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METHODOLOGY

Prospective, Multicenter Clinical Trial to Evaluate the Safety of the Stella® Intragastric Balloon at 7 Months and the Balloon Delivery System

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Abstract

Background The intragastric balloon (IGB) is a well-established treatment for obesity. However, several models have been developed to optimize outcomes and procedural efficiency.

The Stella®-IGB is a novel, double-lumen device, designed for guidewire-assisted placement to improve procedural safety and patient comfort.

Methods This is a prospective, multicenter, longitudinal, non-randomized study aimed to demonstrate the safety and feasibility of the Stella®-IGB system. Balloon insertion, delivery system, 6-month permanence integrity, 7-month adverse events (AEs) according to Clavien-Dindo AGREE classification, intolerance rate, weight loss and metabolic improvement were investigated.

Results Sixty-nine patients (72.46% females), median age of 42.0 years (IQR 34, 52) and BMI of 33.5 kg/m^2 (IQR 31.0, 36.1) were included.

Adequate balloon insertion and 6-month good integrity permanence were obtained in 66/69 (95.65%). Three dysfunction cases were observed: one technical deploy difficulty (twisting of the feeding catheter), one device rupture due to extensive fungal colonization of the balloon and one partially deflated balloon. None presented clinical or endoscopic sequelae.

The median balloon insertion time was 4.23 s (IQR 3.04, 5.0), with a first attempt rate of 97.1%. Balloon intolerance was detected in 5.8% of patients. At 6-month follow-up the mean %TWL was 15.39% (95%CI 13.77, 17.00%), with significant metabolic improvement.

Globally, 211 grade I–II minor AEs were reported, with no serious AEs (95%CI 0.98, 1).

Conclusion Stella®-IGB uses a double-lumen probe and a guidewire for a more comfortable and safe placement procedure. No serious AEs were observed. Stella®-IGB could expand current indications to IGB placement for endoscopists-in-training and in case of pharyngo-esophageal anatomical alterations.

Clinical Trial Number NCT06744829.

Keywords Intragastric balloon · Safety · Efficacy · Double-lumen · Obesity

Key points Stella® is a novel, double-lumen IGB designed for guidewire-assisted placement.

Guidewire improves the safety, speed and comfort of placement.

Safe device with no serious AEs.

Expands IGB current indications to in-training and to some anatomical alterations.

Abbreviations

IGB	Intragastric balloon
AE	Adverse event
TWL	Total weight loss
EWL	Excess weight loss
BMIL	Body mass index loss
GERD	Gastroesophageal reflux disease
PPI	Proton pump inhibitors
T2DM	Type 2 diabetes mellitus

Extended author information available on the last page of the article

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Introduction

Since the FDA approved the first intragastric balloon (IGB) in 1985, different IGB concepts, designs and models have emerged [1, 2]. Once numerous efficacy and safety studies have been published, IGB has been shown to be a well-established therapeutic tool for obesity treatment [3, 4]. As an endoscopic approach, it should be positioned between clinical and surgical management [5–8].

Main IGB differences are dwell-time, material, volume and filling characteristics, adjustment's possibility, the number of implanted balloons and even their swallowable implantation.

We present this study to evaluate the new Stella®-IGB (SwanMedical S.L., Barcelona, Spain). It consists of a spherical, silicone, liquid-filled 6-month balloon. As a peculiarity and novelty, it is the first IGB to have a double-lumen in the introducer system. One lumen is intended for the passage of a guidewire, designed to improve the safety, easily and quickly balloon placement, which also requires a previous gastroscopy. The other lumen allows for regular filling (Fig. 1) [9]. Main technical-endoscopic aspects and efficacy results are also evaluated.

Patients and Methods

This is a prospective, multicenter, longitudinal, non-randomized study designed to demonstrate the reliability and safety of the new Stella®-IGB system: insertion, delivery system, 6-month dwelling-time safety and feasibility in a 7-month follow-up are the main analyzed parameters.

Device and Implantation Description

The Stella® introducer system (Fig. 1) consists of a deflated IGB folded on itself inside two silicone covers joined to a polyvinyl-chloride tube: a transporter and a feed channel, 4 × 8 mm outer oval diameter.

A gastroscopy is performed, leaving a guidewire in the duodenum. The endoscope is then removed. The guidewire is passed through the distal end of the device, inside the transporter (or carrier tube). The transporter runs along the guidewire that ensures the balloon path and placement in the stomach. A flexible silicone blunt-end allows it to adapt and travel without injury. Once there, the endoscope is inserted to confirm its correct placement. The feed channel has a capillary tube attached to the balloon via the non-return valve. The guidewire is removed, and the balloon is filled like other models to be adjusted from 400 to 700 cc saline solution. Once the balloon is completely filled, the valve vacuum is created and the catheter is pulled away from the balloon and removed along with the endoscope.

Special Manufacturing Conditions

The device was manufactured following the ISO-14607 "*No-active surgical implants. Breast implants*" reference and was carried out in ISO-7 and ISO-8 cleanrooms. Medical grade implantable silicone was used for tips, cones, balloons and sleeves.

