



Australian Government
Department of Health and Ageing



Horizon Scanning Technology
Prioritising Summary
Laparoscopic sleeve gastrectomy
February 2007



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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PRIORITISING SUMMARY

REGISTER ID: S000020 REFERRAL FROM HEALTHPACT

NAME OF TECHNOLOGY: LAPAROSCOPIC SLEEVE GASTRECTOMY

PURPOSE AND TARGET GROUP: MORBIDLY OBESE PATIENTS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input checked="" type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|--|-------------|-----|
| <input type="checkbox"/> Yes | ARTG number | N/A |
| <input type="checkbox"/> No | | |
| <input checked="" type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia		✓	
Brazil	✓		
Canada		✓	
India		✓	
United Kingdom		✓	
Switzerland	✓		
United States		✓	

IMPACT SUMMARY:

Laparoscopic sleeve gastrectomy is available in Australia through bariatric surgeons for the treatment of morbid obesity.

BACKGROUND

Obesity is a condition in which sufferers have excessive fat deposits to a point where the person is at an increased risk of various health conditions and increased mortality. Obesity is measured through the Body Mass Index (BMI), a measurement calculated by dividing a person's weight (kg) by their height (cm). People are considered to be overweight at a BMI of 25 or more and obese at a BMI of 30 or more (Table 1) (Australasian Society for the Study of Obesity 2005).

Classification	BMI
Underweight	< 18.5
Normal weight range	18.5 to 24.9
Overweight	25 to 29.9
Obese	≥ 30
Morbidly obese / Severely obese	≥ 40
Super-obese	≥ 50

Table 1: Classification of overweight and obesity.

Waist circumference is also used in assessing obesity (Australasian Society for the Study of Obesity 2005). Table 2 provides waist circumference levels used to define overweight and obesity in Caucasian populations only (the relationship between waist circumference and body fat differs with age and between ethnic groups) (Department of Health and Ageing 2002). In addition to being an indicator of obesity waist circumference can also serve as an indicator of increased risk of cardiovascular disease, diabetes and cancer (Department of Health and Ageing 2002).

	Males	Females
Overweight	> 94 cm	> 80 cm
Obese	> 102 cm	> 88 cm

Table 2: Classification of overweight and obesity using circumference levels in Caucasian populations.

Obesity is a disorder of energy balance. People who are overweight or obese have a positive energy balance in which the energy which they consume through food or drink exceeds the energy used (Lean et al. 2006). This can be caused by a variety of underlying reasons including genetics, physical disorders (e.g. metabolic syndrome, hypothyroidism), psychological disorders (e.g. comfort eating) (wrongdiagnosis.com 2006). However, often obesity is a result of lifestyle (i.e. too much energy, too little activity) (Department of Health and Ageing 2002).

Long-term studies have shown that conservative medical treatments are ineffective in patients with morbid obesity, with relapse rates of up to 90% irrespective of the choice of conservative treatment (Miller and Hell 2003). As a result of this, surgical treatments (bariatric surgery) have been increasingly utilised as a means of achieving weight loss in these patients. One of the latest surgical procedures currently being utilised is sleeve gastrectomy (also known as the gastric sleeve procedure or laparoscopic tube gastrectomy). Laparoscopic sleeve gastrectomy (LSG) is actually the restrictive part of the more extensive mixed restrictive and malabsorptive operation known as biliopancreatic diversion or duodenal switch. It involves the surgical removal of the left side of the stomach resulting in a stomach which is approximately the size and shape of a banana (Surgicallyslim 2006) and does not require re-routing of intestines or implantation of an artificial device in the abdomen. Weight loss is achieved by the reduction in stomach size; therefore presumably satiety is induced faster with less food. LSG has also been utilised as the first treatment step in super-obese patients or patients with high operative risk prior to performing more complicated procedures such as laparoscopic Roux-en-Y gastric bypass (LRYGBP).

