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SURGICAL ENDOSCOPY
and Other Interventional Techniques

A 6-year experience with the Swedish adjustable gastric band

Prospective long-term audit of laparoscopic gastric banding

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Abstract

Background: In morbid obesity conservative therapy often fails to reduce overweight permanently. As a consequence, several bariatric surgical procedures have been developed to achieve permanent excess weight loss. Among these, the laparoscopic restrictive procedures seem to be the least invasive. The aim of this prospective study was to assess and analyze the effects, complications, and outcomes after the implantation of the Swedish adjustable gastric band (SAGB) in long-term follow-up.

Methods: All consecutive patients with implantation of a SAGB between August 1996 and August 2002 were prospectively investigated. The placement of the SAGB was done by laparoscopy in all cases. Success was rated by the reduction of body mass index (BMI) excess weight loss (EWL), and reduction of comorbidities. "Nonresponders" to SAGB were defined as $<30\%$ EWL after a 3-year follow-up. Band-related complications were recorded and classified. Patient's outcome was assessed after 6 months and subsequently each year postoperatively.

Results: A total of 190 patients received a SAGB, 97% of whom could be followed up with a mean follow-up period of 39.4 months (duration of follow-up, 6–72). During follow-up, a significant reduction or improvement of BMI, EWL, and comorbidities were found. Nineteen percent of patients were identified as nonresponders. Early intraoperative and postoperative complications related to SAGB were one perforation of the gastric fundus (0.5%), one conversion (0.5%), one bleeding (0.5%), and two band infections (1.1%). The SAGB-related complications encountered during long-term follow-up were three port problems (1.6%), four band migrations (2.1%), five slipping/pouch dilatations (2.6%), and two band leakages (1.1%). All intra- and postoperative SAGB-related complications accounted for a total morbidity of 10.5%. Operative mortality was 0%. The overall reoperation rate was 8.5%.

Conclusions: In long-term follow-up, SAGB is safe and effective. Our results demonstrate a significant EWL of 50% during the first 24 months. However, patient selection has to be improved to reduce the nonresponder rate. SAGB leads to a significant reduction of obesity-related comorbidities. SAGB is an attractive alternative in the surgical treatment of morbid obesity.

Key words: Morbid obesity — Gastric banding — Comorbidities — Long-term follow-up

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In Western countries morbid obesity is an important medical, social, and economic issue. Conservative approaches to morbidity obesity often fail to reduce overweight permanently, as demonstrated by long-term results [7]. As a consequence, several surgical methods have been developed for the treatment of morbid obesity. Three different kinds of surgical procedures are in use: restrictive or malabsorptive methods and their combination.

Gastric (reservoir) reduction was introduced in 1976 in open surgery by Wilkinson and Peloso [30] as a restrictive treatment modality. Because of considerable side effects, the operation did not gain wide acceptance. The breakthrough in gastric banding began with the development and introduction of an adjustable gastric band in 1985. Almost simultaneously, the LAP-Band (Bioenterics, Carpinteria, CA, USA; developed by Kuzmak) and the Swedish adjustable gastric band (SAGB) (Obtech AG, Ethicon Surgery, Zug, Switzerland; developed by Hallberg and Forsell) became available for clinical use [12, 16]. In the beginning the adjustable gastric band was implanted by open surgery. In 1993, Belachew et al. [2] first implanted a LAP-Band laparoscopically. The success of this operation was followed by a rapid distribution of laparoscopic gastric banding procedures. Reasons for the wide acceptance among surgeons were that neither the stomach nor the

intestinal tract is opened or resected during the procedure, the operation can be performed by laparoscopy, and the procedure is reversible.

During the past decade, some modifications of the gastric bands and improvements in the laparoscopic technique of implantation have been made. In Europe, the SAGB is widely used and its beneficial effect has been demonstrated in several series. However, most series report on small patient numbers and have a short follow-up of 1 or 2 years.

The aim of this prospective study was to assess and analyze the long-term effects, outcomes, and complications after implantation of SAGB in a reasonable number of patients. Furthermore, we wanted to assess the long-term influence of SAGB on the comorbidities of morbid obesity.

