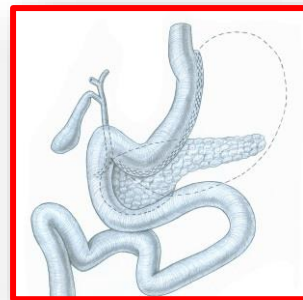
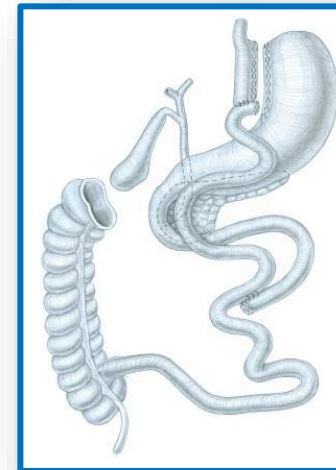


Outcomes Beyond 10 Years of Laparoscopic Roux-en-Y Gastric Bypass vs. Laparoscopic Sleeve Gastrectomy for Obesity: Weight Loss, Comorbidities, and Reoperations of the **SM-BOSS Trial**

Marko Kraljević, Julian Süsstrunk, Marc Slawik, Thomas Peters, Marco Bueter, Daniel Gero, Bernd Schultes, Bettina Wölnerhanssen, Romano Schneider, Ralph Peterli



vs



Prof. Ralph Peterli

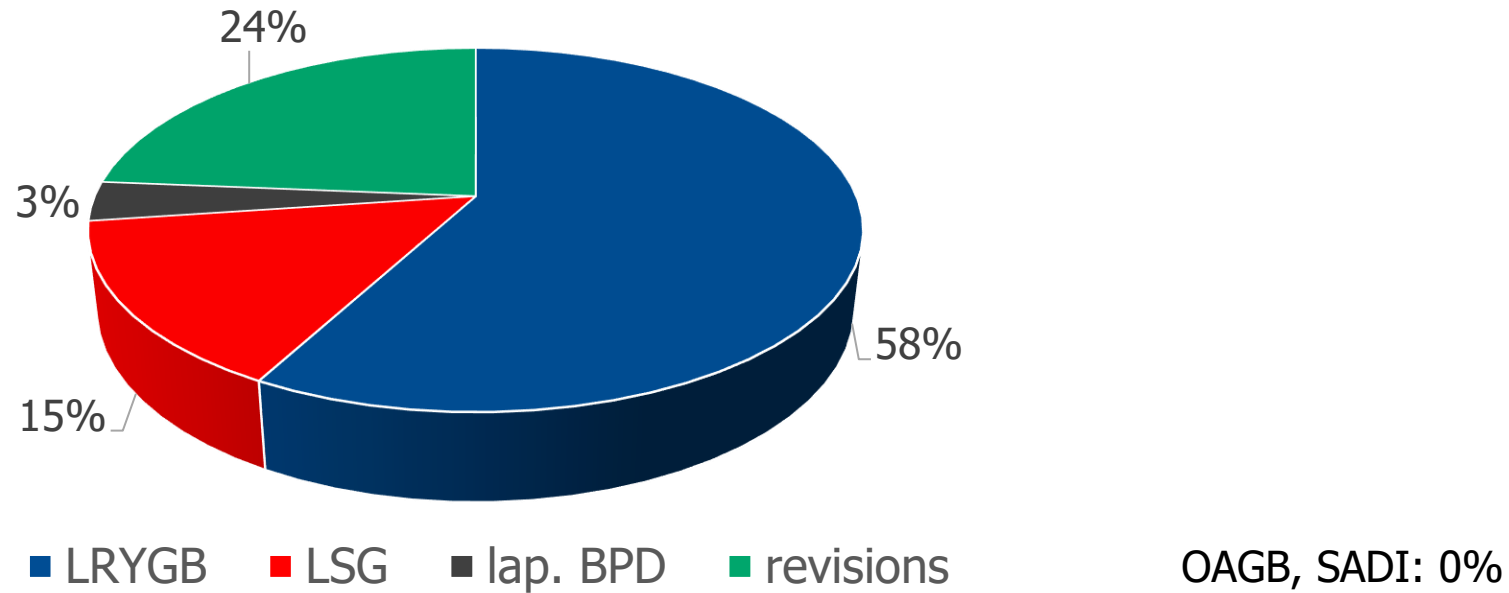
Senior Consultant Visceral Surgery and Head of Metabolic-Bariatric Surgery

Clarunis: University Digestive Health Care Center, St. Clara Hospital and University Hospital Basel, Switzerland



Disclosure

- Research grants: Swiss National Science Foundation, J&J, Hirzbrunnen Foundation
NovoNordisk, UKBB, Novartis
- Lecture/consulting fees: Ethicon Endosurgery, Viatris, Falk Foundation, NovoNordisk, Lilly
- Case mix disclosure



SM-BOSS: Swiss Multicentre Bypass Or Sleeve Study

Methods

- Multicentre:

stClaraspital
In besten Händen.



**UniversityHospital
Zurich**

INSELSPITAL
UNIVERSITÄTSSPITAL BERN
HOPITAL UNIVERSITAIRE DE BERNE
BERN UNIVERSITY HOSPITAL

Kantonsspital
St.Gallen **H**
eSwiss
MEDICAL & SURGICAL CENTER **eS**

- Endpoints:

- Primary: Weight loss (excess BMI loss) at 5 y, **comparative** trial
- Secondary: Reduction of co-morbidity

QoL

Safety

(Peterli, Ann Surg 2013, Peterli Ann Surg 2017)

Metabolic effects (gut hormones, adipokines, bile acids, ...)

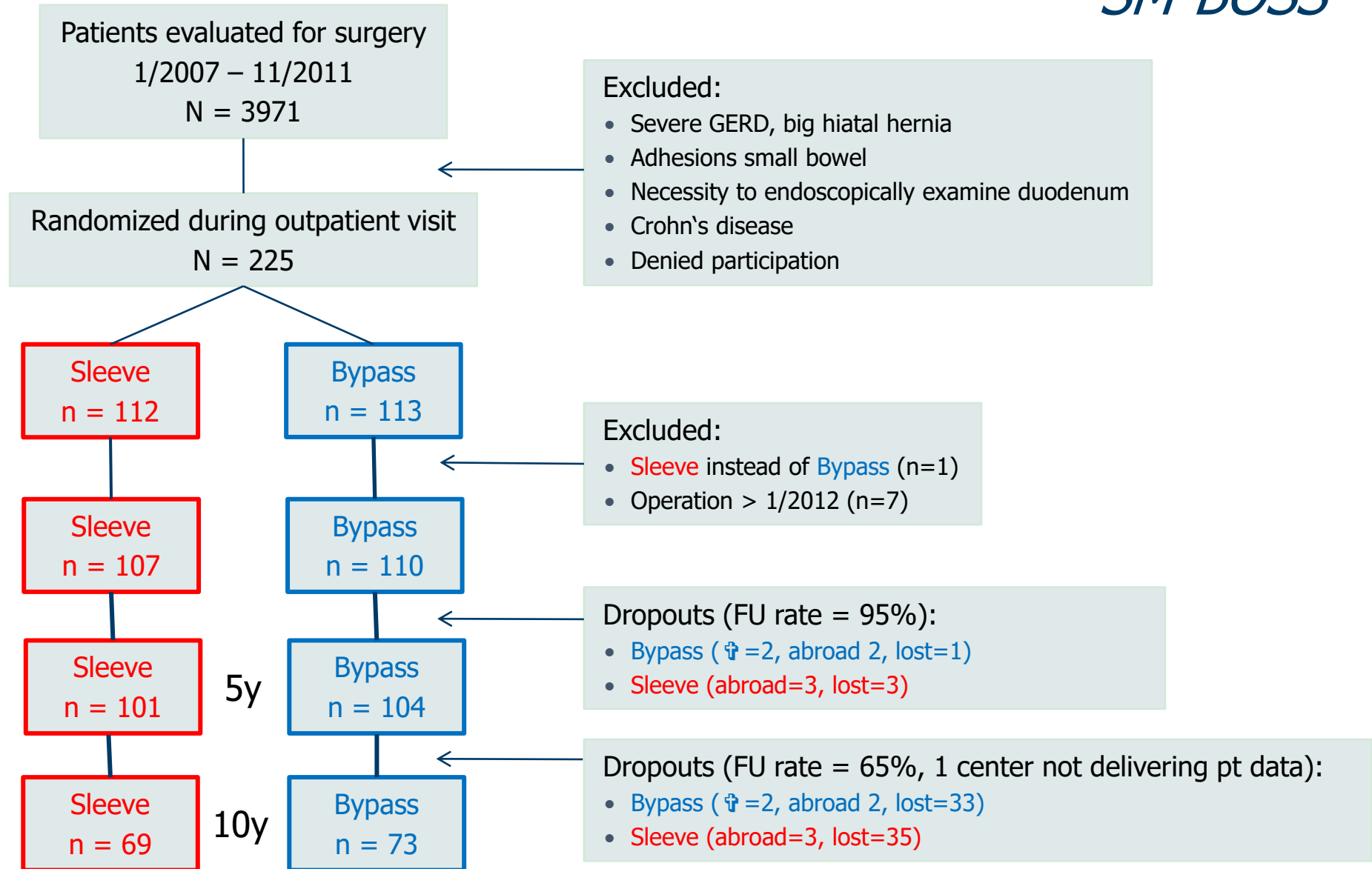
(Peterli, Ann Surg 09, Obes Surg 12, Wölnerhanssen SOARD 11, Steiner Obesity 13)

