

# Randomized clinical trial of laparoscopic gastric bypass *versus* laparoscopic duodenal switch for superobesity

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**Background:** Laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic biliopancreatic diversion with duodenal switch (LDS) are surgical options for superobesity. A randomized trial was conducted to evaluate perioperative (30-day) safety and 1-year results.

**Methods:** Sixty patients with a body mass index (BMI) of 50–60 kg/m<sup>2</sup> were randomized to LRYGB or LDS. BMI, percentage of excess BMI lost, complications and readmissions were compared between groups.

**Results:** Patient characteristics were similar in the two groups. Mean operating time was 91 min for LRYGB and 206 min for LDS ( $P < 0.001$ ). One LDS was converted to open surgery. Early complications occurred in four patients undergoing LRYGB and seven having LDS ( $P = 0.327$ ), with no deaths. Median stay was 2 days after LRYGB and 4 days after LDS ( $P < 0.001$ ). Four and nine patients respectively had late complications ( $P = 0.121$ ). Mean BMI at 1 year decreased from 54.8 to 38.5 kg/m<sup>2</sup> after LRYGB and from 55.2 to 32.5 kg/m<sup>2</sup> after LDS; percentage of excess BMI lost was greater after LDS (74.8 *versus* 54.4 per cent;  $P < 0.001$ ).

**Conclusion:** LRYGB and LDS can be performed with comparable perioperative safety in superobese patients. LDS provides greater weight loss in the first year. Registration number: NCT00327912 (<http://www.clinicaltrials.gov>).

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## Introduction

Bariatric surgery improves quality of life and obesity-related co-morbidity, leading to a reduction in long-term mortality in morbidly obese patients<sup>1–4</sup>. Laparoscopic Roux-en-Y gastric bypass (LRYGB) provides significant and sustained weight loss<sup>2,5</sup>. Long-term follow-up studies of superobese patients with a body mass index (BMI) of 50–60 kg/m<sup>2</sup> have, however, shown high weight loss failure rates following this procedure<sup>6,7</sup>.

The technically more complex procedure of laparoscopic biliopancreatic diversion with duodenal switch (LDS) is a surgical option for superobesity, although it may be associated with a higher risk of nutritional deficiency than LRYGB owing to the malabsorptive aspect of the procedure<sup>8</sup>. Operative safety, weight loss and long-term complications of the two techniques have not been evaluated in a randomized trial.

This study was a prospective two-centre randomized trial comparing LRYGB and LDS for superobese patients. The primary endpoint was weight loss after surgery. Secondary endpoints included perioperative and late complications, changes in body composition and co-morbidity, nutritional status and quality of life. This report presents the

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The Editors are satisfied that all authors have contributed significantly to this publication

perioperative results and 1-year morbidity and weight loss data.

## Methods

Both participating hospitals, Oslo University Hospital Aker and Sahlgrenska University Hospital, Gothenburg, are public centres performing more than 200 bariatric procedures annually. Before the study, bariatric surgical experience at Aker included 123 LRYGBs (performed by two surgeons) and 15 LDS procedures (performed by one of the two surgeons), and at Sahlgrenska 435 LRYGBs (three surgeons) and 18 LDS procedures (one of the three surgeons). All surgeons had performed at least 50 bariatric operations previously. The study protocol was approved by local ethics committees in the two countries. LRYGB and LDS were considered to be established surgical options for superobese patients. Participation in the study was voluntary and all patients were informed of the expected outcome and common side-effects of both procedures. Signed informed consent was obtained from all patients.

Patients were recruited from referrals for bariatric surgery between March 2006 and August 2007. Inclusion criteria were a BMI of 50–60 kg/m<sup>2</sup> at referral, age 20–50 years, and signed informed consent. 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). Eligible patients were consulted, informed and enrolled by dedicated persons at both centres. Preoperative investigation included assessment of co-morbid conditions. No preoperative ultrasonography of the gallbladder was performed.

Patients consumed a low-calorie diet (1000 kcal/day) for 3 weeks before surgery. Total intravenous anaesthesia with target-controlled infusion was used for both procedures. Bupivacaine was injected at the trocar sites at the start of the procedure. During surgery, 500 ml dextran was infused as thrombosis prophylaxis, and single prophylactic doses of 1500 mg metronidazole and 400 mg doxycycline were given.

Patients were randomized to LRYGB or LDS and stratified according to surgical centre, sex, age (20–35 or 36–50 years) and BMI (50–55 or 56–60 kg/m<sup>2</sup>). Randomization was performed at Sahlgrenska with LabVIEW™ version 7.1 (National Instruments, Austin, Texas, USA). The result of randomization was known only to the doctors enrolling the patients and the personnel scheduling the operation. Patients were informed of the planned procedure 1 week before surgery.

