Randomized clinical trial

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Effect of different limb lengths on quality of life, eating patterns and gastrointestinal symptoms after Roux-en-Y gastric bypass in superobese patients: randomized study

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Background: **Distal Roux-en-Y gastrojejunal bypass (DRYGJB) gives better weight reduction than standard Roux-en-Y gastric bypass (RYGB) but at the risk of increased malnutrition side-effects. This study compared the effects of RYGB and DRYGJB on gastrointestinal symptoms, eating patterns and health-related quality of life (QoL).**

Methods: **This was a single-blind RCT from a university-affiliated obesity centre. Patients with a BMI of 50 kg/m^2 or above were invited to participate. Treatment arms were standard gastric bypass with an alimentary limb of 150 cm and a biliopancreatic limb of 60 cm, with a variable common channel length, or DRYGJB with biliopancreatic limb of 200 cm, common channel limb of 150 cm and variable alimentary limb length. Baseline and follow-up data to 5 years on quality of life, obesity-related problems and gastrointestinal symptoms were collected using prospectively created and validated questionnaires.**

Results: **Some 140 patients were included. Those with a DRYGJB had better weight loss at 5 years (mean(s.d.) 68·3(21·8) kg *versus* 55·7(19·8) kg for standard RYGB; $P = 0{\cdot}011$). Eating patterns improved, with no difference between the groups. Gastrointestinal symptoms (diarrhoea, indigestion) worsened significantly in both groups, but only patients with DRYGJB had significantly worse diarrhoea at the end of the study than at baseline ($P = 0{\cdot}006$). Both groups had improved perceived generic QoL over baseline, and obesity-related problems were markedly reduced.**

Conclusion: **Standard RYGB and both improved generic and disease-specific QoL and eating behavioural pattern. Diarrhoea was increased more following DRYGJB than after RYGB. Registration number: NCT 01514799 (https://clinicaltrials.gov).**

Funding information
No funding

Paper accepted 6 July 2020

Published online 15 September 2020 in Wiley Online Library (www.bjsopen.com). **DOI:** 10.1002/bjs5.50334

Introduction

Effective treatments for obesity must be identified and their safety profiles established. Only surgery provides an effective durable treatment. Rates of superobesity, where BMI is at least 50 kg/m^2, have increased sixfold in recent decades[1], associated with increased co-morbidity[2]. Biliopancreatic diversion and duodenal switch are effective in terms of weight loss, but burdened by problems of malabsorption[3]. Several modifications of the classic Roux-en-Y gastric bypass (RYGB) have been introduced to investigate the effects of varying the amount of gut mucosa exposed to food. One such procedure is the distal Roux-en-Y gastrojejunal bypass (DRYGJB) with a long biliopancreatic limb and short common channel. This approach has been shown to improve weight loss better than standard RYGB in superobese patients[4–8].

The present randomized study examined the effects of DRYGJB compared with standard RYGB. The primary objective of the study was to investigate the effects on gastrointestinal symptomatology, eating behavioural patterns and quality of life (QoL) in patients in whom the effect on body weight had been ascertained.

Methods

The study was approved by the Lund ethics committee and was registered as NCT 01514799, and for the reference group of patients by the regional ethics committee of Stockholm, Sweden. The study was conducted according

to the Helsinki protocol; patients were informed orally and in writing, and signed consent forms were obtained from all participants.

In line with policy for all patients in Sweden who undergo surgery for obesity, patients in this study received questionnaires at baseline and follow-up to 5 years. The generic QoL instrument Short Form 36 (SF-36®; Rand Corporation, Santa Monica, California, USA), in which eight different domains were assessed for physical and mental QoL, and the Obesity-related Problems scale (OP-9)[9], were used. Results of the OP-9 are expressed as a compound score. Higher scores indicate more problems.

These standard data were stored in the Scandinavian Obesity surgery Registry (SOReg)[10]. In addition, two more tools were added for the purpose of this study: the Three-Factor Eating Questionnaire (TFEQ)[11], which measures cognitive restraint, uninhibited eating and emotional eating, and the Gastrointestinal Symptom Rating Scale (GSRS)[12,13]. The GSRS is a validated questionnaire specific for gastrointestinal complaints; it consists of 16 gastrointestinal symptoms, each scored on a seven-point Likert scale. The following clusters were defined: abdominal pain (abdominal pain, hunger pain and nausea), reflux syndrome (heartburn and acid regurgitation), diarrhoea syndrome (diarrhoea, loose stools and urgent need for defaecation), indigestion syndrome (borborygmus, abdominal distension, eructation and flatus) and constipation syndrome (constipation, hard stools and feeling of incomplete evacuation). Data from the TFEQ and GSRS were stored in a proprietary database to which only the authors had access.

