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

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Summary

Background One anastomosis gastric bypass (OAGB) is increasingly used in the treatment of morbid obesity. However, the efficacy and safety outcomes of this procedure remain debated. We report the results of a randomised trial (YOMEGA) comparing the outcomes of OAGB versus standard Roux-en-Y gastric bypass (RYGB).

Methods This prospective, multicentre, randomised non-inferiority trial, was held in nine obesity centres in France. Patients were eligible for inclusion if their body-mass index (BMI) was 40 kg/m² or higher, or 35 kg/m² or higher with the presence of at least one comorbidity (type 2 diabetes, high blood pressure, obstructive sleep apnoea, dyslipidaemia, or arthritis), and were aged 18–65 years. Key exclusion criteria were a history of oesophagitis, Barrett's oesophagus, severe gastro-oesophageal reflux disease resistant to proton-pump inhibitors, and previous bariatric surgery. Participants were randomly assigned (1:1) to OAGB or RYGB, stratified by centre with blocks of variable size; the study was open-label, with no masking required. RYGB consisted of a 150 cm alimentary limb and a 50 cm biliary limb and OAGB of a single gastrojejunal anastomosis with a 200 cm biliopancreatic limb. The primary endpoint was percentage excess BMI loss at 2 years . The primary endpoint was assessed in the per-protocol population and safety was assessed in all randomised participants. This study is registered with ClinicalTrials.gov, number NCT02139813, and is now completed.

Findings From May 13, 2014, to March 2, 2016, of 261 patients screened for eligibility, 253 (97%) were randomly assigned to OAGB (n=129) or RYGB (n=124). Five patients did not undergo their assigned surgery, and after undergoing their surgery 14 were excluded from the per-protocol analysis (seven due to pregnancy, two deaths, one withdrawal, and four revisions from OAGB to RYGB) In the per-protocol population (n=117 OAGB, n=117 RYGB), mean age was 43·5 years (SD 10·8), mean BMI was 43·9 kg/m² (SD 5·6), 176 (75%) of 234 participants were female, and 58 (27%) of 211 with available data had type 2 diabetes. After 2 years, mean percentage excess BMI loss was –87·9% (SD 23·6) in the OAGB group and –85·8% (SD 23·1) in the RYGB group, confirming non-inferiority of OAGB (mean difference –3·3%, 95% CI –9·1 to 2·6). 66 serious adverse events associated with surgery were reported (24 in the RYGB group *vs* 42 in the OAGB group; p=0·042), of which nine (21·4%) in the OAGB group were nutritional complications versus none in the RYGB group (p=0·0034).

Interpretation OAGB is not inferior to RYGB regarding weight loss and metabolic improvement at 2 years. Higher incidences of diarrhoea, steatorrhoea, and nutritional adverse events were observed with a 200 cm biliopancreatic limb OAGB, suggesting a malabsorptive effect.

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Introduction

Obesity and its comorbidities remain a priority public health issue for most countries worldwide.[1] Several prospective trials and meta-analyses have shown the efficacy of bariatric surgery, not only in terms of weight loss, but also glycaemic control and decrease of cardiovascular risk.[2–5] Since the early 2000s, the number of bariatric procedures has increased exponentially.[6] In parallel, surgical techniques have evolved with the objective to find the best procedure in terms of weight loss and metabolic control that is associated with the fewest side-effects and complications, and decreased invasiveness.[7] Several obesity and diabetes societies have published guidelines regarding validated bariatric procedures,[8,9] but the many emergent techniques are not well evaluated in terms of outcomes and safety.

With more than 40 years of use in clinical practice, the Roux-en-Y gastric bypass (RYGB) remains one of the gold standard procedures for patients with morbid obesity and metabolic disorders.[10] A new modified gastric bypass that consists of a single gastrojejunal anastomosis between a long gastric pouch and a jejunal

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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 Nov 1, 2018, comparing one anastomosis gastric bypass (OAGB) with Roux-en-Y gastric bypass (RYGB) using the search terms "one anastomosis gastric bypass", "minigastric bypass", "omega loop gastric bypass", "Roux-en-Y gastric bypass", "bariatric surgery", "biliary reflux", and "malnutrition". Published data are mostly from retrospective studies, including one meta-analysis, most of which suggest similar weight loss and metabolic outcomes with both procedures, or even better outcomes with OAGB. To our knowledge, two randomised trials comparing OAGB with RYGB have been published, but neither have previously published protocols on official sites and they do not meet high quality criteria. The first of these trials had a small sample size that was calculated on the basis of a difference in operative time, although they concluded on the efficacy and safety. In this study, with no clear hypothesis or primary endpoint, both procedures achieved similar weight loss and metabolic outcomes at 2 years, with OAGB appearing to be the simpler and safer procedure. The methodology of the second trial comparing OAGB with RYGB and sleeve gastrectomy can also be criticised, with a lack of data regarding selection of patients and biological outcomes, and also missing data that were not reported. Nevertheless, controversy exists regarding the risk of dysplastic modifications of oesophageal and gastric mucosa because of biliary exposure after OAGB, and a potential higher nutritional risk.

Added value of this study

This multicentre randomised trial was designed to address controversial issues regarding weight loss, metabolic outcomes, and safety regarding gastrointestinal and nutritional consequences. Our findings indicate that OAGB is not inferior to RYGB in terms of weight loss and metabolic improvement at 2 years; however, the higher incidence of diarrhoea, steatorrhoea, and nutritional adverse events observed with OAGB than in the RYGB group indicate that a nutritional risk is associated with OAGB when the length of the biliopancreatic limb is 200 cm or longer. By use of endoscopy, we found that 16% of patients in the OAGB group had bile exposure in the stomach at 2 years, advocating for other studies with endoscopic data over the long term.

