-year follow-up

Figure 1. Flow of Participants Through the SLEEVEPASS Trial of Laparoscopic Sleeve Gastrectomy vs Laparoscopic Roux-en-Y Gastric Bypass

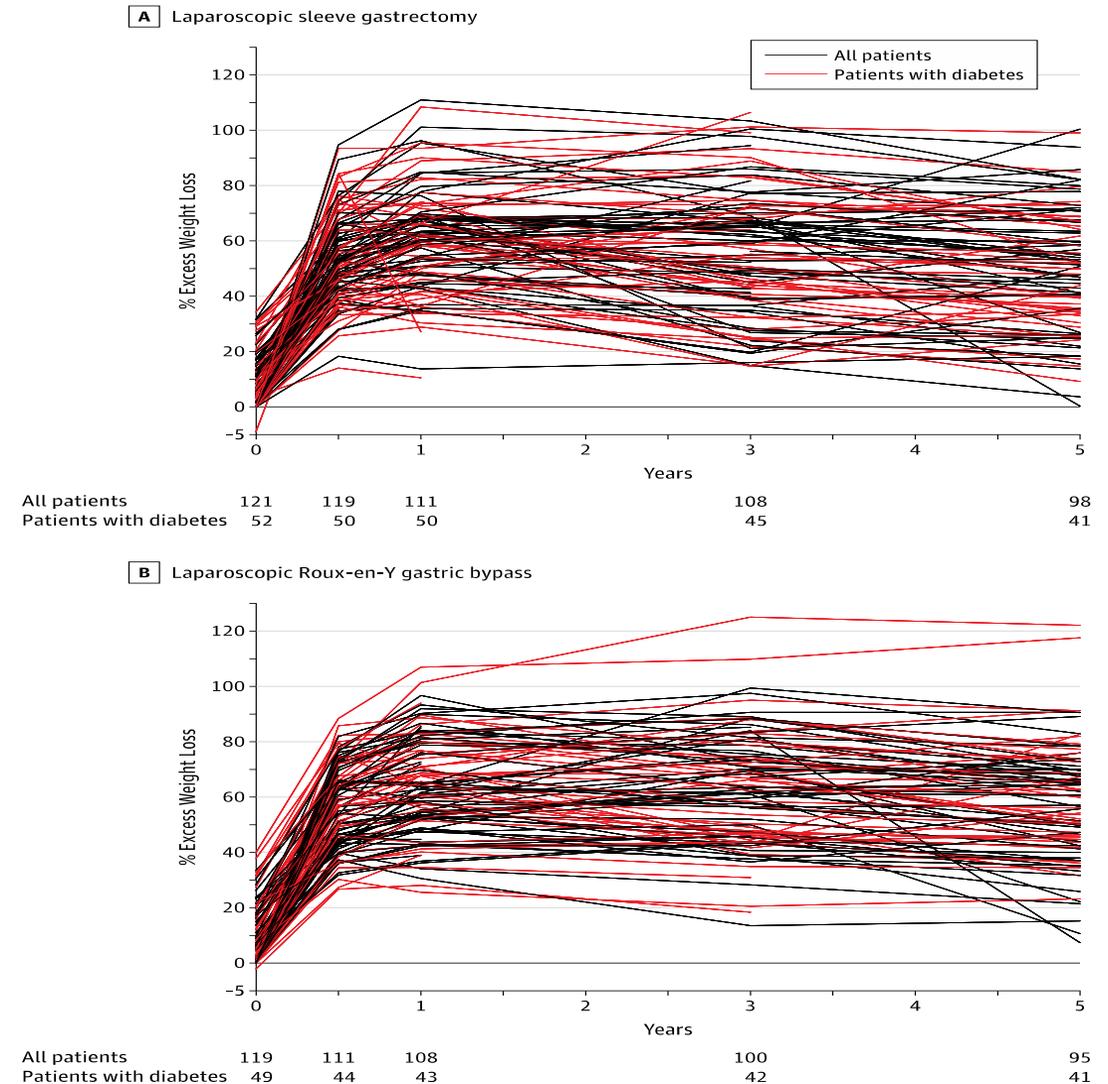


5-year follow-up rate 80.4%

%EWL at 5 years

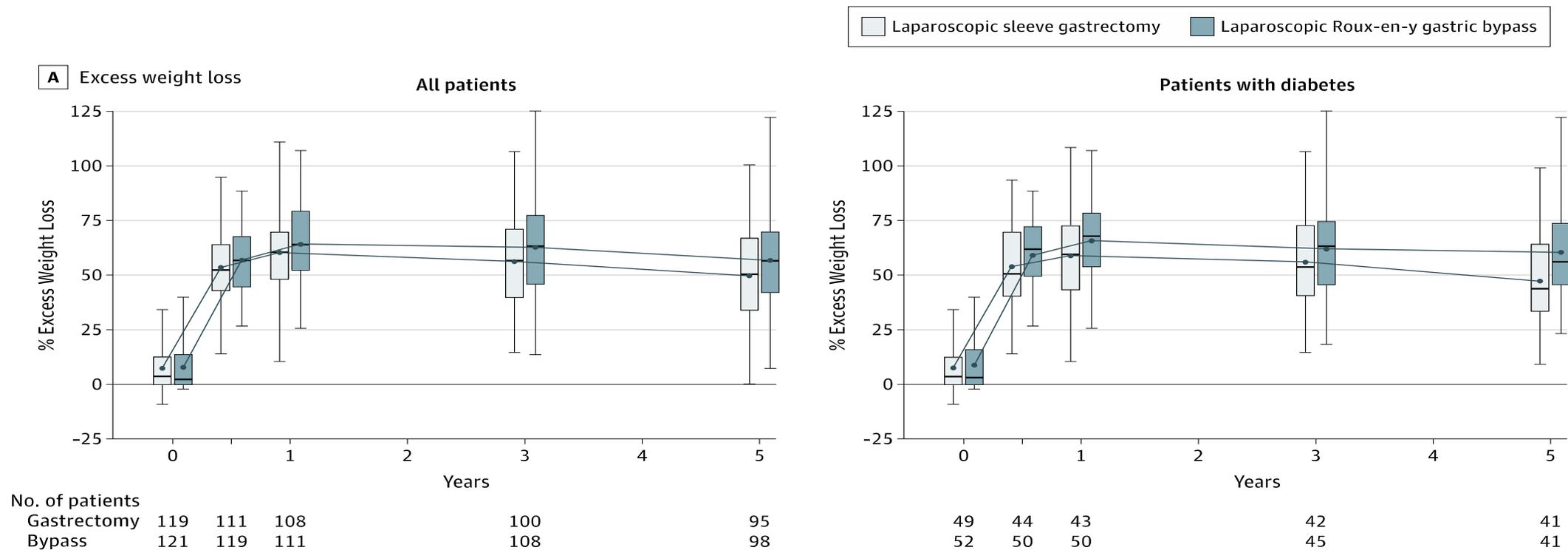
- LSG 49% (95%CI, 45%-52%)
- LRYGB 57% (95%CI, 53%-61%)
- Difference 8.2 percentage units (95%CI, 3.2%-13.2%)
- Post hoc outcomes in patients with diabetes
 - %EWL difference 11.7% (95%CI, 3.7%-19.7%)

Figure 2. Percentage Excess Weight Loss Over 5-Year Follow-up for Individual Patients After Laparoscopic Sleeve Gastrectomy (n = 121) and Laparoscopic Roux-en-Y Gastric Bypass (n = 119)



%EWL at 5 years: 0, 1, 3, and 5 years

Figure 3. Percentage Excess Weight Loss and Body Mass Index for the Whole Study Group and by Procedure Over 5-Year Follow-up



Weight loss difference (kg): All patients median 6.6 kg, patients with T2DM median 9.7 kg

