Obesity Facts

Systematic Review

Obes Facts 2025;18:415–427
DOI: 10.1159/000542921

Received: May 5, 2024
Accepted: November 29, 2024
Published online: February 13, 2025

The Efficacy and Safety of Adjustable Intragastric Balloon for Weight Loss: A Systematic Review and Meta-Analysis

Chuqi Xia[a] Yinuo Wang[a] Guowu Sun[b] Wanyang Lei[c] Daoming Liang[a]

[a]Department of Gastrointestinal Surgery, The Second Affiliated Hospital of Kunming Medical University, Kunming, PR China; [b]Department of Gastrointestinal Surgery, Jinan Zhangqiu District People's Hospital, Jinan, PR China; [c]Department of Clinical Laboratory, The Second Affiliated Hospital of Kunming Medical University, Kunming, PR China

Keywords

Obesity · Weight loss · Adjustable intragastric balloon · Spatz3 · Systematic review

Abstract

Introduction: Adjustable intragastric balloon (aIGB), known as a novel minimally invasive therapy for obesity, provides a sustained alternative for weight loss. Weight loss is achieved by implanting a balloon into the patient's stomach, with the volume of the balloon being adjustable through the injection or extraction of physiological saline. Its key distinction from other intragastric balloons lies in post-implantation volume control. Currently, the efficacy and safety of aIGB have not been well described. ***Methods:*** MEDLINE, Embase, and the Cochrane Library were searched for relevant articles. Efficacy and safety of aIGB were evaluated by total body weight loss (TWL) after treatment and severe adverse events. ***Results:*** A total of 12 eligible studies with 4,981 patients were included. The average inserting time was 9.9 months, and the pooled mean TWL was 16.4% (95% CI: 0.153–0.175, I^2 = 91.2%). The pooled prevalence of patients choosing upward balloon adjustment was 34.2% (95% CI: 0.220–0.485, I^2 = 96.5), and all reported additional weight loss with a mean of 6.3 (4.8–9.3) kg. The pooled prevalence of patients choosing downward balloon adjustment was 9.2% (95% CI: 0.065–0.119, I^2 = 73.9%), and the pooled prevalence of alleviating intolerance in these patients was 90.8% (95% CI: 0.817–0.974, I^2 = 53.4%). The pooled prevalence of intolerance and early removal within 3 months was 5.7% (95% CI: 0.035–0.078, I^2 = 79.8%), and the pooled prevalence of stomach ulcer was 1.1% (95% CI: 0.008–0.014, I^2 = 5.1%). There was no obvious publication bias detected for these outcomes. Leave-one-out and subgroup analysis demonstrated the results were statistically reliable. ***Conclusion:*** aIGB has the ability of significant and sustained weight loss and can effectively manage both intolerance and weight loss plateaus by adjusting the balloon volume during treatment.

Chuqi Xia, Yinuo Wang, and Guowu Sun contributed equally to this work.
Guarantor of the article: Daoming Liang, MD.

karger@karger.com
www.karger.com/ofa

Karger
OPEN ACCESS

Correspondence to:
Wanyang Lei, dr_leiwanyang@163.com
Daoming Liang, daomingliangkm@163.com

Introduction

Obesity has emerged as a global health priority due to its escalating prevalence and its association with a myriad of complications, encompassing but not limited to type 2 diabetes, cardiovascular disease, osteoarthritis, obstructive sleep apnea, and various malignancies [1]. According to published literature, more than 10% weight loss can improve lipid metabolism, reduce the compression of the respiratory tract by visceral fat, thereby decreasing the incidence of type 2 diabetes, hypertension, fatty liver disease, and obstructive sleep apnea and improving the quality of life for patients [1]. Lifestyle interventions targeting modifications in dietary habits and physical activity stand as the first approach to weight management, owing to their cost-effectiveness and the minimal risk of associated complications [2]. Nevertheless, achieving enduring weight loss has proven to be challenging even within the framework of rigorous clinical trials [3].

Endoscopic therapies provide a sustained alternative for weight loss, exhibiting less invasiveness than bariatric surgery and greater effectiveness than conventional lifestyle interventions [4]. The intragastric balloons (IGBs) have been in clinical use for over 3 decades, substantiating their safety and effectiveness in facilitating weight loss [5, 6]. However, as IGBs lack adjustability, most patients can only be inserted for 6–8 months [7]; 2–9% of patients encounter intolerance, leading to early balloon extraction [8]; and some patients experienced variability in response and reduced efficacy after 1–3 months [9]. Therefore, the FDA approved the first adjustable intragastric balloon (aIGB), Spatz3 (Spatz Medical), in 2021. The balloon design facilitates the removal of fluid in cases of intolerance or the addition of extra fluid to enhance weight-loss outcomes [10]. In the latest multicentre randomized controlled trial (RCT) about aIGB, the mean total body weight loss (TWL) at 32 weeks was 15.0%; clinical response was observed in 92% of patients, upward volume adjustment enabled an additional mean of 5.2% TWL, and downward volume adjustment allowed 75% patients to complete the full duration of therapy [11]. Overall, the adjustability of balloon volume permitted individualized therapy, optimizing both weight loss and tolerance.

To date, no meta-analysis has assessed the efficacy and safety of aIGB for weight loss. For these reasons, we comprehensively evaluated the effectiveness and safety of aIGB through systematic review and meta-analysis. Additionally, we provided a more referenced assessment by reviewing all case reports about aIGB.

Methods

Study Protocol

This study followed the latest version of Meta-Analysis of Observational Studies in Epidemiology (MOOSE) and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [12, 13]. The methodology of the research was recorded in PROSPERO (CRD42023478559).

Data Sources and Search Strategy

A comprehensive search of the literature was performed on October 31, 2023, in multiple bibliographic databases (PubMed, Embase, and the Cochrane Database), without time or language restrictions. The primary items were searched in the Medical Subject Headings database and relevant articles, and the keywords finally included “adjustable intragastric balloon” OR “Spatz.” The search was applied to all fields. The references from the retrieved articles were also manually reviewed for any missed articles. Two investigators (Guowu Sun and Yinuo Wang) conducted the systematic search. Disagreements were resolved by consensus with the intervention of a third reviewer (Chuqi Xia).

Study Selection and Quality Assessment

Predefined inclusion criteria were retrospective, prospective or cross-sectional studies, cross-sectional or cohort studies, or RCTs with studies reporting weight loss results of inserting the latest aIGB (Spatz3) in adult patients, and the sample of studies was >80, the age of patients was over 18 years old. Exclusion criteria were animal studies, commentaries, reviews, overlapping patients, and publications in a language other than English. If multiple articles were on the same study sample with the same exposure and outcome, the publication with the largest sample size was retained. In addition, case reports about the latest aIGB were aggregated for description and were not included in the calculation. All studies were evaluated for quality independently by 2 investigators (Guowu Sun and Yinuo Wang). RCTs’ risk-of-bias assessment was done using the Cochrane Collaboration risk of bias tool, and case-control and cohort studies’ quality were assessed by the Newcastle-Ottawa scale (NOS) [14]. If studies received 6 out of 9 possible points in NOS, we consider their quality acceptable.

