

# XXVIII IFSO World Congress

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## Ring-Augmented versus Non-Ring Augmented Sleeve Gastrectomy in Patients with BMI > 50 kg/m<sup>2</sup>: A 3-Year Follow-up of a Randomized Controlled Trial

**Prof. Mohamed Hany**

**IFSO 2025 Santiago**

Combined Therapies, The Dawn of a New Era

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# Disclosure



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**Nothing to disclose**

# Introduction

## The Problem with Standard Sleeve Gastrectomy

- Despite widespread adoption, SG is prone to late recurrent weight gain
- 27.8% experience RWG at  $\geq 7$  years (meta-analysis)
- 19.9% require revision surgery
  
- 13.1% due to RWG
- 2.9% due to GERD
  
- Mechanisms: pouch dilation and neuro-hormonal adaptations  $\rightarrow$  diminished restriction



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# BMI > 50 kg/m<sup>2</sup>- A Special Challenge

## Peak weight loss after SG:

30-35% TWL at 18-24 months

## Long-term outcomes after SG:

22-25% TWL at 5 years

Looks "adequate" but often insufficient for sustained remission

Catheline JM, Fysekidis M, Dbouk R, Boschetto A, Bihan H, Reach G, Cohen R: **Weight loss after sleeve gastrectomy in super superobesity.** *Journal of obesity* 2012, **2012**:959260 doi: 10.1155/2012/959260.

Arapis K, Macrina N, Kadouch D, Ribeiro Parenti L, Marmuse JP, Hansel B: **Outcomes of Roux-en-Y gastric bypass versus sleeve gastrectomy in super-super-obese patients (BMI ≥60 kg/m(2)): 6-year follow-up at a single university.** *Surg Obes Relat Dis* 2019, **15**(1):23-33 doi: 10.1016/j.soard.2018.09.487.

# Evidence in BMI > 50 kg/m<sup>2</sup> with LSG



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Lemanu et al.  
Greater absolute WL  
in super-obese, but  
less durable relative  
outcomes

Ece et al. %EWL  
lowest in BMI ≥ 60

Samuel et al.  
Median %EWL  
39.2% in super-  
obese vs 52.6% in  
BMI 40–49

Khan et al. Short-  
term %TWL similar,  
but %EWL  
consistently lower  
in BMI ≥ 50

Hoyuela et al.  
Poorer long-term  
results, higher  
revision rates in  
super-obese

Lemanu DP, Srinivasa S, Singh PP, MacCormick AD, Ulmer S, Morrow J, Hill AG, Babor R, Rahman H: Single-stage laparoscopic sleeve gastrectomy: safety and efficacy in the super-obese. *J Surg Res* 2012, 177(1):49-54 doi: 10.1016/j.jss.2012.01.011.  
Ece I, Yilmaz H, Alptekin H, Yormaz S, Colak B, Yilmaz F, Sahin M: Comparative Effectiveness of Laparoscopic Sleeve Gastrectomy on Morbidly Obese, Super-Obese, and Super-Super Obese Patients for the Treatment of Morbid Obesity. *Obes Surg* 2018, 28(6):1484-1491 doi: 10.1007/s11695-017-3053-3.  
Samuel N, Jalal Q, Gupta A, Mazari F, Vasas P, Balachandra S: Mid-term bariatric surgery outcomes for obese patients: does weight matter? *Ann R Coll Surg Engl* 2020, 102(1):54-61 doi: 10.1308/rcsann.2019.0100.  
Khan IA, K AA, Asghar M, Abbas K: Comparative Effectiveness of Laparoscopic Sleeve Gastrectomy in Morbidly Obese and Super Obese Patients. *Cureus* 2021, 13(12):e20767 doi: 10.7759/cureus.20767.  
Hoyuela C: Five-year outcomes of laparoscopic sleeve gastrectomy as a primary procedure for morbid obesity: A prospective study. *World J Gastrointest Surg* 2017, 9(4):109-117 doi: 10.4240/wjgs.v9.i4.109.

# Ring-Augmented Sleeve Gastrectomy

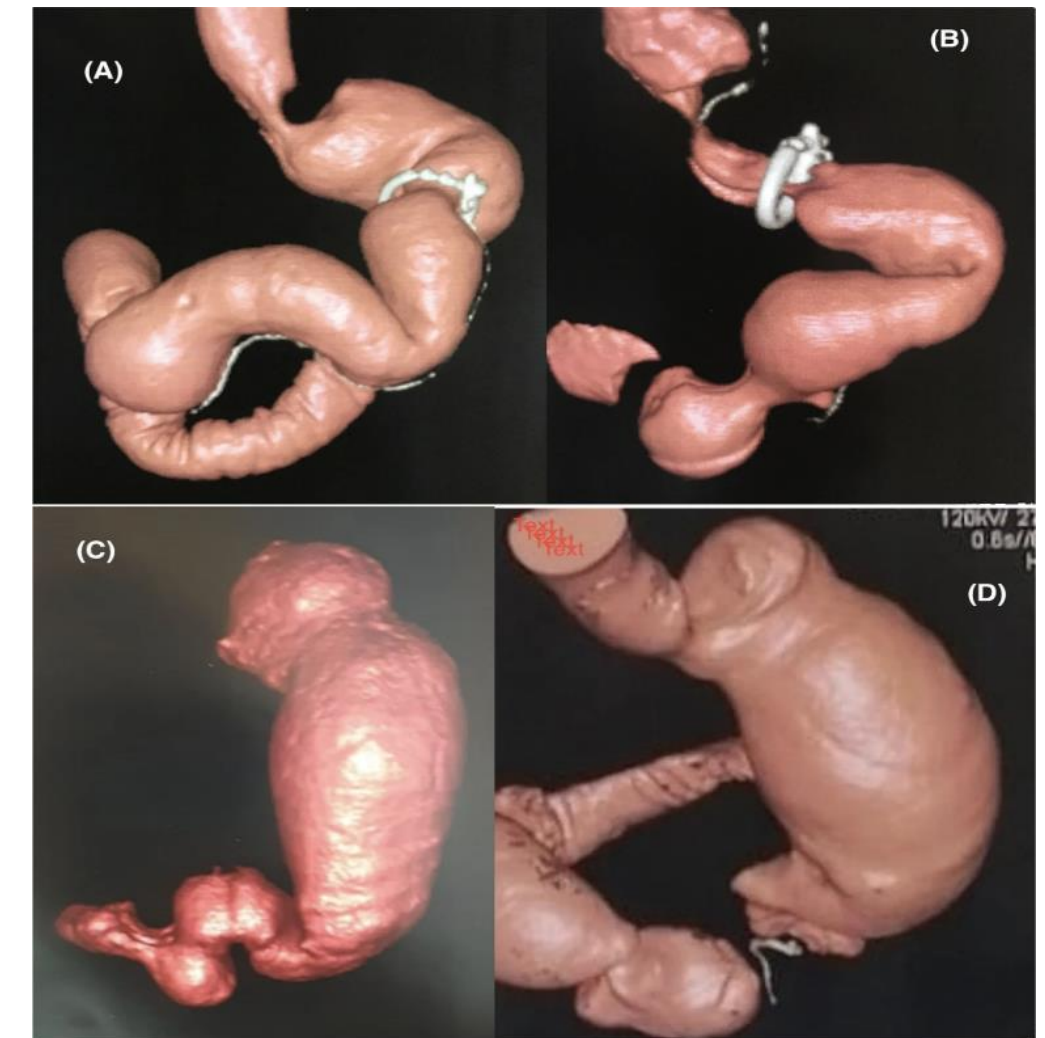


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- Non-adjustable ring placed around proximal sleeve **3-5cm from GE junction**
- Maintains restriction & prevents dilation
- Hypothesis: **improve long-term durability**
- **Key difference** from adjustable gastric bands: Fixed, non-adjustable silicone ring



