

Predictors of early removal of intragastric balloon due to intolerance: Insights from a multiethnic Asian cohort

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ABSTRACT

Introduction: Intolerance frequently limits the use of intragastric balloons (IGBs) in the treatment of obesity. This includes refractory nausea, vomiting and abdominal discomfort. Our study aims to identify predictors of balloon intolerance and early removal, which will help to guide patient selection for this intervention and peri-procedure care.

Method: We conducted a retrospective cohort study of 54 consecutive patients who underwent IGB insertion from July 2017 to July 2022 in a single tertiary institution in Singapore. Forty-seven (87.0%) patients completed therapy, while 7 patients (13.0%) had early removal of the balloon due to intolerance. Characteristics of both groups were compared.

Results: Multivariate analysis revealed significant associations between early balloon removal and both depression ($P=0.012$) and anxiety ($P=0.001$) after adjusting for age, sex, ethnicity, height, nulliparity, balloon type and volume. Univariate analysis revealed that anxiety was the main risk factor ($P=0.004$, odds ratio 9.111, 95% confidence interval 1.624–51.124), while depression was no longer a significant predictor.

Conclusion: Identifying predictors of balloon intolerance and early removal can enhance patient selection and improve peri-procedural care. In patients with a history of depression or anxiety, it is important to ensure adequate counselling and preparation prior to balloon insertion.

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Keywords: early removal, elipse, intolerance, intragastric balloon, obesity, orbera, spat, weight loss

INTRODUCTION

Obesity, affecting over 2.1 billion people globally, is an escalating health crisis with serious economic consequences.¹ It is associated with multiple comorbidities including type 2 diabetes mellitus

CLINICAL IMPACT

What is New

- Our study identified depression and anxiety as significant predictors of intragastric balloon intolerance and early removal.

Clinical Implications

- Peri-procedural support is crucial for patients with depression and anxiety, including counselling on physiological changes and setting realistic treatment goals.
- Optimising psychiatric comorbidities prior to intragastric balloon insertion and involving families in the process are also beneficial.
- One can also consider admitting these patients for monitoring and intravenous anti-emetics after balloon insertion, rather than performing it as an ambulatory procedure.

(T2DM), hypertension, coronary artery disease, stroke, sleep apnea, osteoarthritis and even certain cancers.² In the US alone, USD190 billion per year is spent on the treatment of obesity and obesity-related complications.³ When compared with normal weight individuals, obese patients are responsible for 46% higher inpatient costs, 27% more outpatient visits and 80% higher spending on prescription medications.⁴

Clinically significant weight loss of 5–10% from baseline can substantially reduce cardiovascular risk factors and improve obesity-related comorbidities, such as obstructive sleep apnea, non-alcoholic fatty liver disease and the prevention or delay in development of type 2 diabetes.⁵ Lifestyle interventions, including a low-calorie diet, increased

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physical activity and behaviour modification, is the first line for weight loss. Unfortunately, physiologic adaptations to weight loss result in increased appetite, decreased resting metabolic rate and consequently weight regain. As a result, most patients fail to achieve sustained weight loss with lifestyle interventions alone.⁶ Pharmacotherapy is an important adjunct to lifestyle and behavioural modifications, and even in patients post-bariatric surgery. However, while glucagon-like peptide-1 (GLP-1) agonists have been shown to be effective in weight loss, its cost has deterred its usage as a first-line therapy. Furthermore, there are also misconceptions about the safety of obesity pharmacotherapy. For example, in Singapore, a survey of the public who attended an obesity forum revealed that 65.1% believed that weight loss medications are dangerous, and only 20.6% thought they were effective for weight loss.⁷

Metabolic-bariatric surgery (MBS) is the most effective treatment for severe obesity and its metabolic complications, with the percentage of excess weight loss ranging from 60% to 87% in randomised controlled trials.⁸ Yet, only 1% of patients who qualify for MBS undergo the procedure as it is associated with peri-operative risks.⁹

