

Review

Incidence of nausea and vomiting after intragastric balloon placement in bariatric patients – A systematic review and meta-analysis

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ABSTRACT

Objectives: This systematic review and meta-analysis was performed to examine the rates of nausea and vomiting along with other common side effects reported from different subtypes of intragastric balloons (IGBs) placed in obese adults.

Methods: The online databases of Pubmed, Cochrane Database, and Web of Science were searched to include studies conducted from 09/31/2012 to 09/31/2017 in English using keywords to identify articles relevant to this study. Two independent reviewers performed a full text review to ensure quality of studies and report rates of primary end point of interest: nausea and vomiting post IGB placement.

Results: Ten studies fulfilled the inclusion criteria. The treatment group's sample size comprised of 688 patients and adverse events' sample size comprised of 938 patients. We 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. Total 564 patients reported experiencing nausea which provided a meta-analytic rate of 63.33% (95% CI 61.49%–65.16%), and 507 patients reported experiencing vomiting which resulted in a 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.

Conclusions: Based on the findings from previous studies scrutinizing side effects of different types of IGB offered on the market, it has been concluded that nausea and vomiting are very common side effects post gastric balloon placement.

1. Introduction

Morbid obesity is a growing global health epidemic with an increasing number of patients in need for bariatric surgery [1]. According to the Centers for Disease Control and Prevention (CDC), more than one-third (36.5%) of adults in the United States suffer from obesity [2]. Obesity-related conditions, including heart disease, stroke, type 2 diabetes, and certain types of cancer are some of the leading preventable causes of death in the obese population [3]. However, recent evidence-based data suggests that commercial web-based interventions and organized self-help programs result in minimal weight loss. While pharmacotherapeutic interventions modestly reduce weight, they present with adverse effects [4–6]. In contrast, endoscopic weight loss interventions are gaining acceptance as more effective modes of treatment compared to dietary and lifestyle modification alone and are considered less invasive procedures compared to weight loss surgery [7].

Modern endoscopically inserted intragastric balloons (IGB) are reversible, space-occupying devices designed to induce satiety and reduce food intake, which ultimately results in weight loss. IGBs are a weight loss aid for obese adults with a body mass index (BMI) in the 30–40 kg/m² range, who have tried other weight loss programs such as following a supervised diet, exercise, and behavior modification programs but were unable to successfully lose weight. Several models of IGBs that are FDA approved and commercially available in the U.S. include the ORBERA Intragastric Balloon System, ReShape Integrated Dual Balloon System, Obalon Balloon System, Elipse Balloon, and Spatz Adjustable Balloon System [8].

In our review, we focused on four major types of IGB: Elipse, Obalon, ORBERA, and ReShape. All balloons are designed for use in patients with a BMI of 30–40, after dietary and lifestyle modifications fail. Elipse (Allurion Technologies, Wellesley, MA, USA) is fluid-filled balloon system with fill volume 550 ml, with swallowed capsule

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Table 1
Risk of bias summary of included randomized controlled studies.

Author Year	Selection Bias	Selection Bias	Performance Bias	Detection Bias	Attrition Bias	Reporting Bias	Other Biases	
	Random Sequence Generator	Allocation concealment	Blinding of Participants	Blinding of Outcome Assessors	Incomplete collection/outcome data	Selective reporting	Baseline Confounders	Co-intervention confounders
Machytka, 2017 [13]	-	-	-	-	+	+	+	?
Machytka, 2016 [14]	-	-	-	-	+	+	+	?
FDA, SMART, 2016 [15]	+	+	-	+	+	+	+	+
Nobili, 2015 [16]	-	-	-	-	+	+	+	+
Mion, 2013 [17]	-	-	-	-	+	+	?	?
FDA, IB-005, 2015 [18]	+	+	-	+	+	+	+	+
Mitura, 2015 [11]	-	-	-	-	+	+	+	?
Fuller, 2013 [19]	-	-	-	-	+	+	+	?
FDA, REDUCE, 2015 [20]	+	+	-	+	+	+	+	+
Ponce, 2013 [21]	?	+	-	+	+	+	+	+

Key chart.

+ Component present and adequate.

- Component absent or inadequate.

