The Swallowable Balloon – Professional treatment of obesity or preventive lifestyle intervention that anyone can apply

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SRI AUROBINDO UNIVERSITY

VISION WITH ACTION

INDORE, INDIA

MOHAK BARIATRIC AND ROBOTIC SURGERY CENTER INDORE, INDIA (MBRSC)

MOHAK BARIATRICS ROBOTICS WEIGHT LOSS & DIABETES SURGERY CENTRE

IFSO NAPOLI 2023

DISCLOSURE

Mohit Bhandari MD

Consultant to:

- Johnson and Johnson
- Medtronic
- Bariatric Solution
- Intuitive Surgical
- Karl Storz
- Stryker
- Apollo Endo-surgery
- Pentax
- Olympus

Mathias Fobi MD FACS, FICS, FACN

- Founding President, Bariatec Corporation

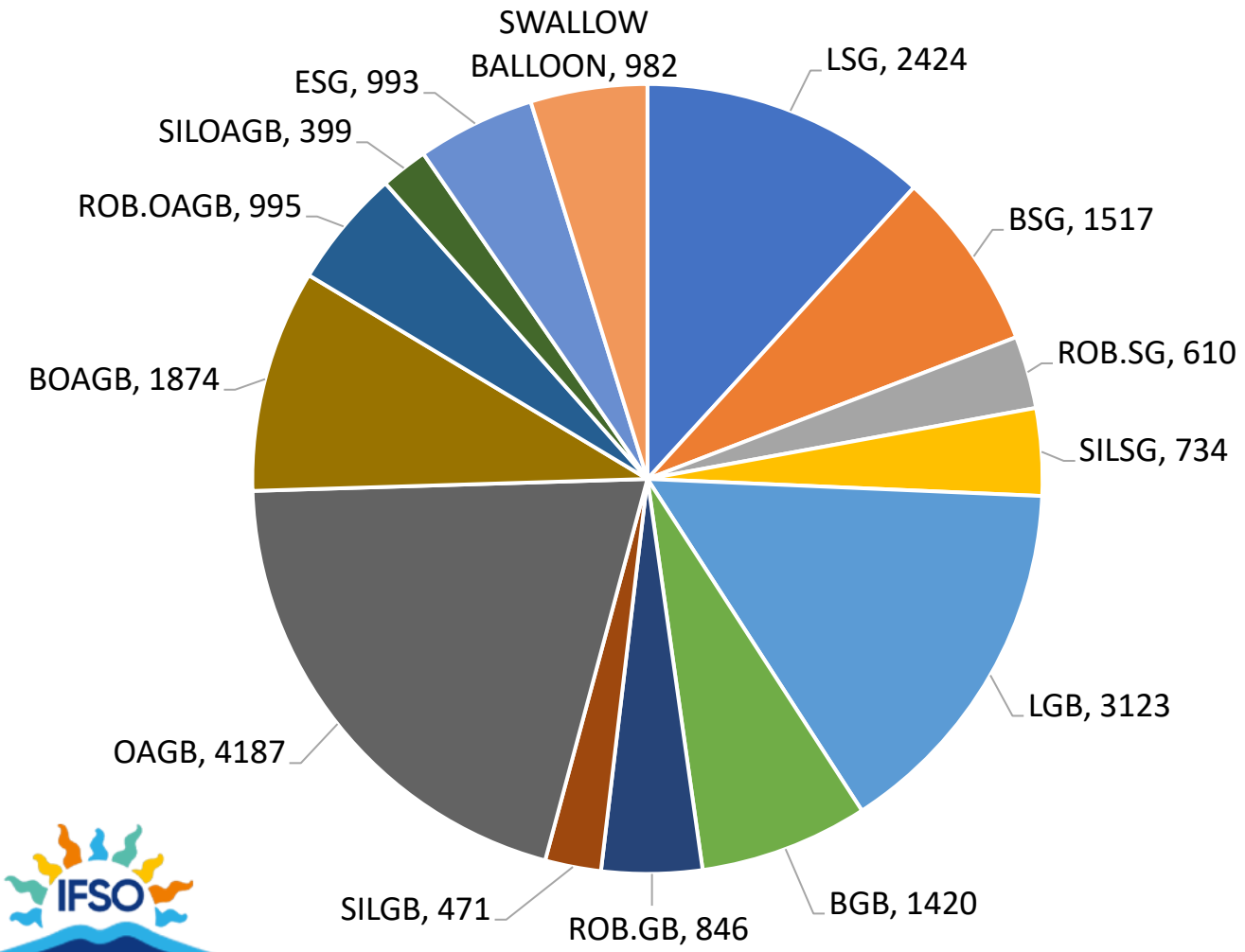
Manoel Galvao Neto

- Director Bariatric Endoscopy

BARIATRIC PROCEDURES MIX DISCLOSURES MBRSC
January 2010 – July 2023

CASE MIX DISCLOSURE
2010- 2023

TOTAL	22080
LSG	5285
LGB	5860
OAGB	7455
ESG	993
SWALLOW BALLOON	982
Other	1505



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Dr Manoel Galvao Neto

Clinical Director- Dept Bariatric Endoscopy

Mohak Bariatric and Robotic Surgery Center

Indore- Mumbai- Hyderabad- Bangaluru

Some hard facts we should know

- Obesity is a chronic disease
- It is the most re calcitrant disease on earth
- It has the power to fight back with double the thrust
- It is like a malignancy
- We are still pondering over with many medications going and coming by ands almost a 50 plus different metabolic bariatric procedures .
- Are we aware of one final treatment of choice for obesity
- Are we looking at some path breaking research in the field of obesity where upon we look ar some substantial remission period of 25 plus years.

Let's look at the patient behavior

Only 1% of patients who deserve a bariatrics surgery get it done.

85% patients do not give a consent to disclose that they had a weight loss surgery.

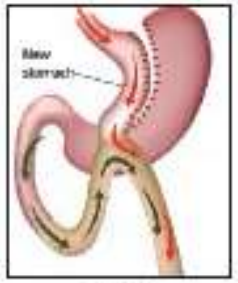
92% of patients who underwent bariatrics surgery do not want to disclose it anonymity.

85% of patients who underwent a surgery are giving opinion that they would have undergone a nonsurgical weight loss method if they had known about it

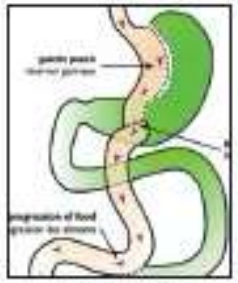
10% of total weight loss is good enough to give patients resolution of their comorbidities associated with Obesity.

Gastric Bypass

Banded Gastric Bypass



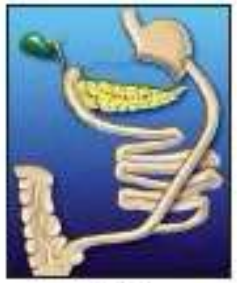
MGB



Diverted OAGB/MGB

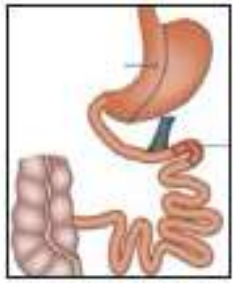
Banded OAGB/MGB

BPD-DS



BPD

DJ Bypass

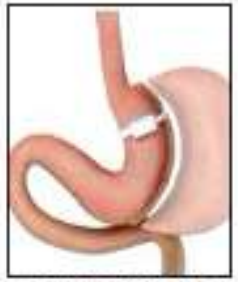


Ilei Interposition

Gastric Plication

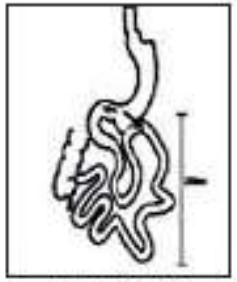
Banded Gastric Plication

Sleeve Gastrectomy

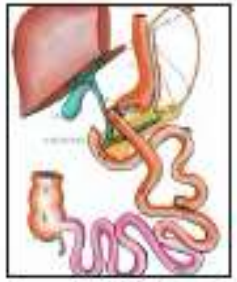


Banded Sleeve Gastrectomy

Endoscopic Sleeve Gastroplasty

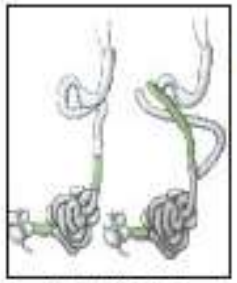


SG with BP Jejunostomy



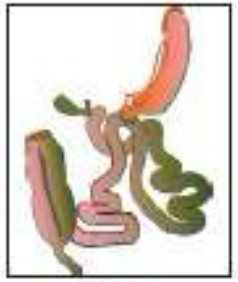
SG with RY DJB

SG with loop DJB



SG with Ileal Interpostion

SG with Enteral Bypass



SADI

SG with Jejuno-Ileal Anastomosis bypass

SASI

SAGI (Single Anastomosis Gastro Ileal)

