



Bypass Equipoise Sleeve trial *a Swedish-Norwegian RCT*

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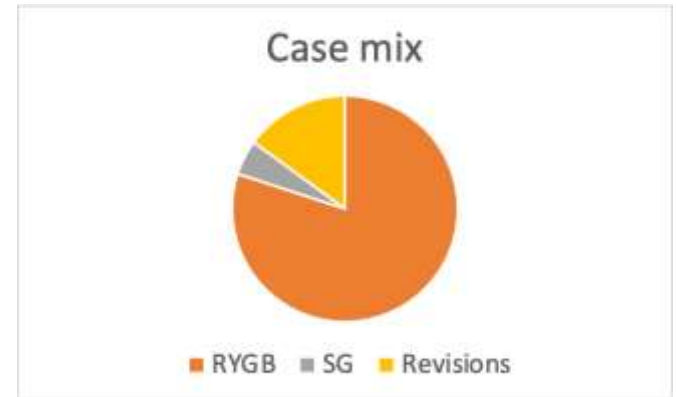
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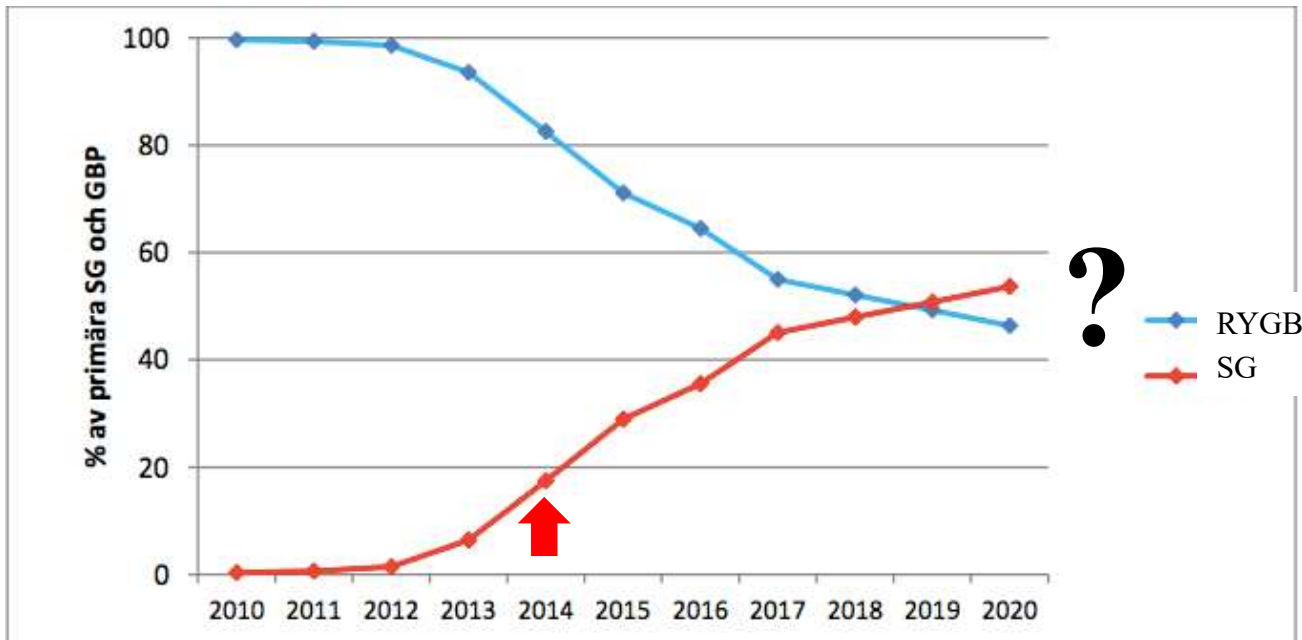
Disclosures

Johnson & Johnson- *Advisory board and Educational activities*
NovoNordisk- *Advisory board and Educational activities*