? Component unclear or data unavailable.

delivery device that does not require endoscopy for placement, implanted up to 4 months, does not require endoscopy for deflation and removal, and designed to pass through the gastrointestinal tract and be excreted at a pre-determined time. Although Elipse has been proven to be a safe and effective device in the Europe, it has not been approved for use by FDA in the USA. In contrast, other IGB types have been approved [9]. Obalon (Obalon Therapeutics Inc, Carlsbad, Calif) is a gas-filled multiballoon system with fill volume 250 ml, up to 3 balloons placed one month apart, with swallowed capsule delivery device that does not require endoscopy for placement. Obalon could be implanted for up to 6 months and requires endoscopy only for deflation and removal, with all 3 balloons removable at the same time [10,11]. Orbera (Apollo Endosurgery, Austin, Tex) is a saline-filled single balloon system with fill volume of 500–750 ml. It is placed endoscopically for up to 6 months and requires endoscopy for deflation and removal [10,11]. ReShape Duo (ReShape Medical, San Clemente, Calif) is a saline-filled double balloon system with fill volume of 450 ml/balloon for a total of 900 ml, placed endoscopically for up to 6 months and also requires endoscopy for deflation and removal [10,11].

Although most patients tolerate the placement of IGBs, some report adaptive symptoms and complications [12]. Side effects that may result from the use of IGBs include the risks associated with the methods used in this procedure, as well as the patient's ability to tolerate a space-occupying object placed in the stomach. Accommodative side effects include persistent nausea, vomiting, generalized abdominal pain and/or discomfort, back pain, and acid reflux. These side effects are common after insertion of the IGB and are usually self-limiting. Serious adverse events (SAE) include partial or complete gastrointestinal obstruction; adverse health consequences resulting from weight loss; gastric outlet obstruction; bacterial overgrowth in the fluid filling the balloon which can lead to infection; injury to the lining of the digestive tract, stomach, or esophagus; and perforation [13].

In spite of the long 20 year history usage of IGBs, the cumulative data on the incidence of the most common accommodative symptoms such as nausea and vomiting have been inconsistent, presenting in the range from 57.9% to 86.9% [14]. The main objective of this study is to conduct a systematic literature review to calculate point estimates and 95% confidence intervals for rates of our primary outcome of interest: nausea and vomiting post IGB placement. Additionally, we would like to estimate rates of secondary end points: dyspepsia/gastroesophageal

reflux disease, generalized abdominal pain, mild or moderate adverse events (AE), and serious adverse events (SAE).

2. Methods

2.1. Data sources

We conducted a systematic literature review utilizing Pubmed, Cochrane Database, and Web of Science (for cited articles) to identify studies relevant to the study. The work has been reported in line with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Guidelines. Initially, broad search terms were used including “MORBID OBESITY”, “INTRAGASTRIC BALLOON”, “INTRAGASTRIC BALLOONS”, “GASTRIC BALLOON”, “ENDOSCOPIC BARIATRIC THERAPY”, “INCIDENCE”, “NAUSEA”, “VOMITING”, “DYSPEPSIA”, “ABDOMINAL PAIN”, “ADVERSE EVENTS”, “COMPLICATIONS”.

2.2. Data selection

Studies focusing on common accommodative symptoms such as nausea and vomiting after IGB insertion were included. The inclusion criteria were as follows: studies in patients undergoing weight loss surgery for treatment of morbid obesity, rates of nausea/vomiting after IGB insertion in obese patients, clinical and procedural characteristics associated with nausea/vomiting. We included retrospective and prospective observational studies, evaluation studies, randomized controlled clinical trials, and validation studies published in English from 09/31/2012–09/31/2017. We excluded grey literature, case reports, case series, reviews, and systematic reviews. The electronic search was supplemented by a manual search of reference lists of the available relevant literature. The search was performed by professional librarians.

2.3. Quality assessment of included studies

This study has adhered to the quality assessment tool for quantitative studies as described in the Cochrane Handbook of Systematic Reviews of interventions [15]. It contains 6 components, each rated as high risk of bias, low risk of bias, or unclear. We applied the Cochrane Collaboration's tool for assessing risk of bias for sequence generation