Intragastric balloon (IGB) therapy has been proposed as a less invasive and reversible approach to weight loss that bridges the gap between lifestyle interventions or pharmacotherapy and MBS. It is a space-occupying device that is either inserted endoscopically or swallowed, which results in gastric distention, delayed gastric emptying, increased satiety and consequently reduced intake.¹⁰ IGBs vary in terms of material, duration of therapy, balloon volume, adjustability, method of insertion and removal. Currently, the 3 IGBs approved by the United States Food and Drug Administration are the Obalon, Orbera and ReShape balloons. Additional balloons approved for use in Europe include the Elipse, End-Ball, Heliosphere BAG, Lexbal, MedSil and Spatz3. Orbera, one of the oldest IGBs still in use, is composed of silicon, filled with 400 to 700 mL of saline and inserted endoscopically into the stomach for up to 6 months. ReShape balloon is similarly inserted endoscopically for up to 6 months and filled with approximately 750 to 900 mL of saline. Both the Obalon and Elipse balloons are swallowed and do not require endoscopy for insertion; however, Elipse is the only IGB that is removed via natural excretion. Spatz3 balloon is unique as its volume can be adjusted.¹¹

IGBs have been shown to be safe and effective for treating obesity and its metabolic complications, producing an initial weight loss between 6% and

15%, which is superior compared to 1% to 5% with lifestyle modifications alone.¹² Nonetheless, it is difficult to achieve sustained weight loss with the IGBs, as weight regain is expected to occur after removing the balloon. Furthermore, intolerance of the IGB also limits its use. As the balloon rapidly fills with fluid within the stomach, unwanted symptoms may develop. Nausea and vomiting are the most common symptoms of intolerance, the duration and severity of which vary between individuals. Profuse vomiting with poor intake may also result in dehydration and electrolyte imbalance. Other symptoms of intolerance include abdominal pain, cramps as well as heartburn.¹³ The incidence of early removal of IGB due to intolerance ranges from 0.44% to 20% across several studies worldwide.^{13–36} Many studies have evaluated the safety and efficacy of IGBs, but few have scrutinised the predictors of intolerance and early removal. Our study aims to identify predictors of early removal of IGB due to intolerance, which will help to guide patient selection and peri-procedural care.

METHOD

We conducted a retrospective cohort study on 54 consecutive patients who underwent IGB insertion between July 2017 and July 2022 at the Singapore General Hospital. Indications for IGB insertion in our institution include patients with obesity (body mass index [BMI] ≥ 27.5 kg/m²) who do not qualify, decline or are unsuitable for MBS and who have been unsuccessful in achieving or maintaining weight loss despite dietary and lifestyle modifications. Contraindications to IGB insertion include patients with large hiatal hernia (larger than 5 cm), active ulcers in the stomach or duodenum, upper gastrointestinal bleeding, prior gastric surgeries, coagulopathy, severe liver disease, those who are pregnant or desire to become pregnant, or have any contraindications to undergo oesophagogastroduodenoscopy. All patients received standardised pre-procedure counselling, including informational handouts provided during clinic visits. All patients were evaluated at our weight management unit by a multidisciplinary team consisting of endocrinologists, surgeons, dietitians, physiotherapists, psychiatrists or psychologists prior to commencement of IGB therapy. We optimise the management of any existing psychiatric disorders through medication or therapy to ensure patient is stable prior to the procedure. Post-procedure, our psychologist will continue follow-up and support patients if needed.

Three types of IGB were used in our institution, the Orbera365, Elipse and Spatz3 balloons. The Orbera365 system (Apollo Endosurgery, Austin,

TX, US) is a spherical balloon that is filled with 400–700 mL of saline. It is inserted and removed endoscopically and can remain in the stomach for up to 12 months.¹⁰ Elipse (Allurion Technologies, Wellesley, MA, US) is the first swallowable gastric balloon that does not require endoscopy or sedation for insertion or removal. The balloon is contained in a capsule and once in the stomach, the capsule dissolves and the balloon is filled with 550 mL of fluid via a catheter. The catheter is dislodged from the balloon once filling is completed and withdrawn through the patient's mouth. The balloon self-deflates after 4 months and is naturally excreted.³⁷ Spatz3 Adjustable Balloon System (Spatz Medical, Great Neck, NY, US) is a silicone spherical IGB with a catheter that allows adjustments. It is inserted endoscopically and filled with 400 to 700 mL of saline. The volume can be adjusted downwards to improve tolerability or upwards to improve weight loss. It has an implantation duration of up to 12 months before it is removed endoscopically.¹² The type of balloon was chosen after a discussion with the patient based on the method of insertion, need for endoscopic removal, adjustability, cost and duration of implantation.

