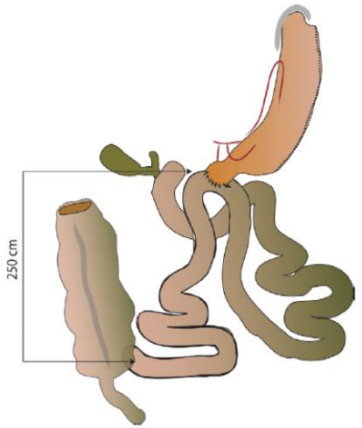
Hospices Civils de Lyon

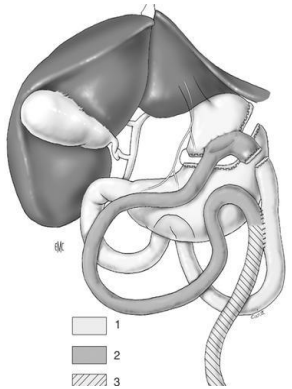
Université Claude Bernard Lyon 1

The SADISLEEVE RCT



Prof. Maud ROBERT
University Hospital of Edouard Herriot, Lyon

On behalf of the SADISLEEVE study group



Robert M et al, The Lancet, 2025

Disclosure Slide

Lilly®: consulting

Novonordisk®: consulting

Viatris®: consulting

Medtronic®: consulting

Intuitive surgery®: expenses

Background and current status of the SADI-S

- Described in 2007 by Sanchez-Pernaute and Torres

Sánchez-Pernaute A et al. Obes Surg 2007

- 1rst endorsement by the ASMBS in 2016

Kim J et al SOARD 2016

- endorsed by the IFSO in 2018

Obes Surg 2018

- Lack of level 1 evidence

Ponce de Leon-Ballesteros G et al. IFSO Position Statement-Update 2023. Obes Surg 2024

no published RCTs comparing SADI-S with RYGB, a long-established and validated standard in bariatric surgery

Direction Générale de l'Offre de Soins

The SADISLEEVE RCT

NCT03610256

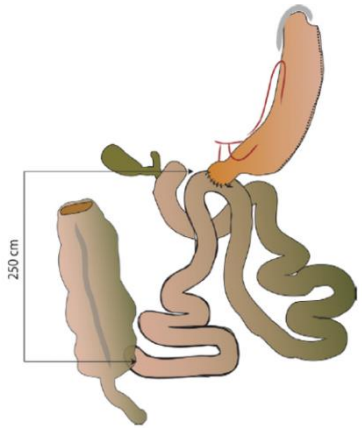
Nationwide multicenter randomized trial of superiority comparing the efficacy and safety of SADI-S versus RYGB, designed in **2017**

Main objective : to demonstrate the **superiority of SADI-S towards RYGB for weight loss** outcomes, using percentage **Excess Weight Loss** (%EWL) criteria at **2 years** post-surgery (Hypothesis: +10% EWL)

Surgical technique

SADI-S or RYGB **as a primary surgery or after suboptimal clinical response of sleeve gastrectomy**

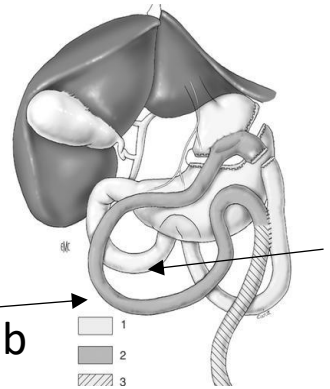
Why including revisional cases? because Sleeve represents > 60% of all bariatric procedures, with up to 30% of recurrent weigth gain : **clinical applicability**