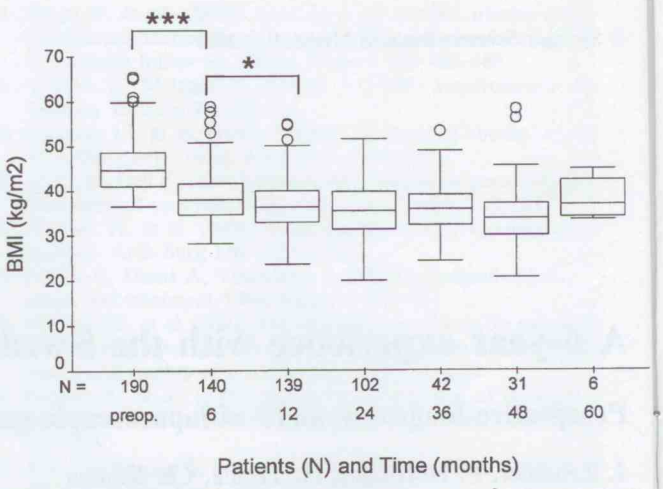

Fig. 1. Time course of body mass index (BMI) (kg/m^2) after SAGB. *p < 0.05; ***p < 0.0005.

Materials and methods

Patient data

Between August 1996 and August 2002, the SAGB was implanted by laparoscopy by a single surgeon (Ch.K.) in 190 patients. The preoperative management of patients followed the protocol of the Swiss Study Group for Morbid Obesity and was done by a multidisciplinary team. Operative data, outcomes, and complications related to the SAGB, as well as the influence on comorbidities of SAGB, were prospectively recorded using Excel software (Microsoft, Redmond, WA, USA). Success of treatment was rated by the reduction of body mass index (BMI) and by excessive weight loss (EWL) in percent, as well as by a reduction of comorbidities. For the latter, the parameters of the "metabolic syndrome" were measured and analyzed. This term includes dyslipidemia (total cholesterol-to-HDL cholesterol ratio >5), type 2 diabetes and impaired glucose tolerance (HbA1c >6%), and hypertension (systolic and diastolic blood pressure >160 and >95 mmHg, respectively). Hyperuricemia (urea > 360 µmol/L) was also included in the analysis of the metabolic syndrome. Patient follow-up was performed once a month for the first 3 months and once after 6 months. Thereafter, patients showing an uneventful course were seen once per year. We further evaluated the patients for failure of the restrictive procedure. Favretti et al. [11] defined patients showing less than 30% EWL at long-term follow-up of 36 months as "nonresponders." In this subgroup of patients, we analyzed the changes in the comorbidity rates separately.

Data are expressed as mean ± SD unless stated otherwise. Normal distribution of data was tested using the Lilliefors Test (software SPSS 10.0, SPSS Inc., Chicago, IL, USA). Where appropriate, differences between groups were tested for significance using the Mann-Whitney U test (software SPSS 10.0). $p < 0.05$ was considered significant. For Figs. 1–6 box plots were used. All box plots show the median score as a black center line and the first (25th percentile) and third quartiles (75th percentile) as the lower and upper hinges of the box. The whiskers are within 1.5 times the interquartile range. Circles represent values outside the inner fence (minor outliers); stars represent values outside the outer fence (major outliers).

Indications for surgery

In several European countries there are strict decrees from the health insurance companies to cover the costs of bariatric surgery. Until 2000, the laparoscopic gastric banding procedure was covert in Switzerland for patients with a BMI >40 kg/m^2. In patients with a BMI between 35 and 40 kg/m^2 the existence of one comorbidity was mandatory. Since 2001, the costs of bariatric surgery have been covert only for patients with a BMI >40 kg/m^2. Table 1 gives the indications and contraindications to perform laparoscopic gastric banding as proposed by the Swiss Study Group of Morbid Obesity.

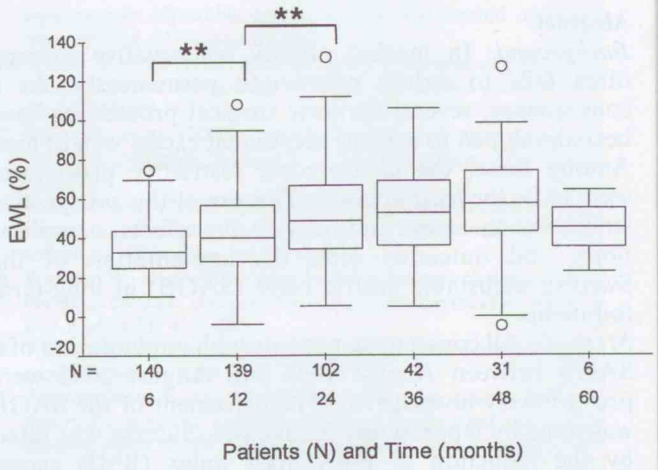

Fig. 2. Time course of excess weight loss (EWL) (%) after SAGB. **p < 0.005.

