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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.

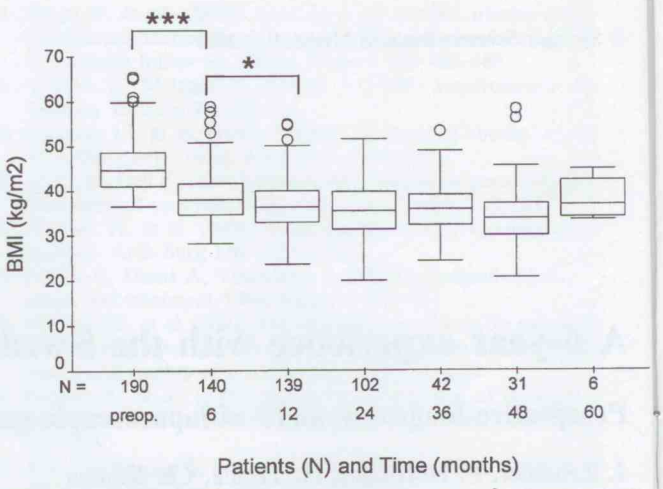

Fig. 1. Time course of body mass index (BMI) (kg/m^2) after SAGB. *p < 0.05; ***p < 0.0005.

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.

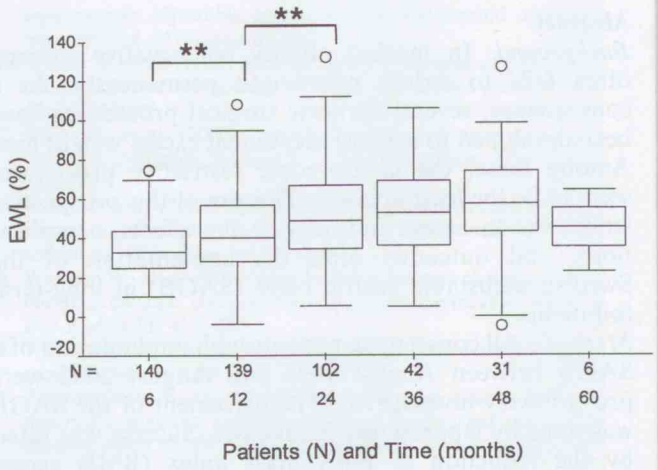

Fig. 2. Time course of excess weight loss (EWL) (%) after SAGB. **p < 0.005.

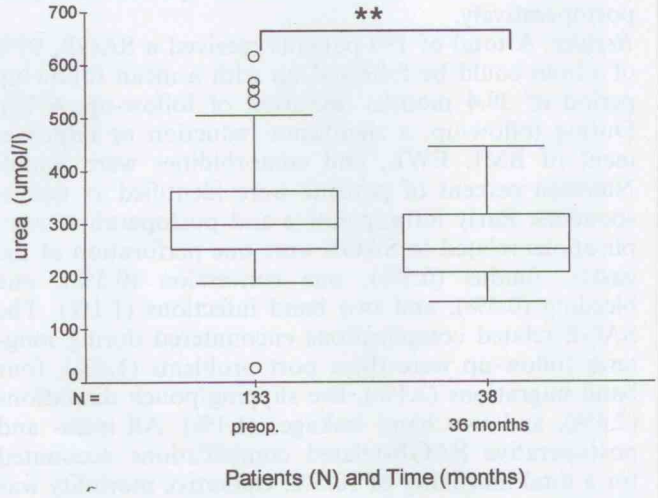

Fig. 3. Influence of SAGB on hyperuricemia at 3-year follow-up. **p < 0.005.