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Clinical Studies of Reshaped Integrated Dual Balloon System in Obese Patients

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Abstract : Obesity is an abnormal accumulation of body fat usually 20% or more over an individual's ideal body weight; obesity is associated with increased risk of illness, disability and death. For individuals seeking to improve their health the weight loss journey may provide two few options in the gap between diet and exercise and bariatric surgery. Now by the end of July 2015 United States Food and Drug Administration (USFDA) approved a new intra gastric balloon system for the treatment of obesity i.e Re-Shaped Integrated Dual Balloon System. In this article we are going to discuss the clinical trials evaluating the safety and effectiveness of intra gastric balloons. The Re-Shape Integrated Dual Balloon has been marketed in Europe under a ConformiteEuropéene (CE) mark received in 2007. A CE mark was obtained for the Re-Shape Removal Catheter in 2010. The Re-Shape Integrated Dual Balloon, Re-Shape Delivery Catheter, and Re-Shape Removal Catheter were approved by Health Canada in 2010. The Re-Shape Integrated Dual Balloon has not been withdrawn from marketing for any reason related to its safety or effectiveness. Re-shape has already released impressive postmarketing data, which it attributes largely to the unusual motivation and dedication of the patients and healthcare proveders.
Key Words: Obesity, Re-Shaped Balloon, Clinical Trials.

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Introduction[1-2]

The Re-Shape Integrated Dual Balloon System is a weight-loss system of gastric balloons that occupy space in the stomach. The system consists of two attached balloons that are filled and sealed separately. The balloons are placed into the stomach through the mouth using a minimally invasive endoscopic procedure while the patient is under mild sedation. Once in place, the balloons are filled with about 2 cups of salt water (saline) and a blue dye (methylene blue). If a balloon breaks, blue dye will appear in the patient's urine. When it is time to remove the balloons, they are first deflated then removed using another endoscopic procedure.

The Re-Shape Dual Balloon takes up space in the stomach to help patients lose weight. The system is temporary and should be removed after 6 months.

Re-Shape Integrated Dual Balloon System was approved by the FDA on July 28, 2015, based on the REDUCE pivotal trial. This study was a prospective, sham-controlled, double-blind, randomized multicentre United States clinical study that enrolled 326 patients with obesity and followed them for 48 weeks. Participants were between 21 and 60 years of age with a baseline Body Mass Index (BMI) between 30kg/m2 and 40kg/m2. Participants also presented with one or more obesity-related comorbid conditions, including type 2 diabetes mellitus, obstructive sleep apnea (OSA), and hypertension.

Patients were randomized into two groups. The DUO group (n=187) underwent the Re-Shape Integrated Dual Balloon procedure plus diet and exercise counselling. The diet group (n=139) underwent sham endoscopy plus diet and exercise alone. DUO patients had the device removed after 24 weeks and continued with diet and exercise counselling for an additional 24 weeks. After 24 weeks, the patients in the DUO group had significantly greater weight loss than the diet group. DUO patients had a 28 percentExcess Weight Loss(EWL) and 2.3 times as much weight loss compared to the diet group.

Twenty-four weeks after balloon removal, DUO patients maintained a mean of 66 percent of their initial weight loss. More than half of the subjects still had more than 25 percent EWL compared to baseline weight, and 25 percent of subjects continued to lose additional weight following device removal.

Clinically and statistically significant comorbid improvements were observed in diabetic, hypertensive, and hyper lipidemicoutcomes and these improvements were sustained through 48 weeks of follow up. Quality of life assessments demonstrated substantial improvements in subjects' sense of well-being as measured by both obesity-specific and general instruments, and measures of patient satisfaction with the results of the procedure were high. In addition, of the patients who completed treatment, two-thirds reported that they would undergo it again, and 77 percent said they would recommend it to a friend.

Clinical Benefits of Intragastric Balloon Systems[3-4]

In both randomized, clinical studies, the intragastric balloon resulted in better weight loss compared to diet and exercise alone. In addition to positive patient results, surgeons may find that the system offers other clinical benefits. Personally, I find that endoscopic placement of the balloon is not complicated. The stomach should be inspected and known to be normal prior to implantation, and the device can be placed and removed under conscious sedation in an outpatient procedure. I also find that since the procedure is not a traditional weight loss surgery, such as laparoscopic Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy, and therefore does not alter the anatomy, patient acceptability is high. Patients with BMIs between 30 and 40kg/m^2 may also find the intragastric balloon procedure attractive if they are not ready or do not qualify for surgery. Lastly, unlike pharmaceuticals, there is no daily decision for the patient to make about whether to follow the program, thus adherence may be improved, compared to those individuals who use lifestyle modifications alone or in combination with pharmaceuticals.