CLINICAL NEED AND BURDEN OF DISEASE

Being overweight or obese can have serious implications for the affected person. Many health problems have been associated with being overweight or obese, including musculoskeletal problems, cardiovascular disease, some cancers, sleep apnoeas, type 2 diabetes and hypertension among others (Access Economics 2006). People who suffer extreme forms of obesity are not likely to respond to diet, behavioural therapy or medication (Miller et al. 2003). Therefore for many of these patients surgery presents the most effective way of achieving weight loss and addressing any associated co-morbidities.

In the United States the prevalence of obesity is over 30%, in most of Europe the figure is over 20% while in the Gulf States and Polynesian nations it is between 40 and 70% (Lean *et al.* 2006). In Australia, it is estimated that 62% of men and 45% of women are overweight or obese (Australian Bureau of Statistics 2006). Importantly the proportion of adults considered overweight or obese increased from 52 to 62% in men and from 37% to 45% in women over the ten years between 1994/1995 and 2004/2005 indicating that this is a growing problem (Australian Bureau of Statistics 2006). These figures translate to approximately 3.24 million Australians being obese (15.1% of all males and 16.8% of all females) in 2005.

The costs of obesity to the community are substantial. In the United States the direct costs of obesity have been estimated at approximately 9% of total health care costs (Australian Bureau of Statistics 2006, Lean *et al.* 2006). In 2005 Access economics was commissioned by Diabetes Australia to estimate the economic cost of obesity on Australia (Access Economics 2006). The study estimated that the total financial cost of obesity for 2005 was \$3.767 billion. When categorised by the types of cost this translates to cost to health system (\$873 million), productivity costs (\$1.7 billion), carer cost (\$804 million), deadweight loss from transfers (lost tax revenue, welfare, govt payments: \$358 million) and other indirect costs of \$40 million (Access Economics 2006).

DIFFUSION

Laparoscopic sleeve gastrectomy is currently offered in various obesity treatment centres in Australia. Due to the current obesity epidemic, it is likely that LSG will gain substantial widespread use if it is proven to be more effective than other available procedures (e.g. laparoscopic gastric banding).

COMPARATORS

While surgery is considered the most effective way of reducing weight and maintaining weight loss in morbidly obese (BMI>40) and severely obese (BMI>35) patients, there is no surgical procedure which is regarded as the 'gold-standard' of obesity surgery (Miller 2004). Liposuction is currently used for cosmetic reasons but has no medical benefits in terms of co-morbidities linked to obesity (Miller 2004). The following is a list of comparators to laparoscopic sleeve gastrectomy:

- Roux-en-Y gastric bypass (RYGBP)
- Biliopancreatic diversion (BPD)/Duodenal switch (DS)
- Magenstrasse and Mill procedure
- Vertical banded gastroplasty (VBG)

- Adjustable gastric band (AGB)
- Gastric pacemaker

SAFETY AND EFFECTIVENESS ISSUES

A total of 8 case series studies (two retrospective, the rest were prospective) have been selected for inclusion in this summary. Clinically, a BMI of 40 or more constitutes obesity that makes a patient a candidate for surgical treatment (Miller 2004). Hence the majority of patients evaluated in the studies presented have a BMI above 40. For those patients not above a BMI of 40 but between 35 and 40, the presence of associated co-morbidities which may improve with weight loss makes these patients possible candidates for surgical treatment (Miller 2004). Therefore in the studies presented the majority of patients above or below the BMI 40 threshold suffer from one or more associated co-morbidities.

Milone and colleagues (United States) compared LSG with the BioEnterics Intra-gastric Balloon (BIB) as the first stage procedure for effective initial weight loss before further definitive surgery (Milone et al. 2005). In this study 20 patients (13 men and 7 women) who had undergone LSG were compared to a historical control group of 57 patients (33 men and 24 women) from two large series that had undergone BIB. Patients were follow-up for a period of six months.

The authors used a retrospective chart review approach of 20 consecutive patients with a BMI ≥ 50 who underwent LSG. The stomach was reduced to 150-200ml. The baseline characteristics of the three groups are outlined in Table 3.

