



# 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

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## Summary

**Background** The multicentre randomised trial YOMEGA (NCT02139813) comparing the one anastomosis gastric bypass (OAGB) with the Roux-en-Y gastric bypass (RYGB) confirmed the non-inferiority of OAGB on weight loss outcomes at 24 months. We aimed to report weight loss, metabolic, and safety outcomes at 5 years.

**Methods** YOMEGA is a prospective, open-label, non-inferiority, randomised trial conducted at nine centres in France. Inclusion criteria were BMI of 40 kg/m<sup>2</sup> or more, or 35 kg/m<sup>2</sup> or more with comorbidities. Key exclusion criteria were severe gastro-oesophageal reflux disease or Barrett's oesophagus and previous bariatric surgery. Patients were randomly assigned (1 :1) to OAGB (one gastrojejunal anastomosis with a 200 cm biliopancreatic limb) or RYGB (with a 150 cm alimentary limb and a 50 cm biliary limb), stratified by centre, with blocks of variable size. The primary endpoint of this extension study was percentage excess BMI loss and was analysed in the per-protocol population, including patients with data who were operated on with the technique randomly assigned to them and excluding patients with major deviations from the protocol during the follow-up (change of surgical technique, death, or withdrawal of consent). Non-inferiority was concluded for the primary endpoint if the upper bound of the CI was less than the non-inferiority limit (7 percentage points). YOMEGA is registered with ClinicalTrials.gov, NCT02139813, and the 5-year follow-up of YOMEGA is registered with ClinicalTrials.gov, NCT05549271.

**Findings** Between May 13, 2014, and March 2, 2016, 253 patients were randomly assigned to OAGB (n=129) or RYGB (n=124), and from these patients 114 in the OAGB group and 118 in the RYGB group were included in the per-protocol analysis. In the per-protocol population, at baseline, mean age was 43.0 years (SD 10.8), mean BMI was 44.0 kg/m<sup>2</sup> (5.6), 54 (23%) patients were male and 178 (77%) were female; 55 (27%) of 207 patients had type 2 diabetes. After 5 years, mean percentage excess BMI loss was -75.6% (SD 28.1) in the OAGB group versus -71.4% (SD 29.8) in the RYGB group, confirming non-inferiority (mean difference -4.1% [90% CI -12.0 to 3.7], p=0.0099). Remission of type 2 diabetes was similar in both groups. Nutritional status did not differ; the most common adverse event was clinical gastro-oesophageal reflux disease, occurring in 27 (41%) of 66 patients in the OAGB group versus 14 (18%) of 76 patients in the RYGB group (p=0.0030). Among serious adverse events, ten (8%) of 127 patients converted from OAGB to RYGB. 171 (68%) of 253 patients were followed up.

**Interpretation** OAGB was not inferior to RYGB regarding percentage excess BMI loss at 5 years with similar metabolic outcomes. The high rate of clinical gastro-oesophageal reflux disease after OAGB raises questions about its long-term consequences, which need to be further investigated.

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## Introduction

For more than 45 years, the Roux-en-Y gastric bypass (RYGB) has remained one of the standard procedures in the bariatric field and one of the most efficient procedures in weight loss and metabolic improvement, especially in the long term.<sup>1,2</sup> The laparoscopic RYGB is technically demanding with a high learning curve<sup>3</sup> and a rate of serious complications of about 13% in the 5-year follow-up.<sup>4</sup> The one anastomosis gastric bypass (OAGB), which

aims to ease the procedure by creating one anastomosis instead of two, while offering as good results as the RYGB, has rapidly gained in popularity over the past 20 years, despite a scarcity of strong scientific evaluation of the outcomes. The omega loop reconstruction, which is at risk of biliary reflux, with potential harmful consequences in the long term, remains a concern for many bariatric teams and fuels the controversy surrounding this operation.<sup>5</sup> There is also no consensus

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## Research in context

### Evidence before this study

We searched PubMed, with no language restrictions, for randomised controlled trials published between Jan 1, 2000, and July 31, 2023, comparing one anastomosis gastric bypass (OAGB) with Roux-en-Y gastric bypass (RYGB), with at least 2 years of follow-up. Search terms were “one anastomosis gastric bypass”, “Roux-en-Y gastric bypass”, “minigastric bypass”, “bariatric surgery”, “weight loss”, “gastro esophageal reflux disease (GERD)”, and “type 2 diabetes”. Published data on OAGB are mostly retrospective, with only one randomised controlled trial published before the YOMEGA trial. This trial was published in 2005 and included 2 years of follow-up. Another randomised controlled trial was published in 2023, focusing on type 2 diabetes remission at 4 years of follow-up, but it had a small sample size. There are still no long-term data of high level of evidence on OAGB outcomes, especially on the rate of postoperative biliary reflux and its consequences. There is still no consensus regarding the length of the biliopancreatic limb to perform, but several publications have reported a higher nutritional risk if the length is 200 cm or more. In 2022, the American Society for Metabolic and Bariatric Surgery discussed whether to endorse the OAGB procedure despite its superiority on weight loss and metabolic outcomes compared with RYGB having not been established and in the light of the persisting controversy of a potential degenerative risk of gastric or oesophageal mucosa in the long term. OAGB has been approved but is still a controversial procedure that is currently being debated.

### Added value of this study

To our knowledge, the YOMEGA study is the first randomised controlled trial to compare weight loss, metabolic outcomes, and safety with OAGB versus standard RYGB, providing mid-term data with 5 years of follow-up. Weight loss outcomes were not inferior in the OAGB group compared with the RYGB group,

the type 2 diabetes remission rate was similar in both groups, and the nutritional risk, diarrhoea, and frequency of serious adverse events in the OAGB group seemed to improve with time. The frequency of early dumping syndrome was significantly lower in the OAGB group than in the RYGB group; we observed twice the proportion of clinical gastro-oesophageal reflux disease in the OAGB group than in the RYGB group (41% vs 18%), which seemed to worsen with time. The conversion rate from OAGB to RYGB was higher than previously described (8% vs 2%) and mainly due to gastro-oesophageal reflux disease, but also due to vitamin deficiencies and diarrhoea. Despite similar weight loss and metabolic results between the two techniques, these findings do not end the controversy about the risk of exposure to biliary reflux after OAGB.

