Retrospective study of laparoscopic adjustable silicone gastric banding for the treatment of morbid obesity: results and complications in 127 patients

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SUMMARY

Objectives: Laparoscopic gastric banding is currently the most popular surgical technique for morbid obesity. This widespread use of surgery has been evaluated by a number of clinical studies, particularly on weight change.

Methods: In a retrospective study of 127 obese patients operated between 1996 and 2000, data were collected for weight change, medical and surgical complications.

Results: Of 127 patients, failures of gastric banding were noted during 2 surgical operations. The average follow-up period was 33 ± 20 months. Average weight loss in all patients was 19.9 ± 5.3 kg (15.3 ± 4.2%). No difference in weight loss was observed between diabetic and non-diabetic patients. During the follow-up, data were collected on 53 complications (42.4% of all gastric banding operations). 3 main types of complication were found: access port related complications (22.6% of the total), band slippage (20.7% of the total) and tubing related complications (16.9% of the total). No prognostic factor for these complications could be identified from multivariate analysis.

Conclusions: Our results are very similar to those of other weight evolution studies. We found that there was a significant incidence of surgical and medical complications during the follow-up because of the meticulous way all complications were recorded, even the most insignificant. This morbidity must be borne in mind before surgery is performed.

Key-words: Gastric banding · Morbid obesity · Coelioscopy · Lapband.

Étude rétrospective du traitement de l’obésité morbide par pose laparoscopique d’anneau périgastrique en silicone ajustable : résultats et complications chez 127 patients

Objectif : La mise en place d’un anneau périgastrique par voie coelioscopique connaît un grand succès dans la prise en charge de l’obésité morbide. Cette technique chirurgicale a fait l’objet de nombreuses évaluations cliniques, centrées particulièrement sur l’évolution pondérale.


Résultats : Deux échecs de mise en place de l’anneau périgastrique ont été relevés sur les 127 patients opérés. Le suivi moyen de l’étude a été de 33 ± 20 mois. La perte de poids moyenne pour l’ensemble des patients a été de 19.9 ± 5.3 kg (15.3 ± 4.2 %). Aucune différence de perte de poids n’a été notée entre les patients diabétiques et non diabétiques. Au cours du suivi, 53 complications ont été observées (42.4 % des interventions). Trois principales complications sont apparues : complications liées au boitier (22.6 % du total des complications), bascule de l’anneau (20.7 % du total) et complications liées à la tubulure (16.9 % du total). Aucun facteur pronostique d’apparition de ces complications n’a pu être mis en évidence par l’analyse multivariée.

Conclusions : L’évolution pondérale au cours de notre étude est comparable à celle d’autres travaux publiés. Cependant, nous avons retrouvé plus de complications médicales et chirurgicales au cours du suivi du fait de la prise en compte de tous les incidents, même les plus anodins. Ces résultats doivent être présents à l’esprit avant mise en place d’un anneau périgastrique.

Mots-clés : Gastroplastie · Obésité morbide · Coelioscopie · Lapband.

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Laparoscopic adjustable silicone gastric banding is currently the most popular surgical procedure for patients with morbid obesity. This technique is attractive because it is minimally invasive, totally reversible and can be adjusted to patients’ needs [1]. In the United States, the NIH consensus concluded in 1991 that this procedure was justified and safe for treating morbid obesity [2] because of its low operative risk and few long-term complications. In France, the ANAES Institute has made recommendations for carrying out and following up bariatric surgery on obese patients [3] since this technique has been used all over the world, especially in Europe and Australia [4, 5, 6]. Two years ago it was officially approved by the FDA for use in the USA [7]. To date, at least 100,000 gastric bands have been fitted worldwide [5]. Over the past few years there has been an increasing use of the technique worldwide in the treatment of morbid obesity. Although there has been several studies of the technique, data on the results of gastric banding with respect to weight change and the incidence of complications have proved difficult to gather because of the lack of adequate follow-up and loss of contact with many patients. This is an important point, especially for late complications which may be more frequent than studies published so far would suggest. The present study is based on the retrospective collection of data relating to weight change and the incidence of complications in obese patients after a procedure of gastric banding carried out by coelioscopy in the Department of Digestive Surgery at the University Hospital, Strasbourg. Data on all types of complication were collected, even when they were deemed to be benign and further surgical procedures considered to be unwarranted.

