Band Leakage after Laparoscopic Adjustable Gastric Banding

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Background: Laparoscopic adjustable gastric banding is effective in inducing weight loss, as well as being minimally invasive, totally reversible, and adjustable to the patient’s needs. Nevertheless, leakage of the adjustable balloon is a known complication. The aim of this study was to assess the incidence and reasons for balloon leakage of the Swedish adjustable gastric band (SAGB).

Patients and Methods: Between January 1996 and December 2002, 566 patients (475 women, 91 men) underwent a laparoscopic SAGB implantation. Two groups of patients were analyzed: patients with early postoperative leakage (Group E) and patients with late postoperative leakage (Group L). All data (age, gender, pre- and postoperative weight, time of weight gain, band filling status) were prospectively collected in a computerized data bank. For the detection of gastric band leakage, radiography and the technetium-99m colloid scintigraphy was used.

Results: 25 band leakages were observed in 22 patients (4.4%). All these patients had a silent presentation of band leakage, with weight regain and an ability to eat without major restriction. Band leakages in group E were detected during the band filling period after a median follow-up of 8 months and after 30.3 months (P<0.0001) in group L. In group E, all 13 leakages possibly resulted from inappropriate handling of the device during surgery. In 2 cases in group L, a tear of the balloon had occurred where it is fixed to the band. The other 10 bands showed breaks at the edges of the inner side of the balloon. All leakages could be detected by ⁹⁹mTc colloid scintigraphy, whereas only 58% of the leakages could be detected by radiography.

Conclusion: Band leakage is a rare complication and should be considered if a patient starts to regain weight. Operative failure as well as material defects may account for this complication. The balloon leakage can effectively be detected by ⁹⁹mTc colloid scintigraphy.

Key words: Band leakage, morbid obesity, bariatric surgery, laparoscopic gastric banding, ⁹⁹mTc-pertechnetate colloid scintigraphy

Introduction

In Austria and Germany, 30% of the adult population is overweight, 10% are obese and 1% (900,000 adults) are now classified as morbidly obese.¹ In the United States, obesity is a serious health problem, with more than 20% of the adult population affected. An estimated 58% of the adult population in the USA are overweight, and about 12 million Americans are morbidly obese.² This increase has been accompanied by the attendant health risks of obesity, including coronary artery disease, hypertension, diabetes, gallstones, breast cancer, orthopedic problems, sleep apnea, and general debility.³ The International Association for the Study of Obesity estimates that the costs for these co-morbidities (2-8% of the total costs of Public Health) are as high as complete cancer therapy.⁴ In the USA, the costs caused by obesity amount to 100 billion dollars a year,⁵ and the estimated number of annual deaths attributable to obesity among US adults is approximately 280,000.⁶ As diet regimes fail to provide long-term weight reduction in morbidly obese patients, the only hope for these patients is bariatric surgery.
The advantages of laparoscopy over open surgery are well known, and therefore the popularity of laparoscopic techniques has led to an increasing use in obesity surgery. Due to the safety and efficacy of adjustable gastric bands for the treatment of morbid obesity, this method has gained high acceptance especially in European bariatric centers. Nevertheless, a known complication of gastric banding is band leakage.

The purpose of this prospective study was to assess the incidence of band leakage and to evaluate the effectiveness of radiography and $^{99m}$Tc-colloid scintigraphy with the Regions of Interest (ROI) analysis.

Patients and methods

Patients

From January 1996 until December 2002, we operated consecutively on a total of 566 patients (475 women, 91 men), who received a laparoscopically placed Swedish adjustable gastric band (SAGB, Obtech associated with Ethicon EndoSurgery). Data from patients undergoing bariatric surgery have been entered prospectively in a database since the first laparoscopic gastric banding in January 1996. These include demographic and morphologic data, co-morbidities, operative data, and follow-up data. Patients with a BMI >40 kg/m$^2$ or between 35 and 40 kg/m$^2$ with additional obesity-related co-morbidities, were considered for SAGB implantation.

Leakage was suspected if patients were asymptomatic except for unexpected weight gain during the follow-up. The study patients were divided into two groups: patients presenting with insufficient weight loss within 1 year resulting from early postoperative band leakage (Group E) and patients presenting with late postoperative leakage following an uneventful postoperative course (Group L). Jopamiro 200®, the contrast fluid recommended by the manufacturer, was used for system filling, because it meets the standards for physiological molecular weight. As an early event of system leakage, discrepancy of filling volumes was observed in all patients. Repeated volume augmentation resulted in a spontaneous decrease of the entire filling volume.

