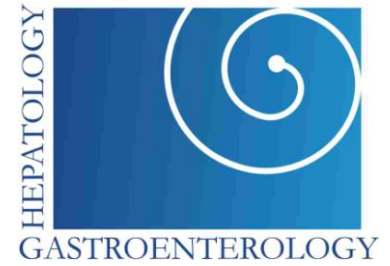


Intragastric Intragastric Balloon



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Introduction

In Australia 60% of adults are obese or overweight. Many health problems are associated with increased body weight including hypertension, ischemic heart disease, obstructive sleep apnoea, type 2 diabetes, reflux oesophagitis, fatty liver, gout, osteoarthritis of weight bearing joints, polycystic ovary syndrome and pelvic floor dysfunction and increased risk of malignancies. Patients with a body mass index BMI of >35 have twice the mortality of matched controls.

Goals

The initial goals of weight loss are to ► reduce body weight by approximately 10% from baseline, ► over a 6 month timeline, and ► maintain that weight loss for at least 2 years. Although the weight loss may seem insignificant 10% weight loss has been shown to ■ reduce blood pressure by 10-15mm Hg ■ reduce cholesterol by 10% and triglycerides by 30% ■ improve sugar control and reduce diabetic mortality rates ■ improve ovarian function.

Lifestyle measures

Changing lifestyle is critical to long term success. The first approach to reducing weight loss should consist of a combination of an energy-restricted diet, physical activity and behaviour modification (reduce stress, allow more time for one self, eliminate bad habits associated with increased food intake).

The Orbera Intragastric Balloon

Many people have failed lifestyle measures and the Orbera Intragastric Balloon can be a useful adjunct to these measures. This silastic balloon is placed in the top of the stomach under sedation and filled with 600-700mls of saline (dyed with blue). The balloon remains in place for 6-9 months and then must be removed. The removal is performed under general anaesthetic. The balloon works at a local and a central level. Locally the balloon fills the gastric lumen, causing a sense of fullness and slows gastric emptying which in itself reduces sense of hunger. The balloon also distends the gastric wall receptors and stimulates the brain centrally in the tractus solitarius and paraventricular nucleus which has also been shown to reduce appetite.

How effective is the balloon in the short term?

Overall the balloon is more than twice as effective as diet and drugs over the period of time that the balloon is in situ. It is not as effective as gastric banding or other weight loss surgery.

| | Diet/exercise | Wt loss drugs | IG Balloon | Bariatric Surgery |
|--|---------------|---------------|------------|-------------------|
| % Average weight loss compared to initial body weight at 6 months | <6% | 6% | 15% | 20% |

How effective is the balloon in the long term?

Critics have suggested that the balloon may fail to be effective when it is removed and that there may be no long term benefit from this therapy. In fact we know from previous studies that dietary/exercise intervention often results in no overall weight loss and sometimes even gain at 1-2 years post intervention. A recent study by Negrin Dastis in Switzerland Endoscopy, 2009 Jul;41(7):578-80) reports encouraging data for the balloon.

| | During balloon insertion in first 6 months | 2 years after removal of balloon | 4 years after removal of balloon |
|--|--|----------------------------------|----------------------------------|
| Number of patients treated with IGB achieving >10% weight loss | 63% | 24% | 28% |

The data showed that patients who maintained a fibre-enriched, low fat diet and regular exercise regimen were more likely to have long term success with the balloon.

Is it possible to have another balloon inserted after the first one?

Yes, and this is not uncommon. The technique is no more difficult than the first time. The amount of weight lost tends to be less than the first time the balloon was inserted.

What are the side effects and dangers?

During the first 3 days after insertion it is very common to feel very nauseated. To reduce this problem a combination of 3-4 drugs are given during this time. You will not be able to work during this time. Usually at some time during the first week this nausea suddenly switches off. However the feeling is often overwhelming and many patients have to be encouraged to keep the balloon in place.

The endoscopic insertion is usually very safe but there are always small risks related to sedation and anesthesia. The specific concerns that relate to the balloon insertion are that

- balloon deflation (4% patients) (characterized by appearance of blue urine)
- continued nausea and intolerance of the balloon past 2 weeks (7%)
- ulceration of the gullet or flare up of heartburn symptoms (16%)
- balloon migration, possible bowel obstruction or pancreatitis (<0.05%)
- perforation, tearing or bleeding of the stomach or oesophagus (very rare) (<0.01%)
- hyperinflation of the balloon causing severe pain or perforation (0.3%)
- death is a remote possibility with any surgical intervention (<0.01%, less than one in 10,000)

Monitoring after the IG balloon?

During the first 21 days after the balloon insertion I will contact you and review you in my rooms. You will organize regular visits to a dietitian and when you are feeling well in 4-6 weeks you should start a regular exercise regimen. Exercise programs are often more successful if you engage a personal trainer. Go slowly at first please. I will then see you regularly over the next 6-9 months of the balloon. At the end of this period the aging balloon must be removed.

Consent

I, the undersigned agree to Orbera balloon placement and removal at 6-9 months. I have read and understood the information above.

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Date:.....