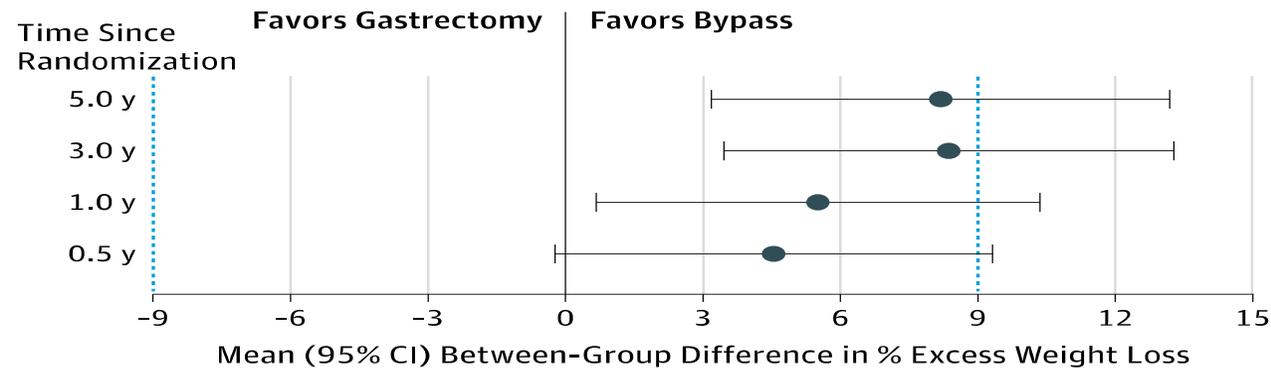
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Figure 4. Differences in Estimates of Mean Percentage Excess Weight Loss Between Laparoscopic Sleeve Gastrectomy and Laparoscopic Roux-en-Y Gastric Bypass Over 5-Year Follow-up



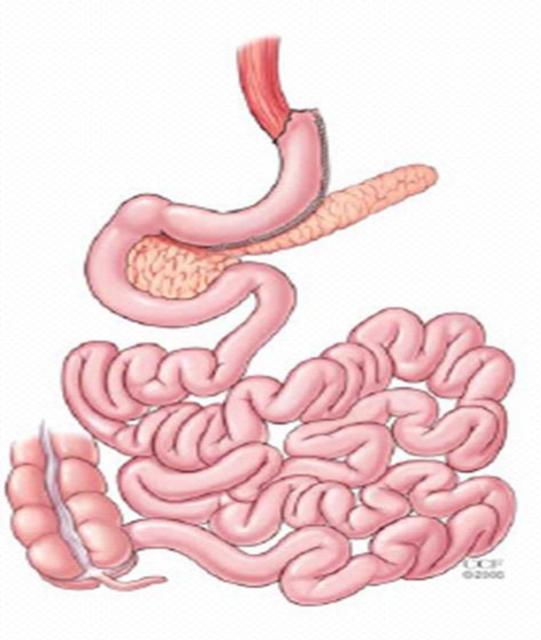
Prespecified equivalence margins (blue dotted lines) for the clinical significance of weight loss differences between gastric bypass and sleeve gastrectomy were -9% to +9% excess weight loss. Error bars indicate 95% confidence intervals.

Weight loss after LSG vs. LRYGB did not meet criteria for equivalence, no statistically significant difference based on the prespecified equivalence margins.

T2DM remission at 5 years: ADA criteria ($p>0.99$), baseline $n=101$ (42%)