Intragastric Ballon

V Bloc

Aspire Assist

Endo-Barrier

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There is whole new treasure

Why people may prefer swallow balloons

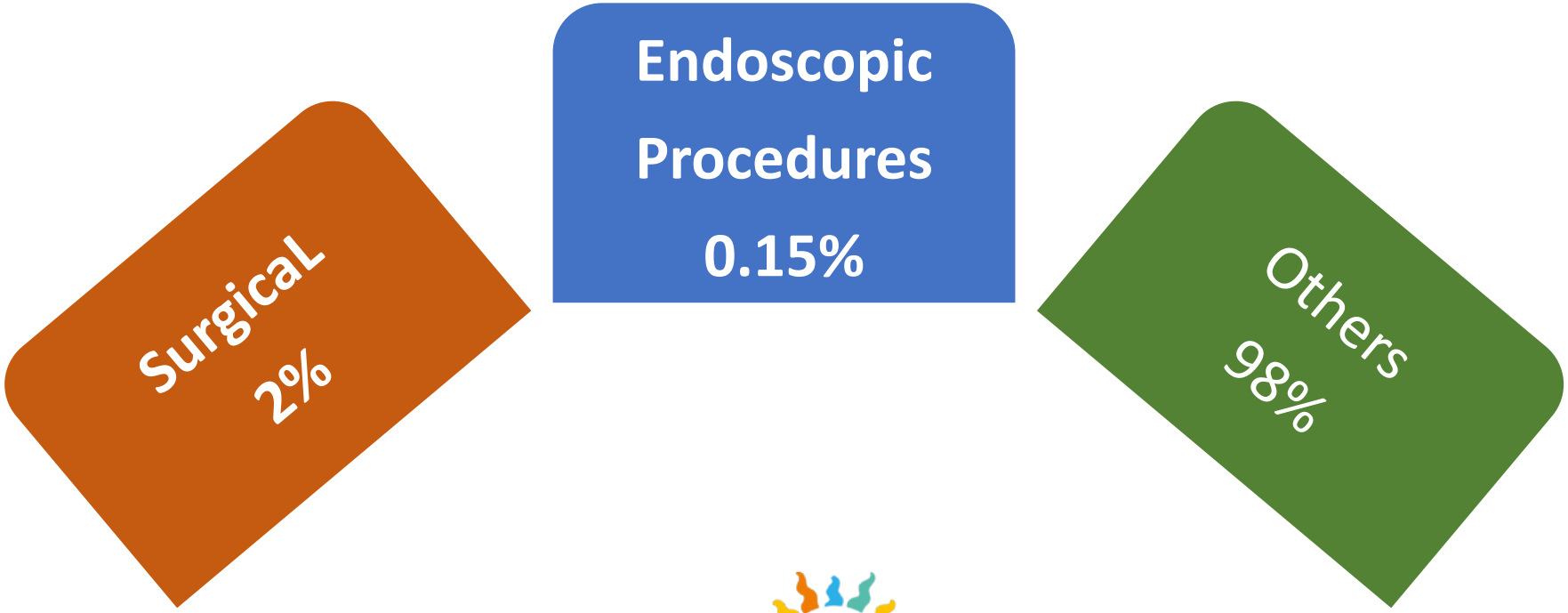
1. **Less Invasive:** Balloon placement is a less invasive procedure than weight loss surgery. It doesn't involve major surgery, incisions, or alteration of the digestive tract.
2. **Temporary:** Balloons are typically temporary and can be removed after a few months, whereas weight loss surgery is often permanent and involves significant changes to the digestive system.
3. **Lower Risk:** The risks associated with intragastric balloons are generally lower than those of weight loss surgery. Surgical procedures can have complications and longer recovery times.
4. **Reversible:** Since balloons are temporary, they offer reversibility. If a person experiences adverse effects or isn't satisfied with the results, the balloon can be removed.
5. **Minimal Lifestyle Changes:** Balloon placement often requires less drastic lifestyle changes compared to surgery. Patients still need to make dietary and lifestyle adjustments, but these may be less extensive.
6. **Risk:** No risk of general anaesthesia

What the patient wants ?

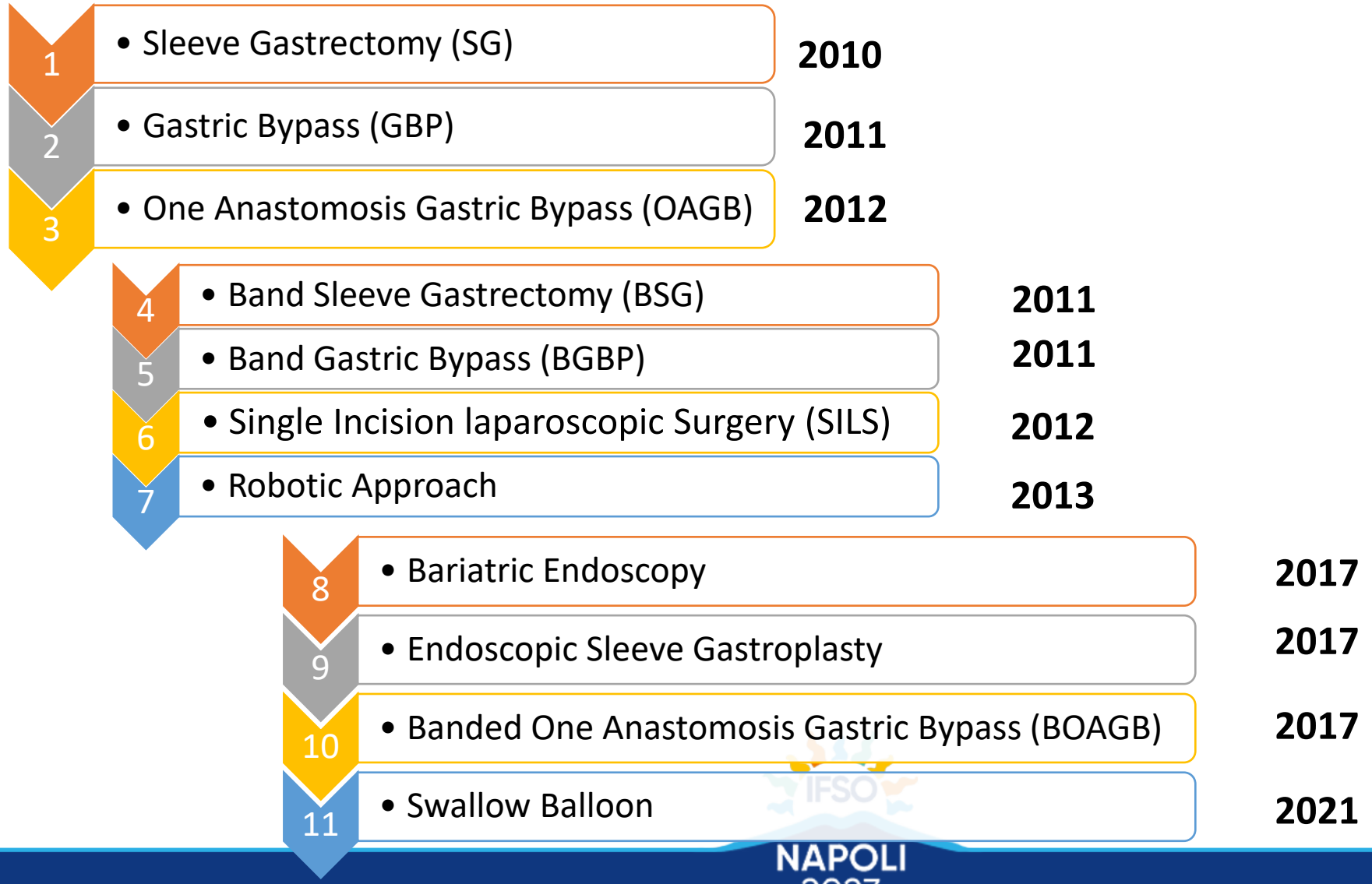
- Confidentiality
- Discreteness
- Safety
- Something Non surgical
- No hospital admission
- Out patient procedure
- No surgery ,no anesthesia ,no endoscopy