### Implications of all the available evidence

OAGB was not inferior to RYGB regarding weight loss and metabolic outcomes at 5 years of follow-up. The improvement of the nutritional risk and diarrhoea rate in the OAGB group, even with a 200 cm biliopancreatic limb, suggest an intestinal adaptation with time that could contribute to lowering the late complication rate related to malabsorption. Nevertheless, the frequency of gastro-oesophageal reflux disease after OAGB is much higher than previously described in other retrospective studies and seems to worsen over time, suggesting the need for regular clinical and endoscopic surveillance, as recommended by many scientific societies. Given these data, shortening or tailoring the biliopancreatic limb of OAGB, as previously proposed by many bariatric surgeons, has to be assessed to determine whether this might decrease side-effects of the procedure. Further trials of high scientific value are naturally needed to confirm these findings and provide solid data regarding indications and technical aspects of the OAGB.

regarding the ideal length of the biliopancreatic limb, and several publications have reported a higher nutritional risk if it is 200 cm or longer.<sup>6,7</sup>

Published data on OAGB are mostly retrospective, with only one randomised controlled trial<sup>8</sup> comparing OAGB with RYGB published before the YOMEGA trial.<sup>9</sup> The randomised controlled trial reported 2-year outcomes with similar weight loss and metabolic efficacy, concluding that OAGB is simpler, with only one anastomosis instead of two and shorter operating time, and safer than RYGB.<sup>8</sup> The multicentre randomised trial YOMEGA comparing OAGB with RYGB confirmed the non-inferiority of OAGB in terms of weight loss and metabolic improvement at 24 months.<sup>9</sup> However, significantly more serious adverse events and nutritional complications were observed in the OAGB group with a biliopancreatic limb of 200 cm, suggesting a higher malabsorptive effect, than in the RYGB group. There are

still no long-term data of high level of evidence regarding OAGB outcomes and especially regarding the frequency of postoperative gastro-oesophageal reflux disease and its consequences.

Here, we report an analysis of the 5-year extension study of the YOMEGA trial cohort. We present weight loss and metabolic outcomes, with a focus on side-effects and safety.

## Methods

### Study design and participants

YOMEGA is a prospective, open-label, non-inferiority, randomised controlled trial done across nine high-volume bariatric institutions in France (each doing over 150 procedures a year). The study design and methods of the YOMEGA trial have been previously reported.<sup>9</sup> The main inclusion criteria were age 18–65 years, BMI 40 kg/m<sup>2</sup> or higher, or BMI 35 kg/m<sup>2</sup> or higher associated

with at least one comorbidity (type 2 diabetes, arterial hypertension, obstructive sleep apnoea, dyslipidaemia, or arthritis) and previous upper gastrointestinal endoscopy with biopsy samples taken. Main exclusion criteria were severe gastro-oesophageal reflux disease or Barrett's oesophagus and a previous bariatric surgery. The complete list of inclusion and exclusion criteria is in the protocol (appendix pp 5–6). The study was initially approved by the French National Ethics Committee (CPP Sud-Est IV 14/027) and by the Agence Nationale de Sécurité du Médicament (ANSM 140244B-21). All patients provided written informed consent at inclusion.

### Randomisation and masking

Patients were randomly assigned (1:1) to OAGB or RYGB using a computer-generated sequence, stratified by centre with blocks of variable size. Patients were assigned the day before surgery by the bariatric surgeons of each centre by use of sealed envelopes. Because of differences between the procedures, the study was open label.

### Procedures

The surgical techniques have been described previously. Bariatric procedures were done laparoscopically and were standardised. The OAGB consisted of a long and narrow gastric tube, calibrated with a 37 French bougie, and a unique gastrojejunal anastomosis with a biliopancreatic limb of 200 cm.<sup>9</sup> The RYGB consisted of a small gastric pouch (30 mL), a 150 cm antecolic alimentary limb, a 50 cm biliary limb, and closure of the mesenteric defects (appendix p 1).

Previous follow-up points were 1, 3, 6, 12, 18, and 24 months, then annually. Adverse events were recorded at each visit, including surgical and non-surgical adverse events, and distinguished as being procedure-related or not. Serious adverse events were defined as any adverse event requiring hospitalisation. For the analysis of this 5-year extension study, the data collected were compared between the two groups after obtaining informed consent from the patients. In case of missing data at 5 years in the electronic hospital records, patients were contacted for a clinical visit or by phone. Patients were considered as lost to follow-up if data were not available for more than a year.

### Outcomes

The primary endpoint was percentage excess BMI loss at 5 years after surgery (baseline), defined as  $[(\text{BMI at 5 years} - \text{initial BMI}) / (\text{initial BMI} - \text{ideal BMI } 25)] \times 100$ .

As secondary endpoints, weight loss was also expressed as percentage excess weight loss at 5 years of follow-up  $(((\text{weight at 5 years} - \text{initial weight}) / (\text{initial weight} - \text{ideal weight})) \times 100)$  and percentage total weight loss at 5 years of follow-up  $((\text{weight loss at 5 years in kg}) / (\text{divided by initial weight in kg}) \times 100)$ . Other predefined secondary outcomes included evolution of weight and BMI from baseline to 5 years of follow-up, evolution of type 2

diabetes and remission of comorbidities. Remission of type 2 diabetes was defined according to the new recommendations of the American Diabetes Association:<sup>10</sup> HbA<sub>1c</sub> less than 6.5% (48 mmol/mol) for at least 3 months without any antidiabetic drug. Remission or improvement of other metabolic comorbidities were assessed by the cessation or decrease in the number of antihypertensive treatments and lipid-lowering treatments used, and discontinuation of continuous positive airway pressure for obstructive sleep apnoea.

