

Summary of Post-Market Studies of the Eclipse Gastric Balloon

Author (year)	Reference	Study Type/ N Population	Performance Outcomes	Complications	Conclusions
Al-Subaie et al (2017)	International Journal of Surgery 48 (2017):16-22	<p>Singe-center prospective pilot</p> <p>N = 53</p> <p>BMI within 27-40kg/m2.</p> <p>Subjects classified into three categories: Overweight - 32.1% Class I - 55.6%</p> <p>Class II - 13.3%</p> <p>Follow-up: 4 mo.</p>	<p>Baseline mean weight was 83.9±12.3 kg, mean BMI was 32.1 kg/m2 (27.3-39.7kg/m2), and mean WC was 95.3±9.2 cm.</p> <p>At 4 months, the mean weight loss was 8.84 kg (-6 to +21.5 kg), mean %TBWL was 10.44% (-8 and +23%), mean %EWL was 40.84% (-24 and +78%), the mean change in BMI was 3.42 kg/m2, and mean WC reduction was 8.62 cm (-10 and +31 cm) (p < 0.001).</p>	<p>AEs:</p> <p>5 early for intolerance (9.8%)</p> <p>1 early deflation (2%)</p> <p>1 vomited the balloon (2%)</p> <p>Weakness (38.4%)</p> <p>Abdominal pain (35.1%)</p> <p>Vomiting (16.5%)</p> <p>Nausea (10%)</p> <p>During excretion 28 cases (64.4%) had no symptoms, 8 had diarrhea (17.8%), 4 had mild abdominal discomfort (8.5%), two had abdominal pain (4.4%), and two had a history of constipation (4.4%). Symptoms resolved spontaneously in 25 cases (57.8%), 42.2% needed over-the-counter medications. Most cases (82.2%) did not notice the balloon excreted.</p>	<p>The authors concluded that the Allurion gastric balloon resulted in good weight loss after 4 months.</p> <p>There were 3 drawbacks mentioned:</p> <ul style="list-style-type: none"> • high symptom severity in 1st 72 hrs that led to 5 removals • high percentage of cases that needed alternative imaging to confirm balloon excretion • concern over early deflation <p>Ultimately, they felt the device was safe and effective.</p>

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Al-Sabah et al (2018)	SOARD, Volume 14, Issue 3, P311-317	Two-center prospective cohort N = 135 Patients choosing against bariatric surgery. Follow-up: 4 mo.	Baseline mean BMI of 33.7 kg/m ² (range 26.5-43.6). At 4 months mean weight was 75.75kg (range 55.1-117.0). Decrease of 13.0kg (range -13.4-29.8, p=0.000). At 4 months, the mean BMI was 28.8 kg/m ² (range 20.5-38.8, p=0.000), a decrease of 4.9 units (ITT). Mean %TBWL loss was 15.1%. Only one subject failed to lose weight (0.7%).	SAE's: 1 SBO (0.7%) AEs: 2 early intolerance (1.5%)* 2 vomited the balloon (1.5%) 1 early balloon deflation (0.7%) *One subject with early intolerance experienced abdominal pain and mildly elevated levels of amylase and lipase. 35 vomiting (25.9%), 29 abdominal pain (21.5%) 18 diarrheas (13.3%). Nausea was experienced by all subjects on the day of insertion that resolved in 1 week.	The authors concluded that the Allurion gastric balloon can be safely and successfully swallowed, filled, imaged and passed. In addition, it was able to effectively aid in weight loss and that the risk (SAEs) and AE rates are better than previously published studies with other weight-loss balloons.
Genco et al (2018)	Obesity Surgery (2018) 28:405-409	Singe-center prospective study N = 38 BMI ≥ 27 kg/M2, <45 kg/m ² Females (73%) Males (27%)	Baseline mean weight 109.7 ± 21.9 kg, mean BMI 38.6 ± 6.7 kg/m ² . End mean weight loss was 12.7 kg, mean BMI reduction was 4.2 points kg/m ² , mean %EWL was 26%, and mean TBWL was 11.6%.	No severe complications. VAS scores on day of insertion / @4wks: Nausea 6 ± 3.1 / 0 Vomiting 2.6 ± 3.8 / 0 ^a Regurgitation 3.8 ± 3.6 / 0.3 ± 1.2 Satiety 9.3 ± 1.4 / 4.5 ± 2.3 Cramping 6.7 ± 2.6 / 0 Abdominal pain 4.2 ± 3.4 / 0 Difficulty w/liquids 3.2 ± 3.6 / 0 Difficulty w/solids 2.2 ± 3.4 (at 1 week) / 0 ^a One subject had persistent nausea and vomiting that resolved @ at 10wks with treatment.	The authors concluded that the Elipse balloon was safe, effective, and well accepted. The lack of need for endoscopy and sedation was seen as a big advancement for patients.