FUTURE TRENDS FOR OBESITY & DIABETES

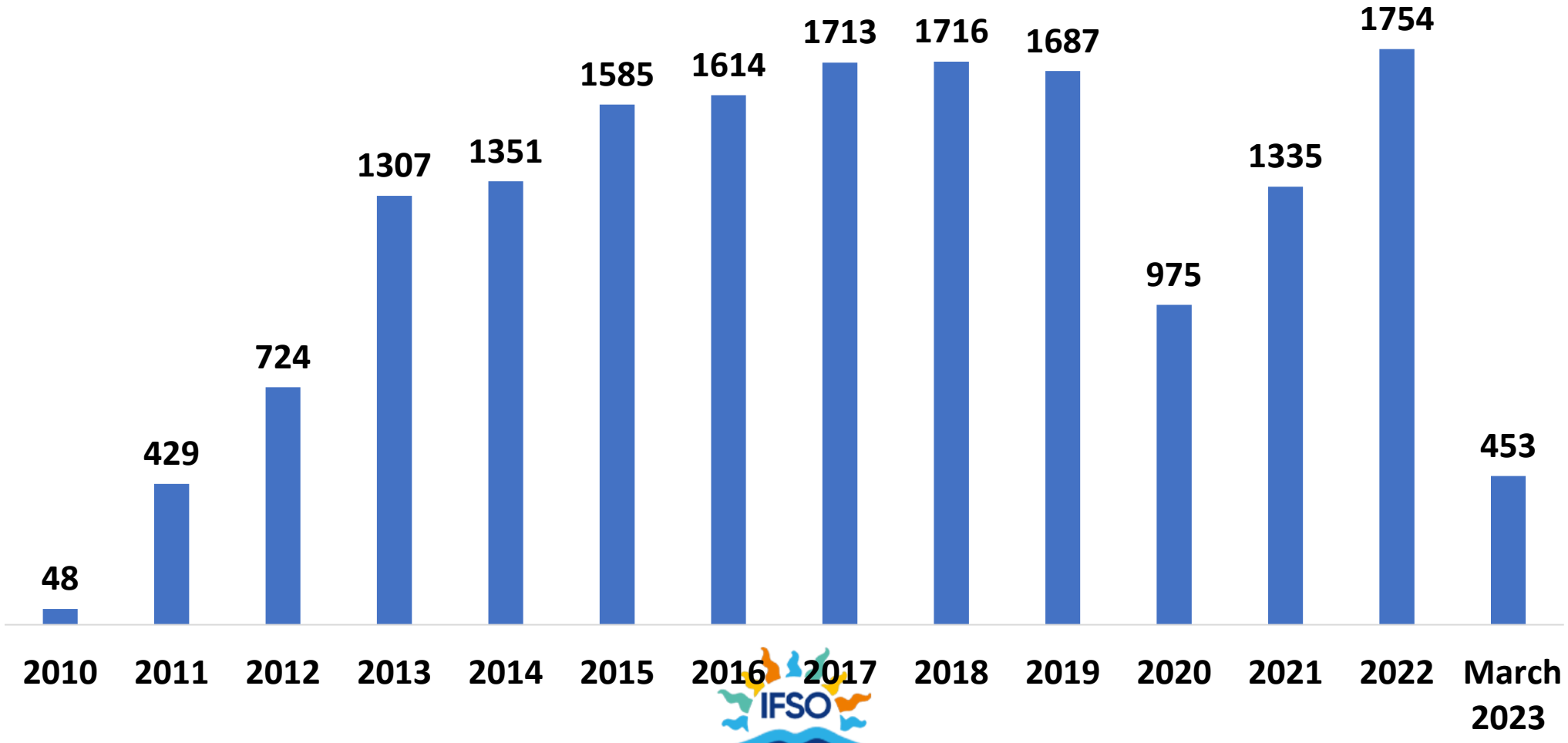
METABOLIC BARIATRIC SURGERY



Planned and Metered growth of the MOHAK program



Progression from 48 cases to 1400 cases A Year



What options do we have?

- Exercise is a big no for just weight loss
- Lifestyle modification –Oh yes!!!
- But what if this fails ???
- Surgery ???

- Some other solution !!!!!!!

ALLURION BALLOON

- The **Allurion Balloon** is the first swallowable gastric balloon that requires no surgery, endoscopy*, or anaesthesia – allowing the patient to remain conscious throughout the procedure.
- The soft balloon is designed to help you reduce your food intake by taking up space in your stomach, much like the intragastric balloon.
- This helps to create a feeling of fullness, and a decrease in hunger levels leads to lesser consumption during mealtimes, resulting in weight loss.

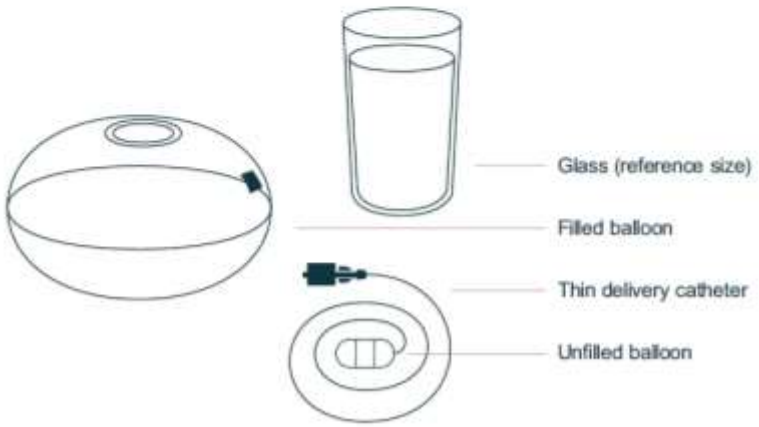
According to the IFSO global registry, the number of surgical procedures has stagnated over the last 5 years. The type of surgeries have changed but the overall number remains stagnant with no major increase.

- Throughout the last decade, the treatment of obesity has slowly undergone a paradigm shift.
- The advent of Swallow Balloon Process has had a profound impact on long-term weight management.

INTRODUCING THE ALLURION SWALLOW CAPSULE WITH PROGRAM

How?

Gastric balloons induce weight-loss by increasing satiety (fullness), delaying gastric emptying, and reducing the amount of food eaten at each meal.



15 MIN

The Elipse Swallow Pill experience takes place during a brief 15-minute walk-in placement.