Disscussion[3]

Clinical data supporting the safety and effectiveness of the Re-Shape Integrated Dual Balloon System are available from two clinical studies

A. Investigational Device Exemption (IDE) feasibility study and

B. IDE pivotal study.

The Re-Shape Integrated Dual Balloon System was referred to as the "Duo" during the feasibility study and the REDUCE Pivotal Trial. The data obtained from the pivotal study, conducted under IDE G090121, constitutes the main dataset to support safety and effectiveness of the Re-Shape device.

A. Feasibility Study:

The feasibility study, initiated in 2010, was a prospective, randomized, non-blinded multicenter feasibility study in which 30 subjects were enrolled and randomized in a 2:1 randomization scheme to either treatment with the Re-Shape Duo Balloon (Treatment Group) or to diet and exercise alone (Control Group). Treatment Subjects underwent immediate insertion of the Re-Shape Duo Balloon, and all subjects received diet and exercise intervention with close follow-up. The Re-Shape Duo device was retrieved at 24 weeks and all study subjects were followed for a total of 48 weeks. Thirty (30) subjects (21 treated and 9 control) were enrolled at three (3) study sites. Weight loss data showed that Re-Shape Duo Balloon treated subjects had a mean weight loss greater than that of the control subjects at every point of follow-up. All study subjects experienced at least one adverse event (AE). The most common AEs were nausea and vomiting, gastroesophageal reflux, and abdominal discomfort/pain.

B. Pivotal Study:

The REDUCE Pivotal Trial, was a prospective, sham-controlled, double-blinded, randomized multicenter clinical study which would enroll an initial cohort of 330 eligible obese subjects. Patients in the pivotal study were treated between August 2012 and February 2013. The database for this Pre-Market Approval(PMA) reflected data collected through February 2014 and included 187 Treatment and 139 Control Subjects. There were eight (8) investigational sites. Screened subjects who met inclusion and exclusion criteria, were to be randomized in a 1:1 ratio to the Treatment Group (use of the Re-Shape dual balloon plus a medically managed diet and exercise program) or to an active sham Control Group (to undergo an endoscopic procedure plus a medically managed diet and exercise program), to yield an estimated 300 evaluable subjects.

Safety and Efficacy of Re-Shaped Integrated Balloon in Obese Patients[4-5-6-9]

1. Descriptive Information

a. Brief Title: The Safety and Efficacy of the Re-Shape Intragastric Balloon in Obese Subjects

b. Official Title: IDE G090121 a Prospective, Randomized Multicenter Study to Evaluate the Safety and Efficacy of the Re-Shape Intragastric Balloon (RIBTM) in Obese Subjects

c. Purpose of the study: The study evaluated the safety and efficacy of the Re-Shape Intragastric Balloon as an adjunct to diet and exercise in obese patients compared with diet and exercise alone. The study device is designed to occupy space within the stomach and induce satiety. After approval from the Institutional Review Board (IRB), patients provided written consent and were randomized to the treatment group (with endoscopic placement of study device) or the control group (no placement of study device) on an unblinded basis. Both groups received similar diet and exercise counselling. After 24 weeks, the device was removed. Patient weight, adverse events, and quality of life data were evaluated throughout the 48-week study duration.

d. Detailed Description: Not Provided
e. Study Type: Interventional
f. Study Phase: Not Provided
g. Study Design:

- Allocation: Randomized
- Endpoint Classification: Safety/Efficacy
- Intervention Model: Parallel Assignment
- Masking: Open Label
- Primary Purpose: Treatment

The Reduce Pivotal Trial was a prospective, sham-controlled, double-blinded, randomized multi-centre clinical study which would enrol an initial cohort of 330 eligible obese subjects. Patients in the pivotal study were treated between August 2012 and February 2013. The database for this PMA reflected data collected through February 2014 and included 187 Treatment and 139 Control Subjects. There were eight (8) investigational sites.

h. Condition: Obesity
i. Intervention: Device:

- Device: Re-Shape Intra-Gastric Balloon
  Placement of Re-Shape Medical Intra-Gastric Balloon for twenty-four weeks
- Other: Control Arm
  Behavioural Modification (Diet and exercise counselling) alone

j. Study Arm (s):