Recruitment

Between August 2011 and May 2015, 3758 patients had surgery for morbid obesity at Aleris Obesity Skåne, a university affiliated centre in southern Sweden. Of these, 768 (20·4 per cent) met the inclusion criterion of a BMI of 50 kg/m^2 or more (*Fig. 1*). Exclusion criteria were previous bariatric or major abdominal surgery, disabling cardiopulmonary disease, malignancy, oral steroid treatment and conditions associated with poor compliance (drug abuse or severe psychiatric illness), and inability to use the Swedish language. All patients eligible for participation in the study were informed of its existence by the surgeon and 285 went on to be seen by a research nurse for extended information about the study; 140 patients accepted participation, filled out the GSRS and TFEQ questionnaires, and signed the consent form, including willingness to participate in the follow-up protocol. All patients were also urged to lose weight before operation, scheduled for, on average, 6–8 weeks later. The present study contained data recorded to 15 January 2020.

Data from the 483 patients who met the weight inclusion criterion, but had other exclusion criteria, were pooled with those of the 145 patients who declined participation in the study. These 628 patients formed a reference group to ascertain comparability of the study patients with this group in general. Baseline data from the SF-36® and OP-9 questionnaires for the reference group were recovered from the SOReg database and compared with data for the study groups.

Randomization technique

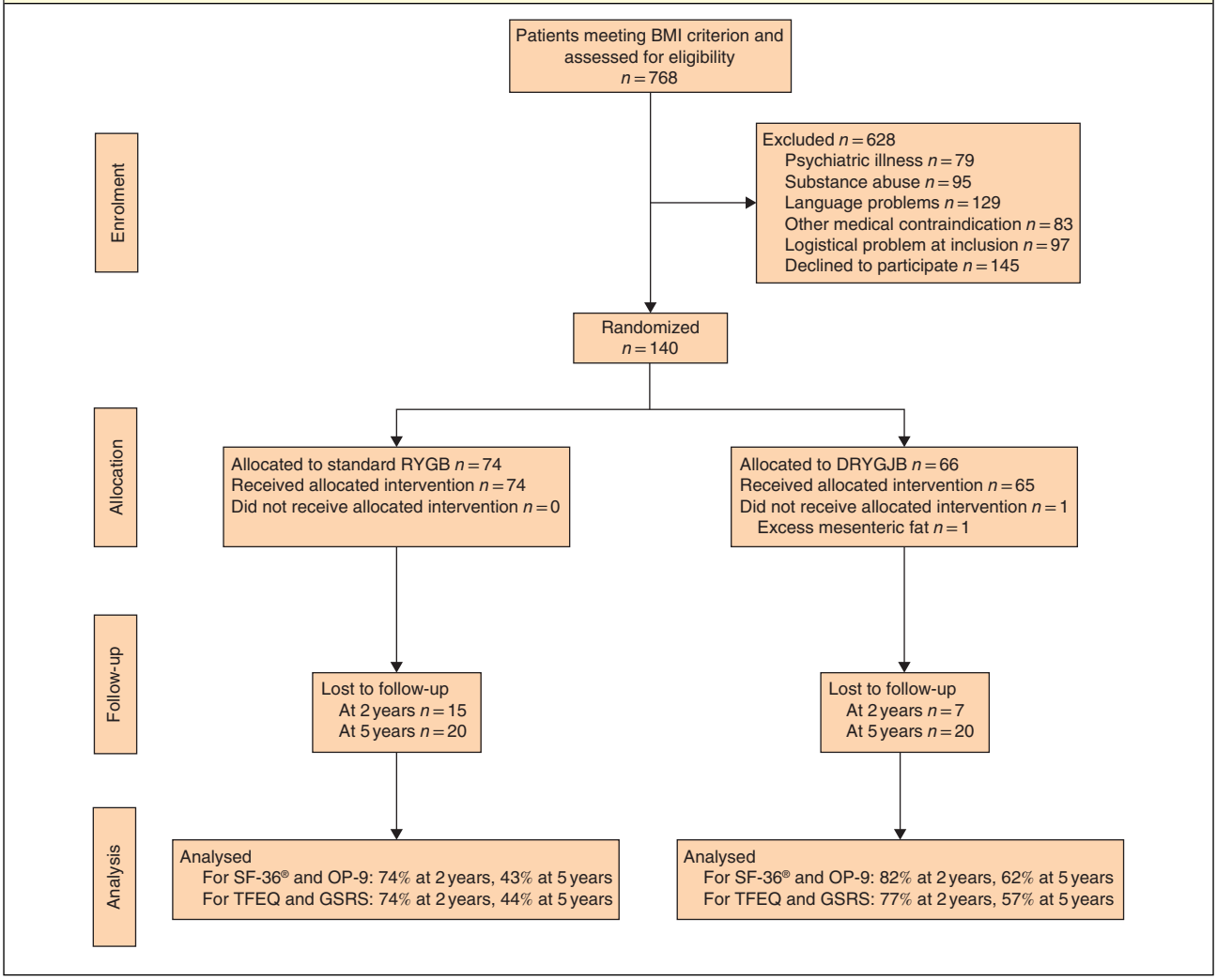
Opaque, unmarked and closed envelopes were prepared beforehand, containing a paper note indicating either 'standard' or 'long'. These envelopes were put 3 + 3 in two boxes in the operating theatre, with separate randomization for the two surgeons. When all six envelopes in a box had been drawn, it was replaced with a new one.