Reimbursement to my institution



Primary bariatric surgery in Sweden

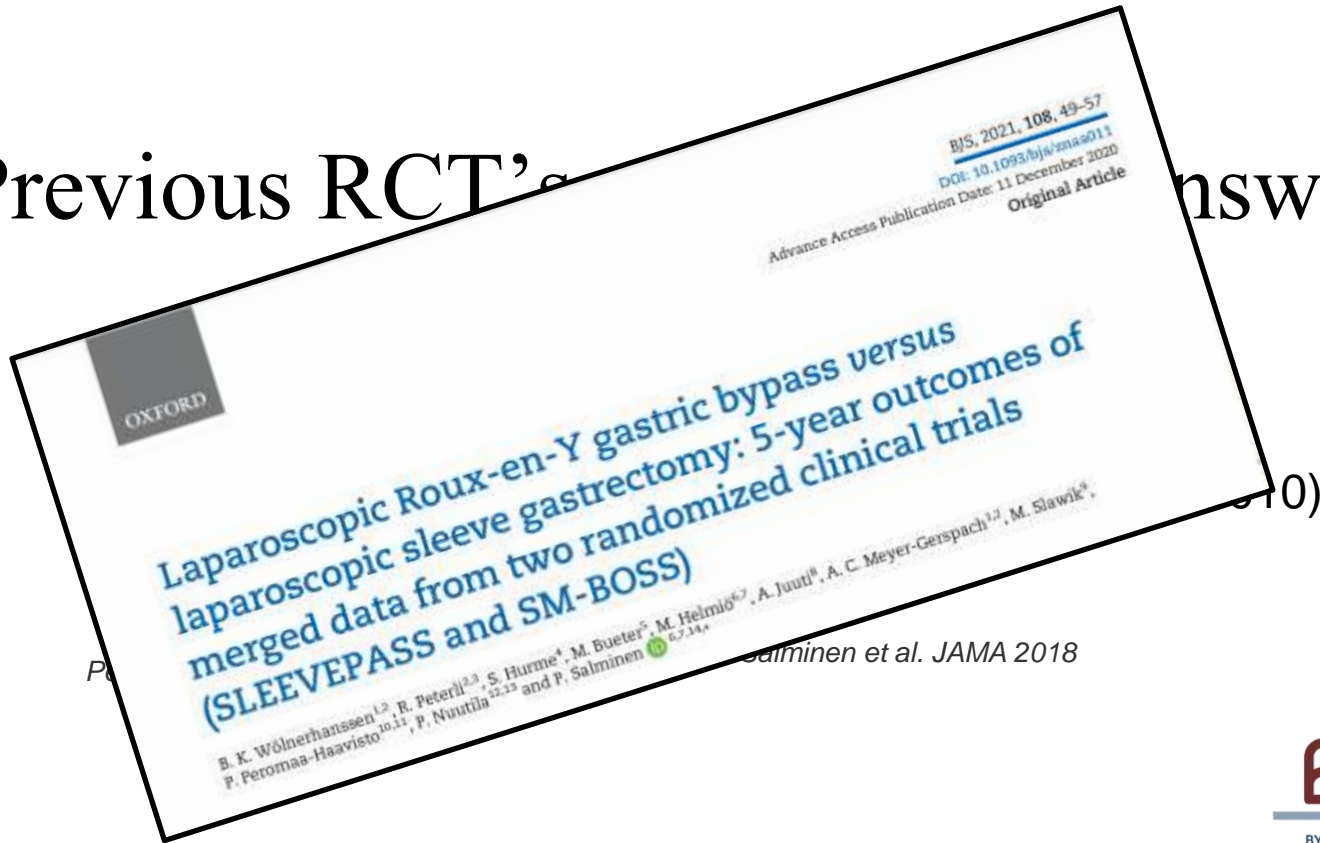


“ - The patient requests the x technique!”

Our information (preference) is usually the basis for the patients preference..

Previous RCT's

Answer



Inclusion criteria:

- >18 years of age
- BMI 35-50 kg/m²
- Suitable for both sleeve and gastric bypass

Exclusion criteria:

- Previous bariatric or anti-reflux surgery.
- Moderate-severe GERD or a known hiatal hernia >4 cm
- Inflammatory bowel disease



BEST – hypothesis

Combined primary endpoint at **5 years**:

- SG is **non-inferior** as compared to RYGB for weight-loss if <5% difference
- **Superiority** for SG if >35% less substantial adverse events



Substantial adverse event (over 5 years)