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Ernesti et al (2018)	Journal of Obesity and Nutritional Disorders, 2018. 2018(01): p. 1-4	<p>Single-center study N = 42</p> <p>BMI ≥ 27 kg/M2, <45 kg/m2</p> <p>Specific focus on change in metabolic parameters</p> <p>Females (69%) Males (31%)</p>	<p>Baseline mean weight was 110.5 ± 21.9 kg and mean BMI was 39.2 ± 6.7 kg/m2.</p> <p>End mean weight loss was 12.9 kg, mean BMI reduction was 4.5 points kg/m2, mean %EWL was 27%, and mean TBWL was 11.9%.*</p> <p>There was a significant reduction of metabolic syndrome factors:</p> <p>blood pressure (p < 0.02)</p> <p>WC (p < 0.002)</p> <p>triglycerides (p < 0.0001)</p> <p>blood glucose (p < 0.001)</p> <p>HOMA-IR index (p < 0.001)</p> <p>At the start of the study 91% met the criteria for metabolic syndrome. At the conclusion of the study only 27.5% met the criteria for metabolic syndrome.</p>	<p>No severe complications.</p> <p>Nausea, vomiting, cramping, abdominal pain, regurgitation, difficulty in swallowing liquid and solid foods) were self-limiting and almost all resolved by week 1.</p>	<p>The authors concluded that the Allurion device was safe and this study showed statistically significant, and clinically relevant, improvements in the co-morbidities related to metabolic syndrome.</p>
Jamal et al (2019)	Obesity Surgery volume 29, pages1236–1241(2019)	<p>Single-center, prospective cohort</p> <p>N = 112</p> <p>Follow-up: 12 mo.</p> <p>Minimum BMI of 27.5 kg/m2.</p> <p>Females: 73.6%</p> <p>Males: 26.4%.</p>	<p>Baseline mean weight and BMI of the subjects were 92.2 kg and 34.3 kg/m2.</p> <p>Mean TBWL at 6 months was 10.9%.</p> <p>At last F/U, over 12 months following balloon passage, the overall mean TWL% was 7.9% with a mean BMI change of 2.95.</p>	<p>SAE's: 1 SBO (0.9%)</p> <p>AEs:</p> <p>3 Early deflation (2.7%)</p> <p>6 intolerance (5.4%)</p> <p>13 diarrhea (9%)</p> <p>49 abdominal pain (46.2%)</p> <p>76 nausea and vomiting (71.7%)</p>	<p>Authors concluded their results were comparable to other intragastric balloons and showed safe and effective treatment especially in with BMI's below 34.9 Most significantly, the study concluded that with patients following the complete Allurion program 72% of the weight loss was sustained over 1 year after the passage of the Allurion balloon.</p>

