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RESEARCH ARTICLE

Successful Multi-Intervention Treatment of Severe Obesity: A 7-year Prospective Study with 96% Follow-up

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Abstract
Background No long-term, high participation study of the outcome of bariatric surgery has examined how a multi-intervention approach to the treatment of severe obesity can achieve and sustain weight loss after an initial bariatric procedure.
Methods We employed a multi-intervention treatment that combines adjustable gastric banding with intensive follow-up to support patient life-style change and use of an algorithm allowing reoperation—to bypass, if necessary—in the event of complications. Four hundred four severely obese patients with an average BMI=42.6 at the outset had initial AGB surgery and were followed with a high rate of face-to-face consultations for 7 years. Seventy-five percent of the patients retained a gastric band throughout the study. Weight loss, complications, and comorbidities were studied, and quality of life was assessed using Bariatric Analysis and Reporting Outcome System (BAROS).
Results Three hundred eighty-eight (96%) patients completed the 7-year follow-up. Average BMI reduction at 5 years was 28% and remained stable through year 7, at which the mean excess weight loss was 61%. The preoperative prevalence of metabolic syndrome, 59.7%, decreased to 13.3% at 7 years and was abolished for patients with more than 40% loss of initial BMI. Similar changes were seen for all components of metabolic syndrome. More than 60% of patients had a "good" or higher BAROS score; 10.1% were considered failures. Patients converted to gastric bypass, and those retaining gastric bands throughout the study had very similar outcomes.
Conclusions Long-term, multi-intervention treatment of severe obesity can achieve and preserve weight loss and thus improved quality of life and sustained reduction or disappearance of all components of metabolic syndrome, for a high proportion of severely obese patients with preoperative BMI between 35 and 55.

Keywords Severe obesity · Gastric banding · Metabolic syndrome · Quality of life · BAROS · Long-term outcome · Multi-intervention strategy

Introduction

Bariatric surgery has proven effective in the treatment of severe obesity [1, 2], yet uncertainty remains [3]. Although the recent meta-analysis by Buchwald et al. shows bariatric procedures to be safe and effective, a large majority of the 134 primary studies of gastric banding and bypass surgery with weight-loss data included in their meta-analysis reported outcome data at follow-up times less than or equal to only 2 years [2]. Relevant studies often are of short duration, or in reports of longer case series, the mean length of patient follow-up still remains relatively short, which compromises assessment and understanding of bariatric complications and comorbidities. Additionally, the long-term risk of weight regain after bariatric surgery has been established. The Swedish Obese Subjects (SOS) Study's comparatively high follow-up rates of 86.6% at 2 years and

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74.5% at 10 years lend confidence to the finding that irrespective of the type of bariatric procedure used, nearly one third of the weight lost by SOS patients 2 years after operation was regained at 10 years [1].

There is still much to learn. Following bariatric surgery, what happens in the long term with respect to complications, the improvement or new development of obesity comorbidities, and procedure-dependent improvement of quality of life? What should be done to reverse weight regain and sustain long-term weight loss? These questions and the need for effective long-term treatment have compelled our development and study of a multi-intervention strategy for the treatment of severe obesity. This treatment program begins with restrictive bariatric surgery and situates follow-up in a long-term framework of intensive life-style consultation and support that also addresses postoperative complications by pursuing, when necessary, reoperation.

We employ adjustable gastric banding (AGB) as our initial bariatric intervention. Following the introduction of AGB over 20 years ago, failures were reported that led many surgeons to choose gastric bypass over gastric banding, particularly as the former came to be performed laparoscopically [4]. However, that preference for gastric bypass often reflected the AGB learning curve, paucity of information regarding evolution of band-related complications over the long term, and low rates of participation or infrequent face-to-face consultations in follow-up [5–7]. Yet adjustable gastric banding offers a flexibility that other restrictive procedures such as Roux-en-Y gastric bypass or vertical banded gastroplasty lack: Restriction can be adjusted individually and reversibly according to patient needs during postoperative follow-up [8].

Given the increasing use of AGB in Europe since 1993 and in the USA since 2001, the short mean follow-up time of many AGB studies (3 years or even less) [9, 10] and high participation rates, achieved only via telephone or the post, not direct consultation, the need for long-term study of AGB with the fullest participation in face-to-face follow-up and postsurgical management of technical and functional complications is clear. Also, important factors, including procedural mortality, weight loss, band-related complications, quality of life, improvement in comorbid conditions, and what constitutes failure are not clearly defined or are missing in the existing literature, making comparisons difficult. Because effective treatment of severe obesity entails lifetime follow-up [11], long-term study is essential, as are consistent definitions and standards of comparison [12]. Since bariatric surgery does not always yield sufficient or sustained weight loss, a multi-intervention strategy that encompasses education and support for life-style changes and allows reoperation in the event of primary treatment failure is needed for long-term success of the primary procedure [13].