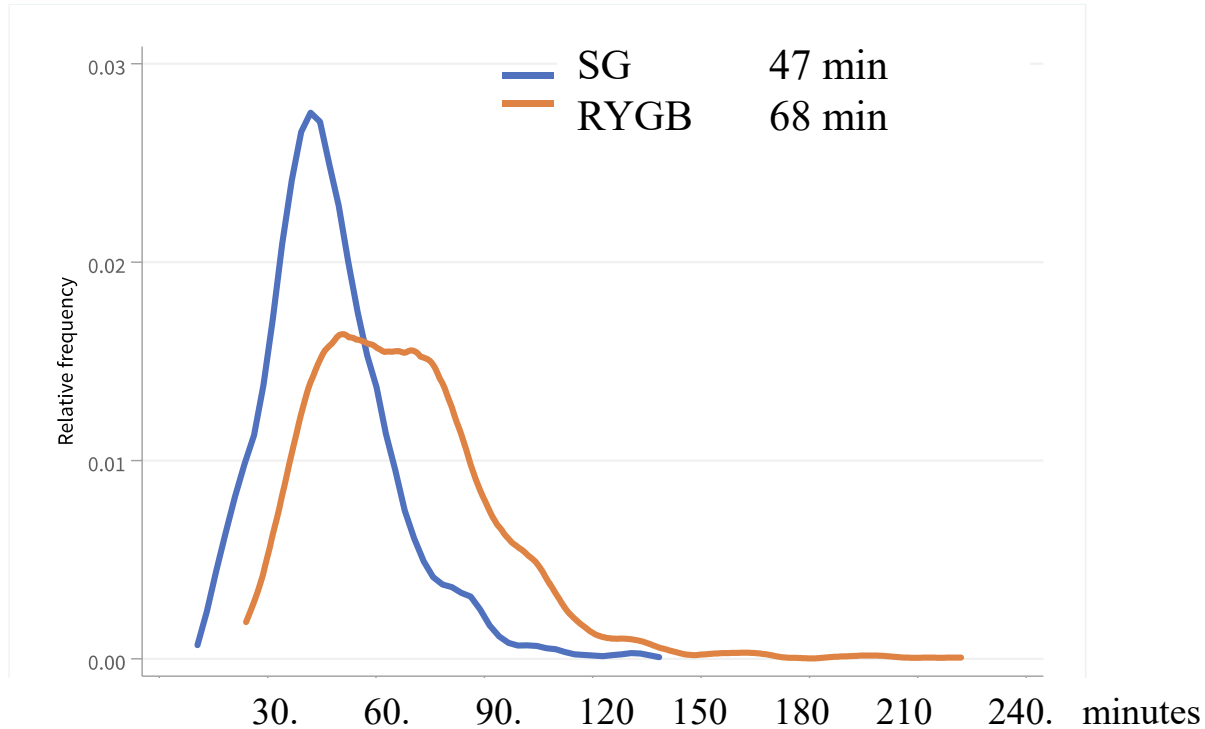
- Intervention under general anesthesia (Clavien-Dindo 3B or higher)
- Admission to an intensive care unit
- Revisional surgery- conversion or reversal
- In hospital care for complications related to the surgery
- Need of enteral or parenteral supplemental nutrition
- Chronic abdominal pain (>6 months)
- Frequent and severe food-related problems affecting everyday life
- Severe hypoglycemia
- Severe gastro-esophageal reflux or Barrett's esophagus
- Clinically relevant, symptomatic vitamin and/or mineral deficiencies
- Severe anemia

**Either
0 or 1**

	Sleeve gastrectomy	Roux-en-Y gastric bypass
Number of patients	878	858
Women	660 (75.2)	622 (72.5)
Age, years	42.9 (11.3)	43.0 (11.0)
Weight, kg	117 (18)	118 (18)
Height, cm	169 (9)	170 (9)
BMI, kg/m ²	40.8 (3.7)	40.9 (3.8)
Waist circumference, cm ^b	123 (13)	125 (13)
Diabetes	106 (12.1)	118 (13.8)
Dyslipidemia	116 (13.2)	111 (12.9)
Hypertension	251 (28.6)	259 (30.2)
Sleep apnea	124 (14.1)	118 (13.8)
Dyspepsia	36 (4.1)	42 (4.9)
Depression	124 (14.0)	107 (12.5)
Prior DVT or PE	27 (3.1)	19 (2.2)
Smoking ^a	74 (8.5)	95 (11.1)

Baseline

Operating time



Adverse Events – 30 days

Any Adverse Event

SG: 40/878 (4.6%) vs. RYGB: 54/857 (6.3%) p=0.11

OR 0.71 (95% CI 0.47–1.08).

