La saga du bypass en Oméga: d'YOMEGA-1 à YOMEGA-2

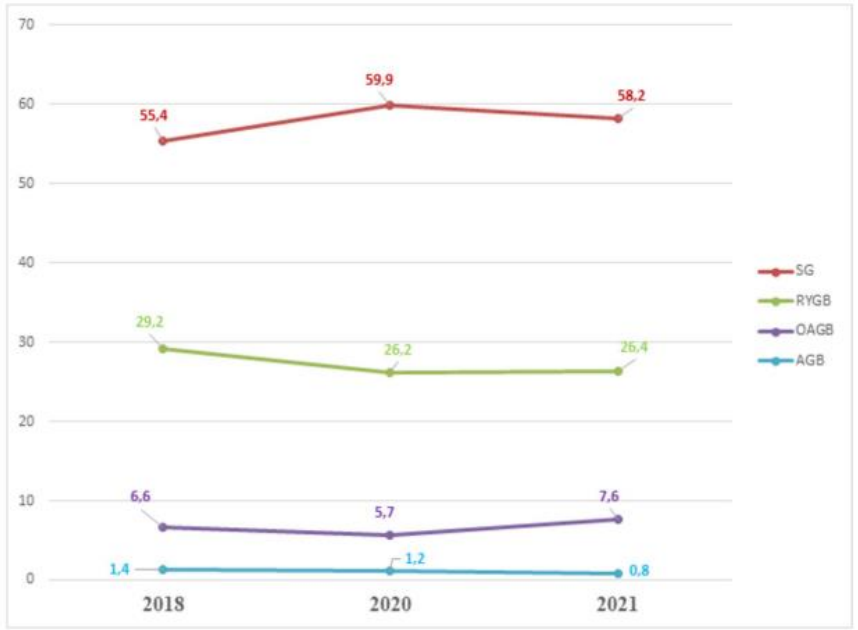
Tigran Poghosyan

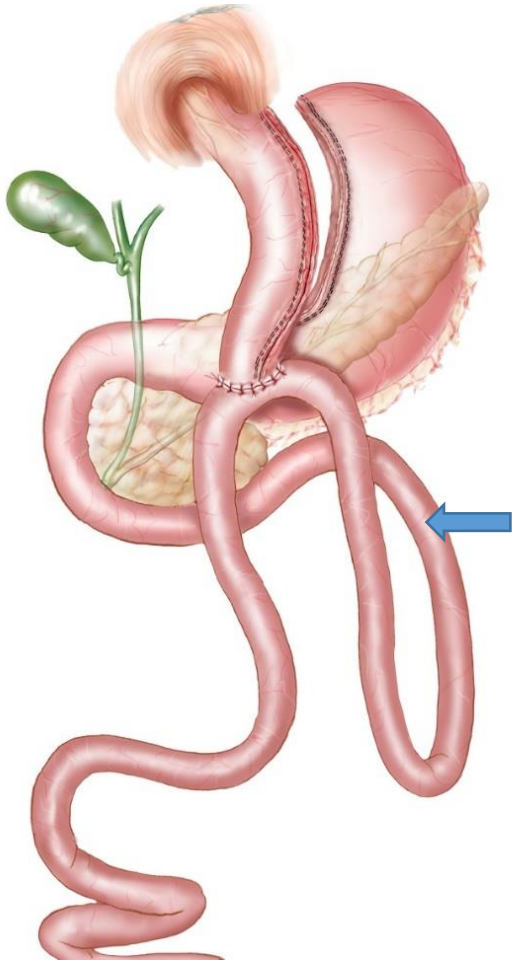
Hôpital Bichat Claude-Bernard AP-HP

Université Paris Cité

Contexte: One-Anastomosis Gastric Bypass (OAGB)

- Décrit en 2001 par Rutledge (USA)
- Actuellement 3ème intervention la plus réalisée dans le monde (7,6%)
- Facilité technique
  - Une seule anastomose
  - Facilement reproductible
  - Gain de temps
- Morbidité précoce faible
- Perte pondérale efficace et durable +++
- Amélioration des comorbidités +++





Anse bilio-pancréatique: 200cm

Rutledge Obes Surg 2001

Angrisani *et al.* Obes Surg 2024

YOMEGA-1

Dénutrition

ORIGINAL CONTRIBUTIONS

A 7-Year Clinical Audit of 1107 Cases Comparing Sleeve Gastrectomy, Roux-En-Y Gastric Bypass, and Mini-Gastric Bypass, to Determine an Effective and Safe Bariatric and Metabolic Procedure

Table 2 Comparative complications between procedures

Procedure	LSG	RYGB	MGB
No. of bariatric surgery performed	339	295	473
No. of leaks	5	1	0
Mild hypoalbuminemia (3.5–2.5 g/dl)	0	6	44
Severe hypoalbuminemia (<2.5 g/dl)	0	0	18
Anemia	12	14	23
Gerd	32	5	3
Internal hernia	0	6	0
Dumping	0	8	28
Mortality	7	1	0
Less of excess weight loss (%EWL <50 %)	45	19	0
Weight regain	48	25	0

Jammu et al Obes Surg 2016

Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass for obesity (YOMEGA): a multicentre, randomised, open-label, non-inferiority trial

	Total (n=66)	RYGB group (n=24)	OAGB group (n=42)
Nutritional complications	9 (14%)	..	9 (21%)
Anastomotic ulcer	5 (8%)	3 (13%)	2 (5%)
Reflux	3 (5%)	..	3 (7%)
Bowel obstruction	4 (6%)	3 (13%)	1 (2%)
Abdominal pain	5 (8%)	5 (21%)	..
Diarrhoea or anal fissures	6 (9%)	..	6 (14%)
Vesicular lithiasis	13 (20%)	5 (21%)	8 (19%)
Urinary lithiasis	3 (5%)	..	3 (7%)
Early peritonitis	4 (6%)	1 (4%)	3 (7%)
Abdominal wall haematoma or abscess	3 (5%)	3 (13%)	..
Vomiting	2 (3%)	2 (8%)	..
Incisional hernia	1 (2%)	..	1 (2%)
Haemoperitoneum	1 (2%)	1 (4%)	..
Kidney failure by dehydration	1 (2%)	..	1 (2%)
Gastrogastric fistula	1 (2%)	1 (4%)	..
Anticoagulant overdose	1 (2%)	..	1 (2%)
Revision from OAGB to RYGB	4 (6%)	..	4 (10%)

Data are n (%). p value for difference in frequency nutritional complications between the RYGB group and OAGB group is 0·0034. RYGB=Roux-en-Y gastric bypass. OAGB=one anastomosis gastric bypass.

Table 5: Serious adverse events associated with surgery at 2 years of follow-up

Robert et al Lancet 2019

Dénominateur commun → Anse BP: 200 cm ou plus

YOMEGA-1

Reflux biliaire?

	Total (n=66)	RYGB group (n=24)	OAGB group (n=42)
Nutritional complications	9 (14%)	..	9 (21%)
Anastomotic ulcer	5 (8%)	3 (13%)	2 (5%)
Reflux	3 (5%)	..	3 (7%)
Bowel obstruction	4 (6%)	3 (13%)	1 (2%)
Abdominal pain	5 (8%)	5 (21%)	..
Diarrhoea or anal fissures	6 (9%)	..	6 (14%)
Vesicular lithiasis	13 (20%)	5 (21%)	8 (19%)
Urinary lithiasis	3 (5%)	..	3 (7%)
Early peritonitis	4 (6%)	1 (4%)	3 (7%)
Abdominal wall haematoma or abscess	3 (5%)	3 (13%)	..
Vomiting	2 (3%)	2 (8%)	..
Incisional hernia	1 (2%)	..	1 (2%)
Haemoperitoneum	1 (2%)	1 (4%)	..
Kidney failure by dehydration	1 (2%)	..	1 (2%)
Gastrogastric fistula	1 (2%)	1 (4%)	..
Anticoagulant overdose	1 (2%)	..	1 (2%)
Revision from OAGB to RYGB	4 (6%)	..	4 (10%)

Data are n (%). p value for difference in frequency nutritional complications between the RYGB group and OAGB group is 0·0034. RYGB=Roux-en-Y gastric bypass. OAGB=one anastomosis gastric bypass.