Implications of all the available evidence

The entirety of evidence and the results of the present study support the efficacy of OAGB in terms of weight loss and metabolic improvement as compared with the validated RYGB, and is in favour of a malabsorptive effect of the OAGB. The higher nutritional risk we observed with a 200 cm biliopancreatic limb in the OAGB indicates that close follow-up should be carried out by physicians with specific bariatric training. Other studies with long-term follow-up are needed to determine the consequences of biliary exposure and dispel ambiguity and avoid any controversy. This study promotes further discussion on potential modifications of the technical aspects of OAGB, such as length of the biliary limb, with a view to restrict postoperative side-effects.

omega loop has been described.[11] This new procedure, initially called a mini-gastric bypass or one anastomosis gastric bypass (OAGB), seemed to have the advantage of being less technically demanding and potentially less morbid. Weight loss and metabolic outcomes initially published were as good as those reported for the RYGB or better.[12–15] Nevertheless, OAGB, which is derived from the loop gastric bypass initially described by Mason and Ito,[16] is considered by many surgeons to be at risk for biliary reflux and anastomotic ulcers.[17–19] Many surgeons who do not undertake the procedure give concern over the risk of gastric and oesophageal cancer as one of their reasons.[20–22] Published data on OAGB essentially come from retrospective studies[11–14] and one meta-analysis,[23] although two randomised trials comparing OAGB to RYGB have been reported.[12,15] The first by Lee and colleagues[12] was published in 2005 and included 80 patients. The authors concluded that OAGB is a simpler and safer procedure at 2 years follow-up than RYGB; however, the statistical power of this study and, in particular, the methodology used to calculate the sample size, is open to criticism. The second randomised trial was recently published by Ruiz-Tovar and colleagues,[15] and compared 200 patients who underwent OAGB with 200 who underwent RYGB and 200 who underwent sleeve gastrectomies. The authors concluded that OAGB achieved better weight loss and remission of comorbidities than the two other procedures. Nevertheless, the methodology of this trial is also questionable, with a lack of data regarding selection of patients and biological outcomes, but also missing data were not reported. Therefore, despite strong initial enthusiasm, the value of this procedure remains debated. In the absence of high-level evidence regarding the efficacy and safety of OAGB, we undertook the Omega Loop Versus Roux-en-Y Gastric Bypass (YOMEGA) randomised controlled trial to compare the omega loop to the validated RYGB.

Methods

Study design and inclusion criteria

In this prospective, open-label, non-inferiority, randomised controlled trial, patients were recruited from nine high-volume bariatric institutions in France (Lyon, Saint Etienne, Lille, Saint Grégoire, Paris, Guilherand-Granges, Saint-Germain-en-Laye, and Grenoble; each doing over 150 procedures a year). Key inclusion criteria included body-mass index (BMI) of 40 kg/m² or higher, or 35 kg/m² or higher with the presence of at least one comorbidity (eg, type 2 diabetes, high blood pressure,

obstructive sleep apnoea, dyslipidaemia, or arthritis); age 18–65 years; a multidisciplinary evaluation by the bariatric team including a surgeon, diabetologist, nutritionist, dietitian, and mental health specialist; a preoperative upper gastrointestinal (GI) endoscopy with biopsy samples taken; and willingness to give written informed consent. Key exclusion criteria included a history of oesophagitis, severe gastro-oesophageal reflux disease resistant to proton-pump inhibitors, Barrett's oesophagus, and previous bariatric surgery. Full inclusion and exclusion criteria are in the appendix.

The study was 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.

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 (MR, PE, EP, RC, AS, LK, TP, J-MC, VM, EC, FR, AT, FP) by use of sealed envelopes. Because of differences between the procedures, the study was open-label and no masking of patients or surgeons was done.

Procedures

Bariatric procedures were done laparoscopically and were standardised. RYGB consisted of a small gastric pouch (30 cc), a 150 cm alimentary limb, and a 50 cm biliary limb (figure 1A). Mesenteric defects were closed. OAGB consisted of a long gastric tube beginning at the landmark of the incisura angularis and calibrated with a 37 French bougie. A single gastrojejunal anastomosis was done using a linear stapler with a biliopancreatic limb of 200 cm (figure 1B). A systematic supplementation of multivitamins, iron, calcium, vitamin B12, and vitamin D was prescribed associated with 40 mg of proton-pump inhibitor and 500 mg of ursodeoxycholic acid for the first 6 months after surgery to prevent marginal ulcer and gallstones. Participants were followed-up for 2 years, with the last visit of the last patients being data cutoff. Patients were considered as lost to follow-up if no information was obtained before database lock.

Patients were asked to come back to their study center for a medical visit with the investigator at 1, 3, 6, 12, 18, and 24 months after surgery.

Adverse events were recorded at each medical visit by the investigator and reported in the medical file and case report form. Serious adverse events were defined as any untoward medical occurrence that results in death; is life-threatening; requires in-patient treatment in hospital, or extension of treatment in hospital; results in persistent or substantial disability or incapacity; is a congenital anomaly or birth defect, according to the European and French Medicines Agency definition.

Outcomes

The primary endpoint was percentage excess BMI loss at 2 years after randomisation, defined as (BMI at 2 years–initial BMI)/(initial BMI–25). The secondary endpoints were weight and BMI, measured at 1, 3, 6, 12, 18, and 24 months of follow-up; early and late complications and their severity at 2 years; mean length of stay; duration of surgery; quality of life within 2 years of surgery; the incidence of gastro-oesophageal reflux disease and diarrhoea (gastrointestinal quality of life index [GIQLI] self-administered questionnaire[24]); steatorrhoea at 6 months (g of lipids per 100 g of stools on the 24 h stools), dumping syndrome at each follow-up visit (Sigstad score >7); metabolic profile, evaluated by measuring fasting glycaemia, HbA_{1C}, triglycerides, HDL cholesterol, LDL cholesterol, and total cholesterol; antidiabetic, antihypertensive, and lipid-lowering medications were recorded; and histological modifications of gastric and oesophageal mucosa 2 years after surgery.

See Online for appendix

Diabetes remission status at 2 years was defined as complete remission if HbA_{1C} was less than 6% (42 mmol/mol) and fasting glycaemia was less than 5·6 mmol/L without active pharmacological therapy or ongoing procedures, and partial remission if HbA_{1C} was more than 6·5% (47·5 mmol/mol) and fasting glycaemia was 5·6–6·9 mmol/L without active pharmacological therapy or ongoing procedures. Nutritional status was assessed via serum albumin, prealbumin, haemoglobin, ferritin, transferrin saturation coefficient, parathyroid hormone, calcaemia, and vitamins B1, B9, B12, and D. Malnutrition was defined as albumin concentration of less than 30 g/L or prealbumin concentration of less than 0·20 g/L, or both. A patient was considered as having vitamin deficiency if he or she had at least one of the following: vitamin B1 concentration of less than 66 nmol/L, vitamin B9 concentration of less than 6 ng/mL, vitamin B12 concentration of less than 145 pmol/L, vitamin D concentration of less than 50 nmol/L, or parathyroid