Tailored common channel

300 cm if initial BMI < 50

250 cm if initial BMI ≥ 50



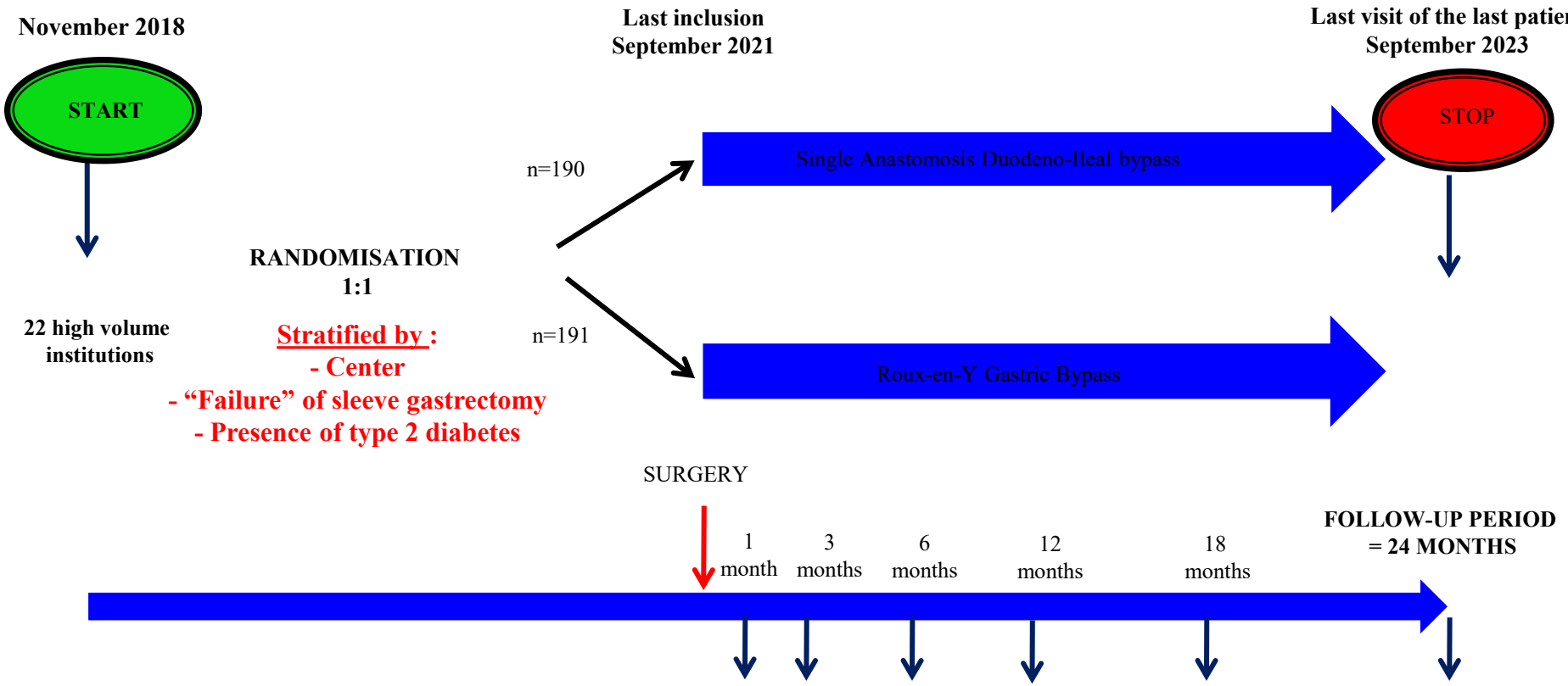
alimentary limb

= 1 m 50

biliary limb

= 50 cm

Design of the study

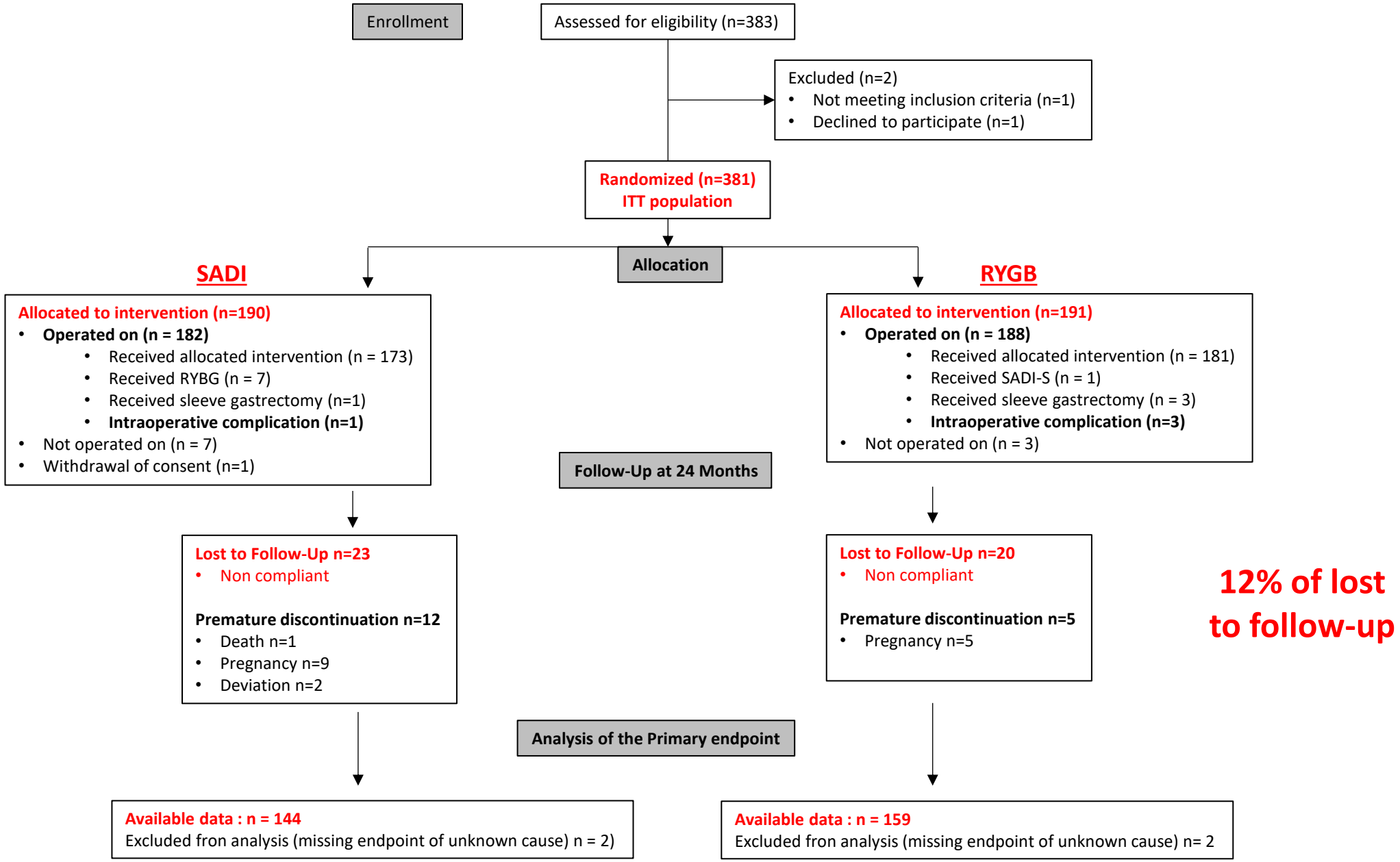


Main Inclusion Criteria
- **BMI ≥ 40 kg/m2 or BMI ≥ 35 kg/m2 +/- comorbidities**
- **SADI-S or RYGB as a primary surgery or after failure of sleeve gastrectomy**

Main Exclusion Criteria
- **History of previous bariatric surgery other than SG**
- **History of type 1 diabetes**

- **Primary outcome**: **%EWL**
- **Secondray outcomes:**
  Weight, %EBL, **%TWL**
  Metabolic profil : Fasting glycemia, HbA1c, HDL, LDL, TG and cholesterol, T2D remission
  Nutritional profil : vitamins A-B1-B9-B12-C-D-E, hemoglobin, albumin, prealbumin, ferritin, saturation coefficient, calcium, iron
  Average number of stools/day, steatorrhea
  Complications rate / Adverse events
  Quality Of Life (SF36, GIQLI)
  Antidiabetic, antihypertensive and antilipidemic treatments
  Use of Continuous Positive Airways Pressure for obstructive sleep apnea
  Dumping syndrome (Sigstad)

Flow chart


Enrollment
Assessed for eligibility (n=383)
Excluded (n=2)
• Not meeting inclusion criteria (n=1)
• Declined to participate (n=1)
Randomized (n=381)
ITT population
Allocation
SADI
RYGB
Allocated to intervention (n=190)
• Operated on (n = 182)
• Received allocated intervention (n = 173)
• Received RYBG (n = 7)
• Received sleeve gastrectomy (n=1)
• Intraoperative complication (n=1)
• Not operated on (n = 7)
• Withdrawal of consent (n=1)
Allocated to intervention (n=191)
• Operated on (n = 188)
