Australian Government
Department of Health
Therapeutic Goods Administration

Intragastric balloon systems

TGA product safety review

18 July 2018

The TGA has conducted a product safety review of two intragastric balloon systems included on the Australian Register of Therapeutic Goods (ARTG). The TGA's review follows information published by the USA Food and Drug Administration (FDA) (https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm570707.htm) about deaths and serious injuries to patients associated with use of intragastric balloons to treat obesity.

The intragastric balloon systems involve endoscopic insertion of a balloon into the stomach and inflation of the balloon with liquid. The space-occupying fluid-filled balloon aims to achieve temporary weight loss by delaying gastric emptying, which can create a feeling of fullness.

The TGA has received 19 adverse event reports since 2009 regarding the intragastric balloon systems that are currently being supplied in Australia. These reports include three patient deaths.

In conducting the review we have asked the sponsors of the intragastric balloons to provide: post-market safety data, the current Instructions for Use; a clinical evaluation report; and risk assessment documentation.

The information requested has undergone review and the TGA is working with sponsors and manufacturers to ensure clinicians and patients are fully informed of the risks with this type of device.

The FDA (https://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm609761.htm) has similarly approved new labelling which adds information to the Instructions for Use about certain adverse events and the effects of these events including death.

Information for consumers

Some people should not have an intragastric balloon due to the risk of complications. For example, an intragastric balloon should not be used in patients who:

- are under 18 years of age
- have had previous upper gastrointestinal surgery
- regularly take aspirin, non-steroidal anti-inflammatory agents, COX-2 inhibitors, anti-coagulants or anti-platelet agents
- are pregnant

- have a clinically significant hiatus hernia
- have a history of inflammatory disease of the gastrointestinal tract

There are other conditions that may also preclude use of an intragastric balloon, and so it is important that you discuss your complete medical history with your medical practitioner.

If you or someone you provide care for has an intragastric balloon system in place, please be alert to potential issues. Complications, although rare, may include gastric ulcer, pancreatitis, perforation of the stomach, obstruction of the inlet or the outlet of the stomach, or bowel obstruction if the balloon deflates and travels into the intestine. These complications may require abdominal surgery, or have serious consequences including death.

Symptoms to watch out for include persistent or recurrent abdominal pain; swelling of the abdomen; vomiting; difficulty breathing; or back pain. **Do not ignore these symptoms - seek medical attention as soon as possible**. If you have any questions or concerns about this issue speak to the specialist who inserted the intragastric balloon or your referring general practitioner. If you attend a hospital Emergency Department or not your regular doctor, be sure to show staff the Patient Card you were given when the balloon was inserted, so that they can see details of the intragastric balloon you have in place.

Information for health professionals

If you are treating a patient who has an intragastric balloon be alert to symptoms that might indicate there is an issue associated with the device. Adverse events associated with these devices include:

- obstruction
- ulceration
- necrosis
- ischaemia (gastric or intestinal)
- spontaneous hyperinflation of the balloon
- perforation (oesophageal, gastric or intestinal)
- gastritis/ gastric erosions
- acute pancreatitis

TGA recommends that you ensure the intragastric balloon is not inserted where contraindications exist. Refer to the Instructions For Use for the complete list of contraindications.

Where relevant, patients should be advised to take the necessary precautions to prevent pregnancy prior to placement and throughout the duration of treatment, and be instructed to inform you as soon as possible if pregnancy is confirmed during treatment, so that removal of the device can be arranged.

TGA recommends that you monitor patients closely during the entire term of treatment with intragastric balloon systems for possible complications. In particular, please be aware that patients with an intragastric balloon who present with severe abdominal pain and have a negative endoscopy and x-ray, may still require a CT scan to definitively rule out a perforation.

Please submit reports of any adverse events to help us better understand any complications arising

from the use of these devices.

Reporting problems

Consumers and health professionals are encouraged to report problems with medical devices (//www.tga.gov.au/reporting-problems). Your report will contribute to the TGA's monitoring of these products. For more information see the TGA Incident Reporting and Investigation Scheme (IRIS) (//www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.

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