ACG CASE REPORTS JOURNAL

CASE REPORT | ENDOSCOPY

Concurrent Placements of a Duodenal-Jejunal Bypass Liner and an Intragastric Balloon Among Severely Obese Patients: A Case Series

Adrian Sartoretto, BMedSC, MBBS, FRACP[1,2], George Marinos[1], and Zhixian Sui, PhD, MHlSc[1,3]

[1]*The BMI Clinic, Double Bay, New South Wales, Australia*
[2]*School of Medicine, The University of Sydney, Camperdown, Australia*
[3]*School of Public Health and Community Medicine, The University of New South Wales, Kensington, New South Wales, Australia*

ABSTRACT

The duodenal-jejunal bypass liner and the intragastric balloon are endoscopically deployed devices used in the treatment of obesity and diabetes. These devices use differing mechanisms of action, and concurrent use may lead to improved efficacy. Three obese patients who suffered from weight loss plateau with the liner had the intragastric balloon inserted concurrently. All 3 patients reported subsequent significant weight loss. None of the patients reported any symptom that indicate the interference between the devices. This is the first case series in humans of successfully combining 2 independent endoscopic bariatric therapies to overcome weight loss plateau in the primary treatment of obesity.

INTRODUCTION

Obesity is described by the World Health Organization as one of the most blatantly visible, yet most neglected health problems globally.[1] Endoscopic bariatric therapies (EBTs) have the potential to bridge the gap between dietary and lifestyle counseling and irreversible bariatric surgeries and offer as an efficacious and minimally invasive option. Currently available EBTs typically alter either gastric or small bowel physiology to elicit their effects.

The duodenal-jejunal bypass liner (EndoBarrier; GI Dynamics, Inc., Lexington, MA) is a Teflon-coated liner that is endoscopically placed in the duodenal bulb to create a barrier between chyme and the small bowel and remains in situ for a period of 12 months (Figure 1). The putative mechanism of action is to induce malabsorption both by mechanical means and by delaying the admixture of chyme with biliopancreatic juices. The Orbera intragastric balloon (Orbera IGB, previously marketed as the BioEnterics Intragastric Balloon, BIB; Apollo Endosurgery, Inc., Irvine, CA) is a fixed-volume, silicone balloon that can be filled with up to 700 mL saline-methylene blue solution. The Orbera remains in situ for 6 months and provides gastric restriction and alters gastric emptying to modulate appetite and satiety in a reversible fashion.

CASE REPORT

Patient 1: Patient 1 is a 20-year-old woman with baseline body mass index (BMI) of 36.6 kg/m^2 (excess weight [EW] 27.5 kg). She elected to undergo EndoBarrier insertion and lost 5.3 kg (change of BMI [ΔBMI] 2.2 kg/m^2, total body weight loss [TBWL] 6.1%, excess weight loss [EWL] 19.3%) and entered a weight loss plateau (Figure 2). The patient then decided to undergo concurrent treatment with an Orbera IGB inserted while having the EndoBarrier in situ. In total, the patient had lost 20.0 kg when both devices were removed (ΔBMI 8.4 kg/m^2, TBWL 23%, EWL 72.7%). However, following the uneventful deflation and retrieval of the balloon, the removal of the EndoBarrier liner resulted in a laceration within the duodenal bulb. The patient was then admitted to a hospital where she remained systemically well and was managed conservatively with intravenous antibiotics, gut rest, and intravenous fluids for 5 days before being discharged without sequelae. Two months after the removal, the patient elected to undergo insertion of

ACG Case Rep J 2019;6:1–4. doi:10.14309/crj.0000000000000101. Published online: June 25, 2019

Correspondence: Zhixian Sui, The BMI Clinic, 451 New South Head Rd, Double Bay, NSW 2028, Australia (suiz@bmiclinic.com.au).