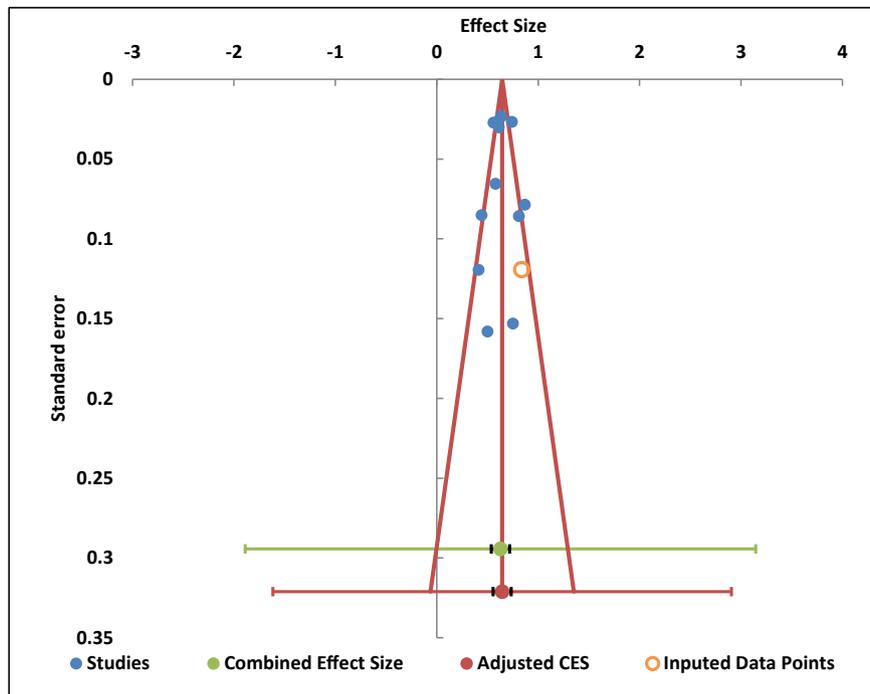


Fig. 1. Funnel Plot studies SE vs. Rates Nausea.

entry [16]. The summary of each study's risks of biases are summarized in Table 1.

2.4. Data extraction and statistical analysis

Two independent reviewers performed data extraction (S.L. and J.T.) from each selected citation. When an ambiguity of outcome determination was present, a third reviewer was consulted and the outcome was determined by consensus [17]. Data was combined into a single weighted rate using the random effects meta-analytical method presented by Einarson et al. (1997) [18]. Einarson presented adaptation of the method of DerSimonian and Laird that combines data across studies or arms of studies to produce a point estimate and a 95% confidence interval (CI) for clinical and epidemiologic data [19]. That method weighs each rate both by within-study variance with larger sample sizes receiving greater weights and also by between-study variance. That approach permits for differences in study design or data collection methods, allowing incorporation of the maximum number of studies which yields the highest degree of representation of the population. Studies that did not report the side effects of interest were excluded from analysis (see Fig. 1, Fig. 2).

3. Results

3.1. Study characteristics

The initial search yielded a total of 183 references. Two researchers (S.L. and J.T.) screened titles and abstracts independently for relevance. After excluding duplicated references selected from more than one database, 104 references remained. From these, 71 references were excluded because they were not relevant to the study. From the remaining 33 articles, full texts were screened for relevance. Finally, 10 studies were found eligible involving a total of 688 patients. The process of data selection is summarized in Fig. 3.

Study characteristics, basic patient demographics, weight loss outcomes, and adverse events were collected from each study as reported by authors. Study characteristics, basic patient demographics, and weight loss outcomes were calculated and reported based on treatment

group sample size. Study characteristics included publication or study title, subgroup of IGBs, country, design, years of study, IGB placement duration, and treatment sample size. Patient demographics consisted from age range and mean, percentage of females in the study, baseline weight mean and range (lbs), baseline BMI mean and range, and weight lost at 6 months. Serious adverse events, adverse events, nausea, vomiting, dyspepsia/GERD, and generalized abdominal pain were calculated and reported by authors based on adverse events sample size that comprised treatment and run-on groups. Primary end points of interest were total rates of nausea and vomiting, rates of nausea and vomiting by balloon subtypes. Secondary end points of were rates of dyspepsia/GERD, generalized abdominal pain, total mild/moderate adverse events and serious adverse events.

3.2. Data evaluation

A total of ten studies were included in this systematic review (n = 688): five prospective, randomized, controlled multicenter trials and five prospective observational non-randomized studies [9,14,20–27]. The treatment group's sample size comprised of 688 patients and adverse events' sample size comprised of 938 patients. Meta-analytic rates were calculated based on adverse events' sample size of 938. Four studies were conducted in the United States, one in Australia, four in Europe, and one did not state which country (Table 2). Three studies used the ORBERA IGB, two studies used the ReShape Integrated Dual Balloon System, three studies used the Obalon IGB, and two used the Elipse IGB. The mean patient age was 40.5 ± 1.4 years, with 71% ± 27.9% of patients being female (Table 2). The mean baseline weight and BMI were 241.65 ± 14.1 lbs and 34.68 ± 2.11 kg/m², respectively.

