



Doctor's Handbook

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Understanding the Balloon:

1. Prior to implanting intragastric balloons (IGBs) in your patients it is important to understand how intragastric balloons work. Most people believe that balloons work by occupying space in the stomach which limits the amount of food intake thereby creating satiety and decreased appetite. That is far from reality and exists in less than 10% of balloon patients!!! It is my belief, based on experience with more than 1,000 patients and confirmed by a recent publication, [Victoria Gomez, George Woodman, Barham K. Abu Dayyeh. Delayed Gastric Emptying as a Proposed Mechanism of Action During Intragastric Balloon Therapy: Results of a Prospective Study. *Obesity* (2016) 24, 1849–1853. doi:10.1002/oby.21555] that the mechanism of action of IGBs is via delayed gastric emptying. Normal stomachs have gastric retention of 20% of their meal 2 hours after eating. According to the AbuDayyeh study, IGB patients retain more than 60% of their food at 2 hours after ingestion. So their food accumulates over days within the stomach which exerts pressure on the gastric walls – that pressure expresses itself differently in people. Some have belches (foul smelling due to accumulated food that decays in the stomach), fullness, bloating, pain etc. If patients continue to eat too much, these symptoms eventually worsen and lead to GERD symptoms, nausea or vomiting. You need to transmit this to your patients so that they understand this. For more than 90% of patients the appetite returns within the first month and hunger prevails throughout the year. So in essence, the balloon is your police officer that lets you know when your stomach is overloaded – but does not prevent you from overeating. That is why having ongoing support from dieticians and psychologists (that understand balloons) is very important for weight loss success and change in eating habits. The first week after IGB implantation is different – the stomach is in severe stress and shock from the entrance of this heavy weight that it cannot expel – only during the first week does the balloon really prevent you from eating. By the second week the stomach accommodates and eating progresses forward at a pace that is very individual.

Benefits:

- Non-surgical
- lower risk procedure
- out-patient procedure
- Non-scarring
- May be repeated if weight returns after balloon removal
 - Weight regain after surgery is a problem
 - 2nd surgery difficult
- Customize to patient needs
 - Adjustable balloon volume
 - Increase or decrease balloon volume as needed
 - Avoid early removal for intolerance (3-4% with other balloons)
 - 2nd wave of weight loss after adjustment
- 1 year balloon
 - Others are 6 months (BIB, Orbera, Silimed, Heliosphere, Reshape etc.)
- Mean 16- 24 kg weight loss/year

Risks:

- Ulcer (<1%)
- Nausea, vomiting , discomfort after implantation (most patients)
- Bleeding (<<1%)
- Obstruction (<<1%)
- Perforation (<<1%)

Choice of Patient:

Choosing the correct patient is one of the keys to success. A BMI > 27 is not the only criterion for inclusion. The patient should be motivated, cooperative and willing to undertake frequent follow-up after the balloon is implanted. This includes not only follow up office visits monthly, but also phone call follow up. Patients must be strong enough physically, medically and emotionally to undergo several days of nausea, vomiting, abdominal pain and dehydration. If they are on medications, they may need permission from their doctors – as they may miss doses of medications for a few days.

CONTRAINDICATIONS

- Prior gastrointestinal surgery with sequelae, i.e. obstruction, and/or adhesive peritonitis or known abdominal adhesions.
- Prior open or laparoscopic bariatric surgery.
- Prior surgery of any kind on the esophagus, stomach or any type of hiatal hernia surgery.
- *Any* inflammatory disease of the gastrointestinal tract including esophagitis, Barrett's esophagus, gastric ulceration, duodenal ulceration, cancer or specific inflammation such as Crohn's disease.
- Potential upper gastrointestinal bleeding conditions such as esophageal or gastric varices, congenital or acquired intestinal telangiectasias, or other congenital anomalies of the gastrointestinal tract such as atresias or stenoses.
- A gastric mass
- A hiatal hernia > 3 cm or ≤3 cm with associated severe or intractable gastro-esophageal reflux symptoms.
- Acid reflux symptoms to any degree that require more than one medication for symptom control
- Hepatic insufficiency or cirrhosis
- A structural abnormality in the esophagus or pharynx such as a stricture or diverticulum that could impede passage of the balloon alongside the endoscope.
- Achalasia or any other severe esophageal motility disorder that may pose a safety risk during the removal of the device
- Severe coagulopathy