- Experimental: Re-Shape Intra-Gastric Balloon
  Patients receiving the Re-Shape Intra-Gastric Balloon
  Intervention: Device: Re-Shape Intra-Gastric Balloon
- Control Arm
  Weight loss using behaviour modification (diet and exercise counselling) alone
  Intervention: Other: Control Arm

2. Recruitment Information:

a. Recruitment Status: Completed
b. Enrolment: 30
c. Completion Date: July 2011
d. Primary Completion Date: March (final data collection date for primary outcome measure)
e. Primary Outcome Measures:%Excess Weight Loss [Time Frame: 36 Weeks]
[Designated as safety issue: No.] the difference between the %EWL between treatment and control groups must be clinically significant
f. Secondary Outcome Measures: Percentage of Subjects With >=25% Excess Weight Loss (EWL) [Time Frame: 12 months] [Designated as safety issue: No]a between-group comparison of percentage of treatment subjects achieving >=25% EWL (using the Metropolitan Life Tables (ML) method) compared to the percentage of control group subjects achieving >= 25%EWL at 12 months
g. Study Start Date: February 2010
h. Study Completion Date: July 2011
i. Arms:

- Experimental: Re-Shape Intragastric Balloon

Patients receiving the Re-Shape Intragastric Balloon

- Control Arm

Weight loss using behaviour modification (diet and exercise counselling) alone

j. Assigned Interventions:

- Device: Re-Shape Intragastric Balloon

Placement of Re-Shape Medical Intragastric Balloon for twenty-four weeks

- Other: Control Arm

Behavioural Modification (Diet and exercise counselling) alone

k. Eligibility Criteria

Screened subjects who met inclusion and exclusion criteria, were to be randomized in a 1:1 ratio to the Treatment Group (use of the Re-Shape dual balloon plus a medically managed diet and exercise program) or to an active sham Control Group (to undergo an endoscopic procedure plus a medically managed diet and exercise program), to yield an estimated 300 evaluable subjects.

i. Inclusion Criteria:

- Subjects aged ≥ 20 years and ≤ 60 years;
- At screening, body mass index (BMI) ≥ 30 Kg/m^2 and ≤ 40 Kg/m^2;
- Have a history of obesity (BMI ≥ 30 kg/m^2) for at least 6 months and have failed other weight-reduction alternatives, such as supervised diet, exercise and behavioral modification programs;
- Subject is willing to commit to a long-term low calorie (1000-1500 calories/day) supervised diet;

- Subject has reasonable weight loss expectations (accept a goal of losing up to 15% of body weight after 24 weeks);
- At screening, total Beck Depression Inventory (BDI) score < 12 points, and BDI affective subscale score < 7 points.
- Subject is able to follow requirements outlined in the protocol, including complying with the visit schedule, and willing to undergo protocol-specific procedures, e.g., endoscopy, local sedation, general anaesthesia, electrocardiography (ECG), and/or clinical laboratory testing;
- Subject is willing to take prescribed proton pump inhibitors (PPIs);
- Subject is able to provide written informed consent;
- If female of child-bearing potential, the subject is willing to use contraception (e.g., birth control pills, condoms, abstinence) and avoid pregnancy during the study.

ii. Exclusion Criteria:

- Participating in an organized weight loss program (e.g., Weight Watchers);
- Parkinson's disease;
- Chronic narcotic use;
- Clinically relevant abdominal adhesions (e.g., history of bowel obstruction);
- History or symptoms of gastrointestinal (GI) surgery (excluding uncomplicated appendectomy and cholecystectomy), obstruction, and/or adhesive peritonitis;
- History or symptoms of clinically significant oesophageal or GI motility disorders;
- A hormonal or genetic cause for subject's obesity;
- A history of myocardial infarction in the previous 6 months, current New York Heart Association (NYHA) Functional Class III or IV (heart failure) or cardiac arrhythmia (e.g., atrial fibrillation);
- History or symptoms of varices, bowel obstruction, congenital or acquired GI anomalies (e.g., atresia's, stenosis, stricture, and/or diverticula), severe renal, hepatic, and/or pulmonary disease;
- History or symptoms of inflammatory bowel disease, such as Crohn's disease;
- History or symptoms of uncontrolled or unstable thyroid disease
- Subjects with a positive breath test for Helicobacter pylori at screening;
- History or symptoms in the past 12 months of significant irritable bowel disease, peritonitis, active esophagitis, gastric or duodenal ulceration, or GI bleeding;
- History of oesophageal and/or stomach cancer.
- Type I diabetes;
- Placement of previous intragastric balloon or similar device with associated adverse; or any endogastric procedure within the last 6 months;
- Ongoing treatment with anticoagulants, steroids, aspirin (> 81 mg/day), non-steroidal anti-inflammatory drugs (NSAIDS), or other medications known to be gastric irritants or to reduce GI motility, and unwillingness to discontinue the use of these concomitant medications;
- Concomitant use of prescription, non-prescription, or over-the-counter weight loss medications or supplements at any time during the study;
- Evidence of untreated psychiatric or eating disorders, such as major depression, schizophrenia, substance abuse, binge eating disorder, or bulimia;
- Pregnancy, breast feeding, or intention of becoming pregnant during the study (if female of childbearing potential);
- Known allergy to silicone;
- A history of anemia
- Participation in another investigational trial within 1 month of screening or planned enrollment during the study period.
- Presence of peptic ulcerations, hiatal hernia (> 2 cm), patulous pyloric channel, erosive esophagitis, varices, angiectasia, Barrett's oesophagus or other findings deemed exclusionary in the opinion of the investigator.

l. Gender: Both

m. Age:20-60 years

n. Accepts Healthy Volunteers: Yes

o. Study Assessments: 594 subjects were formally screened and 268 failed to meet clinical and endoscopic entry criteria. The remaining 326 subjects were randomized approximately 1:1 (187 treatment and 139 control), and 293 of these (89.9%, 167 treatments and 126 control subjects) recorded a weight at Week 24. Of these 293 at Week 24, 3 treatment subjects were lost to follow-up and 49 control subjects declined the Re-Shape dual balloon treatment or were deemed ineligible at 24 weeks and did not crossover. Therefore, 241 subjects entered the 24-48-week interval, which included 164 treatment subjects and 77 crossover control subjects who were successfully implanted with a Re-Shape dual balloon. 200 of the 241 continuing subjects (83.0%) recorded a weight at Week 48. At the time of database lock, 72.7% of Treatment Subjects (136/187) had completed 48 weeks of follow-up and 90.6% of Control Subjects (126/139) had completed 24 weeks of follow-up. Additionally, 77 Control Subjects were successfully implanted with the device at 24 weeks, and 83.1% of those subjects (64/77) completed an additional 24 weeks of follow-up.

3. Administrative Information:

a. National clinical trial (NCT) Number: NCT01061385
b. Other Study ID Numbers: REDUCE-IDE
c. Has Data Monitoring Committee: Yes
d. Plan to Share Data: Not Provided
e. IPD Description: Not Provided
f. Responsible Party: Re-Shape Medical, Inc.
g. Study Sponsor: Re-Shape Medical, Inc.
h. Collaborators: Not Proved
i. Investigators:

Study Director	Mary Lou Mooney	Re-Shape Medical

j. Information Provided By: Re-Shape Medical, Inc.
k. Verification Date: April 2016

Results[8-9]

Study Type	**Interventional**
Study Design	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel assignment;Masking: Open Label; Primary Purpose: Treatment
Condition:	Obesity
Interventions:	Device: Re-Shape Intra-Gastric Balloon Other: Control Arm

Participant Flow:

Reporting Groups:

	Description
Re-Shape Intra-Gastric Balloon	Patients receiving the Re-Shape Intra-Gastric Balloon Re-Shape Intra-Gastric Balloon: Placement of Re-Shape Medical Intra-Gastric Balloon for twenty-four weeks
Control Arm	Patients presenting for weight loss using behaviour modification (diet and exercise) alone. Behavioural modification: Diet and exercise

Participant Flow Overall Study:

	Re-Shape Intragastric Balloon	**Control Arm**
Started	21	9
Completed	20	8
Not Completed	1	1
Lost to Follow up	0	1

Base Line Characteristics

Population Description:

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants meeting study inclusion/exclusion criteria

Reporting Groups

	Description
Re-Shape Intragastric Balloon	Patients receiving the Re-Shape Intragastric Balloon Re-Shape Intragastric Balloon: Placement of Re-Shape Medical Intragastric Balloon for twenty-four weeks
Control Arm	Patients presenting for weight loss using behaviour modification (diet and exercise) alone. Behavioural modification: Diet and exercise
Total	Total of all reporting groups

