



TITLE: Duodenal Switch Procedure for the Treatment of Morbid Obesity

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DUODENAL SWITCH PROCEDURE FOR THE TREATMENT OF MORBID OBESITY

INTRODUCTION

The California Technology Assessment Forum is requested to review the scientific evidence for the use of the duodenal switch operation for the treatment of morbid obesity.

BACKGROUND

Obesity is a chronic disease that is increasing rapidly in the United States. Degree of obesity is usually described using body mass index (BMI). It is calculated as weight (in kilograms) divided by height (in meters) squared. Obesity is defined as a BMI ≥ 30 kg/m² and morbid obesity as a BMI ≥ 40 kg/m². Patients with a BMI > 50 kg/m² are sometimes classified as super-obese. The percentage of obese men in the US nearly doubled between 1991 and 1998, and the percentage of obese women increased by 50 percent. During this same period, the number of states in the United States in which more than 15 percent of the people were obese increased from 8 percent to 79 percent (Mokdad *et al.* 1999). The measured prevalence of obesity is 30.5 percent based upon data collected for NHANES between 1999 and 2000 (Flegal *et al.* 2002). In addition, the Center for Disease Control has reported that the prevalence of morbid obesity has increased from 0.78 percent in 1990 to 2.2 percent in 2000 (Freedman *et al.* 2002).

Obesity, weight loss, and health outcomes

Obesity is associated with premature death as well as an increased risk for diabetes, hypertension, hypercholesterolemia, heart disease, osteoarthritis, sleep apnea and gall bladder disease. Studies have demonstrated that weight loss is associated with a decreased risk for development of these diseases. The Nurses' Health Study, a cohort study of over 100,000 women aged 30 to 55 years found that weight loss above 5 kg was associated with a graded decrease in the risk of diabetes mellitus (Colditz *et al.* 1995). A second cohort study of 28,388 overweight women aged 40 to 64 years found that intentional weight loss of more than 9.1 kg was associated with a 25 percent decrease in all-cause, cardiovascular and cancer mortality (Williamson *et al.* 1995). In addition, among 15,069 women with co-morbid conditions such as heart disease or diabetes mellitus, any amount of intentional weight loss was associated with a 10 percent reduction in cardiovascular disease, a 20 percent reduction in all-cause mortality, a 30 to 40 percent reduction in mortality from diabetes, and a 40 to 50 percent reduction in mortality from cancers related to obesity. Weight loss lowers blood pressure in more than one-half of treated subjects (Huang *et al.* 1998). On average, the blood pressure falls 0.3 to 1.0 mmHg for every 1.0 kg of weight that is lost. Those who maintain weight loss maintain lower blood pressure than those who regain weight (Stevens *et al.* 1993).

Finally, weight loss is associated with a decreased risk of osteoarthritis. In a study of 800 women, a decrease in BMI of 2 kg/m² or more during the previous ten years decreased the odds for developing osteoarthritis by over 50 percent (Felson *et al.* 1992). This benefit extended to women with a high risk for osteoarthritis due to a high baseline BMI (25 kg/m²).

Furthermore, the social stigma associated with obesity leads to decreased quality of life. Weight loss has been shown to improve both social functioning and quality of life (Rand *et al.* 1990; Fine *et al.* 1999).

Treating obesity

Behavior modification, diet, and exercise are the primary treatments for obesity. More aggressive therapy with medications (orlistat, sibutramine) may be indicated for patients who have medical complications of obesity, but drug therapy is limited by side effects. Regaining lost weight is a common problem in treating obesity. Of those subjects who lose weight during any treatment program, most do not maintain the weight loss. Identification of those subjects who will succeed in losing weight is difficult. Characteristics of patients who maintain weight loss include a weight loss of more than 2 kg in four weeks, frequent and regular attendance at a weight loss program, and the subject's belief that his or her weight can be controlled. Systematic reviews of behavioral and drug therapy report average long term weight loss of between 4 and 7 kilograms (Glenny *et al.* 1997; Douketis *et al.* 1999; Arterburn *et al.* 2001; McTigue *et al.* 2003).

Gastrointestinal surgery for obesity

Surgery is another option for patients at high risk of complications from obesity. It has the advantage of being a long-term treatment for a chronic health problem. In addition, surgery leads to more substantial weight loss than the other treatment options. However, surgery for morbid obesity is a major intervention with risks of significant early and late morbidity and of perioperative mortality.