Group (n)	Average* Age (years)	Average* BMI	Average* Weight (kg)	Follow-up (months)
LSG (n = 20)	43 (range: 27 to 63)	68.8 (range: 60.0 to 85.1)	200 (range: 157 to 247)	6
BIB1 (n = 17)	38 (range: 20 to 56)	60.2 (range: 58.0 to 72.0)	195 (range: 205 to 275)	4
BIB2 (n = 43)	43 (range: 33 to 54)	58.4 \pm 6.6	171 (range: 134 to 205)	5.4

Table 3: Baseline characteristics

*Paper does not state whether mean or median

Milone et al. 2005

Only one post-operative complication was reported in the LSG group (trochar-site infection). Table 4 shows the weight related parameters of the LSG group versus the BIB2 group (these parameters were not available for the BIB1 group) at baseline. After the procedures every patient from each of the groups experienced improvements in co-morbidities with the improvements being accompanied by a decrease in the use of medications.

Co-morbidities	LSG (n = 20)	BIB2 (n = 43)
Hypertension	11 (55%)	30 (69.8%)
Sleep apnea	12 (60%)	29 (67.4%)
Diabetes	6 (30%)	19 (44.2%)
Osteoarthritis	19 (95%)	30 (69.8%)
Gastroesophageal reflux	5 (25%)	-
Hypercholesterolemia	6 (30%)	12 (27.9%)
Depression	14 (70%)	6 (14.0%)

Table 4: Co-morbidities in the LSG and BIB groups

Milone et al. 2005

Patients in the BIB groups experienced a mean reduction in BMI of 9.4 and 6.4 respectively while patients in the LSG group experienced a greater mean reduction of 15.9. Similarly, patients in the LSG group experienced greater mean weight loss of 45.5 kg compared to 26 and 18 kg in the BIB groups. Overall the mean BMI for patients in the LSG group reduced

from 69 to 53 while those patients in the BIB groups experienced a reduction from 59 to 51 (Milone et al. 2005).

Baltasar et al (2005) published the results of a study of 31 patients undergoing laparoscopic sleeve gastrectomy in Spain. The patients in the study were categorised into four different groups:

1. Super obese – seven patients with BMI between 61 and 74 (mean BMI 65) who had LSG as first stage of laparoscopic duodenal switch.
2. BMI > 40 with severe medical illness – seven patients with severe medical conditions preventing duodenal switch (four patients had cirrhosis of the liver, one had Crohn's disease and previous right hemicolectomy, one had severe pulmonary poisoning and one was HIV positive).
3. Lower BMI – 16 patients with BMI between 35 and 43 with at least one co-morbidity
4. Conversion from prior gastric banding – one patient (with normal BMI) with severe symptoms.

A gastric tube of < 60ml was created in all patients, and the mean procedure time for patients with BMI < 60 was 49 minutes (range: 40 to 60 minutes). In order to rule the presence of any leaks as a result of the surgery patients underwent an oral methylene blue dye test and a gastrografen X-ray study on the first post-operative day. Patients were discharged on the second post-operative day. For the first two weeks following surgery only small sips of liquids were taken by patients. After the first two weeks patients resumed small amounts of normal consistency intake. After four to six weeks patients were required to adhere to a 600-800 calorie/day solid diet until the goal weight was achieved.

Two patients suffered trocar-related intra-abdominal bleeding. One of these patients died while the second required laparoscopic exploration. There were no reports of deep venous thrombosis, pulmonary emboli, pneumonia, acute respiratory distress syndrome, splenectomy, gastric leak and fistula or small bowel obstruction. One patient in the lower BMI group ruptured the sutured working-trocar access-site while coughing followed by intra-abdominal bleeding. This patient required re-operative laparoscopic aspiration of 400 cc hemoperitoneum and suture of the abdominal opening.