We followed severely obese patients for 7 years after initial surgery to evaluate the effects of AGB and our intensive follow-up and reoperation algorithm. Here, we report patient outcomes, including quality of life, which was assessed using the Bariatric Analysis and Reporting Outcome System (BAROS) [14] as a way to address the lack of standards for comparison of outcomes of bariatric surgery [12].

Methods

Patients

Between 28 May 1997 and June 30 1999, 404 consecutive severely obese patients laparoscopically received a Swedish Adjustable Gastric Band (Obtech, Baar, Switzerland) at our centers (Zürich, Bern, Aarau, and Visp Switzerland). Inclusion criteria for gastric banding were BMI below 55, above 40, or above 35 kg/m^2, with at least one obesity-related comorbidity: dyslipidemia, type 2 diabetes mellitus, hypertension, obesity-related infertility, sleep apnea syndrome, degenerative joint disease of the lower extremities related to obesity, cardiovascular disease, or left-sided heart failure related to obesity. All levels of Swiss health insurance, which include compulsory basic and higher levels of coverage, were operated at our privately funded institution. Exclusion criteria were age under 16 or over 70 years, large hiatus hernia, geographic factors making regular follow-up difficult, inability to understand necessary follow-up and operative procedures, manic disorder or schizophrenia, alcohol or drug abuse as determined by the obesity specialist during the preoperative evaluation or through information from the family or referring physician, creatinine level >200 μmol/l, or liver cirrhosis. A multidisciplinary team consisting of a physician specializing in obesity, a bariatric surgeon, a dietician, and a psychologist assessed each patient before laparoscopic surgery.

Among the original 404 patients, there were five deaths unrelated to bariatric surgery (two had cardiac causes, two were due to carcinoma, one to liver failure due to autoimmune hepatitis). Eleven of the remaining patients were otherwise lost to follow-up. Three hundred eighty-eight patients (96%) completed a full 7-year follow-up: 299 women and 89 men. Presurgical patient characteristics are given in Table 1.

Gastric Banding

Laparoscopic adjustable gastric banding was performed as previously described [8]. Four to six weeks postoperatively, the band was inflated for the first time using contrast (Iopamiro 200 [iopamidol]; Bracco, Milan, Italy). Adjust-

Table 1 Pre-operative patient characteristics, overall and by postoperative course

Data as mean±SD (range)	All	Adjustable gastric band[a]	Converted to bypass
N (women/men as percentage)	388 (77/23)	292 (79/21)	91 (75/25)
Age	42.7±10 (16–70)	42.9±10 (16–70)	42.2±10 (18–63)
Weight (kg)	118.6±16 (80–175)	118.1±17 (80–175)	120.6±14 (89–166)
BMI (kg/m^2)	42.6±4 (35–55)	42.3±5 (35–55)	43.7±5 (35–55)
Excess body mass (kg)	55.9±14 (24–98)	55.4±14 (24–98)	58.0±11 (33–96)

[a] Omits the five patients whose bands were removed, who declined further bariatric intervention

ments of filling volume were made as needed every 2 months. Clinical indications for inflation were less than 1 kg weight loss per month or absence of fullness reported during a semi-structured interview. Deflation or no inflation was indicated for obstruction, severe solid-food intolerance, nightly aspiration, vomiting more than twice per week, or achievement of the patient's weight-loss goal.

Follow-up of Patients

Following initial banding, patients were seen by the obesity specialist every 2 months for the first year, every 3 months during the second, and every 4 months thereafter or as was judged necessary by the internist. This consultation framework resulted in an average of 8.7 (±2.0) visits per patient in our centers during the first year following initial surgery. Yearly follow-up declined slowly to an average of 4.2 (±2.9) per patient visits during year 7. In all, 15,892 face-to-face consultations were conducted over 7 years with the 388 patients participating in the study. If necessary, the obesity specialist consulted according to the clinical situation with members of the multidisciplinary team mentioned above. Outcome was followed by monitoring weight, blood pressure, and pulse rate, and fasting blood was drawn to monitor components of metabolic syndrome and other obesity-associated comorbidities. Complications associated with surgery and reoperation and concurrent medications were recorded at each visit. During an office visit at the end of year 7, patients completed the BAROS questionnaire. Additionally, a four-level vomiting score was determined (0, absence of vomiting; 1, vomiting associated with rapid eating or stressful circumstances; 2, vomiting once or less weekly; 3, vomiting more than once weekly, but unrelated to stress or eating). Further, the level of suffering from vomiting was assessed on a visual analogue scale ranging from 1 to 10.