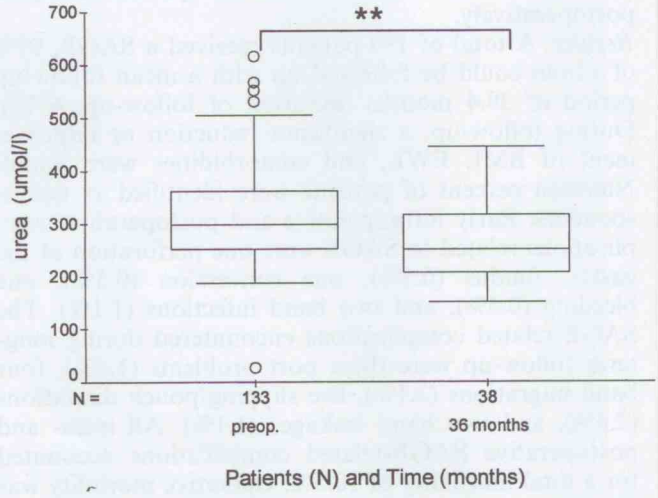

Fig. 3. Influence of SAGB on hyperuricemia at 3-year follow-up. **p < 0.005.

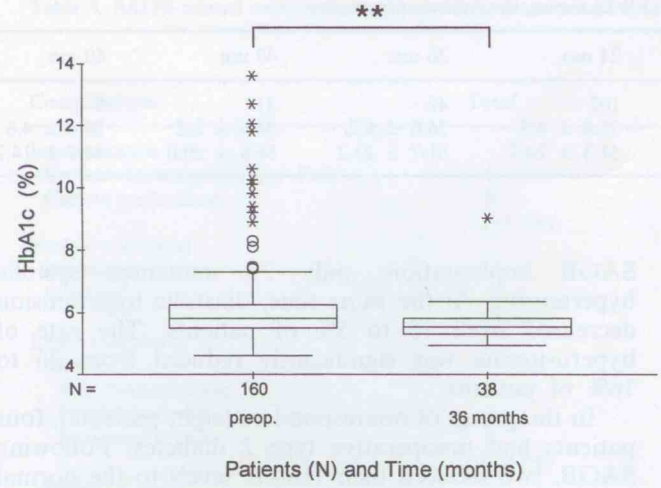

Fig. 4. Influence of SAGB on type 2 diabetes at 3-year follow-up. $^{**}p < 0.005$.

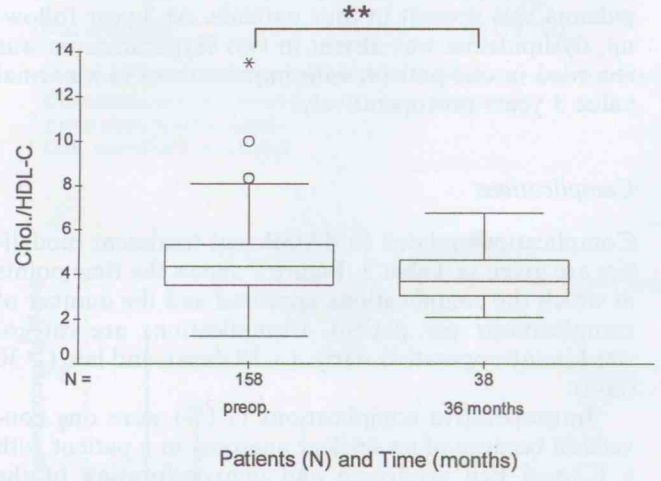

Fig. 5. Influence of SAGB on dyslipidemia at 3-year follow-up. $^{**}p < 0.005$.

Implantation of SAGB

The technique of proper implantation of SAGB by laparoscopy has been described in detail elsewhere [15]. In summary, CO_2 pneumoperitoneum is installed after inserting the Veress needle into the left hypochondrium. A 10-mm camera trocar is inserted paramedian left approximately 12 cm caudal to the xiphoid. A 25° Panoview-optic (Wolf, Knittlingen, Germany) is inserted and held in place by a robotic arm (AESOP 3000, Computer Motion, Goleta, CA, USA). Under laparoscopic view, a 10/5-mm Versaport trocar (Tyco, Wollerau, Switzerland) is inserted on the left costal arch. A static Nathanson liver retractor (Cook, Sursee, Switzerland) is inserted near the xiphoid. Installation is accomplished by inserting a 5-mm trocar paramedian right and a 15-mm trocar on the left lateral side.

