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Between the Hope of Major Weight Loss and the Risk of Medical Complications: How Safe is the Gastric Balloon for Patients? A Case Study

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Abstract

Two gastric balloons were given approval for the US market by the American health authority FDA (Food and Drug Admin- istration). The approved balloons were the fluid-filled intragastric balloons Orbera (produced by Apollo Endosurgery) and ReShape (produced by Re- shape Medical, later acquired by Apollo Endosurgery).2 These were the first two intragastric balloons to be approved for the treatment of obesity in the US since 1985. In 1985 the Garren-Edwards Gastric Bubble became the first gastric balloon to be approved in the United States.

Keywords: Overweight, Obesity, Gastric Balloon (Obesity), Complications (Side Effects).

Introduction

Background

In 2015, two gastric balloons were given approval for the US market by the American health authority FDA (Food and Drug Admin- istration). The approved balloons were the fluid-filled intragastric balloons Orbera (produced by Apollo Endosurgery) and ReShape (produced by Re- shape Medical, later acquired by Apollo Endosurgery).2 These were the first two intragastric balloons to be approved for the treatment of obesity in the US since 1985. In 1985 the Garren-Edwards Gastric Bubble became the first gastric balloon to be approved in the United States. The FDA withdrew its approval for the Bubble seven years later, however, because some patients had experienced major complications (gastric balloons remained banned in the US until 2015, although permitted in some other countries).3 On June 4, 2018, the FDA then reported that 12 deaths had resulted from gastric bal- loon treatments worldwide (seven of which occurred in the US: four involving the Orbera balloon and three from ReShape).4 How safe is the intragastric balloon procedure in the treatment of obesity)? What types of serious com- plications can this procedure have? What preventive measures can be implemented to reduce the risk for the patient? Given its potential benefits and risks, can gastric balloon therapy be considered an established medical measure for reducing obesity?

Motivation

Motivation As a specialist for internal medicine (former senior consultant at St. Willehad Hospital in Wilhelmshaven) and later as an independent doctor at Medical One in Hamburg, I have been involved in the implantation of more than 2,000 gastric balloons (Medsil, Orbera, Orbera 365 and Spatz 3) in out- patient procedures performed by various clinics in Germany (St. Willehad Hospital Wilhelmshaven, Medical One Clinic in Hamburg and Berlin, Berg- mann Medical One Clinic in Hamburg, Weight Doctors in Hamburg and Ber- lin). I have experienced some serious complications (eight cases, some of which were life-threatening, including tears in the esophagus and stomach). In addition to the clinical implantation work, I found it particularly important to carry out some fundamental research on the subject of gastric balloon treatment for obesity. The following studies I have carried out include the following:

- The general effect of the gastric balloon (treatment lasting 12 months / 6 months)
- MRT study (effect of the gastric balloon) at the University of Ulm (medical facul- ty / Radiology)
- Hormone study of the causes of obesity in Hamburg (Medical One) Howe- ver, I noticed early on that relatively little research has been performed on the subject of complications during gastric balloon implantation (covering patient safety, how to avoid complications, new procedures, better treatment):

- There is a quantitative deficiency, with studies generally covering few cases
- There is a qualitative deficiency, with complications described in little detail
- Very short study periods, with no long-term studies) I therefore conducted a large-scale case study / observation study on complications in gastric balloon treatment on the basis of my own examination data involving 930 patients (Me- dical One, Hamburg) in the period of 2014–2020 (six years).

Methodology

This paper is an empirical case study. The scope of the study was defined as follows:

- **Time:** The study covers examinations from the period from January 1, 2014, to April 1, 2020 (roughly six years).
- **Geography:** There were no restrictions to the geographical origin of patients (99% German / 1% non-German).
- **Treatment Type:** All patients were obese (obesity class I, II, III, and above) and treated with a gastric balloon.
- **Place of Treatment:** The treatment was performed at the Medical One Clinic in Hamburg (Germany) on an outpatient basis.

Type of gastric balloon implanted (model / length of placement / refillability):

1. 394 Sparrow 3 (1-year balloon / refillable)
2. 536 Medsil (6-month balloon / non-refillable)
3. We treated a total of 930 patients (including both placement and removal of the balloon).

Type of procedure (balloonmodel / intubation / anesthesia / duration / anesthetist):

1. Spatz 3 (intubated / general anesthesia / 20–25 minutes / with anesthetist)
2. Medsil (short-term anesthesia / 10 minutes / with anesthetist).

We aimed to answer the following general questions:

A) How many complications have occurred in total?
B) What type of complications occurred?
C) Which particular models of gastric balloon were involved in the complications?
D) How severe were the complications?
E) What were the causes of the complications?
F) Were the complications related to the patient's previous medical history?
G) What treatment was needed following the complications?
H) What can be done to prevent complications in the future?