Data were recorded prospectively on designated case record forms. The perioperative period was defined as within 30 days of surgery. Weight change after surgery was reported as BMI (kg/m<sup>2</sup>) and the percentage of excess BMI lost ((preoperative BMI – current BMI)/(preoperative BMI – 25) × 100)<sup>9</sup>. A planned separate evaluation of the early results with emphasis on surgical safety was agreed before the start of the study.

## Surgical procedures

In both procedures, pneumoperitoneum was established by visual introduction of the first trocar 15 cm below the xiphoid. Limb lengths were measured sequentially by placing a 20-cm band adjacent to the small bowel.

For LRYGB, the stomach was divided horizontally and vertically with linear staplers to create a 25-ml gastric pouch. An antecolic antegastric gastrojejunostomy was created between the pouch and the jejunum 50 cm distal to the ligament of Treitz using a 45-mm stapler cartridge and completed with a running suture. The omentum was not transected routinely. The alimentary limb was measured to 150 cm, and a side-to-side jejunojejunostomy created using a 45-mm stapler cartridge and closed with a running suture. The Roux-en-Y configuration was completed by dividing the jejunum between the anastomoses with a stapler. Patency of the gastrojejunostomy was evaluated by instilling diluted methylene blue via a nasogastric tube while clamping the small bowel.

For LDS, a sleeve gastrectomy was performed with repeated firings of 60-mm linear stapler cartridges from the antrum to the angle of His along a nasogastric tube of 30–32 Fr. The duodenum was mobilized and transected 4 cm distal to the pylorus with a 60-mm stapler cartridge. The small bowel was measured from the caecum for a common channel length of 100 cm and an alimentary limb length of 200 cm, then anastomosed to the duodenum with a handsewn two-layer anastomosis with 2/0 or 3/0 absorbable suture. The enteroenterostomy was created with a 45-mm cartridge and closed with a running suture. The small bowel was divided between the two anastomoses, and the duodenoileostomy tested with methylene blue.

Mesenteric defects were not closed in any procedure. A cholecystectomy was performed in patients with symptomatic gallstone disease. Liver biopsy and appendicectomy were not performed.

## Postoperative care

Patients received a liquid diet from the first postoperative day, a semiliquid diet after 1 week, with a gradual return

to normal food intake after 2 weeks. Low molecular weight heparin was administered daily according to weight from the day after the procedure. Postoperative outpatient follow-up (by surgeon and dietician) was at 6 weeks, 6 months and 1 year. Patients received a standard daily supplement of multivitamins, iron, calcium and vitamin D. Patients who underwent LRYGB were prescribed additional vitamin B<sub>12</sub>. Ursodeoxycholic acid was prescribed for 6 months, except in patients who had undergone cholecystectomy.

### Statistical analysis

A retrospective analysis of the 3-year weight loss data of superobese patients submitted to LDS and LRYGB at Sahlgrenska was performed. The mean(s.d.) change in BMI was 24.9(5.0) kg/m<sup>2</sup> after LDS and 18.0(6.7) kg/m<sup>2</sup> after LRYGB. Applying these data, a sample size of 60 patients would give a greater than 90 per cent power (two-sided *t* test, *P* = 0.050) to detect a difference in the change in BMI between the groups. The sample size estimation was performed with SamplePower<sup>®</sup> version 2.0 (SPSS, Chicago, Illinois, USA).

Normally distributed values are reported as mean(s.d.) and non-normally distributed values as median (range).  $\chi^2$  or Fisher's exact test was used to compare proportions between groups. Student's *t* test or Mann-Whitney