Baseline Measures

	Re-Shape Intragastric Balloon	**Control Arm**	**Total**
Number of Participants [units: participants]	21	9	30
Age [units: years] Mean (Full Range)	38.9 (26 to 59)	45.3 (37 to 55)	40.8 (26 to 59)
Gender [units: participants]			
Female	17	9	26
Male	4	0	4

Outcome Measures

1. Primary: %Excess Weight Loss [Time Frame: 36 Weeks]

Measure Type	**Primary**
Measure Title	%Excess Weight Loss
Measure Description	the difference between the %EWL between treatment and control groups must be clinically significant
Time Frame	36 Weeks
Safety Issue	No

Reporting Groups

	Description
Re-Shape Intragastric Balloon	Patients receiving the Re-Shape Intragastric Balloon Re-Shape Intragastric Balloon: Placement of Re-Shape Medical Intragastric Balloon for twenty-four weeks
Control	Control subjects receiving diet and exercise counselling only

Measured Values

	Re-shape Intragastric Balloon	**Control**
Number of Participants Analysed [units: participants]	21	9
%Excess Weight Loss [units: percent excess weight loss] Mean (Standard Deviation)	20.2 (16.7)	12.7 (19.3)

Statistical Analysis for %Excess Weight Loss

Groups	**All groups**
Method	t-test, 1 sided
P Value	0.2922
Mean Difference (Net)	7.5
95% Confidence Interval	-6.8 to 21.7

2. Secondary: Percentage of Subjects With >=25% Excess Weight Loss (EWL) [Time Frame: 12 months]

Measure Type	**Secondary**
Measure Title	Percentage of Subjects With >=25% Excess Weight Loss (EWL)
Measure Description	a between-group comparison of percentage of treatment subjects achieving >=25% EWL (using the Metropolitan Life Tables (ML) method) compared to the percentage of control group subjects achieving >= 25%EWL at 12 months
Time Frame	12 months
Safety Issue	No

Reporting Groups

	Description
Re-Shape Intragastric Balloon	Patients receiving the Re-Shape Intragastric Balloon Re-Shape Intragastric Balloon: Placement of Re-Shape Medical Intragastric Balloon for twenty-four weeks
Control Arm	Patients presenting for weight loss using behaviour modification (diet and exercise) alone. Behavioural modification: Diet and exercise

Measured Values

	Re-Shape Intragastric Balloon	**Control Arm**
Number of Participants Analysed [units: participants]	20	8
Percentage of Subjects With >=25% Excess Weight Loss (EWL) [units: percentage of subjects]	30	25

Statistical Analysis for Percentage of Subjects with >=25% Excess Weight Loss (EWL)

Groups	**All Groups**
Mean Difference (Net)	5
95% Confidence Interval	-37.7 to 38.0

Serious Adverse Events:

	Re-Shape Intragastric Balloon	**Control Arm**
Total, serious adverse events		
• Participants affected / at risk	3/21 (14.29%)	0/9 (0.00%)
Eye disorders		
Periorbitaledema		
• participants affected / at risk	1/21 (4.76%)	0/9 (0.00%)

• events	1	0
Gastrointestinal disorders		
Nausea and vomiting		
• Participants affected / at risk	1/21 (4.76%)	0/9 (0.00%)
• events	1	
Respiratory, thoracic and mediastinal disorders		
Hypoxia		
• participants affected / at risk	1/21 (4.76%)	0/9 (0.00%)
• events	1	0

Other Adverse Events:

Time Frame	**48 Weeks**
Additional Description	Not Entered

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Re-Shape IntragastricBalloon	Patients receiving the Re-Shape Intragastric Balloon Re-Shape Intragastric Balloon: Placement of Re-Shape Medical Intragastric Balloon for twenty-four weeks
Control Arm	Patients presenting for weight loss using behaviour modification (diet and exercise) alone. Behavioural modification: Diet and exercise

Other Adverse Events

	Re-Shape Intra-Gastric Balloon	**Control Arm**
Total, other (not including serious) adverse events		
• Participants affected / at risk	21/21 (100.00%)	6/9 (66.67%)
Gastrointestinal disorders		
Nausea		
• Participants affected / at risk	21/21 (100.00%)	0/9 (0.00%)
• Events	27	0
Vomiting		
• Participants affected / at risk	18/21 (85.71%)	0/9 (0.00%)
• Events	25	0
Eructation		
• participants affected / at risk	10/21 (47.62%)	0/9 (0.00%)
• events	11	0
Abdominal pain upper		
• Participants affected / at risk	9/21 (42.86%)	0/9 (0.00%)
• Events	10	0
Gastroesophageal reflux disease		
• Participants affected / at risk	9/21 (42.86%)	0/9 (0.00%)

