NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of swallowable gastric balloon capsule for weight loss

In this procedure, a person who is overweight or obese swallows a capsule attached to a thin tube. The capsule contains a small inflatable balloon. Once in the stomach, the capsule dissolves and the balloon is inflated by filling it with liquid through the tube. The tube is then disconnected and pulled back up the throat and removed through the patient's mouth. The balloon stays in the stomach for around 4 months. It deflates over time and is passed out naturally through the bowel. The aim is to give a feeling of fullness and temporarily restrict the size of the stomach, leading to weight loss. This procedure must be combined with appropriate dietary and lifestyle changes.

Contents

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in December 2019 and updated in April 2020.

Procedure name

- Swallowable gastric balloon capsule for weight loss

Specialist societies

- British Obesity and Metabolic Surgery Society
- British Society of Gastroenterology
- The British Dietetic Association (BDA)
- Royal College of Physicians and Surgeons of Glasgow
- Royal College of Surgeons of England
- Royal College of Surgeons of Edinburgh
- Royal College of Physicians of London
- Royal College of Physicians of Edinburgh

Description of the procedure

Indications and current treatment

Overweight is defined as a body mass index (BMI) of 25 kg/m^2 to 29.9 kg/m^2, and obesity is defined as a BMI of 30 kg/m^2 or more. Overweight and obesity increase people's risk of type 2 diabetes, coronary heart disease and hypertension. Weight loss reduces these risks and improves life expectancy.

Obesity is managed by dietary advice, physical activity and exercise, lifestyle and behavioural changes, and medication. Bariatric surgery is considered as a

treatment option for people whose BMI is over 40 kg/m^2, or over 35 kg/m^2 if they have significant comorbidities. Surgery is considered if people have not been able to reach or maintain a clinically beneficial weight using non-surgical measures. Surgical procedures include gastric banding, sleeve gastrectomy, Roux-en-Y gastric bypass or other diversion procedures.

People unable to lose weight by non-surgical measures who do not want invasive surgery can have less invasive bariatric procedures. Examples are endoscopic intragastric balloons, gastrointestinal bypass sleeves, endoscopic sleeve gastroplasty and endoluminal restrictive surgical techniques.

What the procedure involves

A swallowable gastric balloon capsule for weight loss must be used with a nutrition and behaviour modification programme supervised by a suitably qualified and registered healthcare professional. It takes about 16 weeks.

The procedure is usually done in an outpatient setting without endoscopy or sedation. The patient swallows a capsule containing the deflated balloon, which is attached to a fine delivery catheter, with water. If they have difficulty swallowing the capsule, a stylet can be fed through the catheter to stiffen it. This allows the doctor to help push the catheter during swallowing. After the capsule reaches the stomach this stylet is removed. The position in the stomach is confirmed by X-ray using guide marks on the catheter. The capsule disintegrates and the balloon is inflated with a fixed amount of fluid (for example, distilled water and citric acid) through the connected catheter. After the balloon is inflated, the catheter is detached by pulling it firmly from the patient's mouth. Imaging is done to recheck position and inflation. After a short wait to make sure the patient can tolerate the balloon, they are discharged with medication including anti-emetics, antispasmodics and proton pump inhibitors. About 4 months later, a resorbable material element of the balloon degrades, which then allows a release valve to open and expel the fluid into the stomach gradually. The deflated balloon then passes through the gastrointestinal tract to be excreted through the bowel.

Efficacy summary

Changes in weight and BMI

In a large registry of 1,770 patients (with a mean weight of 94.6 kg, plus or minus 18.9, and a mean BMI of 34.4 kg/m^2 plus or minus 5.3) who had a swallowable gastric balloon capsule, at 4 months, the mean overall weight loss was 13.5 kg plus or minus 5.8, and the mean BMI reduction was 4.9 kg/m^2 plus or minus 2.0.[2]

In a multicentre prospective case series of 135 patients with a mean BMI of 33.7 kg/m^2 who had a swallowable gastric balloon capsule, at 4 months, the

mean weight of the patients decreased (from 88.8 kg at baseline to 75.75 kg; a reduction of 13 kg, p=0.000) and mean BMI also reduced (from 33.7 kg/m^2 at baseline to 28.8 kg/m^2, a reduction of 4.9 units, p=0.000) respectively.[3]

In a case series of 112 patients with a mean BMI of 34.3 kg/m^2 who had a swallowable gastric balloon capsule, the average weight statistically significantly reduced from 92.2 kg at baseline to 82.8 kg at 3 months (p=0.001), 83.5 kg at 6 months (p=0.003) and 85.2 kg at last follow up (p=0.014). The average change in weight was 7.2 kg at last follow up (at least 1 year after excretion). The average BMI also statistically significantly reduced from baseline (34.3 kg/m^2) to 30.9 kg/m^2 at 3 months and 6 months (p<0.000) and 31.7 kg/m^2 at last follow up (p=0.001). The mean change in BMI was 2.9 kg/m^2 at last follow up.[4]

In a case series of 51 patients with a mean BMI of 32.1 kg/m^2, the mean weight decreased from 83.9 kg at baseline to 75 kg at 3 months. At the end of 4 months, the mean weight loss was 8.84 kg. The mean BMI also reduced from 32.1 kg/m^2 baseline to 28.7 kg/m^2 at 3 months. At the end of 4 months, the mean change in BMI was 3.42 kg/m^2. The mean waist circumference also reduced from baseline 95.3 cm to 86.7 cm at 3 months. At 4 months, the mean waist circumference reduction was 8.62 cm (p<0.001).[5]

In a case series of 38 overweight or obese patients (with a mean BMI of 38.6 kg/m^2) who had a swallowable gastric balloon capsule, the mean weight loss from baseline (109.7 kg) was 12.7 kg. The mean BMI also reduced by 4.2 kg/m^2 at 4 months.[6]

In a case series of 34 patients with a mean BMI of 34.8 kg/m^2 who had a swallowable gastric balloon capsule, BMI reduction and waist circumference reduction were 3.9 kg/m^2 and 8.4 cm respectively at 4 months (all p<0.001).[7]

In a case series of 12 patients with a mean BMI of 35.9 kg/m^2 who had a swallowable gastric balloon capsule, at balloon excretion (4 months), there was a statistically significant reduction in BMI from 36.1 kg/m^2 at baseline to 30.7 kg/m^2 (p<0.001), in weight from 103.5 kg at baseline to 88.1 kg (p=0.001), in body fat from 50.7 kg at baseline to 34.6 kg (p=0.001), in waist circumference from 117.6 cm at baseline to 102.8 cm (p<0.001). These improvements were not statistically significant at 12 months (BMI 33.8 kg/m^2, weight 97 kg, body fat 44.7 kg, waist circumference 111.2 cm).[9]

Percentage of total body weight loss

In a meta-analysis of 6 studies (of 2,013 patients with a mean BMI of 30.6 kg/m^2 to 36.2 kg/m^2) the pooled percentage of total body weight loss after treatment (4 months to 6 months) was 12.8% (95% CI 11.6 to 13.9; I^2 83%) and at 12 months was 10.9% (95% CI 5.0 to 16.9, I^2 98%; in 2 studies).[1]

In the registry of 1,770 patients, the mean percentage of weight loss at 4 months was 14.2%.[2]

In the case series of 135 patients, on an intention-to-treat analysis, the mean percentage of total body weight loss at 4 months was 15%. When stratified according to BMI status, patients with a BMI of less than 30 kg/m^2 (n=18) lost 14.8%; those with a BMI of 30 kg/m^2 to 35 kg/m^2 (n=69) lost 13.5% and those with a BMI of more than 35 kg/m^2 (n=48) lost 17.5%.[3]

In the case series of 112 patients, total body weight loss was 10.7%, 10.9% and 7.9% at 3 months, 6 months and last follow up (at least 1 year after balloon excretion). When stratified according to BMI status, patients with a BMI between 27.5 kg/m^2 to 34.9 kg/m^2 lost 10.2%, 10.6% and 8.8% at 3 months, 6 months and last follow up. Those with a BMI between 35 kg/m^2 and 49 kg/m^2 lost 11.5%, 11.2% and 6.6% at 3 months, 6 months and last follow up.[4]

In the case series of 51 patients, the total body weight loss was 10.44% (range -8% to +23%) at 4 months.[5]

In the case series of 38 patients, the mean total body weight loss was 11.6% ($p<0.0001$) at 4 months.[6]

In the case series of 34 patients, the mean total body weight loss was 10% ($p<0.001$) at 4 months.[7]

In the case series of 12 patients, the mean total body weight loss was 14.6% at balloon excretion (4 months) and 5.9% at 12-month follow up.[9]

Percentage of excess weight loss

In the registry of 1,770 patients, the mean percentage of excess weight loss at 4 months was 67.0%.[2]

In the case series of 112 patients, when stratified according to BMI status, patients with a BMI between 27.5 kg/m^2 and 34.9 kg/m^2 (n=64) lost excess weight of 55.4%, 71.9% and 48.6% at 3 months, 6 months and last follow up (at least 1 year after balloon excretion). Those with a BMI between 35 kg/m^2 and 49 kg/m^2 (n=39) lost 32.7%, 31.8% and 18.7% at 3 months, 6 months and last date of follow up. There was a statistically significant difference between the 2 groups at all follow-up times.[4]

In the case series of 51 patients, the mean excess weight loss was 40.84% (-24% to +78%) at 4 months.[5]

In the case series of 38 patients, the mean excess weight loss was 26% at 4 months.[6]

In the case series of 12 patients, the mean excess weight loss was 50% at balloon excretion (4 months) and 18% at 12-month follow up. Baseline BMI, weight and excess weight were not statistically significantly correlated with excess weight loss. There was a positive correlation between weight loss and duration of treatment, but it was not statistically significant.[9]

Metabolic parameters

In the registry of 1,770 patients, all metabolic parameters improved at 4 months: triglycerides from 145.1 mg/dl plus or minus 62.8 to 99.4 mg/dl plus or minus 21.8, p<0.0001; LDL from 133.1 mg/dl plus or minus 48.1 to 106.9 mg/dl plus or minus 27.9, p<0.0001; HbA1c from 5.1% plus or minus 1.1 to 4.8% plus or minus 0.8, p<0.0001.[2]

