

Resolution of Diabetes with Swallowable Balloon Therapy



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Resolution of Diabetes with Swallowable Balloon Therapy

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SRI AUROBINDO UNIVERSITY

VISION WITH ACTION

← INDORE, INDIA



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



NAPOLI 2023

DISCLOSURE

Mohit Bhandari MD

Consultant to:

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

Winnie Mathur

- No conflicts of interest

Mathias Fobi MD FACS, FICS, FACN

- Founding President, Bariatec Corporation

Manoel Galvao Neto

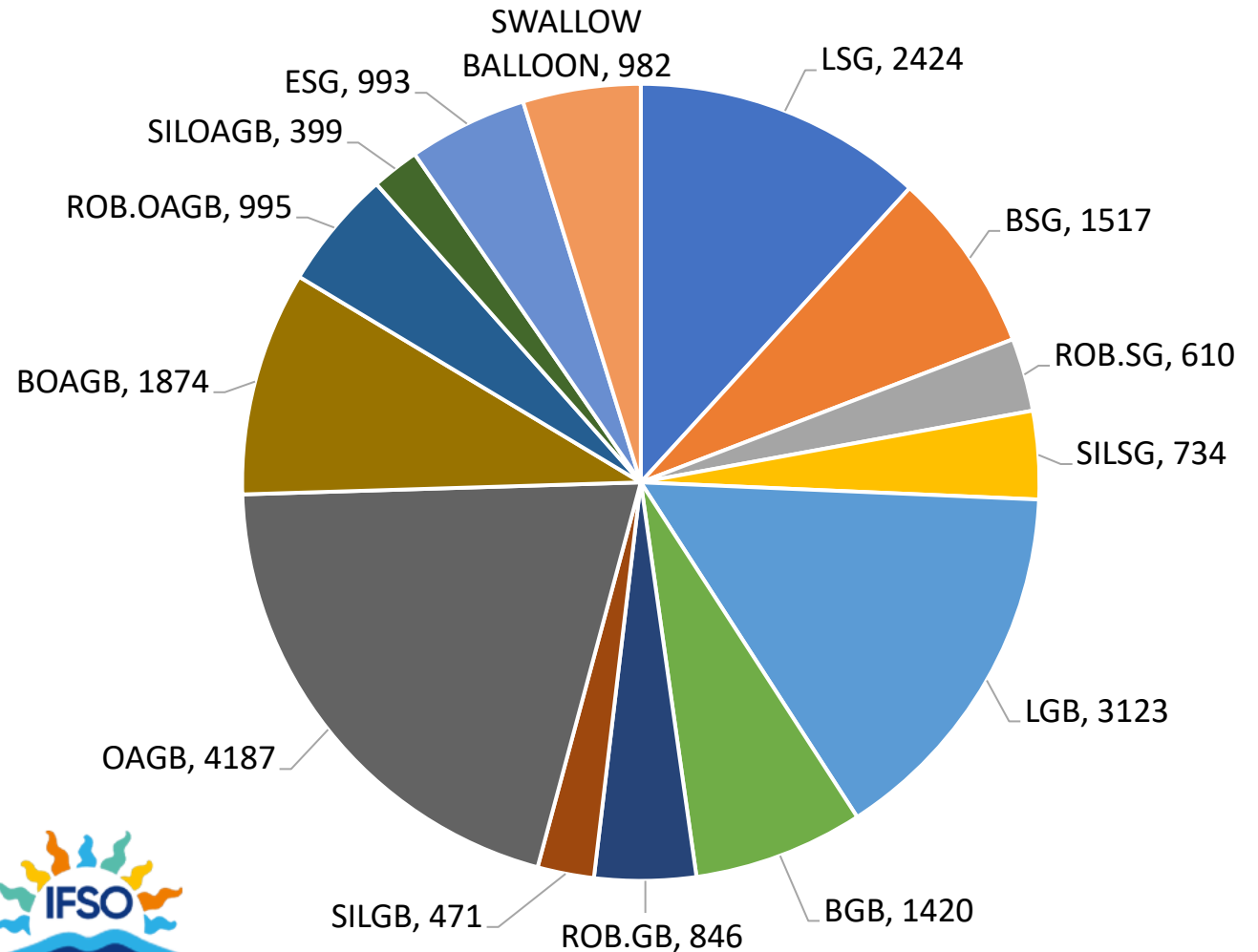
- Director Bariatric Endoscopy

BARIATRIC PROCEDURES MIX DISCLOSURES MBRSC

January 2010 – Jun 2023

CASE MIX DISCLOSURE
2010- 2023

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



Dr Manoel Galvao Neto

Clinical Director- Dept Bariatric Endoscopy
Mohak Bariatric and Robotic Surgery Center
Indore- Mumbai- Hyderabad- Bangaluru



There are various treatment approaches for diabetes, depending on the type and severity of the condition.