Two patients who previously suffered hypertension and diabetes no longer required medication. The percentage of excess weight loss (%EWL)¹ and the percentage of excess BMI loss (%EBMIL)² were used to determine weight loss. Complications related to haemorrhage at the working port led to the death of one patient in the super obese group. Follow-up measurements were taken at 4 to 27 months and patients had a mean %EWL of 56.1% and %EBMIL of 63.1%. Only one patient from this group went on to the second stage of the DS. Patients in the BMI > 40 with severe medical illness also experienced weight loss. At 16 months the patient with Crohn's disease had %EWL of 59.5% and %EBMIL of 66%. The woman with pulmonary condition had %EWL of 72.5 and %EBMIL of 76% at 14 months. The HIV positive patient had %EWL of 33.6% and %EBMIL of 36.8% at four months. The cirrhotic patients had mean %EWL of 71 and %EBMIL of 76 without any worsening of liver function. At 3 to 27 months patients in the third group (lower BMI) had mean %EWL of 62.3% and %EBMIL of 68.5%. Finally, the patient with conversion from gastric banding had %EBMIL of 13% and her quality of life improved significantly. No %EWL was reported for this patient (Baltasar et al. 2005).

The results of 60 morbidly obese Korean patients who had undergone LSG and had >1 year of regular follow-up were published in 2005 (Moon Han et al. 2005). These patients were a subset of a larger patient cohort of 130 patients (80 men and 52 women) who had an average

¹ %EWL = [(Operative – Follow-up weight)/Operative excess weight] x 100

² %EBMIL = 100 – [(Follow-up BMI – 25 / Beginning BMI – 25) x 100]

BMI of 37 (range 30-56). Patients were enrolled with the principle method being a two-stage operation, the first being the restrictive LSG and the second being the malabsorptive duodenal switch. Patient evaluation at 1-year post-LSG would determine if the patient would proceed to the second stage (duodenal switch). The patients in this study were left with a 50 to 60 ml stomach. Patients were discharged 2 days post-LSG with a clear liquid diet which later progressed to a full liquid diet for one week (stage I diet). A soft diet (stage II diet) was later followed for three weeks which then advanced to a regular diet (stage II) by the fifth week. Changes in EWL and abdominal fat were measured every three months. Additionally the patients' subjective view on appetite (with baseline pre-operative appetite considered as 100%), amount of food consumption and satisfaction with operation were also assessed. The mean (\pm s.d.) EWL achieved was $54.8 \pm 15.9\%$ at three months, $71.6 \pm 21.9\%$ at six months, $78.3 \pm 25.4\%$ at nine months and $83.3 \pm 28.3\%$ at 12 months. BMI decreased from a baseline of 37.2 to 31.3 ± 4.8 at three months, 29.4 ± 4.9 at six months, 28.6 ± 4.9 at nine months and 28.0 ± 5.1 at 12 months. When grouped according to preoperative BMI categories of ≥ 50 , 40 to 49.9, 35 to 35.9 and 30 to 34.9 it was revealed that at each of the follow-ups those with baseline BMI of 30 to 34.9 performed best in terms of %EWL followed by those in 35 to 39.9, 40 to 49.9 and ≥ 50 groups (no p-values reported). Fifty patients had at least one co-morbidity, with a total of 127 co-morbidities between the patients. Improvements are presented in Table 5.

Co-morbidity	Number of patients	6 months		12 months	
		Resolved (%)	Improved (%)	Resolved (%)	Improved (%)
Fatty liver	40	100	-	-	-
Arthritis/joint pain	21	76	23.8	100	-
Dyslipidemia	20	45	30	65	10
Hypertension	14	93	7	93	7
Sleep apnea	14	100	-	-	-
Diabetes mellitus	8	100	-	-	-
Reflux esophagitis	5	80	20	100	-
Amenorrhea	4	75	25	100	-
Asthma	1	100	-	-	-

Table 5: Outcome of co-morbidities in 60 patients 1 year post-LSG.