Table 5: Serious adverse events associated with surgery at 2 years of follow-up

	RYGB group (n=63)	OAGB group (n=58)
Gastritis	4 (6%)	11 (19%)
Presence of bile in the stomach	0	9 (16%)
Oesophagitis	2 (3%)	6 (10%)
Grade A	1	4
Grade B	1	1
Grade C	0	1
Gastric biopsy	63	57
Normal mucosa	51 (81%)	44 (77%)
Gastritis	11	12
Metaplasia	0	1
Oesophageal biopsy	59	56
Normal mucosa	51 (86%)	43 (77%)
Oesophagitis	8	12
Metaplasia	0	1

Data are n (missing data), n (%), or n. RYGB=Roux-en-Y gastric bypass. OAGB=one anastomosis gastric bypass.

Table 4: Endoscopic findings at 2 years of follow-up

Robert et al Lancet 2019

HAUTE AUTORITÉ DE SANTÉ

Concernant le BPGO réalisé avec une anse BP à 150 cm, trop peu de données sont actuellement disponibles - en particulier pas de données comparatives par rapport au BPGY et uniquement des « avis d'experts » - pour pouvoir conclure quant à son efficacité et sa sécurité. **Le BPGO avec une anse BP à 150 cm relève donc à ce jour du champ de la recherche clinique et devrait bénéficier de la réalisation d'études contrôlées randomisées multicentriques permettant d'évaluer son efficacité et sa sécurité**. L'évaluation de l'efficacité devrait se fonder sur un critère composite intégrant, en plus de la perte de poids à long terme (cinq ans), la résolution des comorbidités et la qualité de vie mesurée par des scores validés. L'évaluation de la sécurité devrait intégrer un examen par fibroscopie à cinq ans compte tenu du risque de cancer du bas œsophage. Le taux de perdus de vue de-

Bypass gastrique en oméga

Mini Gastric Bypass-One Anastomosis Gastric Bypass (MGB-OAGB)-IFSO Position Statement

Reconnu en 2018 par IFSO

Reconnu en 2023 par ASMBS

Recommendation of the IFSO MGB-OAGB Taskforce

Based on the existing data, we recommend the following:

1. OAGB should be the identifier for this procedure in future publications.
2. Whilst early results are promising in terms of weight and T2DM management, there is a lack of long-term evidence for durability of effect as well as long-term nutritional complications. Bile reflux is either under reported or does not seem to be a major issue, but remains a theoretical risk. Patients should be encouraged to remain in long-term multidisciplinary care.
3. Patients undergoing OAGB in the revisional setting have less weight loss and more complications than with primary procedures.
4. Surgeons performing this, as well as any other bariatric/metabolic procedure, are encouraged to participate in a national or international registry so that long-term data may be more effectively identified.
5. OAGB is a recognised bariatric/metabolic procedure and should not be considered investigational.

OAGB vs RYGB

Résultats à 5 ans du PHRC YOMEGA-1

Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass at 5 years (YOMEGA): a prospective, open-label, non-inferiority, randomised extension study

Maud Robert, Tigran Poghosyan, Delphine Maucort-Boulch, Alexandre Filippello, Robert Caiazzo, Adrien Sterkers, Lita Khamphommala, Fabian Reche, Vincent Malherbe, Adriana Torcivia, Toufic Saber, Dominique Delaunay, Carole Langlois-Jacques, Augustin Suffisseau, Sylvie Bin, Emmanuel Disse, François Pattou

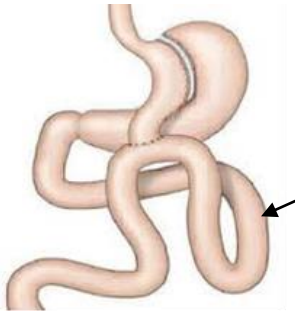
Lancet Diab Endocrinol 2024

Methods

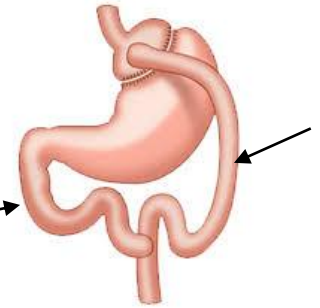
YOMEGA = multicenter randomized controlled trial of non inferiority designed in **2013 comparing OAGB to RYGB**

ClinicalTrials.gov NCT02139813

Technique:



biliopancreatic limb
= 200 cm

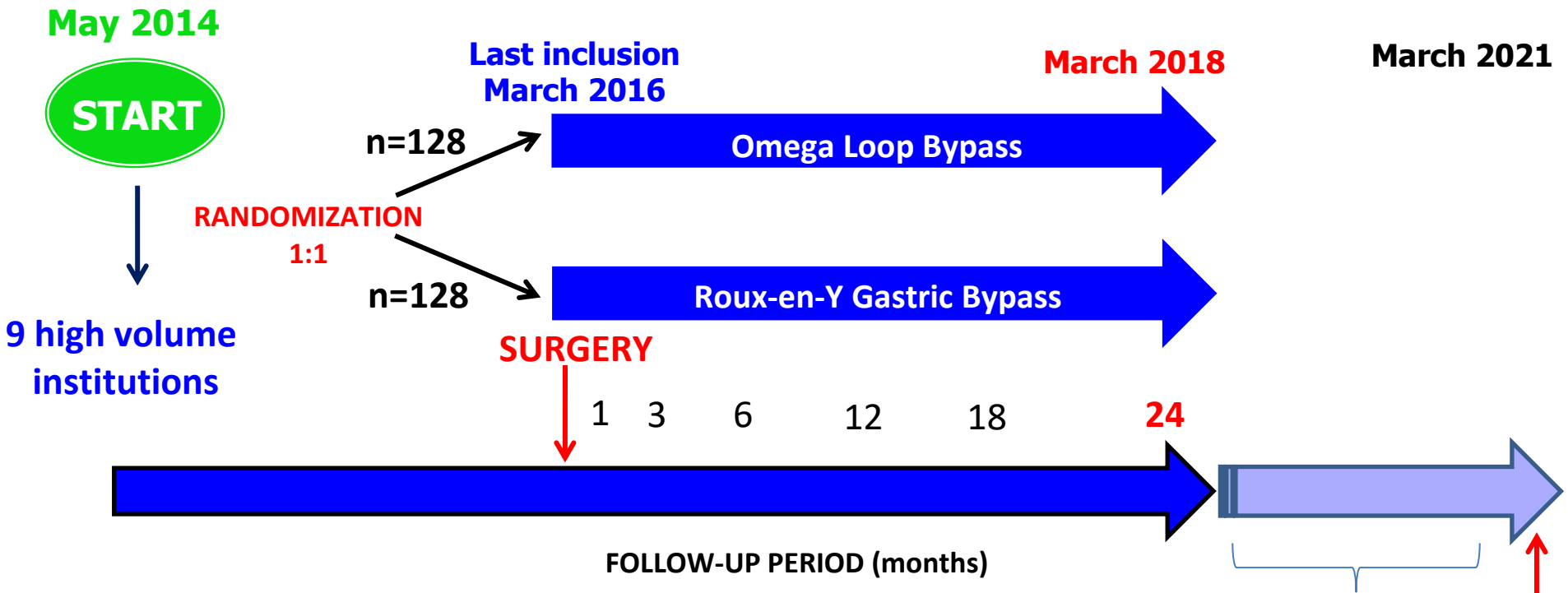


alimentary limb
= 150 cm

biliary limb
= 50 cm

Primary end point: EBL% at 2 years *Lancet 2019*
and **at 5 years**

Study Design



Inclusion Criteria

BMI ≥ 40 kg/m2

or BMI ≥ 35 kg/m2 +/- comorbidities

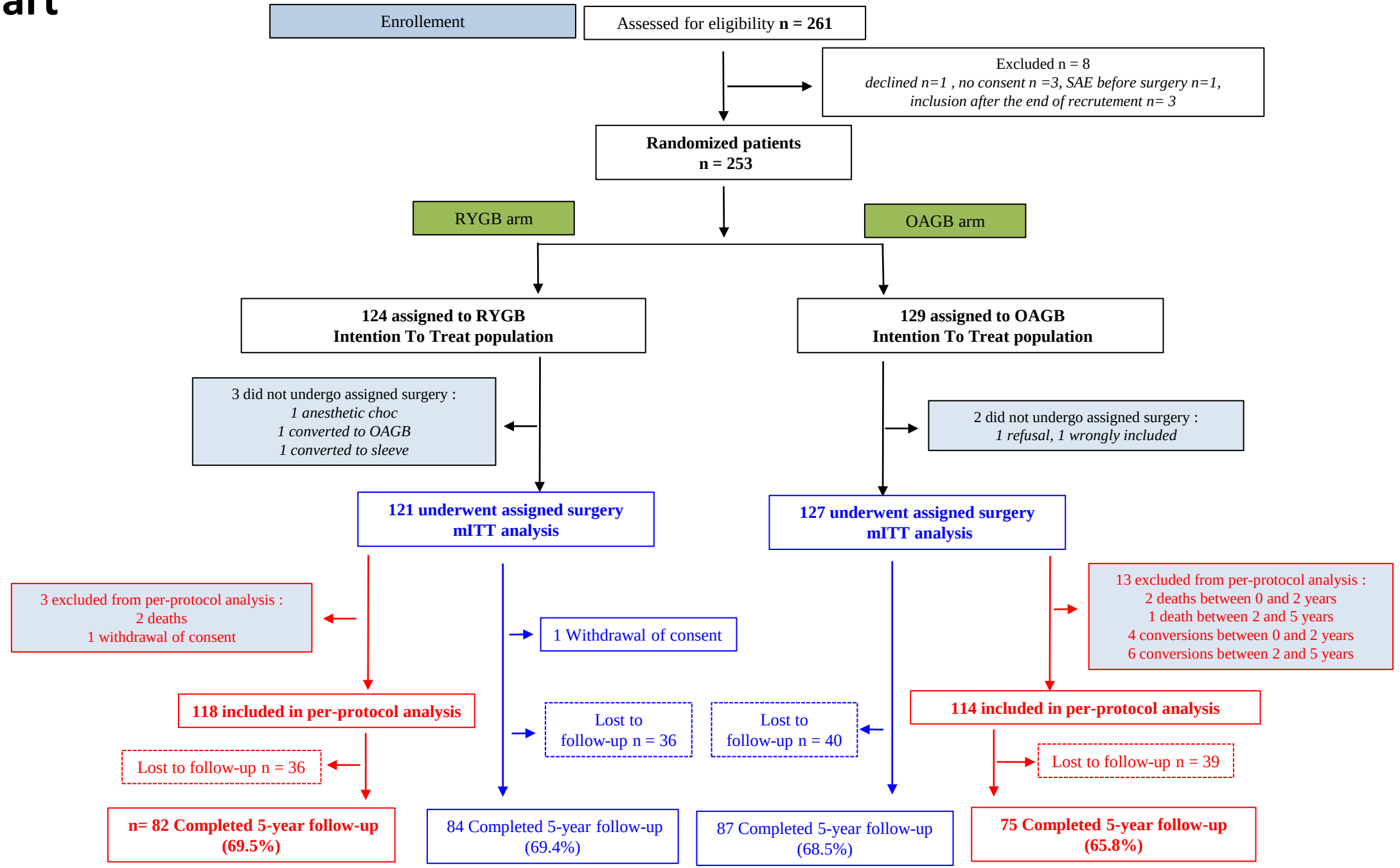
Exclusion Criteria

History of esophagitis or Barrett

Severe GERD

History of previous bariatric surgery

Flow-chart


Enrollement
Assessed for eligibility n = 261
Excluded n = 8
declined n=1 , no consent n =3, SAE before surgery n=1,
inclusion after the end of recrutement n= 3
Randomized patients
n = 253
RYGB arm
OAGB arm
124 assigned to RYGB
Intention To Treat population
129 assigned to OAGB
Intention To Treat population
3 did not undergo assigned surgery :
1 anesthetic choc
1 converted to OAGB
1 converted to sleeve
2 did not undergo assigned surgery :
1 refusal, 1 wrongly included
121 underwent assigned surgery
mITT analysis
127 underwent assigned surgery
mITT analysis
3 excluded from per-protocol analysis :
2 deaths
1 withdrawal of consent
1 Withdrawal of consent
13 excluded from per-protocol analysis :
2 deaths between 0 and 2 years
1 death between 2 and 5 years
4 conversions between 0 and 2 years
6 conversions between 2 and 5 years
118 included in per-protocol analysis
Lost to
follow-up n = 36
Lost to
follow-up n = 40
114 included in per-protocol analysis
Lost to follow-up n = 36
Lost to follow-up n = 39
n= 82 Completed 5-year follow-up
(69.5%)
84 Completed 5-year follow-up
(69.4%)
87 Completed 5-year follow-up
(68.5%)
75 Completed 5-year follow-up
(65.8%)

Results

Baseline characteristics of the per-protocol (PP) population

	RYGB (n=118)	OAGB (n=114)	TOTAL (n=232)
Mean Age in Years (SD)	**42.2 (10.29)**	**43.8 (11.31)**	**43.0 (10.81)**
Male Gender, n (%)	25 (21.2%)	29 (25.4%)	54 (23.3%)
Mean Initial BMI in Kg/m² (SD)	**44 (5.11)**	**44 (6.08)**	**44 (5.6)**
Initial BMI $\geq$ 50, n (%)	13 (11%)	15 (13.2%)	28 (12,1%)
Type 2 diabetes, n (%)	**28 (26.7%)**	**27 (26.5%)**	**55 (26.6%)**

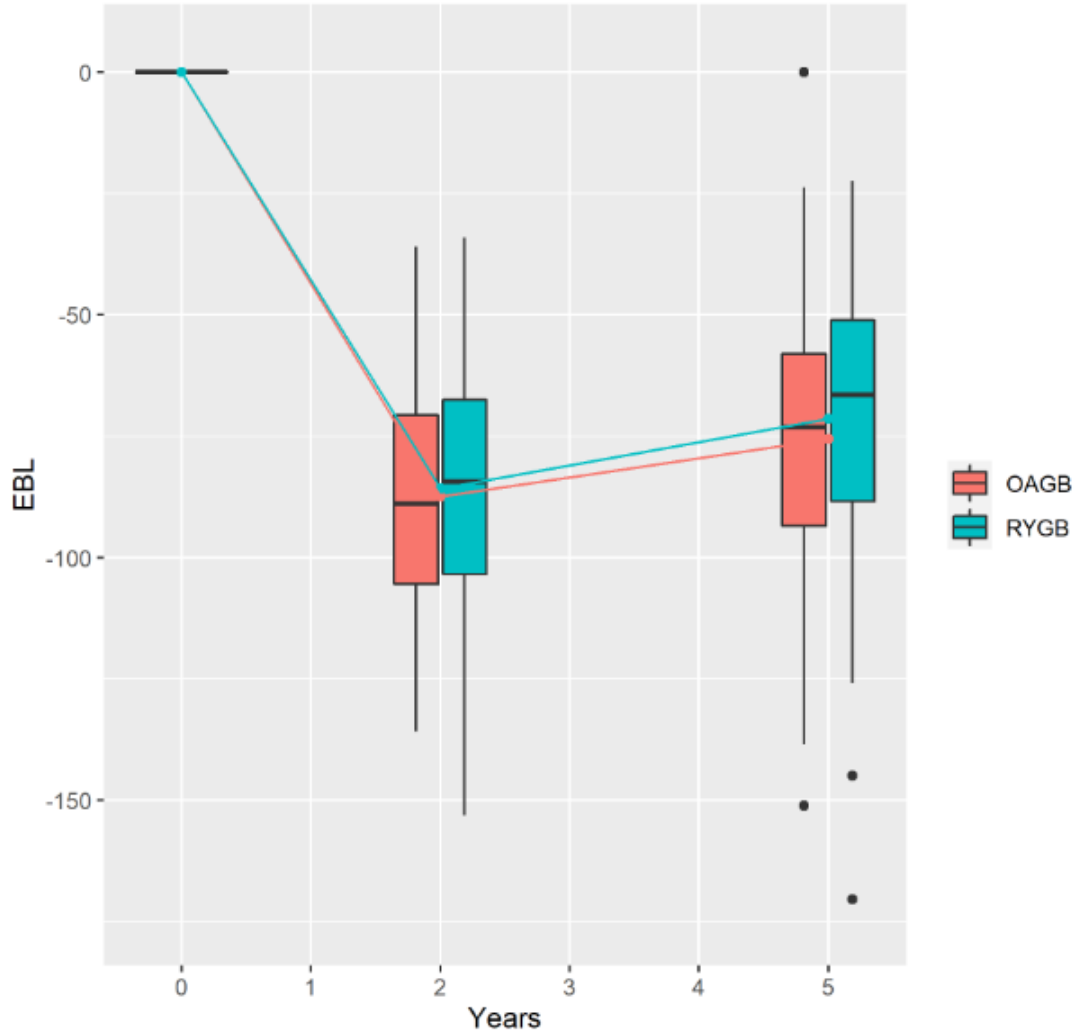
Results

Baseline characteristics of the population with Type 2 Diabetes (T2D)