Biocompatibility was demonstrated with chemical characterization, toxicological evaluation, cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, pyrogens, LAL-test, intramuscular implantation, genotoxicity and in vitro genetic mutation assay in mammalian cells studies.

Adaptability was demonstrated with dimensional verification, tightness, unfolding, detachment, valve integrity and sealing, puncture, elongation, permanent tensile deformation, sutures and breaking force tests.

Mechanical tests of fatigue, impact and stomach resistance, and microbiological controls were carried out in the implantable state, as well as a 2-year aging simulation.

Clinical Investigation Plan

It started on April 1, 2022, and was completed on December 5, 2023. It was carried out in six reference Spanish hospitals, all using the same clinical protocol. All endoscopists involved had more than 10 years of IGB experience.

According to the Spanish Consensus Document [7], the following were included: patients with grade II overweight, patients with grade I–II obesity, patients with severe obesity (BMI > 40 kg/m^2) not given the surgical option and extremely obese patients prior to bariatric surgery (Suppl. Table A). All patients were of legal age, underwent prior dietitian and psychological assessment and a specific Informed Consent Document was signed. No patient met any of the exclusion criteria. A strict visit timeline was established (Suppl. Table B).

The procedures were performed with conventional single-channel gastroscopes (Olympus, Fuji or Pentax), depending on the availability of the participating centers. Balloon placement was performed with deep sedation with Propofol in all cases. Its removal was performed with deep sedation or with general anesthesia with oro-tracheal intubation, depending on the protocol and usual practice of each hospital. In all cases, sedation was administered by an anesthesiologist.

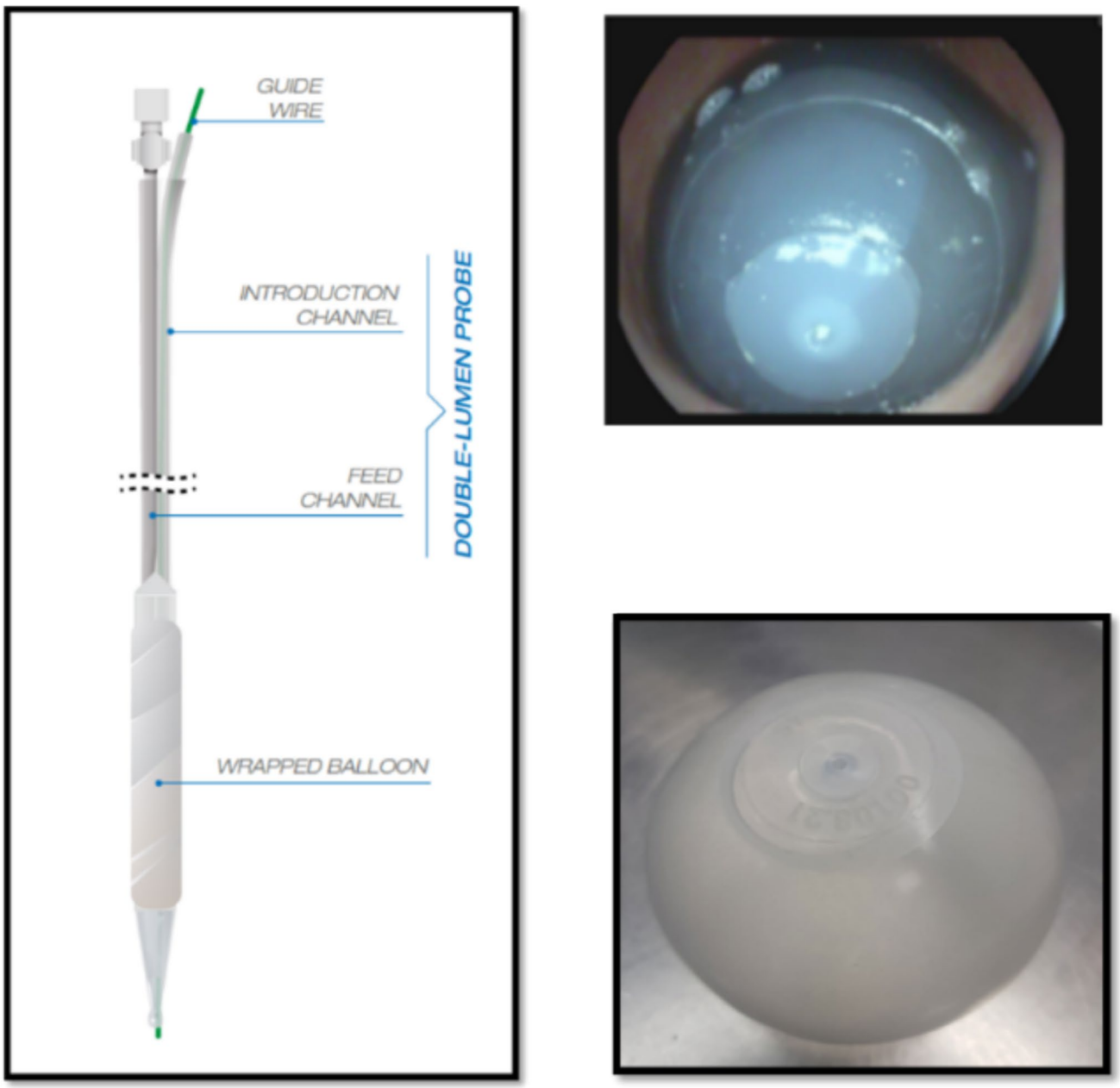

Fig. 1 Stella®-IGB introducer system and the filled balloon

Clinical Investigation Objectives

The **primary objective** was to demonstrate the reliability and safety of the balloon delivery system, the 6-months dwelling-time balloon integrity, and the safety at 7-month follow-up.