In addition to following patient adaptation to the band and adjustment of band volume, patients participated in an intensive program of life-style consultation that was substantially the same as that in which nonsurgical, conservatively treated obese patients participate. Patients were advised about living with a band and reducing their intake of energy-dense food and liquid calories. No matter their starting point, they were assisted with increasing their physical activity and using a pedometer where they could. Smoking cessation also was undertaken. Above all else, follow-up consultation was patient-centered and potentially offered assistance and positive reinforcement for any aspect of life-style, even if seemingly distal from obesity. Priorities were determined by patient expectations in order to improve daily life, optimize treatment of comorbidities (including the option of pharmacotherapy), and meet individual goals for weight loss assess and aggressively treat impending complications at an early stage (see below) and achieve ≥50% loss of excess weight (when desired by the patient). Loss of <50% of excess weight was considered a treatment failure, not, we emphasize, noncompliance of the patient.

Postoperative Management of Complications

Management of complications that arose within this framework of consultation was guided by the algorithm of Biertho et al. [13]. Port infection, site discomfort, and tube or port leakage were reoperated on an outpatient basis. Band leakage and slippage were confirmed radiologically and migration [15] by endoscopy; band intolerance or infection was diagnosed clinically. Band replacement was performed for leakage or slippage, while conversion to gastric bypass was selected for band migration, infection, intolerance, or recurrent slippage.

Insufficient weight loss—defined as less than 50% excess weight loss or greater than 10% weight regain from the nadir reached at more than 50% excess weight loss—was treated with the addition of a malabsorptive procedure (alimentary limb 250 cm, common channel 50 to 100 cm) with or without duodenal switch [13]. Two hundred ninety-two patients (75%) retained a gastric band throughout the 7 years of study. Forty-four reoperations were necessary for slippage/pouch dilatation (22 patients), leakage (20), or migration (2). Early complication rate (within 30 days) for CO_2 embolus, band infection, wound dehiscence, port infection, intraperitoneal bleeding, and pneumonia was 2.6%. Complications after 30 days are given in Table 2.

Sixty-eight patients (17.5%) were converted to Roux-en-Y gastric bypass (RYGB) due to band intolerance, while 23

Table 2 Complications necessitating reoperation

Results as a percentage of all patients, n=388	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Mean
Band slippage/dilatation	–	0.5	1.8	1.5	1.0	1.0	0.8	1.0
Band leakage	–	–	–	0.8	1.8	1.5	0.5	0.7
Band migration	–	–	–	–	0.5	0.3	0.3	0.1
Band intolerance	0.5	1.5	3.9	3.6	3.4	3.1	1.8	2.5
Insufficient weight loss	–	1.8	1.5	0.8	1.3	–	0.3	0.8
Band removal	0.3	–	–	–	0.3	0.5	0.3	0.2
Total	0.8	3.8	7.2	6.7	8.2	6.4	3.9	5.3

After initial banding, slippage/pouch dilatation peaked at year 3 and decreased thereafter. In contrast to band slippage, band leaks appeared 4 years after implantation, with a constant rate thereafter, which is suggestive of progressive fatigue of the implanted material. To the best of our knowledge, this is the first study reporting annual rates of band intolerance, which peaked in year 3 and progressively decreased thereafter. Overall, the yearly technical complication rate (total minus insufficient weight loss and intolerance rates) peaked at 3.5% in year 5 and declined to 1.8% in year 7.

patients (5.9%) were converted to biliopancreatic diversion (BPD) due to insufficient weight loss, seven with band removal and 16 without. Of this total of 91 reoperated patients, 70 (76.9%) were operated laparoscopically with a conversion rate of 2.9%, while the remaining 21 (23.1%, all BPD) were operated through laparotomy. Overall, five patients (1.3%) had their band removed (three due to band infection and one each due to band slippage and band migration) and not replaced in accord with patient wishes. Early complications following conversion to gastric bypass included bleeding (5.5%), pouch/anastomotic leaks (5.5%), pneumonia (6.6%), early postoperative ileus (1.1%), and wound infections (3.3%), subphrenic abscess without leak (1.1%). Operative complications 30 days after conversion to gastric bypass are given in Table 3.

Data and Statistics

Data were entered prospectively into our computerized database, ObesityBase 2000 (Obesity Centre, Winterthur, Switzerland). Using Microsoft Access, BAROS scores were calculated from records of patient excess weight loss, cumulative reoperations, and complications, as well as quality-of-life and comorbidity data from patient questionnaires. Differences between groups were investigated using analysis of variance for repeated measures or the Mann–Whitney U test, where appropriate, and were corrected for multiple comparisons (SPSS version 11 0 for Windows, Chicago, IL, USA). Reported p values are two-sided, accepting levels of $p<0.05$ as significant. Results are presented as mean±standard deviation (SD), or where indicated as ±standard error of the mean (SEM).

Patients were fully informed about all procedures and gave written consent to use of data from their charts for research purposes. The study was approved by the local ethics committee and complied with the Helsinki Declaration.