No surgery.
No endoscopy.
No anesthesia.
Just results.

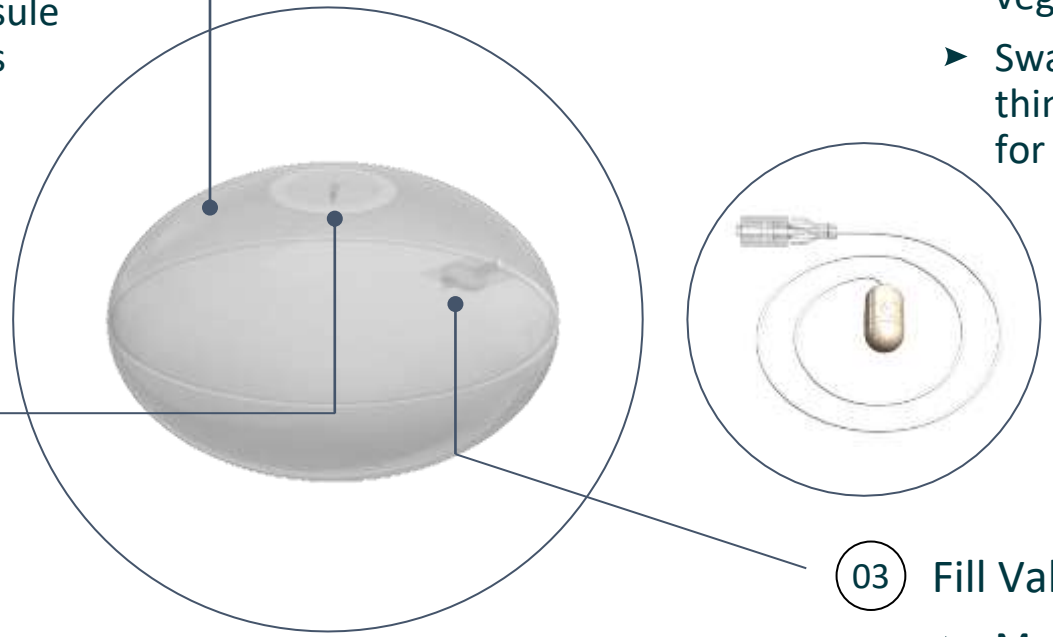
Swallow Balloon

01 Balloon Film

- Much thinner than silicone balloons
- Flexible enough to fold into a capsule and, at end of therapy, safely pass through the GI tract
- Durable enough to spend months in the stomach

02 Swallowing

- Balloon is rolled into a vegan capsule
- Swallowed along with a thin Delivery Catheter for filling

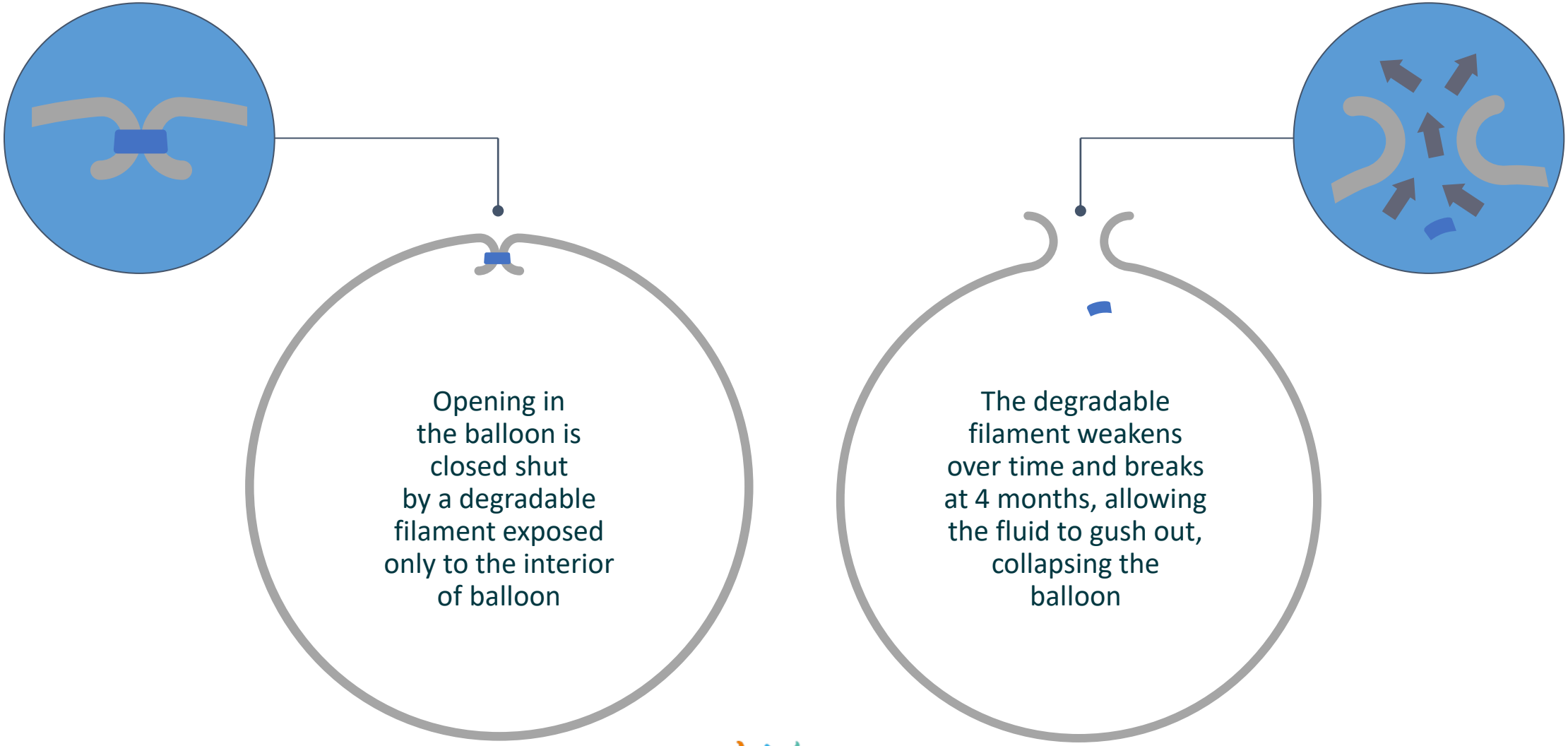


04 Release Valve

- Made from thin film with a hole, closed shut by a degradable filament
- Exposed only to the constant environment inside the device
- Filament weakens over time, then breaks and opens the hole allowing the balloon to empty at a pre-determined time

03 Fill Valve

- Made entirely from thin film
- Seals shut after Delivery Catheter is pulled out


Opening in the balloon is closed shut by a degradable filament exposed only to the interior of balloon
The degradable filament weakens over time and breaks at 4 months, allowing the fluid to gush out, collapsing the balloon

The Revolutionary Allurion Balloon

A best-in-class consumer experience from start to finish with the world's first and only procedureless weight loss device. All in just a 15 minute office visit.