Data Extraction and Measures

Data were extracted by 3 authors (Chuqi Xia, Guowu Sun, and Yinuo Wang) independently and then compared. The baseline information included (1) the first author’s name, (2) the year of publication, (3) the country, (4) the study design, (5) the setting of the

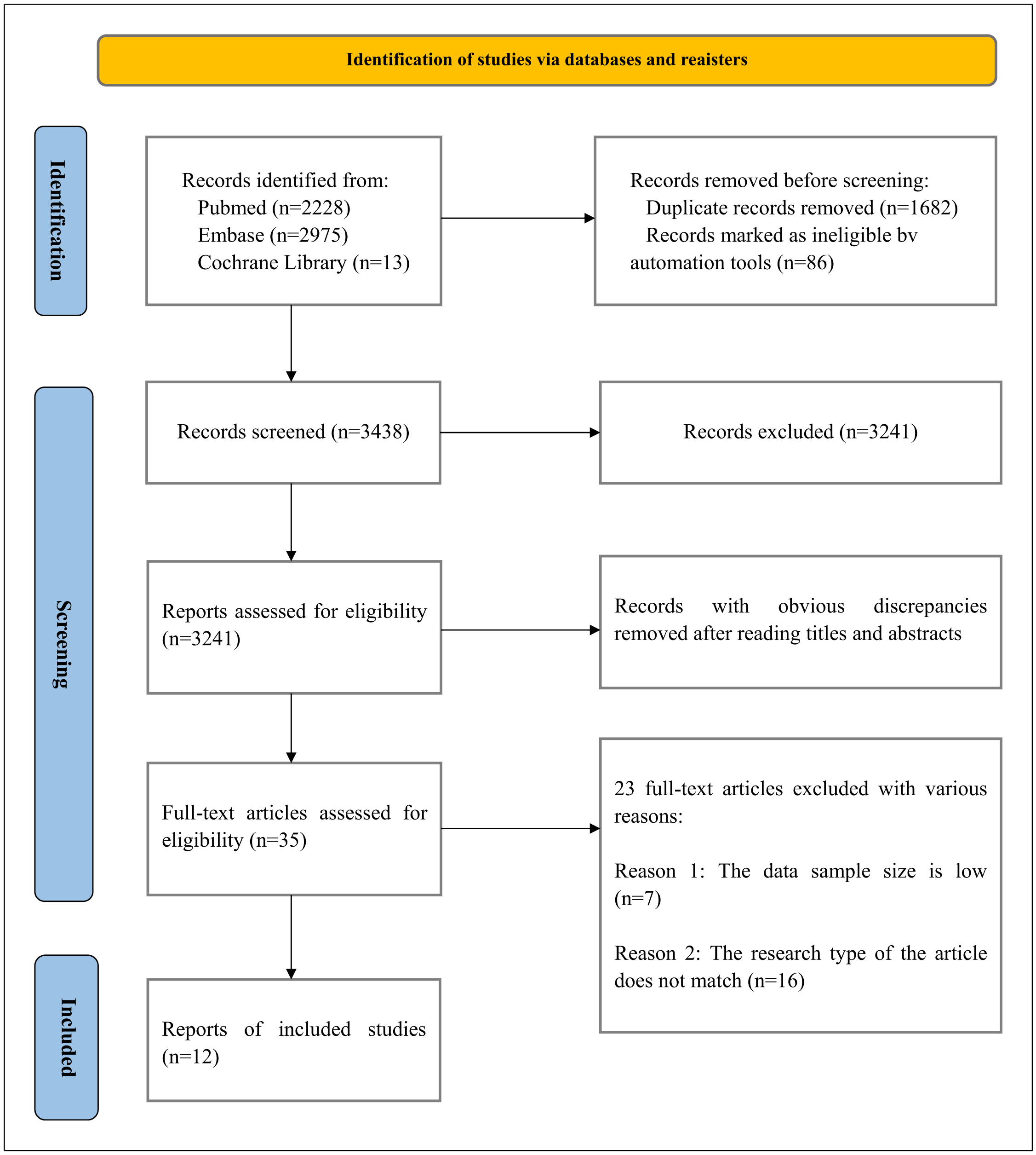


Fig. 1. Summary of the process of study selection.

research center, (6) patient demographics (age, gender, BMI, weight), (7) sample of patients, (8) inserting time. The outcome indicators included (1) TWL after treatment, (2) number of upward adjustment and additional weight loss after upward adjustment, (3) number of downward adjustment and number of alleviating intolerance after downward adjustment, (4) number of adverse events (early removal within 3 months, gastric ulcer, migration with intestinal occlusion, esophagitis, and balloon leaks). When data could not be extracted or calculated from the text, the corresponding author was contacted to obtain further information. Efficacy and safety were evaluated by calculating TWL and severe adverse event rates reported in the included studies.

Data Synthesis and Analysis

The mean or standard deviation (sd) for continuous data (TWL) and number of events or total sample for each categorical factor were obtained or calculated when possible. The pooled TWL and proportions of the event

