

Outcome after Laparoscopic Adjustable Gastric Banding, Using the Lap-Band[®] and the Heliogast[®] Band: A Prospective Randomized Study

R. Blanco-Engert¹; S. Weiner²; I. Pomhoff³; R. Matkowitz¹; R. A. Weiner³

¹Division of Surgery, Rotes Kreuz Krankenhaus, Frankfurt am Main; ²University of Würzburg;

³Department of Surgery, Krankenhaus Sachsenhausen, Frankfurt am Main, Germany

Background: A study was performed to assess the usefulness and efficacy of a new type of band (Heliogast[®]) for laparoscopic adjustable gastric banding (LAGB) for the treatment of morbid obesity, compared with the Lap-Band[®].

Method: From January to May 2001, a prospective randomized study of 60 LAGB procedures was conducted: group I (n=30), the Lap-Band[®] system (INAMED); group II (n=30), the Heliogast[®] band (Hélioscopie). We implanted the devices using the 2-step technique (pars flaccida to peri-gastric) by laparoscopy. Port systems were placed on the rectus sheath and were fixed by non-absorbable sutures. Follow-up of all patients was a minimum of 12 months.

Results: There were no differences in operating-time, intra-operative complications, or weight loss during the first 4 weeks after surgery. However, with increasing time, more complications with the Heliogast[®] band and differences in weight loss favoring the Lap-Band[®] became significant.

Conclusion: Based on the results of this study, we recommend that new bands have independent clinical evaluation before commercialization.

Key words: Morbid obesity, bariatric surgery, laparoscopic adjustable gastric banding, complications, weight loss

Introduction

Within the past 8 years, laparoscopic adjustable gastric banding (LAGB) has been established as a generally effective and safe treatment for morbid obesity. More than 100,000 LAGB operations have been performed. The Lap-Band[®] system (INAMED Health, Santa Barbara, CA, USA), designed for

Reprint requests to: Rafael Blanco-Engert, MD, Am Dornbusch 2, 60320 Frankfurt am Main, Germany.
E-mail: blancomd@hotmail.com

laparoscopic use, was first used in 1993 after evaluation in animals and was introduced commercially in 1994 after clinical evaluation. It is the most frequently used band and is approved for use in the United States.

Recently, new bands have emerged on the international market without published clinical studies. Technical shortcomings of band designs may result in complications and revision surgeries. An example is the Gastrobelt,¹ designed with hooks for anchorage to the stomach; Zieren et al² found that 13 out of 15 implanted Gastrobelts required removal because of band breakage.

A more recent adjustable band proposed for laparoscopic use is the Heliogast[®] band (Hélioscopie, Chateau de Malissol, France), introduced commercially in Europe in 2000. The band is less expensive and has an unlockable buckle, and has superficial similarities to the Lap-Band[®]. Reports by a surgeon who participated in the development of the Heliogast[®] band indicated that the band was functioning appropriately in the short-term.^{3,4} The Lap-Band[®] and Heliogast[®] band were compared in a prospective randomized study. This study was not sponsored by any manufacturer.

Patients and Methods

Study Design

From January to May 2001, 60 LAGB procedures were performed. In a prospective randomized trial, 30 Lap-Bands[®] (10.0 cm) and 30 Heliogast[®] bands were implanted. The 30 Heliogast[®] bands included three of the first-generation, later designated as

“large”, and 27 of the second-generation design, designated as “medium”. This early change was made when it was found that the original design could not be inflated to the size required to create appropriately small stoma-size. All procedures were performed by a single surgeon with a prior experience of >1,000 LAGB procedures.

Patient Characteristics

All patients had a >5-year history of morbid obesity. Patient characteristics in both groups are shown in Table 1.

Surgical Therapy

The bands were implanted in the two-step technique (pars flaccida to peri-gastric), as reported by Weiner in 1999.⁵ The Lap-Band[®] was not filled during surgery. The Heliogast[®] band was filled with 1.5 cc of saline during surgery to secure the self-locking system, as recommended by the manufacturer. In both groups, the port system was placed in the left upper abdomen and fixed with non-absorbable sutures to the anterior rectus sheath.

Follow-Up

A treatment team that included two surgeons and a radiologist followed all patients. Patients were seen at similar intervals during the study. Before surgery and 1 year after surgery, patients completed both the BAROS and the SF-36 quality-of-life questionnaires.^{6,7}

Statistical Analyses

Differences in postoperative weight loss and frequency of complications between the two groups were measured using two-tailed t-tests (significance set at $P < 0.05$).