Dissection begins with isolation of the left crus and creation of an opening in the avascular part of the gastrophrenic ligament between the esophagus and the left crus. This space is widened dorsally with the "goldfinger" (Obtech). After incision of the pars flaccida, the retroperitoneum at the bottom of the right diaphragmatic crus is opened and dissection is continued behind the cardia. During further preparation the esophagus is identified dorsal in the fat by oral insertion of a 40-Fr gastric balloon tube. Dissection is continued above the left gastric artery and vagus branch followed by insertion of the goldfinger from the right to the angle of His.

The Swedish band is tested for proper function by immersing it in NaCl and filling it with air. The band is inserted into the abdomen through the 15-mm trocar. By attaching the band to the goldfinger, it is easily pulled around the back of the stomach through the opening on the lesser curvature. The inserted gastric balloon is filled to a size of 10 ml and drawn back to form the desired gastric pouch. The SAGB is then adjusted to its final position and closed and secured with two 2–0 Ethibond (Ethicon, Spreitenbach, Switzerland) threads. The flaps are then pushed as far as possible to the greater curvature in a stable position. Three or four band-overlying sutures are placed on the anterior side of the stomach. The connecting tube is pulled out through the incision site of the liver retractor and all trocars are removed under laparoscopic control.

The SAGB port is implanted approximately 6 cm cranial to the xyphoid and fixed to the periost of the sternum with two nonresorbable threads. The procedure is accomplished by connecting the silicone tube to the port.

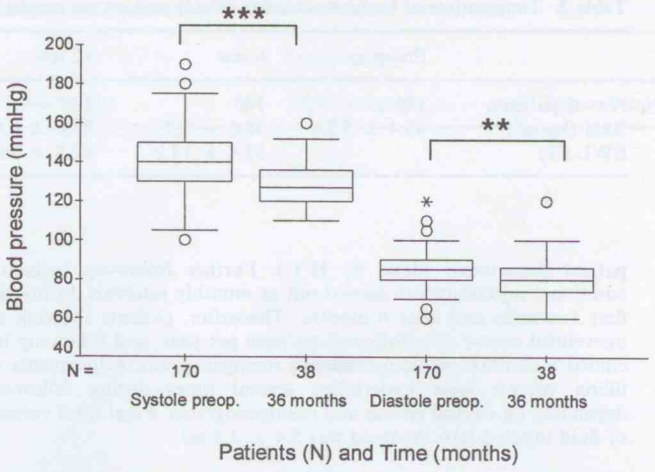

Fig. 6. Influence of SAGB on systolic and diastolic hypertension at 3-year follow-up. $^{**}p < 0.005$; $^{***}p < 0.0005$.

Table 1. Indications and contraindications for laparoscopic bariatric surgery as proposed by the Swiss Study Group for Morbid Obesity

Indications
1. BMI between 40 and 60 kg/m^2
2. Failure of competent conservative treatment
3. Compliance: patients are able and willing to comply with dietary restrictions by this procedure
4. Not older than 60 years in general
Contraindications
1. Endogenous depression or drug and alcohol abuse
2. Non-adult patient without a specific medical indication
3. Severe cardiopulmonary disease or any other serious organic disease
4. Pregnancy
5. Esophageal disease or upper gastrointestinal bleeding conditions
6. Emotional instability or noncompliance
7. Autoimmune connective tissue disease or inflammatory disease in the gastrointestinal tract

BMI, body mass index

Postoperative follow-up

By use of Telebrix (Guerbet AG, Zurich, Switzerland), a contrast medium-enhanced roentgenogram was usually performed in the evening of the operating day to exclude esophagogastric leackage. If the findings were favorable, patients were put on a structured liquid diet for the first 4 weeks after the operation.