	RYGB (n=28)	OAGB (n=27)	TOTAL (n=55)
Mean duration of T2D in years (SD)	**6.8 (7.09)**	**7.8 (6.12)**	**7.3 (6.6)**
Mean HbA1c % (SD)	**7.5 (1.77)**	**7.7 (1.56)**	**7.6 (1.66)**
Mean fasting glycemia in mmol/l (SD)	8 (2.36)	8.9 (3.12)	8.5 (2.77)
On insulin, n (%)	**7 (25%)**	**9 (33.3%)**	**16 (29.1%)**
On oral antidiabetic treatment, n (%)	21 (75%)	21 (71.4%)	42 (76.4%)
On GLP1 analogs, n (%)	6 (21.4%)	7 (25.9%)	13 (23.6%)

Results

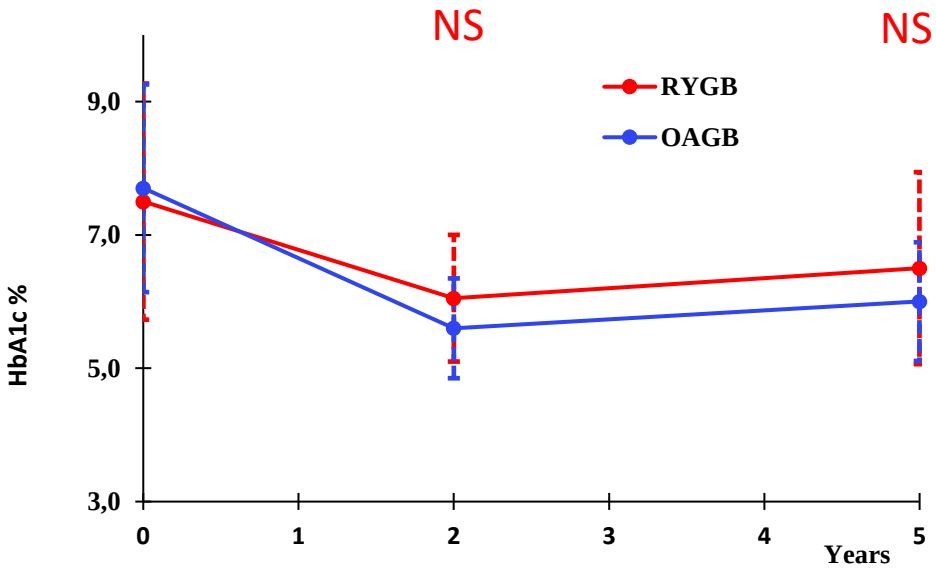
EBL% at 5 years (PP Population)



	baseline	2 years	5 years
OAGB (n)	114	-87.4% (71)	-75.6% (72)
RYGB (n)	118	-85.8% (85)	-71.4% (78)
		-1.55 % 90% CI p non-inferiority = 0.01	-4.15 % 90% CI (12-6.7) p non-inferiority = 0.001

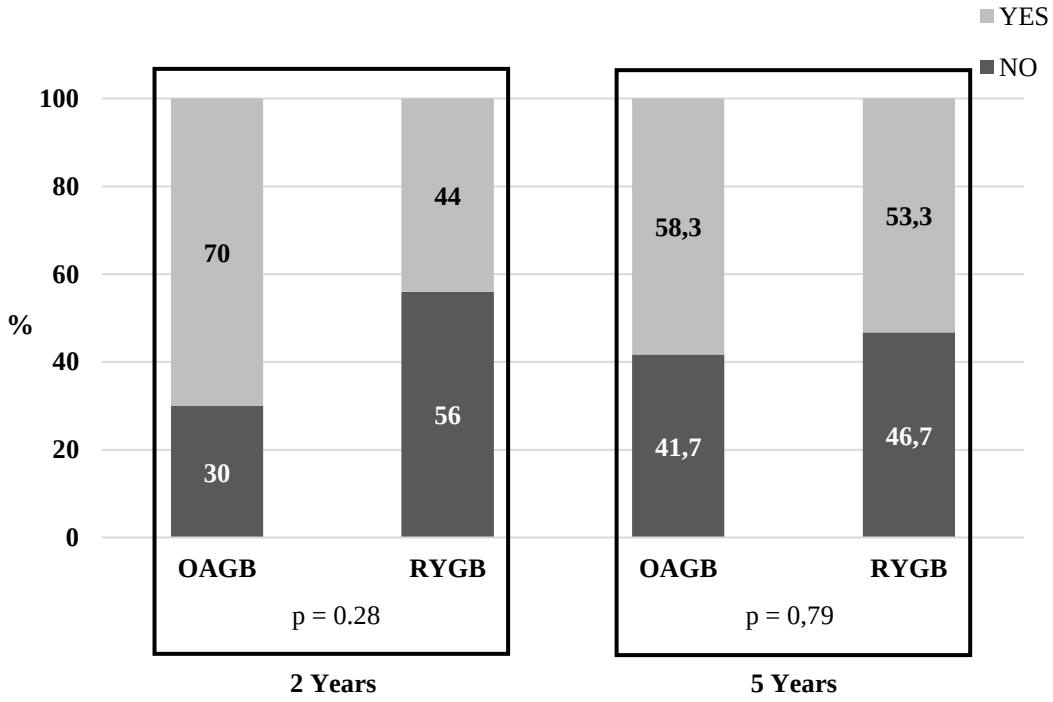
Results

Metabolic results in patients with T2D at 5 years



	baseline	2 years	5 years
OAGB	n=26	5.6% (0.77)	6.0% (0.89)
RYGB	n=28	6.1% (0.95)	6.5% (1.44)

Evolution of HbA1c (Per-Protocol population)



Remission of Type 2 Diabetes

HbA1c < 6.5%, with no antidiabetic drugs

Results

Evolution of T2D treatments

	RYGB group (n=28)			OAGB group (n=27)			p value for baseline	p value for 2 years of follow-up	p value for 5 years of follow-up
	Baseline	2 years of follow-up	5 years of follow-up	Baseline	2 years of follow-up	5 years of follow-up			
Oral antidiabetic agents	21 (75%)	6 (21%)	0	21 (78%)	4 (15%)	4 (15%)	0·81	0·53	0·034
GLP-1 agonist	6 (21%)	2 (7%)	3 (11%)	7 (26%)	0	0	0·69	0·16	0·080
Insulin	7 (25%)	3 (11%)	4 (14%)	9 (33%)	2 (7%)	1 (4%)	0·49	0·67	0·17

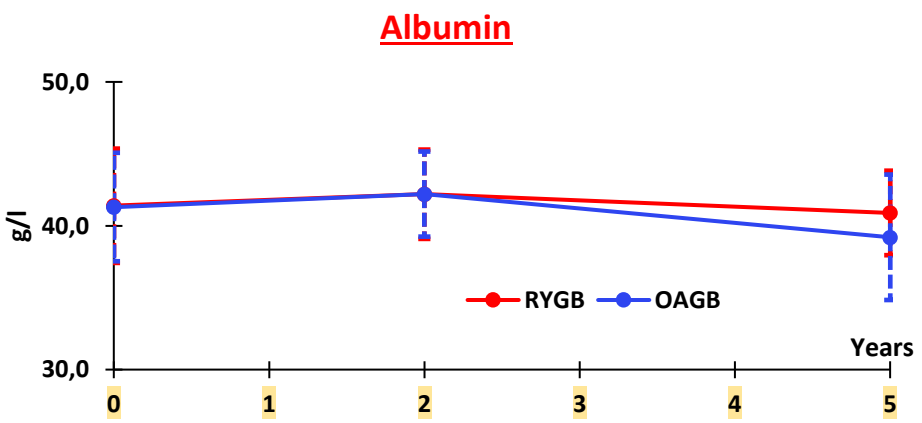
OAGB=one anastomosis gastric bypass. RYGB=Roux-en-Y gastric bypass.