Safety outcomes (assessed in the intention-to-treat and per-protocol populations) included nutritional status assessed by measuring concentrations of vitamins B1, B12, and D, albumin, prealbumin, ferritin, and haemoglobin. Severe malnutrition was defined as albumin less than 30 g/L, prealbumin less than 0.20 g/L, or both, or a BMI of less than 18.5 kg/m<sup>2</sup>. The frequency of medical and surgical complications was recorded, including anastomotic ulcers confirmed with an upper gastrointestinal endoscopy. Clinical signs of early dumping syndrome based on symptoms described in the Sigstad questionnaire<sup>9</sup> (occurring within the first hour after a meal) were reported as well as signs of late dumping syndrome (clinical signs of hypoglycaemia occurring 1–3 h after a meal). Serious adverse events were identified through the number of re-admissions because of medical or surgical complications, and number of deaths with causes were reported. The reoperation frequency was recorded, and the indications analysed to identify bowel obstruction and internal hernia, anastomotic stenosis, acute or chronic ulcer, dismantling of the gastric bypass, conversion of the omega loop to a RYGB or other changes in the initial technique, cholecystectomy, redo for weight regain, incisional hernia, or any other reason.

Additional post-hoc outcomes added in the study protocol at 5 years included the number of intravenous iron infusions, use of enteral or parenteral artificial nutrition for malnutrition, and the average number of stools per day, which can reflect malabsorption (four or more stools per day were diagnosed as diarrhoea). The number of nephrolithiasis and cardiovascular events were recorded as secondary outcomes in the 5-year protocol. The prevalence of gastro-oesophageal reflux disease was systematically assessed by the presence of at least two of the following clinical signs: heartburn, regurgitation, positional syndrome, nocturnal cough, and the use and dose of proton pump inhibitors in mg. An additional upper gastrointestinal endoscopy could be prescribed either to follow the guidelines of the French society of bariatric surgery (SOFFCO MM) or in case of clinical symptoms of gastro-oesophageal reflux disease and its complications, but the prescription of gastrointestinal endoscopy was not systematic: the description of a Barrett's oesophagus, oesophagitis according to the Los Angeles classification, anastomotic ulcers, the presence of bile, and gastritis were recorded, and biopsies

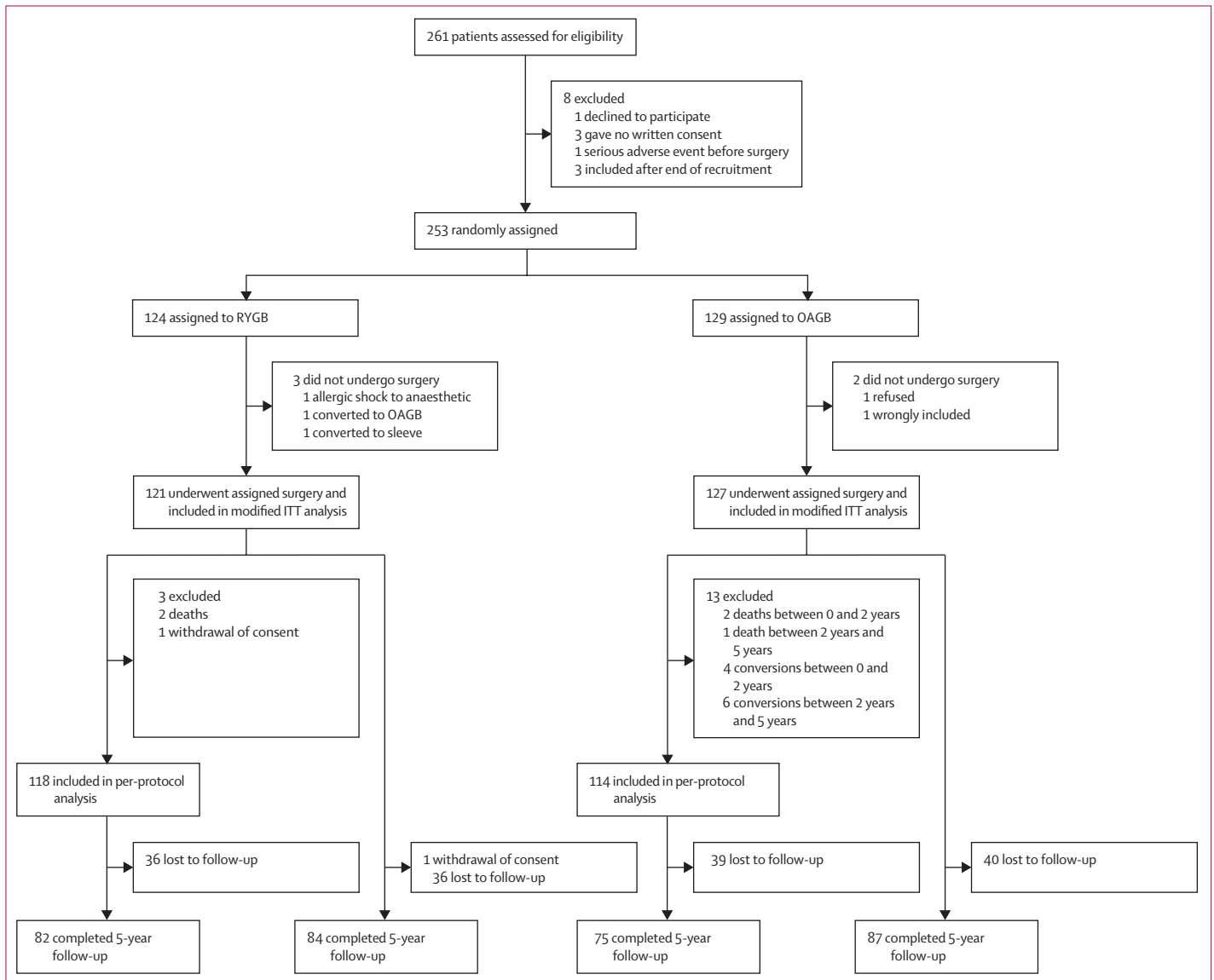
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were performed on the oesophagus and gastric mucosa that were classified as normal, presence of metaplasia, dysplasia, or carcinoma. Further details are provided in the protocol appendix (p 5).