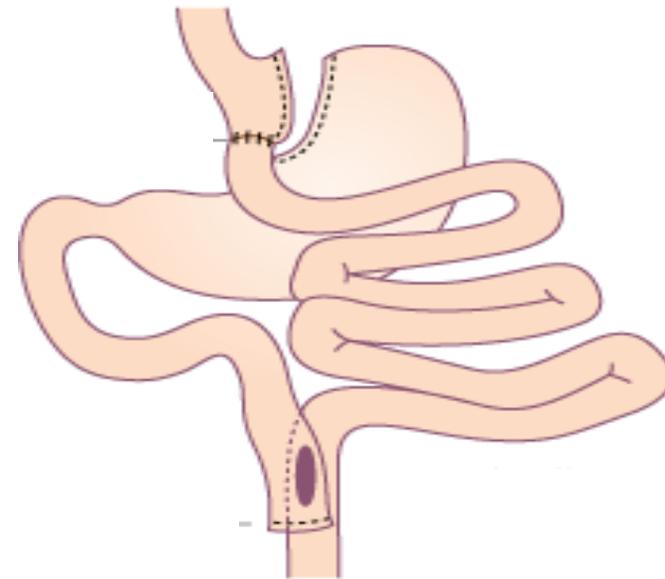
LSG

- Complete or partial remission 37%



LRYGB

- Complete or partial remission 45%



Glycemic status at 5 years

	Model-Based Mean (95% CI) in Operations	Baseline	0.5 y	1 y	3 y	5 y	P Value for Effects in ANOVA
Fasting glucose, mmol/L ^a							.03 for operation × time interaction
Sleeve gastrectomy							
No.		52	50	50	46	41	
Model-based mean (95% CI)		7.5 (6.9 to 8.1)	6.2 (5.9 to 6.5)	6.4 (6.0 to 6.7)	6.6 (6.2 to 7.0)	7.5 (6.9 to 8.2)	
Gastric bypass							
No.		49	43	43	42	40	
Model-based mean (95% CI)		7.8 (7.2 to 8.5)	6.1 (5.7 to 6.4)	5.9 (5.6 to 6.3)	6.7 (6.2 to 7.2)	6.7 (6.1 to 7.3)	
P value (corrected with step-down Bonferroni)			>.99	.30	>.99	.21	
Glycated hemoglobin, % ^a							.05 for operation × time interaction
Sleeve gastrectomy	6.6 (6.4 to 6.8)						.93 for main effect of operation
Gastric bypass	6.6 (6.4 to 6.8)						
Model-based means (95% CI) in time points		7.2 (7.0 to 7.5)	6.6 (6.2 to 6.5)	6.2 (6.1 to 6.4)	6.4 (6.2 to 6.6)	6.7 (6.5 to 6.9)	<.001 for main effect of time
Glycemic status, No./total (%)							

Glycemic status at 5 years: fasting glucose

LSG 7.5 mmol/L vs. LRYGB 6.7 mmol/L (p=0.052)

	Model-Based Mean (95% CI) in Operations	Baseline	0.5 y	1 y	3 y	5 y	P Value for Effects in ANOVA
Fasting glucose, mmol/L ^a							.03 for operation × time interaction
Sleeve gastrectomy							
No.		52	50	50	46	41	
Model-based mean (95% CI)		7.5 (6.9 to 8.1)	6.2 (5.9 to 6.5)	6.4 (6.0 to 6.7)	6.6 (6.2 to 7.0)	7.5 (6.9 to 8.2)	
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Glycemic status, No./total (%)							

Dyslipidemia resolution at 5 years (p=0.15), baseline n= 84 (35%)

- Dyslipidemia resolution = discontinuing medication
 - Resolution **LSG 47%** vs. **LRYGB 69%** (dyslipidemia baseline 35%)
 - Less medications LSG 20% vs. LRYGB 5%
 - No improvement LSG 33% vs. LRYGB 35%
- True dyslipidemia resolution = discontinuing medication + normal lipid values (LDL < 3.0 mmol/L)
 - 22/38, **LSG 20%** vs. **LRYGB 40%**

Lipid profiles at 5 years

- LDL-C: **LRYGB 2.5 mmol/L** vs. **2.7 mmol/L LSG** (p=0.02)
- Total cholesterol **LRYGB 4.6 mmol/L** vs. **4.9 mmol/L LSG** (p=0.053)

Table 4. Lipid Profiles for the Whole Study Group After Laparoscopic Sleeve Gastrectomy and Laparoscopic Roux-en-Y Gastric Bypass at Baseline, 6 Months, and 1, 3, and 5 Years