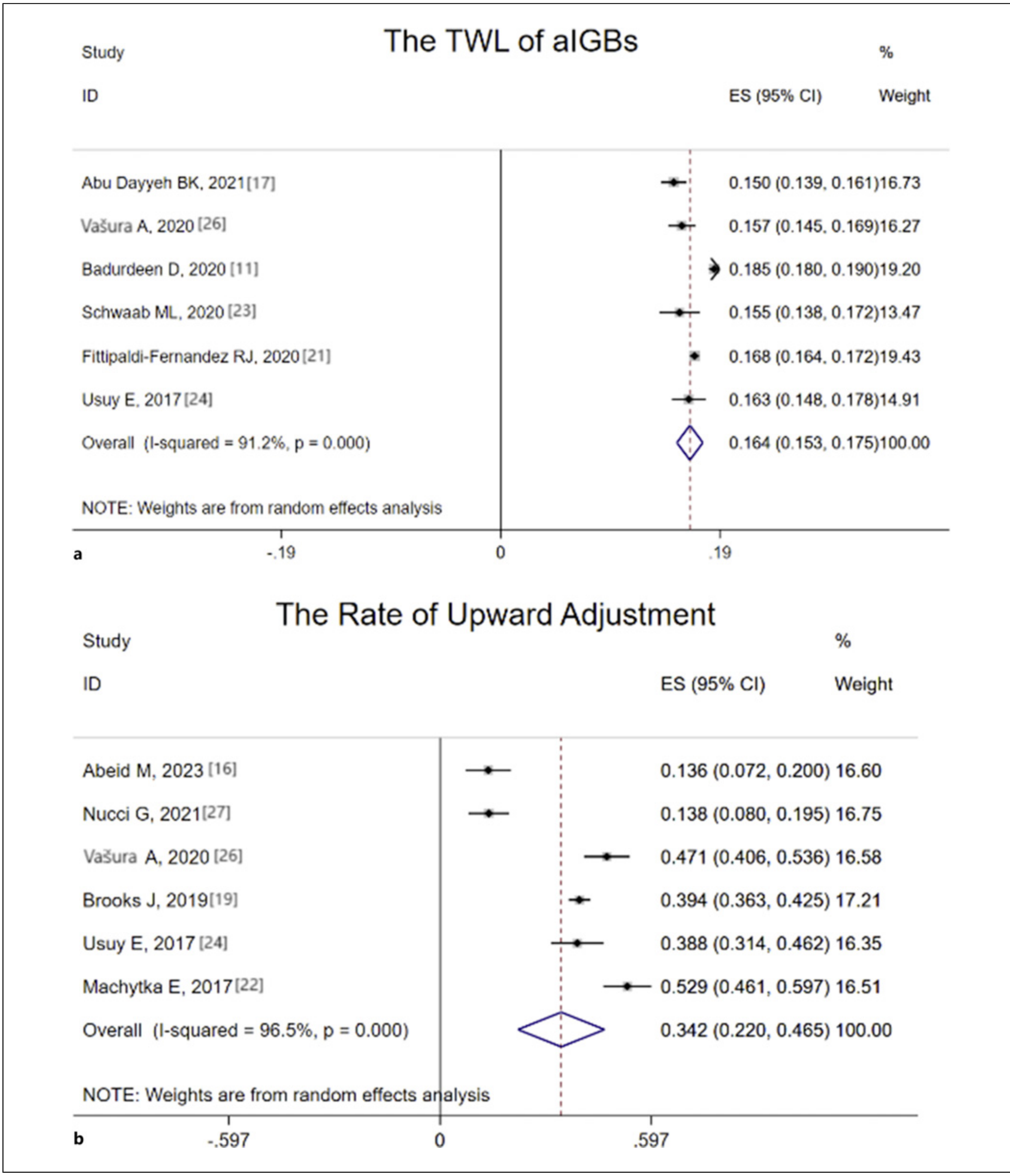
Table 1. Baseline characteristics of included studies

First author, year	Country	Study type	Setting	Sample	Male	Age	Weight	BMI	Insert time
Espinet Coll et al. [28] (2023)	Spain	Observational	Multicenter	2,349	–	–	–	–	–
Abeid and Zaitoun [16] (2023)	Egypt	Observational	Single center	110	34	38.4	105.9	37.0	10.0 mo
Abu Dayyeh et al. [17] (2021)	America	RCT	Multicenter	187	25	44.4	–	35.8	8.0 mo
Nucci et al. [27] (2021)	Italy	Observational	Multicenter	138	–	47.8	–	40.2	–
Vašura et al. [26] (2020)	Czech Republic	Observational	Multicenter	277	51	41.0	99.6	35.9	10.3 mo
Badurdeen et al. [18] (2021)	Brazil	Observational	Multicenter	270	212	38.1	98.2	–	–
Schwaab et al. [23] (2020)	Brazil	Observational	Single center	116	32	39.7	–	–	–
Fittipaldi-Fernandez et al. [21] (2020)	Brazil	RCT	Single center	86	30	40.4	108.7	38.3	7.1 mo
Brooks [19] (2019)	Israel	Observational	Single center	967	230	–	98.0	–	9.4 mo
Usuy and Brooks [25] (2018)	Germany	Observational	Single center	110	39	40.3	115.7	–	12.0 mo
Usuy [24] (2017)	Brazil	Observational	Multicenter	165	34	42.4	99.1	35.7	12.0 mo
Machytka et al. [22] (2017)	Czech Republic	Observational	Multicenter	206	47	42.0	99.9	35.9	12.0 mo

Table 2. Efficacy of aIGB

First author, year	Sample	TWL		Upward adjustment		Downward adjustment	
		mean	SD	*N*	additional weight loss, kg	*N*	alleviating intolerance, *n*
Abeid and Zaitoun [16] (2023)	110	–	–	15	5.2	6	6
Abu Dayyeh et al. [11] (2021)	187	15.0	7.7	–	–	28	21
Nucci et al. [27] (2021)	138			19	4.8	9	9
Vašura et al. [26] (2020)	227	15.7	9.2	107	8.5	15	12
Badurdeen et al. [18] (2021)	270	18.5	4.1	–	–	–	–
Schwaab et al. [23] (2020)	116	15.5	9.6	–	–	–	–
Fittipaldi-Fernandez et al. [21] (2020)	86	16.8	1.9	–	–	–	–
Brooks [19] (2019)	967	–	–	381	5.1	120	107
Usuy and Brooks [24] (2017)	165	16.3	9.6	64	5.7	20	20
Machytka et al. [22] (2017)	206	–	–	109	9.3	15	12

were then computed using either fixed-effects or random-effects models, depending on study homogeneity or heterogeneity, and the statistical heterogeneity was evaluated using I^2 statistics and Cochran Q test values [15]. An I^2 value >50% was considered high statistical heterogeneity ($I^2 > 50\%$ and $p < 0.05$). For the main outcomes that failed the homogeneity test, we searched for potential sources of heterogeneity, including study type, study setting, average age, and sample and evaluated these via subgroup analysis, where TWL was the summary outcome. As fewer than 10 studies were included in this meta-analysis, Egger's publication bias plot was generated to evaluate the possibility of publication bias. All statistical analyses were performed using Stata SE.



2

(Figure continued on next page.)