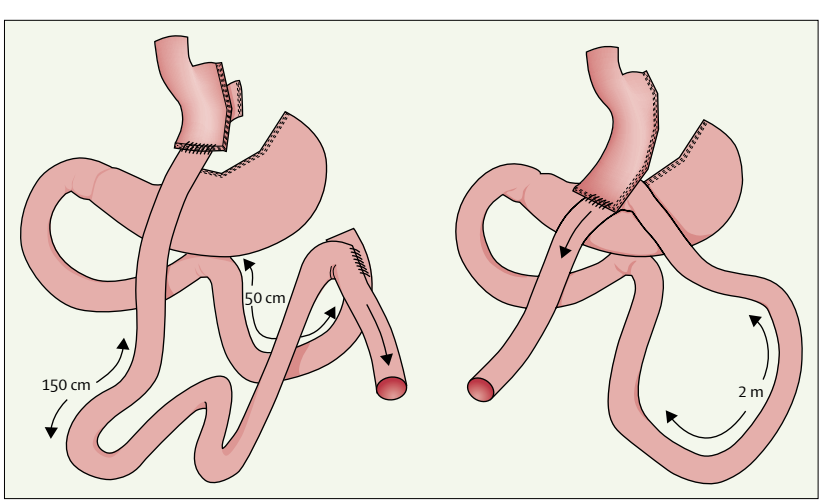

Figure 1: Roux-en-Y gastric bypass (A) and one anastomosis gastric bypass (B) surgical procedures

hormone concentration of more than 50 pg/mL. If a patient had a haemoglobin concentration of less than 12 g/dL they were considered as having anaemia, and iron deficiency was defined as ferritin concentration of less than 15 µg/L or a transferrin saturation coefficient of less than 20%, or both. An upper gastrointestinal endoscopy was done at 2 years of follow-up with systematic biopsies to evaluate histological modifications of the gastric and oesophageal mucosa. Quality of life was assessed with self-administered questionnaires: the bariatric analysis and reporting outcome system (BAROS)[25] that has five levels (failure, fair, good, very good, and excellent) and the impact of weight on quality of life (IWQOL) assessment tool.[26] The IWQOL questionnaire consists of 31 items exploring five dimensions: mobility, self-esteem, social life, working conditions, and sexual life, the most pejorative score being 155 whereas the best score is 31.

We also recorded the overall number and type of serious adverse events and those related to surgery and early (within 30 days of surgery) and late (over 30 days after surgery) surgical complications.

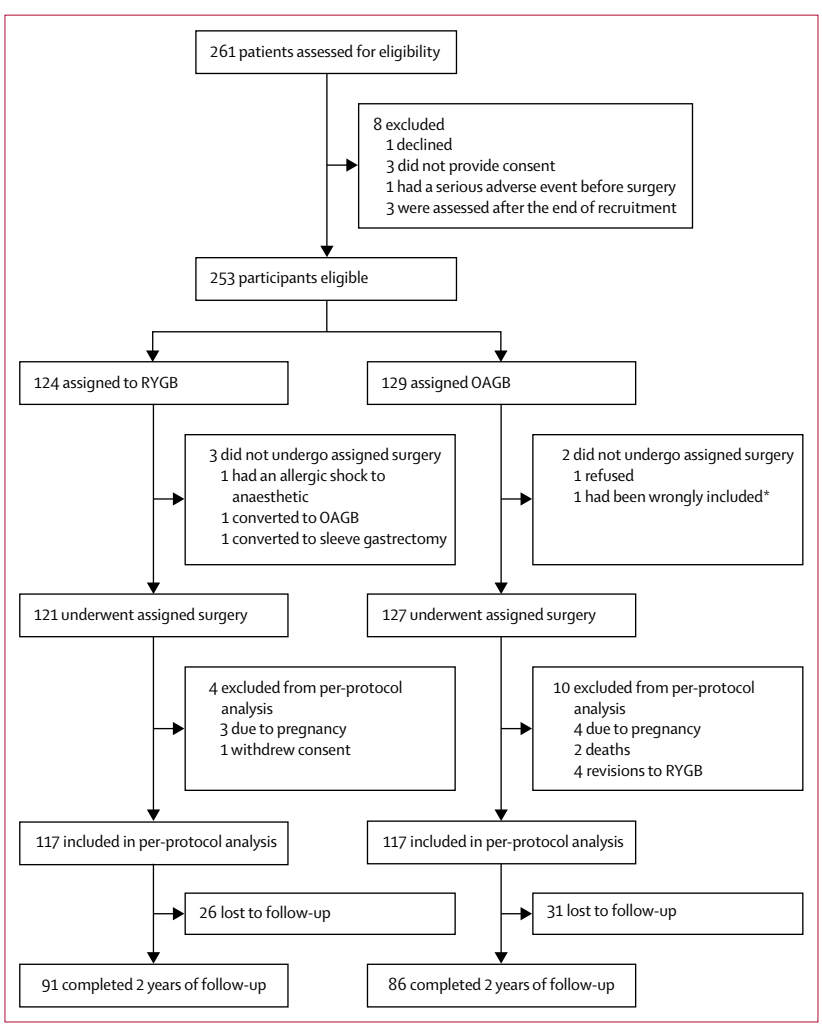

Figure 2: **Study profile**
*Patient had a history of gastric banding.

Statistical analysis

Considering a mean percentage excess BMI loss of 60% in the RYGB group at 2 years,[9,10] we hypothesised that OAGB would not be inferior to RYGB if the difference in excess BMI loss was less than 7% (≤5 kg). We assumed an SD of 21% in both groups with a 10% loss to follow-up, 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 α risk of 5%.

We analysed the primary and secondary efficacy outcomes in the per-protocol population, which included all patients randomly assigned to surgery who contributed data and excluded those with major deviations from the protocol (pregnancy, death, withdrawal of consent, switch of surgical procedure). We determined a 90% CI of the difference for the primary endpoint (one-sided 5% α level) so that non-inferiority was concluded if the upper bound of this interval was inferior to the non-inferiority limit (7 percentage points). We did not correct the analyses of secondary outcomes for multiple comparisons, so the results cannot be used for hypothesis testing or inference. We did comparisons using Student's *t* test or the non-parametric Wilcoxon test for quantitative endpoints, and the χ^2 test or Fisher's exact test for categorical endpoints. For quantitative normal endpoints, we give the bilateral 95% CIs for the mean difference (two-sided 5% α level). We compared the incidence of serious adverse events per patient in both groups using the likelihood test from Poisson regression.