Operative technique

All operations were performed laparoscopically, as described previously[14,15]. Either of the two surgeons performed all operations. The first step was inspection of the abdomen. Once normal anatomy with no signs of disease had been ascertained, randomization was performed in the operating room by a nurse randomly drawing one envelope from the box. The operation was commenced by isolating a small (15 ml) gastric pouch. The bowel was brought up, first as an omega loop in antecolic and antegastric fashion, and the gastrojejunal anastomosis was created by stapling the jejunum to the posterior wall of the gastric pouch using a linear (3·5 mm) stapler. At the standard RYGB operation the biliopancreatic limb was measured to be 60 cm, and at the DRYGJB operation as 200 cm. The enteroanastomosis was created (2·5-mm stapler) 150 cm below the gastrojejunal anastomosis in the standard group (alimentary limb length 150 cm) and 150 cm from the ileocaecal junction in the DRYGJB group (common channel length 150 cm).

The jejunum was divided just orally to the gastrojejunostomy and, after a leak test, the mesenteric openings were closed as described previously[16]. One patient, randomized to have a DRYGJB, had so much mesenteric fat that the surgeon felt it unsafe to go ahead and a standard RYGB was performed. This patient's data were excluded from further analysis.

Fig. 1 CONSORT diagram showing enrolment of patients in the study



RYGB, Roux-en-Y gastric bypass; DRYGJB, distal Roux-en-Y gastrojejunal bypass; SF-36®, Short Form 36; OP-9, Obesity-related Problems scale; TFEQ, Three-Factor Eating Questionnaire; GSRS, Gastrointestinal Symptom Rating Scale.

A formalized enhanced recovery protocol was employed. Patients were usually discharged on the first postoperative day with full supplementations for vitamin B12, iron, calcium and vitamin D. Patients were informed that the operation had gone well, but not about the length of their biliopancreatic limb. Study patients had all follow-up visits in the hospital outpatient unit, but were also referred to their primary care physician after 1 year to enable supplementation of anthropometric data.

Data management and statistical analysis

An initial power analysis was based on weight data from an ongoing longitudinal study in Oslo, Norway, indicating that 140 patients would suffice to ascertain weight development. No data were available for a power analysis on QoL data, and the follow-up period of 5 years was arbitrary.