Fluoroscopic Radiography

The system was filled with Jopamiro 200® up to an entire volume of 10 ml, which was the maximum filling volume tolerated by the patients. Fluoroscopy was performed in A.P. and left-oblique view. The system remained filled for at least 10 minutes to allow the contrast to migrate slowly. After the examination, the entire volume was withdrawn to observe any contrast outside the balloon.

$^{99m}$Tc-colloid Scintigraphy

$^{99m}$Tc-labelled human serum albumin colloid was prepared according to the instructions of the manufacturer (Senti-Scint, Medi-Radiopharma). Using the access-port needle (deflected tip, Huber type), the balloon was deflated completely. Then the system was filled up to an entire volume of 10 ml, which included a dose of 2 ml 74 MBq and 8 ml sodium chloride. Imaging was started immediately after the dose application with the patient lying on left side of the body, thus obtaining a left lateral projection. During the first minute, images were acquired dynamically every 2 seconds. After the initial method, a static image was obtained every 10 minutes, up to 60 minutes post-injection. The study was analyzed by using the Regions of Interest (ROI) technique localized to the following positions: distal connecting tube, anterior band, posterior band. An adjacent region close to the band was taken as background. Thereafter, the system was emptied in order to visualize extravasated tracer and any tracer reabsorption during the following 60 minutes.

Statistical Analysis

Continuous variables were expressed as median (range), and were analyzed with analysis of variance (ANOVA). A $P$-value of $\leq 0.05$ was considered statistically significant. Statistical analysis was performed with the program StatView SAS®, 6.12.

Results

Twenty-five band leakages were observed in 22 patients (4.4%). Early postoperative band leakages
(group E) were detected in 10 patients with 13 band leakages after a median follow-up of 8 months; late postoperative band leakages (group L) were detected in 12 patients with 12 band leakages after 30.3 months (Table 1). The patients in group E showed insufficient weight loss or spontaneously decreasing band filling-volume. All patients in group L had a silent presentation of band leakage, with weight regain and ability to eat without major restriction.

In group E, all leakages have been supposed to be caused by the surgeon accidentally damaging the band during the operative procedure. In two patients in group L, a tear of the balloon had occurred where it is fixed to the band (Figure 1). The other possible reasons accounting for band leakage were material break at the inner side of the balloon that could be generated by kinking of the balloon due to high filling-volumes or contact of these sites with the non-absorbable gastro-gastric sutures acting like a saw.

A marked band leakage was revealed immediately by fluoroscopic radiography in 14 patients (58%). However, radiographic technique initially failed to detect small leakages in 10 cases (42%). On the other hand, all band leakages could be detected and located by $^{99m}$Tc-colloid scintigraphy (100%).

ROI analysis of the scintigraphic approach showed a clear diminution in the number of counts contained in the defect parts of the band within 30 to 60 minutes, whereas it remained fairly constant in the other locations. Emptying the system after 1 hour revealed tracer accumulation adjacent to the defect site of the band. This leaked scintigraphic activity decreased gradually within another 30 to 60 minutes, indicating tracer reabsorption in the peri toneal tissue.

Twenty-one patients underwent uneventful laparoscopic reoperation. During the operation, leakage sites of the explanted bands were confirmed and new bands (SAGBs) were placed without complications (Figure 2). One patient underwent only band removal because of unclear intraoperative gastric wall laceration, but received a new SAGB laparoscopically after an uneventful period of 2 months. The postoperative course was uncomplicated in all patients.

**Discussion**

Obesity is a chronic disease that is increasing in prevalence in the United States and Europe. Unfortunately, the trend continues. The prevalence of obesity in the United States increased from 17.9 percent in 1998 to 19.8 percent in 2000. A rare complication (1.8% - 2.9%) but one that requires surgical revision is leakage of the adjustable gastric balloon. Only one report showed a high leakage rate of 17%, but this was found in a limited series of 29 patients in 1996. Leakages of the balloon are described as late complications and are first suspected by insufficient filling and deflating of the

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**Table 1. Band leakage – patient characteristics**