We have formulated the following hypotheses, partly on the basis of our treatment experience:

A) The number of minor and serious complications is likely much higher than re- ported.
B) In the case of certain diseases (e.g. sleep apnea), gastric balloon treatment can lead to serious complications, including death.
C) The main complications are:
a) tear (perforation) of the stomach and esophagus
b) bleeding and inflammation of the esophagus (esophagitis)
c) water and electrolyte imbalance
d) stomach paralysis (atony)
e) intestinal obstruction (ileus)

When complications occur, patients usually experience symptoms in the first three to five days.

Overall, the following medications are recommended for gastric balloon treatment:

- Early administration of infusions
- Administration of acid blockers (proton pump inhibitors)
- Treatment with antiemetics
- Treatment with painkillers (Novalgin/Buscopan or similar) as needed (PRN)

The Spatz 3 gastric balloon has more complications but patients lose more weight (slightly greater risk but greater success).

For reasons of patient safety, an anesthetist (and a specialist nurse) should be present during every gastric balloon procedure.

Obesity Basics

The World Health Organization (WHO) describes obesity as a global health ep- idemic, affecting all countries, social groups, and age classes. Overall, obesity affects one third of the world's population (approx. 2 billion people). Every year roughly 3 million people die from being overweight. The economic costs are roughly 3 billion US dollars. Interestingly, Egypt ranks highest in the world for the number of obese adults. The US ranks highest for the number overweight children (under 14 years of age).5 The World Health Organization (WHO) defines obesity as a diet-related disease with excessive fat accumulation and that presents a risk to health. A body mass index of over 30 is considered obese. 6

Obesity is described in European literature as far back as the 14th century, at the beginning of modern medicine. Obesity was seen as a sign of social prosperity and wealth, being particularly prevalent among social elites.7

Causes for obesity are:

1. Genetic causes
2. Excessive calorie intake
3. Lack of movement (resulting from sedentary jobs, modern transport, lack of exercise´)
4. Other factors (diseases, medications, sleeping habits, etc.) 8

The long-term consequences of being obese include a shorter lifespan (with a reduction of approx. 10 years for body mass indexes over 40). In addition, quality of life decreases (less physical activity, mental illness, social problems, exclusion, etc.). There are also a number of physical illnesses that occur:

1. Cardiovascular diseases (heart attack, stroke, vascular diseases, etc.)
2. Metabolic diseases (diabetes, liver diseases, metabolic syndrome)
3. Cancer (of the liver, kidneys, pancreas, gastrointestinal area, esophagus, etc.)
4. Musculoskeletal disorders (gout, arthritis, degenerative diseases)

1. This case study essay is dedicated to Professor Dr. Michael Gebel (Hannover), who has been involved as a physician for the German-Turkish Congress (Istanbul) and German-Asian Medical Congress (Azerbaijan/Uzbekistan) for more than 30 years, as a bridge-builder for the medical community
2. UPDATE: Potential Risks with Fluid-Filled Intragastric Balloons U.S. Food and Drug Administration (FDA) Letter to Health- care Providers, p.4 (Background) dated April 27, 2020) (https://www.fda.gov/medical-devices/letters-health-care-provid- ers/update-potential-risks-liquid-filled-intragastric-balloons-letter-health-care-providers-1)
3. Wikipedia, "Magenballon" [gastric balloon], 2021, p. 4 (https://de.wikipedia.org/wiki/Magenballon)

5. Mental illnesses (depression/anxiety, social problems) 9

There are three options for treating obesity. First, conventional forms of treatment such as diets, sports therapies, and psychological treatments (with a success rate of less than 20%). Medical therapy is also offered (with the preparations orlistat, lorcaserin, or L 112, for example). However, the weight reduction is very small (approx. 3 kg / over 4 years) and long-term cardiological and gastroenterological complications can occur. A second option is surgery.

Reduction of the gastric volume (gastrectomy, lap banding, bypass). This enables up to 25% of the original weight to be lost and the cases of death resulting from obesity can be reduced by 30%. A third treatment option is gastroenterological (without surgery, involving only gastroscopy through the esophagus, for example), with a gastric balloon or an endoscopic stomach reduction (POSE).10

Gastric Balloon Basics

The gastric balloon procedure is defined as an interventional, endoscopic me- thod for treating obesity. The gastric balloon is pushed into the stomach through the esophagus during a gastroscopy, with no surgical operation or scars. The intragastric balloon takes up space in the stomach, resulting in a reduction in the stomach volume. As a result, the patient can eat less food and the vagus nerve (stomach wall) reports to the brain that the stomach is full earlier on, which results in an earlier feeling of satiety.11

