

# Impact of Laparoscopic Adjustable Gastric Banding on Obesity Co-morbidities in the Medium- and Long-Term

M. Korenkov<sup>1</sup>; S. Shah<sup>1</sup>; S. Sauerland<sup>2</sup>; F. Duenschede<sup>1</sup>; Th. Junginger<sup>1</sup>

<sup>1</sup>Department of Surgery, University of Mainz, Germany; <sup>2</sup>Institute for Research in Operative Medicine, University of Witten/Herdecke, Cologne, Germany

**Background:** The authors evaluated the impact of laparoscopic adjustable gastric banding (LAGB) on obesity-associated diseases in a series at 3 to 8 years postoperatively, namely diabetes, pulmonary disease, hypertension and knee joint pain.

**Methods:** 145 morbidly obese patients underwent LAGB with mean age 38 years and preoperative BMI 48.5 kg/m<sup>2</sup> (range 34-77). Changes in BMI and excess BMI loss (EBL) were evaluated.

**Results:** 138 of the 145 patients (95%) were available for full follow-up. At last follow-up, BMI had dropped to 34.0 ± 6.4 SD kg/m<sup>2</sup>, and mean EBL was 61.9 ± 26.1 %. Prevalence of obesity-associated disease was significantly reduced: diabetes decreased from 10% to 4%, treatment-requiring pulmonary disease from 15% to 5%, hypertension from 43% to 27%, and knee pain from 47% to 38%.

**Conclusion:** Following gastric banding, >75% of patients suffering from obesity-related disease had significant decrease or resolution of their co-morbidities.

**Key words:** Morbid obesity, obesity surgery, laparoscopic, gastric banding, obesity-associated diseases

## Introduction

In the past few decades, obesity has increased dramatically in the developed world to a life-threatening epidemic.<sup>1</sup> In addition to the serious co-morbidities and deterioration in quality of life, the life expectancy of these patients is decreased. There is a

close correlation of obesity and type 2 diabetes mellitus (DM), hypertension, sleep apnea syndrome, and arthritis, especially of the knees.

By conventional therapy of diet, physical and behavior therapy together with medication, <5% of morbidly obese patients sustain weight loss.<sup>2</sup> This has resulted in a worldwide increase in bariatric surgery.<sup>3</sup> The two most common surgical procedures currently are laparoscopic adjustable gastric banding (LAGB) and laparoscopic Roux-en-Y gastric bypass (LRYGBP). The most popular bariatric operation in Europe and Australia is LAGB, whereas LRYGBP is most common in North America.<sup>3</sup> The LAGB is a simple and relatively safe procedure with a low rate of complications.<sup>4,5</sup> However, the influence of LAGB on the co-morbidities has raised questions by some surgeons.<sup>6,7</sup>

The purpose of this study is to evaluate the impact of LAGB on the obesity-related disorders of diabetes, obstructive sleep apnea and hypoventilation syndrome, hypertension and degenerative arthritis of the knee in a series of patients with a mean follow-up of 5 years.

## Methods

### Demographic Data

The series consisted of 145 patients (105 female and 40 male) who underwent LAGB from July 1997 to July 2004 through the University Clinic for General and Abdominal Surgery, Mainz. The Lap-Band® (Inamed/Allergan) of 9.5 cm (11 cm with BMI >55)

Correspondence to: Associate Professor Dr. Michael Korenkov, Department of Abdominal Surgery, University of Mainz, Langenbeckstrasse 1, D-55101 Mainz, Germany. Fax: ++49 6131 176630; e-mail: korenkov@ach.klinik.uni-mainz.de

was used to create a tiny proximal gastric pouch, with the band fixed by 3 or 4 anterior imbricating gastro-gastric sutures. The perigastric technique was used for most of the series, with the pars flaccida approach towards the very end.<sup>8</sup> The indications for operations were based on the recommendations of the NIH Consensus Conference<sup>9</sup> and the guidelines of the German Adipositas Society. Each patient had undergone multiple conservative therapies for morbid obesity unsuccessfully over a period of 5 or more years. The information on each patient from the diagnostic and clinical investigations prior to the operation were accurately recorded.

In addition to physical examination, complimentary data were registered from laboratory evaluations, lung function tests, ECG, gastroscopy and abdominal sonography. The co-morbidities of each patient were specifically recorded.

For each patient suffering from diabetes, fasting blood sugar was determined, HbA1c values were measured, and oral and insulin dosage was evaluated. Hypertension was assumed if systolic and diastolic levels were above 190/90 mmHg or if there was a history of antihypertensive medication. To evaluate the level of pain in the knees, the validated numeric rating scale (NRS) of 0-10 was used.

