Surgical Treatment of Severe Obesity With a Low-Pressure Adjustable Gastric Band
Experimental Data and Clinical Results in 625 Patients

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Objective
To evaluate the use of a low-pressure gastric band in the treatment of severe obesity in a prospective study.

Summary Background Data
Gastric banding for severe obesity has been associated with erosion and perforation of the stomach. The Swedish adjustable gastric band (SAGB) has been proposed as a low-pressure device.

Methods
From January 1998 to October 2001, 625 patients underwent laparoscopic SAGB. Median age was 36 years, and 80.4% of patients were female. Median preoperative body mass index (BMI) was 40. Previous upper abdominal surgery was reported in 36 (6%) patients. A five-trocar technique was used without a calibration balloon.

Results
Median follow-up was 19.5 months. All patients were treated laparoscopically with a median operating time of 80 minutes. Conversion was necessary in two patients (0.3%): one trocar injury of the mesentery and one esophageal perforation. Median hospital stay was 3 days; there were no 30-day deaths. Early morbidity was present in 27 patients (4.3%). Late band reoperation was necessary in 49 patients (7.8%). Indications for reoperation were band slippage or pouch dilation, acute total dysphagia, and band leakage or malfunction. Median excess weight loss was 45.8%, 49.9%, and 47.4% after 1, 2, and 3 years, respectively, with a measurable beneficial effect on arterial hypertension, sleep apnea syndrome, and diabetes control.

Conclusions
SAGB is a safe and effective new method in the management of severe obesity. Long-term follow-up (>3 years) is necessary to confirm its effectiveness and safety.

Obesity is a major healthcare issue in both industrialized and industrializing nations.1 The prevalence of obesity (body mass index [BMI] 30 or more) in the United States was 19.8% in 2000.2 Well-known adverse effects of obesity include cardiovascular disease, diabetes mellitus, and various types of cancer.

Surgical treatment can be offered to patients with clinically severe (morbid) obesity (BMI > 40 or > 35 with associated morbidities) in whom dietary and medical therapies have failed. A variety of restrictive and malabsorption-inducing procedures have been proposed to treat clinically severe obesity. Laparoscopic gastric banding offers the advantages of minimally invasive surgery, adjustability, and reversibility. Mainly in Europe and Australia, a large experience exists with the original Lap-Band device (BioEnterics, Carpinteria, CA).3,4 Concern exists, however, regarding band erosion, slippage, and pouch or esophageal dilatation, leading to reoperation in up to 50% of patients.5,6 Some of these adverse effects could be related to the relatively high pressure exerted by the band on the esophageal and gastric wall. The Swedish adjustable gastric band (SAGB) (Obtech Medical, Baar, Switzerland) was engineered as a low-pressure device and has been introduced...
into clinical practice.7–9 We previously reported superior results with this new band and have not used the Lap-Band since 1998.10 This article reports the first large consecutive series of prospectively followed severely obese patients treated with the SAGB.

METHODS

Preliminary In Vitro Study

To verify our clinical impression of the SAGB as a low-pressure device, an experiment was set up to determine the pressure–volume relationship in two gastric band models (Lap-Band and SAGB). A calibrated quantity of isosmolar fluid was injected via a T-shaped connecting piece into the band’s catheter. The other end of this T-piece was connected to a precision digital manometer. Pressure readings were expressed as kilopascal (kPa; 1 pascal = 1.45 × 10⁻⁴ pounds per square inch). For each band type, two data sets were obtained. Compliance of each device was calculated as volume change (mL) per unit of pressure increase (kPa). Compliance values were compared using the two-tailed Student t test.

Preoperative Evaluation

Patients were seen during a multidisciplinary consultation attended by a surgeon, an endocrinologist, and a dietitian. Patients were considered as candidates for SAGB placement when the following conditions were met: more than 18 years old, BMI > 40 or > 35 with important comorbidities, no significant intake of sweets or alcohol, and no concurrent psychiatric illness. Esophageal contrast or functional studies, cardiac evaluation, and pulmonary function testing was performed only when clinically indicated. All patients were repeatedly instructed concerning the importance of an adapted diet and disciplined eating habits. More specifically, patients were advised to take frequent, small meals, avoiding liquid calories or sweets, fibrous meat, and white bread. Written informed consent was obtained from all patients. High-dose low-molecular-weight heparin starting 5 days before surgery was routinely prescribed.