These may include lifestyle modifications, such as dietary changes and increased physical activity, oral medications, injectable medications (such as insulin), and sometimes surgical interventions.

Weight loss interventions, such as bariatric surgery

It has been found to have a positive impact on diabetes management and may even result in remission for some individuals.

One such recent advance is the introduction of **Swallow Balloon**

FUTURE TRENDS FOR OBESITY & DIABETES

METABOLIC BARIATRIC SURGERY



What the patient wants ?

Confidentiality

Discreteness

Safety

Something Non-surgical

No hospital admission

Outpatient procedure

No surgery, no anaesthesia, no endoscopy



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.



Allurion swallowable pill process is a new way for the treatment of obesity and type 2 diabetes (T2DM).

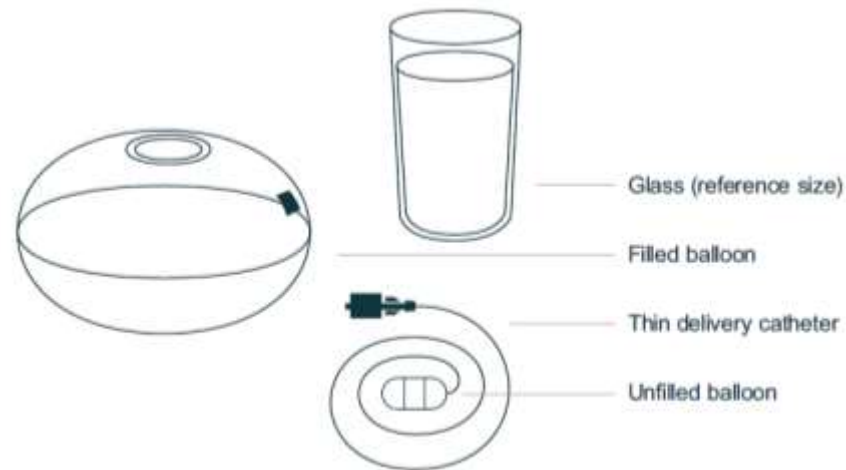


Swallow Balloon

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

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

The Revolutionary Allurion Balloon

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



NAPOLI
2023

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

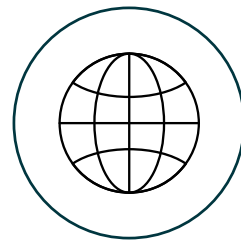


ORIGINAL CONTRIBUTIONS



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

R. Ienca¹ • Mohammed Al Jarallah² • Adelardo Caballero³ • Cristiano Giardiello⁴ • Michele Rosa⁵ • Sébastien Kolmer⁶ • Hugues Sebbag⁷ • Julie Hansoulle⁸ • Giovanni Quartararo⁹ • Sophie Al Samman Zouaghi¹⁰ • Girish Juneja¹¹ • Sébastien Murcia¹² • Roman Turro¹³ • Alberto Pagan¹⁴ • Faruq Badiuddin¹⁵ • Jérôme Dargent¹⁶ • Pierre Urbain¹⁷ • Stefan Paveliu¹⁸ • Rita Schiano di Cola⁴ • Corrado Selvaggio⁵ • Mohammed Al Kuwari¹⁹



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

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



Results

Allurion International Multicenter Registry

Conclusions

- ▶ 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.

• 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/m ²) | 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 |



Patient demographics

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

Patient demographics before Allurion Balloon treatment

| | |
|-------------------------------|----------------------|
| Sex | F 135 / M 91 (60/40) |
| Mean Weight (kg) | 108.4 \pm 21.7 |
| Mean BMI (kg/m ²) | 37.3 \pm 5.7 |
| Mean HbA1c (%) | 6.3 \pm 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