• Received allocated intervention (n = 181)
• Received SADI-S (n = 1)
• Received sleeve gastrectomy (n = 3)
• Intraoperative complication (n=3)
• Not operated on (n = 3)
Follow-Up at 24 Months
Lost to Follow-Up n=23
• Non compliant
Premature discontinuation n=12
• Death n=1
• Pregnancy n=9
• Deviation n=2
Lost to Follow-Up n=20
• Non compliant
Premature discontinuation n=5
• Pregnancy n=5
12% of lost to follow-up
Analysis of the Primary endpoint
Available data : n = 144
Excluded fron analysis (missing endpoint of unknown cause) n = 2)
Available data : n = 159
Excluded fron analysis (missing endpoint of unknown cause) n= 2

Baseline characteristics of the ITT population

	SADI-S Group (n=190)	RYGB Group (n=191)	ITT population (n=381)
Mean age, years (Range)	44·0 (10.5)	44·8 (10.8)	44·4 (20-65)
Male gender, n (%)	57 (30%)	58 (30%)	115 (30%)
Mean BMI, kg/m^2 (SD)	46·1 (6·4)	46·3 (6·4)	46·2 (6·4)
BMI ≥ 50 kg/m^2, n (%)	46 (24%)	53 (28%)	99 (26%)
Type 2 Diabetes, n (%)	59 (31%)	60 (31%)	119 (31%)
Mean HbA1c, % (SD)	7·4 (1.8)	7·2 (1.5)	7·3 (1.6)
Mean Duration of diabetes , years (SD)	7·7 (7·3)	5·7 (5·3)	6·7 (6·4)
On diabetes treatment, n (%)	53 (90%)	52 (87%)	105 (88%)
On oral anti-diabetic agents, n (%)	51 (96%)	50 (96%)	101 (96%)
On GLP-1 agonist, n (%)	24 (45%)	22 (42%)	46 (44%)
On Insulin, n (%)	19 (36%)	14 (27%)	33 (31%)
Arterial hypertension, n (%)	82 (43%)	86 (45%)	168 (44%)
Dyslipidaemia, n (%)	69 (37%)	63 (33%)	132 (35%)
Arthrosis, n (%)	55 (29%)	69 (36%)	124 (33%)
Sleep apnoea, n (%)	127 (67%)	135 (71%)	262 (69%)
Primary Sleeve gastrectomy, n (%)	38 (20%)	41 (22%)	79 (21%)