In the case series of 38 patients, there was a statistically significant reduction in metabolic factors: blood pressure (p<0.02), waist circumference (p<0.002), triglycerides (p<0.0001), blood glucose (p<0.001) and HOMA-IR (Homeostatic Model Assessment for Insulin Resistance) index (p<0.001).[6]

In the case series of 34 patients, there were improvements in haemoglobin A1c (HbA1c) (0.16 mg/dL), triglycerides (16.4 mg/dL), low density lipoprotein (9.7 mg/dL) and diastolic and systolic blood pressure (9.6 mmHg and 5.8 mmHg) respectively. Reductions were statistically significant for HbA1c and blood pressure.[7]

In the case series of 12 patients, there were statistically significant improvements in diastolic blood pressure (baseline 89.1 mmHg) to 76.4 mmHg (p=0.0004), HbA1c (baseline 5.26 mmol/mol) to 5.04 mmol/mol (p=0.01), cholesterol (baseline 216 mg/dL) to 186 mg/dL (p=0.02), thyroid stimulating hormone (baseline 2.048 µIU/mL) to 1.614 µIU/mL (p=0.02), albumin (baseline 4.88) to 4.52 mg/dL (p=0.008), aspartate transaminase (baseline 24.3 U/l) to 15.7 U/l (p=0.0016), and alanine transaminase (baseline 35.54 U/l) to 15.27 U/l (p=0.0068) at excretion.[9]

Maintenance of weight loss at 12 months

In the case series of 12 patients, 55% (6/11) of patients maintained more than 40% of their weight loss at 12-month follow up. 27% (3/11) of patients maintained less than 40% of their weight loss and 18% (2/11) of patients gained more weight than they lost.[9]

Technical outcomes of balloon placement

In the meta-analysis of 6 studies, all balloons were successfully administered except for 1 patient who had the capsule retained in the lower oesophagus.[1]

In the registry study of 1,770 patients, 99.9% (1769/1770) of patients were able to swallow the device with 35.9% (636/1770) needing stylet assistance. Balloon placement failed in 1 patient.[2]

In the case series of 135 patients, balloons were successfully placed and filled with no need for sedation or endoscopy. 32% of patients needed the assistance of a stylet to insert the balloon.[3]

In the case series of 51 patients, balloons were successfully placed with water in 91% (47/51) of patients. A stylet was used during balloon insertion in 9% (4/51) of cases.[5]

In the case series of 38 patients, balloons were successfully placed with water in 95% (36/38) of patients. A stylet was used during balloon insertion in 5% (2/38) of cases.[6]

In the case series of 34 patients, balloons were successfully placed with water in 62% (21/34) of patients. A stylet was used during balloon insertion in 46% (13/34) of cases. 97% (33/34) of balloons were deployed and filled with fluid. In 1 patient deployment was aborted (because the capsule was stuck in the lower oesophageal sphincter despite drinking more water). This was managed by detaching the catheter, after which the capsule entered the stomach spontaneously. The empty balloon was left in the stomach and excreted in stools after 1 day.[7]

In the case series of 12 patients, the balloon was successfully placed with water in 50% (6/12) of patients. A stylet was used during balloon insertion in 50% of (6/12) cases. 92% (11/12) of balloons were deployed and filled with fluid. In 1 patient deployment was aborted because the capsule was stuck in the lower oesophageal sphincter despite drinking more water. This was managed by detaching the catheter, after which the capsule entered the stomach spontaneously. The empty balloon was left in the stomach and excreted in stools after 1 day.[9]

Balloon excretion: time and route

In the meta-analysis of 6 studies (of 2,013 patients), balloon excretion was reported in 2 studies (n=146). Balloons were passed in stools in 73 patients, orally in 10 patients and unnoticed in 58 patients.[1]

In the registry study of 1,770 patients, balloons were excreted in stools in 96% (1692/1770) of patients and orally (vomited early) in less than 1% of patients (11/1770).[2]

In the case series of 112 patients, 46% (49/106) of patients noticed balloon excretion. Of these, 6% (3/49) noticed the balloon less than 2 months after

placement, 61% (30/49) noticed it between 3 and 4.5 months later, 4.7% (5/49), noticed it after more than 4.5 months, and 22.5% (11/49) could not remember the time. The excretion route of those who noticed was through the rectum in 88% (43/49) of patients and orally in 12% (6/49) of patients. Over 45% (48/106) of excretions were unnoticed and 8.5% (9/106) were unknown.[4]

In the case series of 51 patients, 82% (41/51) of patients did not notice the balloon excretion but 18% (10/51) of patients did. This was confirmed by imaging in 40% of patients.[5]

In the case series of 34 patients, balloons were excreted in stools in 88% (30/34) of patients. In 12% (4/34), balloons were expelled uneventfully in emesis after 16 weeks. Patients experienced nausea before vomiting. These symptoms resolved after balloon expulsion with no further intervention.[7]

In the case series of 12 patients, balloons were excreted in stools in 75% (9/12) of patients. Six patients had no side effects but 2 reported large bowel movement and discomfort which resolved after excretion. 25% (3/12) of balloons were expelled uneventfully in emesis after 16 weeks. Patients experienced nausea and vomiting but these symptoms resolved after balloon expulsion with no further intervention.[9]

Satisfaction

In the case series of 51 patients, the overall satisfaction was 6.5, rated using a subjective scale of 0 to 10. The ratings were: for ease of procedure (9), satisfaction with outcome (8), costs (7.5) and symptom severity (1.5).[5]

In the case series of 12 patients, 91% (10/12) of patients reported that they would repeat the treatment if they had an opportunity and all patients would refer a friend. No patient requested the balloon to be decompressed and removed early.[9]

Quality of life

In the case series of 34 patients, all aspects of quality of life (measured using the impact of weight on quality of life [IWQOL] questionnaire) reported statistically significant improvements across all domains (a score greater than 7 was considered statistically significant). Overall quality of life, physical function, self-esteem, sexual life, public distress and work-related quality of life scored 12.2, 12.9, 18.8, 7.7, 7.7 and 8.2 respectively.[7]

In the case series of 12 patients, authors reported an improvement in quality of life as measured by the IWQOL-lite questionnaire at excretion (4 months) and 12 months. No further information available from the study.[9]

Safety summary

Gastric perforation

In the meta-analysis of 2,013 patients, there was 1 gastric perforation that was repaired by laparoscopic surgery. No further details were given.[1]

In the registry study of 1,770 patients, 1 patient (0.06%) had a gastric perforation needing laparoscopic surgical repair and removal of balloon.[2]

Small bowel obstruction

In the meta-analysis of 2,013 patients, there were 3 small bowel obstructions. One patient needed colonoscopy with ileoscopy, and the other 2 had laparoscopic enterotomy for balloon removal. No further complications were reported.[1]

In the registry study of 1,770 patients, 3 small bowel obstructions (0.17%) were reported early in the study from an earlier generation balloon. All these needed laparoscopic surgical removal of the balloon.[2]

In the case series of 135 patients, 1 patient with a medical history of caesarean section experienced a small bowel obstruction 16 weeks after balloon insertion. She experienced 2 days of abdominal pain, vomiting and constipation. The patient had laparoscopic enterotomy for balloon extraction and recovery was uneventful.[3]

In the case series of 112 patients, 1 patient had a small bowel obstruction due to a fault in the balloon valve mechanism and early incomplete deflation. This was managed by a small laparoscopic enterotomy and the balloon was removed from the distal jejunum. Recovery was uneventful and the patient was discharged after 2 days.[4]

In a case report of a patient who had balloon placement, there was severe abdominal pain, nausea, vomiting and no bowel movement for a day. Imaging showed gastric dilatation and air fluid levels in the small bowel. CT revealed a small bowel obstruction due to the presence of a partially desufflated balloon in the jejunal tract after 6 weeks of placement. This was managed by antibiotic therapy and intravenous fluid and guided aspiration of fluid from the device. As symptoms persisted and conditions deteriorated further, a laparoscopy was done but the device was not found in the small bowel. A Foley catheter inserted in the rectum with contrast medium revealed the balloon in the descending colon. This was removed by colonoscopy and there were no further complications.[10]

Early removal or explant of balloon (before 4 months of study period) as a result of vomiting, early deflation or balloon intolerance

In the meta-analysis of 6 studies (of 2,013 patients), early balloon expulsion by emesis and early deflation were seen in 3 and 9 patients, respectively.[1]

In the registry study of 1,770 patients, 3% of patients (52/1770) reported intolerance needing endoscopic balloon removal. Eleven balloons (less than 1%) deflated early (in under 3 months) and passed uneventfully. Four balloons (less than 1%) were endoscopically removed after these patients were found to have had prior contraindicated surgery.[2]

In the case series of 135 patients, early removal or explant of balloon was reported in 6% (8/135) of patients (2 before 1 month, 3 at 2 months, 2 at 3 months and 1 at 4-month follow up). Balloons were vomited early in 2% (2/135) of patients, early deflation of the balloon was noted in 2% (3/135) of patients and balloon intolerance with abdominal pain was reported in 2% (3/135) of patients. In 1 of these patients elevated levels of amylase and lipase were reported and the balloon was removed endoscopically.[3]

In the case series of 112 patients, early balloon deflation was reported in 3% (3/112) of patients. Balloon intolerance with repeated nausea and vomiting associated with epigastric pain was reported in 5% (6/112) of patients. All balloons were removed endoscopically.[4]

In the case series of 51 patients, balloon intolerance as a result of high symptom severity was reported in 10% (5/51) of patients. This was managed by removing balloons through gastroscopy or endoscopy (4 after 3 days and 1 after a month). Early balloon deflation at week 6 (suspected after weight gain) was reported in 1 patient (2%) and the balloon was vomited early in 1 patient (2%) at week 10 without any complications. Recovery was uneventful in all cases.[5]