The National Institutes of Health consensus conference on obesity surgery recommends that surgery be considered only in the following populations (NIH 1991):

- Patients with a BMI >40 kg/m²
- Patients with a BMI >35 kg/m² who also have serious medical problems, (diabetes, obstructive sleep apnea) that would improve with weight loss.

All patients must have failed sustained weight loss programs, have acceptable operative risk, and be committed to life long follow-up.

Surgical procedures of the upper gastrointestinal tract that are designed to induce weight loss are collectively referred to as bariatric surgery. Bariatric surgery is either restrictive, malabsorptive, or a combination of both. Restrictive procedures reduce the size of the stomach leading to early satiety and decreased total caloric intake.

Malabsorptive procedures create separate intestinal pathways (limbs) for food and biliary/pancreatic secretions. They eventually connect but the length of small intestine that is common to both food and the secretions is short, leading to decreased absorption of both calories and nutrients.

Restrictive procedures

Purely restrictive procedures reduce food intake, but do not disrupt normal digestion. Usually a small pouch is made in the stomach that holds only about 1 ounce of food and has a small outlet. Thus, patients are unable to eat large amounts of food at one sitting without significant discomfort and nausea. This requires significant changes in the patients eating habits. Common restrictive procedures include adjustable gastric banding (AGB) and vertical banded gastroplasty (VGB). See Figures 1 and 2:

Figure 1: Adjustable gastric banding

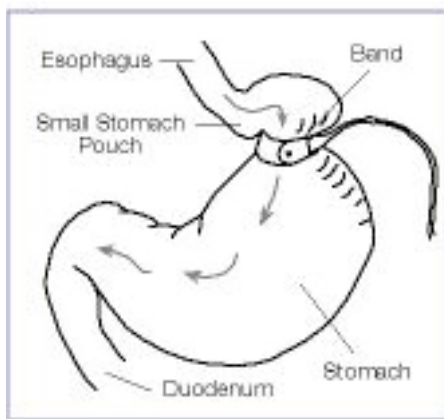
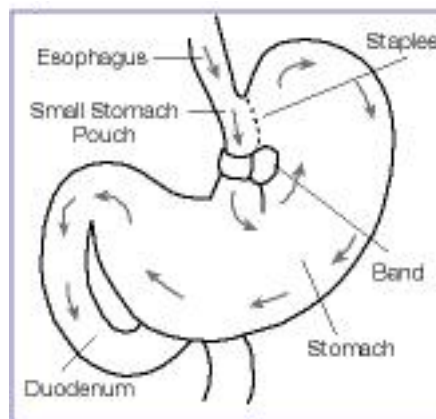


Figure 2: Vertical banded gastroplasty



Adjustable gastric banding (Figure 1)

Gastric banding limits food intake by placing a ring around the stomach just below the gastroesophageal junction. The band used includes an inflatable balloon that allows adjustment of the size of the outlet (de Wit *et al.* 1999). These procedures are now primarily performed laparoscopically. Adding or removing saline through a subcutaneous port changes the diameter of the outlet. Complications include splenic injury, esophageal injury, wound infection, band slippage, reservoir deflation/leak, persistent vomiting, failure to lose weight and acid reflux.

Vertical banded gastroplasty (Figure 2)

Vertical banded gastroplasty is commonly performed and can be done laparoscopically. The surgeon places a staple line vertically in the part of the stomach with the least curvature and thickest wall to limit stretching. A polypropylene band is typically placed around the lower end of the vertical pouch to prevent stretching. Complications with a low postoperative mortality rate are relatively rare, although revision rates requiring further surgical intervention are common. Specific complications include bolus obstruction, leakage, stenosis, ulcer, incisional hernia, wound infection, staple line disruption, pouch dilation and band erosion. It is a reversible procedure.

Malabsorptive procedures

Malabsorptive operations are more commonly used for weight loss. The procedures currently performed combine some degree of restriction with a reconstruction of the intestinal pathways designed to decrease food absorption. These procedures induce long-term vitamin deficiency, so patients are required to take supplemental vitamins and calcium and to be tested regularly for evidence of related diseases (hyperparathyroidism, osteoporosis, anemia, etc.).