Results

Procedural mortality due to gastric banding and bypass surgery was zero, and the five patient deaths we observed yield a mortality rate from all causes of 18 deaths per 10,000 person-years. For the 96% of our patients who continued in treatment for 7 years, we observed a mean loss of excess weight at year 7 of 61%, a decrease of 12 BMI units averaging 28% of BMI (Fig. 1). These results are similar to those reported in other recent studies of AGB [4,

Table 3 Complications after conversion to RYGB

Results as a percentage of patients converted to gastric bypass, n=91	Year 1	Year 2	Year 3	Year 4	Mean
Anastomosis stenosis with endoscopic dilatation	19.3	1.4	3.8	5.6	7.5
Internal hernia	2.4	4.2	1.9	2.8	2.8
Incisional hernia	2.4	9.9	5.7	13.9	8.0
Anastomotic ulcer without stenosis	2.4	4.2	1.9	–	2.1
Total	24.1	19.7	13.2	16.7	18.4

Among converted patients, the most frequent complication, stenosis of the upper anastomosis, required a total of 45 endoscopic dilatations; 14 patients were dilated once, ten patients twice, and two patients three or more times. The procedure was most frequent in the first year and much less so thereafter. This contrasts with incisional hernias, which increased with time after conversion to bypass. No patient had more than one hernia repair. Internal hernias, which occurred in 18 patients with 22 interventions, peaked in year 2, while anastomotic ulcers disappeared after the third year following conversion.

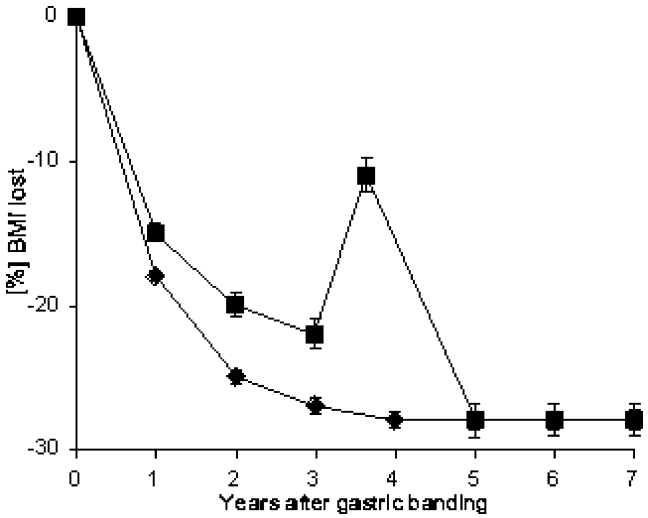

Fig. 1 BMI lost after gastric banding, Values are given yearly as mean±SEM: *diamond* gastric banding, *square* initial gastric banding and conversion to gastric bypass 3.6±0.2 years. Subjects with band removal (N=5) are not included in the analysis. Patients with band intolerance or insufficient weight loss were converted to bypass on average 3.6 years after initial gastric banding. These patients achieved and maintained a similar loss of BMI after 5 years (ANOVA for repeated measures)

7, 9, 16, 17], with important differences, discussed below. The overall efficacy of the multi-intervention approach as estimated by BAROS was 90% (Table 4).

At year 5, both patients with gastric bands and those converted to gastric bypass achieved and thereafter maintained the same weight loss (Fig. 1). Interestingly, average individual weight loss correlated linearly with the number of consultations per patient (percent BMI lost: ≤30 consultations, 26; ≥51 consultations, 31; r=0.3, p<0.001).

Nonmedication-based smoking cessation was undertaken during follow-up with patients who smoked, and a gender-independent decline was observed in the initial smoking rate of 67% to 35% at 7 years. The average vomiting score at 7 years was higher in gastric banding patients compared to patients converted to bypass (1.4±0.2 vs. 0.8±0.1, p< 0.001). The level of suffering from vomiting also was higher in banding patients compared to those converted to bypass (3.1±0.3 vs. 2.0±0.2, p<0.001).

Metabolic Syndrome and its Components

Prevalence of metabolic syndrome initially was 59.7%, a typical rate that was higher, as expected, in men than women [1, 18, 19]. At 7 years, metabolic syndrome dropped to 13.3% (Table 5). The rate of persisting metabolic syndrome, 11.4% overall, was higher in men than women (18% vs. 10%, p<0.01), while the rate of newly developed metabolic syndrome was low (1.9%) and the same for men and women. Prevalence of metabolic syndrome was independent of both initial BMI and the final bariatric procedure: The rate was similar for patients carrying a gastric band throughout the study and those converted from gastric band to bypass (12% vs. 14%). Symptoms of metabolic syndrome were observed in 32.3% of patients (39% men, 29% women) who lost less than 20% of their initial BMI, but no patient with 40% or greater loss of initial BMI had metabolic syndrome.

Hypertension

Before surgery, 69.1% of all patients had elevated blood pressure or were taking antihypertensives. At 7 years, 49.2% were hypertensive. The rate of persisting hypertension, 42.1% overall, was higher in men than women (55 vs. 39%, p<0.01), while newly developed hypertension (7%) did not differ by gender. Prevalence of hypertension at 7 years was independent of both initial BMI and the final bariatric procedure. Both overall prevalence of hypertension and newly developed hypertension were inversely related to BMI lost (both p<0.001); 72.2% (75.2% men, 70.2% women) of patients who lost less than 20% of their initial BMI were still hypertensive, while among patients losing more than 40% of their initial BMI, 28.6% (32% women and no men) were still hypertensive.

