

Long-Term Outcomes of SADI-S versus RYGB

From a national randomized trial to the long-term evidence horizon

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SADI-S: a powerful procedure, lack of level-1 evidence



Why SADI-S spread fast

- Technically easier than a Roux limb, even in high-BMI patients
- Fewer anastomoses → potentially fewer complications (leaks, internal hernias, ulcers)
- Reproducible, powerful weight-loss and metabolic effect
- Pylorus preservation : less dumping syndrome and bile reflux

CLOSING THE GAP

SADISLEEVE — the first RCT of SADI-S vs RYGB

NCT03610256 · Robert M et al, *The Lancet*, 2025

381

patients randomized 1:1

22

high-volume French centers

24

months of follow-up

+10%

EWL superiority hypothesis

Population

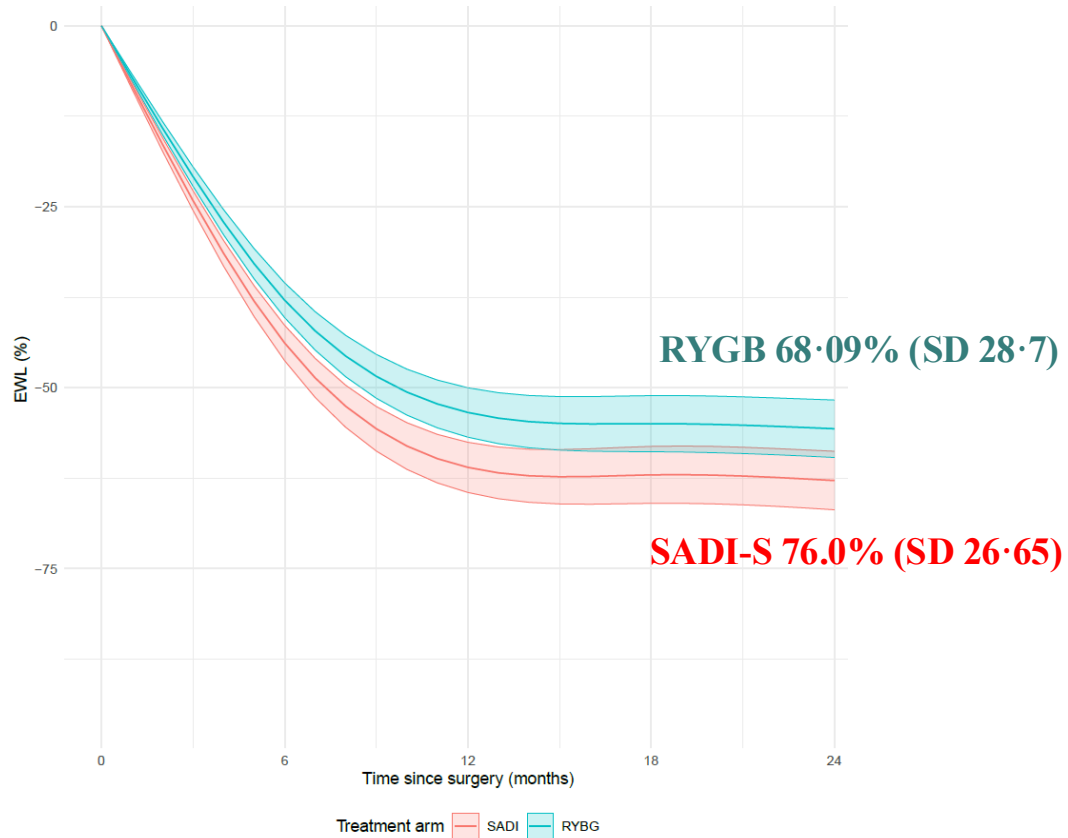
- BMI ≥ 40 , or ≥ 35 with comorbidities
- Primary surgery OR after suboptimal response to sleeve gastrectomy (21% of cohort)
- Stratified by center, prior SG, T2D status (31%)

Primary endpoint

- %EWL at 24 months
- Secondary: %TWL, metabolic, nutritional, QoL (SF-36, GIQLI), safety

Weight loss: the primary endpoint

%EWL at 24 months (ITT)



Mean difference: -6.71% EWL

95% CI -12.64 to -0.80 · p = 0.026

→ confirms the pre-specified hypothesis of superiority of SADI-S

%TWL at 24 months (secondary endpoint)

● RYGB -30.2% (SD 12.4)

● SADI-S -33.3% (SD 11.8)

Adjusted difference -2.98 % [-5.46; -0.49], p = 0.019

Sensitivity analysis: -3.74 % [-6.17; -1.30], p = 0.0028

Longitudinal mixed-effects model, linear predicted trajectories

Metabolic control and nutritional profile



Type 2 diabetes remission at 2 years

- RYGB 61.5%
- SADI-S 56.6%

p = 0.61 (NS)

Post-Hoc analysis: No remission difference despite better %EWL for SADI-S and longer duration of T2D at baseline (+ 2 years) and more insulin (+9%), *p* < 0,05

Strongest predictor of remission: insulin use at baseline (OR 0.17 [0.06–0.50]; *p* = 0,0019)
not the procedure itself (OR 1.23 [0.43–3.57]; *p* = 0,69 for SADI-S vs RYGB)



Nutritional status at 2 years

	SADI-S	RYGB	
Malnutrition*	11.7%	10.6%	NS
Albumin, g/L	41.1	41.1	0.88
Vitamin A, D, E, B9	Lower but above treshold	Above deficiency treshold	<0.03
Vitamin B12	higher	Above deficiency treshold	<0.001