01 - Swallow

The Allurion Balloon is swallowed in a capsule

02 - Fill

Once in the stomach, the Allurion Balloon is filled with 550ml of liquid

03 - Disappear

16 weeks later, the Allurion Balloon self-empties through our patented ReleaseValve™ and passes naturally

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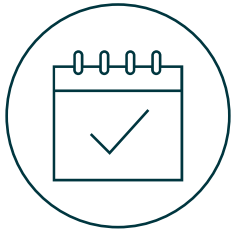
The Allurion program is more than just a balloon

Program Overview

Month 1

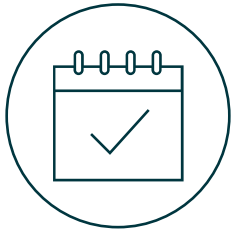
Meet the team,
kick off nutritional
and exercise coaching



Month 2-5

The Allurion program helps you maintain a low-calorie diet as you lose weight;

Your team guides food and exercise behavior change



Month 6

After balloon passage, support from your team continues

The Allurion Weight Loss Program

An integrated, commercially proven experience that combines a revolutionary medical device, cutting-edge digital therapeutic, and nutritional program

The Allurion Balloon

The world's first and only procedureless™ weight loss device

No surgery, endoscopy, anesthesia

Delivered in 15 minutes

Covered by over 40 patents

The Virtual Care Suite

A Suite of tools for your patients: the Allurion App, Connected Scale, and Health Tracker Watch

A Suite of tools for you: the Allurion Assurance Plus Warranty, Clinic Dashboard, Allurion Insights, and comprehensive training and patient selection tools

Nutrition & behavior change program

Customized support for healthy and effective long-term behavior change

Teaches lifestyle modification strategies to lose weight while feeling full

Difficulty swallowing	Predisposition to bowel obstruction	Predisposition to gastric perforation	GI bleeding	Other conditions
Esophageal motility disorder	Crohn's disease	Previous bariatric, gastric, or esophageal surgery	History of vascular lesions	Eating disorders
Structural esophageal abnormality	History of bowel obstruction or small bowel surgery	Laparoscopic band ligation	Recent history of inflammatory conditions, including gastric ulcers	Pancreatitis
	Perforated abdominal viscus	Anti-reflux surgery	Liver cirrhosis, coagulopathy, or anticoagulants	Pregnant or nursing
				Cancer

For a complete list of contraindications, consult the Instructions for Use (IFU)

Managing patient expectations

The Allurion Balloon is not a magic bullet

- ✓ Set and agree to reasonable weight loss-expectations
- ✓ Create a custom-made follow up plan that is based on patient needs
- ✓ Remind patients about the symptoms – many do not experience any and there are a variety of responses to the balloon
- ✓ Direct patients as to when they should contact their physician
- ✓ Detail medical therapies to manage symptoms
- ✓ Communicate that compliance to the follow-up program is crucial
- ✓ Ensure access to medical care in the event of an emergency...one contact number is essential

Placement day preparation

The day before placement:

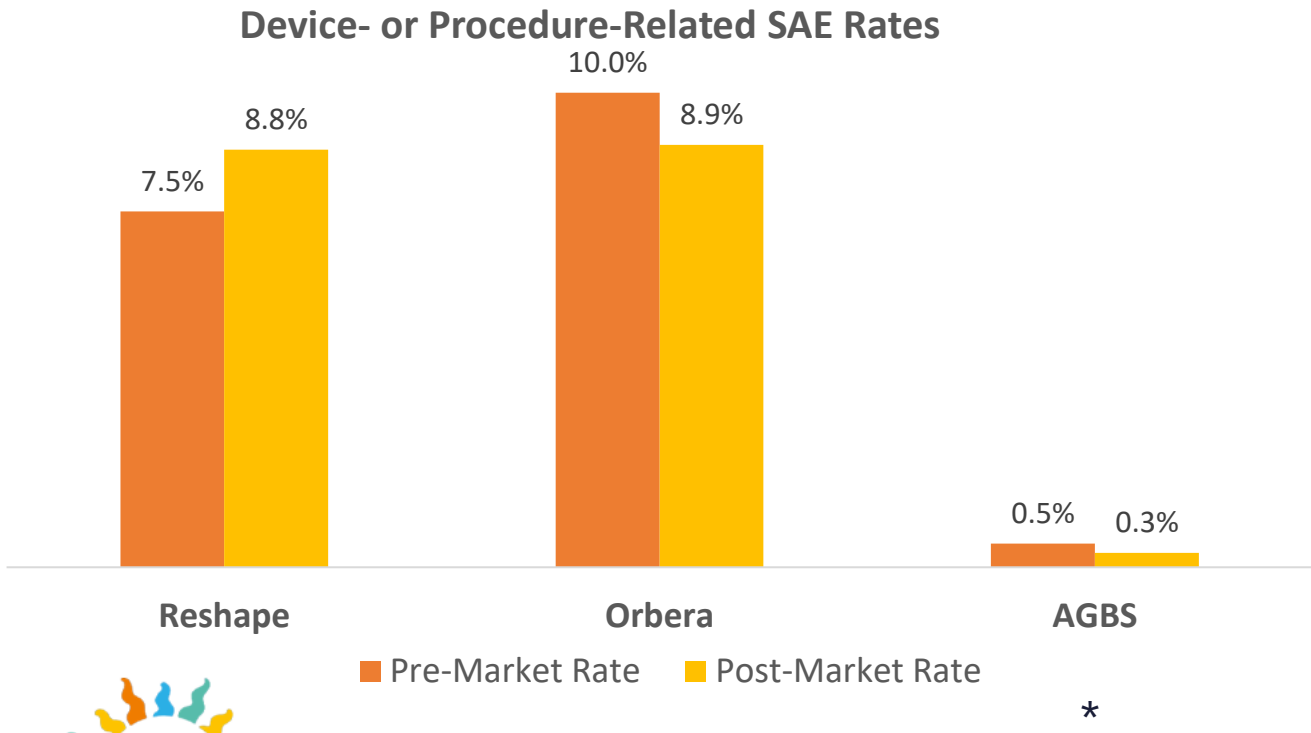
- Drink fluids and be well hydrated before placement (this helps to cope with reduced intake for the first few days)
- Take medications as prescribed
- Patients can have a light dinner the day before if placement is the next morning

Day of placement:

- Consume only clear liquids 8 hours prior to placement (for example; water, strained clear consommé or soup, herbal teas, diluted juice)*
- Stop all clear liquids 2 hours prior to placement (in order to reduce risk of vomiting)

ENLIGHTEN study and post market study demonstrated that Allurion is 93-95% safer than other liquid filled balloons

- Allurion Balloon does not require Endoscopy or Anesthesia for either placement or removal, hence eliminating two high risk procedures and the risks of anesthesia.
- Allurion Balloon has a malleable polyurethane design vs. rigid silicone design of Orbera & ReShape.



*

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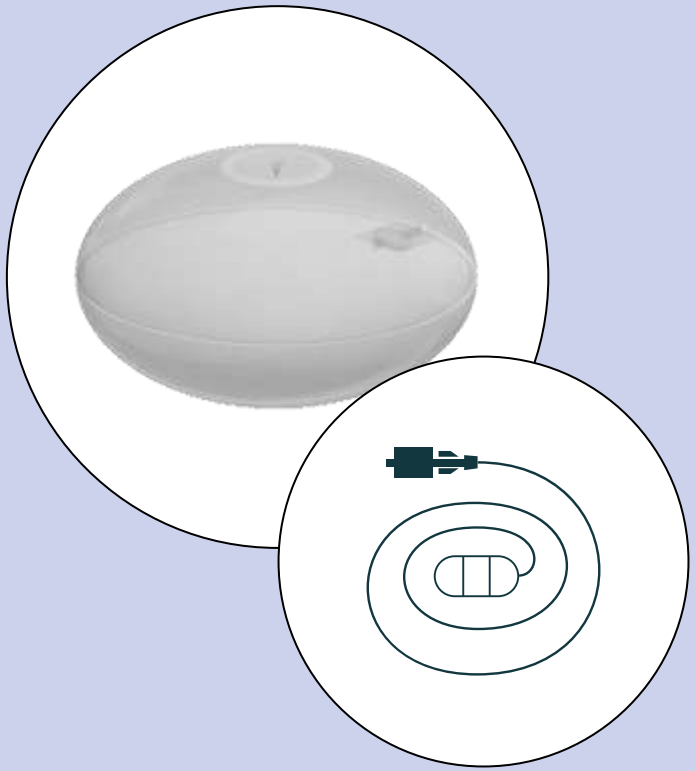
Symptoms related to balloons are NORMAL and EXPECTED