We imputed missing data in the primary outcome analysis using multiple imputation techniques (five imputed datasets)[27] with prediction based on surgical group, sex, age, and weight at baseline. We did sensitivity analyses for the primary outcome on the basis of three scenarios: first, the full per-protocol population dataset; second, all the included patients according to their randomly allocated surgery, irrespective of actual surgery undertaken, with multiple imputation; and third, the per-protocol population with multiple imputation and addition of 7% to the imputed values in the OAGB group.

We assessed safety endpoints in all patients who were randomly assigned (safety population).

We did analyses using SAS software, version 9.4 (SAS Institute, Cary, NC, US). This study is registered with ClinicalTrials.gov, number NCT02139813, and is now completed.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. MR, ED, SB-D, and DM-B had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between May 13, 2014, and March 2, 2016, 261 patients were assessed for eligibility, of whom 253 (97%) were randomly assigned to OAGB (n=129) or RYGB (n=124; safety population). 234 (92%) of 253 participants contributed data to the study (n=117 in both groups, the per-protocol population; figure 2). 31 (24%) of 129 participants in the OAGB group and 26 (21%) of 124 in the RYGB group were lost to follow up for the primary endpoint; therefore, a hypothetical weight was imputed for these missing data so as to contribute to the analysed sample. In the per-protocol population, mean age was 43·5 years (SD 10·8), mean BMI was 43·9 kg/m² (SD 5·6). 176 (75%) of 234 participants were female and 58 (27%) of 211 with available data had type 2 diabetes. Characteristics of the per-protocol population are in table 1. The last visit of the final patient enrolled was March 26, 2018, and the database was locked to new data on Oct 18, 2018.

Mean percentage excess BMI loss at 2 years was –85·8% (SD 23·1) in the RYGB group and –87·9% (SD 23·6) in the OAGB group (figure 3). The mean difference of percentage excess BMI loss was –3·3% (90% CI –9·1 to 2·6) in favour of OAGB, and the upper bound of the 90% CI was 2·6% ($p_{non\text{-}inferiority}$=0·0024). This upper bound was lower than the non-inferiority limit of 7%, confirming that OAGB is not inferior to RYGB in terms of excess BMI loss.

Mean percentage total bodyweight loss at 2 years was –35·4% (SD 8·1) in the RYGB group versus –37·1% (SD 10·3) in the OAGB group, confirming non-inferiority (mean difference –1·4%, 90% CI –3·7 to 1·0; $p_{non\text{-}inferiority}$<0·0001). The mean operative time was significantly shorter in the OAGB group (85 min [SD 35]) than in the RYGB group (111 min [SD 42]; p<0·0001). The median duration of hospital stay was 5 days for both groups (OAGB, IQR 4–5; RYGB, IQR 4–6). Intraoperative complications occurred in four (3%) of 117 participants in the RYGB group (haemorrhage n=3, bowel injury n=1) compared with eight (7%) of 117 participants in the OAGB (haemorrhage n=4, bowel injury n=2, stapling of the nasogastric tube n=2). Two (2%) of 124 participants assigned to the RYGB group had to switch technique: one had a sleeve gastrectomy because of severe bowel adhesions and the other one had OAGB because of the thickness of the mesenteric fat and intraoperative difficulties. In the per-protocol population, in the RYGB group the frequency of early surgical complications was 6·8% (eight of 117) and of late complications was 12·8% (15 of 117) versus in the OAGB group the frequency of early complications was 3·4% (four of 117; p=0·24) and of late complications was 16·2% (19 of 117; p=0·45). In the RYGB group, among the early surgical complications we observed one bowel obstruction, two wall abscesses, one wall haematoma, one haemoperitoneum, two trocar haemorrhages, and one case of severe constipation; only two of these complications (bowel obstruction and haemoperitoneum) were over grade 3 by use of the Dindo-Clavien score and required surgical management. In the OAGB group, among the early surgical complications we observed one case of peritonitis, one stenosis of the gastrojejunal anastomosis, one wall haematoma, and one haematoma of the gastrojejunal anastomosis; only one of these early complications (peritonitis) was over grade 3 by use of the Dindo-Clavien score and required surgical management.

In the per-protocol population, mean HbA_{1c} at 2 years was not significantly different between the OAGB group (5·2% [SD 0·6]; 33 mmol/mol [SD 6·5]) and RYGB group (5·5% [SD 0·7]; 37 mmol/mol [SD 7·7]; p=0·066). The mean decrease in HbA_{1c} at 2 years was significantly greater in the OAGB group (–1·2% [SD 1·4]) than in the RYGB group (–0·6% [SD 0·8]; p=0·0037). This difference

	Per-protocol population (n=234)	RYGB group (n=117)	OAGB group (n=117)
Age, years	43·5 (10·8)	42·6 (10·2)	44·4 (11·4)
n (missing data)	234 (0)	117 (0)	117 (0)
Sex			
Male	58 (25%)	26 (22%)	32 (27%)
Female	176 (75%)	91 (78%)	85 (73%)
n (missing data)	234 (0)	117 (0)	117 (0)
Weight, kg	120·5 (21·7)	119·91 (18·7)	121·2 (24·4)
n (missing data)	234 (0)	117 (0)	117 (0)
BMI, kg/m²	43·9 (5·6)	43·9 (5·1)	43·8 (6·1)
n (missing data)	234 (0)	117 (0)	117 (0)
BMI ≥50 kg/m²	29 (12%)	14 (12%)	15 (13%)
n (missing data)	234 (0)	117 (0)	117 (0)
Type 2 diabetes	58 (27%)	30 (29%)	28 (26%)
n (missing data)	211 (23)	105 (12)	106 (11)
HbA_{1c}, % (mmol/mol)	7·6% (1·8; 60 [19·2])	7·5% (1·7; 59 [18·8])	7·8% (1·8; 62 [19·7])
n (missing data)	57 (1)	30 (0)	27 (1)
Duration of diabetes, years	7·8 (7·2)	7·8 (8·4)	7·8 (6·1)
n (missing data)	48 (10)	23 (7)	25 (3)
On oral anti-diabetic drugs	43 (90%)	22 (92%)	21 (88%)
n (missing data)	48 (10)	24 (0)	24 (0)
On glucagon-like peptide-1 agonist	13 (27%)	6 (25%)	7 (29%)
n (missing data)	48 (0)	24 (0)	24 (0)
On insulin	18 (38%)	8 (33%)	10 (42%)
n (missing data)	48 (0)	24 (0)	24 (0)
Duration of insulin therapy, years	8·3 (8·5)	11·5 (10·4)	5·5 (5·5)
n (missing data)	17 (1)	8 (0)	9 (1)
Arterial hypertension	71 (31%)	33 (28%)	38 (33%)
n (missing data)	231 (3)	116 (1)	115 (2)
Dyslipidaemia	42 (18%)	20 (17%)	22 (19%)
n (missing data)	231 (3)	116 (1)	115 (2)
Sleep apnoea	128 (56%)	68 (59%)	60 (54%)
n (missing data)	228 (6)	116 (1)	112 (5)