All Elipse balloons were inserted without sedation or anesthesia. The Orbera365 and Spatz3 balloons were inserted endoscopically under sedation (i.e. IV Midazolam). In the first post-procedure day, all patients were commenced on our post-MBS protocol, which included small quantities of clear fluids, progressing to a full liquid diet by the afternoon. Patients will stay on liquid diet for 1 week and gradually progress to stage 3 diet (soft food) under the supervision of our dietician. For anti-emesis, oral Aprepitant (125 mg on night before deployment day, 80 mg daily for 2 days) was prescribed in combination of Ondansetron 4 mg (3 times per day) and Metoclopramide 10 mg (3 times per day) for 5 days. For balloon intolerance, patients were offered option of admission for intravenous Dexamethasone 4 mg (4 times per day) and intravenous hydration to avert early removal if possible. Patients were reviewed by our multidisciplinary team at 2 weeks post-procedure, followed by review at 1 month, 3 months, 6 months and subsequently annually. Fig. 1 illustrates a typical patient's journey prior to IGB insertion and post-procedure follow up.

Our study aims to identify clinical predictors of early removal of IGB due to intolerance. Intolerance referred to patients who experienced accommodative symptoms such as nausea, vomiting, abdominal discomfort or cramps that were severe enough to warrant early removal. Early removal

referred to patients who had the balloon removed before the intended treatment duration was completed, i.e. less than 4 months for Elipse and less than 12 months for Orbera365 and Spatz3 balloons. Variables of interest were identified based on clinical observation and literature review. These include the type of balloon, balloon volume, length of stay following IGB insertion, age, sex, ethnicity, height, nulliparity, presence of psychiatric disorder such as anxiety or depression, use of antidepressants or antipsychotics, presence of T2DM and whether proton pump inhibitor was prescribed. This information was retrieved from a prospectively collected database that was kept for all patients who underwent IGB insertion at our institution.