Common:

- Nausea
- Vomiting
- Abdominal pain
- Abdominal cramps
- Esophageal reflux

Uncommon:

- Chest pain
- Constipation
- Diarrhea
- Fatigue



Note:
Many patients have no symptoms at all

Suggested medication schedule*

Pre-placement

01 **Oral PPI for 1-2 weeks** (Omeprazole 40 mg OD or 20 mg BID)

02 **Anxiolytic, if necessary, the night before placement** (Ativan 1-2 mg PO BID or Xanax 0.25-0.5 mg TID or similar medications)

Day of placement

03 **Antiemetic** (a and b, OR c)

a. Zofran 8 mg PO/SL QID for at least 24 hours and up to 3-4 days
b. Emend 125 mg the morning of placement and 80 mg OD on the 2nd and 3rd day
c. Akynzeo, if available, as a single pill the morning of placement

04 **Antispasmotic** (a or b)

a. Buscopan, only if needed for severe cramps, one pill as needed every 6 hours, up to 4 times per 24 hours
b. Levsin, only if needed for severe cramps, 0.125-0.25 mg SL or PO, up to 6 doses per 24 hours

Post-placement

05 **Oral PPI throughout balloon residence** Omeprazole 40 mg OD or 20 mg BID…switch to different PPI if patient has diarrhea

*Note: These drugs may not be indicated for this specific use

Papademetriou and Popov. Gastrointest Endoscopy Clin N Am. 2017; 27:245-56.
Machytka et al. Endoscopy. 2017; 49:154-60.
Ienca R, et al. Obes Surg. 2019;29(9):2952-2956.

Post-placement practices: Advice during balloon passage

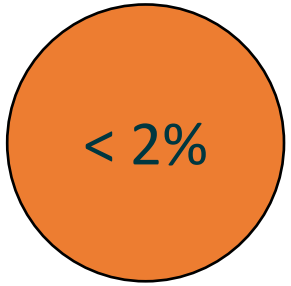
- ✓ The balloon is designed to empty and pass in **approximately** 16 weeks, but can pass a couple of weeks earlier or later
- ✓ Patient may have mild cramps and occasional diarrhea at the time of balloon passage
- ✓ Rarely, as the balloon is emptying, if the patient simultaneously eats a heavy meal, the near empty balloon may get temporarily wedged at the pylorus and stimulate vomiting. Occasionally, included in the vomitus is also the empty, or nearly empty balloon.
- ✓ Although vomiting of the empty balloon may be startling to the patient, it has not been associated with any adverse events.

Adverse Events

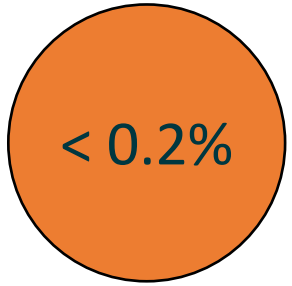
- Early deflation
- Intolerance
- Dehydration
- Esophageal obstruction
- Gastric dilation
- Gastric outlet obstruction
- Gastritis
- Gastric or Duodenal Ulceration
- GI Bleeding
- Gastric perforation
- Pancreatitis
- Hyperinflation
- Small bowel obstruction or perforation
- Pulmonary aspiration
- Infection
- Death

Important notes:
Vomiting of the empty balloon at the end of residence in 1-2% of patients is normal

Total adverse Event Rate is

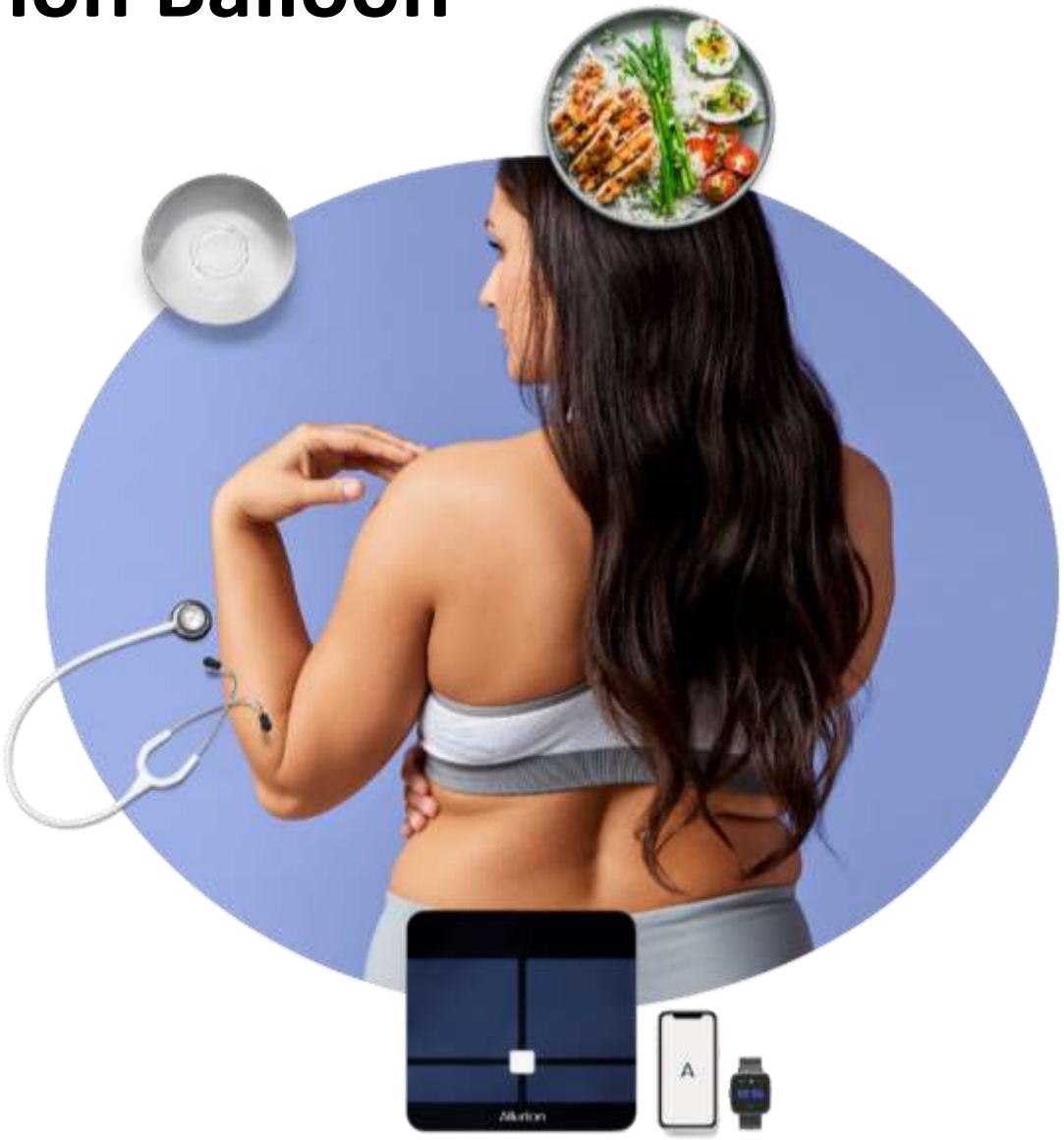


Serious Adverse Event (SAE) rate is



Profile of Patient Receiving an Allurion Balloon

- Average Age of Allurion Patient: 40 years
- Average BMI of Allurion patient: 35 mg/kg^2
- Average Sex Distribution: Female 70%, Male 30%
- Cancer is a contraindication
- Smoking is not a contraindication



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THE SCIENCE BEHIND BALLOONS

Obesity Surgery (2020) 30:3354–3362
https://doi.org/10.1007/s11695-020-04539-8

ORIGINAL CONTRIBUTIONS

The Procedureless Elipse Gastric Balloon Program: Multicenter Experience in 1770 Consecutive Patients

R. Ienca[1] · Mohammed Al Jarallah[2] · Adelardo Caballero[3] · Cristiano Giardiello[4] · Michele Rosa[5] · Sébastien Kolmer[6] · Hugues Sebbag[7] · Julie Hansoulle[8] · Giovanni Quartararo[9] · Sophie Al Samman Zouaghi[10] · Girish Juneja[11] · Sébastien Murcia[12] · Roman Turro[13] · Alberto Pagan[14] · Faruq Badiuddin[15] · Jérôme Dargent[16] · Pierre Urbain[17] · Stefan Paveliu[18] · Rita Schiano di Cola[4] · Corrado Selvaggio[5] · Mohammed Al Kuwari[19]

Allurion (formerly known as Elipse)
International Multicenter Registry Trial
(1,770 Patients)

Ienca, R., Al Jarallah, M., Caballero, A., et al. The procedureless Elipse gastric balloon program: Multicenter experience in 1770 consecutive patients. Obesity Surgery. 2020 (30):3354-3362.