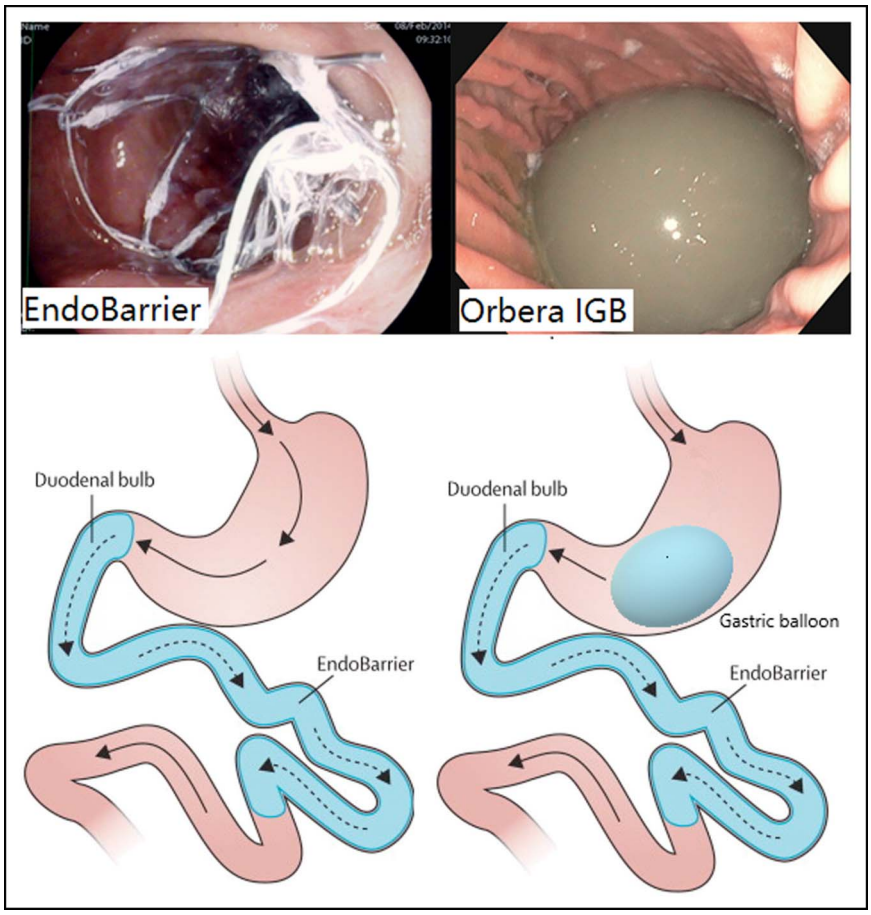

Figure 1. Visual demonstration of EndoBarrier and Orbera intragastric balloon working concurrently through different mechanisms as obesity treatment.

a second IGB (Spatz3) for weight loss maintenance. The patient had Spatz3 implantation for 12 months and weight loss was maintained at 15.3 kg (ΔBMI 6.5 kg/m^2, TBWL 17.7%, EWL 56.0%). The follow-up weight loss at 6 months after balloon removal was 17.1 kg (TBWL 19.7%).

Patient 2: Patient 2 is a 42-year-old man (baseline BMI 37.9 kg/m^2, EW 37.2 kg) and had a medical history of hyperlipidemia, sleep apnea, reflux esophagitis, and chronic back pain. The patient tolerated the EndoBarrier well and lost 16.4 kg (ΔBMI 5.7 kg/m^2, TBWL 15.0%, EWL 44.1%) before reaching a weight loss plateau (Figure 2). The patient then underwent insertion of an Orbera IGB and lost 29.9 kg at removal of both devices (ΔBMI 10.4 kg/m^2, TBWL 27.4%, EWL 80.8%). Then, the patient elected to undergo further intragastric balloon treatment. A Spatz3 IGB (500 mL) was inserted for weight loss maintenance. At month 21, after removal of the Spatz3 IGB (650 mL), the patient's weight loss was maintained at 31.3 kg (ΔBMI 10.8 kg/m^2, TBWL 28.6%, EWL 84.3%). The follow-up weight loss at 6 months after balloon removal was 32.5 kg (TBWL 29.7%).