In the case series of 38 patients, early balloon removal was reported in 1 patient who had a binge eating disorder. The patient had persistent nausea and vomiting. The balloon was punctured endoscopically and removed after 22 days of treatment.[6]

In the case series of 34 obese patients, balloon intolerance was reported at day 1 and 8 weeks in 6% (2/34) of patients. These balloons were decompressed on patient request through endoscopy. They were punctured in multiple locations and were left in the stomach, and eventually excreted in stools uneventfully.[7]

In the case series of 12 patients, accommodative symptoms (abdominal pain, nausea, emesis, constipation, gastroesophageal reflux disease) were seen within 2 weeks after deployment and around balloon elimination. The mean duration of

symptoms was 2 days to 10 days, peaking in the first 2 days and improving by day 4.[9]

In the pilot study of 8 patients, early balloon deflation (at 11 days due to a manufacturing defect) was reported in 1 patient. This balloon was punctured through endoscopy and passed in the stool 4 days later. In another patient, early balloon decompression at patient request was done (at 19 days as 'she did not enjoy eating'). The balloon was punctured, and this passed in the stool 4 days later.[8]

Nausea, vomiting and abdominal pain

In the meta-analysis of 2,013 patients, accommodative symptoms such as abdominal pain and nausea or vomiting were frequently reported and successfully managed with medication.[1]

In the case series of 135 patients, 26% (35/135) of patients experienced vomiting during the course of their treatment. All patients reported nausea in the first day after balloon insertion but reported complete resolution by 1 week. Colicky abdominal pain (in the week of balloon deflation) was reported in 22% (29/135) of patients.[3]

In the case series of 112 patients, abdominal pain was reported in 46% (49/112) of patients, and nausea and vomiting were reported in 72% (76/112) of patients after the procedure.[4]

In the case series of 51 patients, after balloon placement, weakness, abdominal pain, nausea and vomiting were reported in 38%, 35%, 17% and 10% of patients respectively. Symptom severity was rated 9.5 (on a subjective scale of 0 to 10) during the first 3 days. These symptoms were managed with medication (in 71%), intravenous drip (in 13%) and in 16% cases resolved spontaneously. During balloon excretion, 4 patients had mild and self-limiting abdominal discomfort (10%) and 2 had constipation and abdominal pain (5%).[5]

In the case series of 38 patients, the most common side effects reported were nausea, vomiting, cramping, abdominal pain, satiety, regurgitation, and difficulty swallowing liquids or solid foods. Symptoms were scored using a visual analogue scale (VAS) of 0 to 10 at different time points (on the day of balloon placement, at 1 week, 2 weeks, 1 month, 2 months, and at the end of the treatment). They were self-limiting or resolved with medication during the treatment. 1 patient had persistent nausea and vomiting that resolved at 10 weeks with medication.[6]

In the case series of 34 patients, 64% (18/28) had vomiting, 54% (15/28) had nausea, 25% (7/28) had abdominal pain,18% (5/28) had constipation, 11% (3/28) had gastrointestinal reflux disease and 1 had abdominal distention. All adverse

events were self-limiting or resolved with medication. A combination of anti-emetic drugs was used to reduce intolerance associated with treatment.[7]

In the pilot study of 8 patients, 6 had nausea, 5 had vomiting and 3 had abdominal cramping. All these events were mild and self-limiting, or resolved with medication.[8]

Diarrhoea

In the case series of 135 patients, diarrhoea (over 3 to 4 days) around balloon deflation time was reported in 13.3% (18/135) of patients.[3]

In the case series of 112 patients, diarrhoea was reported in 9% (13/112) of patients during balloon excretion.[4]

In the case series of 51 patients, diarrhoea (attributed to spillage of balloon fluid into the gastrointestinal tract) was reported during balloon excretion in 18% (8/51) of patients.[5]

Balloon hyperinflation

In the registry study of 1,770 patients, 4 events (less than 1%) of spontaneous hyperinflation of the balloon (presenting with mild to moderate intolerance symptoms) occurred during balloon placement. These balloons were endoscopically removed without complications.[2]

Other adverse events

In the registry study of 1,770 patients, there was 1 case (less than 1%) each of oesophagitis, pancreatitis (both needed endoscopic balloon removal), gastric dilation (15 days after balloon placement, resolved by switching from solid to liquid diet for 48 hours), gastric outlet obstruction, and delayed intestinal balloon transit (both needed endoscopic removal of balloon).[2]

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, specialist advisers listed the following anecdotal adverse events: distress after balloon placement and very early deflation. They considered that the following were theoretical adverse events: structural abnormalities that may cause problems after swallowing the balloon, misplacement into the trachea or elsewhere, and balloon migration.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to a swallowable gastric balloon capsule for weight loss. The following databases were searched, covering the period from their start to 13.03.2019: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients who are overweight (BMI over 27 kg/m^2) or obese (BMI over 30 kg/m^2).
Intervention/test	Swallowable gastric balloon capsule for weight loss.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 2,014 patients from 1 meta-analysis[1], 8 case series[2-8], 1 case report[10, 9]. There is an overlap of patients between the meta-analysis and other studies included in table 2.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are in the list of additional relevant papers.

Table 2 Summary of key efficacy and safety findings on swallowable gastric balloon capsule for weight loss

Study 1 Vatanasiri K (2020)

Details

Study type	Meta-analysis and systematic review
Country	USA
Study period	Inception to November 2019; databases searched were Ovid MEDLINE(R) and epub ahead of print, in-process & other non-indexed citations, Ovid EMBASE, Ovid Cochrane Central Register of Controlled Trials, and Scopus.
Study population and number	n=**6 prospective cohort studies (n=2013 patients with mild to moderate obesity)** (4 published studies- Machykta 2016, Al Sabah 2017, Jamal 2019, Espinet 2019 2 conference abstracts -Ienca 2019, Raftopoulos 2019) mean baseline BMI ranged from 30.6 to 36.2
Age and sex	Average age range 31-43 years; 72.8% (1466/2013) female
Study selection criteria	Eligible studies with participants older than 18 years who had Elipse intragastric balloon implantation, reporting percent total weight loss (%TWL) after completion of treatment and adverse events.
Technique	Elipse intragastric balloon placement done (as described above under procedure description) and followed by multidisciplinary teams.
Follow-up	**Varied follow-up (4 months in 4 studies and 12 months in 2 studies)**
Conflict of interest/source of funding	Authors declared no conflict of interest.

Analysis

Follow-up issues: varied follow-up.

Study design issues: comprehensive search strategy used; conference abstracts included, quality assessment done using the National Institutes of Health (NIH) quality assessment tool. Data were analysed using random effects model, generic inverse variance method and publication bias was assessed using funnel plots. Treatment protocols, lifestyle interventions and dietary follow-up may be varied between studies.

Study population issues: diverse population from different countries were included.

Key efficacy and safety findings

Efficacy & safety

Number of patients analysed: **2013**

Balloon placement

All balloons were successfully administered except for 1 patient that had the capsule retained in the lower oesophagus.

%TBWL after treatment (at 4-6 months) in 6 studies

In a metanalysis of 6 studies (of 2013 patients with a mean BMI of 30.6 to 36.2 kg/m2) the pooled %TWL after completion of treatment (4–6 months) was 12.8% (95% CI, 11.6–13.9%; I^2 83%).

%TBWL at 12 months (2 studies)

In a metanalysis of 2 studies (of 114 patients) the pooled %TWL and at 12 months was 10.9% (95% CI, 5.0–16.9%, I^2 98%).

Early balloon removal due to intolerance (6 studies)

The pooled early removal rate was 2.3%(95%CI, 1.1–3.5%; I2 31%).

Balloon excretion route (reported in 2 studies, n=146)

stools 73, oral 10, unnoticed 58

Adverse events

	N
Gastric perforation (needing surgery)	1
Small bowel obstruction (one patient needed colonoscopy with ileoscopy, 2 patients had laparoscopic enterotomy for balloon removal without any complications)	3
abdominal pain and nausea/vomiting (managed with medications)	Frequently observed
Esophagitis	1
Early balloon expulsion by emesis	3
Early deflation	9

Abbreviations used: BMI, body mass index; %EWL, percent excess weight loss; %TBWL, percent total body weight loss; WL, weight loss.

Study 2 Ienca R (2020)

Details

Study type	**Case series (multicentre registry data)**
Country	International (7 countries-Europe & Middle East, 19 centres)
Recruitment period	2016-2019
Study population and number	n=**1770 overweight or obese patients** mean BMI 34.4 kg/m^2; mean weight 94.6 kg
Age and sex	Mean age 39 years; 72% (1171/1623) female
Patient selection criteria	Inclusion criteria: patients between 18 and 65 years and body mass index (BMI) greater than 27 kg/m^2 with previous failed dietary treatments. Exclusion criteria: caesarean sections, patients with swallowing problems, previous intestinal obstruction, hiatal hernia, gastrointestinal cancer and bleeding, severe coagulopathy, or severe psychological or eating disorders, and conditions that predispose to bowel obstruction and gastric perforation.
Technique	Elipse™ Balloon (Allurion Technologies) procedure done (as described above under procedure description) and followed by a multidisciplinary team. Patients had medications as per protocol. Only fluid hydration was permitted for the first 24 hours and a gradual progression towards a semi-solid diet, and subsequently solid diet, was carried out over 1 to 2 weeks. The diets were administered by a nutritionist or dietitian who supported patients for the entire treatment period. Nutritional counselling was provided. Digital tools like the digital scale and smartphone app were used during treatment and after balloon excretion to manage weight loss tracking and communication with the patient.
Follow-up	**4 months**
Conflict of interest/source of funding	2 authors are consultants for the manufacturer and one author is an advisor.

Analysis

Follow-up issues: rate of follow-up was high and only 3.6% patients (63/1770) did not complete the program. They had the balloon removed before 4 months due to intolerance or other adverse events.