Allurion International Multicenter Registry

Results

- Efficacy of Allurion Treatment

4 Month Results	Mean (SD)	P value (from baseline)
Weight loss (kg)	13.5 ± 5.8	p < .0001
%TBWL	14.2 ± 5.0	p < .0001
%EBWL	67.0 ± 64.1	p < .0001
BMI decrease (kg/m²)	4.9 ± 2.0	p < .0001

Metabolic Parameters

Baseline	4 Month Results	p value	Baseline
Triglycerides (mg/dL)	145.1 ± 62.8	99.4 ± 21.8	p < .0001
LDL (mg/dL)	133.1 ± 48.1	106.9 ± 27.9	p < .0001
HbA1c (%)	5.1 ± 1.1	4.8 ± 0.8	p < .0001

Conclusions of 1,770 patient study

- Allurion Balloon demonstrates excellent safety and efficacy

- 14.2% TBWL compares well with longer-duration, endoscopic gastric balloons

- Allurion Program enables much wider application of gastric balloon technology

- Small bowel obstructions occurred in 2016 with an earlier version of the device. None since 2017 with current device.

Patient demographics

- Total patients at 5 obesity centers: n = 226
  - 148 (65%) Pre-Diabetic
    (HbA1c : 5.7- 6.4%)
  - 78 (35%) Diabetic
    (HbA1c ≥ 6.5%)

Patient demographics before Allurion Balloon treatment

Sex	F 135 / M 91 (60/40)
Mean Weight (kg)	108.4 ± 21.7
Mean BMI (kg/m²)	37.3 ± 5.7
Mean HbA1c (%)	6.3 ± 0.6%

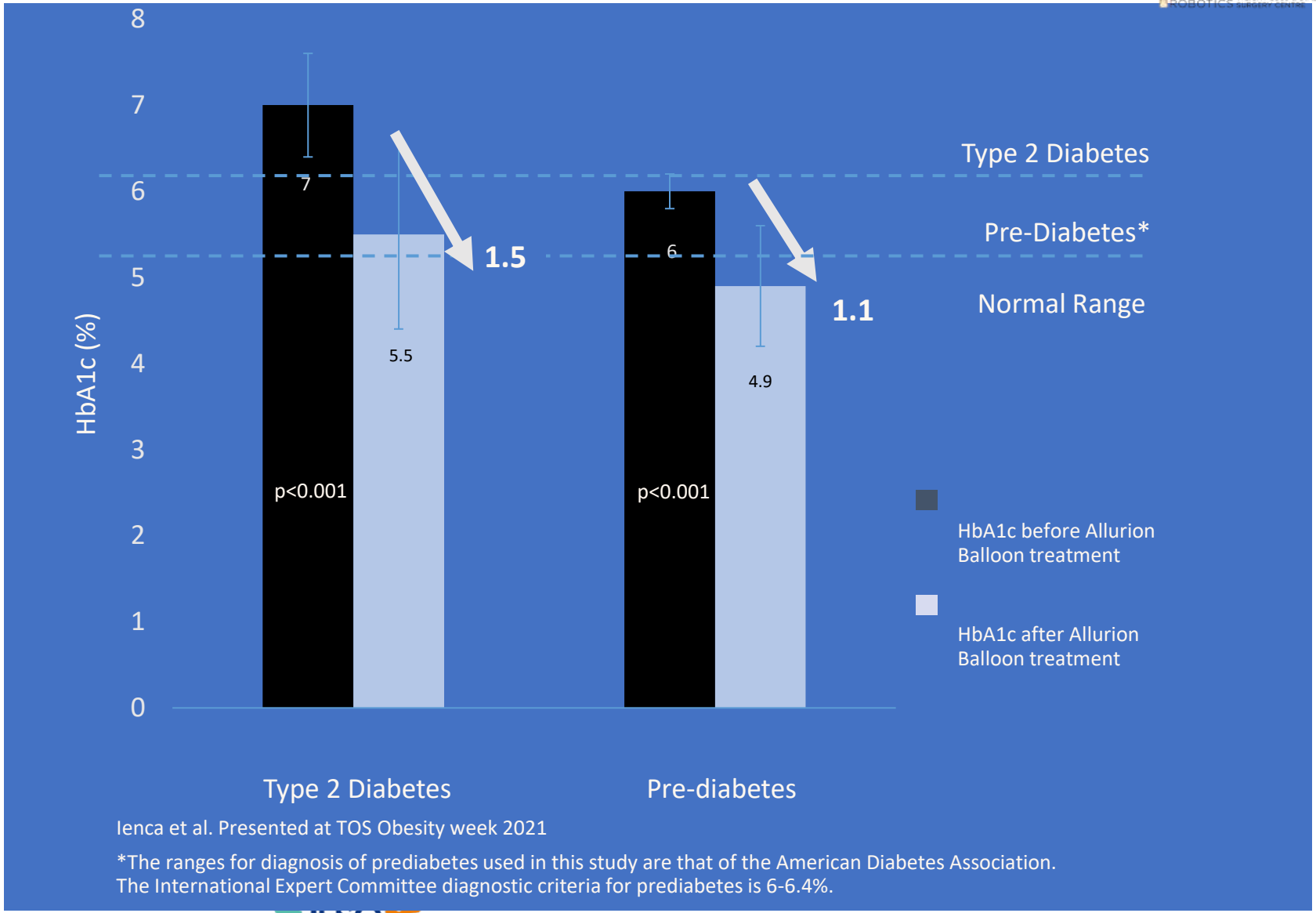
Emerging Role of the New Swallowable Gastric Balloon in Type 2 Diabetes and Prediabetes Treatment

Ienca et al. Presented at TOS Obesity Week 2021

Allurion Balloon Treatment for patients living with Type 2 Diabetes and Prediabetes

After 4 months of treatment
(all patients)

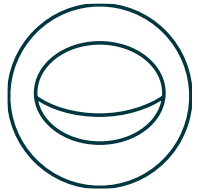
Weight loss (kg)	17.7
%TBWL	16.2
%EWL	57
BMIL (mg/kg^2)	6.1



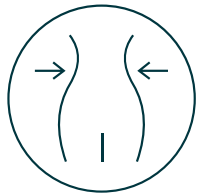
Ienca et al. Presented at TOS Obesity week 2021

*The ranges for diagnosis of prediabetes used in this study are that of the American Diabetes Association. The International Expert Committee diagnostic criteria for prediabetes is 6-6.4%.