3.3. Meta-analysis of rates of nausea, vomiting, and rates of nausea and vomiting by balloon type

Ten studies with total SAE reporting consist of a sample size of 938 patients. Of these patients, 564 patients reported experiencing nausea, resulting in a meta-analytic rate of 63.33% (95% CI 61.49%–65.16%) (Table 2). There were 507 patients who reported vomiting which

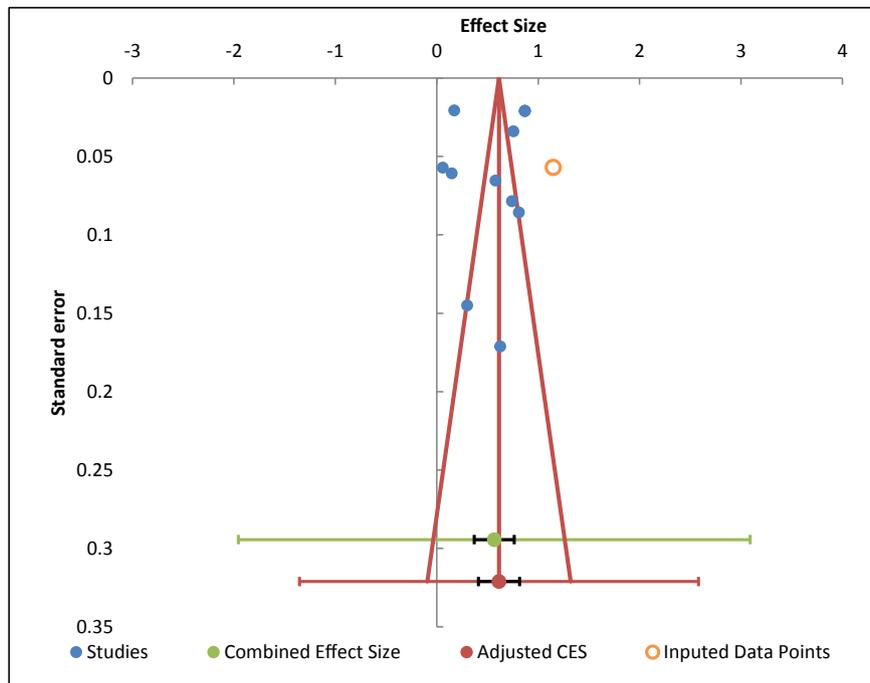


Fig. 2. Funnel Plot studies SE vs. Rates Vomiting.