The history of the gastric balloon begins in the late 1970s. Intragastric balloons, in the form of 250 ml flasks, were implanted in dogs in an experimental trial.12 In 1982, Ole Nieben and Henrik Harboe reported in The Lancet (a UK medical journal) that they had implanted a rubber gastric balloon in five overweight women. The gastric balloon remained in the patient's stomach for up to 3 weeks and the weight loss was approximately 5 kg. There were no complications. The authors considered the procedure to be of interest, but only if new gastric balloons were to become availa- ble that could retain air for prolonged period.13 In 1985, the Taylor gastric balloon was introduced in the UK. It was filled with 550 ml of saline (with a blue marker fluid in case the balloon bursts). According to the manufacturer, it should remain in the stomach for four months. In a multicenter clinical study, involving four test clinics and 60 people, the patients lost an average of more than 10% of their body weight over the four-month period.14 In 1985 the US Food and Drug Administration (FDA) also tentatively approved the Garren-Edwards Bubble as a weight-loss device. The FDA then withdrew this preliminary approval in 1992, however, following serious complications and limited weight loss in the affected patients. In 1988 the Ballo- bes Balloon was introduced in Denmark. This gastric balloon is filled with air rather than liquid. A randomized, double-blind study with three-month placement of the balloons showed no significant success in weight reduction.15 In 1991, the com- pany Bioenterics developed the Obalon "BIB" gastric balloon). It is used in South America, Europe, the Middle East, and Asia.16 Gastric balloons were not approved again in the US until 2015, when the FDA approved two gastric balloons (ReShape Duo and Orbera).17 In general, medical devices generally need to have received worldwide approval before they can be placed on the medical market. In the US, a government agency (the FDA) is responsible for this.

In Europe, on the other hand, companies have to carry out a CE-conformity pro- cedure for their medical products at a notified body (testing institute). The legal basis for gastric balloons is Directive 90/385/EEC on active implantable medical devices. The procedure involves testing the gastric balloon as a medical device on the basis of a type examination (a technical test performed by TÜV or VDE, for example). In addition, medical companies must demonstrate quality management and submit technical documentation for their product to the notified body in order to be given the CE-conformity mark.18

The purpose of the gastric balloon is primarily to support weight loss by norma- lizing the patient's metabolism, with the long-term goal of holistically healing of the patient, resulting in them having an appropriate weight and healthy lifestyle.19

The effect of the gastric balloon is that it takes up space in the stomach, physically reducing the gastric volume. In addition, the stomach's gastric satiety receptors are activated earlier, even with small amounts of food. Gastric hormones (ghrelin, leptin, peptide) are released, which stimulate the satiety center in the brain. In addition, gastric emptying is slowed down, giving the patient a longer feeling of satiety. 20

The gastric balloon is suitable for patients with a body mass index (BMI) of 27 or more, and in the case of metabolic diseases, even with a BMI of 26. 21

The intragastric balloon is not suitable in the following cases:

5. For people with severe organ disease (heart, liver, kidney, lung, etc.)
6. For people with severe gastrointestinal diseases (diaphragmatic hernia, in- flammation)
7. For bleeding disorders (coagulation disorders)
8. In the case of severe mental illnesses (e.g. depression/anxiety)
9. For severe addictions (drugs/alcohol).22

The various models of gastric balloon can be classified systematically as follows: In terms of form, gastric balloons can have one or two balloons, with one balloon now the common form. Gastric balloons can be filled with either air or saline (with a color indicator). Common medical practice today is to use liquid-filled balloons, as these have a lower risk of volume loss and turn the urine blue when deflated. Gastric balloons remain in the stomach for a period of either six months or one year. Some models are refillable, and can be adjusted with a valve, while others have a constant volume, without a valve.

A selection of the main gastric balloons models that are currently implanted in the treatment of obesity is given below: 23

ORBERA Intragastric Balloon (Apollo Endosurgery, Austin, USA, formerly BIB (BioEnterics intragastric balloon), the most Commonly Implanted Gastric Balloon)

4. UPDATE: Potential Risks with Fluid-Filled Intragastric Balloons. US Food and Drug Administration (FDA) Letter to Health- care Providers, p. 2 (Additional Information on Death Reports), June 4, 2018 (https://www.fda.gov/medical-devices/ letters-health-care-providers/update-potential-risks-liquid-filled-intragastric-balloons-letter-health-care-providers-1)
5. Uyak, POSE, Wilhelmshaven, 2019, p. 2 (PowerPoint presentation)
6. Wikipedia, "Fettleibigkeit" [obesity], 2019, p. 5 (https://de.wikipedia.org/wiki/Fettleibigkeit)
7. Uyak, POSE, Wilhelmshaven, 2019, S.1, (PowerPoint presentation)