### Follow-up Investigations

Follow-up was performed at 6 weeks, 6 months, 1 year, and then yearly. Data collected focused on body weight, blood pressure, and dyspeptic symptoms such as dysphagia, heartburn, regurgitation, emesis, chest and epigastric pain. Patients were asked specifically about prescribed medication. As needed, fasting blood sugar and HbA1c values were established. Any complications due to the LAGB were also registered.

### Statistics

Body mass index (BMI) and excess BMI loss (EBL) were calculated. The following formula was used to calculate %EWL:<sup>10</sup>

$$[(\text{BMI preop} - \text{BMI current}) / (\text{BMI preop} - 25)] \times 100$$

Improvement of a co-morbidity was defined by reduction or discontinuation of associated medication. If there was a pain reduction  $\geq 2$  points on the NRS in patients with knee arthritis, this was defined as a relevant improvement.

According to distribution, either mean  $\pm$  standard deviation or median values and interquartile range (IQR) were calculated. Box-plots were used to present data in graphic form. The individual comparison of parameters before and after operation were analyzed using *t*-test, Wilcoxon-test or McNemar-test. *P*-value  $\leq 0.05$  was considered significant.

### Results

In the 145 patients, mean age was  $37.5 \pm 9.7$  years (range 17-62). BMI was  $48.5 \pm 8.1$  (range 34-77). Sixty patients (41%) were suffering from hypertension, 48 were on antihypertensive medication, and 68 patients suffered from knee pain.

Mean operating time was 95 minutes (950-360). Five patients underwent simultaneous cholecystectomy. Five patients required conversion to an open procedure: in three patients because of bleeding, one because of adhesions, and in one, hypertrophy of the left lobe of the liver denied good access to the cardia region. The data of patients who needed conversion is presented in Table 1.

No patient has died during the operation or in the follow-up period. After the operation, only three patients developed early postoperative complications. A perforation in the gastric wall was detected in one patient on routine Gastrografin<sup>®</sup> x-ray study. Dysphagia was found in two patients, as a result of slippage of the gastric band, which was confirmed by x-ray study. In one of these patients, the gastric band dislocation could be corrected laparoscopically. In the other patient, partial necrosis of the gastric wall due to the slippage required removal of the band.

A total of 138 patients (95%) returned for all follow-up visits. In five patients, the follow-up was not

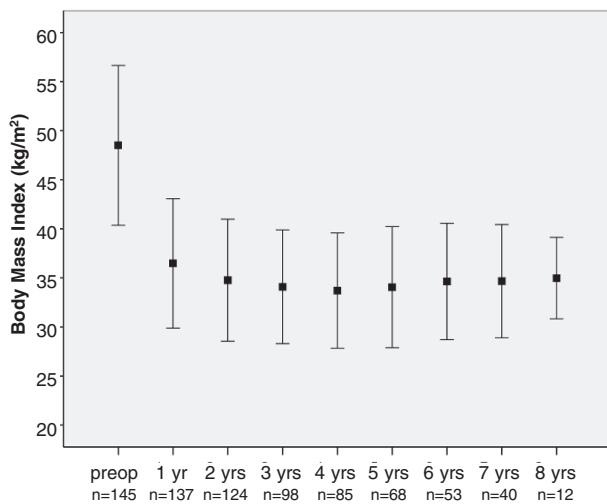
**Table 1. Data of patients who required conversion**

n	Sex	Age	BMI	Cause of Conversion
1	m	46	52	Bleeding
2	w	34	56	Bleeding
3	m	42	61	Bleeding
4	m	53	58	Hypertrophy of liver
5	w	42	46	Adhesions after other abdominal surgery

possible due to their residence abroad. Mean length of follow-up was  $5 \pm 2.3$  years (range 2-8).

In eight patients, the gastric band had to be removed later. One patient suffered from pouch dilatation and two patients developed a dilatation of the esophagus. Two patients experienced migration of the gastric band. Three patients with a good functioning band decided on band removal. Because of a slippage, eight patients (5.8 %) required laparoscopic relocation or gastric band change. The slippages occurred in patients who had been operated by the perigastric technique. A total of 24 patients required reoperation for port-site complications. There have been no other complications.

BMI decreased to an average of  $34 \pm 6.4$  kg/m<sup>2</sup> (range 22.2-56.2) at latest follow-up (Figure 1). This corresponds to a lowering of the BMI of 14.2 kg/m<sup>2</sup> on average. Mean EBL was  $61.9\% \pm 26.1$ . In total, 97 of the 138 patients have achieved EBL of >50%. As shown in Table 2, antihypertensive, antidiabetic and pulmonary drug therapy diminished after the operation. No patient needed continuous positive airway pressure (CPAP) or insulin administration after the operation. Oral medication due to the above-mentioned co-morbidities was able to be reduced or stopped. In patients with hypertension, systolic/diastolic pressure dropped to an average of 126/80 mmHg. This distinction was highly significant ( $P < 0.001$ , paired *t*-test).