**Statistical analysis**

Similar statistical analyses were performed as in the previous report at 2 years of follow-up.<sup>9</sup> Considering a mean percentage excess BMI loss of 60% in the RYGB group at 2 years, we hypothesised that OAGB would not be inferior to RYGB if the difference in percentage excess BMI loss was less than 7% ( $\leq 5$  kg). We assumed an SD of 21% in both groups with a 10% loss to follow-up at 2 years, which meant 128 patients per group (256 in total) were needed to

conclude the non-inferiority of OAGB with a statistical power of 80% and an  $\alpha$  risk of 5%.<sup>9</sup> The primary endpoint was analysed in the per-protocol population, including patients with data who were operated on with the technique randomly assigned to them and excluding patients with major deviations from the protocol during the follow-up (change of surgical technique, death, or withdrawal of consent), and in the intention-to-treat (ITT) population (all randomly assigned patients) as a post-hoc sensitivity analysis. Secondary efficacy endpoints were analysed in the per-protocol population. Evolution of type 2 diabetes was based on HbA<sub>1c</sub> level (% , mmol/mol) from baseline to 5 years of follow-up, percentage decrease in HbA<sub>1c</sub> from baseline to 5 years of follow-up, and use of antidiabetic treatments (oral, or



**Figure 1: Trial profile**  
ITT=intention to treat. OAGB=one anastomosis gastric bypass. RYGB=Roux-en-Y gastric bypass.

insulin or other injectable treatment). Safety endpoints were analysed in the ITT population and the modified ITT population (excluding patients who did not undergo the assigned surgery after randomisation). Bilateral CIs were provided for the mean difference at 90% for the primary endpoint (two-sided 5%  $\alpha$  level) and 95% CI for the other endpoints. Non-inferiority was concluded for the primary endpoint if the upper bound of the CI was inferior to the non-inferiority limit (7 percentage points).

As in the original study, we imputed missing data in the primary outcome analysis using multiple imputation techniques (five imputed datasets) with prediction based on surgical group, sex, age, and weight at baseline.<sup>9</sup> Statistical comparisons were performed using Student's *t* test or the non-parametric Wilcoxon test for quantitative endpoints, and the  $\chi^2$  test or Fisher's exact test for categorical endpoints. The normality of the data distribution was tested using the Kolmogorov and Shapiro tests. Analyses were performed using SAS software (version 9.4) and R (version 4.3.1). The study of the 5-year data is registered with ClinicalTrials.gov, NCT05549271.

### Role of the funding source

The funder had a role in data collection but did not in study design, data analysis, data interpretation, or writing of the report.

### Results

Between May 13, 2014, and March 2, 2016, 261 patients were assessed for eligibility, and 129 patients randomly assigned to OAGB and 124 to RYGB were included in the ITT analysis (figure 1). 127 patients in the OAGB group and 121 in the RYGB group underwent the surgical procedure assigned to them and corresponded to the modified ITT population. 16 patients were excluded because of major protocol deviations (change of surgical technique in ten patients, five deaths, and one withdrawal of consent); the remaining patients were included in the per-protocol population (114 in the OAGB group and 118 in the RYGB group). Four causes of death were unrelated to the surgical procedure (one medulloblastoma, one mesenteric ischaemia, one cardiovascular event, and one metastatic adenocarcinoma), and one death was of unknown cause. The last patient was included on March 2, 2016. The 5-year follow-up visit of the final enrolled patient was April 26, 2021, and the database was locked to new data on March 29, 2022. 171 (68%) of 253 patients completed the 5-year follow-up.

In the per-protocol population, at baseline, mean age was 43.0 years (SD 10.8), mean BMI was 44.0 kg/m<sup>2</sup> (5.6), 54 (23%) of 232 patients were male and 178 (77%) were female; 55 (27%) of 207 patients with data had type 2 diabetes (table 1).

At 5 years of follow-up, mean percentage excess BMI loss was -75.6% (SD 28.1) in the OAGB group (n=72)

	Per-protocol population (n=232)	RYGB group (n=118)	OAGB group (n=114)
Age, years	43.0 (10.8)	42.2 (10.3)	43.8 (11.3)
Sex			
Male	54 (23%)	25 (21%)	29 (25%)
Females	178 (77%)	93 (79%)	85 (75%)
Weight, kg	120.8 (21.5)	120.1 (18.6)	121.4 (24.2)
BMI, kg/m <sup>2</sup>	44.0 (5.6)	44.0 (5.1)	44.0 (6.1)
BMI $\geq$ 50 kg/m <sup>2</sup>	28 (12%)	13 (11%)	15 (13%)
HbA <sub>1c</sub>			
%	6.0% (1.3)	6.0% (1.3)	6.0% (1.2)
mmol/mol	42 (14)	42 (14)	42 (14)
Missing	19 (8%)	9 (8%)	10 (9%)
Fasting glycaemia, mmol/L	6.4 (2.1)	6.2 (1.8)	6.6 (2.5)
Missing	105 (45%)	48 (41%)	57 (50%)
Type 2 diabetes	55/207 (27%)	28/105 (27%)	27/102 (26%)
HbA <sub>1c</sub>			
%	7.6% (1.7)	7.5% (1.8)	7.7% (1.6)
mmol/mol	60 (19)	58 (20)	61 (18)
Missing	1 (2%)	0	1 (4%)
Fasting glycaemia, mmol/L	8.5 (2.8)	8.0 (2.4)	8.9 (3.1)
Missing	17/55 (31%)	9/28 (32%)	8/27 (30%)
Duration of diabetes, years	7.3 (6.6)	6.8/28 (7.1)	7.8 (6.1)
Missing	8/55 (15%)	6/28 (21%)	2/27 (7%)
On oral antidiabetic agents	42/55 (76%)	21/28 (75%)	21/27 (78%)
On GLP-1 agonist	13/55 (24%)	6/28 (21%)	7/27 (26%)
On insulin	16/55 (29%)	7/28 (25%)	9/27 (33%)