Figure 3: Roux-en-Y gastric bypass

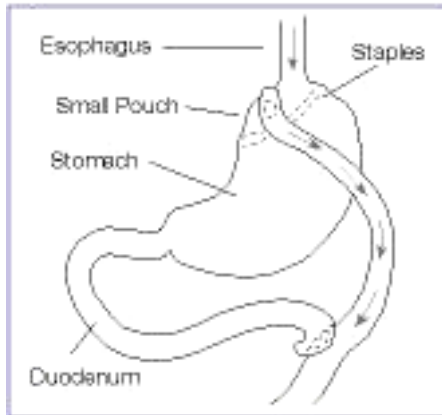
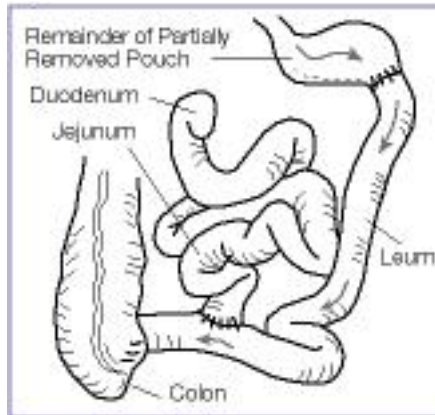


Figure 4: Biliopancreatic diversion



Roux-en-Y gastric bypass (Figure 3)

The Roux-en-Y gastric bypass (Roux-en-Y gastric bypass) is the most common form of bariatric surgery in the US (about 70% of all procedures). First a small stomach pouch is made to restrict food intake. Then a portion of the jejunum is attached to the pouch to allow food to bypass the distal stomach, duodenum, and proximal jejunum (Figure 3). Bypassing this segment of the small intestine reduces food absorption. The length of the common limb is usually between 50 and 100 cm in length. Shorter common limbs lead to greater malabsorption. Complications associated with gastric bypass include failure of the gastric partition, leaks at the junction of the stomach and small intestine, and acute gastric dilatation either spontaneously or secondary to a blockage at the Y-shaped anastomosis. Other complications following surgery include vomiting, incisional hernias, obstruction, and dumping syndrome. Rapid gastric emptying, or dumping syndrome, happens when jejunum fills quickly with undigested food from the stomach. Symptoms such as nausea, vomiting, bloating, diarrhea, and shortness of breath may occur within minutes of a meal. Patients with dumping syndrome can minimize symptoms by eating several small meals a day that are low in carbohydrates and drinking liquids between meals, not with them. The symptoms are thought to aid weight loss by conditioning the patient against eating sweets though they can have a dramatic impact on a patient's quality of life.

Biliopancreatic diversion (Figure 4)

Biliopancreatic diversion (BPD) is a more complicated operation that includes a distal gastrectomy. The small remaining portion of the stomach is connected directly to the ileum, diverting food past the biliary and pancreatic secretions and inducing malabsorption (Figure 4). Although this procedure successfully induces weight loss, it has

been associated with significant nutritional deficiencies and is rarely performed today. Complications include loose stools, stomal ulcers, offensive body odor and foul smelling stools and flatus. Serious complications include anastomotic ulceration, protein malnutrition, hypoalbuminemia, anemia, edema, asthenia and alopecia (Scopinaro *et al.* 1998). In an attempt to overcome these complications, several variants of the procedure have been developed including the duodenal switch (described below).

Comparisons between procedures

Gastric bypass with Roux-en-Y anastomosis has been considered the surgery of choice in the US. Comparative trials (n = 13 studies, over 4000 participants) have demonstrated that this procedure leads to greater weight loss than vertical banded gastroplasty, horizontal gastroplasty, and open gastric banding with fewer re-operations and minimally higher morbidity. No controlled trials have been done comparing Roux-en-Y gastric bypass to BPD. Case series suggest that the degree of weight loss obtained with BPD is comparable to that obtained with Roux-en-Y gastric bypass, but there are concerns about morbidity.

The comparative trials between surgical treatments demonstrate that all of the approaches result in substantial, prolonged weight loss averaging 17- 65 kilograms over 1 to 5 years of follow-up (Glenny *et al.* 1997; Douketis *et al.* 1999; Arterburn *et al.* 2001; McTigue *et al.* 2003). This degree of weight loss is considerably higher than the 4-7 kilogram weight loss observed in clinical trials of behavioral interventions and drug therapy (orlistat, sibutramine).