# Current Evidence Gap



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## Existing Evidence:

- Fink et al. RCT: +9% EWL at 5 years; 20% vs 11.9% conversion rate
- Chaouch meta-analysis: +8-10% EWL at 1-3 years

## The Gap:

- Mixed BMI populations
- Limited data in Class IV, V obesity specifically
- Need for a dedicated RCT in the BMI > 50 kg/m<sup>2</sup> cohort

Fink JM, Reutebuch M, Seifert G, Laessle C, Fichtner-Feigl S, Marjanovic G, Fink M: **Banded Versus Non-banded Sleeve Gastrectomy: 5-Year Results of a 3-Year Randomized Controlled Trial.** *Obesity Surgery* 2024, **34**(2):310-317 doi: 10.1007/s11695-023-06982-9.

Chaouch MA, Yang W, Gouader A, Krimi B, Carneiro da Costa A, Pourcher G, Oweira H: **Banded versus non-banded sleeve gastrectomy: A systematic review and meta-analysis.** *Medicine (Baltimore)* 2023, **102**(15):e32982 doi: 10.1097/md.00000000000032982.

# Trial Design & Methods

Clinicaltrial.gov: **NCT07100327**



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Single Center, Single-blinded RCT

Intervention: Ra-SG vs standard SG

Follow-up: 36 months

Primary endpoint: %TWL at 36 months

Secondary endpoints: RWG, gastric pouch volumetry, AMPs relapse, complications, endoscopic findings at 3 years, laboratory parameters, and patient-reported outcomes (SF-36, Suter).

# Inclusion and Exclusion Criteria

- **Inclusion Criteria:**

1. BMI > 50 kg/m<sup>2</sup>, age: 18-60 years
2. Provided informed consent to take part in the trial.

- **Exclusion Criteria:**

1. Active/previous GERD or hiatal hernia
2. Prior bariatric surgery
3. Refusal of ring placement
4. Planned pregnancy during follow-up.
5. Active malignancy, uncontrolled psychiatric disorders, substance abuse



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# Primary Outcome Definition

Recurrent Weight Gain (RWG) Definition:  
According to IFSO Delphi consensus

- Gaining >30% of initial surgical weight loss from nadir

**OR**

-Recurrence/worsening of obesity-related complication that was an indication for surgery

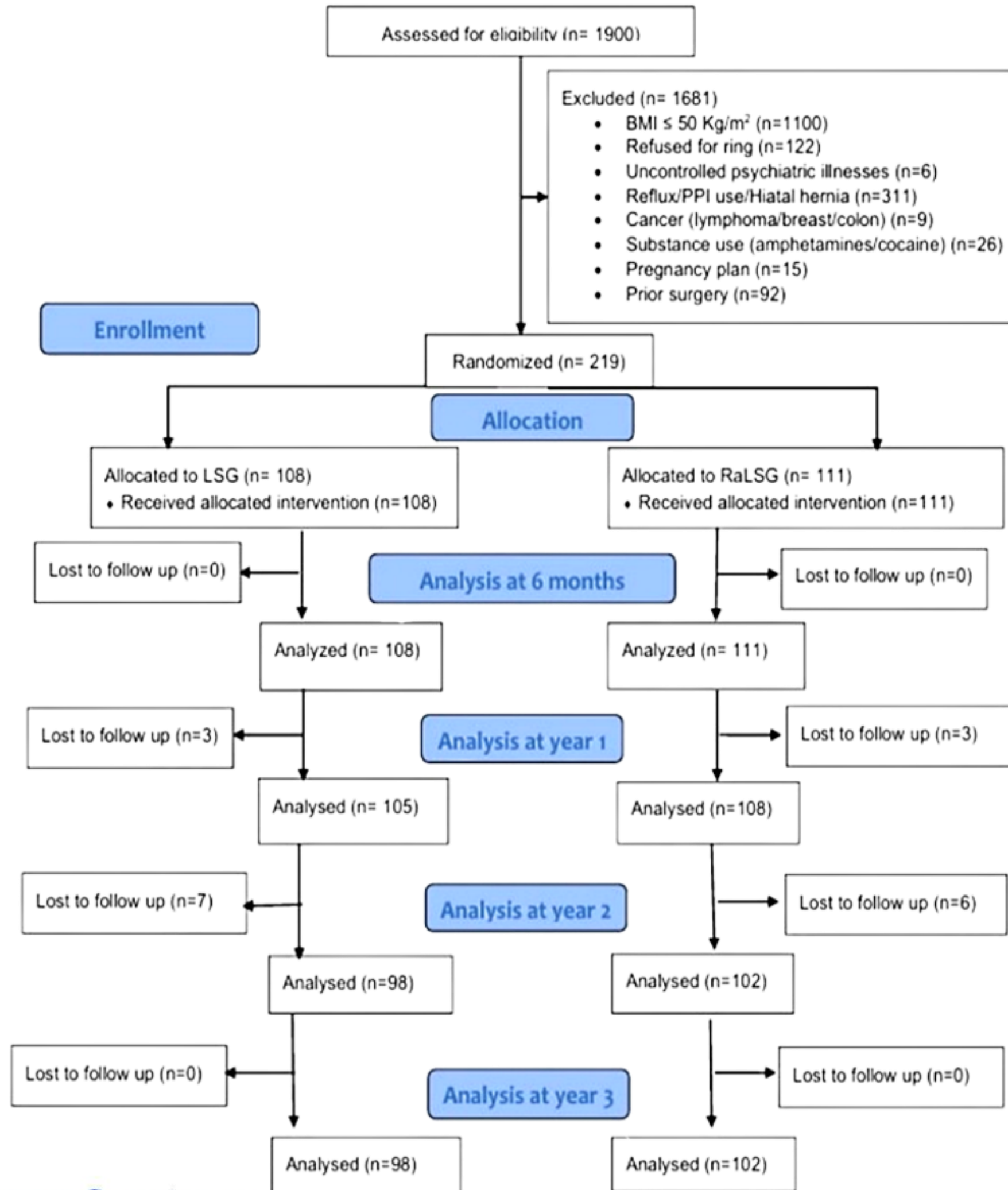
Salminen P, Kow L, Aminian A, Kaplan LM, Nimeri A, Prager G, Behrens E, White KP, Shikora S: **IFSO Consensus on Definitions and Clinical Practice Guidelines for Obesity Management-an International Delphi Study**. *Obes Surg* 2024, **34**(1):30-42 doi: 10.1007/s11695-023-06913-8.