- Type of gastric balloon (form/material): silicone balloon (saline filling / 450–700 ml)
- Placement time: 6 months
- Weight loss effectiveness: up to approx. 17 kg

Spatz (Sparrow FGIA / Fort Lauderdale, USA)
- Type of gastric balloon (form/material): silicone balloon (saline filling / 400– 600 ml / refillable / with valve)
- Placement time: 12 months (one year)
- Weight loss effectiveness: up to approx. 24 kg

Reshape (Reshape Medical / San Clemente, USA)
- Type of gastric balloon (form/material): silicone balloon (saline filling / two balloons / up to 900 ml)
- Placement time: 6 months
- Weight loss effectiveness: up to approx. 25 kg.

Ellipse (Allurion Technologies / Natick, USA)
- Type of gastric balloon (form/material): swallowable silicone balloon (sa- line filling / 450–500 ml)
- Placement time: 6 weeks
- Weight loss effectiveness: approx. 2.5 kg.

Obalon (Obalon Therapeutics / Carlsbad, USA)
- Type of gastric balloon (form/material): swallowable silicone gastric bal- loon (filled with air / 250 ml)
- Placement time: 3 months
- Weight loss effectiveness: up to 5 kg.

Heliosphäre BAG (Helioscopie / Vienne, France)
- Type of gastric balloon (form/material): silicone balloon (filled with air / 900 ml)
- Placement time: 6 months
- Weight loss effectiveness: up to approx. 23 kg

In summary, using gastric balloon as an endoscopic/non-surgical method for re- ducing body weight has the following advantages: 24

No surgical procedure is needed, as the balloon is placed by means of a gas- troscopy.
- No surgical risks (no life-threatening complications, infections, or other conse- quential harm)
- The gastric balloon is a reversible measure, as it can be removed at any time.
- The patient is not restricted in what they can eat.
- The gastric balloon "punishes" bad eating habits, making the patient less likely to eat excessively or eat too much fatty food.
- The average weight loss over a six-month period is 15–25 kg.

The disadvantages of gastric balloon treatment are as follows: 25
- Possible complications of the gastric balloon treatment (tears in the stomach wall, intestinal obstruction, bleeding, inflammation, gastric paralysis, mental illness, etc.)
- Symptoms in the first 3–5 days (malaise, nausea, vomiting)
- After removal of the gastric balloon, patients may gain weight again (with roughly 60% gaining weight after three years). In the long term, a gastric bal- loon can only bring about a change in behavior, enabling more exercise and different eating habitsas a "door-opener" for weight loss.

Complications resulting from gastric balloon treatment can be roughly categorized as follows:
- Early (occurring after a few days) and late (occurring after a week)
- Mild (non-life-threatening) and severe (life-threatening)
- Complication types, in terms of pathological consequences
- Complications with different treatments (inpatient/outpatient)

Case Study

Introduction

We carried out our empirical case study with 930 gastric balloon patients at the Medical One Clinic in Hamburg (Germany) in the period from 2014 to 2020, fo- cusing on complications. 26 We have experienced eight cases of with severe com- plications, some with life-threatening consequences such as esophageal tears and Boerhaave syndrome and some similar to the FDA cases, with esophageal bleeding and renal insufficiency, so we were surprised that there were relatively few studies on the subject of complications. In addition, there are no practical guidelines for the attending physician regarding safe treatment with intragastric balloons. After all, patient safety plays a particularly important role in ensuring patient acceptance and confidence in treatment with the gastric balloon. Further- more, legal factors (involving criminal, civil, or disciplinary law) and ethical factors (autonomy, fairness, openness) also play a role in the critical, and open, handling of the topic of complications in obesity treatment with a gastric balloon.

Results

General scope
- **Treatment:** 930 gastric balloons
- **Time period:** January 1, 2014, to April 1, 2020
- **Location:** Medical One Hamburg, Germany

Gastric balloon models used
- 536 Medsil (6-month balloon)
- 394 Spatz 3 (12-month balloon / refillable)

Type and severity) of complications

Medical complications
- **Serious complications:** 2 cases (tear of stomach/esophagus)
- **Moderate complications:** 24 cases (esophageal bleeding, esophagitis, ulcers)
- **Minor complications:** 30 cases (esophagitis, abdominal pain, severe nausea and vomiting)
- Other problems (technical/pregnancy)

Technical problems (balloon defects): 14 cases of balloon defects, 13 cases with Spatz 3, 1 case with Medsil
- **Pregnancy:** 8 cases of pregnancy