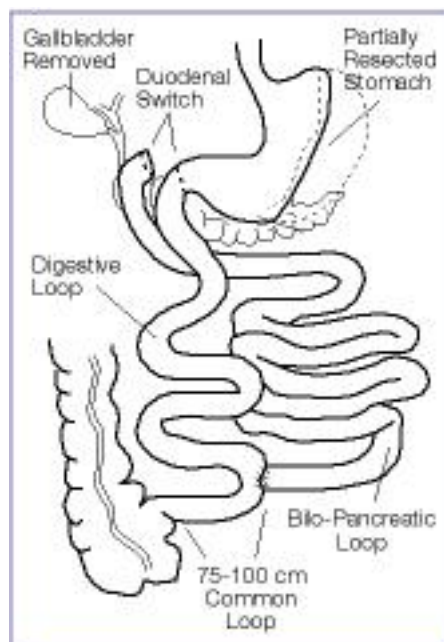
The Swedish Obese Subjects (SOS) study is the largest prospective study on the effects of operative treatment for obesity. A total of 1000 patients are being allocated to one of the three surgical procedures (gastric banding; vertical banded gastroplasty; or gastric bypass) and 1000 controls (matched for age, sex, BMI, clinical site, and co-morbidities) are being followed for 10 years (Sjostrom *et al.* 1992; Torgerson *et al.* 2001). Preliminary analyses at 2-years found that surgical patients had lost 28 kg and controls had lost 0.5 kg. The patients treated with gastric bypass lost significantly more weight (44 kg) than those who had either of the other two procedures (31 kg VGB, 26 kg AGB) (Sjostrom *et al.* 1999). As compared with a control group of patients of similar weight at baseline, the two-year incidence rates of diabetes mellitus and hypertension were lower in the surgically treated patients, and they had less hyperinsulinemia and hypertriglyceridemia and higher serum high-density-lipoprotein (HDL) cholesterol concentrations (Sjostrom *et al.* 1999). In continued follow-up of these patients, the initial reduction in blood pressure gradually returned to baseline by the third to fourth year post-operatively (Sjostrom *et al.* 2000)..

Duodenal switch

The duodenal switch operation was initially developed as a way to prevent bile reflux gastritis and other symptoms in patients after distal gastrectomy and gastroduodenostomy (DeMeester *et al.* 1987. Hess modified the procedure to treat morbid obesity by adding a 75% longitudinal gastrectomy and extending the biliopancreatic limb to induce fat malabsorption (Hess *et al.* 1998). It is a variant of the biliopancreatic diversion described above. A sleeve, rather than

distal gastrectomy is usually performed leaving a larger gastric pouch and preserving the pyloric valve (Figure 5). This allows patients to eat normal meals and may decrease the dumping syndrome.

Figure 5: Biliopancreatic diversion with duodenal switch



It has not been widely adopted for several reasons. The procedure is longer and more technically demanding than other bariatric procedures and it is difficult to perform laparoscopically. Additionally, it is historically related to other malabsorptive procedures that have been abandoned due to high morbidity and mortality.

Proponents of the procedure argue that it has a good safety profile and that it produces and maintains significant weight loss, particularly in patients with very high BMI's (≥ 50 kg/m²). They argue that the less restrictive gastric pouch, compared to the Roux-en-Y gastric bypass, and preservation of the pyloric valve are key improvements that allows for less restriction in food intake and less risk for the dumping syndrome. There is also no direct anastomosis of small intestine to the stomach, so no risk of stenosis, obstruction, or erosion at the gastric outlet.

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.

The duodenal switch operation is a surgical procedure and thus is not subject to FDA approval.

TA Criterion 1 is met.

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The literature search identified publications describing several variations of the duodenal switch (Tables 1 and 2). There were four uncontrolled case-series describing results obtained from almost 1500 patients using the biliopancreatic diversion with duodenal switch performed with an open laparotomy (Hess *et al.* 1998; Baltasar *et al.* 2001; Anthone *et al.* 2003; Hamoui *et al.* 2003). One case series with historical controls compared the duodenal switch (n=105) to Roux-en-Y gastric bypass (n=138) performed by the same surgeon before he began doing the duodenal switch (Rabkin 1998). There was one additional case-series with historical controls that compared biliopancreatic diversion with duodenal switch (n=457), to biliopancreatic diversion using a distal gastrectomy (n=233) (Marceau *et al.* 1998). More recently, the procedure has been performed laparoscopically. There were three case series of the duodenal switch procedure performed laparoscopically (Ren *et al.* 2000; Baltasar *et al.* 2002; Rabkin *et al.* 2003) and one small study comparing the procedure performed laparoscopically to open laparotomy (Kim *et al.* 2003). Finally, one study reported on 5 patients treated with adjustable gastric banding combined with a duodenal switch (Gagner *et al.* 2003); because of the limited experience with this procedure, it will not be discussed further in this review.

