The Duodenal-Jejunal Bypass Sleeve (EndoBarrier Gastrointestinal Liner) for Weight Loss and Treatment of Type II Diabetes

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Introduction

Obesity has reached epidemic proportions in the western world. Reaching epidemic status on a global scale is inevitable as more than 300 million people worldwide are now obese, defined by a Body Mass Index (BMI) greater than 30 kg/m² [1]. This has resulted in a recent boom in novel techniques for treating obesity. It is widely acknowledged that conservative interventions such as dietary and behavioural modification as well as pharmacological therapy have less than favourable long-term outcomes [2, 3]. Indeed, surgical intervention is now the most effective modality with which to treat severe obesity.

Patient criteria for selection is controversial, but under the 1991 National Institutes of Health (NIH) guidelines, surgery is an option for well-informed and motivated patients who have a BMI of at least 40 or a BMI of at least 35 with serious co-morbid conditions [4]. However, surgical

interventions, despite producing sustainable weight loss, have been shadowed by relatively high re-operative rates and variable long-term weight loss results.

Therefore, there have been numerous strategies employed in an effort to improve long-term surgical outcomes. One of these is to induce pre-operative weight loss, which has been shown to positively correlate with long-term post-operative weight loss [5]. Pre-operative weight loss by low energy diet has consistently been proven ineffective and so there has been a new focus on minimally invasive techniques to achieve the desired result. The duodenal-jejunal bypass sleeve is one such technology that theoretically can be used as a method of inducing weight loss.

Weight loss in the setting of Type II diabetes mellitus can prove difficult to manage. Diet and lifestyle changes are important, but as with bariatric results outside of the diabetes arena, they are often not enough. Pharmacological interventions are again not effective and are plagued with side effects. Surgical procedures such as laparoscopic banding, gastric bypass and sleeve gastrectomy are effective. However, patients fear surgery and the permanence of this option. There is an alternative that has recently surged to the forefront of our arena. With promising trial results in the settings of isolated weight loss and in type II diabetes, as well as having a less invasive nature when compared with surgery, more patients and bariatric specialists are turning to the EndoBarrier.

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The Duodenal-Jejunal Bypass Sleeve

The Duodenal-jejunal bypass sleeve (DJBS, EndoBarrier Gastrointestinal Liner; GI Dynamics Inc., Lexington, Massachusetts, USA) is an endoscopically and fluoroscopically inserted implant (Fig. 1). It is an impermeable fluoropolymer sleeve that is reversibly fixated to the duodenal bulb and

Fig. 1 The duodenal-jejunal bypass sleeve (taken from Gersin et al. 2010 [10])

extends 80 cm into the small bowel, usually terminating in the proximal jejunum [6]. It allows transit of chyme from the stomach through to the jejunum without contact with the duodenal wall. By not allowing mixing with pancreatic exocrine secretions and bile in the jejunum, it mimics a duodenal-jejunal bypass and encourages weight loss through malabsorption. It is the only endoluminal technology to be studied in human subjects that works in this way [7]. It is inserted endoscopically and may be aided with fluoroscopic guidance. Due to the device being in its infancy, procedures undertaken thus far have been under general anaesthetic but there is potential for future conversion to standard gastrointestinal endoscopic protocol with sedation. This procedure helps patients regain metabolic control of Type II diabetes and aid in weight loss. It is a new class of treatment that fits between pharmaceutical regimens and surgery. It is performed with relative technical ease and speed. There are no incisions and insertion takes only a few hours in hospital. The Endobarrier is contained within a capsule and is inserted in the duodenum endoscopically. The sleeve is then deployed distally into the proximal jejunum under fluoroscopic control.

Efficacy and Safety

As would be expected for a technology in its infancy, there are only a handful of reported series regarding the use of the EndoBarrier in the literature (Table 1). They have all used

excess weight loss (EWL) after 12 weeks as their primary outcome measure. The first reported human case series was by Rodriguez et al. in 2008, which showed a 12-week EWL of 23.6 % [8]. 3 other studies, which are also shown in Table 1, have trialled the EndoBarrier in a randomised fashion against either sham endoscopic procedures or low energy diets. They showed 12-week EWLs ranging from 11.9 % to 22 % [6, 9, 10] and greater weight loss compared with controls to statistically significant levels. These levels of excess weight loss are encouraging and suggest that the device may be useful in effectively inducing pre-operative weight loss before definitive surgery.