Data from the SOReg database were retrieved and pooled with the locally stored TFEQ and GSRS data. Excel® (Microsoft, Redmond, Washington, USA) and the Windows® System Assessment Tool (WinSTAT) for Excel® package (Kalmia, New York, USA) were used. Data were analysed for distribution patterns with the Kolmogorov–Smirnov test; statistical differences were determined using the Wilcoxon test for within-group analyses over time, and the Mann–Whitney *U* test or χ^2 (with Yates' correction) for between-group analyses, as

Table 1 Anthropometric data for the two groups throughout the study

	DRYGJB	Standard RYGB	*P**
Baseline	*n* = 66	*n* = 74	
Sex ratio (M : F)	24 : 42	33 : 41	0·390†
Age at inclusion (years)	39(10)	38(11)	0·879
Bodyweight (kg)	165(26)	165(27)	0·833
Height (m)	171(10)	172(10)	0·881
BMI (kg/m^2)	55·8(6·0)	55·6(6·0)	0·382
Waist (cm)	138(10)	147(16)	0·789
Treatment for diabetes	15	15	–
Treatment for hypertension	19	23	–
1-year follow-up	*n* = 65	*n* = 72	
Bodyweight (kg)	103·1(21·2)	106·4(21·3)	0·462
BMI (kg/m^2)	35·0(5·7)	35·9(5·6)	0·462
Weight loss (kg)	62·1(15·3)	58·5(17·1)	0·098
BMI loss (kg/m^2)	21·2(4·2)	19·8(5·1)	0·102
%EWL	69(4)	65(3)	0·096
Waist (cm)	106(14)	109(14)	0·200
2-year follow-up	*n* = 59	*n* = 59	
Bodyweight (kg)	96·6(19·9)	99·4(19·8)	0·526
BMI	32·8(5·8)	34·1(5·7)	0·319
Weight loss (kg)	68·4(18·3)	64·0(18·7)	0·211
BMI loss	23·3(5·6)	21·8(5·4)	0·216
EWL%	76(4)	71(3)	0·153
Waist (cm)	99(14)	103(13)	0·194
5-year follow-up	*n* = 36	*n* = 33	
Bodyweight (kg)	97·8(19·4)	102·1(21·8)	0·397
BMI (kg/m^2)	33·1(6·7)	34·7(5·4)	0·216
Weight loss (kg)	68·3(21·8)	55·7(19·8)	0·011
BMI loss (kg/m^2)	22·8(5·9)	19·0(6·1)	0·024
%EWL	75(18)	65(18)	0·085
Waist (cm)	107(16)	112(23)	0·648
At last follow-up			
Treatment for diabetes	0	2	–
Treatment for hypertension	5	11	–

Values are mean(s.d.) except where numbers of patients are shown. DRYGJB, distal Roux-en-Y gastrojejunal bypass; RYGB, Roux-en-Y gastric bypass; %EWL, percentage excess weight loss. *Mann–Whitney *U* test, except †χ^2 test.

Table 2 Complications in the two study groups over the 4–6-year study period

	DRYGJB	Standard RYGB
Early		
Bleeding	1	1
Late		
Internal herniation	3	2
Enteroanastomosis 'kinking' due to adhesions	1	1
Incarcerated umbilical hernia	2	–
Stomal ulcer	1	1
Gallstone disease	4	2

DRYGJB, distal Roux-en-Y gastrojejunal bypass; RYGB, Roux-en-Y gastric bypass.

Table 3 Quality-of-life data for the two study groups

	DRYGJB	Standard RYGB	*P*†
Baseline	*n* = 66	*n* = 74	
SF-36® compound physical	30·7(11·2)	29·7(11·9)	0·909
SF-36® compound mental	40·7(13·8)	37·9(15·0)	0·343
OP-9	74·3(21·8)	75·5(20·9)	0·769
1-year follow-up			
Compliant with follow-up	65	74	
Compliant with follow-up*	65 (98)	72 (97)	0·920‡
SF-36® compound physical	51·1(8·9)	50·1(8·8)	0·841
SF-36® compound mental	48·3(12·1)	47·7(12·5)	0·661
OP-9	25·6(24·3)	27·7(26·9)	0·888
2-year follow-up			
Available for follow-up	65	74	
Compliant with follow-up*	59 (89)	59 (80)	0·182‡
SF-36® compound physical	46·8(15·7)	52·2(7·6)	0·204
SF-36® compound mental	44·2(17·0)	45·9(13·5)	0·648
OP-9	25·0(23·1)	24·7(25·6)	0·706
5-year follow-up			
Available for follow-up	65	73	
Compliant with follow-up*	31 (47)	33 (45)	0·903‡
SF-36® compound physical	49·2(9·9)	47·1(16·7)	0·817
SF-36® compound mental	44·8(15·1)	43·2(15·7)	0·577
OP-9	20·5(20·0)	25·4(29·9)	0·923

Values are mean(s.d.) scores unless indicated otherwise; *values in parentheses are percentages. Higher Short Form 36 (SF-36®) scores indicate better quality of life; lower values in the Obesity-related Problems scale (OP-9) indicate fewer problems. DRYGJB, distal Roux-en-Y gastrojejunal bypass; RYGB, Roux-en-Y gastric bypass. †Mann–Whitney *U* test, except ‡χ^2 test.

appropriate. $P < 0{\cdot}050$ was taken to indicate significance. Data are presented as mean(s.d.) values, unless stated otherwise. No attempt was made to calculate *P* values for treatment effects on co-morbidity as the study was underpowered for dichotomous variables.