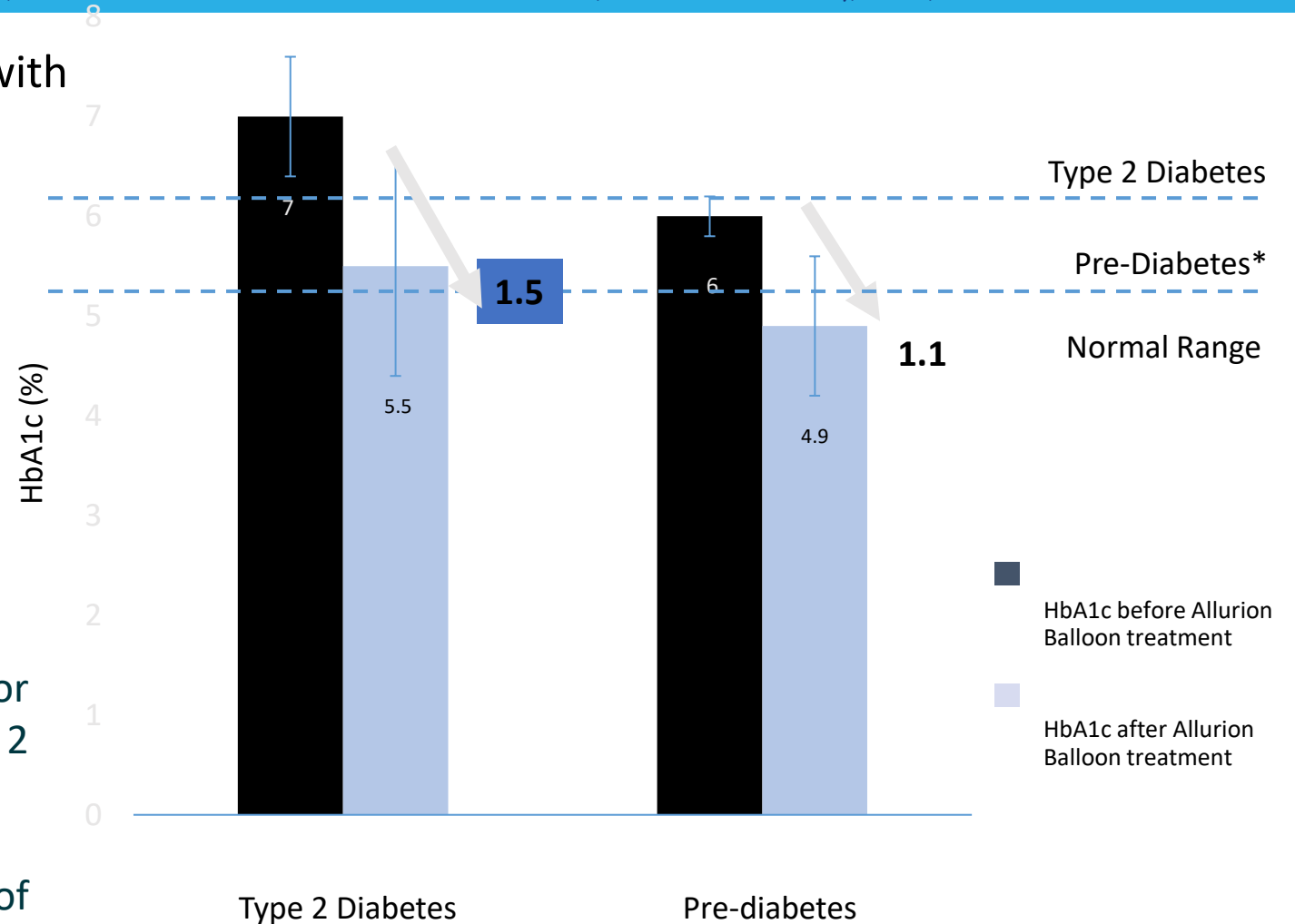
After 4 months of treatment

(all patients)

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

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





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.

- We treated 42-----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.