- Funding:

- Swiss National Science Foundation
- Ethicon Endosurgery, USA

Patients

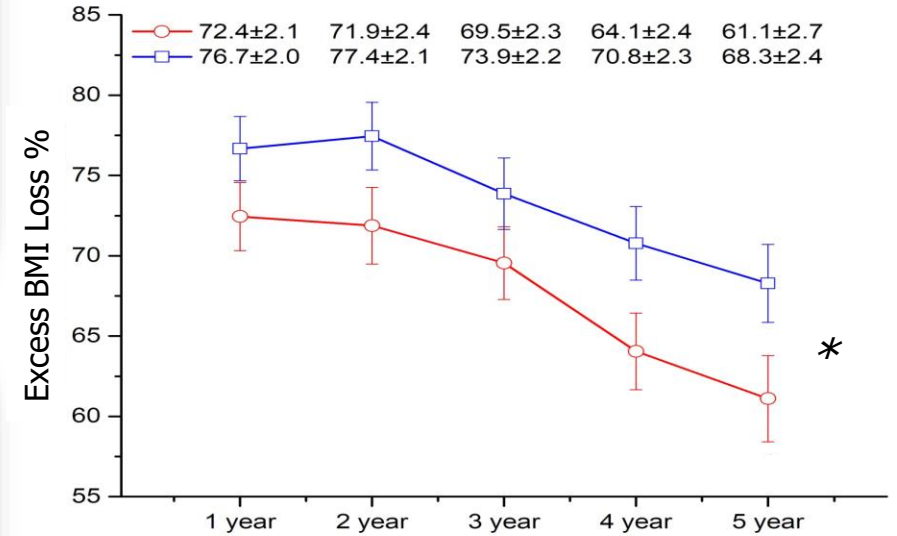
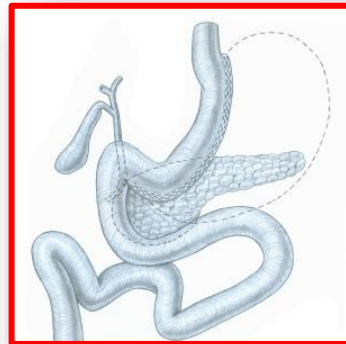
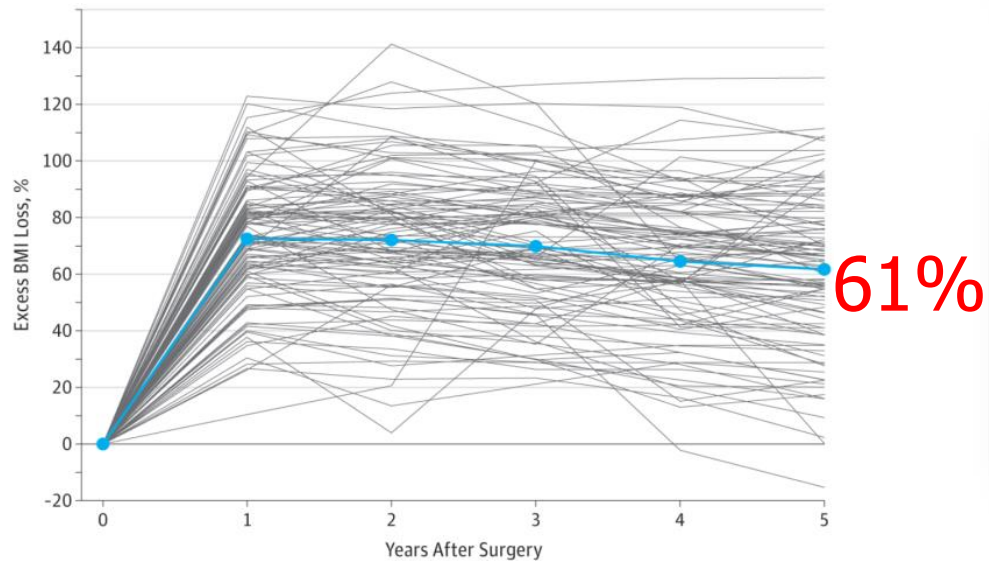
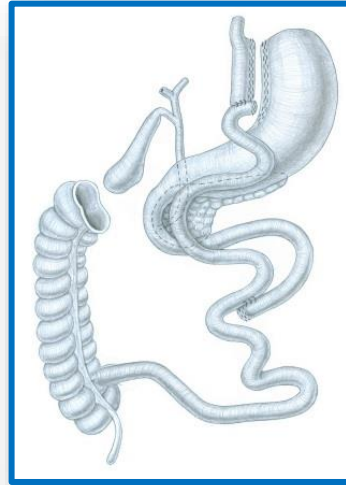
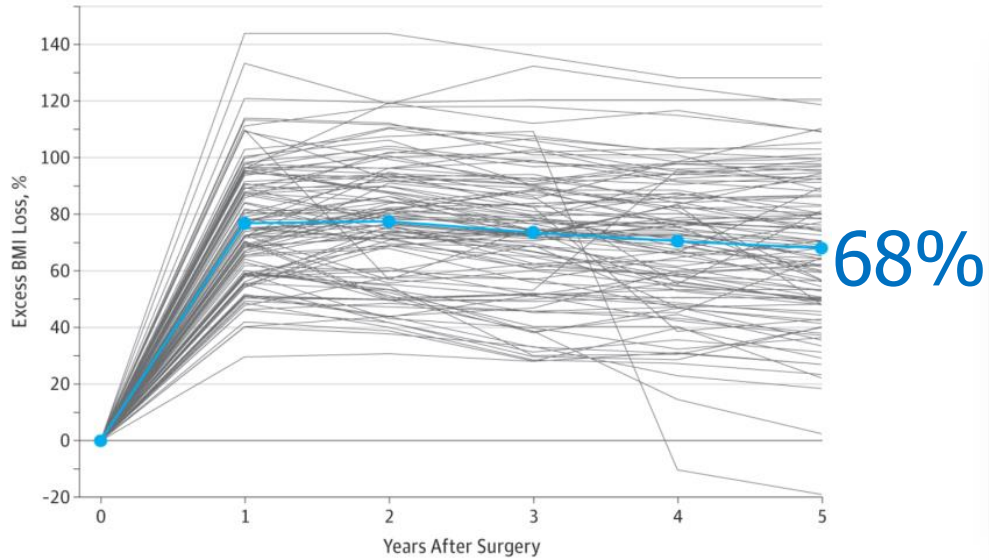
SM-BOSS