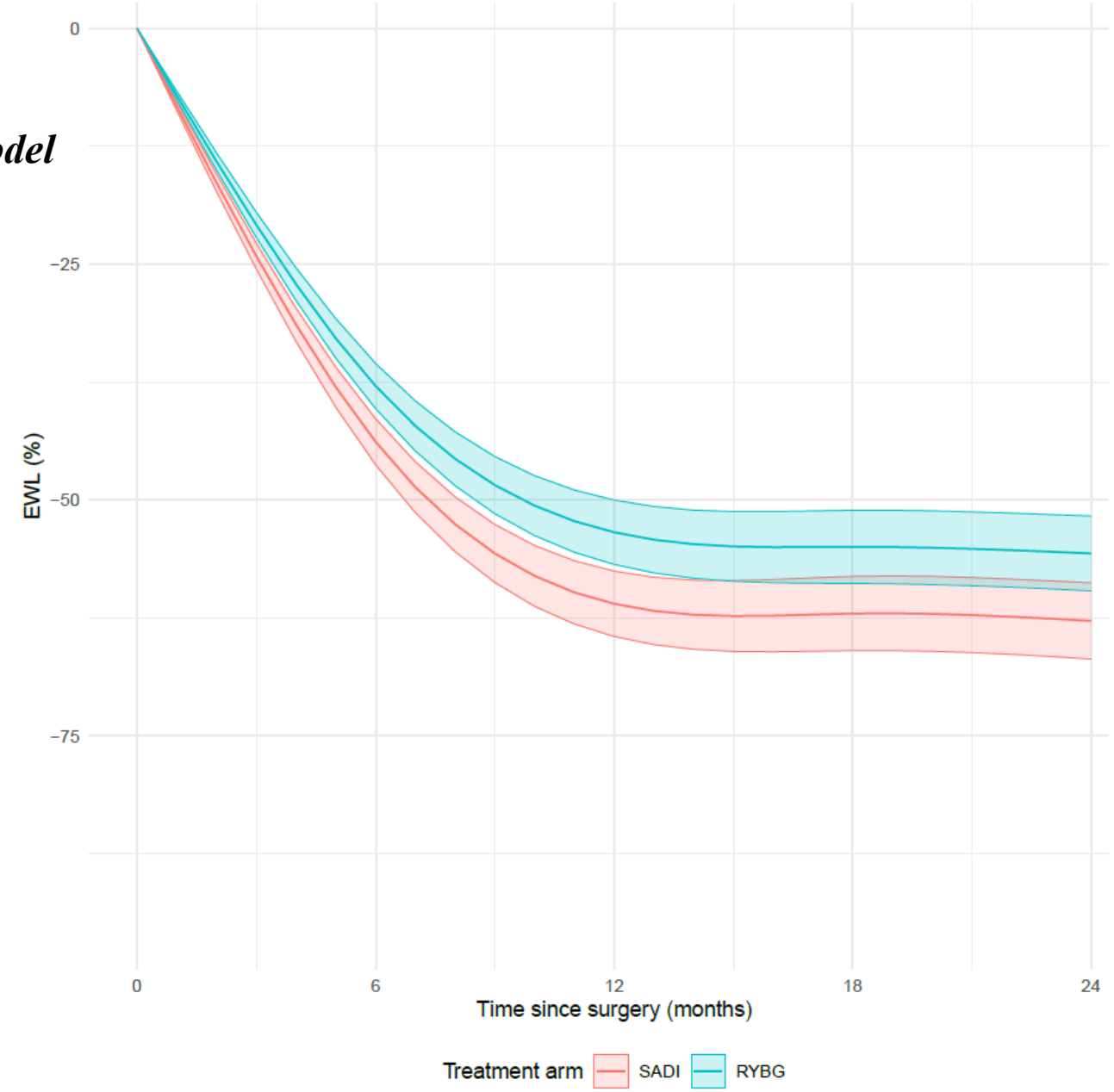
post-hoc analysis

p=0.23

p=0.33

Primary endpoint: %EWL at 2 years (ITT)

Predicted trajectories
linear mixed-effects model



68·09% (SD 28·7)

76.0% (SD 26·65)

mean difference of -6·71% (95% CI: -12·64 to -0·80, p=0·026) confirming the hypothesis of superiority of SADI-S

Secondary endpoint: %TWL at 2 years

Population of analysis	RYBG	SADI	Primary analysis Regression model at 24 months with imputation		Sensitivity analysis Longitudinal regression model	
			Adjusted absolute difference 95% CI	p	Adjusted absolute difference 95% CI	p
ITT	n=191	n=190				
Mean %TWL (SD)	**-30.22 (12.37)**	**-33.30 (11.81)**	**-2·98 [-5·46;-0·49]**	**0·019**	**-3·74 [-6·17;-1·30]**	**0·0028**

Secondary endpoint: glycemic control

	SADI-S Group(n=59)		RYGB Group(n=60)		p
	Baseline	2 Years	Baseline	2 Years	
Patients on medication for diabetes, n (%)	53 (90%)	21 (36%)	52 (87%)	18 (30%)	0·52
n (missing)	59 (0)	59 (0)	60 (0)	60 (0)	
Patients on oral anti-diabetic agents, n (%)	51 (96%)	17 (29%)	50 (96%)	16 (27%)	0·79
n (missing)	53 (6)	59 (0)	52 (8)	60 (0)	
Patients on GLP-1 agonist, n (%)	24 (45%)	3 (5.0%)	22 (42%)	4 (7%)	0·71
n (missing)	53 (6)	59 (0)	52 (8)	60 (0)	
Patients on Insulin, n (%)	19 (36%)	9 (15%)	14 (27%)	8 (13%)	0·76
n (missing)	53 (6)	59 (0)	52 (8)	60 (0)	
Mean HbA1c					
% (SD)	7·4 (1·8)	5·9 (1·3)	7·2 (1·5)	5·8 (1·0)	0·23
mmol/mol (SD)	57·15 (19·10)	40·63 (14·05)	54·94 (16·35)	40·37 (10·64)	
n (missing)	57 (2)	46 (13)	58 (2)	41 (19)	
Remission, n (%)		30 (56·6%)		32 (61·5%)	0·61
n (missing)		53 (6)		52 (8)	