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Ienca et al. 2020	Obesity Surgery volume 30, pages 3363–3364	Multicenter, prospective, non-randomized, open label registry study N=1,770 Females=1264 Males=506 BMI > 27 (mean 34.4±5.3)	Weight loss (kg) 13.5 ± 5.8 %TBWL 14.2 ± 5.0 %EWL 67.0 ± 64.1 BMI decrease (kg/m ²) 4.9 ± 2.0 All changes were statistically significant at p<.0001	Intolerance (endoscopic removal) 52 (2.9%) Early deflation (< 3 months) 11 (0.6%) Spontaneous hyperinflation 4 (0.2%) Small bowel obstruction 3 (0.17%) Gastric dilation 1 (0.06%) Esophagitis 1 (0.06%) Pancreatitis 1 (0.06%) Gastric perforation 1 (0.06%) Delayed intestinal transit 1 (0.06%) Gastric outlet obstruction 1 (0.06%)	Study demonstrates the safety and efficacy of the Elipse Gastric Balloon Program, including the Balloon, body composition scale, and smartphone app. The 14.2% TBWL compares well with the weight loss achieved by other longer-duration, endoscopic gastric balloons Small bowel obstruction in 3 patients occurred in 2016 with an earlier version of the device There were no obstructions from 2017 onwards with the introduction of the current generation device
Vantansiri et al 2020	Obesity Surgery volume 30, pages 3341–3346	Mayo Clinic Systemic review and Meta-Analysis of all 6 published Elipse studies that qualified N=2,016 Mean BMI 30.6–36.2	%TBWL (at 4–6 months) 12.8% %TBWL (at 12-month f/u) 10.9%	Early removal 2.3% Early deflation 0.45% Early expulsion by emesis 0.15% Small bowel obstruction 0.15% Gastric perforation 0.05%	This large meta-analysis demonstrates that Elipse is a safe device offering effective weight loss Serious adverse events are rare, and the rate of early removal is low

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Taha et al 2020	Obesity Surgery https://doi.org/10.1007/s11695-020-05086-y	Single Center Retrospective Study from Egypt N= 96 (68F, 28M) BMI range between 28 and 45 (mean 33.6). Age 16 years and 54 years (mean 28.9 years) Follow-up: 4 months	Mean Weight Loss: 11.2 Kg Mean BMI reduction: 4.9 kg/m ² Mean %TBWL: 12.1% Waist Circum reduction:10.9 cm All outcomes were statistically significant with p<.0001 3 patients vomited the empty balloons at end of residence	1.1% Early deflation at 6 weeks 3.1% had intolerance requiring endoscopic removal. Adverse events minor and expected, and resolved within a few days. 11.5% had diarrhea and cramps around the time of deflation and passage No SAE's	The Elipse™ balloon is safe, effective, and could be well accepted by patients due to the lack of endoscopy and sedation for placement and removal. It has an accepted weight loss and clinical improvement in factors related to the metabolic syndrome. 100% patients able to swallow the device with 42% requiring stylet assistance Thin-film design of the Elipse™ balloon compared to the thick rigid designs of the traditional balloon make it better tolerated.

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Schiavo et al. 2020	Obesity Surgery https://doi.org/10.1007/s11695-020-05133-8	Prospective Randomized Controlled Trial comparing effect of LCKD and LCD in patient receiving Elipse on Fat-Free mass (FFM) loss, Fat Mass (FM) loss and Weight loss (WL) LCKD: n=24, Mean Age 39 yrs, Mean BMI 37.8 kg/m ² . LCD: n=24, Mean Age 41, Mean BMI 37.2 kg/m ²	100% of patients swallowed the Elipse with only 6.3% requiring stylet assistance. All balloons were naturally excreted in stools Patients that followed the LCKD lost less FFM at 4 months after EIGB placement than patients who followed the LCD (3.55 vs 14.3%, p < 0.001). Patients in the LCKD group lost significantly more FM at 4 months after EIGB placement than patients who followed the LCD (41.6 vs 33.1%, p = 0.0606, despite a significantly lower WL (18 vs 21%, p < 0.001).	The most common adverse events after EIGB placement were nausea and vomiting (73% (35/48) and 50% (24/48) of patients, respectively). All nausea and vomiting were either self-limiting or resolved with medications in 2-3 days. No SAEs were observed	In patients undergoing Elipse IGB, LCKD is associated with an increased FM loss while reducing the FFM loss.
Salmi et al. 2020	Journal of Ultrasound (2020) 23:593-597 https://doi.org/10.1007/s40477-020-00499-y	Demonstrate the feasibility of real-time ultrasound-assisted insertion of the Elipse intragastric balloon N=36 Consecutive patients with mean BMI of 35 kg/m ²	The capsule was detected in the fundus gastric lumen in all 36 patients. The US hyperechoic signal (like a "fluttering fish") of the capsule obtained by traction of the catheter was visible early on and was confirmed after the injection of a few milliliters of saline solution in the capsule of the cyst-like shape in the fundus gastric lumen.	One patient had intolerance at 3 months requiring endoscopic removal. No SAEs were reported	After a learning curve, the authors were able to demonstrate the placement of the balloon capsule inside the fundus of the stomach under ultrasound guidance without fluoroscopy in all patients in an outpatient setting.