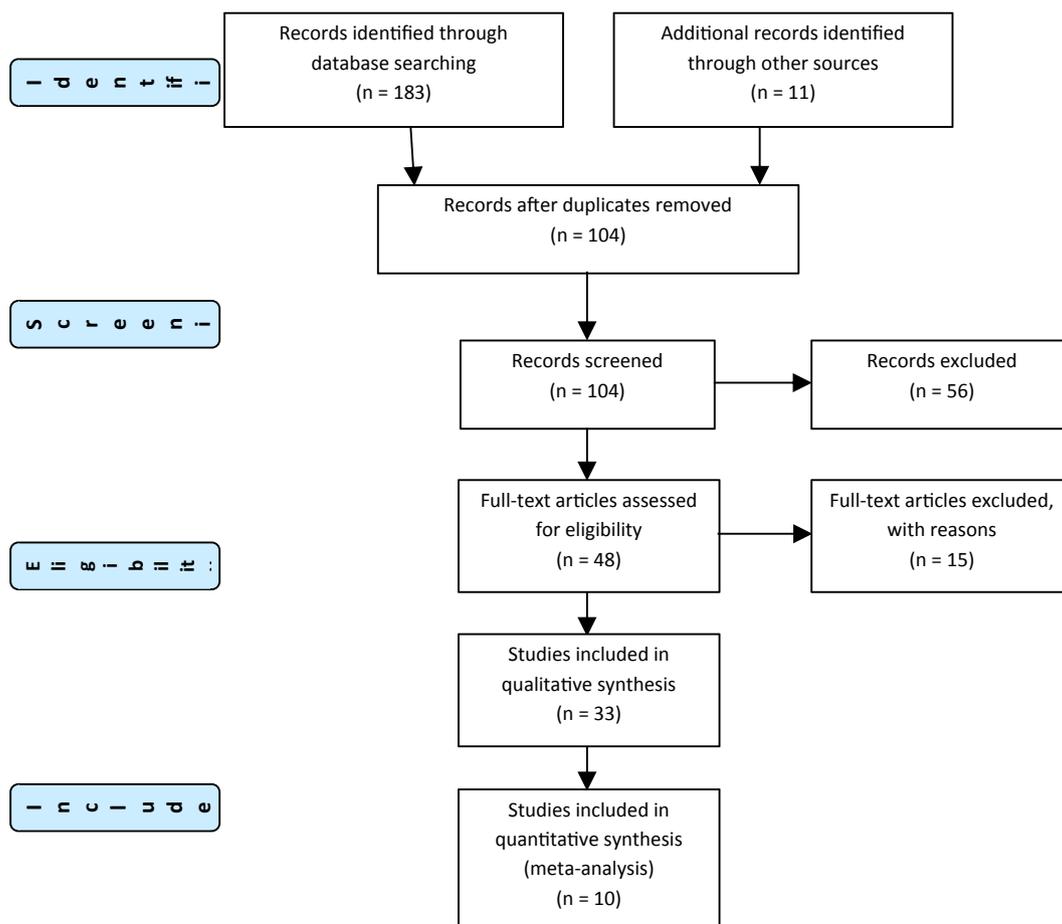


Fig. 3. PRISMA flow diagram of study selection process.

Table 2
Studies included in the systematic review and meta-analyses.

Study	IGB Sub-group	Country	Study Design	Years of Study	Balloon Duration	Sample Size	Mean Age Range (years)	Gender	Mean Weight Range (lbs)	BMI Mean Range (kg/m ²)	Weight Lost at 6 mo
Machyrtka, 2017 [13]	Elipse	Czech Republic, Greece	Prospective, observational, open-label	11/2014–12/2015	6 wks	34	42 (18–59)	F 23 M 11	224 (161–295)	34.8 (27–40)	3.9 BMI
Machyrtka, 2016 [14]	Elipse	Greece	Prospective, non-randomized	2015	6 wks	8	40 (24–60)	F 7 M 1	194 (165–249)	31 (27–35)	5.5 lbs
FDA, SMART, 2016 [15]	Obalon	USA	Prospective, sham-controlled, double-blinded, randomized, multicenter, clinical	03/2015–05/2016	24 wks	198	42.6 (22–64)	F 86.4% M 171	215.7	35.1 (30–40)	
Nobili, 2015 [16]	Obalon	Italy	Observational, prospective		3 mo	10	13.3 (9–17)	F 5 M 5	218	36.7 (30–40)	12.6 lbs
Mion, 2013 [17]	Obalon	Belgium, France	Observational, prospective		12 mo	17	39 (23–54)	F 15 M 2	187.8	31 (27–35)	11 lbs
FDA, IB-005, 2015 [18]	ORBERA	USA	Multicenter, prospective, randomized, open-label, comparative, pivotal	06/2008–10/2010	12 mo	125	38.7 (18–65)	F 89.6% M 112	216	35 (30–40)	19.4 lbs
Mitura, 2015 [11]	ORBERA	Poland	Prospective, Observational, non-randomized	01/2012–10/2012	6 mo	57	39.5 (17–65)	F 51 M 6	229 (172–309)	37.2 (29.8–48.1)	35 lbs
Fuller, 2013 [19]	ORBERA	Australia	Prospective, randomized, Controlled, parallel-arm	04/2008–02/2010	12 mo	31	43.4 (18–60)	F 68% M 21	230.6	36 (30–40)	41.7 lbs
FDA, REDUCE, 2015 [20]	ReShape	USA	Prospective, controlled, double-blinded, randomized, multicenter, clinical	08/2012–02/2013	6 mo	187	43.8 (21–60)	F 95% M 5%	209.2 (154–303)	35.3 (30–40)	
Ponce, 2013 [21]	ReShape	USA	Prospective, randomized, controlled, multicenter	02/2010–03/2010	24 wks	21	38.9	F 81% M 19%	222.2	34.7 (30–40)	%EWL 31.8%