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Randomised n=219

Completed n=200 (96%)

91% completed 3-year follow-up – One patient at year 2 with ring removal.

Recruitment between Jan 2021 and Jan 2022

The mean **age: 37.7 ± 10.2 years**, with no significant difference between groups (p=0.928).

Females constituted 66.7% (n=146) of participants, without significant differences between groups (p=0.474).

**The mean BMI was 53.8 ± 2.9 kg/m<sup>2</sup> (p=0.847)**

No differences in AMPs.

Some differences in the lab values.



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# Surgical Technique

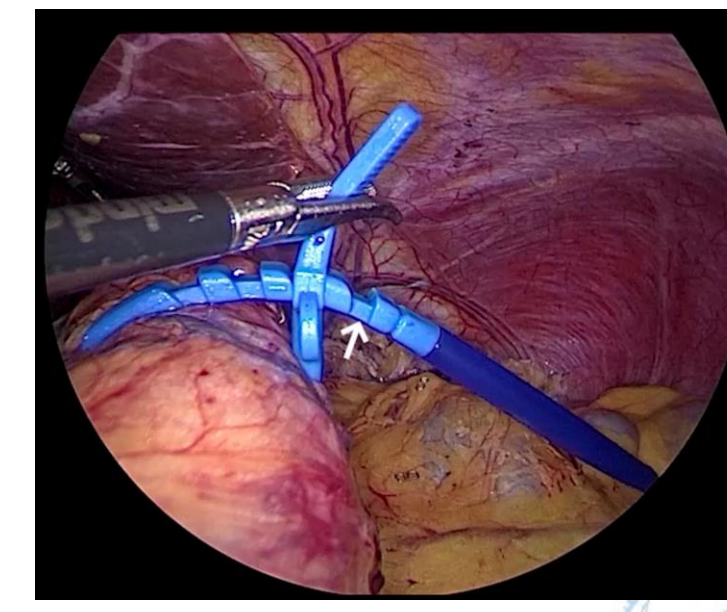
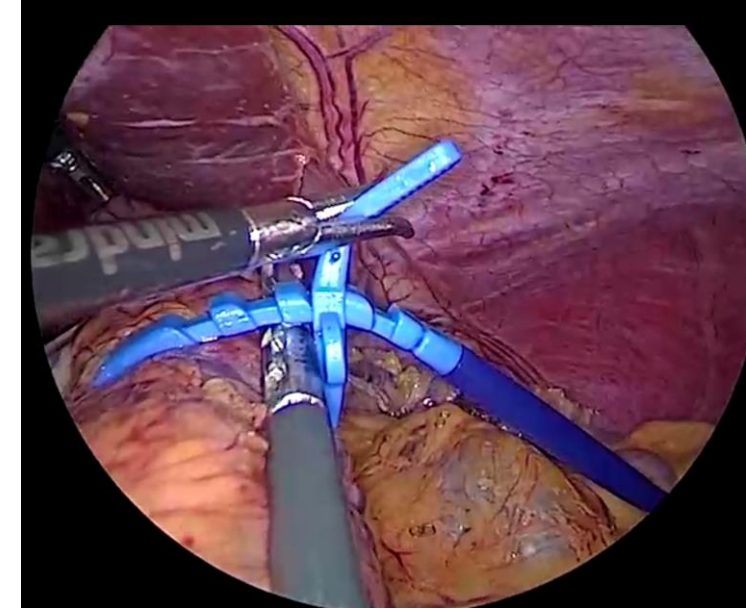
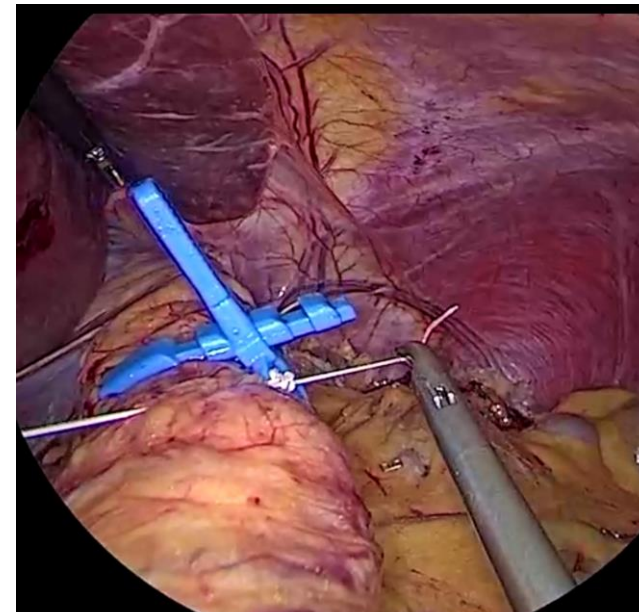
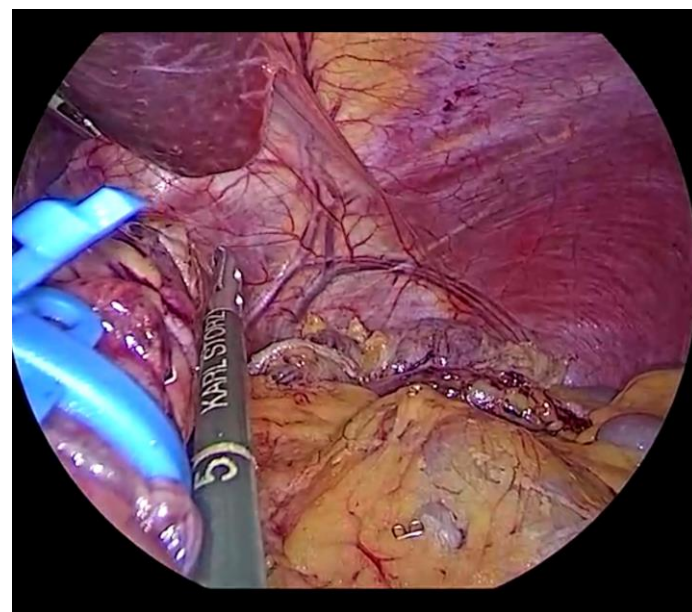
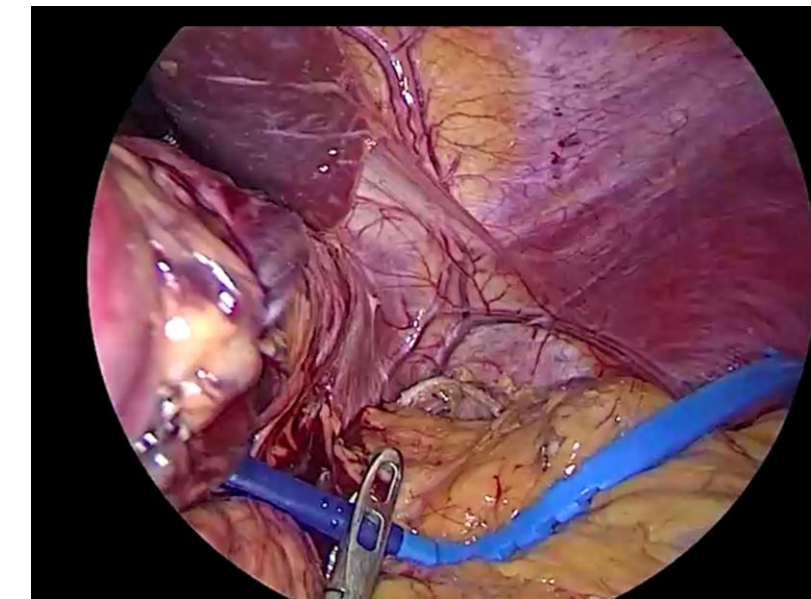
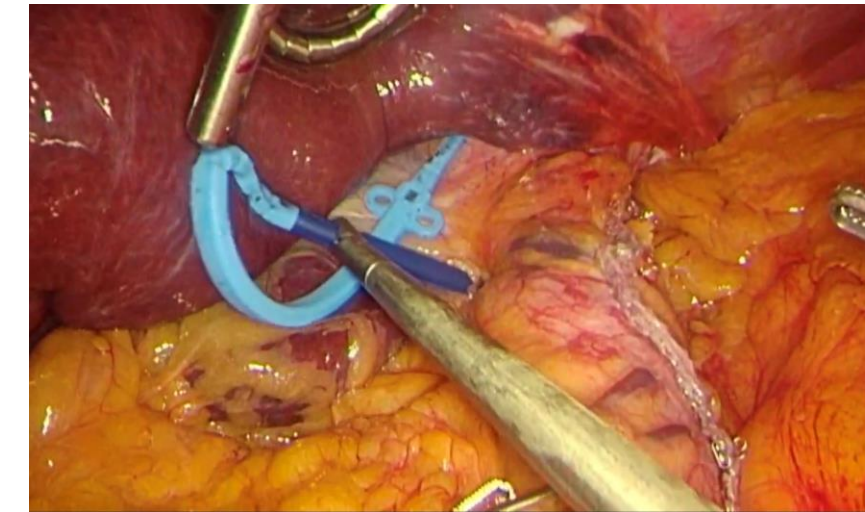
## Techniques of Placement:

**Perigastric tunnel** – created close to the gastric wall.

**Pars flaccida approach** – through the gastro-hepatic ligament

**Avoid Excess Tightness**

**Instrument Passage Check**





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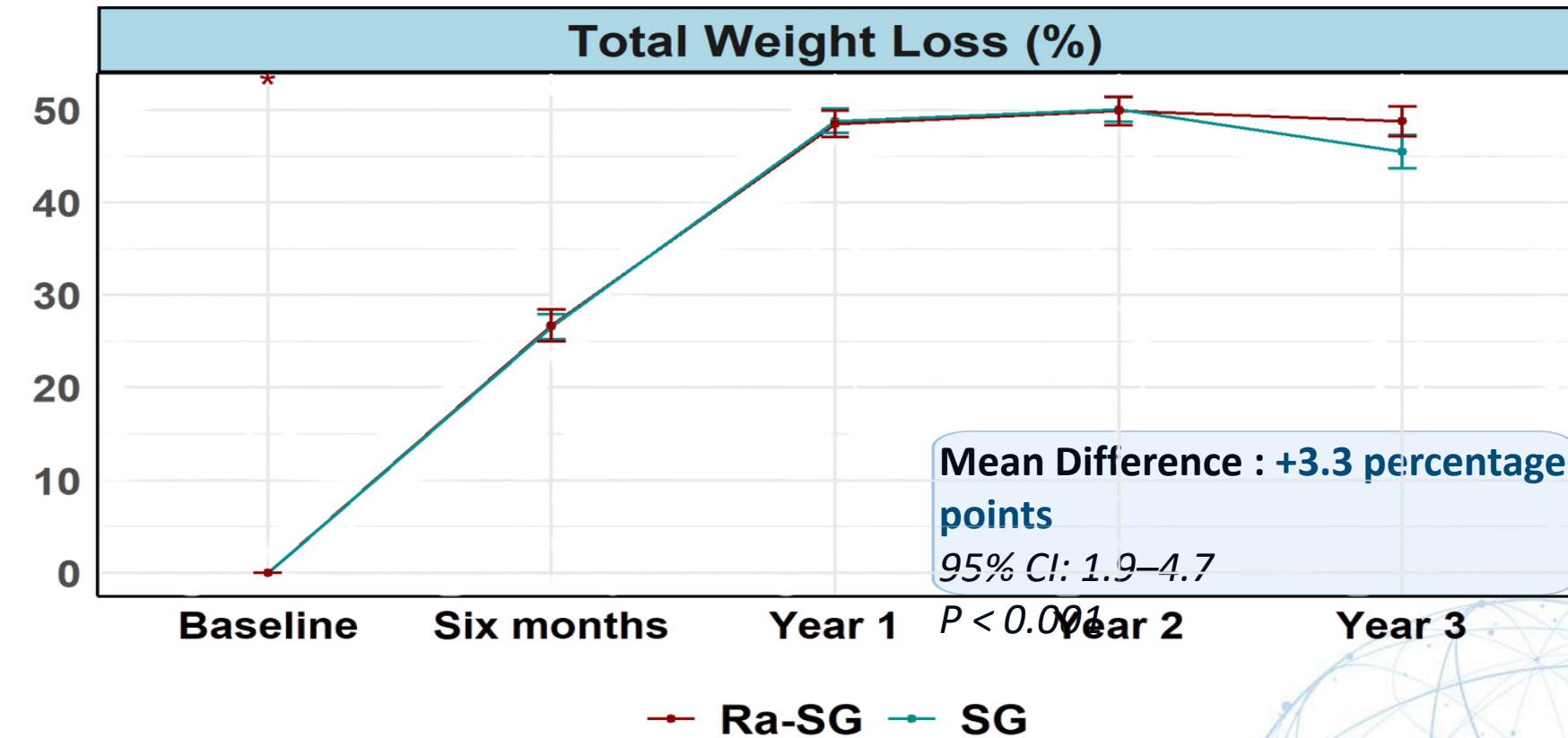
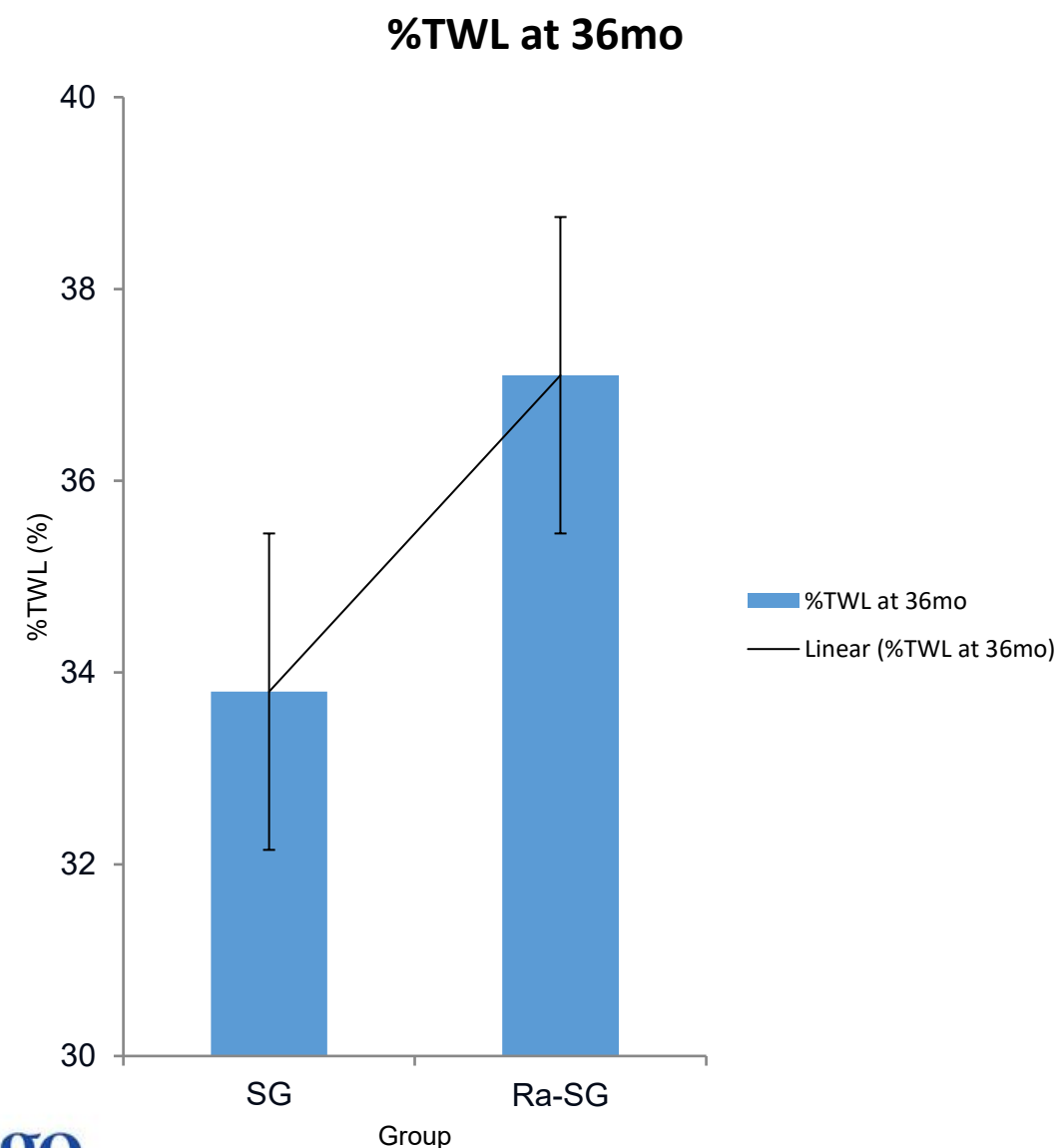
# Primary Outcome - %TWL at 36 Months