Study design issues: a large prospective non-randomised registry study conducted in various obesity treatment centres; custom made database was used to collect prospective data about treatment program. Metabolic data was only collected in a few centres with an interest in metabolic disorders.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **1770**

Balloon placement outcomes

	% (n)
Swallowed	64 (1133/1770)
Swallowed with stylet assistance	35.9 (636/1770)
Balloon placement failed	0.06 (1/1770)

Weight loss and metabolic outcomes

	Baseline	After treatment	P value
Overall WL (kg)	94.6 ± 18.9	81.8 (reduced 13.5 ± 5.8)	<0.0001
% TBWL		14.2 ± 5.0	<0.0001
% EWL		67.0 ± 64.1	<0.0001
BMI (kg/m2)	34.4 ± 5.3	29.5 (reduced 4.9 ± 2.0)	<0.0001
Triglycerides (mg/dL)	145.1 ± 62.8	99.4 ± 21.8	<0.0001
LDL (mg/dL)	133.1 ± 48.1	106.9 ± 27.9	<0.0001
HbA1c (%)	5.1 ± 1.1	4.8 ± 0.8	<0.0001

Subgroup analysis according to BMI

BMI*	% TBWL mean (SD)
< 30 (n = 302)	13.3 ± 4.7
30–40 (n = 1230)	14.4 ± 4.9
> 40 (n = 196)	14.7 ± 4.2

Results also were similar in males and females.

*BMI data not available for 42 patients.

Safety

Adverse events and complications

	% (n=1770)
Intolerance requiring endoscopic removal	2.9 (52)
Early balloon deflation (< 3 months) passed uneventfully	0.6 (11)
Spontaneous balloon hyperinflations (presenting with mild to moderate intolerance symptoms), endoscopically removed without complications	0.2 (4)
Small bowel obstructions (needed laparoscopic surgical removal of balloon) *	0.17 (3)
Gastric dilation (15 days after treatment, resolved after switching from solid to liquid diet for 48 hours)	0.06 (1)
Esophagitis (needed endoscopic removal of balloon)	0.06 (1)
Pancreatitis (needed endoscopic removal of balloon)	0.06 (1)
Gastric perforation (needed laparoscopic surgical repair and removal of the balloon)	0.06 (1)
Delayed intestinal balloon transit (needed endoscopic removal of balloon)	0.06 (1)
Gastric outlet obstruction (needed endoscopic removal of balloon)	0.06 (1)

* All 3 occurred in 2016 from an earlier design of the balloon.

Balloon passage

	% (n)
Stools	95.6 (1692/1770)

	Vomited balloon early (with no associated events) *	0.6 (11/1770)
	Endoscopic removals (all causes)	3.6 (63/1770)
	Surgical removals	0.02 (4/1770)
	*the rest were excreted in stools.	
Abbreviations used: BMI, body mass index; HbA1c, glycated haemoglobin; LDL, low density lipoprotein; %EWL, percent excess weight loss; SD, standard deviation; %TBWL, percent total body weight loss; WL, weight loss.		

Study 3 Al-Sabah S (2018)

Details

Study type	**Case series (prospective)**
Country	Kuwait
Recruitment period	2016-2017
Study population and number	n=**135 overweight or obese patients** baseline mean BMI 33.7kg/m^2 (range 26.5-43.6); mean weight 88.8 kg (range 64-143 kg)
Age and sex	Mean age 33.5 years; 87.4% (111/135) female
Patient selection criteria	Inclusion criteria: obese patients for who bariatric surgery was not indicated, morbidly obese patients refused to have bariatric surgical procedure, nor a procedure that requires general anaesthesia consulting for an alternative method of weight reduction. Exclusion criteria: history of small bowel obstruction, any signs or symptoms of oesophageal, gastric, or intestinal disease, inflammatory bowel disease or cancer. Large hiatal hernia, history of previous abdominal surgery or laparoscopic abdominal surgery, history of smoking in the past 12 months, conditions that require the use of chronic non-steroidal anti-inflammatory drug medications.
Technique	Intragastric balloon (Elipse device-Allurion technologies) procedure (done as described above under procedure description)- Non-steroidal anti-inflammatory drugs were stopped 14 days before the procedure and continued 14 days after the procedure. Weight loss medications were stopped during the study. Participants were given oral omeprazole 1 week before procedure and continued for 16 weeks after procedure, anti-emesis drugs were given 1 day before or on day of procedure and continued for a week. Patients were recommended to follow healthy lifestyle and also followed up by a dietician after the procedure. They were seen every 2 weeks after the procedure by a physician. An electronic scale is provided and linked to a phone application for ease of follow-up of patient's progress.
Follow-up	**4 months**
Conflict of interest/source of funding	Authors declare no commercial associations.

Analysis

Follow-up issues: 5.9% (8/135) patients did not complete the study period and had the balloon removed before 4 months (2 prior to 1 month, 3 at 2 months, 2 at 3 months and 1 at 4 months follow-up). Study doesn't not follow-up patients after the course of treatment.

Study design issues: prospective cohort study in 2 centres evaluating safety and effectiveness. Some patients in the study followed an exercise regimen after the procedure. Primary outcomes were changes in weight, BMI, and percent total weight loss and adverse events. A modified intention-to-treat analysis done.

Study population issues: all patients had some form of initial treatment failures.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **135**

All devices were successfully placed and filled with no need for sedation or endoscopy. 31.8% patients needed the assistance of stylet for insertion of the balloon.

Efficacy outcomes

	Baseline	**4 months**	**Difference; p value**
BMI (kg/m^2), mean (range)	33.7 (26.5-43.6)	28.8 (20.5-38.8)	4.9 BMI units (p=0.000)
Weight (kg), mean, (range)	88.8 (64-143)	75.75 (55.1-117.0)	13.0 (-12.4 -29.8; p=0.000)
Mean %TWL		15.1%	

%TWL relative to BMI

Patients with a BMI of less than 30 (n=18) showed a %TWL of 14.8±4.8, those with a BMI of 30 to 35 (n=69) showed a %TWL of 13.5±6.6 and those with a BMI more than 35 (n=48) showed a %TWL of 17.5±13.3.

Safety

Adverse event

	% (n)
Vomiting (during course of treatment)	25.9% (35/135)
Colicky abdominal pain (in the week of balloon deflation)	21.5 (29/135)
Diarrhoea (over 3-4 days around balloon deflation time)	13.3 (18/135)
Nausea*	100
Small bowel obstruction (noted after 16 weeks, laparoscopic enterotomy was done and balloon removed, recovery was uneventful)	0.7 (1/135)
Early removal/explant of balloon (before 4 months of study period)	**5.9 (8/135)**
Vomited balloons early	1.5 (2/135)
Early deflation of balloon	2.2 (3/135)
Balloon intolerance (abdominal pain reported in all and mildly elevated levels of amylase and lipase reported in 1, device removed endoscopically in 1)	2.2 (3/135)

*all patients reported nausea on first day but resolved by 1 week.

Abbreviations used: BMI, body mass index; %TWL, percent total weight loss.

Study 4 Jamal MH (2019)

Details

Study type	**Case series (prospective)**
Country	Kuwait (single centre)
Recruitment period	2016-2017
Study population and number	n=**112 overweight or obese patients** baseline mean weight 92.2 kg; mean BMI 34.3kg/m^2.
Age and sex	Mean age 31.3 years; 73.6% (78/106) females.
Patient selection criteria	Inclusion criteria: patients aged 18 years and above, with a minimum BMI of 27.5 kg/m^2 Exclusion criteria: contraindications for balloon placement including eating disorders including Bulimia nervosa and anorexia nervosa, previous open abdominal surgery, history of Crohn's disease, severe gastroesophageal reflux disease with hiatal hernia, multiple laparoscopic surgery, bleeding disorders or patients on anticoagulation, history of varices, history of acute pancreatitis, pregnancy, laparoscopic surgery for perforated viscus, and previous gastric surgery. Also excluded patients with balloon intolerance.
Technique	Ellipse intragastric balloon (Allurion Technologies) procedure (done as described above under procedure description)- patients fasted 8 hours prior to procedure and had a single anti emetic dose 4 hours before procedure. Post insertion for the first 48 hours patients had antiemetics and pain killer every 6-8 hours. If patients were dehydrated due to nausea or vomiting, intravenous hydration and anti-emetics were given. Omeprazole was started 1 week prior to placement and continued till end of treatment. Fluids were given for first 24 hours followed by semi-liquid diet for the first week and followed up by the dietician to administer a high-protein low-calorie diet from second week.
Follow-up	**12 months post excretion of balloon (19.6±4.7 months)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: patients were followed up at out-patient clinics and through phone interviews at time intervals of 1 month, 3 months, 6 months and last day of follow-up. 85% (90/106) patients where followed up for 1-year post-expulsion. Overall, 15% patients were lost to follow-up at the end of study.

Study design issues: prospective study in only 1 centre performed by one surgeon. At 1-month follow-up, patients answered a questionnaire about the symptoms that occurred immediately after the procedure. At 3 and 6-months follow-up, the weight and method of excretion as well as symptoms experienced were collected. At last follow-up (1 year from balloon excretion), phone interviews with a short questionnaire (assessing weight, post-procedural symptoms as well as, the time of balloon extraction and the route of extraction) were done.