5-year Results

Excess BMI loss

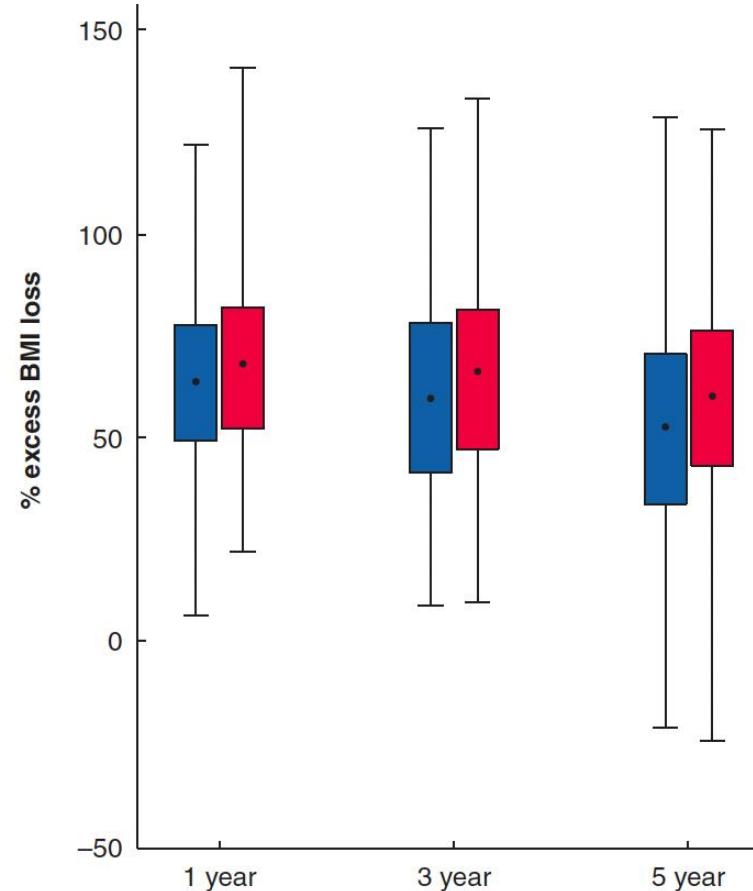
SM-BOSS



SM-BOSS & SLEEVEPASS

5 years

- Both RCT: merged data (N= 398)
 - Superiority trial:
 - Primary endpoint: %EBMIL



5y: Bypass 62.2 %
(51.1 , 73.2)

p<0.001

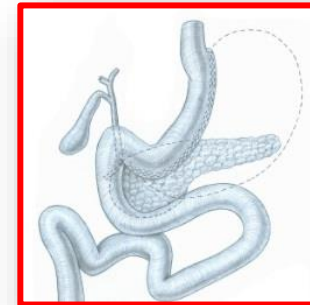
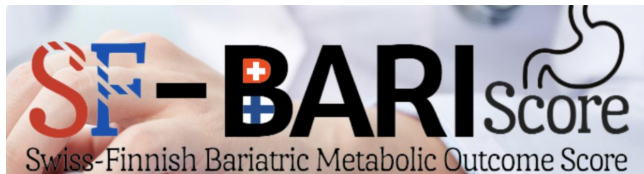
5y: Sleeve 54.1 %
(43.1 , 65.1)

No. of patients		1 year	3 year	5 year
LSG	218	212	199	
LRYGB	217	207	199	

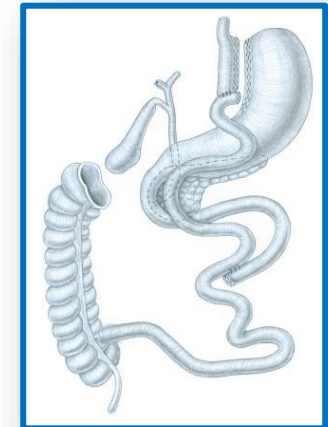
SM-BOSS: 10 y Results

Aim

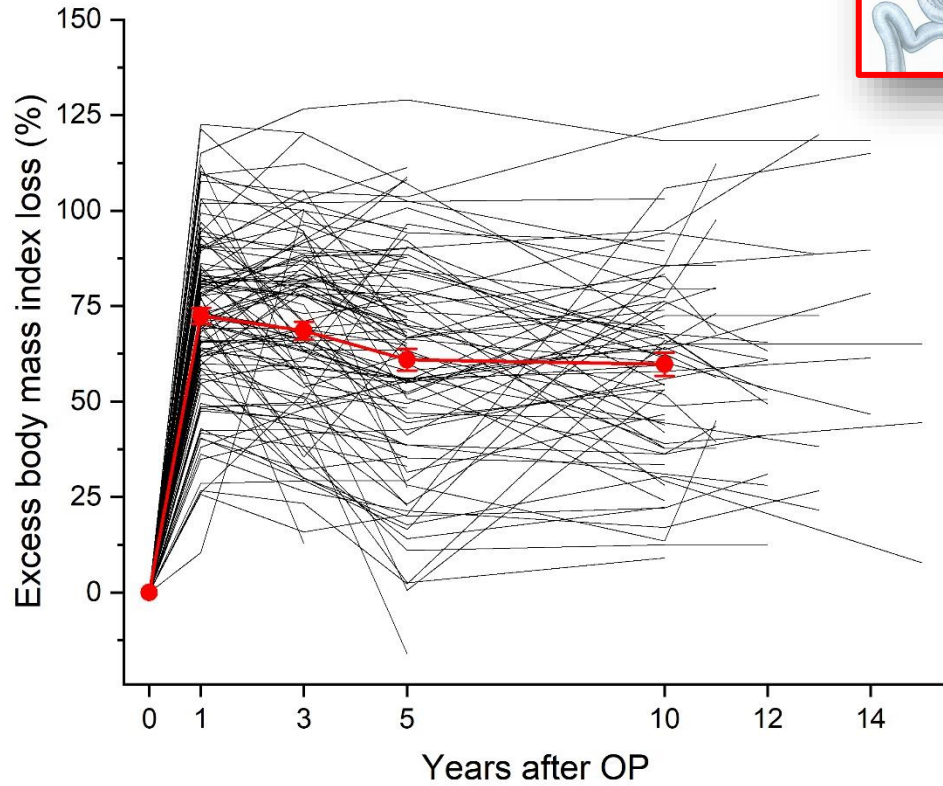
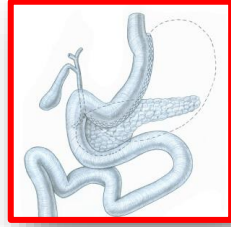
- Primary endpoint: %EBMIL
- Secondary endpoints:
 - Percentage total weight loss (%TWL)
 - Comorbidities
 - Complications CD \geq III (CCI) i.e. reoperations
 - SF-Bari Score



