

The Swallowable Gastric Balloon: Global Experience in 5003 Consecutive Patients - The Largest Gastric Balloon Study in the World

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Conflict Of Interest Disclosure

I am a scientific consultant for Allurion Technologies



Background



- The Swallowable Gastric Balloon (SGB) is a 4-month intragastric balloon that does not require endoscopy or sedation for placement or removal.
- Over 130,000 patients have been treated in 70 countries in 7 years.
- The Allurion Program is a 6-month behavior change and weight loss program to complement the swallowable intragastric balloon.
- The program includes a unique Virtual Care Suite that provides remote patient monitoring, secure messaging, and telehealth via a Bluetooth connected scale, health tracker and smartphone app.
- The aim of this study was to evaluate the safety and efficacy of the AGB Program in a large, diverse global population.

Methods



- Multicenter, retrospective, non-randomized, open-label, registry study.
- Data from 5,003 consecutive patients receiving the SGB was analyzed.
- Overweight and obese individuals were enrolled consecutively at the centers.
- 26 international obesity centers in 10 countries in Europe, Middle East, Latin America.
- In-person nutritional follow-up was performed at least monthly.
- The Bluetooth-connected scale and mobile App allowed an augmented “virtual follow-up” adding close support to the patients (between live visits).

Patient demographics at baseline



n=5003 PATIENTS	
Sex	F 72.1%/M 27.9%
Age (yrs)	42.5 ± 12.5
Weight (kg)	95.0 ± 19.2
BMI (kg/m ²)	34.1 ± 5.4
Triglycerides (mg/dl)	128.3 ± 66.76
LDL Cholesterol (mg/dl)	127.9 ± 37.78
HgbA1c (%)	5.43 ± 0.93

Results in Enrolled Patients at 4 months

Weight loss parameters

PARAMETER	N	MEAN (SD)	P VALUE
WL (kg)	4607	13.46 ± 6.14	p < .0001
%TBWL	4607	14.04 ± 5.09	p < .0001
BMIL (kg/m ²)	4607	4.84 ± 2.08	p < .0001

4.98% OF PATIENTS WERE LOST TO FOLLOW-UP

Responder Analysis (N = 3524)

%TBWL	% OF PATIENTS
≥ 5%	96.6%
≥ 10%	80.4%
≥ 15%	40.9%
≥ 20%	11.2%

Metabolic parameters

PARAMETER	N	MEAN (SD)	P VALUE
TG DECREASE	1046	27.0 ± 50.7	P < .0001
LDL DECREASE	1045	14.0 ± 38.7	P < .0001
HGBA1C DECREASE	1015	0.42 ± 0.94	P < .0001

Balloon performance

Placement

Successful placement	99.96%
Swallowed with Stylet Assistance	51%
Placement failed	0.04%

Balloon Passage

In stool	91%
Vomited empty balloon	1.4%
Endoscopic removals (all causes)	2.9%
Surgical removals	0.1%
Unknown passage	4.7%