- **Uncomplicated balloon insertion**. In-duodenum positioned guidewire, balloon deployment, release and implantation, complete 500 cc filling (400–700 cc with 10 cc of methylene blue), final position and absence of leaks or balloon defects were documented.
- **6-month IGB fully filled**. Balloon structural defects, internal volume loss (deflation), colored (bluish) urine or need for urgent endoscopy were registered.
- **Safe balloon removal**. Six months after placement the balloon was removed according to usual endoscopic technique. Deflation/tension-loss, difficult balloon puncture or any incidence were documented.

- **Adverse event assessment (AEs).** All AEs detected during the 6-month balloon permanence and including 1 month after removal follow-up were recorded: (1) AE itself. (2) Severity (mild, moderate or serious). (3) Clavien-Dindo classification adapted to endoscopy (AGREE) [10]. (4) Seriousness. (5) Duration. (6) Device and implantation AE relationship (unrelated, possible, likely or causal, when the probability to be related to the event was < 10%, 10–50%, 50–90% and > 90% respectively, according to investigator criteria). (7) Resolution (full and complete recovery without sequelae or persistent AE). (8) Treatment (number of patients, drugs requirement and need for endoscopic, radiological or surgical treatment).

First week after balloon placement accommodative symptomatology (related to nausea, vomiting and abdominal pain and cramping limited to 3–7 days and systematically treated with PPIs, antiemetics and analgesics per protocol) and cases of intolerance were documented but were not considered an AE.

Clinical (heart rate, temperature, systolic and diastolic BP) and analytical (Hemoglobin, Hematocrit, Leukocytes, Platelets, Iron, Amylase, Urea, Creatinine, Chlorine, Sodium, Potassium and Calcium) safety parameters were baseline, 3 and 6 months determined.

As **secondary objectives**, the following hypotheses were proposed:

1. Speed of balloon delivery time to the stomach from Killian's mouth. We have chosen an arbitrary time of less than 10 s to consider a fast insertion.
2. Ease of balloon placement, when implanted in ≤ 3 attempts.
3. Throat discomfort after balloon insertion.
4. Intolerances (including early removal) and abdominal pain tolerability (Visual Analogue Pain Scale—VAS) were baseline and at 10 days, 3, 6 and 7 months determined [11].
5. Weight loss efficacy (%TWL, %EWL, %BMIL, % of patients with TWL > 10% and % of patients with EWL > 25%) and improvement on metabolic parameters (systolic and diastolic BP, total cholesterol, HDL, LDL, triglycerides, blood glucose, GPT, GGTP and TSH) were baseline and at 3 and 6 months determined [12].

Statistical Analysis

Sample size was based in a reliability demonstration test of the proportion of patients without AEs. Considering a true reliability of 0.975, an alpha error of 0.05, a power of 91%, a minimum reliability of 0.89 and a maximum severe AEs < 4%, a total of 69 patients were required to be included.

Continuous variables were described, depending on their distribution, using median and interquartile range, or 95% confidence intervals for the mean and counts and percentages for categorical variables. Recommended, Wilson confidence interval was calculated when proportion of events was 1.

PASS 2020 v 20.0.1 Power-Analysis and Sample-Size Software (NCSS, LLC. Kaysville, UT, USA) was used for statistical analysis and STATA 17 (StataCorp. 2021. College Station, TX: StataCorp LLC) for data management and analysis.

Results

Seventy-five patients were initially evaluated. Six were excluded (Fig. 2). Finally, 69 patients were included. Early balloon removal was performed in five cases (7.24%). Finally, we obtained complete follow-up to 7 months in 64 patients.