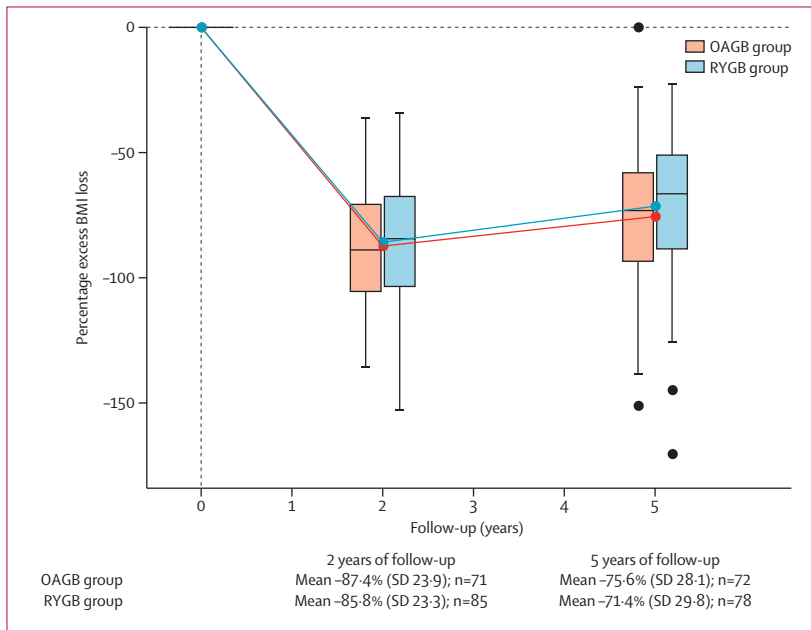
Data are mean (SD), n (%), or n/N (%). OAGB=one anastomosis gastric bypass. RYGB=Roux-en-Y gastric bypass.

**Table 1: Baseline characteristics of the per-protocol population**

versus -71.4% (29.8) in the RYGB group (n=78; figure 2): the mean difference in percentage excess BMI loss was -4.1% (90% CI -12.0 to 3.7) in favour of OAGB, and the upper bound of the 90% CI was less than the non-inferiority limit of 7 percentage points ( $p_{\text{non-inferiority}}=0.0099$ ), confirming that OAGB is not inferior to RYGB in terms of excess BMI loss. After imputation of missing data, the results of the primary endpoint analysis confirmed the non-inferiority of OAGB versus RYGB (appendix p 13). Mean percentage total weight loss was -31.3% (SD 11.2) in the OAGB group versus -29.2% (10.8) in the RYGB group ( $p=0.25$ ). Mean percentage excess weight loss was -67.9% (SD 24.7) in the OAGB group versus -63.9% (25.5) in the RYGB group ( $p=0.33$ ; appendix p 22). Both results are consistent with the primary endpoint. Weight regain between 2 years and 5 years was similar in both groups and occurred in 49 (43%) of 114 patients in the OAGB group (mean 8.1 kg [SD 10.1]) versus 61 (52%) of 118 patients in the RYGB group (7.3 kg [7.2];  $p=0.88$ ; appendix p 22).

In the ITT analysis, the results did not differ, with a mean percentage excess BMI loss of -75.3% (SD 28.1)

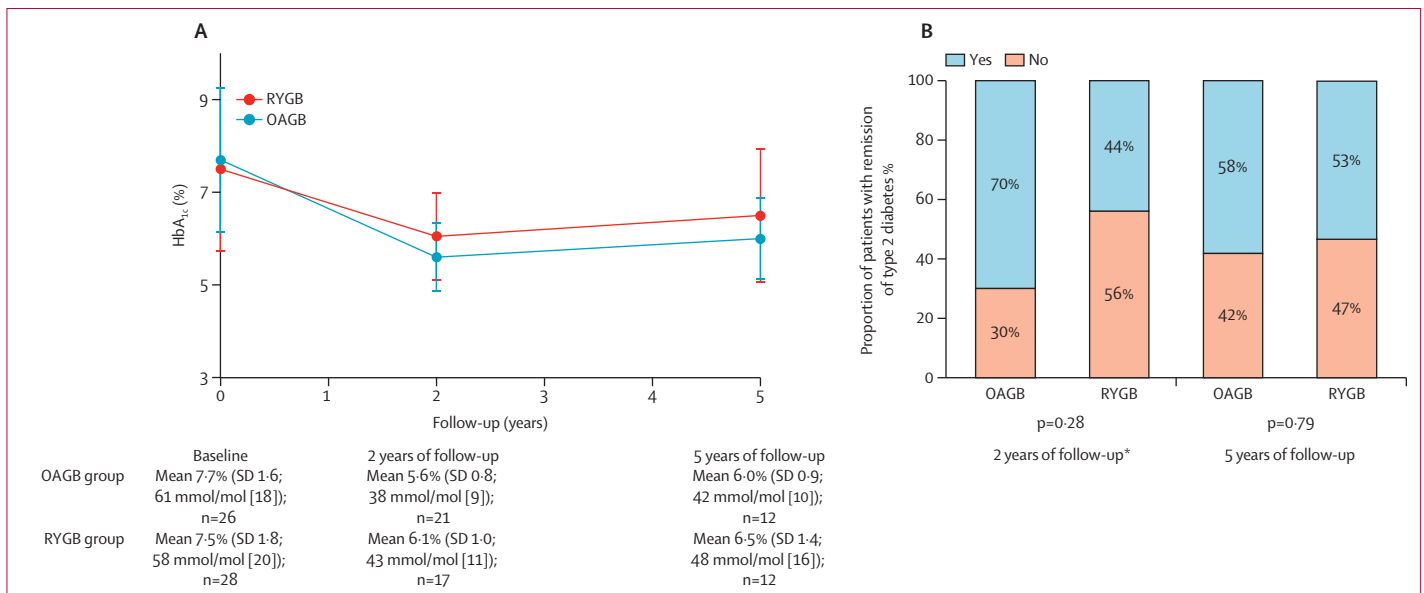
in the OAGB group versus  $-71.8\%$  (30.0) in the RYGB group (appendix p 15; baseline characteristics of the ITT population are shown in the appendix p 14): the mean difference in percentage excess BMI loss was  $-4.1\%$  (90% CI  $-12.0$  to  $3.7$ ) in favour of OAGB, and the upper bound of the 90% CI was  $3.4\%$  ( $p_{\text{non-inferiority}}=0.0077$ ). The extent of missing data was similar in both groups, and missing data were assumed to be lost at random (appendix p 15).



