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Title:
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Intragastric balloon to treat obesity. An old friend with new horizons. About The first Spanish device (Stella®)

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Dear Editor,

Since the first FDA-approved intragastric balloon (IGB) (*Garren-Edwards Gastric-Bubble®)* was designed in 1985, different IGB concepts, designs and models have emerged. The main differences are dwell time, material, volume and filling characteristics, the possibility of adjustment, the number of implanted balloons and

even their swallowable implantation.

Once numerous safety and efficacy studies have been published, the IGB has been shown to be a well-established therapeutic tool for obesity treatment [1,2]. The Spanish Bariatric Endoscopy Group (Gettemo-SEED and SEPD) has developed, in a pioneering way, multiple initiatives: consensus documents, specific informed consents, monographic training courses (Enbarna), ... [3-5].

Currently, we have successfully completed the Clinical Trial of the first Spanish intragastric balloon: the Stella® balloon (SwanMedical, Barcelona). It is a spherical, silicone, 6-month liquid-filled device. As peculiarity, it has a double lumen in the introducer system (Fig. 1). The first one is intended for the passage of a guidewire to insert the balloon quickly and safely, which also requires prior gastroscopy. The second lumen allows for regular filling. Therefore, Stella® accepts all current IGB indications, improving on existing balloons in terms of its specific applicability for endoscopists in training and for some pharyngo-oesophageal anatomical alterations (difficult necks, diverticula or oesophageal motor disorders, etc.) that could make it difficult or impossible to insert another IGB model.

This Spanish multicentre, prospective, longitudinal, non-randomised case series trial was designed to demonstrate the safety of the balloon and its delivery system in 69 patients. We achieved an adequate introduction and the IGB remained in good condition in 66/69 (95.65%), with 3 cases (4.35%) with some dysfunction: a technical difficulty to deploy, a deflation caused by a *'severe fungal colonization'* and a partially deflated balloon. No serious complications were reported, concluding that the device is reliable in terms of safety.

Technically, the procedure was fast (mean oesophageal passage: 4.23 seconds) and easy (introduction on the first attempt: 97.1%). Clinically, it showed few intolerances (5.8%) and a good efficacy profile: mean %TBWL: 15.39% (TBWL>10% in 83.33% of patients) and with clinical and analytical metabolic parameters improvement.

Some limitations could be the small number of patients, especially morbidly obese patients (BMI>40kg/m^2); the absence of a control group; the limited follow-up to 7 months; and the participating centres high level of expertise in IGB.

In conclusion, preliminary results suggest that Stella® IGB could have efficacy and safety values comparable to those of the leading currently approved intragastric balloons. Final certification and market release of the device is expected by the end of 2024.

**Preliminary results. Pending publication of the final article with the definitive results.*

Patent: Ep22800309nwa1. **Publication:** 04.09.2024. **Bulletin**: 2024/36. **Application number:** 22800309.1**. Filing date:** 19.10.2022. **National distribution:** Saescomedical.

Conflict of interest

All authors are part of the research group of the Clinical Trial, whose development has been funded by Mikromic-SwanMedical. Dr Abad-Belando is part of the team that invented the device.

Statement on Generative AI and AI-assisted technologies in the drafting process

The authors declare that they have not used artificial intelligence (AI) or any tool that uses AI in the writing of this article.

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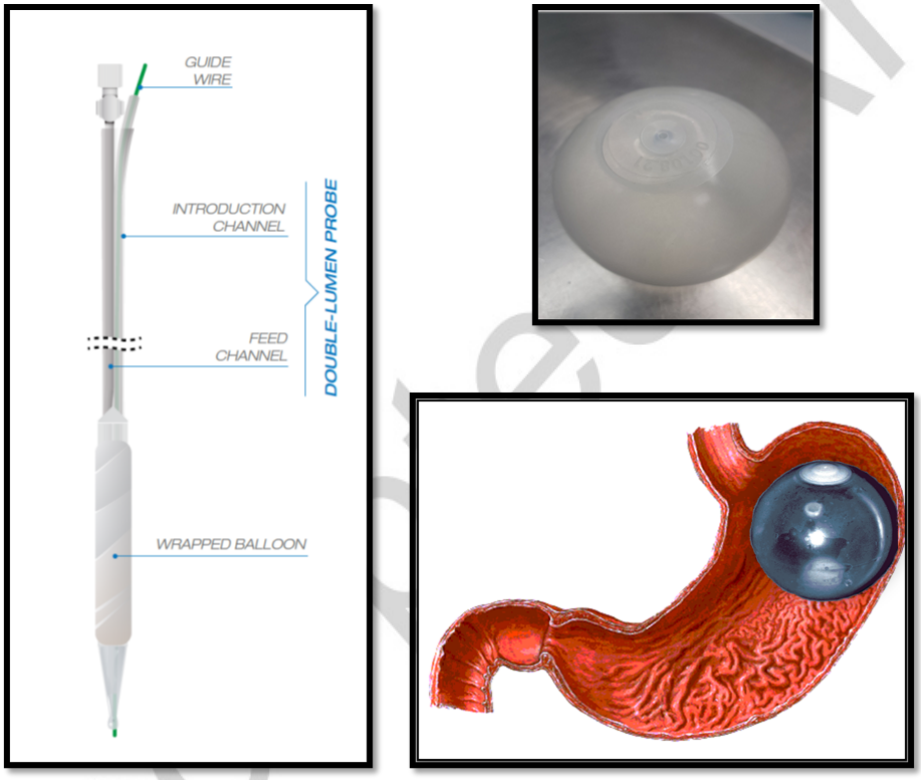

Figure 1. Design of the new Stella® intragastric balloon with guidewire.