Type 2 Diabetes (T2D)

Before surgery, 14.2% of patients had type 2 diabetes (T2D). At 7 years, 6.8% were diabetic. Persisting T2D, 5.8% overall, was significantly higher in men than women (10% vs. 5%, p<0.01), whereas percentage of newly developed T2D was

Table 4 Overall outcome as estimated by BAROS

Score values given as percentage of the respective group	Overall, band and bypass (388 patients)	Adjustable gastric band (292)	Converted to gastric bypass (91)
Excellent	4.6%	5.8%	1.1%
Very good	24.0%	30.5%	2.2%
Good	31.7%	34.6%	24.2%
Fair	29.6%	21.9%	54.9%
Failure	10.1%	7.2%	17.6%
Average quality-of-life subscore (±SD)	1.16 (±1)	1.21 (±1)	1.04 (±0.9)

Table 5 Prevalence of metabolic syndrome and its components before AGB and at 7 years

Results as percentage overall, n=388 (percentage of men/women)	Year 0	Year 7, all	Year 7, <20% BMI lost	Year 7, >40% BMI lost
Metabolic syndrome	59.7 (73/56)	13.3 (20/12)	32.3	0
Hypertension (BP>130/85 mm Hg and/or antihypertensives)	69.1 (80/66)	49.2 (63/45)	72.2 (75.2/70.2)	28.6 (0/32)
T2D (HbA1c ≥7% and/or antidiabetic drugs)	14.2 (24/12)	6.8 (11/6)	18.7 (20.8/17.6)	0
HTG (elevated triglycerides and/or lipid-lowering drugs)	43.7 (59/39)	7.8 (17/5)	16.4 (24.2/12.5)	2.4 (0/2.7)
L-HDL (low HDL and/or lipid-lowering drugs)	61.1 (51/64)	11.1 (8/12)	9.6 (4.2/12.3)	7 (0/7)

Metabolic syndrome components were defined according to guidelines of the National Cholesterol Education Program (NCEP) expert panel (ATP III) [20], with minor modifications [21]. Blood data were obtained by standard methods using local laboratories at the respective hospitals.

similar (1.6% vs. 0.9%). Prevalence of T2D at 7 years was independent of both initial BMI and final bariatric procedure. Prevalence of T2D was inversely related to BMI lost ($p<0.001$); 18.7% of patients who lost less than 20% of their initial BMI (20.8% men, 17.6% women) were diabetic, while no patient losing more than 40% of initial BMI was diabetic.

Hypertriglyceridemia (HTG)

Before surgery, 43.7% of patients had elevated triglycerides or were taking lipid-lowering drugs. At 7 years, 7.8% had elevated triglycerides (17% men, 5% women). Persisting hypertriglyceridemia (HTG), 6.1% overall, was higher among men than women (12% vs. 4%, $p<0.01$), as was the rate of newly developed HTG (4.5% men, 0.9% women, $p<0.01$). Prevalence of HTG at 7 years was independent of both initial BMI and final bariatric procedure; 16.4% of patients who lost less than 20% of their initial BMI (24.2% men, 12.5% women) still had elevated triglycerides compared to 2.4% of patients losing more than 40% of their initial BMI (no men, 2.7% women).

Low HDL Cholesterol (L-HDL)

Before surgery, 61.1% of patients had low HDL cholesterol (L-HDL) or were taking lipid-lowering drugs. At 7 years, 11.1% had L-HDL cholesterol (8% men, 12% women). Persistence of L-HDL was similar in men and women (8% vs. 11%), while the overall rate of newly developed L-HDL was 1% (no men, 1.3% women). Prevalence of L-HDL at 7 years was independent of both initial BMI and BMI loss beyond 15%; 9.6% of patients (4.2% men, 12.3% women) who lost less than 20% of their initial BMI still had low HDL cholesterol, compared to 7% of patients (no men, 7% women) who lost more than 40% of their initial BMI.

Quality of Life

The BAROS system defines five outcome categories based on a scoring system that adds or subtracts points by evaluating three main areas of interest—excess weight loss, various comorbidities, and quality of life—with added adjustment for complications and reoperations [14, 22]. BAROS results are summarized in Table 4.