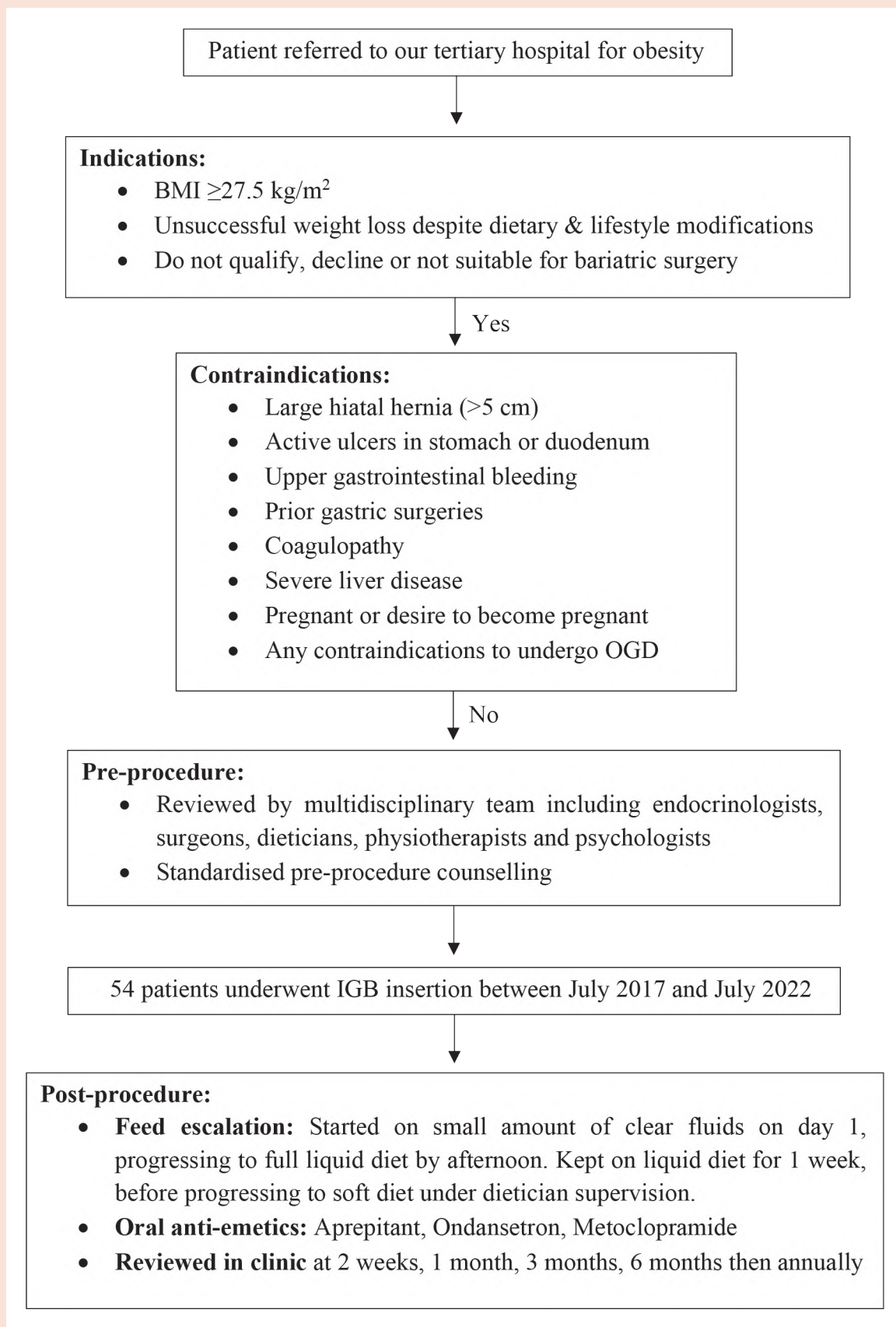
Statistical analysis

All categorical variables were given as percentages (%) of subjects affected, and normally distributed continuous variables were presented as the mean $\pm$ standard deviation (SD). Patients were divided into those who had early removal and those who completed therapy. Characteristics of these 2 groups were compared using Student's t-test for continuous variables or chi-square test for categorical variables. When analysing the relationship between multiple independent and dependent variables, a linear and logistic regression model was used. $P < 0.05$ was taken to indicate statistical significance. All analyses were performed using Stata version 16 software (Lakeway Drive, TX, US).

RESULTS

Fifty-four consecutive patients who underwent IGB insertion in a single tertiary institution in Singapore between July 2017 and July 2022 were included in our study. Thirteen patients (24.1%) experienced symptoms of intolerance including nausea, vomiting and abdominal pain, to varying severities. Eight patients (14.8%) required readmission for intravenous hydration and anti-emetics due to persistent vomiting and abdominal pain. Five of these patients experienced improvement in symptoms with medical therapy and eventually completed therapy. One patient had downsizing of the Spatz3 balloon volume from 700 mL to 500 mL and eventually completed therapy. The other 2 patients had requested for early removal of IGB during the admission due to persistent symptoms. A further 5 patients also had early removal of IGB due to intolerance symptoms, but they were not keen for a trial of admission to hospital for symptomatic treatment first. Out of 54 patients in our study, a total of 7 patients (13.0%) had early removal of the balloon due to

Fig. 1. Flowchart illustrating a typical patient's journey prior to IGB insertion and post-procedure follow-up.



BMI: body mass index; IGB: intragastric balloon; OGD: oesophagogastroduodenoscopy

intolerance while 47 (87.0%) patients completed therapy.

The mean duration of therapy was 263.5 days in those who completed therapy, and 7 days in the early removal group. Consequently, those who had the balloon removed early achieved less weight loss of 4.4 ± 3.6 kg compared to 11.7 ± 6.7 kg in those who completed therapy. The average length of stay post-procedure was comparable between the 2 groups (Table 1).