	Model-Based Mean (95% CI) in Operations	Baseline	0.5 y	1 y	3 y	5 y	P
Total cholesterol, mmol/L ^a							
Sleeve gastrectomy							
No.		106	115	110	108	97	
Model-based mean (95% CI)		4.5 (4.4 to 4.7)	4.5 (4.3 to 4.7)	4.7 (4.5 to 4.8)	5.0 (4.8 to 5.1)	4.9 (4.7 to 5.0)	
Gastric bypass							
No.		106	107	105	100	91	
Model-based mean (95% CI)		4.6 (4.4 to 4.8)	4.1 (4.0 to 4.3)	4.3 (4.1 to 4.5)	4.5 (4.4 to 4.7)	4.6 (4.5 to 4.8)	
Difference			0.4 (0.1 to 0.6)	0.4 (0.1 to 0.6)	0.4 (0.2 to 0.7)	0.2 (-0.003 to 0.5)	
P value (corrected with step-down Bonferroni)			.008	.006	<.001	.053	
LDL-C, mmol/L ^b							
Sleeve gastrectomy							
No.		101	111	109	107	95	
Model-based mean (95% CI)		2.6 (2.4 to 2.8)	2.6 (2.5 to 2.8)	2.6 (2.5 to 2.8)	2.8 (2.7 to 2.9)	2.7 (2.6 to 2.9)	
Gastric bypass							
No.		103	107	104	100	91	
Model-based mean (95% CI)		2.6 (2.4 to 2.7)	2.3 (2.2 to 2.4)	2.3 (2.2 to 2.4)	2.4 (2.3 to 2.5)	2.5 (2.3 to 2.6)	
Difference			0.3 (0.1 to 0.5)	0.3 (0.2 to 0.5)	0.4 (0.2 to 0.6)	0.2 (0.04 to 0.5)	
P value (corrected with step-down Bonferroni)			.006	.003	<.001	.02	

Hypertension resolution at 5-year follow-up, $p=0.02$ baseline $n=170$ (71%)

- Evaluation criteria:
 - No medications = resolution
 - less medications
 - no change in medications (baseline 71%)
- No objective measurements
- Resolution: **LSG 29%** vs. **LRYGB 51%**
- Less medications: LSG 35% vs. LRYGB 30%
- No improvement: LSG 35% vs. LRYGB 19%

Overall morbidity at 5-year follow-up (30 days to 5 years)

Overall morbidity

- **LSG 19%** vs. **LRYGB 26%** (p=0.19)
- Minor complication rate = Clavien-Dindo I-IIIa (p=0.96)
 - LSG 10.7% vs. LRYGB 10.9%
- Major complication rate = Clavien-Dindo IIIb (p=0.10)
 - LSG 8.3% vs. LRYGB 15.1%

Reoperations

- = Clavien-Dindo IIIb
- **LSG n= 10**
 - GERD n= 7
 - Incisional hernia n= 3
- **LRYGB n= 18**
 - Suspected internal herniation n= 17
 - Incisional hernia n= 1

Overall early (<30 d) and late (>30 d) morbidity

Complication Category and Type	Sleeve Gastrectomy (n = 121)	Gastric Bypass (n = 119)	P Value
Minor Early (<30 d) Complications, No. (%)			
Bleeding	3 (2.5)	2 (1.7)	
Intra-abdominal infection/infection of unknown origin	2 (1.7)	8 (6.8)	
Pneumonia	1 (0.8)	6 (5.1)	
Superficial wound infection	2 (1.7)	3 (2.6)	
Troacar site pain	1 (0.8)		
Dehydration		1 (0.9)	
Total	9 (7.4)	20 (17.1)	.02
Major Early (<30 d) Complications, No. (%)			
Bleeding	3 (2.5)	7 (6.0)	
Intra-abdominal infection/infection of unknown origin	1 (0.8)	3 (2.6)	
Pneumonia	1 (0.8)		
Bowel perforation	1 (0.8)		
Torsion of the enteroanastomosis		1 (0.9)	
Outlet obstruction	1 (0.8)		
Total	7 (5.8)	11 (9.4)	.29
Minor Late (>30 d) Complications, No. (%)			
Vomiting/dehydration		3 (2.5)	
Gastroesophageal reflux	11 (9.1)		
Ulcer/stricture at gastrojejunal anastomosis	2 (1.7)	6 (5.0)	
Dumping		3 (2.5)	
Nonspecific abdominal pain		1 (0.8)	
Total	13 (10.7)	13 (10.9)	.96
Major Late (>30 d) Complications, No. (%)			
Gastroesophageal reflux	7 (5.8)		
Internal herniation		17 (14.3)	
Incisional hernia	3 (2.5)	1 (0.8)	
Total	10 (8.3)	18 (15.1)	.10