8. Wikipedia, "Fettleibigkeit" [obesity], 2021, p. 3–4 (https://de.wikipedia.org/wiki/Fettleibigkeit) Uyak, POSE, Wilhelmshav- en, 2019, p. 10 (PowerPoint presentation)
9. Wikipedia, "Übergewicht" [overweight], 2021, p. 6–7 (https://de.wikipedia.org/wiki/%C3%9Cbergewicht#Medizinische_Per- spektive:_H%C3%A4ufig_beobachtete_Folgeerkrankungen) Uyak, POSE, Wilhelmshaven, 2019, p. 11, (PowerPoint presentation)
10. Uyak, POSE, Wilhelmshaven, 2019, p. 16–17 (PowerPoint presentation) Stavrou / Tsaousi / Kotzampassi, Life-threatening visceral complications after intragastric balloon insertion, In: Endoscopy International Open, No. 07, 2019, p. E 123
11. Wikipedia, "Magenballon" [gastric balloon], 2021, p. 1 (https://de.wikipedia.org/wiki/Magenballon)

Causes for gastric balloon removal
- Medical treatment: 0 cases
- Gastric balloon defect: 14 cases
- Severe complaints/pregnancy: 38 cases

- **Severe complaints:** 30 cases
- **Pregnancy:** 8 cases

Theses

The number of minor and serious complications is likely much higher than reported. In our gastric balloon treatments (case study of 930 patients in 2014–2020) there were at least 8 cases of serious complications (esophageal bleeding, esophageal tear, gastric tear, respiratory failure, acute kidney fail- ure). Without the case study, covering a large number of patients over a longer period of time, the related serious complications would not have been system-atically recorded and examined, and there would be a lack of awareness of potential serious complications. Accordingly, a central reporting office (e.g. at the Federal Institute for Drugs and Medical Devices) is needed for the compli- cations of gastric balloon treatment (similar to the FDA reporting platform in the US). Reporting complications with gastric balloons should be made mandatory (with the possibility of sanctions if reports are not filed).

In the case of certain diseases (e.g. sleep apnea), gastric balloon treatment can lead to serious complications, including death. All eight cases of severe complications were potentially life-threatening (bleeding, organ tears, respira- tory failure, etc.).

Complications mainly cover three areas (bleeding/inflammation, water and electrolyte disorders, intestinal obstruction). In our case study, we focused on the following complications:
- **Respiratory arrest:** 3 cases
- **Renal failure (acute):** 2 cases
- **Bleeding (tears/perforations):** 3 cases
- **Water/electrolyte balance disorders:** 7 cases
- **Intestinal obstruction:** No cases

In addition to the severe complications (respiratory arrest/kidney failure), the main general complications in our study were, interestingly, bleeding (tears) and dis- ruption to the water and electrolyte balance. When complications occur, patients usually experience symptoms in the first three to five days. In the author's expe- rience with gastric balloon treatment, complications occur in the first three to five days after the time of the implantation. Complaints that occur later than this are not usually caused by the intragastric balloon, but by other diseases that occur subsequently (flu infection, gastrointestinal infection, inflammation of the bile ducts and pancreas, etc.).

Overall, the following medications are recommended for gastric balloon treatment:
- Early administration of infusions (liquid and proton pump inhibitors): In the case of severe symptoms (sickness / nausea / abdominal pain) and inade- quate water intake saline solution infusions should be provided.
- Administration of acid blockers (proton pump inhibitors). In our experience, patients should take acid blockers (proton pump inhibitors) (40 mg / day) 3–4 days before the gastric balloon procedure. After the placement, an acid blocker (40 g / day) should be taken for six weeks (and thereafter as needed).
- Treatment with painkillers (such as Buscopan / Novalgin) as needed.

The Spatz 3 gastric balloon has more complications but patients lose more weight (greater risk but greater success). Out of the 14 gastric balloon defects, 13 involved Spatz 3 balloons (with only one involving Medsil). In our study, the Spatz 3 therefore poses more risks. However, patients with the Spatz 3 gastric balloon have greater success, losing roughly 6 kg more than with comparable gastric balloons.

For reasons of patient safety, an anesthetist (and a specialist nurse) should always be present during every gastric balloon procedure. In the author's ex- perience as a physician, if the treatments covered in this case study had been performed without an anesthetist present, there could have had life-threatening consequences such as respiratory arrest (sleep apnea, anesthetic overdose during short-term anesthesia, etc.). In addition, in the case of longer treatments (such refilling or removing a gastric balloon), intubation anesthesia, which is performed by the anesthetist, must be carried out anyway. It can thus be con- cluded that an anesthetist being present during gastric balloon treatment is an important recommendation for patient safety.