**Figure 1.** Body mass index (BMI) over time. Points are mean values and bars are standard deviations.

In 14 diabetic patients, fasting blood sugar fell to 118 mg/dl (before operation  $141 \pm 12$  mg/dl). Before operation, average HbA1c was 7.3% in diabetics on treatment, and after the operation  $6.3\% \pm 0.3$ . In both parameters, the change was highly significant ( $P < 0.001$ ). Of the 65 patients who complained of knee pain before the operation, the pain intensity dropped from a median value of 3 (IQR 2-4) to 1 (IQR 1-2;  $P < 0.001$ , Wilcoxon test) (Figure 2). However, there was no correlation between the degree of weight loss and the improvement in pain intensity. In total, 63 (81%) of the 78 patients suffering from these obesity-associated disorders experienced a significant improvement of at least one related illness, although a strong correlation between the actual degree of weight loss and disorder improvement could not be found (Figure 3).

## Discussion

LAGB is the most commonly performed bariatric operation in Europe. In major studies, the morbidity and mortality levels of this operation have been evaluated.<sup>5,11</sup> However, the outcome on associated diseases would benefit from further data.

Obesity is a major risk factor for type 2 DM. This study revealed a significant long-term influence of the LAGB on DM. Prevalence was reduced by 6% (before operation 10%, after operation 4% but with considerable individual improvement). Studies in patients with type 2 DM have revealed a marked improvement in glycemia modulation and insulin sensitivity after a weight loss of only 10-20%.<sup>12,13</sup> This perhaps explains why a correlation between actual degree of weight loss and reduction of this co-morbidity was not found. However, after LAGB, the number of patients without relief of associated diseases was low.

The high prevalence of hypertension in the morbidly obese is one of the main risk factors for cardiovascular disease. In our study, we found that in 5 years, hypertension was reduced by 16% (43% before to 27% after). This data corresponds to the results of Ponce et al.<sup>14</sup> Like others,<sup>15,16</sup> our data also revealed a significant reduction of obesity-associated lung dysfunction (15% before to 5% after). A very strong therapeutic effect of the bariatric surgery was

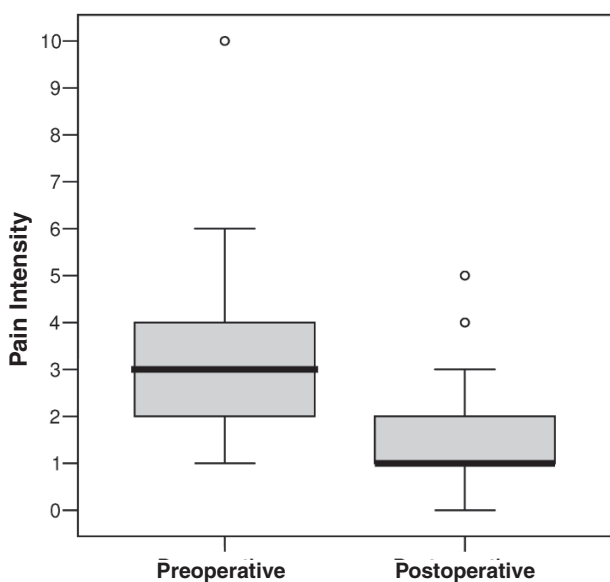
**Table 2. Frequency of of obesity-related co-morbidities in 138 patients before LAGB and after 3-8 years**

	Preoperative	Postoperative	P-value*
Diabetes mellitus	14 (10%)	6 (4%)	0.008
Requiring insulin therapy	5 (4%)	0 (0%)	
Necessitating oral drugs	12 (9%)	6 (4%)	
Pulmonary disease	21 (15%)	7 (5%)	<0.001
Requiring CPAP therapy	14 (10%)	0 (0%)	
Necessitating drug therapy	7 (5%)	7 (5%)	
Hypertension	59 (43%)	37 (27%)	<0.001
Necessitating drug therapy	47 (34%)	34 (25%)	
Significant knee pain	65 (47%)	52 (38%)	<0.001

\*McNemar's test

seen in patients who had sleep apnea syndrome. None of our patients required CPAP after surgery.