<table>
<thead>
<tr>
<th>Patients</th>
<th>Group E (early) (n=10)</th>
<th>Group L (late) (n=12)</th>
<th>P-value ≤0.05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>43.1 (23-62)</td>
<td>40.4 (26-66)</td>
<td>NS</td>
</tr>
<tr>
<td>Gender</td>
<td>f = 8, m =2</td>
<td>f = 10, m =2</td>
<td>NS</td>
</tr>
<tr>
<td>Asymptomatic except for weight gain</td>
<td>10 (100%)</td>
<td>12 (100%)</td>
<td>NS</td>
</tr>
<tr>
<td>Initial weight (kg)</td>
<td>122.9 (97–160)</td>
<td>133.3 (105–195)</td>
<td>NS</td>
</tr>
<tr>
<td>Initial BMI (kg/m$^2$)</td>
<td>42.9 (38-52)</td>
<td>46.3 (40-55)</td>
<td>NS</td>
</tr>
<tr>
<td>Weight (kg) at time of weight gain</td>
<td>105.7 (85–140)</td>
<td>102.8 (75–140)</td>
<td>NS</td>
</tr>
<tr>
<td>BMI (kg/m$^2$) at time of weight gain</td>
<td>36.5 (30-47)</td>
<td>30.8 (27–45)</td>
<td>NS</td>
</tr>
<tr>
<td>Date of implantation</td>
<td>04/98 – 11/01</td>
<td>01/96 – 10/00</td>
<td>NS</td>
</tr>
<tr>
<td>Detection of band leakage (months)*</td>
<td>8 (5-10)</td>
<td>30.3 (17-40)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Maximal band filling (ml)</td>
<td>5.8 (4-8)</td>
<td>6.6 (4-9)</td>
<td>NS</td>
</tr>
<tr>
<td>Laparoscopic reoperation</td>
<td>12**</td>
<td>11</td>
<td>NS</td>
</tr>
</tbody>
</table>

Data: median (range), NS = not significant, f = female, m = male, * after initial laparoscopic implantation of SAGB, ** 10 patients with 13 band leakages.
band combined with unexplained loss of eating restriction. In our series band leakage was observed in 4.4%. Band leakages may be attributed to the handling of the band during surgery. The tear of the balloon may occur as a result of traction on the gastric band during its placement around the stomach. Another suggested factor is the puncture of the balloon while the gastric band is being fixed to the anterior gastric wall by gastro-gastric sutures.

In our study, all of the early postoperative leakages were found to be caused by the surgeon accidentally hurting or perforating the band during surgery. One obvious explanation for late postoperative leakages was a tear of the balloon where it is fixed to the band. As a precaution, the manufacturer has reinforced the fixation site at boths ends. The other suggested reasons for band leakages were a break at the edges of the inner side of the balloon due to material fatigue or material damage due to a narrow tunneling of the band that allows direct contact with the non-absorbable sutures.

Generally, fluoroscopic radiography detects the site of the leakage, although viscous radiopaque solutions may potentially block the band system. Small leaks sometimes remain undetectable because contrast fluid fails to show a marked extravasation, although high filling volumes (10 ml) are used. A recent study demonstrated small leakage assessment by $^{99m}$Tc-pertechnetate scan in adjustable silicone gastric bands, devices that are comparable to the SAGBs that were used in our series. In our series fluoroscopic radiography immediately revealed band leakages in only 58%, whereas 100% of the band leakages could be detected by means of $^{99m}$Tc-human colloid scintigraphy. Band leakage should be considered if weight loss is insufficient or patients show weight regain and an ability to eat without major restriction. In our series, 100% of the patients were asymptomatic except for these observations. Asymptomatic weight gain might also result from port disconnection or leakage. This is of concern because redo-surgery is possibly performed under local anesthesia in the case of a port disconnection. To differentiate these complications, fluoroscopic radiography should be performed. Negative results should advocate immediate scintigraphy to avoid further time loss and weight regain.

In summary, although laparoscopic gastric banding has met the criteria for a safe method to treat morbid obesity with effective weight loss, individual adjustment, minimally invasiveness and total reversibility, band leakage is still a matter of concern. Operative failure as well as material defects due to direct contact with the non-absorbable gastro-gastric sutures acting like a saw emphasize the importance of correct operative technique. However, material fatigue may account for this complication in later follow-up. Balloon leakage can effectively be detected by $^{99m}$Tc colloid scintigraphy, and surgical re-do can be managed safely by laparoscopy.

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**Figure 1.** A tear of the balloon (arrow) had occurred where it is fixed to the band.

**Figure 2.** One end-flap of the in situ band and one end-flap of the new SAGB were fixed together (arrow) and then pulled through the existing scarred tunnel (arrow).
References


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