



Bariatric Endoscopic Therapy: A Novel Approach to Obesity

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Editorial

Obesity has become an epidemic worldwide, especially in Western countries, and several medical societies have stated it as a chronic medical disease [1,2]. Lifestyle habits have worsened during the last decades, and precooked food and saturated fat ingestion have been included in many people's routine diet. It has been well known since decades that obesity dramatically increases mortality, according to its higher rate of cardiovascular diseases and metabolic disorders, but it also favors obstructive sleep-apnea or osteoarticular diseases. Furthermore, its role as a decisive risk factor for colorectal cancer and other neoplasias has emerged.

Diet and lifestyle modifications, weight loss drugs and bariatric surgery were, until now, the available measures to stop this scourge, but for several reasons, obesity expansion keeps increasing. Hypocaloric diets and physical activity have shown an overall fair efficacy in terms of total body weight loss and, especially, in durability [3,4]. Regarding to approved pharmacotherapy agents for long term weight management, their efficacy is still controversial, achieving only a 5 to 10% of total body weight loss, and being not exempt from adverse effects [5]. Bariatric surgery is, no doubt, very effective for weight loss, but highly invasive, with a not negligible mortality and morbidity rates [6,7].

In this broth, during the last decade, some promising endoscopic weight loss therapies have appeared. Some of them are still under development, but others have already been approved by the FDA in the USA, or are currently used in Europe and South America. Its main assets are its higher safety profile, its greater effectiveness as compare with hypo-caloric diets and modification of habits, and its lower price and greater availability than bariatric surgery. Endoscopic bariatric therapies, as it has recently been stated by the American Society for Gastrointestinal Endoscopy (ASGE), represents a viable and safe alternative for

patients unable to success at weight loss with diet and exercise and could also be appropriate for those who are not good candidates or reject surgical procedures [8].

Intra-gastric balloon was first reported in 1982 and is, by far, the most used device among endoscopic bariatric therapies, having proved to be highly effective for short and medium term weight loss in several clinical trials and meta-analysis, especially the ORBERA balloon (Apollo Endosurgery Inc., Austin, TX, USA). Its application must be performed in patients within a BMI range of 30-40kg/m² within a multidisciplinary management program that allow the patient to maintain its weight loss after balloon removal, usually 6 months after insertion. In one meta-analysis, the ORBERA balloon obtained a 32.1% excess weight loss (EWL) at 6 months [9-11]. Several new balloons have been recently released, and most of them have shown to be effective and rather safe, although some adverse events have been reported, especially during removal. To stand out among them, the SPATZ balloon (Spatz FGIA Inc., Jericho, NY, USA), which can be refilled or emptied if needed and permits longer duration (12months) leading to a greater weight loss, but with some cumbersome side effects due to filling catheter impactions [12]. And the OBALON (Obalon Therapeutics, Carlsbad, CA, USA), that can be swallowed without endoscopy and anesthesia.

In the last decades, several endoscopic suturing systems have appeared. Among all these, the following stand out: POSE procedure and Apollo Overstitch Sleeve Gastroplasty. Both systems share some characteristics (incisionless full-thickness plications, short procedure time, and rapid recovery with discharge in less than 24 hours) and its main indications would be patients with type 1 and type 2 obesity (BMI 30-40kg/m²), but its technical solutions differ significantly [13,14].

POSE procedure (acronym of Primary Obesity Surgery Endolumenal) modifies stomach size by using the Incisionless

Operating Platform (IOP; USGI Medical, San Clemente, CA, USA), a flexible multilumen access device provided with four working channels. The IOP is introduced by mouth into the stomach with a 4.9 mm video-endoscope within, a tissue helix (g-Lix), a rotatable tissue grasper (g-Prox) and a suture anchor deployment catheter (g-Cath). Gastric wall is grasped and plicated by opposing tissue, deploying and anchoring full-thickness stitches. First, retroflex is used to plicate fundal apex with 7-9 sutures, to limit gastric fundal accommodation, and then, after restoring forward viewing 4-8 more sutures are deployed between gastric body and antrum, across the incisura, to delay gastric emptying. Promising results have been reported from two different Spanish groups and this have been recently confirmed in both multicenter randomized controlled trials, the European "MILEPOST Study" [15,16] and the American "the ESSENTIAL Trial" [17]. Both trials showed clinically and statistically significant weight loss at 12 months (about 45-49% EWL) with a very low rate of side adverse effects. Early satiety has also been reported with this procedure.

Apollo overstitch (Apollo Endosurgery, Austin, TX, USA) is a non-suction endoscopic suturing device that places full-thickness stitches in different patterns along the greater curvature for endoscopic sleeve gastropasty (ESG) creation. After ablation of the mucosa of the stomach with Argon plasma coagulation to expose the substrate collagen required for durable tissue apposition, the dual channel endoscope is withdrawn and the suturing device is then attached to its tip. Once in the stomach, several applications are done using 2-0 prolene sutures from anterior to posterior wall along the greater curvature leading to a tube-like passage. Sutures can be performed in different stitching patterns and techniques, and a total body weight loss of 45-54% [17-19] has been reported. Preliminary reports indicate that ESG may decrease fasting and postprandial ghrelin levels and decrease caloric intake needing [20-22]. As with the POSE, the long-term durability of the sutures must still to be proven. Both devices (POSE and Overstitch) have been also successfully used (with mild modifications) for the endoscopic revision of gastric bypass.

There are some other new therapies, like aspiration methods (Aspire Bariatrics, King of Prussia, Penn, USA), in which patients attach an aspiration syphon to a previously inserted 30Fr gastrostomy tube and aspirate gastric content 20 min after ingestion. A 40-54.6% EWL has been reported and no compensating increased food intake or binge eating were observed [23,24]. The endoscopic duodeno-jejunal bypass sleeve (Endo-Barrier) seems capable to significantly improve diabetes and be successful in terms of weight loss (35.3% EWL), although a multicenter US pivotal trial had to be stopped due to infectious complications. Other promising devices were abandoned at the closure of the company due to lack of funding.

In conclusion, obesity has become a widespread epidemic, especially in Western countries. Despite the fact that the governments are becoming aware that it is imperative to carry

out global campaigns to promote healthy eating and changes in the standard of living, new strategies like bariatric endoscopic therapies associated to a multidisciplinary weight management program should be well received, as they may contribute to improve the overall health of the population through technically feasible methods, which are safer for patients, and easily accessible to all audiences and almost all pockets. Larger multicenter randomized controlled trials are needed to confirm these promising results.

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