There were no clinical trials using randomized or concurrent controls that compared biliopancreatic diversion with duodenal switch to the current standard surgery for morbid obesity, Roux-en-Y gastric bypass.

TA Criterion 2 is met

Level of Evidence: 3, 4, and 5

Table 1: Case series of duodenal switch procedure for morbid obesity: study design and patient characteristics

Study	Procedure	N	Design	Age, yrs	Sex, %F	BMI, kg/m ²	Follow-up, mo	Wt loss (kg)	%EBWL
Antone 2003	BPD-DS	701	RCS	42.3 (10.4)	78.3	52.3 (9.6)	06 n=435 12 n=333 36 n=71 60+ n=50	40 (12) 58 (19) 60 (22) 54 (21)	50 (15) 69 (14) 73 (18) 66 (17)
Gagner 2003	AGB-DS	5	RCS	33.6	100	52.2	12 NR	52	66
Kim 2003	Open DS	28	RCS, concurrent controls	42 (8)	46	68.9 (10.1)	06 n=27 12 n=20	44 (6) 57 (26)	NR
	Lap DS	26		42 (8)	66	66.9 (7.5)	06 n=26 12 n=20	57 (20) 77 (20)	
Rabkin 2003	Lap DS	345	RCS	43	87	50	06 18 24	NR	51 89 91
Baltasar 2002	Lap DS	16	RCS	23-50	88	43-56	NR	NR	NR
Baltasar 2001	BPD-DS	125	RCS	37	77	50	12 n=96 24 n=75 36 n=64 48 n=54 60 n=332	NR	70 75 75 81 81
Ren 2000	Lap DS	40	RCS	43	70	60	6 n=19 9 n=3	48 109	46 65
Hess 1998	BPD-DS	440	RCS	40	78	50	12 n=345 24 n=264 36 n=187 48 n=132 60 n=92	55 59 57 56 54	74 78 77 75 73
Marceau 1998	BPD-DS	457	RCS, historical controls	37 (10)	80	47 (9)	51 (mean)	46 (20)	73 (21)
	BPD-DG	233		37 (9)	80	46 (9)	100 (mean)	37 (21)	61 (22)
Rabkin 1998	BPD-DS	105	RCS, historical controls.	44	70	49	12 24 36 48	NR	64 78 56 73
	RGB	138		41	85	49	12 24 36 48		61 74 74 69

Lagace 1995 and Hamoui 2003 not included as data reported more fully in other referenced publications.

Table 2: Case series of duodenal switch procedure for morbid obesity: Adverse events

Study	Procedure	N	Perioperative mortality, %	<u>Short term complications, %</u>	Re-operation, %	<u>Long term complications, %</u>
Antone 2003	BPD-DS	701	1.4	Leak 1.0 Splenectomy 0.4 Ex-Lap 0.6 Gluteal Rhabdomyolysis 0.9 Wound dehiscence 0.7	5.7	Malnutrition 4.9 Diarrhea 0.6 Abdominal pain 0.3 Low albumin 1.7 Low calcium 29.3 Anemia 48.3 Liver problems 0.0
Gagner 2003	AGB-DS	5	0	0	0	Malnutrition 0.0 Low albumin 0.0
Kim 2003	Open DS	28	3.5	Leak 0 Wound dehiscence 3.5 Abscess/infection 7	NR	NR (short follow-up)
	Lap DS	26	7.6	Leak 3.8 Wound dehiscence 0 Abscess/infection 7.6		
Rabkin 2003	Lap DS	345	0	Conversion to open 2.0 DVT or PE 1.4 Leak 3.2 Obstruction 1.5 Anastomotic stricture 1.7 Readmission 6.1	Peri-operative 4.1 Revision 1.7	NR
Baltasar 2002	Lap DS	16	0	Bleeding 6.2 Stenosis 6.2 Wound infection 18	Peri-operative 12.5	NR (short follow-up)
Baltasar 2001	BPD-DS	125	0 (0/102 primary) 8.7 (2/23 secondary)	Leak 4.0 Obstruction 1.6	Peri-operative 5.6 Revision 2.4	Death (liver Failure) 0.8 Death (malnutrition) 0.8 Incisional hernia 5.8
Ren 2000	Lap DS	40	2.5	Conversion to open 2.5 Leak 2.5 DVT 2.5 Hemorrhage 10 Abscess 2.5	Peri-operative 5.0	Death (Leak, sepsis) 2.5
Hess 1998	BPD-DS	440	0.5	Perforation 0.5 Leak 3.6 DVT/PE 1.2 Splenectomy 0.9 Abscess 0.2	3.9	Obstruction 2.8 Incisional hernia repair 25