A month after surgery, inflation of SAGB was commenced by injecting 3 or 4 ml of a radiology contrast medium (Iopamiro isotonic 200 mg IO; Bracco, Milan, Italy) under aseptic conditions in an out-

Table 2. Time course of body mass index (BMI) and excess weight loss (EWL) during the follow-up period

	Preop.	6 mo	12 mo	24 mo	36 mo	48 mo	60 mo
No. of patients	190	140	139	102	42	31	6
BMI (kg/m^2)	45.4 ± 5.7	38.6 ± 5.7	37.0 ± 6.0	35.4 ± 6.3	36.0 ± 6.2	34.6 ± 8.2	38.0 ± 4.6
EWL (%)		35.4 ± 14.2	42.8 ± 20.1	51.3 ± 24.7	51.7 ± 23.2	56.8 ± 30.0	44.7 ± 14.7

patient department (done by H.T.). Further follow-up including additional injections was carried out at monthly intervals during the first 3 months and after 6 months. Thereafter, patients showing an uneventful course were followed up once per year, and follow-up included a contrast medium-enhanced roentgenogram. Adjustments of filling volume were undertaken several times during follow-up depending on clinical course and roentgenograms. Final total volume of fluid injected into the band was 5.4 ± 1.7 ml.

Results

From August 1996 to August 2002, 190 patients (156 women and 34 men) received SAGB by laparoscopy. The mean age was 40 years (range, 18–64). Mean preoperative weight was 120 kg (range, 89–197) and the mean preoperative BMI was 45.4 ± 5.7 kg/m^2 (range, 36.4–65.4).

The mean operating time was 102 ± 31 min (range, 45–235). Time of surgery gradually became shorter with experience and decreased from 112 ± 35 min for the first half of procedures to 91 ± 21 min for the second half ($p < 0.0005$). The average length of hospital stay was 6 ± 1.7 days (range, 4–21). Of the 190 patients who underwent SAGB, 184 (97%) could be followed up (mean, 39.4 ± 18.4 months; duration of follow-up, 6–72 months). There were two deaths not related to the implantation of SAGB (one road accident and one acute heart failure).

Follow-up in weight loss

Postoperative time courses of BMI and EWL are given in Table 2 and Figs. 1 and 2. Mean EWL surpassed 50% after 24 months and reached 56.8% after 48 months.

According to the definition given by Favretti et al. [11], there were eight nonresponders (19%) out of 42 patients with a follow-up time of 36 months. The effect of SAGB on comorbidities was analyzed at this follow-up time.

Effect on comorbidities

The effect of SAGB on morbid obesity-related comorbidities at 3 year follow-up is shown in Figs. 3–6. All values of the studied parameters of the metabolic syndrome including hyperuricemia were significantly reduced. The rate of dyslipidemia decreased from 31% preoperatively to 13%. There was a remission of type 2 diabetes from 38% preoperatively to 13% postoperatively. Systolic hypertension was present in 24% of patients preoperatively. At 36 months after SAGB implantation, only 3% remained systolic hypertensive. At the same time, diastolic hypertension decreased from 15 to 5% of patients. The rate of hyperuricemia was significantly reduced from 26 to 16% of patients.

In the group of nonresponders (eight patients), four patients had preoperative type 2 diabetes. Following SAGB, two reduced their HbA1c levels to the normal range. Systolic hypertension was present in four patients before operation. After 36 months, all patients showed a normalized systolic blood pressure. Preoperative dyslipidemia was present in four patients. At 3-year follow-up, dyslipidemia was absent in two Hyperuricemia was recorded in one patient, with improvement to a normal value 3 years postoperatively.

Complications

Complications related to SAGB and treatment modalities are given in Table 3. Figure 7 shows the time points at which the complications appeared and the number of complications per patient. Complications are categorized in intraoperative, early, (< 30 days), and late (> 30 days).

Intraoperative complications (1.1%) were one conversion because of an unclear anatomy in a patient with a Klippel–Feil syndrome and one perforation of the gastric fundus, which could be oversewn and repaired laparoscopically. Early complications were found in 1.6% of patients and included two band infections and one bleeding complication of the short gastric vessels. Late complications were found in 7.9% of patients and included port malfunction in 1.6%, development of incisional hernia in 0.5%, band migration in 2.1%, pouch dilatation/slippage in 2.6%, and band leakage in 1.1%. Total morbidity rate for the implantation of SAGB was therefore 10.5%. The reoperation rate was 7.4%, including a conversion rate of 0.5%. Of the 14 reoperations, eight (57%) were performed laparoscopically. SAGB-related mortality rate was 0% during the entire study period.