Patients and methods

Patients

Selection criteria for patients were defined by the NIH conference in 1991 and approved by ANAES in 2000 [2, 3]. They are as follows:

- Body Mass Index (BMI) > 40 kg/m²
- BMI between 35 and 40 kg/m² and presence of comorbidities that are severe and resistant to medical treatment: hypertension, diabetes mellitus, sleep apnea syndrome, osteoarthritis abnormalities proven by radiology.
- Age: over 18 years.
- Obesity stability for more than 5 years.
- Unsuccessful controlled dietary care or medical treatment for at least one year.
- Absence of endocrine pathology.
- Cooperative and compliant patient.
- No alcohol or drug dependency.
- Acceptable surgical risks.

The initial follow-up of patients was carried out by a multi-disciplinary team, including a physician specialised in endocrinology and nutrition, a dietician and a psychiatrist. If the need for a surgical procedure was confirmed, there was a regular follow-up of the patient for at least 6 months prior to the operation. Before surgery, a number of tests were conducted: metabolic blood test, cardiovascular examination with echocardiography, respiratory test, examination of the digestive tract by oesogastric endoscopy, and abdominal echography. If there were no contra-indications, the patient was admitted to the department of digestive surgery at the University Hospital of Strasbourg.

Surgical Procedure

Two surgeons have performed 80% of all surgical procedures since 1996 (67% of all interventions for one surgeon, 13% for the other).

The gastric banding (Lapband, Inamed Health, La Garenne-Colombes, France) was fitted using coelioscopy under general anaesthetic with thromboprophylaxis provided by low molecular weight Heparin and systematic anti-bioprophylaxis by first generation injectable cephalosporin. The size of the gastric pouch was set at 15 ml. Two surgical techniques were used: retro-gastric passage from January 1996 until January 2001 (Technique 1, 87.7% of bandings) and retro-oesophagean passage after January 2001 (Technique 2, 12.3% of bandings). The minimum delay prior to inflation of the banding was set at 6 weeks. No banding was inflated at the time of fitment so as to avoid immediate localized inflammation. Liquid nutrients were fed to the patient on the day after surgery and semi-liquids with effect from day three. Mixed feeding was then recommended for the remainder of the time in hospital and for six weeks during the recovery period at home.

The patient was then seen again regularly by both the surgeon and the nutritionist (a systematic assessment every 3 months was proposed) for monitoring purposes and to detect any post-operative surgical or nutritional complications.

Statistical Analysis

Patients data relating to their surgical procedures and post-operative follow-up consultations were mainly collected retrospectively using their hospital medical records. For patients for whom contact had been lost quite quickly, and to obtain current information on those who had not been seen again for several months, a letter was sent out and telephone contact subsequently established to arrange for clinical check ups and other appropriate examinations, including a check of banding tolerance.

Statistical analysis was carried out using the Pearson Chi 2 test for comparing qualitative variables and the Student test or variance analysis for quantitative variables. Research of prognostic factors relating to weight evolution and/or the incidence of post-operative complications also made use of multivariate analysis. P values < 0.05 or less were considered
statistically significant. Statistical tests were carried out using SPSS 10.0 (SPSS Inc, Chicago, Illinois, USA).

Results

Weight Evolution

For the purpose of this study, patients who were selected had been followed up for at least 6 months and examined less than one year ago. 106 patients were selected (25 men and 81 women), representing 83.5 % of the total sample. The average length of time spent in hospital for gastric banding was 6.8 ± 1.8 days. The average follow up was 33 months and results are given for every follow up between 6 and 72 months. However, patients were not always the same ones for each follow-up, consequently inter-group comparison may be difficult.

Weight Loss for the Entire Patient Sample

Weights and numbers of patients consulted at the time of follow-up demonstrate a decline in weight during the first year, followed by a period of stabilisation of up to 60 months. Then weight seems to increase again, but this is in part due to the high proportion of patients with a BMI > 50 kg/m² in this group (39%) and the large number of complications (61.1%), especially banding ablation (22.2%). In this 60 month group, 4 patients (3 women, 1 man) presented with an average weight gain of 9.2 ± 5.0 kg (5 to 16 kg). For the entire sample, the average weight loss observed during the study was 19.9 ± 5.3 kg. Relative weight loss between the groups is roughly the same with a maximum of 20.0 ± 16.4% of initial weight lost by the 36 month group. The average relative weight loss for the entire sample was 15.3 ± 4.2%.

