

The Journey of Intra-gastric Balloon from Past to Today, Future Perspective

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As the overweight and obesity are the significant public health concern and rises globally; scientist, surgeons, bariatrician and pharmacists are in a serious attempt to treat this syndrome by different way of approach. New medication and occasional devices are coming on board and introduced to this field.

According to Noah Yuval Hariri “A Brief History of Tomorrow” in 2012 about 56 million people passed away throughout the entire world; 620,000 of them died because of human violence (war killed 120,000 people, and crime killed another 500,000). In contrast, 800,000 committed suicides happened and 1.5 million died of diabetes. He concludes that Sugar and obesity in follow is more dangerous than gun power (1).

Although intra gastric balloon is not a new device in the world, it was introduced to the United States for weight loss purpose relatively in a recent time. DeBakey’s review in 1938 showed that bezoars led to weight loss (2). Free floating intra-gastric balloons were used by Neiben and Harboe in 1982 (3). In 1985 the Garren-Edwards Bubble was introduced as the first food and drug administration (FDA)-approved device, but the approval was withdrawn seven years later because of its accompanied complication (4). Analysis of its problems led to recommendations for non-invasive design. While numbers of further developed devices were used outside of the United States, mostly in Europe and South America, the FDA did not approve any new devices until 2015 (4).

The device is intended to be used in patients with a body mass index (BMI) of 30 to 40 kg/m². (5). Since intra gastric balloon became available to bariatric surgeons in the United States, over 5000 patients have been done and the number of surgery is increasing.

Currently there are three FDA approved balloons in the USA. Studies have suggested that fluid is superior to air for distending gastric balloons. Inflated balloons reduce the operative volume capacity of the stomach. While the typical gastric volume is about 900 mL, an inflated balloon

may take up most of the space, about 700 (+/- 100) mL (6).

Initial side effects of the balloon are common and may consist of nausea, vomiting, reflux, and stomach cramps. Other side effects or complications could be indigestion, bloating, flatulence, and diarrhea. Rare side effects include esophagitis, gastric ulcer formation, or gastric perforation (7). The device could become deflated and slip into the lower intestines. Migration of a balloon could lead to bowel obstruction and potentially perforation (8).

Gastric balloons are generally considered to be safe and effective in the short run. There could be procedure-related side effects due to endoscopy and anesthesia. Rarely, the endoscopic placement of a balloon could lead to death.

According to The US FDA there are five reports of unanticipated deaths that occurred from 2016 to the present in patients who received a liquid-filled intra-gastric balloon to treat obesity. Four reports involve the orbera intra-gastric balloon system (Apollo Endosurgery) and one report involves the ReShape integrated dual balloon system (ReShape Medical). All five patients died within 1 month or less of balloon placement. Three patients died 1 to 3 days after the balloon was placed. Today’s safety alert has been sent to healthcare providers for close monitoring of patients with liquid-filled intra-gastric balloon systems used to treat obesity. Since then, both companies have revised their product labeling to address these risks, per FDA recommendation (9).

Nowadays, the FDA continues to recommend that healthcare providers closely monitor patients treated with these devices for complications and report any adverse events related to intra-gastric balloon systems through MedWatch, the FDA Safety Information and Adverse Event Reporting Program. However, despite those events FDA has not prevented production of this device yet and they are still available (9).

The weight loss result of intra gastric balloon placement is very variable. Since this weight loss method is

very subjective, different patient population with variable lifestyle and eating habit may have different outcomes. Results are short term and influenced by the adherence to nutritional and dietary programs. The long term follow-up are less conducted and need further studies in this field.

Intra gastric balloon may have some potential changes in future by providing some alteration in current condition such as material, change in insertion and removal techniques, sufficient symptoms control, and more predictable in weight loss. However in present circumstances, safety, efficacy, financial effect, patient intolerance, and more factors is holding the intragastric balloon under a big question mark for future.

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