- Subjects with any serious health condition unrelated to their weight that would increase the risk of endoscopy
- Chronic abdominal pain
- Patients who are pregnant or breast-feeding
- Patients who are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of the device implant.
- Patients receiving daily prescribed treatment anti-inflammatory agents, anticoagulants or other gastric irritants (aspirin up 100 mg daily is allowed).
- Motility disorders of the GI tract such as gross esophageal motility disorders, gastroparesis or intractable constipation
- *Patients who have ever developed a serotonin syndrome + are currently taking any drug known to affect the levels of serotonin in the body [e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs)] should not undergo placement of the device. (Use of SSRI without a history of serotonin syndrome is not a contraindication)*
- *Subjects diagnosed with any eating disorders, i.e. bulimia, binge eating, or compulsive overeating*
- Alcoholism or drug addiction
- Serious or uncontrolled psychiatric illness or disorder that could compromise patient understanding of or compliance with follow up visits and removal of the device.
- Patients unwilling to participate in an established medically-supervised diet and/or behavior modification program, with routine medical follow-up.
- *Subjects with Severe cardiopulmonary disease or other serious organic disease which might include known history of coronary artery disease, Myocardial infarction within the past 6 months, poorly-controlled hypertension, required use of NSAIDs*
- *Subjects taking medications on specified hourly intervals that may be affected by changes to gastric emptying, such as anti-seizure or anti-arrhythmic medications*
- *Subjects with Insulin Dependent Diabetes Mellitus that are poorly controlled or difficult to control.*

Office Consultation/ Patient Preparation

As you know, almost 100% of patients suffer from nausea, vomiting, and abdominal discomfort for 2-5 days after the implantation. A patient who is fully aware and is willing to undergo these difficult days will have an easier time. It is our experience that the more time you spend with patients **and their family members** reviewing these difficult days – the better. Many patients hear it, but don't believe they will have it. **Better to exaggerate the symptoms than to let them**

leave the consultation feeling that it won't happen to them or it won't be so bad. It's also important to tell them that about 3-5% of patients will be so uncomfortable that they will request removal within 1-2 weeks. For those patients, we can offer a balloon volume adjustment (endoscopy procedure) to remove only 150 cc of fluid (or 100 cc if they start with 400 cc) which alleviates symptoms in 85% of patients – and they feel the difference right away.

Please let them know that we will prescribe anti-nausea medications, but it only helps partially at best. Since we started using Emend (Aprepitant 125 mg on the day of procedure, 80 mg the day after and 80 mg two days after) and Ondansetron (8 mg QID) together for 3 days, we have noted the following symptoms: 90% have 3-4 days of nausea; 20% have vomiting for 3-4 days and 20% have abdominal pain/spasms for 3-5 days. If Emend is not used and if it is replaced with Metoclopramide, the incidence of vomiting rises to 78% of patients (3-15 times a day for 3-4 days).

It's vital that you spend the time with your patients and describe the symptoms of the first few days. Tell them how bad it can be:

If you tell them:

“You may have nausea and vomiting for a few days, and it could get very uncomfortable, but we will give you medicines to help you.”

That is a true statement **but**, they will walk out thinking that they won't have it so bad and if necessary, they can take medicine which will alleviate the symptoms. That is really not the way it happens. I promise you that if this is all you say to your patients – many patients will come back angry and feel like they were misled.

Spend the time, like I am spending in this writing, and explain it all. Tell them it may very well be horrible and extremely difficult, and medications only help partially – but, when it passes, they will lose weight and be happy they did it.

Expect 3-4 days off from work.

Some patients may need IV fluid (1 liter NS or LR) in the first week if they are unable to progress their oral intake.

Patients should be seen by a dietician/nutritionist prior to the procedure and then regularly thereafter.

A psychologist with training in CBT (cognitive behavioral therapy) offers patients a better chance at changing their ways and maintaining their weight loss after balloon extraction.