Ra-SG: 37.1 ± 5.4% TWL

SG: 33.8 ± 4.6% TWL

Mean difference: +3.3 percentage points (95% CI: 1.9-4.7)

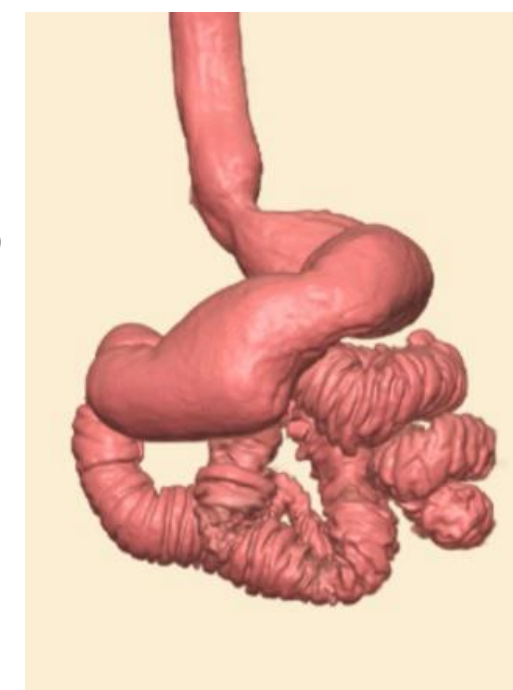
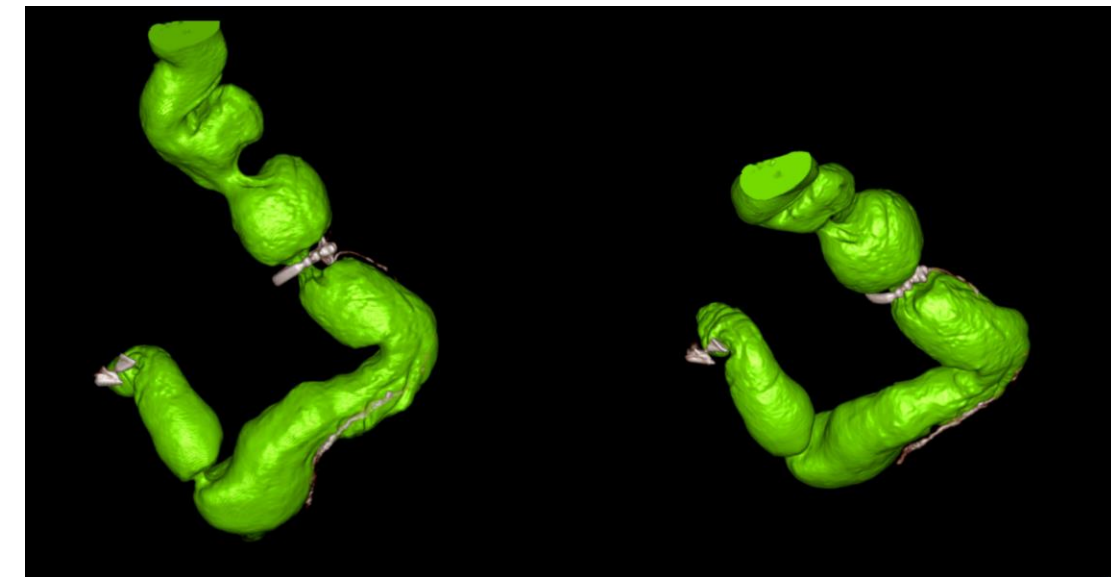
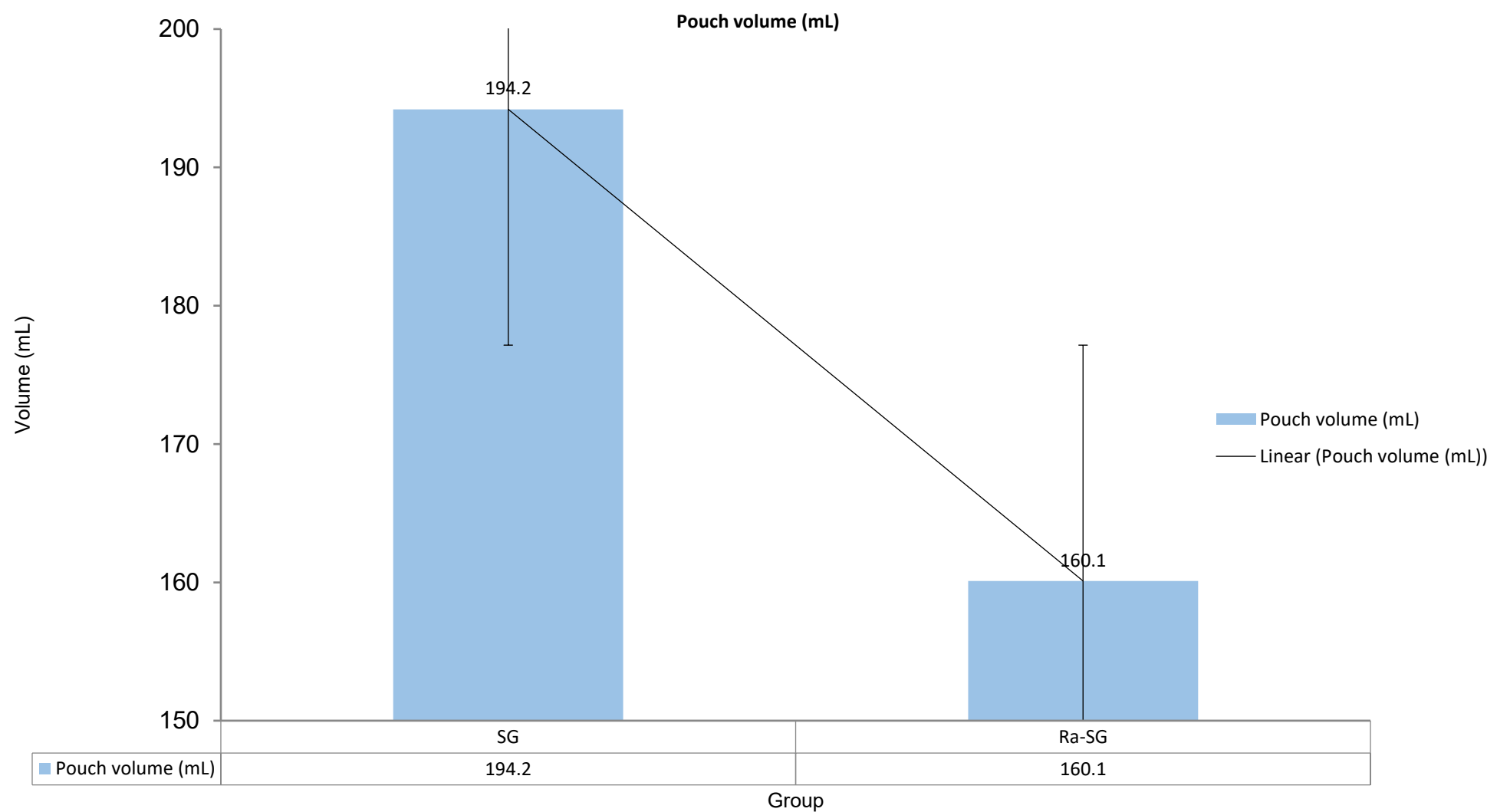
p < 0.001