Table 2 compares the baseline characteristics of patients who had early IGB removal with those who completed therapy. There were no significant

differences between the 2 groups in terms of age, sex, ethnicity, type of IGB or balloon volume. The pre-operative weight, BMI and height of patients in both groups were also similar, suggesting that these factors were not statistically significant predictors of intolerance and early removal. Among those who received the Spatz3 adjustable balloon, 3 patients experienced intolerance where 2 opted for the balloon to be removed while 1 had the balloon downsized from 700 mL to 500 mL and eventually completed 12 months of therapy. Another 5 patients had their balloon volume increased for weight stagnation.

Table 1. Effects of treatment.

	Early removal (n=7)	Completed therapy (n=47)	P value
Nadir weight (kg $\pm$ SD)	91.4 $\pm$ 18.5	86.2 $\pm$ 18.5	0.490
Weight loss (kg $\pm$ SD)	4.4 $\pm$ 3.6	11.7 $\pm$ 6.7	0.008*
Procedure duration (min $\pm$ SD)	25 $\pm$ 7.6	29.2 $\pm$ 5.1	0.060
Length of stay (day $\pm$ SD)	1.6 $\pm$ 1.1	1.8 $\pm$ 1.5	0.661
Duration of therapy (day $\pm$ SD)	7 $\pm$ 7.3	263.5 $\pm$ 21.4	<0.000*

SD: standard deviation

Table 2. Baseline characteristics.

	Early removal (n=7)	Completed therapy (n=47)	P value
Age (year $\pm$ SD)	36.3 $\pm$ 13.1	38.5 $\pm$ 12.1	0.658
Sex, no. (%)			
Male	2 (28.6)	15 (31.9)	0.862
Female	5 (71.4)	32 (68.1)	
Ethnicity, no. (%)			0.459
Chinese	3 (42.9)	22 (46.8)	
Malay	3 (42.9)	7 (14.9)	
Indian	1 (14.3)	12 (25.5)	
Others	0	6 (12.8)	
Balloon type, no. (%)			0.741
Orbera365	1 (14.3)	4 (8.5)	
Spatz	2 (28.6)	23 (48.9)	
Ellipse	4 (57.1)	20 (42.6)	
Balloon volume, no. (%)			0.892
400–500 cc	1 (14.3)	11 (23.4)	
500–600 cc	5 (71.4)	26 (55.3)	
600–700 cc	1 (14.3)	10 (21.3)	
Pre-operative weight (kg $\pm$ SD)	95.8 $\pm$ 18.9	97.9 $\pm$ 19.9	0.800
Height (cm $\pm$ SD)	162.3 $\pm$ 10.0	164.5 $\pm$ 8.6	0.529
Pre-operative BMI (kg/m ² $\pm$ SD)	36.7 $\pm$ 8.6	36.0 $\pm$ 6.3	0.799

BMI: body mass index; SD: standard deviation

Table 3 compares several clinical parameters, such as nulliparity, depression, anxiety, use of antidepressants or antipsychotics, presence of T2DM or the use of proton pump inhibitors, among those who had early removal and those who completed therapy. On univariate analysis, we found that anxiety disorder was associated with risk of early removal ($P=0.004$, odds ratio 9.111, 95% confidence interval 1.624–51.124). Logistics regression was used to estimate the relationship between a dependent variable and independent variables. After adjusting for age, sex, ethnicity, height, nulliparity, balloon type and volume, multivariate analysis revealed significant associations between early balloon removal and both depression ($P=0.012$) and anxiety ($P=0.001$).