Stress the importance of taking ulcer meds (PPI) daily for 1 year even if they have no symptoms, because it reduces risk of ulcer and prolongs balloon life.

START PPI 1-2 WEEKS BEFORE PROCEDURE and continue entire year!!!!

Stress the importance of avoiding NSAIDs and alcohol. Alcohol increases the ulcer risk and should be kept to a minimum (1-2 alcoholic drinks per week – maximum).

Consent Form

Intragastric balloon insertion, adjustment, and extraction.

The intragastric balloon (“balloon”) is inserted into the stomach of the patient as part of a program whose goal is to affect weight loss.

The balloon is inserted through the mouth with the use of endoscopy and without need for surgery. The procedure is performed under conscious sedation administered by the endoscopist or an anesthesiologist. The adjustment and extraction procedures are done under the same conditions.

It is understood that a situation may arise that contraindicates the insertion of the balloon, that could not be known prior to the procedure- such as an asymptomatic ulcer, erosive gastritis, large hiatal hernia or diverticulum, for example. In that case the balloon will not be implanted at that time. Some situations may allow implantation at a later date after appropriate treatment – such as ulcer and gastritis.

Complications of the balloon procedures (implantation, adjustment and extraction) and during the year of implantation include ulceration of the esophagus, stomach, duodenum and small and large intestines; pancreatitis; bleeding/hemorrhage; obstruction of the esophagus, stomach, duodenum and small and large intestines; perforation of the esophagus, stomach, duodenum and small and large intestines; bleeding or tear of the lining of the esophagus, stomach, duodenum and small and large intestines; injury to teeth, and mouth. These complications could potentially lead to surgery or death.

During the period of balloon implantation, there are expected uncomfortable side effects that include nausea, vomiting, abdominal pain, and heartburn (acid reflux), which could lead to weakness, dehydration, fainting and falling episodes.

It is the responsibility of the patient to report immediately to the doctor or Clinic any and all symptoms which include changes in appetite; loss of balloon sensation; changes in symptoms of nausea/vomiting/abdominal pain/bleeding; and any change that affects your daily living; in order to address any issues in a timely fashion.

Procedure Requirements

Training

- Standard Endoscopic skills
- Observation of videos
- Trained by certified Spatz trainer

Equipment

- Standard endoscope – **DO NOT USE THERAPEUTIC ENDOSCOPE!**
- Large snare (30-40 mm)
- Grasping forceps (rat tooth or pelican)
- Balloon extraction needle (not sclerotherapy needle)
- 500 cc bag of saline connected to IV tubing for balloon inflation
- The procedure kit provides the 50-60 cc syringe
- 2 cc of methylene blue 1% solution

Sedation

- Standard sedation (narcotic + midazolam)
- Propofol is best, but not required
- General anesthesia is not necessary, but if your hospital insists on endotracheal intubation, the implantation can still be safely done

Personnel

- Endo nurse
- Office staff

- call patients daily for the first 4-6 days
- weekly for the next 2 weeks
- monthly thereafter

Preparation for Procedures

- Implantation Procedure
 - NPO after midnight
- Adjustment and Extraction Procedures
 - 3 day diet prep
 - 48 hours of full liquids followed by 24 hours of clear liquids
 - NPO after midnight

Procedure Tips (see IFU and videos for full details)

- Pull the bands off with “Band-Off”
- Push the “valve-hold” into the white catheter before insertion. This will prevent the inflation tube from tearing, should there be a kink in the inflation tube somewhere distally.
- Connect the extension tube to the valve tightly
- Remember to dry the endoscope very very well before placing the insertion facilitator on (or it will slip off)
- Change to a new dry pair of gloves before placing it
- The distal edge of the balloon must touch the rolled edge of the insertion facilitator.
- Lubricate the balloon only after the balloon is in the insertion facilitator
- Lubricate the inside of the mouth guard also