Study population issues: all patients had prior complete blood count, renal profile and thyroid function tests.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **106**

Overall outcomes

	Baseline Mean±SD	**3 months Mean±SD, p value**	**6 months Mean±SD, p value**	**At last follow-up Mean±SD, p value**
Average weight (kg) range	92.2±20.7 (53-149)	82.8±17.3 (55-139); 0.001	83.5±20.0 (53-141); 0.003	85.2±19.2 (54-145); 0.014
Average BMI (kg/m^2) range	34.3±5.1 (27.5-49)	30.9±4.6 (22.8-46); <0.000	30.9±5.2 (22.3-45.6); <0.000	31.7±5.1 (22.7-44.8); 0.001
Change in BMI		3.7±2.2	3.7±2.6	2.95±4.0
Average weight loss		10.1±6.8	10.1±7.1	7.2±6.7
Average %TWL		10.7±5.5	10.9±6.9	7.9±6.7

Outcomes according to BMI

	Group 1 BMI 27.5 to 34.9 (n=64)	**Group 2 BMI 35 to 49 (n=39)**	**P value**
Initial BMI	31.2±2.6	39.6±3.9	<0.000
Initial weight	81.4±12.2	109.8±20.2	<0.000
3 months			
Change in BMI	3.2±1.4	4.5±2.9	0.283
%TWL	10.2±4.1	11.5±7.1	<0.895
%EWL	55.4±35.7	32.7±19.8	<0.000
6 months			
Change in BMI	3.3±1.7	4.4±3.5	0.467
%TWL	10.6±5.2	11.2±8.9	0.520
%EWL	71.9±98.1	31.8±26.7	0.002
At last follow-up			
Change in BMI	3.2±4.5	2.6±3.1	0.826
%TWL	8.8±5.6	6.6±8.0	<0.264
%EWL	48.6±45.9	18.7±24.7	<0.000

Balloon excretions, time and route

Balloon excretion	**N=106**

Safety

Adverse events (n=112)

	% (n)
Abdominal pain	46.2 (49/112)
Nausea and vomiting	71.7 (76/112)
Diarrhoea	9 (13/112)
Balloon intolerance (due to repeated nausea, vomiting and epigastric pain-device removed endoscopically)	5.4 (6/112)
Early balloon deflation	2.7 (3/112)
Small bowel obstruction (managed laparoscopically, small enterotomy done and balloon removed from distal jejunum, uneventful recovery and discharged after 2 days)- this was due to a fault in the balloon valve mechanism	1

Noticed	46.2 (49/106)		
Unnoticed	45.3 (48/106)		
Unknown	8.5 (9/106)		
Time of balloon excretion if noticed	**n=49**		
Less than 2 months	6.1 (3/49)		
3 to 4.5 months	61.2 (30/49)		
More than 4.5 months	4.7 (5/49)		
Cannot remember	22.5 (11/49)		
Balloon excretion route	**N=49**		
Rectum	88 (43/49)		
Orally (caused psychological distress)	12 (6/49)		

Abbreviations used: BMI, body mass index; %EWL, percent excess weight loss; %TWL, percent total weight loss; SD, standard deviation.

Study 5 Al-Subaie (2017)

Details

Study type	**Case series (prospective) NCT03160469**
Country	Kuwait (single centre)
Recruitment period	2016-2017
Study population and number	n=**51 overweight or obese patients (BMI 27-40 kg/m^2)**
Age and sex	Mean age 33.6 years (range 18-65 years); 92% (47/53) females.
Patient selection criteria	Inclusion criteria: patients aged 18-65 years with BMI of 27-40kg/m^2, unsatisfied with traditional diet and exercise programs that do not achieve results, motivated with realistic weight loss expectations, ready and committed to follow a physician guided weight loss program. Exclusion criteria: psychologically driven eating disorders, with a history of abdominal or pelvic surgery before 12 months excluding caesarean section, diagnostic laparoscopy, laparoscopic appendectomy or cholecystectomy, previous bariatric or gastric surgery, history of acute pancreatitis, small bowel obstructions, history of signs or symptoms of oesophageal, gastric or duodenal disease, hiatal hernias, inflammatory diseases, cancer and varices, those with an abnormal swallowing mechanism, history of bleeding, or other gastrointestinal disorders, those who are pregnant and breast feeding.
Technique	Ellipse intragastric balloon (Allurion Technologies) procedure (done as described above under procedure description)- fluid diet was given 1 day before the procedure followed by 10 hours fasting. Resistance due to catheter kink during inflation was overcome by force injection busting with 30ml syringe. All patients had anti emetic and anti-spasmodic as necessary. Proton pump inhibitors were given one week before procedure and for 2 weeks for those with gastroesophageal reflux disease or gastritis. If uncontrolled severe symptoms occur patients were given intravenous drip and medications on an outpatient basis. Patients were instructed to take liquid diet and refrain from ulcerogenic products and followed up by a dietician every month.
Follow-up	**4 months (until expected day of excretion)**
Conflict of interest/source of funding	No conflicts of interest and no funding was received.

Analysis

Follow-up issues: short follow-up only until balloon was present; patients who had balloon removal endoscopically or vomited the balloon and were excluded from primary outcome evaluation but included in secondary outcome assessment.

Study design issues: small prospective pilot study done in 1 centre by 1 surgeon. Outcomes assessed include total weight loss, % EWL, % TWL and change in BMI and waist circumference. A short survey was done to evaluate symptoms, complications and overall satisfaction at 4 months. There were high non-compliance rates with use of electronic scales at home to record body composition.

Study population issues: at baseline according to BMI patients were classified into 3 categories: 32.1% patients were overweight, 55.6% were obese class I, and 13.3% were obese class II.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **51**

Procedure outcomes

	% (n)
Successful insertion with water	91.2 (47/51)
Use of stylet device during insertion	8.7 (4/51)
Low calorie diet program during treatment	64.4
Non-compliant to diet program	35.6
Non-compliant to exercise during treatment	71.1
Moderate exercise	15.5
Highly active	13.3

Body composition changes during treatment time

	Baseline	**1st month**	**2nd month**	**3rd month**	**4th month**
Weight, kg	83.9±12.3	79.0±11.6	76.9±11.3	75.0±1.5	0.000
BMI, kg/m^2	32.1±3.2	30.2±2.9	29.4±2.8	28.7±3.0	0.000
Waist circumference, cm	95.3±9.2	90.6±7.2	-	86.7±8.1	0.000

Changes in indicators of weight loss at 4 months

Mean weight loss, kg (range)	8.84 kg (-6 to +21.5 kg)
Mean % TBWL	10.44% (-8 to +23%)
Mean % EWL	40.84% (-24 to +78%)
Mean change in BMI, kg/m^2	3.42 kg/m^2
Mean waist circumference reduction, cm	8.62 cm (-10 to +31) P<0.001

Satisfaction (assessed on a subjective scale 0-10)

Overall satisfaction	6.50
Ease of procedure	9.00
Symptom severity	1.50
Satisfaction with results	8.00
Satisfaction with costs	7.50

Safety

Adverse events (n=51)

	% (n)
Balloon removal (by gastroscopy/endoscopy; 4 after 3 days and 1 after a month, due to high symptom severity; all uneventful)	9.8 (5/51)
Vomited the balloon (at week 10 without complications; cause unknown)	2 (1/51)
Early deflation of balloon (at week 6 suspected after weight gain, uneventful)	2 (1/51)
Symptoms after insertion*	
Weakness	38.4 %
Abdominal pain	35.1 %
Vomiting	16.5 %
Nausea	10%
Symptoms during balloon excretion^	
No symptoms	64.4 (28/51)
Diarrhoea (attributed to spillage of balloon fluid into GI tract)	17.8 (8/51)
Mild abdominal discomfort	4.5 (2/51)
Constipation	4.5 (2/51)
Balloon excretion^^	
not noticed during excretion	82.2 (41/51)
Noticed during excretion	17.6 (10/51)

*symptom severity (assessed on a subjective scale 0-10) was 9.5 during first 72 hours. Symptoms resolved by medications in 71% cases, spontaneously in 15.6%

	cases and by intravenous drip in 13.3% cases. ^symptoms resolved spontaneously in 57.8% (25/51) cases, and 42.2% needed medications. ^^ x-ray was needed to confirm balloon excretion in 40% cases and 1 needed additional ultrasound.
Abbreviations used: BMI, body mass index; %TBWL, percent total body weight loss; %EWL, percent excess weight loss.	

Study 6 Genco A (2018)

Details

Study type	Case series (prospective)
Country	Italy
Recruitment period	January and June 2016
Study population and number	n=**38 overweight or obese patients.** Mean BMI at baseline 38.6±6.7 kg/m^2
Age and sex	Mean age 46.4 ± 10.6 years, 73% (28/38) female
Patient selection criteria	Inclusion criteria: patients aged 18-65 years with BMI of greater than or equal to 27kg/m^2 and less than 45kg/m^2 Exclusion criteria: previous bariatric or gastric surgery or more than one other abdominal/gynaecological operation, history of bowel obstructions, hiatal hernia (>5 cm), heart failure, eating disorders (bulimia, night eating syndrome or binge eating disorder), blood coagulation disorders, and certified pregnancy.
Technique	Elipse™ Balloon (Allurion Technologies) procedure (done as described above under procedure description)- patients fasted 8 hours before procedure and had anti-emetics 4 hours before deployment. After balloon deployment they had intravenous anti-emetics and hydration for 24 hours. Anti-emetics and anti-spasmodic were given for 2 days. Proton pump inhibitors were given one week before procedure and continued till end of treatment. Dietary advice administered by a nutritionist included gradual progression to semi-liquid diet in the first week, and a hypo-caloric texture diet plan from second week. Daily intake was of 1000-1200 kcal ad regular physical activity was suggested.
Follow-up	**4 months**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: one patient withdrew from the study after 22 days due to binge eating disorder (not diagnosed at screening) leading to balloon intolerance symptoms.

Study design issues: small prospective study at a single centre; all patients had detailed screening (medical and obesity history, clinical and anthropometric evaluation, blood, liver and lipid profiles and psychiatry and alimentary behaviour assessment). Patients had clinical and anthropometric assessment every week for first month, then every two weeks until 4 months. Medications were recorded in a dairy. Symptoms were measured by a visual analogue scale (0 to 10, with 10 being more severe) at different time points.

Study population issues: patients were compliant with nutritional recommendations. Ultrasound evaluation was done in 7 patients who reported gastrointestinal symptoms during screening.

Other issues: there is no data after device expulsion.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **38**

Procedure outcomes

	%(n)
Successful insertion with water	94.8 (36/38)
Assistance with a stylet device during insertion	5.2 (2/38)

Change in weight loss at 16 weeks

Mean weight at baseline, kg	109.7±21.9 kg
Mean BMI at baseline	38.6±6.7 kg/m^2
Mean weight loss, kg	12.7 kg
Mean BMI reduction, kgm^2	4.2 points kg/m^2
Mean % EWL	26%
Mean % TBWL	11.6%

There was a statistically significant reduction in metabolic syndrome factors: blood pressure ($p<0.02$), waist circumference ($p<0.002$), triglycerides ($p<0.0001$), blood glucose ($p<0.001$) and HOMA-IR index ($p<0.001$).