Secondary endpoint: nutritional status

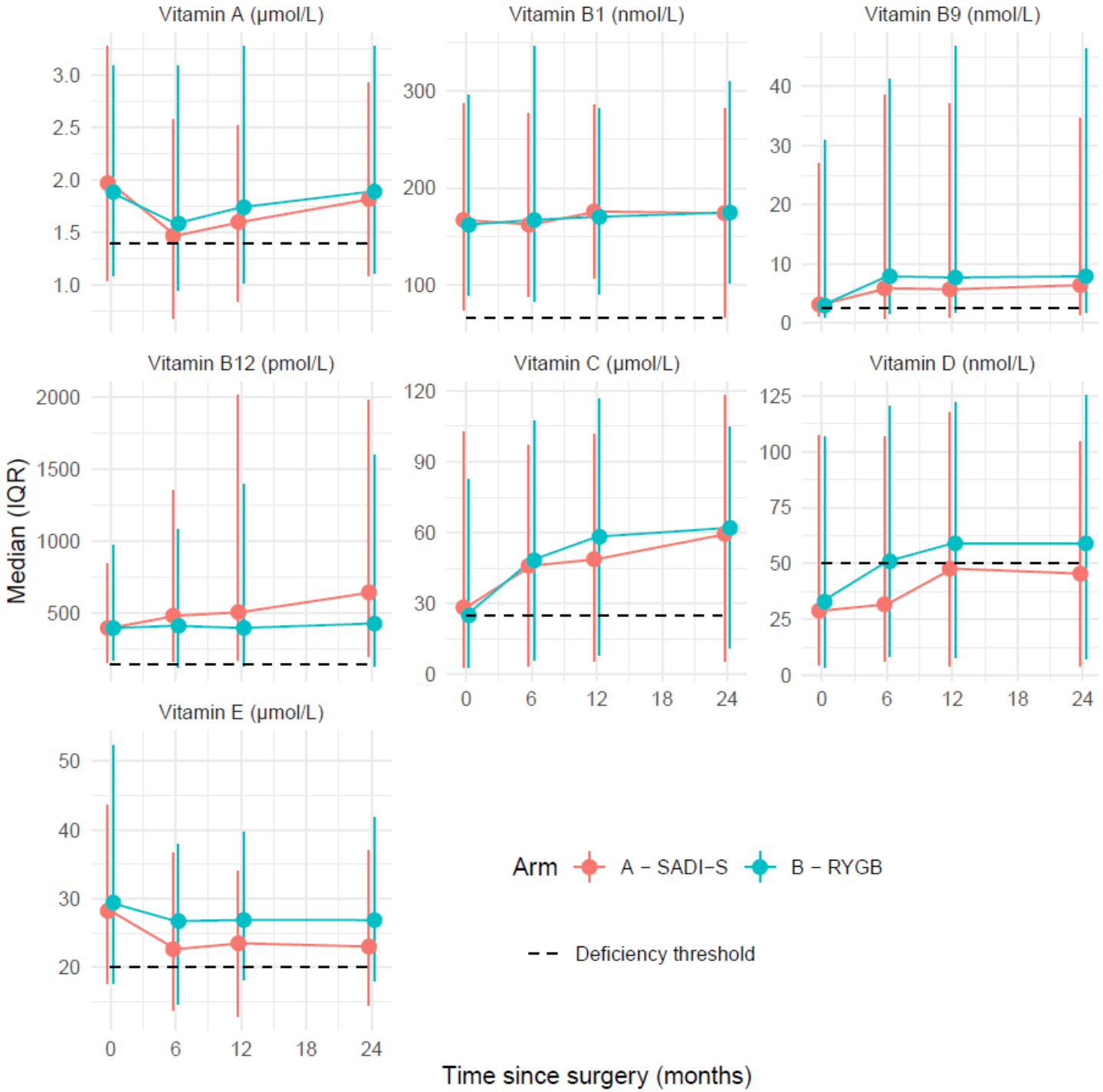
	SADI-S n=190	RYGB n=191	p
Mean albuminemia at 2 years	41·1 g/L (SD 3·37)	41·1 g/L (SD 3·32)	0.88
Mean prealbuminemia	0·24 g/L (SD 0·05)	0·20 g/L SD (0·05)	0.98
Malnutrition*	11.7%	10.6%	NS
Rehospitalization (n)	1	1	

* serum albumin <30 g/L and/or prealbumin <0·20 g/L, or a BMI <18·5 kg/m²

Secondary endpoint: nutritional status

fat-soluble vitamins (A, D, E) and B9 tended to be lower over time in the SADI-S group