**Figure 2: Percentage excess BMI loss from baseline to 5 years of follow-up in the per-protocol population**  
Black circles represent all values outside the IQR times 1.5, plotted individually and therefore clearly identifiable as outliers. OAGB=one anastomosis gastric bypass. RYGB=Roux-en-Y gastric bypass.

Regarding the evolution of comorbidities at 5 years of follow-up, mean HbA<sub>1c</sub> in patients with type 2 diabetes was  $6.0\%$  (SD 0.9; 42 mmol/mol [10]; n=12) in the OAGB group versus  $6.5\%$  (1.4; 48 mmol/mol [16]; n=12) in the RYGB group ( $p=0.49$ ; figure 3A). The mean change in HbA<sub>1c</sub> between 2 years and 5 years was  $-0.2\%$  (SD 0.7; 2 mmol/mol [8]) in the OAGB group versus  $-0.6\%$  (1.1; 7 mmol/mol [12]) in the RYGB group ( $p=0.22$ ). Remission of type 2 diabetes was similar in both groups at 5 years (seven [58%] of 12 patients in the OAGB group vs eight [53%] of 15 in the RYGB group;  $p=0.79$ ; figure 3B). The evolution of antidiabetic drugs between baseline, 2 years of follow-up, and 5 years of follow-up is shown in table 2. At 5 years, comparing the remission rates of comorbidities between OAGB and RYGB, we found ten (48%) of 21 versus nine (39%) of 23 patients with remission of arterial hypertension ( $p=0.57$ ), five (45%) of 11 versus eight (62%) of 13 patients with remission of dyslipidaemia ( $p=0.43$ ), and 34 (97%) of 35 versus 37 (93%) of 40 patients with remission of obstructive sleep apnoea ( $p=0.37$ ; appendix p 22).

During the follow-up period from 2 years to 5 years, we observed a decrease in the number of serious adverse events related to surgery in the OAGB group, with no difference observed between groups (23 in the OAGB group vs 22 in the RYGB group;  $p=0.70$ ; table 3). No patients required a hospitalisation for malnutrition and artificial nutrition, but two patients of the OAGB group required a conversion to RYGB because of chronic vitamin deficiencies, diarrhea with steatorrhea, or both. Nevertheless, the nutritional status did not differ in both groups at 5 years: the mean concentrations of albumin, prealbumin, haemoglobin, ferritin, and



**Figure 3: Evolution of HbA<sub>1c</sub> and remission of type 2 diabetes in patients with type 2 diabetes in the per-protocol population**

(A) Evolution of HbA<sub>1c</sub> from baseline to 5 years of follow-up. (B) Remission of type 2 diabetes at 2 years and 5 years of follow-up. \*Data are previously published.<sup>9</sup>

	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**

vitamins B1, B12, and D are shown in the appendix (pp 18–19). The number of patients requiring at least one intravenous iron infusion was similar in both groups (nine [12%] of 76 patients in the OAGB group vs 11 [16%] of 71 patients in the RYGB group;  $p=0.52$ ; table 3). Between 2 years and 5 years, 24 (31%) of 77 patients in the OAGB group versus 20 (26%) of 78 patients in the RYGB group had surgical complications ( $p=0.45$ ; table 3).

Focusing on adverse events and safety in the per-protocol population in post-hoc analyses, the incidence of gastro-oesophageal reflux disease increased in both groups between 2 years and 5 years: four (6%) of 71 patients versus 27 (41%) of 66 in the OAGB group and one (1%) of 71 versus 14 (18%) of 76 in the RYGB group (appendix p 22).<sup>9</sup> The frequency of gastro-oesophageal reflux disease was significantly higher in the OAGB group than in the RYGB group at 5 years ( $p=0.0030$ ), with a higher number of patients using proton pump inhibitors (minimum of 20 mg per day): 29 (42%) of 69 patients in the OAGB group versus 19 (25%) of 77 patients in the RYGB group ( $p=0.026$ ; appendix p 22). In the ITT population, 60 (24%) of 253 patients had an upper gastrointestinal endoscopy between 2 years and 5 years: 32 in the OAGB group and 28 in the RYGB group. Macroscopic results were normal in 17 (57%) of 30 patients in the OAGB group versus 17 (65%) of 26 patients in the RYGB group ( $p=0.50$ ; appendix p 16). In the OAGB group, five patients converted to RYGB because of pathological results at the upper gastrointestinal endoscopy: two had Barrett's oesophagus, one had an anastomotic ulcer with bleeding (this patient had an oesophageal metaplasia on biopsies at 2 years), one had symptomatic gastritis, and one had gastric metaplasia on biopsy. We observed three anastomotic ulcers in the OAGB group, which all required a surgical treatment. In the RYGB group, two patients had an anastomotic ulcer that resolved with medical treatment (appendix p 16). At 5 years of follow-up, ten (8%) of 127 patients were converted from OAGB to RYGB: four within the 2 years following surgery and six between 2 years and 5 years of follow-up; seven of ten conversions were due to gastro-oesophageal reflux disease, anastomotic ulcers, or both (appendix p 17).

	Modified intention-to-treat population (n=248)	RYGB group (n=121)	OAGB group (n=127)	p value
Serious adverse event related to the technique				
Between baseline and 2 years*	66	24	42	0.042
Nutritional complications	9	0	9	0.0034
Between 2 years and 5 years	45	22	23	0.70
Nutritional complications	0	0	2	..
Iron infusion		9/76 (12%)	11/71 (16%)	0.52
Surgical complications between 2 years and 5 years				
Number of patients	44/155 (28%)	20/78 (26%)	24/77 (31%)	0.45
Acute anastomotic ulcer	2	0	2	..
Chronic anastomotic ulcer	1	0	1	..
Internal hernia	2	2	0	..
Cholecystectomy	14	8	6	..
Incisional hernia	6	1	5	..
Weight regain	1	1	0	..
Conversion to RYGB	6	0	6	..
Others	19	10	9	..
Total surgical complications	51	22†	29‡	..

Data are n or n/N (%). OAGB=one anastomosis gastric bypass. RYGB=Roux-en-Y gastric bypass. \*Data published at 2 years.<sup>9</sup> †Two patients had at least two complications. ‡Five patients had at least two complications.