Discussion

Surgery for morbid obesity should be safe and effective, as indicated by long-term follow-up. This study shows that significant EWL is obtained during the first 24 months after implantation of a SAGB. During this time period, most patients will achieve a reduction of more than 50% of the initial excess body weight and will be able to stabilize their weight in the further course. In our

Table 3. SAGB-related complications divided into intraoperative, early, and late complications and their treatment modalities

Complications	Total	Treatment		
		Conservative	Open surgery	Laparoscopy
Intraoperative				
Unclear anatomy (Klippel–Feil)	1		1[a]	
Gastric perforation	1			1
	2 (1.1%)			
Early (< 30 days)				
Port/band infection	2			2
Bleeding[b]	1		1	
	3 (1.6%)			
Late (> 30 days)				
Minor				
Port disconnection	2		1	1
Painful port site	1		1	
Incisional hernia	1	1		
	4 (2.1%)			
Major				
Band migration	4 (2.1%)	1	2	1
Pouch dilatation/slippage	5 (2.6%)	2	1	2
Band leakage	2 (1.1%)			2
	11 (5.8%)	4	6	8
Total morbidity	20 (10.5%)			
		Reoperation rate[c]		14 (7.4%)

[a] Conversion to open surgery
[b] From short gastric vessels
[c] Only complications related

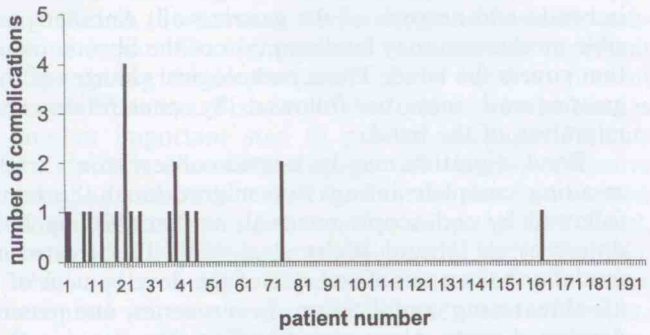

Fig. 7. Time points and numbers of SAGB-related complications.

study group of 190 patients with a mean follow-up of 39.4 months, failure of the restrictive procedure was noted in eight patients. Failure of the restrictive procedure was defined as a reduction of less than 30% of EWL in the long-term follow-up of 36 months. Of the 42 patients with this follow-up time, eight (19%) were classified as nonresponders according to the definition by Favretti et al. [11]. However, these so-called nonresponders did respond with regard to obesity-related comorbidities because in 62.5% of them at least one comorbidity was reduced. Patients with an unsatisfactory EWL after SAGB may therefore at least show improvement in their comorbidities. These patients usually did not comply with the dietary, psychological, and surgical advice given to them. Two of these patients were reoperated and received a gastric bypass. A combination of restrictive and malabsorptive surgical treatment may help these patients to achieve satisfactory EWL. It seems that especially patients who eat sweets or binge eat may show unsatisfactory results after restrictive procedures and may not qualify for gastric banding. However, this hypothesis is not proven and is controversial.

Laparoscopic implantation of the SAGB is a minimally invasive technique with the advantage of preserving the anatomy of the gastrointestinal tract. Nevertheless, the procedure is technically demanding and should be restricted to experienced laparoscopic surgeons with a sufficient caseload. In our series, most complications occurred in the first 50 patients. In our opinion, this is due in part to the learning curve but also to the longer follow-up in this group of patients. To prevent early complications it is important that SAGB be implanted by well-instructed surgeons. Only in this way will it be possible to improve the learning curve to an adequate number of operations, which we believe is in the range of 25–50.

After the initial disappointing results of the Food and Drug Administration (FDA) trial A of the LAP-Band, as reported by DeMaria et al. [5], recent studies from the United States have shown comparable results to those obtained in Europe and Australia. Ren et al. [22] have reported their experience with the LAP-Band system after FDA trials A and B. They conclude that laparoscopic gastric banding is safe in qualified hands. Because most studies of laparoscopic gastric banding cover only a short follow-up time, we wanted to analyze our results in the long-term follow-up because with time the number of complications and the number of "treatment failures" might increase. Our complication rate of 10.5% during the longest reported follow-up

Table 4. Comparison of reported SAGB studies in the literature with a minimal caseload of 100 patients

Reference	No. of patients	Follow-up (mo)	Port revisions (%)	Band migration (%)	Band leakage (%)	Pouch dilatation/slippage
Forsell et al. [13]	326	28	2.1	4.6	1.8	0.6
Miller et al. [17]	158	28	0.6	0.6	2	1.3
Hauri et al. [14]	207	12	2.9	1.0	2.9	0
Nehoda et al. [18]	320	18	8.1	1.6	2.3	0.9
Victorzon and Tolonen [25]	110	27	4.5	1.8	4.5	2.7
Ceelen et al. [3]	625	19.5	2.5	0	0.3	5.6
Current study	190	39.4	1.6	2.1	1.1	2.6

period of SAGB is comparable to the rates given in the literature (Table 4).