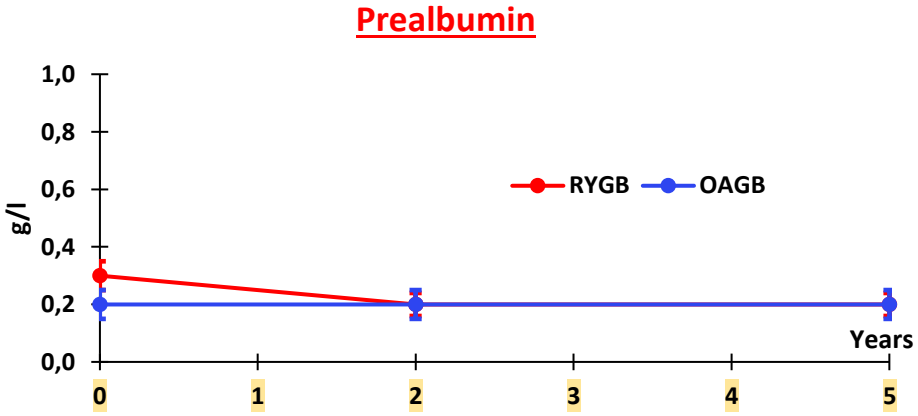
Table 2: Antidiabetic drugs at baseline, 2 years of follow-up, and 5 years of follow-up in patients with type 2 diabetes in the per-protocol population

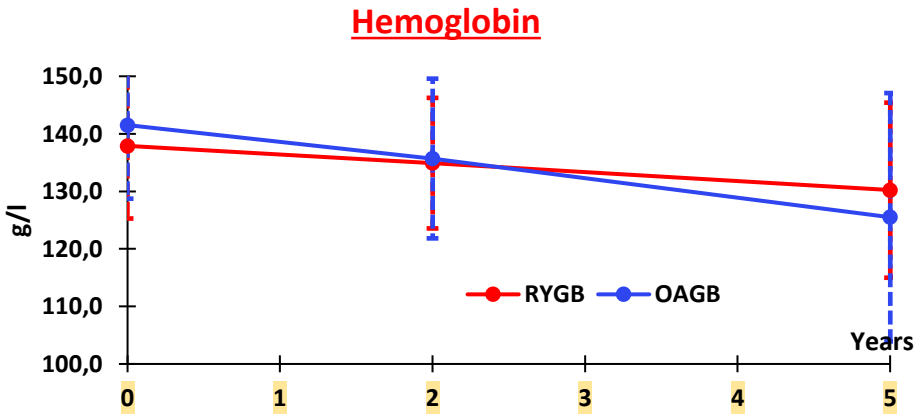
Results

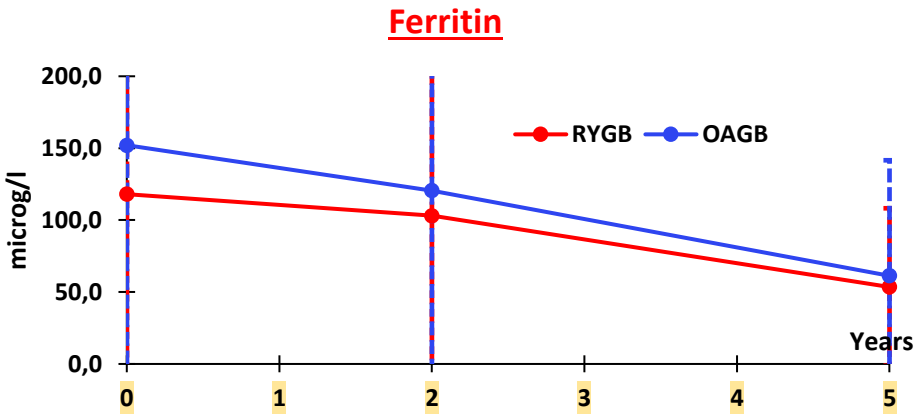
Evolution of Nutritional Status between 0, 2 and 5 years (PP Population)

NS





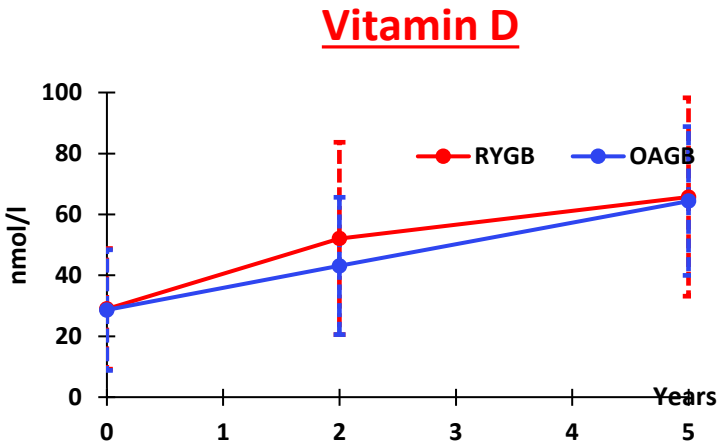


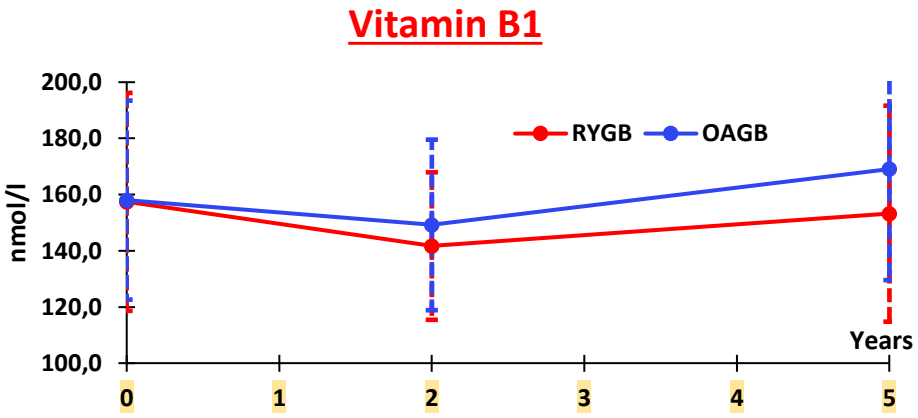


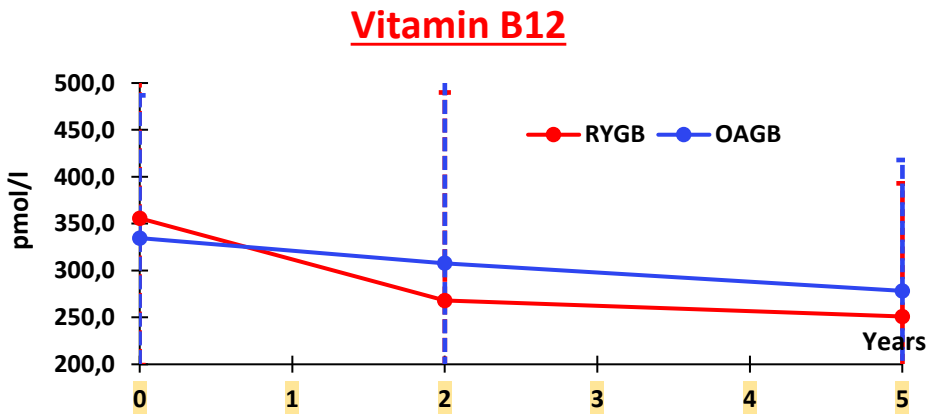
Results

Evolution of Nutritional Status between 0, 2 and 5 years (PP Population)