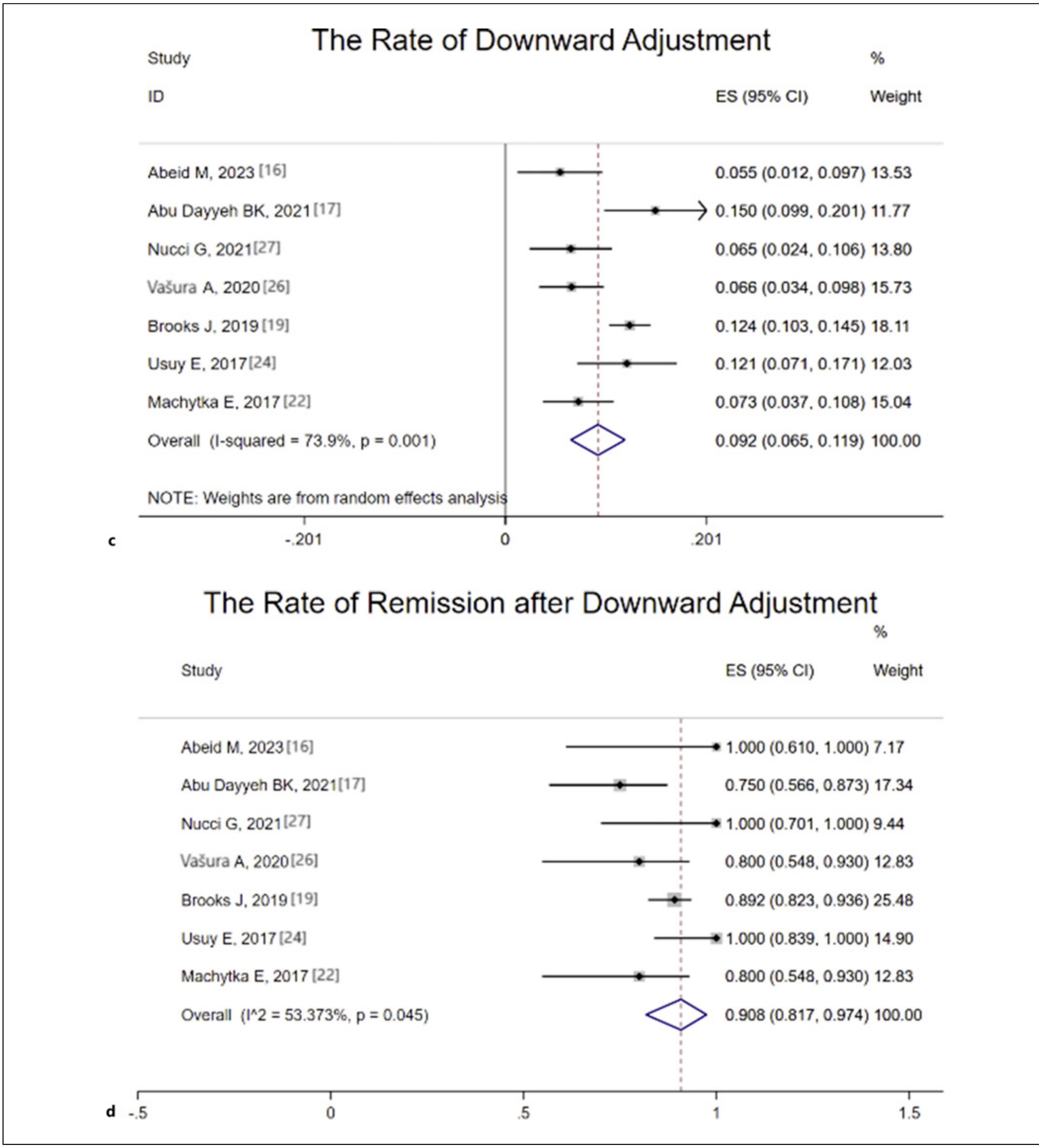


Fig. 2. Forest plots showing the efficacy of aIGB. **a** Pooled mean TWL of patients after aIGB treatment. **b** Pooled prevalence of patients choosing upward balloon adjustment during treatment. **c** Pooled prevalence of patients choosing downward balloon adjustment during treatment. **d** Pooled prevalence of alleviating intolerance or relieving symptoms after patients choosing downward balloon adjustment.

Table 3. Safety of aIGB

First author, year	Sample	Early removal, %	Gastric ulcer, %	Migration with intestinal occlusion	Esophagitis	Balloon leaks
Studies of adverse events after aIGB						
Espinet Coll et al. [28] (2023)	2,349	110 (4.68)	29 (1.23)	1 (0.04)	329 (14.00)	–
Abeid and Zaitoun [16] (2023)	110	14 (12.73)	–	–	–	8 (7.27)
Abu Dayyeh et al. [17] (2021)	187	26 (13.90)	7 (3.74)	–	–	1 (0.53)
Nucci et al. [27] (2021)	138	8 (5.80)	–	–	–	–
Vašura et al. [26] (2020)	227	10 (4.41)	2 (0.88)	–	–	–
Schwaab [23] (2020)	116	10 (8.62)	2 (1.72)	–	–	–
Brooks [19] (2019)	967	–	8 (0.83)	–	–	–
Uyak [25] (2018)	110	2 (1.82)	1 (0.91)	2 (1.82)	–	1 (0.91)
Usuy and Brooks [24] (2017)	165	3 (1.82)	5 (3.03)	0 (0)	–	–
Machytka et al. [22] (2017)	206	–	2 (0.97)	–	–	–

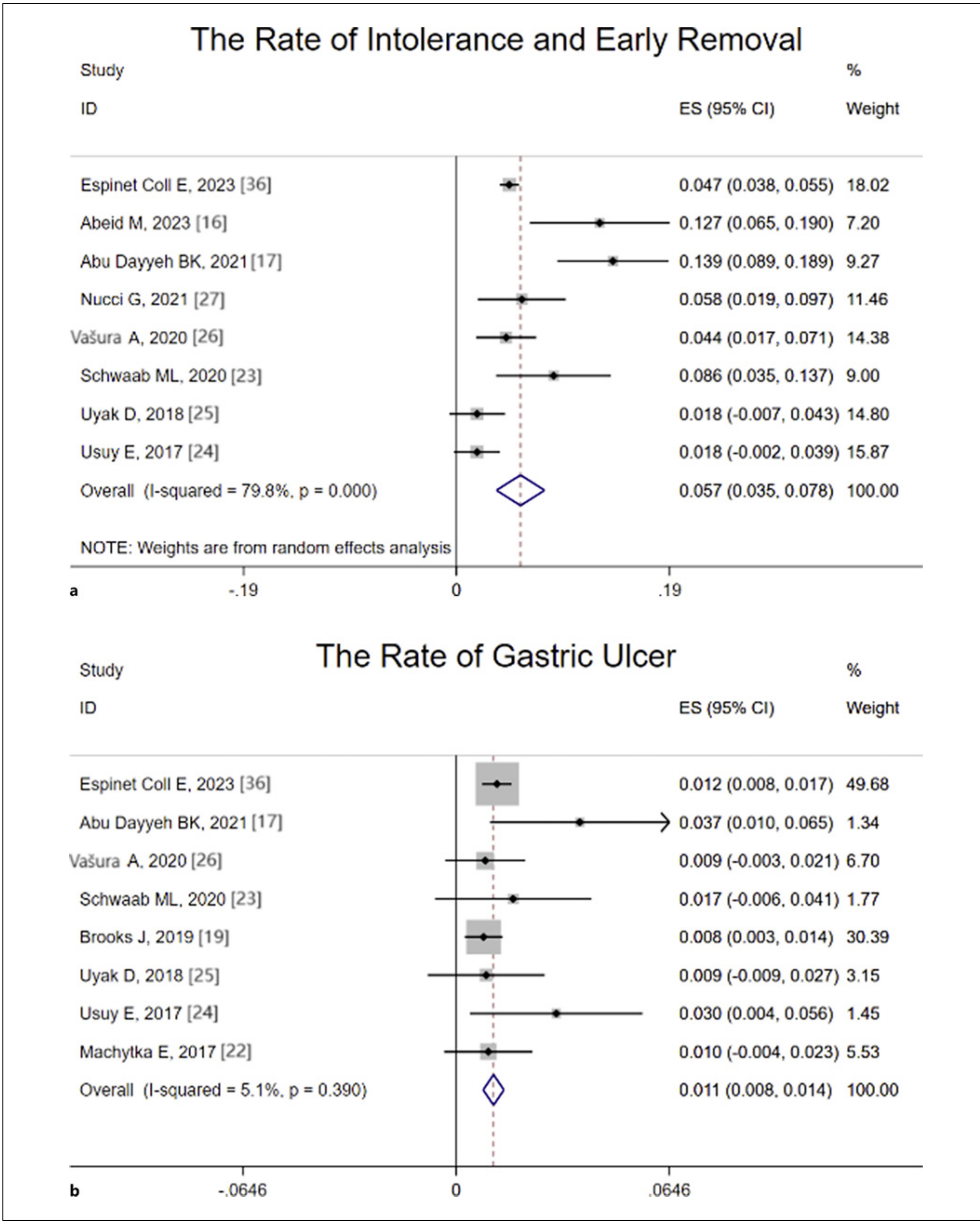
First author, year	Age/gender	Weight/BMI	Insert time	Adverse event	Treatment	Outcome
Reports of adverse events after aIGB						
Tan et al. [29] (2022)	45/F	103 kg/35.6	7 mo	Small bowel obstruction	Laparotomy	WL 7 kg
Xie et al. [30] (2021)	41/F	–/25.8	1 week	Gastric outlet obstruction	Remove the balloon	–
Usuy et al. [31] (2020)	62/F 34/F	70.5 kg/30 69.7 kg/28	6 mo 10 mo	Hyperinflation Hyperinflation	Refill the balloon Substitute with another balloon	WL 10.5 kg WL 9.3 kg
Alqabandi et al. [32] (2020)	30/M	110 kg/35.1	12 mo	Pancreatitis	Remove the balloon	–
Barrichello et al. [33] (2019)	60/F 36/F	88 kg/33 87 kg/34	– –	Perforation Perforation	Laparoscopic repair of gastric perforation Laparoscopic repair of gastric perforation	– –
Daniel et al. [34] (2015)	45/F 24/F	75 kg/31 –/30.7	5 mo 7 mo	Tear of gastric wall Perforation	Laparotomy Laparotomy	Died intraoperatively Recovery