Other Findings (Experience/Observations)

Anesthesia during the gastric balloon procedure:
- It was possible to treat breathing arrests during short-term anesthesia with propofol effectively by intubation by the anesthetist, with the patient being discharged three hours later.
- As a rule (in 100 patients) we used a dosage of 220 mg propofol (sedation).
- In the case of Spatz gastric balloon implantations, nasal intubation (ventilat- ing the patient through a tube in their nose) is highly beneficial as it leaves more space in the mouth for the balloon to be inserted into the esophagus.
- In all gastric balloon operations (930 patients), an anesthetist was part of the treatment team (placement, removal, adjustments, etc.).

Complete rejection of the gastric balloon (intolerance): in 3.2% of the treated patients (30 cases). The main causes are assumed to be physical (dehydra- tion/demineralization) and psychological.

Duration of symptoms (nausea, vomiting, pain, etc.)

a) Males 3–4 days (on average)
b) Females 5–6 days (on average)

Pain: 20%–30% of the patients experienced pain. This was often colic-like, ap- parently caused by the increased gastric peristalsis, with the stomach attempt- ing to transport the balloon into the small intestine.

12. Gleysteen, A history of intragastric balloons, in: PubMed, 2016, 12 (2) (https://pubmed.ncbi.nlm.nih.gov/26775045/)
13. Nieben / Harboe, Intragastric balloon as an artificial bezoar for treatment of obesity, in: The Lancet, January 23, 1982, p. 198–199 (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(82)90762-0/fulltext)
14. Neto / Silva/ Campos, Intragastric Balloon for Weight Management, 2020, p. 5
15. Neto / Silva / Campos, Intragastric Balloon for Weight Management, 2020, p. 5
16. Vyas / Deshpande / Pandya, Advances in endoscopic balloon therapy for weight loss and its limitations, 2017, Figure 1 (History of Intragastric Balloons)

Inflammation of the Pancreas
In our case study, a total of three patients expe- rienced inflammation of the pancreas. However, none of the three cases were caused by the gastric balloon (one patient had autoimmune pancreatitis, one had chronic recurrent pancreatitis, and one had biliary pancreatitis).

Stomach Ulcer
We only had one patient with a stomach ulcer.

Diarrhea
We did not have any patients with diarrhea (only constipation was experienced, as the result of acid blockers).

Nausea (Vomiting)
Almost all of the 930 gastric balloon patients (99.5%, all but 5 cases) experienced nausea (severe nausea: 10% / moderate nausea: 70% / slight nausea: 20%).

Delayed Defecation
After placement of the gastric balloon, patients' occasion- ally experienced delayed defecation. The emptying of the intestines quickly returned to normal, without medication.

Spontaneous discharge of the gastric balloon. A total of three patients experi- enced spontaneous passage of the balloon from the stomach (two weeks after passing the blue urine marker). Three patients passed the balloon completely with the stool. Two patients passed the balloon after two to three weeks. In one person, the balloon was passed after six weeks. None of these patients had complaints (abdominal pain, etc.) after the loss of the gastric balloon.

Gastric balloon remaining in place for too long: Three patients did not comply with the placement period of the gastric balloon (despite repeated requests for removal). In one patient, the placement period was exceeded by 30 months (approx. 2.5 years). The balloon was no longer in the stomach (it has been excreted). Another patient exceeded the placement period by 36 months (3 years). The gastric balloon (Spatz 3) remained in the stomach and was not damaged, and was subsequently removed. A third patient exceeded the placement period by 43 months (approx. 3.5 years). No balloon was found in the stomach (it had been excreted).

Pregnancy
We had eight cases of pregnancy during gastric balloon treatment in our case study. In five cases, the implanted balloon was removed during pregnancy (14 weeks gestation). Three patients had the balloon removed after delivery (3 months / 6 months post-delivery). There were no complications.

Patients with kidney problems (removed kidney / severe kidney infection) should always receive saline solution infusions in the first few days. They should also drink plenty of liquid to remain hydrated.

Permanent long-term complaints (lasting long after the placement) If any com- plaints persist three to four weeks after the placement, they are usually not caused by the balloon treatment, instead being the result of infections and other diseases.