Marceau 1998	BPD-DS	457	1.9	Leak 0.9 Abscess/infection 3.4	0.1/year	Vomiting > 1/week 2 Frequent liquid stool 20 Daily bloating 15 Low Fe 25 High PTH 17
	BPD-DG	233	1.6	Leak 0.4 Abscess/infection 1.2	1.7/year	Vomiting > 1/week 8 Frequent liquid stool 29 Daily bloating 15 Low Fe 40 High PTH 30
Rabkin 1998	BPD-DS	105	0	Incompletely reported. Among the 1 st 37 patients with BPD-DS, there were 2 peritonitis, 1 pancreatitis, 1 pulmonary embolus, and 2 wound infections.	Incompletely reported. 10% (4/49) BPD-DS re-operated for excess weight loss or symptoms.	Incompletely reported (n=37) Gas/diarrhea 22 Incisional Hernia 24
	RGB	138		Not reported for RGB.		

Abbreviations

- BPD Biliopancreatic diversion
- BPD-DS Biliopancreatic diversion with duodenal switch
- BPD-DG Biliopancreatic diversion with distal gastrectomy
- Lap DS Biliopancreatic diversion with duodenal switch performed laparoscopically
- Open DS Biliopancreatic diversion with duodenal switch performed with traditional open laparotomy
- NR Not reported
- AGB-DS Adjustable gastric band with duodenal switch
- GB Roux-en-Y gastric bypass
- RCS Retrospective case-series

TA Criterion 3: The technology must improve the net health outcomes.

The primary health outcome of interest is weight loss. This is usually reported as the percentage of excess body weight lost (%EBWL), but absolute weight loss, change in BMI, and post-surgical BMI are also commonly reported. Ideally, changes in obesity related conditions such as diabetes, hypertension, sleep apnea, joint pain, and hyperlipidemia would also be reported. There should also be demonstrable improvements in the patients' quality of life. These benefits must be balanced against the risks of peri-operative mortality; short term morbidity from wound infections, pulmonary emboli, bleeding, bowel obstruction, splenic injury and anastomotic leaks; and long term morbidity from re-operations, incisional hernias, marginal ulcers, malnutrition, and vitamin deficiency.

It is apparent from the studies that biliopancreatic diversion with duodenal switch induces substantial weight loss (Table 1). The clearest data come from the recent study by Anthone *et al.* The records for 701 patients who underwent biliopancreatic diversion with duodenal switch at one clinical center between 1992 and 2002 were reviewed (Anthone *et al.* 2003). Operative morbidity and mortality, weight loss, volume of food intake, and bowel function were recorded. Sequential measurements of serum albumin, hemoglobin, and calcium levels were obtained to assess metabolic function and nutrient absorption. The average body mass index (BMI) was 52.8 (range, 34-95). Perioperative mortality was 1.4%, and morbidity (including leaks, wound dehiscence, splenectomy, and postoperative hemorrhage) occurred in 21 patients (2.9%). For patients with data at one year of follow-up (n=333), weight loss averaged 58 kg (69% EBWL). The 71 patients (10%) followed for three years lost an average of 60 kg (73% EBWL) and those followed for five years (n=50) lost 54 kg (66% EBWL). The mean number of bowel movements was fewer than three per day. Patients reported and maintained a mean restriction of 63% of their preoperative intake (approximately 1600 calories), with no specific food intolerance, at three or more years follow-up. At three years, serum albumin remained at normal levels in 98% of patients, hemoglobin in 52%, and calcium in 71%. No patients reported dumping, and marginal ulcers were not seen.