Our morbidity-related reoperation rate of 7.4% is acceptable but may be reduced by improving the surgical technique of SAGB implantation, as discussed later. Taking in to account the two reoperations performed for nonresponders, the total reoperation rate was 8.5%.

Port complications

Port complications occurred in three patients (1.6%), which all had to be reoperated. To prevent port complications and/or port malfunctioning, it is important to perform proper implantation of the port system as described by Weiss et al. [27]. We prefer to fix the port with periostal stitches in the lower third of the sternum because this helps reduce possible twisting or moving of the port. Fabry et al. [10] described an alternative technique by suturing the port onto a polypropylene mesh, which is secured to the rectus fascia in the left hypochondrium using a Tacker stapling device. Despite proper placement of the port, careful disinfection of the punction area as well as the proper punction of the port are of utmost important to prevent port complications. For the latter, ultrasonographic control prior to punction of the port is advised to prevent tube damage by the needle.

Band migration

Band migration is a major complication of SAGB since it may lead to perforation and/or vascular erosion if left untreated. In our patient group, band migration occurred in four patients (2.1%). These patients showed unexplained weight gain after initial weight loss. Diagnosis of band migration is usually made by endoscopy or by contrast medium-enhanced roentgenogram. It is possible that there may be a higher incidence of band migration in the asymptomatic patients of our series because we routinely performed contrast medium enhanced roentgenogram but not endoscopy during follow-up.

One reason for band migration is an overfilling of the band, which leads to pressure-induced erosion of the band through the gastric wall. Forsell et al. [13] showed that all patients with migrated bands had an overfilled band system in which the average fluid content of the balloon was 12.6 ml. In our study, one patient developed a band migration with a filling volume of 12.5 ml. However, in the other three patients with band migration, the filling volume was <7.5 ml. Overfilled band systems may be caused either by high injection volumes or by fluid osmosis through the semipermeable membrane (dilution occurs through the silicone membrane of the balloon) as shown by Wiesner et al. [29] for the LAP-Band. For the SAGB, a spontaneous volume change has not been described but may exist. As a consequence, it is recommended that the band filling should never exceed 9 ml. Furthermore, continuous follow-up of the band filling volume is strongly recommended because an uncontrolled patient may develop an overfilled band system. We believe that overfilling the band leads to ischemia and necrosis of the gastric wall. Another possible mechanism may be disruption of the fibrotic tissue that covers the band. These pathological changes of the gastric wall may be followed by penetration and migration of the band.

Band migration may be treated conservatively while awaiting complete intragastric migration of the band followed by endoscopic retrieval, as described by Baldinger et al. [1] and Weiss et al. [28]. This treatment modality has an undefined risk of the development of a life-threatening complication. In our series, one patient developed acute intragastric bleeding after conservative treatment of a band migration. In this patient, urgent laparotomy with band evacuation and bleeding control had to be performed.

A newer form of operative treatment for intragastric band migration is endoscopic removal of the band using a band cutter [28]. As we experienced in two patients not included in this study (operated on at other institutions), the band cutter can also successfully be used in patients with only partial band migration [21]. In our opinion, waiting for complete band intragastric migration cannot be recommended because the patient may develop a life-threatening complication.