Weight Loss and Sex

Changes in weight for women and men are reproduced in figure 1. Maximum weight loss was achieved at 36 months for women with an average of 29.2 ± 26.9 kg compared to a maximum for men achieved at 48 months with an average of 32.6 ± 24 kg. The average weight loss for women during the period of the study is 19.6 ± 6.4 kg and 20.4 ± 8.9 kg for men (NS).

Weight Loss and Diabetes

Of the 106 patients, 32 (30.2%) were type 2 diabetic. Weight changes in the type 2 diabetic and non-diabetic patients are shown in figure 2.

No significant difference between the two groups was found for the various times. Average weight loss in diabetic patients was 17.1 ± 7.0 kg and 21.8 ± 5.3 kg for non-diabetics (NS).

Weight Loss and Super-Obesity (BMI > 50 kg/m²)

Of the 106 patients, 34 (32.1%) had a BMI > 50 kg/m². The weight changes in these patients (SO) compared to the non-super obese are shown in figure 3. Weight loss was

Figure 1
Evolution of average weight loss by gender.
greater in the SO than in other patients at 24, 36, 48 and 60 months (p < 0.01). The average weight loss for the SO during the study period was 25.3 ± 8.4 kg compared to 16.9 ± 5.0 kg for BMI < 50 kg/m² (p < 0.01). Using relative weight loss, this difference was no more significant: 17.3 ± 5.9 compared to 14.2 ± 4.2% (NS).

Figure 2
Evolution of average weight loss: diabetic patients compared to non-diabetic patients.

Figure 3
Evolution of weight loss: superobese patients compared to non-superobese patients (BMI<50 kg/m²).
Surgical Complications

Analysis of surgical complications was carried out for 125 patients fitted with a gastric band of one of 3 different diameters: 9.75 mm – 62 cases (49.6%), 10 mm – 45 cases (36%), 11 mm – 18 cases (14.4%) using anterior band placement in 85 patients (68%), antero-lateral in 33 (26.4%), antero-posterior in 5 (4%) and antero-lateral-posterior in 2 (1.6%). 68% of total surgical complications occurred in the first two years compared to 36% for the first 100 patients thereafter. The characteristics of patients operated on are summarized in Table I.

Perioperative Complications

During the course of coelioscopic surgery, 2 bands could not be fitted because of difficulties exposing the hiatal area (major hepatomegaly of left lobe, severe hiatal hernia) and 3 laparotomy secondary conversions were necessary because of major technical difficulties. Six perioperative haemorrhages were controlled without difficulty; 3 in the area of a trocar orifice and 3 in the dissection area. We found no cases of perioperative mortality.

Long-term Complications

In total, 43 out of the 125 patients presented with at least one complication (34% of patients fitted with bands), and 53 complications were found (42.4% of bands fitted). The average length of time for a complication to present was 20.1 ± 18.7 months and the average period spent in hospital because of a complication was 5.6 ± 4.8 days. We found no cases of mortality during the post-operative follow-up period. Analysis of the prognostic factors associated with complications showed that the retro-gastric or retro-oesophagean passage had no effect on post-operative complications or the type of complication, nor did the presence of diabetes affect the onset of complications or their type. Finally, complications were not more frequent in the super-obese (BMI > 50 kg/m²).

Band-related Complications

6 cases were identified where the band had slipped without causing neo gastric dilatation within an average period of 21.2 ± 13.7 months, 7 cases of slippage with neo gastric dilatation within an average period of 19.0 ± 15.4 months, and 4 cases of neo gastric dilatation with no slippage of the band within an average period of 37 ± 25.0 months. We also found one case of an infected band within 2 months of surgery, one of erosion of the upper gastric pylorus within 12 months of the band fitment and 2 cases of post-operative perigastric oedema with total aphagia. The reduction of pouch volume to 15 ml, high retro-cardial fitting of the band, or absence of post-surgical inflation of the banding have contributed to the reduced number of post-banding complications. In our experience, they were applied with effect from March 2001 since when the incidence of slippage and pouch dilatation has decreased from 16.3% for the first 100 patients to 3.7% for the 27 patients operated with the second surgical technique.

Port-related Complications

Eight cases were identified during the post-operative follow-up where the band port had slipped within an average period of 10.1 ± 10.3 months. In 3 of these cases, the port was hyperalgic, necessitating surgery within 15.7 ± 6.0 months. One case of an infected port was noted, but did not require surgery. This infection occurred early, appearing only one month after the band was fitted.