# Secondary endpoint: Pouch Volume Analysis

CT volumetry at 36 months showed:

Ra-SG:  $160.1 \pm 8.9$  mL  
SG:  $194.2 \pm 10.3$  mL  
 $p < 0.001$



# Secondary endpoint: Recurrent Weight Gain

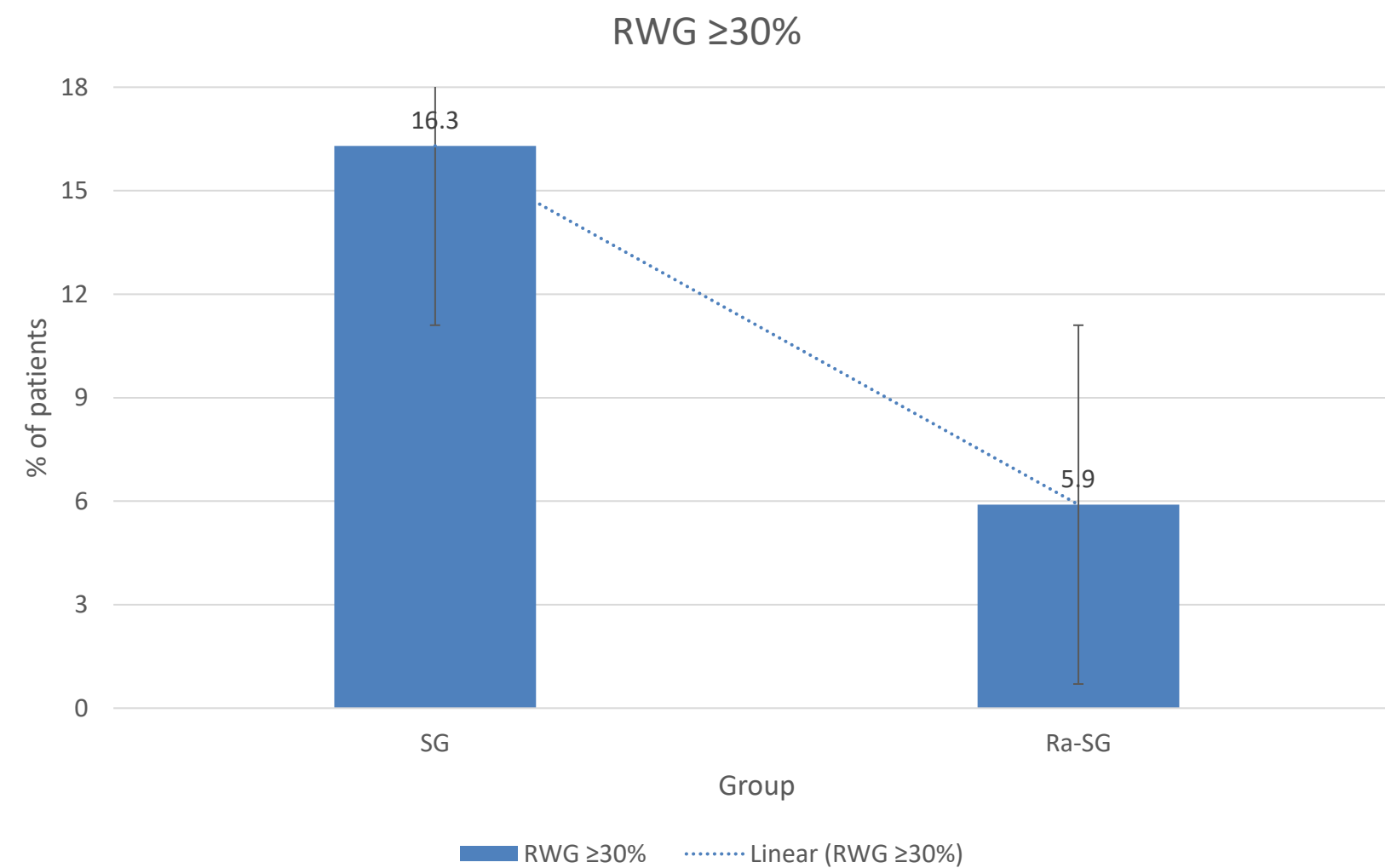
## Clinically significant RWG ( $\geq 30\%$ ):