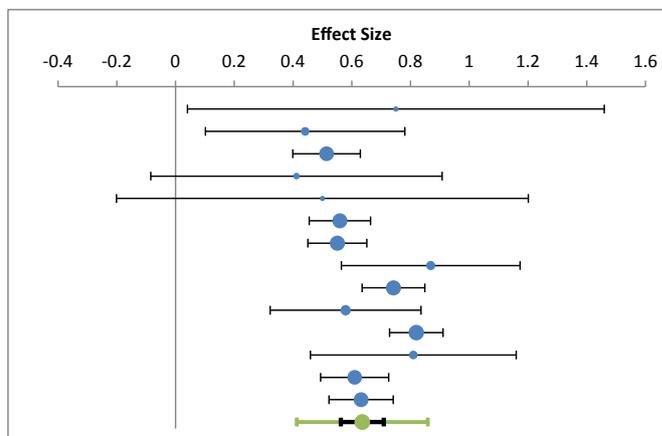


Fig. 4. Forest Plot Rates of Nausea by IGB type.

resulted in a meta-analytic rate of 55.29% (95% CI 53.59%–56.99%).

Our meta-analysis comprised four subtypes of IGBs: Elipse, Obalon, ORBERA, and ReShape. Out of these subtypes, the Elipse, ORBERA, and ReShape are fluid-filled balloons. Seven studies with fluid-filled IGB placement reported nausea in 394 out of 575 patients with a meta-analytic rate of 72.99% (95% CI 69.54%–76.45%) and vomiting in 434 out of 575 patients with rate of 76.95% (95% CI 73.86%–80.05%). In contrast, Obalon is the only gas-filled IGB approved by FDA. Three studies with Obalon IGB placement reported nausea in 200 out of 363 patients with a meta-analytic rate of 55.10% (95% CI 50.00%–60.00%) and vomiting in 62 out of 363 patients with rate of 16.20% (95% CI 12.43%–19.96%).

Two studies with Elipse IGB placement reported nausea in 21 out of 42 patients with a meta-analytic rate of 51.42% (95% CI 46.00%–57.00%) and vomiting in 23 out of 42 patients with rate of 12.48% (95% CI 8.51%–16.44%). Three studies with Obalon IGB placement reported nausea in 200 out of 363 patients with a meta-analytic rate of 55.10% (95% CI 50.00%–60.00%) and vomiting in 62 out of 363 patients with rate of 16.20% (95% CI 12.43%–19.96%). Three studies with ORBERA placement reported nausea in 195 out of 248 patients with meta-analytic rate of 81.97% (95% CI 77.00%–87.00%) and vomiting in 177 out of 248 patients with rate of 72.16% (95% CI 66.65%–77.67%). Two studies with ReShape placement reported nausea in 178 out of 285 patients with meta-analytic rate of 63.18% (95% CI 58.00%–69.00%) and vomiting in 246 out of 285 patients with rate of 86.42% (95% CI 82.44%–90.39%) (Fig. 4, Fig. 5).

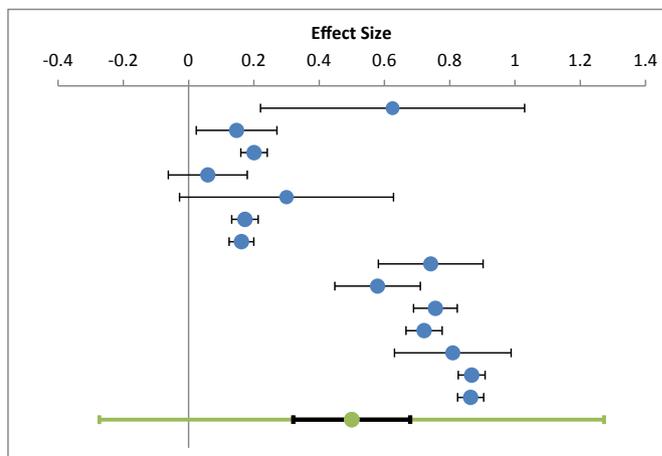


Fig. 5. Forest Plot Rates of Vomiting by IGB type.

Table 3 Summary of rates of nausea, vomiting, abdominal pain, GERD, mild or moderate adverse events and serious adverse events post IGB placement.