DISCUSSION

Intragastric balloons act as an artificial bezoar that occupies space in the stomach, resulting in early satiety, reduced food intake and consequently weight loss.⁴⁴ Unlike MBS, they are reversible and do not alter gastrointestinal anatomy. In a meta-analysis of 5 randomised controlled trials^{38–42} with a total of 903 patients (506 in the IGB group and 397 in the control group), Kotinda et al. showed that the mean percentage of excess weight loss difference between the groups was 17.98% ($P<0.00001$), significantly in favour of the IGB group over sham and lifestyle intervention.¹² Studies have also examined the sustainability of weight loss following balloon removal. In a randomised sham-controlled study with crossover at 3 months, Genco et al. showed that the group that had the balloon inserted for 3 months continued to lose weight at a greater rate in the 3 months following balloon removal, compared to the group that started out without a balloon for 3 months.⁴² Beyond weight loss, IGBs also induce significant decrease in

hepatic steatosis, insulin resistance and improvement in other obesity-associated comorbidities.¹⁹

While IGBs are safe and effective, its use is limited by intolerance.⁴³ Table 4 summarises the current literature on the experience with IGB worldwide, where the incidence of early removal due to intolerance varies between 0.44% and 20%. However, data on predictors for intolerance has been relatively scarce, with only 2 prior studies reporting on such predictors in the Caucasian population. The first study by Vargas et al. in the US²⁴ showed that the use of selective serotonin or serotonin-norepinephrine reuptake inhibitors (SSRI/SNRI) at time of balloon placement was associated with increased odds of early removal before 8 weeks. The second study by Luisa de-Castro et al. in Spain²¹ showed that intolerance was more frequent in females and in patients who complained of digestive symptoms beyond the first month. Our study represents the first and only study of these predictors in an Asian population.

In fact, our study showed that the early removal rate for intragastric balloons was significantly higher in the Asian population (13%) compared to Caucasian populations, which is consistent with the paper by Ganesh et al.¹⁶ The only other study conducted specifically in an Asian patient cohort found that 20% of patients required early balloon removal due to refractive nausea and epigastric discomfort, and concluded that intragastric balloons are poorly tolerated by Asian patients even when lower volumes are infused into the balloon to compensate for the smaller Asian stature. Insights into the predictors of early IGB failure in an Asian population represent an important addition to the limited existing literature in this field. By identifying the key predictors of early balloon failure in this population, clinicians

Table 3. Predictors of early removal of intragastric balloon due to intolerance (univariate analysis).

	Early removal (n=7)	Completed therapy (n=47)	Odds ratio	95% confidence interval	P value
Nulliparous, no. (%)	3 (60.0)	21 (65.6)	0.786	0.114–5.425	0.807
Depression	1 (14.3)	10 (21.3)	0.617	0.066–5.731	0.671
Anxiety	4 (57.1)	6 (12.8)	9.111	1.624–51.124	0.004*
Other psychiatric disorders	0	5 (10.6)	0.515	0.026–10.320	0.665
Antidepressants	2 (28.6)	5 (10.6)	3.36	0.511–22.104	0.207
Antipsychotics	1 (14.3)	5 (10.6)	1.400	0.139–14.120	0.775
Type 2 diabetes mellitus	0	9 (19.2)	0.270	0.014–5.159	0.385
Proton pump inhibitor	3 (42.9)	19 (40.4)	1.105	0.222–5.509	0.903

Table 4. Summary of experiences with intragastric balloons in terms of the incidence and predictors of early removal due to intolerance.