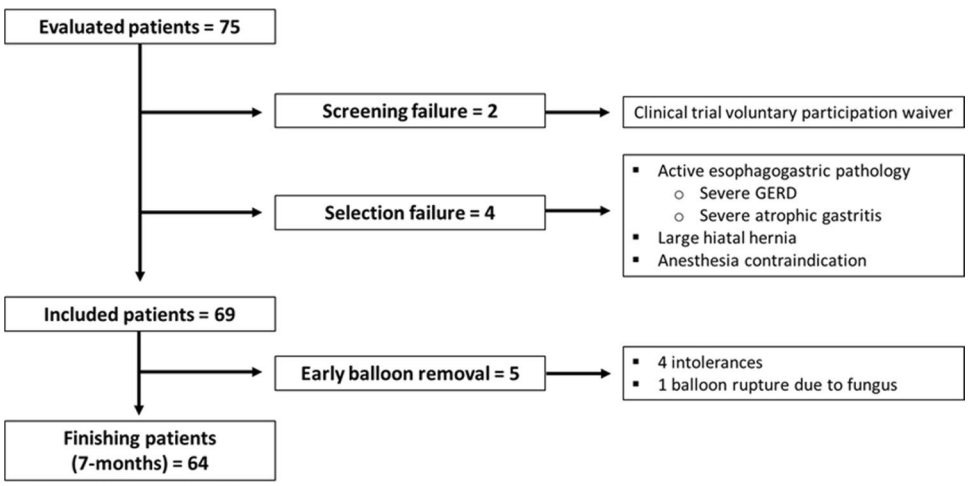

Fig. 2 CONSORT flow chart. Inclusion and exclusion criteria

At baseline time, there were 50 (72.46%) females, median age of 42.0 years (IQR 34, 52) and median BMI of 33.5 kg/m^2 (IQR 31.0, 36.1). A total of 87 obesity-associated complications were observed (Table 1).

Feasibility of the STELLA® Intragastric Balloon

Uncomplicated balloon insertion. It was possible to correctly position the guidewire, release the balloon from the introducer system, and complete a proper implantation, filling and positioning in all cases (100%). No leaks or balloon defects were seen. Only one technical deployment difficulty (1.45%) due to a forced opening manoeuvre of the balloon sheath with an involuntary twisting of the feeding catheter was observed. The balloon was immediately removed, replaced and correctly deployed by the same endoscopist.

After balloon placement, one single 5-mm cardia superficial erosion after catheter removal with self-limiting drooling blood that did not require targeted therapy was noted.

6-month IGB fully filled. Early device removal was required in five cases (7.24%): four intolerances (5.80%) at 1, 3, 3 and 5 months, and one deflation-rupture (1.45%) at 5 months. This was due to an extensive fungal colonization of the balloon reaching its inner layer *(*Fig. 3*)* and detected as the only case of bluish urine. Endoscopy and balloon removal were performed at 72 h. No esophagogastric lesions were detected and the patient remained asymptomatic.

Safe balloon removal. In 61/64 cases (95.3%) the balloon was in perfect condition and correctly positioned and filled at removal time. Two cases of balloon wall tension loss and one partial deflation (emptied) were observed, with technically difficult puncture but no associated mucosal lesions.

In the previous balloon removal endoscopy, three inflammatory lesions were observed: two GERD Los Angeles grade-B esophagitis and one atrophic gastritis. Endoscopic removal resulted in two mild mucosal lesions (2.90%): a balloon esophageal friction and an oral erosion. None required any specific treatment.

Safety of the Stella-IGB®

At 7-month follow-up, 57 patients (82.61%) had reported at least one AE, totaling 211 AEs: 137 (64.9%) were mild and 73 (34.6%) moderates. Except for one pregnancy erroneously classified as serious AE, no serious AEs were described (Wilson 95%CI: 0.98, 1). All of them corresponded to grade I ($n=187$, 88.63%) or II ($n=24$, 11.37%) Clavien-Dindo classification. Abdominal pain (59.4%), nausea and/or vomiting (52.1%), dyspepsia (30.4%), GERD (26.1%) and meteorism (21.7%), all predominantly mild and self-limited, were the most common AEs detected (Table 2).

A causal relationship rate of 16.1% and 2.8% between AE and device and AE and implantation was detected.

When the study finished, 201/211 (95.3%) AEs were completely resolved. No persistent AE was related to the device or its implant.

In addition to usual PPIs and excluding first week accommodative symptoms treatment, 37 patients (53.62%) required some occasional drug: antiemetics and prokinetics (22.9%), increased doses of PPIs (22.1%) and antispasmodics (17.8%) were the most frequently used (Suppl. Table C).

No significant variations were observed in clinical and laboratory safety parameters, even improvement in systolic and diastolic BP (Table 3).

Secondary Objectives

Balloon placement was considered: (a) Fast, with median esophageal passage time of 4.23 s (IQR 3.04, 5.0) with only one patient reported longer than 10 s (18 s), (b) Easy, introduced at first attempt in 97.1%, and no patient required ≥ 3 attempts and (c) Throat tolerance was good, with mild discomfort in 5.8% patients.

Clinical intolerance was reported in 5.8% with no balloon defects or esophagogastric lesions. Abdominal pain decreased as time progressed: 62.32%, 23.19% and 7.58% at 72 h, 10 days and 3 months. The average pain intensity was mild, drugs controlled. No patients experienced significant pain at 6- and 7-month follow-up.

Mean %TWL of 15.39% *(95%CI 13.77%, 17.00%)* and mean %EWL of 64.71% *(95%CI 56.96, 72.46),* with TWL > 10% and EWL > 25% in 83.33% and 96.88% of treated patients at 6-month follow-up were observed. Blood pressure, cholesterol, triglycerides, GPT and GGTP significative improvements were also reported *($p < 0.05$)* (Table 3).

Discussion

The Stella®-IGB uses an introducer system with a double-lumen probe and a guidewire, allowing the balloon to be inserted quickly and safely. This clinical trial demonstrates insertion, delivery, 6-month permanence, removal and 7-month follow-up feasibility and safety [9].