Summary
Overall, in our gastric balloon case study (with 930 patients over a period of six years), there were fewer complications than expected (7% of patients / 69 cases). In terms of the type of complications, our patients experienced no life-threatening complications. There were fewer cases of intestinal obstructions than expected, for example (not a single case). The same applied for bleeding (two cases) and inflammation (seven cases). In 14 cases the gastric balloon burst and a new bal- loon was implanted. The complications predominantly involved gastrointestinal complaints such as nausea and vomiting and problems with the water and elec- trolyte balance (dehydration / kidney failure). Treatment with the active ingredient ondansetron (e.g. Zofran Sublingual) is particularly helpful for nausea and vom- iting. This drug treatment enormously reduced the early complications (nausea/ vomiting). It is also important for an anesthetist to always be present during the gastric balloon treatment. We had three cases of complications (e.g. respiratory failure) during short-term anesthesia (analgo-sedation) that would probably have been life-threatening if no anesthetist had been present. Nasal intubation is ad- vantageous, especially when treating with the Spatz balloon, as it provides more space in the oropharynx and is faster and safer. What was interesting in our case study was that patients who had the gastric balloon in place for too long (for up to three years, as they simply did not come to have the balloon removed) expe- rienced no complications, and the balloon would be excreted naturally. Even in the case of pregnancy, three patients only had the gastric balloon removed after delivery (six months). Again, there were no complications (neither for the mother nor for the child). The early administration of saline solutions infusions can be used to treat most of the symptoms of water and electrolyte disorders. The gastric balloon treatment can also be used in patients who are severely overweight (over 150 kg / obesity class III and higher / BMI over 40) to reduce weight in preparation for a safe stomach reduction operation, with the gastric balloon serving a double purpose by reducing the surgery risk. In general, the legislator should consider whether the health insurance costs for gastric balloon treatment should be cov- ered for patients with a BMI of 35 or more (obesity class II), as early treatment increases the patient's life expectancy and quality of life of the patient, resulting in fewer illnesses and lowering health insurance costs overall. It should also be considered important for more information to be provided within the healthcare system about treatment with the gastric balloon (covering technical knowledge / methodology / social skills). Some hospitals sent patients home untreated during our case study. This sometimes-had life-threatening consequences (imminent kidney failure, stomach paralysis, cardiovascular problems). Therefore, research and teaching at universities should also cover the subject of treating obesity with gastric balloons in greater detail. In conclusion, it can be said that the gastric balloon does not mean absolute healing for patients who are obese. However, the gastric balloon can be a door-opener in the treatment of obesity,

17. Gleysteen, A history of intragastric balloons, in: PubMed, 2016, 12 (2) (https://pubmed.ncbi.nlm.nih.gov/26775045/)
18. Federal Institute for Drugs and Medical Devices, Placing Medical Devices on the Market, 2021, p. 1–3 Wikipedia, "Magen- ballon" [gastric balloon], 2021, p. 4 Johner Institute, Approval of medical devices, 2021, p. 1–2
19. Kim / Chun / Choi, Current Status of Intragastric Balloon for Obesity Treatment, 2016, p. 8
20. Kim / Chun / Choi, Current Status of Intragastric Balloon for Obesity Treatment, 2016, p. 1
21. Case study of 930 gastric balloon implantations (2014–2020, Medical One Hamburg / Germany)

improving me- tabolism, breaking down fat cells, improving diabetes through regression of insulin resistance, etc., as a simple procedure, with no surgery, good results, and low risk. Good organizational framework conditions are important for gastric balloon treatment (see our recommendations for action / gastric balloon guidelines). All in all, given the right framework conditions, the gastric balloon is an effective method with few complications (as other studies have also shown) 27 in the fight against the widespread disease of obesity, and its poor reputation is unjustified.

Recommendation for Action (Our Gastric Balloon Guidelines)
Measures in preparation for placement

- Good treatment management (close monitoring by physicians, profession- als, general management)
- Consultation of the patient provided by an interdisciplinary advisory com- mittee (a team made up of doctors, psychologists, ethicists, lawyers, nutri- tionists, etc.) regarding electrolyte disorders, stomach paralysis, general intervention risks, etc. resulting from gastric balloon treatment
- Patients should be instructed to immediately consult with their doctor or to go to an emergency room if they experience on certain severe symptoms (nausea, vomiting, pain, balance disorders, dizziness, etc.).
- Preventive acid blockers should be taken (40 mg / day) three days before the treatment.

Measures During the Placement Procedure
The procedure should only be carried out with an anesthetist (and a spe- cialist anesthesiology nurse).

Intubation anesthesia should be performed immediately in the following cases:

- Treatment lasting longer than 10–15 minutes (short-term anesthesia no lon- ger applicable)
- Patients with a BMI of 35
- All patients with sleep apnea

Intubation anesthesia should be performed in the supine position (this makes work easier for everyone involved).

- Removal of the gastric balloon should be stopped if a large amount of food is found in the stomach (risk of aspiration/ poor visibility with the gastro- scope).
- Before each balloon placement, a gastroscopy is necessary, as there is a pathological finding in 1–2% of cases (such as ulcer, severe mucosal ero- sions and rare malignancies) without any complaints from the patient.