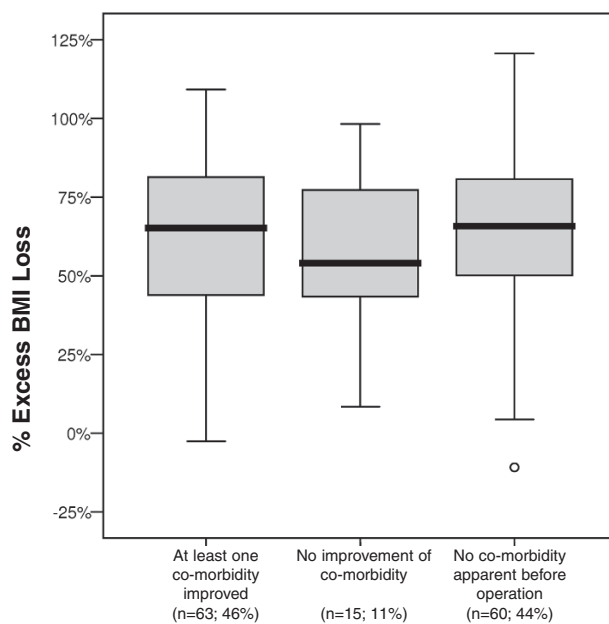
One of the most frequent complications in our patients was pain in weight-bearing joints, especially the knees. Collectively among our patients, a decrease from 47 to 38% was found. Although statistically significant, a clinical improvement was often not noted, likely because the degenerative joint damage is irreversible.



**Figure 2.** Intensity of knee pain before and after LAGB as measured with the numerical rating scale (NRS). Included are only patients who noted pain before or after surgery (i.e. at latest follow-up). (Bars indicate medians, and boxes show quartiles) Circles indicate outlier value (SPSS Program).

### Conclusion

LAGB is an effective option in the surgical armamentarium for morbid obesity. Not only was the excess weight reduced, but also the associated diseases were significantly improved. Especially in patients with sleep apnea syndrome, this treatment was found to be very effective. The success of LAGB should be judged not only by the level of weight loss, but also by the improvement of obesity-associated co-morbidities.



**Figure 3.** %EBL in relation to decrease of co-morbidities. (Bars indicate medians, and boxes show quartiles). Right column shows %EBL in patients with no co-morbidity. Circle indicates outlier value (SPSS Program).

## References

1. WHO. Obesity - Preventing and managing the global epidemic. Report of a WHO consultation on Obesity. Geneva 1997:3-5.
2. Solomon CG, Dluhy RG. Bariatric surgery – quick fix or long-term solution? *N Engl J Med* 2004; 351: 2751-3.
3. Buchwald H, Williams SE. Bariatric surgery worldwide 2003. *Obes Surg* 2004; 14: 1157-64.
4. O'Brien PE, McPhail T, Chaston TB et al. Systematic review of medium-term weight loss after bariatric operations. *Obes Surg* 2006; 16: 1032-40.
5. Favretti F, Segato G, Ashton D et al. Laparoscopic adjustable gastric banding in 1,791 consecutive obese patients: 12-year results. *Obes Surg* 2007; 7: 168-75.
6. Iannelli A, Gugenheim J. Laparoscopic Roux-en-Y gastric bypass, but not rebanding, should be proposed as a rescue procedure for patients with failed laparoscopic gastric banding. *Ann Surg* 2005; 241: 383-4.
7. Mognol P, Chosidow D, Marmuse JP. Laparoscopic gastric bypass versus laparoscopic adjustable gastric banding in the super-obese: a comparative study of 290 patients. *Obes Surg* 2005; 15: 76-81.
8. O'Brien PE, Dixon JB, Laurie C. A prospective randomized trial of placement of the laparoscopic adjustable gastric band: comparison of the perigastric and pars flaccida pathways. *Obes Surg* 2005; 15: 820-6.
9. Gastrointestinal surgery for severe obesity. National Institutes of Health Consensus Development and Conference Draft Statement. *Obes Surg* 1991; 2: 257-66.
10. Deitel M, Greenstein RJ. Recommendations for reporting weight loss. *Obes Surg* 2003; 13: 159-60.
11. Deitel M. Overview of operations for morbid obesity. *World J Surg* 1998; 22: 913-8.
12. Lean MEJ, Powrie JK, Anderson AS. Obesity, weight loss and prognosis in type 2 diabetes. *Diabetic Med* 1990; 7: 228-33.
13. Busetto L, Pisent C, Rinaldi D et al. Variation in lipid levels in morbidly obese patients operated with the Lap-Band® adjustable gastric system: effects of different levels of weight loss. *Obes Surg* 2000; 10: 569-77.
14. Ponce J, Haynes B, Paynter S et al. Effect of Lap-Band-induced weight loss on type 2 diabetes mellitus and hypertension. *Obes Surg* 2004; 14: 1335-42.
15. Davila-Cervantes A, Dominguez-Cherit G, Borunda D et al. Impact of surgically-induced weight loss on respiratory function: a prospective analysis. *Obes Surg* 2004; 14: 1389-92.
16. Valencia-Flores M, Orea A, Herrera M et al. Effect of bariatric surgery on obstructive sleep apnea and hypopnea syndrome, electrocardiogram, and pulmonary arterial pressure. *Obes Surg* 2004; 14: 755-62.

*(Received December 30, 2006; accepted March 29, 2007)*