Balloon Insertion

Placement procedure could be correctly and safely performed in the great majority of patients. Only two incidents were described: a technical balloon deploying difficulty and a cardia Mallory-Weiss mild lesion. The first was caused by *"a forced opening manoeuvre of the balloon sheath with an involuntary twisting of the feeding catheter",* requiring IGB removal, and then replaced and filled without problem by the same endoscopist. This could be secondary to an angled or twisted catheter position, or its junction to the balloon valve.

Table 1 Demographic characteristics and baseline data

Gender: Males/Females (n, %)	19 (27.54%)/50 (72.46%)
Age (years) (IQR, median)	42.0 (34, 52)
Weight (kg) (IQR, median)	92.1 (82.7, 103.5)
BMI (kg/m2) (IQR, median)	33.5 (31.0, 36.1)
Patients with grade II overweight (BMI 27.00–29.99 kg/m2) or grade I obesity (BMI 30.00–34.99 kg/m2)	45 (65.2%)
Patients with grade II obesity (BMI 35.00–39.99 kg/m2) with ≤ 3 major associated obesity complications	22 (31.9%)
Patients with grade III–IV extreme obesity (BMI ≥ 40 kg/m2) as a bridging strategy to subsequent bariatric surgery	2 (2.9%)
Obesity complications ($n = 87$)	
Endocrine:	13 (14.9%)
Dyslipidemia	6 (6.9%)
Hypothyroidism	4 (6.9%)
T2DM	1 (1.1%)
Hyperuricemia	2 (2.3%)
Digestive:	14 (16.1%)
Small hiatus hernia	7 (8.0%)
GERD ± Short Barrett's	2 (2.3%)
Steatohepatitis	1 (1.1%)
Colon polyps	1 (1.1%)
Cholelithiasis (cholecystectomy)	1 (1.1%)
Acute pancreatitis	1 (1.1%)
Intrinsic factor deficiency (B12)	1 (1.1%)
Cardiovascular:	14 (16.1%)
HTA	14 (16.1%)
Respiratory:	16 (18.4%)
Smoking	11 (12.6%)
Bronchial asthma	4 (4.6%)
Pulmonary emphysema	1 (1.1%)
Musculoskeletal:	2 (2.3%)
Arthropathy in load-bearing joints	1 (1.1%)
Herniated disk	1 (1.1%)
Rheumatological/Neurological:	5 (5.8%)
Rheumatoid arthritis	1 (1.1%)
Fibromyalgia	1 (1.1%)
Sjögren's syndrome	1 (1.1%)
Psoriasis	1 (1.1%)
Multiple sclerosis	1 (1.1%)
Gynecological:	10 (11.5%)
Gynecological surgeries	5 (5.7%)
PCOS	1 (1.1%)
Premature menopause	3 (3.5%)
Endometriosis	1 (1.1%)
Psychiatric:	9 (10.3%)
Anxious-depressive syndrome	7 (7.8%)
Attention deficit/hyperactivity disorder	1 (1.1%)
Consumption of intoxicants	1 (1.1%)
Allergic:	4 (4.6%)
Food allergies	2 (2.3%)
Penicillin allergy	1 (1.1%)
Allergic rhinopharyngitis	1 (1.1%)

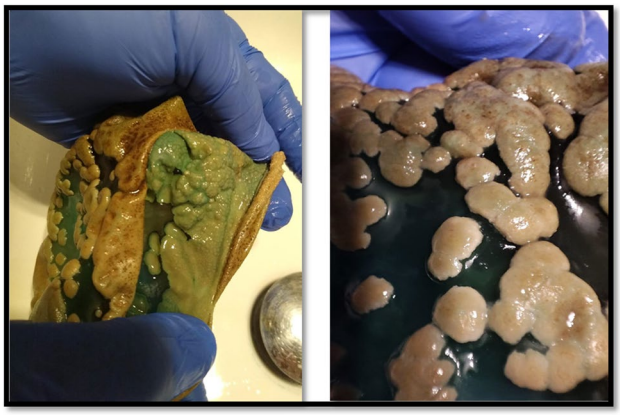

Fig. 3 A severe fungal colonization reaching the balloon inner layer

So, it is recommended to maintain a straight catheter position, avoiding angulations that could promote filling fluid reflux, valve leakage or early catheter dislodgement [1, 2]. The second was related to the catheter traction manoeuvre to dislodge from the balloon valve. This can be avoided by placing the end of the endoscope in the cardia [13, 14].

Balloon Removal

Only one significant internal volume loss and partially deflated balloon was observed. A laborious puncture with two extraction attempts were required. Depending on IGB model it is described in up to 6% [15, 16]. Valve or silicone-pores chronic microscopic leakage should be considered, since no bluish urine was observed.

Two mild esophageal mucosal lesions were caused by the balloon passage, a frequent occurrence described [17].