Results

There were no significant differences before surgery between study patients and the reference group in terms of physical ($P = 0{\cdot}721$) or mental ($P = 0{\cdot}863$) QoL, or in terms of obesity-related problems ($P = 0{\cdot}579$).

There were no differences between the two study groups at baseline in terms of weight, height, BMI, waist circumference, age or sex distribution (*Table 1*). Duration of surgery was longer in the DRYGJB than in the standard RYGB group (53·1(13·1) *versus* 37·6(10·2) min respectively; $P < 0{\cdot}001$). Two patients had

postoperative bleeding episodes, one in each group, and total postoperative hospital stay did not differ (1·1(0·5) days for both groups; $P = 0·713$). Late complications were evenly distributed between groups (*Table 2*). Patients in both groups lost weight throughout the study; those in the DRYGJB group had lost 12·6 kg more at 5 years ($P = 0·011$), but there were no significant differences in weight loss between the groups at earlier time points (*Table 1*).

Compliance with filling out the questionnaires decreased over time, but did not differ between the groups throughout the study (*Table 3*). There were also variations in the filling-out of the questionnaires. Some patients provided answers by post and declined visits to the outpatient clinic.

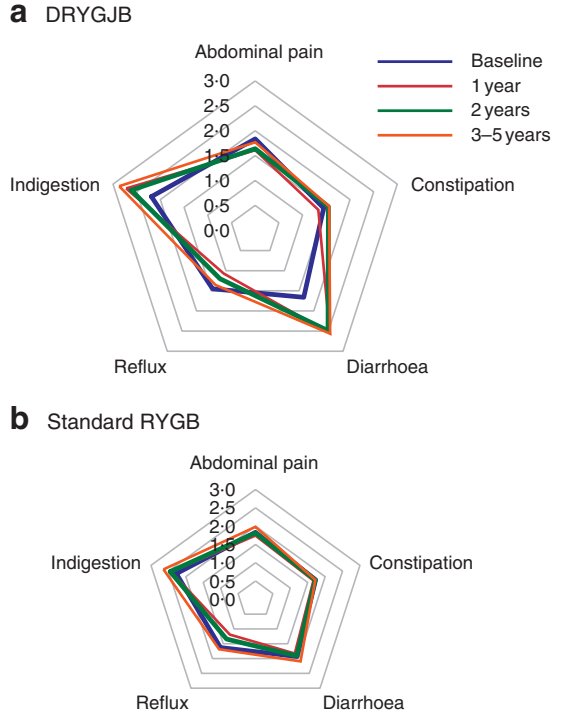
The GSRS questionnaire showed that at 1 year after surgery both groups of patients had developed increased indigestion compared with basal values. This pattern persisted throughout the study. At 2 years, patients in the DRYGJB group had significantly more diarrhoea in the form of loose stools than those having a standard RYGB ($P = 0·027$), but this difference did not persist at 5 years. At this last follow-up point, scoring for diarrhoea had reached significant values compared with baseline in the DRYGJB group ($P = 0·006$) but not in the RYGB group ($P = 0·300$) (*Fig. 2*). Other GSRS domains did not change over the study period in either group.

At 1 year, reductions in uninhibited eating and emotional eating were observed in both groups. In parallel, the score for cognitively restrained eating was increased (*Fig. 3*). There were no differences between groups and the pattern persisted throughout the study.

Patients started with a low level of QoL, expressed in all domains of the SF-36®. Compound score values are given in *Table 3*. A graphical presentation of the effects over time in the various domains is shown in spider charts for each study group (*Fig. 4*). There were no differences between the groups at any time point. With time, all aspects of QoL improved significantly for both mental and physical aspects, as shown by the compound scores.