VS

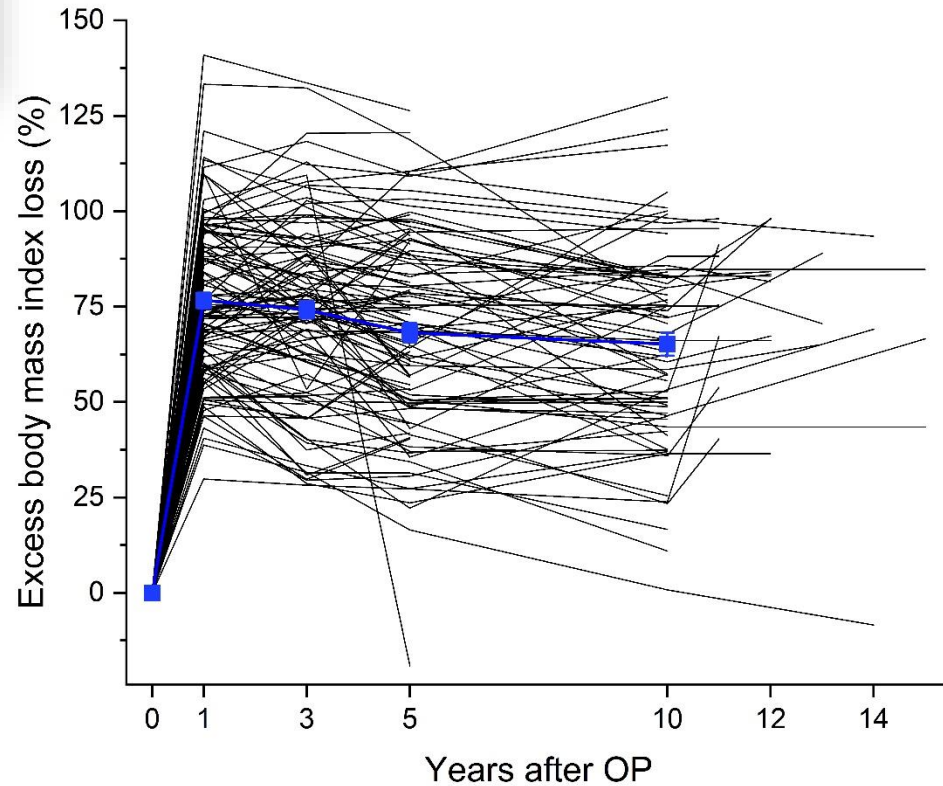
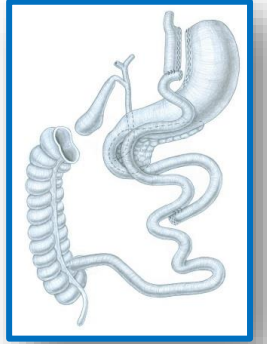


SM-BOSS: 10 y Results



10y: Sleeve 60.6 ±26 %

%EBMIL for ITT Population



ns

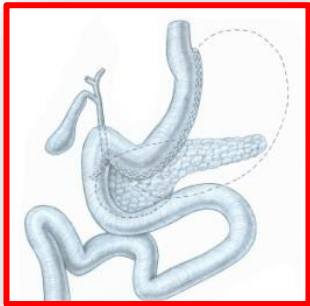
10y: Bypass 65.2 ±26 %

SM-BOSS: 10 y Results

Conversion to different anatomy

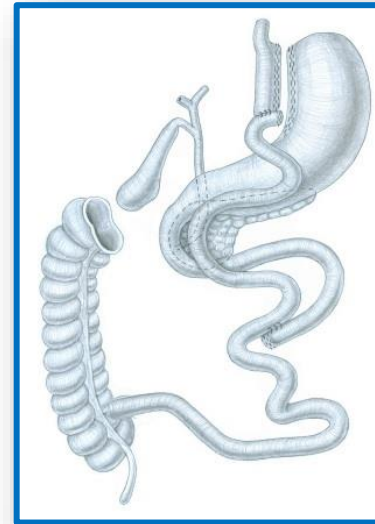
- **Sleeve** group had significantly higher rates of conversion (34.4% vs. 6.3%, $p < 0.01$)