Results

Study Selection, Characteristics, and Quality Assessment

The flow diagram, Figure 1, summarizes the process of study selection. The initial search yielded 5,216 potentially relevant articles (2,228 articles from PubMed, 2,975 articles from Embase, and 13 articles from the Cochrane Database), of which 1,682 were duplicates. The remaining 3,241 articles underwent title and abstract review, then 3,206 irrelevant articles that did not fulfill the eligibility criteria were excluded. A total of 35 articles performed a full-length review, and 23 articles were excluded according to the exclusion

3



(For legend see next page.)

criteria. Finally, 12 unique studies which are fulfilling the redefined inclusion criteria were included in this meta-analysis [16–27]. One study with 2 cohorts' results was pooled into one cohort [21]. The characteristics of the included studies are comprehensively described in Table 1. Twelve studies with a total of 4,981 patients were included in this meta-analysis: 2 were RCTs, 10 were observational studies without randomization, 7 were multicenter, and 5 were single-center. In terms of patients' baseline information, 734 patients were men, 1,760 patients were women, the mean age was 41.4 years old, the mean baseline weight was 100.20 kg, the mean baseline BMI was 36.64 kg/m^2, and the average implantation time was 9.9 months.

Ten observational studies were assessed for bias using NOS; the maximum score of them is 9 points, while the minimum score is 6 (online suppl. Table 1; for all online suppl. material, see https://doi.org/10.1159/000542921). RCTs' risk-of-bias assessment was done using the Cochrane Collaboration risk-of-bias tool (online suppl. Fig. 1). The quality of these articles was all considered to be acceptable.

Efficacy of aIGB

Table 2 summarizes the efficacy of aIGB, outcome indicators including TWL after treatment, number of upward adjustment additional weight loss after upward adjustment, number of downward adjustment, and number of alleviating intolerance after downward adjustment. The TWL after aIGB treatment was reported in 6 studies [17, 18, 21, 23, 24, 26]. Pooled estimation of a meta-analysis showed the pooled mean TWL after aIGB treatment was 16.4% (95% CI: 0.153–0.175, I^2 = 91.2%, p < 0.001) (Fig. 2a), and the Egger's test showed p = 0.252 (online suppl. Fig. 2a). All researchers claim to have provided health education to patients, including dietary intervention and exercise guidance, but the contribution of these lifestyle interventions to weight loss seems to be non-significant. In one of the studies, the researchers reported a TWL of 15% for the aIGB group, while the TWL for the group with lifestyle intervention alone was only 3% [17].

Six studies reported data of upward adjustment [16, 19, 22, 24, 26, 27], and all reported additional weight loss with a mean of 6.3 (4.8–9.3) kg. Pooled prevalence of patients choosing upward balloon adjustment during treatment was 34.2% (95% CI: 0.220–0.485, I^2 = 96.5% p < 0.001) (Fig. 2b), and the Egger's test showed p = 0.763 (online suppl. Fig. 2b).

Seven studies reported the data of downward adjustment [16, 17, 19, 22, 24, 26, 27]. Pooled prevalence of patients choosing downward balloon adjustment during treatment was 9.2% (95% CI: 0.065–0.119, I^2 = 73.9%, p = 0.001) (Fig. 2c), and the Egger's test showed p = 0.487 (online suppl. Fig. 2c). All studies reported that downward adjustment could alleviate intolerance or relief symptoms (pain, nausea, vomiting, abdominal pressure, and so on); 3 reported a remission rate of 100% [16, 24, 27], and the minimum remission rate was 75% [17]. Pooled estimation of a meta-analysis showed a remission rate of 90.8% (95% CI: 0.817–0.974, I^2 = 53.4% p < 0.045) (Fig. 2d), and the Egger's test showed p = 0.893 (online suppl. Fig. 2d).

Safety of aIGB

Table 3 summarizes clinical studies and all reports of adverse events after aIGB. According to the descriptions in these articles, the health status of all reported patients prior to balloon implantation met the conditions required for the procedure, and no contraindications were present. Ten studies reported data of serious adverse events [16, 17, 19, 20, 22–27], and there was no mortality. Eight studies reported the occurrence rate of intolerance and early removal within 3 months; the pooled estimate of occurrence rate was 5.7% (95% CI: 0.035–0.078, I^2 = 79.8% p < 0.001) (Fig. 3a), and Egger's test showed p = 0.303 (online suppl. Fig. 2e). Eight studies reported the occurrence rate of stomach ulcer [17, 19, 20, 22–26]; the pooled estimate of prevalence of stomach ulcers was 1.1% (95% CI: 0.008–0.014, I^2 = 5.1%, p = 0.390) (Fig. 3b), and Egger's test showed p = 0.186 (online suppl. Fig. 2f). In addition, 3 studies reported the prevalence of balloon leaks was 7.3% (8/110) [16], 0.5% (1/187) [17], and 0.9% (1/110) [25], respectively. Two articles reported that the prevalence of migration with intestinal occlusion was 0.04% (1/2,349) [20] and 1.8% (2/110) [25]. Only 1 literature reported the prevalence of esophagitis was 14.0% (329/2,349) [20].