Complications Associated with Catheter Rupture or Maladjustment

Nine cases were identified as having occurred within an average period of 23.9 ± 22.4 months.

Parietal Complications

Four cases of eventration of the scar trocar orifice occurred within an average period of 28.5 ± 12.0 months and one case of scar infection with the early appearance of a post-operative abscess.

Oesophagean Complications

One case of gastro-oesophagean reflux was documented 24 months after surgery and one of pseudo-achalasia with iterative vomiting was discovered 8 months after surgery necessitating deflation of the band and initiation of a course of treatment with nifedipin. Finally, a case of oesophagean stasis with bronchial inhalation occurred 42 months after the initial operation.

All complications are summarized in Table II. When all complications were not more frequent in the super-obese (BMI > 50 kg/m²).

<p>| Table I |
| Operated patients baseline characteristics. |</p>
<table>
<thead>
<tr>
<th>All patients (n = 127)</th>
<th>Women (n = 94)</th>
<th>Men (n = 33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>41.9 ± 9.2</td>
<td>41.2 ± 9.2</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>130.8 ± 23.2</td>
<td>124.1 ± 18.1</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>47.1 ± 7.23</td>
<td>46.6 ± 6.7</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>58 (45.7%)</td>
<td>38 (40.4%)</td>
</tr>
<tr>
<td>Dyslipaemia</td>
<td>53 (41.7%)</td>
<td>40 (42.5%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>40 (31.5%)</td>
<td>28 (29.8%)</td>
</tr>
<tr>
<td>Depression</td>
<td>24 (18.9%)</td>
<td>19 (20.2%)</td>
</tr>
<tr>
<td>Hiatal hernia</td>
<td>23 (18.1%)</td>
<td>19 (20.2%)</td>
</tr>
<tr>
<td>Sleep apnea</td>
<td>21 (16.5%)</td>
<td>8 (8.5%)</td>
</tr>
</tbody>
</table>
The majority of them can be considered as "no major" complications because they did not need a rapid surgical treatment with band removal.

Treatment of post-operative complications

A total of 19 cases of complications (35.8% of all complications and 15.2% of bands) required surgical removal of the band, 26 (49.06% of all complications and 20.8% of bands) required surgery without removal of the band, and 8 required medical treatment (15.1% of all complications, 6.4% of bands).

Discussion

In the present paper, our attempt to summarize experience of gastric banding using laparoscopy has been retrospective. For that reason, some results are missing, although we did try to contact all patients who had not been followed up after their gastric banding operations or who had not been seen again for at least one year. Patients were contacted by mail or phone and asked to attend a consultation in our department. Notwithstanding this methodology, results for 15.2% of patients are lacking. However, this is still a better result than that achieved by the majority of studies published to date [8]. In our study, 72.8% of patients were followed up for at least one year after gastric banding, although in number of published studies follow up for periods longer than one year usually affected less than 10% of patients [9]. As regards weight loss, our results are comparable to those of other studies, with a maximum of 10 kg/m² of BMI being lost by month 36 [10]. We found that there was a weight gain in the 60 month group which was associated with the presence in this group of a higher proportion of patients with an initial BMI of over 50 kg/m². Another attributive factor was the necessity in 4 cases to remove gastric bands because of surgical complications, thereby leading to an increase in weight. We did not find any correlation between weight loss and the presence of diabetes mellitus, as in other studies [11], although some studies indicated a less significant loss of weight attributable to diabetes mellitus one year after gastric banding [12]. Unfortunately, we were unable to obtain metabolic parameters for a significant majority of patients and were therefore not able to demonstrate a beneficial effect of weight loss on glycaemic or lipidic parameters in the type 2 diabetic population as some other studies have done [11]. There was a positive correlation between BMI before gastric banding and weight loss, but weight changes in super-obese patients were the same as those in patients with a BMI less than 50 kg/m² when relative weight loss was studied. Despite a more significant loss of weight in the super-obese patients, the average BMI was still above 45 kg/m² in the 60 and 72 month groups (data not shown). Despite the fact that our study has been a retrospective one, our results with regard to weight loss do not therefore seem to be noticeably different from the majority of other studies.

As regards post-operative complications, our results show more differences with previously published data. One explanation for this may be the type of complications used in compiling the statistics. We collected carefully not only those complications which led to secondary surgery under general anaesthetic, but all clinical problems occurring at long term and necessitating any medical or surgical treatment, includ-

Table II
Summary of post-operative complications.