Study	IGB Sub-group	Treatment Sample Size	SAE* Sample Size	Nausea N	Nausea %	Vomiting N	Vomiting %	Abdominal Pain N	Abdominal Pain %	GERD N	GERD %	AE N	AE %	SAE N	SAE %
Machyrka, 2017 [13]	Elipse	34	34	15	44.12	18	52.94	7	20.50	0	0	24	70.59	0	0
Machyrka, 2016 [14]	Elipse	8	8	6	75.00	5	62.50	3	37.50	0	0	0	0	0	0
FDA, SMART, 2016 [15]	Obalon	198	336	261	77.68	58	17.26	244	72.62	57	16.96	300	89.29	1	0.30
Nobili, 2015 [16]	Obalon	10	10	5	50.00	5	50.00	5	50.00	4	23.53	5	50.00	3	33.00
Mion, 2013 [17]	Obalon	17	17	7	41.18	3	17.65	13	76.47	4	23.53	16	94.12	0	0
FDA, IB-005, 2015 [18]	ORBERA	125	160	139	86.88	121	75.63	92	57.50	48	30.00	139	86.87	17	10.63
Mittra, 2015 [11]	ORBERA	57	57	33	57.89	33	57.89	13	22.81	27	47.37	55	96.49	0	0
Fuller, 2013 [19]	ORBERA	31	31	23	74.19	24	77.42	0	0	0	0	0	0	1	3.23
FDA, REDUCE, 2015 [20]	ReShape	187	264	64	24.24	229	86.74	144	54.55	47	17.80	262	99.24	20	7.58
Ponce, 2013 [21]	ReShape	21	21	11	52.38	11	52.38	0	0	0	0	7	33.33	0	0
Total		688	938	564	63.33% (61.49% - 65.16%)	507	55.29% (53.59% - 56.99%)	521	58.55% (56.41% - 60.68%)	183	20.57% (18.47% - 22.67%)	808	89.88% (89.05% - 90.71%)	42	5.24% (4.84% - 5.64%)
Meta-analytic average (95% CI)															

3.4. Meta-analysis of rates of dyspepsia and abdominal pain

Eight studies with total SAE reporting consists of a sample size of 886 patients, with 521 patients experiencing generalized abdominal pain. Provided rates concluded a meta-analytic rate of 58.55% (95% CI 56.41%–60.68%) (Table 2). There were 183 patients stated they experienced reflux/GERD which resulted in a meta-analytic rate of 20.57% (95% CI 18.47%–22.67%).

3.5. Meta-analysis of rates of serious adverse events and mild or moderate adverse events after IGB insertion

Five studies with total SAE reporting consists of a sample size of 801 patients, with 42 patients experiencing SAE. Provided rates accounted for a meta-analytic rate of 5.24% (95% CI 4.84%–5.64%) (Table 3). Out of 899 patients, 801 patients stated they experienced AE which resulted in a meta-analytic rate of 89.88% (95% CI 89.05%–90.71%) (Table 3).

4. Discussion

Our review of ten studies presenting rates of accommodative symptoms such as nausea and vomiting revealed that nausea and vomiting are common after IGB placement. We also examined rates of mild or moderate adverse events and serious adverse events discussed in these studies. Of the ten studies reviewed, the highest rates for nausea, vomiting, AE, and SAE were reported by randomized clinical trial (RCT) conducted by the Food and Drug Administration (FDA). It might be explained by close monitoring, precise recording and reporting of accommodative symptoms, AE, and SAE. Additionally, ORBERA IGBs seem to have the highest rates of nausea and vomiting among all balloon systems. Finally, IGB placement in pediatric population could potentially contribute to relatively high rates of SAE [22].

We found a wide range of reported accommodative symptoms as well as serious and non-serious side effects. It might be caused by procedure related factors such as subtypes of IGBs, level of qualification of surgeons, types of antiemetic and pain medications, dosage and frequency of antiemetic, and pain medications utilized during specific study. Additionally, there are discrepancies in the reporting systems when defining “serious” and “non-serious” side effects. Quality and frequency of monitoring patients after IGB placement could affect rates as well. For example, rates of AE after ReShape IGB insertion ranged from 33.33% in the study by Ponce et al. to 99.24% in the FDA report. Even a relatively objective parameter such as vomiting has a range from 24.24% to 52.38% after ReShape IGB insertion [26,27]. Great variability in reporting are present as several authors noted total frequency of vomiting during the treatment, several presented frequencies by weeks, and several authors reported only by intensity measured by Rodex Nausea and Vomiting Index.

