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Review article

A history of intragastric balloons

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Abstract The history of intragastric balloons (IGBs) began in 1985 with the Garren-Edwards Bubble. It was approved by the U.S. Food and Drug Administration (FDA) for temporary use as a weight loss device, but its manufacture was discontinued in 1988, and approval was withdrawn in 1992 because of significant complications and limited and recidivistic weight loss. A number of IGBs have appeared since that time, mostly originating in Europe or South America, but none has acquired FDA approval until recently; the ReShape Duo Integrated Dual Balloon System (ReShape Medical Inc., San Clemente, California) received FDA approval in August 2015.

The conclusions of an important 1987 international conference on IGBs and the characteristics, effectiveness, and problems of most other IGBs are described in this text. The common purpose of these devices as preliminary interventions before gastric bariatric surgery and their favorable effects on this purpose are emphasized and may have played a key role in the FDA's change of outlook of the IGB. (Surg Obes Relat Dis 2015;▮:00–00.) © 2015 American Society for Metabolic and Bariatric Surgery. All rights reserved.

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—NBSR Newsletter report of 1986 Fourth Annual Symposium on Surgical Treatment of Obesity [1].

The Garren-Edwards Gastric Bubble (GEGB) was approved by the U.S. Food and Drug Administration (FDA) in December 1984 as an intragastric balloon for obesity. The Garrens, who were both gastroenterologists, were notified of the decision in September 1985. Their bubble was then manufactured by American Edwards Laboratories of Santa Ana, California. The GEGB was a polyurethane, cylindrical device with a hollow central channel (Fig. 1) and a self-sealing valve. It was designed to be inserted endoscopically in the stomach, filled with 200–220 mL air to capacity, and left free floating. The hollow central channel was a protective feature to permit easier movement about the stomach. It was designed as a temporary device that required endoscopic removal at 4 months.

During the first few years of its production, the GEGB was used extensively across the world, and several reports, both randomized trials and retrospective reviews, were published on weight loss achieved and device complications [2–4]. By 1989 it was reported that 7–10 kg of weight could be lost, but it would slowly return, and some GEGBs would deflate spontaneously or position themselves obstructively

Drs. Lloyd and Mary Garren of Delaware updated the progress of the work on their intragastric balloon, the Gastric Bubble. The Bubble can be placed in as few as seven minutes using endoscopy. Once in place, the cylindrical Bubble is inflated with 200 cc of air. More than this can cause discomfort and ulceration. Fluid is not used since that stimulates the antral pump. A Bubble is usually used for only four months at a time and most patients have at least two implantations. Patients with a mean implant duration of five months did better after removal than those patients with a mean of 3.2 months. The Garrens stressed that the Bubble is only temporary and patients must have dietary and behavior modification programs in order to be successful. Like dieting, jaw wiring, and supervised in-hospital weight loss programs, the remaining question for the Bubble is what the weight loss will be a year after the treatment has ended….

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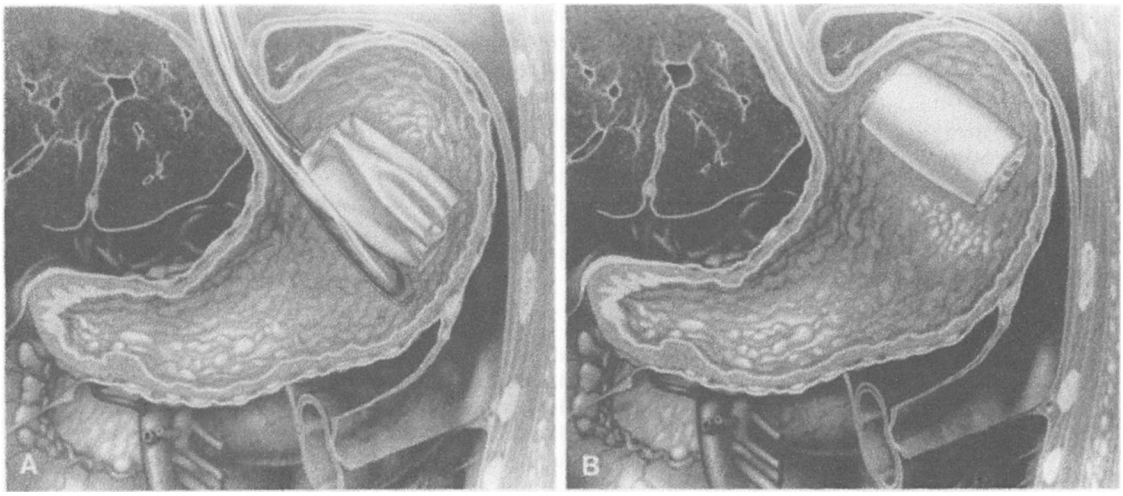