It should be noted that in all 4 of the reports, there were complications that led to either failed implantation or early extraction of the device. Reasons for failed implantation included anatomical difficulties that were encountered when anchoring onto a small duodenal bulb [10]. Early extractions were present in all studies and were secondary to instances of abdominal pain, sleeve migration, anchor dislocation, sleeve obstruction and haematemesis [6, 8–10]. Furthermore, in the first case series, minor surgical trauma, in the form of oropharyngeal and oesophageal mucosal tears were reported upon removal of the sleeve after 12 weeks. Endoscopically guided implantation has been reported to carry a higher rate of complications compared to implantation under fluoroscopic guidance [6]. Further studies are needed to analyse incidences of such complications. It should be noted that the EndoBarrier is very much in its infancy and that these complications are to be expected; they will inevitably become less frequent as familiarity with the practical procedure of implantation increases. The authors have performed 20 Endobarrier insertions as part of a multicentre UK trial with encouraging results in terms of weight loss and control of type II diabetes [unpublished data, series report in preparation]. Most patients experienced clinically significant weight loss, with evidence of reduced insulin resistance. It is thought that the EndoBarrier also may have a positive impact on cardiovascular risk factors including a reduction in lipid levels and blood pressure.

The Future

The first series published on the use of the EndoBarrier uncovered a resolution of type II diabetes mellitus in 3 out

Table 1 Studies reporting weight loss outcomes following the use of the EndoBarrier

Author and year	Type of study	Number of subjects	12-Week EWL (%)
Rodriguez et al. 2008 [8]	Case Series	12	23.6
Tarnoff et al. 2009 [9]	Randomised trial	25 (vs. 14 diet control)	22.0 (vs. 5.0; $P<0.001$)
Gersin et al. 2010 [10]	Randomised trial	25 (vs. 24 sham control)	11.9 (vs. 2.7; $P<0.05$)
Schouten et al. 2010 [6]	Randomised trial	30 (vs. 11 diet control)	19.0 (vs. 6.9; $P<0.002$)

EWL excess weight loss

of 4 affected subjects [8]. Interestingly, there was no difference in weight loss between diabetic and non-diabetic patients. This therefore brought up the possible role of the EndoBarrier in treating type II diabetes mellitus independently of weight loss. This notion has been substantiated this year by a team in Brazil that carried out an investigation into use of the EndoBarrier for 52 weeks in patients with type II diabetes mellitus. They reported statistically significant reductions in fasting blood glucose, fasting glucose and HbA1c by the end of the 52 weeks in 13 patients [11]. The EndoBarrier's effect of reversing diabetes will need to be investigated by randomisation trials before it gets as widely accepted as its effect on weight loss. It is also important to note for future protocols that the benefits achieved while the device is in place will undoubtedly be maximized when patients participate in a multidisciplinary support program alongside having the EndoBarrier. This will include patients partaking in behavior modification, receiving nutritional counseling and participating in exercise regimes. As with any bariatric intervention, patient compliance with such regimes will continue to have a major impact on any success the EndoBarrier may have.

Conclusion

The duodenal-jejunal bypass sleeve is the first endoluminal device to effectively cause weight loss through malabsorption in obese individuals. Its use is associated with difficulties regarding implantation as well as complications requiring early extraction. These will be reduced with increased use of the device. The application of the device in reported studies have primarily used 12-week excess weight loss as a primary end point and so, at this stage, one must only consider it as a method of inducing temporary weight loss. It may therefore be suitable to use before more definite interventions by pre-operatively reducing BMI, a factor known to influence long-term success in bariatric surgery. No studies have looked at the effects of the EndoBarrier beyond one year and so the long term effects in terms of

diabetes control and weight loss will need to be investigation further. The use of the EndoBarrier in reversing type II diabetes mellitus independently of weight loss will require further study but initial results from studies are encouraging. The EndoBarrier has the potential to revolutionise the way in which we can effectively and safely manage weight loss and type II diabetes mellitus.

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