Patient 3: Patient 3 is a 50-year-old man (baseline BMI 37.6 kg/m^2, EW 40.3 kg). The patient had EndoBarrier and lost 12.4 kg (ΔBMI 3.9 kg/m^2, TBWL 10.3%, EWL 30.8%) before reaching a weight loss plateau (Figure 2). The patient then decided to undergo concurrent Orbera IGB therapy. In total, the patient lost 21.4 kg (ΔBMI 6.7 kg/m^2, TBWL 17.8%, EWL 53.1%). Both the gastric balloon and the EndoBarrier were removed at 14 months after initial insertion without complication. The patient then elected to undergo insertion of a Spatz3 IGB for weight loss maintenance contemporaneously. At month 27, after removal of the Spatz3 IGB (700 mL), the patient's weight loss was maintained at 22.9 kg (ΔBMI 7.1 kg/m^2, TBWL 19.0%, EWL 56.8%). The follow-up weight loss at 6 months after balloon removal was 20.5 kg (TBWL 17.0%).

DISCUSSION

We report the first 3 human cases of concurrent-multimodal, and consecutive, EBTs to address weight loss plateau, augment efficacy of the primary intervention, and maintain weight loss after device retrieval. These cases confirm the feasibility of concurrent multimodal EBT and provide pilot data on the augmented efficacy and reasonable safety profile of this approach. Importantly, the major complication encountered on removal of the EndoBarrier in patient A resolved without the need for surgery and is a well-documented complication of EndoBarrier, which has been previously attributed to the flawed

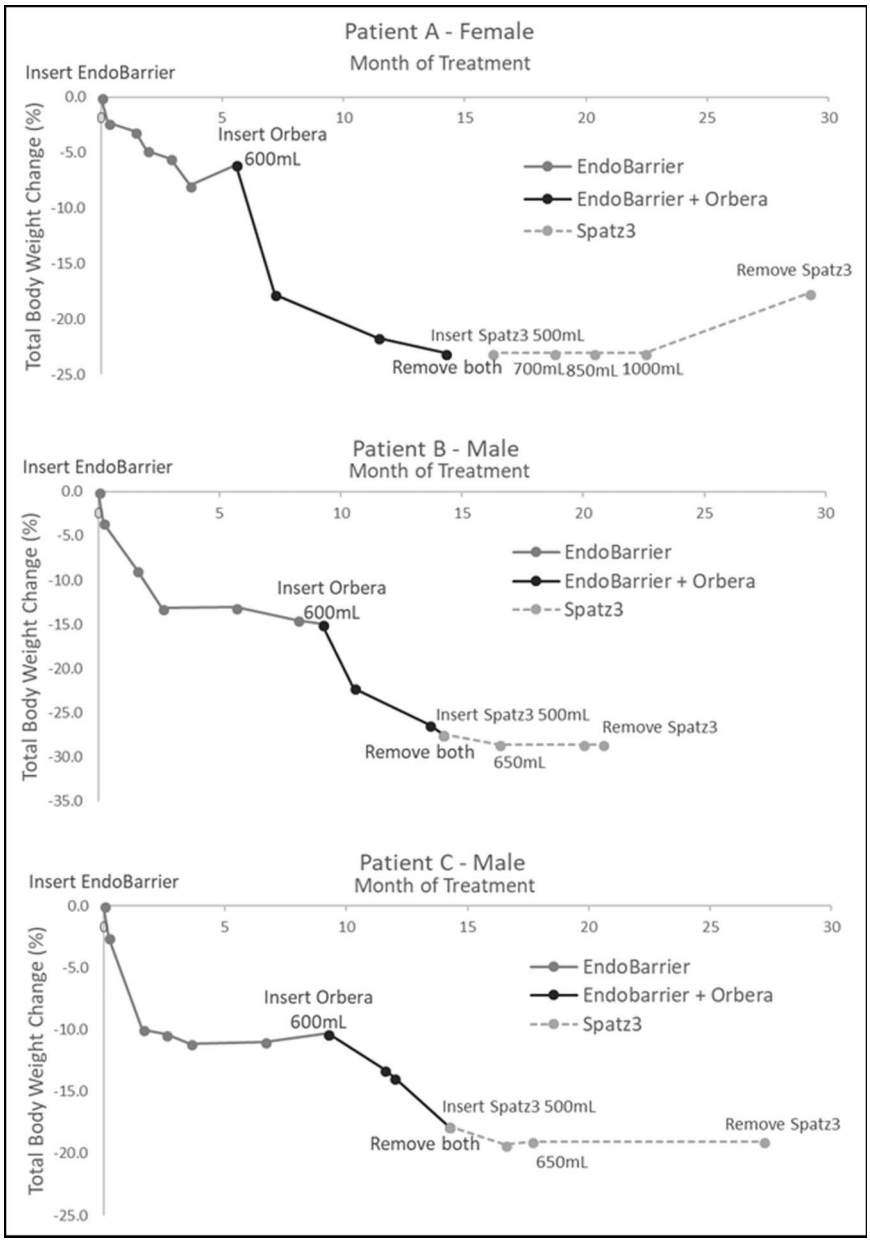

Figure 2. Weight loss time line of the 3 patients.