**Table 3: Serious adverse events related to surgery in the modified intention-to-treat analysis**

With regards to side-effects at 5 years in the per-protocol population, there was no significant difference in the frequency of diarrhoea between the groups (nine [17%] of 53 in the OAGB group vs seven [12%] of 60 in the RYGB group,  $p=0.42$ ; appendix p 20). Regarding the evolution of dumping syndrome, we observed a significantly lower frequency of early dumping syndrome in the OAGB group than in the RYGB group (11 [16%] of 68 vs 28 [36%] of 77;  $p=0.0060$ ; appendix p 20). The frequency of late dumping syndrome did not differ between groups (three [4%] in the OAGB group vs five [6%] in the RYGB group;  $p=0.58$ ; appendix p 21). Between 2 years and 5 years of follow-up, we observed a higher frequency of nephrolithiasis in the OAGB group than in the RYGB group (seven [12%] of 60 vs five [7%] of 76;  $p=0.29$ ; appendix p 21). The number of cardiovascular events was similar in both groups (four [6%] of 67 [one stroke, two cardiac arrhythmia, and

one other unknown cause] in the OAGB group vs four [5%] of 76 (one myocardial infarction, two cardiac arrhythmia, and one other unknown cause;  $p=0.85$ ; appendix p 22).

## Discussion

As previously reported at 2 years of follow-up,<sup>9</sup> we found that at 5 years of follow-up OAGB was not inferior to RYGB in terms of percentage excess BMI loss, using a 200 cm biliopancreatic limb in the OAGB group. Regarding metabolic outcomes, there was no significant difference between groups in the frequency of type 2 diabetes remission at 5 years; mean decrease in HbA<sub>1c</sub> between 2 years and 5 years did not differ between both procedures. With regard to the side-effects initially highlighted after OAGB at 2 years, and in particular diarrhoea,<sup>9</sup> we observed a slight decrease in the frequency of diarrhoea between 2 and 5 years. We observed at 5 years a higher frequency of early dumping syndrome in the RYGB group than at 2 years, and it was significantly higher than in the OAGB group at 5 years. The frequency of gastro-oesophageal reflux disease increased between 2 years and 5 years in both groups. The frequency of gastro-oesophageal reflux disease was significantly higher in the OAGB group than in the RYGB group at 5 years, with a higher number of patients using proton pump inhibitors. Ten patients were converted from OAGB to RYGB.

Regarding weight loss outcomes at 5 years in the YOMEGA trial, the results in the OAGB group are slightly inferior to those previously published in retrospective studies including more than 1000 patients with 3–6 years of follow-up on average;<sup>11–15</sup> the authors reported a mean percentage excess weight loss of 71.5% (SD 26.5) up to 87%,<sup>12,13</sup> with biliopancreatic limb lengths ranging from 150 cm to 300 cm, sometimes tailored depending on the initial BMI,<sup>15</sup> a previous bariatric procedure, and the total length of the bowel. In these studies, weight loss results did not seem to be correlated to the length of the biliary limb. Nevertheless, several studies<sup>6,7,16</sup> have shown that a biliary limb longer than 200 cm seems to be correlated with a higher risk of malnutrition and vitamin deficiencies and a higher risk of diarrhoea, as we also reported in the YOMEGA trial at 2 years.<sup>9</sup> At 5 years, we observed an improvement in side-effects related to malabsorption in the OAGB group with a 200 cm biliary limb: between 2 years and 5 years of follow-up, no patients required hospitalisation for malnutrition and artificial nutrition, whereas nine patients had a serious adverse event related to malnutrition within 2 years of follow-up (21% of the serious adverse events in the OAGB group at 2-year follow-up).<sup>9</sup> An intestinal adaptation after malabsorptive procedures has been previously described in humans and rats that could explain an improvement of nutritional status and metabolic outcomes over time.<sup>17,18</sup> Other animal and human studies also showed that after

gastric bypass, exposure of the Roux limb to undigested nutrients determines an adaptation of intestinal glucose metabolism, such as changes in glucose transporter and glucose uptake with improvement in glucose metabolism after gastric bypass.<sup>19,20</sup>

Remission of type 2 diabetes was similar in both groups at 5 years but appeared to decrease with time in the OAGB group compared with the results at 2 years. We found at 2 years that the mean decrease in HbA<sub>1c</sub> from baseline was significantly greater in the OAGB group than in the RYGB group in patients with type 2 diabetes;<sup>9</sup> this difference between groups was no longer significant between 2 years and 5 years. Better rates of type 2 diabetes remission after OAGB have previously been reported in retrospective studies, with 84.1% remission at 3 years in one study<sup>11</sup> and 93.2% remission at 6 years in another study.<sup>13</sup> Our data are consistent with two recently published randomised trials<sup>21,22</sup> comparing OAGB with RYGB. One trial included patients with type 2 diabetes and an initial BMI of more than 30 kg/m<sup>2</sup> who were randomly assigned to OAGB ( $n=24$ ) or RYGB ( $n=25$ ), focusing on type 2 diabetes remission, with a 4-year follow-up.<sup>21</sup> No difference was found in terms of remission at 1 year and 4 years. The other trial included 61 patients randomly assigned to RYGB and 60 to OAGB, and 45% of patients had type 2 diabetes: similar metabolic improvement, especially of diabetes, was observed at 1 year.<sup>22</sup>

In terms of adverse events, although the frequency of diarrhoea was significantly higher in the OAGB group at 3 months and 2 years,<sup>9</sup> there was no significant difference at 5 years compared with the RYGB group. The proportion of patients with diarrhoea decreased from 26% at 3 months to 17% at 5 years in the OAGB group, whereas the proportion increased in the RYGB group (3% at 3 months and 12% at 5 years). This increase in the proportion of patients with diarrhoea in the RYGB group could be related to the occurrence of bacterial overgrowth, but could also be due to the increase in the frequency of dumping syndrome. The 36% rate of dumping syndrome reported is consistent with that observed in patients undergoing gastric surgery;<sup>23</sup> the higher frequency of dumping syndrome after RYGB was also reported in a study comparing 324 patients who underwent OAGB with 288 who underwent RYGB at 3 years.<sup>24</sup> The longer gastric pouch made when performing the OAGB is responsible for a less rapid contact of hyperosmolar food material with the jejunum, which could be part of the explanation. The long and narrow gastric pouch of the OAGB is also an argument used to defend the low impact of biliary reflux on the oesophageal mucosa despite the omega loop reconstruction;<sup>25</sup> the long-term consequences of biliary reflux remain a concern for many bariatric teams and fuels the controversy surrounding this operation.<sup>5,26</sup>