SG: 16.3% (16 patients)

Ra-SG: 5.9% (6 patients)

**Absolute risk difference: -10.4% (95% CI: -19.6 to -1.2)**

**p = 0.033**



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# Secondary endpoint: Patient-Reported Outcomes



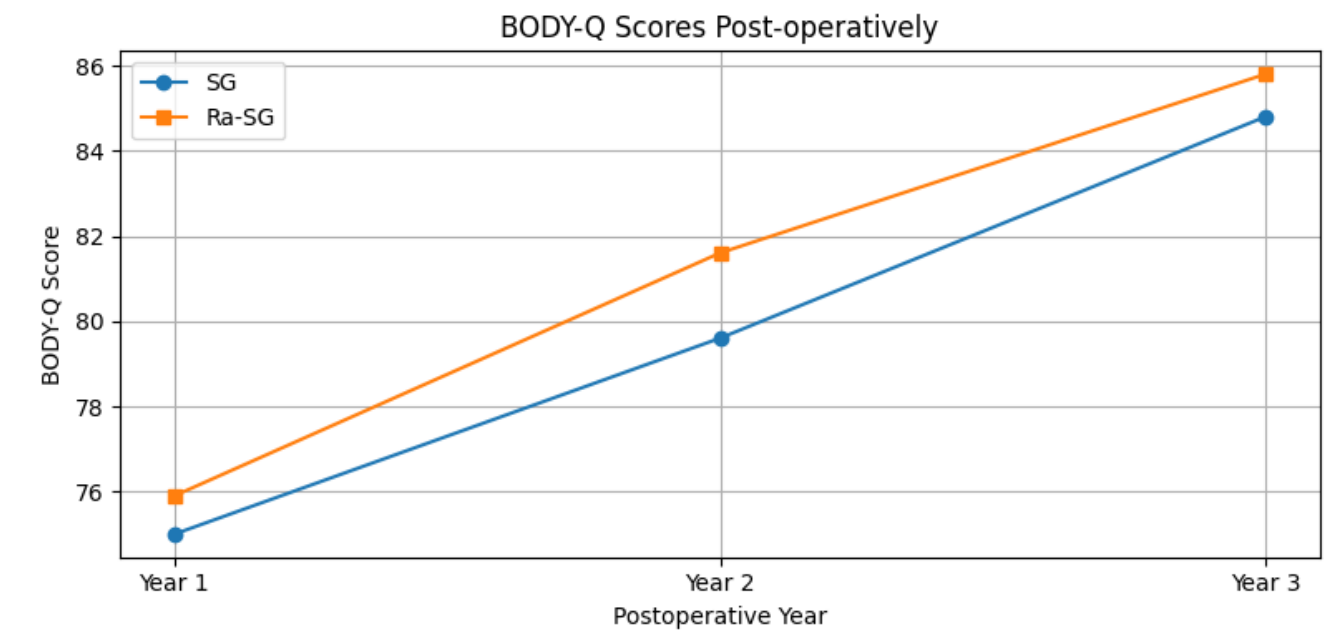
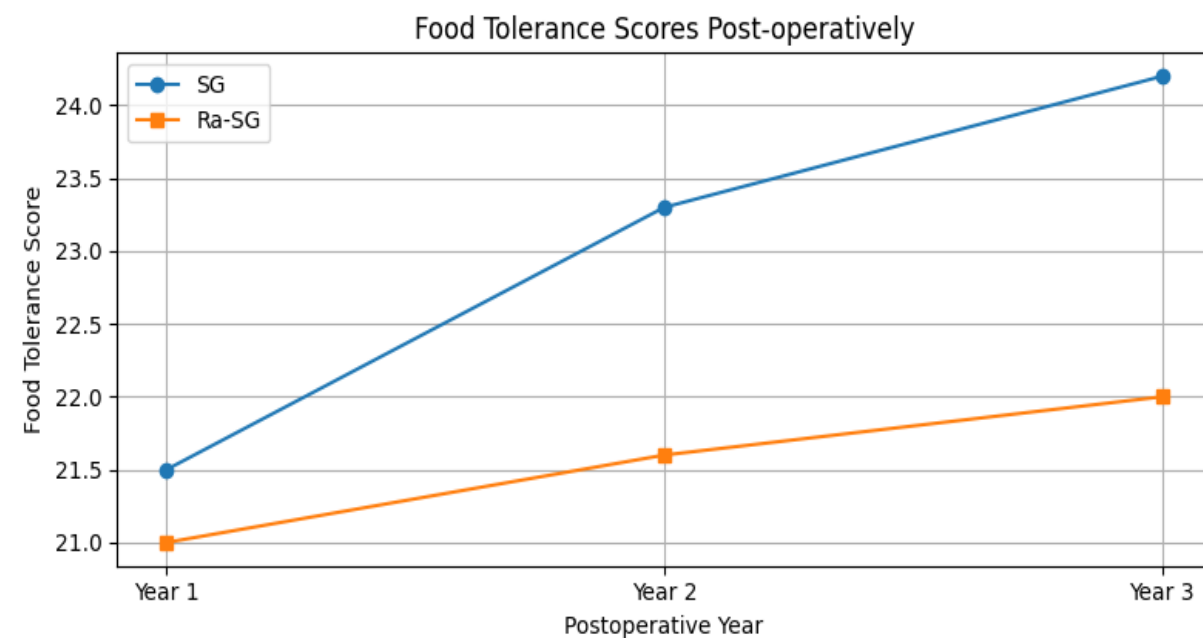
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## Food tolerance

- Consistently better in SG group (all time points,  $p < 0.05$ )
- Expected trade-off for improved weight control

- Both groups: significant improvements in SF-36. No significant differences between groups at 36 months



# Secondary endpoint: Safety Profile



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Similar operative times (41.2 vs 41.8 minutes)

## Perioperative Complications:

Comparable early complications (leak 1 SG treated with stent; bleeding, 1 in each arm, blood transfusion)

The proportion of patients experiencing relapse of any obesity-related disease was significantly higher in SG (15.3%) than in Ra-SG (2.9%,  $p = 0.003$ ), especially dyslipidemia and hypertension.

**No increase in GERD at 3 years (17.3% vs 19.6%). Esophagitis grade B and C in 2% vs 1%**

## Ring-Specific Issues:

Ring removal: 2 patients (1.8%). No erosion/slippage.

Most food intolerances were managed conservatively.

Revision rate: At year 3, conversional RYGB was performed in **7.2%** (8) of SG versus **2.0%** of Ra-SG (2).