An obvious concern about these data is the rapid drop off in follow-up. By three years of follow-up, only 10% of the patients contributed data. Given the limited number of patients at three years, there is tremendous uncertainty about the validity of the long-term complication rates. Remarkably, in almost all of the other studies, the number of patients contributing data at the different time points is not reported. However, the estimates of weight loss are fairly consistent. Most of the studies summarized in Table 1 report patients losing between 40 and 60 kg (50-75% EBWL) by one year of follow-up and weight loss was maintained for at least 5 years. The degree of weight loss appears similar if the duodenal switch is performed laparoscopically (Kim *et al.* 2003; Rabkin *et al.* 2003) as compared to Roux-en-Y gastric bypass (Rabkin 1998) or the older biliopancreatic diversion performed in conjunction with distal gastrectomy (Marceau *et al.* 1998).

Given reasonably similar degrees of weight loss, short and long term complications will be important in assessing the net health outcomes. Major abdominal surgery in the morbidly obese is difficult. The larger case series report peri-operative mortality rates (usually defined as 30 day mortality) to range from 0.5 to 1.9% (Hess *et al.* 1998; Marceau *et al.* 1998; Anthone *et al.* 2003).

Laparoscopic duodenal switch procedures are becoming increasingly popular. One small study (Kim *et al.* 2003) with concurrent controls compared laparoscopic duodenal switch (n=26) to the same procedure performed with an open laparotomy (n=28). They reported greater weight loss at one year in patients treated laparoscopically (77 kg vs. 57 kg), but mortality was higher in the laparoscopically treated patients (7.6% vs. 3.5%) (Kim *et al.* 2003). The remarkably high mortality in both groups may be due to the high BMI. All patients in this study were required to have a BMI \geq 60 kg/m². High BMI has been reported to be associated with increased mortality in bariatric procedures (Livingston *et al.* 2002; Anthone *et al.* 2003). A much larger, uncontrolled case series reported no peri-operative deaths in 345 laparoscopic duodenal switch procedures (Rabkin *et al.* 2003). The mean BMI of patients treated by Rabkin was 50 kg/m² compared to a mean BMI of 66.9 kg/m² in the report by Kim *et al.* The high variability in mortality rates highlights the importance of carefully controlled studies when comparing surgical procedures. Patient characteristics, co-interventions, surgical skill, and surgical center characteristics all can have large impact on outcomes.

Perioperative morbidity was also high and quite variable in the laparoscopically treated patients. Kim *et al.* reported a 23% complication rate (Kim *et al.* 2003) versus the 10% rate reported by Rabkin (Rabkin *et al.* 2003). These numbers are much higher than the 2.9% rate reported in the large series of open procedures (Anthone *et al.* 2003).

TA Criterion 3 is met for duodenal switch performed with an open laparotomy.

TA Criterion 3 is not met for duodenal switch performed laparoscopically.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

Conclusions about the comparative efficacy of different procedures are best made from comparative trials using concurrent, ideally randomized controls. Surgical procedures are prone to variability between surgeons, surgical centers, and technical improvements over time. The quality of nursing staff, ancillary services, and the volume of procedures performed all can have substantial impact on outcomes. Additionally, bariatric surgical mortality has consistently been shown to be related to the age, sex, pre-operative BMI, and co-morbidities of the patient (Livingston *et al.* 2002; Anthone *et al.* 2003).

Roux-en-Y gastric bypass is the bariatric procedure of choice in the United States. It has been shown to produce better weight loss than alternative procedures in multiple clinical trials and has acceptable morbidity and mortality. All other bariatric procedures should be considered investigational. Given the promising data discussed above, it would be reasonable to perform a randomized clinical trial comparing biliopancreatic diversion with duodenal switch to Roux-en-Y gastric bypass. Key outcomes to assess would be surgical and long-term mortality, surgical complications, weight loss, change in co-morbidities, and quality of life. Unfortunately, no randomized trials have been published.

Only one study compared biliopancreatic diversion with duodenal switch to Roux-en-Y gastric bypass (Rabkin 1998). It is a retrospective case series with historical controls from the records of one surgeon. The author performed Roux-en-Y gastric bypass from 1985 – 1993 and then switched to biliopancreatic diversion with duodenal switch. He reports on 138 cases of RBG and 105 cases of biliopancreatic diversion with duodenal switch. The results are summarized in Tables 1 and 2. Weight loss is similar for patients receiving the 2 procedures. Unfortunately, short and long term complications are minimally reported. Short-term complications are described for the first 39 patients receiving biliopancreatic diversion with duodenal switch and the re-operation rate is described for the first 49 patients. No comparable information is given for patients treated with Roux-en-Y gastric bypass. The age and sex of the patients differed which could limit the comparability of the two groups. More importantly, the Roux-en-Y gastric bypass-treated patients are historical controls. In the classic paper by Sacks et al (Sacks *et al.* 1982) comparing the results of studies using randomized controls to those of the same intervention using historical controls, the authors state that “biases in patient selection may irretrievably weight the outcome of historical controlled trials in favor of new therapies.” For each therapy, those in the new treatment arm had comparable results in both types of studies, but participants in the control arm did worse in studies with historical controls than controls in the randomized studies.