Vit B12 was significantly higher in the SADI-S group



Secondary endpoint: surgical complications

	SADI-S Group (n=190)	RYGB Group (n=191)	p-value
Patients with Early surgical complications <30 days, n (%)	**10 (5·6%)**	**3 (1·6%)**	**0·042**
Duodeno-ileal anastomotic leaks	3 (1·7%)	0 (0·0%)	
Gastro-jejunal anastomotic leaks	0 (0·0%)	1 (0·5%)	
Acute anastomotic ulcer	1 (0·6%)	0 (0·0%)	
Intraperitoneal collection	2 (1·1%)	1 (0·5%)	
Wall abscess	2 (1·1%)	1 (0·5%)	
Wall hematoma	3 (1·7%)	1 (0·5%)	
Patients with Late surgical complications >30 days,n (%)	**3 (1·7%)**	**18 (9·4%)**	**0·0009**
Internal hernia	0 (0·0%)	5 (2.6%)	
Bowel occlusion	0 (0·0%)	4 (2.1%)	
Acute anastomotic ulcer	1 (0·5%)	4 (2.1%)	
Incisional hernia	2 (1·1%)	4 (2·1%)	
Vomiting and food intolerance	0 (0·0%)	2 (1·0%)	

Secondary endpoint: early medical complications

	SADI-S Group (n=190)	RYGB Group (n=191)	p
Patients with Early medical complications <30 days, n (%)	**48 (27%)**	**48 (26%)**	**0·85**
Vomiting	18 (10%)	12 (7%)	
Abdominal pain	15 (9%)	9 (5%)	
Diarrhea	21 (12%)	9 (5%)	
Constipation	3 (2%)	5 (3%)	
Symptomatic vitamin deficiency	0 (0·0%)	1 (0·5%)	
Pulmonary embolism	1 (1%)	0 (0·0%)	
Pneumonia	0 (0·0%)	1 (1%)	
Respiratory distress	0 (0·0%)	1 (1%)	
Cardiovascular event	0 (0·0%)	2 (1·1%)	
Anorexia	1 (1%)	0 (0·0%)	
Early Dumping syndrome	8 (4%)	19 (10%)	
Late dumping syndrome	2 (1%)	4 (2%)	

Secondary endpoint: late medical complications

	SADI-S Group (n=190)	RYGB Group (n=191)	p
Patients with Late medical complications **>30 days**, n (%)	76 (43%)	91 (50%)	0·18
Vomiting	17 (9%)	25 (13%)	
Abdominal pain	**15 (8%)**	**26 (14%)**	
Diarrhea	**41 (22%)**	**12 (6%)**	
Constipation	7 (4%)	9 (5%)	
Food intolerance	3 (2%)	3 (2%)	
Protein deficiency	9 (5%)	4 (2%)	
Symptomatic vitamin deficiency	15 (8%)	12 (6%)	
Phlebitis	0 (0%)	0 (0%)	
Pulmonary embolism	0 (0%)	0 (0%)	
Pneumonia	0 (0%)	0 (0%)	
Respiratory distress	0 (0%)	0 (0%)	
Cardiovascular event	0 (0%)	2 (1%)	
Dysphagia	1 (1%)	2 (1%)	
Early Dumping syndrome	0 (0%)	2 (1%)	
Late dumping syndrome	1 (1%)	2 (1%)	

Secondary endpoint: specific medical complications

	SADI-S Group (n=190)	RYGB Group (n=191)	p
Kidney stones (at least once during follow-up)	**10 (5%)**	**8 (4%)**	**0·62**
Surgical treatment for kidney stones	3 (2%)	2 (1·0%)	
Clinical GERD at 2 years	**27 (19%)**	**12 (8%)**	**0.004**
PPI use in GERD patients	26 (18%)	11 (7%)	
Early dumping syndrome (clinical symptoms) at 2 years	**6 (5%)**	**16 (11%)**	**0.039**
Sigstad score >=7 at 2 years	6 (4%)	13 (8%)	0.095
Overall complications of Grade ≥3 (Dindo-Clavien classification)	**13 (13·3%)**	**21 (18·6%)**	**0.29**
Reoperations (early)	4 (7%)	3 (6%)	0.81
Mean hospital stay (days)	**4.8 (SD 7·47)**	**2.8 (SD 2·85)**	**<0.001**
30-day readmission rate	3 (2%)	5 (3%)	0.49

