



Issue 79
January 2006

Issues in Emerging Health Technologies

Intragastric Balloons: A Temporary Treatment for Obesity

Summary

- ✓ **Intragastric balloons are a temporary non-surgical obesity treatment that induces short-term weight loss by partially filling the stomach to achieve satiety and reduce food intake.**
- ✓ **Moderate weight loss may be achieved if patients adhere to a weight-reduction program. Weight gain often recurs when the balloon is removed after six months.**
- ✓ **Abdominal pain, nausea, and vomiting are common, particularly in the first week after balloon implantation.**
- ✓ **More data on benefits, harm, and cost-effectiveness are required before the intragastric balloon can be compared with other short-term weight loss interventions, including low-calorie diets.**

The Technology

The Heliosphere® Intragastric Balloon System is a temporary non-surgical obesity treatment that induces short-term weight loss by partially filling the stomach to achieve satiety. Manufactured by Helioscopie in Vienne, France, and distributed by Montreal-based Triumph Medical Products, the 30 g Heliosphere is a double-bagged polymer balloon covered with silicone. The deflated balloon is inserted into the stomach through the mouth



The Heliosphere® Intragastric Balloon (deflated and fully inflated with air)

Photo courtesy of Helioscopie

using an endoscope. It is then filled with air to a final volume of 650 mL to 750 mL, and released to float freely in the stomach. The balloon is used with a supervised calorie-restricted diet, and must be removed after six months.¹

Another type of intragastric balloon is the BioEnterics® Intragastric Balloon System (BIB®) produced by INAMED Health. It is a silicone balloon filled with saline.

Regulatory Status

The Heliosphere® Intragastric Balloon System was licensed by Health Canada in December 2004.² It is not approved for use in the US. Approximately 2,400 balloons have been sold worldwide in Europe, Brazil, Jordan, Mexico, Panama, and the Dominican Republic (Dr. Tarek Hamza, Helioscope, Vienne, France: personal communication, 2005 Oct 24).

Health Canada's licensing approval of the Heliosphere® is based on clinical data from previous balloon systems (Dr. Tarek Hamza: personal communication, 2006 Jan 13). The Garren-Edwards and the Ballobes balloons were air-filled intragastric balloons that were widely used in the 1980s, but subsequently abandoned because of placement problems and a high rate of complications, such as intolerance, gastric mucosal damage, and premature balloon deflation leading to small bowel obstruction.³⁻⁵

In 1987, a panel of 75 international experts outlined the criteria for an optimal intragastric balloon design. These criteria included the stipulation that the balloon be filled with fluid, not air.^{3,6} In 1991, INAMED Health introduced the saline-filled BioEnterics® Intragastric Balloon System (BIB®), which met all of the panel's criteria. The BIB® is not approved for sale in

Canada or the US. It is licensed for use in Europe and in several countries in South America, the Middle East, and Asia (Vernon Vincent, INAMED Health, Santa Barbara, CA: personal communication, 2005 Nov 1).

Patient Group

Obesity is measured by using body mass index (BMI) (weight in relation to height). An individual with a BMI ≥ 30 kg/m² is considered to be obese.⁷ Obesity increases the risk of premature death from coronary heart disease, stroke, type 2 diabetes, gallbladder disease, and some cancers.⁸ According to the 2004 Canadian Community Health Survey, 23.1% of adult Canadians (or 5.5 million adults) are obese.⁷

The Heliosphere[®] balloon is indicated for use for up to six months in patients with a BMI from 30 kg/m² to 40 kg/m², who have significant obesity-related health risks. It is also indicated for use in morbidly obese individuals, defined as those having a BMI >40 or a BMI <35 with serious physiological risks, who refuse surgery or who have a high surgical risk due to their excessive weight. Weight reduction through the use of the intragastric balloon may help to reduce surgical risk before bariatric (weight-loss) or other surgery.¹

Current Practice

Lifestyle intervention, including a combination of low-calorie diet, behavioural modification, and physical activity, is recommended for weight loss. Anti-obesity drug therapy may be used as an adjunct to lifestyle intervention; in Canada, orlistat and sibutramine are approved for long-term obesity management.⁹

Bariatric surgery is a treatment option that can provide long-term weight loss when lifestyle interventions have failed. It is used in selected patients with a BMI ≥ 40 or in patients with a BMI ≥ 35 with co-morbid conditions.⁹ Bariatric surgeries include intestinal bypass procedures, such as biliopancreatic diversion, and gastric-restrictive operations, such as laparoscopic adjustable gastric banding and vertical banded gastroplasty.

The Evidence

A comprehensive literature search located abstracts describing Heliosphere[®] use in two small uncontrolled case series in France. In the first case series, the Heliosphere[®] balloon was placed in 32 patients (mean BMI of 34.8 kg/m²) whose caloric intake was limited to 1,300 kcal per day during the first eight weeks. A mean weight loss of 9.8% (an estimated 9.4 kg) was reported at the end of four months.¹⁰ In the second study, the Heliosphere[®] balloon was compared to literature data for the BIB[®] from five uncontrolled case series.¹¹ Six months after the Heliosphere[®] balloon was implanted, the reported weight loss was 13.1 kg in 32 patients who had a baseline BMI of 36.75 kg/m². This was comparable to a mean weight loss of 13.7 kg measured four to seven months after the BIB[®] was placed in 688 patients.^{5,6,12-14}

A review of several randomized controlled studies of the BIB[®] found no increase in weight loss when intragastric balloon plus dieting was compared with dieting alone.¹⁵