- When the valve is seen at the patient's mouth, it starts getting a little harder to push the device forward. That is expected – because the proximal end of the balloon is the widest part and as it passes through the upper esophageal sphincter - the valve reaches the patients mouth. You need to torque right and left and gently push forward with the patient's neck hyperextended.
- As per the instructions, once you retroflex the endoscope and confirm that the balloon has passed into the stomach, you straighten the scope and commence inflation. Keep the scope straight while inflating.
- PLEASE DO NOT REPEAT RETROFLEXING TO GET A VIEW OF THE BALLOON DURING THE INFLATION!!!
- This can change the position of the valve and cause a kink in the inflation tube.
- THE NURSE SHOULD REPORT IF THERE IS ANY DIFFICULTY IN INFLATION.
- If this happens,
 - 1) STOP INFLATION IMMEDIATELY
 - 2) push the endoscope forward 5-10 cm
 - 3) resume inflation
- If it is still difficult, repeat steps 1,2 and 3.
- Training the nurse to be aware of the pressure that is normally felt on the syringe is vital to a successful procedure
- Inflate to 500 cc.
- GERD patients may need 400-450 cc
-

Post Procedure- Acute Follow Up

- Intravenous Hydration
 - Please give at least 1 liter before discharge
- Medications
 - Anti-nausea/vomiting – 2 possible regimens:
 - Best Regimen** {
 - Emend (Aprepitant) 125 mg PO 2 hours before the procedure and then 80 mg daily for the next 2 days
 - +
 - Zofran 8 mg QID
 - OR**
 - Take the following starting immediately after the procedure. DO NOT WAIT FOR THE NAUSEA TO START. **Take both the Zofran and Haloperidol**
 - Zofran 8 mg QID **NOT prn**
 - Haloperidol 3-5 mg BID **NOT prn** (works synergistically with Zofran)
 - (Metoclopramide 10 mg QID prn as a substitute for Zofran, but it really does not work)
 - Anti-spasmodic
 - Buscopan QID prn
- Phone call follow up by office/clinic staff
 - # of vomiting episodes – any bleeding?
 - Abdominal pain
 - Abdominal spasms that last < 10 seconds each but recur frequently
 - Hot water bottle may help!!
 - Signs/symptoms of dehydration
 - Teach them to look for concentration of urine
 - Assure that they are taking medications
 - call patients daily for the first 4-6 days
 - weekly for the next 2 weeks (monthly thereafter)
- Oral intake

- The first night is difficult with the onset of nausea(90%), vomiting(20%) and stomach pains/spasms (20%) approximately 2-8 hours after the procedure (usually 6 hours after)
- The next 2-3 days will be difficult with nausea in 90% and vomiting in 20% (3 to 20 vomiting episodes if not taking Emend, but it should decrease over the following 3 days)
- As such, don't expect to drink too much fluid
 - ½ cup of water every 1- 2 hours is a reasonable place to start
 - Every patient is different and they should push forward at their own pace

Post Procedure- Chronic Follow Up

- assure that they avoid NSAIDs, alcohol and they are taking PPI daily
- renewed onset of symptoms suggests a problem and needs evaluation (office visit, x-ray, ? endoscopy)
 - maybe they are eating too much or maybe their balloon migrated to the distal antrum
 - some patients do better sleeping with the left side down
- For recurrent nausea or reflux
 - Adjust diet
 - Avoid any and all PO ingestion 3-4 hours before sleep
 - Add antacids or increase PPI to BID
 - Add metoclopramide
- Diarrhea > 3-4 times daily (20% of patients)
 - May be due to bacterial overgrowth
 - Treat with Metronidazole 500 mg TID X 5days
 - Improves after the first day (make sure they complete 5 days)
 - May recur 1-3 times during year
- Burps or belching – **VERY COMMON**
 - Always due to air swallowing
 - Patients swallow saliva to relieve stomach discomfort
 - An air bubble accompanies the saliva
 - Usually a sign of overeating and/or balloon intolerance
- Follow up with dietician/nutritionist monthly
- CBT therapy by psychologist is effective for many

- Some patients that experience minor symptoms such as bloating, fullness, belching are under the false impression that it will not get any worse – so they continue to eat more than they should. PLEASE EXPLAIN TO THEM THAT CONTINUED MINOR SYMPTOMS WILL EVENTUALLY TURN INTO SEVERE SYMPTOMS THAT MAY REQUIRE BALLOON REMOVAL PREMATURELY.