Table 1. Demographics and operating time

	Heliogast [®] band	Lap-Band [®]
Age (mean)	34 years	32 years
Male/Female	4/26	6/24
BMI (kg/m ²)	41.2	43.4
Operating-time	54 minutes	50 minutes

Results

Weight Loss

There was no significant difference between the groups in postoperative weight loss during the first 4 weeks. At 6 months, the percentage of excess weight loss (%EWL) in the Heliogast[®] group was significantly lower (Table 2). Two out of the three patients that received the Heliogast[®] “large” band had gained weight (6 kg, 4 kg). The other patient with the Heliogast[®] “large” band had lost 20 kg (%EWL 35.7).

Complications

There were significantly more complications in the Heliogast[®] group (Table 3). There was no band erosion, band defect or inadequate stoma-size in the Lap-Band[®] group. In the Heliogast[®] group, there was one band erosion (3.3%), 3 band defects (10%) and 26 patients in whom the band could not be inflated to an adequate stoma-size (87%). In the Lap-Band[®] group, port-related complications were limited to one infection (3.3%); In the Heliogast[®] band group, there were 6 rotations (20%) and 2 infections (7%).

Four weeks after implantation of the three “large” Heliogast[®] bands, after adjustments under radiological control revealed insufficient decrease in stoma-size, a new “medium” (second-generation) Heliogast[®] band became available. However, inflation of this band to a functional internal diameter following the manufacturer’s volume recommendations (5 cc) were unsuccessful. When contacted, the Heliogast[®] band manufacturer recommended an increase in the fill volume from 5 to 9 cc, and described theirs as a “high pressure” band. However, even with the increase in fill volume, we were not able to reach a functional stoma-size in 26

Table 2. Percent excess weight loss

	1 mon	3 mons	6 mons	12 mons
Group I Lap-Band [®]	4.2	12.2	26.4	41.7
Group II Heliogast [®]	4.8	9.4	17.1	28.3

Table 3. Complications

	Patients n (%)	Band slippage n (%)	Band migration n (%)	Band defect n (%)	Inadequate stoma-size n (%)	Port-related Rotation/Infection/Break n (%)
Group 1 Lap-Band®	30 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0) / 0 (1) / 1 (3.3)
Group 2 Heliogast®	30 (100)	0 (0)	1 (3.3)	3 (10)	26 (87)	6 (20) / 2*(7) / 0 (0)

*One after revision, one in combination with band-migration

out of the 30 patients (87%). Filling the bands to 9 cc increased the external diameter of the device, and 14 patients showed signs suggestive of vagus reactions (nausea, bradycardia, sweating and pain).

As radiological control did not show decrease in stoma-size with the increased fill volume, the possible explanation for the vagal reactions is the increased pressure of the expanded band on the over-sutured stomach. This is also a possible explanation for the one gastric erosion with the Heliogast® band. This patient developed an ulcer at the fundus followed by port infection 1 year after implantation, and the Heliogast® band had to be removed, and this patient lost only 12 kg in 1 year. At revision, the band was removed, sutures closed the defect at the fundus, and a laparoscopic Roux-en-y gastric bypass (LRYGBP) was performed.

High pressure in the inflatable part of the Heliogast® band could lead to mechanical failure (Figure 1). We had one case of band rupture (3%), 12 months after Heliogast® implantation. The other two defects (6%) with this band were aneurysms of the inflatable portion. Subsequent attempts to inflate the bands enlarged the aneurysms and did not attain an adequate stoma-size. The band was removed and a LRYGBP operation was performed.

Discussion

Our study found that the Lap-Band® yielded a better outcome than the Heliogast® band. We found inferior weight loss and a higher rate of band-related complications with the Heliogast® band. The Lap-Band® has been found to be safe and effective for LAGB by this and other longer-term studies.^{8,9}

Our study affirms the necessity for careful design qualification and long-term clinical evaluation of new bands before general use.

Products that look similar can function differently. This was true of the inflatable part of the bands in this study. The Lap-Band® consistently created a functional stoma-size without change in the external size of the band. We were unable to reach adequate radiologic or endoscopic decrease in stoma diameter with the Heliogast® “large” band.

The limited effect of the Heliogast® band (large, medium) on dietary restriction, followed by insufficient weight loss and increased frequency of complications, led us to discontinue use of that band. These bands may be implanted for up to 60 years. Inadequate design could result in leaks, erosions, and possibly vagal complications. Subsequent to



Figure 1. Mechanical failure of Heliogast® band 12 months after placement.

this study, our attempts to inflate Heliogast® bands to reach the internal diameter of Lap-Bands® in the *in vitro* environment were unsuccessful.

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