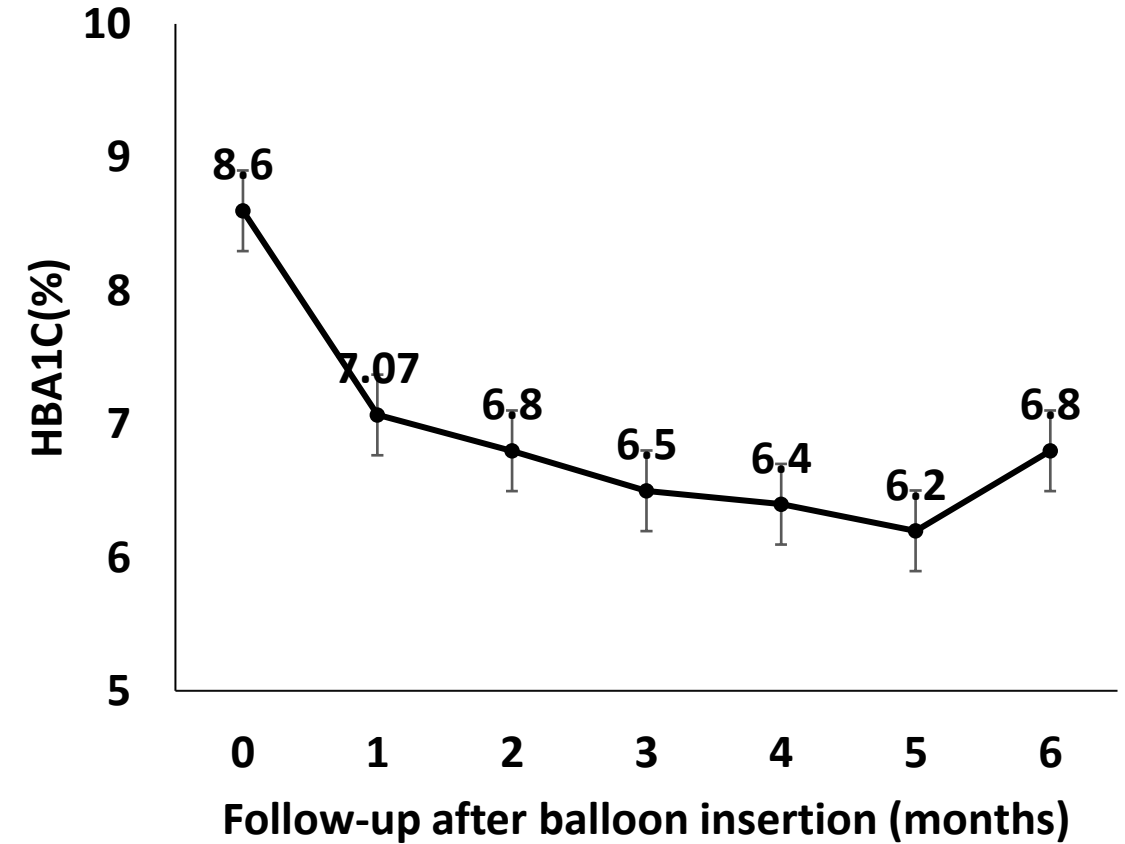
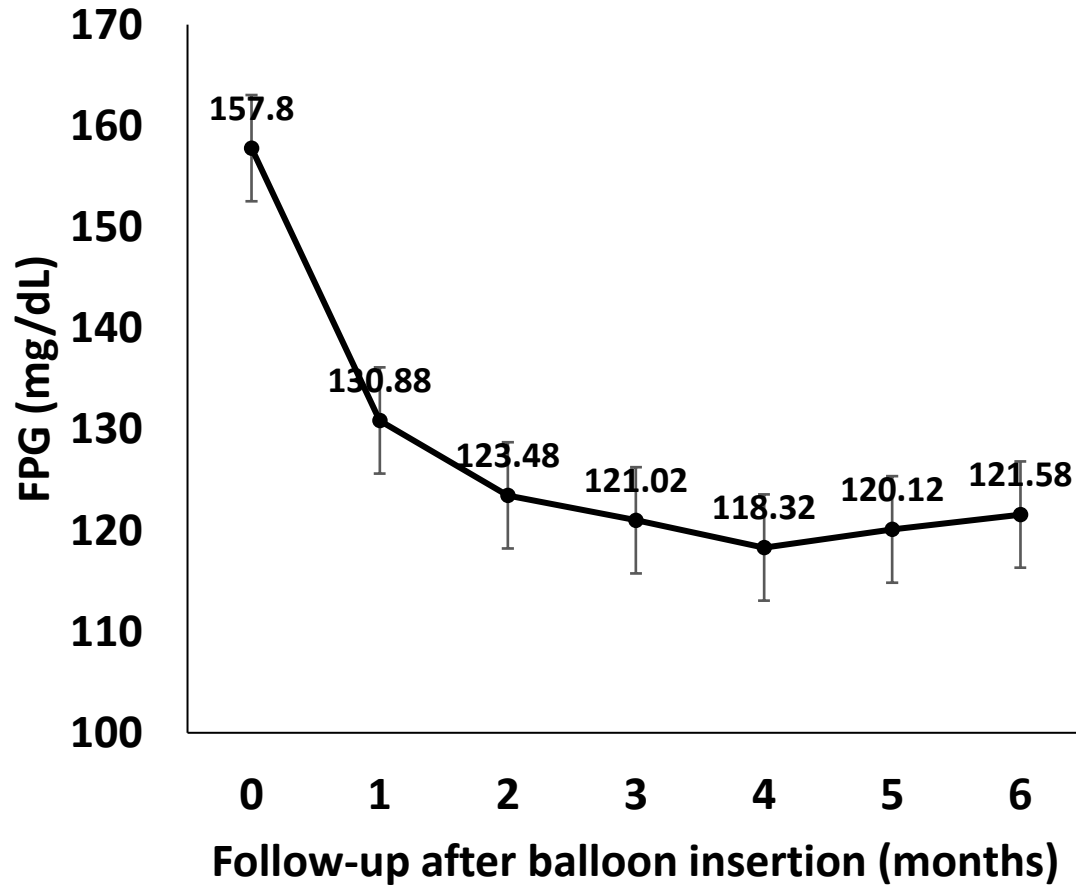
| Patients Characteristics (n= 42) | |
|--|--------------|
| Male: n (%) | 15 (35.7%) |
| Female: n (%) | 27 (64.3%) |
| Age (years): Mean (range) | 39.6 (17-61) |
| Height: (cm): Mean (SD) | 167.9(12.9) |
| Weight (kg): Mean (SD) | 112.5 (28.0) |
| BMI (kg/m ²) Mean (SD) | 39.7 (13.3) |
| Diabetics profile | |
| HbA1C (%): Mean (SD) | 8.6 (0.9) |
| FPG (mg/dL): Mean (SD) | 157.8 (21.2) |
| Oral Diabetics Drug: n (%) | 34 (81) |
| Insulin usage: n (%) | 5 (11.9) |
| Oral + Insulin: n (%) | 3 (7.1) |
| Duration of Diabetics (Years): Mean (range) | 3.31 (1-11) |
| Comorbidity profile | |
| HTN: n (%) | 12 (28.6) |
| DLP: n (%) | 15 (35.7) |