• Events	12	0
Abdominal discomfort		
• Participants affected / at risk	8/21 (38.10%)	0/9 (0.00%)
• Events	8	0
Dyspepsia		
• Participants affected / at risk	7/21 (33.33%)	0/9 (0.00%)
• Events	7	0
Gastric dilatation		
• Participants affected / at risk	7/21 (33.33%)	0/9 (0.00%)
• Events	8	0
Diarrhoea		
• Participants affected / at risk	6/21 (28.57%)	0/9 (0.00%)
• Events	7	0
Abdominal pain		
• Participants affected / at risk	3/21 (14.29%)	0/9 (0.00%)
• Events	3	0
Constipation		
• Participants affected / at risk	2/21 (9.52%)	0/9 (0.00%)
• Events	2	0
Infections and infestations		
Sinusitis		
• Participants affected / at risk	2/21 (9.52%)	2/9 (22.22%)
• Events	2	2
Upper respiratory tract infection		
• Participants affected / at risk	2/21 (9.52%)	0/9 (0.00%)
• Events	3	0
Urinary tract infection		
• Participants affected / at risk	2/21 (9.52%)	0/9 (0.00%)
• Events	2	0
Nasopharyngitis		
• Participants affected / at risk	0/21 (0.00%)	1/9 (11.11%)
• Events	0	1
vaginal infection		
• Participants affected / at risk	0/21 (0.00%)	1/9 (11.11%)
• Events	0	1
Injury, poisoning and procedural complications		
Ligament rupture		
• Participants affected / at risk	0/21 (0.00%)	1/9 (11.11%)
• Events	0	1
Post-traumatic pain		
• Participants affected / at risk	0/21 (0.00%)	1/9 (11.11%)
• Events	0	1
Metabolism and nutrition disorders		
Dehydration		
• Participants affected / at risk	5/21 (23.81%)	0/9 (0.00%)
• Events	5	0
Musculoskeletal and connective tissue disorders		
Back pain		
• Participants affected / at risk	2/21 (9.52%)	2/9 (22.22%)
• Events	2	2
Pain in extremity		
• Participants affected / at risk	1/21 (4.76%)	1/9 (11.11%)
• Events	1	1

Musculoskeletal stiffness		
• Participants affected / at risk	0/21 (0.00%)	1/9 (11.11%)
• Events	0	1
Nervous system disorders		
Headache		
• Participants affected / at risk	3/21 (14.29%)	0/9 (0.00%)
• Events	3	0
Migraine		
• Participants affected / at risk	0/21 (0.00%)	1/9 (11.11%)
Psychiatric disorders		
Anxiety		
• participants affected / at risk	3/21 (14.29%)	0/9 (0.00%)
• Events	3	0
Reproductive system and breast disorders		
Vaginal haemorrhage		
• Participants affected / at risk	0/21 (0.00%)	1/9 (11.11%)
• Events	0	1
Respiratory, thoracic and mediastinal disorders		
Sinus congestion		
• Participants affected / at risk	2/21 (9.52%)	1/9 (11.11%)
• Events	2	1
Hiccups		
• Participants affected / at risk	2/21 (9.52%)	0/9 (0.00%)
• Events	2	0
Hypoxia		
• Participants affected / at risk	2/21 (9.52%)	0/9 (0.00%)
• Events	2	0
Oropharyngeal pain		
• participants affected / at risk	2/21 (9.52%)	0/9 (0.00%)
• Events	2	0
Cough		
• Participants affected / at risk	0/21 (0.00%)	1/9 (11.11%)
• Events	0	1

Conclusion:

Studies have shown that intragastric balloon systems are an effective means of weight loss in patients suffering from obesity with BMIs 30 to 40kg/m2 compared to diet/exercise management alone (2–3 times better weight loss). Risk factors/limitations of the device include poor weight loss in up to 25 percent of the patients, nausea and vomiting in 60 to 90 percent, intolerance requiring early removal in 7.5 percent, and ulcers in 2 to 10 percent. Balloons are an effective and welcomed addition to the bariatric surgeon's armamentarium for obesity treatment.

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