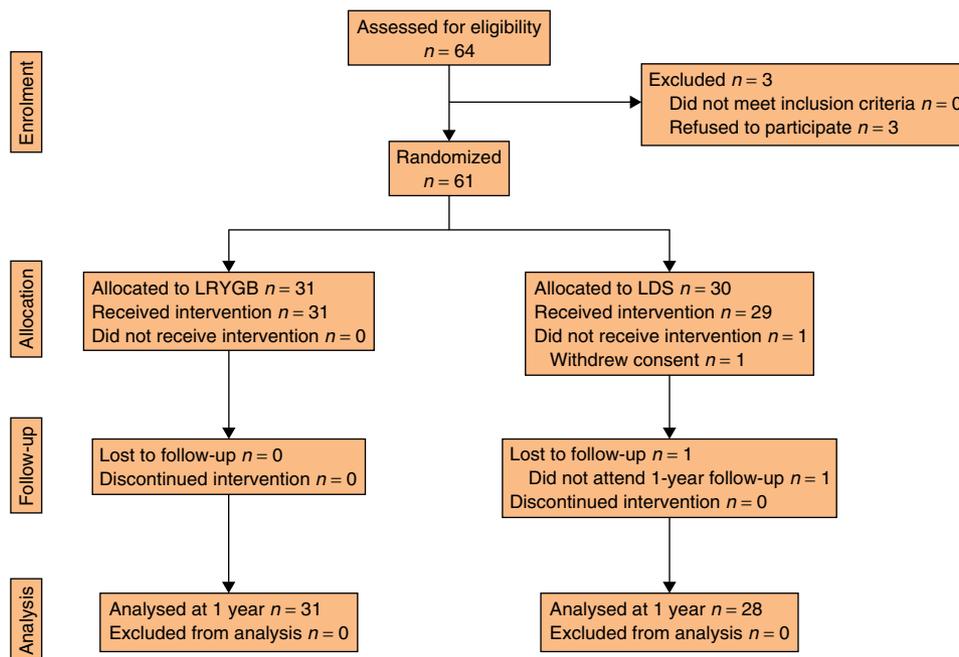
*U* test was applied for comparison of continuous variables, as appropriate. Two-sided *P* < 0.050 was considered statistically significant. Statistical analyses were performed with SPSS<sup>®</sup> version 15.0 for Windows<sup>®</sup> (SPSS).

### Results

A total of 61 patients were included in the study; one patient withdrew after randomization, but was not aware of the planned procedure. LRYGB was performed in 31 patients and LDS in 29. All patients completed the 6-month follow-up, although one patient missed the 1-year visit (*Fig. 1*). Fifteen LRYGB and 15 LDS procedures were performed at Aker, with 16 and 14 procedures respectively at Sahlgrenska. Patient characteristics are shown in *Table 1*.

### Perioperative results

Mean(s.d.) operating time was 91(33) min for LRYGB and 206(47) min for LDS (*P* < 0.001). One LDS procedure was converted to open surgery because of the thickness and rigidity of the abdominal wall. A cholecystectomy was performed in one patient in the LDS group. Complications occurred in four patients after LRYGB and in seven after



**Fig. 1** CONSORT diagram of the study. LRYGB, laparoscopic Roux-en-Y gastric bypass; LDS, laparoscopic biliopancreatic diversion with duodenal switch

**Table 1** Patient characteristics

	LRYGB (n = 31)	LDS (n = 29)
Age (years)*	35(7)	36(5)
Sex ratio (F : M)	23 : 8	19 : 10
Weight (kg)*	162(24)	162(20)
Body mass index (kg/m <sup>2</sup> )*	54.8(3.2)	55.2(3.5)
Systolic blood pressure (mmHg)*	134(20)	138(20)
Diastolic blood pressure (mmHg)*	83(12)	88(13)
Waist circumference (cm)*	150(13)	153(13)
Hip circumference (cm)*	153(12)	157(13)
Waist : hip ratio*	0.98(0.11)	0.98(0.09)
ASA score*	2.6(0.6)	2.8(0.5)
Previous abdominal surgery	3	2
Co-morbidity		
Joint pain	16	13
Depression	5	12‡
Hypertension	8	8
Asthma	8	5
Urinary incontinence	5	7
Sleep apnoea	5	6
Gastro-oesophageal reflux disease	5	4
Diabetes mellitus†	5	3
Hypothyroidism	3	3
Gallstones	2	1
Hyperlipidaemia	0	3
Gout	1	1

\*Values are mean(s.d.). †One patient had type 1 diabetes mellitus. LRYGB, laparoscopic Roux-en-Y gastric bypass; LDS, laparoscopic biliopancreatic diversion with duodenal switch; ASA, American Society of Anesthesiologists. ‡ $P = 0.045$  versus LRYGB (Fisher's exact test). There were no other significant differences between the groups.

LDS ( $P = 0.327$ ) (Table 2). Two LRYGB procedures were complicated by leaks from the gastroenterostomy, and two leaks from the duodenal stump occurred after LDS. Abscesses located lateral to the spleen and subcutaneously were drained percutaneously in one patient in the LDS group, but no bowel leakage was identified by computed tomography or endoscopy. One patient in the LDS group had a stenotic ileoduodenostomy dilated endoscopically 25 days after surgery. Two patients in the LRYGB group and one in the LDS group required reoperation ( $P = 1.000$ ), all laparoscopic. Reoperations after LRYGB were for anastomotic leaks, performed on days 1 and 15 after surgery (one leak presented as an intra-abdominal abscess 13 days after surgery). One duodenal stump leak necessitated reoperation on the third day after operation; the other was treated conservatively by percutaneous drainage of an intra-abdominal abscess.