Data are mean (SD), n (%), or n (missing data). BMI=body-mass index. HbA_{1c}=glycated haemoglobin. OAGB=one anastomosis gastric bypass. RYGB=Roux-en-Y gastric bypass.

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

in the decrease in HbA_{1c} was also significant in the subgroup of participants with type 2 diabetes; the mean decrease in HbA_{1C} was –2·3% (SD 1·6) in the OAGB group versus –1·3% (SD 1·0) in the RYGB group (p=0·025; table 2). In the OAGB group, the proportion of participants with type 2 diabetes who went into complete remission was 60% (12 of 20 participants), and the proportion who went into partial remission was 10% (two of 20), whereas in the RYGB group the proportion of participants who had complete remission was 38% (six of 16) and of partial remission was 6% (one of 16). The proportions of type 2 diabetes remission were not significantly different between the treatment groups (p=0·28; figure 4). We saw no significant difference at 2 years between groups in the values and decrease of fasting glycaemia, triglycerides, LDL cholesterol, HDL cholesterol, and total cholesterol (table 2).

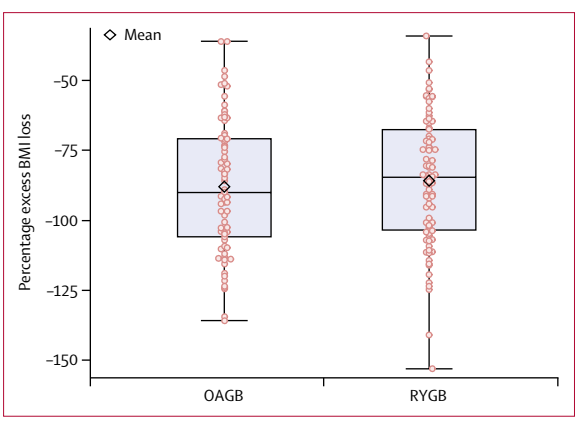

Figure 3: **Weight loss outcomes at 2 years for per-protocol population**
The boxes show the median and IQR, with the diamond indicates the mean, and the whiskers the upper and lower range of values. OAGB=one anastomosis gastric bypass. RYGB=Roux-en-Y gastric bypass.

In the per-protocol population, mean serum albumin and prealbumin concentrations were not significantly different between groups at 2 years (albumin, OAGB 42·1 g/L [SD 3·0] *vs* RYGB 42·2 g/L [SD 3·08], p=0·51; prealbumin, OAGB 0·25 g/L [SD 0·05] *vs* RYGB 0·24 g/L [SD 0·04], p=0·78). The incidence of malnutrition at 2 years was also not significantly different between the groups (OAGB 10·8% [seven of 65] *vs* RYGB 16·7% [ten of 60]; p=0·34). We observed a significant difference in the mean decrease in haemoglobin in the OAGB group (–10·3 g/L [SD 20·6]) compared with the RYGB group (–3·0 g/L [SD 10·1]; p=0·036; table 3); and no significant difference was seen between the groups in the incidence of anaemia or iron deficiency (OAGB: 28·3% [17 of 60] *vs* RYGB: 36·2% [21 of 58]; p=0·36). We did not observe any significant difference in the concentrations of vitamins or the frequency of vitamin deficiencies between the two groups at 2 years of follow-up (vitamin deficiencies, OAGB: 84·5% [49 of 58] *vs* RYGB: 83·3% [40 of 48]; p=0·87).

The incidence of diarrhoea was significantly higher in the OAGB group than in the RYGB group at 3 months (26% [25 of 96] *vs* 3·2% [three of 94], p=0·0003; odds ratio [OR] 11·53, 95% CI 3·03–43·86) and at 2 years (19·7% [14 of 71] *vs* 7% [five of 71], p=0·04; OR 3·07, 1·04–9·08). Median steatorrhoea was also significantly higher in the OAGB group at 6 months than in the RYGB group (11 g of lipids per 100 g stools [IQR 7·9–12·8] *vs* 7 g of lipids per 100 g stools [IQR 5·5–10·0]; p=0·0002). Dumping

	Per-protocol population (n=234)	RYGB (n=117)	OAGB (n=117)	p value
Participants with type 2 diabetes (n=58)				
HbA_{1c}, % (mmol/mol)	5·8% (0·9; 40 [9·4])	6·1% (0·9; 43 [10·3])	5·6% (0·8; 38 [8·2])	0·055
n (missing data)	39 (19)	17 (13)	22 (6)	..
Decrease in HbA_{1c} from baseline, %	–1·9 (1·5)	–1·3 (1·0)	–2·3 (1·6)	0·025
n (missing data)	38 (20)	17 (13)	21 (7)	..
Fasting glycaemia, mmol/L	5·8 (2·2)	6·1 (2·9)	5·6 (1·5)	0·801
n (missing data)	42 (16)	20 (10)	22 (6)	..
Decrease in fasting glycaemia from baseline, mmol/L	–3·6 (4·3)	–2·6 (4·8)	–3·8 (3·8)	0·505
n (missing data)	42 (16)	20 (10)	22 (6)	..
Per–protocol population (n=234)				
Decrease in LDL-C from baseline, mmol/L	–0·4 (1·0)	–0·4 (1·0)	–0·4 (1·1)	0·97
n (missing data)	102 (132)	49 (68)	53 (64)	..
Increase in HDL-C from baseline, mmol/L	0·3 (0·3)	0·3 (0·3)	0·3 (0·3)	1
n (missing data)	105 (129)	50 (67)	55 (62)	..
Decrease in total cholesterol from baseline, mmol/L	–0·3 (1·0))	–0·3 (1·0)	–0·4 (1·1)	0·82
n (missing data)	105 (129	49 (68)	56 (61)	..
Decrease in triglycerides from baseline, mmol/L	–0·6 (1·2)	–0·6 (0·62)	–0·7 (1·5)	0·31
n (missing data)	107 (127)	49 (68)	58 (59)	..