** serum albumin <30 g/L and/or prealbumin <0.20 g/L, or BMI <18.5*

Comparable overall nutritional safety — a distinct micronutrient signature under close supplementation

Every procedure trades one risk profile for another

	SADI-S	RYGB	
Early surgical complications (<30 days)	5.6%	1.6%	p=0.042
Late surgical complications (>30 days)	1.7%	9.4%	p=0.0009
Clinical GERD at 2 years	19%	8%	p=0.004
Early dumping syndrome	5%	11%	p=0.039
Late diarrhea (>30 days)	22%	6%	
Grade ≥3 complications (Dindo–Clavien)	13.3%	18.6%	p=0.29
Abdominal pain (> 30 days)	8%	14%	

More early / anastomotic and GI-functional issues with SADI-S · more late surgical complications (internal hernia, occlusion, ulcers) and dumping with RYGB



SADISLEEVE stops at 24 months, awaiting 5-year results...

**What does the literature say
beyond 2 years?**

Weight-loss durability holds up in observational long-term data

Meta-analysis, 2025

10-year comparative cohort

8 studies · 1625 SADI-S vs 2634 RYGB (2 large registries dominate the RYGB arm; MBSAQIP) · mean follow-up 3.93 years (1.79) *depending on outcome* · **all observational, no RCT**

- **%TWL** +10.03 pts favoring SADI-S
p<0.001
- **%EWL** +10.15 pts favoring SADI-S
p<0.01
- **Post-op BMI** -3.8 kg/m² vs RYGB
p<0.01

T2D remission: OR 3.48 [2.02–6.02], p<0.001 ·

fewer long-term complications: OR 0.19 [0.03–1.36], p=0.1

both favoring SADI-S, high heterogeneity

THE ORIGINATORS' OWN EXPERIENCE

Sánchez-Pernaute & Torres — 10-year outcomes

164 consecutive patients · Madrid · index surgery 2007–2015 · Obes Surg 2022

%EWL

87% → **80%**

at 5 years

at 10 years

%TWL

38% → **34%**

at 5 years

at 10 years

Metabolic control — durable, with a late uptick

- Insulin-treated patients: 41 preop → 7 at 5y → 12 at 10y
- Mean HbA1c: 5.51% at 5y → 5.86% at 10y
- Mean fasting glycemia: 104 mg/dL at 5y → 118 mg/dL at 10y

Safety over 10 years

- No mortality in the series
- 1 gastric leak, 2 anastomotic leaks overall
- **12/164 (7.3%) revised for hypoproteinemia/malnutrition**
- 25% lost to follow-up at 10 years

A DISTINCT CLINICAL QUESTION

Revisional surgery: SADI-S vs RYGB as a second step after failed sleeve

Thomopoulos et al , Langenbeck's Arch Surg 2024 (RYGB vs SADI as revisional procedures) ·

Pooled analysis, 2024 · 7 studies · 419 revisional patients · baseline BMI 51.8 · median 48-month follow-up after revision

Mean %TWL at 5 years:

RYGB : mean of 18%, heterogeneity ++

SADI-S: mean of 30%, more homogeneous

Favors SADI-S	Favors RYGB
- T2D remission 44–94% vs 22–33% - Severe complications (Gr III–IV): 8% vs 14% - Median LOS: 1.6 vs 2.3 days	- GERD / functional symptom resolution up to 90% - RYGB remains the reference when reflux drives the revision

Timing matters too

Harker M et al, Obes Surg 2025 (5-y primary vs secondary SADI-S, n=103)

Dutch multicenter cohort, primary SADI:n=19, secondary SADI:n=84:
5-year %TWL 34.8% after primary SADI-S vs 15.9% after secondary SADI-S (p<0.001);
BODY-Q quality-of-life scores also higher after primary surgery.

SADI-S as a primary procedure offers better results than a secondary procedure

WHAT THE EVIDENCE STILL OWES US

Filling the long-term evidence gap



No study — randomized or observational — has directly compared SADI-S with RYGB beyond ~5 years. Every long-term comparison to date is observational, and none has confirmed durability of weight, metabolic, or safety outcomes with level-1 evidence.



BYPSADIS trial

- RCT · 6 centers, Spain & Portugal · n=450 (1:1), primary procedures only, BMI 40-50
- Co-primary endpoints: %TWL >30% and severe complications at 5 years
- Recruiting since Feb 2025



SADISLEEVE extension study

- Same 381 patients, same 22 centers
- 5-year and 10-year follow-up planned
- **Data currently under analysis**

Closest level-1 signal beyond 5 years comes from classic (double-anastomosis) BPD/DS vs RYGB at 15 years : wider weight gap (%TBWL 37.5% vs 22.8%, $p<0.01$) but more complications (2.7 vs 0.9 events/patient, $p<0.004$) — not SADI-S, but the only long-term RCT in the duodenal-switch family.

Two effective procedures, two distinct long-term profiles

- 1 SADI-S delivers superior weight loss and a trend toward better metabolic control — confirmed at 2 years by RCT, and supported beyond that by consistent observational long-term data.
- 2 That advantage comes with more early surgical complications, more GERD and diarrhea — RYGB trades this for more late mechanical complications and dumping.
- 3 As a revisional procedure after sleeve, SADI-S seems to outperform RYGB on weight and metabolic outcomes (but better outcomes with a primary SADI-S) ; RYGB remains preferred when reflux drives the indication.
- 4 No study, randomized or observational, has directly compared the two procedures beyond 5 years — real answers are coming from the SADISLEEVE extension (5–10y) and the BYPSADIS trial.

One size does not fit all — procedure choice should be individualized.

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