Adverse events

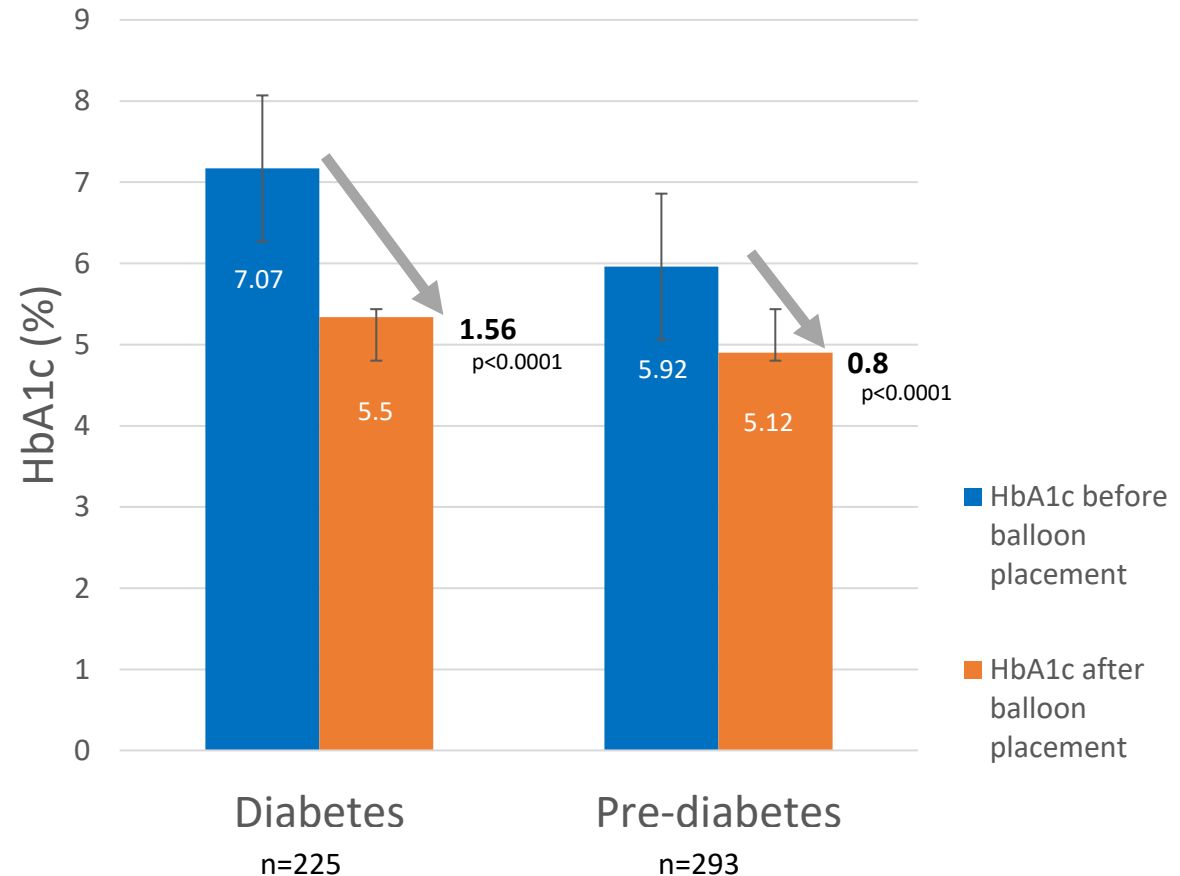
ADVERSE EVENTS	
Intolerance requiring balloon removal	2.1%
Early deflations	0.4%
Spontaneous hyperinflation	0.2%
Gastric dilation	0.09%
Esophagitis	0.05%
Delayed intestinal balloon transit	0.01%
Totals	2.85%

SERIOUS ADVERSE EVENTS	
Small bowel obstruction	0.08%
Gastric outlet obstruction	0.07%
Gastric Perforation	0.04%
Pancreatitis	0.01%
Totals	0.2%

Results for patients with type 2 diabetes or pre-diabetes

Patient demographics before Allurion Program	
Pre-diabetes / Diabetes (N=518)	293 / 225
Sex	F 338 / M 180
Mean Weight (kg)	105.32 ± 21.63
Mean BMI (kg/m ²)	36.99 ± 5.57

After 4 months of treatment	
WL (Kg)	17.39 ± 7.02
%TBWL	16.38 ± 5.49
BMIL (kg/m ²)	6.11 ± 2.36



The ranges for diagnosis of prediabetes used in this study are that of the American Diabetes Association; 5.7-6.4% for pre-diabetes, ≥ 6.5% for diabetes). The International Expert Committee diagnostic criteria for prediabetes is 6-6.4%.

Results in Adolescents

- Of the 5003 subjects evaluable for 4-month weight loss, 57 were adolescents (13-17 years)
- No serious adverse events observed

% Total Body Weight Loss at 4 months in Adolescents

AGE	N	MEAN %TBWL (SD)
13-17	57	12.41 ± 4.62

Responder Analysis (N = 57)

%TBWL	% OF PATIENTS
≥ 5%	93.0%
≥ 10%	71.9%
≥ 15%	29.8%
≥ 20%	3.5%

Results for different BMI categories

BMI (kg/m ²)	N	BMI (kg/m ²) baseline	BMI loss (kg/m ²)	%TBWL
< 27	75	25.93±0.96	3.10±1.32	11.97±5.11
27-29.9	926	28.55±0.89	3.80±1.30	13.32±4.55
30-34.9	1861	32.38±1.43	4.38±1.47	13.50±4.48
35-39.9	1177	37.04±1.37	5.59±2.06	15.08±5.49
40+	568	44.57±5.46	6.72±2.93	15.13±6.27

Conclusion



01

The largest study of the Allurion Gastric Balloon Program with 5003 consecutive patients confirms a TBWL of 14% at approximately 4 months, significantly improved metabolic parameters, and consistent safety in diverse, global populations.

02

The unique Virtual Care Suite facilitates close follow-up to optimize safety and efficacy.

Thank you for your attention!

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