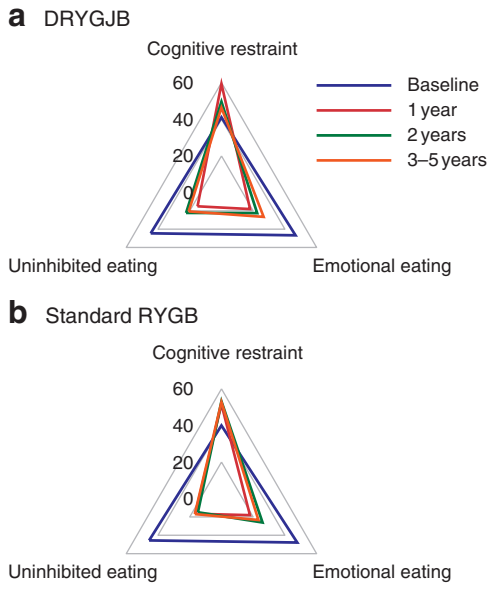
Both patient groups reported a high level of obesity-related problems at baseline. This variable was also markedly improved after surgery, with no differences between groups (*Table 3* and *Fig. 5*).

Fig. 2 Change over time in the domains of the Gastrointestinal Symptom Rating Scale for the two treatment groups



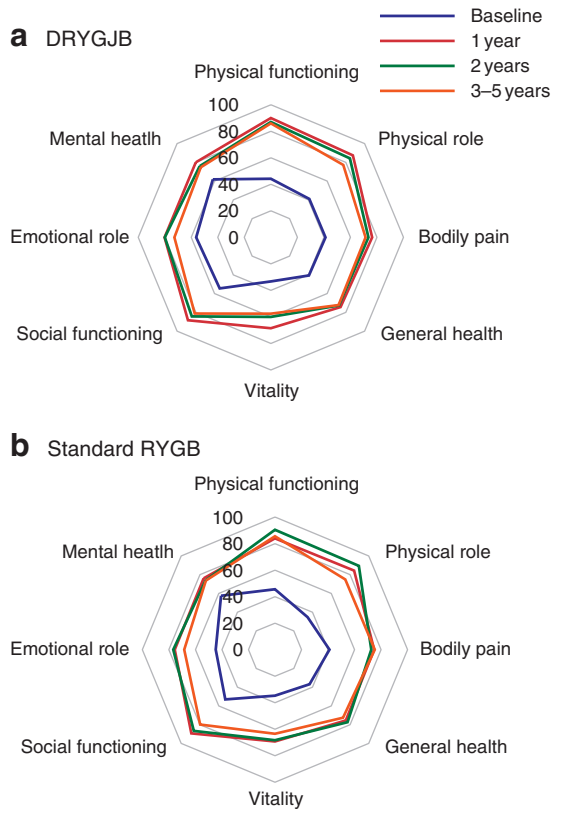
a Distal Roux-en-Y gastrojejunal bypass (DRYGJB); **b** Roux-en-Y gastric bypass (RYGB). Increases over baseline scores for diarrhoea and indigestion were statistically significant for the DRYGJB group ($P = 0·006$ and $P = 0·031$ respectively, Wilcoxon test).

Fig. 3 Change over time in Three-Factor Eating Questionnaire scores for the two treatment groups



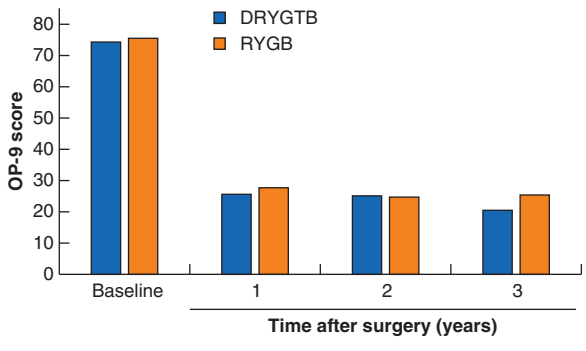
a Distal Roux-en-Y gastrojejunal bypass (DRYGJB); **b** Roux-en-Y gastric bypass (RYGB). Each variable within the Three-Factor Eating Questionnaire was compared between patient groups at four points in time using the Mann–Whitney *U*-test. RYGB patient values were higher ($P = 0·018$) at 2 years, but did not differ between groups at any other time point. There were no differences between groups for the other variables.