NS

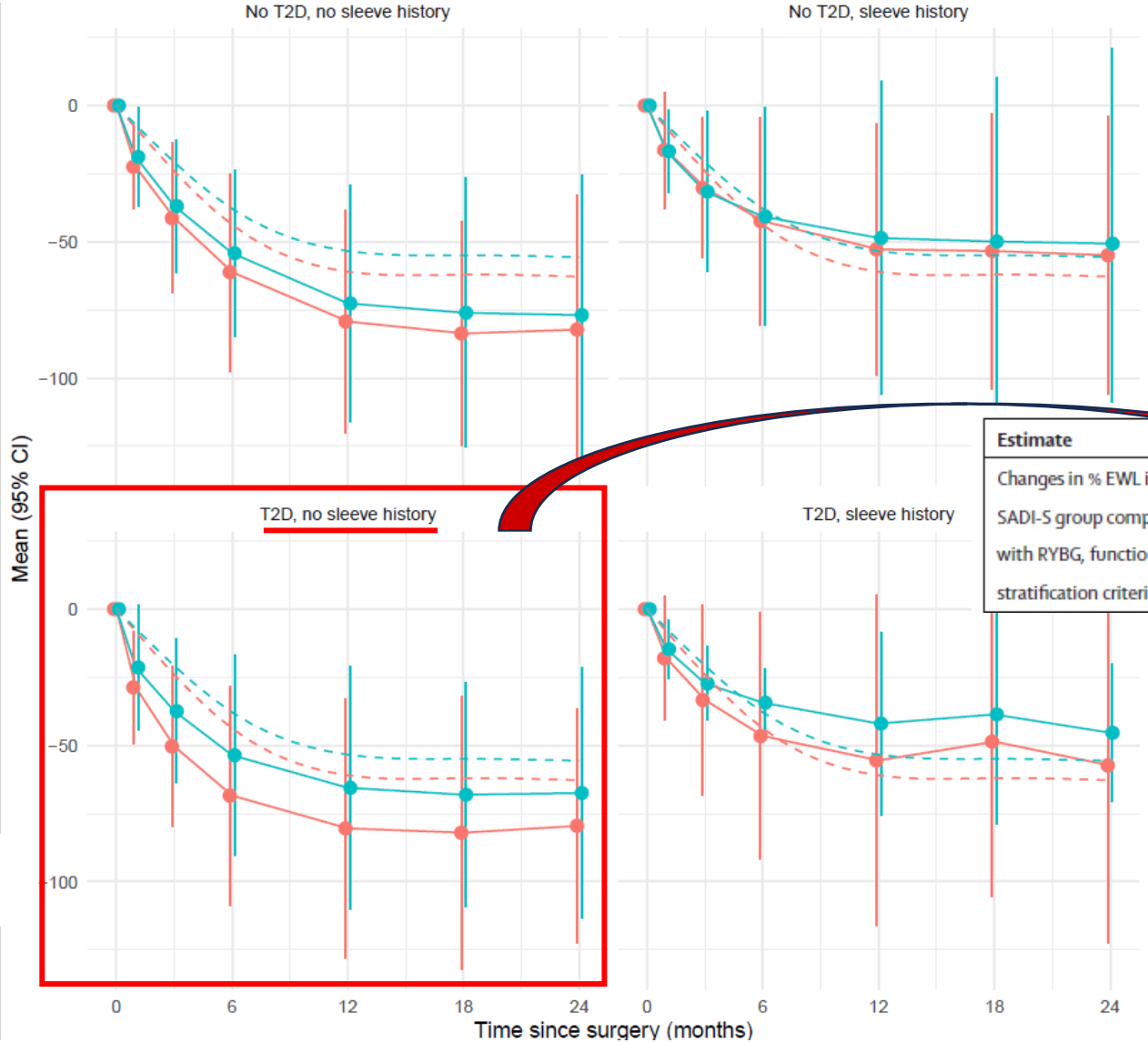
Secondary endpoint: Serious Adverse Events

≥ Grade 3 Dindo-Clavien

	SADI-S Group (n=40)		RYGB Group (n=35)		Safety population (n=175)
	n	Grade	n	Grade	
Abdominal Pain	3 (7·5%)	3	5 (14·4%)	3	8 (10·7%)
Anastomotic ulcer	2 (5·0%)	3	1 (2·8%)	3	3 (4·0%)
Anastomotic leak	3 (7·5%)	grade 4: n=1 grade 3: n=2	1 (2·8%)	3	4 (5·3%)
Nephrolithiasis treated surgically	2 (5·0%)	3	2 (5·7%)	grade 4: n=1 grade 3: n=1	4 (5·3%)
Diarrhea	5 (12·5%)	3	--		5 (6·7%)
Diarrhea with renal failure	2 (5·0%)	3	--		2 (2·6%)
Diarrhea with hypokalemia	1 (2·5%)	3	--		1 (1·3%)
Intraabdominal collection	2 (5·0%)	3	1 (2·8%)	3	3 (4·0%)
Acute myocardial infarction	--		1 (2·8%)	4	1 (1·3%)
Anal fissure	1 (2·5%)	3	--		1 (1·3%)
Anorexia	1 (2·5%)	3	--		1 (1·3%)
Bile duct leak	1 (2·5%)	4	--		1 (1·3%)
Cholelithiasis	6 (15·0%)	3	6 (17·5%)	3	12 (16·0%)
Depression with Suicide attempt	--		1 (2·8%)	4	1 (1·3%)
Completed suicide	1 (2·5%)	5	--		1 (1·3%)
Inadequate control of T2D	1 (2·5%)	3	--		1 (1·3%)
Duodenal injury	1 (2·5%)	3	--		1 (1·3%)
Food intolerance and vomiting due to hiatal hernia	1 (2·5%)	3	--		1 (1·3%)
Gastrointestinal anastomotic leak	1 (2·5%)	3	1 (2·8%)	3	2 (2·7%)
Gastrointestinal hemorrhage	--		1 (2·8%)	3	1 (1·3%)
Hypoglycemia	--		1 (2·8%)	3	1 (1·3%)
Ileal stenosis due to ischemia	--		1 (2·8%)	3	1 (1·3%)
Incision site abscess	1 (2·5%)	3	--		1 (1·3%)
Incisional hernia	1 (2·5%)	3	3 (8.8%)	3	4 (5·3%)
Internal hernia			5 (14.4%)	grade 4: n=1 grade 3: n=4	5 (6·7%)
Liver failure due to Malnutrition and cirrhosis	1 (2·5%)	4	--		1 (1·3%)
Malnutrition	--		1 (2·8%)	3	1 (1·3%)
Mesenteric hematoma/ileus	--		1 (2·8%)	3	1 (1·3%)
Peritoneal hematoma	1 (2·5%)	3	--		1 (1·3%)
Postoperative ileus	1 (2·5%)	3	--		1 (1·3%)
Pulmonary embolism	1 (2·5%)	3	--		1 (1·3%)
Splenic infarction	--		1 (2·8%)	3	1 (1·3%)
Strangulated umbilical hernia	--		1 (2·8%)	3	1 (1·3%)
Intraoperative ventilation problems	--		1 (2·8%)	3	1 (1·3%)