Measures Following Placement

- Intensive medical monitoring immediately after the procedure, in the recov- ery room
- Close monitoring after the gastric balloon implantation, with availability of the doctor / 24-hour emergency hotline
- Accompanying persons (relatives/friends) should take patients home (to prevent accidents/medical incidents).
- The patient should be given one week of sick leave.

General Recommendations (standards)

- Certification (quality management) of the (outpatient / inpatient) clinics as "gastric balloon outpatient clinic"
- Development of guidelines (standards) for gastric balloon implantation
- More basic research on gastric balloon treatment for obesity
- Complications should be reported to (international/national) government agencies.
- The treatment should be covered by health insurance companies (for pa- tients with a BMI over 35, for example).
- 24-hour advice hotline.

Conflicts of Interest

The author carried out the gastric balloon case study on the topic of complica- tions during treatment on his own initiative without the influence of third parties (no financing or other influence—no conflict of interest). His son collaborated in the study as the co-author.

References

1. Federal Institute for Drugs and Medical Devices Marketing of Medical Devices (Overview) Bonn (2021).
2. Doheny, Kathleen Intragastric Balloon Death: What the FDA wants you tob- know. https://www.endocrineweb.com/news/obesity/58270-intragastric-.
3. Food and Drug Administration (FDA). (2020). UPDATE: Potential Risks with Liquid-filled Intragastric Balloons (Letter to Healthcare Providers) Silver Spring .
4. Gleysteen, J. J. (2016). A history of intragastric balloons. Surgery for Obesity and Related Diseases, 12(2), 430-435.
5. Johner, C., Hölzer-Klüpfel, M., & Wittorf, S. (2020). Basiswissen medizinische Software: Aus-und Weiterbildung zum certified professional for medical software. dpunkt. verlag.
6. [Approval of medical devices: approval procedures in the EU and the US] Konstanz (2021)
7. Kim, S. H., Chun, H. J., Choi, H. S., Kim, E. S., Keum, B., & Jeen, Y. T. (2016). Current status of intragastric balloon for obesity treatment. World journal of gastroenterology, 22(24), 5495.
8. Media info (press release) Wilhelmshavener Arzt bringt Magenballon (zur Ge- wichtsabnahme) in die USA [Doctor from Wilhelmshaven brings gastric balloon (for weight reduction) to the USA] (congress / New Orleans) Wilhelmshaven (2010)
9. Muniraj, T., Day, L. W., Teigen, L. M., Ho, E. Y., Sultan, S., Davitkov, P., ... & Murad, M. H. (2021). AGA clinical practice guidelines on intragastric balloons in the management of obesity. Gastroenterology, 160(5), 1799-1808.
10. Galvao Neto, M., Silva, L. B., Usuy, E. N., & Campos, J. M. (2020). Brazilian Experience on the Use of Intragastric Balloons. Intragastric Balloon for Weight Management: A Practical Guide, 27-32.
11. Nieben, O. G., & Harboe, H. (1982). Intragastric balloon as an artificial bezoar for treatment of obesity. The Lancet, 319(8265), 198-199.
12. Stavrou, G., Tsaousi, G., & Kotzampassi, K. (2019). Life-threatening visceral complications after intragastric balloon insertion: Is the device, the patient or the doctor to blame? Endoscopy International Open, 7(02), E122-E129.

22. Kim / Chun / Choi, Current Status of Intragastric Balloon for Obesity Treatment, 2016, p. 8 Wikipedia "Magenballon" [gastric balloon], 2021, p. 2
23. Kim / Chun / Choi, Current Status of Intragastric Balloon for Obesity Treatment, 2016, p. 3–7
24. Media info, Wilhelmshavener Arzt bringt Magen-Ballon in die USA [Doctor from Wilhelmshaven brings gastric balloon to the USA], 2010, p. 3
25. Doheny, Intragastric Balloon Death: What the FDA wants you to know, 2021, p. 1–2 FDA, UPDATE: Potential Risks with Liquid-filled Intragastric Balloons, 2020, p. 1–2
26. The study was carried out by the author on his own and without outside help (no influence, no financing, no third-party participation)—no conflict of interest
27. Muniraj / Day / Teigen, AGA Clinical Practice Guidelines on Intragastric Balloons in the Management of Obesity, Bethesda, 2021, p. 1803

13. Uyak, Deniz. (2019). (PowerPoint presentation) POSE (Primary Obesity Surgery En- doluminal) A new therapy (endoscopic) to fight overweight (adiposity) Wilhelmshaven.

14. Vyas, D., Deshpande, K., & Pandya, Y. (2017). Advances in endoscopic balloon therapy for weight loss and its limitations. World Journal of Gastroenterology, 23(44), 7813.