Safety

Symptoms assessed on VAS scale 0-10

Symptoms	On day of deployment	End of treatment (16 weeks)
Nausea	6±3.1	0±0
Vomiting	2.6±3.8	0±0
Regurgitation	3.8±3.6	0.3±1.2, $p<0.001$
Satiety	9.2±1.4	4.5±2.3
Cramping	6.7±2.6	0±0
Abdominal pain	4.2±3.4	0±0
Difficulty of liquid consumption	3.2±3.6	0±0
Difficulty of solid consumption	-	0±0

All symptoms: nausea, vomiting, cramping, abdominal pain, regurgitation, satiety, difficulty in swallowing liquid, and solid foods were self-limiting or resolved with medications during the treatment.

1 patient had persistent nausea vomiting that resolved at 10 weeks with medications.

Balloon removals

	%(n)
Early balloon removal (due to binge eating disorder, patient had nausea, vomiting so balloon was punctured endoscopically and removed after 22 days of treatment)	(1/38)

All other balloons were excreted at 16 weeks with no events.

There were no gastric perforations, symptoms of ulceration, intestinal obstruction and gastrointestinal haemorrhage.

Abbreviations used: BMI, body mass index; %EWL, percent excess weight loss; HOMA-IR index, Homeostatic Model Assessment of Insulin Resistance; % TBWL, percent total body weight loss; VAS; visual analogue scale.

Study 7 Machytka E (2017)

Details

Study type	**Case series (prospective) NCT02802007**
Country	International (2 sites-Czech Republic, Greece)
Recruitment period	November 2014 to December 2015
Study population and number	n=**34 overweight or obese patients** mean BMI 34.8kg/m^2; mean baseline weight: 101.8±17.1 kg (range 73-134 kg)
Age and sex	Mean age 42 years (range 18-59 years); 68% (23/34) female
Patient selection criteria	Inclusion criteria: patients had a BMI of 27 to 40 kg/m^2. Those with a history of caesarean section, laparoscopic cholecystectomy or appendectomy or laparoscopy more than 12 months prior to procedure. Exclusion criteria: history of small bowel obstruction, signs or symptoms of oesophageal, gastric or intestinal disease, inflammatory bowel disease, or cancer, large hernia, history of previous open or laparoscopic abdominal surgery, or history of smoking in past 12 months.
Technique	Elipse™ Balloon (Allurion Technologies) procedure (done as described above under procedure description)-patients stopped NSAIDs 2 weeks prior to and 2 weeks after the procedure, weight loss medications were stopped during procedure. Proton pump inhibitors were started 3 days before and continued during treatment period. Anti-emetics were given in the first week. Patients had nutritional counselling and encouraged to follow high protein diet, 1000-1200 kcal/day. First 28 patients had treatment with a device containing radiopaque marker and made of non-radiopaque film. Last 6 patients had treatment with an experimental design made of radiopaque film and a smaller capsule.
Follow-up	**4 months**
Conflict of interest/source of funding	2 authors received consulting fees from the manufacturer, one was a consultant and 2 other authors are shareholders in the company.

Analysis

Study design issues: small prospective multicentre study; primary outcome was frequency of adverse events and secondary outcomes included weight loss (measured every 2 weeks), metabolic parameters and quality of life (assessed at baseline and end of study-16 weeks).

Study population issues: 10 patients in the study had a history of abdominal surgery.

Other issues: authors state that the use of experimental film was abandoned because of its effect on the valve which led to high variable residence time.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **34**

Procedure outcomes

Successful insertion with water*	62% (21/34)
Assistance with a stylet device during successful insertion	46% (13/34)
Balloons deployed and filled with fluid	n=33
Aborted deployment (capsule was stuck in lower oesophageal sphincter, catheter detached, and capsule entered stomach, and empty balloon excreted after 1 day)	n=1
Mean procedure time, minutes	22±8
Mean residence time of balloon in stomach (n=25)^	117±14 days

*includes 6 patients with a smaller capsule swallowed without the need for a stylet.

*in 6 patients with experimental radio-plaque film, residence time varied from 30 to 141 days.

Weight loss and metabolic parameter outcomes at 16 weeks

	n	Reduction mean±SD (95% CI)	P value
%TBWL	25	10.0±6.6 (7.28 to 12.72	<0.001
BMI kg/m2	25	-3.9±3.1 (-5.18 to -2.62)	<0.001
Waist circumference, cm	25	-8.4 ±6.5 (-11.08±5.72)	<0.001
HbA1c, mg/dl	22	-0.16±0.16 (-0.231 to -0.089)	<0.001
LDL	24	-9.7 ±27.6 (-21.35 to 1.95)	0.099
Triglycerides	24	-16.4±50.9 (-37.9 to 5.1)	0.128
Systolic blood pressure	25	-9.6±16.1 (-16.25 to -2.95)	0.006

Safety

Adverse events

	%(n)
Balloon intolerance (at day 1 and 8 weeks, endoscopy done, and balloon punctured but not removed, both excreted in stools uneventfully)	(2/34)
Balloon excretion in stool	88 (30/34)
Balloon expelled in emesis after 16 weeks (nausea and vomiting experienced, resolved after expulsion with no further intervention)	12 (4/34)
Gastrointestinal adverse events related to procedure (n=28)	
Abdominal distention	3.6 (1/28)
Abdominal pain	25 (7/28)
Constipation	17.9 (5/28)
Gastrointestinal reflux disease	10.7 (3/28)
Nausea (events 19)	53.6 (15/28)
Vomiting (events 21)	64.3 (18/28)
Total (60 events)	85.7 (24/28)

Al adverse events were self-limiting or resolved with medication. A combination of anti-emetic drugs used reduced intolerance associated with treatment.

There were no gastric/oesophageal perforations, symptoms of ulceration, intestinal obstruction and gastrointestinal bleeding.

Diastolic blood pressure	25	-5.8±7.9 (-9.06±-2.54)	0.001

Change in IWQoL scores from baseline to end of treatment (n=27, assessed)^

Overall	+12.2
Physical function	+12.9
Self esteem	+18.8
Sexual life	+7.7
Public distress	+7.7
Work	+8.2

^Improvements greater than or equal to 7.7 are considered statistically significant.

Abbreviations used: BMI, body mass index; CI, confidence intervals; IWQoL, impact of weight on quality of life; LDL, low density lipoprotein; SD, standard deviation.

Study 8 Machytka E (2016)

Details

Study type	Case series (prospective)
Country	Czech Republic
Recruitment period	October and December 2013.
Study population and number	n=**8 overweight or obese patients** (mean BMI 31 kg/m^2, mean weight 88 kg [range 74.8-112.8 kg]).
Age and sex	Mean age 40 years (range 24-60); 90% (7/8) female.
Patient selection criteria	Inclusion criteria: patients with a BMI of 27-35kg/m^2. Exclusion criteria: history of previous abdominal surgery, small bowel obstruction, signs or symptoms of oesophageal, gastric, or intestinal disease, intestinal strictures, inflammatory bowel disease or cancer.
Technique	Prototype version of an Elipse balloon designed to remain in stomach for 6 weeks, self-empty and pass was inserted. Balloon was filled with 450 ml fluid. Patients returned every 2 weeks for ultrasound. No specific diet or exercise plan prescribed. patients stopped NSAIDs 2 weeks prior to and 2 weeks after the procedure, weight loss medications stopped during procedure. Proton pump inhibitors started 3 days before and continued during treatment period. Anti-emetics were given in the first week. At 2, 4 and 6 weeks ultrasound imaging was done to assess balloon position and volume and nutritional counselling also given.
Follow-up	**6 weeks**
Conflict of interest/source of funding	3 authors declared that they have no competing interests. 2 authors received consulting fees from the manufacturer, one was a consultant and 2 other authors are shareholders in the company.

Analysis

Follow-up issues: very short follow-up period.

Study design issues: this is a small proof of concept study that used a small and shorter duration prototype version of device. Outcomes included ability to swallow device, residence in stomach for 6 weeks and passage/excretion of balloon through intestinal tract.

Study population issues: patients were asymptomatic at baseline and did not receive any screening endoscopy. this study patients are part of the multicentre trial of 34 patients (study 5 in table 2). So, there is an overlap of patient population.

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 8
Procedure outcomes
<table>
<tr><td>Successful swallowing</td><td>100% (8/8)</td></tr>
<tr><td>All balloons filled</td><td>100% (8/8)</td></tr>
<tr><td>Mean visit time</td><td>26 minutes</td></tr>
<tr><td>Balloons self-emptied and expelled</td><td>75% (6/8)</td></tr>
<tr><td>Mean weight loss after 6 weeks</td><td>2.4 kg</td></tr>
<tr><td>Mean % EWL</td><td>12.4%</td></tr>
</table></td><td>Adverse events
<table>
<tr><th></th><th>% (n)</th></tr>
<tr><td>Early balloon deflation (at 11 days due to a manufacturing effect, endoscopy was done, balloon punctured and passed in stool 4 days later)</td><td>12.5 (1/8)</td></tr>
<tr><td>Early balloon decompression (as requested by patient at 19 days as ‘she did not enjoy eating’, balloon punctured and passed in stool 4 days later)</td><td>12.5 (1/8)</td></tr>
<tr><td>Nausea</td><td>75 (6/8)</td></tr>
<tr><td>Vomiting</td><td>62.5 (5/8)</td></tr>
<tr><td>Abdominal cramping</td><td>37.5 (3/8)</td></tr>
</table>
All adverse events (mainly mild) are self-limiting or resolved with medications.