In addition, there are 6 articles reporting 9 cases of serious adverse events after aIGB (Table 3) [29–34]. Out of these, 8 (88.9%) were female, the mean age of the patients was 41.9 (24–62) years, and the mean inserting time was 6.75 (0.25–12) months. Out of 9 patients, 3 (33.3%) presented with perforation, 2 (22.2%) had

Fig. 3. Forest plots showing the safety of aIGB. **a** Pooled occurrence rate of intolerance and early removal within 3 months. **b** Pooled prevalence of stomach ulcer.

balloon hyperinflation, and the remaining 4 cases reported small bowel obstruction [29], gastric outlet obstruction [30], pancreatitis [32, 33], and tear of gastric wall separately [34]. In terms of treatment, 3 underwent laparotomy [29, 34], 2 underwent laparoscopic repair of gastric perforation [33], 2 removed the balloon [30, 32], 1 refilled the balloon [31], and 1 substituted with another balloon [31]. 88.9% (8/9) of patients recovered after treatment and even succeeded in losing weight. Only one 45-year-old female had an urgent laparotomy for a huge tear of the greater curvature of the stomach, but unfortunately passed away intraoperatively despite all resuscitative measures [34].

Publication Bias, Sensitivity Analysis, and Subgroup Analysis

Publication bias was assessed for all 6 outcomes by Egger's test. All 6 egger's tests were not significant ($p > 0.05$), showing that there was no obvious publication bias detected for these outcome measures (online suppl. Fig. 2). There was significant heterogeneity present in TWL outcomes and most single rate outcomes. We investigated the influence of a single study on the overall percentage of TWL, remission rate after downward adjustment, and the rate of early removal by omitting 1 study at a time. The omission of any one study showed no clinically significant difference in the results, indicating that the results were statistically reliable (online suppl. Fig. 3). However, after omitting the study of Badurdeen et al. [18], the heterogeneity of TWL decreased to 67.3%, and the heterogeneity of this study may stem from its unique gender ratio as it is the only study involved in which more men than women participated. After omitting the study of Usuy and Brooks [24], the heterogeneity of TWL decreased to 33.7%, but the result (87.9%) was still stable.

Multiple preplanned subgroup analyses were performed to assess the stability of these findings and identify potential sources of heterogeneity. Study setting, age, sample, and study type did not explain study heterogeneity (online suppl. Fig. 4). There was only 1 study that had a significant difference in baseline BMI from the other ones [18]; when omitting this study, the result was still statistically reliable.

Conclusion

This meta-analysis included 12 studies with a total of 4,981 patients. The results demonstrate that aIGB therapy is capable of achieving significant weight loss. The average insertion time was 9.9 months, with a pooled mean total weight loss (TWL) of 16.4%. Adjusting the balloon volume during treatment effectively managed both intolerance and weight loss plateaus.

Specifically, 34.2% of patients opted for upward balloon adjustments, reporting additional weight loss with a mean of 6.3 kg. Furthermore, 9.2% of patients chose downward balloon adjustments, with 90.8% of these patients experiencing alleviation of intolerance. The incidence of early intolerance and removal within 3 months was 5.7%, and the incidence of stomach ulcers was 1.1%. No significant publication bias was detected for these outcomes.

In summary, aIGB not only demonstrates excellent overall weight loss but also significantly improves patient tolerance and weight loss outcomes through volume adjustments. These findings are statistically reliable, indicating that aIGB is an effective weight loss and management strategy.

Discussion

Despite a three-decade history and various iterations of intragastric balloons (IGBs), their broad-based adoption as a remedy for the burgeoning obesity epidemic has been significantly hindered by two critical issues: patient intolerance and weight loss plateau [14]. In response to these issues, the design of the aIGB (Spatz3) incorporates a feature allowing for control over its volume not merely at the point of implantation but continuously throughout the treatment duration. However, to achieve its adjustable functionality, the Spatz3 deviates from the completely smooth surface characteristic of conventional designs, the site for insertion of the filling valve forming a sort of "tail." Currently, the efficacy and safety of aIGB have not been well described. Therefore, we conducted the first meta-analysis and systematic review to assess this issue.

Numerous studies have demonstrated the effectiveness of IGBs in weight loss, and the current models of IGBs include Orber, Reshape Duo, Obalon, Ellipse, etc. [35, 36]. This was confirmed in a recent RCT: 45.6% of Orbera patients achieved 10% TWL [15]. For aIGBs, our pooled result found that the inserting time of aIGB was 7–12 months, and the mean TWL was 16.4%, indicating significant and sustained weight loss, and even more favorable outcomes when compared to other IGBs. Additionally, compared to other weight-loss surgery methods, aIGB also has certain advantages. A clinical study involving 227 patients showed that patients who underwent endoscopic sleeve gastrectomy had a TWL of

16.6% 1 year post-surgery [16], similar to the weight-loss effect of aIGB (TWL 16.4%) we compiled. Since aIGB does not change the anatomical structure and does not require the removal of any tissue, it is undoubtedly a better option than endoscopic sleeve gastrectomy, when the weight-loss effects are comparable, as it inflicts less damage on the patient.

Meanwhile, regarding safety, the aIGB (Spatz3) has demonstrated substantial improvements over its predecessors. Espinet-Coll et al. [28] conducted a multicentre study on Spatz2 (predecessor of Spatz3) and found that out of 225 patients, 4 serious complications, 34 gastric ulcers, 7 migration, and 1 acute pancreatitis, but the complication rate of Spatz2 was lower when compared to other IGBs. Our data also indicated a very low rate of adverse event rates: 4% of early balloon removal, and 1.22% of gastric ulcers. In comparison, studies have shown that approximately 9%–12% of patients who undergo weight-loss surgeries such as RYGB and SG experience one or more adverse events within the first 5 years after surgery [17]. Therefore, aIGB is undoubtedly a safer method for weight loss. It is worth noting that although the effectiveness and safety of aIGB have been proven, this assistance is likely to be temporary. From the data we retrieved, the longest implantation time was 12 months, and longer follow-up data are lacking. However, compared to other weight-loss surgeries, aIGB still demonstrates superior effectiveness.

The biggest advantage of aIGB is that the volume can be adjusted during the treatment period. On the one hand, many patients experienced intolerance in the early stage of inserting IGBs, such as pain, nausea, vomiting, abdominal pressure, and so on. FDA trials of Reshape Duo and Orbera IGBs reported 14 and 22% early extraction rates, respectively [37]. In this study, 9.2% of patients underwent a downward balloon adjustment, resulting in 87.79% of patients avoiding intolerance and early removal, and completing treatment. On the other hand, most of the patients had a weight loss plateau after the initial strong balloon effect and requested a second round of rapid weight loss [38]. In this study, 34.2% of patients chose to upward balloon adjustment, which led to additional weight loss in all patients, with an average loss of 6.3 kg, a maximum of 9.3 kg, and a minimum of 4.8 kg. Consequently, we believe that the aIGB is capable of effectively managing both intolerance and weight-loss plateaus, maintaining the efficacy of weight loss in the process.

