Proposed Addendum to Position Statement on Intragastric Balloon Therapy
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The FDA has issued two warnings to call public attention to complications which were not seen during the United States clinical trials of intragastric balloons. The 2/9/17 FDA statement highlighted pancreatitis and hyperinflation. The rate of pancreatitis was reported as 0.1% by one company and 0.07% by another. Hyperinflation, a phenomenon in which the intragastric balloon spontaneously increases in size, occurred at a rate of 0.02% and 0.04%.

On August 10, 2017 the FDA issued a statement about mortalities worldwide. There have been four mortalities of patients with intragastric balloon in the US since 2015. This rate of 4 in an estimated 10651 implants calculates to a mortality rate of 0.037%. Most were associated with esophageal or gastric perforation.

Gastritis, ulceration, early retrieval, GERD, nausea and vomiting, bowel obstruction, severe dehydration, renal insufficiency, and cardiac arrhythmia have all been documented at a level below 1%.

As with all procedures, it is important that patients give informed consent and are aware of potential adverse events. Laypeople may need to be counseled to correct a misperception that endolumenal treatments are nonsurgical and thus risk-free.

When less powerful treatments are chosen, behavioral modification increases in importance and there is risk of weight regain after the device is retrieved. The ASMBS routinely advocates for multidisciplinary care and support of the weight loss patient, and this recommendation is even more crucial for intragastric balloon recipients.