Adverse Effects

The 30 g air-filled Heliosphere[®] balloon was designed to cause less abdominal pain, nausea, and vomiting than the 650 g saline-filled BIB[®]. In two small studies that enrolled a total of 64 patients, these symptoms were reported in 10% to 84% of patients, particularly in the first week after the Heliosphere[®] was implanted. Balloon intolerance led to early removal in four patients (6.3%), and premature deflation occurred in one patient (1.6%). No serious adverse events were reported.^{10,16}

More information is available on the adverse effects of the BIB[®]. Minor adverse complications include nausea and vomiting, gastroesophageal reflux, gastric erosions, gastroduodenal ulcer formation with pain and bleeding, and premature balloon deflation. Studies have reported balloon intolerance requiring early removal in 3.4% to 8.5% of BIB[®] placements.^{3-6,13,17} Premature BIB[®] deflation was reported in 0% to 28.6% of patients.^{3-6,13,17} Reports of life-threatening adverse events

include intestinal obstruction (ranging from 0.3% to 4.8% in three studies^{4,6,13}) and gastric perforation (2.9% in one study⁵).

Administration and Cost

The manufacturer of the Heliosphere[®] Intra-gastric Balloon System recommends balloon insertion and removal while patients receive general anesthesia with tracheal intubation, although they are aware that some physicians are performing the procedure using mild sedation (Dr. Tarek Hamza: personal communication, 2005 Dec 21).

Because obese patients face increased surgical risks, many surgeons elect to insert the BIB[®] in patients under general anesthesia with tracheal intubation.^{5,6,13,17,18}

After six months, the Heliosphere[®] balloon is punctured and removed using the same procedure. Removal has been reported to be more difficult than insertion.¹⁰ Consecutive balloons can potentially be placed to extend treatment.

Patients pay from C\$3,500 to C\$4,000 at private clinics for the Heliosphere[®] balloon, including gastroscopic insertion and removal (Dr. Clifford Albert, Triumph Medical Products, Montreal: personal communication, 2005 Nov 3).

Concurrent Developments

Implanted battery-operated devices that deliver an electrical charge to the stomach to induce an early sensation of fullness are being developed for the treatment of obesity. Medtronic's Transcend[®] Implantable Gastric Stimulator received Health Canada licensing approval in December 2004.² Implantation of the device costs about C\$24,000,¹⁹ with batteries expected to last from three to five years, at which point a repeat surgery is required to replace the device.

Rate of Technology Diffusion

Physicians who are skilled in performing gastroscopy for obese patients require additional training before they can perform balloon placement and removal.

Canadian marketing of the Heliosphere[®] balloon began in August 2005. To date, 30 gastroenterologists and surgeons have received training to insert the balloon gastroscopically. Patients receive intravenous sedation during the 15-minute outpatient procedure (Dr. Clifford Albert: personal communication, 2005 Nov 3). Two patients in Montreal had a Heliosphere[®] balloon implanted under sedation in November 2005.²⁰

Implementation Issues

More clinical data are required to directly compare the benefits, harm, and cost-effectiveness of the Heliosphere[®] balloon with other short-term weight-loss interventions, including low-calorie diets. Data are also needed to confirm the superiority of the Heliosphere[®] balloon over previous generations of air-filled balloons that were abandoned because of harmful events.

The intra-gastric balloon may be useful when obesity is not severe enough to justify bariatric surgery, or when patients refuse surgery. The intra-gastric balloon is less invasive than surgery, can be repeated, and is reversible.¹⁷ The balloon is not an alternative to surgery for individuals with morbid obesity, because it is designed to stay in the stomach for only six months. Most studies show that weight loss reverses after balloon removal.^{3,13,17,21}

The intra-gastric balloon may be used as a "pre-operative test" to detect compliant patients who may be suited for a restrictive surgical procedure. If patients show poor compliance with a restricted diet, a procedure such as a gastric bypass or biliopancreatic diversion may be more appropriate.^{4,12,14}

A modest pre-operative weight loss of 10% to 20% can reduce the complications of surgery.²¹ Studies with the BIB[®] show that the balloon may be useful to achieve some initial weight loss and to lower the risk of subsequent surgery (bariatric or other).^{5,21} Intra-gastric balloons may also serve as a bridge therapy if there are long waiting lists for surgery.²¹ If the manufacturer's recommendation is followed to implant the Heliosphere[®] under general anesthesia, this would remove its advantage as a "bridging" or

preoperative treatment to lower surgical risk in extremely obese individuals.

Canadian physicians are being trained to implant and remove the Heliosphere® under mild sedation. The implications of implanting and removing the balloon under mild sedation have yet to be demonstrated.

Although patients must pay to have the balloon implanted at a private clinic, there are implications for the public health care system if the balloon spontaneously deflates or migrates, and urgent removal is required in hospital. The risk of balloon deflation and intestinal obstruction is significantly higher after six months of implantation. Patients must be warned about this risk, and efforts must be made to ensure that patients return for balloon removal.

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Cite as: Allison C. *Intragastric balloons: a temporary treatment for obesity* [Issues in emerging health technologies issue 79]. Ottawa: Canadian Coordinating Office for Health Technology Assessment; 2006.

CCOHTA appreciates comments from its reviewers.

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This report and the French version entitled *Le ballon gastrique : un traitement temporaire de l'obésité* are available on CCOHTA's web site.

Production of this report is made possible by financial contributions from Health Canada and the governments of Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nova Scotia, Nunavut, Ontario, Prince Edward Island, Québec, Saskatchewan, and Yukon. The Canadian Coordinating Office for Health Technology Assessment takes sole responsibility for the final form and content of this report. The views expressed herein do not necessarily represent the views of Health Canada or any provincial or territorial government.

ISSN 1488-6324 (online)
ISSN 1488-6316 (print)
PUBLICATIONS MAIL AGREEMENT NO. 40026386
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CANADIAN COORDINATING OFFICE FOR
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