<table>
<thead>
<tr>
<th>Complications</th>
<th>Percentage of complications</th>
<th>Percentage of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection port related complications</td>
<td>22.6</td>
<td>9.6</td>
</tr>
<tr>
<td>Late band slippage* (&gt; 1 month)</td>
<td>20.7</td>
<td>8.8</td>
</tr>
<tr>
<td>Connecting tube related complications</td>
<td>17.0</td>
<td>7.2</td>
</tr>
<tr>
<td>Parietal complications</td>
<td>9.4</td>
<td>4.0</td>
</tr>
<tr>
<td>Gastric pouch dilatation**</td>
<td>7.5</td>
<td>3.2</td>
</tr>
<tr>
<td>Esophageal motility disorders</td>
<td>5.7</td>
<td>2.4</td>
</tr>
<tr>
<td>Band intolerance</td>
<td>5.7</td>
<td>2.4</td>
</tr>
<tr>
<td>Early band slippage (&lt; 1 month)</td>
<td>3.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Post-operative peri gastric oedema</td>
<td>3.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Gastric erosion</td>
<td>1.9</td>
<td>0.8</td>
</tr>
<tr>
<td>Band infection and septicaemia</td>
<td>1.9</td>
<td>0.8</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>42.4%</td>
</tr>
</tbody>
</table>

* with or without gastric pouch dilatation, ** without band slippage.
ing surgery under local anaesthetic. That was not the case in other studies that focused only late complications requiring surgical treatment under general anaesthetic [13, 14, 15, 16]. Our study revealed a complication occurrence frequency of 42.4%, which is significantly higher than other studies. Evolution of surgical complications showed that 68% of these complications occurred in the first two years compared to 36% for the first 100 patients thereafter. Other factors may also be responsible for the decrease in the number of complications, such as the reduction of pouch volume to 15 ml, high retro-cardial fitting of the band, or absence of post-surgical inflation of the banding, leading to the reduced number of post-banding complications which decreased from 16.3% for the first 100 patients to 3.7% for the 27 patients operated on using the second surgical technique, with an observation period of 15 months, compared to an average of 6.2% in the ANAES report [3]. Like other studies [10, 21], we did not find any predictive factor for slippage or pouch dilatation in our multivariate analysis, although there was a higher incidence of slippage in women than in men (p = 0.051). However, we cannot rule out the influence of other parameters such as compulsive eating disorder, or banding too tight or inadequately attached. Our study revealed a high incidence of port and tubular complications which are responsible for some 40% of all complications and affect 17% of all patients. This result is higher than other studies with an incidence of between 1 and 30%. This seems to be associated with a higher incidence of tubular disconnections or ruptures which have usually led to surgical treatment under local anaesthetic and necessitated a modification of the device by the manufacturer. In our study, secondary surgery was necessary in 34.4% of complications (43 operations) and this frequency is higher than most other studies. However, 21% of the secondary operations were performed under local anaesthetic, and these are usually not taken into account in other studies [22, 23, 24]. Our study also showed that the gastric band had to be removed again in 15.2% of all cases. Compared to the results of other studies, where this was necessary in 1% to 10% of cases, ours are higher because we had no incidences of gastric band coelioscopic repositioning, as opposed to 1 to 11% in the other studies [25, 26]. Of the gastric band removals performed in our study, 89.5% were carried out using the laparoscopic technique. Of the total number of complications, 11.3% were resolved solely by medical treatments, 28.3% required surgery under local anaesthetic, 24.5% under general anaesthetic and non-emergency conditions, and 35.8% were classified as major complications requiring emergency surgery under a general anaesthetic.

In conclusion, to summarize, although the present study was retrospective, weight evolution following gastric banding was not significantly different from that observed in other prospective studies. Our study showed that post gastric banding weight changes were not influenced by sex, the presence of diabetes, or a BMI in excess of 50 kg/m² prior to surgery (in our opinion, these patients should preferably be oriented towards gastric bypass rather than gastric banding). All complications recorded during the follow-up period demonstrate a higher incidence compared to most other published studies. This is because we took into account minor complications that were resolved by medical treatments or by surgery under local anaesthetic. These are usually ignored in most other studies but should be taken into consideration for guidance purposes when conducting gastric banding procedures and for patient quality of life.

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References