n = 32



- GERD 47%
- Weight loss issue 28%
- Both 19%
- Stricture 6%

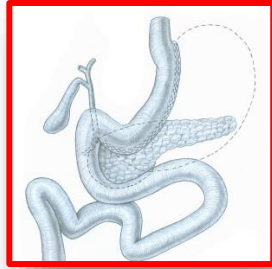
n = 6



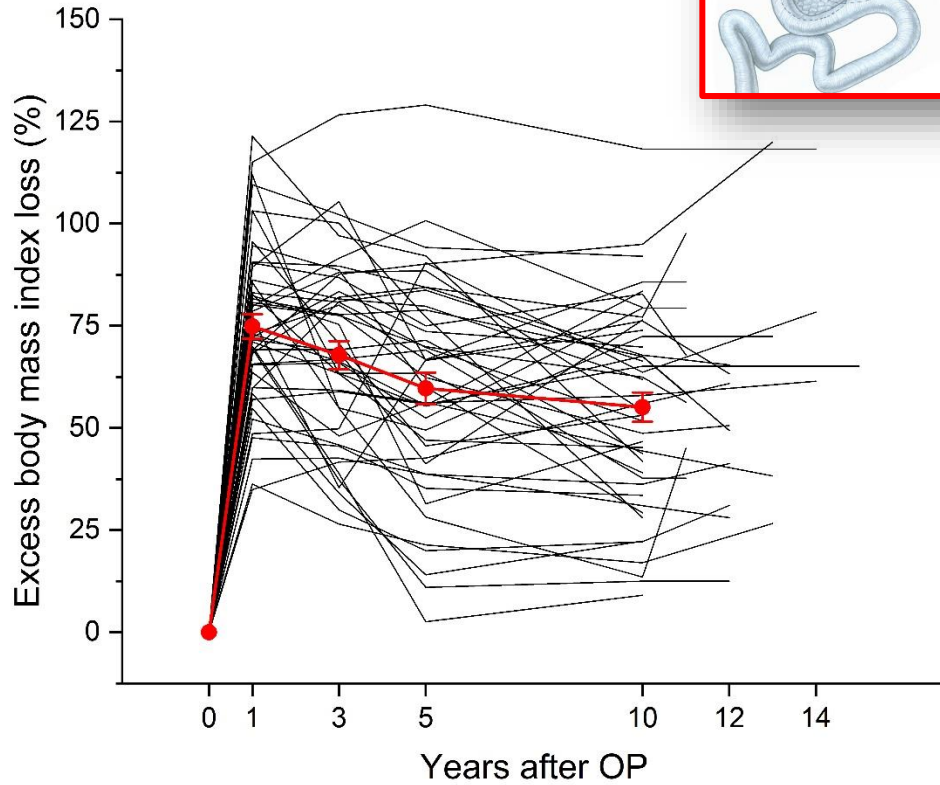
- Weight loss issue 100%

SM-BOSS: 10 y Results

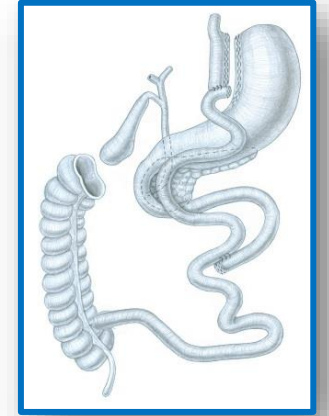
%EBMIL for PP Population



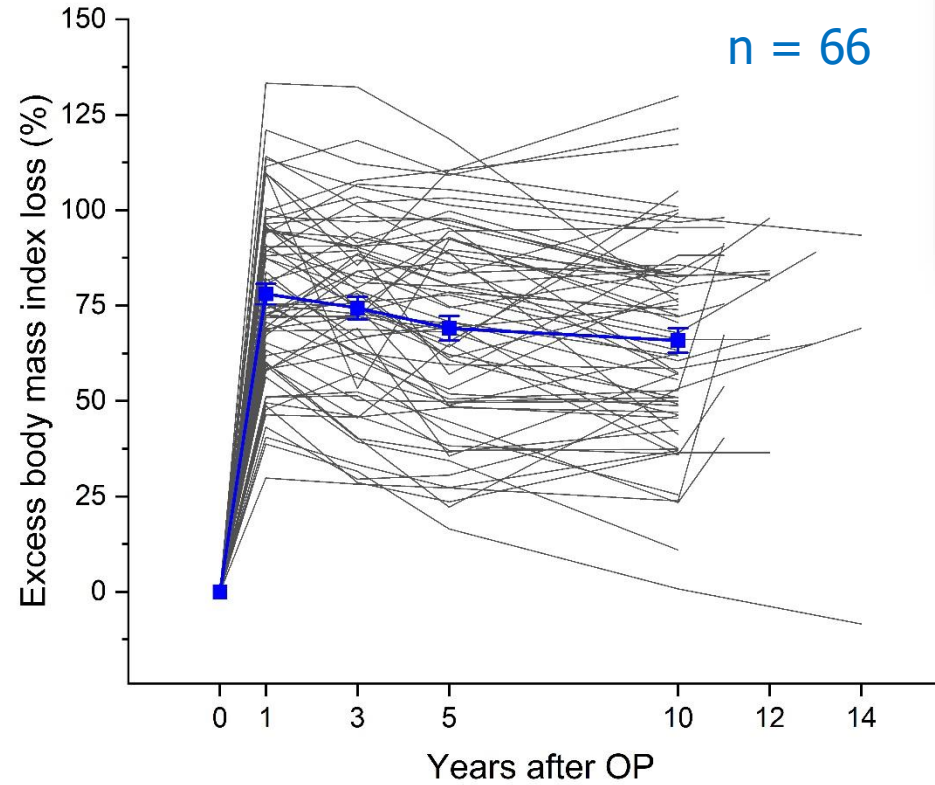
n = 48



Sleeve 56.1 ±25.2%



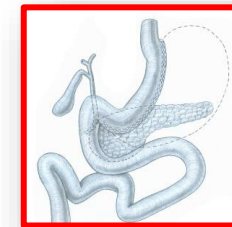
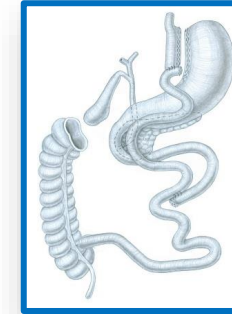
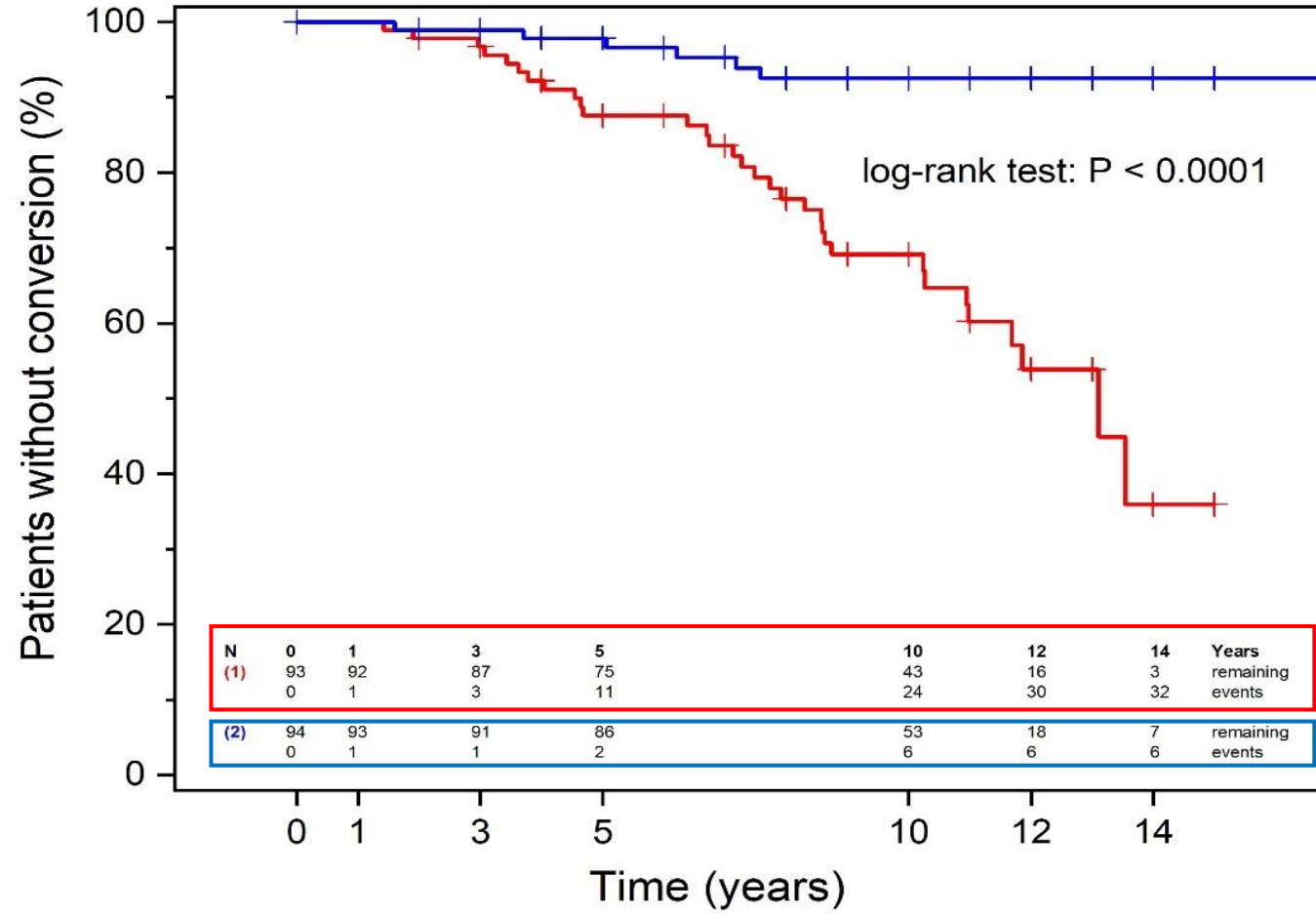
n = 66



Bypass 65.9 ±26.3%

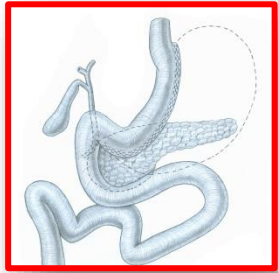
$p = 0.048$

Probability of Conversion over time

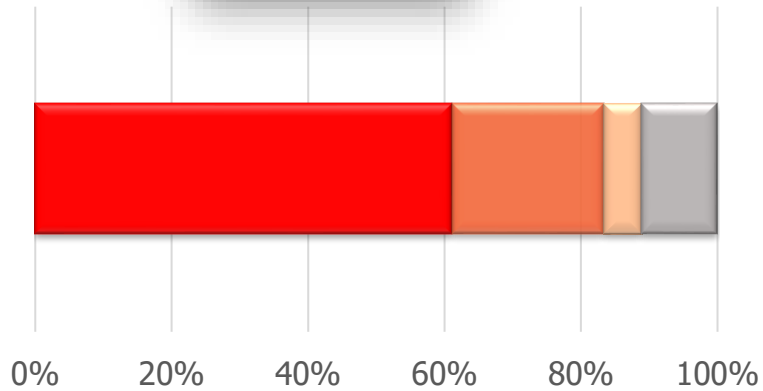


T2 Diabetes

SM-BOSS 10 years

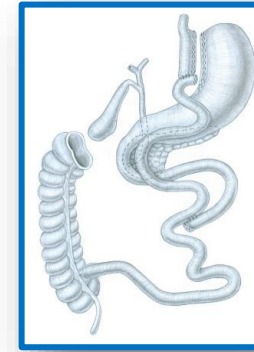


26%



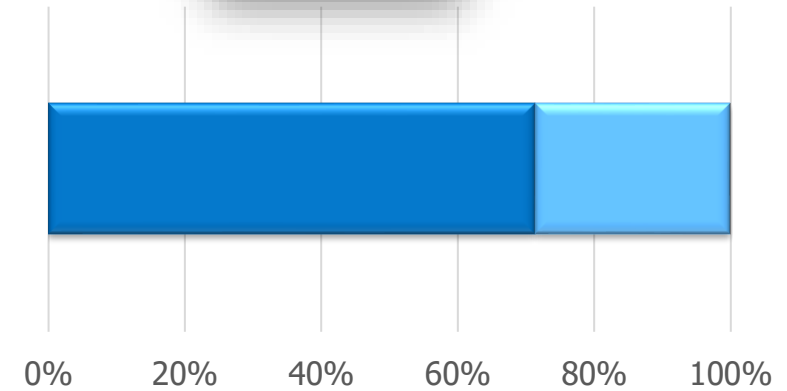
■ remission ■ improved
■ unchanged ■ worsened

