Title:	Intragastric balloons for the temporary management of morbid obesity
Agency:	Medical Services Advisory Committee (MSAC) MDP 106 Commonwealth Department of Health and Ageing GPO Box 9849 Canberra ACT 2601 <u>http://www.msac.gov.au</u>
Reference:	MSAC 1112 Assessment report First printed July 2008 ISBN (Print) 1-74186-630-8, ISBN (Online) 1-74186-631-6

### Aim:

To evaluate the safety, effectiveness, and cost considerations associated with intragastric balloons for the temporary management of morbid obesity in addition to conventional therapies (diet  $\pm$  physical activity  $\pm$  behavioural therapy  $\pm$  drug therapy) versus conventional therapies alone; and used prior to obesity surgery, versus obesity surgery alone.

## **Results and Conclusions:**

Safety:

Intragastric balloons are less safe than conventional therapy. Serious complications such as death, gastrointestinal obstruction, gastric perforation, oesophageal rupture and biliary pancreatitis occurred in less than 1 per cent of patients. Minor complications such as nausea and vomiting were frequently reported (32 - 100% of patients). Two per cent of patients required early removal of the balloon due to intolerance.

Two studies provided limited evidence that super-obese patients have improved safety outcomes when they receive intragastric balloon therapy prior to obesity surgery, relative to surgery alone.

# Effectiveness:

The evidence consistently showed that patients, on average, lost weight while undergoing intragastric balloon therapy (with/without conventional therapies). However, the three small randomised controlled trials identified were inconclusive as to whether intragastric balloons are as, or more, effective than conventional therapies alone at assisting weight loss. Intragastric balloons made no difference to long term weight loss when patients also underwent obesity surgery.

### Cost considerations:

There was insufficient information on which to base a cost-effectiveness analysis. Based on an estimated 4,903 - 8,000 intragastric balloons being inserted/removed per year, an additional 19,236,067 - 330,535,600 would potentially be incurred per annum by the Australian healthcare system. These costs would be in addition to the costs associated with conventional management of obesity.

### **Recommendation:**

The MSAC has considered the safety, and clinical effectiveness of intragastric balloons for the temporary management of morbid obesity in addition to conventional treatment such as diet, exercise and behaviour modification. The MSAC finds that intragastric balloons used for the temporary management of morbid obesity pose additional risks to patients when compared to the standard treatment for morbid obesity and that they do not provide additional clinical benefits over standard treatment.

There may be a role for the temporary placement of intragastric balloons for the management of the super obese patient prior to bariatric surgery however, evidence to support this approach is limited.

The MSAC finds that the use of intragastric balloons for the temporary management of morbid obesity is less cost-effective than standard treatment for morbid obesity.

The MSAC recommends that public funding is not supported for this procedure.

The Minister for Health and Ageing endorsed this recommendation on the 20th May 2008.

#### Method:

Medline, Embase, The Cochrane Library, and several other biomedical databases, HTA and other internet sites were searched (1990- June 2007). Specific journals were handsearched and reference lists pearled. Studies were assessed for inclusion in the review using predetermined PICO selection criteria and reasons for exclusion were documented. Study quality was appraised, data extracted in a standardised manner, and findings synthesised narratively.

Prepared by Adelaide Health Technology Assessment (AHTA) on behalf of the MSAC