(Moon Han et al. 2005)

In the complete group of 130 patients, five cases of early complications (within the first post-operative month) were reported. Two patients suffered major complications, leakage in one and delayed bleeding in the other (this patient underwent laparoscopic re-operation for irrigation and drainage). Minor complications occurred in two occasions with one patient developing atelectasis and the other suffering from nausea and vomiting for 21 days after the procedure (patient required parenteral nutrition and symptoms disappeared at 21 days). One death was reported at three weeks post-operatively. In this patient no leakage or strangulation was found, however, primary peritonitis was diagnosed. Short gastric bleeding in another patients required conversion to laparotomy (Moon Han et al. 2005).

Changes in appetite were evident at the three month follow-up, with appetite being 42.3% of the baseline appetite. However, appetite gradually increased at each of the follow-ups to 49.2% (six months), 50.1% (nine months) and 54.6% (12 months). A similar pattern was observed with the amount of food consumed. At the three month follow-up intake amount was 20.1% but gradually increased to 40.6% at the 12 month follow-up. A small increase in patient satisfaction was seen over the twelve months after the procedure (Moon Han et al. 2005). Only one patient was deemed to have failed to achieve satisfactory weight loss one year post-LSG. This patient had achieved 21.3% EWL and BMI fell from 56.1 to 50.5 and underwent Roux-en-Y gastric bypass as a second stage intervention. Follow-up of patients beyond one year has revealed a further four patients who are likely to require second-stage surgery, duodenal switch (Moon Han et al. 2005). It should be noted that most patients who required second-stage surgery had a baseline BMI of ≥ 50 (Moon Han et al. 2005).

Cottam and colleagues (United States) evaluated the outcomes of 126 patients undergoing LSG as the first stage of two-stage treatment (second treatment laparoscopic Roux-en-Y gastric bypass). Fifty-three percent of patients were women with a mean age of 49.5 ± 10 years and mean BMI of 65.4 ± 9 . Forty-two percent of patients were American Society of Anesthesiologists (ASA) grade III (patient with severe systemic disease) and 52% were ASA grade IV (patient with severe systemic disease that is a constant threat to life). Significant co-morbid conditions were present pre-operatively in most patients with the mean number of co-morbidities being 9.4 ± 3 per patient. The co-morbidities reported included all those presented in Table 6 as well as peripheral oedema, degenerative joint disease, low back pain, gastroesophageal reflux disease, elevated triglycerides, depression and coronary artery disease. The mean operative time was 143 ± 28 minutes and the mean hospital stay was 3 ± 1.7 days. Peri-operatively there were no deaths reported, however there was one late death in a woman who received conversion to open sleeve gastrectomy with previous abdominal injuries. The patient developed pulmonary embolus three months after surgery and did not recover. Eighteen post-operative complications were reported including five strictures, two leaks, two pulmonary embolisms, five patient requirements for > 24 hour ventilator support and four patients who developed renal insufficiency without the need for dialysis. Patients who experienced strictures returned for dilatation several weeks after the LSG procedure. The effects of LSG on co-morbidities at 12 months are outlined in Table 6 in the 36 (out of 126) patients who underwent completion to Roux-en-Y gastric bypass.

Condition	Resolved	Improved
Sleep apnea	80	7
Peripheral edema	91	3
Hypertension	78	7
Degenerative joint disease	85	6
Type II diabetes	81	11
Low back pain	44	10
Gastroesophageal reflux disease	70	8
Elevated triglycerides	73	5
Depression	67	9

Table 6: Co-morbid conditions in patients who underwent completion Roux-en-Y gastric bypass at 6 months follow-up.