Study	Type of IGB	Country	Sample size	Incidence of early removal of IGB due to intolerance, no. (5)	Reason for intolerance of IGB	Predictors of intolerance of IGB
Roman et al. (2004) ¹⁴	BioEnterics Intragastric Balloon (BIB)	France	176	15 (8.5%)	Vomiting, abdominal pain	Not applicable
Genco et al. (2005) ¹⁵	BIB, now known as Orbera	Italy	2515	11 (0.44%)	Psychological intolerance	Not applicable
Ganesh et al. (2007) ¹⁶	BIB	Singapore	20	4 (20%)	Refractory nausea, retching, epigastric discomfort	Higher early removal rate among Asian patients despite lower volume of balloon filling compared to the Caucasian experience with BIB
Imaz et al. (2008) ¹⁷	BIB	Meta-analysis of 17 studies including 2 RCTs	3442	104 (3.0%)	Voluntary removal, nausea, vomiting, abdominal pain, dehydration	Not applicable
Dastis et al. (2008) ¹⁸	BIB	Switzerland	100	14 (14%)	Nausea, vomiting, abdominal pain	Not applicable
Forlano et al. (2010) ¹⁹	BIB	Italy	130	6 (4.6%)	Nausea, vomiting, abdominal pain	Not applicable
Lopez-Nava et al. (2011) ²⁰	BIB	Spain	714	31 (4.3%)	Psychological intolerance, gastroparesis	Not applicable
Luisa de-Castro et al. (2013) ²¹	BIB and Heliosphere Bag balloon	Spain	91	12 (13.2%)	Psychological intolerance, persistent vomiting	Intolerance more frequent in females ($P=0.03$) and in patients who complained of digestive symptoms beyond the first month ($p=0.001$)
Ghoneim et al. (2014) ²²	BIB	Egypt	101	3 (3%)	Not mentioned	Not applicable
Mitura et al. (2015) ¹³	Orbera	Poland	57	1 (1.7%)	Persistent vomiting, dehydration, electrolyte imbalance	Not applicable
Silva et al. (2018) ²³	Orbera	Portugal	51	7 (13.7%)	Abdominal pain, nausea, vomiting	Not applicable

Table 4. Summary of experiences with intragastric balloons in terms of the incidence and predictors of early removal due to intolerance. (Cont'd)

Study	Type of IGB	Country	Sample size	Incidence of early removal of IGB due to no. (%)	Reason for intolerance of IGB	Predictors of intolerance of IGB
Vargas et al. (2018) ²⁴	Orbera	Minnesota (Mayo clinic's database)	321	54 (16.6%)	Symptoms necessitating early balloon removal include: vomiting (36%), nausea (21%), abdominal pain (8%), troublesome gastroesophageal reflux (8%) and a combination of above symptoms (4%)	Use of selective serotonin or serotonin-norepinephrine reuptake inhibitors (SSRI/SNRI) at time of balloon placement was associated with increased odds of early removal before 8 weeks. Aprepitant use appeared to be protective.
Fittipaldi-Fernandez (2020) ²⁵	Orbera	Brazil	5874	357 (6.1%)	Not mentioned	Not applicable
Neto et al. (2017) ²⁶	Orbera, Medicone, Silimed, Spatz, Helioscopie	Brazil	41,866	928 (2.2%)	Not mentioned	Not applicable
Schwaab et al. (2019) ²⁷	Orbera (non-adjustable) and Spatz3 (adjustable)	Brazil	470 326 Orbera 144 Spatz3	30 (6.4%) 22 (6.7%) Orbera 8 (5.6%) Spatz3	Not mentioned	Higher incidence of early removal due to intolerance for non-adjustable balloons
Machytko et al. (2017) ²⁸	Elipse	US	34	2 (5.9%)	Not mentioned	Not applicable
Al-Subaie et al. (2017) ²⁹	Elipse	Kuwait	51	5 (9.8%)	Not mentioned	Not applicable
Alsabah et al. (2018) ³⁰	Elipse	Kuwait	135	8 (5.9%)	Nausea, vomiting, abdominal pain	Not applicable
Jamal et al. (2019) ³¹	Elipse	Kuwait	112	6 (5.4%)	Nausea, vomiting, abdominal pain	Not applicable
Ienca et al. (2020) ³²	Elipse	19 international centres across Europe and Middle East	1770	52 (2.9%)	Not mentioned	Not applicable
Taha et al. (2021) ³³	Elipse	Egypt	96	3 (3.1%)	Repeated vomiting	Not applicable
Machytko et al. (2014) ³⁴	Spatz3	Czech Republic and Manchester	77	3 (3.9%)	1 due to GERD, 2 not mentioned	Not applicable
Abu Dayyeh et al. (2021) ³⁵	Spatz3	US	187	31 (17%)	Not mentioned	Not applicable
Ibrahim et al. (2019) ³⁶	MedSil	Egypt	86	7 (8.1%)	Nausea, vomiting, abdominal pain	Not applicable

GERD: gastroesophageal reflux disease; IGB: intragastric balloon; RCTs: randomised controlled trials

can make more informed decisions about patient suitability and tailor their approaches to achieve the best possible results.

