| Citation (APA) | Sample size (N) | Methods | Demographics | Results | Conclusions |
|---|--------------------|--|--|--|--|
| Raftopoulos Y. An Intensive 52-week Nutritional, Exercise and Behavior Modification Program: Comparison With or Without the Elipse Intragastric Balloon ASIMBS 2021 | 79 | 1 Y follow-up Lifestyle intervention involves: included a structured curriculum- based nutrinoal, exercise and behavior modification program | Mean BMI (Elipse): 36.2 ± 5.2 Mean BMI (LI):36.8 ± 5 Mean age (Elipse): 43 ± 10.8 Mean age (LI):48.3 ± 12.4 | % TBWL (Elipse): 13,3 ± 4,7 %TBWL (LI): 6,4 ± 6,4 Remaining N: 22 vs 122 Week 52: %TBWL (Elipse): 14 ± 6,2 %TBWL (LI): 7,9 ± 7,5 Remaining N: 11 vs 141 | Elipse is an independent and highly significant contributor of WL when added to a 52-week lifestyle intervention. Elipse greatly improves the % of patients achieving a meaningful weight loss and patients' adherence to the lifestyle intervention program. |
| Genco A. Effects of a New Procedureless Intragastric Balloon on Weight Loss and Metabolic Syndrome: Multicenter Registry Experience with 1 Year Follow-up. ASMBS 2021 | 324 | Multicenter | 191 women 133 men Mean age: 45 Mean weight: 103,99 kg Mean BMI: 36,8 kg/m² | After 16 weeks: mean weight loss: 14.3 kg TBWL: 13.75% EWL: 43.3% BMI reduction: 5 kg/m2 At 1-year follow-up: TBWL: 10.1% EWL: 31 % EML: 31 % BMI reduction: 3.7 kg/m2 The overall incidence of the metabolic syndrome at baseline, 4 months and 1 year after balloon excretion was 43.5%, 15.7% and 17.9% respective), 73% sustained weight-loss No SAE | Elipse®, a procedureless intragastric balloon treatment, appears to be safe and effective in inducing TBWL of 13.75% at 4 months that was still maintained at 10.1% one year following balloon excretion (73% sustained weight-loss). In addition, there was a significant reduction in obesity-related metabolic syndrome that reduction persisted a year later. |
| Ienca R., Caballero A., Giardiello C., Schiano di Cola R., Schiavo L., Pagan A., M Kuwari M., Al Samman Zouaghi S., Turro R., Urrita L., Kayassa A., Al Jarallah M. Innovative Swallowable Gastric Balloon for Weight Loss Studied en Yeaten's Younger Than Eighted en Years: A Multicenter Study. ASMBS 2021 | 42 | Multicenter | Age between 13,5 and 17,5 Mean weight: 99,9 kg Mean BMI: 35,4 kg/m² | At 4 months: %TBWL: 13% Mean WL: 12,9 Mean %EWL: 53% Mean BMI reduction: 4,6 kg/m² No complication | Elipse is safe and effective for the treatment of obesity in patients aged less than 18 years. It may be considered a very useful therapeutic option for this difficult to manage category of patients. |
| Raftopoulos Y. The Swallowable Gastric Balloon Significantly Enhances an Intensive Lifestyle Intervention Program for Weight Loss: Final Short and Long Term Results up to 1 Year after Balloon Placement. ASMBS 2021 | 140 | ILI for both groups included a structured curriculum-based nutritional, exercise and behavior modification program. WL results are recorded every month 1Y follow-up | Mean BMI (Elipse): 36,2 ± 5,2 Mean BMI (ILI):36,8 ± 5 | At 4 months, % TBWL: Elipse group: 14,9 LLI group: 6,3% At 12 months, % TBWL: Elipse group: 16,9 LLI group: 7,9 Percentage of Elipse patients achieving 5% TBWL (98.1% vs. 29.7%), 10% TBWL (83.4% vs. 8.2%) and 20% TBWL (18.3% vs. 0.05%) at 1% weeks were all significantly greater (p<0001), 94.7%, 71% and 39.5% of Elipse patients maintained a 5%, 10% and 30.5% of Elipse patients | Elipse IGB remains an independent and highly significant contributor of weight loss when added to a 1 year intensive lifestyle intervention. Furthermore, even after passage of Elipse balloon, 93% of weight loss achieved was maintained at 1 year after placement. |