NS



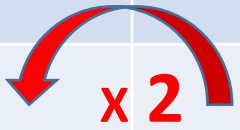




Results

GERD at 5 years (PP Population)

	OAGB (n=114)	RYGB (n=118)	p
Clinical GERD* at 2 years	5.6%	1.4%	0.15
Cinical GERD* at 5 years	**40.9%**	**18.4%**	**0.03**
Use of PPI ≥ 20 mg/ day at 5 years	**42%**	**24.7%**	**0.026**



* regurgitations, heartburn, positional syndrome, nocturnal cough and the use of PPI in mg

Results

Endoscopic findings at 5 years of follow-up (mITT population)

Upper GI endoscopy	OAGB (n=127) n=32	RYGB (n=121) n=27	p
Macroscopic results			
Normal, n (%)	17 (56.7%)	16 (64.0%)	n.S
missing	*2*	*2*	
Barrett's esophagus, n	2	0	n.s
Esophagitis, n	0	2	n.s
Anastomotic ulcer, n	3	2	n.s
Surgical treatment	3	0	n.s
Bile in the stomach, n	3	0	n.s
Gastritis, n	5	4	n.s
Biopsies			
Normal gastric mucosa, n (%)	30 (93·7%)	25 (92·6%)	n.s
Gastric Metaplasia, n	1	0	n.s
+/- Dysplasia, n	0	0	n.s
Carcinoma	0	0	n.s

2 converted to RYGB between 2-5years

1 converted to RYGB between 2-5years

1 converted to RYGB between 2-5years

1 converted to RYGB between 2-5 years

Results

Conversion from OAGB to RYGB (mITT)

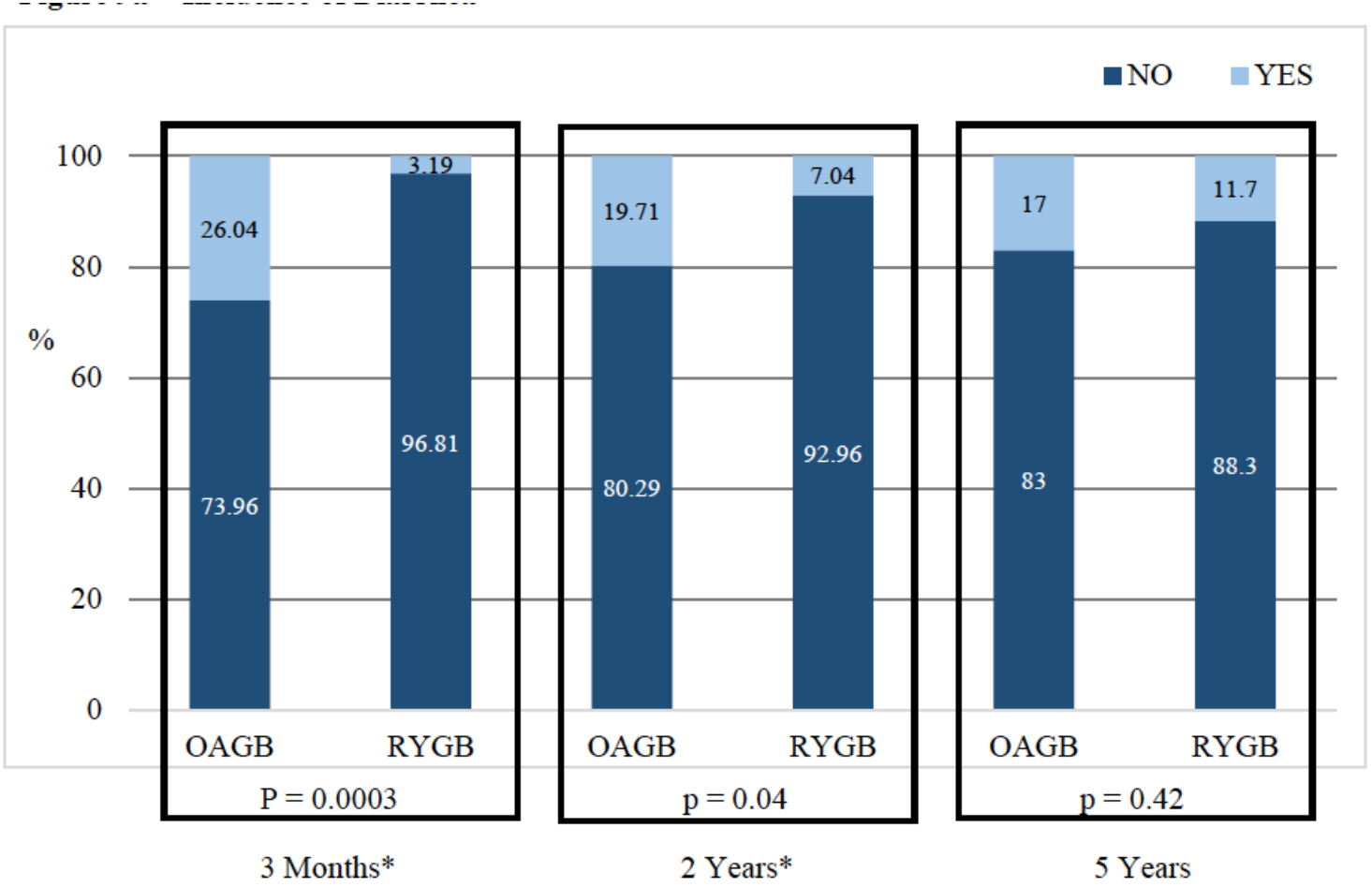
	Patient	Conversion due to					Comments
		GERD	Ulcer +/- Esophagitis	Vitamin deficiencies	Diarrhea	Anastomotic leak	
Between 0-2 years	02-016					+	
	04-031			+			Wernicke encephalopathy
	07-002	+	+				
	08-003	+		+	+		
Between 2-5 years	02-009	+	+				
	02-018	+					
	04-005			+			
	04-006		+				
	04-042	+		+	+		
	09-005	+	+				

Conversion rate of 8% at 5 years

Results

Diarrhea (PP Population)