Weight loss outcome post balloon insertion

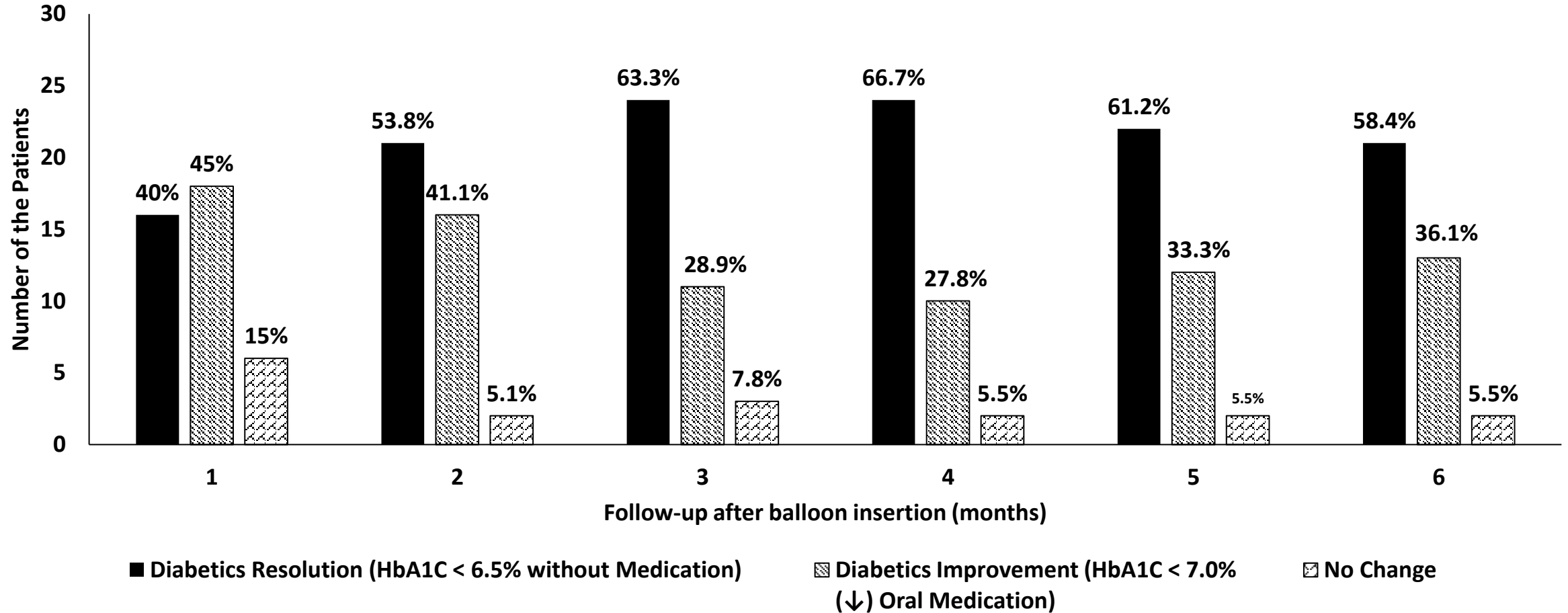
| | Follow-up (n=41) (%) | Weight (kg) Mean (SD) | %TWL Mean (SD) | %EWL Mean (SD) | Paired Differences | 95 % CI (Kgs) | p- value |
|-------------------------------|---------------------------------|----------------------------------|---------------------------|---------------------------|-------------------------------|--------------------------|---------------------|
| 1 Month | 40 (97.5%) | 106.5 (26.9) | 6.5(1.3) | 14.9 (5.3) | Pre-1M | 7.5-8.3 | 0.001 |
| 2 Months | 39 (95.1%) | 102.4 (26.3) | 10.1 (1.8) | 23.0 (7.8) | 1M-2M | 3.9-4.8 | 0.001 |
| 3 Months | 38 (92.6%) | 99.6 (23.8) | 12.7 (2.3) | 28.2 (7.7) | 2M-3M | 2.4-5.1 | 0.001 |
| 4 Months | 36 (87.8%) | 96.2 (18.5) | 15.1 (2.0) | 34.2 (8.3) | 3M-4M | 2.4-3.9 | 0.001 |
| 5 Months | 36 (87.8%) | 98.9 (19.0) | 14.7 (2.1) | 33.3 (8.4) | 4M-5M | 1.1-0.4 | 0.001 |
| 6 Months | 36 (87.8%) | 100.1 (18.9) | 14.4 (2.1) | 32.7 (8.2) | 5M-6M | 0.3-0.04 | 0.012 |
| Nadir Mean (95%CI) | - | 96.2 (93.9-101.4) | 15.1 (14.5-15.8) | 34.2 (31.4-37.1) | Regain | 2.9 kgs | |