Cottam et al. (2006)

At the 12 month follow-up (12 months after LSG), 46% of patients were available and had a mean EWL of $45 \pm 17\%$. A total of 36 patients went on to stage II with a mean interval of 12 ± 5 months. Of the patients who underwent the second stage, the patients experienced a decrease in BMI to 49.5 ± 8 with a mean weight loss of 43.6 kg (mean follow-up for these patients were 7.1 ± 5 months). At 12 months, patients achieved an overall weight loss from 177 kg to 131 kg ($p = 0.05$) and BMI was significantly reduced from 65 ± 9 to 49 ± 8 ($p < 0.05$). In addition to this, the number of co-morbidities 12 months post-LSG decreased from 9 ± 3 to 6 ± 3 . Finally, at baseline 94% of patients were $ASA \geq 3$, this reduced to 44% at 12 months. The authors feel that LSG does not sufficiently address medical problems associated with morbid obesity and recommend patients be evaluated for second stage gastric bypass to ensure long term weight loss (Cottam et al. 2006).

A retrospective review of 30 Korean patients (7 men and 23 women) (mean age 40; range: 17 to 69) who underwent LSG and completed a three month and six month follow-up visits was published earlier this year (Roa et al. 2006). The approximate capacity of the created gastric sleeve was 150 mL. All patients underwent Gastrografin study on the first operative day. Pre-operatively, the mean weight was 118.2 kg with a mean BMI of 41 (range: 33 to 59). At the first follow-up visit (three months) the mean weight loss was 22.6 kg while at six months it was 30.5 kg. At three months the mean %EWL was 40.7 and at six months it was 52.8%. The patients' mean BMI at three months was 34 and at six months was 32. Mean procedure time

was 80 minutes (range: 65 to 130) with a mean hospital stay of 3.2 days (range: 2 to 25). Early post-operative complications were reported in four patients. Three of these required re-admission due to dehydration and their complications were considered to be mild. The remaining patient suffered a leak from the staple line which was detected by the Gastrografin study conducted on the first post-operative day. The patient underwent surgical intervention the same day (results not reported). This was considered a major complication. There were no other complications reported during the six month study period. No deaths were reported (Roa et al. 2006).

Silecchia and colleagues (Italy) evaluated the effects of LSG on a variety of major co-morbidities (hypertension, type 2 diabetes, obstructive sleep apnoea and ASA score) in 41 high risk super obese patients as the first stage of a two stage LBPDS. A 120-150mL gastric pouch was created with a 48 Fr bougie. Gastrografin was performed on the second post-operative day followed by liquid diet for one week, then soft diet for four weeks, followed by long-term hypocaloric, protein-enriched solid diet. The 41 patients (28 females, 13 males) were mean (\pm sd) 44.6 ± 9.7 years old and had a mean baseline BMI of 57.3 ± 6.5 . The mean procedure time for these patients was 111 ± 31 minutes and the mean hospital stay was 5.7 ± 2.8 days. The co-morbidities of these patients are presented in Table 7.

Co-morbidity	Number of patients
Hypertension	25
Obstructive sleep apnoea syndrome	17
Type 2 diabetes/impaired glucose tolerance	17
Degenerative joint disease	14
Venous insufficiency	13
Dyslipidemia	12
Hyperuricemia	7

Table 7: Co-morbidities registered in 41 patients undergoing laparoscopic sleeve gastrectomy
Silecchia et al. (2006)

Of the 41 patients nine had BMI ≥ 60 , 17 were on continuous positive airway pressure (C-PAP) therapy and 46.3% had at least two major co-morbidities. At the time of surgery 17 patients were classified as ASA grade 4 and 24 patients were classified as ASA grade 3. Fourteen patients had previously had unsatisfactory bariatric surgery prior to LSG (10 received one or more intragastric balloons and 4 LAGB). No deaths were reported. Major post-operative complications were reported in five patients. This included two re-admissions (one for staple-line leakage at 3 weeks and the other for bleeding), one case of staple-line extraluminal bleeding on first post-operative day (requiring laparoscopic re-intervention), one case of staple-line endoluminal bleeding (treated conservatively) and one case of transient acute renal failure. At the 12 month follow-up 57.8% of patients were free of co-morbidities and 31.5% had only one co-morbid condition. At the time of restaging 20% of patients remained ASA 4 (Patients with obstructive sleep apnoea syndrome that required continuous positive airway pressure therapy), 37.5% were ASA 3 and 35% were down-graded to ASA 2. The mean ASA score improved from 3.5 ± 0.5 at baseline to 2.7 ± 0.8 at 12 months ($P < 0.001$). Only two patients did not show any clinical improvements. These patients had 3 co-morbidities and their BMI remained above 50. BMI improved from mean 57.3 ± 6.5 at baseline to 44.5 ± 8.1 at six months after LSG and 40.8 ± 8.5 at 12 months after LSG. Patients were followed-up for a mean period of 22.2 ± 7.1 months with 16 completing the 24 month follow-up and 8 completing the 30 month follow-up. Fourteen patients went on to the second step of the two stage LBPDS after a mean of 16 ± 5.4 months (Silecchia et al. 2006).