There were no gastric/oesophageal perforations, symptoms of ulceration, intestinal obstruction and gastrointestinal bleeding.</td></tr>
<tr><td colspan="2">Abbreviations used: % EWL, percent excess weight loss.</td></tr>
</table>

Study 9 Raftopoulos I (2017)

Details

Study type	**Case series (prospective)**
Country	Greece
Recruitment period	Not reported
Study population and number	n=**12 overweight or obese patients (BMI range 27-40kg/m2)** mean BMI 36.9kg/m^2.
Age and sex	Mean age 41 years (range 18-59); 58.3% (7/12) females
Patient selection criteria	Inclusion criteria: age 18-65 years, BMI 27-40kg/m^2, <5% total weight loss previous 6 months, contraception for females in reproductive age, less than 72 miles from study centre, ambulatory without chronic orthopaedic disease, no weight loss medications for 30 days before procedure, no abdominal surgery, cholecystectomy, appendectomy, laparoscopy, or caesareans section more than 12 months before, no history of venous thromboembolism, smoking, alcohol or drugs for more than 12 months, no anticoagulation, NSAIDs, aspirin for study duration (14 days prior to and after treatment). Exclusion criteria: heart failure, arrhythmia, unstable coronary artery disease, chronic obstructive pulmonary disease, pneumonia, lung cancer, history of bariatric surgery, gastric balloon, no contraception, pregnancy, lactation, history of pancreatitis or small bowel obstruction, inflammatory disease, cancer, hiatal hernia >2cm, renal or hepatic insufficiency, abdominal surgery not listed in inclusion criteria, diabetes, hypothyroidism, immunosuppression, steroids use, active infection, uncontrolled psychiatric disease, night eating syndrome, bulimia, binge eating syndrome.
Technique	Elipse™ Balloon (Allurion Technologies) procedure (done as described above under procedure description)- all patients had detailed screening (medical and obesity history, 7 day diet log, clinical and anthropometric evaluation, blood, liver, lipid, thyroid, chemistry profiles and psychiatry and alimentary behaviour assessment). Proton pump inhibitors started 3 days before and continued during treatment period. Anti-emetics were given in the first week. During treatment patients were encouraged to follow a high protein 1000-1200 calorie diet/day and engage in a specific exercise regimen that included treadmill and weights 3-5 times/week.
Follow-up	**12 months**
Conflict of interest/source of funding	The author received consulting fees from the manufacturer.

Analysis

Follow-up issues: patients followed up every 2 weeks from device insertion. 1 patient in whom procedure was aborted was excluded from the analysis. No patient was lost to follow-up.

Study design issues: very small prospective study with longer follow-up (post treatment outcomes). Patient self-assessment scores were scored based on predetermined score rating system on a scale 1-5, and those with score of 3 or above were included in the study. Food intake, symptoms, and exercise were recorded for first 14 days. After balloon elimination, quality of life (QOL) was assessed using IWQoL-Lite questionnaire, clinical and anthropometric evaluations were done. After 12 months, QOL and anthropometric assessments were repeated.

Study population issues: 2 patients had a history of laparoscopic cholecystectomy and one had a previous caesarean section.

Other issues: this study patients are part of the multicentre trial of 34 patients (study 5 in table 2). So, there is an overlap of patient population.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **12**

Procedure outcomes

Successful insertion with water*	50 (6/12)
Assistance with a stylet device during successful insertion	50 (6/12)
Mean ease of swallow (VAS score 0-10)	6.6±3.9
Balloon successfully deployed and filled with water	92 (11/12)
Aborted deployment (capsule was stuck in lower oesophageal sphincter, catheter detached, endoscopy showed that capsule entered stomach, balloon was not filled and empty balloon excreted after 12 hours)	n=1
Mean procedure time, minutes	16.3±4.7
Mean residence time of balloon in stomach	121.4 days (range 100-142)
Average fluid intake during first 14 days	1518±175 ml
Average protein intake during first 14 days	29.7±12.2 g

Change in anthropometric and clinical outcomes

	Baseline	**Balloon excretion**	**12 months**
BMI, kg/m^2	36.1±3.2	30.7±4.0 P<0.001	33.8±4.1 P=NS
Weight, kg	103.5±15.8	88.1±16.3 P=0.001	97±15.9 P=NS
Body fat, kg	50.7±9.6	34.6±10.3 P=0.001	44.7±15.5 P=NS
Lean mass, kg	14.1±3.3	14.5±3.2 P=NS	14±3.1 P=NS
Waist circumference, cm	117.6±14.9	102.8±13.1 P<0.001	111.2±11.8 P<0.05
Systolic BP, mmHg	130.9±11.4	119.1±26.0 P=0.12	
Diastolic BP, mmHg	89.1±7.4	76.4±4.5 P=0.0004	
Glucose, mg/dL	105.2±8.6	101.3±9.1 P=0.12	
HbA1c	5.26±.18	5.04±.19 P=0.01	
Cholesterol, mg/dL	216.1±51.7	186.6±37.6 P=0.02	

Safety

Adverse events

	%(n)
Balloon excretion in stool (6 had no symptoms but 2 reported large bowel movement and discomfort, resolved after excretion)	75 (9/12)
Balloon expelled in emesis (nausea, epigastric pain and vomiting experienced, resolved after expulsion with no further intervention)	25 (3/12)
Significant water retention (no obvious reason noted)	1

Duration of gastrointestinal symptoms

Abdominal pain	2.3±1.5 days
Nausea	3.2±1.2 days
Emesis	2.4±2.6 days
Gastroesophageal reflux disease	5±3.6 days
Constipation	9.7±7.1 days

A combination of anti-emetic drugs improved symptoms.

LDL, mg/dL	138.9±52.7	119.0±35.0 P=0.08	
HDL, mg/dL	52.8±16.2	49.4±8.5 P=0.3	
Triglycerides, mg/dL	121.9±64.2	91.5±33.7 P=0.11	
Albumin, mg/dL	4.88±0.2	4.52±0.21 P=0.008	
Total protein, mg/dL	7.05±0.26	6.87±0.27 P=0.12	
TSH, µIU/mL	2.048±1.074	1.614±1.036 P=0.02	
Free T4, ng/dL	0.97±0.11	0.95±0.08 P=0.45	
AST, U/l	24.3±9.96	15.7±4.54 P0.0016	
ALT, U/l	35.54±23.52	15.27±6.32 P=0.0068	

Weight loss

	Balloon excretion	**At 12 months**
Mean %TWL	14.6±8.3% (-0.2-27.1%)	5.9% (-12.6-18%)
Mean %EWL*	50.2±25.6% (-0.5-83.4%)	17.6% (-62.1-58.1%)
Mean % fat mass loss	85.4 ±44.5%	
Weight maintenance status^		
Maintained >40% of weight lost	-	54.5% (6/11)
Maintained <40% of weight lost	-	27.3% (3/11)
Gained more weight than lost	-	18.2% (2/11)

*At balloon excretion 1 patient failed to reach the 25% EWL cut-off mark

^ 1 patient was not included in the analysis because balloon was not deployed.

There was no significant correlation between baseline BMI (p=0.35), weight (p=0.27), or excess weight (p=0.29) and % EWL.

There was a positive correlation between weight loss and duration of treatment but did not reach statistical significance (p=0.87).

Quality of life (measured by IWQoL-Lite questionnaire)

There was an improvement in quality of life as measured by the IWQoL-lite at excretion and 12 months.

Satisfaction 90.9% (10/12) patients reported that they would repeat the treatment if they had an opportunity and all patients would refer a friend. No patient requested the balloon to be decompressed and removed early.	
Abbreviations used: ALT, alanine transaminase; AST, aspartate transaminase; BMI, body mass index; BP, blood pressure; HDL, high density lipoprotein; LDL, low density lipoprotein; IWQoL-Lite, impact of weight on quality of life; NS, not significant; TSH, thyroid stimulating hormone; T4, thyroxine; VAS, visual analogue scores.	

Study 10 Angirsani A (2018)

Details

Study type	**Case report**
Country	Italy
Recruitment period	2016
Study population and number	n=**1 overweight patient with hepatic steatosis** mean BMI 33.3 kg/m^2; weight 102 kg
Age and sex	55 year old man
Patient selection criteria	-
Technique	Elipse™ Balloon (Allurion Technologies) procedure (done as described above under procedure description)
Follow-up	**4 months**
Conflict of interest/source of funding	None

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **1** After 6 weeks of balloon placement, patient reported severe abdominal pain, nausea, vomiting and no bowel movement for a day. Imaging showed gastric dilatation and air fluid levels in the small bowel. Antibiotics and intravenous fluid were given. CT revelated small bowel obstruction due to the presence of a partially desufflated balloon in the jejunal tract. The balloon slowly progressed to the anterior abdominal wall allowing a guided aspiration of fluid from the device. Symptoms persisted and conditions deteriorated further. A laparoscopy was done but device was not found in the small bowel. A foley catheter inserted in the rectum with contrast medium revealed the balloon in the descending colon. This was removed by colonoscopy. There were no further complications and patient was discharged on second day. A few months later patient regained weight.	
Abbreviations used:	

Validity and generalisability of the studies

- Most of the studies were case series assessing the effects of the balloon after 4 months of treatment as a temporary solution for weight loss. One of the pilot studies included a prototype device.
- There are no studies comparing it with other similar types of weight loss treatment.
- The evidence mainly comes from studies in the Middle East and Europe (but none from the UK).

- Studies included patients with a body mass index of more than 27.
- There are very little data after balloon expulsion and how long the beneficial effect (weight loss) may be maintained.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Implantation of a duodenal–jejunal bypass sleeve for managing obesity. NICE interventional procedure guidance IPG471 (2013). Available from https://www.nice.org.uk/Guidance/IPG471

NICE guidelines

- Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition. NICE clinical guideline 32 (2006, updated 2017). Available from www.nice.org.uk/CG32
- Obesity: clinical assessment and management. NICE quality standard 127 (2016). Available from https://www.nice.org.uk/guidance/qs127
- Obesity: prevention. NICE clinical guideline 43 (2006, updated 2015). Available from www.nice.org.uk/CG43
- Obesity: identification, assessment and management. NICE clinical guidance 189 (2014). Available from www.nice.org.uk/CG189
- Managing overweight and obesity in adults – lifestyle weight management services. NICE guidelines PH53 (2014). Available from http://www.nice.org.uk/guidance/PH53

Additional information considered by IPAC

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Three Specialist Advisor Questionnaires for swallowable gastric balloon capsule for weight loss were submitted and can be found on the NICE website.