De novo: 2.5 %



19%

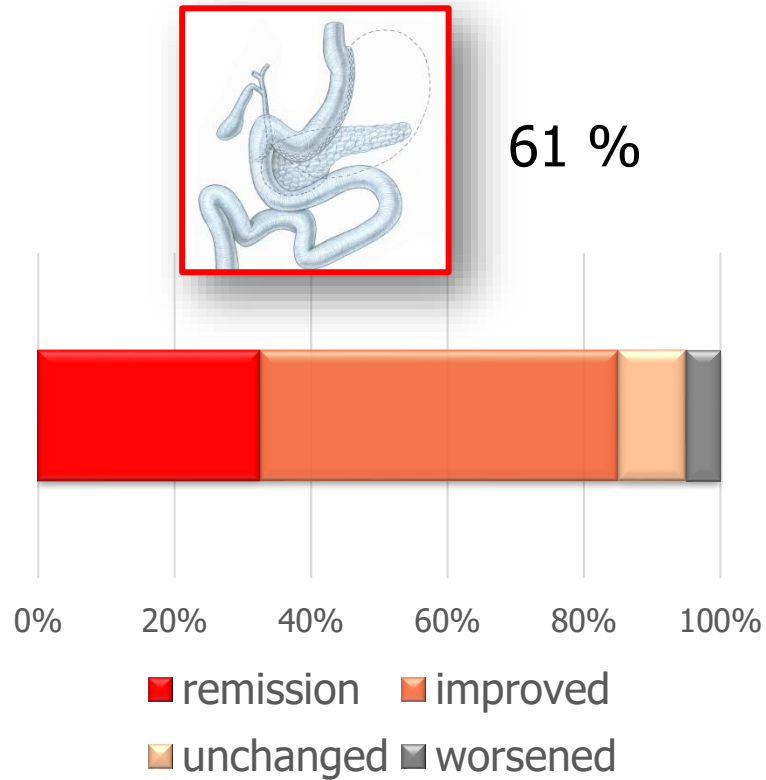
n.s.