While Vargas et al.²⁴ found that the use of SSRI/SNRI was significantly associated with balloon intolerance and early removal, our study did not find this association to be statistically significant ($P=0.195$). A possible explanation could be that the presence of underlying depression or anxiety that necessitated the use of SSRI/SNRI may have been a confounder to the results in Vargas et al. Similar to how depression, anxiety and stress are associated with functional dyspepsia and irritable bowel syndrome,⁴⁴ we postulate that these psychiatric disorders contribute to visceral hypersensitivity via complex brain-gut neural pathways, resulting in an increased perception of bloating and nausea following IGB insertion.

In terms of the type of IGB, Al-Subaie et al. reported that patients with the Elipse balloon experienced higher symptom severity immediately after insertion, possibly due to an underestimation of the symptoms since the insertion is procedure-less.²⁹ However, Elipse was found to be rapidly tolerated after the first 72 hours, and Alsabah et al. postulated that its thin polymer film design makes it better tolerated in the stomach compared to the rigid designs of other balloons.³⁰ On the other hand, Spatz3 is an adjustable IGB, where the volume of saline within the balloon can be reduced to improve tolerance. In a retrospective review of 165 consecutive patients who underwent Spatz3 balloon insertion, Usuy et al. showed that downward adjustments of balloon volume alleviated early intolerance in 80% of patients.⁴⁵ In our study, 1 patient with Spatz3 had the balloon downsized from 700 mL to 500 mL for persistent nausea and vomiting, and eventually completed 12 months of therapy. Overall, our results nonetheless found that there was no statistically significant association between the type of balloon ($P=0.741$) or balloon volume ($P=0.892$) on intolerance and early removal. Other factors—including age, sex, ethnicity, pre-operative weight, BMI, height, nulliparity, T2DM and the use of proton pump inhibitors—were not significant predictors of intolerance and early removal.

A limitation of our study is its small sample size, which reduces its statistical power and increases the possibility of a type 2 error. With 3 different IGBs with different proposed dwell times (4 versus 12 months) and different methods of insertion and management (2 with fixed volumes and 1 adjustable), it may be difficult to conclusively tease

out the factors for intolerability. Furthermore, as a retrospective review of a single-centre experience, this limits the generalisability of our findings and larger confirmatory studies are needed. With a larger sample size, it may be possible to do a case-matched control study to investigate the incidence and factors for intolerance across the various IGBs. Nonetheless, our study hopes to be hypothesis-generating as there is currently no data available on predictors for early removal of intragastric balloon. Given that depression and anxiety are significantly associated with balloon intolerance and early removal, we hope that this information will help to guide patient selection and pre-procedure counselling. In patients with pre-existing depression or anxiety, peri-procedural support is imperative. This includes counselling them on the physiological changes to be expected post-procedure, clarifying the role of the intragastric balloon and to set realistic treatment goals. It is also equally important to adequately optimise the patient's underlying psychiatric comorbidities prior to IGB insertion. Involving families in process has also been shown to be beneficial, especially for adolescent patients. It may also be worthwhile to admit these patients for close monitoring and IV anti-emetics after balloon insertion rather than performing it as an ambulatory procedure.

CONCLUSION

In conclusion, while IGBs are a promising, less-invasive alternative to MBS in the treatment of obesity and its metabolic complications, intolerance is a problem especially in Asian populations where the rates of early balloon removal are significantly higher than in Caucasian populations. Identifying patients at risk of intolerance and early removal enables the healthcare team to implement necessary countermeasures, reducing this risk and increasing the success of IGB therapy. It allows clinicians to make informed decisions about patient suitability and tailor their approach to achieve best possible results for each patient.

Declaration

No funding was received for this work. The authors declare they have no affiliations or financial involvement with any commercial organisation with a direct financial interest in the subject or materials discussed in the manuscript.

Ethics statement

Formal consent is not sought as this is a retrospective study that does not use any identifying data.

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