Data are mean (SD) or n (missing data). RYGB=Roux-en-Y gastric bypass. OAGB=one anastomosis gastric bypass. HbA_{1c}=glycated haemoglobin.

Table 2: **Metabolic outcomes at 2 years of follow-up for the per-protocol population**

syndrome occurred at a significantly lower frequency in the OAGB group than in the RYGB group at 3 months (8·4% [eight of 95] *vs* 23·9% [22 of 92], p=0·004; OR 0·29 95% CI 0·12–0·68), and with no significant difference in frequency between the groups at 2 years (14% [ten of 71] *vs* 15·4% [11 of 71], p=0·82; OR 0·91, 95% CI 0·39–2·14). The frequency of gastro-oesophageal reflux disease was 5·6% (four of 71) in the OAGB group versus 1·4% (one of 71) in the RYGB group (p=0·15; OR 0·05, 95% CI 0·19–1·30). 121 (52%) of 234 participants (n=58 OAGB group, n=63 RYGB group) had an upper gastrointestinal endoscopy at 2 years of follow-up (table 4). In the OAGB group, 11 (19%) of 58 participants had gastritis and six (10%) had oesophagitis versus four (6%) of 63 participants with gastritis and two (3%) with oesophagitis in the RYGB group. In the OAGB group, nine (16%) of 58 participants had bile in the gastric pouch versus none in the RYGB group, and one patient in the OAGB group had intestinal metaplasia on the gastric and oesophageal biopsies (table 4).

At 2 years of follow-up, almost twice as many overall serious adverse events and serious adverse events associated with surgery occurred in the OAGB group compared with the RYGB group (overall 67 *vs* 38, p=0·009; associated with surgery 42 *vs* 24, p=0·042). Data for overall serious advserse events are in the appendix. Among the serious adverse events associated with surgery, nine (21%) were nutritional complications in the OAGB group versus none in the RYGB group (p=0·0034; table 5). Among these nine patients with nutritional complications, all had at least one vitamin deficiency, malnutrition, anaemia, or iron deficiency, or a combination of these (table 6); the mean absolute weight loss in this subgroup was 58·4 kg (SD 28·8). Most of the serious adverse events associated with surgery in the RYGB group were admitted to and treated in hospital because of abdominal pain (five [21%] of 24), which was not reported in the OAGB group. In the safety population, we observed no significant difference in the proportion of participants with at least one serious adverse events between the groups (OAGB: 28 [22%] of 129 *vs* RYGB: 19 [15%] of 124; p=0·19). A significantly higher number of serious adverse events associated with surgery per patient occurred in the OAGB group (p=0·042). Four (3%) of 127 patients with OAGB who underwent assigned surgery required conversion to RYGB: one for an anastomotic leak, one for Wernicke encephalopathy, and two because of severe biliary reflux reluctant to medical therapy.

At 2 years of follow-up, the improvement in quality of life was not significantly different between the groups, with good, very good, and excellent BAROS scores for 54 (86%) of 63 patients in the RYGB group versus 63 (94%) of 67 in the OAGB group (p=0·15; data not shown for each score). Regarding IWQOL scores, all dimensions explored improved significantly with both techniques during the 2 year follow-up (p<0·0001), except for sexual life, which was not assessed because of missing data for this item (data not shown). No significant difference was seen between the groups in the scores of the four dimensions studied: mean physical function improved by 20·4 points (SD 11·9) in the OAGB group versus 21·5 points (SD 8·4)

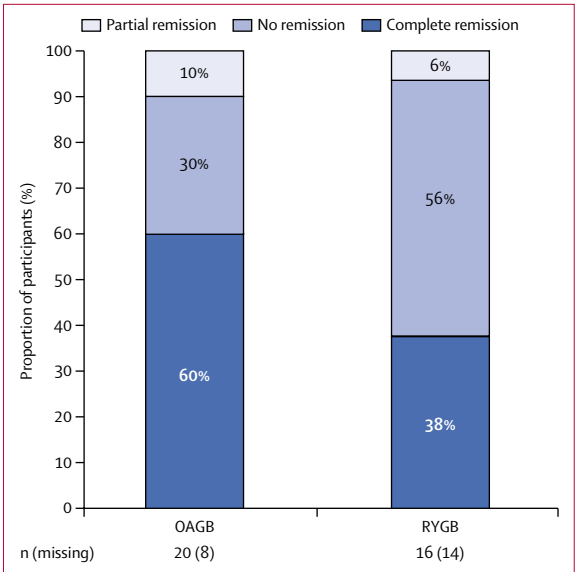

Figure 4: **Frequency of type 2 diabetes remission, by treatment group**
Data are for participants with type 2 diabetes at baseline who had available follow-up data at 2 years. OAGB=one anastomosis gastric bypass. RYGB=Roux-en-Y gastric bypass.

	Per-protocol population (n=234)	RYGB group (n=117)	OAGB group (n=117)	p value
Haemoglobin, g/L	–6·6 (16·5)	–3·0 (10·0)	–10·3 (20·6)	0·036
n (missing data)	129 (105)	65 (52)	64 (53)	..
Albumin, g/L	0·3 (3·7)	0·1 (3·5)	0·5 (3·9)	0·51
n (missing data)	124 (110)	61 (56)	63 (54)	..
Prealbumin, g/L	–0·0 (0·1)	–0·0 (0·1)	–0·0 (0·1)	0·78
n (missing data)	113 (121)	54 (63)	59 (58)	..
Ferritin, in µg/L	–27·9 (174·3)	–31·3 (136·6)	–24·7 (204·1)	0·85
n (missing data)	119 (115)	57 (60)	62 (55)	..
Transferrin saturation coefficient, %	6·0 (14·00)	5·8 (10·3)	6·2 (16·9)	0·94
n (missing data)	99 (135)	49 (68)	50 (67)	..
Vitamin B1, nmol/L	–2·0 (28·4)	–0·6 (25·5)	–3·2 (31·1)	0·57
n (missing data)	73 (161)	35 (82)	38 (79)	..
Vitamin B9, ng/L	12·9 (20·6)	15·5 (21·8)	10·0 (19·2)	0·12
n (missing data)	91 (143)	47 (70)	44 (73)	..
Vitamin B12, pmol/L	10·9 (174·6)	–6·4(136·6)	28·5 (206·0)	0·94
n (missing data)	119 (115)	60 (57)	59 (58)	..
Vitamin D, nmol/L	21·3 (32·1)	25·2 (34·5)	17·4 (29·5)	0·51
n (missing data)	114 (120)	56 (61)	58 (59)	..
Parathyroid hormone, pg/mL	–0·7 (32·2)	–8·2 (27·7)	5·2 (34·5)	0·1
n (missing data)	89 (145)	39 (78)	50 (67)	..