■ remission ■ improved
■ unchanged ■ worsened

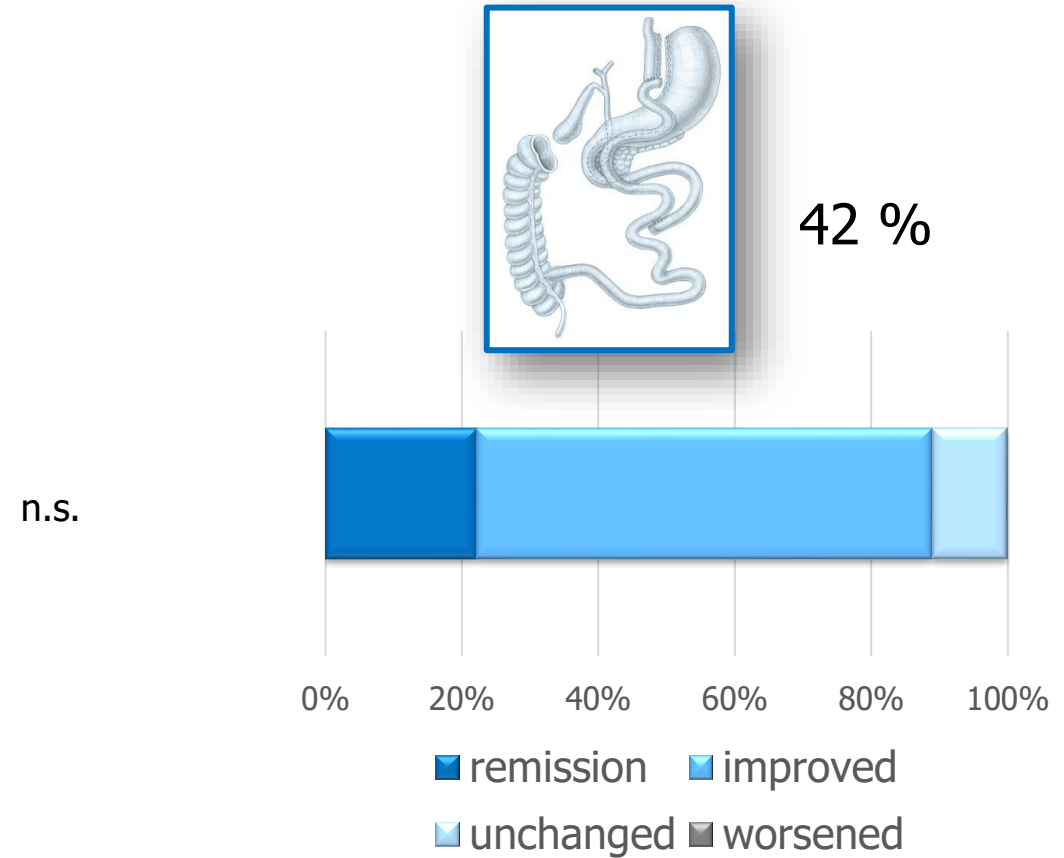
De novo: 1.8 %

Dyslipidemia



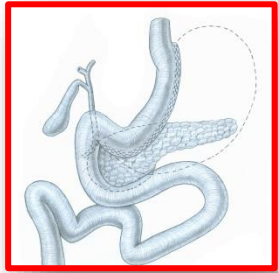
De novo: 11 %

SM-BOSS 10 years

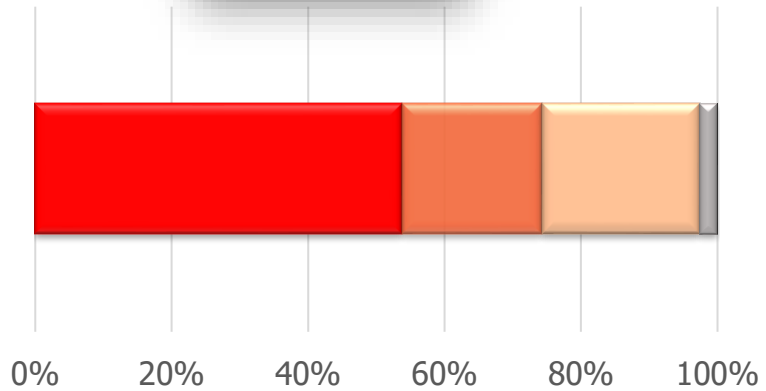


De novo: 12.4 %

Hypertension



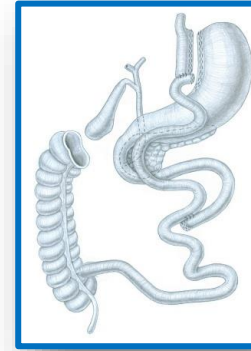
58 %



■ remission ■ improved
■ unchanged ■ worsened

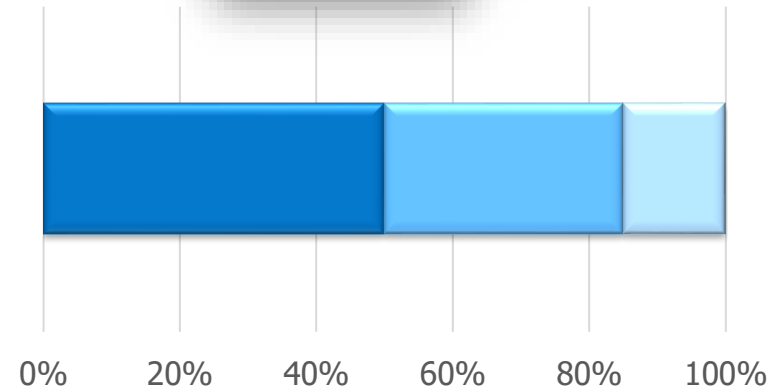
De novo: 0

SM-BOSS 10 years



56 %

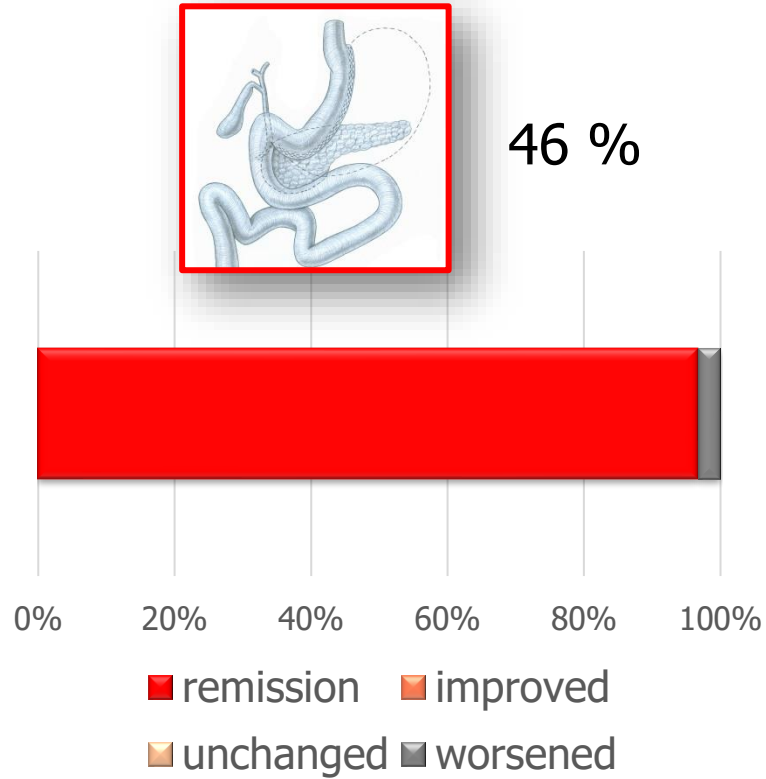
n.s.



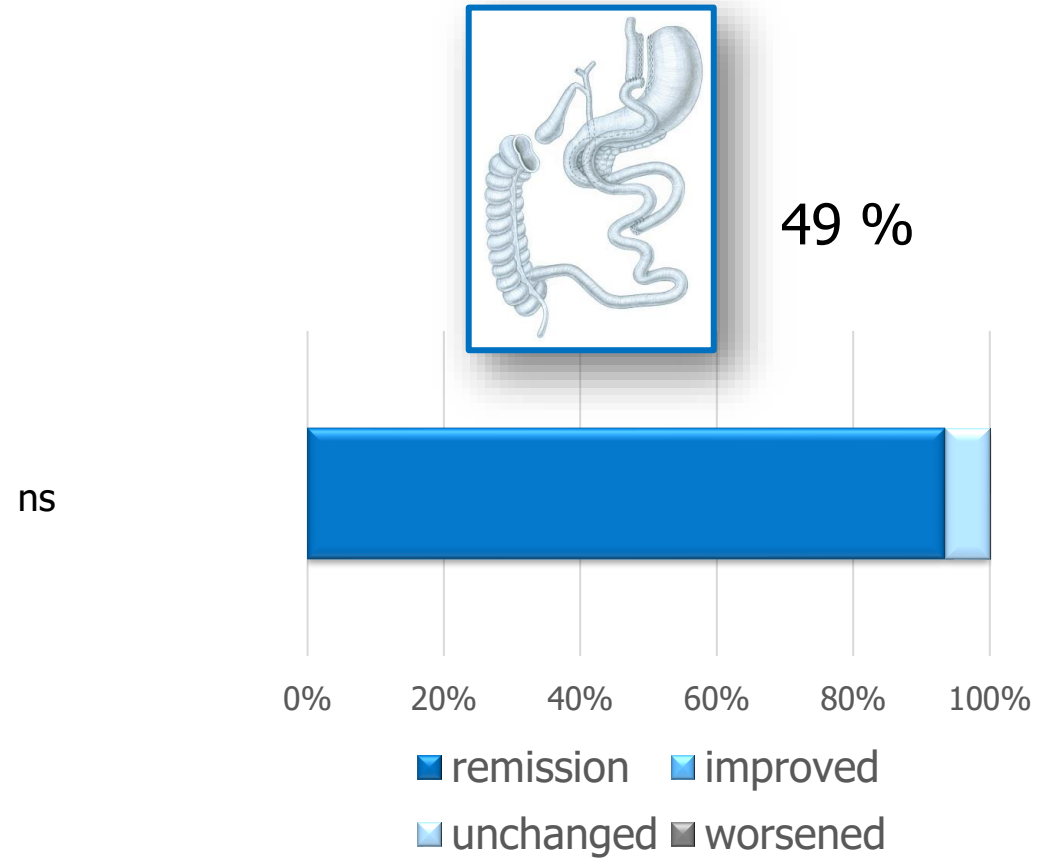
■ remission ■ improved
■ unchanged ■ worsened