IGB Permanence

Five patients (7.2%) required early device removal; lower than 18.8% FDA-PMA 6-month Orbera® balloon (reference balloon) describes [18]:

- Clinical intolerance in four cases (5.8%), a similar rate to other large series (2–10%) [1, 2, 6, 13, 15, 16, 19].
- One case (1.4%) of device rupture and extensive fungal colonization of the balloon was presented, confirmed visually and via culture. Spontaneous balloon hyperinflation and risk of rupture are widely described (5.8% and 0.9%) [1, 20, 21], usually by overgrowth of Candida-sp and detected by blue urine. High doses of PPIs are another potential contributing factor [20, 21]. When hyperinflation remains asymptomatic, no treatment is required. But when it causes symptoms, medical treatment and balloon removal are required [1]. As is our case, an early endoscopic removal within 72 h must be done. If delayed, bowel migration (1.4%) [6] even leads to small bowel obstruction (0–4%) [1, 2, 6, 13] can occur. No esophagogastric lesions were detected, and the patient remained asymptomatic. For this reason, the need for antifungal treatment was not considered.

Adverse Effects (AEs)

According to most international consensus, IGB should be considered a safe procedure, with a maximum serious complications rate < 5% (ideally < 1%), as in our study (0.0%), surgical requirements < 0.1% (0.0% in our study) and a mortality close to 0% (0.0% in our cohort) [5–8]. These results confirm the Stella®-balloon is within safety standards.

Severe AEs rate is variable and depends on experience and balloon model [1, 2, 5, 6, 13, 14, 19]. ASGE Bariatric Endoscopy Task Force [6, 19] concluded a 1.4% migration, 0.3% bowel obstruction, 0.1% perforation and 0.08% mortality. Up to 10% of severe AEs were seen with 6-month Orbera®-balloon [18]. According to three scales (Severity, Clavien-Dindo and Seriousness) [10], no case of severe AE occurred in our series.

A mean of 3.0 mild-moderate AEs/patient was described in our study, lower than 5.0 AEs/patient described in the FDA-PMA approval 6-month Orbera®-balloon [18]. At 7-month follow-up, 95.3% of AEs were totally resolved in a conservative way. None required endoscopic, radiological or surgical treatment. Only ten persistent AEs were detected, none was serious nor IGB related.

An individualized very narrow window visits period was prospectively designed. A thorough detection and reporting of any AEs present was ensured. This is why no serious AEs may have been missed.

Secondary Objectives

Balloon placement was fast, easy and safe, also related to extensive endoscopists experience. Future studies should estimate the complete sedation and endoscopy time, not only through-the-esophagus passage time. There are no studies describing IBG placement time and throat discomfort. In any case, our incidence was low and probably comparable to conventional gastroscopy. Patient's pain proportion decreased over time. Mean pain intensity measured with VAS-scale was mild and could be controlled with standard painkillers. After 3 months, no patient had significant pain, supporting the good device tolerability.

As effectiveness, IGB requires a mean %TWL > 10%, a mean %EWL > 25% and a TWL > 10% or EWL > 25% in more than 75% of treated patients [5–8]. All these values were obtained. No GLP-1 analogs were used. The 15.39% TWL in our series is higher than most FDA-approval balloons obtained [4]. We also obtained significative

Table 2 Description of adverse events (AEs)

