

Study of procedure-free gastric balloon shows they are safe, lead to similar weight loss as other balloon procedures

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New research on the first procedure-free gastric balloon, presented at this year's European Obesity Summit (EOS) in Gothenburg, Sweden (June 1-4) shows it is safe and results in similar weight loss to other balloon procedures that use endoscopy. The study is by Dr Ioannis Raftopoulos, Weight Management Program, Holyoke Medical Center, Holyoke, MA, USA, and colleagues.

Traditional gastric balloons for [weight loss](#) require endoscopy for placement and removal. However, a new type of balloon called Elipse (Allurion Technologies, Wellesley, MA, USA) is the first procedureless gastric balloon. The balloon is swallowed, resides in the stomach for 4 months, and is then excreted.

In this new study, 34 patients swallowed one Elipse device, which was filled with 550mL of filling fluid through a thin delivery catheter that was then removed. Each device was designed to remain in the stomach for 4 months and then open, and be excreted naturally. Weight was measured every 2 weeks, and metabolic parameters were assessed at baseline and the end of the study. The Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire was administered at baseline and the end of the study to measure the effects of weight loss on physical function (PF), self-esteem (SE), sex life (SL), public distress (PD), work (W), and overall (O).

The 34 participants had a mean BMI of 34.4 kg/m². All 34 patients successfully swallowed the Elipse device. As expected with balloon therapy, some patients experienced nausea, vomiting, and abdominal cramps during the first 48 hours. All adverse events were either self-limiting or resolved with medication (antiemetics and/or antispasmodics).

The researchers found that at 4 months, the mean weight loss was 10 kg, per cent total body weight loss was 9.5%, and per cent excess weight loss was 37.2%. All balloons were safely excreted. Mean waist circumference and haemoglobin A1c (HbA1c) (a measure of blood sugar control) were reduced by 8 cm and -0.16%, respectively. Improvements were also seen in triglycerides and levels of bad cholesterol. At trial exit, IWQOL-Lite mean scores improved across all domains: +13.7, +17.7, +6.0, +7.7, +7.9, and +11.9 for PF, SE, SL, PD, W, and O, respectively. An improvement of greater than 7.7 in any domain is considered statistically significant.

Dr Raftopoulos concludes: "These results demonstrate clinically significant weight loss with Elipse, the first procedure-free gastric balloon. The weight loss observed was similar to that seen in prior studies of endoscopically placed balloons. There were no serious adverse events. In addition, Elipse therapy led to a significant improvement in waist circumference, blood sugar control, and overall quality of life."

He adds that 90% of patients reported satisfaction with the procedure and indicated that they would recommend it to a friend, and concludes: "As a temporary intervention that does not require anatomic modification, Elipse is a less invasive and reversible path to weight loss. Elipse may enable patients to remain at a healthy weight through repeat use of the device without requiring anaesthesia, incisions, or surgical risks."

Allurion, the manufacturer, now intends to conduct a larger, randomised, controlled clinical trial in the USA.

Provided by European Association for the Study of Obesity

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