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Raftopoulos et al. 2019 (Abstract)	Presented at American Society for Metabolic and Bariatric Surgery	Two center study comparing intense medical weight loss (IMWL) plus Elipse balloon with IMWL alone in matched controls IMWL plus Elipse balloon N=97 and BMI 35.86 ± 5.29 IMWL alone N=413 and BMI 36.87 ± 5.02	%TBWL at 16 weeks: IMWL alone %TBWL was 6.36 IMWL plus Elipse balloon %TBWL was 14.3 The difference was statistically significant at p<.001 >5% TBWL was achieved in 95.3% of the IMWL plus Elipse balloon group and 29.6% of IMWL alone group >10%TBWL was achieved in 85.2% of the IMWL plus Allurion balloon group and 8.2% of the IMWL alone group. >20%TBWL was achieved in 17.1% of the IMWL plus Elipse balloon group and in 0.05% of IMWL alone group All of these differences were statistically significant with p<.0001 At the end of one year after Elipse balloon placement the %TBWL was 13.3%	There were no serious adverse events. All adverse events were common to IGBs including abdominal pain, nausea and vomiting. The author has not listed severity and duration of adverse events in the abstract	IMWL plus Elipse balloon lead to nearly 2.5 times the weight loss at 16 weeks than IMWL alone 93% of weight loss was maintained at 1 year after placement in the IMWL and Elipse Balloon group. 10 times more patients achieved > 10% TBWL with IMWL plus Elipse balloon than with IMWL alone. 17% of patients with IMWL plus Elipse balloon achieved > 20% TBWL
Ienca et al 2019 (Abstract)	Presented at European Congress on Obesity (ECO)	Multicenter study evaluating safety and effectiveness of Elipse placement by non-endoscopists specializing in obesity medicine N= 150 Mean age 44.3 years Mean weight 107.3 Kg Mean BMI 36.6	Mean %TBWL at 4 months: 18% Mean %EWL at 4 months: 52.7% Mean weight loss: 19.4 Kg Mean reduction in BMI: 6.6 points	No SAEs were reported	Elipse intra-gastric balloon treatment administered by non-endoscopist obesity clinicians is not only safe, but can produce best-in-class efficacy results The extension of the intra-gastric balloon management to other specialists allows its availability to a greater number of patients.

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lenca et al 2020 (Abstract)	Accepted for presentation at the 2020 International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Congress.	Multicenter study using 2 sequential Elipse balloons over 1 year with a 1-5 month balloon free period in-between N=42 Females 32 Males 10 Mean BMI 36.8 Mean weight 94.6 Kg	Mean %TBWL with first balloon 14.4% Mean %TBWL with second balloon 10.0% Mean %TBWL after two sequential balloons 22.8% Maximum %TBWL after two sequential balloons 40.9%	No SAEs were observed One patient had a planned endoscopic removal due to a history of appendicitis	Elipse sequential balloon placement enhances weight loss in overweight and obese patients Sequential balloon weight loss approximates what can be achieved with bariatric surgery at 1-year
lenca et al 2020 (Abstract)	Accepted for presentation at the 2020 International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Congress.	Multicenter study with long-term follow up 1 year after the passage of Balloon. Utilization of the Bluetooth connected scale and cell phone app for follow-up. N=509 Females 321 Males 188 Mean weight 102 Kg Mean BMI 35.9	After 4 months: Weight loss: 14.4 Kg %TBWL: 13.9% %EWL: 55.5% 1 Year after balloon passage: Weight loss: 14.1Kg %TBWL: 13.3% %EWL: 50.8%	Intolerance requiring endoscopic removal 1.2% Gastric dilation 0.2% Gastritis 0.2% Gastric perforation requiring laparoscopic repair 0.2% Excretion of empty balloon via vomiting at end of residence occurred in 1.3% and was not considered an adverse event	Elipse balloon demonstrated excellent short and long-term weight loss with very few adverse events This resulted in a 13.9% TBWL at 4 months and 13.3% TBWL 1 year after balloon passage, a 95% maintenance of %TBWL.