Vitamin deficiencies at 5 years, p = ns

- Median micronutrient levels regardless of possible vitamin supplementation
- Vitamin D: **LSG** 83 nmol/L vs. **LR YGB** 77 nmol/L (p=0.24)
- B₁₂ vitamin: **LSG** 409 pmol/L vs. **LR YGB** 357 pmol/L (p=0.07)
- Albumin: **LSG** 37 g/L vs. **LR YGB** 38 g/L (p=0.28)
- Folate: **LSG** 743 nmol/L vs. **LR YGB** 801 nmol/L (p=0.78)

In conclusion: SLEEVEPASS 5-year follow-up

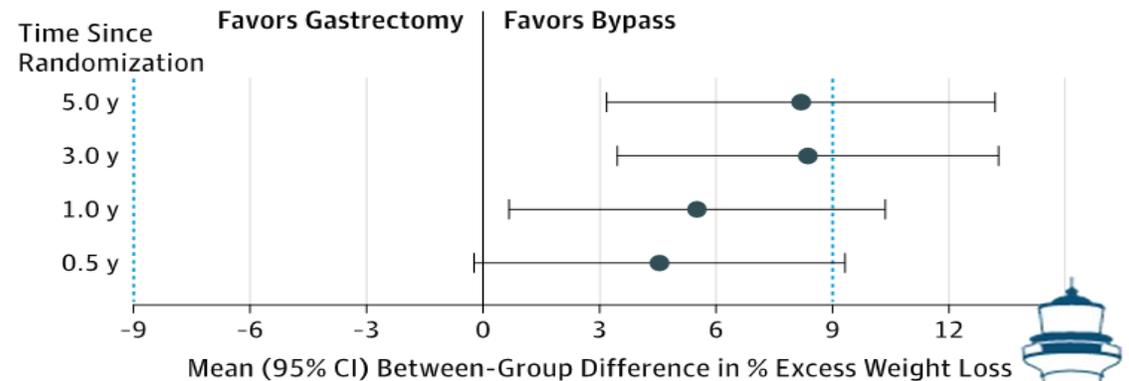
CONCLUSIONS AND RELEVANCE Among patients with morbid obesity, use of laparoscopic sleeve gastrectomy compared with use of laparoscopic Roux-en-Y gastric bypass did not meet criteria for equivalence in terms of percentage excess weight loss at 5 years. Although gastric bypass compared with sleeve gastrectomy was associated with greater percentage excess weight loss at 5 years, the difference was not statistically significant, based on the prespecified equivalence margins.

- Weight loss:
 - No statistically significant difference in %EWL, but greater %EWL after LRYGB
- T2DM total / partial remission: no difference
- Dyslipidemia: no difference in remission, better LDL values after LRYGB
- Hypertension resolution: LRYGB? (definition?)
- No differences in micronutrient deficiencies
- LSG: GERD / LRYGB: closure of the defects

How to choose the optimal bariatric procedure?

- Patient related factors
- Obesity associated comorbidities
 - Duration?
- GERD?
- SM-BOSS + SLEEVEPASS
 - 217 + 240 = 457

Figure 4. Differences in Estimates of Mean Percentage Excess Weight Loss Between Laparoscopic Sleeve Gastrectomy and Laparoscopic Roux-en-Y Gastric Bypass Over 5-Year Follow-up



Prespecified equivalence margins (blue dotted lines) for the clinical significance of weight loss differences between gastric bypass and sleeve gastrectomy were -9% to +9% excess weight loss. Error bars indicate 95% confidence interval.