Diet

The dietician should provide dietary instruction to the patient prior to the procedure. The days after the procedure will be difficult – do not expect much oral intake.

Here is a several stage diet that you can use. Remember – each patient advances at their own pace.

Dietary Guidelines after the Balloon procedure

Dear patient ,

The procedure you went through is your first step in weight loss and good health. Adaptation to the new situation requires patience and forbearance.

Return to normal eating is done in stages. The progress from stage to stage is ultimately personal.

Stage A: liquids: 1-7 days after the Balloon procedure:

On the first day: one glass of water every hour (divided by a quarter to half a cup each time) later in the day also weak tea.

On the second day: You can add broth (chicken cooked with vegetables and oil - filtered) pure juices: grape apple pear, etc..

On the third day : You can add a drink of milk, coffee (recommended on the basis of milk), fruit and vegetable juices filtered, jelly, liquid yogurts without pieces of fruit, no carbonated drinks

Important rules for this stage:

1. Be sure to drink in the first days at room temperature not too hot nor too cold.
2. Do not drink more than a quarter to half a cup at a time.
3. Make sure to drink slowly in small sips and avoid swallowing air while drinking (do not drink with straw).
4. Do not drink carbonated beverages.
5. Make sure to drink 10 cups of fluids throughout the day.
6. To get enough calories and protein it's recommended to keep most of the drinking based **on dairy products**.
7. Make sure to add one tablespoon a day of good fats like olive oil or canola oil, tahini or avocado - to provide essential fatty acids and prevent complications.

Example of daily routine days 3 -7 :

8:00 a cup of coffee on a half cup milk, ½ cup water

9:00 1 / 2 cup of yogurt Bio 3% or 3 tablespoons cream cheese 3%

10:00 clear juice

11:00 a glass of water

12:00 1 cup of broth (chicken cooked with vegetables and oil - filtered)+1 teaspoon of olive oil

13:00 a glass of water

14:00 a cup of coffee with half cup of milk

15:00 1 / 2 cup of yogurt or white cheese 3%

16:00 a glass of water

17:00 clear juice

18:00 1 cup of broth +1 teaspoon olive oil

19:00 a glass of water

20:00 3 teaspoons of cream cheese or cottage 3%

21:00 a glass of water

Stage B – Blender / soft diet 7-14 days after the Balloon

procedure

In addition to foods you drank or ate at stage A , gradually add the following foods in the following order:

1. Soft white cheese or cottage 3% / tahini or hummus (preferably low fat) guacamole (mashed well) , Oatmeal based on rice flour or corn flour.
2. Egg - after 12-11 days, soft or hardboiled egg mashed in a blender, Moss tuna (tuna in a blender with some olive oil / tahini / avocado or mayonnaise 5%).
3. Purees of vegetables and fruit without seeds, cooked and peeled and ground (zucchini squash, carrot, banana ,apple, pear) Peeled tomato, crushed in a blender (or mix with a teaspoon of olive oil - can help if constipation appears)
4. Fish / chicken (no skin) / turkey - After 8-9 days, ground in a blender .

Important rules for this stage:

1. The Progress at this stage should be gradual - a new food every day.

If after adding a certain food you do not feel well (pain or suffocation, etc.) stop it and try it again a few more days.

2. it's recommended to start with 2 tablespoons of food several times a day and increase gradually the amount by personal feeling.
3. Keep on chewing slowly. Each meal should take 20-30 minutes at least
4. Check how you feel during meal time and stop after a few tablespoons according to how you feel.
5. Be sure to drink throughout the day 8-10 glasses of fluids (to prevent constipation).
6. Continue to take 1 multivitamin each day.
7. It is important to eat a small meal every 2-4 hours. Do not get hungry before meals to avoid eating fast or too much.
8. Make sure to keep proper eating habits: eating and sitting at a table without doing another activity (like watching TV).
9. At this stage it is important to avoid drinking sweetened drinks or high-fat foods that can

cause obesity or prevent a decrease in weight.