There were no deaths. The median (range) length of postoperative hospital stay was 2 (2–15) days after LRYGB and 4 (2–43) days after LDS ( $P < 0.001$ ). The number of patients readmitted within 30 days of surgery was similar in the two groups (Table 2).

**Table 2** Perioperative complications and readmissions

	LRYGB (n = 31)	LDS (n = 29)
Abscess		
Intra-abdominal	1	2
Cutaneous	1	1
Acute abdominal pain	2 (2)	0
Anastomotic leak	2 (1)	0
Leak from duodenal stump	0	2 (1)
Haemorrhage		
Intraluminal	1 (1)	1
Subcutaneous	1	0
Stenosis of duodenoileostomy	0	1 (1)
Pneumonia	1 (1)	1
Hyperglycaemia	1 (1)	0
Infection of unknown origin	0	1 (1)
Dyspnoea and chest pain	0	1 (1)
Gluteal musculature ischaemia	0	1
Total no. of complications	10	11
No. of patients with complications	4	7*
Total no. of readmissions	6	4
No. of patients readmitted	4	4†

Values in parentheses are number of readmissions for treatment of the complication. LRYGB, laparoscopic Roux-en-Y gastric bypass; LDS, laparoscopic biliopancreatic diversion with duodenal switch. \* $P = 0.327$ , † $P = 1.000$  versus LRYGB (Fisher's exact test).

## Follow-up results

Four patients in the LRYGB group and nine in the LDS group had late complications ( $P = 0.121$ ) (Table 3). Reoperations were performed in three patients after LDS, but none after LRYGB ( $P = 0.107$ ). Omental resection by open surgery, owing to an inflammatory reaction of unknown origin in the transverse mesocolon, was performed in one patient 4 months after LDS. Another patient underwent laparotomy 10 months after the primary operation for peritonitis, with ascites as the only finding. The third reoperation was for common bile duct stones; the patient underwent laparoscopic bile duct exploration and cholecystectomy 11 months after LDS. The patient was not known to have gallstones before the original bariatric operation.

The number of patients readmitted between 30 days and 1 year after surgery was similar in the two groups (Table 3). Mean weight at 1 year was 114 kg following LRYGB and 95 kg after LDS. The BMI and percentage of excess BMI lost at 6 weeks, 6 months and 1 year of follow-up are shown in Table 4. Two of 28 patients in the LDS group had a severe metabolic disturbance (hypoalbuminaemia and iron deficiency) during follow-up, whereas none was identified in the LRYGB group.

**Table 3** Late complications and readmissions

	LRYGB (n = 31)	LDS (n = 29)
Vomiting	0	3 (1)
Abdominal pain	2 (1)	1
Diarrhoea	1 (2)*	1
Inflammation of transverse mesocolon	0	1 (2)
Common bile duct stones	0	1 (1)
Intra-abdominal abscess	0	1 (1)
Pneumonia	0	1 (1)
Severe oedema of lower extremities	0	1 (1)†
Peritonitis	0	1 (1)‡
Psychiatric disorder	1 (1)	0
Iron deficiency	0	1
Cholecystolithiasis	1	0
Total no. of complications	5	12
No. of patients with complications	4	9§
Total no. of readmissions	4	8
No. of patients readmitted	2	5¶

Values in parentheses are number of readmissions for treatment of the complication. \**Clostridium difficile* enterocolitis; †required nutritional support for hypoalbuminaemia; ‡acute peritonitis. LRYGB, laparoscopic Roux-en-Y gastric bypass; LDS, laparoscopic biliopancreatic diversion with duodenal switch. § $P = 0.121$ , ¶ $P = 0.247$  versus LRYGB (Fisher's exact test).

**Table 4** Body mass index and percentage excess body mass index lost after surgery

Time after surgery	BMI (kg/m <sup>2</sup> )			Percentage of excess BMI lost		
	LRYGB	LDS	$P^*$	LRYGB	LDS	$P^*$
6 weeks	48.2(3.0)	46.7(3.3)	0.093	22.3(5.9)	28.1(6.8)	0.001
6 months	41.7(3.8)	38.1(3.3)	<0.001	44.0(10.7)	56.9(9.6)	<0.001
1 year	38.5(4.0)	32.5(3.2)	<0.001	54.4(12.8)	74.8(11.2)	<0.001

Values are mean(s.d.). BMI, body mass index; LRYGB, laparoscopic Roux-en-Y gastric bypass; LDS, laparoscopic biliopancreatic diversion with duodenal switch. \*Student's  $t$  test.