≥ 4 stools/ day at 5 years

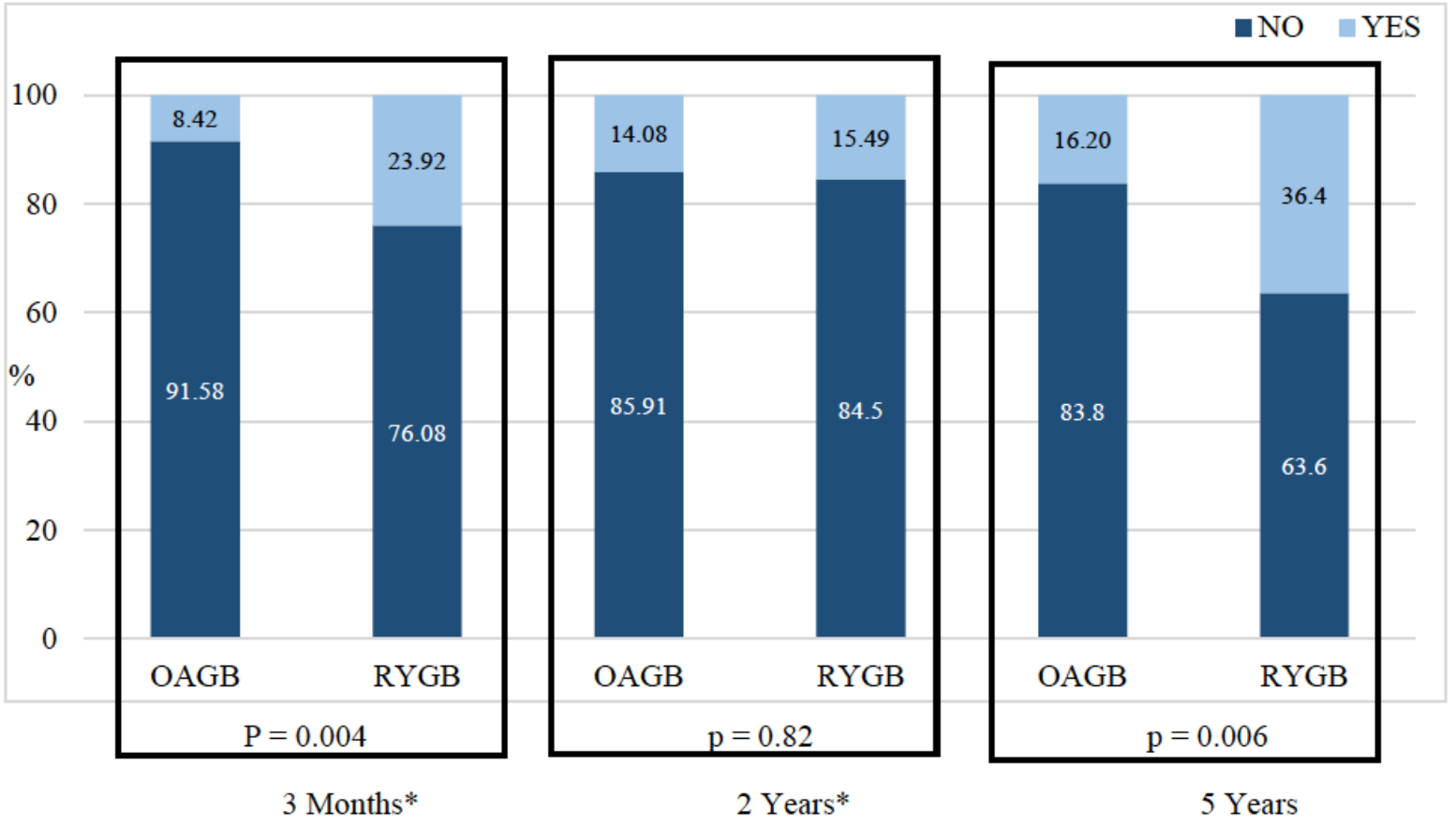


*** Data published at 2 years [9]**

Results

Early Dumping Syndrome at 5 years (PP Population)

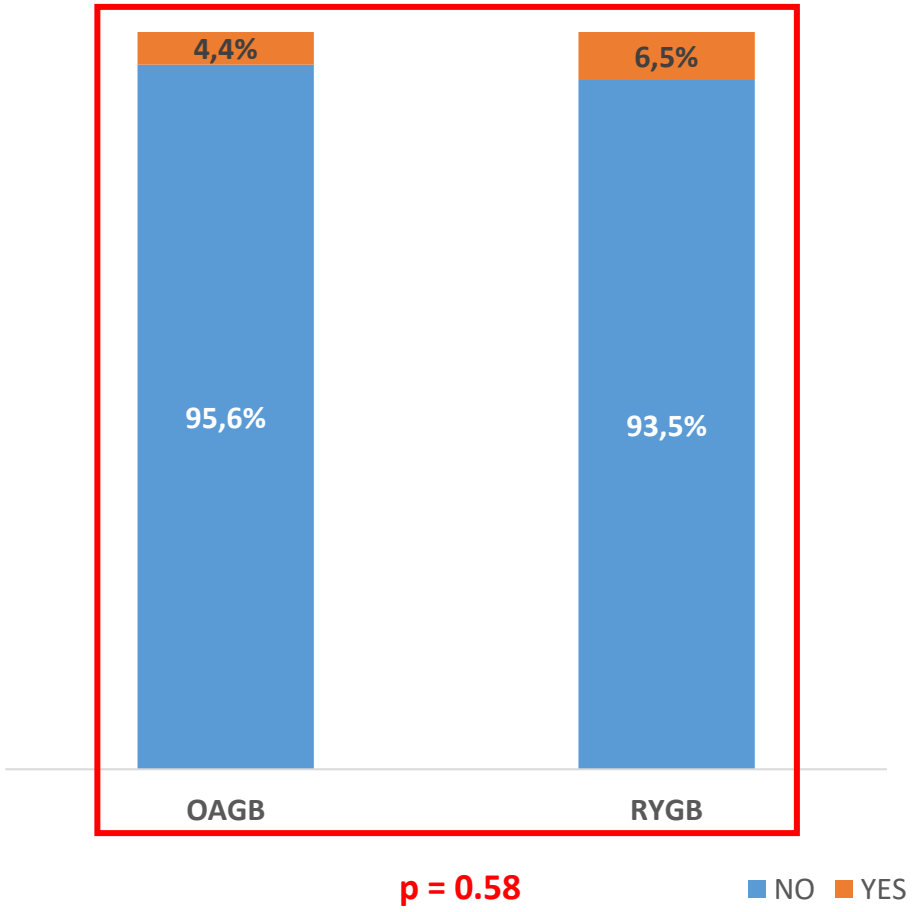
Figure 9b = Incidence of Early Dumping Syndrome



*** Data published at 2 years [9]**

Results

Late Dumping Syndrome at 5 years (PP Population)



Results

Safety: Serious Adverse Events related to surgery (mITT Population)

	TOTAL (n=248)	RYGB Group (n=121)	OAGB Group (n=127)	p
SAE related to the technique				
Between 0 and 2 years	65	24	42	0·042
Nutritional complications	9	0	9	0·0034
Between 2 and 5 years	45	22	23	0·7
Nutritional complications	0	0	2	
Surgical Complications between 2 to 5 years				
Nb of patient (%) (missing data)	44 (28·4%) (93)	20 (25.6%) (43)	24 (31·1%) (50)	0·45
Acute anastomotic ulcer (n)	2	0	2	
Chronic anastomotic ulcer (n)	1	0	1	
Internal hernia (n)	2	2	0	
Cholecystectomy (n)	14	8	6	
Incisional hernia (n)	6	1	5	
Weight regain (n)	1	1	0	
Conversion to RYGB (n)	6	0	6	
Others (n)	19	10	9	
Surgical Complications (TOTAL)	51	22*	29**	

x 2

*2 patients had at least 2 complications

**5 patients had at least 2 complications

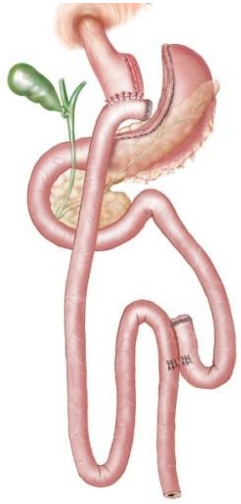
Conclusion

- **OAGB: similar weight loss and metabolic effect**
- **The nutritional risk, SAE and diarrhea rate seem to improve with time**
  → intestinal adaptation
- **40.9% of OAGB patients suffer from GERD, 42% using PPI**
  → twice as much as RYGB
- **8% of conversion from OAGB to RYGB**
- **Upper GI endoscopic controls are required**
- **Every surgical technique has it pros and cons!**

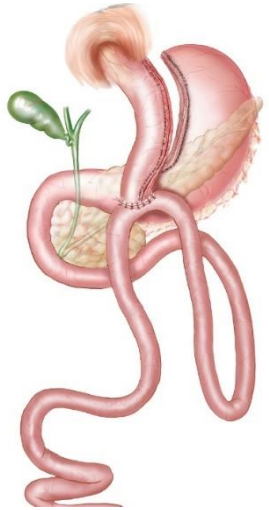
Randomized controlled non-inferiority trial evaluating the safety and efficacy of the omega gastric bypass with 150 cm biliopancreatic loop length compared to the Roux-en-Y gastric bypass: YOMEGA-2 study

PHRC-N 2020

Coordonnateur : Pr Tigran POGHOSYAN



versus



Randomized controlled non-inferiority trial evaluating the safety and efficacy of the omega gastric bypass with 150 cm biliopancreatic loop length compared to the Roux-en-Y gastric bypass: YOMEGA-2 study