Event	Percent *% over 211 AEs*	Percent *% out of 69 patients*	Severity *Mild* *Moderate* *Serious*	Seriousness *No* *Yes*	Clavien-Dindo *I to V*	Device Relation *Unrelated* *Possible* *Likely* *Causal*	Implant Relation *Unrelated* *Possible* *Likely* *Causal*	Resolution *Complete* *Persisting*
Abdominal pain ($n=41$)	**19.41%**	**59.4%**	**Mi = 19** **Mo = 22** **S = 0**	**No = 41** **Yes = 0**	**I = 41** **II = 0** **III = 0** **IV = 0** **V = 0**	**U = 2** **P = 10** **L = 18** **C = 11**	**U = 9** **P = 23** **L = 7** **C = 2**	**C = 41** **P = 0**
Nausea and/or vomiting ($n=36$)	**17.0%**	**52.1%**	**Mi = 25** **Mo = 11** **S = 0**	**No = 36** **Yes = 0**	**I = 36** **II = 0** **III = 0** **IV = 0** **V = 0**	**U = 1** **P = 6** **L = 15** **C = 14**	**U = 15** **P = 12** **L = 7** **C = 2**	**C = 36** **P = 0**
Dyspepsia ($n=21$)	**9.9%**	**30.4%**	**Mi = 15** **Mo = 6** **S = 0**	**No = 21** **Yes = 0**	**I = 21** **II = 0** **III = 0** **IV = 0** **V = 0**	**U = 2** **P = 4** **L = 10** **C = 5**	**U = 5** **P = 13** **L = 3** **C = 0**	**C = 21** **P = 0**
GERD ($n=18$)	**8.5%**	**26.1%**	**Mi = 12** **Mo = 6** **S = 0**	**No = 18** **Yes = 0**	**I = 17** **II = 1** **III = 0** **IV = 0** **V = 0**	**U = 0** **P = 7** **L = 10** **C = 1**	**U = 6** **P = 9** **L = 2** **C = 1**	**C = 18** **P = 0**
Meteorism ($n=15$)	**7.1%**	**21.7%**	**Mi = 11** **Mo = 4** **S = 0**	**No = 15** **Yes = 0**	**I = 15** **II = 0** **III = 0** **IV = 0** **V = 0**	**U = 4** **P = 7** **L = 3** **C = 1**	**U = 11** **P = 4** **L = 0** **C = 0**	**C = 15** **P = 0**
Constipation ($n=12$)	**5.7%**	**17.4%**	**Mi = 9 Mo = 3** **S = 0**	**No = 12** **Yes = 0**	**I = 12** **II = 0** **III = 0** **IV = 0** **V = 0**	**U = 0** **P = 10** **L = 2** **C = 0**	**U = 6** **P = 5** **L = 1** **C = 0**	**C = 12** **P = 0**
Aerophagia ($n=10$)	**4.7%**	**14.5%**	**Mi = 9** **Mo = 1** **S = 0**	**No = 10** **Yes = 0**	**I = 10** **II = 0** **III = 0** **IV = 0** **V = 0**	**U = 0** **P = 2** **L = 8** **C = 0**	**U = 6** **P = 3** **L = 1** **C = 0**	**C = 10** **P = 0**
Diarrhea ($n=9$)	**4.3%**	**13.0%**	**Mi = 6** **Mo = 3** **S = 0**	**No = 9** **Yes = 0**	**I = 9** **II = 0** **III = 0** **IV = 0** **V = 0**	**U = 5** **P = 4** **L = 0** **C = 0**	**U = 7** **P = 2** **L = 0** **C = 0**	**C = 9** **P = 0**
Oropharyngeal pain ($n=6$)	**2.8%**	**8.7%**	**Mi = 5** **Mo = 1** **S = 0**	**No = 6** **Yes = 0**	**I = 6** **II = 0** **III = 0** **IV = 0** **V = 0**	**U = 5** **P = 1** **L = 0** **C = 0**	**U = 1** **P = 1** **L = 3** **C = 1**	**C = 6** **P = 0**
Anxiety ($n=6$)	**2.8%**	**8.7%**	**Mi = 2** **Mo = 4** **S = 0**	**No = 6** **Yes = 0**	**I = 0** **II = 6** **III = 0** **IV = 0** **V = 0**	**U = 6** **P = 0** **L = 0** **C = 0**	**U = 6** **P = 0** **L = 0** **C = 0**	**C = 3** **P = 3**

Table 2 (continued)

Event	Percent *% over 211 AEs*	Percent *% out of 69 patients*	Severity *Mild* *Moderate* *Serious*	Seriousness *No* *Yes*	Clavien-Dindo *I to V*	Device Relation *Unrelated* *Possible* *Likely* *Causal*	Implant Relation *Unrelated* *Possible* *Likely* *Causal*	Resolution *Complete* *Persisting*
Vitamin deficiency ($n=5$)	**2.4%**	**7.2%**	**Mi = 4** **Mo = 1** **S = 0**	**No = 5** **Yes = 0**	**I = 0** **II = 5** **III = 0** **IV = 0** **V = 0**	**U = 5** **P = 0** **L = 0** **C = 0**	**U = 5** **P = 0** **L = 0** **C = 0**	**C = 1** **P = 4**
Dehydration ($n=5$)	**2.4%**	**7.2%**	**Mi = 2** **Mo = 3** **S = 0**	**No = 5** **Yes = 0**	**I = 1** **II = 4** **III = 0** **IV = 0** **V = 0**	**U = 0** **P = 0** **L = 5** **C = 0**	**U = 0** **P = 3** **L = 2** **C = 0**	**C = 5** **P = 0**
Other ($n=27$)	**12.9%**	**38.7%**	**Mi = 18** **Mo = 8**[1] **S = 1**[2]	**No = 27** **Yes = 0**	**I = 19** **II = 8**[3] **III = 0** **IV = 0** **V = 0**	**U = 21** **P = 4**[4] **L = 0** **C = 2**[5]	**U = 24** **P = 3**[6] **L = 0** **C = 0**	**C = 24** **P = 3**[7]
Total ($n=211$)	**100.0%**		**Mi = 137** **Mo = 73** **S = 1**[2]	**No = 211** **Yes = 0**	**I = 187** **II = 24** **III = 0** **IV = 0** **V = 0**	**U = 51** **P = 55** **L = 71** **C = 34**	**U = 101** **P = 78** **L = 26** **C = 6**	**C = 201** **P = 10**

[1]Musculoskeletal pain (two cases), headache, syncope, biliary colic, renal colic, abortion, acute gastroenteritis

[2]Pregnancy

[3]Allergic reaction, syncope (two cases), urinary tract infection (two cases), biliary colic, abortion, omalgia

[4]Musculoskeletal pain, headache (two cases), asthenia

[5]Asthenia, syncope

[6]Headache, asthenia, syncope

[7]Pregnancy, rhinopharyngitis, hepatic steatosis

improvements *($p < 0.05$)* in most clinical and analytical metabolic syndrome parameters, like blood pressure, cholesterol, triglycerides, GPT and GGTP (Table 3).