Langer et al. (2006) (Austria) investigated the effect of gastric dilatation on the success of sleeve gastrectomy as a sole operation for morbid obesity. In this study 23 patients (17 women and 6 men), the majority of patients were morbidly obese ($n = 15$). At baseline the

mean BMI was 48.5 ± 6.9 and the mean weight of the patients was 129 ± 20.1 kg. Investigators used a 48- Fr bougie. Post-operative care was similar to that of previously described studies. In patients who had completed follow-up for over one year, an upper GI contrast study was performed to rule out dilatation of the gastric tube, which was defined as broadening of the gastric tube to > 4 cm. Patients were followed-up for a mean of 20 months (range: 5 to 29). These patients achieved a mean EWL of $21 \pm 6\%$, $46 \pm 13\%$ and $56 \pm 18\%$ at one (n = 23), six (n = 23) and 12 months (n = 18) respectively. Their weight also reduced from mean of 129 ± 20.1 kg at baseline to 119 ± 17 kg at one month, 102 ± 20 kg at six months and 95 ± 22 at 12 months. No iron, vitamin B12 or folate deficiencies were revealed through scheduled blood tests. Two patients required conversion of the LSG to a LRYGBP (one due to severe gastro-oesophageal reflux at 15 months and another with unsatisfactory weight loss at 1 year and complete weight regain at 2 years). Three patients demonstrated partial weight regain within the median follow-up of 20 months, fourteen patients who reached follow-up of > 1 year underwent upper GI series in order to rule out dilatation of gastric tube. Only one patient experienced gastric dilatation. However this patient nonetheless achieved EWL of 59% at the 12 month follow-up, has had a stable weight through to the 30 month follow-up and experiences early satiety. However no conclusions can be drawn as this is only one patient observation (Langer et al. 2006).

Santoro et al. (2006) (Brazil) evaluated laparoscopic sleeve gastrectomy in combination with omentectomy and enterectomy (to retain 3 m of small bowel) in 100 patients (52 women and 48 men), mean age 43.7 years, mean body weight 114.2 kg and mean BMI 40.1. Prior to surgical treatment, orthopaedics problems were diagnosed in 32 patients, essential hypertension in 43, diabetes in 34, hypertriglyceridemia in 59, hypercholesterolemia in 49 and respiratory problems in 21. The complete procedure took a mean of 210 minutes (range: 150 to 300 minutes). While no deaths were reported, there were seven cases of post-operative complications. These included perisplenic abscess, gastric laceration outside mechanical suture, abdominal wall bleeding at trocar site, supraumbilical hernia and gastric fistula, each reported once in five separate patients. Additionally, internal bleeding was reported in two patients. Gallbladder lithiasis developed in four patients with one requiring surgical resection 14 months later. After the procedure six patients had complaints such as moderate intestinal constipation and one patient had occasional dyspepsia that did not require continuous medication. The mean BMI of all patients decreased from 39.9 at baseline to 35.6 at 1 month. There were 81 patients available for a minimum four month follow-up, their mean BMI decreased from 40.2 to 32.1. Sixty-four patients were available for a minimum 6 month follow-up, their mean BMI decreased from 41.3 to 31.2. Thirty-nine patients were available for a minimum 12 month follow-up, their mean BMI decreased from 41.0 to 30.3. Improvements in co-morbidities of patients are outlined in Table 8. All patients improved (reduction in medication or better objective laboratory results or fewer symptoms) or had their conditions resolved (disappearance of problem or withdrawal of medication) (Santoro et al. 2006).