Ceelen et al. [3] reported a 0% rate of band migration in 625 patients receiving a SAGB during a mean follow-up of 19.5 months. The authors conclude that the reason for this is that SAGB a low-pressure device in contrast to the LAP-Band, which has less than half the surface area of the SAGB. Our results show a long-term rate of 2.1% for SAGB band migration. We believe that a band migration rate of 0% will be difficult to achieve in the long term because this complication cannot be com-

Table 5. Comparison of reported LAP studies in the literature with a minimal caseload of 60 patients

Reference	No. of patients	Follow-up (mo)	Port revisions (%)	Band migration (%)	Band leakage (%)	Pouch dilatation/slippage
Favretti et al. [11]	830	—	11	0.5	0	10
Zinzindohoue et al. [31]	500	13	6.6	0	0	11
Dargent [4]	1,104	—	—	1.7	—	8.7
O'Brien et al. [20]	709	—	3.6	2.8	0.1	12.5
Rubenstein [23]	63	—	7.9	1.5	0	14.2
Evans et al. [9]	95	—	3.2	1	0	9.5
Szold and Abu-Abeid [24]	715	17	2.5	0.4	0.3	7.4
Niville et al. [19]	301	39	—	1.66	—	—
Weiner et al. [26]	146	—	4.1	1.4	0	5.2
Dukhno et al. [8]	250	—	2	1.2	0.4	5.2

pletely prevented by technical and operative improvements alone.

Pouch dilatation or slippage

Since the development of the SAGB implantation procedure, the "Swedish technique" advocated implantation of the band proximal to the bursa omentalis. When applying this technique for the LAP-Band, this operative step was called the "pars flaccida" approach.

It is difficult to distinguish pouch dilatation from slippage. In principle, the mechanisms that lead to this complication are the same: the formation of a pouch that is too large, band placement that is too distal, weak band fixation, and/or overeating associated with a stoma that is too narrow. Performing the Swedish technique or pars flaccida approach is one of the important steps during the implantation of the band to prevent pouch dilatation. Fixation of the fundus over the band is another important step to prevent slippage. Patients with pouch dilatation/slippage will develop excessive vomiting and problems of food intake due to a narrow stoma. Especially in early studies using the LAP-Band, the incidence of this complication was high (10–14%), which led to a high reoperation rate (Table 5). After technical improvements of the bands and after performing the pars flaccida approach, this complication was markedly reduced. In our study, the rate of pouch dilatation/slippage was 2.6%, similar to rates reported in the literature. We recommend performing contrast medium-enhanced roentgenograms on a yearly basis with immediate adjustment of the filling volume when beginning of pouch dilatation is noted. A conservative treatment for this complication is then possible, as shown in two patients in our series. Otherwise, treatment of this complication includes replacing or repositioning the band by laparoscopy.

Esophageal dilatation, which may be due to overeating associated with a stoma that is too narrow, was not evaluated in our series because this problem was not of clinical importance in our patients.

Band leakage

Band leakage occurred in two patients (1.1%) and appeared 45 and 62 months after primary surgery. This complication is diagnosed by filling the band system with a contrast medium (Iopamiro isotonic 200 mg IO; Bracco). Band leakage may be caused by iatrogenic intraoperative damage of the band or accidental puncture of the tube. Problem pressure zones of the balloon may be another reason for band rupture. However, this mechanism has not been proven, and the SAGB was modified in 1997 to reinforce a possible weak part of the band.

When band leakage occurs, patients normally need to be reoperated with reimplantation of a new band, as was the case in our two patients, who showed an uneventful course.

Metabolic syndrome

It is increasingly recognized that diseases related to the metabolic syndrome provide the greatest health risk to overweight or obese patients [6]. Three years after implantation of SAGB, we found a significant reduction of all comorbidities related to the metabolic syndrome. Dyslipidemia, hyperuricemia, and hypertension were reduced to normal in two-thirds of patients who had pathological values before surgery. The improvement in type 2 diabetes was also significant because pathologic values for HbA1c declined from 38% before surgery to 13% 3 years after the procedure. Our results show that surgical intervention using SAGB is a safe and effective method of achieving and sustaining beneficial effects on obesity-related comorbidity. Even for patients with unsatisfactory EWL, comorbidity is reduced in two-thirds of these nonresponders. SAGB therefore provides a clear improvement in quality of life and health status of these patients, together with a marked reduction of comorbidity-related medication use [31].

Conclusion

SAGB shows good to very good results in the long-term follow-up in terms of EWL and reduction of obesity-related comorbidities. In our opinion, SAGB is the least invasive procedure in bariatric surgery since it can be totally reversed.

The operative and postoperative morbidity is acceptable, and most complications can be safely treated by laparoscopy. However, lifelong follow-up of these patients is mandatory since operative-related complications may occur late.

A relatively small number of patients will show unsatisfactory EWL in the long-term follow-up, and further studies are needed to identify and exclude these patients from SAGB.

We conclude that SAGB is an attractive therapeutic option in the field of bariatric surgery.

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