COMPOSITE MAIN OBJECTIVE	To demonstrate that at 2 years after surgery, OAGB with 150 cm biliopancreatic limb is not inferior to RYGB on: - Nutritional complication rate (safety): B1, B12, albumin and hemoglobin - Weight loss (efficacy)
SECONDARY OBJECTIVES	1) Nutritional status during the study, 2) Metabolic efficiency on glucose homeostasis and lipid profile 3) Overall complication rates within 2 years after surgery, 4) Gastro-esophageal reflux rate and histologic modifications of gastric and esophageal mucosa 2 years after surgery, 5) Patient's quality of life and dumping syndrome

YOMEGA-2 study

December 2023

ClinicalTrials.gov ID NCT06057597

Last patient last visite planned
December 2027

Start

Randomization
1:1
- Center
- Type 2 diabetes
- BMI >50

Stop

17 french high volumes institutions

368 patients

n=184 **One Anastomosis Gastric Bypass**

n=184 **Roux en Y gastric bypass**

Surgery

Follow-up période =24 months

1m **3m** **6m** **12m** **18m** **24m**

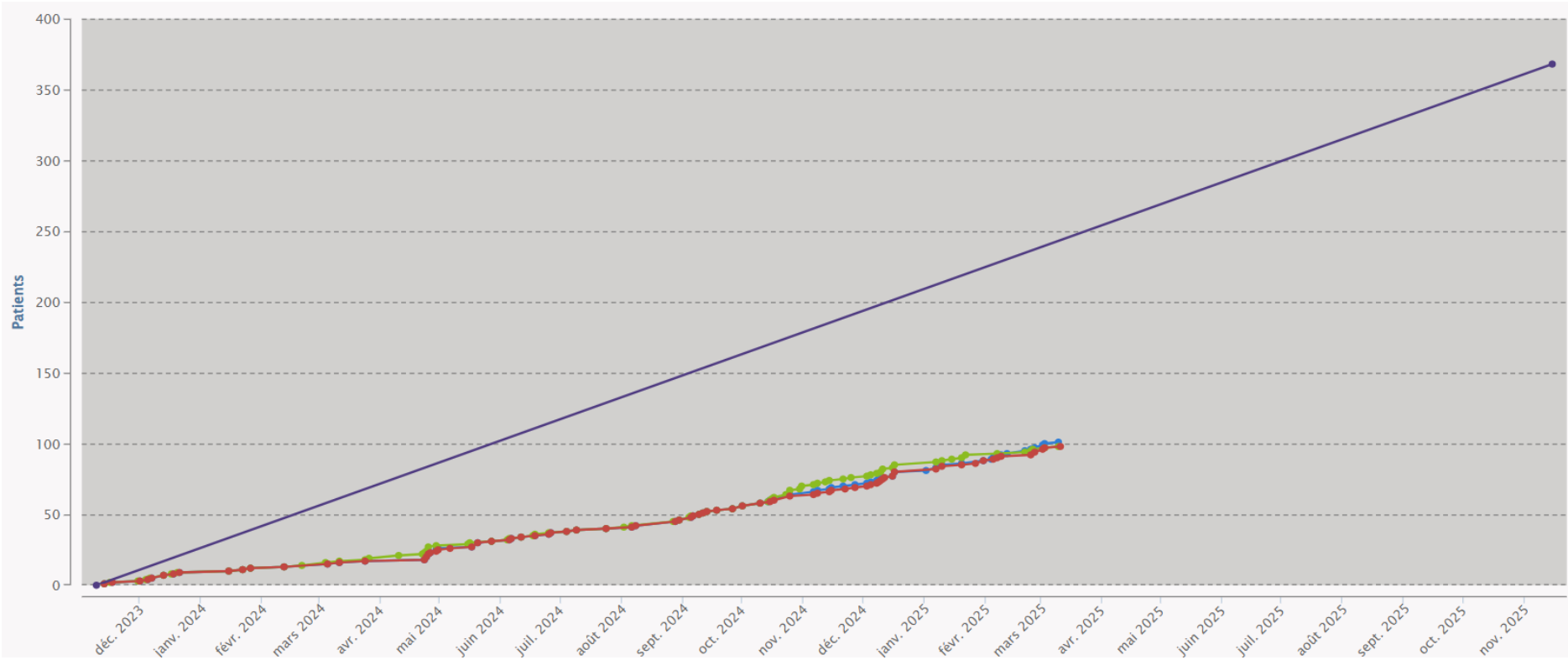
Main inclusions criteria
- BMI>40 or BMI-35-40 with comorbidity
- Primary procedure

- Weight, %EWL, %TBWL
- Metabolic and nutritional profil, stool examination for steatorrhea (6months)
- Complication rate, adverse events
- Quality of life (SF36, GICLI, Sigstad)
- Antidiabetic, antihypertensive and antilipedemic treatment
- Endoscopy, pH impedance monitoring (at 2 years)

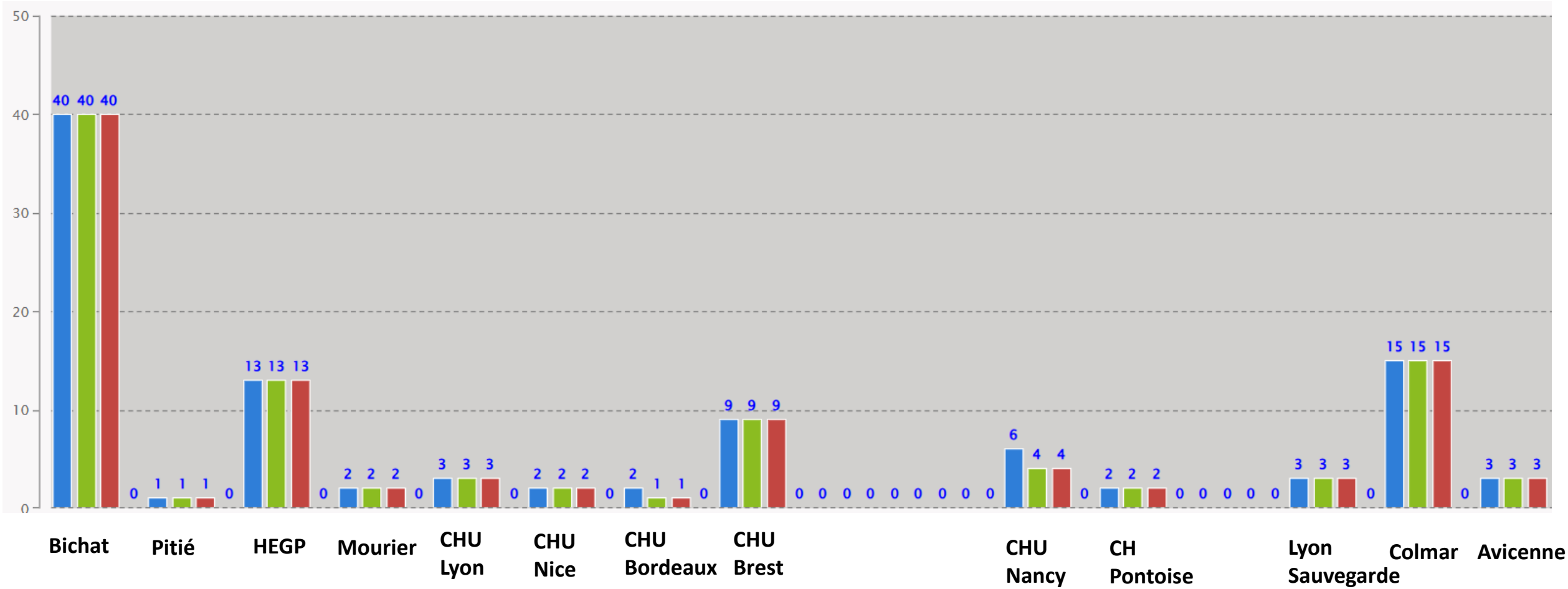
YOMEGA-2: Etat des lieux

Total prévus: n=368

Total inclus: n=106 (29%)



YOMEGA-2: Zoom par centre



Conclusion

- **OAGB has not yet said its last word**
- **We have a body of arguments which suggests that shortening the biliary loop to 150cm will reduce nutritional complications rate without significant impact on weight loss**
- **See you in 4 years**