| Resolution of Comorbidities | |
|--|-------|
| HTN | 75.0% |
| DLP | 73.3% |
| There was a significant ($p < 0.001$) resolution in diabetes related comorbidities | |

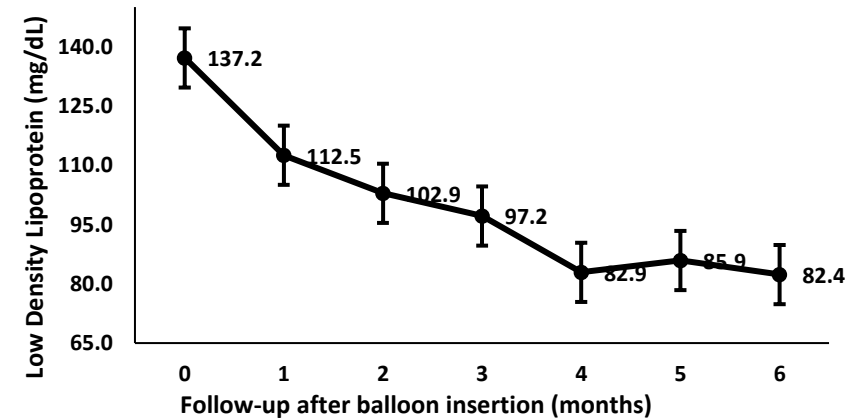
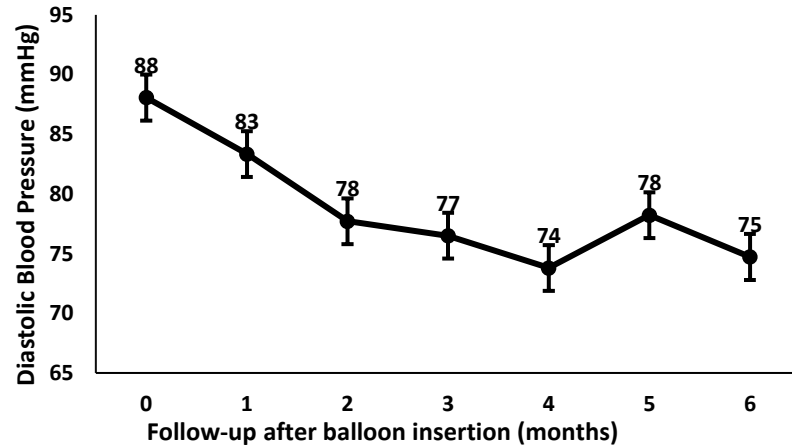
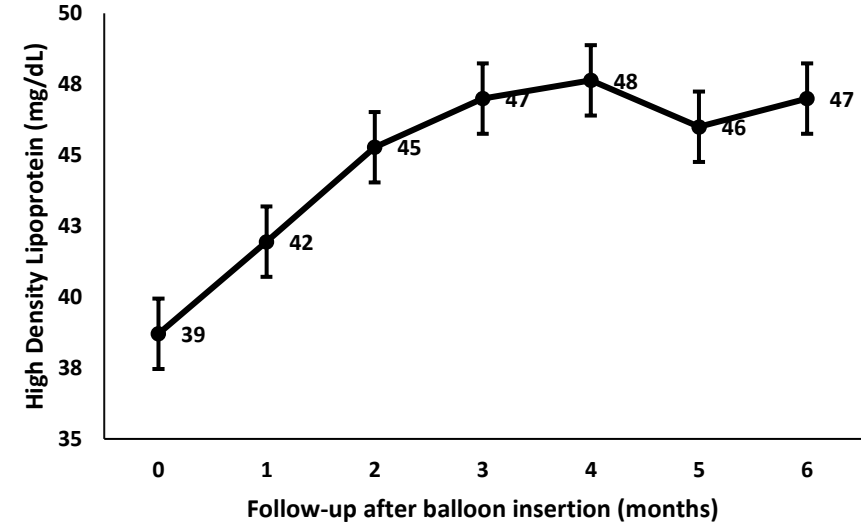
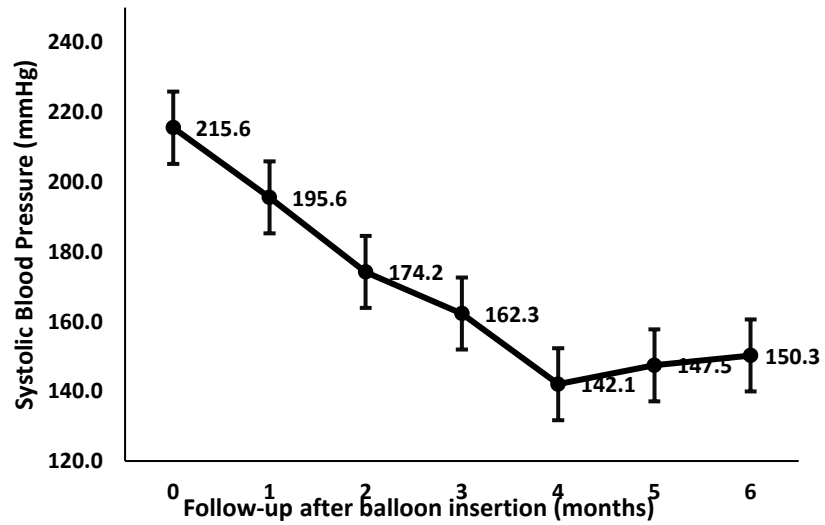
Improvement in diabetes during 6 months post balloon insertion