Post-Hoc analysis: impact of T2D and history of SG (stratification criteria) on %EWL trajectories

Predicted trajectories
linear mixed-effects model



Estimate	Subgroup	Coefficient	CI	p value
Changes in % EWL in the SADI-S group compared with RYBG, function of stratification criteria	No sleeve history, no T2D	−4·56	−12·96 to 3·84	0·2861
	Sleeve history, no T2D	−5·69	−20·42 to 9·04	0·4479
	No sleeve history, T2D	−11·75	−22·71 to −0·79	0·0357
	Sleeve history, T2D	−6·70	−32·65 to 19·25	0·6118

Solid lines: subgroup data
Dashed lines: overall population

Post-hoc analysis: effect of %EWL and surgical procedure on T2D remission (after adjusting for baseline diabetes duration and insulin use)

	Odds Ratio (OR)	CI	p value
OR for a -10 %EWL	0·99	[0·79;1·23]	0·8987
OR for the SADI vs. RYBG	1·23	[0·43;3·57]	0·6899
OR for +1 year duration of T2D before surgery	0·93	[0·85;1·03]	0·1495
OR for insulin use at baseline (yes vs. no)	0·17	[0·06;0·50]	0·0019

No effect of %EWL on T2D remission

Insulin use at baseline is a strong negative predictor of remission

for each additional year of T2D duration, the probability of remission decreased by approximately 7%

higher probability of remission for SADI-S compared with RYBG but not significant

Conclusion

- SADI-S > RYGB in terms of %EWL at 2 years
- Comparable safety, no severe malnutrition under appropriate supplementation and close follow-up
- more early surgical complications but less late surgical complications
- Increased rate of diarrhea, less dumping syndrome
- SADI-S is a valid bariatric procedure, especially for patients without a history of previous SG and with T2D

Acknowledgements

Prof Tigran Poghosyan MD, Department of Digestive, oncologic and Bariatric Surgery, Paris AP-HP

Dr Nicolas Romain-Scelle MD, Biostatistics Department, Hospices Civils de Lyon,

Prof Sebastien Czernikow MD, Department of Nutrition, Hôpital Européen Georges Pompidou

Dr Dominique Delaunay PhD, Department of Digestive and Bariatric Surgery, Hospices Civils de Lyon

Dr Adrien Sterkers, MD, Department of Digestive, Hepatobiliary Surgery, Centre Hospitalier Privé Saint Grégoire, Dr Lita Khamphommala MD,, Centre Hospitalier Privé Saint Gregoire,

Dr Andréa Lazzati MD, Department of Digestive and Bariatric Surgery, AP-HP

Prof Claire Blanchard MD, Chirurgie Cancérologique, Digestive Et Endocrinienne, Nantes
Prof Robert Caiazzo MD, General and Endocrine Surgery Department, Huriez Hospital, Lille

Professor François Pattou MD, General and Endocrine Surgery Department, Huriez Hospital, Lille, Université Lille 2, France

Professor Emmanuel Disse MD, Department of Endocrinology,, Hospices Civils de Lyon

Professor Caroline Gronnier MD, Department of Digestive and Endocrine Surgery, Université de Bordeaux
Professor Fabian Reche MD, Digestive Surgery Department, Grenoble

Doctor Philippe Topart MD, Digestive and visceral Surgery, Angers

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Doctor Philippe Raffaitin MD, Clinique Mutualiste de l'Estuaire- Digestive, Endocrine and Bariatric Surgery Deparment, Saint Nazaire

Doctor Nelson Trelles MD, Digestive Surgery Department, Cergy-Pontoise

Doctor Iole Siciliano MD, Hopitaux Civils de Colmar, Hopital Louis Pasteur, Digestiveand thoracic Surgery Colmar

Professor Laurent Brunaud MD, Department of Digestive, Hepatobiliary, Endocrine Surgery, and Surgical Oncology, Nancy

Doctor Daniel Krawczykowski MD, Centre Hospitalier Jean Marcel, Digestive and visceral Surgery Department, Brignoles

Doctor Géraud Tuyeras MD, Digestive Surgery Department, Hôpital Rangueil - CHU de Toulouse
Doctor Adriana Torcivia MD, Department of Digestive, Hepatobiliary Surgery, Hôpital Pitié Salpétrière, Paris

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