10. It is important to include protein in every meal.

**Feeling of pressure or choking in the chest area usually indicates a large amount of eating or eating too fast. In this situation stop eating and do a little walking. The feeling will pass within 10 - 15 min. next time you try to eat less and slower.

Example of daily routine days 7-14 :

07:00 a cup of coffee with 1/2 cup of milk, sugar-free .

8:00 **Breakfast:** porridge based on milk or 2-3 tablespoons of white cheese 3% + soft-boiled egg, tomato.

1 glass of water

10:00 1 cup of Bio yogurt 3% without fruit + fruit puree

a glass of water

13:00 **Lunch:** soup ground in a blender containing 50 grams of chicken / turkey cooked + carrot, pumpkin, zucchini or Carrot + Potato + teaspoon of oil. We recommend this meal to eat twice a day.

15:00 ½ cup orange juice / grapefruit juice or vegetable juice

a glass of water

17:00: 2 tablespoons of tuna or boiled egg or 2 tablespoons of white cheese + 1tsp of tahini.

a glass of water / cup of coffee and milk based

19:30 **dinner:** 2 teaspoons avocado, yogurt bio 3% or as lunch or morning

a glass of water, 1 / 2 cup juice

21:00 **Night:** yogurt

Stage C - soft diet (not ground) 14 -21 days after the procedure

The transition to this phase is only if you manage with stage B .

it should be gradual and carefully, according to the following order:

1. Meatballs (beef chicken turkey or fish), cooked - mashed with a fork, bolognese, fish- cooked or baked and later on also soft and well-cooked chicken .

2. Cooked noodles or and later well-cooked rice.
3. Cooked vegetables, peeled and mashed with a fork and fruit peeled, soft, without seeds.
4. bread or toast and cereal not sweetened.
5. Fresh fruit and vegetables peeled, without seeds, chopped (tomato, cucumber and soft peach pear)
6. It's recommended to add only one new food each day.

Important rules for this stage:

1. Continue chewing and eating slowly.
2. Eat calmly and orderly. Do not get nervous or too hungry before meals.
3. Each meal should be eaten in stages: first drinking, then eating raw or fresh vegetables, eating protein and finally eating carbohydrates
4. it's recommended to keep eating in small volumes of food to avoid feeling pressure and nausea. If you feel such feelings it's important to reduce the size of the meal.
5. Keep 3-4 hours between meals.
6. Keep on drinking water 8-10 glasses throughout the day.
7. Continue to take a multivitamin - one each day.

Example of daily routine – days 14-21 :

07:00 a cup of coffee with 1/2 cup of milk, sugar-free

8:00 **Breakfast:** 1 glass of water , 1/ 2 vegetable + tuna or egg + 1 slice of toast + 1 spoon of avocado or tahini,

10:00 1 cup of yogurt bio 3%without fruit

1 glass of water

13:30 **Lunch:** Sugar Free Drinks

2 tablespoons cooked vegetables or vegetables soup or fresh vegetables

+ 1-2 meatballs chicken / fish / meat not fried

+ 2 tablespoons of rice / noodles / mashed potatoes / small potato

16:30 fresh fruit or yogurt or 1 slice of toast +1 tablespoon of white cheese / tahini / hummus

drinks: a glass of water / cup of coffee with milk

19:30 **Dinner** : Drinks – sugar free

1-2 fresh vegetable+ 2 tablespoons with cottage 3% or 1 slice of yellow cheese 9% or 2 tablespoons of tuna + 2-3 cracker or a slice of toast

21:00 **Night**: yogurt 3% + 2 tablespoons of cornflakes

3 -4 weeks after the procedure:

You can gradually return to normal eating with good chewing and eating slowly in small amounts at a time.

At this time it's important to start gradually exercise –like walking. Maintaining regular physical activity is important from now on and will help you to achieve normal weight.

It's Recommended 150-200 minutes per week: 3-4 times 45-50 minutes

Important rules for all to process (in addition to all the rules mentioned so far)

1. Throughout the entire process you should be in follow up by the dietician. The purpose of this follow up is to support and assist in solving problems that can occur after the procedure and allow weight loss at your own rate.
2. It's very important to be attentive to the stomach and not to the head and to pay attention to the sense of hunger - satiation. Stop eating when satiated.
3. Planning - This is the key in the process of weight loss.