AIGB also has postoperative adverse events. These adverse events mainly include perforation, obstruction, and inflammation, which are primarily related to the compression of the gastric wall by the balloon. An oversized balloon volume and improper positioning may be factors contributing to the occurrence of these adverse events [31]. In addition, overexpansion of the balloon is also a relatively common adverse event. Overexpansion occurs when, for some reason, the internal pressure of the balloon exceeds the set upper limit and compresses the surrounding tissue. The two reported cases of balloon overexpansion associated with aIGB were both caused by bacterial contamination [31], which suggests that clinicians need to ensure strict aseptic techniques when implanting aIGB and adjusting the balloon's capacity. Early diagnosis and timely intervention are relatively effective methods to prevent the occurrence of malignant complications. When patients experience unexplained abdominal pain, bloating, nausea, vomiting, and other symptoms after the implantation of an aIGB, it is important to promptly check the status of the balloon and consider reducing the balloon's volume or even removing the balloon [29].

Our study has several limitations. First, the sample size was relatively small and the number of RCTs reporting TWL was insufficient. Second, substantial heterogeneity based on I^2 statistics was present in many outcomes. This may be due to differences in baseline patient characteristics and treatment regimens in some of the included studies. Third, the long-term effects are still unclear as only a few studies reported results at inserting 12 months. Fourthly, although we have conducted thorough and comprehensive searches and provided the most extensive summary to date, our research still has room for improvement in studying complications due to limited data. Some situations, such as compliance with treatment recommendations, medication use, medical history, and family history, were not included in the data we found. According to related research, the occurrence of complications could also be influenced by adherence to management recommendations, general health status of patients, and genetic factors [38, 39]. We look forward to more abundant data in the future to address these gaps.

In summary, this meta-analysis demonstrated that aIGB is a reasonably safe and effective device and could become a practical tool for weight loss. However, given its potentially serious complications, we also need to keep an eye on the patient's condition. Nevertheless, the limited quality of the available literature leads to several constraints discussed above. To more comprehensively evaluate its effectiveness compared to other IGBs, further prospective studies, ideally RCTs, are warranted.

Statement of Ethics

An ethics statement is not applicable because this study is based exclusively on published literature.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

This study is funded by the National Natural Science Foundation of China (8236030102, Daoming Liang), Joint Special Fund of Applied Fundamental Research of Kunming Medical University granted by Science and Technology Office of Yunnan (202301AY070001-025, Daoming Liang) (202401AY070001-363, Chuqi Xia), and Yunnan Revitalization Talent Support Program (XDYC-MY-2022-0100, Daoming Liang).

Author Contributions

Chuqi Xia, Yinuo Wang, and Guowu Sun contributed equally to this study and performed analysis and interpretation of the data. Yinuo Wang and Guowu Sun contributed to the drafting of the article. Chuqi Xia, Wanyang Lei, and Daoming Liang contributed to the conception, design, and critical revision of the article for important intellectual content. All authors gave final approval of the article.

Data Availability Statement

All data generated or analyzed during this study are included in this article and its supplementary material files. Further inquiries can be directed to the corresponding author.

References

1 Perdomo CM, Cohen RV, Sumithran P, Clément K, Frühbeck G. Contemporary medical, device, and surgical therapies for obesity in adults. Lancet. 2023;401(10382):1116–30. https://doi.org/10.1016/S0140-6736(22)02403-5
2 Heymsfield SB, Wadden TA. Mechanisms, pathophysiology, and management of obesity. N Engl J Med. 2017;376(3):254–66. https://doi.org/10.1056/NEJMra1514009
3 Popov VB, Ou A, Schulman AR, Thompson CC. The impact of intragastric balloons on obesity-related Co-morbidities: a systematic review and meta-analysis. Am J Gastroenterol. 2017;112(3):429–39. https://doi.org/10.1038/ajg.2016.530
4 Wei Y, Li P, Zhang S. From surgery to endoscopy: the evolution of the bariatric discipline. Chin Med J Engl. 2022;135(20):2427–35. https://doi.org/10.1097/CM9.0000000000002409
5 Crossan K, Sheer AJ. Intragastric Balloon', in StatPearls (Treasure Island (FL) ineligible companies. Disclosure: amy Sheer declares no relevant financial relationships with ineligible companies: StatPearls publishing copyright © 2023, StatPearls Publishing LLC; 2023.
6 Imaz I, Martínez-Cervell C, García-Alvarez EE, Sendra-Gutiérrez JM, González-Enríquez J. Safety and effectiveness of the intragastric balloon for obesity. A meta-analysis. Obes Surg. 2008;18(7):841–6. https://doi.org/10.1007/s11695-007-9331-8
7 Silva LB, Neto MG. Intragastric balloon. Minim Invasive Ther Allied Technol. 2022;31(4):505–14. https://doi.org/10.1080/13645706.2021.1874420
8 Ribeiro da Silva J, Proença L, Rodrigues A, Pinho R, Ponte A, Rodrigues J, et al. Intragastric balloon for obesity treatment: safety, tolerance, and efficacy. GE Port J Gastroenterol. 2018;25(5):236–42. https://doi.org/10.1159/000485428
9 Fernandes M, Atallah AN, Soares BG, Humberto S, Guimarães S, Matos D, et al. Intragastric balloon for obesity. Cochrane Database Syst Rev. 2007;2007(1):Cd004931. https://doi.org/10.1002/14651858.CD004931.pub2
10 Popov V, Storm AC. Toward a better understanding of endoscopic bariatric therapies. Clin Gastroenterol Hepatol. 2023;21(6):1422–6. https://doi.org/10.1016/j.cgh.2023.01.043
11 Abu Dayyeh BK, Maselli DB, Rapaka B, Lavin T, Noar M, Hussan H, et al. Adjustable intragastric balloon for treatment of obesity: a multicentre, open-label, randomised clinical trial. Lancet. 2021;398(10315):1965–73. https://doi.org/10.1016/S0140-6736(21)02394-1
12 Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis of Observational Studies in Epidemiology (MOOSE) group. JAMA. 2000;283(15):2008–12. https://doi.org/10.1001/jama.283.15.2008
13 Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ. 2021;372:n71. https://doi.org/10.1136/bmj.n71
14 Stang A. Critical evaluation of the Newcastle-Ottawa scale for the assessment of the quality of nonrandomized studies in meta-analyses. Eur J Epidemiol. 2010;25(9):603–5. https://doi.org/10.1007/s10654-010-9491-z.
15 Hoaglin DC. Misunderstandings about Q and "Cochran's Q test" in meta-analysis. Stat Med. 2016;35(4):485–95. https://doi.org/10.1002/sim.6632
16 Abeid M, Zaitoun N. SPATZ3 adjustable balloon: safety and efficacy in the management of obesity. Gastrointest Endosc. 2023;97(6):AB41. https://doi.org/10.1016/j.gie.2023.04.104
17 Abu Dayyeh BK, Maselli DB, Rapaka B, Lavin T, Noar M, Hussan H, et al. Adjustable intragastric balloon for treatment of obesity: a multicentre, open-label, randomised clinical trial. Lancet. 2021;398(10315):1965–73. https://doi.org/10.1016/S0140-6736(21)02394-1
18 Badurdeen D, Hoff AC, Barrichello S, Hedjoudje A, Itani MI, Farha J, et al. Efficacy of liraglutide to prevent weight regain after retrieval of an adjustable intra-gastric balloon—a case-matched study. Obes Surg. 2021;31(3):1204–13. https://doi.org/10.1007/s11695-020-05117-8
19 Brooks J. Mo1017 adjustable intragastric balloon experience in 967 patients in a private clinic. Gastrointest Endosc. 2019;89(6):AB410. https://doi.org/10.1016/j.gie.2019.03.626
20 Espinet Coll E, Del Pozo García AJ, Turró Arau R, Nebreda Durán J, Cortés Rizo X, Serrano Jiménez A, et al. Spanish Intragastric Balloon Consensus Statement (SIBC): practical guidelines based on experience of over 20 000 cases. Revista Espanola de Enfermedades Digestivas. 2023;115(1):22–34. https://doi.org/10.17235/reed.2022.9322/2022
21 Fittipaldi-Fernandez RJ, Zotarelli-Filho IJ, Diestel CF, Klein MRST, de Santana MF, de Lima JHF, et al. Randomized prospective clinical study of Spatz3® adjustable intragastric balloon treatment with a control group: a large-scale Brazilian experiment. Obes Surg. 2021;31(2):787–96. https://doi.org/10.1007/s11695-020-05014-0
22 Machytka E, Divi VP, Saenger F, Sorio R, Brooks J. Mo1296a adjustable balloons for weight loss: a higher yield of responders compared with non-adjustable balloons. Gastrointest Endosc. 2017;85(5):AB495. https://doi.org/10.1016/j.gie.2017.03.1146