The frequency of postoperative gastro-oesophageal reflux disease increased overtime and is higher in this study than that observed in other retrospective studies including more than 1000 patients who underwent OAGB with more than 3 years of follow-up, which report rates between 0.3% and 2%.<sup>11,12,15,27</sup> This decreased frequency is possibly related to the retrospective design of these studies and an absence of systematic and standardised assessment of postoperative gastro-oesophageal reflux disease. A randomised trial comparing 40 patients assigned to OAGB with 40 assigned to RYGB analysed the evolution of pre-existing mild-to-moderate gastro-oesophageal reflux disease at 1 year of follow-up using a standardised questionnaire assessing symptoms, upper gastrointestinal endoscopy, 24 h pH monitoring, and manometry.<sup>25</sup> The authors found a significant improvement of postoperative symptoms and a significant decrease in the use of proton pump inhibitors in both groups with no difference at 1 year.<sup>25</sup> The study showed a significant decrease in percentage total oesophageal acid exposure in both groups with no significant difference between groups.<sup>25</sup> Nevertheless, the number of alkaline reflux events was significantly higher in the OAGB group than in the RYGB group (4.25 [SD 1.77] vs 2.35 [1.03],  $p=0.0001$ );<sup>25</sup> this could be a concern in the long term because bile reflux is a risk factor for Barrett's oesophagus and can lead to gastro-oesophageal cancer in humans.<sup>28</sup> In the OAGB group in the present study, five patients were converted to RYGB because of pathological symptoms and upper gastrointestinal endoscopy findings. The three anastomotic ulcers in the OAGB group all required surgical treatment, whereas the two in the RYGB group could be treated medically. The need for surgical treatment was probably due to the toxicity of bile, which prevents the ulcer from healing. The 8% conversion rate from OAGB to RYGB in our study is higher than previously reported in retrospective series, which ranged from 0.28% to 2.8%.<sup>11,12,14,15,27</sup> It is possible that the high proportion of patients lost to follow-up in the bariatric surgery population and the retrospective design of the studies could explain these possibly underestimated data. The clinical follow-up and upper gastrointestinal endoscopic controls remain a challenge for all bariatric teams worldwide, as shown by the low proportion of patients who had upper gastrointestinal endoscopy in our study population at 5 years (24%) and also by the absence of endoscopic data in most publications on OAGB. Given the high rate of gastro-oesophageal reflux disease after OAGB, which appeared to worsen over time in the YOMEGA trial, regular clinical and endoscopic surveillance is suggested.

Among the limitations of the study, it is of note that gastro-oesophageal reflux disease assessment was based on clinical symptoms and use of proton pump inhibitors, which are not objective markers of reflux, with no possible differentiation between alkaline or acid reflux. Other limitations of the YOMEGA trial are the 68% rate of follow-up with missing data at 5 years:

this could affect the power of the results even though sensitivity analyses were performed. The missing data could also result in some adverse events not being recorded. However, the rate of loss to follow-up at 5 years is lower than that reported in France, according to data extracted from the French National Health Insurance database; short-term and long-term follow-up rates after bariatric surgery vary considerably in the literature and can also decrease down to 60% at 1 year even in high-volume centres, even if lifelong follow-up is mandatory according to the American and European guidelines.<sup>29</sup> The reasons for poor follow-up after bariatric surgery have been studied, and several factors have been identified that can be applied to the YOMEGA trial. The first reason of non-attendance was considering follow-up as unnecessary; other reasons for attrition were geographical distance, and family, professional, or health problems.<sup>30</sup> In addition, the change in medical staff that we observed in two of the nine centres involved in the trial might explain some of the missing data. The low proportion of patients with type 2 diabetes included in the study (27%) is also a weakness for the analysis of the metabolic effect of both techniques as a secondary endpoint. The multi-centre design of this nationwide study, involving public and private institutions of high bariatric activity volume with previous expertise in OAGB, can be considered a strength of the study.

In conclusion, OAGB was not inferior to RYGB regarding weight loss and metabolic outcomes at 5 years of follow-up. The improvement in nutritional risk and decrease in the frequency of diarrhoea in the OAGB group suggests an intestinal adaptation with time that could contribute to lowering late complication rate related to malabsorption. Nevertheless, the rate of gastro-oesophageal reflux disease after OAGB is much higher than previously reported in other retrospective studies and appears to worsen over time.

#### Contributors

MR, ED, DD, TS, DM-B, and SB set up the project. MR and DD drafted the Article. SB developed the methodology. TP, AF, RC, FP, AS, LK, FR, AT, ASu, and VM collected the data in their own institution. DD and TS were responsible for data acquisition and resolution of queries. DM-B and CL-J were responsible for data storage and analysis. MR and DM-B verified and interpreted the data. DM-B, TP, ED, and FP critically reviewed the manuscript for important intellectual content. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the Article are appropriately investigated and resolved. MR, ED, FP, DD, and DM-B had full access to all the data in the study and had final responsibility for the decision to submit for publication

#### Declaration of interests

TP reports fees for participation as an expert in a workshop organised by GORE and leadership in Bariatek board outside the submitted work. DM-B report personal fees from Maat Pharma outside of the submitted work. All other authors declare no competing interests.

#### Data sharing

All individual-participant data collected during this trial will be available to access, after de-identification. Data and documents, including the study protocol, statistical analysis plan, analytic code, and

informed consent forms (in French) will be available. Data will only be available for use in individual participant data meta-analyses, and access will be provided to researchers after a proposal has been approved by an independent review committee identified for this purpose. Data will be available beginning at 3 months and ending at 24 months after publication of this Article. Proposals should be directed to the corresponding author; to gain access, data requesters will need to sign a data access agreement, and the de-identified database will be transferred by email.

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