Fig. 4 Developments over time in the various domains of the Short Form 36 questionnaire for the two treatment groups



a Distal Roux-en-Y gastrojejunal bypass (DRYGJB); **b** Roux-en-Y gastric bypass (RYGB). Higher values indicate better quality of life.

Fig. 5 Compound scores for the Obesity-related Problems scale for the two treatment groups



Lower values indicate fewer problems (higher quality of life). OP, Obesity-related Problems scale. Reduction from baseline values to 1-, 2- and 5-year scores was highly significant. There were no differences between distal Roux-en-Y gastrojejunal bypass (DRYGJB) and standard Roux-en-Y gastric bypass (RYGB) groups at any time point.

Discussion

Patients who participated in this study were comparable to superobese patients in general. The main findings of the study were that both procedures achieved weight loss over a 5-year period, with significantly greater mean weight loss of 12·6 kg in the DRYGJB group at this time ($P = 0·011$). Although all patients reported increased diarrhoea during follow-up, this remained statistically significant at 5 years compared with baseline only for the DRYGJB group. Improvements in health-related QoL were similar between the groups throughout follow-up.

Surgical treatment of superobesity is difficult, balancing the effect on weight with side-effects and malnutrition. Several modifications of operative techniques have been described, but a clear recommendation on which to use cannot yet be made, although it is established that bariatric surgery is justified in these patients and international guidelines have been presented[17,18]. Ineffectiveness of standard RYGB in some studies[19–21] has led to modifications in which longer segments of gut are bypassed. Whether these procedures are effective as a result of a reduction in the amount of gut mucosa exposed to food or by altering signalling pathways from the bowel that influence eating behaviour, or both, is still incompletely understood[22].

The serious and frequent side-effects of biliopancreatic diversion and duodenal switch have been well documented[3], and their routine use has been largely abandoned, comprising only 0·8 per cent of primary procedures in Sweden in 2018[23]. It is already known that distal RYGB with a short common channel (75–100 cm) as well as a long Roux limb (type 2 distal bypass) with unchanged total alimentary tract length are associated with similar long-term weight loss and more nutritional complications than standard RYGB[24–26]. In the present study, a distal bypass with long biliopancreatic limb (type 1, or Sugerman type[27]) was used, where the total alimentary tract length is shortened. This technique has already been demonstrated to improve long-term weight loss results compared with standard RYGB[4].

A main determinant when choosing operative technique should be the expected outcome on patient QoL. The main question in this study was whether the beneficial weight results obtained with DRYGJB would be offset by increased side-effects, possibly influencing generic QoL. The study confirmed that patients in the DRYGJB group lost statistically more weight compared with baseline values than patients having standard RYGB. Eating behaviour, as measured by the TFEQ, was altered at 1 year, with emotional and uninhibited eating being greatly reduced and cognitively restrained eating increasing. This effect of

RYGB surgery has already been shown for standard-limb RYGB[28], and the effects of surgery lasted throughout the study period.

Standard RYGB is known to cause gastrointestinal symptoms, and the present study has confirmed these earlier findings. Patients who underwent DRYGJB experienced more diarrhoea than those having standard RYGB, and both groups had more indigestion but no increase in abdominal pain, as has been reported previously[28] using the same instrument. The clinical importance of these differences remains doubtful, as patient-assessed generic QoL was not influenced negatively. Other effects of the better weight loss following DRYGJB may possibly offset the gastrointestinal symptomatology. One possibility is that patients who had DRYGJB were more compliant with dietary instructions, eating less fat and thereby achieving better weight loss, so that diarrhoea was less problematic.

A shortcoming of the present study was follow-up rate. Patients who drop out are thought to have worse clinical outcomes[29]. The two patient groups did, however, have the same rates of follow-up, so the comparison between groups was unlikely to be influenced by such an effect. The better weight loss achieved by DRYGJB is, however, known to be associated with a higher need for supplementation in order to prevent malnutrition, stressing the importance of long-term nutritional follow-up for these patients[16,30].

DRYGJB in gastric bypass surgery for superobesity improved weight results significantly, without increased perioperative morbidity, time to discharge, or increased adverse events during follow-up. The duration of surgery is longer, and DRYGJB results in more diarrhoea than standard RYGB, although this may be of limited clinical significance as improvement in QoL, as well as absolute values of QoL at the end of the study, were similar in the two groups.

Disclosure

The authors declare no conflict of interest.

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