Operative Technique

Patients were placed in a half-sitting (maximal reverse Trendelenburg) position and a nasogastric tube was inserted. Antibiotic prophylaxis (cefazolin 2 g intravenous) was given during induction. Pneumoperitoneum was installed with a Veress-type needle introduced at the left subcostal margin and was maintained at 18 to 20 mm Hg. A five-trocar technique was used. In patients with a massive left liver lobe, a sixth trocar was sometimes necessary to provide for an additional retractor. Following opening of the left phrenoesophageal and gastrohepatic ligaments, blunt dissection was performed to create a passage between the diaphragmatic pillars and the posterior aspect of the gastroesophageal junction. The vagal nerve, vagal branches in the cranial part of the gastrohepatic ligament, and any left hepatic artery originating from the left gastric artery were routinely spared. The empty band was then inserted through a 15-mm trocar and pulled through the retrogastric tunnel with the help of the Goldfinger instrument. No calibration balloon or catheter was used; instead, a ligature was placed just distal to the esophagogastric junction before closing the device. This ligature was kept cranially under tension while closing the band and was used as a landmark for the gastrosagramatic sutures, as described previously.11 In patients with a large amount of periesophageal fat, the closing mechanism was not used; instead, the band was closed with a nonabsorbable suture to prevent early dysphagia. From the year 2000 on, modifications in the technique were made to prevent the stomach from slipping through the device. These modifications included minimal posterior dissection, creation of a virtual pouch just beneath the Belsey fat pad, and rotation of the closing mechanism toward the left, as advocated by Klaiber et al.12 The catheter was then exteriorized through the 15-mm trocar opening and connected to the fluid reservoir, which was implanted on the rectus fascia medially in the upper abdomen. The fascial incision around the catheter was carefully closed with a resorbable suture. At the end of the procedure, the nasogastric tube was removed in most cases. In redo surgery, a dye test was performed during surgery and the nasogastric tube was left in place. It was removed on the second day after a contrast x-ray study of the gastroesophageal region.

Patients were permitted to start a semiliquid diet immediately and were discharged on the first or second postoperative day. At discharge, detailed dietary instructions were provided.

Follow-Up Protocol

Patients were seen after 4 weeks for initial filling of the device. Initial and subsequent fillings of the device were performed by a radiologist with contrast visualization of the esophagus, stomach, and SAGB. Further filling of the band was performed two or three times during the next 9 to 12 months as clinically indicated. Follow-up visits were planned every 3 months during the first year postoperatively and every 6 months thereafter. Regular feedback from the dietitian was ensured.

End Points

Metabolic effectiveness (weight loss) was considered the primary end point. Secondary end points were early (within 30 days) and late complication rate and mortality. Complications were defined as any untoward event related to the procedure and resulting in medical therapy, reoperation, or prolongation of hospital stay.
Data Acquisition

A computerized database was used to prospectively gather patient data. Statistical analysis was performed with a commercial software package (Prism 3.0, GraphPad software, San Diego, CA). Differences between means and fractions were evaluated with the Mann-Whitney and chi-square tests, respectively. Statistical significance was assumed at $P < .05$. Unless stated otherwise, quantitative results are expressed as median with 95% confidence interval.

RESULTS

Manometry Data of Gastric Banding Devices

The Lap-Band device developed a much steeper pressure–volume curve compared with the SAGB (Table 1, Fig. 1). The compliance of the SAGB device was sevenfold higher compared to the compliance of the Lap-Band (0.25 vs. 0.035 mL* kPa$^{-1}$). The maximal pressure inside the Lap-Band also exceeded that of the SAGB (154.78 vs. 136 kPa). The SAGB therefore permits smoother filling and more precise tuning of the device while maintaining relatively low pressures inside the balloon.

Demographic Data

From January 1998 until October 2001, 625 consecutive patients underwent SAGB. Median age was 36 years (range 36.3–38), and 80.4% of patients were female. Previous open surgery in the upper abdomen had been performed in 6% of the study population (Table 2).

Median preoperative BMI was 40 (range 40.2–41.3). Obesity-related comorbidity necessitating medical treatment was present in the large majority of patients. Median follow-up was 19.5 months (range 20.6–22.4).