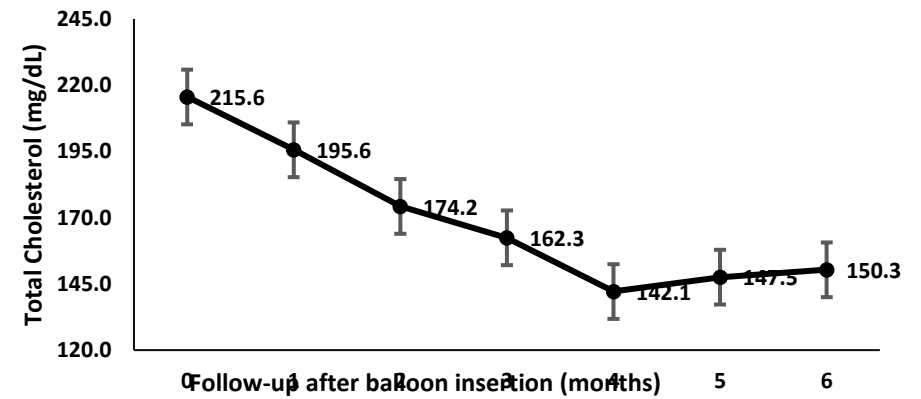
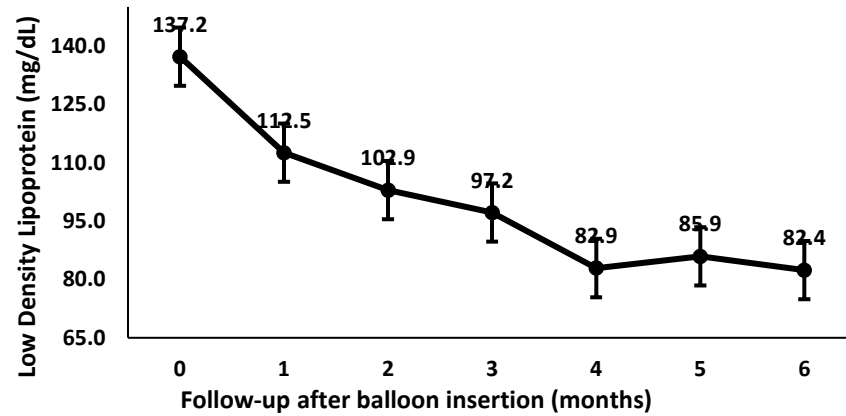
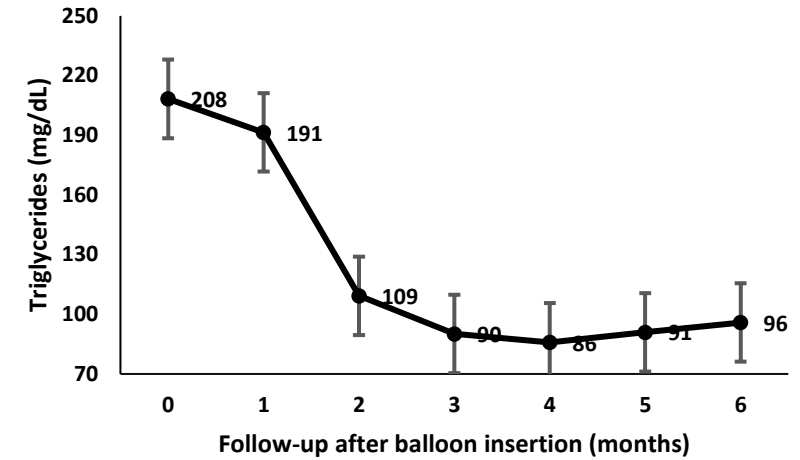
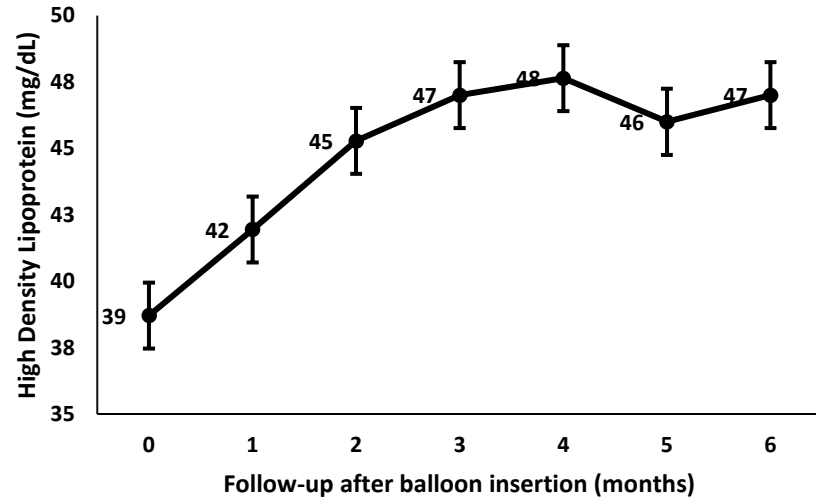
Improvement in diabetes during 6 months post balloon insertion



Improvements in blood pressure during 6 months post balloon insertion



Improvements in lipid levels during 6 months post balloon insertion



Adverse Effects after balloon insertion procedure

| Adverse Effects | N=36 |
|--|-----------|
| Nausea and Vomiting: n (%) | 17 (47.2) |
| Nausea and Vomiting extending beyond one week: n (%) | 4 (11.1) |
| Remove Balloon: n (%) | 1 (2.7) |

Conclusion

- The new emerging swallowable balloon process is excellent and limits the size of the stomach for food and helps change the eating habits of people.
- Our finding shows after four months of treatment, there was a reduction in HbA1c level among T2DM patients.
- It indicates that there are other mechanisms at work as well as, hormonal mechanisms related to the balloon when it comes to the improvement of diabetes.
- The results of this procedure lead to a significant amount of weight loss and diabetes control.
- Safety, efficacy, and short-term durability will determine the role that such a process will serve in the treatment of obesity and metabolic diseases.
- However, the balloon stays for a temporary period in the stomach.
- It is important to maintain a healthier lifestyle for the treatment of obesity and T2DM.





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