Data are mean (SD) or n (missing data) and results of blood test samples. RYGB=Roux-en-Y gastric bypass. OAGB=one anastomosis gastric bypass.

Table 3: **Nutritional status, difference between baseline and 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**

	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**

in the RYGB (p=0·57); mean self-esteem improved by 11·2 points (SD 9·3) in the OAGB group versus 12·1 points (SD 6·8) in the RYGB group (p=0·52); mean public distress improved by 5·5 points (SD 6·2) in the OAGB group versus 6·1 points (SD 3·8) in the RYGB group (p=0·52); and mean working conditions improved by 4·0 points (SD 3·2) in the OAGB group versus 4·7 points (SD 3·3) in the RYGB group (p=0·26).

The primary efficacy outcome result was confirmed by the sensitivity analyses, with a maximal upper bound of 90% CI of 3·9% in the first scenario (p=0·0066); 2·2% in the second scenario (p=0·0028); and 5·9% in the third scenario (p=0·024).

Discussion

We found that OAGB is not inferior to RYGB in terms of percentage excess BMI loss at 2 years, using a 200 cm biliopancreatic limb in the OAGB group and a 150 cm alimentary limb and 50 cm biliopancreatic limb in the RYGB group. This finding is in accordance with the first randomised trial comparing these two techniques published by Lee and colleagues in 2005,[12] who reported 64·4% excess weight loss in the OAGB group (n=40) at 2 years of follow-up versus 60% in the RYGB group (n=40; p=0·154). In their study, the length of the afferent limb of the OAGB was also 200 cm, which is the standard and initially described in the first report of the technique.[11] In the second randomised trial of comparing OAGB with RYSG and sleeve gastrectomy by Ruiz-Tovar and colleagues,[15] the authors found a significantly higher percentage excess BMI loss in the OAGB group than in the RYGB group at 2 years of follow-up (103·4% *vs* 87·2%; p<0·001), which was also found at 5 years, but with a lack of information regrading missing data. In their study, the length of the biliopancreatic limb was longer than in our study; varying from 200 cm to 350 cm depending on the length of the total bowel by use of the ratio of 60% biliopancreatic limb to 40% common limb.[15] The longer afferent limb could explain the increased weight loss observed in Ruiz-Tovar and colleagues' study compared with herein. However, the validity of this result could be questioned. Although the authors reported a low loss to follow-up (9% [54 of 600] at 5 years),[15] which has rarely been reached before in bariatric studies, the number of missing data for the calculation of percentage excess BMI loss is unclear, even though excess BMI loss was the primary endpoint.

Regarding glucose homoeostasis in the per-protocol population, we found the decrease in HbA_{1c} was more significant at 2 years in the OAGB group than in the RYGB group. Among patients with type 2 diabetes, a better improvement in HbA_{1c} was seen in the OAGB group than in the RYGB group; however, despite more participants achieving remission of type 2 diabetes in the OAGB group than in the RYGB group, the difference was not significant. This result might be associated with the low number of participants with type 2 diabetes included in our study, leading to a lack of power of the statistical analysis. This hypothesis is supported by the findings of Magouliotis and colleagues in their meta-analysis,[23] in which they identified the frequency of remission of type 2 diabetes was greater with OAGB than with RYGB. Regarding the lipid profile, we found no significant difference between treatment groups, which is in accordance with this previous meta-analysis.[23]

The good weight loss and metabolic outcomes of OAGB could be explained by the malabsorptive effect of the procedure. This hypothesis seems to be supported by the

	Type of nutritional complication	Mean weight loss (kg)	Vitamin deficiency	Malnutrition	Anaemia or iron deficiency	Steatorrhoea >7 g per 24 h
Participant 1	Wernicke encephalopathy	64; converted to RYGB	Yes	Yes	No	25
Participant 2	Malnutrition	52	Yes	No	No	9·74
Participant 3	Malnutrition	Data missing; converted to RYGB	Yes	No	No	Data missing
Participant 4	Severe diarrhoea or malnutrition	39	Yes	Yes	No	Data missing
Participant 5	Malnutrition or anorexia	40	Yes	Yes	Yes	14
Participant 6	Feeding difficulties	53	Yes	Yes	Yes	Data missing
Participant 7	Anorexia	126	Yes	Yes	Yes	Data missing
Participant 8	Food intolerance	38	Yes	Yes	Yes	10
Participant 9	Anaemia	55	Yes	Yes	Yes	Data missing