### Table 1. PRESSURE–VOLUME RELATIONSHIP AND COMPLIANCE OF TWO GASTRIC BANDING DEVICES

<table>
<thead>
<tr>
<th>Volume (mL)</th>
<th>SAGB Data set 1</th>
<th>SAGB Data set 2</th>
<th>Lap-Band Data set 1</th>
<th>Lap-Band Data set 2</th>
<th>$P$</th>
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<td>95.75</td>
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<tr>
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<td>—</td>
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<td>117.64</td>
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<tr>
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<td>—</td>
<td>—</td>
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<td>113.63</td>
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<tr>
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<td>136.00</td>
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<td>136.00</td>
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</tr>
<tr>
<td>10.00</td>
<td>136.00</td>
<td>132.25</td>
<td>136.00</td>
<td>132.25</td>
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</tr>
<tr>
<td>Compliance (ml * kPa$^{-1}$)</td>
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<td>0.27</td>
<td>0.035</td>
<td>0.035</td>
<td>.002*</td>
</tr>
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</table>

SAGB, Swedish adjustable gastric band.

* Two-tailed Student t-test.

![Figure 1. Pressure–volume curves of two gastric banding models (two data sets), SAGB, Swedish adjustable gastric band.](image)
Surgical Outcome

The procedure was performed by several staff surgeons and could easily be taught to senior residents. Median operating time was 80 minutes (range 82.8–88.5). Concurrent cholecystectomy was performed in three patients. Conversion was necessary in two patients (conversion rate 0.3%): in one patient a trocar injury caused bleeding from the transverse mesocolon, and in the second case a seromuscular tear of the esophagus was repaired. In both patients the SAGB was implanted after repair of the injury and recovery was uneventful.

Early Complications

Median hospital stay was 3.0 days (range 3.4–3.6). None of the patients needed intensive care unit admission postoperatively. There were no deaths in this series. Early complications requiring therapy occurred in 27 patients (Table 3). Early reoperation was performed in two patients (0.3%) who developed acute total dysphagia due to band misplacement (too low on the stomach). One pneumothorax was caused by injury to the mediastinum with the Goldfinger instrument and was treated with oxygen administration. In two patients abscesses developed around the fluid reservoir, necessitating its temporary removal. In these patients, the band itself was preserved by anchoring the catheter to the inside of the abdominal wall, away from the infectious area. Erosion and migration into the stomach were absent in this series.

Late Morbidity

Late reoperation was indicated in 49 patients (7.8%; Table 4). The need for reoperation developed after a median of 12.5 months (range 10–15.5). Following adaptation of our surgical technique, the band reoperation rate gradually declined over time from 24% to 2.8% (Table 5). The large majority of reoperated patients developed slipping of the stomach or dilatation of the gastric pouch. A complete lack of dietary discipline was noted in most of these cases. Clinically, either of two syndromes developed: sudden near-total dysphagia or progressively worsening reflux, vomiting, and epigastric complaints. In two patients, the device was incorrectly placed around periesophageal fatty tissue. All reoperations were completed laparoscopically.

Esophageal dilatation was noted in seven patients (1.1%) and was treated with temporary deflation of the balloon. Two patients (0.3%) developed a leak of the device situated at the edge of the balloon. Refixation of the access port under local anesthesia was performed in 16 patients (2.6%) who developed inversion of the port.

Metabolic Results

Complete follow-up data were available from 588 patients (94%). Median excess weight loss after 1, 2, and 3
years was 45.8% (range 44.8–51.8%), 49.9% (47.3–56%), and 47.4% (42.6–56.5%), respectively (Fig. 2). Median BMI decreased from 40.1 (range 40.2–41.3) preoperatively to 31.6 (31.2–33), 31.8 (30.6–32.3), and 32 (30.5–33.8), respectively, after 1, 2, and 3 years (Fig. 3). Total lack of efficacy was noted in three noncompliant patients (0.5%), who were later converted to gastric bypass.

Weight evolution of redo SAGB patients showed a drop after a period of about 1 year, reflecting the timing of reoperation in these patients. Afterward, however, weight loss reached the same level as patients who did not require reoperation (Fig. 4).

Surgery significantly decreased the incidence of hypertension, osteoarticular disease, and diabetes mellitus requiring medical treatment (Table 6).