Fig. 1. The Garren-Edwards Gastric Bubble after endoscopic insertion into the stomach and inflation with 200 mL air. (From Velchik MG, Kramer M, Stunkard AJ, Alavi A. Effect of the Garren-Edwards Gastric Bubble on gastric emptying. J Nucl Med. 1989;30:692–6. ©Society of Nuclear Medicine and Molecular Imaging, Inc.)

in the intestine [2,3]. In addition, gastric erosions or ulcers were not uncommon [3,4]. These complications, coupled with disappointing weight loss, led American Edwards Laboratories to discontinue manufacture and sale of the GEGB in 1988. In 1992 Dr. Lloyd Garren withdrew the device from the market. The FDA did not approve use of another IGB in the United States until this year (2015), which is probably why the public, and even many bariatric surgeons, had presumed the device would no longer be used in bariatric practice.

The GEGB was conceived as an alternative to bariatric surgery for endoscopy-practicing gastroenterologists during the 1980s in what was becoming a bariatric surgical world. Soon after, only 1 other IGB was developed in the United States (by BioEnterics Corporation, Carpinteria, California), although it was never approved for use in the United States or Canada. A number of IGBs of varying technical descriptions, however, have been engineered and sold in other countries across the world. Contemporary surgeons now use IGBs as preliminary therapy, usually before restrictive gastric surgery. Therefore, a review of the history of the bubble concept is appropriate.

The IGB appeared and was first used clinically in the mid-1980s. This period was early in the era of bariatric surgery. Historically, the jejunoileal bypass appeared in 1969 (Payne and DeWind) [5] and its clinical use had largely disappeared by the 1980s because its favorable effect on weight loss had been supplanted by the results of gastric procedures. Dr. Edward Mason's gastric surgeries began in 1966, and the prospective study of gastric bypass versus jejunoileal bypass published by Dr. Ward Griffen in 1977 [6] demonstrated equivalent weight loss results. The many fewer side-effects with gastric bypass focused future interest on gastric restriction for weight loss. Italian surgeons, notably Drs. Nicola Scopinaro and Ezio Gianetta and others [7], devised and published favorable weight loss results starting in the late 1970s using subtotal gastrectomy coupled with biliopancreatic bypass, a construction that diverted biliopancreatic flow directly to the distal small bowel in addition to significant gastric resection [7,8]. Although popular in Europe, these procedures had little clinical usage in the United States during that time. Gastric bypass (with gastroenterostomy), Roux-en-Y gastric bypass, and transverse and vertical banded gastroplasty were the more common surgical procedures used for weight control in "morbid" obesity patients during the mid-1980s in the United States.

The objective of IGB was to be a temporary aid for those interested in weight loss who were not sufficiently large enough (morbid) for a gastric procedure or were "super-obese" with very high surgical risks and wished (or were told) to lose some weight to safely undergo surgery [9]. The IGB was not to be used in patients who had undergone prior gastric surgery, and this exclusion criterion has not changed. Having lived and practiced through the entirety of the history of gastric bariatric surgery, it is the author's opinion that the IGB was designed to provide an alternative to gastric surgery.

Also during the 1980s, 2 IGBs were developed and used in Europe. The Taylor balloon (1985, Mill-Rose Technologies, Cleveland, Ohio) was developed in the United Kingdom and was silicone, pear-shaped, and filled during endoscopy with 500–600 mL saline [10]. It was to be retained in the stomach for 4 months. The designers believed that the larger size was preferable because gastric volumes in obese patients were estimated at nearly 2000 mL. Marshall et al. [11] reported on a multicenter study in the United States that gastric inflammatory side-effects and deflations with the Taylor balloon were less serious and less frequent than those with GEGB, but weight loss and body