More than 60% of all patients scored good or higher (234 of 388), while 10.1% (39) were considered failures; 71% of patients carrying a gastric band throughout the study (207 of 292) achieved a BAROS score of good or higher, while among the 7.2% of AGB-only patients who were considered failures, 62% (13 of 21) had insufficient weight loss. Reoperations were omitted in these patients in accord with patient wishes. In converted patients, 28% had a BAROS score of good or higher (25 of 91); 17.6% (16) were considered failures. The difference in failure rates between converted and AGB patients is significant ($p<0.001$). However, the fact that reoperation results in BAROS score deductions accounts for most of the difference. Omitting the deductions for reoperation and complications that are specified by BAROS yields similar good or higher score totals of 78.6%, 79.1%, and 78.0%, respectively, for all patients, AGB patients, and converted patients. Overall BAROS scores omitting these deductions were similar for the AGB and converted patients (4.7±1.7 vs. 4.4±1.9, both in the BAROS "good" category).

The BAROS quality-of-life (QoL) subscores yield similar results. BAROS QoL subscores can range from −3 to +3, with 0 representing no change. There are five QoL subscore components: self-esteem, physical activity, social life, work conditions, and sexual activity. The difference in work components of 0.20 for the banded patients and 0.13 for the patients converted to bypass is significant ($p<0.05$), although the other four QoL subscores were equally improved in both groups at 7 years. Irrespective of the final bariatric procedure used, all components of the quality-of-life subscore increased with increasing weight loss ($r=0.39$, $p<0.001$). The difference between the average QoL subscores of patients carrying a gastric band throughout the study and those converted to bypass (1.21±1 vs. 1.04±0.9) is not significant. Improvement of quality of life depends upon weight loss, not the final bariatric procedure by which it is achieved.

Discussion

This is the first study of a multi-intervention approach to the treatment of severely obese patients that begins with adjustable gastric banding and relies upon intensive consultation centered on life-style and an algorithm to guide treatment decisions for patients with postoperative complications. It also is the first of a restrictive bariatric procedure to report results based upon long-term face-to-face follow-up with a participation rate well above 90%. We therefore are able to show that the typically observed weight regain that can follow primary bariatric procedures, which is documented by the SOS study [1], can be reversed, and long-term weight loss and its concomitant reduction in comorbidities and improvement of quality of life sustained (Fig. 1, Tables 4 and 5).

The strengths of this study include its combination, to date unprecedented in the literature of bariatric surgery, of equally long-term, face-to-face follow-up for all patients with an exceptionally high rate of participation. Most of the important dimensions of the outcome of this approach to treatment of severe obesity–including, in addition to weight loss, complications, metabolic disease, mortality, and quality of life–could thus be assessed. The study's lack of control patients might be taken as a weakness. However, the SOS study as well as many others presents adequate opportunity for comparison of the outcome of our multi-intervention approach and its reoperation algorithm with that of primary bariatric surgical intervention alone. Continued study of these patients, and only that, can further inform this approach.

In the treatment of severe obesity, persistence pays off not only short term, as previously described [23, 24], but even more, as our results demonstrate, over the long term. Education and support for life-style improvements and the resolution of complications both require long-term, face-to-face follow-up. Our observation of a statistically significant relationship between number of consultations per patient and weight loss, showing 20% greater weight loss at 7 years by patients who had 51 or more total consultations than those with 30 or fewer, suggests that face-to-face follow-up and how much of it patients receive matter. But the effectiveness of long-term intensive follow-up after bariatric surgery, integral to which is an algorithm guiding management of postoperative complications, is perhaps most clearly evident in the comparison of patients who underwent reoperation to gastric bypass (with or without malabsorption) with patients who tolerated their gastric band well over the same 7 years (Figs. 1 and 2).

The combination of smoking and obesity is complex and consequential for health [25]. The fear that quitting smoking increases the risk of weight gain may have influenced our patients who did not quit smoking. However, almost half our patients quit, which may indicate that long-term treatment that protects against weight regain can aid smoking cessation. Understanding these and other relations—such as how smoking increases the risk of metabolic syndrome and diabetes and that smoking cessation thus could play a role in the reduction of metabolic syndrome and T2D—awaits elucidation. But the smoking cessation result we observed further suggests that long-term intensive follow-up is as important in the treatment of severe obesity as surgical intervention, each contributing to the success of the other.

Observation over time also suggests that the trend in yearly reoperation rates might be more important than their overall average. It was suggested recently that annual complication rates might follow a linear pattern [4]. We observed a peak in the annual rate of complications resulting in reoperations in year 5 that was more than halved by year 7 (Table 2). Regardless of the precise shape of the annual complication rate curve, lowering those rates