**DISCUSSION**

Surgical treatment has an established role in the treatment of clinically severe obesity. Malabsorption-inducing procedures such as the Roux-en-Y gastric bypass are generally effective in inducing at least 60% of long-term excess weight loss. These procedures cause a predictable micronutrient deficiency that can be largely avoided by early supplementation. According to the International Bariatric Surgery Registry, the mortality rate associated with open bariatric procedures is 0.3%, with a major morbidity rate of 2%.15

Since its introduction by Kuzmak and Forsell, the gastric banding restrictive procedure has been adapted for minimally invasive surgery and is currently widely performed. Recently, the Lap-Band device was approved by the U. S. Food and Drug Administration. Besides the obvious assets of laparoscopic surgery, the proposed advantages of gastric banding include reversibility and the possibility of adjusting the band’s stoma size. A recent randomized trial comparing open to laparoscopic gastric banding found a significantly shorter hospital stay and fewer readmissions associated with the laparoscopic procedure.16

The original Lap-Band silicone band has been associated with migration or erosion of the stomach wall in up to 6% of patients and a significant long-term reoperation rate for slipping or gastric pouch dilatation. Surgical technique and the patient’s eating behavior postoperatively are factors influencing the incidence of these side effects. The design of the banding device, however, could be an important factor. One important variable is the relatively high pressure exerted on the esophageal and gastric walls. The SAGB has been engineered as a low-pressure device. We confirmed the much higher compliance and more favorable pressure–volume curve associated with this device in an experimental setting. Given that the width of the Lap-Band is less than half that of the SAGB, it is probable that a higher pressure exerted on the tissues explains the frequently reported occurrence of erosion and migration with the former device. In our experience, the physical properties of the SAGB allow better regulation of the stoma size and have completely prevented band migration.

In agreement with others, we found a very low 30-day morbidity and mortality rate, with only two conversions and three severe complications in this series. The procedure is straightforward and could easily be performed by senior residents, resulting in a comparable outcome. Placement of the SAGB is therefore not limited to expert surgeons but can be mastered by any digestive surgeon with basic laparoscopic skills.

The reoperation rate remains the Achilles heel of the

**Table 5. EVOLUTION OF BAND REOPERATION RATE OVER TIME**

<table>
<thead>
<tr>
<th>Period</th>
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<tr>
<td>1/98–1/99</td>
<td>18/75</td>
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<td>1/99–1/00</td>
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<tr>
<td>1/01–1/01</td>
<td>5/174</td>
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</table>

* Reoperated patients/total number of patients operated.
gastric banding operation. With modification of surgical technique and strict patient selection and education, we were able to reduce the reoperation rate due to slipping or pouch enlargement to 3%. We consider minimal posterior dissection and creation of a very small (virtual) gastric pouch without calibrating the balloon key elements in preventing postoperative slipping. The device is gradually filled over several sessions to allow a smooth increase in the pressure exerted on the gastroesophageal junction. Patients should be instructed to eat very slowly and to take regular, small meals to avoid dilatation of the gastric pouch. In patients who do need reoperation, a laparoscopic approach is safe and effective. Weight loss after successful reoperation is usually comparable to that seen in patients who do not require reoperation.

Concern has recently arisen regarding esophageal function after gastric banding. In our experience, the gastric band acts partially as an acid reflux barrier. Indeed, the majority of patients with acid reflux noted amelioration or disappearance of reflux symptoms after surgery. We therefore no longer consider acid reflux symptoms to be a contraindication to gastric banding. Reflux did develop, however, in patients with slipping or pouch enlargement. Esophageal manometry was performed in a sample of five asymptomatic patients 1 year after surgery and was normal (unpublished data). In contrast to DeMaria et al’s results, esophageal dilatation was not common in this series. It occurs mainly in patients who overeat and use their distal esophagus as a reservoir. Strict preoperative selection for compliance and motivation is therefore essential. Moreover, differences in diet and eating habits between the European and U.S. population could partially explain this discrepancy. Nevertheless, long-term esophageal function following SAGB remains to be studied in detail and is the subject of a current prospective study in our department.

Metabolic goals were largely achieved. Half of the excess weight was lost after 15 months, but little additional effect was noted after this period. This is in contrast with the results of O’Brien et al, who reported continuing weight loss 4 years after surgery. Others have, however, found the same peak in weight loss after 12 to 18 months, followed by a gradual decline in effect. Gastric banding should therefore be avoided in extremely obese patients (BMI > 50) in whom adequate weight loss will probably not be reached with this method. Sweets-eaters generally have poor weight loss after SAGB and should be offered a different surgical technique. In keeping with other reports, weight loss after SAGB was associated with a significant improvement of diabetes control, blood pressure, and osteoarticular complaints.

In conclusion, SAGB is safe and effective for achieving weight loss and improving comorbidity in the severely obese. Band erosion and migration are prevented by the low-pressure design. Long-term follow-up will be needed to confirm the durability of these results.

Acknowledgments

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Table 6.  EFFECT OF SURGERY ON COMORBIDITIES

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<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Hypertension</td>
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<tr>
<td>Diabetes</td>
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<td>7</td>
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* Chi-square test.

References