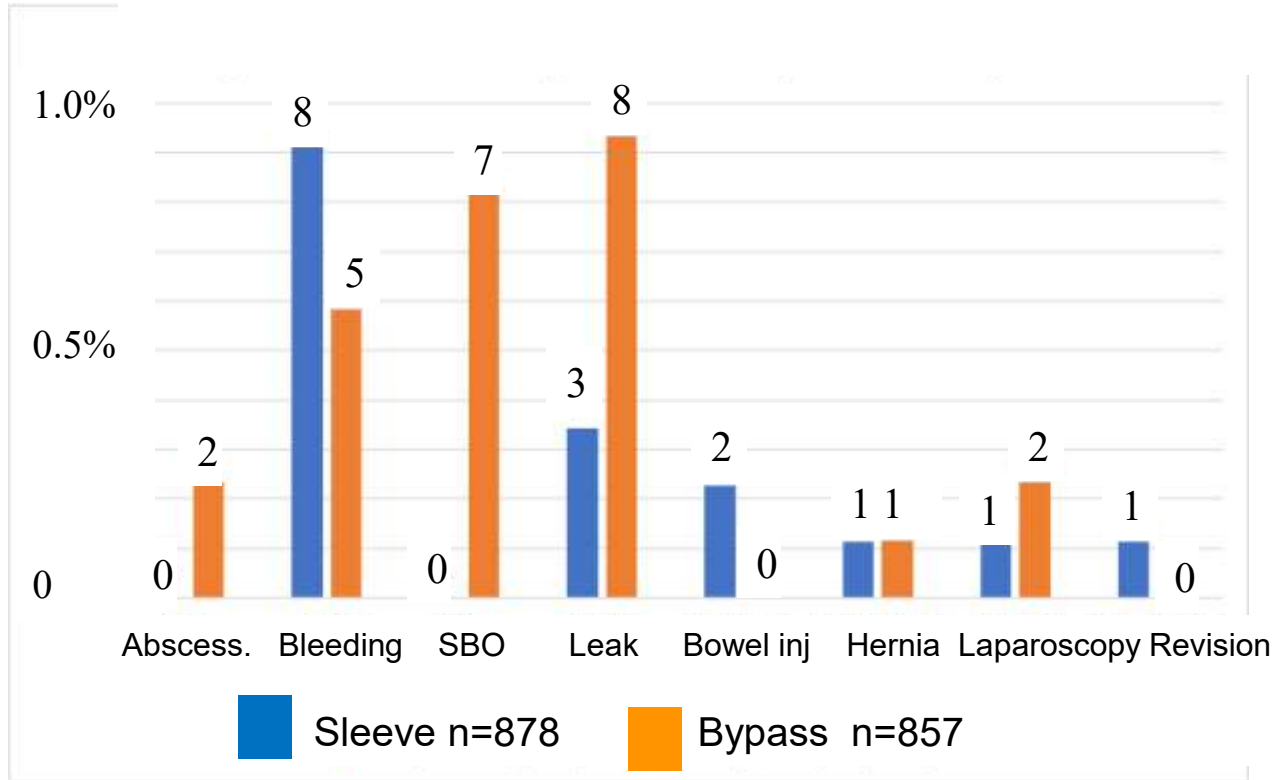
Serious Adverse Events

SG: 15/878 (1.7%) vs. RYGB: 23/857 (2.7%) p=0.19

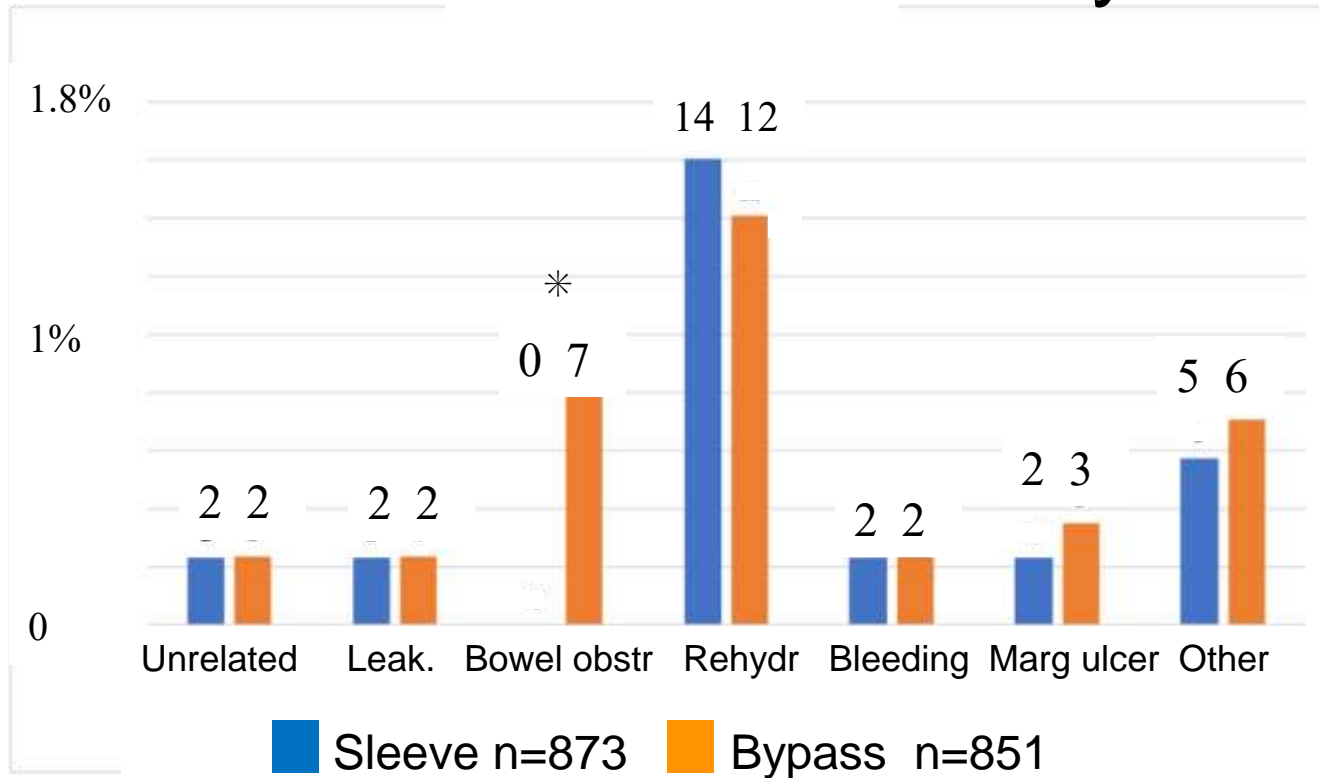
OR 0.63 (95% CI 0.33–1.22).

No mortality, 90d

Reoperations day 0-30 postop



Reasons for readmission day 0-30



Conclusion

- Sleeve and RYGB can both be performed safely, and with a comparable perioperative risk.
- The pattern of complications may differ



Preliminary data 2 years

Weight loss- *Preliminary data*

Preop			2 y					
	Weight	BMI	Weight	Weight loss	BMI	BMI reduction	TWL (%)	EBMIL >50 %
RYGB	118,0	40,9	80,1	37,7	27,8	-13,1	32,0	93.9%
<i>n</i>	814	814	628	628	628	628	<i>n</i> =628	
SG	116,8	40,8	85,7	31,4	29,9	-11,0	26,8	76.9%
<i>n</i>	833	833	637	637	637	637	<i>n</i> =637	

Revisional surgery- *Preliminary data*

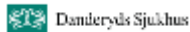
- SG n=16 (1.8%) Conversion to RYGB
- RYGB n=6 (0.7%) Revision 3, Reversal 3

Surgical philosophy..

- What is the gold standard?
- What is the mechanisms of action?
- Define: 1. Effect 2. Side effect
- Change to a new technique or improve the standard?

A big thank to BEST collaborators!

Trial Steering Committee: Anders Thorell, Johan Ottosson, Johanna Österberg, Ellen Andersson, Erik Näslund, Martin Neovius, Suzanne Hedberg, Jarl Torgerson, Erik Stenberg, Anna Laurenus, Marius Svanevik, Jens Kristoffer Hertel, Markku Peltonen, Torsten Olbers



- Ersta
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- GB Obesitas
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