| Raftopoulos Y. The Swallowable Gastric Balloon: A Teleheatth Approach with Best- in-Class Weight-loss Results. An open randomized trial with remote follow-up through asynchronous or synchronous communication. ASMBS 2021 | 140 | Patients are not seen in person (except for placement) | l Mean BMI: 36,7 kg/m² | % TBWL.at 16 weeks was 14.9. % TBWL.at 16 weeks (156 vs. 155, p=004), 16 weeks (156 vs. 155, p=004), 20 weeks (18.5 vs. 13.6, p=0003, n=19 vs.47) 24 weeks (18.7 vs. 13.5, p=0001, n=23 vs.39). On regression analysis adjusting for age, BMI and gender, only the follow-up group had a significant effect on 16-week % TBWL. No SAEs were observed. | Elipse's unique non-invasive profile and its Bluetooth connected scale and smartphone app can achieve safe and effective weight-loss by RFUP alone without physical visits. Synchronous patient communication achieved an excellent mean %TBWL of 18.7 % at 24 weeks. |
| lenca R., Caballero A., Kolmer S., Juneja G., Murcia S., Al Kuwari M., Quartararo G., Rosa M., Karlson R., Giardiello C. Sequential Elipse Balloon Treatment 1-Vear Weight Loss Results Approximate Bariatric Surgery Results. TOS 2020 | 42 | 2 sequential balloons 1Y follow-up 9 international obesity centers | 32 Women 10 Men Mean age: 42 2±11.2 yrs, Mean weight: 102.4±19.2 kg Mean BMI : 36.8±5.4 kg/m2 | At 4 month (1st balloon removed): Mean weight bass : 14.7±4.4 kg, %TBWL: 14.4±3.6%, %EWL: 67 ± 64,1%, change in BML: 45 ± 2 kg/m2, At 2nd balloon placement: Mean weight: 80,1±18.0 kg Mean EBML: 31.9±4.7 kg/m2 Sequential balloon resulted in additional: | Sequential Elipse Balloon treatment is safe and effective if additional weight loss is indicated following the passage of the first Elipse Balloon. The mean %7 tRVL of 22.8% at the end of one- year approaches results seen with weight loss surgery. |
| Ienca R., Caballero A., Giardiello C., Pagan A., Rosa M., Badiuddin F., Junejia G., Formiga A., Murcia S. Long-Term Efficacy of the Elipse Gastric Balloon System: An International Multicentier Study TOS 2020 | 509 | 1 Y follow-up 9 international obesity centers | 321 women 188 men Mean weight: 102.6±21.3kg Mean BMI: 35,9 ± 5,8 kg/m2 | at 4 Months : weight loss : 14.4±7.7kg %EWL : 55.5±36.5% %EWL : 55.5±36.5% Milloss : 51.4±2.7kg Metabolic parameters improved significantly. At 1 Y : weight loss : 41.4±11.7kg %TBWL : 13.3±9.5% %EWL : 60.8±44.0% Milloss : 43.4±0.0%m2 AEs: Intolerance 1.2%, gastritis 0.2% and gastric perforation requiring laparoscopic repair 0.2%. Seven patients (1.3%) passed the balloon by vomting at the end of balloon residence. | EGBS demonstrated excellent short and long- term weight loss results. Very few adverse events occurred during the treatment. "Vrtual follow-up" enhanced weight loss during EGBS treatment . Continued "Vrtual follow-up" after balloon passage enabled a significant weight loss maintenance. This resulted in a 13.9% TBWL at 4 months and 13.3% TBWL 1 year after balloon passage, a 95% maintenance of %TBWL. |
| Ienca R, Rosa, M, Selvaggio, C, Shi G, Alfaro, C, Aldaguer, M, Alvarez, M. Expanding the reach of Intragastric Balloons; First multicenter results of Elipse Balloon in non-core user group. SOARD, 2018, 14, S99-S196 | 64 | Multicenter | 39 women 29 men Mean age : 45,1 ± 10,7 Mean BMI: 35 ± 4,6 kg/m2 Mean weight: 101,4 ± 19,6 kg | % TBWL : 16 ± 6 %, % EWL : 64 ± 5 %, change in BMI : 57, ± 2.6 kg/m2, Triglycendes and LDL decreased significantly, 1 before amount due to interference. No SAE | This study demonstrates for the first time that Elipse administrated by internists is safe and effective: The results from these non-core user groups appear superior to most published data from core user groups; internists' motivation of patients may have been a factor. |
| . Genco A, Giardiello C, Lucchese M. Rosa M, Rovati, M. Giuseppe S, Formiga A, Ernesti I, Xappa M Effects of New Procedureless Intragastric Balloon (Elipse ®) on Metabolic Syndrome and Pre- Diabetes: tilatian Group's Experience on 324 Patients with Overweight and Obesity. SOARD, 2018, 14, S56-S66 | 324 | Multicenter | 191 women 133 men Mean age: 45 Mean weight: 103,99 kg Mean BMI: 36,8 kg/m² | Mean WL: 14,3 kg TBWL: 13,75% Excess weight loss: 51,3% Positive effect on glucose metabolism No SAE | Elipse is a safe and effective in including weight loss and results in a significant reduction in obesity-related metabolic diseases including metabolic syndrome and pre-diabetes |