design of the system.[2,3] Given this event occurred after the removal of the Orbera, it is not considered to be the result of concomitant therapy. EndoBarrier was registered in Australia as a weight loss intervention at the time of this study.

Of interest, most patients were actively losing weight at the removal of both devices. The weight loss effects of multimodal EBT (TBWL 17-29%) appeared additive when compared against typical weight loss results since with either device alone (TBWL EndoBarrier 5%–10% and Orbera 12%).[2,4–6] Although the application of a second solitary IGB did not seem to improve weight loss, it appears that such use may be an effective weight stabilization approach, although this requires further investigation. Furthermore, these patients received minimal adjunctive lifestyle intervention, which is now established as being a significant determinant of weight loss efficacy with all forms of EBT.[7]

Previous research has found that patients experienced with intragastric balloons reported significantly less weight loss than those naïve to endoscopic bariatric procedures.[8] Given that EBTs are likely to become much more widespread due to the current obesity epidemic, we highlight the urgent need to study the implications of repeating EBTs, including anatomy change and relevant clinical outcomes.[9]

This case series is of course limited in its interpretation owing to the retrospective nature and small number of cases. However, it firmly establishes the feasibility of a novel approach of combination and multimodal EBTs to augment weight loss efficacy

and the management of weight loss plateau. Further studies are urgently needed to further establish the safety, optimal timing, and optimal combinations and/or sequences of EBTs, lifestyle therapy, and pharmacotherapy.

DISCLOSURES

Author contributions: All authors wrote the article together. G. Marinos is the article guarantor.

Financial disclosure: A. Sartoretto is consultant with Apollo Endosurgery and BAROnova. G. Marinos is consultant with BAROnova.

Informed consent was obtained for this case report.

Received November 1, 2018; Accepted April 3, 2019

REFERENCES

1. World Health Organization. Obesity—overweight and obesity fact sheet. Health topics. (http://www.searo.who.int/topics/obesity/en/) 2018. Accessed June 22, 2018.
2. Forner PM, Ramacciotti T, Farey JE, Lord RV. Safety and effectiveness of an endoscopically placed duodenal-jejunal bypass device (EndoBarrier®): Outcomes in 114 patients. *Obes Surg* 2017;27(12):3306–13.
3. *GI Dynamics. TGA Cancellation of EndoBarrier Listing.* Press Releases, 2016; (http://gidynamics.com/2016/10/24/tga-cancellation-of-endobarrier-listing/). Accessed 11/06/2018 2018.
4. Patel SR, Hakim D, Mason J, Hakim N. The duodenal-jejunal bypass sleeve (EndoBarrier Gastrointestinal Liner) for weight loss and treatment of type 2 diabetes. *Surg Obes Relat Dis* 2013;9(3):482–4.
5. Rohde U, Hedbäck N, Gluud LL, Vilsbøll T, Knop FK. Effect of the EndoBarrier gastrointestinal liner on obesity and type 2 diabetes: A systematic review and meta-analysis. *Diabetes Obes Metab* 2016;18(3): 300–5.
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.
7. Schwartz J, Chaudhry UI, Suzo A, et al. Pharmacotherapy in conjunction with a diet and exercise program for the treatment of weight recidivism or weight Loss Plateau post-bariatric surgery: A retrospective review. *Obes Surg* 2016;26(2):452–8.
8. Sartoretto A, Sui Z, Hill C, et al. Endoscopic sleeve gastroplasty (ESG) is a reproducible and effective endoscopic bariatric therapy suitable for widespread clinical adoption: A large, international multicenter study. *Obes Surg* 2018;28:1812–21.
9. Sui Z, Raman J, Han B, et al. Recent trends in intensive treatments of obesity: Is academic research matching public interest? *Surg Obes Relat Dis* 2019. [Epub ahead of print January 24, 2019.]