Most of the studies reported zero or very low rates of SAE after IGB insertion, and that may be due to a small sample size and/or healthier patient cohorts were selected since there are case reports presenting sporadic serious side effects in the general population. Although initial clinical research, observational studies, and RCT data showed that the use of IGBs are safe and mainly free from serious complications, studies of application in patients and FDA post-market safety monitoring revealed new and rare side effects. Recently, the FDA reported cases of new adverse events after liquid-filled Orbera and ReShape Balloon insertion that may present initially with nausea and vomiting as spontaneous overinflation and acute pancreatitis [28]. As the current labeling for saline-filled intragastric balloons do not address the issue of spontaneous over-inflation, health care providers-including ER professionals-should be aware that the symptoms could potentially be related to an over-inflated balloon and pancreatitis.

4.1. Limitations

We limited our review to a time frame of five recent years and to English language publications only. Definition of severity of nausea and vomiting might differ in various studies and mild forms may be underreported in observational studies and over-reported in FDA conducted RCTs. Another limitation is that we combined rates of accommodative and adverse events after intragastric insertion of four different IGB subtypes. The rates might be caused by specific details of that particular balloon that may affect our final estimates. However, we used meta-analytical methods when accounting for both within-study and between-study variances, adjusting for differences in study design or data collection methods. Additionally, serious adverse effects were reported only in five studies and mild or moderate side effects were reported in eight studies out of ten. Therefore, there were no standard definitions and uniform reporting system in place. Lastly, we did not examine the requirements for narcotic medications or injectable antiemetic medications applied in the different studies, and the difference in rates may be due to differences in medication use.

4.2. Strengths

We followed a standard guideline, and our literature search was performed by professionals (L. D. and J. G.) with careful literature review and selection process. Manuscripts were evaluated by two independent reviewers (S.L. and J.T.). Most studies on the effectiveness of IGB report nausea, vomiting, and other minor symptoms as common adverse effects of the IGB. However, to our knowledge, only a few studies have focused on these minor adverse effects and none of those studies stated whether or not physicians explained potential adverse effects of IGB procedures to their patients. With the rates compiled from ten different studies, this systematic review will provide some necessary information that both physicians and patients can utilize when they consider IGBs.

Though IGBs are effective treatments of refractory morbid obesity in the U.S., it is a commercial elective procedure not covered by private health insurances, Medicare, or Medicaid. In addition to effectiveness of weight reduction, safety profile and accommodative symptoms affecting quality of life of patient are characteristics affecting the surgeon's decision. Our study underlines an importance for health care providers to monitor and report frequency, intensity, and outcome of SAE and AE. Though all balloons share similar contraindication profile, physicians are commonly inclined to choose one balloon type over another. Our review suggested that swallowable types of balloons have fewer mild side effects such as nausea and vomiting. For example, Obalon has several advantages: sedation and endoscopy are required only on removal, and number of balloons to swallow depends on tolerability of patient. An advantage of only one endoscopy procedure and sedation on removal adds a safety profile and makes it suitable to a broader range of patients. Therefore, more and more patients are choosing Obalon over other balloon subtypes.

4.3. Implications

Our findings may be of interest to bariatric surgeons by means of providing additional information and guidance to the selection of an IGB system that can fit into the individual profile of each patient.

5. Conclusion

Nausea and vomiting are relatively mild accommodative side effects of IGBs that are very common especially within the first two weeks following balloon insertion. Therefore, health care providers should discuss these side effects with their patients prior to procedure to ensure postoperative lifestyle expectations, adjustments, and satisfactory postoperative course and treatment success. We are interested in

studying the weight loss efficacy of each balloon type, and we think this will impact physician-patient decision making in the future and help to match balloon type to weight loss goal.

Ethical approval

N/A.

Sources of funding

None.

Author contribution

Judy Trang was responsible for research implementation and edited each section of this manuscript. Judy Trang and Sean Lee participated in abstract and full title review, and contributed in writing of background, results, and discussion. Assia Miller was responsible for analysis of data and synthesizing the methods and results sections. Christian Cruz Pico advised development of the methodology section and helped write the introduction. Angelina Postoev contributed to the discussion section. Christopher Ibikunle was responsible for guiding research implementation and conceptualizing the manuscript foci, including biostatistical supports central to data analysis, results and discussion presented. Each author helped to gather literature on the subject matter for this manuscript per their programmatic and research expertise. Each author was central to revisions of the manuscript towards final submission.

Conflicts of interest

None.

Research registration number

reviewregistry449.

Guarantor

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.ijso.2018.06.038>

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