23 Schwaab ML, Usuy EN Jr, Albuquerque MM, Moreira DM, Derossi VO, Usuy RT. Assessment of weight loss after non-adjustable and adjustable intragastric balloon use. Arq Gastroenterol. 2020;57(1):13–8. https://doi.org/10.1590/S0004-2803.202000000-04
24 Usuy E, Brooks J. Response rates with the Spatz3 adjustable balloon. Obes Surg. 2018;28(5):1271–6. https://doi.org/10.1007/s11695-017-2994-x
25 Uyak D. Tu1913 clinical study of a new/an adjustable intragastric-balloon (SPATZ 3) with 110 patients(medical one hamburg/germany). Gastrointest Endosc. 2018;87(6):AB608. https://doi.org/10.1016/j.gie.2018.04.2308
26 Vašura A, Machytka E, Puig-Divi V, Saenger F, Sorio R, Bužga M, et al. Adjustable gastric balloons for weight loss – a higher yield of responders compared to non-adjustable gastric balloons. Gastroenterol Hepatol. 2020;74(6):513–9. https://doi.org/10.48095/ccgh2020513
27 Nucci GD, Simeth C, Reati R, Mandelli ED. Spatz 3 adjustable balloon system: feasibility, efficacy and safety issues of A dual center experience. Endoscopy. 2021;53(S 01):S143–4.
28 Espinet Coll E, Nebreda Durán J, López-Nava Breviere G, Ducóns García J, Rodríguez-Téllez M, Crespo García J, et al. Multicenter study on the safety of bariatric endoscopy. Rev Esp Enferm Dig. 2017;109(5):350–7. https://doi.org/10.17235/reed.2017.4499/2016
29 Tan MY, Fok KY, Nguyen H, Edirimanne S, Devadas M. Small bowel obstruction due to migrated intragastric balloon: a case report and literature review. Case Rep Surg. 2022;2022:1440441. https://doi.org/10.1155/2022/1440441
30 Xie J, Patel M, Aquilina G, Kaspar M. S2919 A novel case of gastric outlet obstruction from Spatz 3 adjustable intragastric balloon. Am J Gastroenterol. 2021;116(1):S1209. https://doi.org/10.14309/01.ajg.0000785208.56590.8f
31 Usuy E, Silva M, Dos Passos Galvão Neto M, Grecco E, Ferreira de Souza T, de Quadros LG. Antibiotics to prevent relapse of adjustable gastric balloon hyperinflation: feasible for balloon maintenance? GE Port J Gastroenterol. 2020;28(1):52–5. https://doi.org/10.1159/000507226
32 Alqabandi O, Almutawa Y, AlTarrah D, Alhajeri M, Jamal MH, Almazeedi S. Intragastric balloon insertion and pancreatitis: case series. Int J Surg Case Rep. 2020;74:263–7. https://doi.org/10.1016/j.ijscr.2020.08.043
33 Barrichello SA, Ribeiro IB, Martins RK, Fittipaldi-Fernandez RJ, Hoff AC, de Moraes MV, et al. Sa2001 gastric perforation following intragastric balloon insertion treated by endoscopic clipping: a case series. Gastrointest Endosc. 2019;89(6):AB279–80. https://doi.org/10.1016/j.gie.2019.03.332
34 Daniel F, Abou Fadel C, Houmani Z, Salti N. Spatz 3 adjustable intragastric balloon: long-term safety concerns. Obes Surg. 2016;26(1):159–60. https://doi.org/10.1007/s11695-015-1897-y
35 Abu Dayyeh BK, Kumar N, Edmundowicz SA, Jonnalagadda S, Larsen M, Sullivan S, et al. ASGE bariatric endoscopy task force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies. Gastrointest Endosc. 2015;82(3):425–38.e5. https://doi.org/10.1016/j.gie.2015.03.1964
36 Courcoulas A, Abu Dayyeh BK, Eaton L, Robinson J, Woodman G, Fusco M, et al. Intragastric balloon as an adjunct to lifestyle intervention: a randomized controlled trial. Int J Obes. 2017;41(3):427–33. https://doi.org/10.1038/ijo.2016.229
37 FDA SSED Orbera Balloon. PMA P140008: FDA summary ofsafety and effectiveness data; 2015.
38 Foula MS, Amer NM, Zakaria H, Ismail MH, Alshomimi SJ, Al Bisher HM, et al. Surgical management of intra-gastric balloon complications, single-center experience, and literature review. Obes Surg. 2023;33(9):2718–24. https://doi.org/10.1007/s11695-023-06716-x
39 Mehta A, Shah S, Dawod E, Hajifathalian K, Kumar R, Igel LI, et al. Impact of adjunctive pharmacotherapy with intragastric balloons for the treatment of obesity. Am Surg. 2023;89(4):707–13. https://doi.org/10.1177/00031348211038579