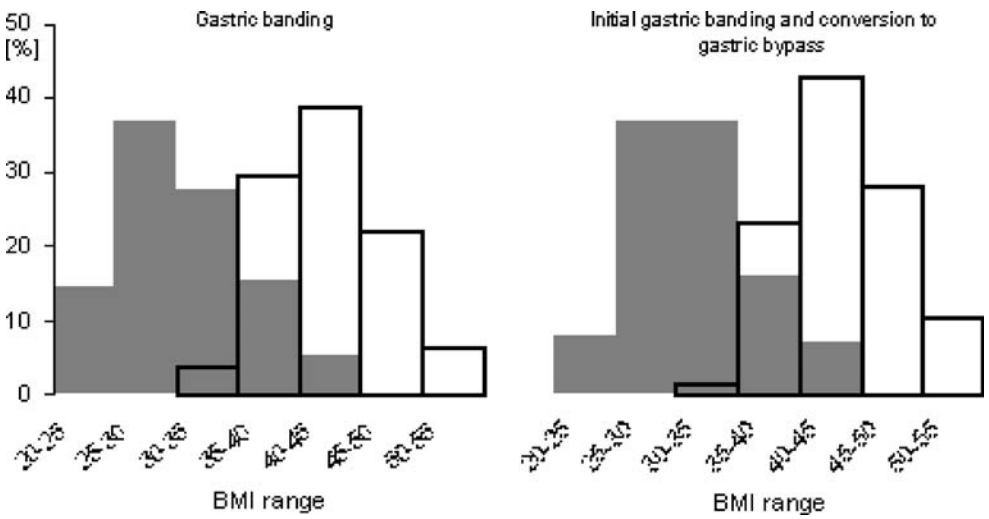

Fig. 2 BMI distribution before and 7 years after gastric banding. Values are given as percentage of respective group: *open square* before gastric banding, *closed square* 7 years after gastric banding. Independent of the final bariatric procedure used, distribution of patients in the different BMI categories 7 years after surgery was similar. Overall, 49% achieved a final BMI below 30. At 7 years, one third of patients demonstrated normal body weight, while only 21.4% still had a BMI above 35

in the years to come might entail preoperative identification of patients prone to band-related complications. Choice of primary bariatric procedure is perhaps better informed by factors preoperatively predicting band intolerance, including male sex and older age [26], binge eating behavior and melanocortin 4 receptor variants [21, 27], long-standing preoperative metabolic syndrome (unpublished data), and other as yet unknown factors, than a final weight-loss goal. Until such data are available, but even thereafter, every bariatric program needs a long-term strategy that addresses technical and functional complications.

Technical complications—band slippage, leakage, or migration—are easier to identify and compare than explain. Band slippage/pouch dilatation was markedly reduced after the introduction of the pars flaccida technique (which we used in all patients) [4, 17, 28, 29]. In studies without perigastric techniques, similar overall low frequencies were seen [7, 17, 30, 31]. Whether the higher frequency of band leaks we observed, compared to other long-term evaluations [4, 7, 17, 30, 32] ranging from 0% to 5%, is due to the type of band or our high rate of long-term follow-up, with routine annual upper GI X-ray and biannual upper endoscopy, awaits further study. Band migrations first appeared in year 5, then declined in the two ensuing years. This is in line with the majority of long-term reports [7, 17, 29–32], although some report higher rates, up to 1% per year [4, 28]. Explanations such as band overfilling, high band pressure, foreign body reaction, or even chronic rejection or fungal infections are debated. It is important to note that band migration did not increase with increasing implantation time.

Functional complications of gastric banding are difficult to assess, and explanations including psychological intolerance, lack of compliance, solid-food intolerance, esophageal dilatation, etc. are ill-defined. We defined band intolerance as nocturnal aspiration or coughing necessitating deflation of the band, followed by weight regain of 5% or more or a loss of less than two BMI units per year (approximately 5–6 kg) [21]. This clear definition resulted in the highest long-term frequency of band intolerance to date, 18%, compared to studies with values between 0.5% and 9.1% [4, 7, 28, 32]. To the best of our knowledge, this is the first study reporting annual rates of band intolerance. Whether lower reported rates of functional complications in other gastric banding studies are due to under-reporting by patients, their loss to follow-up, or other treatment strategies that do not encompass multimodality treatment like ours remains an open question. Teams not considering such rescue surgery are more likely to overcome functional failing of gastric banding through repetitive band deflations in conjunction with dietary and life-style counseling, plus weight-loss medication [29].

Although reoperation, when necessary, is effective, revisional bariatric surgery is demanding. It can entail distorted anatomy and severe adhesions and scarred gastric walls at locations necessary for partitions of bypass pouch formation that can result in potentially life-threatening early complications such as pouch/anastomotic leaks and bleeding. Our result of 5.5% early postoperative complications is in line with three recent studies on conversion of initial banding to bypass [33, 34]. Reassuringly in all, procedural mortality of rescue operations was 0. Anastomotic stricture necessitating one or more dilatations was the most frequent complication and is higher than the rates reported by others [34, 35]. Our high rate may be due either to use of a 21-mm circular stapler or too early dilatation due to initial food intolerance reported by the patient. Internal hernias largely attributable to use of absorbable sutures too close the mesenteric defects were reoperated at a mean annual rate of 2%. Incisional hernias occurred mostly in patients operated through laparotomy. Banding to bypass change is safe and effective, but difficult, and can involve oversewing staple lines, routine drainage of subphrenic space, use of nonabsorbable sutures for closing mesenteric defects, use of a 25-mm instead of 21-mm circular stapler, or other techniques for gastrojejunostomy.