De novo: 3.4 %

OSAS

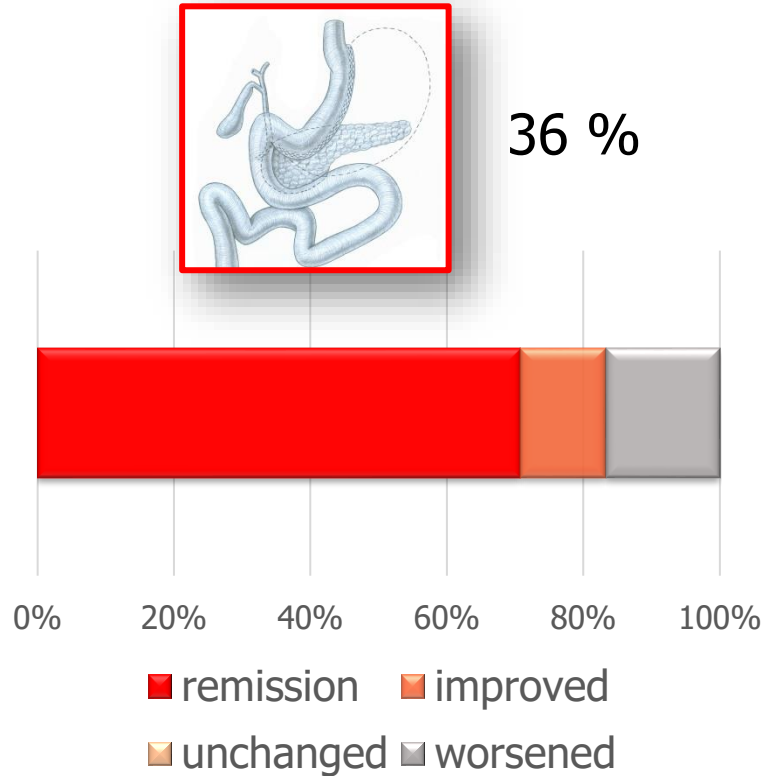


SM-BOSS 10 years

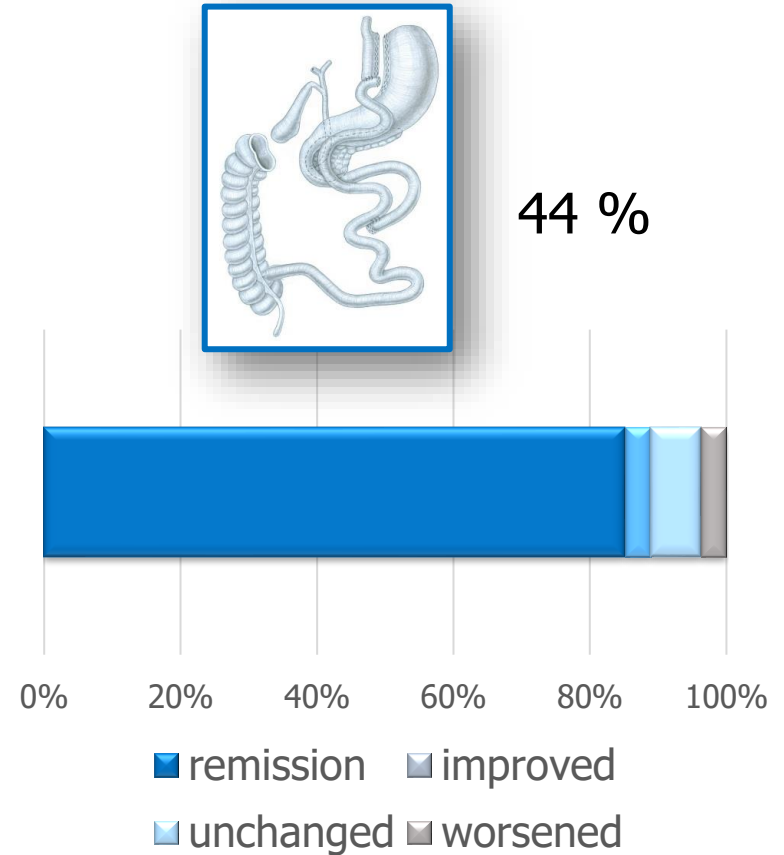


GERD

SM-BOSS 10 years (ITT)



p=0.059



- De novo GERD: 32.4 %
- De novo Barrett (7y)*: 3.6%

vs

- 8 % (p<0.01)
- 1.2%

SM-BOSS: 10 y Results

Late Complications \geq Clavien-Dindo III

	LSG (n = 69)	RYGB (n = 73)	p
Gastroesophageal reflux	15	0	< 0.01
Internal herniation	0	9	< 0.01
Small bowel obstruction	0	1	ns
Incisional hernia	0	2	ns
Abdominal pain	0	3	ns
Dumping	0	3	ns
Stricture/stenosis	2	1	ns
Suboptimal weight loss	9	6	ns
Suboptimal weight loss + reflux	6	0	0.01
Cholelithiasis	1	1	ns
Total intervention/reoperation	33	26	ns
death	0	1	ns
Comprehensive Complication Index (CCI)			
All pts	13.1	11.5	ns
Pts with complications	38.1	38.2	

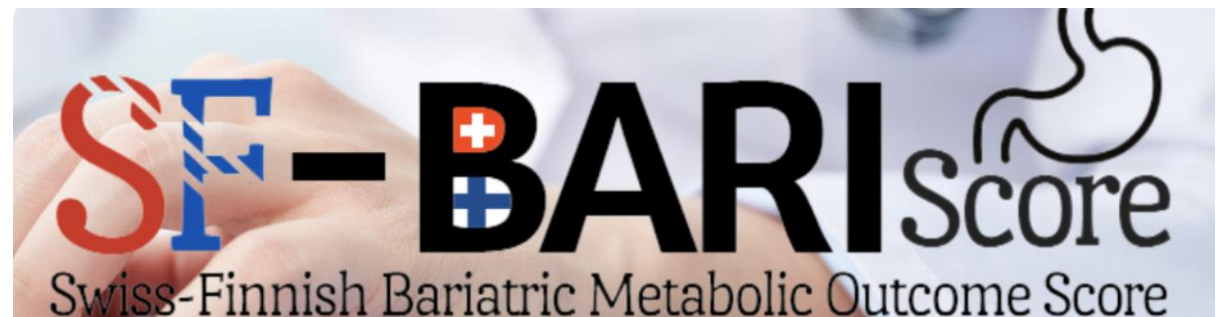
Swiss-Finnish **BARI**atric Metabolic Outcome **Score** * *SM-BOSS 10 years*

- Composite endpoint to compare different treatment modalities / series
 - Weight loss (%WL * 2)
 - Co-morbidities
 - T2DM
 - Dyslipidemia
 - Hypertension
 - OSAS
 - Complications / side effects
 - Comprehension complication index (0 = no complication / 100 = death)
 - (Quality of life)
- No significant difference for SF-BARI Score between

Sleeve and **Bypass** (84.5 ± 30.0 vs. 87.9 ± 35.9 , ns)

Categorization of score

Response	SF-BARI Score
Excellent	≥ 135
Very good	110 to <135
Good	70 to <110
Fair	35 to <70
Suboptimal	<35

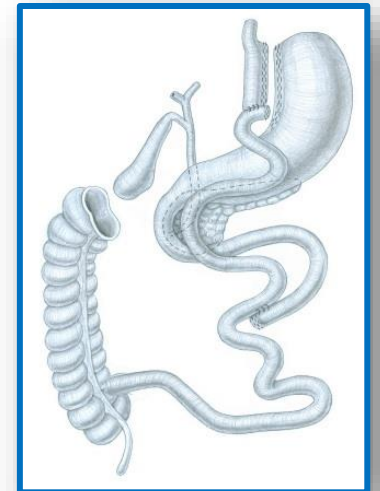
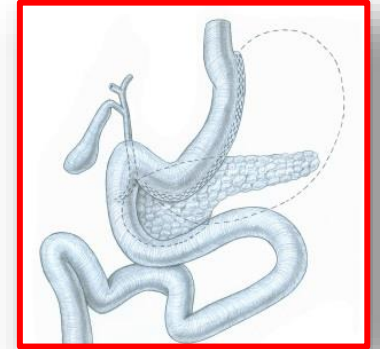


SUMMARY

SM-BOSS 10 years & more

- **Sleeve** vs **Bypass**

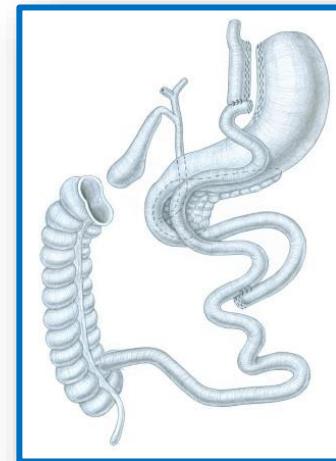
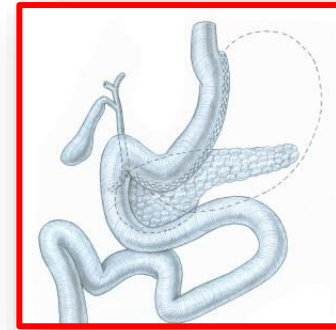
- Weight loss: **Bypass** (pp-population % EBMI 56% vs. 66%)
- Co-morbidities:
 - T2DM: remission: **(Bypass)**
 - Dyslipidaemia: **(Bypass)**
 - GERD: **Bypass**
- Safety:
 - Early: **Sleeve**
 - 5 years: **Sleeve / Bypass**
 - 10 years: **Bypass / Sleeve**
- Other:
 - Reversible **Bypass**
 - Conversion risk **Bypass (34.4% vs. 6.3%)**



CONCLUSION

- Good candidate for **Sleeve**:
 - Very high BMI
 - Necessity of endoscopic access
 - Extensive previous surgery (expected adhesions), big hernias
 - Crohn's disease
 - Professional driver (fear of dumping)
 - Elderly patient
- Good candidate for **Bypass**:
 - GERD, large hiatal hernia
 - Esophageal motility disorder
 - T2DM, dyslipidemia
- Patient selection & information important

choice of procedures



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