When you are away from home be sure to take a light meal such as a fruit / sandwich / energy bar/ yogurt

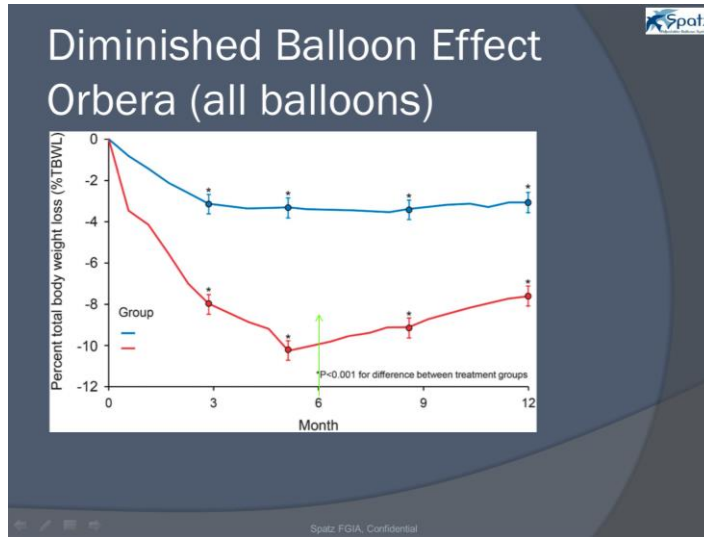
4. Avoidance or reduction of eating fatty foods and high sugar and calories that will prevent the desired weight loss (sweet drinks, milkshake ,fat ice cream ,chocolate cookies, etc.)

5. Maintaining a balanced and varied menu containing all food groups (vegetables , protein, carbohydrates, fat, vitamins and minerals).

Protein must be a part of every meal.

Balloon Volume Adjustments

- Adjustments can be performed more than once or twice
 - **For intolerance**
 - Give the patient lots of encouragement in the first days after implantation – most will **not** need to adjust downward in the first week.
 - Have the patient note the number of vomiting episodes per 24 hours. If they have vomited 10 times on day 1, and 6 times on day 2, and 4 times on day 3 – they are getting better and will be able to avoid a downward adjustment. They may not realize this – so be sure to quantify the episodes each day.
 - If you need to do a downward adjustment
 - Remove 150 cc. They generally feel better right after the procedure
 - Remove 100 cc if the balloon started with 400 cc
 - Some patients are so miserable that they refuse a downward adjustment and insist on balloon extraction.
 - Try to persuade them to undergo an adjustment, and if they are not better within 1 hour after the adjustment – you will promise to remove the balloon. It works almost every time!
 - **For weight loss plateau/loss of balloon effect**
 - **Why do we need to up adjust?**



- - As the graph illustrates – on average patients with IGBs begin to regain weight at month 4-5 while their balloon is still implanted. That’s because the balloon effect wears off. The purpose of up adjustment is to prevent weight regain after 4-5 months.
 - Our experience has taught us that adding 100-200 cc to the balloon does not help most people.
 - Generally, an additional 300 cc is required
 - Patients with controlled GE Reflux during balloon life should get 200 cc
 - If GE reflux uncontrolled , Do not adjust upward
 - If they had a down adjustment: up adjust no earlier than 3-4 months after the down adjust, and add whatever you took out plus another 50 ml. (if they had 150 ml removed , then add 200 ml no earlier than 3-4 months after down adjustment)
- Be prepared for increased GE reflux after upward adjustment
 - Be ready to add the following at the onset of reflux (**DO NOT DELAY**)
 - Add metoclopramide
 - Increase PPI to BID
 - Add antacids prn
 - May need sucralfate suspension (or tablet dissolved in ¼ cup H₂O – PO QID
- How much weight do patients lose after up adjustment?
 - Studies have reported additional mean weight loss of 4.5, 7.4, and 9.3 kg in different publications after the up adjustment.

- Let your patients know that the up adjustment is meant to rejuvenate the balloon effect and to prevent weight regain. So additional weight loss of only 3-4 kg should not be disappointing to patients.