Limitations

The study minimizes heterogeneity in terms of complications and AEs since its prospective nature strictly controls with only minor deviations and no dropped-out patients. In addition, permanent emergency department in all centers involved were requested, which ensured that all major adverse effects could be documented. Power analysis is provided for safety demonstration, but only descriptive analysis is provided for secondary endpoints.

As in the development of any new device, in this study all investigators and centers had extensive IGB experience and used a thorough protocol adherence, which could minimize technical complications and their evolution from mild to severe AEs. First week gastric accommodation symptoms and intolerances were not AE considered. Three patients were detected using GLP-1 for less than 1 week in mid-study (Table C), with no incidence in the safety study and minimal impact on weight loss efficacy results.

A standardized guidewire should be defined as well as balloon placement feasibility without the guide. Patients with esophageal disorders should be specifically considered. The "balloon insertion time" refers only to the passage of the balloon from mouth to stomach, not the total balloon insertion/procedure time, that should be analyzed in future studies. A 12-month balloon extending durability should be valued. Also, there is a possibility of including an x-ray radiopaque marker on the balloon. Microscopic balloon characteristics (silicone) prior placement and after removal could be analyzed. However, longer studies with larger numbers of patients should be carried out, mainly in morbid obese patients.

In conclusion, Stella®-IGB can be considered a safe device, with a low rate of minor AEs and no serious AEs reported. Balloon insertion technique seems straightforward, in a short time and in a single attempt, with little

Table 3 Clinical and analytical safety and efficacy parameters

	Baseline	3 months	6 months
Clinical parameters			
Heart rate (x')	74	75	72
Temperature (°C)	36.3	36.1	36.2
Systolic BP (mmHg)	126	118	116*
Diastolic BP (mmHg)	83	78	76*
Analytical parameters			
Hematocrit (%)	41.7	40.9	41.8
Hemoglobin (g/dL)	14.0	13.6	13.9
Leukocytes (103/µL)	6.9	7.2	6.6
Platelets (103/µL)	265	269	267
Iron (µg/dL)	93.6	87.7	91.0
Amylase (U/L)	57.9	65.1	55.9
Urea (mg/dL)	30.7	29.1	25.6
Creatinine (mg/dL)	0.77	0.76	0.78
Chlorine (mg/dL)	104.3	102.9	103.5
Sodium (mmol/L)	138.8	139.3	139.1
Potassium (mmol/L)	4.55	4.46	4.40
Calcium (mg/dL)	9.43	9.60	9.37
GPT (U/L)	29.3	26.8	20.1*
GGTP (U/L)	34.0	26.7	22.2*
Blood glucosa (mg/dL)	86.6	85.7	80.1
Cholesterol (mg/dL)	198.4	177.4	188.1*
HDL (mg/dL)	53.4	49.8	53.3
LDL (mg/dL)	122.8	108.2	116.4
Triglycerides (mg/dL)	118.6	104.0	91.8*
TSH (mIU/mL)	1.87	1.77	1.63
Weight loss parameters			
Weight (kg), median (IQR) BMI (kg/m2), median (IQR)	92.1 kg (82.7, 103.5) 33.5 kg/m2 (31.0, 36.1)		
%TWL (%), mean (95% CI)		11.32% (10.11, 12.55)	15.39% (13.77, 17.00)
%EWL (%), mean (95% CI)		47.03% (41.20, 52.86)	64.71% (56.96, 72.46)
%BMIL (%), mean (95% CI)		11.29% (10.07, 12.50)	15.46% (13.84, 17.09)
BMIL (kg/m2)		3.75 kg/m2	5.25 kg/m2
% of patients with TWL > 10% (%)		62.12%	83.33%
% of patients with EWL > 25% (%)		87.87%	96.88%
% of patients with BMI < 30 kg/m2 (%)		48.48%	64.06%
% of patients with BMI < 25 kg/m2 (%)		1.52%	14.06%

*Baseline to 6 months $p < 0.05$

throat discomfort. Good tolerance and most remaining correctly and properly implanted, within the expected standards for this type of device, is observed. Finally, the Stella®-IGB price is anticipated to be comparable to other 6-month balloons available on the market.

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Data Availability No datasets were generated or analysed during the current study.

Declarations

Ethical Approval The clinical trial was conducted in accordance with international standards of good clinical practice: International Conference on Harmonization guidelines, Declaration of Helsinki, European Regulation (EU) 536/2014, ISO-14155:2020 Clinical investigation for medical devices for human subjects and Regulation (EU) 2017/745 of the European Parliament and National Royal Decree (1090/2015). The clinical protocol was approved by Dexeus University Hospital Ethics Committee. None of the investigators were members of the Ethics Committee.

All procedures performed in the study were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.
The authors declare that they have not used artificial intelligence (AI) or any tool that uses AI in the writing of this article.

Consent to Participate Informed consent was obtained from all individual participants included in the study.

Clinical Trial Registration and Patent The clinical trial was authorized by the Spanish Agency for Drugs and Medical Devices (AEMPS—Agencia Española de Medicamentos y Productos Sanitarios) under clinical investigation plan (CIP) STELLA 2021, nº 954/21/EC-R. The Clinical Trial was registered with the Number NCT06744829.

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