Condition	Baseline	Resolved	Improved
Orthopaedic problems	32	23	9
Essential hypertension	43	32	11
Diabetes	34	31	3
Hypertriglyceridemia	59	48	11
Hypercholesterolemia	49	28	21
Respiratory problems	21	19	2

Table 8: Co-morbid conditions in 100 patients where LSG was performed in combination with omentectomy and enterectomy.

Santoro et al. (2006)

COST IMPACT

Most insurance companies are reluctant to approve unstaged gastric bypass, and attempts at approval and reimbursement for a staged (e.g. 2 stage gastric bypass, sleeve gastrectomy to

achieve initial weight loss followed by duodenal switch) approach is likely to have great resistance (Cottam et al. 2006). The actual cost of LSG is not known, the following table presents the Medicare Benefits Schedule reimbursements for bariatric surgery (Table 9).

Table 9 Medical Benefits Schedule of fees for bariatric surgery (Medicare Australia 2006)

Category	Item Number	Benefit (AUD)	Number of Claims (July 2005 to June 2006)
Initiation of management of anaesthesia for procedures within the peritoneal cavity in upper abdomen (inc. gastrectomy)	20790	\$140.00	15430
Gastric reduction or gastroplasty by any method for morbid obesity	30511	\$750.70	6080
Gastric bypass for morbid obesity by any method including anastomosis	30512	\$923.80	239
Surgical reversal of morbid obesity by any method (of procedure to which item 30511 or 30512 applies)	30514	\$1360.05	721
Partial gastrectomy	30518	\$872.60	238
Total gastrectomy, including lower oesophagus, performed left thoraco-abdominal incision or opening of diaphragmatic hiatus	30526	\$1905.45	32

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES A randomised safety and efficacy study comparing laparoscopic sleeve gastrectomy to laparoscopic proximal Roux-Y-gastric bypass is currently underway in Switzerland. The expected completion date is December 2011 (Clinicaltrials 2006).

HEALTHPACT CONCLUSION

The studies assessed in this summary indicate that LSG is capable of inducing substantial weight loss in patients and may be suitable as the ideal first stage operation in patients with BMI > 55 (Baltasar et al. 2005). A total of 3 studies reported deaths (one death each) (Baltasar et al. 2005, Moon Han et al. 2005, Cottam et al. 2006) that were related to the procedure, severe complications (intra-abdominal bleeding/leakage, extraluminal bleeding) documented within these studies often required reoperation as well. The historical controlled study with the intragastric balloon suggests that LSG is capable of faster and greater weight loss (Milone et al. 2005), however the lack of concurrent controlled studies with appropriate comparators (e.g. laparoscopic gastric banding, stomach stapling) limits the strength of the current evidence base. Overall, it is possible that LSG may be more appropriate as a first stage treatment in super-obese patients before the implementation of more definitive treatments (e.g. duodenal switch) instead of a stand-alone treatment. Based on the evidence available, it is recommended that a Horizon Scanning Report is produced.

- | | |
|---|--|
| <input checked="" type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input type="checkbox"/> Archive |
| <input type="checkbox"/> Refer | <input type="checkbox"/> Decision pending |

Note: Due to insufficient information, the Horizon Scanning Report will be placed on hold pending the publication of more studies.

SOURCES OF FURTHER INFORMATION:

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LIST OF STUDIES INCLUDED

Total number of studies 8
Level III-3 and level IV interventional evidence

SEARCH CRITERIA TO BE USED:

Sleeve gastrectomy
Gastric sleeve
Tube gastrectomy
Laparoscopic

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