## Discussion

In this randomized trial comparing LRYGB and LDS in superobese patients, both procedures were performed with acceptable safety and no mortality. Complications within 30 days of surgery occurred in seven of the 29 patients who underwent LDS, comparable to the 24 per cent overall morbidity rate described in 100 superobese patients treated by open, laparoscopic or robotic duodenal switch surgery<sup>10</sup>. Other LDS series have also shown that the procedure can be performed safely in superobese patients<sup>11,12</sup>. The perioperative morbidity rate after LRYGB in the present study was also similar to that of other large series<sup>12,13</sup>. Two anastomotic leaks occurred after LRYGB in the present study, compared with an average leak rate after

LRYGB at one of the study centres (Aker) of 1.4 per cent<sup>14</sup>. The duodenal stump leaks after LDS may indicate that oversewing of the distal duodenal staple line, or applying staple-line reinforcement, should be considered.

Participating surgeons were more experienced in LRYGB than LDS, and this may have influenced the perioperative results. An attempt was made to minimize this bias by allocating all LDS procedures to one surgeon at each study centre, both with extensive laparoscopic surgical experience. Even so, these surgeons had both performed fewer than 20 LDS procedures at the start of the study, and a reduction in operating time and morbidity rate might be expected with increased experience.

Both patients with metabolic disturbances were in the LDS group and, although this is a small number at 1 year, a difference in clinically important metabolic complications between the two procedures may be revealed with extended follow-up. The bougie size applied for the sleeve gastrectomy in LDS in this study was smaller than that described by some authors<sup>15</sup>. A narrow gastric tube is a possible mechanism for the persistent vomiting that affected three patients who underwent LDS in the present study. The larger number of patients with complications and readmissions following LDS, although not statistically significant, may indicate a higher frequency of late complications with this procedure. A larger study is needed to address this issue.

Patients allocated to LDS had superior weight loss. BMI was significantly lower after LDS at 6 months after surgery, and at 1 year the BMI following LDS was 32.5 kg/m<sup>2</sup>, compared with 38.5 kg/m<sup>2</sup> for LRYGB. Deveney and colleagues<sup>16</sup> observed no difference in the percentage of excess bodyweight lost after gastric bypass versus duodenal switch. Two other retrospective comparisons of the two procedures, where patients selected the procedure performed, provide weight loss data that support the present findings<sup>17,18</sup>. In all of these studies the preoperative BMI of patients submitted to duodenal switch was significantly higher than in those subjected to LRYGB.

Restriction of food intake and changes in appetite and satiety associated with alterations in gut hormones are probably key mechanisms for weight loss after LRYGB<sup>19,20</sup>. An increase in the malabsorptive aspect of the operation, as in the 'distal' gastric bypass, could be associated with a risk of metabolic disturbance<sup>21,22</sup>. Modifying the procedure by lengthening the Roux or biliopancreatic limbs might improve weight loss. Such alterations seem to promote an increased weight loss in superobese patients, but not in patients with a lower initial BMI<sup>23-27</sup>.

LDS is a modification of the biliopancreatic diversion, with the potential benefits of increased weight loss, lower revisional surgery rates, and reduced frequencies of anastomotic ulcer and protein malabsorption<sup>8,15,28–30</sup>. Even so, the malabsorptive aspect of both procedures implies a risk of nutritional deficiency and metabolic disturbance<sup>31,32</sup>. In a study with long-term follow-up after duodenal switch, 76 per cent of patients reached a BMI of less than 35 kg/m<sup>2</sup>, from a baseline BMI of 52 kg/m<sup>2</sup>, with a 0.7 per cent rate of revisional surgery for malnutrition<sup>33</sup>. The large difference in BMI at 1 year between LRYGB and LDS in the present study (6 kg/m<sup>2</sup>), and the stability of the weight loss after duodenal switch shown by others<sup>33</sup>, suggest that LDS is better at promoting short- and long-term weight loss in superobese patients. In selected high-risk patients, LDS may be performed as a second procedure after laparoscopic sleeve gastrectomy<sup>34</sup>. A randomized trial of LRYGB versus two-stage LDS in such a group of patients could be performed to evaluate the potential benefits of staged surgery.

The sample size estimate in the present study was based on assumptions regarding weight loss following the procedures. Thus, a true difference in perioperative and long-term complication rates may not have been identified owing to type II statistical error. Larger study groups would, however, increase surgical experience, potentially reducing perioperative complication rates, particularly for LDS.

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