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

Table 6: **Nutritional complications among nine participants in the OAGB group**

significantly higher incidence of diarrhoea and higher mean steatorrhoea in the OAGB group than in the RYGB group at 2 years. Another strong argument in favour of this malabsorptive effect is the high frequency of nutritional complications among the serious adverse events associated with surgery; all participants who had such complications had at least vitamin deficiency, malnutrition, anaemia, or iron deficiency, or a combination of these. Despite systematic use of multivitamin supplementation and close follow-up, one participant in the OAGB group had a case of Wernicke encephalopathy that required conversion to RYGB. However, notably, publications in the past 2 years have also reported severe nutritional complications after OAGB. For instance, Genser and colleagues[28] published a report on 26 patients with severe and refractory malnutrition after OAGB leading to reversal to normal anatomy; the mean delay of reversal surgery was 20·9 months (SD 13·4). Intraoperative measurement of the length of the biliopancreatic limb was assessed in 12 of 26 patients. Eight (67%) of 12 patients had a biliopancreatic limb longer than 200 cm, the mean length of which was 320 cm (SD 63·9), of whom seven (87·5%) had chronic diarrhoea. The mean length of the efferent loop was assessed in nine (35%) of 26 patients and was longer than 400 cm, suggesting that the length of the biliopancreatic limb is the section that is the determinant for nutritional status. Bétry and colleagues[29] also published case reports of 12 patients with severe malnutrition after bariatric surgery and of whom seven (58%) had undergone OAGB. The authors found low concentrations of liposoluble vitamins and two cases of Wernicke encephalopathy in the OAGB group, and concluded that OAGB could be a more malabsorptive procedure, indicating that it is not a so-called mini procedure. Additionally, a study by Poghosyan and colleagues[30] reported case reports of 17 patients who underwent an OAGB converted to RYGB because of severe complications. Of whom, ten (59%) received preoperative nutritional support for undernutrition. The authors concluded that conversion from OAGB to RYGB allows for weight correction in patients with undernutrition, decreases disabling digestive disorders, and improves the nutritional status of patients. A greater incidence of malnutrition after OAGB than after RYGB was also reported in the meta-analysis by Magouliotis and colleagues.[23]

In the YOMEGA trial, we did not observe any biological differences between the surgical groups regarding mean serum albumin, prealbumin, and vitamin deficiencies. We found a significant decrease in haemoglobin in the OAGB group compared with the RYGB group, but the frequencies of anaemia or iron deficiency were not significantly different. One limitation of our study could be that we did not assess specifically concentrations of vitamins A, E, and K, which could be more affected by fat malabsorption than the vitamins examined here (B1, B9, and B12). Regarding the concentration of vitamin D, another fat-soluble vitamin, we saw no significant difference between the groups at 2 years, but this vitamin was systematically supplemented after both procedures; furthermore, missing data could have affected the power of this analysis. Another limitation is that although all patients were supplemented with iron, calcium, and multivitamins, we did not record adherence.

The length of the biliopancreatic limb has been implicated as a strong factor in malnutrition. Since 2017, Mahawar and colleagues and others[31–33] have published several articles regarding the nutritional risk of a biliopancreatic limb that is too long when undertaking OAGB, suggesting not to exceed 150 cm. In Ruiz-Tovar and colleagues' trial,[15] the length of the biliopancreatic limb was between 200 cm and 350 cm. Surprisingly, the authors did not report a high incidence of malnutrition: among the 200 patients who underwent OAGB, only three presented with hypoproteinaemia, coinciding with a period of illness, and who were satisfactorily managed with a course of hyperproteinated supplements. We are again surprised here by the very low frequency of complications in each group in Ruiz-Tovar and colleagues'

study: four internal hernias and three anastomotic ulcers among 200 patients who underwent RYGB, and two uncontrolled biliary reflux, two anastomotic ulcers, and three cases of hypoproteinaemia among 200 patients who underwent OAGB.

Another point to consider is the effect of a short biliopancreatic limb on the incidence of biliary reflux, because the more the afferent limb is shortened the more the bile should be concentrated. The risk of biliary reflux exposure is a matter of concern for most digestive surgeons, as reported in a survey of 417 surgeons who do not undertake OAGBs that aimed to understand their objections: 211 (51%) of 414 were concerned about the risks of gastric cancer and 188 (45%) about the risks of oesophageal cancer.[22] In an experimental study in rats assessing biliary reflux after OAGB, Bruzzi and colleagues[20] reported an increased concentration of bile acid in the oesogastric segment of OAGB rats compared with sham rats. The authors found the mean concentration of bile acid was 2·8 times higher in the OAGB group at 7 weeks than in the sham group, which increased to 4·2 times higher at 16 weeks of follow-up. On gastric cardia biopsy, they reported a significant increase of eosinophilic polynuclear cell infiltration into the chorion of OAGB rats, but no intestinal metaplasia.[20] The authors concluded that the 4-month evaluation in rats is an equivalent exposure to biliary reflux of 12–16 years of human life, which might be insufficient when analysing risk of oesogastric carcinogenesis. In our study, using upper gastrointestinal endoscopies we identified that 16% of patients in the OAGB group had bile in their stomach at 2 years, which was not found in any of the RYGB patients. Furthermore, in the OAGB group 10% of patients had oesophagitis on endoscopic examination, and one patient had intestinal metaplasia identified by use of gastric and oesophageal biopsies, whereas 3% of patients in the RYGB group had oesophagitis and none had intestinal metaplasia. Although we are not able to conclude yet on a potential carcinogenic risk of OAGB associated with biliary reflux in humans because of the lack of long-term data, we should keep in mind that duodeno-oesophageal reflux has been shown to promote oesophageal carcinogenesis in experimental models.[21]

The restricted number of patients included in this trial, the relatively short follow-up, and the low follow-up are limitations of this study. Other complications such as those associated with malabsorption, which can take years to develop, could not be assessed in our trial. In conclusion, OAGB is not inferior to RYGB in terms of weight loss and metabolic improvement at 2 years. Higher incidences of diarrhoea, steatorrhoea, and nutritional adverse events were observed in the OAGB group than in the RYGB group, suggesting a malabsorptive effect of this bariatric procedure. Prospective studies with long-term follow-up are needed, especially to assess the risk of biliary reflux in the long term and the effect of modifying the length of the biliopancreatic limb on outcomes.

Contributors

MR and ED drafted the manuscript. MR, SB-D, DM-B, and DD conceived and designed the study. MR, PE, EP, RC, AS, LK, TP, J-MC, VM, EC, FR, AT, and FP did the surgical procedures. DD and SB-D were responsible for data acquisition. DM-B and CL-J were responsible for analysis. MR, ED, SB-D, DD, CL-J, and DM-B have access to the data. MR, ED, and DM-B interpreted the data. DM-B and FP critically reviewed the manuscript for important intellectual content. All authors agree to be accountable for all aspects of the work and ensuring that questions related to the accuracy or integrity of any part of the Article are appropriately investigated and resolved.

Declaration of interests

DM-B report personal fees from Maat Pharma outside of the submitted work. MR reports fees as a consultant from Medtronic and fees as an expert speaker from Gore outside of the submitted work. FR reports grants from Baxter, Endocontrol, and Takeda outside of the submitted work. All authors report grants from the French Ministry of Health (Direction Générale de l'Offre de Soin, study number 2013-037), during the conduct of the study.

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 maud.robert@chu-lyon.fr; 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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