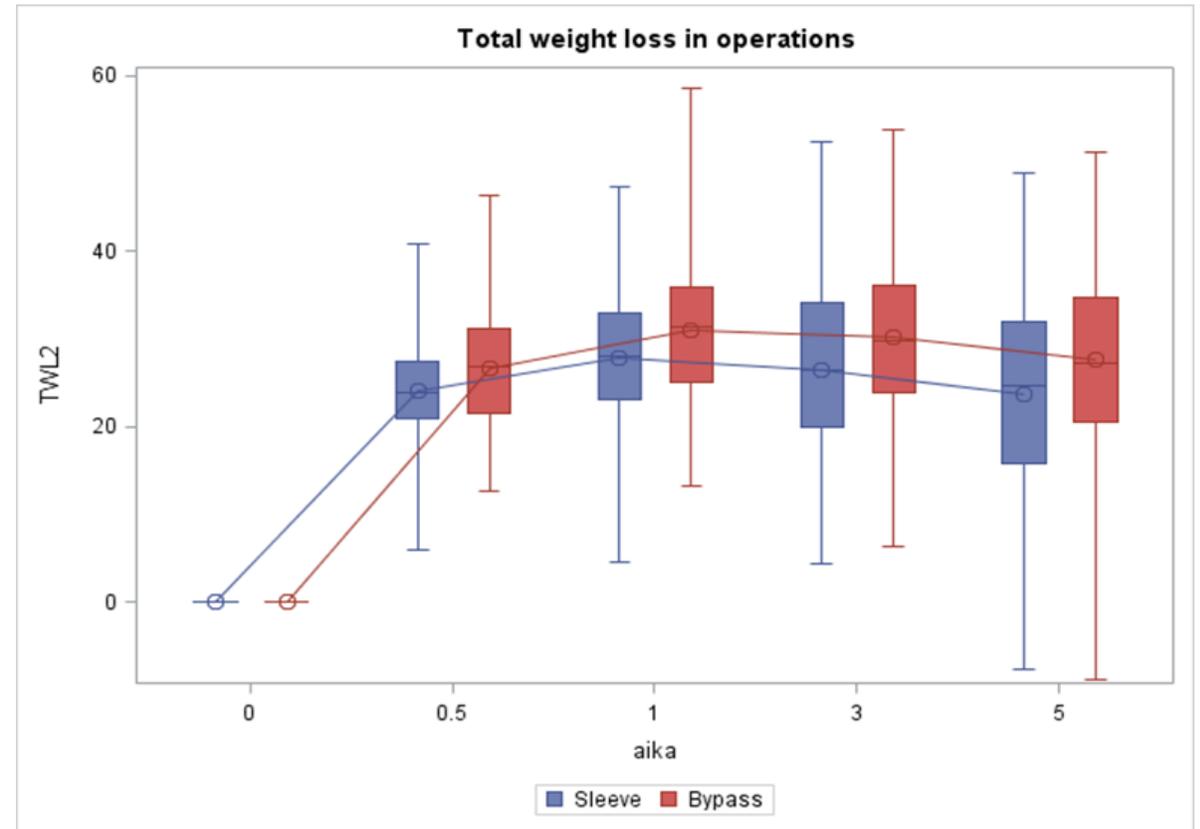
BEST

BYPASS EQUIPOISE SLEEVE TRIAL



SLEEVEPASS + SM-BOSS preliminary analyses

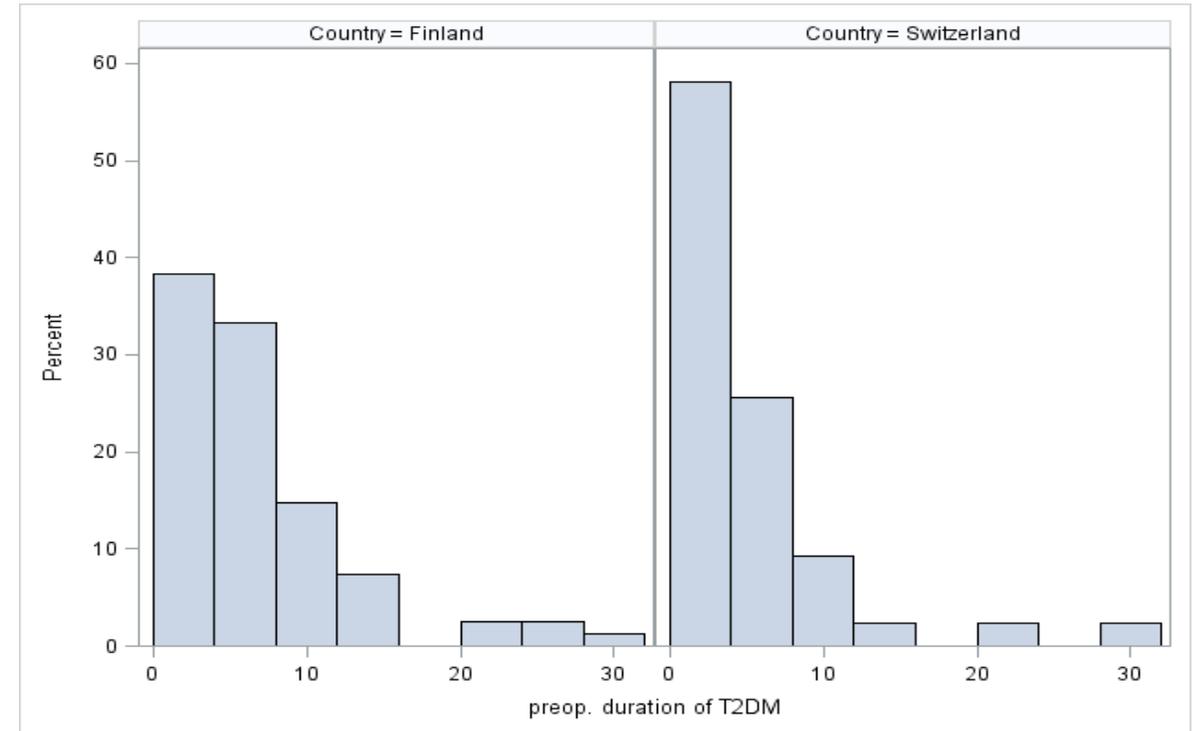
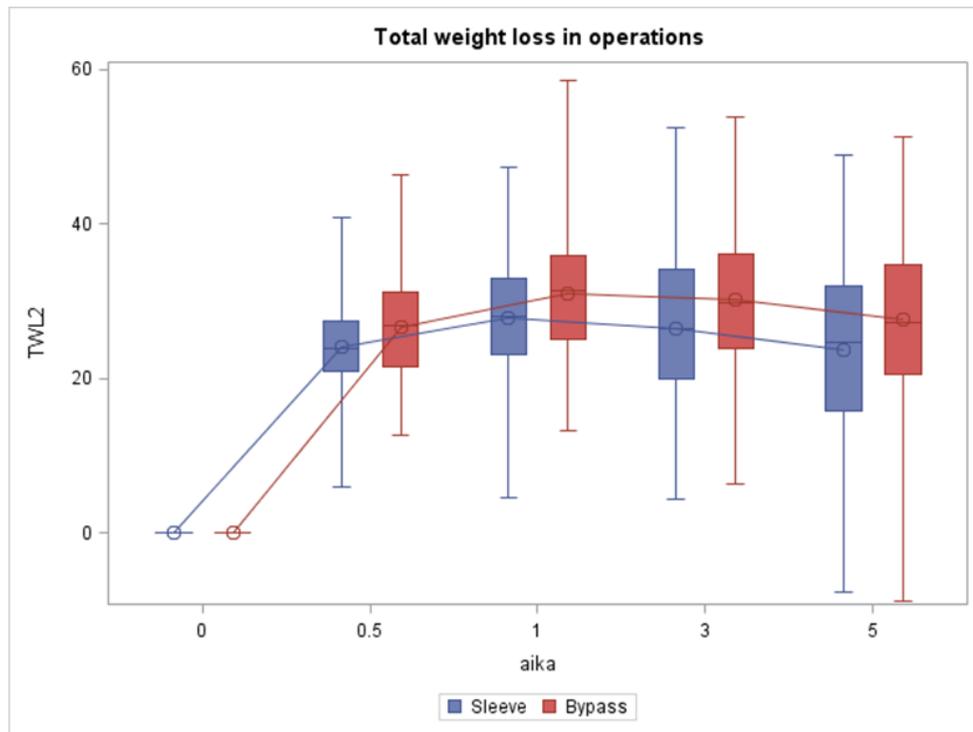
- %TWL is superior in LRYGB (p<0.001)
 - Mean %TWL in LSG 25.4%
 - Mean %TWL in LRYGB 28.7%



Unpublished data

SLEEVEPASS + SM-BOSS preliminary analyses

- %TWL is superior in LRYGB ($p < 0.001$)
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Unpublished data

SLEEVEPASS Study Group – *Thank you!*



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