The lack of well-controlled comparative studies precludes any meaningful assessment of the strengths and weaknesses of duodenal switch compared with Roux-en-Y gastric bypass.

TA Criterion 4 is not met.

TA Criterion 5: The improvement must be attainable outside the investigational settings.

The large number of reports from a variety of settings suggest that the procedure can be done with an open laparotomy with satisfactory surgical results under conditions of usual medical practice. However, the procedure has not yet been compared directly with the established alternative therapy, Roux-en-Y gastric bypass. Furthermore, there is much less experience with laparoscopic DS and some centers report peri-operative mortality rates as high as 7.6%.

TA Criterion 5 is not met.

RECOMMENDATION OF OTHERS

Blue Cross Blue Shield Association Technology Evaluation Center (BCBSA TEC)

The BCBSA TEC conducted a review of *Newer Techniques in Bariatric Surgery for Morbid Obesity* in September 2003 and noted:

"Limited data do not establish that these or other variants (e.g. duodenal switch) have any additional benefits for patients with super-obesity as compared with gastric bypass."

Centers for Medicare and Medicaid Services (CMS)

Several regional CMS carriers consider surgery for morbid obesity including duodenal switch to be reasonable and necessary for those with a BMI greater than 40. Consideration is also given to those with a BMI greater than 35 who have co-morbidities.

The National Coverage Policy (1979) only mentions gastric bypass.

Association for Healthcare Research and Quality (AHRQ)

<http://www.ahrq.gov/clinic/3rduspstf/obesity/obessum.htm>

In 2003, the AHRQ published a report titled *Screening and Interventions for Obesity in Adults* which concluded:

"_____ In selected patients, surgery promotes large amounts of weight loss with rare but sometimes severe complications."

A United States Public Health Services Task Force guideline published in November 2003, *Screening for Obesity in Adults* is based on this AHRQ report.

American Society for Bariatric Surgery (ASBS)

The ASBS provided representation to the meeting who provided testimony in favor of the duodenal switch procedure as a treatment for morbid obesity.

American Gastroenterological Association (AGA)

The AGA provided representation to the meeting. The AGA indicated that they do not have a guideline or specific position on the topic of duodenal switch.

CONCLUSION

The prevalence of morbid obesity is increasing at alarming rates in the United States. The only long-term treatment that has been shown to be effective at achieving and maintaining weight loss with a reduction in obesity related morbidities is bariatric surgery. The current surgical standard is Roux-en-Y gastric bypass, a technique that combines both restrictive and malabsorptive components. Multiple clinical trials have demonstrated its superiority to other commonly used procedures.

Biliopancreatic diversion with duodenal switch is a variation of an older procedure that also combines restrictive and malabsorptive components to achieve long-term weight loss. The gastric pouch created in this procedure is larger than that created with Roux-en-Y gastric bypass and the surgery preserves a functional pyloric valve as the gastric outlet. Proponents of the procedure argue that this allows for a better quality of life because there are fewer restrictions on diet and a lower risk of the dumping syndrome. There may be fewer post-operative complications because there is no need to create an anastomosis between the stomach and distal small intestine. Case series indicate that the degree of weight loss achieved with the duodenal switch procedure is comparable to that obtained with the Roux-en-Y gastric bypass. Thus, the frequency of short and long term complications will likely be the determining factor in the deciding whether the procedures are comparable or if one is superior. However, there are no studies directly comparing the two procedures, making it impossible to draw any firm conclusions regarding the relative benefits and harms of the two procedures. Furthermore, there is no evidence suggesting that the duodenal switch is superior to the Roux-en-Y gastric bypass in super-obese patients.

RECOMMENDATION

It is recommended that the use of biliopancreatic diversion with duodenal switch does not meet technology assessment criteria 4 or 5 for safety, effectiveness, and improvement in health outcomes.

The California Technology Assessment Forum approved the recommendation as presented.

February 11, 2004

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