Patient commentators' opinions

Three commentaries from patients who have had this procedure were discussed by the committee.

Company engagement

A structured information request was sent to 1 company who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- Ongoing studies
  - **NCT03576833:** The BALLOON- (BALLOon Treatment for Obesity in Norway) Pilot Study. Single group assignment; n=20 participants. Status: Recruiting. Location: Norway; estimated completion date: December 2019.
  - **NCT03261453:** THE ENLIGHTEN STUDY. A randomised, multicentre, phased, pivotal safety and efficacy study comparing the Elipse™ gastric balloon system versus sham for the treatment of obese adults, n=400 participants. Status: Active, not recruiting. Location USA; estimated completion date: May 2019.

References

1. Vantanasiri K, Matar R, Beran A (2020). The efficacy and safety of a procedureless gastric balloon for weight loss: a systematic review and meta-analysis. Obesity Surgery https://doi.org/10.1007/s11695-020-04522-3
2. Ienca R, Al Jarallah M, Caballero A, Giardiello C et al. (2020) The procedureless Elipse gastric balloon program: multicenter experience in 1770 consecutive patients. Obesity Surgery, https://doi.org/10.1007/s11695-020-04539-8
3. Alsabah S, Al Haddad E, Ekrouf S et al. (2018) The safety and efficacy of the procedureless intragastric balloon. Surgery for Obesity & Related Diseases 3(14): 311-7
4. Jamal MH, Almutairi R, Elabd R et al. (2019) The safety and efficacy of procedureless gastric balloon: a study examining the effect of Elipse intragastric balloon safety, short and medium term effects on weight loss with 1-Year follow-up post-removal. Obesity Surgery (07) 07 Jan 07.
5. Al-Subaie S, Khalifa S, Buhaimed W et al. (2017). A prospective pilot study of the efficacy and safety of Elipse intragastric balloon: A single-center, single-surgeon experience. International Journal of Surgery (48): 16-22
6. Genco A, Ernesti I, Ienca R et al. (2018) Safety and efficacy of a new swallowable intragastric balloon not needing endoscopy: early Italian experience. Obesity Surgery 2(28): 405-9
7. Machytka E, Gaur S, Chuttani R et al. (2017) Elipse, the first procedureless gastric balloon for weight loss: a prospective, observational, open-label, multicenter study. Endoscopy 2(49): 154-60
8. Machytka E, Chuttani R, Bojkova M et al. (2016) Elipse™, a procedureless gastric balloon for weight loss: a proof-of-concept pilot study. Obesity Surgery 3(26): 512-6
9. Raftopoulos I, Giannakou A. (2017) The Elipse balloon, a swallowable gastric balloon for weight loss not requiring sedation, anaesthesia or endoscopy: a pilot study with 12-month outcomes. Surgery for Obesity & Related Diseases 7(13): 1174-82
10. Angrisani L, Santonicola A, Vitiello A et al. (2018) Elipse balloon the pitfalls of excessive simplicity. Obesity Surgery 28: 1419-21

Additional relevant papers

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Al-Subaie S, Al-Barjas H, Al-Sabah S et al. (2017) Laparoscopic management of a small bowel obstruction secondary to Elipse intragastric balloon migration: A case report. International Journal of Surgery Case Reports 41: 287–291	Case report discusses the possible aetiologies of small bowel obstruction following Elipse insertion and present a brief literature review regarding surgical and nonsurgical management options for such cases.	A small bowel obstruction (SBO) noted. Laparoscopic enterotomy was performed, and the balloon was extracted after it had been incised and emptied. The patient's recovery was uneventful and was discharged on postoperative day4. Although initial data showed the Elipse to be safe, complications can occur and be managed successfully.	Case report
Badiuddin, F.; Lopez, G.; Farhan, F. Case report: Percutaneous aspiration of elipse intragastric balloon for persistent gastric outlet obstruction. Obesity Surgery; 2019; vol. 29 (no. 5supplement); 734	Case report N=29-year-old female with BMI 27 and Swallowable Elipse Balloon had persistent gastric outlet obstruction	Two months post deployment, patient developed persistent symptoms of pain and vomiting. Clinically, balloon was visible and palpable in the epigastrium. Ultrasound showed partial obstruction in the gastric outlet. Endoscopic removal was recommended but endoscopy was refused by patient. Alternative "Percutaneous Aspiration" was considered and patient consented. Under ultrasound guidance, and light sedation the balloon was completely aspirated percutaneously with no adverse events either during the procedure or at day 1, week 1 and week 2 post aspiration.	Large studies already included in table 2.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Espinet Coll, E.; Carrasco Clavijos, S e al (2019). Feasibility, results and endoscopic requirements of the Elipse® swallowable intragastric balloon: initial experience. REV ESP ENFERM DIG 2019:111(12):921-926	Prospective case series N=30 patients (with a basal mean weight and body mass index (BMI) of 83.3 ± 10.7 kg and 30.6 ± 2.7 kg/m²) had EIGB placement by x-ray. Follow-up 16 weeks	All subjects swallowed the capsule with correct x-ray control. The mean weight loss was 11.2 ± 5.5 kg (12.1 ± 5.8% of total weight loss [TWL], 64.7 ± 25% of excess weight loss [EWL]), with a weight loss > 10% in 80% of patients ($p < 0.05$) after 4 months. Early elimination of the balloon with an insufficient duration (< 12 weeks) was observed in 2/24 patients (8.3%). There was an acceptable tolerance in 80%. With regard to adverse effects, one balloon was vomited up, there was one intolerance and the balloon was removed by gastroscopy and one small bowel ileal obstruction, which was removed by ileoscopy. The final satisfaction degree was good in 60% of cases.	Included in systematic review (Vantanasiri K 2020) suggested for inclusion in table 2.
Ienca, R.; Giardiello, C.; Scozzarro, A.et al (2019). Improving Nausea and Vomiting Post-Elipse Balloon: a Novel Single-Dose Regimen of 300 mg Netupitant/0.5 mg Palonosetron Hydrochloride. Obesity Surgery; 2019; vol. 29 (no. 9); 2952-2956	Case series N=30 patients had Elispe placements and a drug netupitant/palonosetron 6 h prior to placement and ondansetron as needed.	4/30 (13%) reported vomiting on days 1, 2, and 3; 9/30 (30%) reported nausea higher than score 4 on days 1, 2, and 3; 8/30 (26.6%) reported gastric pain higher than score 4 on days 1, 2, and 3. The use of a single-pill netupitant/palonosetron was effective in reducing vomit, nausea, and gastric pain in 87%, 70%, and 73.4% patients respectively, ameliorating the post ElipseTM placements symptoms safely.	More relevant studies added to table 2.
Pajot G, Calderon G, Acosta A (2017). Endoscopic treatments for obesity. Curr Treat Options Gastro 15: 660-675.	Review	Endoscopic bariatric therapy (EBT)s are safe and effective therapies for weight loss when used in conjunction with lifestyle changes and fill an important gap in the management of obesity. There are now six FDA-approved EBTs available and several more in ongoing trials with favourable early findings. More study is needed to understand the role of EBTs used in combination or in	Review

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
		sequence with medications and bariatric surgery.	
Trang J, Lee SS, Miller A et al. (2018) Incidence of nausea and vomiting after intragastric balloon placement in bariatric patients-A systematic review and meta-analysis. International Journal of Surgery 57: 22-29.	A systematic review and meta-analysis. N=10 studies evaluated rates of nausea and vomiting of four subtypes of IGB systems: Elipse, Obalon, ORBERA, and ReShape and calculated meta-analytic rates based on adverse events' sample size	564 patients reported nausea -meta-analytic rate of 63.33% (95% CI 61.49%-65.16%), and 507 patients reported vomiting -meta-analytic rate of 55.29% (95% CI 53.59%-56.99%). The ORBERA balloon system had the highest rates of nausea and vomiting compared to other balloon systems. Study concluded that nausea and vomiting are very common side effects post gastric balloon placement.	Different types of intragastric balloons assessed.
	Case report a 55 year man with BMI of 33 kg/m2 had Elipse insertion.		

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	02/04/2020	Issue 4 of 12, April 2020
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	02/04/2020	Issue 4 of 12, April 2020
MEDLINE (Ovid)	02/04/2020	1946 to April 01, 2020
MEDLINE In-Process (Ovid) & Medline ePub ahead (Ovid)	02/04/2020	1946 to April 01, 2020
EMBASE (Ovid)	02/04/2020	1974 to 2020 April 01

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

MEDLINE search strategy

The MEDLINE search strategy was adapted for use in the other sources.

1 gastric balloon/ (599)
2 absorbable implants/ (8702)
3 ((gastric* or intragastric* or "intra gastric*" or stomach* or biodegrad* or swallow* or dissolv* or digest* or absorb*) adj4 (balloon* or implant* or bubble* or ballobe*)).tw. (3648)

4 or/1-3 (11827)
5 obesity/ (177281)
6 overweight/ (24153)
7 (obes* or overweight*).tw. (264095)
8 weight loss/ (35636)
9 ((temporar* or transitor* or passing* or transient* or brief* or limited*) adj4 weight* adj4 (loss* or reduc*)).tw. (568)
10 body mass index/ (124281)
11 body mass index.tw. (151392)
12 BMI.tw. (116373)
13 ((rais* or excess* or enlarg* or increas* or spread* or widen* or dilat* or extend* or unhealthy or risk* or extend* or extru* or pronounc* or protub* or protrus* or obtrus* or bulg*) adj4 (waistline* or "waist line" or ((waist* or midriff*) adj4 (circumference* or girth*)))).tw. (2125)
14 or/5-13 (459155)
15 3 and 14 (652)
16 elipse.tw. (28)
17 15 or 16 (671)
18 animals/ not humans/ (4651925)
19 17 not 18 (632)
20 limit 19 to english language (551)
21 limit 20 to ed=20190313-20200430 (45)