Conclusions



The Allurion Balloon is safe and effective for overweight and obese patients with both Type 2 Diabetes and Prediabetes



Significant reductions in HbA1c in just 4 months of treatment allowed values in both patients living with Type 2 Diabetes and Prediabetes to reach the normal range

ISSN: 2165-7904

Journal of Obesity & Weight Loss Therapy
Open Access

Brief Report ▸ J Obes Weight Loss Ther 2022, Vol 12(12): 535 DOI: 10.4172/2165-7904.1000535

Emerging Outcomes for Treatment of Obesity with Type 2 Diabetes Mellitus: Novel Swallowable Balloon Process

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Background: Swallowable balloon process is a new way for the treatment of obesity and type 2 diabetes (T2DM). The aim of this study was to assess the outcomes of the novel swallowable balloon on T2DM remission, weight loss, and adverse events in individuals with T2DM and obesity.

Methodology: We treated forty-two T2DM patients with obesity at our center with a swallowable balloon. During the 6-month follow-up diabetes remission was defined as HbA1c<6.5% without T2DM medication and diabetic improvement was HbA1c<7.0% with decreased usage of oral diabetes medications.

Results: At 6 months of follow-up, 87.8% of the cohort treated by swallowable balloon experienced diabetes remission. The highest diabetes remission was 66.7% (HbA1c 6.43%; 95%CI 6.2-6.5 and FPG 120.3; 95% CI 111.6- 124.9) occurred between 3-and 4-months post balloon insertion, and 12.5% recrudescence of diabetes during the end of follow-up. Improvement of diabetes without full remission was observed in 27.8% and 36.1% of patients at 4 and 6 months (HbA1c, 6.8% 95% CI 6.5-7.0). These patients achieved diabetes control (HbA1c, 6.8% 95%CI 6.5- 7.0) with decreased usage of oral diabetes medications and withdrawal of insulin when previously used. Significant (p<0.001) improvements in %TWL were 6.5 %,10.1 %, 12.7%, 15.14%,14.7%, and 14.4% at 1-2-3-4-5-6 months, respectively were noted after the insertion of the balloon. There was a significant (p<0.001) resolution in diabetesrelated comorbidities (75% HTN and 73.3% DLP).

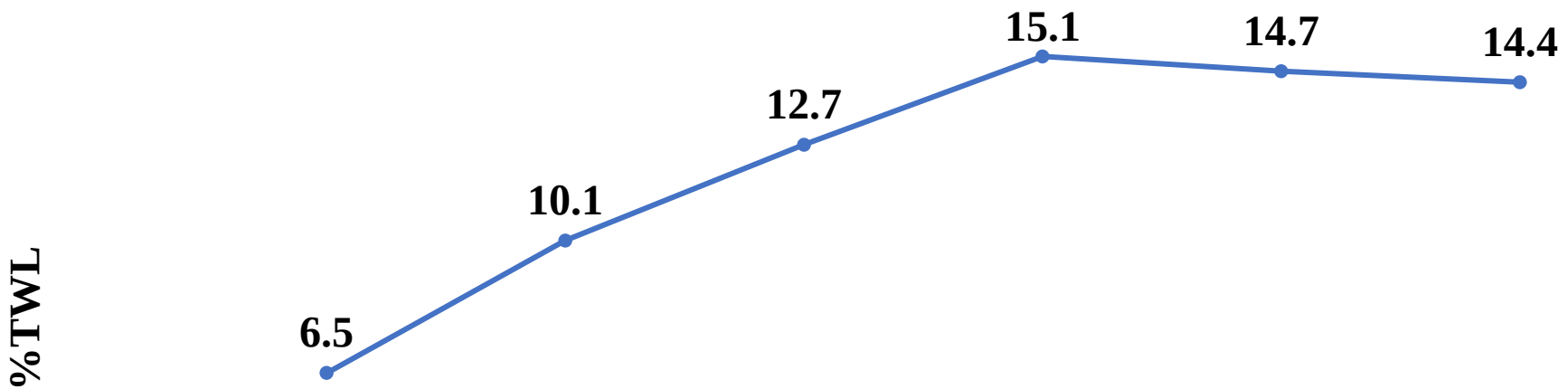
Conclusion: New emerging swallowable balloon process is an effective tool to reduce HbA1c and put T2DM into remission and weight loss.

Patients Characteristics (n= 982)	
Male: n (%)	465 (47.4%)
Female: n (%)	517 (52.6%)
Age (years): Mean (range)	39 (17-61)
Height: (cm): Mean (SD)	166.3(12.9)
Weight (kg): Mean (SD)	106.5 (26.9)
BMI (kg/m^2) Mean (SD)	38.4(13.3)

Comorbidity profile (n= 982)	
T2DM: n (%)	298 (30.3)
HTN: n (%)	272 (27.7)
DLP: n (%)	343 (34.9)

Weight loss outcome post balloon insertion

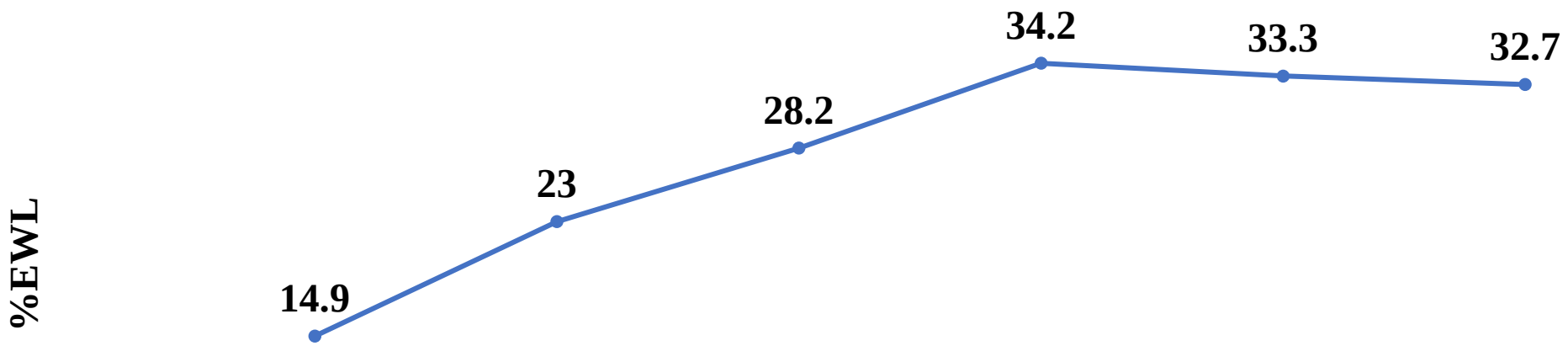
% TWL



	1 Month	2 Months	3 Months	4 Months	5 Months	6 Months
Series1	6.5	10.1	12.7	15.1	14.7	14.4

Weight loss outcome post balloon insertion

% EWL



	1 Month	2 Months	3 Months	4 Months	5 Months	6 Months
Series1	14.9	23	28.2	34.2	33.3	32.7

Resolution of Comorbidities at 6 month	
T2DM	58.0%
HTN	75.0%
DLP	73.2%

Adverse Effects after balloon insertion procedure

Adverse Effects	N=982
Nausea and Vomiting: n (%)	461 (46.9)
Nausea and Vomiting extending beyond one week: n (%)	108 (10.9)

Conclusion

The Swallowable Balloon – Professional treatment of obesity or preventive lifestyle intervention that anyone can apply

As a professional treatment, the swallowable balloon offers a non-invasive and potentially effective method for weight management.

As a preventive lifestyle intervention, the swallowable balloon concept encourages a proactive approach to weight control.

- The technology of swallow-able gastric balloon is excellent and limits the size of the stomach for food and helps change the eating habits of people.
- The results of this procedure leads to significant amount of weight loss.
- However, the balloon stays for temporary period in the stomach.
- It is important to maintain a healthier lifestyle for a sustainable weight loss result.

MOHAK TEAM

THANK YOU

We offer various treatment modalities for obesity. The operation is determined by the profile of the patient and guided by findings from analysis of the data from our prospectively maintained database

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