FDA investigating deaths of patients who had gastric balloon procedure for obesity

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The U.S. Food and Drug Administration has alerted physicians and surgeons who treat obesity that it is investigating whether there is a link between gastric balloons - a new-generation weight-loss device - and the deaths of five patients.

In an alert issued Thursday, the FDA said that from 2016 to the present, five "unanticipated deaths" had occurred within a month or less in patients who had liquid-filled gastric balloon systems implanted in their stomachs. In three of the cases, the agency said that patients died between one and three days after the weight-loss device had been put in place.

"At this time, we do not know the root cause or incidence rate of patient death, nor have we been able to definitively attribute the deaths to the devices or the insertion procedures for these devices," the FDA told physicians.

The agency suggested it would explore the possibility that patients suffered gastric and esophageal perforation or intestinal obstruction, either while the device was being implanted or afterward.

Four of the deaths involved the Orbera Intragastric Balloon System, manufactured by Apollo Endo Surgery of Austin, Texas, and approved by the FDA in August 2015. One of the reports involved the ReShape Integrated Dual Balloon System, manufactured by ReShape Medical Inc. in San Clemente, Calif., and approved by the FDA in July 2015.

The agency said it has received reports of two other deaths since 2016 related to potential complications associated with balloon treatment. In one of those deaths, a patient who had the Orbera Intragastric Balloon System implanted suffered a gastric perforation. In the second death a patient who got the ReShape Integrated Dual Balloon System suffered an esophageal perforation.

The manufacturers of both devices have not responded to the Los Angeles Times' efforts to seek comment.

The FDA's new scrutiny of the weight-loss devices follows earlier safety concerns conveyed to health care providers. In February, the agency warned that it had received reports of adverse event in which liquid-filled gastric balloons, once in patients' stomachs, overinflated with air or liquid - a phenomenon it called spontaneous hyperinflation. The problem required removal of the device ahead of schedule.

The agency also said it had received reports that patients getting the devices developed acute pancreatitis, which also resulted in the need for early removal of the balloons.

Stanford bariatric surgeon Dr. John Morton, who has implanted roughly 70 of the ReShape devices, said he has not seen complications in his patients, who have typically lost weight with the devices.

"Every death is a tragedy, and has to be investigated," said Morton, who is a past president of the American Society for Metabolic and Bariatric Surgery. But as devices used for patients at relatively low levels of obesity, and which promote relatively modest weight loss, the standard of safety they should meet is particularly high, he added.

Both the ReShape and Orbera systems are approved for patients with a body-mass index, or BMI, between 30 and 40. They are generally

considered a less invasive and less costly alternative to bariatric surgery for patients who are less obese or cannot tolerate permanent surgical alteration of their gastrointestinal tract.

"I can only speculate this is likely to do with technique," Morton said. "There's skill involved in the placement of these balloons. Who places them makes a difference. If you're an experienced endoscopist and surgeon you recognize the signs of perforation, which is important, because they're treatable."

Gastric balloons are delivered into the stomach via the mouth in an outpatient procedure considered "minimally invasive." The procedure generally takes less than 30 minutes, during which a patient is under mild sedation. They are designed to be in place for six months.

Once in place, the balloon device is inflated with a sterile solution, which takes up room in the stomach. While nausea and stomach discomfort are expected in the days immediately following the procedure, those symptoms typically abate. While the devices are in place, patients who get them are expected to feel less hungry and typically report losing between 5 percent and 10 percent of their weight.

Apollo's website says that more than 220,000 people worldwide have had its weight-loss balloon implanted. International sales of gastric balloons were estimated to total about $120 million in 2015, driven by broad use in Brazil, Mexico and Europe.

But Morton said that manufacturers report only about 5,000 gastric balloons have been implanted in the United States. The American Society for Metabolic and Bariatric Surgery says facilities it has accredited to perform the procedures have implanted about 1,000 of the devices, and recently reported they have seen no deaths due to complications.

"These devices need to be placed in centers that have adequate follow-up, the resources to provide that follow-up, and the experience to recognize these complications," Morton said.

The FDA said Thursday it "continues to work with Apollo Endo-Surgery and ReShape Medical Inc. to better understand the issue of unanticipated death, and to monitor the potential complications of acute pancreatitis and spontaneous overinflation."

The agency said it "will communicate publicly when we have new information to share." In the meantime, the agency said, "patients should speak to their doctors to determine which obesity treatment option is best for them."