No comparable long-term results on metabolic syndrome have been reported, although similar short-term results exist [18, 19]. The finding that long-term resolution of metabolic syndrome depends upon weight loss, not the type of restrictive surgery by which it is achieved, offers a different perspective on a recent hypothesis that due to duodenal exclusion and related changes in gastrointestinal hormonal response to food ingestion gastric bypass improves components of metabolic syndrome such as T2D better in the short-term than gastric banding [36, 37]. Our data suggest that with increasing time after operation, short-term, bypass-induced hormonal changes play a minor role in the resolution of metabolic syndrome and its components in the long term. The mechanism underlying this observation remains to be elucidated. In any event, our data support the suggestion of Pories et al. that T2D seems to be surgically curable over the long term [38]. If weight loss amounts to less than 40% of the initial BMI and T2D persists, reoperation and conversion to gastric bypass might be discussed.

A similar picture was observed for hypertension. Its occurrence at 7 years in patients who lost more than 40% of their initial BMI was similar to that observed in persons of normal weight, indicating that these weight-reduced patients might suffer from essential hypertension rather than strictly obesity-related hypertension. This finding is in contrast with long-term data from the SOS study, the only comparable long-term study to date, that showed persisting hypertension for bariatric patients 10 years after surgery at a level similar to that of patients on conservative treatment [1]. SOS patients were not reoperated in case of bariatric

failure, and the weight they regained, amounting to about 30% of maximum weight lost, almost certainly accounts for the long-term persistence of hypertension. This reinforces our demonstration that long-term weight loss is a major determinant of resolution of the components of metabolic syndrome.

The same is true for improvement of quality of life. In a recent report on the SOS study, the authors concluded that long-term improvement in quality of life mainly depends upon preservation of weight loss, which fades as weight is regained. They suggested that regained weight should not be ignored [39]. Our demonstration that improvement in quality of life correlates linearly with amount of weight lost reinforces their suggestion. Therefore, given that failure of life-style changes and/or drug treatments to control weight is an indication for bariatric surgery, weight regain is unlikely to be reversed by measures that have failed before. This explains the ascending slope of the peak in Fig. 1. Reoperation strategies should be discussed with patients with significant weight regain. The descending slope of the same peak shows why.

Our face-to-face assessment showed an overall BAROS result of good or higher for 60.3% of patients at 7 years. By comparison, Miller et al. reported good to excellent BAROS results of 83.9% [7], although participation in that study's follow-up was only 23%. Martikainen et al. reported a failure rate of 50%, due mostly to high frequency of reoperation; their follow-up participation in BAROS assessment was 85%, but it was done by mail [28]. Our overall BAROS result is encouraging, but perhaps even more significantly, there is no statistically significant difference between the BAROS quality-of-life subscores for the patients who tolerated gastric banding well for 7 years and those who were converted to gastric bypass (Table 4). Interestingly, although level of suffering from vomiting was significantly higher in gastric banding patients compared to those converted to bypass, no difference in perceived quality of life by patients was reported. This finding suggests again that weight loss is the most important goal for patients with bariatric surgery. Overall reported quality of life was similar in converted patients when compared to banding patients not only using BAROS scores but also using SF36 [40]. Similarly, omitting the BAROS adjustments for complications and reoperations from calculation of overall BAROS scores yields average BAROS results of "good" for both banded and bypass patients. Resolution of metabolic syndrome and improvement of quality of life both appear similarly dependent upon weight loss, not how that weight loss is achieved.

Two studies recently reported relevant mortality results. Adams et al. observed a mortality rate of 37.6 deaths per 10,000 person-years among gastric bypass patients over a mean follow-up interval of 7.1 years [41], while the SOS study reported a mortality rate equivalent to 45.5 deaths per 10,000 person-years among its bariatric surgery patients at 10.9 years [42]. (The studies reported mortality rates of 57.1 and 58.9 for their respective control groups.) Our mortality rate of 18 deaths per 10,000 person-years is lower in part due to our procedural mortality of 0. The extent to which the rest of the 60% decrease in our mortality rate compared to Swedish bariatric patients and the nearly 50% decrease compared to gastric bypass patients in Utah might be explained by our long-term multi-intervention approach.

Korenkov and Sauerland recently concluded an update on bariatric surgery with the observation that no single operation is ideal for all obese patients [43]. We would expand that to say that the best approach to treatment of severe obesity will take a multi-intervention approach that, in addition to a bariatric surgical algorithm allowing reoperation, follows, educates, and supports patients long term. Our data showing weight-loss-dependent normalization of metabolic syndrome and its components, persisting improvement of quality of life, and acceptable perioperative morbidity suggest that treatment can begin, in most cases, with the least invasive, restrictive procedure, adjustable gastric banding, and then allow gastric bypass if necessary to preserve long-term weight loss—the more, the better.

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