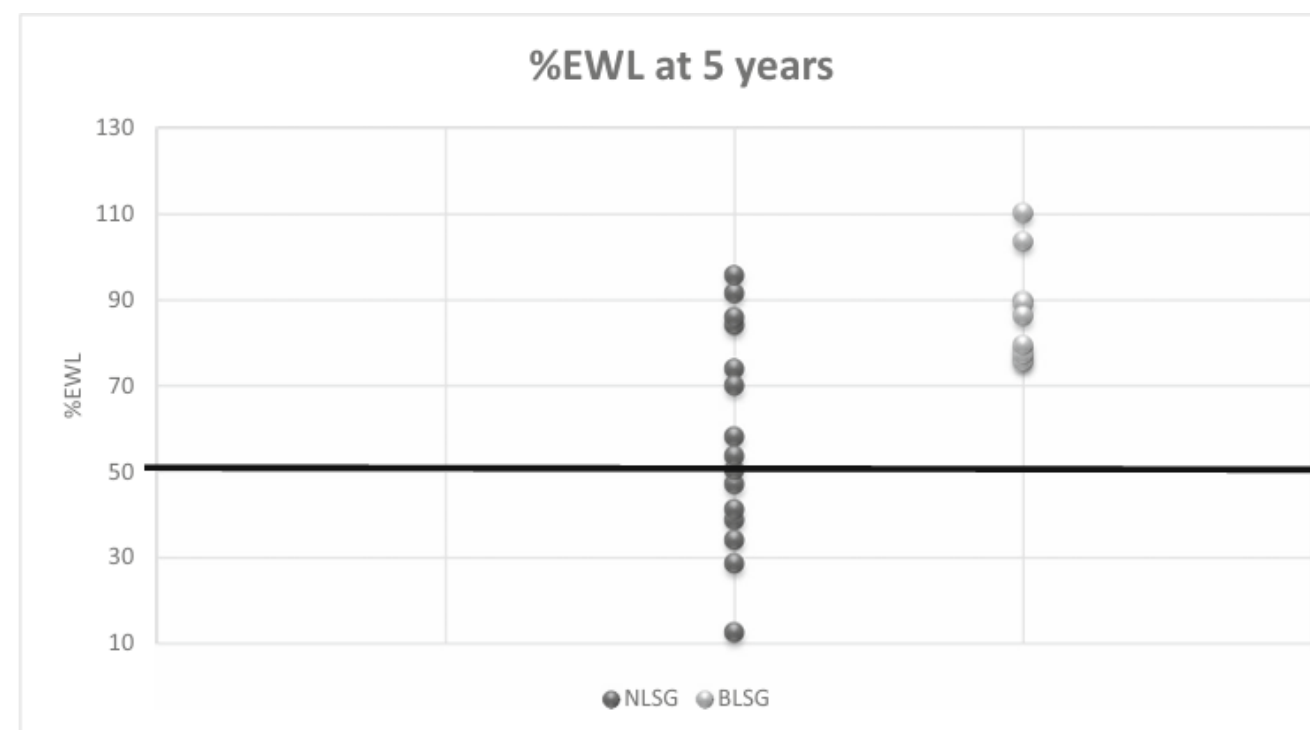




# Comparison with Literature

## Our findings align with prior evidence:

- Lemmens et al.: 78.3% vs 61.6% EWL; 0% vs 35.2% failure rate
- Similar RWG reduction patterns across studies



Obesity Surgery (2023) 33:406–417  
<https://doi.org/10.1007/s11695-022-06404-2>

ORIGINAL CONTRIBUTIONS

### Comparison of Sleeve Volume Between Banded and Non-banded Sleeve Gastrectomy: Midterm Effect on Weight and Food Tolerance—a Retrospective Study

Mohamed Hany<sup>1,2</sup> · Bart Torensma<sup>3</sup> · Ahmed Zidan<sup>1</sup> · Ann Samy Shafiq Agayby<sup>1</sup> · Mohamed Ibrahim<sup>1</sup> · Mohamed El Shafie<sup>4</sup> · Iman El Saved<sup>5</sup>

Obesity Surgery (2024) 34:310–317  
<https://doi.org/10.1007/s11695-023-06982-9>

ORIGINAL CONTRIBUTIONS

### Banded Versus Non-banded Sleeve Gastrectomy: 5-Year Results of a 3-Year Randomized Controlled Trial

Jodok M. Fink<sup>1</sup> · Marina Reutebuch<sup>1</sup> · Gabriel Seifert<sup>1</sup> · Claudia Laessle<sup>1</sup> · Stefan Fichtner-Feigl<sup>1</sup> · Goran Marjanovic<sup>1</sup> · Mira Fink<sup>1</sup>





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## GERD and Ring-Related Complications

- GERD outcomes: no significant difference at 5 years ( $\approx 27\%$  both groups, Fink RCT)
- Chaouch meta-analysis: no increased risk of de novo GERD (OR 0.65,  $p=0.20$ )
- Main added morbidity: occasional dysphagia, mostly diet-managed; rare ring removal.
- Adjustable gastric band  $\rightarrow$  reoperation  $>30\%$  (slippage, erosion, migration)
- Non-adjustable Ra-SG rings  $\rightarrow$  lower complication rates (3–11%)
- Overall, Ra-SG may reduce reoperations compared with SG, where conversion for RWG can approach 30%



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# Mechanisms of Action

## How the ring works:

- Fixed outlet 4-5cm below GE junction
- Prevents reservoir expansion
- Slows gastric emptying
- Activates "ileal brake" → prolonged satiety
- Maintains restriction long-term



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# Clinical Implications

## **Ra-SG as an "anti-regain" strategy:**

- Consider for patients at high risk of RWG
- Particularly valuable in BMI > 50 kg/m<sup>2</sup>
- Preoperative counseling is essential: balance weight durability vs food tolerance
- Most patients adapt to dietary restrictions

# Key Advancement



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- First dedicated RCT in patients with BMI > 50 kg/m<sup>2</sup>
- Confirms benefits extend to most patients with severe obesity.
- Evaluation of patients using endoscopy and studying the pouch volume.

# Study Limitations

- Single-center design - may limit generalizability
- Baseline imbalances in some laboratory parameters
- 36-month follow-up - may miss late complications
- BMI range: 50.2-59.9 kg/m<sup>2</sup>
- Adequate power for weight outcomes, but not all secondary endpoints



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# Future Research Directions

- Multi-center RCTs with extended follow-up ( $\geq 5$  years)
- IFSO registry integration for population-level data
- Cost-effectiveness analyses
- Refined patient selection criteria

## Current Recommendation:

- Consider Ra-SG for high-risk RWG patients, especially those with a BMI  $> 50\text{kg}/\text{m}^2$

# Conclusions

- Ra-SG provides superior midterm weight loss in patients with a BMI > 50 kg/m<sup>2</sup>
- Significant reduction in clinically meaningful recurrent weight gain
- Comparable safety profile to standard SG
- Trade-off: reduced food tolerance for better weight control

## Bottom Line:

For selected patients with severe obesity at high risk of RWG, Ra-SG offers an effective anti-regain strategy that should be considered in our armamentarium.



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# Thank You

Registration

Clinicaltrial.gov: **NCT07100327**

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